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Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with Positional Therapy: A Double-Blind Randomized Sham-Controlled Crossover Trial

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Title: Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with Positional Therapy: A Double-Blind Randomized Sham-Controlled Crossover Trial

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ABSTRACT:

TITLE: Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with Positional Therapy: A Double-Blind Randomized Sham-Controlled Crossover Trial

TRIAL DESIGN: A double-blind, randomized, sham-controlled, crossover trial.

OBJECTIVE: To evaluate whether the proportion of time spent supine during sleep in the third trimester of pregnancy could be reduced using a positional therapy device compared with a sham device.

METHODS: This study was conducted between March 2016 and January 2017, at a single center in Canada. Healthy, third-trimester pregnant women aged 18 years and older were recruited to participate in a two-night, polysomnography study in a sleep laboratory. Participants were randomized by computer-generated, one-to-one, simple randomization to receive either a positional therapy device (PrenaBelt) or a sham device on the 1st polysomnography night and were crossed over to the alternate device on the 2nd night. Allocation concealment was by unmarked, security-tinted, sealed envelopes. The primary outcome was the proportion of time spent supine during sleep. Participants, the recruiter, and personnel involved in setting up, conducting, scoring, and interpreting the polysomnogram were blinded to allocation.

RESULTS: Twenty-three participants were randomly allocated to receive the PrenaBelt (n=13) or the sham (n=10) on the 1st polysomnography night. Twenty participants completed the study protocol, after which, the study was concluded. Twenty participants were included in the analysis of the primary outcome. The PrenaBelt resulted in an absolute reduction in the proportion of sleep time supine by 6.8% (95%CI: 0.3 to 13.3, p=0.04), which is a 38% relative reduction. There were no harms in this study.

CONCLUSIONS: This study demonstrates that the proportion of sleep time supine during late pregnancy can be significantly reduced via positional therapy and has important implications for the prevention of late unexplained stillbirth and for the design of a public health campaign about safe sleep position in late pregnancy.

TRIAL REGISTRATION: ClinicalTrials.gov NCT02377817

Strengths and limitations of this study:

- A double-blind, randomized, sham-controlled, cross-over trial.
- Employed polysomnography, the gold-standard test for investigating sleep physiology and pathophysiology.
- The first to investigate positional therapy during sleep in pregnancy.
- Performed in a controlled sleep laboratory setting over two nights; therefore, caution should be taken when extrapolating the results to the home setting and across the third trimester.
- Due to the small sample, may have been underpowered.

INTRODUCTION

Background

Stillbirth (SB) and low birth weight (LBW) are devastating complications of pregnancy. Recently, four studies have demonstrated an association between maternal supine sleep position in late pregnancy and the risk of late term SB (1–4) and LBW.(1) Results of a fifth study (5) are currently under review. The population attributable risk of supine sleep for SB has been reported as being between 9.4% and 37%,(1–4) suggesting that a significant proportion of late term SB could be averted if supine sleep was avoided. A number of major risk factors for SB and LBW are not modifiable in the course of the pregnancy (e.g., elevated BMI, advanced maternal age); however, maternal supine sleep is potentially modifiable with the majority of third-trimester pregnant women spending up to 25% of their sleep time supine.(6,7)

The contribution of supine sleep to LBW and SB is biologically plausible due to inferior vena cava compression by the gravid uterus, affecting maternal hemodynamics (8–21) and fetal oxygenation.(13,22–24) The supine position also exacerbates sleep disordered breathing (SDB),(25,26) which has been linked to adverse pregnancy outcomes.(27–29) In persons with mild to moderate SDB, the majority experience most of their breathing abnormalities while sleeping supine.(30) Positional therapy (PT) is a simple, safe, and effective treatment that helps individuals with SDB maintain a lateral position while sleeping, thus significantly reducing or eliminating their breathing abnormalities.(30,31) Drawing on the concept of PT for SDB, the authors (AK, AB, KC) designed a PT device for pregnant women called “PrenaBelt” to minimize supine sleep

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3 **(Fig. 1.)**
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8 **Objectives**

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10 The primary objective was to evaluate whether the proportion of time spent supine
11 during sleep in the third trimester of pregnancy could be reduced using the PrenaBelt
12 when compared with a sham. Secondary objectives were to evaluate the effect of the
13 PrenaBelt on maternal sleep architecture and respiration in comparison with a sham,
14 evaluate the accuracy of maternal self-reported sleep position, and collect feedback
15 from the participants regarding the PrenaBelt.
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26 **METHODS**

27 **Trial Design**

28 A single-center, double-blind, randomized (one-to-one), sham-controlled, crossover trial.
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30 No methodological changes were made after trial commencement.
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38 **Participants**

39 Participants were recruited by a trained nurse at the IWK Health Centre – a tertiary and
40 primary care center for women and children with approximately 5000 newborns
41 delivered per year. Overnight polysomnograms (PSGs) were conducted at the Queen
42 Elizabeth II (QEII) Health Sciences Centre Sleep Disorders Clinic. The IWK and QEII
43 are teaching hospitals associated with Dalhousie University in Halifax, Canada. Halifax
44 has a population of approximately 400,000. Participants expressing interest in the study
45 (paper flyer, online advertisement) were screened.
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5 Participants were eligible if they had a low-risk singleton pregnancy and were 18 years
6 of age or older, more than 20 weeks gestation at screening, and residing in the Halifax
7 Regional Municipality. Exclusion criteria included BMI ≥ 35 at the first antenatal
8 appointment for the current pregnancy, pregnancy complicated by obstetric conditions
9 (e.g., hypertension, diabetes, intra-uterine growth restriction), sleep complicated by any
10 medical conditions (e.g., known obstructive sleep apnea, insomnia, musculoskeletal
11 deformity affecting sleep position), multiple pregnancy, known fetal-abnormality, and
12 non-English speaking and reading.
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26 All participants in the trial gave written informed consent. This trial was approved by the
27 IWK Health Centre Research Ethics Board in June 2015 (Project No. 1018753). There
28 was no independent data monitoring committee.
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35 **Interventions**

36 Each participant underwent two overnight PSG studies (not required to be consecutive
37 dates) between 28-37 weeks gestation. The only difference between the two nights was
38 the intervention (PrenaBelt or sham) and that participants completed a demographic
39 questionnaire on the 1st PSG night only. The PrenaBelt is worn at the level of the waist
40 and has four firm plastic balls embedded into foam inserts within the pockets posteriorly
41 (**Fig.1.**). When supine, the balls apply pressure points across the user's lower back,
42 prompting her to reposition herself in a lateral position to maintain comfort. The sham
43 was identical in appearance, materials, and construction to the PrenaBelt, but had soft
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3 foam balls instead of firm plastic balls and did not have foam inserts; as such, the sham
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5 did not provide pressure points. Participants crossed over to the alternative intervention
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7 on the 2nd PSG night.
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12 PSG set-up was by trained research assistants (RAs), in accordance with the American
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14 Academy of Sleep Medicine 2014 guidelines,(32) and in a private clinical room with
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16 continuous monitoring by an RA in a separate room through audio/visual and Embla
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18 Sandman Elite sleep diagnostic software (Natus Medical Incorporated, Pleasanton,
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20 USA).
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26 Immediately before the participant settled to sleep, the unblinded research personnel
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28 (co-PI [AK] or study coordinator [JW]) entered the room to assist her in donning the
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30 assigned intervention (PrenaBelt/sham) without disclosing the identity of the intervention
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32 to the participant or the RA in order to maintain blinding. Upon waking for the day, the
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34 participants immediately removed the intervention and placed it in an opaque closed
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36 box for collection by the unblinded personnel in order to keep it concealed from the RA.
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38 The RA subsequently entered the room and unhooked the PSG equipment. The
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40 participant completed a feedback questionnaire and placed it in a sealed envelope for
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42 the unblinded personnel. The questionnaire elicited participants' perceptions of body
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44 position at sleep onset and waking, changes in position and reason for changes, and
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46 estimates of proportion/time spent in each position during sleep. Participants also
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48 ranked their satisfaction, comfort level, and intention to continue using the PrenaBelt (if
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50 it were available) on a 10-point Likert scale (with 10 out of 10 reflecting the highest
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3 satisfaction, comfort, and intention to use, and 1 out of 10 the lowest). Participants were
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5 permitted bathroom breaks and to remove the intervention and/or PSG equipment at
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7 any point if they became uncomfortable.
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12 Scoring of PSG's was performed by blinded Registered PSG Technicians, and
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14 interpretation was by a blinded sleep medicine physician (DM).
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17 18 19 **Outcomes**

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21 The primary outcome, proportion of time spent supine during sleep, was documented
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23 continuously by an RA via video feed.
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28 Respiration was measured using respiratory inductance plethysmography (Philips
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30 Resironics Pro-Tech zRIP Durabelt, Murrysville, USA). Airflow, including snoring, was
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32 measured by differential pressure transducers (BRAEBON Medical Corporation PT1,
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34 Kanata, Canada) and via audio by an RA. Maternal peripheral oxygen saturation (SpO₂)
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36 was measured via fingertip pulse oximetry. Electrodes (Natus Medical Incorporated,
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38 Pleasanton, USA) for electrocardiography (ECG), electroencephalography (EEG),
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40 electrooculography (EOG), and electromyography (EMG) were applied for
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42 determination of maternal heart rate, sleep architecture, and leg movements.
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49 No changes were made to the trial outcomes after trial commencement.
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52 53 54 **Sample Size**

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3 This is the first trial investigating PT in pregnant women to reduce supine sleep time. A
4 sample size of twenty-five ($n=25$) participants was selected. For a one-sided paired t-
5 test with power (β) of 0.80, significance level (α) of 0.05, $n=25$ pairs enable a detectable
6 effect (d) of -0.5 (difference in mean proportion of time spent sleeping supine by half a
7 standard deviation), which is a medium effect size per the literature regarding
8 Cohen.⁽³³⁾ All statistical analyses were conducted using the R Statistical Software
9 package (version 3.2.4 (2016-03-10)).⁽³⁴⁾ There was no planned interim analysis or
10 stopping guidelines.
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24 **Randomization**

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26 Participants were allocated by computer-generated (R), one-to-one, simple
27 randomization into one of two possible crossover schemes: PrenaBelt on the 1st PSG
28 night followed by sham on the 2nd PSG night, and vice versa (**Fig. 2.**). Allocation
29 sequence was concealed via unmarked, security-tinted, sealed envelopes by an
30 independent statistician (MB). An envelope was drawn at random, opened, and the
31 participant's name and birth date were recorded on the enclosed allocation sheet by the
32 unblinded personnel (AK, JW) on the participant's first PSG night.
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45 **Blinding**

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47 Participants, the recruiter, and personnel involved in setting up, conducting, scoring,
48 and interpreting the PSG were blinded to allocation. The only research personnel
49 unblinded to the allocation were the co-PI (AK) and the study coordinator (JW), which
50 was required in order to provide the appropriate intervention to the participant before
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3 she went to sleep. It was not feasible to blind the researchers analyzing the study data
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5 (AK, JW, MB) to the allocation.
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10 **Statistical Methods**

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12 In the primary analysis, we specified a linear mixed-effects model with the proportion of
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14 time spent supine during sleep as the response variable and the interventions
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16 (PrenaBelt, sham) as the fixed effects. To account for the cross-over design,
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18 participants and PSG night (1st or 2nd) were treated as random effects.
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24 Secondary outcomes were compared between interventions by paired t-tests (normal)
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26 and Wilcoxon signed rank tests (non-normal). Cohen's Kappa (κ) was used to assess
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28 agreement between categorical variables. Spearman's Rho (ρ) and Bland-Altman plots
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30 were used for continuous variables.
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35 For continuous variables, normality was assessed using Q-Q plots and Anderson-
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37 Darling test. All testing was performed at a 0.05 significance level. Treatment effects
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39 (differences in means and odds ratios) and associated confidence intervals were
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41 presented at a 95% confidence level with p-values.
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46 **RESULTS**

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48 Between March 2016 and January 2017, 28 participants were assessed for eligibility
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50 (**Fig. 2.**). Following exclusion of three (11%) who declined participation and two (7%)
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52 who failed to meet eligibility criteria, 23 were randomized. After randomization, there
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3 were three (13%) dropouts – all from the PrenaBelt-then-sham group and after
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5 completing the 1st PSG night. Two were due to transportation/childcare reasons, and
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7 one was due to an unrelated injury preventing her from sleeping in a horizontal position.
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9 Thus, twenty participants – ten from each group – were included in the primary analysis,
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11 which was by original assigned groups and on a complete-case basis (drop-outs
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13 excluded). The originally planned sample size of 25 participants was not reached due to
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15 unforeseen budget restrictions preventing recruitment beyond 20 participants.
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22 **Sample Characteristics**

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24 Baseline demographic, obstetric, and sleep habit characteristics of the 23 randomized
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26 participants are shown in **Table 1**. The two randomized groups were well balanced with
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28 respect to the sample characteristics – there were no statistically significant differences
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30 in baseline characteristics between groups ($\alpha=0.05$). The mean age was 30.4 years.
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32 The majority (83%) were Caucasian. The mean pre-pregnancy BMI was 26.6 kg/m² and
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34 rose to a mean of 30.7 kg/m² at the time of the 1st PSG, which took place at a mean
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36 gestational age of 30.8 weeks. More than half (57%) of participants were nulliparous.
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42 The mean self-reported overnight sleep duration at the time of the 1st PSG was 7.5
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44 hours. In the week previous to the 1st PSG (when pregnant), left was the most common
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46 position at sleep onset (74%) and waking (52%), although a large proportion of women
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48 also reported the supine position at sleep onset and waking (22% and 35%,
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50 respectively). When not pregnant, prone was the most common position at sleep onset
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(57%), and supine was the most common at waking (48%). Most participants used a pillow under their head (78%) and between their knees (61%).

Table 1 | Baseline demographic, obstetric, and sleep habit characteristics*

	PrenaBelt-then-sham (N=13)	sham-then-PrenaBelt (N=10)
Age (years)	30.1 (5.5)	30.7 (4.1)
Caucasian ethnicity	9 (69%)	10 (100%)
Pre-pregnancy BMI (kg/m ²)	26.9 (3.1)	26.2 (3.5)
Current BMI (kg/m ²)	31.3 (3.4)	29.9 (3.6)
Gestational age (weeks)	30.8 (2.7)	30.8 (2.8)
Gravida		
1	7 (54%)	6 (60%)
≥2	6 (46%)	4 (40%)
Sleep duration (hours)	7.4 (1.5)	7.6 (0.5)
In the last week:		
Sleep onset positions:		
Left	7 (54%)	10 (100%)
Supine	3 (23%)	2 (20%)
Right	8 (62%)	3 (30%)
Prone	0 (0%)	0 (0%)
Waking positions:		
Left	8 (62%)	4 (40%)
Supine	4 (31%)	4 (40%)
Right	5 (38%)	6 (60%)
Prone	0 (0%)	0 (0%)
When not pregnant:		
Sleep onset positions:		
Left	2 (15%)	3 (30%)
Supine	3 (23%)	3 (30%)
Right	2 (15%)	4 (40%)
Prone	7 (54%)	6 (60%)
Waking positions:		
Left	5 (38%)	4 (40%)
Supine	4 (31%)	7 (70%)
Right	5 (38%)	2 (20%)
Prone	5 (38%)	4 (40%)
Snores ≥3 nights per week	5 (38%)	3 (23%)
Sleeps with bed partner	10 (77%)	10 (100%)
Pillow use		
Under head	9 (69%)	9 (90%)
Between knees	8 (62%)	6 (60%)
Behind back	3 (23%)	5 (50%)
Under tummy	3 (23%)	4 (40%)
Pregnancy pillow	4 (31%)	1 (10%)

*Data are means (SD) or numbers (%)

Proportions for responses to some questions may add to greater than 100% because some participants checked more than one box in response to a question, e.g., for sleep onset position in the last week, some responded "left" and "right".

Primary Outcome

The mean (SD) proportion of sleep time supine on the PrenaBelt night (n=20) and sham night (n=20) was 11.7% (17.9) and 18.5% (17.6), respectively (**Table 2, Fig. 3**). The linear mixed-effects model estimate of the difference in means was -6.8% (95% CI: -13.3 to 0.3, p=0.04).

Table 2 | Primary outcome: proportion of sleep time supine

	PrenaBelt night (n=20)	sham night (n=20)	PrenaBelt minus sham Difference (95%CI)	p-value
Median	3.5	16.4		
IQR	0 to 16.2	3.5 to 25.3		
Mean (SD)	11.7 (17.9)	18.5 (17.6)	-6.8* (-13.3 to -0.3)	0.04

*Linear mixed effects model

Secondary Outcomes

The estimates, 95% confidence intervals (CI), and p-values for the intervention-associated differences, PrenaBelt versus sham, in the sleep and respiratory variables and user feedback are shown in **Table 3**. The mean (SD) number of minutes spent supine during “time in bed” on the PrenaBelt and sham nights were 44.6 (67.4) and 75.5 (69.7), respectively, and the linear mixed-effects model estimate of the difference in means was -30.9 minutes (95% CI: -53.9 to -7.9), p=0.01. “Time in bed” was the elapsed time from when the participant settled to sleep until the participant woke for the day minus the time the participant was upright (i.e., bathroom break).

Regarding sleep architecture for the complete sample (n=40 nights), the mean (SD) sleep time was 336 minutes (64), sleep efficiency 79% (13.4), sleep latency 19.5

minutes (19.1), REM latency 96 minutes (59.9). The mean (SD) number of stage shifts was 105 (39.3), number of awakenings 19.7 (6.3), and number of REM periods 3.4 (1.2). The mean (SD) proportion of stage 1 sleep was 9.4% (5.6), stage 2 sleep 62.7% (7.9), stage 3 sleep 11.2% (8.3), and REM sleep 16.7% (5.6). For respiratory variables, the mean (SD) apnea-hypopnea index was 2.2 (4.6), respiratory effort-related arousal index 0.5 (1.7), and peripheral oxygen saturation maximum, mean, and minimum during sleep were 99.7% (0.5), 96.3% (1.0), and 89.3% (5.1), respectively. Except for the difference in proportion of REM sleep nearing statistical significance (p-value 0.05), there were no statistically significant differences in sleep architecture, respiration, or user feedback between the PrenaBelt and sham nights on paired testing (n=20 pairs) (Table 3).

Table 3 | Secondary outcomes: time supine, sleep architecture, respiration, user feedback

	PrenaBelt (n=20) Mean(SD)	sham (n=20) Mean(SD)	PrenaBelt minus sham Difference (95%CI)	p-value
Time supine (minutes)	44.6 (67.4)	75.5 (69.7)	-30.9* (-53.9 to -7.9)	0.01
Total sleep time (minutes)	332 (75)	341 (52)	-3.6 [†] (-33.8 to 21.8)	0.81
Sleep latency (minutes)	19.1 (19.8)	20.0 (19.0)	2.0 [†] (-7.2 to 9.4)	0.65
Sleep efficiency (%)	78 (14.5)	80 (12.6)	-1.4 [†] (-5.9 to 3.0)	0.46
Number of stage shifts	103 (38.4)	107 (41.0)	-3.9 [‡] (-14.2 to 6.5)	0.45
Number of awakenings	19.5 (6.5)	20.0 (6.4)	-0.50 [‡] (-3.2 to 2.2)	0.70
Proportion stage 1 sleep (%)	9.1 (5.2)	9.6 (6.0)	-0.50 [‡] (-2.3 to 1.3)	0.56
Proportion stage 2 sleep (%)	64.5 (7.4)	61.0 (8.1)	3.5 [‡] (-0.3 to 7.3)	0.07
Proportion stage 3 sleep (%)	10.9 (8.0)	11.5 (8.8)	-0.63 [‡] (-2.6 to 1.4)	0.52
Proportion REM sleep (%)	15.5 (6.4)	18 (4.6)	-2.5 [‡] (-5.1 to 0.05)	0.05
AHI (events/hour)	2.0 (3.9)	2.4 (5.3)	-0.14 [†] (-0.8 to 0.4)	0.51
RERA index (events/hour)	0.8 (2.3)	0.1 (0.2)	0.15 [†] (-0.4 to 4.6)	0.78
SpO2 during sleep (%)				
Maximum	99.8 (0.4)	99.6 (0.6)	0.25 [‡] (-0.01 to 0.5)	0.06
Mean	96.2 (0.9)	96.5 (1.0)	-0.25 [‡] (-0.6 to 0.1)	0.20
Minimum	90.4 (3.1)	88.2 (6.4)	1.5 [†] (-0.00 to 4.0)	0.08
Satisfaction (out of 10)	7.2 (2.1)	7.5 (1.9)	-0.28 [‡] (-1.0 to 0.5)	0.46
Comfort (out of 10)	7.8 (2.3)	8.6 (1.5)	-1 [†] (-2.8 to 0)	0.06
Intention to use (out of 10)	7.0 (2.3)	7.1 (2.4)	-0.1 [‡] (-1.0 to 0.8)	0.81

*Linear mixed effects model

[†]2-sided Paired Wilcoxon (signed rank)

[‡]Paired t-test

REM = Rapid Eye Movement

AHI = Apnea-Hypopnea Index
 RERA = Respiratory Effort-Related Arousal
 SpO2 = peripheral oxygen saturation

The self-reported sleep data are presented in **Table 4** with the PSG recorded correlates and the statistical analysis of agreement. Participants recalled their sleep onset position accurately for 34 of 40 nights (85%, κ 0.62, moderate agreement). Participants recalled their waking position accurately for 28 of 40 nights (70%, κ 0.42, weak agreement). There was a weak relationship between sleep onset and waking position (κ 0.24). There was no agreement between the self-reported and PSG-reported number of position changes (κ 0.17). Proportion of time in each position, left, supine, and right, as estimated per self-report and measured per PSG had Spearman's ρ of 0.76 (good correlation, $p < 0.01$), 0.27 (poor correlation, $p = 0.11$), and 0.93 (excellent correlation, $p < 0.01$), respectively. Bland-Altman plots (**Fig. 4.**, **Fig. 5.**, **Fig. 6.**) demonstrated that, on average, participants' self-reports tended to overestimate the percentage of left-side and right-side sleep by 5.5% (95%CI -30.2 to 41.2) and 0.5% (95%CI -21.9 to 22.9), respectively, and underestimate the percentage of supine sleep by 7.0% (95%CI -20.1 to 34.1) when compared to the PSG-determined position.

Table 4 | Secondary outcomes: self-reported versus PSG-recorded sleep behaviors

	Self-Report	PSG	Agreement
Sleep onset position (n=40)*			
Left	31 (78%)	29 (73%)	Cohen's κ † 0.62
Supine	2 (5%)	3 (7%)	
Right	7 (17%)	8 (20%)	
Waking position (n=40)*			
Left	28 (70%)	22 (55%)	Cohen's κ † 0.42
Supine	0 (0%)	5 (13%)	
Right	12 (30%)	13 (32%)	
Number of position changes (n=30)**	3 (2-4)	6 (3.3-10)	Cohen's κ ‡ 0.17
% of total sleep time in position (n=35)***:			
Left	59.9 (28.1)	54.4 (26.4)	Spearman's ρ 0.76

Supine	7.8 (20.0)	14.8 (18.7)	Spearman's ρ 0.27
Right	31.3 (27.3)	30.8 (28.5)	Spearman's ρ 0.93

* Count data are presented as: number (%). **Ordinal data presented as: median (interquartile range). ***Continuous data presented as: mean (SD). †Linear/equal weighted Cohen's κ .

‡Unweighted Cohen's κ .

Harms

No participants (including the dropouts) requested to remove the intervention or PSG equipment. There were no known harms related to the interventions or procedures in this study.

DISCUSSION

Principal Findings

Use of the PrenaBelt resulted in a 6.8% absolute reduction (38% relative reduction) in the proportion of sleep time supine in comparison with the sham, and this did not affect maternal sleep architecture or respiration. This 6.8% translates to 23.0 minutes. When time in bed (including both wake and sleep states) was considered, the PrenaBelt resulted in an absolute reduction in supine time of 30.9 minutes (41% relative reduction) in comparison with the sham suggesting that the PrenaBelt reduces time spent supine whether awake or sleeping.

Strengths and Weaknesses in Relation to Other Studies

Our study only included two nights for each participant; therefore, caution should be taken when extrapolating our results across the third trimester with regard to efficacy and compliance – PT in non-pregnant individuals with positional obstructive sleep

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3 apnea (OSA) has sustained efficacy in the long term but decreasing compliance from
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5 93% at 1 month,(35) 74% at three months,(36) and 60% at six months.(37)
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10 In recent studies of PT in non-pregnant individuals with positional OSA, PT devices
11 incorporating active supine sensing technology and vibration mechanisms have been
12 shown to be more effective in reducing supine sleep than inactive pressure-point PT
13 devices like the PrenaBelt.(36,38) In comparison to a study of pressure-point PT in non-
14 pregnant individuals with positional OSA by Heinzer et al.,(36) the PrenaBelt resulted in
15 a lesser reduction in mean proportion of sleep time supine; however, in contrast, we did
16 not have a non-intervention night as Heinzer et al. did. The sham, by intrinsic
17 characteristics, may have caused a reduction in supine sleep in comparison to a non-
18 intervention night. O'Brien and Warland (6) reported a non-interventional, one-night, in-
19 home study of 51 healthy women in their 2nd and 3rd trimester using ambulatory PSG; in
20 a subgroup of participants in their 3rd trimester (n=33), the median proportion of overall
21 sleep time spent supine was 26.5%. McIntyre et al.,(7) in a similar non-interventional,
22 one-night, in-home, ambulatory PSG study in 30 healthy women in the 3rd trimester,
23 reported the median proportion of overall sleep time spent supine to be 19%.
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42 Participants were not asked to adopt or try to maintain any sleep position in either study.
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44 Both of these studies reported a greater median proportion of overall sleep time spent
45 supine than that in the current study (16.4%), which indicates that the sham device may
46 have affected position. This, along with differences inherent to pregnancy (e.g., body
47 habitus, increased sleep disruption) may account for the lesser reduction in mean
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3 proportion of sleep time supine achieved by the PrenaBelt in comparison Heinzer et al.
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10 Zaremba et al. undertook a randomized, cross-over, PSG study in 30 post-partum
11 women sleeping in non-elevated and 45° elevated body position and reported moderate
12 to severe OSA in 20% of the participants.(39) The minimum SpO2 was higher (p 0.03)
13 and AHI was reduced (p 0.03) in the 45° elevated body position in comparison to non-
14 elevated without affecting sleep quantity or quality. This is congruent with our analysis
15 of secondary outcomes, which demonstrated no difference in sleep architecture nor in
16 duration despite a significant difference in body position (less supine time).
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28 Seventy-three percent of participants in the study by McIntyre et al.(7) recalled their
29 sleep onset position accurately (κ 0.52), which is a lower accuracy than our results
30 (85% accurate, κ 0.62) possibly because each of our participants underwent two PSG
31 nights and, after being asked to recall various details about their sleep after their 1st
32 PSG night, may have anticipated these questions again after their 2nd PSG night. Forty
33 percent of McIntyre et al.'s participants recalled their waking position accurately (κ
34 0.24), which is a lower accuracy than our results (70% accurate, κ 0.42). Being an
35 ambulatory PSG, McIntyre et al.'s study did not include electroencephalography (EEG)
36 – they estimated sleep and wake times by pre-defined video criteria (i.e., lack of
37 movement) and not by brain activity and noted that this may have introduced
38 discrepancy between their participants' self-reports and the video assessment criteria,
39 thus reducing their calculated accuracy. We reported a weak relationship (κ 0.24)
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3 between sleep onset and waking position via PSG-determination, whereas previous
4 studies have reported discrepant results – McIntyre et al. reported no relationship (κ -
5 0.13) via video-determination, and the Auckland Stillbirth Study reported a strong
6 relationship (Pearson r 0.72) via self-reports;(2), however, our study has shown self-
7 reports of sleep onset and waking position to have only moderate and weak agreement
8 with the gold standard (PSG), respectively, which points to reliance on non-PSG
9 methods (e.g., self-reports) as a potential source of this discrepancy.
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21 Warland and Dorrian reported a three-night observational study of 30 healthy women in
22 late pregnancy and found moderate basic correlation between self-reported and video-
23 determined time on the left ($r=0.418$);(40) however, they did not report correlations for
24 right or supine sleep. We report a good correlation between self-reported and PSG-
25 determined time on the left (Spearman's ρ 0.76, $p<0.01$). Notably, we found poor
26 correlation between self-reports and PSG-determined supine time and that pregnant
27 women tend to underestimate this value, which could have significant clinical
28 implications if supine sleep needs to be avoided and self-reports are relied upon by
29 maternity care providers for risk stratification. There are only two other studies
30 investigating reliability of adults' self-reports of sleep position;(41,42) both consist of
31 non-pregnant adults, have conflicting results with each other, and are not reported in
32 adequate detail for comparison to our results.
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51 In the non-pregnant population, approximately 20% of a typical night's sleep is spent in
52 the REM state and 80% is spent in the NREM state. The sleep architecture in the
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3 current study is consistent with previously reported patterns during pregnancy, that is,
4 reduced slow-wave sleep (SWS), REM sleep, and sleep efficiency.(43–47)
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10 **Meaning of the Study**

11 The previous studies by Owusu et al.(1) and O'Brien and Warland (6) recommended the
12 development and testing of a PT device for pregnant women. In our study, a PT
13 intervention was implemented in a population of healthy, third-trimester, pregnant
14 women during sleep in a clinical sleep laboratory environment over two nights. This
15 study extends the work of Stacey et al.,(2) Gordon et al.,(3) McCowan et al.,(4) and
16 Warland and Mitchell (48) by finding that supine sleep position in late pregnancy can be
17 reduced with PT.
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31 Left side sleeping is common among pregnant women. This may be a more comfortable
32 position but also may be related to the “sleep-on-side” messages prevalent on the
33 internet and among maternity care providers. Women in our study preferentially settled
34 to sleep on their left for 73% of the nights and right for 20% of the nights. This is
35 corroborated by McCowan et al.(4) who reported a significant increase in left-sided
36 going-to-sleep position (43% to 58%) and small decrease in supine going-to-sleep
37 position (5% to 3.8%) in New Zealand over an approximate 5 year period following
38 publicity of The Auckland Stillbirth Study by Stacey et al.(2) If the supine sleeper is to be
39 identified by history-taking and stratified for targeted education or intervention,
40 obstetricians, midwives, and nurses should be aware that despite sleep-on-side
41 knowledge and high rates of lateral going-to-sleep position, most pregnant women
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3 continue to spend a significant amount of time supine during sleep in late pregnancy.
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5 Also, pregnant women's estimates of time in each sleep position, while relatively
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7 accurate for lateral sleeping positions, underestimate the time they spend supine. This
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9 suggests that any public health education campaign may need to recommend
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11 interventions to prevent unintentional supine positioning during sleep.
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16 17 **Strengths**

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19 Strengths of this study include its robust design and use of the gold-standard sleep
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21 diagnostic test in a controlled laboratory setting. The sham intervention ensured that on
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23 the sham PSG night, participants received any specific benefit of any element of the
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25 PrenaBelt above and beyond all benefits that might be attributed to its ability to cause
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27 pressure points and, thus, reduced treatment bias. The cross-over allowed each
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29 participant to serve as her own control for comparison of intervention effect on
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31 outcomes. Allocation concealment and randomization of participants to intervention
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33 order helped avoid allocation bias and the potential impact of changes to sleep across
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35 the two PSG nights that could have resulted from familiarization with the equipment and
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37 environment. Blinding of the participants, RAs, Registered PSG Technicians, and the
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39 sleep specialist physician further reduced potential sources of bias and strengthened
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41 data integrity.
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49 **Weaknesses**

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51 Weaknesses of this study included that we had no baseline sleep data to which we
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53 could compare the PrenaBelt and sham nights; therefore, conclusions cannot be made
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3 regarding the effect, if any, of the PrenaBelt on sleep architecture and respiration in
4 relation to no intervention. Participants' unfamiliarity with the sleep environment also
5 may have affected sleep quantity and quality; however, we were unaware of any impact
6 reported by participants. On the 2nd PSG night, participants were exposed to the
7 alternate intervention and could have unblinded themselves if they remembered what
8 the intervention felt like on the 1st PSG night; however, we are unaware of what effect
9 this may have had. Finally, the current study was relatively small and conducted in a
10 cohort of healthy, non-obese, and majority Caucasian pregnant women.
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24 **Future Research**

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26 To date, it is unclear whether formal advice, given by a maternity care provider to a
27 pregnant woman, about sleeping position in late pregnancy is less, as, or more effective
28 in reducing supine sleep in comparison to a PT device such as the PrenaBelt. Future
29 research comparing advice versus a PT intervention in the home setting is imperative. If
30 sleeping supine is potentially harmful to the fetus, the amount of supine time that is
31 harmful needs quantification in order to target interventions to avoid this. Given that
32 estimations of time in each body position during sleep are based on the recollection of
33 an unconscious state and thus inherently inaccurate, future research should not rely on
34 self-reports but should incorporate an objective measure of body position during sleep
35 throughout the third trimester allowing body position to be directly linked to pregnancy
36 outcomes. Large, multi-ethnic studies that include women with a range of pregnancy
37 and health conditions are imperative to refute or confirm the findings.
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OTHER INFORMATION

Registration: This trial was registered at ClinicalTrials.gov, NCT02377817, on 17 February 2015 (<https://clinicaltrials.gov/ct2/show/NCT02377817>).

Protocol: Full details of the trial protocol can be found in the Supplementary Appendix, available with the full text of this article at [\[link\]](#).

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Contributors: AK designed the protocol, secured funding, ethics approval, and the research contract, trained the study personnel, maintained the study master record, facilitated PSG studies as an unblinded personnel, monitored data collection, cleaned and analyzed the data, and drafted and revised the paper. He is guarantor. AK and AB conceptualized the PrenaBelt. KC designed and manufactured the PrenaBelt research samples. DM, HS, LMO, AB, MB, KC, and AI designed the protocol. HS oversaw participant recruitment and was the Principal Investigator responsible for all aspects of the trial. DM was the Supervising Investigator, oversaw the PSG studies at the trial site, and interpreted the PSG studies. MB wrote the statistical plan and oversaw the

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3 statistical analysis. JW maintained the study master record, facilitated PSG studies as
4 an unblinded personnel, monitored data collection, and cleaned and analyzed the data.
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7 AI negotiated the research contract and managed the trial funds. DM, HS, LMO, AB,
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10 JW, MB, KC, and AI made intellectual contributions to the paper.
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15 at www.icmje.org/coi_disclosure.pdf and declare: Dr. Borazjani reports grants from
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25 submitted work, no financial relationships with any organizations that might have an
26 interest in the submitted work in the previous three years, and no other relationships or
27 activities that could appear to have influenced the submitted work.
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3 B. Atlee Endowment Award. Grand Challenges Canada is funded by the Government of
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5 Canada.
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10 **Data Sharing:** Statistical code and complete dataset are available from the Dryad
11 repository, DOI: [Will insert DOI for dataset here. Per Dryad, BMJ Open has "integrated
12 article submission with data submission", meaning we will submit our manuscript first,
13 then await journal instructions for data submission and review.]
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Figures and Tables:

Fig. 1. PrenaBelt; BPS = Body Position Sensor.

Fig 2. Enrollment, allocation, and analysis of trial participants.

Fig. 3. Scatter plot of proportion of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).



Fig. 1. PrenaBelt; BPS = Body Position Sensor.

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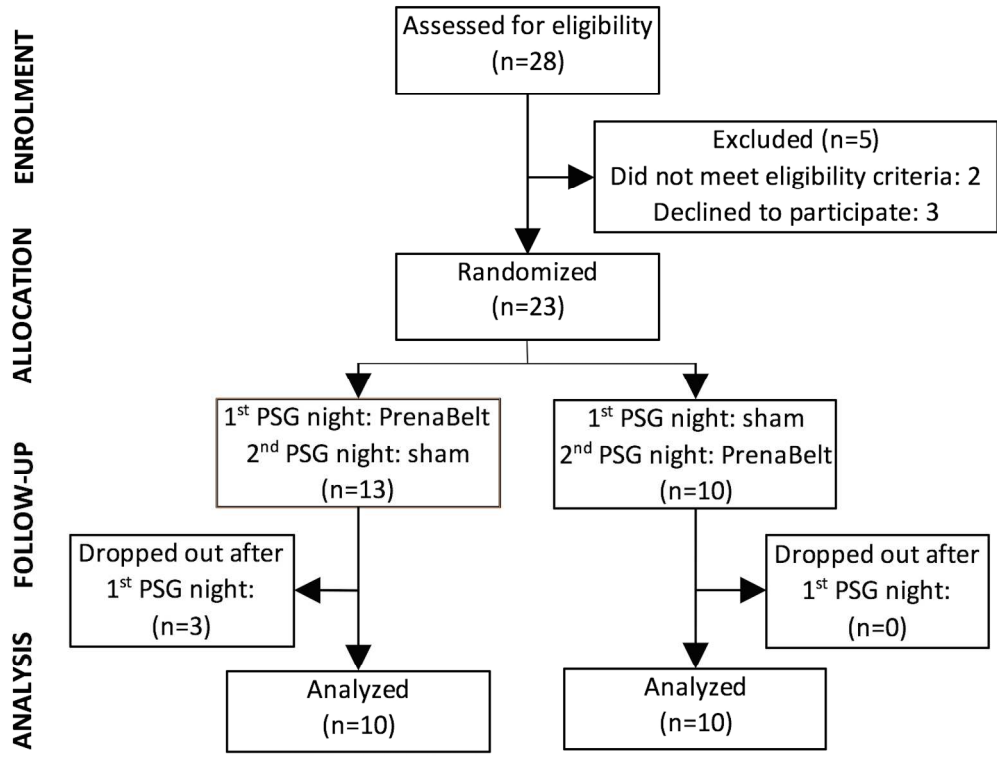


Fig. 2. Enrollment, allocation, and analysis of trial participants.

225x171mm (300 x 300 DPI)

BMJ Open: first published as 10.1136/bmjopen-2017-020256 on 29 August 2018. Downloaded from <http://bmjopen.bmj.com/> on April 20, 2024 by guest. Protected by copyright.

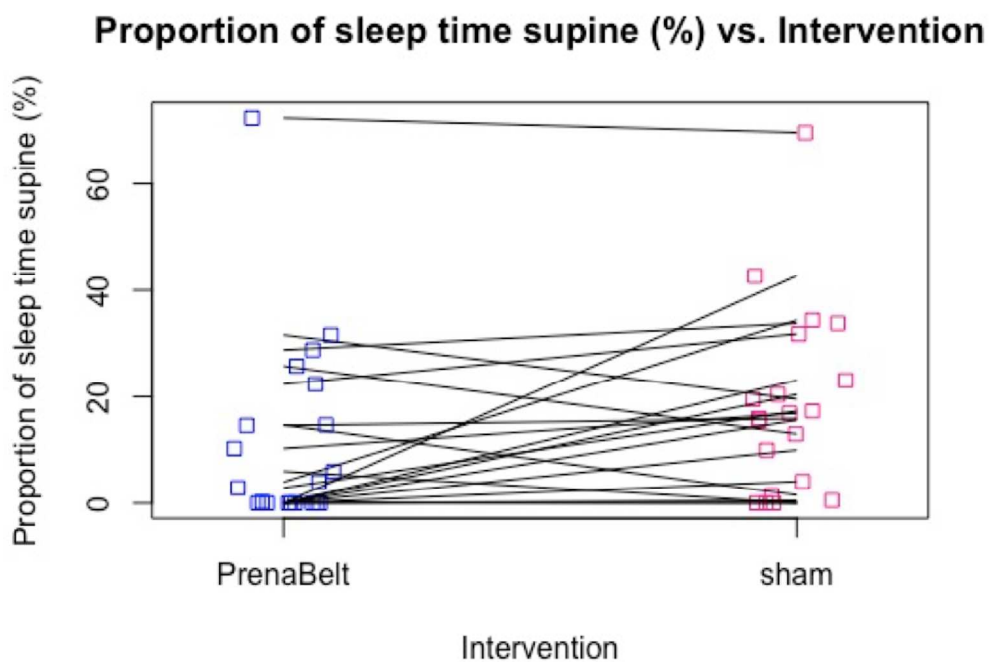


Fig. 3. Scatter plot of proportion of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

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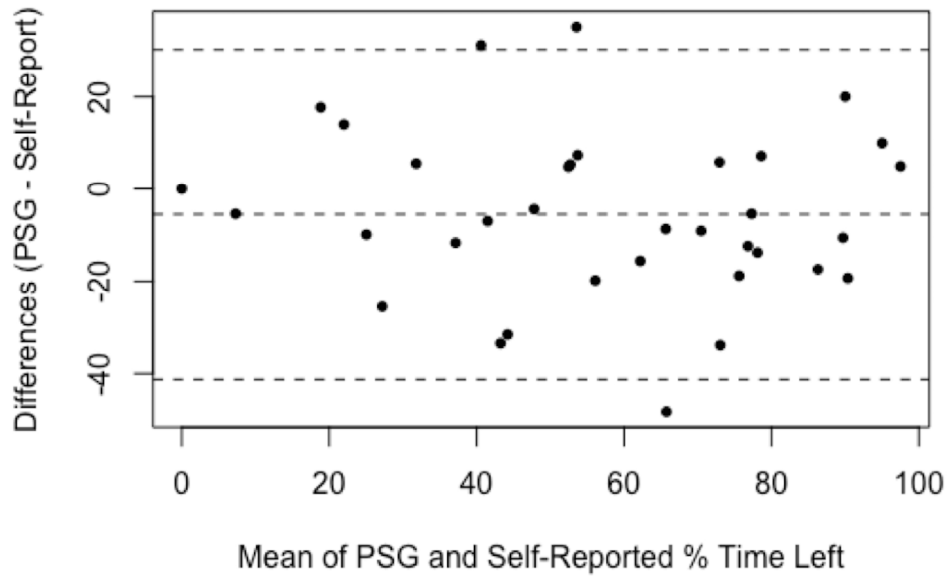


Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

216x162mm (300 x 300 DPI)

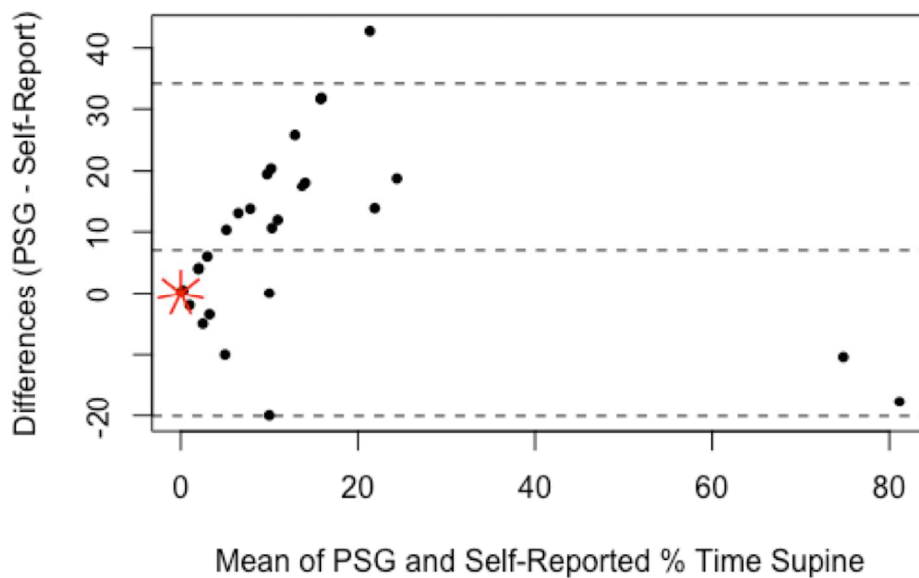


Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

216x162mm (300 x 300 DPI)

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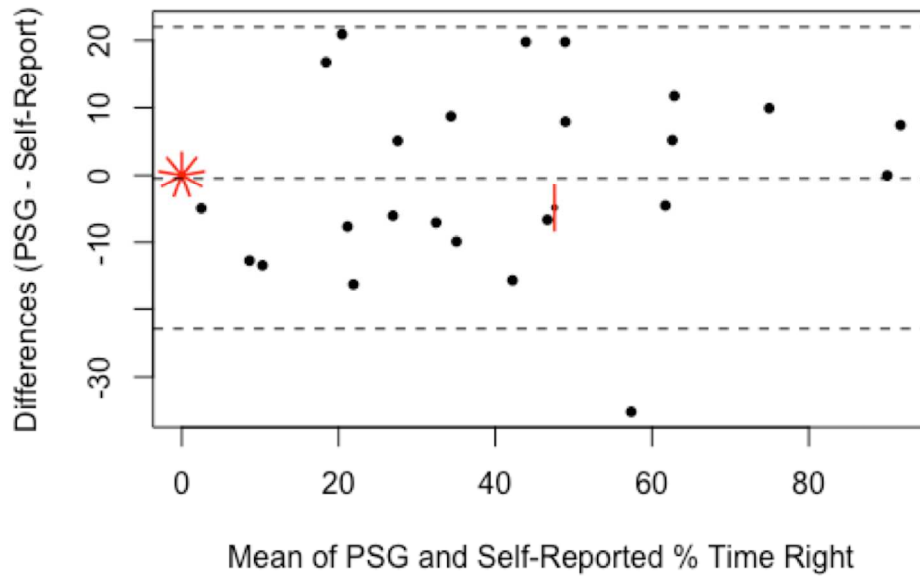


Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

216x162mm (300 x 300 DPI)

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	8
Sample size	7a	How sample size was determined	8-9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	9
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9, 5, 9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7, 9-10

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2		assessing outcomes) and how	
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4		11b If relevant, description of the similarity of interventions	6-7
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	10
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
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8	Results		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	Fig. 2, pages
10	diagram is strongly	were analysed for the primary outcome	10-11
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	10-11
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	10
13		14b Why the trial ended or was stopped	11
14	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	12
15	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	11
16		by original assigned groups	
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18	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	13-16
19	estimation	precision (such as 95% confidence interval)	
20		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
21	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	n/a
22		pre-specified from exploratory	
23			
24	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	16
25			
26	Discussion		
27	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16-20, 21-22
28	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	20-22
29	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16-21
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31	Other information		
32	Registration	23 Registration number and name of trial registry	2, 23
33	Protocol	24 Where the full trial protocol can be accessed, if available	23
34	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	24
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37 *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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BMJ Open

Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with Positional Therapy: A Pilot Trial

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Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	General practice / Family practice, Global health, Respiratory medicine, Neurology, Public health
Keywords:	SLEEP MEDICINE, STILLBIRTH, Maternal medicine < OBSTETRICS, Respiratory physiology < THORACIC MEDICINE, Fetal medicine < OBSTETRICS

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Title: Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with Positional Therapy: A Pilot Trial

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Word Count: 4330

ABSTRACT:

OBJECTIVE: To evaluate whether the percentage of time spent supine during sleep in the third trimester of pregnancy could be reduced using a positional therapy device (PrenaBelt) compared with a sham device.

DESIGN: A double-blind, randomized, sham-controlled, crossover trial.

SETTING: Conducted between March 2016 and January 2017, at a single, tertiary-level center in Canada.

PARTICIPANTS: Twenty-three participants entered the study. Twenty participants completed the study. Participants were low-risk, singleton, third-trimester pregnant women aged 18 years and older with BMI <35 at the first antenatal appointment for the index pregnancy and without known fetal abnormalities, pregnancy complications, or medical conditions complicating sleep.

INTERVENTIONS: A two-night, polysomnography study in a sleep laboratory. Participants were randomized by computer-generated, one-to-one, simple randomization to receive either a the PrenaBelt or a sham-PrenaBelt on the 1st night and were crossed over to the alternate device on the 2nd night. Allocation concealment was by unmarked, security-tinted, sealed envelopes. Participants, the recruiter, and personnel involved in setting up, conducting, scoring, and interpreting the polysomnogram were blinded to allocation.

PRIMARY AND SECONDARY OUTCOME MEASURES: The primary outcome was the percentage of time spent supine during sleep. Secondary outcomes included maternal sleep architecture, respiration, self-reported sleep position, and feedback.

RESULTS: The PrenaBelt resulted in an absolute reduction in the mean percentage of sleep time supine by 6.8% (95%CI: 0.3 to 13.3; p=0.04), which translates to a 24.4 minute (95% CI: 3.9 to 44.8; p=0.01) reduction. We were unable to demonstrate differences in sleep architecture or respiration. Participants underestimated the time they spent sleeping supine by 7.0%, and six (30%) participants indicated they would make changes to the PrenaBelt. There were no harms in this study.

CONCLUSIONS: This study demonstrates that the percentage of sleep time supine during late pregnancy can be significantly reduced via positional therapy.

TRIAL REGISTRATION: ClinicalTrials.gov NCT02377817

Strengths and limitations of this study:

- A double-blind, randomized, sham-controlled, cross-over pilot trial.
- Employed polysomnography, the gold-standard test for investigating sleep physiology and pathophysiology.
- The first to investigate positional therapy during sleep in pregnancy.
- Performed in a controlled sleep laboratory setting over two nights; therefore, caution should be taken when extrapolating the results to the home setting and across the third trimester.
- Due to the small sample, may have been underpowered.

INTRODUCTION

Background

Stillbirth (SB) and low birth weight (LBW) are devastating complications of pregnancy. Recently, five studies have demonstrated an association between maternal supine sleep position in late pregnancy and the risk of late term SB (1–5) and LBW.(1) The population attributable risk of supine sleep for SB has been reported as being between 3.7% and 37%,(1–5) suggesting that a significant proportion of late term SB could be averted if supine sleep was avoided. A number of major risk factors for SB and LBW are not modifiable in the course of the pregnancy (e.g., elevated BMI, advanced maternal age); however, maternal supine sleep is potentially modifiable with the majority of third-trimester pregnant women spending up to 25% of their sleep time supine.(6–8)

The contribution of supine sleep to LBW and SB is biologically plausible due to inferior vena cava compression by the gravid uterus, affecting maternal hemodynamics (9–22) and fetal oxygenation.(14,23–25) The supine position also exacerbates sleep disordered breathing (SDB),(26,27) which has been linked to adverse pregnancy outcomes.(28–30) In persons with mild to moderate SDB, the majority experience most of their breathing abnormalities while sleeping supine.(31) Positional therapy (PT) is a simple, safe, and effective treatment that helps individuals with SDB maintain a lateral position while sleeping, thus significantly reducing or eliminating their breathing abnormalities.(31,32) Drawing on the concept of PT for SDB, the authors (AK, AB, KC) designed a PT device for pregnant women called “PrenaBelt” to minimize supine sleep (Fig. 1.).

Objectives

The primary objective was to evaluate whether the percentage of time spent supine during sleep in the third trimester of pregnancy could be reduced using the PrenaBelt when compared with a sham. Secondary objectives were to evaluate the effect of the PrenaBelt on maternal sleep architecture and respiration in comparison with a sham, evaluate the accuracy of maternal self-reported sleep position, and collect feedback from the participants regarding the PrenaBelt.

METHODS

Pilot Trial Design

A single-center, double-blind, randomized (one-to-one), sham-controlled, crossover trial. No methodological changes were made after trial commencement.

Patient and Public Involvement

Patients and the public were not involved in the development of the research question or outcome measures, design of the study, recruitment process, or conduct of the study. During the consent process, participants indicated whether they wished to receive a copy of their personal study results and/or a summary of the overall study results (to be shared by email).

Participants

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3 Participants were recruited by a trained nurse at the IWK Health Centre – a tertiary and
4 primary care center for women and children with approximately 5000 newborns
5 delivered per year. Overnight polysomnograms (PSGs) were conducted at the Queen
6 Elizabeth II (QEII) Health Sciences Centre Sleep Disorders Clinic. The IWK and QEII
7 are teaching hospitals associated with Dalhousie University in Halifax, Canada. Halifax
8 has a population of approximately 400,000. Participants expressing interest in the study
9 (paper flyer, online advertisement) were screened.
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21 Participants were eligible if they had a low-risk singleton pregnancy and were 18 years
22 of age or older, more than 20 weeks gestation at screening, and residing in the Halifax
23 Regional Municipality. Exclusion criteria included BMI ≥ 35 at the first antenatal
24 appointment for the current pregnancy, pregnancy complicated by obstetric conditions
25 (e.g., hypertension, diabetes, intra-uterine growth restriction), sleep complicated by any
26 medical conditions (e.g., known obstructive sleep apnea, insomnia, musculoskeletal
27 deformity affecting sleep position), multiple pregnancy, known fetal-abnormality, and
28 non-English speaking and reading.
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42 All participants in the trial gave written informed consent. This trial was approved by the
43 IWK Health Centre Research Ethics Board in June 2015 (Project No. 1018753). There
44 was no independent data monitoring committee.
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51 Interventions

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3 There was no run-in measurement of baseline sleep habits. Each participant underwent
4 two overnight PSG studies between 28-37 weeks gestation. The study nights were not
5 required to be consecutive dates, and we did not specify a defined washout period. The
6 only difference between the two nights was the intervention (PrenaBelt or sham) and
7 that participants completed a demographic questionnaire on the 1st PSG night only. The
8 PrenaBelt is worn at the level of the waist and has four firm plastic balls embedded into
9 foam inserts within the pockets posteriorly (**Fig.1**). The mechanism of action of the
10 PrenaBelt is theoretical and based on the tennis-ball technique of PT:(33–35) when
11 supine, the balls apply pressure points across the user's lower back, prompting her to
12 reposition herself in a lateral position to maintain comfort. The sham was identical in
13 appearance, materials, and construction to the PrenaBelt, but had soft foam balls
14 instead of firm plastic balls and did not have foam inserts; as such, the sham did not
15 provide pressure points. Participants crossed over to the alternative intervention on the
16 2nd PSG night.

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38 PSG set-up was by trained research assistants (RAs), in accordance with the American
39 Academy of Sleep Medicine 2014 guidelines,(36) and in a private clinical room with
40 continuous monitoring by an RA in a separate room through audio/visual and Embla
41 Sandman Elite sleep diagnostic software (Natus Medical Incorporated, Pleasanton,
42 USA).

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51 Immediately before the participant settled to sleep, the unblinded research personnel
52 (co-PI [AK] or study coordinator [JW]) entered the room to assist her in donning the
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3 assigned intervention (PrenaBelt/sham) without disclosing the identity of the intervention
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5 to the participant or the RA in order to maintain blinding. Upon waking for the day, the
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7 participants immediately removed the intervention and placed it in an opaque closed
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9 box for collection by the unblinded personnel in order to keep it concealed from the RA.
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11 The RA subsequently entered the room and unhooked the PSG equipment. The
12
13 participant completed a feedback questionnaire and placed it in a sealed envelope for
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15 the unblinded personnel. The questionnaire elicited participants' perceptions of body
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17 position at sleep onset and waking, changes in position and reason for changes, and
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19 estimates of percentage/time spent in each position during sleep. Participants also
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21 ranked their satisfaction, comfort level, and intention to continue using the PrenaBelt (if
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23 it were available) on a 10-point Likert scale (with 10 out of 10 reflecting the highest
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25 satisfaction, comfort, and intention to use, and 1 out of 10 the lowest). Participants were
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27 permitted bathroom breaks and to remove the intervention and/or PSG equipment at
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29 any point if they became uncomfortable.
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38 Scoring of PSG's was performed by blinded Registered PSG Technicians, and
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40 interpretation was by a blinded sleep medicine physician (DM).
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44 **Outcomes**

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46 The primary outcome, percentage of time spent supine during sleep, was documented
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48 continuously by an RA via video feed.
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3 Respiration was measured using respiratory inductance plethysmography (Philips
4 Resironics Pro-Tech zRIP Durabelt, Murrysville, USA). Airflow, including snoring, was
5 measured by differential pressure transducers (BRAEBON Medical Corporation PT1,
6 Kanata, Canada) and via audio by an RA. Maternal peripheral oxygen saturation (SpO₂)
7 was measured via fingertip pulse oximetry. Electrodes (Natus Medical Incorporated,
8 Pleasanton, USA) for electrocardiography (ECG), electroencephalography (EEG),
9 electrooculography (EOG), and electromyography (EMG) were applied for
10 determination of maternal heart rate, sleep architecture, and leg movements.
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24 No changes were made to the trial outcomes after trial commencement.
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28 **Sample Size**

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30 This is the first trial investigating PT in pregnant women to reduce supine sleep time.
31 For a one-sided paired t-test with power (β) of 0.80, significance level (α) of 0.05, and
32 detectable effect (d) of -0.5 (difference in mean percentage of time spent sleeping
33 supine by half a standard deviation), which is a medium effect size per the literature
34 regarding Cohen,(37) a sample size of twenty-five (n=25) participants was required. All
35 statistical analyses were conducted using the R Statistical Software package (version
36 3.2.4 (2016-03-10)).(38) There was no planned interim analysis or stopping guidelines.
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49 **Randomization**

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51 Participants were allocated by computer-generated (R), one-to-one, simple
52 randomization into one of two possible crossover schemes: PrenaBelt on the 1st PSG
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3 night followed by sham on the 2nd PSG night, and vice versa (**Fig. 2.**). Allocation
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6 sequence was concealed via unmarked, security-tinted, sealed envelopes by an
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8 independent statistician (MB). An envelope was drawn in sequence, opened, and the
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10 participant's name and birth date were recorded on the enclosed allocation sheet by the
11
12 unblinded personnel (AK, JW) on the participant's first PSG night.
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15 16 17 **Blinding**

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19 Participants, the recruiter, and personnel involved in setting up, conducting, scoring,
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21 and interpreting the PSG were blinded to allocation. The only research personnel
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23 unblinded to the allocation were the co-PI (AK) and the study coordinator (JW), which
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25 was required in order to provide the appropriate intervention to the participant before
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27 she went to sleep. It was not feasible to blind the researchers analyzing the study data
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29 (AK, JW, MB) to the allocation.
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35 36 37 **Statistical Methods**

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39 In the primary analysis, we specified a linear mixed-effects model with the percentage of
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41 time spent supine during sleep as the response variable and the interventions
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43 (PrenaBelt, sham) as the fixed effects. To account for the cross-over design,
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45 participants and PSG night (1st or 2nd) were treated as random effects.
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50 Secondary outcomes were compared between interventions by paired t-tests (normal)
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52 and Wilcoxon signed rank tests (non-normal). Cohen's Kappa (κ) was used to assess
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3 agreement between categorical variables. Spearman's Rho (ρ) and Bland-Altman plots
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5 were used for continuous variables.
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10 For continuous variables, normality was assessed using Q-Q plots and Anderson-
11 Darling test. All testing was performed at a 0.05 significance level. Treatment effects
12 (differences in means and odds ratio) and associated confidence intervals were
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14 presented at a 95% confidence level with p-values.
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21 RESULTS

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23 Between March 2016 and January 2017, 28 participants were assessed for eligibility
24 (Fig. 2.). Following exclusion of three (11%) who declined participation and two (7%)
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26 who failed to meet eligibility criteria, 23 were randomized. After randomization, there
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28 were three (13%) dropouts – all from the PrenaBelt-then-sham group and after
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30 completing the 1st PSG night. Two were due to transportation/childcare reasons, and
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32 one was due to an unrelated injury preventing her from sleeping in a horizontal position.
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34 Thus, twenty participants – ten from each group – were included in the primary analysis,
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36 which was by original assigned groups and on a complete-case basis (drop-outs
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38 excluded). The originally planned sample size of 25 participants was not reached due to
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40 unforeseen budget restrictions preventing recruitment beyond 20 participants. The
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42 length of time between studies for the same participant (washout period) was a median
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44 of 1 day (IQR 1 – 3.25 days; maximum 13 days).
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54 Sample Characteristics

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3 Baseline demographic, obstetric, and sleep habit characteristics (see **Supplementary**
4 **File 1**) of the 20 participants who completed the study are shown in **Table 1** per
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6 randomized group (n=10 each). The two randomized groups were well balanced with
7
8 respect to the sample characteristics – there were no statistically significant differences
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10 in baseline characteristics between groups ($\alpha=0.05$). The mean (SD) age was 30.9 (5.0)
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12 years. The majority (80%) were Caucasian. The mean (SD) pre-pregnancy BMI was
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14 26.6 kg/m² (3.3) and rose to a mean of 30.4 kg/m² (3.6) at the time of the 1st PSG,
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16 which took place at a median (IQR) gestational age of 30.0 weeks (28-33.1). Half (50%)
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18 of the participants were nulliparous.
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26 The median (IQR) self-reported overnight sleep duration at the time of the 1st PSG was
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28 8 (7-8) hours. In the week previous to the 1st PSG (when pregnant), left was the most
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30 common position at sleep onset (85%) and waking (60%), although a large proportion of
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32 women also reported the supine position at sleep onset and waking (25% and 40%,
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34 respectively). When not pregnant, prone was the most common position at sleep onset
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36 (65%), and supine was the most common at waking (55%). Most participants used a
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38 pillow under their head (90%) and between their knees (70%).
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45 In comparing baseline demographic, obstetric, and sleep habit characteristics between
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47 the participants who completed the study (n=20) and those who did not (n=3), the
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49 groups were similar; however, participants who did not complete the study were
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51 younger (mean 26.7 years), had a higher current BMI (mean 32.5 kg/m²), and had less
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53 self-reported overnight sleep duration (mean 6.8 hours).
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Table 1 | Baseline demographic, obstetric, and sleep habit characteristics*

	PrenaBelt-then-sham (n=10)	sham-then-PrenaBelt (n=10)
Age (years)	31.1 (6.0)	30.7 (4.1)
Caucasian ethnicity	6 (60%)	10 (100%)
Pre-pregnancy BMI (kg/m ²)	27.0 (3.3)	26.2 (3.5)
Current BMI (kg/m ²)	30.9 (3.7)	29.9 (3.6)
Gestational age (weeks)	30.9 (3.0)	30.8 (2.8)
Gravida		
1	4 (40%)	6 (60%)
≥2	6 (60%)	4 (40%)
Sleep duration (hours)	8.0 (7.5-8.0)	7.8 (7.0-8.0)
In the last week:		
Sleep onset positions:		
Left	7 (70%)	10 (100%)
Supine	3 (30%)	2 (20%)
Right	8 (80%)	3 (30%)
Prone	1 (10%)	0 (0%)
Waking positions:		
Left	8 (80%)	4 (40%)
Supine	4 (40%)	4 (40%)
Right	5 (50%)	6 (60%)
Prone	0 (0%)	0 (0%)
When not pregnant:		
Sleep onset positions:		
Left	2 (20%)	3 (30%)
Supine	3 (30%)	3 (30%)
Right	2 (20%)	4 (40%)
Prone	7 (70%)	6 (60%)
Waking positions:		
Left	5 (50%)	4 (40%)
Supine	4 (40%)	7 (70%)
Right	5 (50%)	2 (20%)
Prone	5 (50%)	4 (40%)
Snores ≥3 nights per week	4 (40%)	3 (30%)
Sleeps with bed partner	7 (70%)	10 (100%)
Pillow use		
Under head	9 (90%)	9 (90%)
Between knees	8 (80%)	6 (60%)
Behind back	3 (30%)	5 (50%)
Under tummy	3 (30%)	4 (40%)
Pregnancy pillow	4 (40%)	1 (10%)

Normally distributed continuous variables are reported as mean (SD). Non-normally distributed continuous variables are presented as median (IQR). Count data are presented as frequency (%). Percentages for responses to some questions may add to greater than 100% because some participants checked more than one box in response to a question, e.g., for sleep onset position in the last week, some responded "left" and "right".

Primary Outcome

The primary outcome (see **Supplementary File 2**) was not normally distributed. The median (IQR) percentage of sleep time supine on the PrenaBelt night (n=20) and sham night (n=20) was 3.5% (0-16.6) and 16.4% (3.5-25.3), respectively (**Table 2, Fig. 3.**).

The linear mixed-effects model estimate of the difference in means was -6.8% (95% CI: -13.3 to -0.3, p=0.04).

Table 2 | Primary outcome: percentage of sleep time supine

	PrenaBelt night (n=20)	sham night (n=20)	PrenaBelt minus sham Difference (95%CI)	p-value
Median	3.5	16.4		
IQR	0 to 16.2	3.5 to 25.3		
Mean (SD)	11.7 (17.9)	18.5 (17.6)	-6.8* (-13.3 to -0.3)	0.04

*Linear mixed effects model

Secondary Outcomes

The estimates, 95% confidence intervals (CI), and p-values for the intervention-associated differences, PrenaBelt versus sham, in the sleep and respiratory variables (see **Supplementary File 2**) and user feedback (see **Supplementary File 3**) are shown in **Table 3**. The median (IQR) number of minutes spent sleeping supine and right-lateral was 38.9 (0-72.7) and 90.8 (0-166.1), respectively. The mean (SD) number of minutes spent sleeping left-lateral was 180.9 (97.7). The mean (SD) percentage of time spent sleeping in the left-lateral and right-lateral positions was 54.6% (26.7) and 30.3% (27.8), respectively. No time was spent sleeping prone.

Regarding sleep architecture for the complete sample (n=40 nights), the median (IQR) sleep time was 352 minutes (318-374), sleep efficiency 82% (76-89), and sleep latency 12.8 minutes (6.7-23.9). The median (IQR) total arousal index was 11.3 (8.4-18.0),

spontaneous arousal index 9.8 (7.0-12.0), periodic leg movement arousal index 0 (0-0.8), and respiratory arousal index 0.4 (0-1.0). The mean (SD) percentage of stage 1 sleep was 9.4% (5.6), stage 2 sleep 62.7% (7.9), stage 3 sleep 11.2% (8.3), and REM sleep 16.7% (5.6). For respiratory variables, the median (IQR) apnea-hypopnea index was 0.5 (0-1.5), respiratory effort-related arousal index 0 (0-0.2), respiratory disturbance index (RDI) 0.6 (0-1.6), RDI supine 0 (0-0.9), RDI non-supine 0.5 (0-1.6), peripheral oxygen saturation (SpO₂) maximum and minimum during REM sleep were 98% (98-99) and 92% (90-94), respectively, and SpO₂ maximum and minimum during NREM sleep were 99% (98-100) and 92% (91-94), respectively. The mean (SD) SpO₂ during REM and NREM sleep was 96.0 (1.2) and 96.2 (1.0), respectively. Presence of snoring was detected on 26 of 40 (65%) nights. Six participants (30%) indicated that they would make changes to the PrenaBelt – of these, five were with regard to comfort and one was with regard to sizing. There were no statistically significant differences in sleep architecture, respiration, or user feedback between the PrenaBelt and sham nights on paired testing (n=20 pairs) (**Table 3**).

Table 3 | Secondary outcomes: time supine, sleep architecture, respiration, user feedback

	PrenaBelt (n=20)	sham (n=20)	PrenaBelt minus sham Difference (95%CI)	p-value
Total sleep time (minutes)	353 (318-376)	350 (318-374)	-3.6 [†] (-33.8 to 21.8)	0.81
Supine sleep (minutes)	12.3 (0-53.5)	56.8 (12.4-79.1)	-24.4* (-44.8 to -3.9)	0.01
Left-lateral sleep (minutes)	185.6 (102.5)	176.1 (95.2)	9.5 [‡] (-24.3 to 43.3)	0.56
Right-lateral sleep (minutes)	108.9 (110.1)	101.9 (100.9)	6.9 [‡] (-22.9 to 36.7)	0.63
Percentage sleep left (%)	57.0 (26.9)	52.2 (27.0)	4.8 [‡] (-5.1 to 14.8)	0.32
Percentage sleep right (%)	31.3 (28.8)	29.3 (27.5)	2.0 [‡] (-6.0 to 10.1)	0.60
Sleep latency (minutes)	11.7 (6.7-21.9)	14.5 (7.2-26.2)	2.0 [†] (-7.2 to 9.4)	0.65
Sleep efficiency (%)	81 (76-89)	83 (79-88)	-1.4 [†] (-5.9 to 3.0)	0.46
Total arousal index	11.2 (8.1-18.0)	12.0 (8.5-15.6)	0.60 [†] (-1.5 to 3.5)	0.59
Spontaneous arousal index	10.5 (5.8)	10.3 (5.5)	0.20 [‡] (-2.2 to 2.6)	0.86
PLM arousal index	0 (0-1.0)	0.1 (0-0.7)	0.3 [†] (-1.5 to 16.0)	0.68
Respiratory arousal index	0.4 (0-1.1)	0.4 (0-1.0)	0.1 [†] (-0.5 to 2.1)	0.78
Percent stage 1 sleep (%)	9.1 (5.2)	9.6 (6.0)	-0.50 [‡] (-2.3 to 1.3)	0.56
Percent stage 2 sleep (%)	64.5 (7.4)	61.0 (8.1)	3.5 [‡] (-0.3 to 7.3)	0.07

Percent stage 3 sleep (%)	10.9 (8.0)	11.5 (8.8)	-0.63 [‡] (-2.6 to 1.4)	0.52
Percent REM sleep (%)	15.5 (6.4)	18 (4.6)	-2.5 [‡] (-5.1 to 0.05)	0.05
Apnea Hypopnea Index	0.5 (0-1.5)	0.5 (0-1.5)	-0.14 [†] (-0.8 to 0.4)	0.51
RERA index	0 (0-0.1)	0 (0-0.3)	0.15 [†] (-0.4 to 4.6)	0.78
Respiratory disturbance Index	0.65 (0-1.5)	0.55 (0.15-1.75)	0.2 [†] (-0.6 to 1.2)	0.67
RDI while supine	0 (0-0)	0 (0-1.2)	-1.3 [†] (-11.2 to 2.4)	0.48
RDI while non-supine	0.2 (0-1.5)	0.5 (0-1.75)	-0.05 [†] (-0.85 to 1.0)	0.92
SpO2 during REM (%)				
Maximum	98 (98-99)	98.5 (98-99)	0.0 [†] (-1.0 to 0)	0.28
Mean	95.8 (1.2)	96.2 (1.2)	-0.46 [‡] (-1.1 to 0.15)	0.13
Minimum	92.5 (90.8-94)	92 (89-94)	0.5 [†] (-1.0 to 2.5)	0.40
SpO2 during NREM (%)				
Maximum	99.0 (98-100)	99 (98-100)	0.5 [†] (-1.0 to 1.5)	0.46
Mean	96.1 (0.88)	96.4 (1.0)	-0.29 [‡] (-0.71 to 0.14)	0.17
Minimum	92 (91-94)	92.5 (89-94)	0.5 [†] (-0.5 to 2.5)	0.26
Presence of snoring	15 (75%)	11 (55%)	2.4 ^{**} (0.54 to 11.9)	0.32
Satisfaction (out of 10)	7.5 (6.0-8.3)	7.5 (5.5-9.0)	-0.28 [‡] (-1.0 to 0.5)	0.46
Comfort (out of 10)	9.0 (6.8-9.3)	9.0 (7.8-10)	-1 [†] (-2.8 to 0)	0.06
Intention to use (out of 10)	8.0 (5.8-8.0)	7.0 (6.0-9.0)	-0.1 [‡] (-1.0 to 0.8)	0.81

Normally distributed continuous variables are reported as mean (SD), and paired t-test is used to test for difference and indicated by [‡]. Non-normally distributed continuous variables and discrete data (Satisfaction, Comfort, and Intention to use) are presented as median (IQR), and two-sided paired Wilcoxon signed rank test is used to test for difference and indicated by [†]. Count data (Presence of snoring) are presented as frequency (%).

Units for "index" variables are events per hour.

*Linear mixed effects model

**Fisher's Exact Test ("difference" is odds ratio)

PLM = Periodic Leg Movement

REM = Rapid Eye Movement

NREM = Non-Rapid Eye Movement

RERA = Respiratory Effort-Related Arousal

RDI = Respiratory Disturbance Index

SpO2 = peripheral oxygen saturation

The self-reported sleep data (see **Supplementary File 4**) are presented in **Table 4** with the PSG recorded correlates and the statistical analysis of agreement. Participants recalled their sleep onset position accurately for 34 of 40 nights (85%, κ 0.62, moderate agreement). Participants recalled their waking position accurately for 28 of 40 nights (70%, κ 0.42, weak agreement). There was a weak relationship between sleep onset and waking position (κ 0.24). There was no agreement between the self-reported and PSG-reported number of position changes (κ 0.17). Percentage of time in each position, left, supine, and right, as estimated per self-report and measured per PSG had

Spearman's ρ of 0.76 (good correlation, $p < 0.01$), 0.27 (poor correlation, $p = 0.11$), and 0.93 (excellent correlation, $p < 0.01$), respectively. Bland-Altman plots (**Fig. 4.**, **Fig. 5.**, **Fig. 6.**) demonstrated that, on average, participants' self-reports tended to overestimate the percentage of left-side and right-side sleep by 5.5% (95%CI -30.2 to 41.2) and 0.5% (95%CI -21.9 to 22.9), respectively, and underestimate the percentage of supine sleep by 7.0% (95%CI -20.1 to 34.1) when compared to the PSG-determined position.

Table 4 | Secondary outcomes: self-reported versus PSG-recorded sleep behaviors

	Self-Report	PSG	Agreement
Sleep onset position (n=40)*			
Left	31 (78%)	29 (73%)	Cohen's κ^{\dagger} 0.62
Supine	2 (5%)	3 (7%)	
Right	7 (17%)	8 (20%)	
Waking position (n=40)*			
Left	28 (70%)	22 (55%)	Cohen's κ^{\dagger} 0.42
Supine	0 (0%)	5 (13%)	
Right	12 (30%)	13 (32%)	
Number of position changes (n=30)**	3 (2-4)	6 (3.3-10)	Cohen's κ^{\ddagger} 0.17
% of total sleep time in position (n=35)***:			
Left	59.9 (28.1)	54.4 (26.4)	Spearman's ρ 0.76
Supine	7.8 (20.0)	14.8 (18.7)	Spearman's ρ 0.27
Right	31.3 (27.3)	30.8 (28.5)	Spearman's ρ 0.93

* Count data are presented as: frequency (%). **Ordinal data presented as: median (IQR).

***Continuous data presented as: mean (SD). \dagger Linear/equal weighted Cohen's κ . \ddagger Unweighted Cohen's κ .

Harms

No participants (including the dropouts) requested to remove the intervention or PSG equipment. There were no known harms related to the interventions or procedures in this study.

DISCUSSION

Principal Findings

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3 Use of the PrenaBelt resulted in a 6.8% absolute reduction (38% relative reduction, 24.4
4 minutes) in the mean percentage of sleep time supine in comparison with the sham, and
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6 we were unable to demonstrate an effect on maternal sleep architecture or respiration.
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10 11 12 **Strengths and Weaknesses in Relation to Other Studies** 13

14 Our study only included two nights for each participant and was a pilot trial; therefore,
15 caution should be taken when extrapolating our results across the third trimester with
16 regard to efficacy and compliance – PT in non-pregnant individuals with positional
17 obstructive sleep apnea (OSA) has sustained efficacy in the long term but decreasing
18 compliance from 93% at 1 month,(39) 74% at three months,(40) and 60% at six
19 months.(41)
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30 In recent studies of PT in non-pregnant individuals with positional OSA, PT devices
31 incorporating active supine sensing technology and vibration mechanisms have been
32 shown to be more effective in reducing supine sleep than inactive pressure-point PT
33 devices like the PrenaBelt.(40,42) In comparison to a study of pressure-point PT in non-
34 pregnant individuals with positional OSA by Heinzer et al.,(40) the PrenaBelt resulted in
35 a lesser reduction in mean percentage of sleep time supine; however, in contrast, we
36 did not have a non-intervention night as Heinzer et al. did. The sham, by intrinsic
37 characteristics, may have caused a reduction in supine sleep in comparison to a non-
38 intervention night. O'Brien and Warland (6) reported a non-interventional, one-night, in-
39 home study of 51 healthy women in their 2nd and 3rd trimester using ambulatory PSG; in
40 a subgroup of participants in their 3rd trimester (n=33), the median percentage of overall
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3 sleep time spent supine was 26.5%. McIntyre et al.,(7) in a similar non-interventional,
4 one-night, in-home, ambulatory PSG study in 30 healthy women in the 3rd trimester,
5 reported the median percentage of overall sleep time spent supine to be 19%.
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10 Participants were not asked to adopt or try to maintain any sleep position in either study.
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12 Both of these studies reported a greater median percentage of overall sleep time spent
13 supine than that in the current study (16.4%), which indicates that the sham device may
14 have affected position. This, along with differences inherent to pregnancy (e.g., body
15 habitus, increased sleep disruption) may account for the lesser reduction in mean
16 percentage of sleep time supine achieved by the PrenaBelt in comparison Heinzer et al.
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28 Zaremba et al. undertook a randomized, cross-over, PSG study in 30 post-partum
29 women sleeping in non-elevated and 45° elevated body position and reported moderate
30 to severe OSA in 20% of the participants.(43) The minimum SpO₂ was higher (p 0.03)
31 and AHI was reduced (p 0.03) in the 45° elevated body position in comparison to non-
32 elevated without affecting sleep quantity or quality. In our analysis, we were unable to
33 demonstrate any differences in sleep architecture or duration despite a significant
34 difference in body position (less supine time).
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47 Seventy-three percent of participants in the study by McIntyre et al.(7) recalled their
48 sleep onset position accurately (κ 0.52), which is a lower accuracy than our results
49 (85% accurate, κ 0.62) possibly because each of our participants underwent two PSG
50 nights and, after being asked to recall various details about their sleep after their 1st
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3 PSG night, may have anticipated these questions again after their 2nd PSG night. Forty
4 percent of McIntyre et al.'s participants recalled their waking position accurately (κ
5 0.24), which is a lower accuracy than our results (70% accurate, κ 0.42). Being an
6 ambulatory PSG, McIntyre et al.'s study did not include electroencephalography (EEG)
7 – they estimated sleep and wake times by pre-defined video criteria (i.e., lack of
8 movement) and not by brain activity and noted that this may have introduced
9 discrepancy between their participants' self-reports and the video assessment criteria,
10 thus reducing their calculated accuracy. We reported a weak relationship (κ 0.24)
11 between sleep onset and waking position via PSG-determination, whereas previous
12 studies have reported discrepant results – McIntyre et al. reported no relationship (κ -
13 0.13) via video-determination, and the Auckland Stillbirth Study reported a strong
14 relationship (Pearson r 0.72) via self-reports;(2), however, our study has shown self-
15 reports of sleep onset and waking position to have only moderate and weak agreement
16 with the gold standard (PSG), respectively, which points to reliance on non-PSG
17 methods (e.g., self-reports) as a potential source of this discrepancy.
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40 Warland and Dorrian reported a three-night observational study of 30 healthy women in
41 late pregnancy and found moderate basic correlation between self-reported and video-
42 determined time on the left ($r=0.418$);(8) however, they did not report correlations for
43 right or supine sleep. We report a good correlation between self-reported and PSG-
44 determined time on the left (Spearman's ρ 0.76, $p<0.01$). Notably, we found poor
45 correlation between self-reports and PSG-determined supine time and that pregnant
46 women tend to underestimate this value. There are only two other studies investigating
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3 reliability of adults' self-reports of sleep position;(44,45) both consist of non-pregnant
4 adults, have conflicting results with each other, and are not reported in adequate detail
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6 for comparison to our results.
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12 In the non-pregnant population, approximately 20% of a typical night's sleep is spent in
13 the REM state and 80% is spent in the NREM state. The sleep architecture in the
14 current study is consistent with previously reported patterns during pregnancy, that is,
15 reduced slow-wave sleep (SWS), REM sleep, and sleep efficiency.(46–50)
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24 **Meaning of the Study**

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26 The previous studies by Owusu et al.(1) and O'Brien and Warland (6) recommended the
27 development and testing of a PT device for pregnant women. In our study, a PT
28 intervention was implemented in a population of healthy, third-trimester, pregnant
29 women during sleep in a clinical sleep laboratory environment over two nights. This
30 study extends the work of Stacey et al.,(2) Gordon et al.,(3) McCowan et al.,(4) and
31 Warland and Mitchell (51) by finding that supine sleep position in late pregnancy can be
32 reduced with PT.
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45 Left side sleeping is common among pregnant women. This may be a more comfortable
46 position but also may be related to the “sleep-on-side” messages prevalent on the
47 internet and among maternity care providers. Women in our study preferentially settled
48 to sleep on their left for 73% of the nights and right for 20% of the nights. This is
49 corroborated by McCowan et al.(4) who reported a significant increase in left-sided
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3 going-to-sleep position (43% to 58%) and small decrease in supine going-to-sleep
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5 position (5% to 3.8%) in New Zealand over an approximate 5 year period following
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7 publicity of The Auckland Stillbirth Study by Stacey et al.(2) If the supine sleeper is to be
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9 identified by history-taking and stratified for targeted education or intervention,
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11 obstetricians, midwives, and nurses should be aware that despite sleep-on-side
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13 knowledge and high rates of lateral going-to-sleep position, most pregnant women
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15 continue to spend a significant amount of time supine during sleep in late pregnancy per
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17 our study and previous studies.(6–8) Also, per our study, pregnant women’s estimates
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19 of time in each sleep position, while relatively accurate for lateral sleeping positions,
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21 underestimate the time they spend supine. Together, this suggests that healthcare
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23 providers may need to recommend interventions to prevent unintentional supine
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25 positioning during sleep.
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33 **Strengths**

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35 Strengths of this study include its rigorous methodology and use of the gold-standard
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37 sleep diagnostic test in a controlled laboratory setting. The sham intervention ensured
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39 that on the sham PSG night, participants received any specific benefit of any element of
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41 the PrenaBelt above and beyond all benefits that might be attributed to its ability to
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43 cause pressure points and, thus, reduced treatment bias. The cross-over allowed each
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45 participant to serve as her own control for comparison of intervention effect on
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47 outcomes. Allocation concealment and randomization of participants to intervention
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49 order helped avoid allocation bias and the potential impact of changes to sleep across
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51 the two PSG nights that could have resulted from familiarization with the equipment and
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3 environment. Blinding of the participants, RAs, Registered PSG Technicians, and the
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5 sleep specialist physician further reduced potential sources of bias and strengthened
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7 data integrity.
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10 11 12 **Weaknesses**

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14 Weaknesses of this study included that we had no baseline sleep data (run-in
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16 measurement) to which we could compare the PrenaBelt and sham nights; therefore,
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18 conclusions cannot be made regarding the effect, if any, of the PrenaBelt on sleep
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20 architecture and respiration in relation to no intervention. Participants' unfamiliarity with
21
22 the sleep environment also may have affected sleep quantity and quality; however, we
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24 were unaware of any impact reported by participants. Period effects and carryover may
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26 have occurred due to advancing gestation and familiarization with the sleep
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28 environment/equipment; however, given the median washout period (1 day) was
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30 negligible in the context of a 12-week third trimester, period effects from the washout
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32 were, at most, minimal. Our LME model incorporated the PSG night (1st or 2nd) as a
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34 random effect to control for within-subject variation in our measured outcomes due to
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36 increased familiarity with the process. On the 2nd PSG night, participants were exposed
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38 to the alternate intervention and could have unblinded themselves if they remembered
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40 what the intervention felt like on the 1st PSG night; however, we are unaware of what
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42 effect this may have had. The current study was conducted in a cohort of healthy, non-
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44 obese, and majority Caucasian pregnant women. Due to the small sample size, this
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46 study may be underpowered and potentially overstate the true reduction in percentage
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48 of supine sleep; however, the sleep time in our study was relatively short (median 5.87
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3 hours). Our participants reported a median of 8 hours overnight sleep duration at home;
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5 therefore, even if the reduction in supine sleep is lower than we observed, over a longer
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7 sleep duration, the PrenaBelt is still likely to result in a significant amount of supine
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9 sleep avoided. The power analysis was performed using the one-sided t-test, which
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11 could be a source of systemic confounding. Because of the fragility of our primary
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13 outcome (p 0.04), a confounding could shift our conclusions into statistical non-
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15 significance. This stresses the importance of future research to ascertain if our
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17 observed effects persist.
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24 **Future Research**

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26 To date, it is unclear whether formal advice, given by a maternity care provider to a
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28 pregnant woman, about sleeping position in late pregnancy is less, as, or more effective
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30 in reducing supine sleep in comparison to a PT device such as the PrenaBelt. Future
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32 research comparing advice versus a PT intervention in the home setting is imperative. If
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34 sleeping supine is potentially harmful to the fetus, the amount of supine time that is
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36 harmful needs quantification in order to target interventions to avoid this. Given that
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38 estimations of time in each body position during sleep are based on the recollection of
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40 an unconscious state and thus inherently inaccurate, future research should not rely on
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42 self-reports but should incorporate an objective measure of body position during sleep
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44 throughout the third trimester allowing body position to be directly linked to pregnancy
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46 outcomes. The results of our pilot trial warrant future, large, multi-ethnic studies that
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48 include women with a range of pregnancy and health conditions to ascertain if the
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50 observed effects persist.
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OTHER INFORMATION

Registration: This trial was registered at ClinicalTrials.gov, NCT02377817, on 17 February 2015 (<https://clinicaltrials.gov/ct2/show/NCT02377817>).

Protocol: Full details of the trial protocol are available with the full text of this article (see **Supplementary File 5**).

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Contributors: AK designed the protocol, secured funding, ethics approval, and the research contract, trained the study personnel, maintained the study master record, facilitated PSG studies as an unblinded personnel, monitored data collection, cleaned and analyzed the data, and drafted and revised the paper. He is guarantor. AK and AB conceptualized the PrenaBelt. KC designed and manufactured the PrenaBelt research samples. DM, HS, LMO, AB, MB, KC, and AI designed the protocol. HS oversaw participant recruitment and was the Principal Investigator responsible for all aspects of

1
2
3 the trial. DM was the Supervising Investigator, oversaw the PSG studies at the trial site,
4 and interpreted the PSG studies. MB wrote the statistical plan and oversaw the
5 statistical analysis. JW maintained the study master record, facilitated PSG studies as
6 an unblinded personnel, monitored data collection, and cleaned and analyzed the data.
7
8 AI negotiated the research contract and managed the trial funds. DM, HS, LMO, AB,
9
10 JW, MB, KC, and AI made intellectual contributions to the paper.
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30 submitted work, no financial relationships with any organizations that might have an
31 interest in the submitted work in the previous three years, and no other relationships or
32 activities that could appear to have influenced the submitted work.
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8
9 Canada.
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14 **Data Sharing:** Data analysis scripts and output are attached as supplementary files.
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38 upper body position improves pregnancy-related OSA without impairing sleep
39
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46
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SUPPLEMENTARY APPENDIX

Supplementary File 1: Code and output – demographic analysis

Supplementary File 2: Code and output – PSG analysis

Supplementary File 3: Code and output – feedback analysis

Supplementary File 4: Code and output – self-report accuracy analysis

Supplementary File 5: Research protocol

For peer review only

Figures and Tables:

Fig. 1. PrenaBelt; BPS = Body Position Sensor.

Fig 2. Enrollment, allocation, and analysis of trial participants.

Fig. 3. Scatter plot of percentage of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

Table 1. Baseline demographic, obstetric, and sleep habit characteristics

Table 2. Primary outcome: percentage of sleep time supine

Table 3. Secondary outcomes: time supine, sleep architecture, respiration, user feedback

Table 4. Secondary outcomes: self-reported versus PSG-recorded sleep behaviors

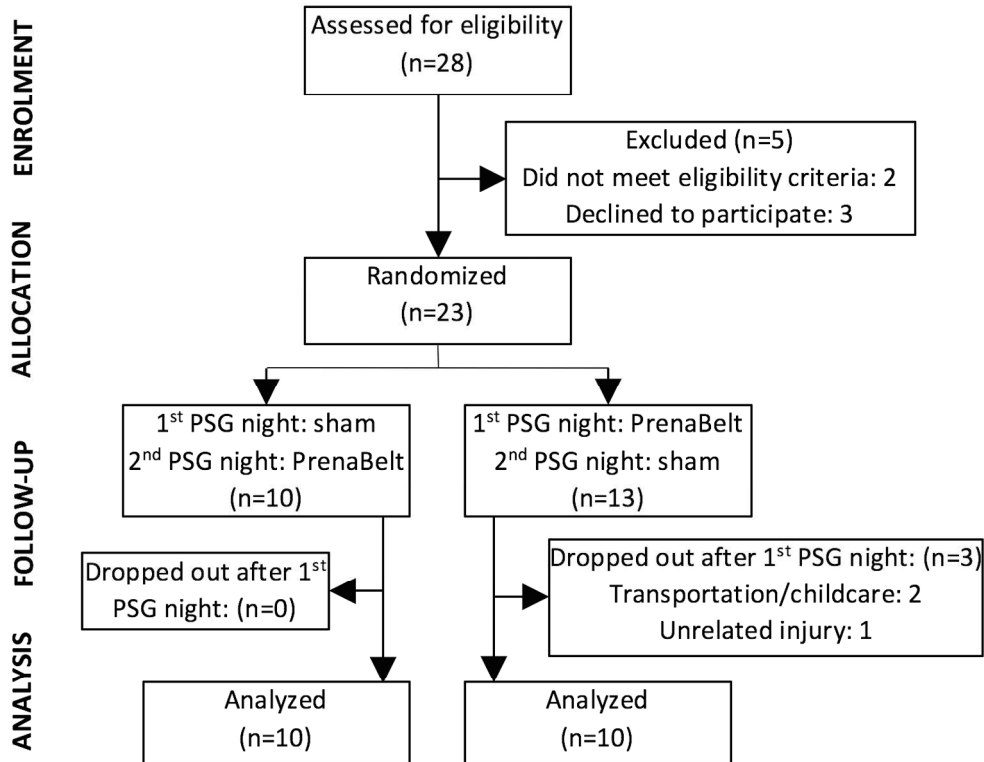
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Fig. 1. PrenaBelt; BPS = Body Position Sensor.

108x63mm (300 x 300 DPI)

review only



Enrollment, allocation, and analysis of trial participants.

293x227mm (300 x 300 DPI)

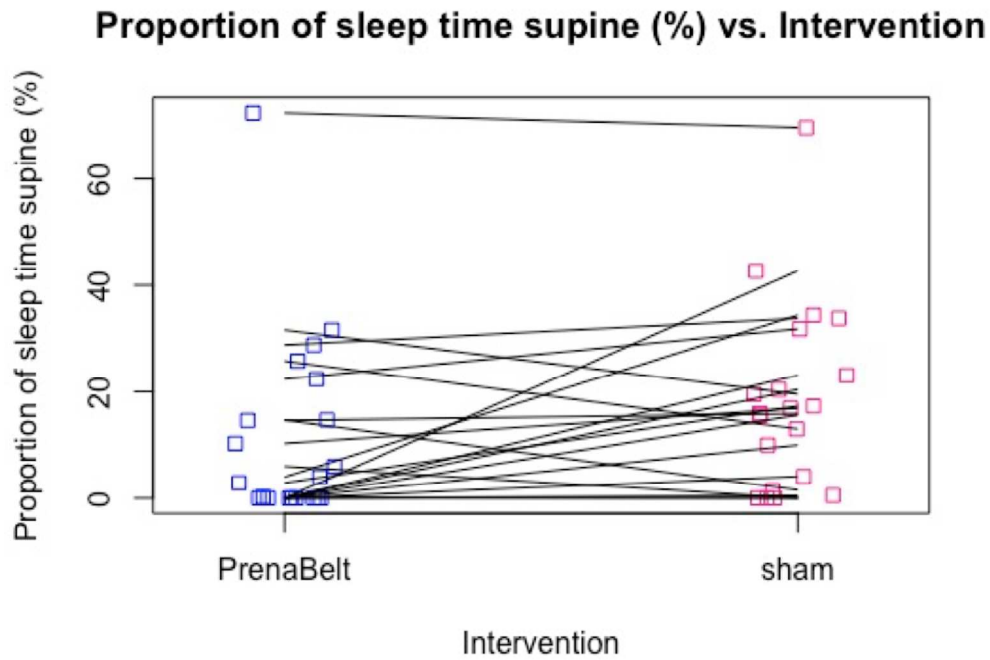


Fig. 3. Scatter plot of percentage of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

216x162mm (300 x 300 DPI)

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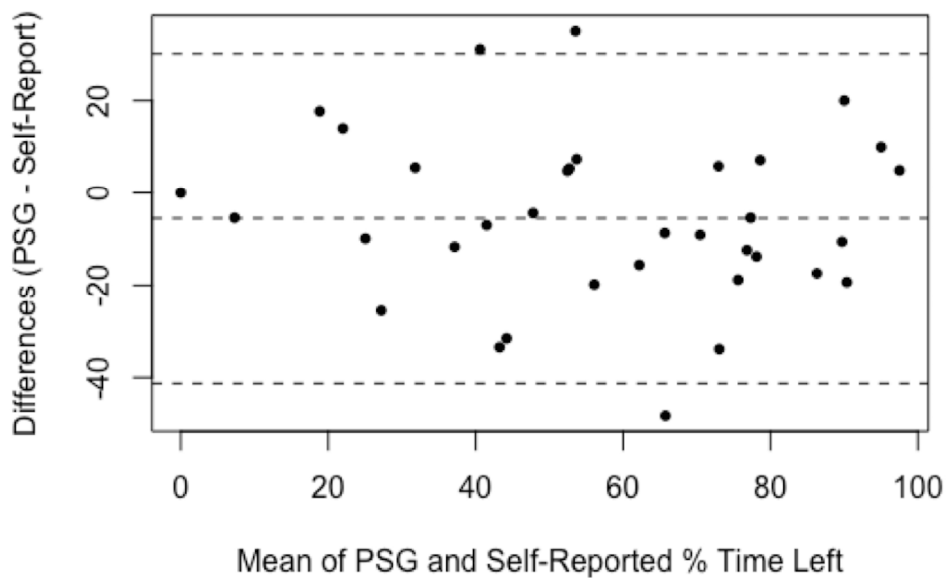


Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

216x162mm (300 x 300 DPI)

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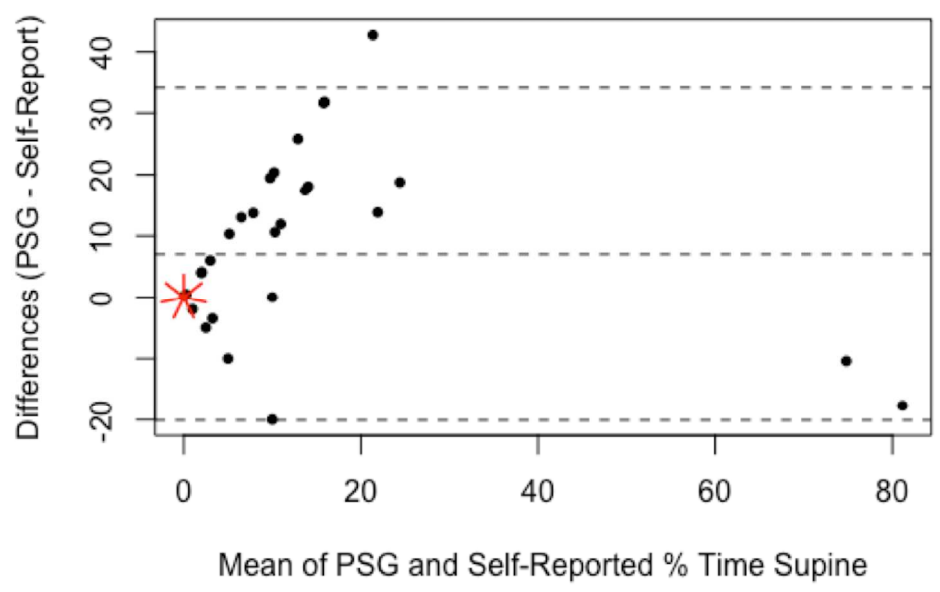


Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

216x162mm (300 x 300 DPI)

Only

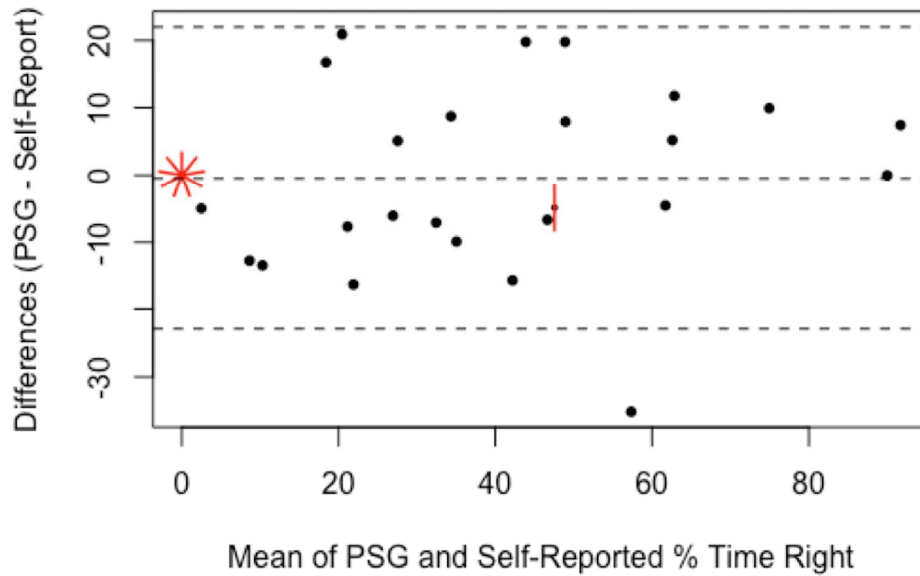


Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

216x162mm (300 x 300 DPI)

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Supplementary file 1: Code and output – demographic analysis

For peer review only

Demographic_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 15:54:34 2018

```
#Description of code:
#This code summarizes the demographic, obstetric, and sleep behaviour of the
participants
#and compares these data between all participants whose first sleep test was
PrenaBelt
#versus all participants whose first sleep test was sham-PrenaBelt.

#Summary:
#08APR2017: There is no difference between groups for any characteristic (ran
domization took
care of it).

#setting the workspace directory
setwd("/Users/Allan/Desktop/HPTStats/08APR2017")

#importing the Data Collection Form (DCF) data
DCFdata=read.csv("DCF Data Halifax - 08APR2017.csv")

#Loading the functions (ad.test, etc.) into your workspace
library(nortest)

#Exclude drop outs
#How many drop outs?
summary(DCFdata$drop.out)

## N Y
## 20 3

#Define drop out group so that differences can be tested for
DropOutdata <- DCFdata[!(DCFdata$drop.out=="N"),]
nrow(DropOutdata)

## [1] 3

#Remove the drop outs ("Y") from DCFdata file
DCFdata <- DCFdata[!(DCFdata$drop.out=="Y"),]
nrow(DCFdata)

## [1] 20
```

```
#####AGES#####
#ages summary
summary(DCFdata$age)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  22.00  27.25  31.50  30.90  35.00  39.00

sd(DCFdata$age, na.rm = TRUE)

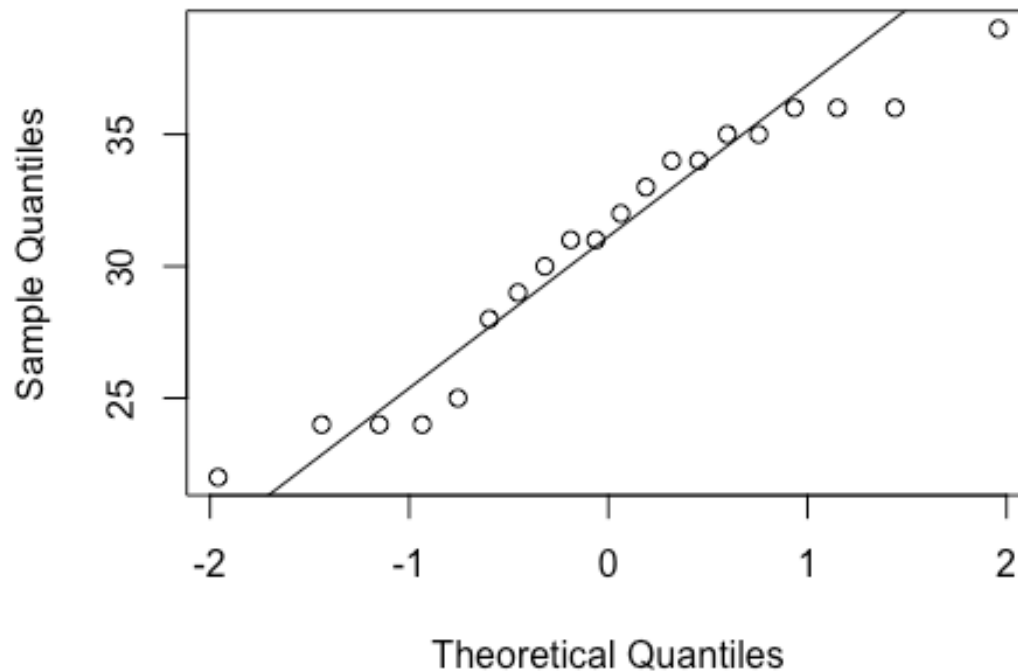
## [1] 4.983129

length(DCFdata$age)

## [1] 20

qqnorm(DCFdata$age)
qqline(DCFdata$age)
```

Normal Q-Q Plot



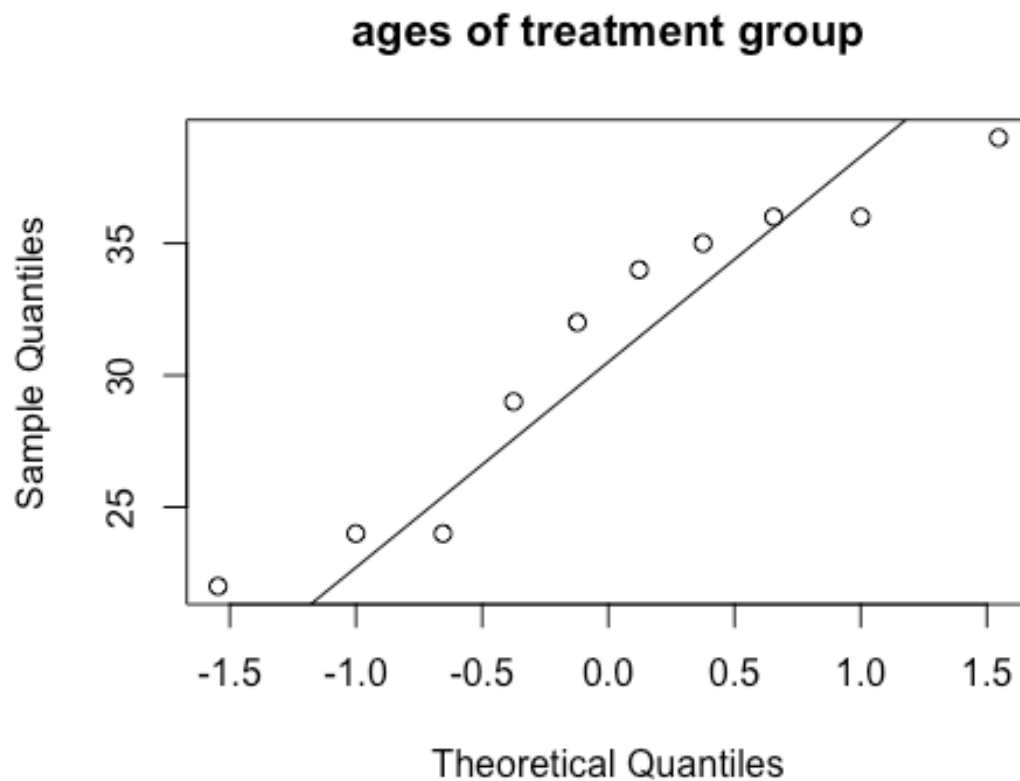
```
ad.test(DCFdata$age)

##
## Anderson-Darling normality test
##
## data: DCFdata$age
## A = 0.52863, p-value = 0.1554
```

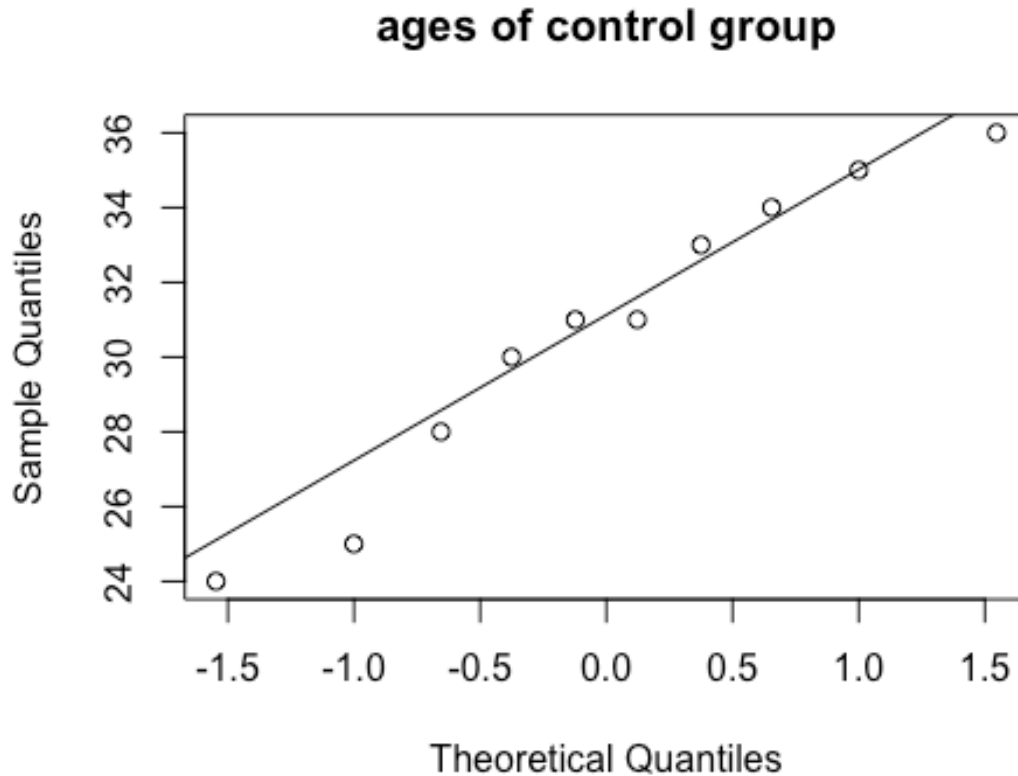
```

1
2
3 #Compare above with those who did not complete the study (n=3):
4 summary(DropOutdata$age)
5
6 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
7 ##  26.00  26.50   27.00   26.67  27.00   27.00
8
9 #Treatment ages
10 treatment.ages=na.omit(subset(DCFdata, intervention == "Treatment")$age)
11 length(treatment.ages)
12
13 ## [1] 10
14
15 summary(treatment.ages)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##  22.00  25.25   33.00   31.10  35.75   39.00
19
20 sd(treatment.ages)
21
22 ## [1] 5.989806
23
24 #check for normality
25 qqnorm(treatment.ages, main = "ages of treatment group")
26 qqline(treatment.ages)
27
28
29
30
31
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```



```
1
2
3 ad.test(treatment.ages)
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: treatment.ages
9 ## A = 0.4521, p-value = 0.2133
10
11 #normal
12
13 #Control ages
14 control.ages=na.omit(subset(DCFdata, intervention == "Control")$age)
15 length(control.ages)
16
17 ## [1] 10
18
19 summary(control.ages)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##  24.00  28.50   31.00   30.70  33.75   36.00
23
24 sd(control.ages)
25
26 ## [1] 4.056545
27
28 #check for normality
29 qqnorm(control.ages, main = "ages of control group")
30 qqline(control.ages)
31
32
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```



```
ad.test(control.ages)
```

```
##
## Anderson-Darling normality test
##
## data: control.ages
## A = 0.24422, p-value = 0.6844
```

```
#normal
```

```
#Perform 2-sample t-test (Welch's t-test) on the ages
```

```
t.test(treatment.ages, control.ages)
```

```
##
## Welch Two Sample t-test
##
## data: treatment.ages and control.ages
## t = 0.17485, df = 15.821, p-value = 0.8634
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -4.454062 5.254062
## sample estimates:
## mean of x mean of y
## 31.1 30.7
```



```

#####GESTATIONAL AGE @ First Sleep Test#####
#summary of gestational age at first sleep test (gar)
summary(DCFdata$gar)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  28.00  28.00  30.00  30.86  33.11  36.00

sd(DCFdata$gar, na.rm = TRUE)

## [1] 2.791784

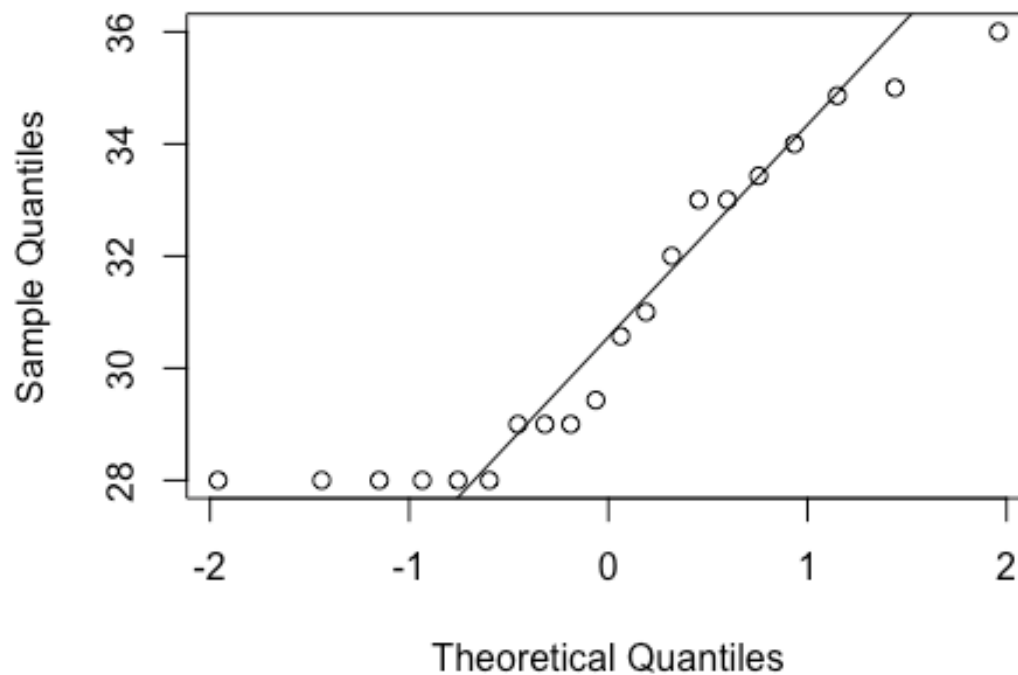
length(DCFdata$gar)

## [1] 20

qqnorm(DCFdata$gar)
qqline(DCFdata$gar)

```

Normal Q-Q Plot



```

ad.test(DCFdata$gar)

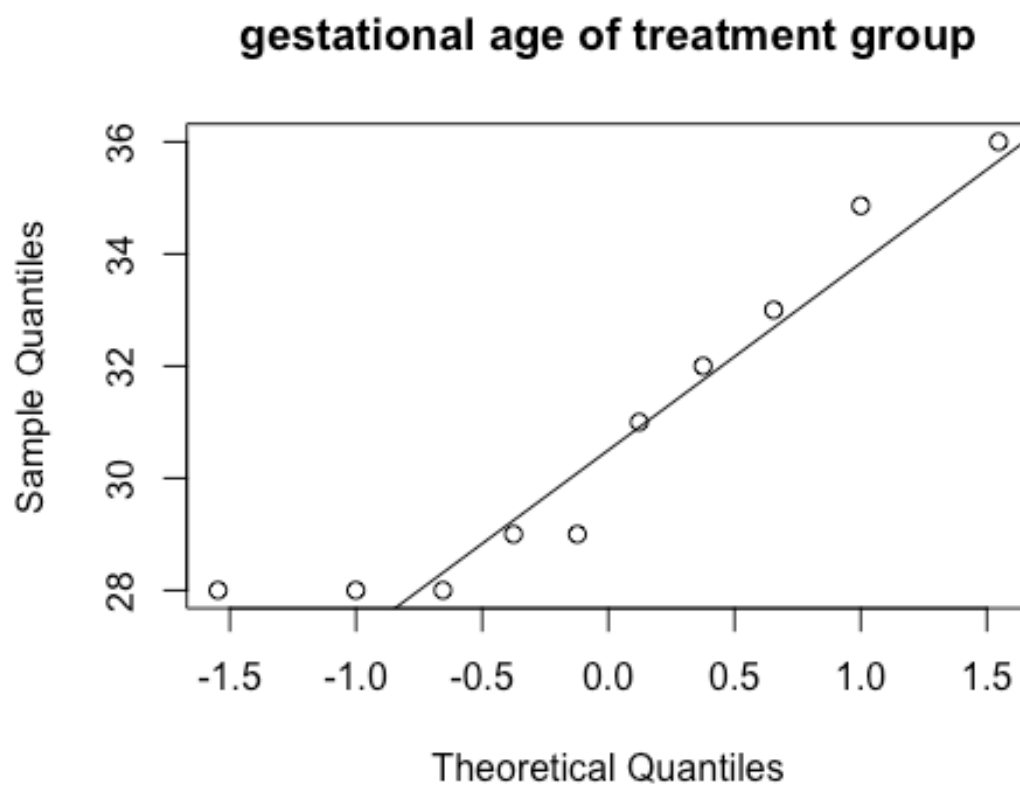
##
## Anderson-Darling normality test
##
## data: DCFdata$gar
## A = 0.96384, p-value = 0.01195

```

```

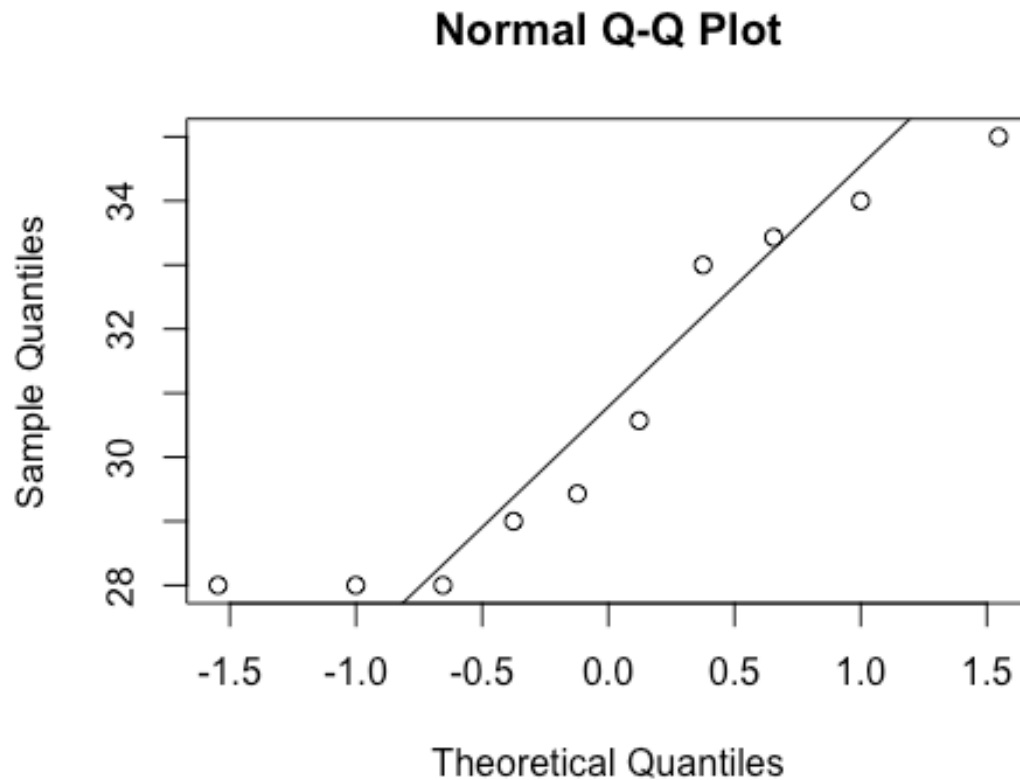
1
2
3 #Compare above with those who did not complete the study (n=3):
4 summary(DropOutdata$gar)
5
6 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
7 ##  29.00  29.50   30.00   30.62  31.43   32.86
8
9 #Treatment gestational age @ First Sleep Test
10 treatment.gar=na.omit(subset(DCFdata, intervention == "Treatment")$gar)
11 length(treatment.gar)
12
13 ## [1] 10
14
15 summary(treatment.gar)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##  28.00  28.25   30.00   30.89  32.75   36.00
19
20 sd(treatment.gar)
21
22 ## [1] 2.977128
23
24 #check for normality
25 qqnorm(treatment.gar, main = "gestational age of treatment group")
26 qqline(treatment.gar)
27
28
29
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```



```
1
2
3 ad.test(treatment.gar)
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: treatment.gar
9 ## A = 0.4918, p-value = 0.1663
10
11 #normal
12
13 #Control gestational age @ First Sleep Test
14 control.gar=na.omit(subset(DCFdata, intervention == "Control")$gar)
15 length(control.gar)
16
17 ## [1] 10
18
19 summary(control.gar)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##  28.00  28.25   30.00   30.84  33.32   35.00
23
24 sd(control.gar)
25
26 ## [1] 2.754959
27
28 #check for normality
29 qqnorm(control.gar)
30 qqline(control.gar)
31
32
33
34
35
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view only



```
ad.test(control.gar)
```

```
##
## Anderson-Darling normality test
##
## data: control.gar
## A = 0.55828, p-value = 0.1111
```

```
#normal
```

```
#Perform 2-sample t-test (Welch's t-test) on gestational age at First Sleep Test
```

```
t.test(treatment.gar, control.gar)
```

```
##
## Welch Two Sample t-test
##
## data: treatment.gar and control.gar
## t = 0.033523, df = 17.893, p-value = 0.9736
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -2.653002 2.739002
## sample estimates:
```

```

1
2
3 ## mean of x mean of y
4 ## 30.886 30.843
5
6 #####GRAVIDITY#####
7 summary(DCFdata$gravidity)
8
9 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
10 ## 1.0 1.0 1.5 1.5 2.0 2.0
11
12 sd(na.omit(DCFdata$gravidity))
13
14 ## [1] 0.5129892
15
16 length(DCFdata$gravidity)
17
18 ## [1] 20
19
20 #Compare above with those who did not complete the study (n=3):
21 summary(DropOutdata$gravidity)
22
23 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
24 ## 1 1 1 1 1 1
25
26 #Treatment gravidity
27 treatment.gravidity=na.omit(subset(DCFdata, intervention == "Treatment")$gravidity)
28
29 length(treatment.gravidity)
30
31 ## [1] 10
32
33 summary(treatment.gravidity)
34
35 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
36 ## 1.0 1.0 2.0 1.6 2.0 2.0
37
38 sd(treatment.gravidity)
39
40 ## [1] 0.5163978
41
42 #Control gravidity
43 control.gravidity=na.omit(subset(DCFdata, intervention == "Control")$gravidity)
44
45 length(control.gravidity)
46
47 ## [1] 10
48
49 summary(control.gravidity)
50
51 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
52 ## 1.0 1.0 1.0 1.4 2.0 2.0
53
54 sd(control.gravidity)
55
56 ## [1] 0.5163978

```

```

1
2
3 #Tabulate the data
4 xtabs(~gravity + intervention, data = DCFdata)
5
6 ##           intervention
7 ## gravity Control Treatment
8 ##           1         6         4
9 ##           2         4         6
10
11 #Perform Fisher's Exact Test
12 fisher.test(xtabs(~gravity + intervention, data = DCFdata))
13
14 ##
15 ## Fisher's Exact Test for Count Data
16 ##
17 ## data:  xtabs(~gravity + intervention, data = DCFdata)
18 ## p-value = 0.6563
19 ## alternative hypothesis: true odds ratio is not equal to 1
20 ## 95 percent confidence interval:
21 ##  0.2773893 19.1425577
22 ## sample estimates:
23 ## odds ratio
24 ##  2.158166
25
26 #####ETHNICITY#####
27 summary(DCFdata$ethnicity)
28
29 ##      caucasian      Filipino      Indian Middle Eastern
30 ##             16             1             1             2
31
32 length(DCFdata$ethnicity)
33
34 ## [1] 20
35
36 #Compare above with those who did not complete the study (n=3):
37 summary(DropOutdata$ethnicity)
38
39 ##      caucasian      Filipino      Indian Middle Eastern
40 ##             3             0             0             0
41
42 #Tabulate the data
43 xtabs(~ethnicity + intervention, data = DCFdata)
44
45 ##           intervention
46 ## ethnicity Control Treatment
47 ## caucasian      10         6
48 ## Filipino       0         1
49 ## Indian         0         1
50 ## Middle Eastern  0         2
51
52 #Perform Fisher's Exact Test
53 fisher.test(xtabs(~ethnicity + intervention, data = DCFdata))
54
55
56
57
58
59
60

```

```

1
2
3
4  ## Fisher's Exact Test for Count Data
5  ##
6  ## data:  xtabs(~ethnicity + intervention, data = DCFdata)
7  ## p-value = 0.08669
8  ## alternative hypothesis: two.sided
9
10 temp_table <- xtabs(~ethnicity + intervention, data = DCFdata)
11 j=nrow(temp_table)
12 ControlCsum=colSums(temp_table)[1]
13 TreatmentCsum=colSums(temp_table)[2]
14 for(i in 1:j) {
15   a=temp_table[i,1]
16   b=temp_table[i,2]
17   c=ControlCsum-a
18   d=TreatmentCsum-b
19   ORtable <- matrix(c(a,c,b,d),nrow = 2)
20   colnames(ORtable) <- c("Control", "Treatment")
21   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
22   print(row.names(temp_table)[i])
23   print(ORtable)
24   print(fisher.test(ORtable))
25 }
26
27
28 ## [1] "caucasian"
29 ##           Control Treatment
30 ## caucasian    10         6
31 ## Other        0         4
32 ##
33 ## Fisher's Exact Test for Count Data
34 ##
35 ## data:  ORtable
36 ## p-value = 0.08669
37 ## alternative hypothesis: true odds ratio is not equal to 1
38 ## 95 percent confidence interval:
39 ##  0.7703894      Inf
40 ## sample estimates:
41 ## odds ratio
42 ##           Inf
43 ##
44 ## [1] "Filipino"
45 ##           Control Treatment
46 ## Filipino     0         1
47 ## Other        10         9
48 ##
49 ## Fisher's Exact Test for Count Data
50 ##
51 ## data:  ORtable
52 ## p-value = 1
53 ## alternative hypothesis: true odds ratio is not equal to 1
54
55
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57
58
59
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```

```

1
2
3  ## 95 percent confidence interval:
4  ##    0.00000 39.00055
5  ## sample estimates:
6  ## odds ratio
7  ##          0
8  ##
9
10 ## [1] "Indian"
11 ##           Control Treatment
12 ## Indian      0          1
13 ## Other      10          9
14 ##
15 ## Fisher's Exact Test for Count Data
16 ##
17 ## data:  ORtable
18 ## p-value = 1
19 ## alternative hypothesis: true odds ratio is not equal to 1
20 ## 95 percent confidence interval:
21 ##    0.00000 39.00055
22 ## sample estimates:
23 ## odds ratio
24 ##          0
25 ##
26 ## [1] "Middle Eastern"
27 ##           Control Treatment
28 ## Middle Eastern  0          2
29 ## Other          10          8
30 ##
31 ## Fisher's Exact Test for Count Data
32 ##
33 ## data:  ORtable
34 ## p-value = 0.4737
35 ## alternative hypothesis: true odds ratio is not equal to 1
36 ## 95 percent confidence interval:
37 ##    0.00000 5.231968
38 ## sample estimates:
39 ## odds ratio
40 ##          0
41 ##
42 ##
43
44 #####HEIGHT.CURRENT#####
45 summary(DCFdata$height.current.inches)
46
47 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
48 ##   59.00  63.75   65.00   64.73  66.62   70.00
49
50 sd(DCFdata$height.current.inches, na.rm = TRUE)
51
52 ## [1] 2.955734
53
54 length(DCFdata$height.current.inches)
55
56 ## [1] 20
57
58
59
60

```



```

#####WEIGHT.CURRENT#####
summary(DCFdata$weight.current.lbs)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  140.0  169.5   177.0   181.2  194.8   252.0

sd(DCFdata$weight.current.lbs, na.rm = TRUE)

## [1] 27.51532

length(DCFdata$weight.current.lbs)

## [1] 20

#####BMI.CURRENT#####
summary(DCFdata$BMI.current)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   25.01  27.45   29.84   30.41  31.50   37.77

sd(DCFdata$BMI.current, na.rm = TRUE)

## [1] 3.592679

length(DCFdata$BMI.current)

## [1] 20

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$BMI.current)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   31.16  31.43   31.71   32.52  33.20   34.69

#Treatment current BMI (at first sleep study... 26-30 weeks)
treatment.current.BMI=na.omit((subset(DCFdata, intervention == "Treatment")$B
MI.current))
length(treatment.current.BMI)

## [1] 10

summary(treatment.current.BMI)

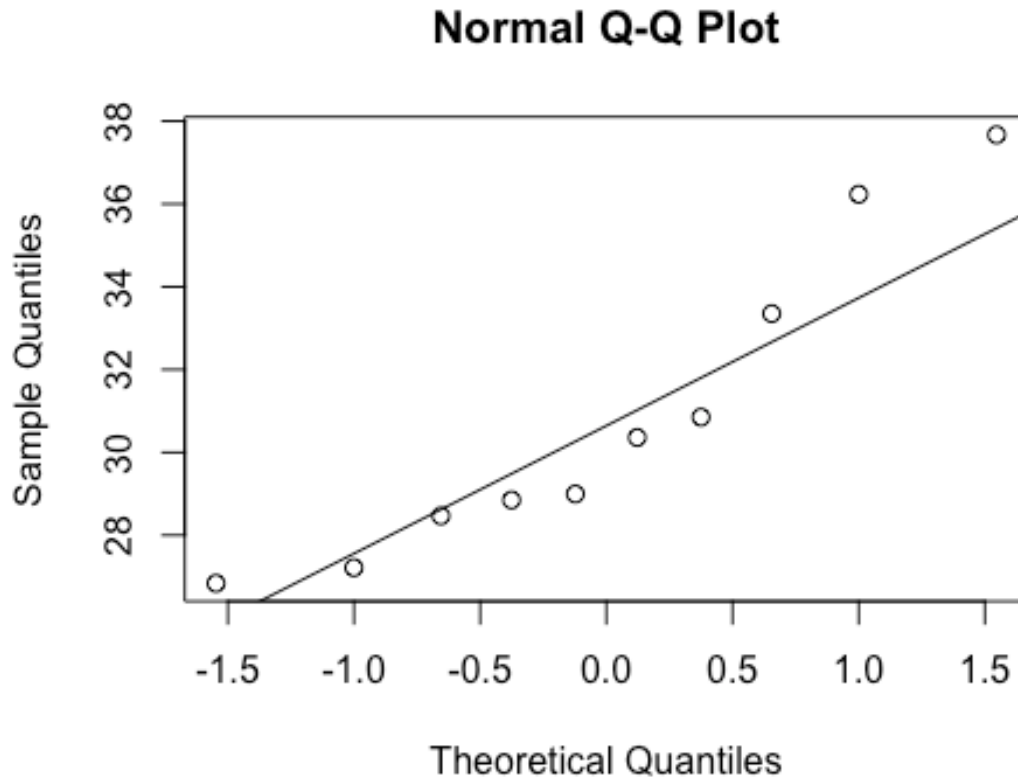
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   26.84  28.56   29.68   30.88  32.73   37.67

sd(treatment.current.BMI)

## [1] 3.717947

#normality check
qqnorm(treatment.current.BMI)
qqline(treatment.current.BMI)

```



```

ad.test(treatment.current.BMI)

##
## Anderson-Darling normality test
##
## data: treatment.current.BMI
## A = 0.48034, p-value = 0.1788

#normal

#Control current BMI (at first sleep study... 26-30 weeks)
control.current.BMI=na.omit((subset(DCFdata, intervention == "Control")$BMI.c
urrent))
length(control.current.BMI)

## [1] 10

summary(control.current.BMI)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 25.01  27.33  29.97  29.93  31.08  37.77

sd(control.current.BMI)

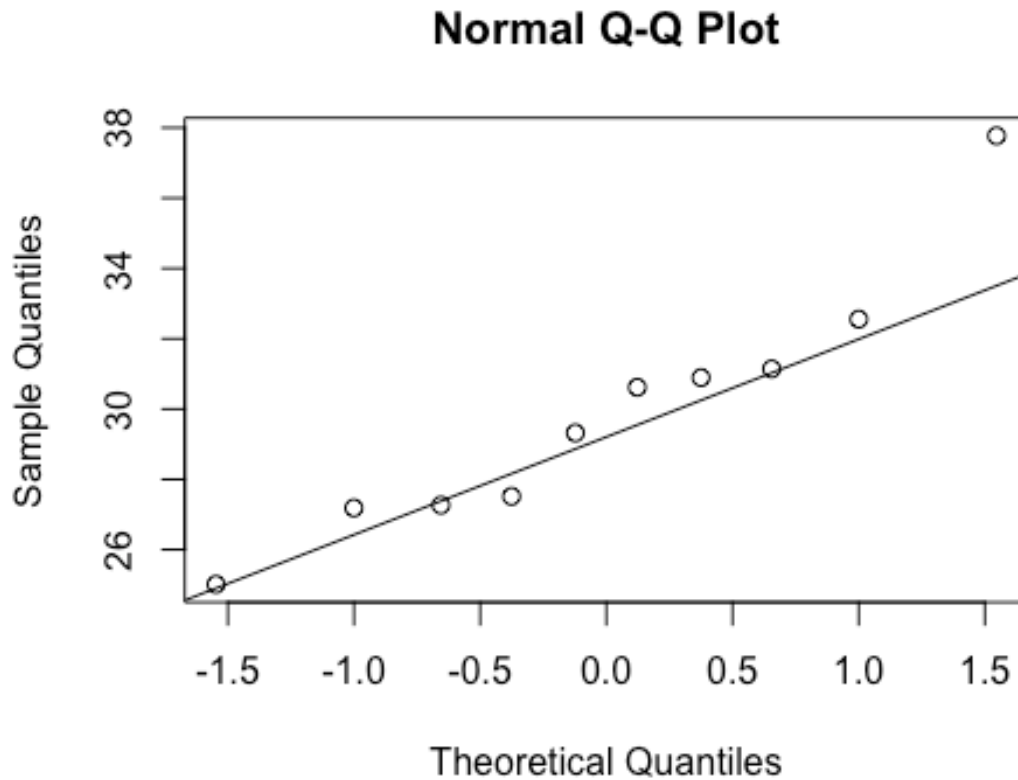
```

```
## [1] 3.594262
```

```
#normality check
```

```
qqnorm(control.current.BMI)
```

```
qqline(control.current.BMI)
```



```
ad.test(control.current.BMI)
```

```
##
```

```
## Anderson-Darling normality test
```

```
##
```

```
## data: control.current.BMI
```

```
## A = 0.35099, p-value = 0.3924
```

```
#normal
```

```
#Perform 2-sample t-test (Welch's t-test) on the current BMIs
```

```
t.test(treatment.current.BMI, control.current.BMI)
```

```
##
```

```
## Welch Two Sample t-test
```

```
##
```

```
## data: treatment.current.BMI and control.current.BMI
```

```
## t = 0.58417, df = 17.979, p-value = 0.5664
```

```

1
2
3  ## alternative hypothesis: true difference in means is not equal to 0
4  ## 95 percent confidence interval:
5  ## -2.480620  4.391192
6  ## sample estimates:
7  ## mean of x mean of y
8  ## 30.88316  29.92787
9

```

```

10 #####WEIGHT.BEFORE#####
11 summary(DCFdata$weight.before.lbs)
12

```

```

13  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14  ##    118.8   148.0   154.5   157.8   171.5   198.0
15

```

```

16 sd(DCFdata$weight.before.lbs, na.rm = TRUE)
17

```

```

18  ## [1] 20.45863
19

```

```

20 length(DCFdata$weight.before.lbs)
21

```

```

22  ## [1] 20
23

```

```

24 #####BMI.BEFORE#####
25 summary(DCFdata$BMI.before)
26

```

```

27  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28  ##     22.44   24.67   26.49   26.57   27.38   35.03
29

```

```

30 sd(DCFdata$BMI.before, na.rm = TRUE)
31

```

```

32  ## [1] 3.347304
33

```

```

34 length(DCFdata$BMI.before)
35

```

```

36  ## [1] 20
37

```

```

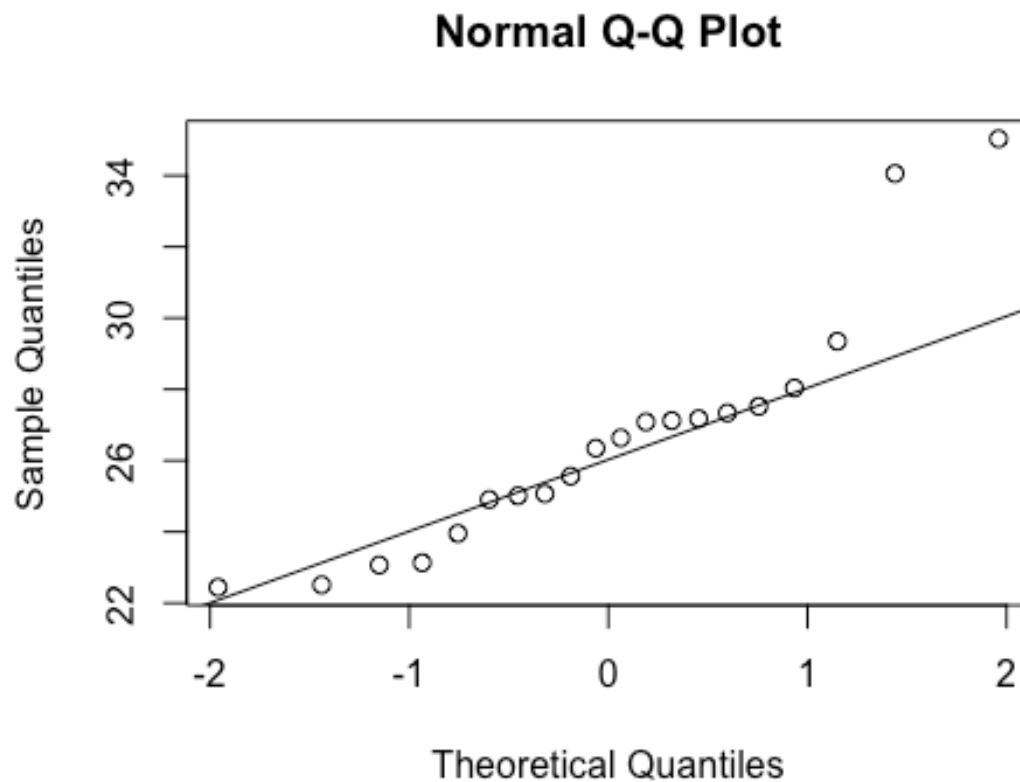
38 qqnorm(DCFdata$BMI.before)
39

```

```

40 qqline(DCFdata$BMI.before)
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```
ad.test(DCFdata$BMI.before)
```

```
##
## Anderson-Darling normality test
##
## data: DCFdata$BMI.before
## A = 0.80016, p-value = 0.03148
```

```
#Compare above with those who did not complete the study (n=3):
```

```
summary(DropOutdata$BMI.before)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 23.83  24.84  25.85  26.64  28.04  30.24
```

```
#Treatment BMI before pregnancy
```

```
treatment.before.BMI=na.omit((subset(DCFdata, intervention == "Treatment")$BMI.before))
```

```
length(treatment.before.BMI)
```

```
## [1] 10
```

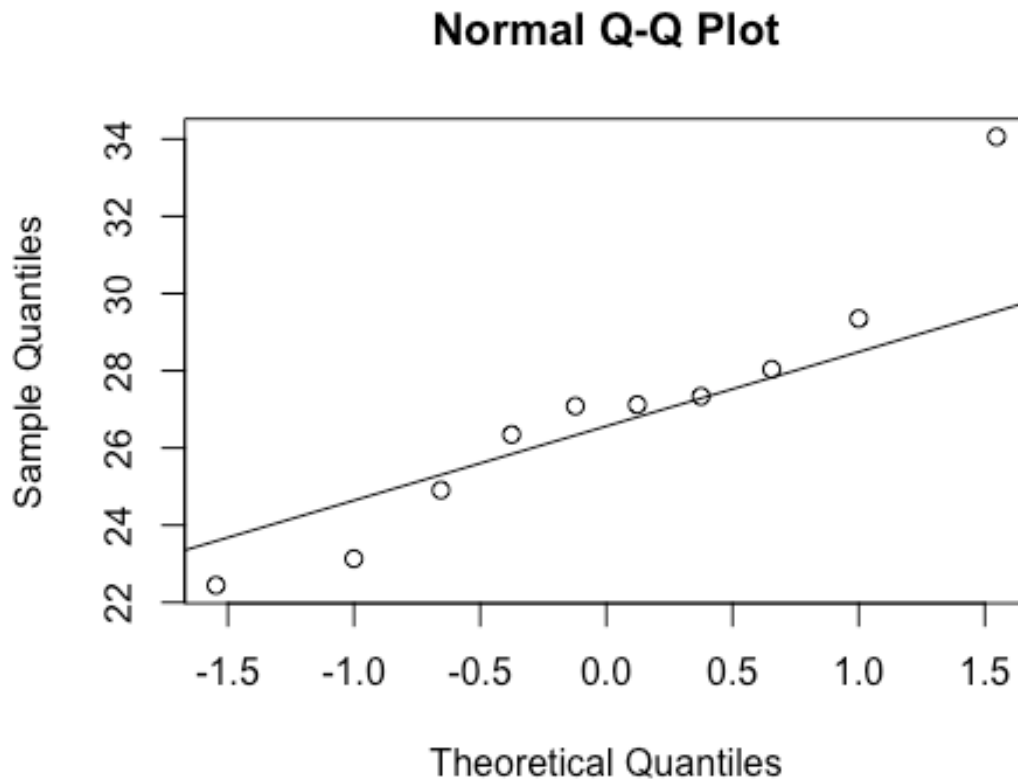
```
summary(treatment.before.BMI)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 22.44  25.27  27.10  26.98  27.86  34.06
```

```

1
2
3 sd(treatment.before.BMI)
4
5 ## [1] 3.283838
6
7 #normality check
8 qqnorm(treatment.before.BMI)
9 qqline(treatment.before.BMI)
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39

```



```

40 ad.test(treatment.before.BMI)
41
42 ##
43 ## Anderson-Darling normality test
44 ##
45 ## data: treatment.before.BMI
46 ## A = 0.35509, p-value = 0.3831
47
48 #normal
49
50 #Control BMI before pregnancy
51 control.before.BMI=na.omit((subset(DCFdata, intervention == "Control")$BMI.be
52 fore))
53 length(control.before.BMI)
54
55 ## [1] 10
56
57
58
59
60

```

```
summary(control.before.BMI)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  22.51  24.22  25.32  26.15  27.04  35.03
```

```
sd(control.before.BMI)
```

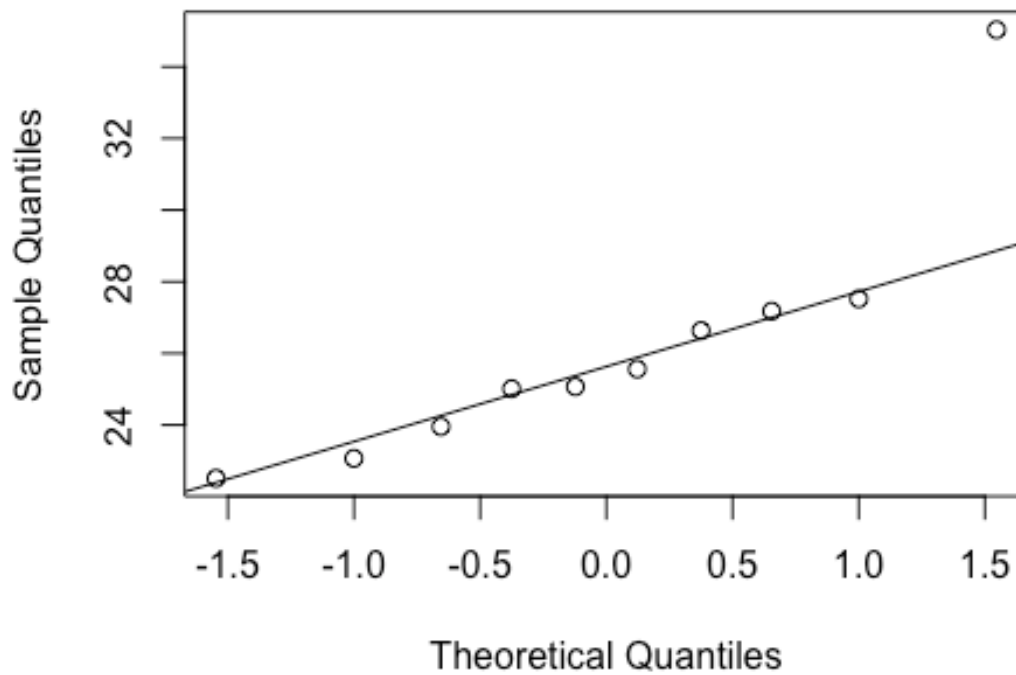
```
## [1] 3.534125
```

```
#normality check
```

```
qqnorm(control.before.BMI)
```

```
qqline(control.before.BMI)
```

Normal Q-Q Plot



```
ad.test(control.before.BMI)
```

```
##
## Anderson-Darling normality test
##
## data: control.before.BMI
## A = 0.71903, p-value = 0.04077
```

```
#non-normal
```

```

1
2
3 #Perform non-parametric method (Wilcoxon rank sum test)
4 wilcox.test(treatment.before.BMI, control.before.BMI, conf.int = TRUE)
5
6 ##
7 ## Wilcoxon rank sum test
8 ##
9 ## data: treatment.before.BMI and control.before.BMI
10 ## W = 60, p-value = 0.4813
11 ## alternative hypothesis: true location shift is not equal to 0
12 ## 95 percent confidence interval:
13 ## -1.728710 3.835403
14 ## sample estimates:
15 ## difference in location
16 ##
17 ## 1.115286
18
19 #####BED TIME#####
20 summary(DCFdata$bedtime.hrs)
21
22 ## 0:00 1:00 21:00 22:00 23:00
23 ## 4 1 1 6 8
24
25 #Tabulate the data
26 xtabs(~bedtime.hrs + intervention, data = DCFdata)
27
28 ## intervention
29 ## bedtime.hrs Control Treatment
30 ## 0:00 2 2
31 ## 1:00 0 1
32 ## 21:00 1 0
33 ## 22:00 3 3
34 ## 23:00 4 4
35
36 #Perform Fisher's Exact Test
37 fisher.test(xtabs(~bedtime.hrs + intervention, data = DCFdata))
38
39 ##
40 ## Fisher's Exact Test for Count Data
41 ##
42 ## data: xtabs(~bedtime.hrs + intervention, data = DCFdata)
43 ## p-value = 1
44 ## alternative hypothesis: two.sided
45
46 temp_table <- xtabs(~bedtime.hrs + intervention, data = DCFdata)
47 j=nrow(temp_table)
48 ControlCsum=colSums(temp_table)[1]
49 TreatmentCsum=colSums(temp_table)[2]
50 for(i in 1:j) {
51 a=temp_table[i,1]
52 b=temp_table[i,2]
53 c=ControlCsum-a
54 d=TreatmentCsum-b
55 ORtable <- matrix(c(a,c,b,d),nrow = 2)
56
57
58
59
60

```



```

1
2
3   colnames(ORtable) <- c("Control", "Treatment")
4   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
5   print(row.names(temp_table)[i])
6   print(ORtable)
7   print(fisher.test(ORtable))
8
9 }
10
11 ## [1] "0:00"
12 ##      Control Treatment
13 ## 0:00      2         2
14 ## Other      8         8
15 ##
16 ## Fisher's Exact Test for Count Data
17 ##
18 ## data:  ORtable
19 ## p-value = 1
20 ## alternative hypothesis: true odds ratio is not equal to 1
21 ## 95 percent confidence interval:
22 ##  0.0585532 17.0784861
23 ## sample estimates:
24 ## odds ratio
25 ##          1
26 ##
27 ## [1] "1:00"
28 ##      Control Treatment
29 ## 1:00      0         1
30 ## Other     10         9
31 ##
32 ## Fisher's Exact Test for Count Data
33 ##
34 ## data:  ORtable
35 ## p-value = 1
36 ## alternative hypothesis: true odds ratio is not equal to 1
37 ## 95 percent confidence interval:
38 ##  0.00000 39.00055
39 ## sample estimates:
40 ## odds ratio
41 ##          0
42 ##
43 ## [1] "21:00"
44 ##      Control Treatment
45 ## 21:00      1         0
46 ## Other      9         10
47 ##
48 ## Fisher's Exact Test for Count Data
49 ##
50 ## data:  ORtable
51 ## p-value = 1
52 ## alternative hypothesis: true odds ratio is not equal to 1
53 ## 95 percent confidence interval:

```

```

1
2
3      ## 0.02564066      Inf
4      ## sample estimates:
5      ## odds ratio
6      ##      Inf
7      ##
8      ## [1] "22:00"
9      ##      Control Treatment
10     ## 22:00      3      3
11     ## Other      7      7
12     ##
13     ## Fisher's Exact Test for Count Data
14     ##
15     ## data: ORtable
16     ## p-value = 1
17     ## alternative hypothesis: true odds ratio is not equal to 1
18     ## 95 percent confidence interval:
19     ## 0.09678719 10.33194569
20     ## sample estimates:
21     ## odds ratio
22     ##      1
23     ##
24     ## [1] "23:00"
25     ##      Control Treatment
26     ## 23:00      4      4
27     ## Other      6      6
28     ##
29     ## Fisher's Exact Test for Count Data
30     ##
31     ## data: ORtable
32     ## p-value = 1
33     ## alternative hypothesis: true odds ratio is not equal to 1
34     ## 95 percent confidence interval:
35     ## 0.118794 8.417935
36     ## sample estimates:
37     ## odds ratio
38     ##      1
39
40     #####WAKE TIME#####
41     summary(DCFdata$waketime.hrs)
42
43     ## 5:00 6:00 7:00 8:00 9:00
44     ## 0 5 8 4 3
45
46     #Tabulate the data
47     xtabs(~waketime.hrs + intervention, data = DCFdata)
48
49     ##      intervention
50     ## waketime.hrs Control Treatment
51     ##      5:00      0      0
52     ##      6:00      4      1
53     ##      7:00      2      6

```

```

1
2
3 ##           8:00           3           1
4 ##           9:00           1           2
5
6 #Perform Fisher's Exact Test
7 fisher.test(xtabs(~waketime.hrs + intervention, data = DCFdata))
8
9 ##
10 ## Fisher's Exact Test for Count Data
11 ##
12 ## data:  xtabs(~waketime.hrs + intervention, data = DCFdata)
13 ## p-value = 0.2044
14 ## alternative hypothesis: two.sided
15
16 temp_table <- xtabs(~waketime.hrs + intervention, data = DCFdata)
17 j=nrow(temp_table)
18 ControlCsum=colSums(temp_table)[1]
19 TreatmentCsum=colSums(temp_table)[2]
20 for(i in 1:j) {
21   a=temp_table[i,1]
22   b=temp_table[i,2]
23   c=ControlCsum-a
24   d=TreatmentCsum-b
25   ORtable <- matrix(c(a,c,b,d),nrow = 2)
26   colnames(ORtable) <- c("Control", "Treatment")
27   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
28   print(row.names(temp_table)[i])
29   print(ORtable)
30   print(fisher.test(ORtable))
31 }
32
33
34 ## [1] "5:00"
35 ##           Control Treatment
36 ## 5:00           0           0
37 ## Other           10          10
38 ##
39 ## Fisher's Exact Test for Count Data
40 ##
41 ## data:  ORtable
42 ## p-value = 1
43 ## alternative hypothesis: true odds ratio is not equal to 1
44 ## 95 percent confidence interval:
45 ##  0 Inf
46 ## sample estimates:
47 ## odds ratio
48 ##           0
49 ##
50 ## [1] "6:00"
51 ##           Control Treatment
52 ## 6:00           4           1
53 ## Other           6           9
54 ##
55 ##
56

```

```

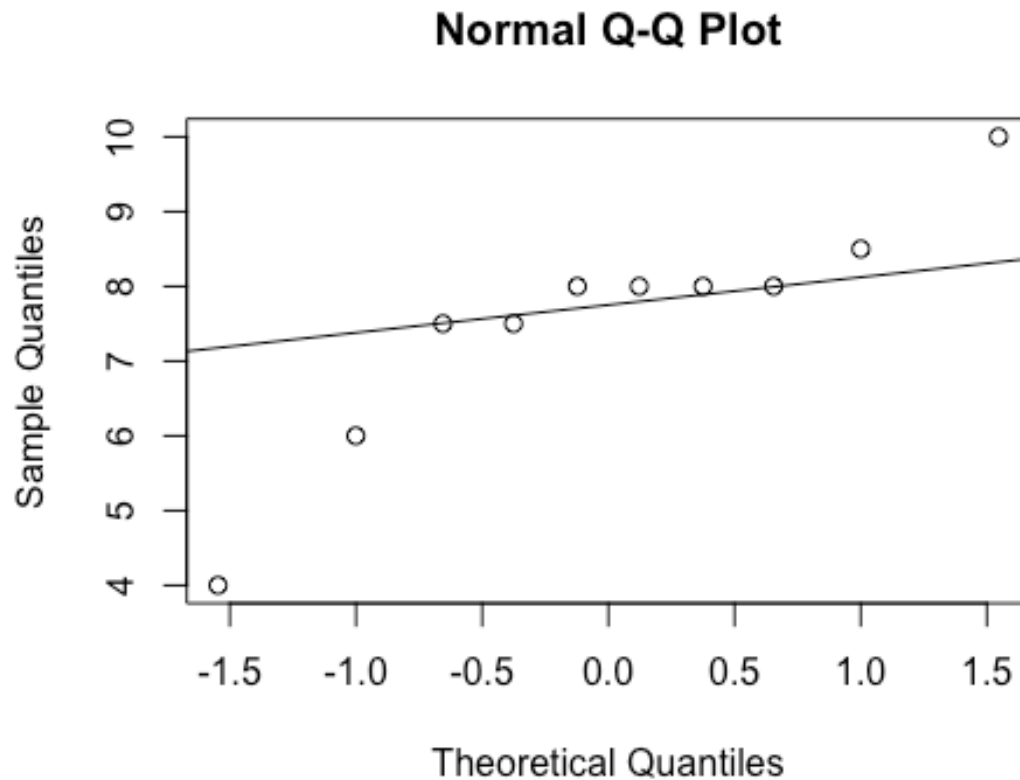
1
2
3  ## Fisher's Exact Test for Count Data
4  ##
5  ## data: ORtable
6  ## p-value = 0.3034
7  ## alternative hypothesis: true odds ratio is not equal to 1
8  ## 95 percent confidence interval:
9  ##    0.4075889 326.8267297
10 ## sample estimates:
11 ## odds ratio
12 ##    5.485861
13 ##
14 ## [1] "7:00"
15 ##      Control Treatment
16 ## 7:00      2      6
17 ## Other      8      4
18 ##
19 ## Fisher's Exact Test for Count Data
20 ##
21 ## data: ORtable
22 ## p-value = 0.1698
23 ## alternative hypothesis: true odds ratio is not equal to 1
24 ## 95 percent confidence interval:
25 ##    0.01252647 1.65925396
26 ## sample estimates:
27 ## odds ratio
28 ##    0.1841181
29 ##
30 ## [1] "8:00"
31 ##      Control Treatment
32 ## 8:00      3      1
33 ## Other      7      9
34 ##
35 ## Fisher's Exact Test for Count Data
36 ##
37 ## data: ORtable
38 ## p-value = 0.582
39 ## alternative hypothesis: true odds ratio is not equal to 1
40 ## 95 percent confidence interval:
41 ##    0.2301177 224.1916418
42 ## sample estimates:
43 ## odds ratio
44 ##    3.610815
45 ##
46 ## [1] "9:00"
47 ##      Control Treatment
48 ## 9:00      1      2
49 ## Other      9      8
50 ##
51 ## Fisher's Exact Test for Count Data
52 ##

```

```

1
2
3  ## data: ORtable
4  ## p-value = 1
5  ## alternative hypothesis: true odds ratio is not equal to 1
6  ## 95 percent confidence interval:
7  ## 0.0067986 10.5137419
8  ## sample estimates:
9  ## odds ratio
10 ## 0.4624944
11
12 #####SLEEP DURATION REPORTED#####
13 summary(DCFdata$sleep.reported.hrs)
14
15 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
16 ##      4.00   7.00   8.00   7.55   8.00   10.00
17
18 sd(DCFdata$sleep.reported.hrs, na.rm = TRUE)
19
20 ## [1] 1.145931
21
22 length(DCFdata$sleep.reported.hrs)
23
24 ## [1] 20
25
26 #Compare above with those who did not complete the study (n=3):
27 summary(DropOutdata$sleep.reported.hrs)
28
29 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
30 ##      5.500   6.250   7.000   6.833   7.500   8.000
31
32 #Treatment sleep duration reported
33 treatment.sleep.reported.hrs=na.omit((subset(DCFdata,
34                                     intervention == "Treatment")$sle
35 ep.reported.hrs))
36 length(treatment.sleep.reported.hrs)
37
38 ## [1] 10
39
40 summary(treatment.sleep.reported.hrs)
41
42 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
43 ##      4.00   7.50   8.00   7.55   8.00   10.00
44
45 sd(treatment.sleep.reported.hrs)
46
47 ## [1] 1.589025
48
49 #normality check
50 qqnorm(treatment.sleep.reported.hrs)
51 qqline(treatment.sleep.reported.hrs)
52
53
54
55
56
57
58
59
60

```



```

ad.test(treatment.sleep.reported.hrs)

##
## Anderson-Darling normality test
##
## data: treatment.sleep.reported.hrs
## A = 0.76112, p-value = 0.03136

#non-normal

#Control sleep duration reported
control.sleep.reported.hrs=na.omit((subset(DCFdata, intervention == "Control")
)$sleep.reported.hrs)
length(control.sleep.reported.hrs)

## [1] 10

summary(control.sleep.reported.hrs)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      7.00   7.00   7.75   7.55   8.00   8.00

sd(control.sleep.reported.hrs)

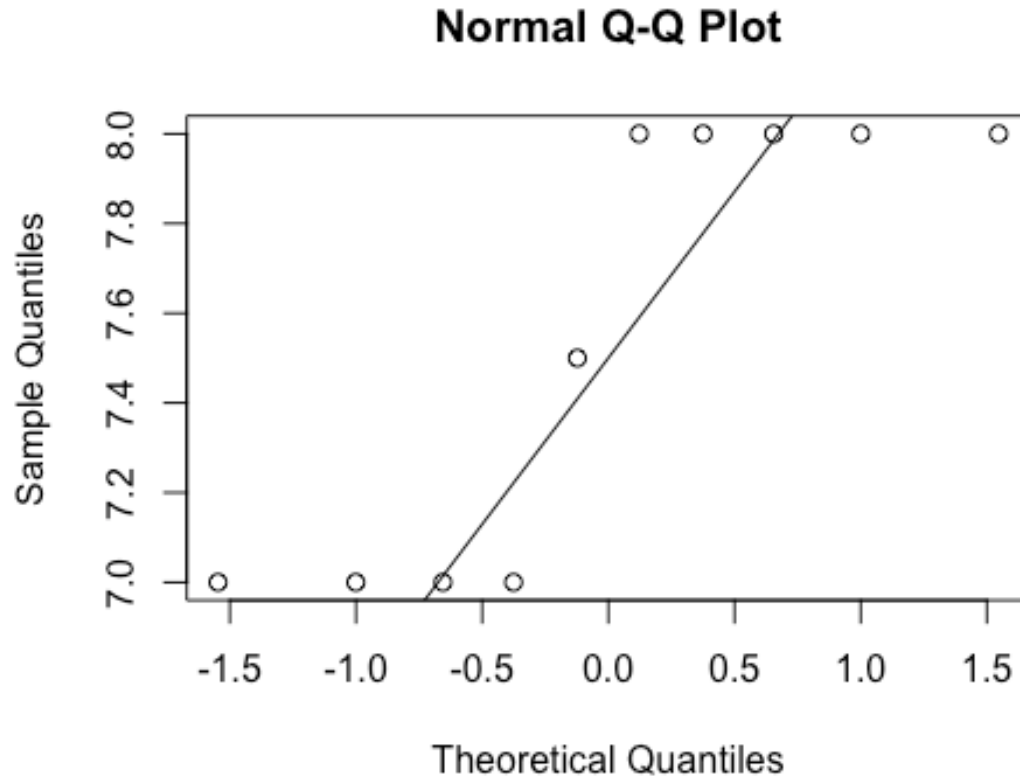
```

```
## [1] 0.4972145
```

```
#normality check
```

```
qqnorm(control.sleep.reported.hrs)
```

```
qqline(control.sleep.reported.hrs)
```



```
ad.test(control.sleep.reported.hrs)
```

```
##
```

```
## Anderson-Darling normality test
```

```
##
```

```
## data: control.sleep.reported.hrs
```

```
## A = 1.2746, p-value = 0.001286
```

```
#non-normal
```

```
#Perform non-parametric method (Wilcoxon rank sum test)
```

```
wilcox.test(treatment.sleep.reported.hrs, control.sleep.reported.hrs, conf.in  
t = TRUE)
```

```
## Warning in wilcox.test.default(treatment.sleep.reported.hrs,
```

```
## control.sleep.reported.hrs, : cannot compute exact p-value with ties
```

```

1
2
3  ## Warning in wilcox.test.default(treatment.sleep.reported.hrs,
4  ## control.sleep.reported.hrs, : cannot compute exact confidence intervals
5  ## with ties
6
7  ##
8  ##  Wilcoxon rank sum test with continuity correction
9  ##
10 ## data:  treatment.sleep.reported.hrs and control.sleep.reported.hrs
11 ## W = 59, p-value = 0.498
12 ## alternative hypothesis: true location shift is not equal to 0
13 ## 95 percent confidence interval:
14 ##  -0.5000247  0.9999945
15 ## sample estimates:
16 ## difference in location
17 ##          3.045828e-05
18
19
20 #####FALL ASLEEP POSITION IN PAST WEEK#####
21 summary(DCFdata$fell.asleep.in.past.week)
22
23 ##           left           left, right  left, right, prone
24 ##           7             4             1
25 ## left, right, supine   left, supine   right
26 ##           3             2             3
27 ##           right, supine
28 ##           0
29
30 length(DCFdata$fell.asleep.in.past.week)
31
32 ## [1] 20
33
34 #Tabulate the data
35 xtabs(~fell.asleep.in.past.week + intervention, data = DCFdata)
36
37 ##           intervention
38 ## fell.asleep.in.past.week Control Treatment
39 ## left           7           0
40 ## left, right    1           3
41 ## left, right, prone  0           1
42 ## left, right, supine  2           1
43 ## left, supine      0           2
44 ## right           0           3
45 ## right, supine     0           0
46
47 #Perform Fisher's Exact Test
48 #fisher.test(xtabs(~fell.asleep.in.past.week + intervention, data = DCFdata))
49 #build 2-row table for fisher test: control vs treatment
50 fell.asleep.in.past.week_table <- matrix(c(10,7,3,8,2,3,0,1),
51                                           nrow = 2)
52
53 colnames(fell.asleep.in.past.week_table) <- c("left", "right", "supine", "prone"
54 )
55 rownames(fell.asleep.in.past.week_table) <- c("Control",
56
57
58
59
60

```



```

1
2
3                                     "Treatment")
4 t(fell.asleep.in.past.week_table)
5
6 ##           Control Treatment
7 ## left           10           7
8 ## right          3           8
9 ## supine         2           3
10 ## prone          0           1
11
12 #Compare above with those who did not complete the study (n=3):
13 summary(DropOutdata$fell.asleep.in.past.week)
14
15 ##           left           left, right  left, right, prone
16 ##           0             1             0
17 ## left, right, supine   left, supine   right
18 ##           1             0             0
19 ##           right, supine
20 ##           1
21
22 #Perform Fisher's Exact Test
23 fisher.test(fell.asleep.in.past.week_table)
24
25 ##
26 ## Fisher's Exact Test for Count Data
27 ##
28 ## data:  fell.asleep.in.past.week_table
29 ## p-value = 0.3141
30 ## alternative hypothesis: two.sided
31
32 temp_table <- t(fell.asleep.in.past.week_table)
33 j=nrow(temp_table)
34 ControlCsum=colSums(temp_table)[1]
35 TreatmentCsum=colSums(temp_table)[2]
36 for(i in 1:j) {
37   a=temp_table[i,1]
38   b=temp_table[i,2]
39   c=ControlCsum-a
40   d=TreatmentCsum-b
41   ORtable <- matrix(c(a,c,b,d),nrow = 2)
42   colnames(ORtable) <- c("Control", "Treatment")
43   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
44   print(row.names(temp_table)[i])
45   print(ORtable)
46   print(fisher.test(ORtable))
47 }
48
49 ## [1] "left"
50
51 ##           Control Treatment
52 ## left           10           7
53 ## Other          5           12
54 ##
55
56
57
58
59
60

```

```

1
2
3  ## Fisher's Exact Test for Count Data
4  ##
5  ## data: ORtable
6  ## p-value = 0.1663
7  ## alternative hypothesis: true odds ratio is not equal to 1
8  ## 95 percent confidence interval:
9  ##  0.680546 18.170891
10 ## sample estimates:
11 ## odds ratio
12 ##  3.299199
13 ##
14 ## [1] "right"
15 ##      Control Treatment
16 ## right      3          8
17 ## Other     12         11
18 ##
19 ## Fisher's Exact Test for Count Data
20 ##
21 ## data: ORtable
22 ## p-value = 0.2714
23 ## alternative hypothesis: true odds ratio is not equal to 1
24 ## 95 percent confidence interval:
25 ##  0.04812652 1.98278653
26 ## sample estimates:
27 ## odds ratio
28 ##  0.3547015
29 ##
30 ## [1] "supine"
31 ##      Control Treatment
32 ## supine      2          3
33 ## Other     13         16
34 ##
35 ## Fisher's Exact Test for Count Data
36 ##
37 ## data: ORtable
38 ## p-value = 1
39 ## alternative hypothesis: true odds ratio is not equal to 1
40 ## 95 percent confidence interval:
41 ##  0.06037268 8.38423263
42 ## sample estimates:
43 ## odds ratio
44 ##  0.8252566
45 ##
46 ## [1] "prone"
47 ##      Control Treatment
48 ## prone       0          1
49 ## Other     15         18
50 ##
51 ## Fisher's Exact Test for Count Data
52 ##

```

```

1
2
3  ## data: ORtable
4  ## p-value = 1
5  ## alternative hypothesis: true odds ratio is not equal to 1
6  ## 95 percent confidence interval:
7  ## 0.00000 49.36267
8  ## sample estimates:
9  ## odds ratio
10 ## 0
11
12 #####FALL ASLEEP POSITION WHEN NOT PREGNANT#####
13 summary(DCFdata$fell.asleep.when.not.pregnant)
14
15 ##           left           left, prone
16 ##           1             1
17 ##           left, right     left, right, supine
18 ##           1             1
19 ## left, right, supine, prone           prone
20 ##           1             8
21 ##           right           right, prone
22 ##           2             1
23 ##           supine           supine, prone
24 ##           2             2
25
26
27 length(DCFdata$fell.asleep.when.not.pregnant)
28
29 ## [1] 20
30
31 #Tabulate the data
32 xtabs(~fell.asleep.when.not.pregnant + intervention, data = DCFdata)
33
34 ##           intervention
35 ## fell.asleep.when.not.pregnant Control Treatment
36 ## left           1           0
37 ## left, prone    1           0
38 ## left, right    0           1
39 ## left, right, supine  0           1
40 ## left, right, supine, prone  1           0
41 ## prone          2           6
42 ## right          2           0
43 ## right, prone   1           0
44 ## supine         1           1
45 ## supine, prone  1           1
46
47
48 #Perform Fisher's Exact Test
49 #fisher.test(xtabs(~fell.asleep.when.not.pregnant + intervention, data = DCFdata))
50
51 #build 2-row table for fisher test: control vs treatment
52 fell.asleep.when.not.pregnant_table <- matrix(c(3,2,4,2,3,3,6,7),
53                                               nrow = 2)
54 colnames(fell.asleep.when.not.pregnant_table) <- c("left", "right", "supine", "prone")
55
56
57
58
59
60

```

```

1 rownames(fell.asleep.when.not.pregnant_table) <- c("Control",
2           "Treatment")
3
4 t(fell.asleep.when.not.pregnant_table)
5
6
7 ##           Control Treatment
8 ## left           3           2
9 ## right          4           2
10 ## supine         3           3
11 ## prone          6           7
12
13 #Compare above with those who did not complete the study (n=3):
14 summary(DropOutdata$fell.asleep.when.not.pregnant)
15
16 ##           left           left, prone
17 ##           0           0
18 ##           left, right   left, right, supine
19 ##           0           1
20 ## left, right, supine, prone   prone
21 ##           0           0
22 ##           right           right, prone
23 ##           0           0
24 ##           supine         supine, prone
25 ##           2           0
26
27
28 #Perform Fisher's Exact Test
29 fisher.test(fell.asleep.when.not.pregnant_table)
30
31 ##
32 ## Fisher's Exact Test for Count Data
33 ##
34 ## data: fell.asleep.when.not.pregnant_table
35 ## p-value = 0.9528
36 ## alternative hypothesis: two.sided
37
38 temp_table <- t(fell.asleep.when.not.pregnant_table)
39 j=nrow(temp_table)
40 ControlCsum=colSums(temp_table)[1]
41 TreatmentCsum=colSums(temp_table)[2]
42 for(i in 1:j) {
43   a=temp_table[i,1]
44   b=temp_table[i,2]
45   c=ControlCsum-a
46   d=TreatmentCsum-b
47   ORtable <- matrix(c(a,c,b,d),nrow = 2)
48   colnames(ORtable) <- c("Control", "Treatment")
49   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
50   print(row.names(temp_table)[i])
51   print(ORtable)
52   print(fisher.test(ORtable))
53 }
54
55
56
57
58
59
60

```

```

1
2
3  ## [1] "left"
4  ##      Control Treatment
5  ## left      3          2
6  ## Other    13         12
7  ##
8  ## Fisher's Exact Test for Count Data
9  ##
10 ## data: ORtable
11 ## p-value = 1
12 ## alternative hypothesis: true odds ratio is not equal to 1
13 ## 95 percent confidence interval:
14 ##  0.1319695 19.0880365
15 ## sample estimates:
16 ## odds ratio
17 ##  1.36981
18 ##
19 ## [1] "right"
20 ##      Control Treatment
21 ## right     4          2
22 ## Other    12         12
23 ##
24 ## Fisher's Exact Test for Count Data
25 ##
26 ## data: ORtable
27 ## p-value = 0.6567
28 ## alternative hypothesis: true odds ratio is not equal to 1
29 ## 95 percent confidence interval:
30 ##  0.2279875 25.5286215
31 ## sample estimates:
32 ## odds ratio
33 ##  1.95517
34 ##
35 ## [1] "supine"
36 ##      Control Treatment
37 ## supine    3          3
38 ## Other    13         11
39 ##
40 ## Fisher's Exact Test for Count Data
41 ##
42 ## data: ORtable
43 ## p-value = 1
44 ## alternative hypothesis: true odds ratio is not equal to 1
45 ## 95 percent confidence interval:
46 ##  0.09371084 7.70893039
47 ## sample estimates:
48 ## odds ratio
49 ##  0.8508967
50 ##
51 ## [1] "prone"
52 ##      Control Treatment

```

```

1
2
3 ## prone          6          7
4 ## Other         10          7
5 ##
6 ## Fisher's Exact Test for Count Data
7 ##
8 ## data: ORtable
9 ## p-value = 0.7131
10 ## alternative hypothesis: true odds ratio is not equal to 1
11 ## 95 percent confidence interval:
12 ##  0.1101751 3.2231312
13 ## sample estimates:
14 ## odds ratio
15 ##  0.6104211
16
17
18 #####WAKE UP POSITION IN PAST WEEK#####
19 summary(DCFdata$woke.up.in.past.week)
20
21 ##                left          left, right left, right, supine
22 ##                3                5                2
23 ##      left, supine          right          right, supine
24 ##                2                4                0
25 ##                supine
26 ##                4
27
28 length(DCFdata$woke.up.in.past.week)
29
30 ## [1] 20
31
32 #Tabulate the data
33 xtabs(~woke.up.in.past.week + intervention, data = DCFdata)
34
35 ##                intervention
36 ## woke.up.in.past.week Control Treatment
37 ## left                1                2
38 ## left, right        1                4
39 ## left, right, supine 1                1
40 ## left, supine        1                1
41 ## right               4                0
42 ## right, supine      0                0
43 ## supine              2                2
44
45 #Perform Fisher's Exact Test
46 #fisher.test(xtabs(~woke.up.in.past.week + intervention, data = DCFdata))
47 #build 2-row table for fisher test: control vs treatment
48 woke.up.in.past.week_table <- matrix(c(4,8,6,5,4,4),
49                                     nrow = 2)
50
51 colnames(woke.up.in.past.week_table) <- c("left", "right", "supine")
52 rownames(woke.up.in.past.week_table) <- c("Control",
53                                           "Treatment")
54 t(woke.up.in.past.week_table)
55
56
57
58
59
60

```

```

1
2
3      ##          Control Treatment
4      ## left           4           8
5      ## right          6           5
6      ## supine         4           4
7
8      #Compare above with those who did not complete the study (n=3):
9      summary(DropOutdata$woke.up.in.past.week)
10
11     ##          left           left, right left, right, supine
12     ##          0             2             0
13     ##    left, supine       right       right, supine
14     ##          0             0             1
15     ##          supine
16     ##          0
17
18     #Perform Fisher's Exact Test
19     fisher.test(woke.up.in.past.week_table)
20
21     ##
22     ## Fisher's Exact Test for Count Data
23     ##
24     ## data:  woke.up.in.past.week_table
25     ## p-value = 0.6555
26     ## alternative hypothesis: two.sided
27
28     temp_table <- t(woke.up.in.past.week_table)
29     j=nrow(temp_table)
30     ControlCsum=colSums(temp_table)[1]
31     TreatmentCsum=colSums(temp_table)[2]
32     for(i in 1:j) {
33       a=temp_table[i,1]
34       b=temp_table[i,2]
35       c=ControlCsum-a
36       d=TreatmentCsum-b
37       ORtable <- matrix(c(a,c,b,d),nrow = 2)
38       colnames(ORtable) <- c("Control", "Treatment")
39       rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
40       print(row.names(temp_table)[i])
41       print(ORtable)
42       print(fisher.test(ORtable))
43     }
44
45     ## [1] "left"
46     ##          Control Treatment
47     ## left           4           8
48     ## Other          10           9
49     ##
50     ## Fisher's Exact Test for Count Data
51     ##
52     ## data:  ORtable
53     ## p-value = 0.4607
54
55
56
57
58
59
60

```

```

1
2
3  ## alternative hypothesis: true odds ratio is not equal to 1
4  ## 95 percent confidence interval:
5  ## 0.07417123 2.49180269
6  ## sample estimates:
7  ## odds ratio
8  ## 0.4618727
9  ##
10 ## [1] "right"
11 ##      Control Treatment
12 ## right      6      5
13 ## Other     8      12
14 ##
15 ## Fisher's Exact Test for Count Data
16 ##
17 ## data: ORtable
18 ## p-value = 0.4775
19 ## alternative hypothesis: true odds ratio is not equal to 1
20 ## 95 percent confidence interval:
21 ## 0.3207388 10.2754454
22 ## sample estimates:
23 ## odds ratio
24 ## 1.765584
25 ##
26 ## [1] "supine"
27 ##      Control Treatment
28 ## supine     4      4
29 ## Other     10     13
30 ##
31 ## Fisher's Exact Test for Count Data
32 ##
33 ## data: ORtable
34 ## p-value = 1
35 ## alternative hypothesis: true odds ratio is not equal to 1
36 ## 95 percent confidence interval:
37 ## 0.1885274 8.8685637
38 ## sample estimates:
39 ## odds ratio
40 ## 1.288954
41
42 #####WAKE UP POSITION WHEN NOT PREGNANT#####
43 summary(DCFdata$woke.up.when.not.pregnant)
44
45 ##          left          left, right
46 ##          3          1
47 ## left, right, prone left, right, supine
48 ##          1          1
49 ## left, right, supine, prone left, supine, prone
50 ##          2          1
51 ##          prone          right
52 ##          2          2
53
54
55
56
57
58
59
60

```



```

1
2
3      ##           right, supine                supine
4      ##                   0                    4
5      ##           supine, prone
6      ##                   3
7
8      length(DCFdata$woke.up.when.not.pregnant)
9
10     ## [1] 20
11
12     #Tabulate the data
13     xtabs(~woke.up.when.not.pregnant + intervention, data = DCFdata)
14
15     ##           intervention
16     ## woke.up.when.not.pregnant   Control Treatment
17     ## left                        2           1
18     ## left, right                 0           1
19     ## left, right, prone           0           1
20     ## left, right, supine         0           1
21     ## left, right, supine, prone  1           1
22     ## left, supine, prone         1           0
23     ## prone                       0           2
24     ## right                       1           1
25     ## right, supine               0           0
26     ## supine                      3           1
27     ## supine, prone               2           1
28
29
30     #Perform Fisher's Exact Test
31     #fisher.test(xtabs(~woke.up.when.not.pregnant + intervention, data = DCFdata)
32     )
33     #build 2-row table for fisher test: control vs treatment
34     woke.up.when.not.pregnant_table <- matrix(c(4,5,2,5,7,4,4,5),
35                                               nrow = 2)
36     colnames(woke.up.when.not.pregnant_table) <- c("left", "right", "supine", "prone")
37     rownames(woke.up.when.not.pregnant_table) <- c("Control",
38                                                    "Treatment")
39
40     t(woke.up.when.not.pregnant_table)
41
42     ##           Control Treatment
43     ## left           4           5
44     ## right          2           5
45     ## supine         7           4
46     ## prone          4           5
47
48
49     #Compare above with those who did not complete the study (n=3):
50     summary(DropOutdata$woke.up.when.not.pregnant)
51
52     ##           left                left, right
53     ##                   0                    0
54     ##           left, right, prone    left, right, supine
55     ##                   0                    1
56     ## left, right, supine, prone    left, supine, prone

```

```

1
2
3     ##                0                0
4     ##                prone            right
5     ##                1                0
6     ##                right, supine    supine
7     ##                1                0
8     ##                supine, prone
9     ##                0
10
11    #Perform Fisher's Exact Test
12    fisher.test(woke.up.when.not.pregnant_table)
13
14    ##
15    ## Fisher's Exact Test for Count Data
16    ##
17    ## data:  woke.up.when.not.pregnant_table
18    ## p-value = 0.56
19    ## alternative hypothesis: two.sided
20
21    temp_table <- t(woke.up.when.not.pregnant_table)
22    j=nrow(temp_table)
23    ControlCsum=colSums(temp_table)[1]
24    TreatmentCsum=colSums(temp_table)[2]
25    for(i in 1:j) {
26      a=temp_table[i,1]
27      b=temp_table[i,2]
28      c=ControlCsum-a
29      d=TreatmentCsum-b
30      ORtable <- matrix(c(a,c,b,d),nrow = 2)
31      colnames(ORtable) <- c("Control", "Treatment")
32      rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
33      print(row.names(temp_table)[i])
34      print(ORtable)
35      print(fisher.test(ORtable))
36    }
37
38    ## [1] "left"
39
40    ##      Control Treatment
41    ## left      4         5
42    ## Other    13        14
43
44    ##
45    ## Fisher's Exact Test for Count Data
46    ##
47    ## data:  ORtable
48    ## p-value = 1
49    ## alternative hypothesis: true odds ratio is not equal to 1
50    ## 95 percent confidence interval:
51    ##  0.13878 5.04642
52    ## sample estimates:
53    ## odds ratio
54    ##  0.8651067
55    ##
56
57
58
59
60

```

```

1
2
3  ## [1] "right"
4  ##      Control Treatment
5  ## right      2          5
6  ## Other     15         14
7  ##
8  ## Fisher's Exact Test for Count Data
9  ##
10 ## data: ORtable
11 ## p-value = 0.408
12 ## alternative hypothesis: true odds ratio is not equal to 1
13 ## 95 percent confidence interval:
14 ##  0.03161314 2.82646603
15 ## sample estimates:
16 ## odds ratio
17 ##  0.3834022
18 ##
19 ## [1] "supine"
20 ##      Control Treatment
21 ## supine     7          4
22 ## Other     10         15
23 ##
24 ## Fisher's Exact Test for Count Data
25 ##
26 ## data: ORtable
27 ## p-value = 0.2814
28 ## alternative hypothesis: true odds ratio is not equal to 1
29 ## 95 percent confidence interval:
30 ##  0.4917611 15.3003743
31 ## sample estimates:
32 ## odds ratio
33 ##  2.553445
34 ##
35 ## [1] "prone"
36 ##      Control Treatment
37 ## prone      4          5
38 ## Other     13         14
39 ##
40 ## Fisher's Exact Test for Count Data
41 ##
42 ## data: ORtable
43 ## p-value = 1
44 ## alternative hypothesis: true odds ratio is not equal to 1
45 ## 95 percent confidence interval:
46 ##  0.13878 5.04642
47 ## sample estimates:
48 ## odds ratio
49 ##  0.8651067
50
51 #####PART OF BED PARTICIPANT SLEEPS ON#####
52 summary(DCFdata$side.of.bed)
53
54
55
56
57
58
59
60

```

```

1
2
3 ##           center           left left, right, center
4 ##           2             8             1
5 ##           right        right, center
6 ##           9             0
7
8 length(DCFdata$side.of.bed)
9
10 ## [1] 20
11
12 #Tabulate the data
13 xtabs(~side.of.bed + intervention, data = DCFdata)
14
15 ##           intervention
16 ## side.of.bed      Control Treatment
17 ## center           0           2
18 ## left             5           3
19 ## left, right, center 0           1
20 ## right            5           4
21 ## right, center     0           0
22
23 #Perform Fisher's Exact Test
24 #fisher.test(xtabs(~side.of.bed + intervention, data = DCFdata))
25 #build 2-row table for fisher test: control vs treatment
26 side.of.bed_table <- matrix(c(5,4,5,5,0,3),
27                               nrow = 2)
28
29 colnames(side.of.bed_table) <- c("left", "right", "center")
30 rownames(side.of.bed_table) <- c("Control",
31                                   "Treatment")
32
33 t(side.of.bed_table)
34
35 ##           Control Treatment
36 ## left       5           4
37 ## right      5           5
38 ## center     0           3
39
40 #Perform Fisher's Exact Test
41 fisher.test(side.of.bed_table)
42
43 ##
44 ## Fisher's Exact Test for Count Data
45 ##
46 ## data:  side.of.bed_table
47 ## p-value = 0.357
48 ## alternative hypothesis: two.sided
49
50 temp_table <- t(side.of.bed_table)
51 j=nrow(temp_table)
52 ControlCsum=colSums(temp_table)[1]
53 TreatmentCsum=colSums(temp_table)[2]
54 for(i in 1:j) {
55   a=temp_table[i,1]
56   b=temp_table[i,2]

```

```

1
2
3   c=ControlCsum-a
4   d=TreatmentCsum-b
5   ORtable <- matrix(c(a,c,b,d),nrow = 2)
6   colnames(ORtable) <- c("Control","Treatment")
7   rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
8   print(row.names(temp_table)[i])
9   print(ORtable)
10  print(fisher.test(ORtable))
11
12 }
13
14 ## [1] "left"
15 ##      Control Treatment
16 ## left      5         4
17 ## Other     5         8
18 ##
19 ## Fisher's Exact Test for Count Data
20 ##
21 ## data:  ORtable
22 ## p-value = 0.6656
23 ## alternative hypothesis: true odds ratio is not equal to 1
24 ## 95 percent confidence interval:
25 ##  0.2637526 15.6036729
26 ## sample estimates:
27 ## odds ratio
28 ##  1.936521
29 ##
30 ## [1] "right"
31 ##      Control Treatment
32 ## right     5         5
33 ## Other     5         7
34 ##
35 ## Fisher's Exact Test for Count Data
36 ##
37 ## data:  ORtable
38 ## p-value = 1
39 ## alternative hypothesis: true odds ratio is not equal to 1
40 ## 95 percent confidence interval:
41 ##  0.1920501 10.2898393
42 ## sample estimates:
43 ## odds ratio
44 ##  1.378598
45 ##
46 ## [1] "center"
47 ##      Control Treatment
48 ## center    0         3
49 ## Other     10        9
50 ##
51 ## Fisher's Exact Test for Count Data
52 ##
53 ## data:  ORtable

```

```

1
2
3  ## p-value = 0.2208
4  ## alternative hypothesis: true odds ratio is not equal to 1
5  ## 95 percent confidence interval:
6  ## 0.000000 2.779036
7  ## sample estimates:
8  ## odds ratio
9  ##          0
10
11 #####BED PARTNER#####
12 summary(DCFdata$sleeps.with.without.partner)
13
14  ##      with without
15  ##      17      3
16
17 length(DCFdata$sleeps.with.without.partner)
18
19  ## [1] 20
20
21 #Compare above with those who did not complete the study (n=3):
22 summary(DropOutdata$sleeps.with.without.partner)
23
24  ##      with without
25  ##      3      0
26
27 #Tabulate the data
28 xtabs(~sleeps.with.without.partner + intervention, data = DCFdata)
29
30  ##                intervention
31  ## sleeps.with.without.partner Control Treatment
32  ##                with      10      7
33  ##                without    0      3
34
35 #Perform Fisher's Exact Test
36 fisher.test(xtabs(~sleeps.with.without.partner + intervention, data = DCFdata
37 ))
38
39  ##
40  ## Fisher's Exact Test for Count Data
41  ##
42  ## data:  xtabs(~sleeps.with.without.partner + intervention, data = DCFdata)
43  ## p-value = 0.2105
44  ## alternative hypothesis: true odds ratio is not equal to 1
45  ## 95 percent confidence interval:
46  ## 0.443414      Inf
47  ## sample estimates:
48  ## odds ratio
49  ##          Inf
50
51 #####PILLOW USE#####
52 summary(DCFdata$pillow)
53
54
55
56
57
58
59
60

```

```

1
2
3     ##                pregnancy pillow
4     ##                2
5     ##                under head
6     ##                1
7     ##                under head and between knees
8     ##                4
9     ##                under head and pregnancy pillow
10    ##                1
11    ##                under head between knees
12    ##                1
13    ##                under head between knees and behind back
14    ##                2
15    ##                under head between knees and pregnancy pillow
16    ##                1
17    ##                under head between knees and under tummy
18    ##                1
19    ## under head between knees behind back and pregnany pillow
20    ##                1
21    ##                under head between knees under tummy
22    ##                1
23    ##                under head between knees under tummy and behind back
24    ##                3
25    ##                under head under tummy and behind back
26    ##                2
27
28
29
30 length(DCFdata$pillow)
31
32 ## [1] 20
33
34 #Tabulate the data
35 xtabs(~pillow + intervention, data = DCFdata)
36
37 ##                intervention
38 ## pillow                Control
39 ## pregnancy pillow                1
40 ## under head                1
41 ## under head and between knees                3
42 ## under head and pregnancy pillow                0
43 ## under head between knees                0
44 ## under head between knees and behind back                1
45 ## under head between knees and pregnancy pillow                0
46 ## under head between knees and under tummy                0
47 ## under head between knees behind back and pregnany pillow                0
48 ## under head between knees under tummy                0
49 ## under head between knees under tummy and behind back                2
50 ## under head under tummy and behind back                2
51 ##                intervention
52 ## pillow                Treatment
53 ## pregnancy pillow                1
54 ## under head                0
55 ## under head and between knees                1

```

```

1
2
3  ## under head and pregnancy pillow 1
4  ## under head between knees 1
5  ## under head between knees and behind back 1
6  ## under head between knees and pregnancy pillow 1
7  ## under head between knees and under tummy 1
8  ## under head between knees behind back and pregnancy pillow 1
9  ## under head between knees under tummy 1
10 ## under head between knees under tummy and behind back 1
11 ## under head under tummy and behind back 0
12
13
14 #Perform Fisher's Exact Test
15 fisher.test(xtabs(~pillow + intervention, data = DCFdata))
16
17 ##
18 ## Fisher's Exact Test for Count Data
19 ##
20 ## data: xtabs(~pillow + intervention, data = DCFdata)
21 ## p-value = 0.7563
22 ## alternative hypothesis: two.sided
23
24 #build 2-row table for fisher test: control vs treatment
25 pillow_table <- matrix(c(1,4,9,9,6,8,5,3,4,3),
26                        nrow = 2)
27 colnames(pillow_table) <- c("pregnancy pillow", "under head", "btw knees", "behind back", "under tummy")
28 rownames(pillow_table) <- c("Control",
29                             "Treatment")
30
31 t(pillow_table)
32
33 ## Control Treatment
34 ## pregnancy pillow 1 4
35 ## under head 9 9
36 ## btw knees 6 8
37 ## behind back 5 3
38 ## under tummy 4 3
39
40 #Compare above with those who did not complete the study (n=3):
41 summary(DropOutdata$pillow)
42
43 ## pregnancy pillow
44 ## 0
45 ## under head
46 ## 0
47 ## under head and between knees
48 ## 1
49 ## under head and pregnancy pillow
50 ## 0
51 ## under head between knees
52 ## 0
53 ## under head between knees and behind back
54 ## 1
55
56
57
58
59
60

```



```

1
2
3     ##           under head between knees and pregnancy pillow
4     ##                                           0
5     ##           under head between knees and under tummy
6     ##                                           1
7     ## under head between knees behind back and pregnany pillow
8     ##                                           0
9     ##           under head between knees under tummy
10    ##                                           0
11    ##           under head between knees under tummy and behind back
12    ##                                           0
13    ##           under head under tummy and behind back
14    ##                                           0
15    ##                                           0
16
17    #Perform Fisher's Exact Test
18    fisher.test(pillow_table)
19
20    ##
21    ## Fisher's Exact Test for Count Data
22    ##
23    ## data: pillow_table
24    ## p-value = 0.6624
25    ## alternative hypothesis: two.sided
26
27    temp_table <- t(pillow_table)
28    j=nrow(temp_table)
29    ControlCsum=colSums(temp_table)[1]
30    TreatmentCsum=colSums(temp_table)[2]
31    for(i in 1:j) {
32      a=temp_table[i,1]
33      b=temp_table[i,2]
34      c=ControlCsum-a
35      d=TreatmentCsum-b
36      ORtable <- matrix(c(a,c,b,d),nrow = 2)
37      colnames(ORtable) <- c("Control","Treatment")
38      rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
39      print(row.names(temp_table)[i])
40      print(ORtable)
41      print(fisher.test(ORtable))
42    }
43
44
45    ## [1] "pregnancy pillow"
46    ##           Control Treatment
47    ## pregnancy pillow      1      4
48    ## Other                24     23
49    ##
50    ## Fisher's Exact Test for Count Data
51    ##
52    ## data: ORtable
53    ## p-value = 0.3517
54    ## alternative hypothesis: true odds ratio is not equal to 1
55    ## 95 percent confidence interval:

```

```

1
2
3    ## 0.004679473 2.727254390
4    ## sample estimates:
5    ## odds ratio
6    ## 0.2455393
7    ##
8    ## [1] "under head"
9    ##           Control Treatment
10   ## under head      9      9
11   ## Other          16     18
12   ##
13   ## Fisher's Exact Test for Count Data
14   ##
15   ## data: ORtable
16   ## p-value = 1
17   ## alternative hypothesis: true odds ratio is not equal to 1
18   ## 95 percent confidence interval:
19   ## 0.3077428 4.1067353
20   ## sample estimates:
21   ## odds ratio
22   ## 1.12245
23   ##
24   ## [1] "btw knees"
25   ##           Control Treatment
26   ## btw knees      6      8
27   ## Other          19     19
28   ##
29   ## Fisher's Exact Test for Count Data
30   ##
31   ## data: ORtable
32   ## p-value = 0.7587
33   ## alternative hypothesis: true odds ratio is not equal to 1
34   ## 95 percent confidence interval:
35   ## 0.1779795 3.0415532
36   ## sample estimates:
37   ## odds ratio
38   ## 0.7541601
39   ##
40   ## [1] "behind back"
41   ##           Control Treatment
42   ## behind back    5      3
43   ## Other          20     24
44   ##
45   ## Fisher's Exact Test for Count Data
46   ##
47   ## data: ORtable
48   ## p-value = 0.4583
49   ## alternative hypothesis: true odds ratio is not equal to 1
50   ## 95 percent confidence interval:
51   ## 0.3355811 14.3021716
52   ## sample estimates:

```

```

1
2
3 ## odds ratio
4 ## 1.973559
5 ##
6 ## [1] "under tummy"
7 ##           Control Treatment
8 ## under tummy      4          3
9 ## Other            21          24
10 ##
11 ## Fisher's Exact Test for Count Data
12 ##
13 ## data: ORtable
14 ## p-value = 0.6983
15 ## alternative hypothesis: true odds ratio is not equal to 1
16 ## 95 percent confidence interval:
17 ## 0.2268471 11.5245873
18 ## sample estimates:
19 ## odds ratio
20 ## 1.511484
21
22
23 #####SNORING#####
24 summary(DCFdata$snore.3.times.or.more.per.week.does.not.snore)
25
26 ## does not snore      snores
27 ##           13          7
28
29 length(DCFdata$snore.3.times.or.more.per.week.does.not.snore)
30
31 ## [1] 20
32
33 #Compare above with those who did not complete the study (n=3):
34 summary(DropOutdata$snore.3.times.or.more.per.week.does.not.snore)
35
36 ## does not snore      snores
37 ##           2          1
38
39 #Tabulate the data
40 xtabs(~snore.3.times.or.more.per.week.does.not.snore + intervention, data =
41 DCFdata)
42
43 ##                               intervention
44 ## snore.3.times.or.more.per.week.does.not.snore Control Treatment
45 ##                               does not snore      7          6
46 ##                               snores              3          4
47
48 #Perform Fisher's Exact Test
49 fisher.test(xtabs(~snore.3.times.or.more.per.week.does.not.snore + intervent
50 ion, data = DCFdata))
51
52 ##
53 ## Fisher's Exact Test for Count Data
54 ##
55 ## data:

```

```

1
2
3  ## p-value = 1
4  ## alternative hypothesis: true odds ratio is not equal to 1
5  ## 95 percent confidence interval:
6  ##   0.1731447 15.0151265
7  ## sample estimates:
8  ## odds ratio
9  ##   1.521346
10
11 summary(DCFdata$how.long.snores)
12
13 ##
14 ##
15 14
16 ##
17 2-3 months
18 ##
19 1
20 ##
21 7.5 months
22 ##
23 1
24 ## I think so, my husband informs me that I do + it gets worse the further al
25 ong in pregnancy (louder/same frequency)
26 ##
27 1
28 ##
29 lifetime
30 ##
31 1
32 ##
33 several years
34 ##
35 1
36 ##
37 Since before I was pregnant
38 ##
39 1
40 ##
41 Since being pregnant
42 ##
43 0
44
45 length(DCFdata$how.long.snores)
46
47 ## [1] 20
48
49 #####PREGNANCY HISTORY#####
50 summary(DCFdata$pregnancy.related.medical.conditions)
51
52 ## none
53 ##   20
54
55
56
57
58
59
60

```

```
1
2
3 length(DCFdata$pregnancy.related.medical.conditions)
4
5 ## [1] 20
6
7 temp <- matrix(c(10,0,10,0), nrow = 2)
8 temp
9
10 ##      [,1] [,2]
11 ## [1,]   10   10
12 ## [2,]    0    0
13
14 fisher.test(temp)
15
16 ##
17 ## Fisher's Exact Test for Count Data
18 ##
19 ## data: temp
20 ## p-value = 1
21 ## alternative hypothesis: true odds ratio is not equal to 1
22 ## 95 percent confidence interval:
23 ##    0 Inf
24 ## sample estimates:
25 ## odds ratio
26 ##          0
27
28 #The End
```

Review only

1
2
3 **Supplementary file 2: Code and output – PSG analysis**
4
5
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For peer review only

PSG_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 16:08:13 2018

```
#Description of code: this code process the polysomnography (PSG) sleep reports in full.
#Within-participant comparisons and between-participant comparisons are computed. Linear
#mixed effects model is constructed for the percentage of time spent sleeping supine and
#the number of minutes spent sleeping supine.

#Summary: results reveal a statistically significant reduction in the percentage of time
#spent sleeping supine and in the number of minutes spent sleeping supine on testing with
#both paired Wilcoxon and linear mixed effects model.

#Notes:
#Regarding ANOVA:
#The result of this calculation is expressed in a test statistic called the F ratio
 #(designated simply as F), the ratio of how much variability there is between the groups
#relative to how much there is within the groups.

#If the null hypothesis is true (in other words, if no true difference exists between the
#groups), then the F ratio should be close to 1.

#The p value can be calculated from the values of F, df1, and df2, and the software
#will perform this calculation for you. If the p value from the ANOVA is significant
 #(less than 0.05 or your chosen alpha level), then you can conclude that the groups
#are not all the same (because the means varied from each other by too large an amount).

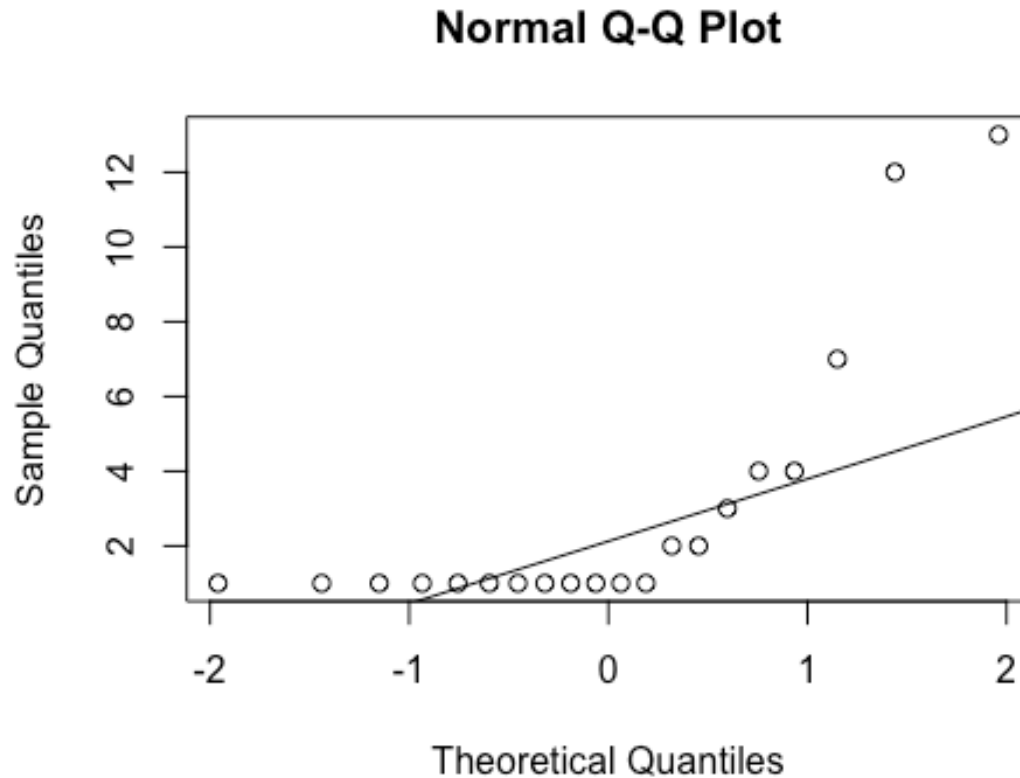
#setting the workspace directory
setwd("/Users/Allan/Desktop/HPTStats/08APR2017")

#importing the sleep study (SS) data
SSdatafull=read.csv("SS Data Halifax - 08APR2017.csv")
#Exclude drop outs
```

```

1
2
3 #How many drop outs?
4 summary(SSdatafull$drop.out)
5
6 ## N Y
7 ## 40 6
8
9 #6 nights = 3 participants
10 #Remove the drop outs ("Y")
11 SSdata <- SSdatafull[!(SSdatafull$drop.out=="Y"),]
12 nrow(SSdata)
13
14 ## [1] 40
15
16 #Loading the functions (ad.test, etc.) into your workspace
17 library(nortest)
18
19 ##### Time between studies (days) #####
20 #Summary
21 summary(SSdata$time.between.studies..days.)
22
23 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
24 ##      1.00   1.00   1.00   2.95   3.25   13.00     20
25
26 sd(SSdata$time.between.studies..days., na.rm = TRUE)
27
28 ## [1] 3.619756
29
30 length(SSdata$time.between.studies..days.)
31
32 ## [1] 40
33
34 #Check for normality
35 qqnorm(SSdata$time.between.studies..days.)
36 qqline(SSdata$time.between.studies..days.)
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

```

ad.test(SSdata$time.between.studies..days.)

##
## Anderson-Darling normality test
##
## data: SSdata$time.between.studies..days.
## A = 3.3009, p-value = 1.32e-08

#non-normal

#####Total sleep time#####
#Summary
summary(SSdata$total.sleep.time)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  154.5  317.6   351.6   336.4   373.5   431.0

sd(SSdata$total.sleep.time, na.rm = TRUE)

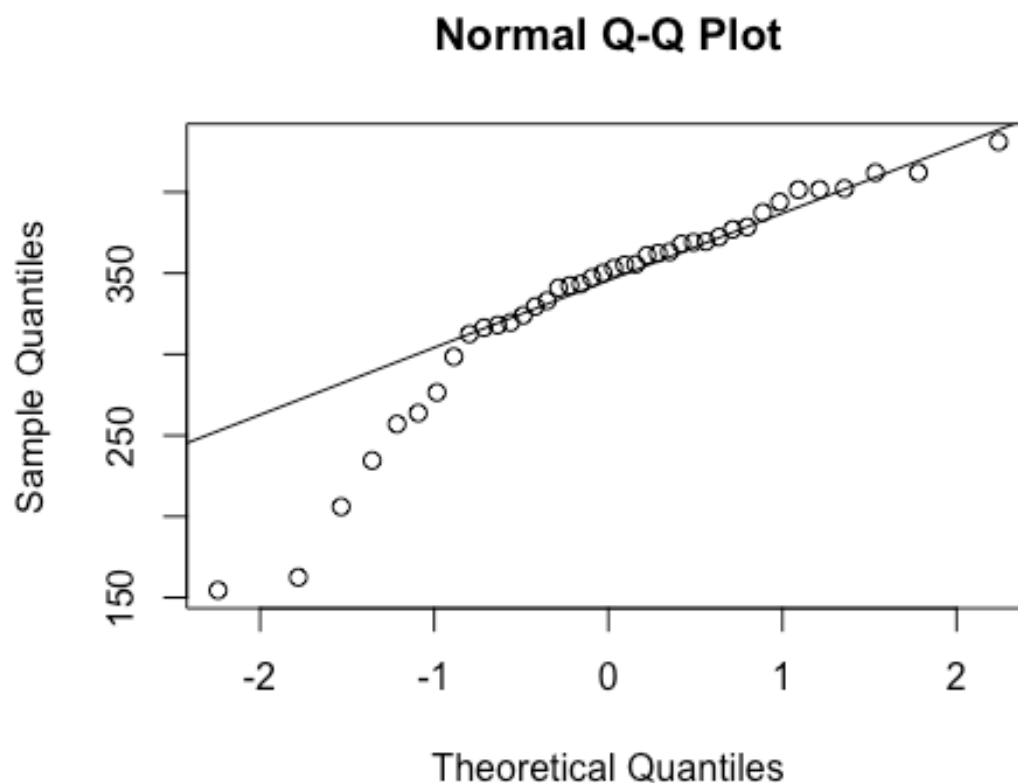
## [1] 63.95136

length(SSdata$total.sleep.time)

## [1] 40

```

```
qqnorm(SSdata$total.sleep.time)
qqline(SSdata$total.sleep.time)
```



```
ad.test(SSdata$total.sleep.time)

##
## Anderson-Darling normality test
##
## data: SSdata$total.sleep.time
## A = 1.3949, p-value = 0.001122

#non-normal

#ANOVA
night_tx_difference <- anova(lm(total.sleep.time ~ intervention*night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: total.sleep.time
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1     659    658.5   0.1527 0.6983
## night           1    3574   3574.0   0.8287 0.3687
```

```

1
2
3 ## intervention:night 1      3      2.8  0.0006 0.9800
4 ## Residuals          36 155266  4312.9
5
6 #No association between intervention or night on sleeptime, even when account
7 ing for
8 #both factors at the same time. It does not matter whether they received the
9 PrenaBelt
10 #on night one or night two.
11
12 #within-participants (paired) comparison
13 #need to remove drop outs in order to have balanced pairs
14 #Exclude drop outs
15 #How many drop outs?
16 summary(SSdata$drop.out)
17
18
19 ## N Y
20 ## 40 0
21
22 #Remove the drop outs ("Y")
23 SSdataCompletes <- SSdata[!(SSdata$drop.out=="Y"),]
24 nrow(SSdataCompletes)
25
26 ## [1] 40
27
28 #Non-normal - perform non-parametric test (Wilcoxon)
29 wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.sleep.time,
30             subset(SSdataCompletes, intervention == "PrenaBelt")$total.sleep.time,
31             paired = TRUE, conf.int = TRUE)
32
33 ##
34 ## Wilcoxon signed rank test
35 ##
36 ## data: subset(SSdataCompletes, intervention == "sham")$total.sleep.time an
37 d subset(SSdataCompletes, intervention == "PrenaBelt")$total.sleep.time
38 ## V = 112, p-value = 0.8124
39 ## alternative hypothesis: true location shift is not equal to 0
40 ## 95 percent confidence interval:
41 ## -21.80  33.75
42 ## sample estimates:
43 ## (pseudo)median
44 ##          3.55
45
46 #between participants (grouped) comparison
47 summary(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
48
49 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50 ##      154.5  317.6   352.6   332.4   375.6   412.1
51
52 sd(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
53
54 ## [1] 75.04747
55
56
57
58
59
60

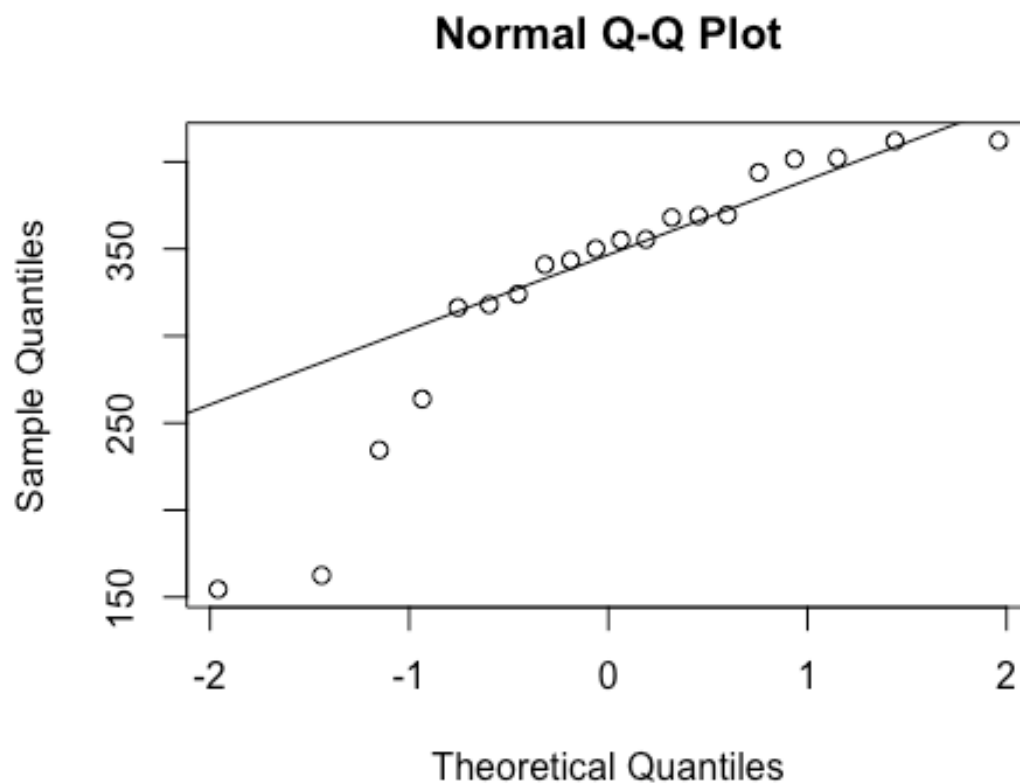
```

```

length(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
qqline(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$total.sleep.time
## A = 1.1032, p-value = 0.005239
##
##non-normal

summary(subset(SSdata, intervention == "sham")$total.sleep.time)
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 206.0   317.8   350.2   340.5   373.5   431.0

sd(subset(SSdata, intervention == "sham")$total.sleep.time)
## [1] 52.23046

```

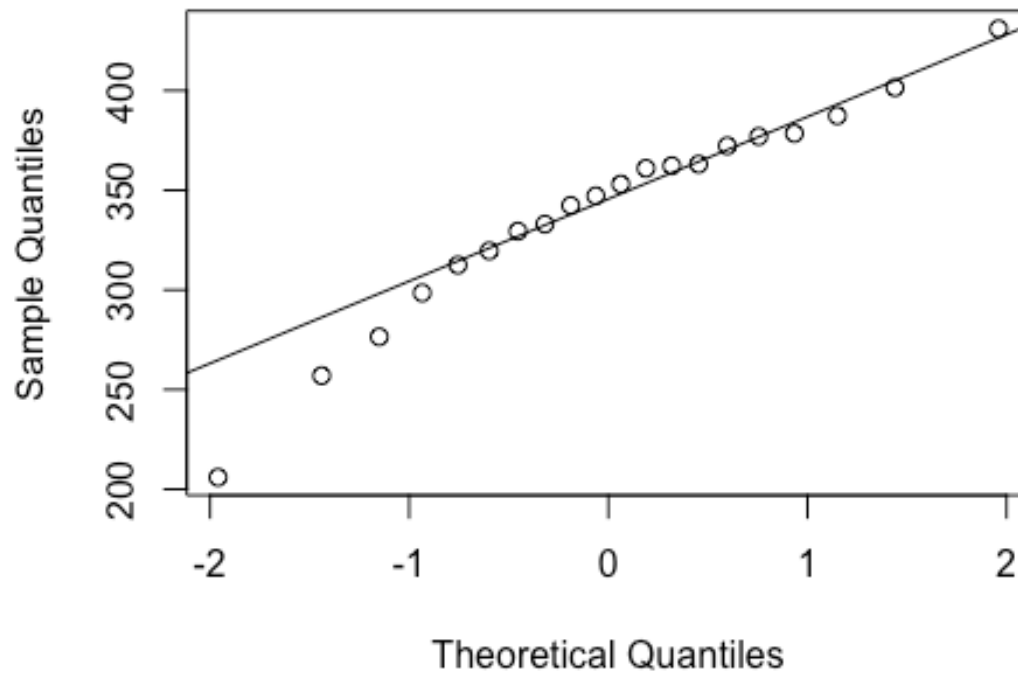
```

length(subset(SSdata, intervention == "sham")$total.sleep.time)
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$total.sleep.time)
qqline(subset(SSdata, intervention == "sham")$total.sleep.time)

```

Normal Q-Q Plot



```

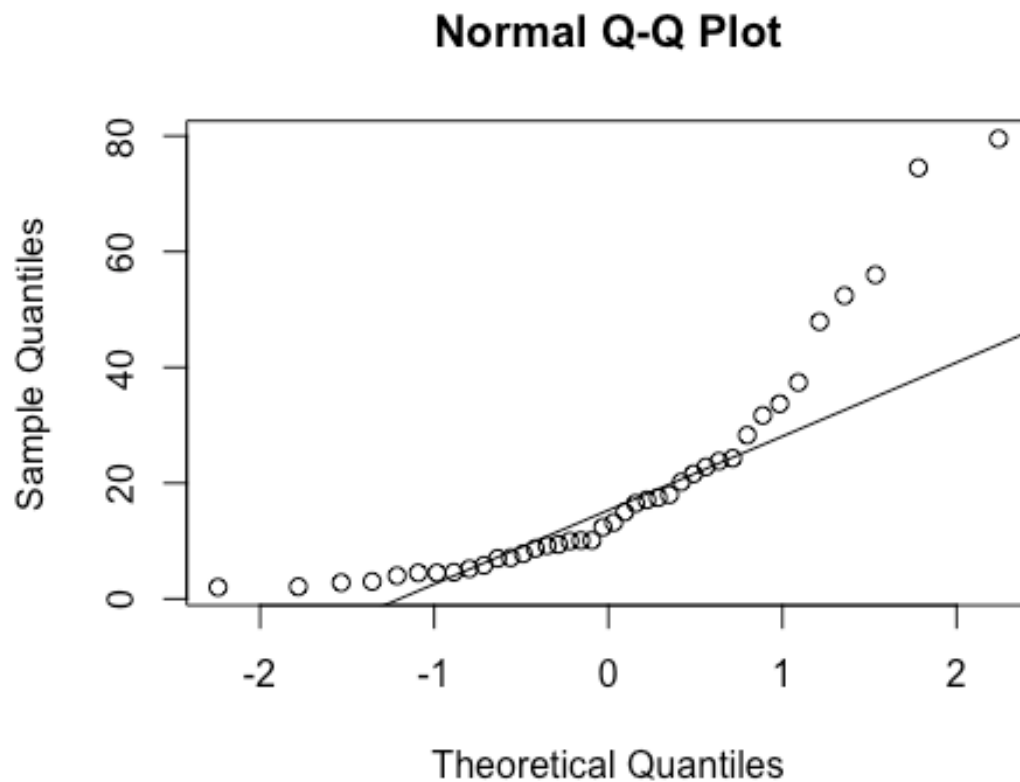
ad.test(subset(SSdata, intervention == "sham")$total.sleep.time)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$total.sleep.time
## A = 0.39153, p-value = 0.3464

#normal

#Non-normal - perform non-parametric test (Wilcoxon)
wilcox.test(subset(SSdata, intervention == "sham")$total.sleep.time,
            subset(SSdata, intervention == "PrenaBelt")$total.sleep.time,
            conf.int = TRUE)
##
## Wilcoxon rank sum test

```

```
1
2
3
4 ##
5 ## data: subset(SSdata, intervention == "sham")$total.sleep.time and subset(
6 SSdata, intervention == "PrenaBelt")$total.sleep.time
7 ## W = 196, p-value = 0.9254
8 ## alternative hypothesis: true location shift is not equal to 0
9 ## 95 percent confidence interval:
10 ## -35.1 32.3
11 ## sample estimates:
12 ## difference in location
13 ## -2.2
14
15 #####Sleep Latency#####
16 #Summary
17 summary(SSdata$sleep.latency)
18
19 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
20 ##      2.00   6.70   12.80   19.54   23.92   79.50
21
22 sd(SSdata$sleep.latency, na.rm = TRUE)
23
24 ## [1] 19.13941
25
26 length(SSdata$sleep.latency)
27
28 ## [1] 40
29
30 qqnorm(SSdata$sleep.latency)
31 qqline(SSdata$sleep.latency)
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(SSdata$sleep.latency)

##
## Anderson-Darling normality test
##
## data:  SSdata$sleep.latency
## A = 2.6549, p-value = 8.053e-07

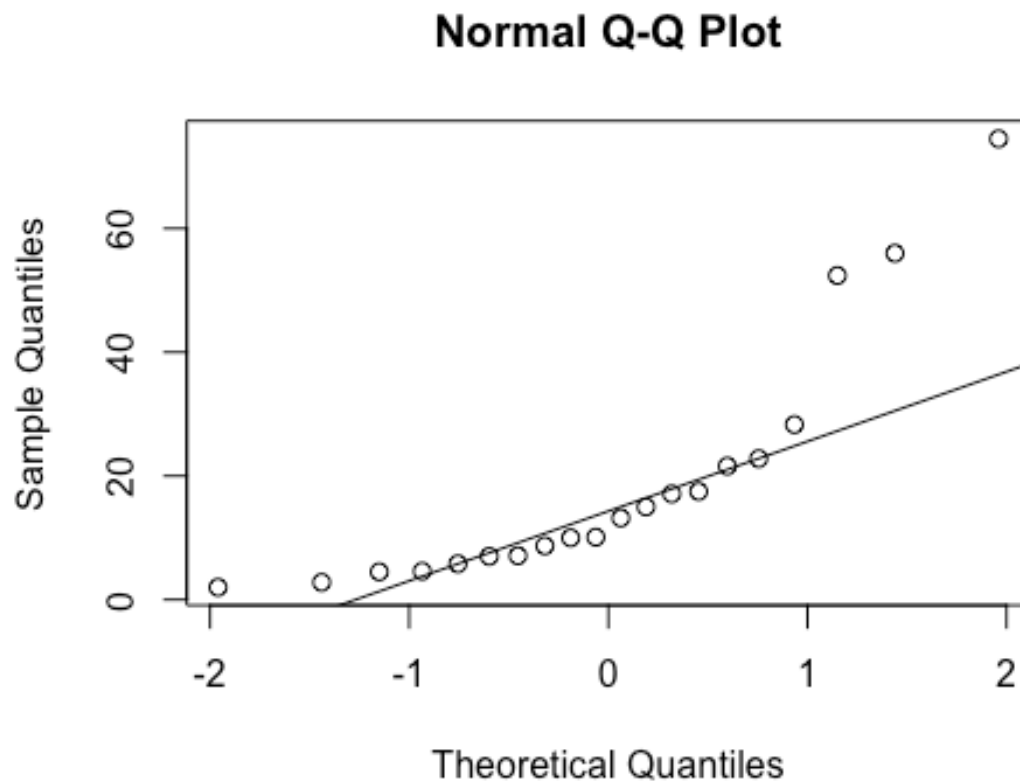
#non-normal

#ANOVA
night_tx_difference <- anova(lm(sleep.latency ~ intervention*night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: sleep.latency
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1     9.7    9.70  0.0247 0.8760
## night           1     1.0     0.99  0.0025 0.9602
## intervention:night 1    144.8  144.78  0.3688 0.5474
## Residuals      36 14130.9  392.52

```

```
1
2
3 #within-participants (paired) comparison
4 wilcox.test(subset(SSdataCompletes, intervention == "sham")$sleep.latency,
5             subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.latency,
6             paired = TRUE, conf.int = TRUE)
7
8 ##
9 ## Wilcoxon signed rank test
10 ##
11 ## data: subset(SSdataCompletes, intervention == "sham")$sleep.latency and s
12 subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.latency
13 ## V = 92, p-value = 0.6477
14 ## alternative hypothesis: true location shift is not equal to 0
15 ## 95 percent confidence interval:
16 ## -9.40 7.15
17 ## sample estimates:
18 ## (pseudo)median
19 ## -2
20
21 #between participants (grouped) comparison
22 summary(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
23
24 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
25 ##      2.00   6.70   11.65   19.05   21.90   74.50
26
27 sd(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
28
29 ## [1] 19.76593
30
31 length(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
32
33 ## [1] 20
34
35 qqnorm(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
36 qqline(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
```

```

ad.test(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$sleep.latency
## A = 1.8095, p-value = 8.14e-05

#Non-normal

summary(subset(SSdata, intervention == "sham")$sleep.latency)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      2.10   7.15   14.45   20.04   26.15   79.50

sd(subset(SSdata, intervention == "sham")$sleep.latency)

## [1] 18.99239

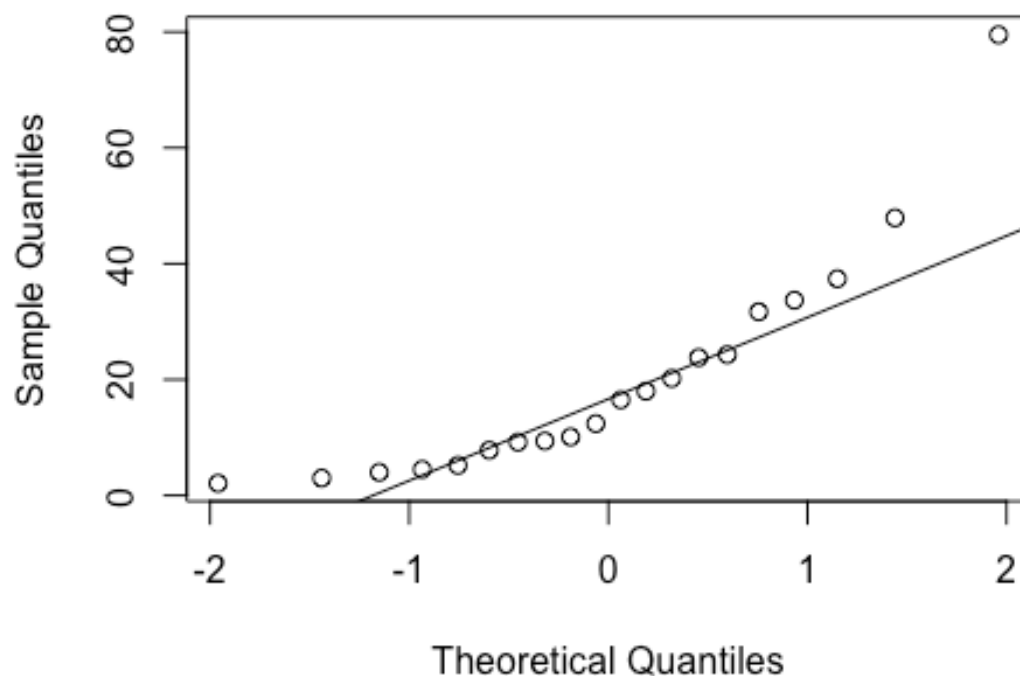
length(subset(SSdata, intervention == "sham")$sleep.latency)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$sleep.latency)
qqline(subset(SSdata, intervention == "sham")$sleep.latency)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$sleep.latency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$sleep.latency
## A = 1.0478, p-value = 0.007272

#Non-normal - perform non-parametric test (Wilcoxon)
wilcox.test(subset(SSdata, intervention == "sham")$sleep.latency,
            subset(SSdata, intervention == "PrenaBelt")$sleep.latency,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sleep.latency, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sleep.latency, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$sleep.latency and subset(SS
ata, intervention == "PrenaBelt")$sleep.latency

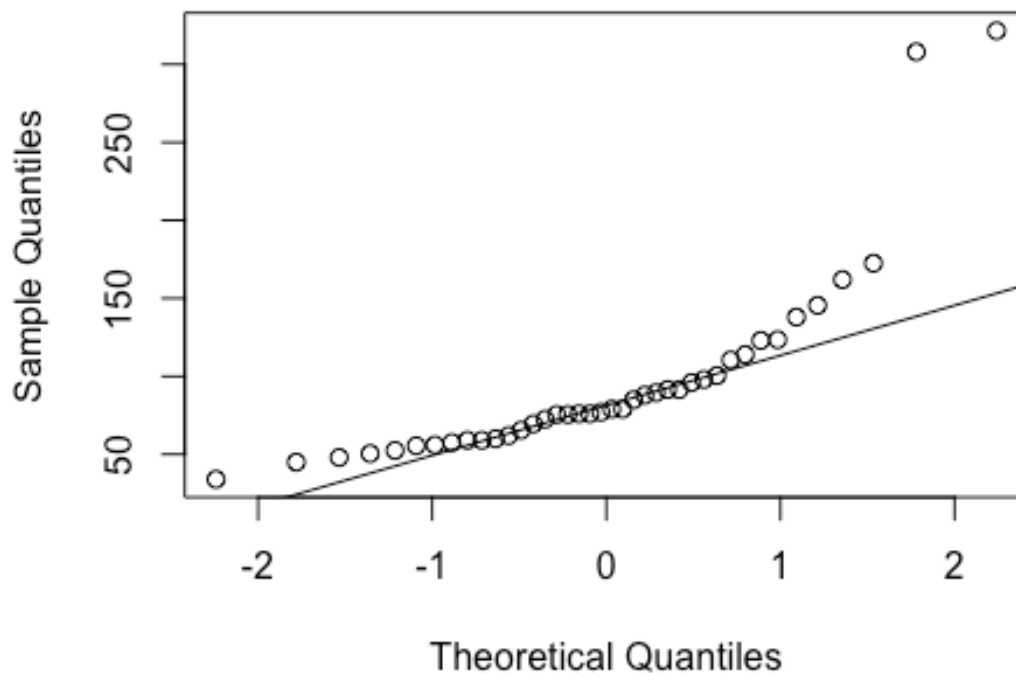
```

```

1
2
3  ## W = 214, p-value = 0.715
4  ## alternative hypothesis: true location shift is not equal to 0
5  ## 95 percent confidence interval:
6  ## -5.700008 10.099985
7  ## sample estimates:
8  ## difference in location
9  ##          1.01358
10
11 #####REM Latency#####
12 #Summary
13 summary(SSdata$rem.latency)
14
15 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
16 ##      34.00  59.75   78.00   96.08 103.00   321.50
17
18 sd(SSdata$rem.latency, na.rm = TRUE)
19
20 ## [1] 59.89655
21
22 length(SSdata$rem.latency)
23
24 ## [1] 40
25
26 qqnorm(SSdata$rem.latency)
27 qqline(SSdata$rem.latency)
28

```

Normal Q-Q Plot



```

1
2
3 ad.test(SSdata$rem.latency)
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: SSdata$rem.latency
9 ## A = 3.4165, p-value = 1.043e-08
10
11 #non-normal
12
13 #ANOVA
14 night_tx_difference <- anova(lm(rem.latency ~ intervention*night,
15                               data = SSdata))
16
17 night_tx_difference
18
19 ## Analysis of Variance Table
20 ##
21 ## Response: rem.latency
22 ##
23 ##           Df Sum Sq Mean Sq F value Pr(>F)
24 ## intervention      1  4580  4579.6  1.2379 0.2732
25 ## night              1  1974  1974.0  0.5336 0.4698
26 ## intervention:night  1   185   184.9  0.0500 0.8244
27 ## Residuals         36 133178  3699.4
28
29 #within-participants (paired) comparison
30 wilcox.test(subset(SSdataCompletes, intervention == "sham")$rem.latency,
31             subset(SSdataCompletes, intervention == "PrenaBelt")$rem.latency,
32             paired = TRUE, conf.int = TRUE)
33
34 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
35 ## "sham")$rem.latency, : cannot compute exact p-value with ties
36
37 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
38 ## "sham")$rem.latency, : cannot compute exact confidence interval with ties
39
40 ##
41 ## Wilcoxon signed rank test with continuity correction
42 ##
43 ## data: subset(SSdataCompletes, intervention == "sham")$rem.latency and sub
44 ## set(SSdataCompletes, intervention == "PrenaBelt")$rem.latency
45 ## V = 80.5, p-value = 0.37
46 ## alternative hypothesis: true location shift is not equal to 0
47 ## 95 percent confidence interval:
48 ## -35.50005  17.50006
49 ## sample estimates:
50 ## (pseudo)median
51 ## -5.190503
52
53 #between participants (grouped) comparison
54 summary(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
55
56
57
58
59
60

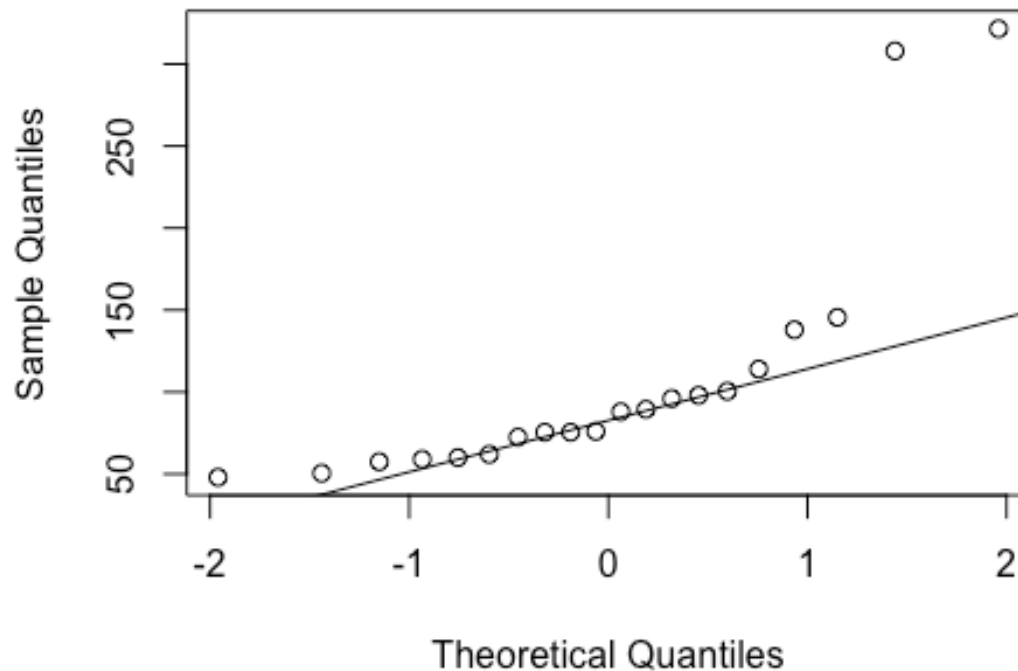
```

```

1
2
3  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4  ##      48.0   61.5   82.0   106.8  103.9   321.5
5
6  sd(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
7
8  ## [1] 75.95402
9
10 length(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
11
12 ## [1] 20
13
14 qqnorm(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
15 qqline(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
16
17
18
19

```

Normal Q-Q Plot



```

45 ad.test(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
46
47 ##
48 ## Anderson-Darling normality test
49 ##
50 ## data: subset(SSdata, intervention == "PrenaBelt")$rem.latency
51 ## A = 2.5226, p-value = 1.24e-06
52
53 #non-normal
54
55
56 summary(subset(SSdata, intervention == "sham")$rem.latency)
57
58
59

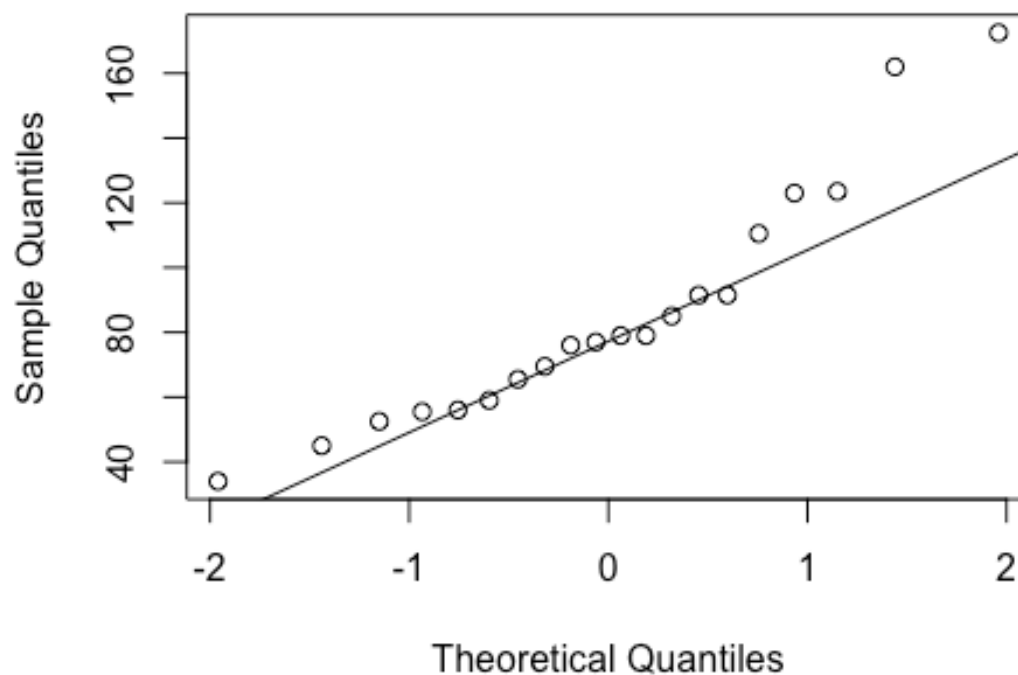
```

```

1
2
3  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4  ##   34.00  58.25   78.00   85.38  96.25  172.50
5
6  sd(subset(SSdata, intervention == "sham")$rem.latency)
7
8  ## [1] 36.79634
9
10 length(subset(SSdata, intervention == "sham")$rem.latency)
11
12 ## [1] 20
13
14 qqnorm(subset(SSdata, intervention == "sham")$rem.latency)
15 qqline(subset(SSdata, intervention == "sham")$rem.latency)
16
17
18
19
20
21
22

```

Normal Q-Q Plot



```

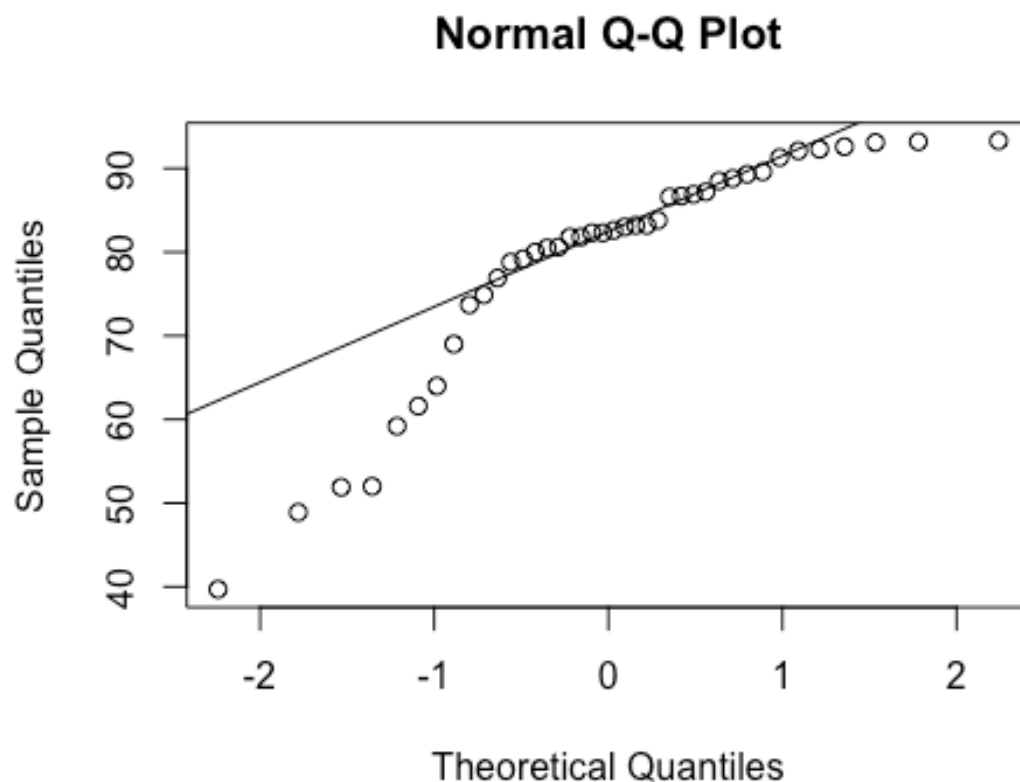
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45 ad.test(subset(SSdata, intervention == "sham")$rem.latency)
46
47 ##
48 ## Anderson-Darling normality test
49 ##
50 ## data: subset(SSdata, intervention == "sham")$rem.latency
51 ## A = 0.68703, p-value = 0.06153
52
53 #Non-normal - perform non-parametric test (Wilcoxon)
54 wilcox.test(subset(SSdata, intervention == "sham")$rem.latency,
55
56
57
58
59
60

```

```

1      subset(SSdata, intervention == "PrenaBelt")$rem.latency,
2      conf.int = TRUE)
3
4      ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
5      ## $rem.latency, : cannot compute exact p-value with ties
6
7      ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
8      ## $rem.latency, : cannot compute exact confidence intervals with ties
9
10     ##
11     ## Wilcoxon rank sum test with continuity correction
12     ##
13     ## data: subset(SSdata, intervention == "sham")$rem.latency and subset(SSdat
14     a, intervention == "PrenaBelt")$rem.latency
15     ## W = 178, p-value = 0.5608
16     ## alternative hypothesis: true location shift is not equal to 0
17     ## 95 percent confidence interval:
18     ## -27.50004 15.50003
19     ## sample estimates:
20     ## difference in location
21     ## -6.499973
22
23     #####Sleep Efficiency#####
24     #Summary
25     summary(SSdata$sleep.efficiency)
26
27     ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28     ## 39.70  76.40  82.45  79.16  88.58  93.30
29
30     sd(SSdata$sleep.efficiency, na.rm = TRUE)
31
32     ## [1] 13.44863
33
34     length(SSdata$sleep.efficiency)
35
36     ## [1] 40
37
38     qqnorm(SSdata$sleep.efficiency)
39     qqline(SSdata$sleep.efficiency)
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(SSdata$sleep.efficiency)

##
## Anderson-Darling normality test
##
## data:  SSdata$sleep.efficiency
## A = 2.2288, p-value = 9.251e-06

#non-normal

#ANOVA
night_tx_difference <- anova(lm(sleep.efficiency ~ intervention*night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: sleep.efficiency
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1   42.0   42.025    0.2179  0.6435
## night           1   36.1   36.100    0.1872  0.6679
## intervention:night 1   32.0   32.041    0.1661  0.6860
## Residuals      36 6943.6  192.877

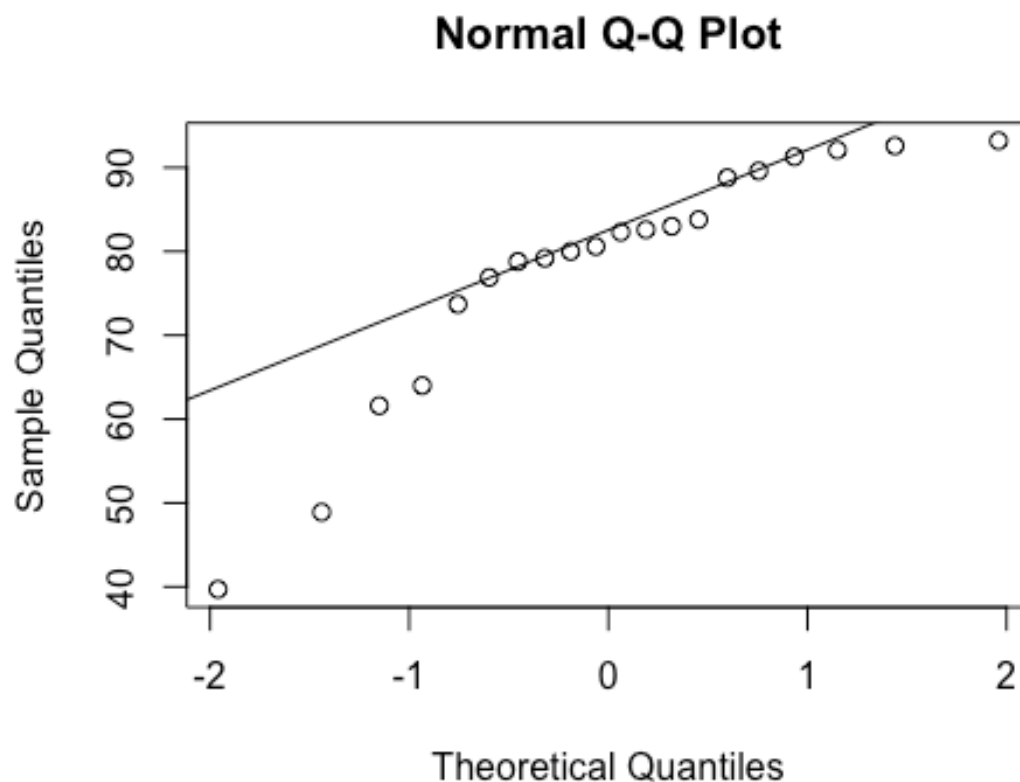
```



```

1
2
3 #within-participants (paired) comparison
4 wilcox.test(subset(SSdataCompletes, intervention == "sham")$sleep.efficiency,
5             subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.efficiency,
6             paired = TRUE, conf.int = TRUE)
7
8 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
9 ## "sham")$sleep.efficiency, : cannot compute exact p-value with ties
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$sleep.efficiency, : cannot compute exact confidence interval with
13 ## ties
14
15 ##
16 ## Wilcoxon signed rank test with continuity correction
17 ##
18 ## data: subset(SSdataCompletes, intervention == "sham")$sleep.efficiency an
19 d subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.efficiency
20 ## V = 125.5, p-value = 0.4552
21 ## alternative hypothesis: true location shift is not equal to 0
22 ## 95 percent confidence interval:
23 ## -3.000041 5.899953
24 ## sample estimates:
25 ## (pseudo)median
26 ## 1.444485
27
28 #between participants (grouped) comparison
29 summary(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
30
31 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
32 ## 39.70  76.10  81.45  78.14  89.00  93.20
33
34 sd(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
35
36 ## [1] 14.47362
37
38 length(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
39
40 ## [1] 20
41
42 qqnorm(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
43 qqline(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency
## A = 1.0955, p-value = 0.005485

#non-normal

summary(subset(SSdata, intervention == "sham")$sleep.efficiency)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  51.90   79.10   83.20   80.18   87.52   93.30

sd(subset(SSdata, intervention == "sham")$sleep.efficiency)

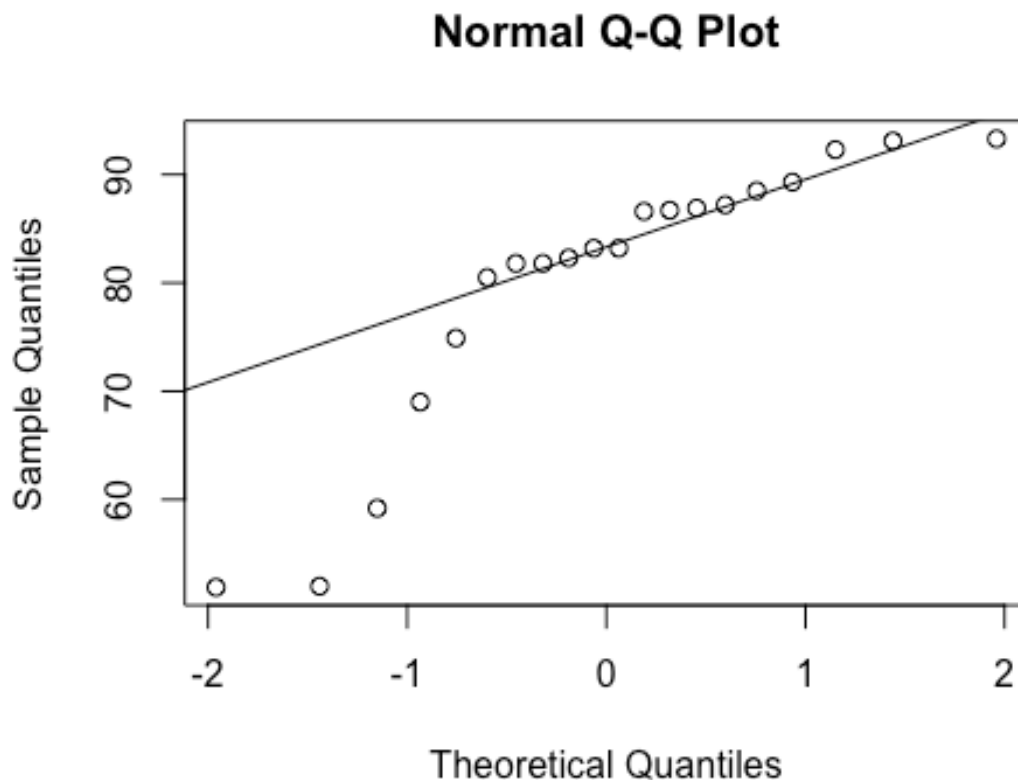
## [1] 12.63143

length(subset(SSdata, intervention == "sham")$sleep.efficiency)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$sleep.efficiency)
qqline(subset(SSdata, intervention == "sham")$sleep.efficiency)

```



```

ad.test(subset(SSdata, intervention == "sham")$sleep.ency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$sleep.ency
## A = 1.4349, p-value = 0.0007392

#non-normal

#Non-normal - perform non-parametric test (Wilcoxon)
wilcox.test(subset(SSdata, intervention == "sham")$sleep.ency,
            subset(SSdata, intervention == "PrenaBelt")$sleep.ency,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sleep.ency, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sleep.ency, : cannot compute exact confidence intervals with ties

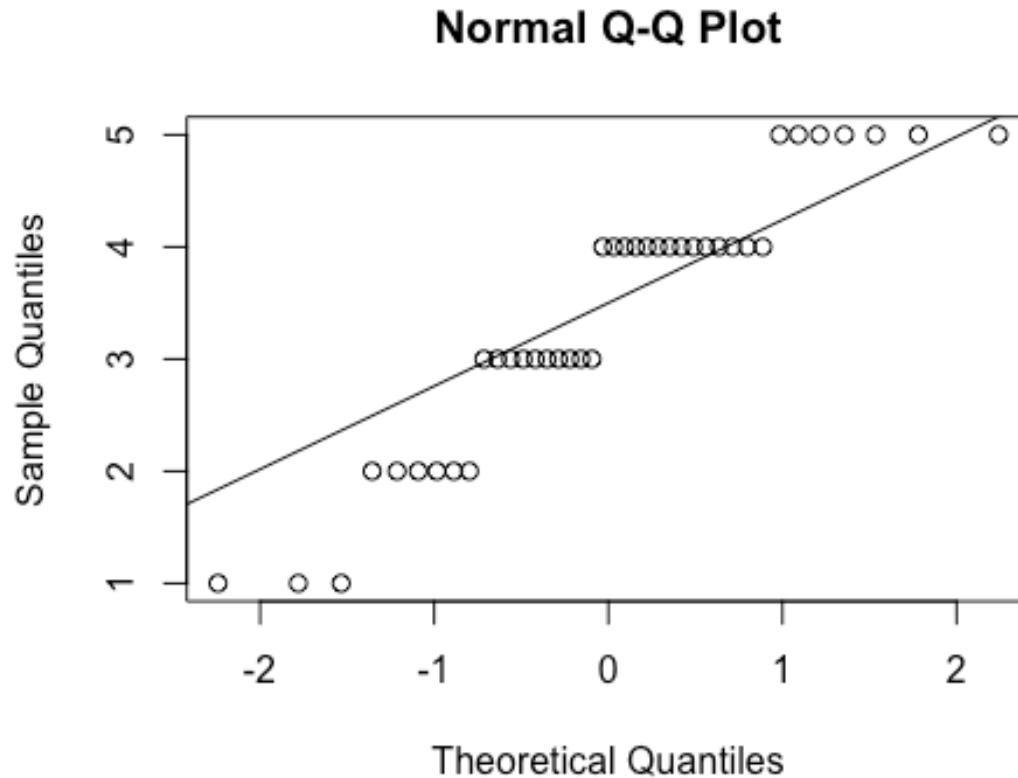
##
## Wilcoxon rank sum test with continuity correction
##

```

```

1
2
3  ## data: subset(SSdata, intervention == "sham")$sleep.efficiency and subset(
4  SSdata, intervention == "PrenaBelt")$sleep.efficiency
5  ## W = 222.5, p-value = 0.5517
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -4.800018  7.900004
9  ## sample estimates:
10 ## difference in location
11 ##          1.799971
12
13 #####Number of REM Periods#####
14 #Summary
15 summary(SSdata$num.rem.periods)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##      1.0    3.0    4.0    3.4    4.0    5.0
19
20 sd(SSdata$num.rem.periods, na.rm = TRUE)
21
22 ## [1] 1.172331
23
24 length(SSdata$num.rem.periods)
25
26 ## [1] 40
27
28 qqnorm(SSdata$num.rem.periods)
29 qqline(SSdata$num.rem.periods)
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```
ad.test(SSdata$num.rem.periods)

##
## Anderson-Darling normality test
##
## data:  SSdata$num.rem.periods
## A = 1.5069, p-value = 0.000588

#Looks non-normal, but it is ordinal data

#ANOVA
night_tx_difference <- anova(lm(num.rem.periods ~ intervention*night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: num.rem.periods
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    0.4  0.4000   0.2903 0.5933
## night           1    3.6  3.6000   2.6129 0.1147
## intervention:night 1    0.0  0.0000   0.0000 1.0000
## Residuals      36   49.6  1.3778
```

```

1
2
3 #within-participants (paired) comparison
4 t.test(subset(SSdataCompletes, intervention == "sham")$num.rem.periods,
5       subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods,
6       paired = TRUE)
7
8 ##
9 ## Paired t-test
10 ##
11 ## data: subset(SSdataCompletes, intervention == "sham")$num.rem.periods and
12 subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods
13 ## t = 0.80943, df = 19, p-value = 0.4283
14 ## alternative hypothesis: true difference in means is not equal to 0
15 ## 95 percent confidence interval:
16 ## -0.3171618  0.7171618
17 ## sample estimates:
18 ## mean of the differences
19 ##
20 ##          0.2
21
22 wilcox.test(subset(SSdataCompletes, intervention == "sham")$num.rem.periods,
23            subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods,
24            paired = TRUE, conf.int = TRUE)
25
26 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
27 ## "sham")$num.rem.periods, : cannot compute exact p-value with ties
28
29 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
30 ## "sham")$num.rem.periods, : cannot compute exact confidence interval with
31 ## ties
32
33 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
34 ## "sham")$num.rem.periods, : cannot compute exact p-value with zeroes
35
36 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
37 ## "sham")$num.rem.periods, : cannot compute exact confidence interval with
38 ## zeroes
39
40 ##
41 ## Wilcoxon signed rank test with continuity correction
42 ##
43 ## data: subset(SSdataCompletes, intervention == "sham")$num.rem.periods and
44 subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods
45 ## V = 73.5, p-value = 0.432
46 ## alternative hypothesis: true location shift is not equal to 0
47 ## 95 percent confidence interval:
48 ## -0.4999577  1.0000552
49 ## sample estimates:
50 ## (pseudo)median
51 ##  4.422455e-05
52
53 #between participants (grouped) comparison
54 summary(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
55
56
57
58
59
60

```

```

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      1.00   2.75   3.00   3.30   4.25   5.00

sd(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)

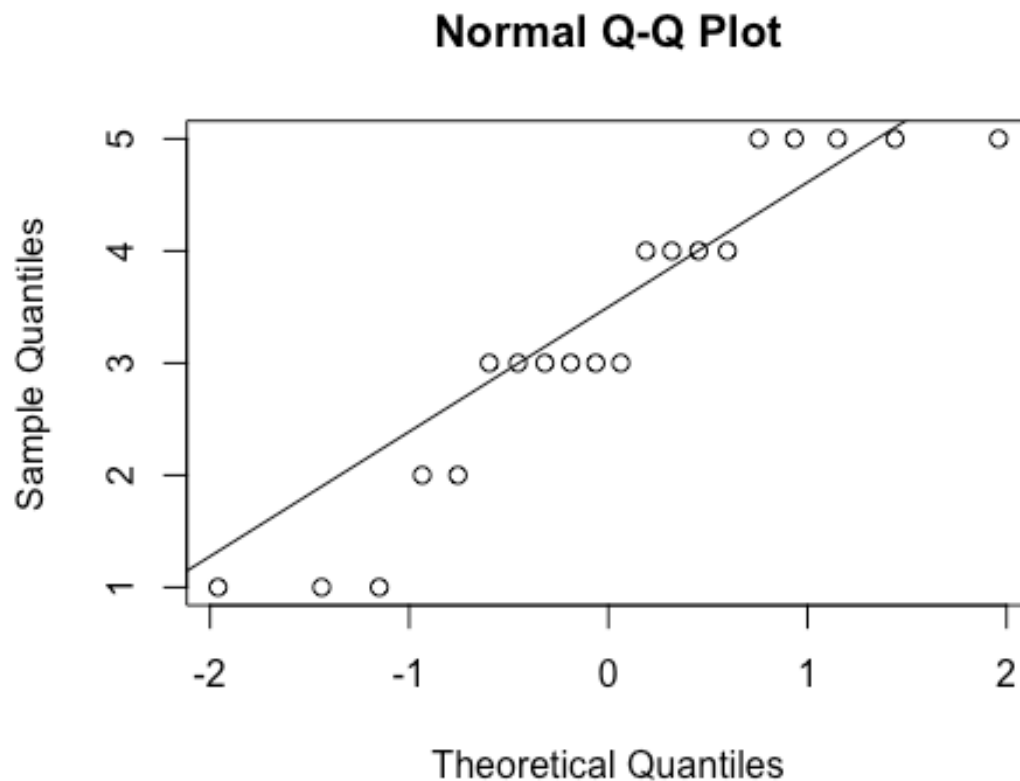
## [1] 1.380313

length(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
qqline(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$num.rem.periods
## A = 0.72773, p-value = 0.04835

#non-normal (ordinal data not held well by q-q plots)

summary(subset(SSdata, intervention == "sham")$num.rem.periods)

```

```

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      2.0    3.0    4.0    3.5    4.0    5.0

sd(subset(SSdata, intervention == "sham")$num.rem.periods)

## [1] 0.9459053

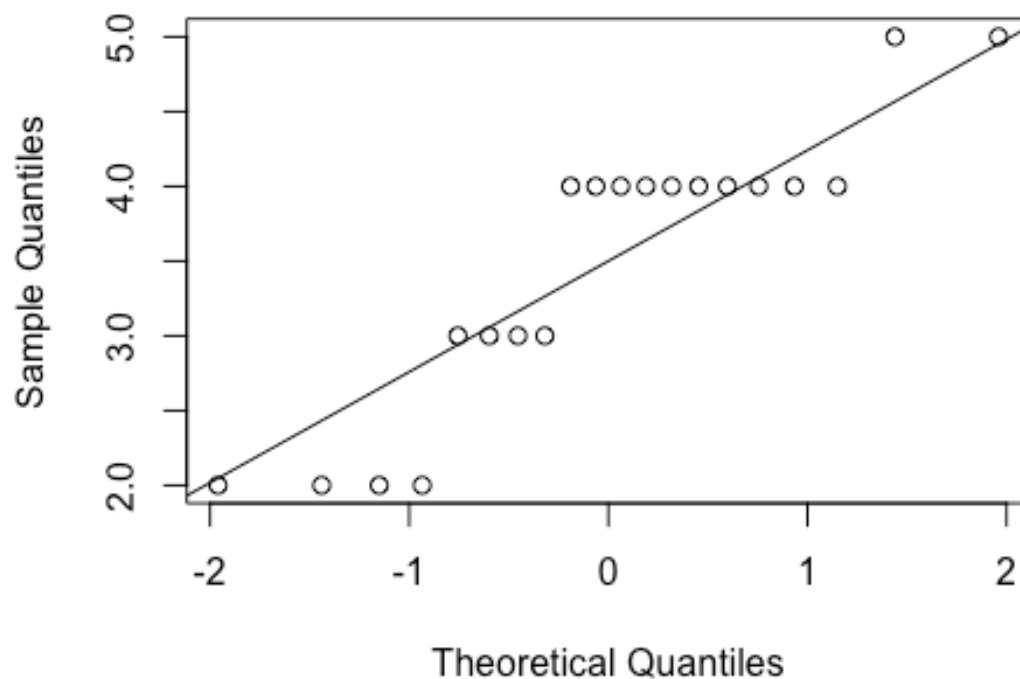
length(subset(SSdata, intervention == "sham")$num.rem.periods)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$num.rem.periods)
qqline(subset(SSdata, intervention == "sham")$num.rem.periods)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$num.rem.periods)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$num.rem.periods
## A = 1.4725, p-value = 0.0005924

#non-normal (ordinal data not held well by q-q plots)

```



```

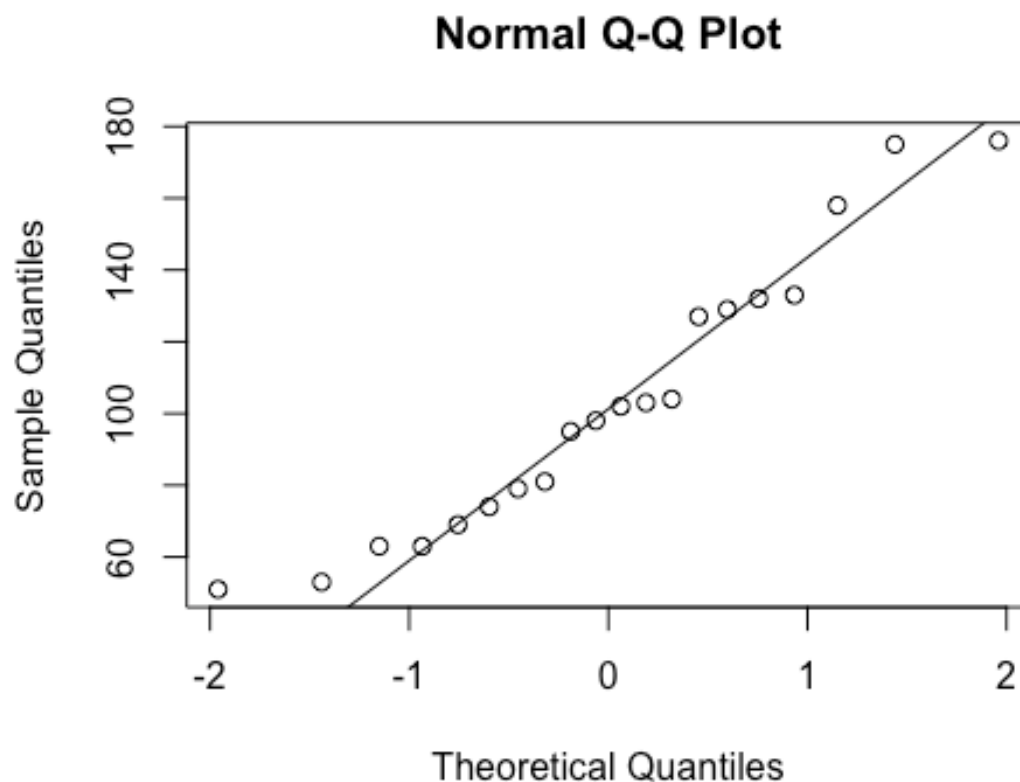
1
2
3 t.test(subset(SSdata, intervention == "sham")$num.rem.periods,
4       subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
5
6 ##
7 ## Welch Two Sample t-test
8 ##
9 ## data: subset(SSdata, intervention == "sham")$num.rem.periods and subset(S
10 Sdata, intervention == "PrenaBelt")$num.rem.periods
11 ## t = 0.53452, df = 33.621, p-value = 0.5965
12 ## alternative hypothesis: true difference in means is not equal to 0
13 ## 95 percent confidence interval:
14 ## -0.5607122 0.9607122
15 ## sample estimates:
16 ## mean of x mean of y
17 ##      3.5      3.3
18
19
20 wilcox.test(subset(SSdata, intervention == "sham")$num.rem.periods,
21            subset(SSdata, intervention == "PrenaBelt")$num.rem.periods,
22            conf.int = TRUE)
23
24 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
25 ## $num.rem.periods, : cannot compute exact p-value with ties
26
27 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
28 ## $num.rem.periods, : cannot compute exact confidence intervals with ties
29
30 ##
31 ## Wilcoxon rank sum test with continuity correction
32 ##
33 ## data: subset(SSdata, intervention == "sham")$num.rem.periods and subset(S
34 Sdata, intervention == "PrenaBelt")$num.rem.periods
35 ## W = 213, p-value = 0.7263
36 ## alternative hypothesis: true location shift is not equal to 0
37 ## 95 percent confidence interval:
38 ## -0.9999963 1.0000309
39 ## sample estimates:
40 ## difference in location
41 ##      1.121393e-06
42
43 #####Number of Stage Shifts#####
44 #Summary
45 summary(SSdata$num.stage.shifts)
46
47 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
48 ##      43.00   72.75   96.50  105.20  133.80  183.00
49
50 sd(SSdata$num.stage.shifts, na.rm = TRUE)
51
52 ## [1] 39.29043
53
54 length(SSdata$num.stage.shifts)
55
56
57
58
59
60

```

```

1
2
3 ## [1] 40
4
5 #ANOVA
6 night_tx_difference <- anova(lm(num.stage.shifts ~ intervention*night,
7                               data = SSdata))
8
9 night_tx_difference
10
11 ## Analysis of Variance Table
12 ##
13 ## Response: num.stage.shifts
14 ##
15 ##           Df Sum Sq Mean Sq F value Pr(>F)
16 ## intervention      1    148   148.22   0.0912 0.7644
17 ## night              1     60    60.03   0.0369 0.8487
18 ## intervention:night 1   1501  1500.63   0.9235 0.3430
19 ## Residuals        36  58497  1624.91
20
21 #within-participants (paired) comparison
22 #Paired t-test
23 t.test(subset(SSdataCompletes, intervention == "sham")$num.stage.shifts,
24        subset(SSdataCompletes, intervention == "PrenaBelt")$num.stage.shifts,
25        paired = TRUE)
26
27 ##
28 ## Paired t-test
29 ##
30 ## data: subset(SSdataCompletes, intervention == "sham")$num.stage.shifts and
31 ## subset(SSdataCompletes, intervention == "PrenaBelt")$num.stage.shifts
32 ## t = 0.77738, df = 19, p-value = 0.4465
33 ## alternative hypothesis: true difference in means is not equal to 0
34 ## 95 percent confidence interval:
35 ## -6.515809 14.215809
36 ## sample estimates:
37 ## mean of the differences
38 ##                3.85
39
40 #between participants (grouped) comparison
41 summary(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
42
43 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
44 ##  51.00  72.75  100.00  103.20  129.80  176.00
45
46 sd(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
47
48 ## [1] 38.44459
49
50 length(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
51
52 ## [1] 20
53
54 qqnorm(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
55 qqline(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts
## A = 0.40309, p-value = 0.3245

#normal

summary(subset(SSdata, intervention == "sham")$num.stage.shifts)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  43.00  80.25   95.00  107.10  147.80  183.00

sd(subset(SSdata, intervention == "sham")$num.stage.shifts)

## [1] 41.02361

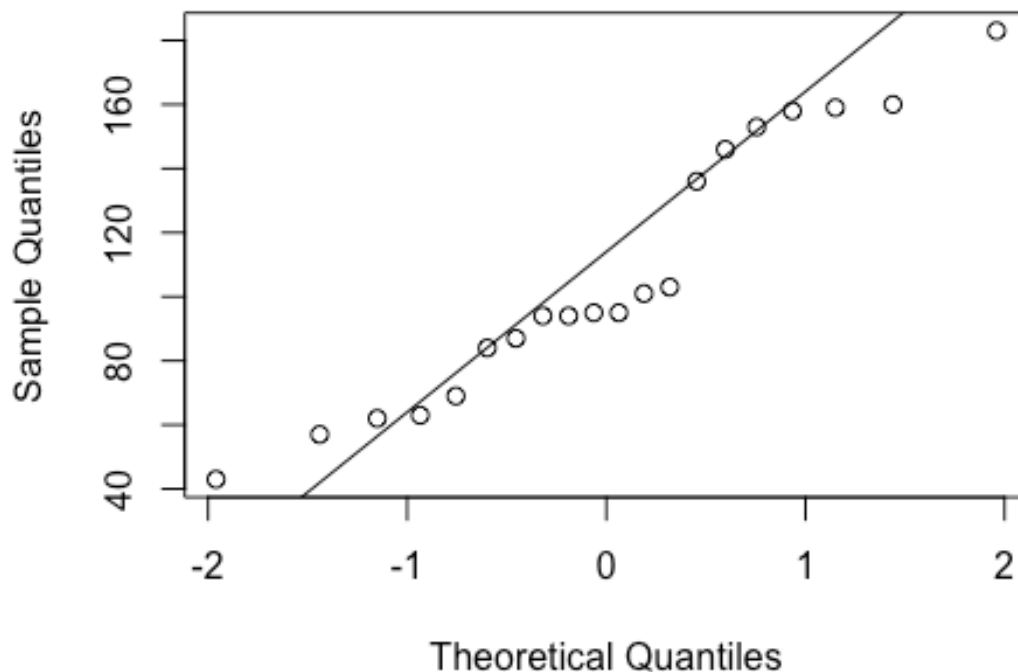
length(subset(SSdata, intervention == "sham")$num.stage.shifts)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$num.stage.shifts)
qqline(subset(SSdata, intervention == "sham")$num.stage.shifts)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$num.stage.shifts)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$num.stage.shifts
## A = 0.64165, p-value = 0.08053

#normal

t.test(subset(SSdata, intervention == "sham")$num.stage.shifts,
       subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$num.stage.shifts and subset(
SSdata, intervention == "PrenaBelt")$num.stage.shifts
## t = 0.30624, df = 37.841, p-value = 0.7611
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -21.60347 29.30347
## sample estimates:

```

```

1
2
3 ## mean of x mean of y
4 ## 107.10 103.25
5
6 #####Awakenings#####
7 #Summary
8 summary(SSdata$awakenings)
9
10 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
11 ## 10.00 14.75 19.00 19.70 24.25 32.00
12
13 sd(SSdata$awakenings, na.rm = TRUE)
14
15 ## [1] 6.329418
16
17 length(SSdata$awakenings)
18
19 ## [1] 40
20
21 #ANOVA
22 night_tx_difference <- anova(lm(awakenings ~ intervention*night,
23 data = SSdata))
24
25 night_tx_difference
26
27 ## Analysis of Variance Table
28 ##
29 ## Response: awakenings
30 ##
31 ## Df Sum Sq Mean Sq F value Pr(>F)
32 ## intervention 1 2.5 2.50 0.0589 0.8096
33 ## night 1 19.6 19.60 0.4617 0.5012
34 ## intervention:night 1 12.1 12.10 0.2850 0.5967
35 ## Residuals 36 1528.2 42.45
36
37 #within-participants (paired) comparison
38 #Paired t-test
39 t.test(subset(SSdataCompletes, intervention == "sham")$awakenings,
40 subset(SSdataCompletes, intervention == "PrenaBelt")$awakenings,
41 paired = TRUE)
42
43 ##
44 ## Paired t-test
45 ##
46 ## data: subset(SSdataCompletes, intervention == "sham")$awakenings and sub
47 et(SSdataCompletes, intervention == "PrenaBelt")$awakenings
48 ## t = 0.38863, df = 19, p-value = 0.7019
49 ## alternative hypothesis: true difference in means is not equal to 0
50 ## 95 percent confidence interval:
51 ## -2.192823 3.192823
52 ## sample estimates:
53 ## mean of the differences
54 ## 0.5
55
56
57
58
59
60

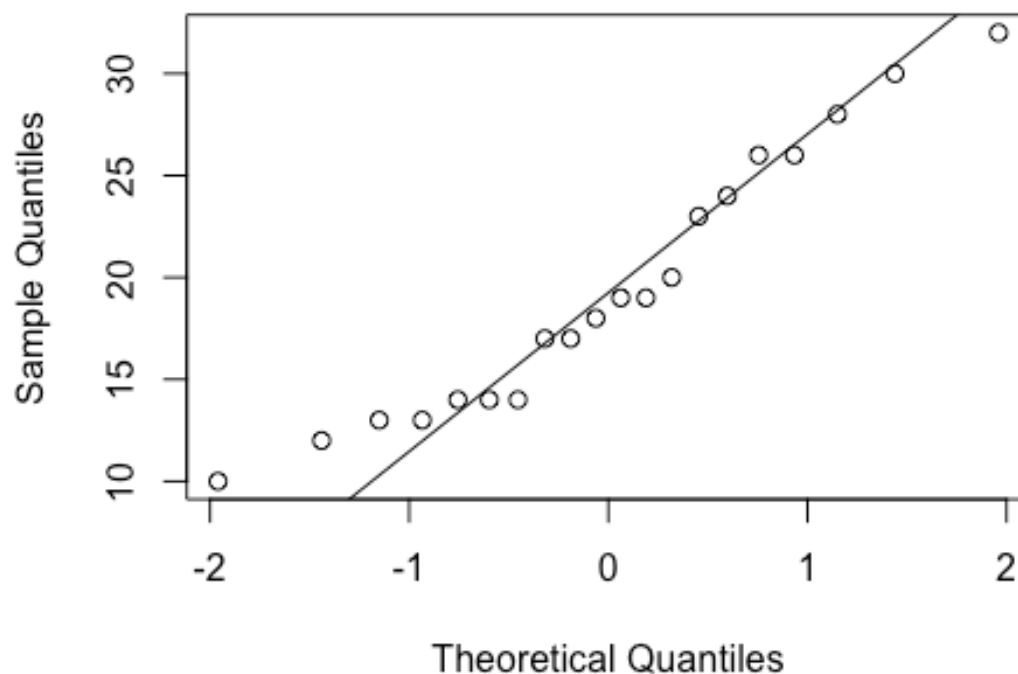
```

```

1
2
3 #between participants (grouped) comparison
4 summary(subset(SSdata, intervention == "PrenaBelt")$awakenings)
5
6 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
7 ##    10.00  14.00   18.50   19.45  24.50   32.00
8
9 sd(subset(SSdata, intervention == "PrenaBelt")$awakenings)
10
11 ## [1] 6.460202
12
13 length(subset(SSdata, intervention == "PrenaBelt")$awakenings)
14
15 ## [1] 20
16
17 qqnorm(subset(SSdata, intervention == "PrenaBelt")$awakenings)
18 qqline(subset(SSdata, intervention == "PrenaBelt")$awakenings)
19

```

Normal Q-Q Plot



```

49 ad.test(subset(SSdata, intervention == "PrenaBelt")$awakenings)
50
51 ##
52 ## Anderson-Darling normality test
53 ##
54 ## data: subset(SSdata, intervention == "PrenaBelt")$awakenings
55 ## A = 0.44596, p-value = 0.2537
56
57
58
59
60

```

```
#normal
```

```
summary(subset(SSdata, intervention == "sham")$awakenings)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    10.00  16.00   19.00   19.95  23.50   31.00
```

```
sd(subset(SSdata, intervention == "sham")$awakenings)
```

```
## [1] 6.353408
```

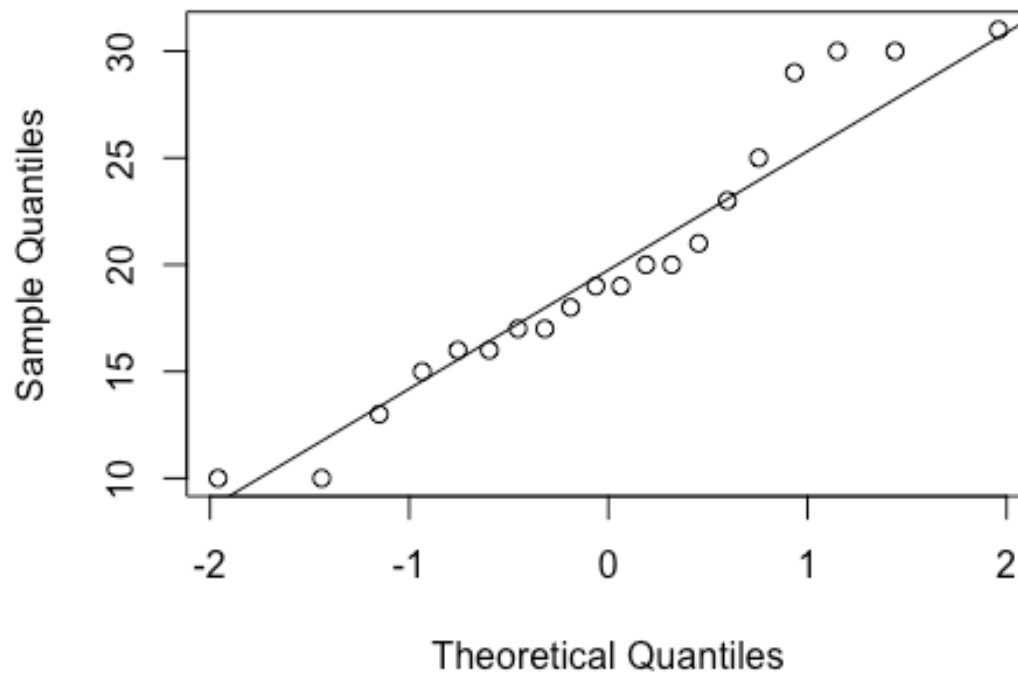
```
length(subset(SSdata, intervention == "sham")$awakenings)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$awakenings)
```

```
qqline(subset(SSdata, intervention == "sham")$awakenings)
```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "sham")$awakenings)
```

```
##
```

```
## Anderson-Darling normality test
```

```
##
```

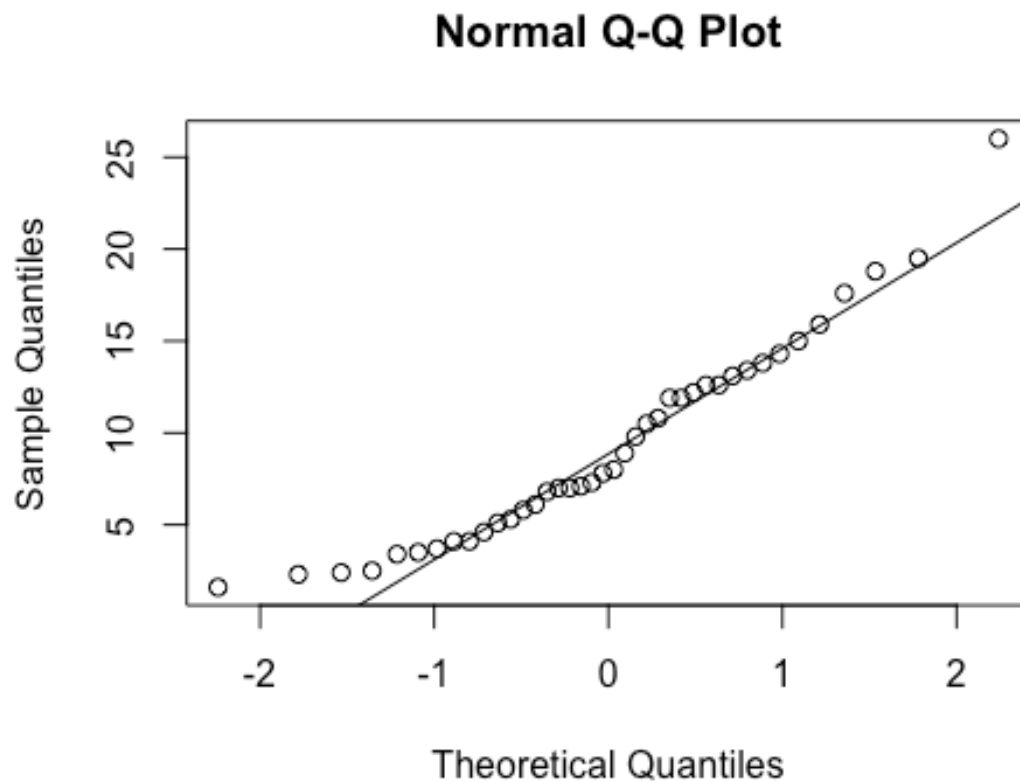
```
## data: subset(SSdata, intervention == "sham")$awakenings
```

```
## A = 0.47198, p-value = 0.2179
```

```

1
2
3 #normal
4
5 t.test(subset(SSdata, intervention == "sham")$awakenings,
6       subset(SSdata, intervention == "PrenaBeIt")$awakenings)
7
8 ##
9 ## Welch Two Sample t-test
10 ##
11 ## data: subset(SSdata, intervention == "sham")$awakenings and subset(SSdata
12 , intervention == "PrenaBeIt")$awakenings
13 ## t = 0.24678, df = 37.989, p-value = 0.8064
14 ## alternative hypothesis: true difference in means is not equal to 0
15 ## 95 percent confidence interval:
16 ## -3.601622 4.601622
17 ## sample estimates:
18 ## mean of x mean of y
19 ## 19.95 19.45
20
21 ##### % Stage 1 Sleep #####
22 #Summary
23 summary(SSdata$Pstage.1)
24
25 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
26 ## 1.600 4.975 7.900 9.353 12.720 26.000
27
28 sd(SSdata$Pstage.1, na.rm = TRUE)
29
30 ## [1] 5.561267
31
32 length(SSdata$Pstage.1)
33
34 ## [1] 40
35
36 qqnorm(SSdata$Pstage.1)
37 qqline(SSdata$Pstage.1)
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

```
ad.test(SSdata$Pstage.1)

##
## Anderson-Darling normality test
##
## data:  SSdata$Pstage.1
## A = 0.60276, p-value = 0.1097

#normal

#ANOVA
night_tx_difference <- anova(lm(Pstage.1 ~ intervention*night,
                               data = SSdata))
night_tx_difference

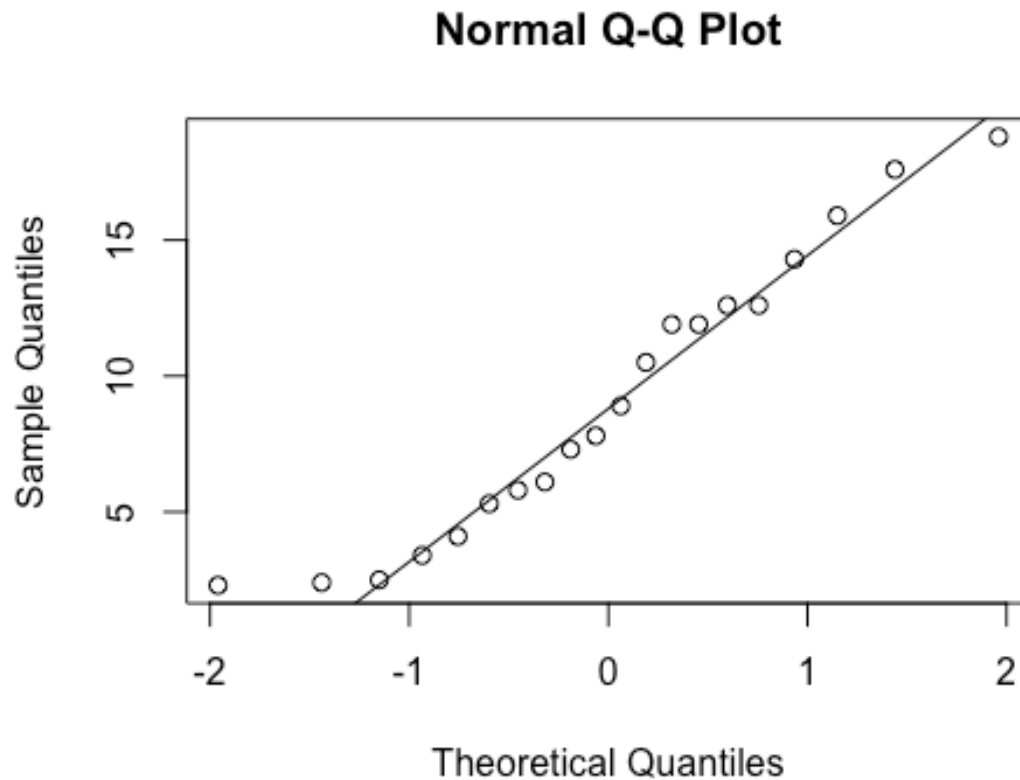
## Analysis of Variance Table
##
## Response: Pstage.1
##
```

	Df	Sum Sq	Mean Sq	F value	Pr(>F)
## intervention	1	2.55	2.550	0.0778	0.7819
## night	1	11.77	11.772	0.3593	0.5527
## intervention:night	1	12.21	12.210	0.3726	0.5454
## Residuals	36	1179.65	32.768		

```

1
2
3 #within-participants (paired) comparison
4 #Paired t-test
5 t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.1,
6        subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.1,
7        paired = TRUE)
8
9 ##
10 ## Paired t-test
11 ##
12 ## data: subset(SSdataCompletes, intervention == "sham")$Pstage.1 and subset
13 (SSdataCompletes, intervention == "PrenaBelt")$Pstage.1
14 ## t = 0.59457, df = 19, p-value = 0.5591
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -1.272708 2.282708
18 ## sample estimates:
19 ## mean of the differences
20 ## 0.505
21
22
23 #between participants (grouped) comparison
24 summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
25
26 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##      2.30   5.00   8.35   9.10  12.60  18.80
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
30
31 ## [1] 5.197368
32
33 length(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
34
35 ## [1] 20
36
37 qqnorm(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
38 qqline(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$Pstage.1
## A = 0.34971, p-value = 0.4374

#normal

summary(subset(SSdata, intervention == "sham")$Pstage.1)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  1.600  4.975   7.550   9.605  13.180  26.000

sd(subset(SSdata, intervention == "sham")$Pstage.1)

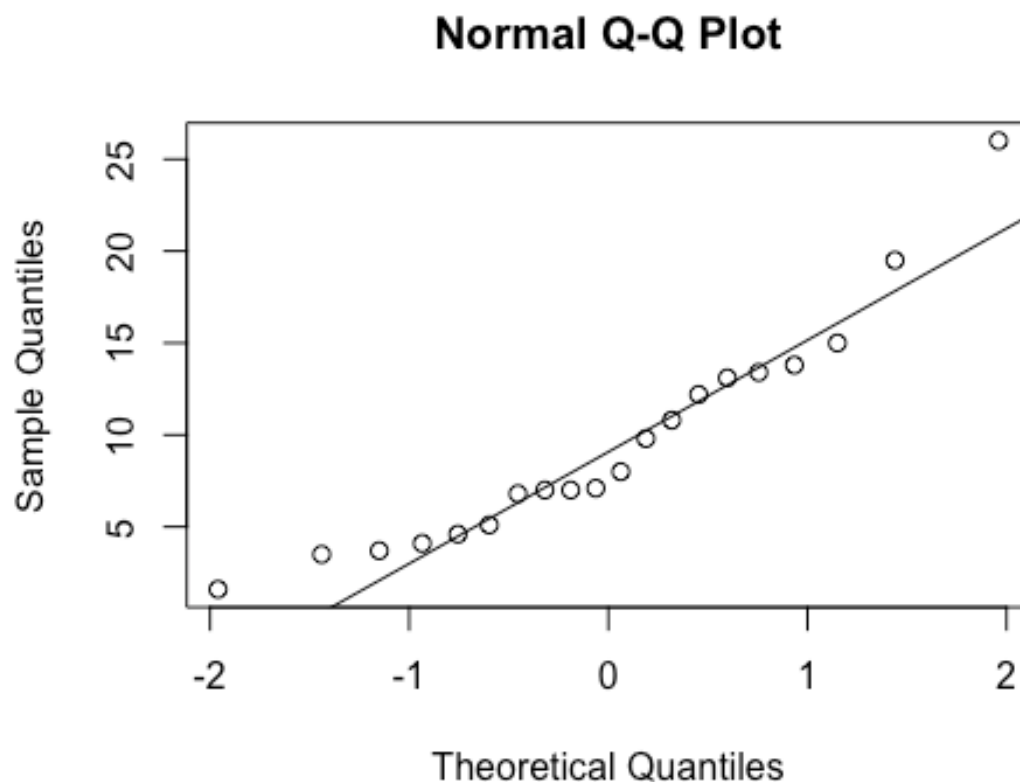
## [1] 6.027959

length(subset(SSdata, intervention == "sham")$Pstage.1)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$Pstage.1)
qqline(subset(SSdata, intervention == "sham")$Pstage.1)

```



```

ad.test(subset(SSdata, intervention == "sham")$Pstage.1)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$Pstage.1
## A = 0.55353, p-value = 0.1336

#normal

t.test(subset(SSdata, intervention == "sham")$Pstage.1,
       subset(SSdata, intervention == "PrenaBelt")$Pstage.1)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$Pstage.1 and subset(SSdata,
## intervention == "PrenaBelt")$Pstage.1
## t = 0.28375, df = 37.194, p-value = 0.7782
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -3.100444 4.110444
## sample estimates:

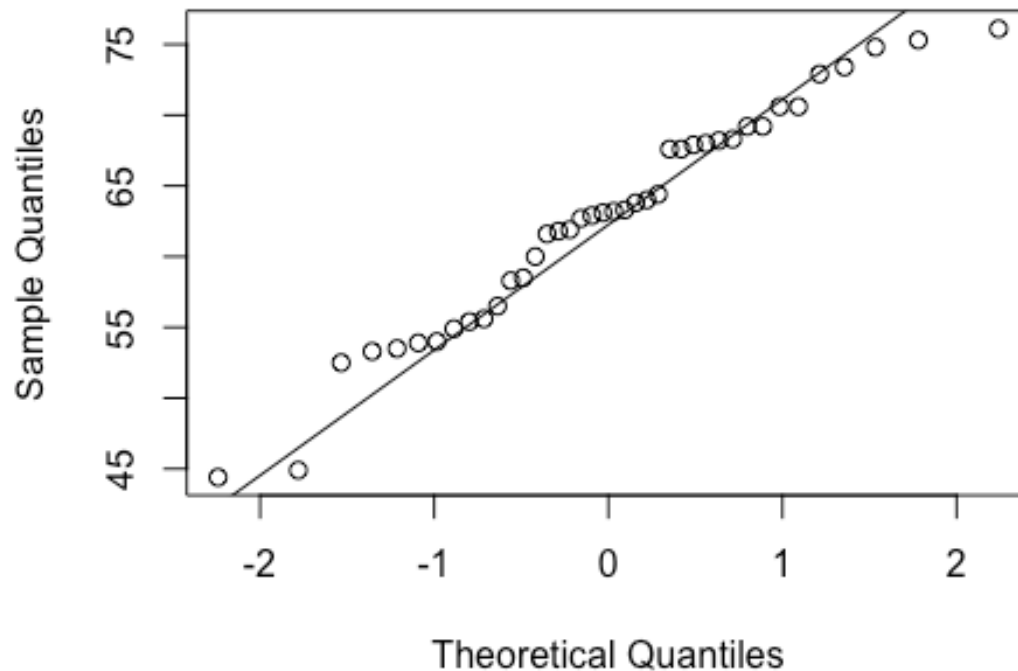
```

```

1
2
3 ## mean of x mean of y
4 ##      9.605      9.100
5
6 ##### % Stage 2 Sleep #####
7 #Summary
8 summary(SSdata$Pstage.2)
9
10 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11 ##      44.40  56.28   63.15   62.70  68.23   76.10
12
13 sd(SSdata$Pstage.2, na.rm = TRUE)
14
15 ## [1] 7.870376
16
17 length(SSdata$Pstage.2)
18
19 ## [1] 40
20
21 qqnorm(SSdata$Pstage.2)
22 qqline(SSdata$Pstage.2)

```

Normal Q-Q Plot



```

52 ad.test(SSdata$Pstage.2)
53
54 ##
55 ## Anderson-Darling normality test
56
57
58
59
60

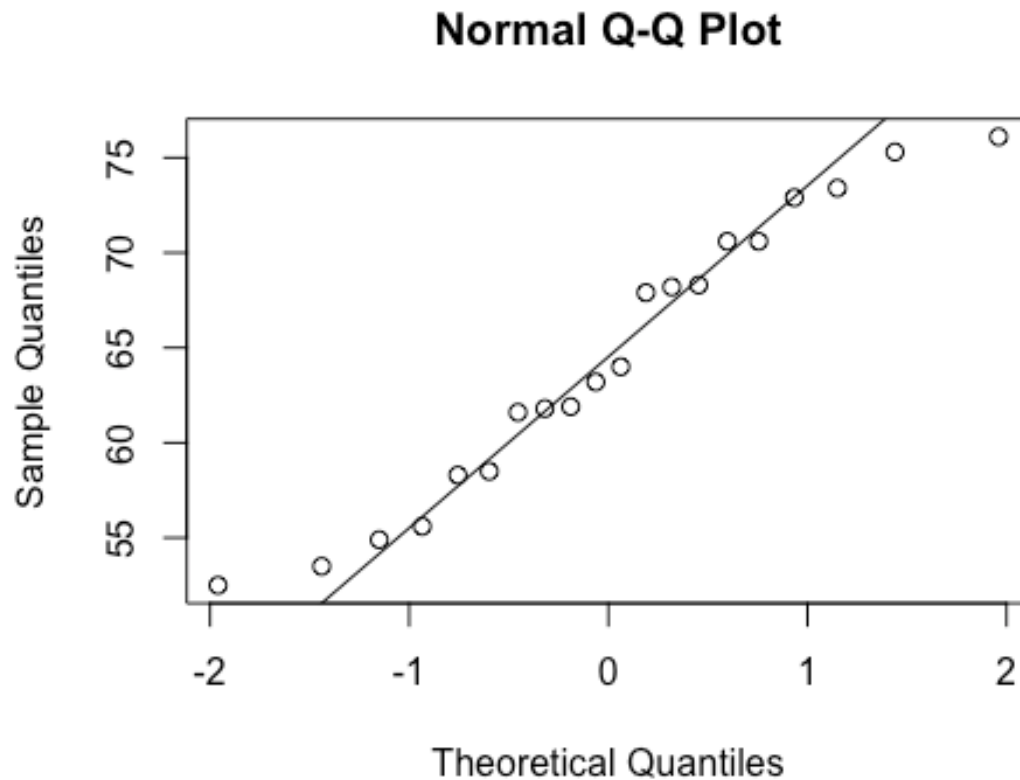
```

```

1
2
3
4 ##
5 ## data: SSdata$Pstage.2
6 ## A = 0.37344, p-value = 0.4014
7
8 #normal
9
10 #ANOVA
11 night_tx_difference <- anova(lm(Pstage.2 ~ intervention*night,
12                               data = SSdata))
13
14 night_tx_difference
15
16 ## Analysis of Variance Table
17 ##
18 ## Response: Pstage.2
19 ##
20 ##           Df Sum Sq Mean Sq F value Pr(>F)
21 ## intervention      1  122.85  122.850    2.0304  0.1628
22 ## night              1   58.32   58.322    0.9639  0.3328
23 ## intervention:night  1   56.41   56.406    0.9323  0.3407
24 ## Residuals        36 2178.19   60.505
25
26 #within-participants (paired) comparison
27 #Paired t-test
28 t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.2,
29         subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.2,
30         paired = TRUE)
31
32 ##
33 ## Paired t-test
34 ##
35 ## data: subset(SSdataCompletes, intervention == "sham")$Pstage.2 and subset
36 (SSdataCompletes, intervention == "PrenaBelt")$Pstage.2
37 ## t = -1.9128, df = 19, p-value = 0.07097
38 ## alternative hypothesis: true difference in means is not equal to 0
39 ## 95 percent confidence interval:
40 ## -7.3402984  0.3302984
41 ## sample estimates:
42 ## mean of the differences
43 ## -3.505
44
45 #between participants (grouped) comparison
46 summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
47
48 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
49 ##  52.50  58.45   63.60   64.46   70.60   76.10
50
51 sd(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
52
53 ## [1] 7.434803
54
55 length(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
56
57 ## [1] 20
58
59
60

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
qqline(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$Pstage.2
## A = 0.30768, p-value = 0.5308

#normal

summary(subset(SSdata, intervention == "sham")$Pstage.2)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 44.40  55.05   63.00  60.95  67.60  74.80

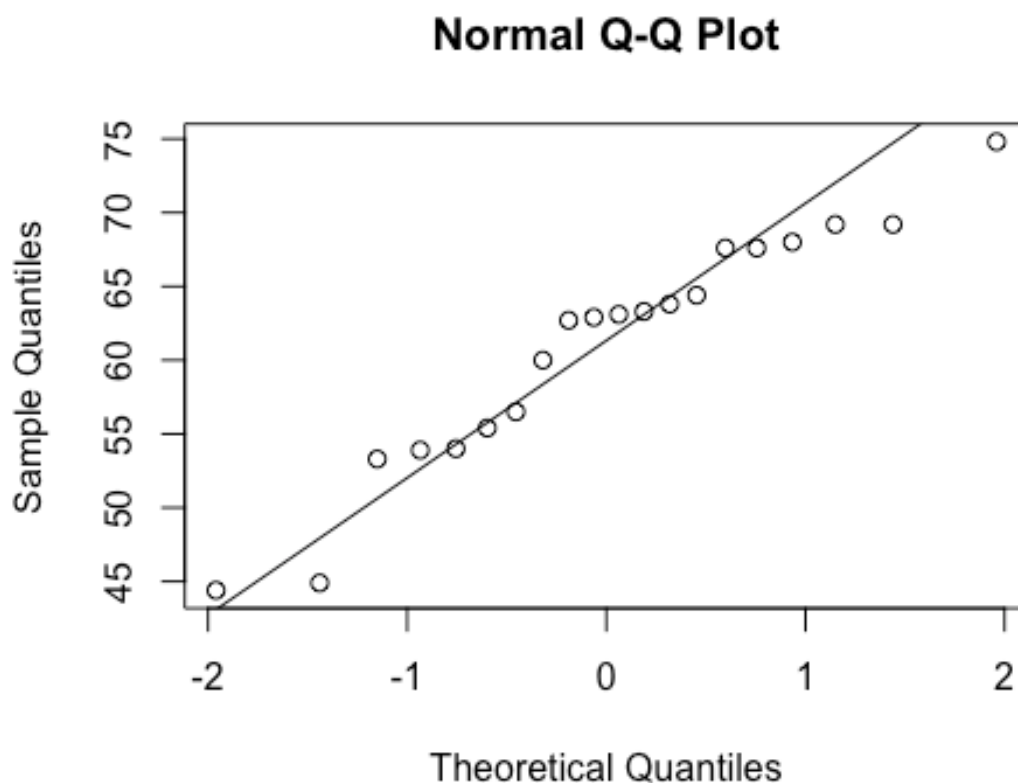
sd(subset(SSdata, intervention == "sham")$Pstage.2)

## [1] 8.087254

length(subset(SSdata, intervention == "sham")$Pstage.2)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$Pstage.2)
qqline(subset(SSdata, intervention == "sham")$Pstage.2)
```



```
ad.test(subset(SSdata, intervention == "sham")$Pstage.2)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$Pstage.2
## A = 0.47938, p-value = 0.2087

#normal

t.test(subset(SSdata, intervention == "sham")$Pstage.2,
       subset(SSdata, intervention == "PrenaBelt")$Pstage.2)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$Pstage.2 and subset(SSdata,
## intervention == "PrenaBelt")$Pstage.2
## t = -1.4269, df = 37.734, p-value = 0.1618
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
```

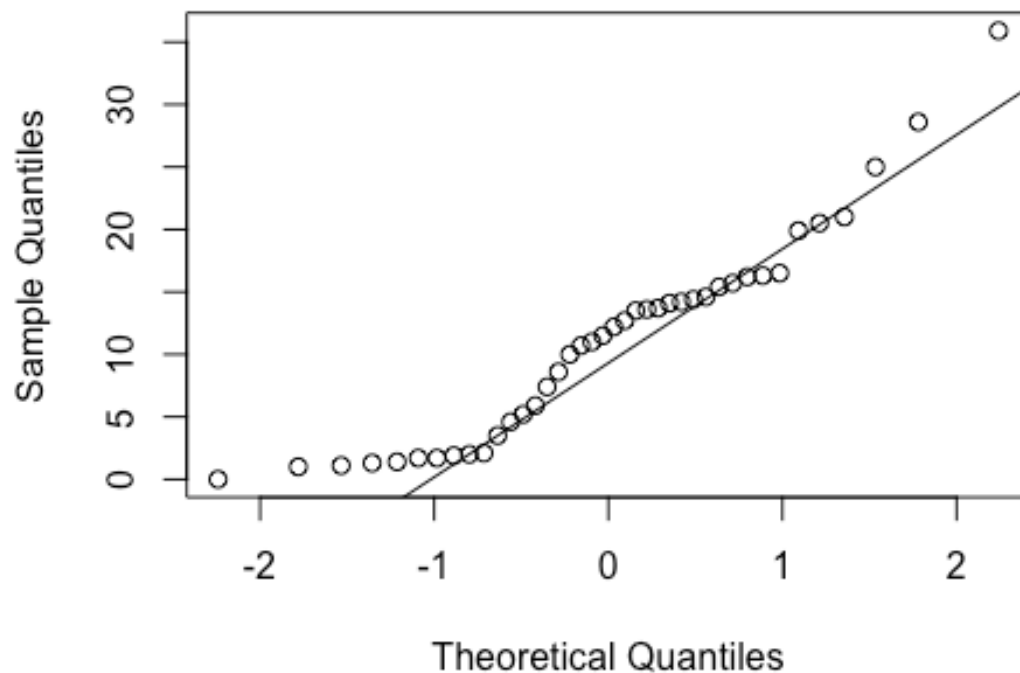


```

1
2
3 ## -8.478912 1.468912
4 ## sample estimates:
5 ## mean of x mean of y
6 ## 60.950 64.455
7
8 ##### % Stage 3 Sleep #####
9
10 #Summary
11 summary(SSdata$Pstage.3)
12
13 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
14 ## 0.00 3.15 11.85 11.16 15.48 35.90
15
16 sd(SSdata$Pstage.3, na.rm = TRUE)
17
18 ## [1] 8.302226
19
20 length(SSdata$Pstage.3)
21
22 ## [1] 40
23
24 qqnorm(SSdata$Pstage.3)
25 qqline(SSdata$Pstage.3)

```

Normal Q-Q Plot



```

54
55 ad.test(SSdata$Pstage.3)
56
57
58
59
60

```

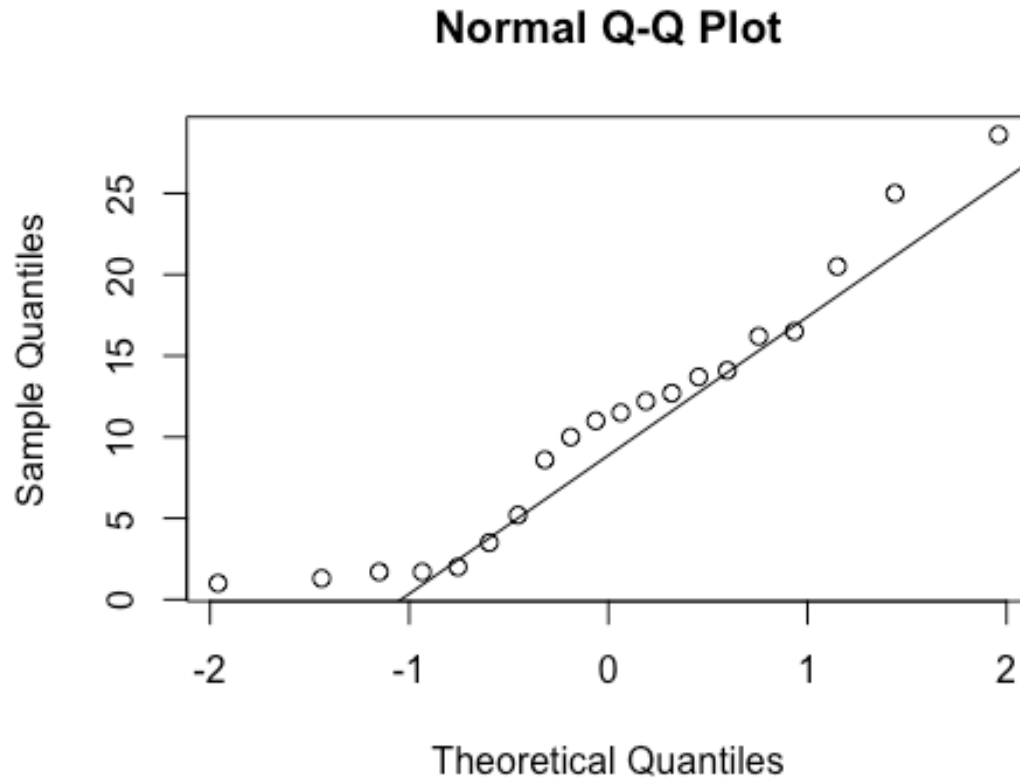
```

1
2
3
4  ## Anderson-Darling normality test
5  ##
6  ## data:  SSdata$Pstage.3
7  ## A = 0.79648, p-value = 0.03569
8
9  #non-normal
10
11  #ANOVA
12  night_tx_difference <- anova(lm(Pstage.3 ~ intervention * night,
13                               data = SSdata))
14
15  night_tx_difference
16
17  ## Analysis of Variance Table
18  ##
19  ## Response: Pstage.3
20  ##
21  ##           Df  Sum Sq Mean Sq F value Pr(>F)
22  ## intervention      1    3.97   3.969   0.0535 0.8184
23  ## night              1    3.60   3.600   0.0485 0.8269
24  ## intervention:night  1   10.40  10.404   0.1403 0.7102
25  ## Residuals        36 2670.18  74.172
26
27  #within-participants (paired) comparison
28  #Paired t-test (individual distributions are normal)
29  t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.3,
30         subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.3,
31         paired = TRUE)
32
33  ##
34  ## Paired t-test
35  ##
36  ## data:  subset(SSdataCompletes, intervention == "sham")$Pstage.3 and subset
37  ## (SSdataCompletes, intervention == "PrenaBelt")$Pstage.3
38  ## t = 0.65795, df = 19, p-value = 0.5185
39  ## alternative hypothesis: true difference in means is not equal to 0
40  ## 95 percent confidence interval:
41  ## -1.374115  2.634115
42  ## sample estimates:
43  ## mean of the differences
44  ##           0.63
45
46  #between participants (grouped) comparison
47  summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
48
49  ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50  ##  1.000  3.125  11.250  10.850  14.620  28.600
51
52  sd(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
53
54  ## [1] 8.010027
55
56  length(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
57
58
59

```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
qqline(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$Pstage.3
## A = 0.44499, p-value = 0.2552
```

```
#normal
```

```
summary(subset(SSdata, intervention == "sham")$Pstage.3)
```

```
##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000  3.975  13.550  11.480  15.480  35.900
```

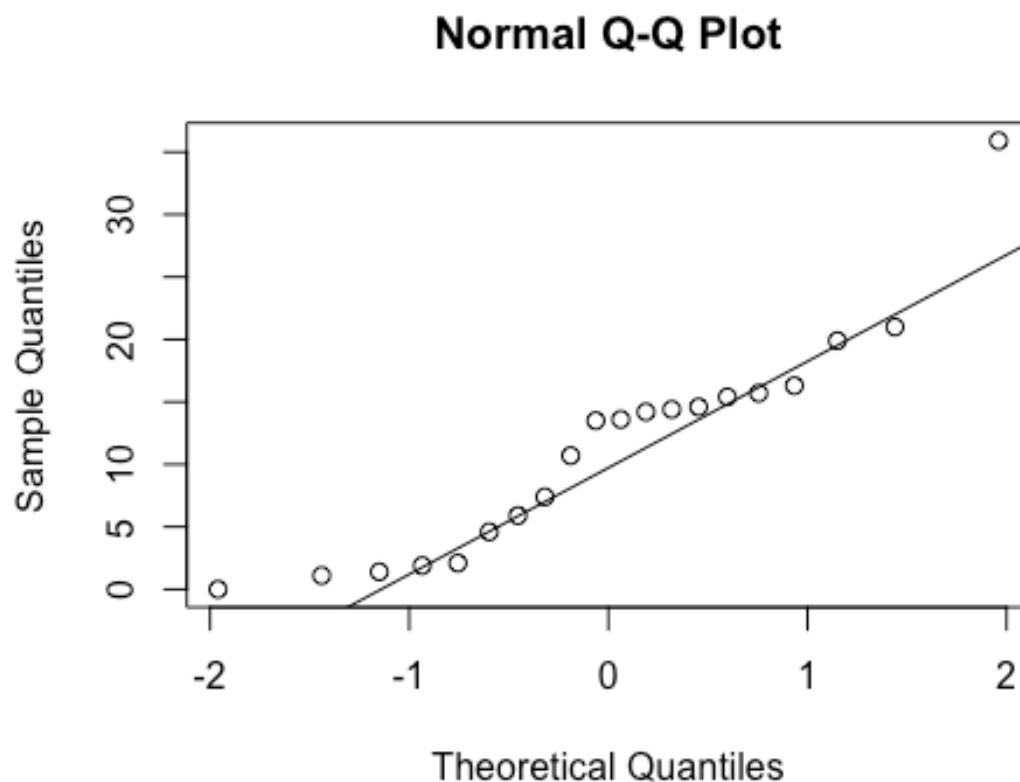
```
sd(subset(SSdata, intervention == "sham")$Pstage.3)
```

```
## [1] 8.781356
```

```
length(subset(SSdata, intervention == "sham")$Pstage.3)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$Pstage.3)
qqline(subset(SSdata, intervention == "sham")$Pstage.3)
```



```
ad.test(subset(SSdata, intervention == "sham")$Pstage.3)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$Pstage.3
## A = 0.5987, p-value = 0.1039
```

```
#normal
```

```
t.test(subset(SSdata, intervention == "sham")$Pstage.3,
       subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
```

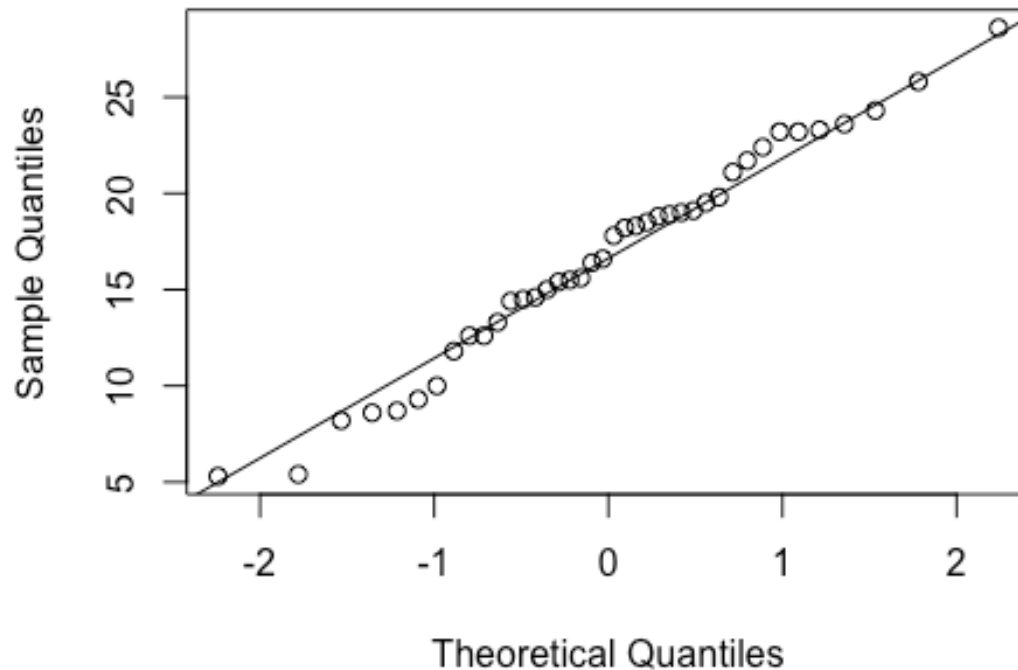
```
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$Pstage.3 and subset(SSdata,
intervention == "PrenaBelt")$Pstage.3
## t = 0.23704, df = 37.683, p-value = 0.8139
```

```

1
2
3  ## alternative hypothesis: true difference in means is not equal to 0
4  ## 95 percent confidence interval:
5  ## -4.75182  6.01182
6  ## sample estimates:
7  ## mean of x mean of y
8  ##      11.48      10.85
9
10 ##### % Stage REM #####
11 #Summary
12 summary(SSdata$Prem)
13
14 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
15 ##      5.30  13.13   17.20   16.72  20.12   28.60
16
17 sd(SSdata$Prem, na.rm = TRUE)
18
19 ## [1] 5.62027
20
21 length(SSdata$Prem)
22
23 ## [1] 40
24
25 qqnorm(SSdata$Prem)
26 qqline(SSdata$Prem)

```

Normal Q-Q Plot



```

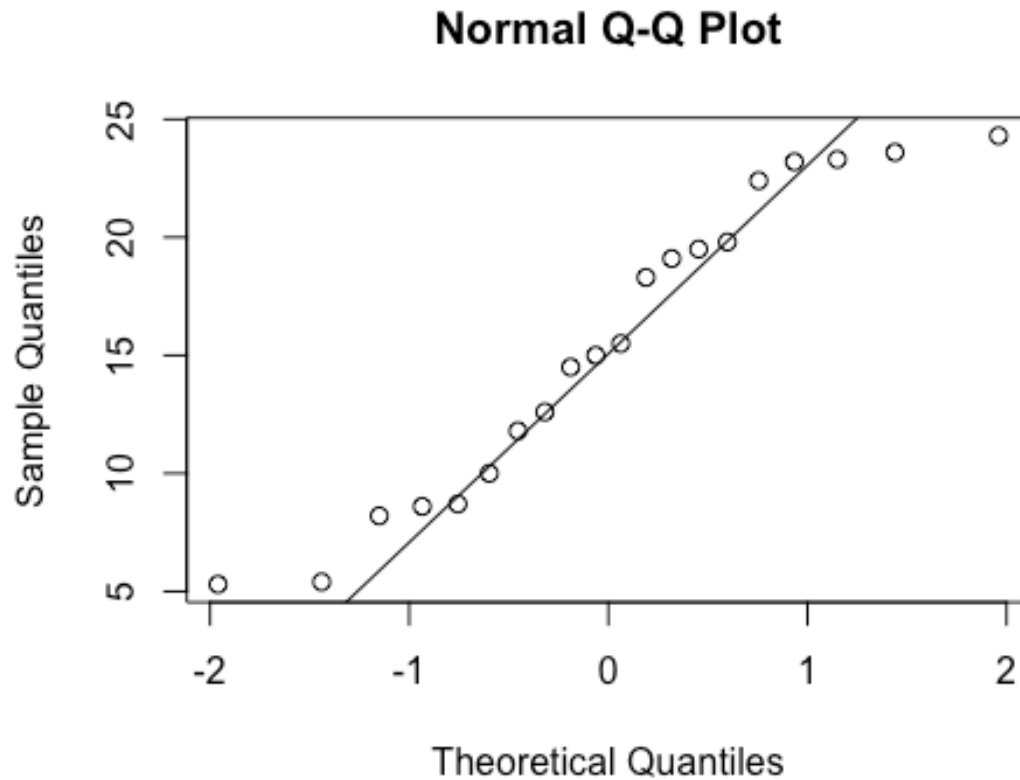
1
2
3 ad.test(SSdata$Prem)
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: SSdata$Prem
9 ## A = 0.23648, p-value = 0.7728
10
11 #normal
12
13 #ANOVA
14 night_tx_difference <- anova(lm(Prem ~ intervention * night,
15                               data = SSdata))
16
17 night_tx_difference
18
19 ## Analysis of Variance Table
20 ##
21 ## Response: Prem
22 ##
23 ##           Df Sum Sq Mean Sq F value Pr(>F)
24 ## intervention      1   64.26   64.262   2.2623 0.14128
25 ## night              1   89.10   89.102   3.1367 0.08501 .
26 ## intervention:night  1   55.93   55.932   1.9690 0.16912
27 ## Residuals        36 1022.61   28.406
28 ## ---
29 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
30
31 #within-participants (paired) comparison
32 #Paired t-test
33 t.test(subset(SSdataCompletes, intervention == "sham")$Prem,
34        subset(SSdataCompletes, intervention == "PrenaBelt")$Prem,
35        paired = TRUE)
36
37 ##
38 ## Paired t-test
39 ##
40 ## data: subset(SSdataCompletes, intervention == "sham")$Prem and subset(SSdataCompletes, intervention == "PrenaBelt")$Prem
41 ## t = 2.0564, df = 19, p-value = 0.05374
42 ## alternative hypothesis: true difference in means is not equal to 0
43 ## 95 percent confidence interval:
44 ## -0.04510822  5.11510822
45 ## sample estimates:
46 ## mean of the differences
47 ##
48 ##           2.535
49
50 #between participants (grouped) comparison
51 summary(subset(SSdata, intervention == "PrenaBelt")$Prem)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##      5.300   9.675  15.250  15.460  20.450  24.300
55
56 sd(subset(SSdata, intervention == "PrenaBelt")$Prem)
57
58
59
60

```

```

1
2
3 ## [1] 6.377714
4
5 length(subset(SSdata, intervention == "PrenaBelt")$Prem)
6
7 ## [1] 20
8
9 qqnorm(subset(SSdata, intervention == "PrenaBelt")$Prem)
10 qqline(subset(SSdata, intervention == "PrenaBelt")$Prem)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

```



```

41 ad.test(subset(SSdata, intervention == "PrenaBelt")$Prem)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: subset(SSdata, intervention == "PrenaBelt")$Prem
47 ## A = 0.44545, p-value = 0.2545
48
49 #normal
50
51 summary(subset(SSdata, intervention == "sham")$Prem)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##      9.30  15.20   18.00   17.99  19.52   28.60
55
56 sd(subset(SSdata, intervention == "sham")$Prem)
57
58
59
60

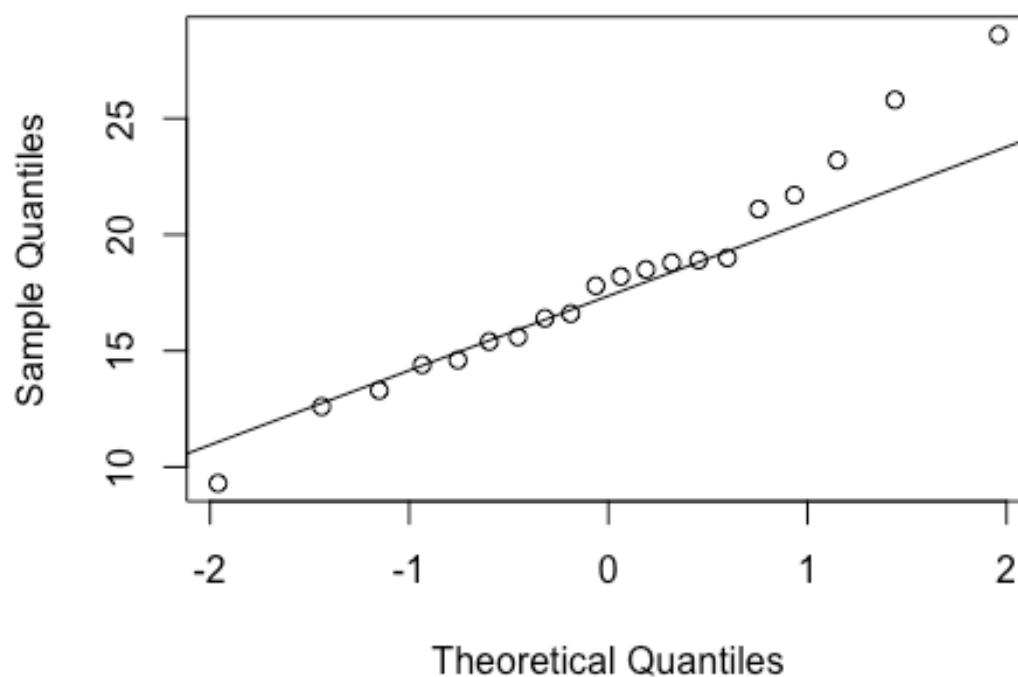
```

```

1
2
3 ## [1] 4.558497
4
5 length(subset(SSdata, intervention == "sham")$Prem)
6
7 ## [1] 20
8
9 qqnorm(subset(SSdata, intervention == "sham")$Prem)
10 qqline(subset(SSdata, intervention == "sham")$Prem)
11
12
13
14
15
16

```

Normal Q-Q Plot



```

37
38
39
40
41 ad.test(subset(SSdata, intervention == "sham")$Prem)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: subset(SSdata, intervention == "sham")$Prem
47 ## A = 0.27628, p-value = 0.6181
48
49 #normal
50
51 t.test(subset(SSdata, intervention == "sham")$Prem,
52        subset(SSdata, intervention == "PrenaBeIt")$Prem)
53
54 ##
55 ## Welch Two Sample t-test
56
57
58
59
60

```

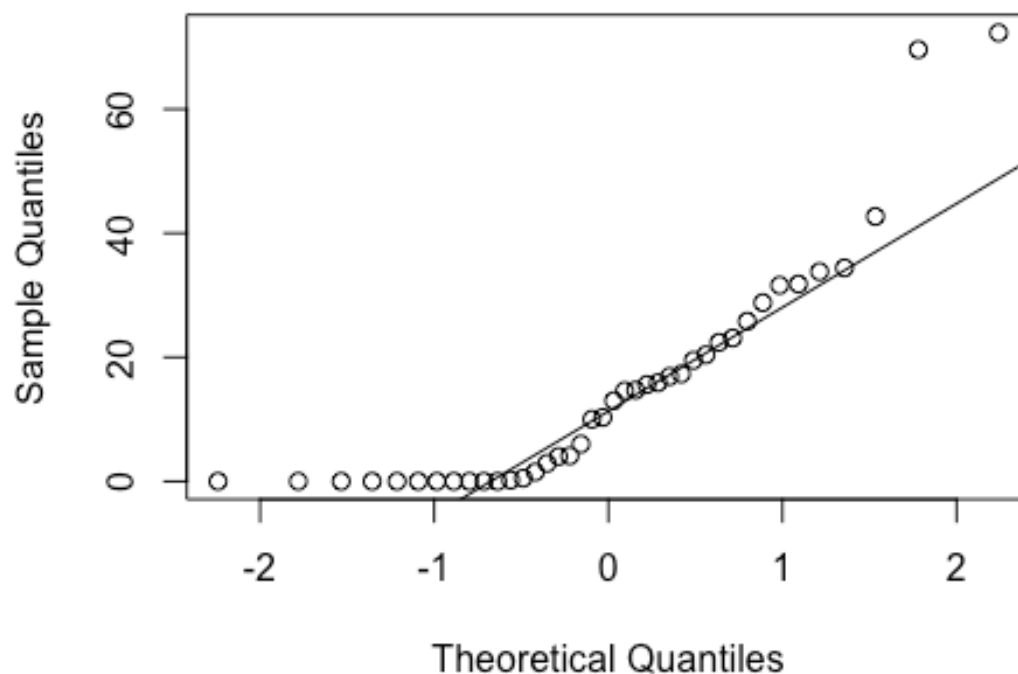


```

1
2
3
4  ##
5  ## data: subset(SSdata, intervention == "sham")$Prem and subset(SSdata, inte
6  rvention == "PrenaBelt")$Prem
7  ## t = 1.4462, df = 34.395, p-value = 0.1572
8  ## alternative hypothesis: true difference in means is not equal to 0
9  ## 95 percent confidence interval:
10 ## -1.025871  6.095871
11 ## sample estimates:
12 ## mean of x mean of y
13 ## 17.990 15.455
14
15 ##### %TST Supine #####
16 #Summary
17 summary(SSdata$PtstSupine)
18
19 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
20 ##      0.00   0.00  11.65   15.09   22.57   72.30
21
22 sd(SSdata$PtstSupine, na.rm = TRUE)
23
24 ## [1] 17.83904
25
26 length(SSdata$PtstSupine)
27
28 ## [1] 40
29
30 #ANOVA
31 night_tx_difference <- anova(lm(PtstSupine ~ intervention * night,
32                               data = SSdata))
33
34 night_tx_difference
35
36 ## Analysis of Variance Table
37 ##
38 ## Response: PtstSupine
39 ##
40 ##      Df Sum Sq Mean Sq F value Pr(>F)
41 ## intervention      1  465.8   465.81   1.4119  0.2425
42 ## night              1   64.8    64.77   0.1963  0.6604
43 ## intervention:night  1    3.4     3.42   0.0104  0.9194
44 ## Residuals        36 11877.0   329.92
45
46 qqnorm(SSdata$PtstSupine)
47 qqline(SSdata$PtstSupine)
48
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```

ad.test(SSdata$PtstSupine)

##
## Anderson-Darling normality test
##
## data:  SSdata$PtstSupine
## A = 2.1537, p-value = 1.423e-05

#data do not follow a normal distribution; perform paired Wilcoxon rank sum t
est

#within-participants (paired) comparison
#Paired Wilcoxon, one-tailed
wilcox.test(subset(SSdataCompletes, intervention == "sham")$PtstSupine,
            subset(SSdataCompletes, intervention == "PrenaBelt")$PtstSupine,
            paired = TRUE, conf.int = TRUE, alternative = "greater")

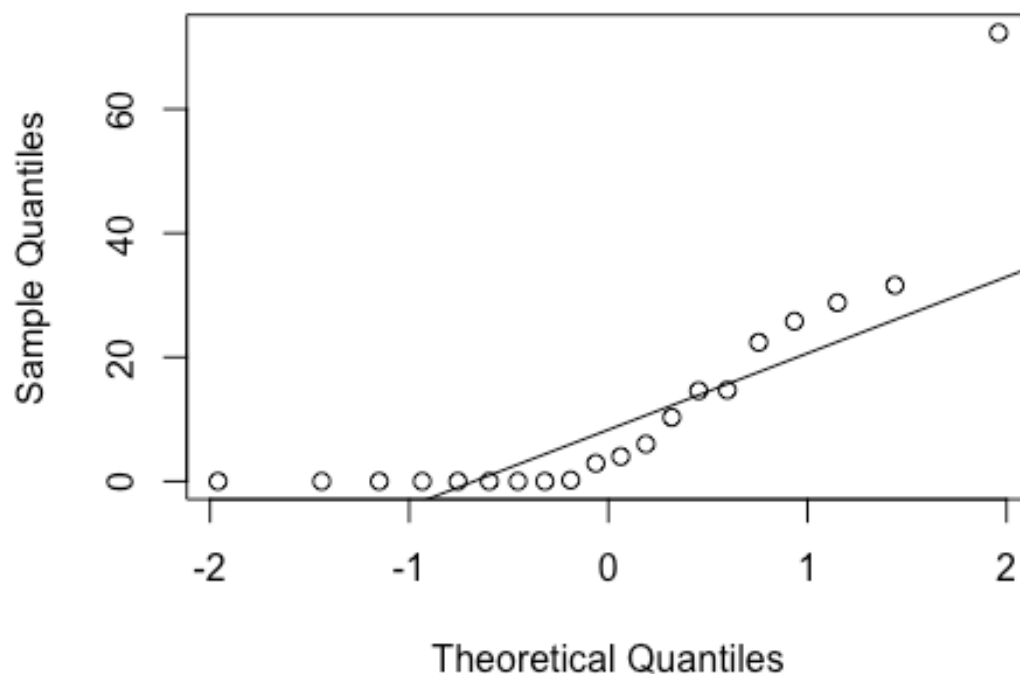
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$PtstSupine, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$PtstSupine, : cannot compute exact confidence interval with zeroes

```

```
1
2
3 ##
4 ## Wilcoxon signed rank test with continuity correction
5 ##
6 ## data: subset(SSdataCompletes, intervention == "sham")$PtstSupine and sub
7 et(SSdataCompletes, intervention == "PrenaBelt")$PtstSupine
8 ## V = 142, p-value = 0.03065
9 ## alternative hypothesis: true location shift is greater than 0
10 ## 95 percent confidence interval:
11 ## 0.7000854      Inf
12 ## sample estimates:
13 ## (pseudo)median
14 ##      5.804603
15
16
17 #between participants (grouped) comparison
18 summary(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
19
20 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
21 ##      0.00   0.00   3.45   11.68   16.62   72.30
22
23 sd(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
24
25 ## [1] 17.9033
26
27 length(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
28
29 ## [1] 20
30
31 qqnorm(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
32 qqline(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$PtstSupine
## A = 1.97, p-value = 3.17e-05

#non-normal

summary(subset(SSdata, intervention == "sham")$PtstSupine)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   3.45   16.40   18.50   25.28   69.60

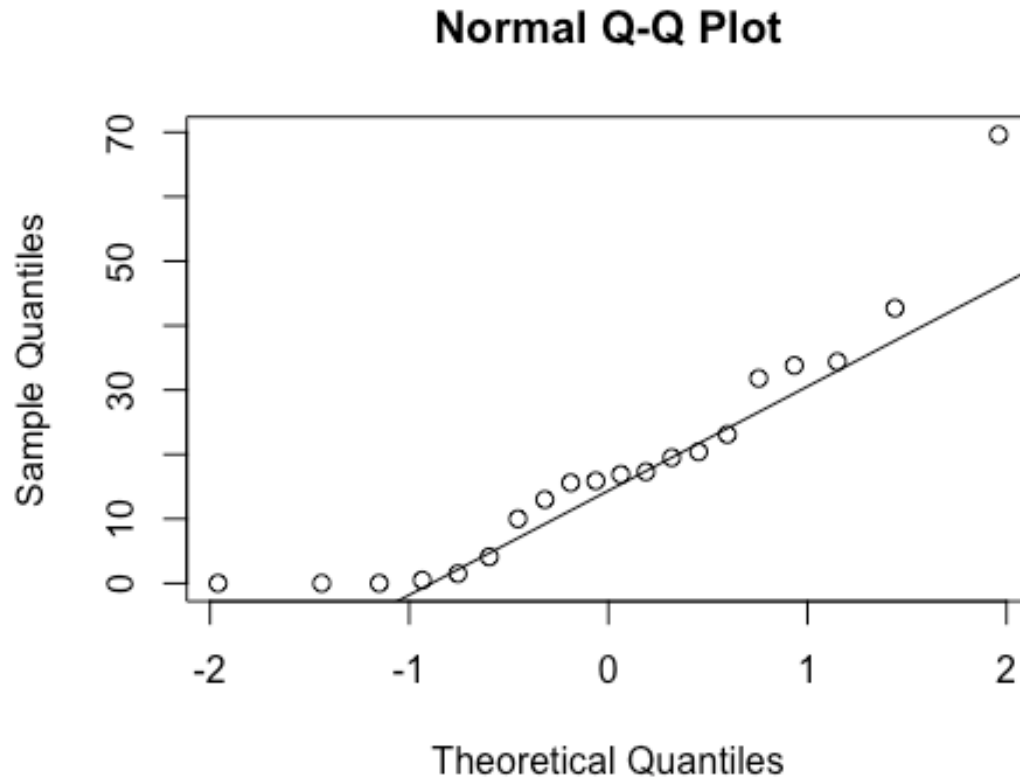
sd(subset(SSdata, intervention == "sham")$PtstSupine)

## [1] 17.55471

length(subset(SSdata, intervention == "sham")$PtstSupine)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$PtstSupine)
qqline(subset(SSdata, intervention == "sham")$PtstSupine)
```



```

ad.test(subset(SSdata, intervention == "sham")$PtstSupine)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$PtstSupine
## A = 0.67467, p-value = 0.06621

#normal

#non-parametric test for differences (one-tailed Wilcoxon)
wilcox.test(subset(SSdata, intervention == "sham")$PtstSupine,
             subset(SSdata, intervention == "PrenaBelt")$PtstSupine,
             conf.int = TRUE, alternative = "greater")

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $PtstSupine, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $PtstSupine, : cannot compute exact confidence intervals with ties

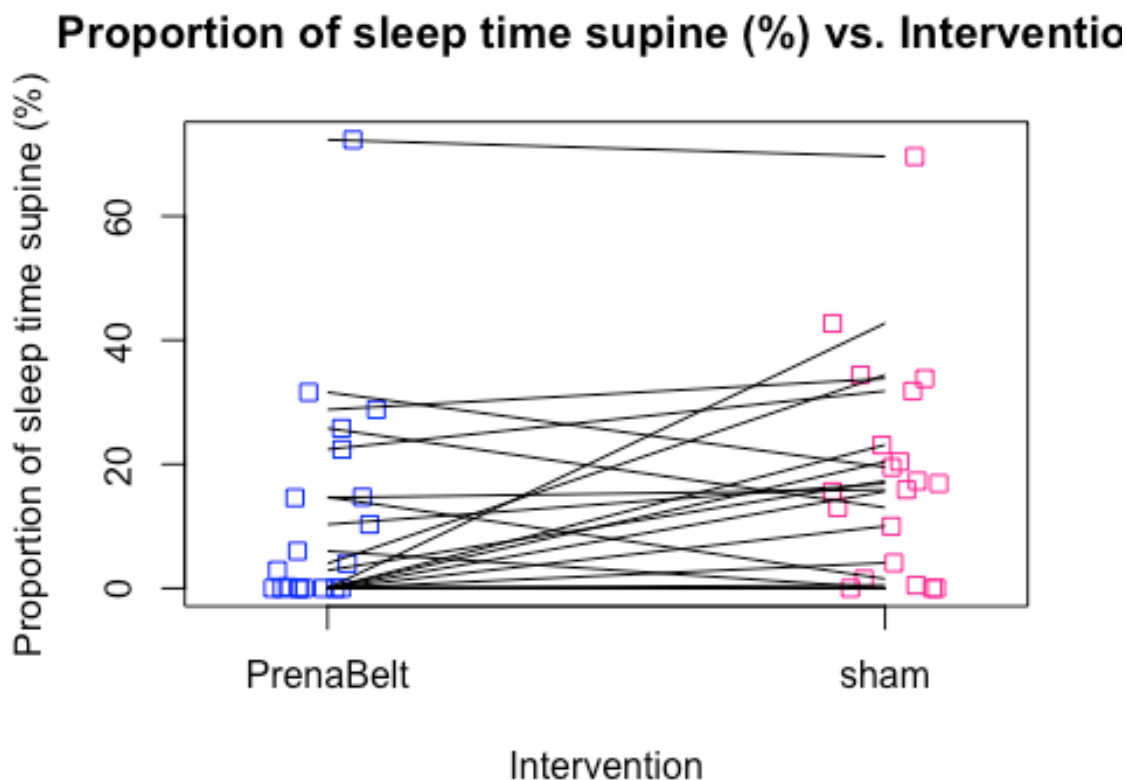
##
## Wilcoxon rank sum test with continuity correction
##

```

```

1
2
3  ## data: subset(SSdata, intervention == "sham")$PtstSupine and subset(SSdata
4  , intervention == "PrenaBelt")$PtstSupine
5  ## W = 267, p-value = 0.03456
6  ## alternative hypothesis: true location shift is greater than 0
7  ## 95 percent confidence interval:
8  ## 2.150084e-05      Inf
9  ## sample estimates:
10 ## difference in location
11 ##          6.666346
12
13  # Use droplevels to remove the empty levels from the list of levels
14  SSdata$intervention <- droplevels(SSdata$intervention)
15  summary(SSdata$intervention)
16
17  ## PrenaBelt      sham
18  ##          20          20
19
20  stripchart(SSdata$PtstSupine~SSdata$intervention,
21            vertical = TRUE, method="jitter", col=c("blue","deeppink"),
22            ylab='Proportion of sleep time supine (%)', xlab='Intervention',
23            main='Proportion of sleep time supine (%) vs. Intervention',)
24
25  for(participant.s.code in split(SSdata, SSdata$participant.s.code))
26    lines(PtstSupine ~ intervention, participant.s.code)
27
28
29
30
31

```



```
##### %TST Right #####
#Summary
summary(SSdata$PtstRight)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   30.10   30.30   45.92   95.40

sd(SSdata$PtstRight, na.rm = TRUE)

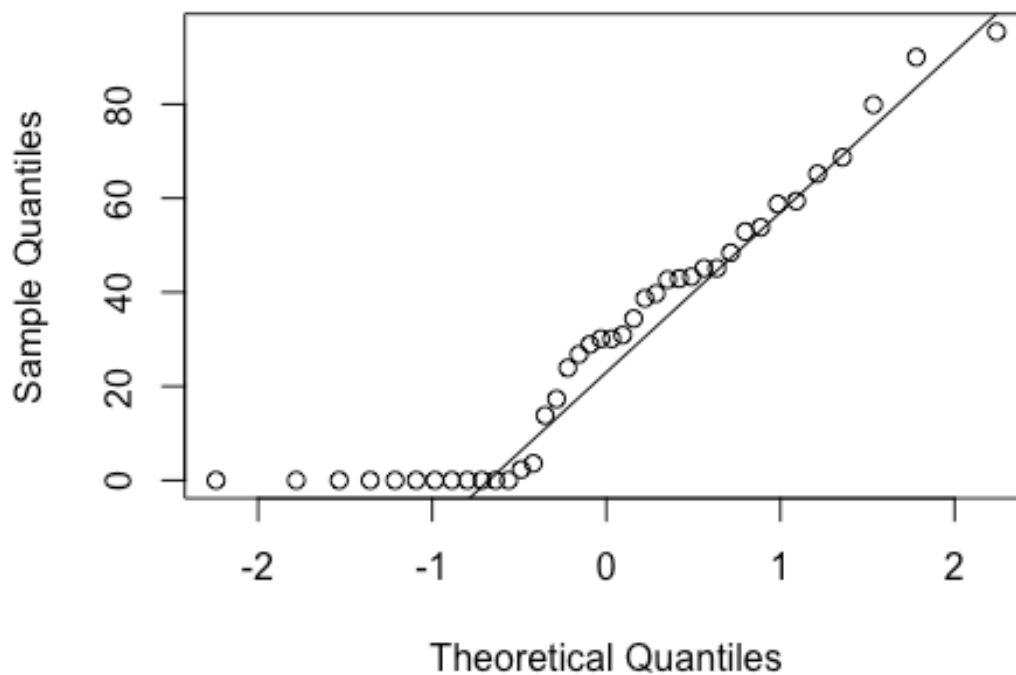
## [1] 27.78612

length(SSdata$PtstRight)

## [1] 40

qqnorm(SSdata$PtstRight)
qqline(SSdata$PtstRight)
```

Normal Q-Q Plot



```
ad.test(SSdata$PtstRight)

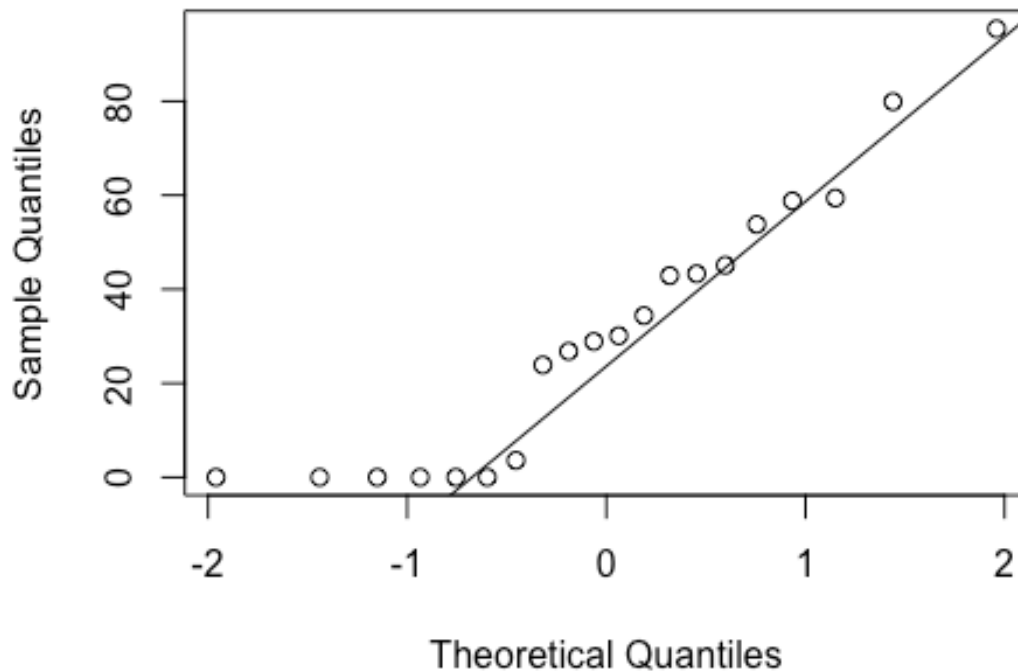
##
## Anderson-Darling normality test
##
## data:  SSdata$PtstRight
## A = 1.2731, p-value = 0.002267
```

```

1
2
3 #non-normal
4
5 #ANOVA
6 night_tx_difference <- anova(lm(PtstRight ~ intervention + night,
7                               data = SSdata))
8
9 night_tx_difference
10
11 ## Analysis of Variance Table
12 ##
13 ## Response: PtstRight
14 ##           Df Sum Sq Mean Sq F value Pr(>F)
15 ## intervention 1  41.0  41.01  0.0508 0.8229
16 ## night        1 202.1 202.05  0.2503 0.6198
17 ## Residuals   37 29867.6 807.23
18
19 #within-participants (paired) comparison
20 #Paired t-test (individual distributions are normally distributed)
21 t.test(subset(SSdataCompletes, intervention == "sham")$PtstRight,
22        subset(SSdataCompletes, intervention == "PrenaBelt")$PtstRight,
23        paired = TRUE)
24
25 ##
26 ## Paired t-test
27 ##
28 ## data: subset(SSdataCompletes, intervention == "sham")$PtstRight and subse
29 t(SSdataCompletes, intervention == "PrenaBelt")$PtstRight
30 ## t = -0.52565, df = 19, p-value = 0.6052
31 ## alternative hypothesis: true difference in means is not equal to 0
32 ## 95 percent confidence interval:
33 ## -10.088139  6.038139
34 ## sample estimates:
35 ## mean of the differences
36 ## -2.025
37
38 #between participants (grouped) comparison
39 summary(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
40
41 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
42 ##   0.00  0.00  29.50  31.32  47.28  95.40
43
44 sd(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
45
46 ## [1] 28.77236
47
48 length(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
49
50 ## [1] 20
51
52 qqnorm(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
53 qqline(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
54
55
56
57
58
59
60

```


Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstRight)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$PtstRight
## A = 0.64629, p-value = 0.07835

#normal

summary(subset(SSdata, intervention == "sham")$PtstRight)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.00   0.00   30.50   29.29   45.92   90.00

sd(subset(SSdata, intervention == "sham")$PtstRight)

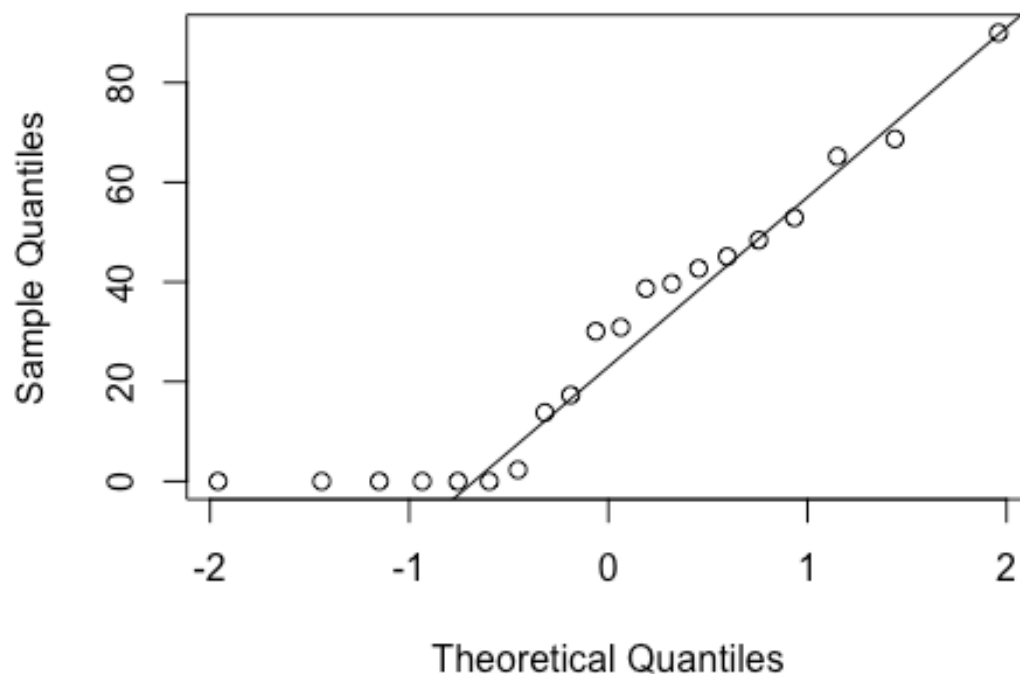
## [1] 27.47299

length(subset(SSdata, intervention == "sham")$PtstRight)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$PtstRight)
qqline(subset(SSdata, intervention == "sham")$PtstRight)
```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$PtstRight)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$PtstRight
## A = 0.70627, p-value = 0.0549

#borderline normal

t.test(subset(SSdata, intervention == "sham")$PtstRight,
       subset(SSdata, intervention == "PrenaBelt")$PtstRight)

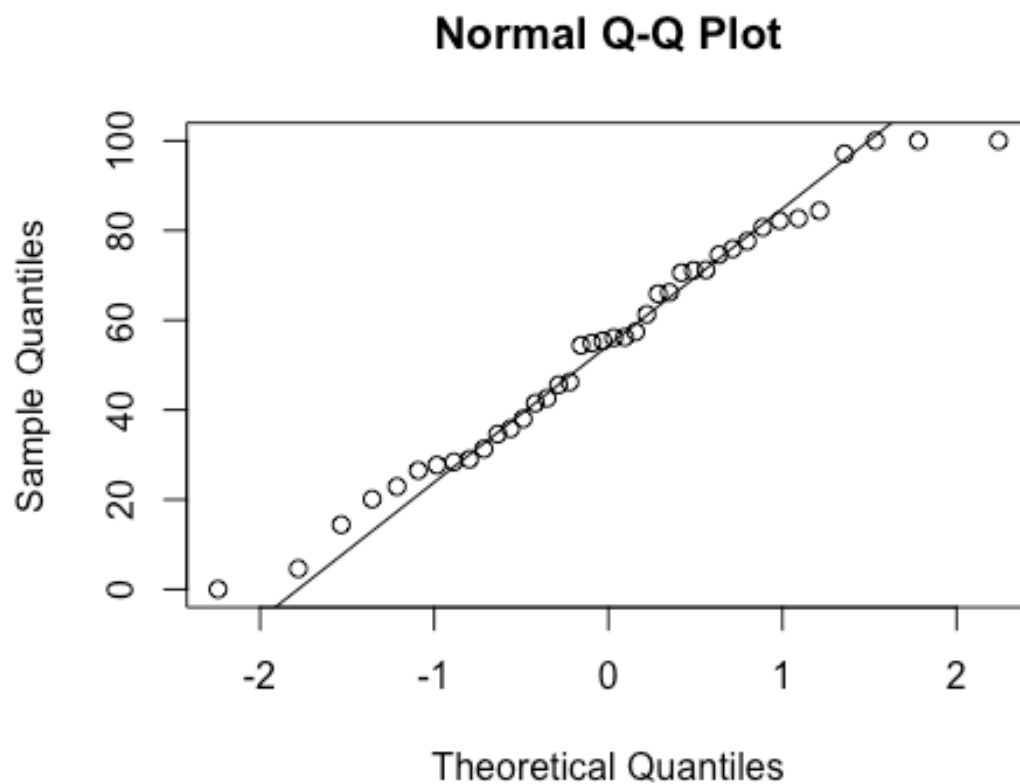
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$PtstRight and subset(SSdata,
## intervention == "PrenaBelt")$PtstRight
## t = -0.22764, df = 37.919, p-value = 0.8211
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -20.03435 15.98435
## sample estimates:

```

```

1
2
3  ## mean of x mean of y
4  ##    29.290    31.315
5
6  wilcox.test(subset(SSdata, intervention == "sham")$PtstRight,
7              subset(SSdata, intervention == "PrenaBelt")$PtstRight,
8              conf.int = TRUE)
9
10 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
11 ## $PtstRight, : cannot compute exact p-value with ties
12
13 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
14 ## $PtstRight, : cannot compute exact confidence intervals with ties
15
16 ##
17 ## Wilcoxon rank sum test with continuity correction
18 ##
19 ## data: subset(SSdata, intervention == "sham")$PtstRight and subset(SSdata,
20 ## intervention == "PrenaBelt")$PtstRight
21 ## W = 195, p-value = 0.9018
22 ## alternative hypothesis: true location shift is not equal to 0
23 ## 95 percent confidence interval:
24 ## -23.89994  14.80004
25 ## sample estimates:
26 ## difference in location
27 ##          -3.997034e-06
28
29 ##### %TST Left #####
30
31 #Summary
32 summary(SSdata$PtstLeft)
33
34 ##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
35 ##    0.00  33.78   55.75   54.63  74.92  100.00
36
37 sd(SSdata$PtstLeft, na.rm = TRUE)
38
39 ## [1] 26.70052
40
41 length(SSdata$PtstLeft)
42
43 ## [1] 40
44
45 qqnorm(SSdata$PtstLeft)
46 qqline(SSdata$PtstLeft)
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(SSdata$PtstLeft)

##
## Anderson-Darling normality test
##
## data:  SSdata$PtstLeft
## A = 0.26013, p-value = 0.6934

#normal

#ANOVA
night_tx_difference <- anova(lm(PtstLeft ~ intervention + night,
                               data = SSdata))
night_tx_difference

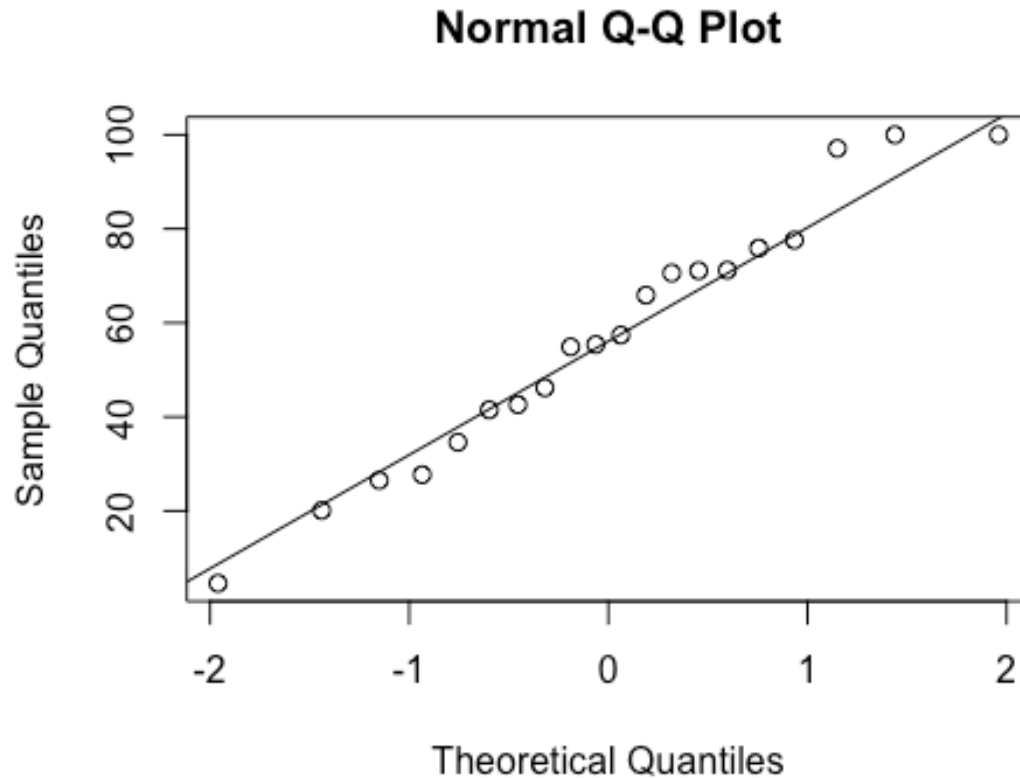
## Analysis of Variance Table
##
## Response: PtstLeft
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention  1   233.8   233.77   0.3141 0.5785
## night         1    35.9    35.91   0.0483 0.8273
## Residuals    37 27534.1   744.17

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired t-test
5 t.test(subset(SSdataCompletes, intervention == "sham")$PtstLeft,
6         subset(SSdataCompletes, intervention == "PrenaBelt")$PtstLeft,
7         paired = TRUE)
8
9 ##
10 ## Paired t-test
11 ##
12 ## data: subset(SSdataCompletes, intervention == "sham")$PtstLeft and subset
13 (SSdataCompletes, intervention == "PrenaBelt")$PtstLeft
14 ## t = -1.0137, df = 19, p-value = 0.3234
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -14.817699  5.147699
18 ## sample estimates:
19 ## mean of the differences
20 ## -4.835
21
22
23 #between participants (grouped) comparison
24 summary(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
25
26 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##      4.60  39.78   56.40   57.04   72.38  100.00
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
30
31 ## [1] 26.8734
32
33 length(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
34
35 ## [1] 20
36
37 qqnorm(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
38 qqline(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$PtstLeft
## A = 0.20177, p-value = 0.86

#normal

summary(subset(SSdata, intervention == "sham")$PtstLeft)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.00  30.72   55.25   52.21  76.12  100.00

sd(subset(SSdata, intervention == "sham")$PtstLeft)

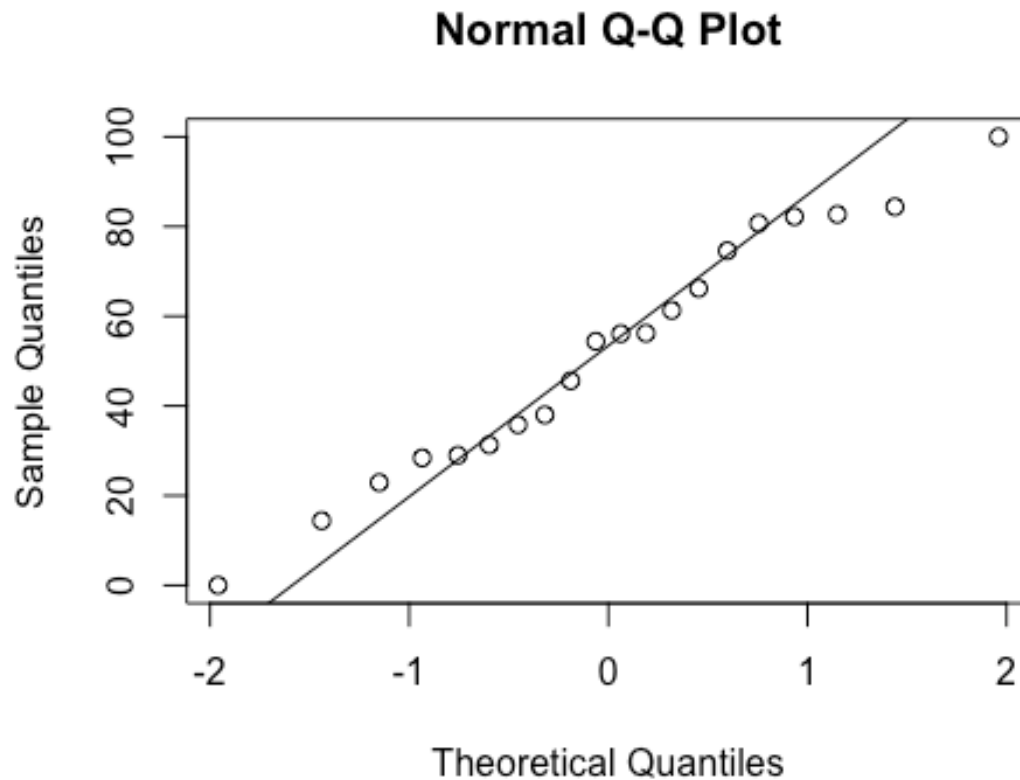
## [1] 26.99768

length(subset(SSdata, intervention == "sham")$PtstLeft)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$PtstLeft)
qqline(subset(SSdata, intervention == "sham")$PtstLeft)

```



```

ad.test(subset(SSdata, intervention == "sham")$PtstLeft)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$PtstLeft
## A = 0.24563, p-value = 0.7241

#normal

t.test(subset(SSdata, intervention == "sham")$PtstLeft,
       subset(SSdata, intervention == "PrenaBelt")$PtstLeft)

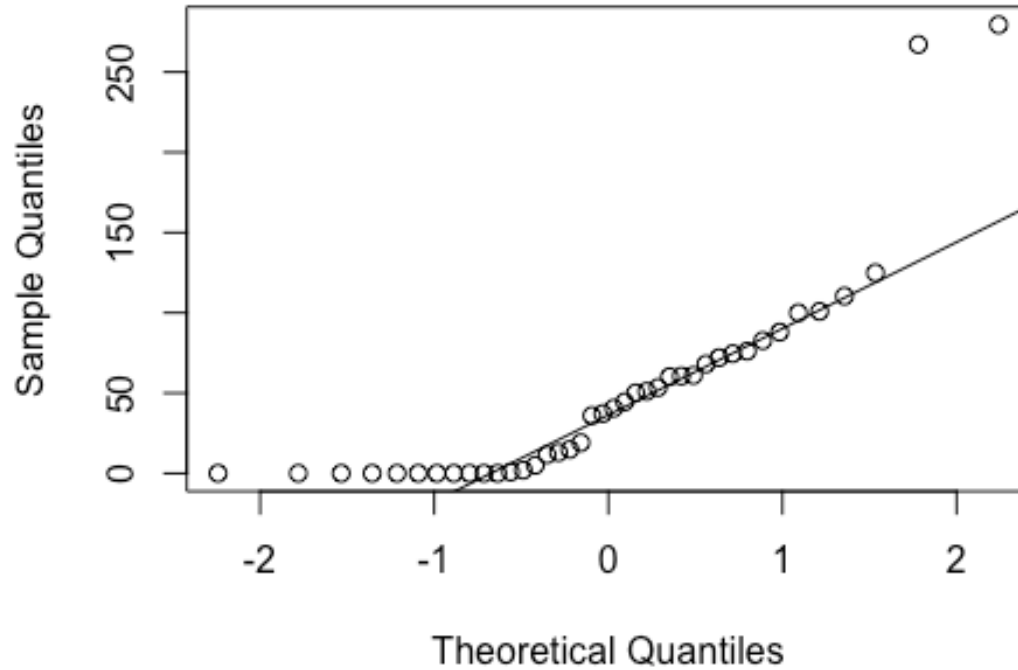
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$PtstLeft and subset(SSdata,
## intervention == "PrenaBelt")$PtstLeft
## t = -0.56764, df = 37.999, p-value = 0.5736
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -22.07837 12.40837
## sample estimates:

```

```
1
2
3 ## mean of x mean of y
4 ##    52.210    57.045
5
6 #no time was spent prone
7 summary(SSdata$PtstProne)
8
9 ##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
10 ##      0      0      0      0      0      0
11
12 sd(SSdata$PtstProne, na.rm = TRUE)
13
14 ## [1] 0
15
16 length(SSdata$PtstProne)
17
18 ## [1] 40
19
20 ##### Minutes Sleeping Supine #####
21 #Summary
22 summary(SSdata$minutesTSTSupine)
23
24 ##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
25 ##    0.00    0.00   38.90   50.13   72.67   279.40
26
27 sd(SSdata$minutesTSTSupine, na.rm = TRUE)
28
29 ## [1] 63.82465
30
31 length(SSdata$minutesTSTSupine)
32
33 ## [1] 40
34
35 qqnorm(SSdata$minutesTSTSupine)
36 qqline(SSdata$minutesTSTSupine)
```

Only

Normal Q-Q Plot



```
ad.test(SSdata$minutesTSTSupine)
```

```
##
## Anderson-Darling normality test
##
## data:  SSdata$minutesTSTSupine
## A = 2.6888, p-value = 6.632e-07
```

```
#data do not follow a normal distribution; perform paired Wilcoxon rank sum t est
```

```
#ANOVA
```

```
night_tx_difference <- anova(lm(minutesTSTSupine ~ intervention * night,
                                data = SSdata))
```

```
night_tx_difference
```

```
## Analysis of Variance Table
```

```
##
```

```
## Response: minutesTSTSupine
```

	Df	Sum Sq	Mean Sq	F value	Pr(>F)
## intervention	1	5927	5927.0	1.4014	0.2442
## night	1	500	499.8	0.1182	0.7330
## intervention:night	1	189	188.9	0.0447	0.8338
## Residuals	36	152254	4229.3		

```

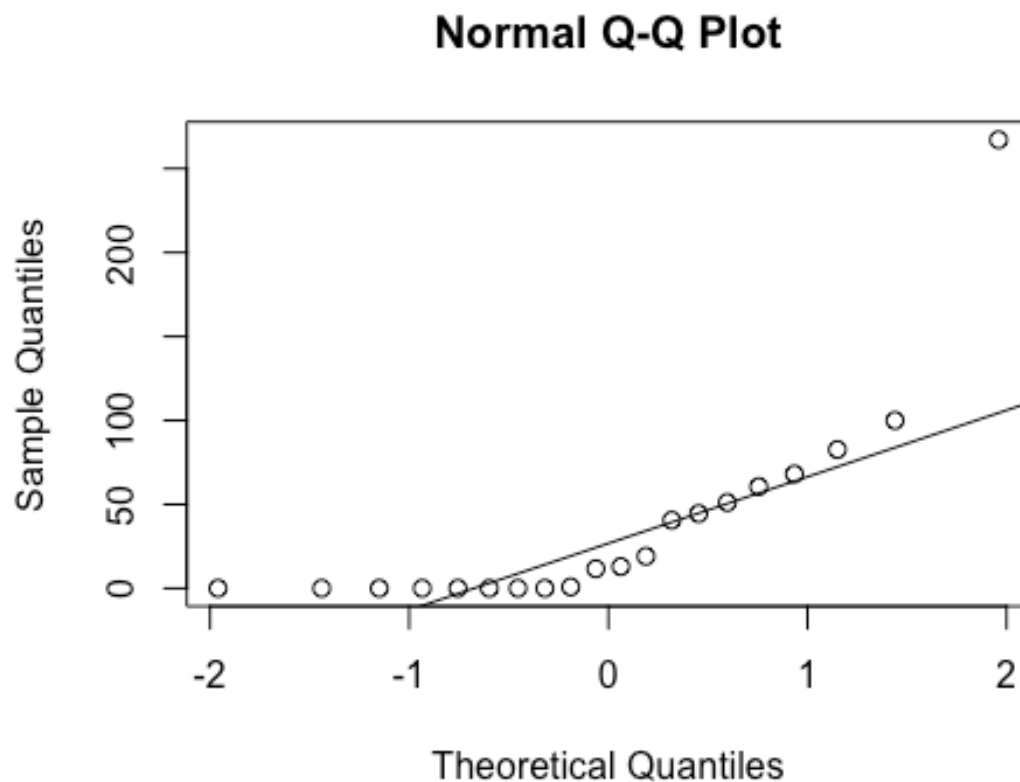
1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSu
7 pine,
8             paired = TRUE, conf.int = TRUE, alternative = "greater")
9
10 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
11 ## "sham")$minutesTSTSupine, : cannot compute exact p-value with zeroes
12
13 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
14 ## "sham")$minutesTSTSupine, : cannot compute exact confidence interval with
15 ## zeroes
16
17 ##
18 ## Wilcoxon signed rank test with continuity correction
19 ##
20 ## data: subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine an
21 d subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine
22 ## V = 150, p-value = 0.01415
23 ## alternative hypothesis: true location shift is greater than 0
24 ## 95 percent confidence interval:
25 ## 7.025017 Inf
26 ## sample estimates:
27 ## (pseudo)median
28 ## 26.37306
29
30
31 #Paired t-test to double check and confirm non-parametric results
32 t.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine,
33        subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine,
34        paired = TRUE)
35
36 ##
37 ## Paired t-test
38 ##
39 ## data: subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine an
40 d subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine
41 ## t = 2.3911, df = 19, p-value = 0.02731
42 ## alternative hypothesis: true difference in means is not equal to 0
43 ## 95 percent confidence interval:
44 ## 3.03469 45.65601
45 ## sample estimates:
46 ## mean of the differences
47 ## 24.34535
48
49
50 #between participants (grouped) comparison
51 summary(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
52
53 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
54 ## 0.00 0.00 12.30 37.95 53.48 267.10
55
56 sd(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
57
58
59
60

```

```

1
2
3 ## [1] 62.65788
4
5 length(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
6
7 ## [1] 20
8
9 qqnorm(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
10 qqline(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
11
12
13
14
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39
40

```



```

41 ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine
47 ## A = 2.2269, p-value = 7.014e-06
48
49 #non-normal
50
51 summary(subset(SSdata, intervention == "sham")$minutesTSTSupine)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##      0.00  12.39   56.80   62.30   79.08  279.40
55
56 sd(subset(SSdata, intervention == "sham")$minutesTSTSupine)
57
58
59
60

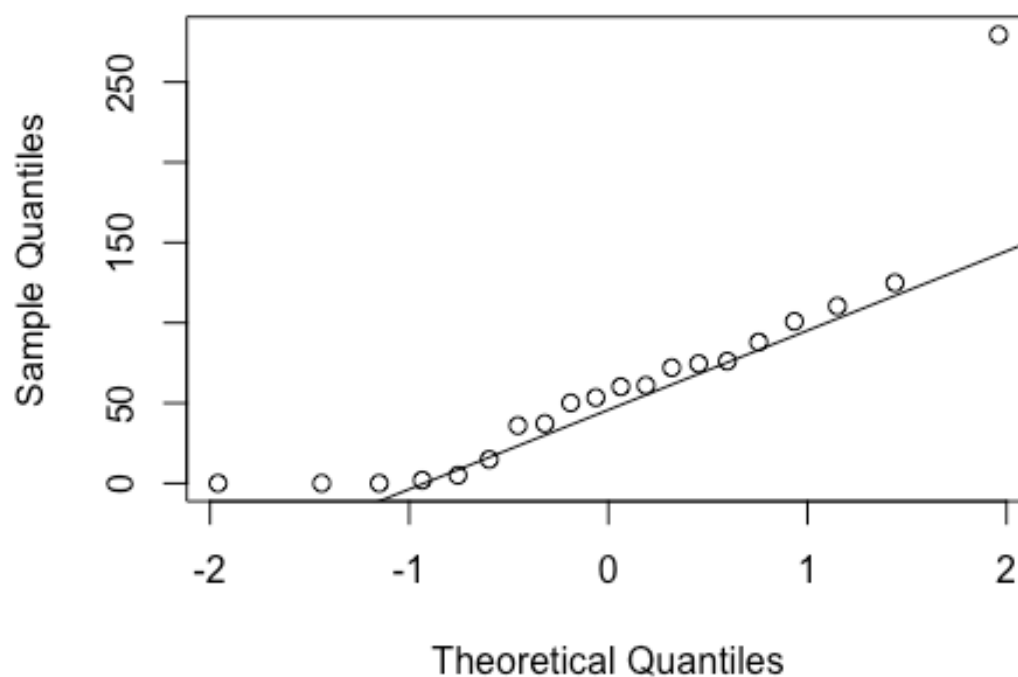
```

```

1
2
3 ## [1] 64.21539
4
5 length(subset(SSdata, intervention == "sham")$minutesTSTSupine)
6
7 ## [1] 20
8
9 qqnorm(subset(SSdata, intervention == "sham")$minutesTSTSupine)
10 qqline(subset(SSdata, intervention == "sham")$minutesTSTSupine)
11
12
13
14
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16
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37
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39
40

```

Normal Q-Q Plot



```

41 ad.test(subset(SSdata, intervention == "sham")$minutesTSTSupine)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: subset(SSdata, intervention == "sham")$minutesTSTSupine
47 ## A = 0.96839, p-value = 0.01163
48
49 #non-normal
50
51 wilcox.test(subset(SSdata, intervention == "sham")$minutesTSTSupine,
52             subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine,
53             conf.int = TRUE, alternative = "greater")
54
55
56
57
58
59
60

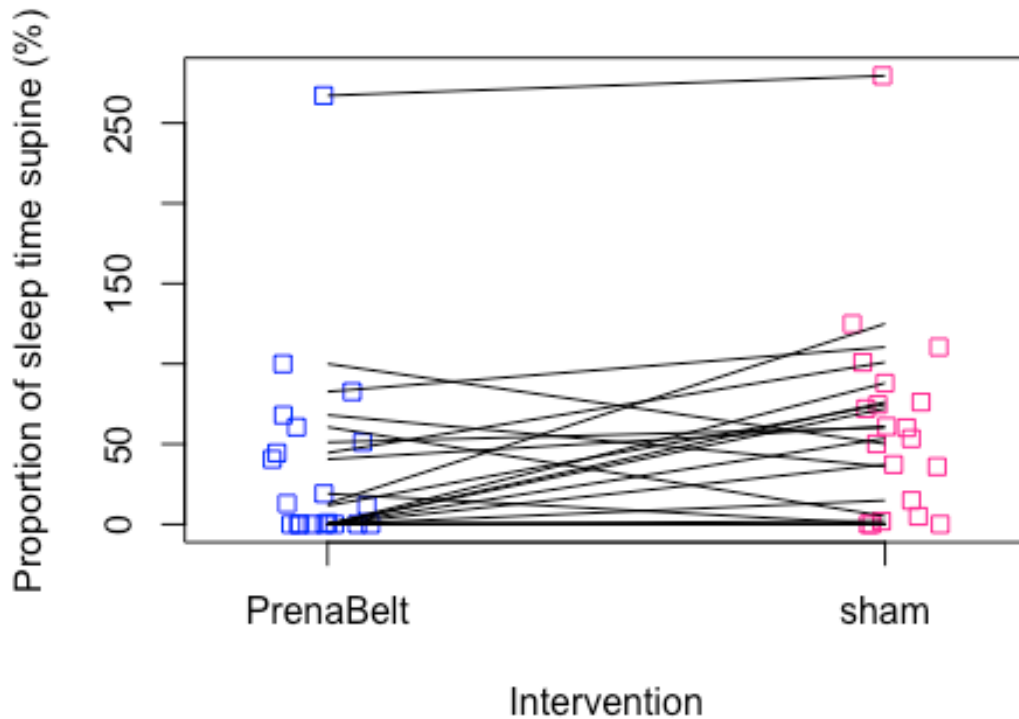
```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
4  ## $minutesTSTSupine, : cannot compute exact p-value with ties
5
6  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
7  ## $minutesTSTSupine, : cannot compute exact confidence intervals with ties
8
9  ##
10 ## Wilcoxon rank sum test with continuity correction
11 ##
12 ## data: subset(SSdata, intervention == "sham")$minutesTSTSupine and subset(
13 SSdata, intervention == "PrenaBelt")$minutesTSTSupine
14 ## W = 271, p-value = 0.02699
15 ## alternative hypothesis: true location shift is greater than 0
16 ## 95 percent confidence interval:
17 ##  6.926608e-05      Inf
18 ## sample estimates:
19 ## difference in location
20 ##                24.28712
21
22
23 # Use droplevels to remove the empty levels from the list of levels
24 SSdata$intervention <- droplevels(SSdata$intervention)
25 summary(SSdata$intervention)
26
27 ## PrenaBelt      sham
28 ##          20      20
29
30 stripchart(SSdata$minutesTSTSupine~SSdata$intervention,
31             vertical = TRUE, method="jitter", col=c("blue","deeppink"),
32             ylab='Proportion of sleep time supine (%)', xlab='Intervention',
33             main='Proportion of sleep time supine (%) vs. Intervention',)
34
35 for(participant.s.code in split(SSdata, SSdata$participant.s.code))
36   lines(minutesTSTSupine ~ intervention, participant.s.code)
37
38
39
40
41
42
43
44
45
46
47
48
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60

```

Proportion of sleep time supine (%) vs. Interventio



```
##### Minutes Sleeping Left #####
#Summary
summary(SSdata$minutesTSTLeft)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.0  114.2  162.6  180.9  225.1  390.0

sd(SSdata$minutesTSTLeft, na.rm = TRUE)

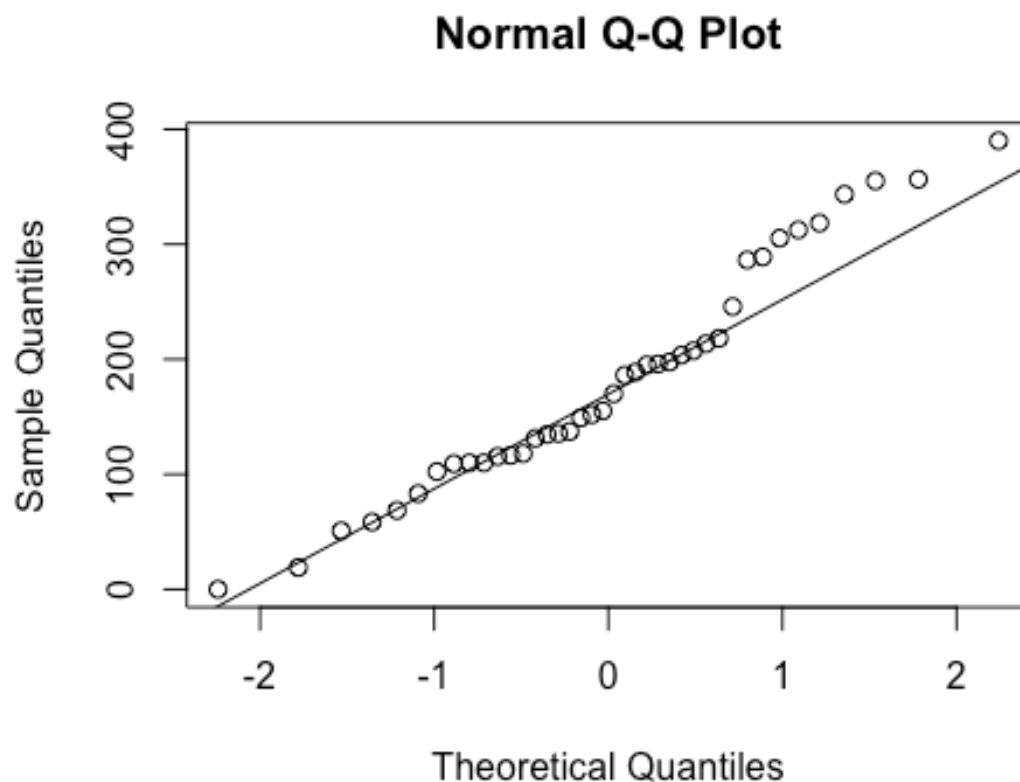
## [1] 97.72311

length(SSdata$minutesTSTLeft)

## [1] 40

qqnorm(SSdata$minutesTSTLeft)
qqline(SSdata$minutesTSTLeft)
```

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```

ad.test(SSdata$minutesTSTLeft)

##
## Anderson-Darling normality test
##
## data:  SSdata$minutesTSTLeft
## A = 0.60089, p-value = 0.1109

#normal

#ANOVA
night_tx_difference <- anova(lm(minutesTSTLeft ~ intervention * night,
                                data = SSdata))
night_tx_difference

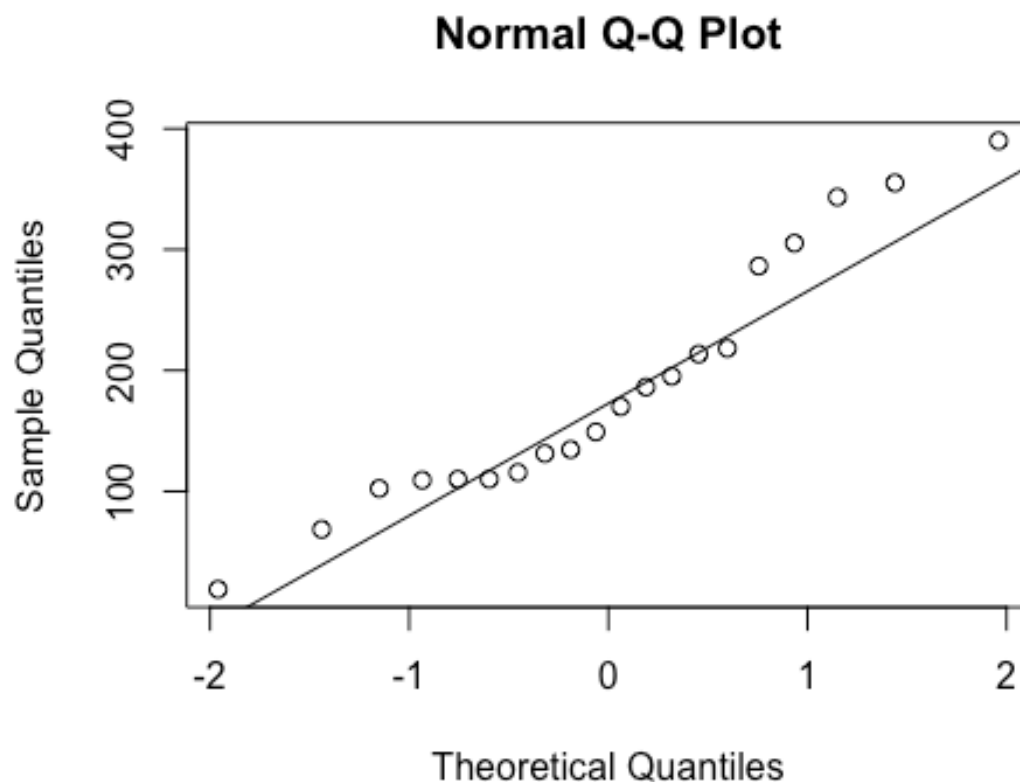
## Analysis of Variance Table
##
## Response: minutesTSTLeft
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1     910    909.5   0.0960  0.7585
## night            1    5161   5160.9   0.5447  0.4653
## intervention:night  1   25295  25294.7   2.6698  0.1110
## Residuals      36  341077   9474.4

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired t-test
5 t.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTLeft,
6       subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTLeft,
7       paired = TRUE)
8
9 ##
10 ## Paired t-test
11 ##
12 ## data: subset(SSdataCompletes, intervention == "sham")$minutesTSTLeft and
13 subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTLeft
14 ## t = -0.59061, df = 19, p-value = 0.5617
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -43.33418 24.26038
18 ## sample estimates:
19 ## mean of the differences
20 ## -9.5369
21
22
23 #between participants (grouped) comparison
24 summary(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
25
26 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##  18.95  110.00  159.60  185.60  235.30  390.00
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
30
31 ## [1] 102.4677
32
33 length(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
34
35 ## [1] 20
36
37 qqnorm(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
38 qqline(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
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```

```

ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft
## A = 0.60013, p-value = 0.103

#normal

summary(subset(SSdata, intervention == "sham")$minutesTSTLeft)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.0  117.6   172.0   176.1  217.0   356.4

sd(subset(SSdata, intervention == "sham")$minutesTSTLeft)

## [1] 95.1564

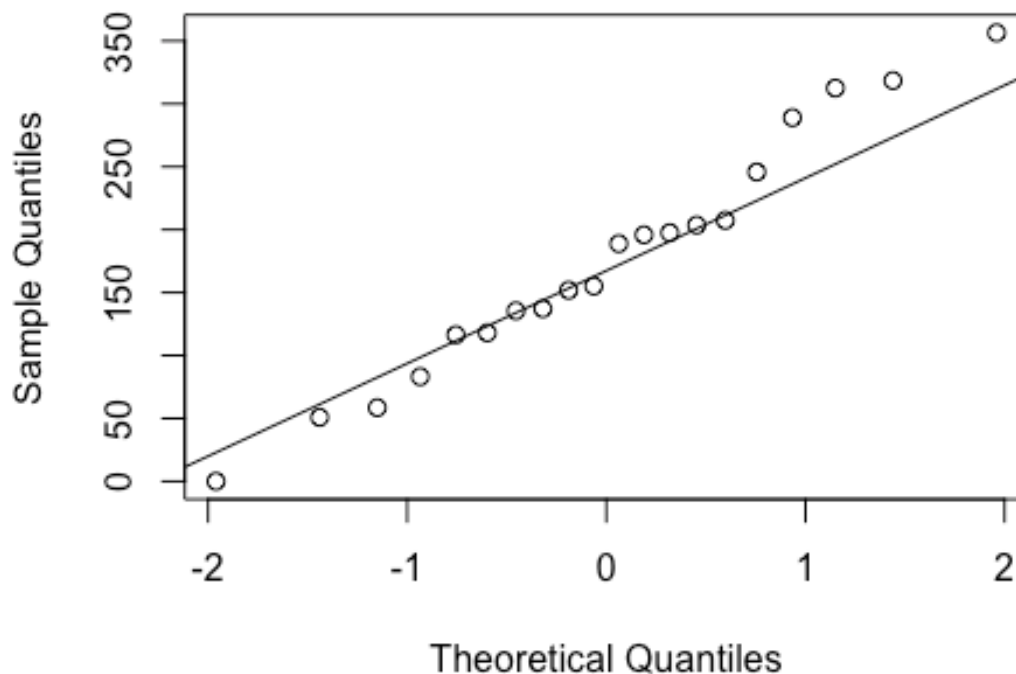
length(subset(SSdata, intervention == "sham")$minutesTSTLeft)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$minutesTSTLeft)
qqline(subset(SSdata, intervention == "sham")$minutesTSTLeft)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$minutesTSTLeft)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$minutesTSTLeft
## A = 0.21195, p-value = 0.8324

#normal

t.test(subset(SSdata, intervention == "sham")$minutesTSTLeft,
       subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$minutesTSTLeft and subset(SS
data, intervention == "PrenaBelt")$minutesTSTLeft
## t = -0.305, df = 37.794, p-value = 0.762
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -72.84799 53.77419
## sample estimates:

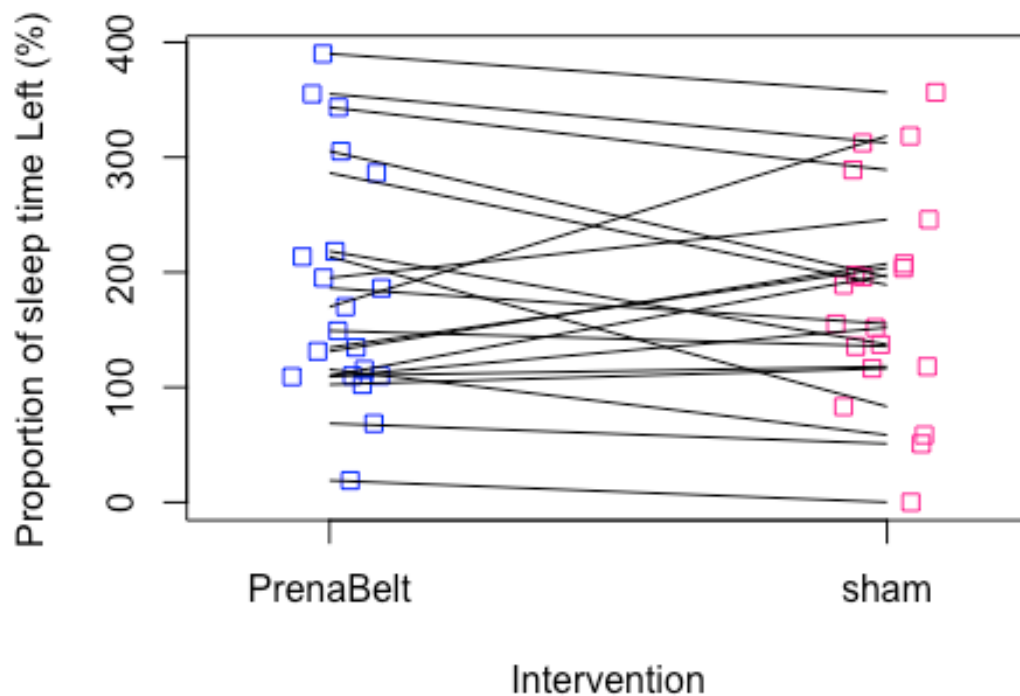
```

```

1
2
3  ## mean of x mean of y
4  ## 176.1083 185.6452
5
6  # Use droplevels to remove the empty Levels from the List of Levels
7  SSdata$intervention <- droplevels(SSdata$intervention)
8  summary(SSdata$intervention)
9
10 ## PrenaBelt      sham
11 ##          20      20
12
13 stripchart(SSdata$minutesTSTLeft~SSdata$intervention,
14            vertical = TRUE, method="jitter", col=c("blue","deeppink"),
15            ylab='Proportion of sleep time Left (%)', xlab='Intervention',
16            main='Proportion of sleep time Left (%) vs. Intervention',)
17
18 for(participant.s.code in split(SSdata, SSdata$participant.s.code))
19   lines(minutesTSTLeft ~ intervention, participant.s.code)
20
21
22
23
24
25
26

```

Proportion of sleep time Left (%) vs. Intervention



```

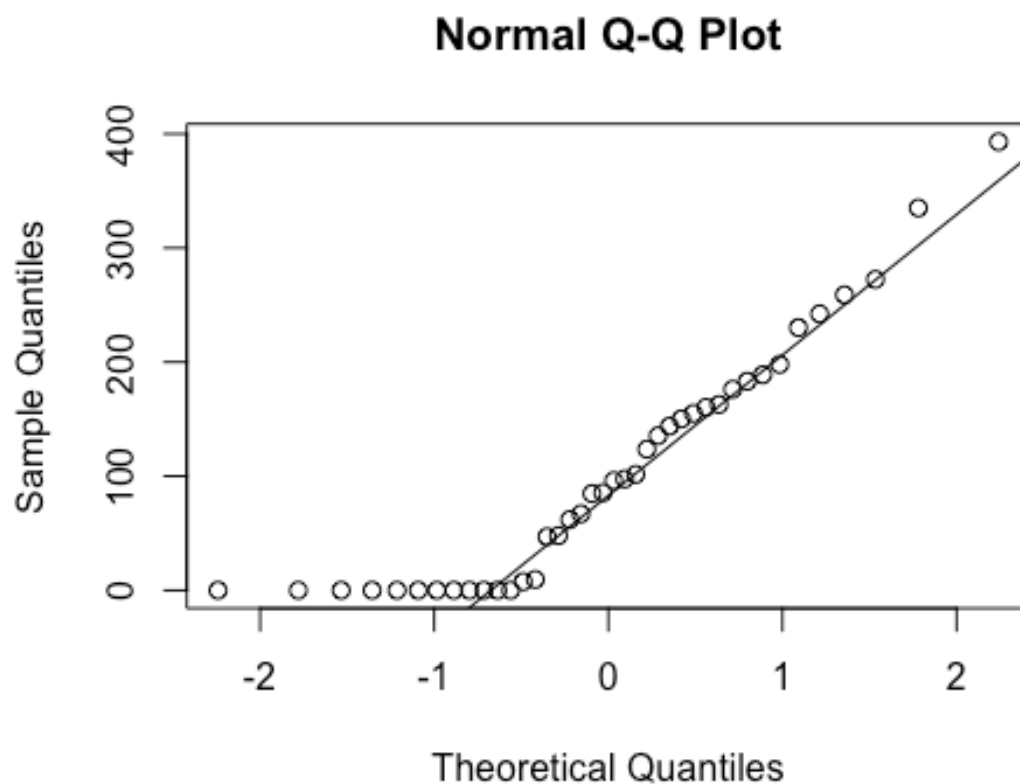
50 ##### Minutes Sleeping Right #####
51 #Summary
52 summary(SSdata$minutesTSTRight)
53
54 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
55 ##   0.00   0.00   90.78  105.40  166.10  393.00
56
57
58
59
60

```

```
sd(SSdata$minutesTSTRight, na.rm = TRUE)
## [1] 104.3365

length(SSdata$minutesTSTRight)
## [1] 40

qqnorm(SSdata$minutesTSTRight)
qqline(SSdata$minutesTSTRight)
```



```
ad.test(SSdata$minutesTSTRight)
##
## Anderson-Darling normality test
##
## data: SSdata$minutesTSTRight
## A = 1.3459, p-value = 0.001489

#non-normal

#ANOVA
night_tx_difference <- anova(lm(minutesTSTRight ~ intervention * night,
```

```

1
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46
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49
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```

```

                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: minutesTSTRight
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention      1    477   477.4    0.0427 0.8374
## night              1   1242  1242.1    0.1111 0.7408
## intervention:night 1  20504 20503.6    1.8346 0.1840
## Residuals        36 402335 11176.0

#within-participants (paired) comparison
#Paired Wilcoxon (non-normal)
wilcox.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTRight,
            subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTRig
ht,
            paired = TRUE, conf.int = TRUE, alternative = "greater")

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$minutesTSTRight, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$minutesTSTRight, : cannot compute exact confidence interval with
## zeroes

##
## Wilcoxon signed rank test with continuity correction
##
## data: subset(SSdataCompletes, intervention == "sham")$minutesTSTRight and
subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTRight
## V = 54, p-value = 0.644
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
## -47.61614      Inf
## sample estimates:
## (pseudo)median
##      -7.343686

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   96.82  108.90  167.50  393.00

sd(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

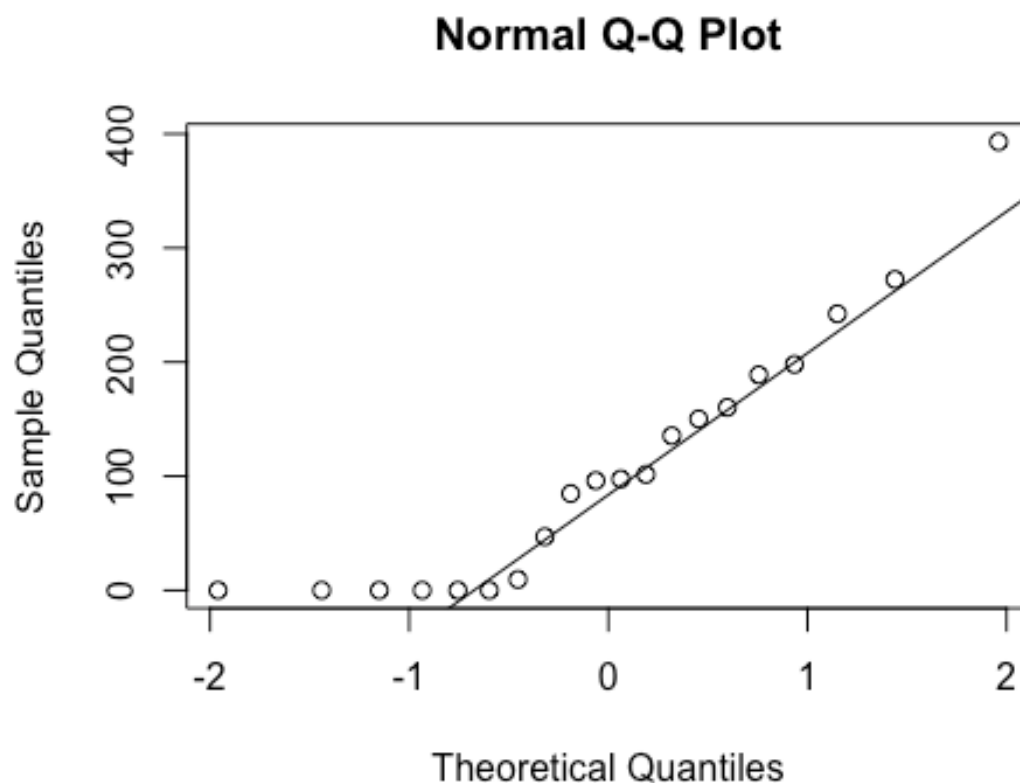
## [1] 110.1396

length(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)
qqline(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight
## A = 0.71202, p-value = 0.05306

#borderline normal

summary(subset(SSdata, intervention == "sham")$minutesTSTRight)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   76.23  101.90  166.10  335.10

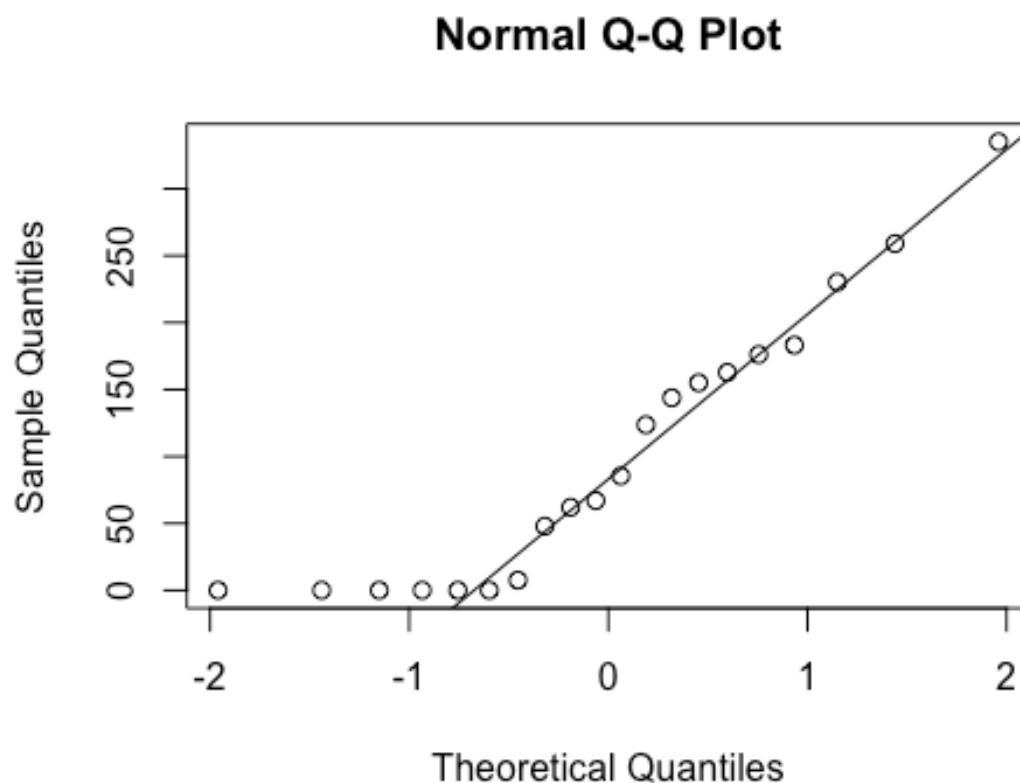
sd(subset(SSdata, intervention == "sham")$minutesTSTRight)

## [1] 100.9421

length(subset(SSdata, intervention == "sham")$minutesTSTRight)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$minutesTSTRight)
qqline(subset(SSdata, intervention == "sham")$minutesTSTRight)
```



```
ad.test(subset(SSdata, intervention == "sham")$minutesTSTRight)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$minutesTSTRight
## A = 0.73955, p-value = 0.04508

#non-normal

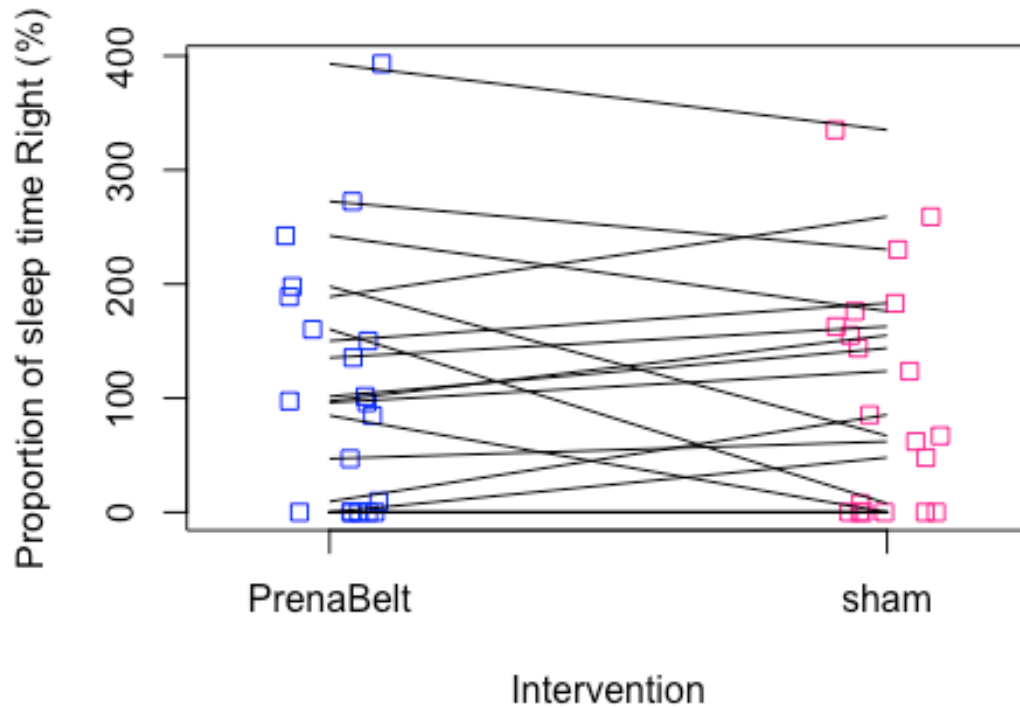
wilcox.test(subset(SSdata, intervention == "sham")$minutesTSTRight,
            subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight,
            conf.int = TRUE, alternative = "greater")

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $minutesTSTRight, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $minutesTSTRight, : cannot compute exact confidence intervals with ties
```

```
1
2
3 ##
4 ## Wilcoxon rank sum test with continuity correction
5 ##
6 ## data: subset(SSdata, intervention == "sham")$minutesTSTRight and subset(S
7 Sdata, intervention == "PrenaBelt")$minutesTSTRight
8 ## W = 195, p-value = 0.5599
9 ## alternative hypothesis: true location shift is greater than 0
10 ## 95 percent confidence interval:
11 ## -54.15088      Inf
12 ## sample estimates:
13 ## difference in location
14 ## -3.909212e-05
15
16
17 # Use droplevels to remove the empty levels from the list of levels
18 SSdata$intervention <- droplevels(SSdata$intervention)
19 summary(SSdata$intervention)
20
21 ## PrenaBelt      sham
22 ##          20          20
23
24 stripchart(SSdata$minutesTSTRight~SSdata$intervention,
25            vertical = TRUE, method="jitter", col=c("blue","deeppink"),
26            ylab='Proportion of sleep time Right (%)', xlab='Intervention',
27            main='Proportion of sleep time Right (%) vs. Intervention',)
28
29 for(participant.s.code in split(SSdata, SSdata$participant.s.code))
30   lines(minutesTSTRight ~ intervention, participant.s.code)
31
32
33
34
35
36
37
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```


Proportion of sleep time Right (%) vs. Intervention



```

#Considering index (events per hour) data now:
##### Central Apnea Index #####
#Summary
summary(SSdata$central.apneas.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  0.060  0.025  0.500

sd(SSdata$central.apneas.index, na.rm = TRUE)

## [1] 0.1236206

length(SSdata$central.apneas.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(central.apneas.index ~ intervention * night,
                               data = SSdata))

night_tx_difference

## Analysis of Variance Table
##
## Response: central.apneas.index
##              Df Sum Sq Mean Sq F value Pr(>F)

```

```

1
2
3 ## intervention      1  0.001 0.001000  0.0679 0.79587
4 ## night            1  0.001 0.001000  0.0679 0.79587
5 ## intervention:night 1  0.064 0.064000  4.3472 0.04422 *
6 ## Residuals       36  0.530 0.014722
7 ## ---
8 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
9
10 #within-participants (paired) comparison
11 #Paired Wilcoxon
12 wilcox.test(subset(SSdataCompletes, intervention == "sham")$central.apneas.in
13 dex,
14           subset(SSdataCompletes, intervention == "PrenaBelt")$central.apneas.in
15 dex,
16           paired = TRUE, conf.int = TRUE)
17
18 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
19 ## "sham")$central.apneas.index, : cannot compute exact p-value with ties
20
21 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
22 ## "sham")$central.apneas.index, : cannot compute exact confidence interval
23 ## with ties
24
25 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
26 ## "sham")$central.apneas.index, : cannot compute exact p-value with zeroes
27
28 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
29 ## "sham")$central.apneas.index, : cannot compute exact confidence interval
30 ## with zeroes
31
32
33 ##
34 ## Wilcoxon signed rank test with continuity correction
35 ##
36 ## data:  subset(SSdataCompletes, intervention == "sham")$central.apneas.inde
37 x and subset(SSdataCompletes, intervention == "PrenaBelt")$central.apneas.ind
38 ex
39 ## V = 26.5, p-value = 0.6746
40 ## alternative hypothesis: true location shift is not equal to 0
41 ## 95 percent confidence interval:
42 ## -0.1500585  0.2000332
43 ## sample estimates:
44 ## (pseudo)median
45 ##      0.04999741
46
47 #between participants (grouped) comparison
48 summary(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
49
50 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
51 ##      0.000  0.000  0.000  0.055  0.000  0.500
52
53 sd(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
54
55 ## [1] 0.1394538
56
57
58
59
60

```

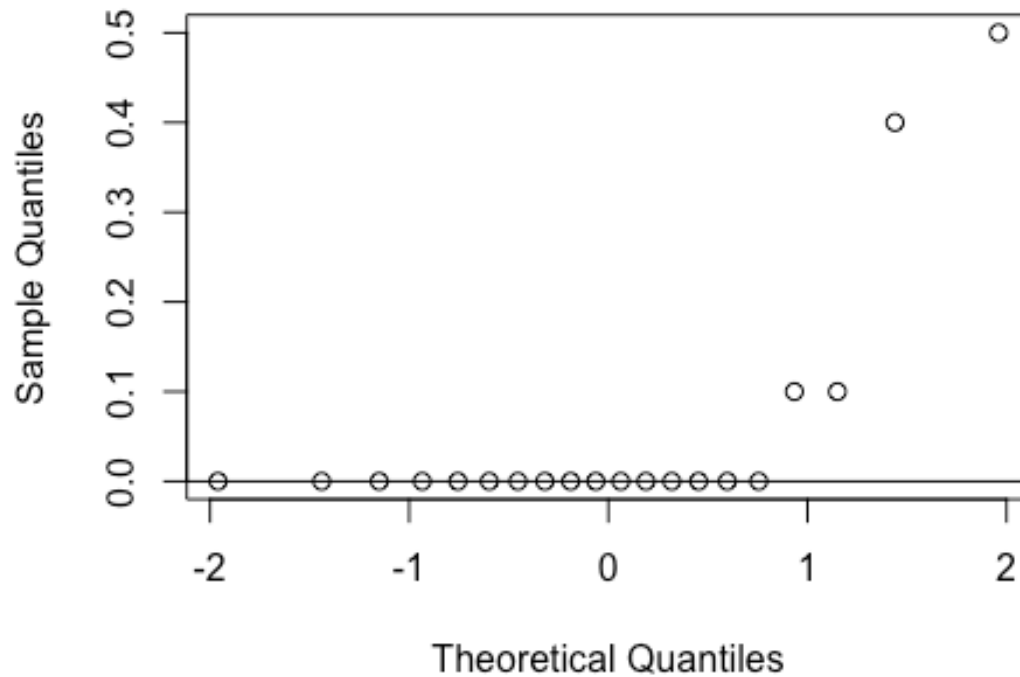
```

length(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$central.apneas.index
## A = 5.0415, p-value = 5.577e-13

#non-norma

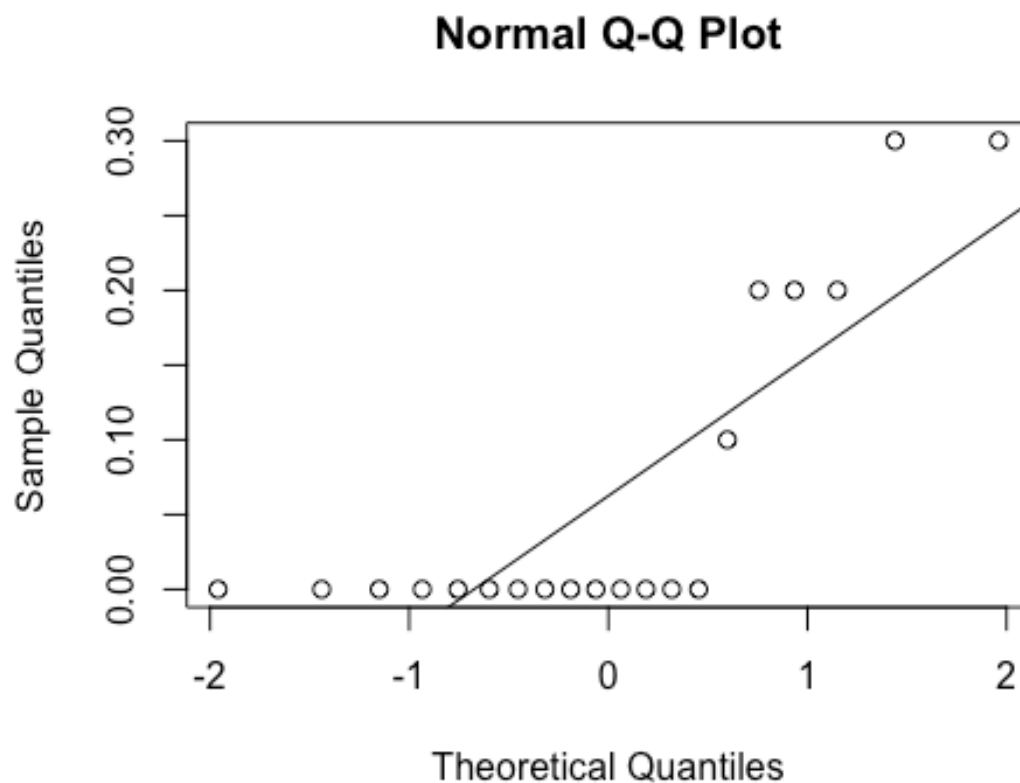
summary(subset(SSdata, intervention == "sham")$central.apneas.index)
##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  0.065  0.125  0.300

sd(subset(SSdata, intervention == "sham")$central.apneas.index)
## [1] 0.1089423

```

```
length(subset(SSdata, intervention == "sham")$central.apneas.index)
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$central.apneas.index)
qqline(subset(SSdata, intervention == "sham")$central.apneas.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$central.apneas.index)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$central.apneas.index
## A = 3.5176, p-value = 3.741e-09

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$central.apneas.index,
            subset(SSdata, intervention == "PrenaBeIt")$central.apneas.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $central.apneas.index, : cannot compute exact p-value with ties
```

```

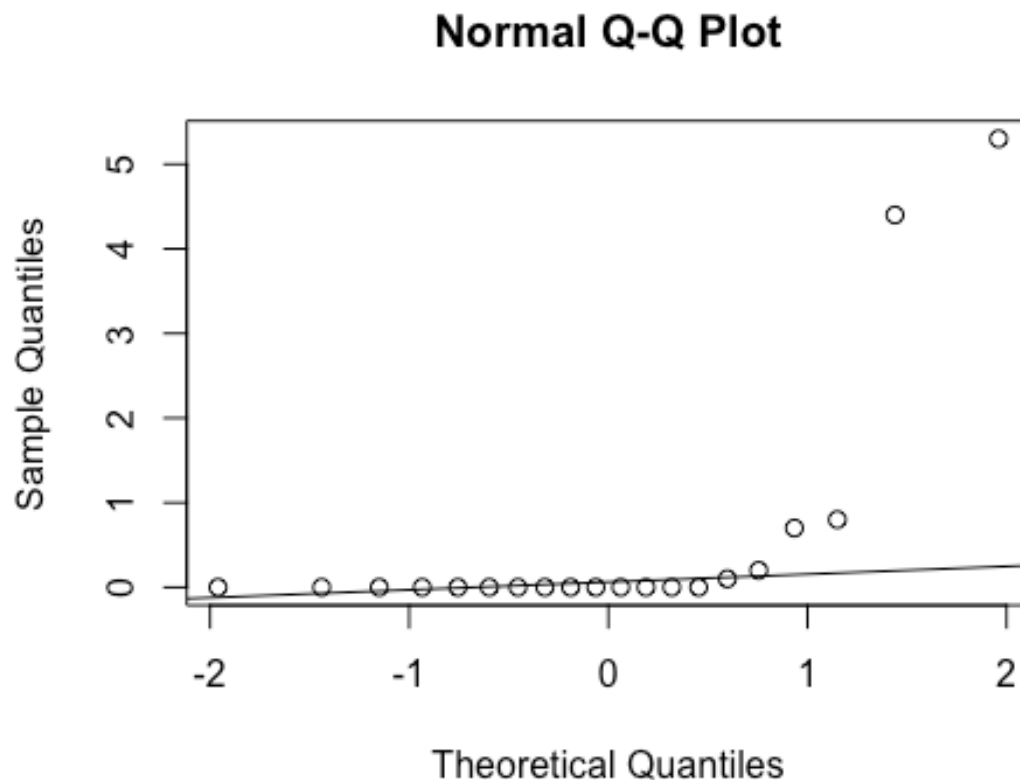
1
2
3  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
4  ## $central.apneas.index, : cannot compute exact confidence intervals with
5  ## ties
6
7  ##
8  ## Wilcoxon rank sum test with continuity correction
9  ##
10 ## data: subset(SSdata, intervention == "sham")$central.apneas.index and sub
11 set(SSdata, intervention == "PrenaBelt")$central.apneas.index
12 ## W = 219, p-value = 0.5102
13 ## alternative hypothesis: true location shift is not equal to 0
14 ## 95 percent confidence interval:
15 ## -6.326233e-05 3.161243e-05
16 ## sample estimates:
17 ## difference in location
18 ## 5.5406e-05
19
20
21 ##### Obstructive Apnea Index #####
22 #Summary
23 summary(SSdata$obstructive.apneas.index)
24
25 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
26 ##    0.000  0.000  0.000  0.730  0.225  11.400
27
28 sd(SSdata$obstructive.apneas.index, na.rm = TRUE)
29
30 ## [1] 2.115171
31
32 length(SSdata$obstructive.apneas.index)
33
34 ## [1] 40
35
36 #ANOVA
37 night_tx_difference <- anova(lm(obstructive.apneas.index ~ intervention + nig
38 ht,
39                               data = SSdata))
40
41 night_tx_difference
42
43 ## Analysis of Variance Table
44 ##
45 ## Response: obstructive.apneas.index
46 ##           Df Sum Sq Mean Sq F value Pr(>F)
47 ## intervention  1  0.961  0.9610  0.2065 0.6521
48 ## night         1  1.369  1.3690  0.2942 0.5908
49 ## Residuals    37 172.154  4.6528
50
51 #within-participants (paired) comparison
52 #Paired Wilcoxon
53 wilcox.test(subset(SSdataCompletes, intervention == "sham")$obstructive.apnea
54 s.index,
55             subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.apnea
56
57
58
59
60

```

```

1
2
3
4 s.index,
5     paired = TRUE, conf.int = TRUE)
6
7 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
8 ## "sham")$obstructive.apneas.index, : cannot compute exact p-value with
9 ## zeroes
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention
12 ## == "sham")$obstructive.apneas.index, : cannot compute exact confidence
13 ## interval with zeroes
14
15 ##
16 ## Wilcoxon signed rank test with continuity correction
17 ##
18 ## data: subset(SSdataCompletes, intervention == "sham")$obstructive.apneas.
19 index and subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.ap
20 neas.index
21 ## V = 18, p-value = 1
22 ## alternative hypothesis: true location shift is not equal to 0
23 ## 95 percent confidence interval:
24 ## -0.7499621  3.5499235
25 ## sample estimates:
26 ## (pseudo)median
27 ## 0.03901549
28
29 #between participants (grouped) comparison
30 summary(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
31
32 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
33 ##  0.000  0.000  0.000  0.575  0.125  5.300
34
35 sd(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
36
37 ## [1] 1.487094
38
39 length(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
40
41 ## [1] 20
42
43 qqnorm(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
44 qqline(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index
## A = 5.1462, p-value = 3.055e-13

#non-normal

summary(subset(SSdata, intervention == "sham")$obstructive.apneas.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  0.885  0.300  11.400

sd(subset(SSdata, intervention == "sham")$obstructive.apneas.index)

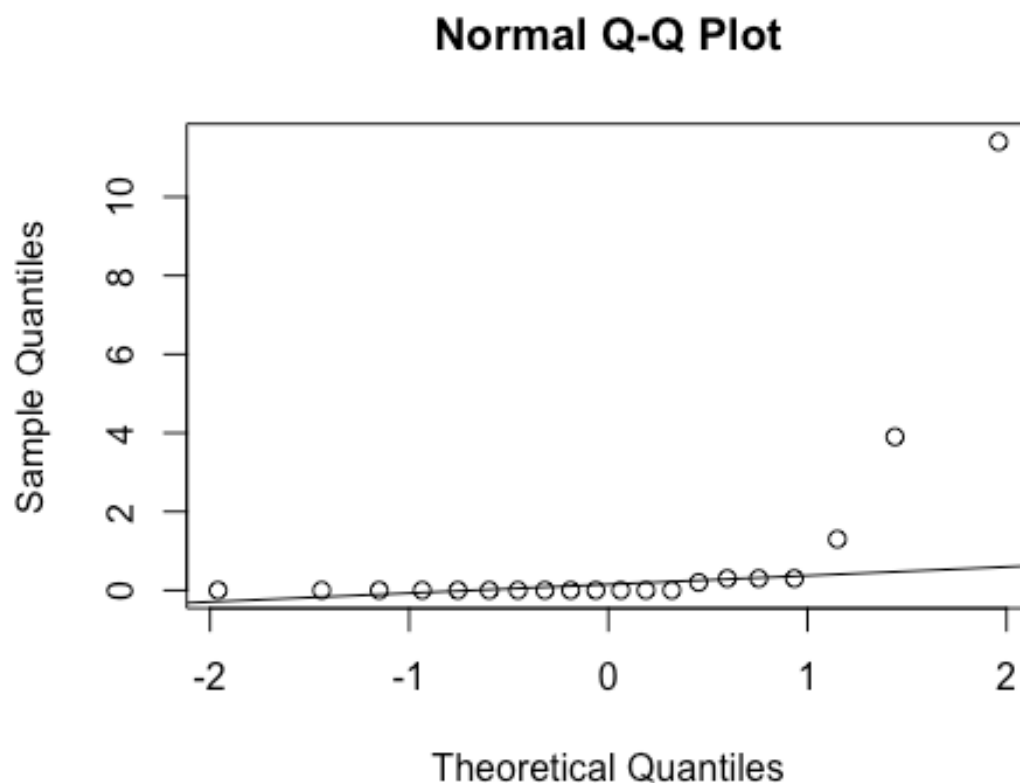
## [1] 2.630844

length(subset(SSdata, intervention == "sham")$obstructive.apneas.index)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "sham")$obstructive.apneas.index)
qqline(subset(SSdata, intervention == "sham")$obstructive.apneas.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$obstructive.apneas.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$obstructive.apneas.index
## A = 5.2073, p-value = 2.15e-13

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$obstructive.apneas.index,
            subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.in
dex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $obstructive.apneas.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $obstructive.apneas.index, : cannot compute exact confidence intervals wit
```



```

1
2
3 h
4 ## ties
5
6 ##
7 ## Wilcoxon rank sum test with continuity correction
8 ##
9 ## data: subset(SSdata, intervention == "sham")$obstructive.apneas.index and
10 subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index
11 ## W = 210.5, p-value = 0.7451
12 ## alternative hypothesis: true location shift is not equal to 0
13 ## 95 percent confidence interval:
14 ## -3.671494e-05 4.691508e-05
15 ## sample estimates:
16 ## difference in location
17 ## 2.019957e-05
18
19
20 ##### Mixed Apnea Index #####
21 #Summary
22 summary(SSdata$mixed.apneas.index)
23
24 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
25 ##         0         0         0         0         0         0
26
27 sd(SSdata$mixed.apneas.index, na.rm = TRUE)
28
29 ## [1] 0
30
31 length(SSdata$mixed.apneas.index)
32
33 ## [1] 40
34
35 #ANOVA
36 night_tx_difference <- anova(lm(mixed.apneas.index ~ intervention + night,
37                               data = SSdata))
38
39 night_tx_difference
40
41 ## Analysis of Variance Table
42 ##
43 ## Response: mixed.apneas.index
44 ##           Df Sum Sq Mean Sq F value Pr(>F)
45 ## intervention  1      0      0
46 ## night         1      0      0
47 ## Residuals    37      0      0
48
49 #within-participants (paired) comparison
50 #distribution is made entirely of zeroes
51 #difference testing not applicable
52
53 #between participants (grouped) comparison
54 summary(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
55
56
57
58
59
60

```

```

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0      0      0      0      0      0

sd(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)

## [1] 0

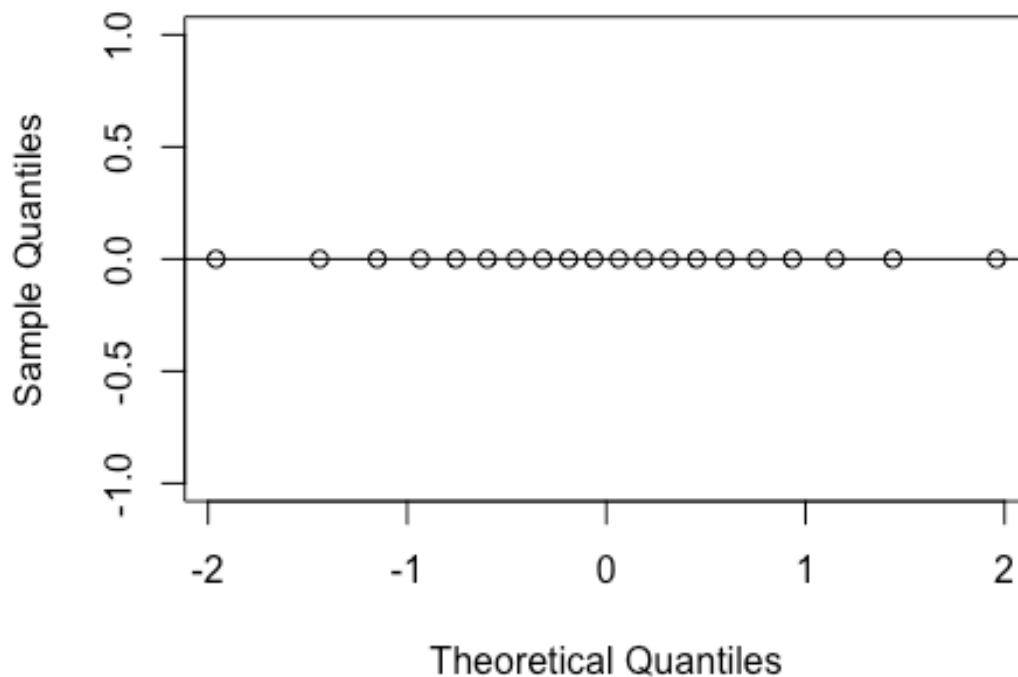
length(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)

```

Normal Q-Q Plot



```

#ad.test(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
#distribution is made entirely of zeroes

```

```
summary(subset(SSdata, intervention == "sham")$mixed.apneas.index)
```

```

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0      0      0      0      0      0

```

```
sd(subset(SSdata, intervention == "sham")$mixed.apneas.index)
```

```
## [1] 0
```

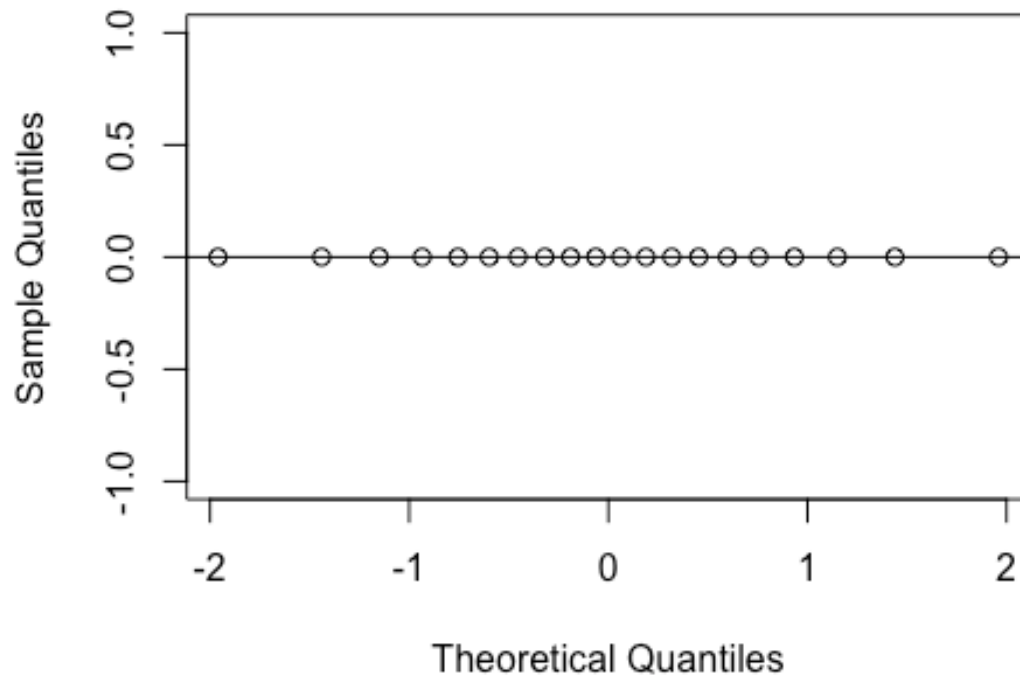
```

length(subset(SSdata, intervention == "sham")$mixed.apneas.index)
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$mixed.apneas.index)
qqline(subset(SSdata, intervention == "sham")$mixed.apneas.index)

```

Normal Q-Q Plot



```

#ad.test(subset(SSdata, intervention == "sham")$mixed.apneas.index)
#distribution is made entirely of zeroes
#difference testing not applicable

##### Obstructive hypopneas Index #####
#Summary
summary(SSdata$obstructive.hypopneas.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.250  1.378  1.225  11.900

sd(SSdata$obstructive.hypopneas.index, na.rm = TRUE)

## [1] 2.738097

length(SSdata$obstructive.hypopneas.index)

## [1] 40

```

```

1
2
3 #ANOVA
4 night_tx_difference <- anova(lm(obstructive.hypopneas.index ~ intervention +
5 night,
6                               data = SSdata))
7
8 night_tx_difference
9
10 ## Analysis of Variance Table
11 ##
12 ## Response: obstructive.hypopneas.index
13 ##           Df Sum Sq Mean Sq F value Pr(>F)
14 ## intervention  1  0.210  0.2103  0.0267 0.8711
15 ## night         1  0.702  0.7023  0.0891 0.7669
16 ## Residuals    37 291.477  7.8778
17
18 #within-participants (paired) comparison
19 #Paired Wilcoxon
20 wilcox.test(subset(SSdataCompletes, intervention == "sham")$obstructive.hypop
21 neas.index,
22             subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.hypop
23 neas.index,
24             paired = TRUE, conf.int = TRUE)
25
26 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
27 ## "sham")$obstructive.hypopneas.index, : cannot compute exact p-value with
28 ## ties
29
30 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
31 ## "sham")$obstructive.hypopneas.index, : cannot compute exact confidence
32 ## interval with ties
33
34 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
35 ## "sham")$obstructive.hypopneas.index, : cannot compute exact p-value with
36 ## zeroes
37
38 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
39 ## "sham")$obstructive.hypopneas.index, : cannot compute exact confidence
40 ## interval with zeroes
41
42 ##
43 ## Wilcoxon signed rank test with continuity correction
44 ##
45 ## data: subset(SSdataCompletes, intervention == "sham")$obstructive.hypopne
46 as.index and subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive
47 .hypopneas.index
48 ## V = 87, p-value = 0.6357
49 ## alternative hypothesis: true location shift is not equal to 0
50 ## 95 percent confidence interval:
51 ## -0.2999835  0.5499741
52 ## sample estimates:
53 ## (pseudo)median
54 ## 0.09999107
55
56
57
58
59
60

```

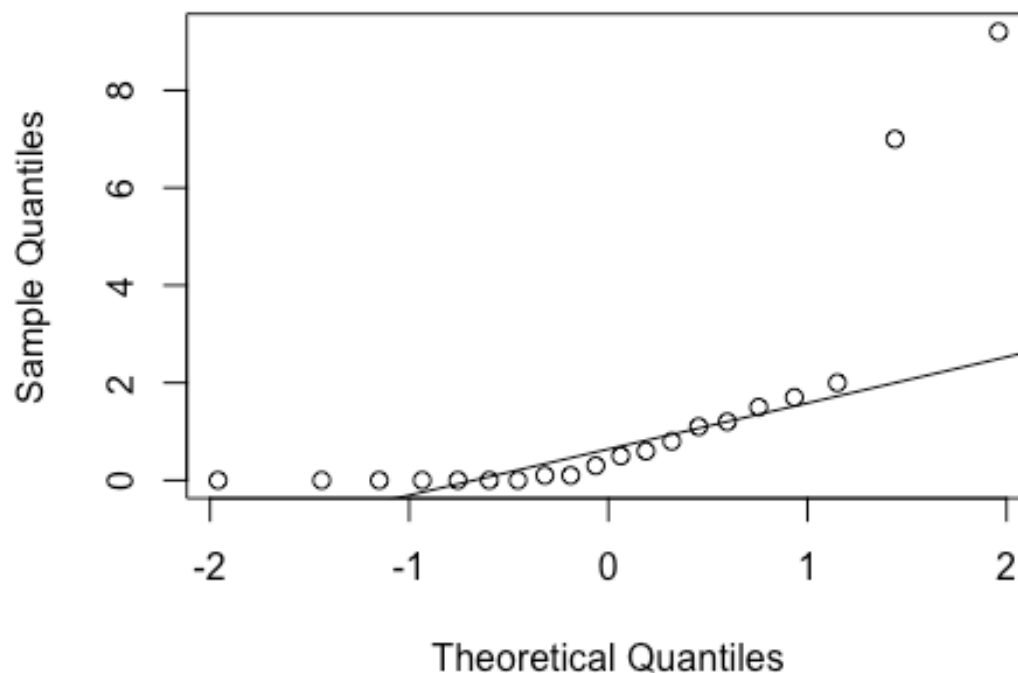
```

1
2
3 #between participants (grouped) comparison
4 summary(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index)
5
6
7 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
8 ##    0.000  0.000  0.400  1.305  1.275  9.200
9
10 sd(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index)
11
12 ## [1] 2.435802
13
14 length(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index)
15
16 ## [1] 20
17
18 qqnorm(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index)
19
20 qqline(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index)
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



Normal Q-Q Plot



```

53 ad.test(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index)
54
55
56
57
58
59
60

```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.i
index
## A = 3.342, p-value = 1.039e-08

#non-normal

summary(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00  0.00  0.20  1.45  1.00  11.90

sd(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

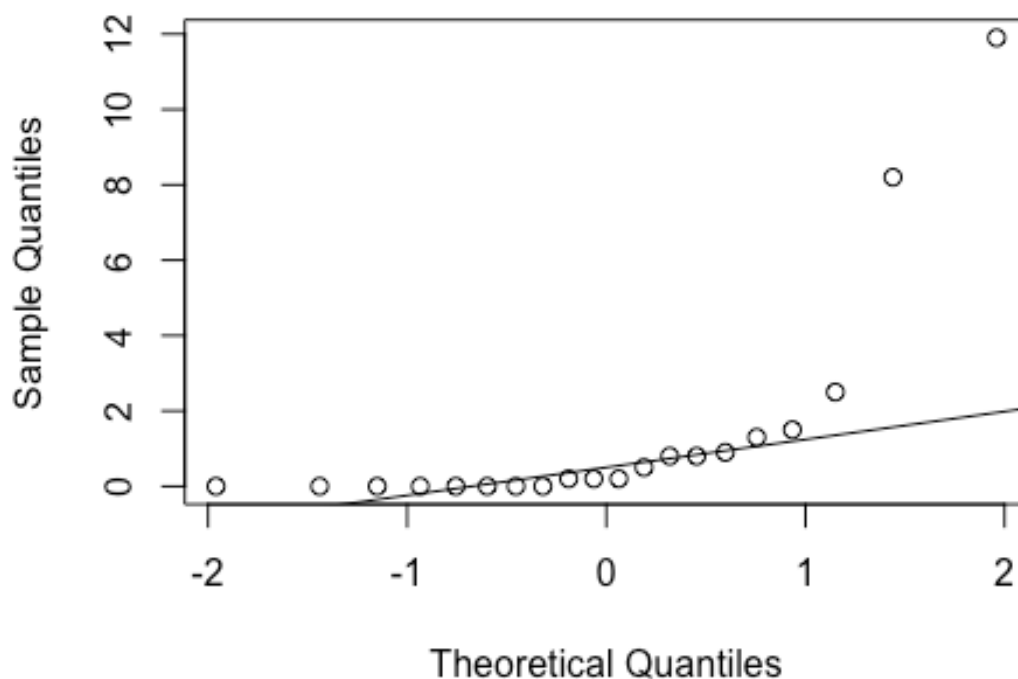
## [1] 3.073229

length(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)
qqline(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)
```

Normal Q-Q Plot

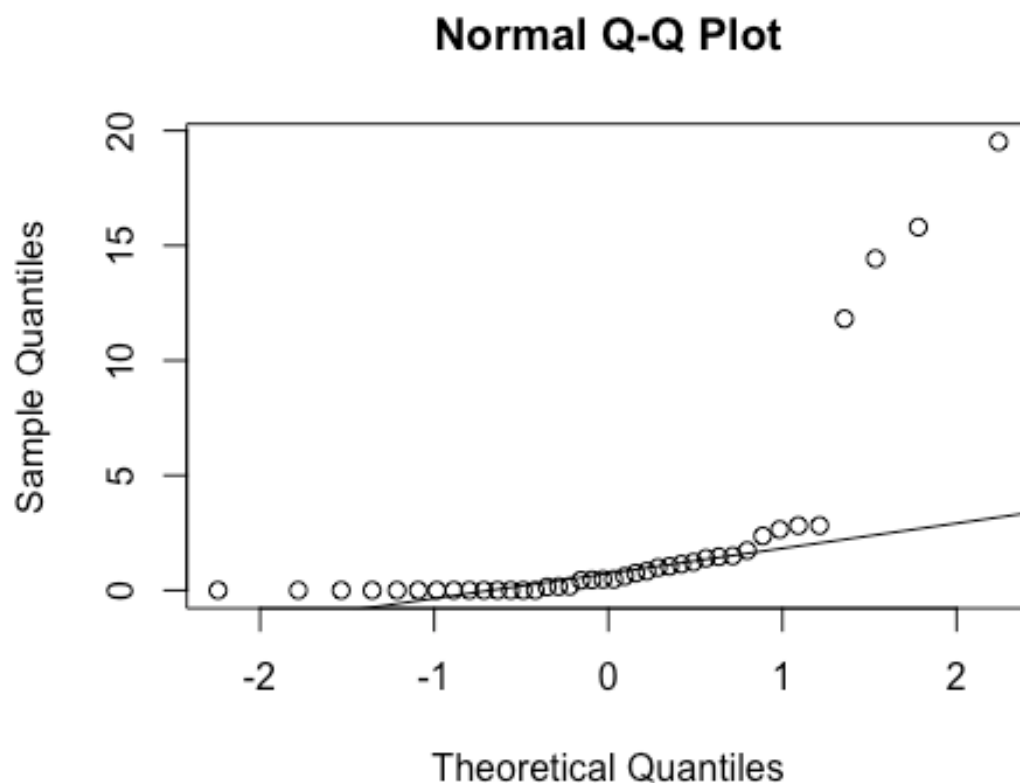


```

1
2
3  ad.test(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)
4
5  ##
6  ## Anderson-Darling normality test
7  ##
8  ## data: subset(SSdata, intervention == "sham")$obstructive.hypopneas.index
9  ## A = 3.9511, p-value = 3.022e-10
10
11  #non-normal
12
13  wilcox.test(subset(SSdata, intervention == "sham")$obstructive.hypopneas.inde
14 x,
15             subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas
16 .index,
17             conf.int = TRUE)
18
19  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
20  ## $obstructive.hypopneas.index, : cannot compute exact p-value with ties
21
22  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
23  ## $obstructive.hypopneas.index, : cannot compute exact confidence intervals
24  ## with ties
25
26  ##
27  ## Wilcoxon rank sum test with continuity correction
28  ##
29  ## data: subset(SSdata, intervention == "sham")$obstructive.hypopneas.index
30  and subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index
31  ## W = 191, p-value = 0.8132
32  ## alternative hypothesis: true location shift is not equal to 0
33  ## 95 percent confidence interval:
34  ## -0.5000080  0.2999871
35  ## sample estimates:
36  ## difference in location
37  ## -1.817308e-06
38
39  ##### Apnea-Hypopnea Index #####
40
41  #Summary
42  summary(SSdata$AHI.calculated)
43
44  ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
45  ##  0.0000  0.0000  0.4765  2.1800  1.4700 19.5100
46
47  sd(SSdata$AHI.calculated, na.rm = TRUE)
48
49  ## [1] 4.622751
50
51  length(SSdata$AHI.calculated)
52
53  ## [1] 40
54
55
56
57
58
59
60

```

```
qqnorm(SSdata$AHI.calculated)
qqline(SSdata$AHI.calculated)
```



```
ad.test(SSdata$AHI.calculated)

##
## Anderson-Darling normality test
##
## data:  SSdata$AHI.calculated
## A = 8.242, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(AHI.calculated ~ intervention * night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: AHI.calculated
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    1.73    1.734   0.0866 0.77027
## night           1    4.60    4.596   0.2295 0.63478
```

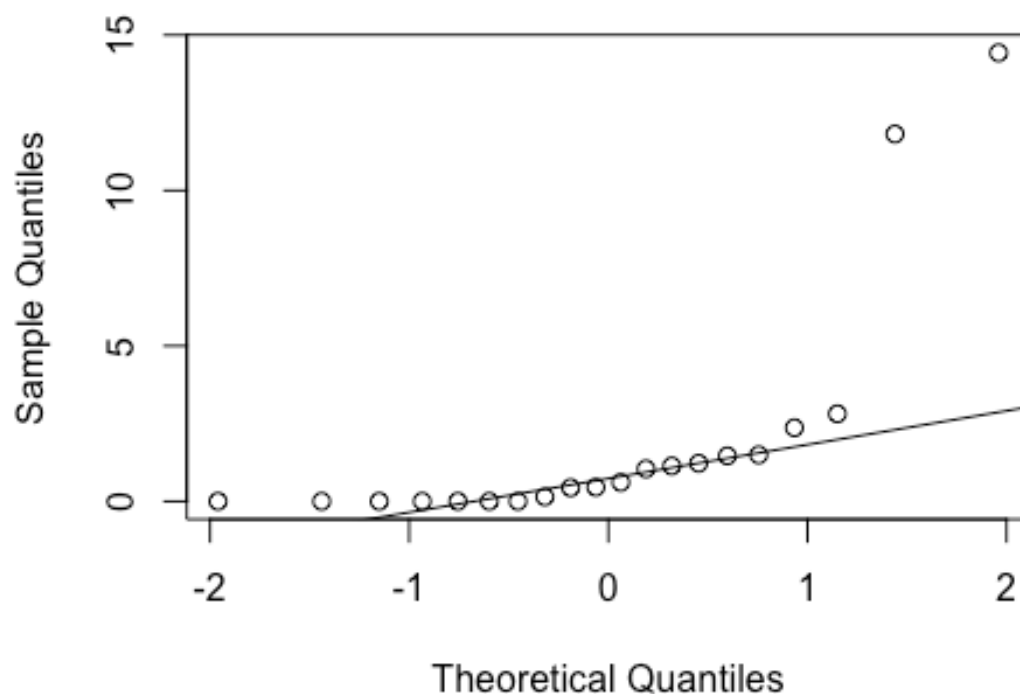


```

1
2
3  ## intervention:night  1 106.12 106.123  5.2990 0.02723 *
4  ## Residuals          36 720.97  20.027
5  ## ---
6  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
7
8  #within-participants (paired) comparison
9  #Paired Wilcoxon
10 wilcox.test(subset(SSdataCompletes, intervention == "sham")$AHI.calculated,
11             subset(SSdataCompletes, intervention == "PrenaBelt")$AHI.calculated,
12             paired = TRUE, conf.int = TRUE)
13
14 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
15 ## "sham")$AHI.calculated, : cannot compute exact p-value with zeroes
16
17 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
18 ## "sham")$AHI.calculated, : cannot compute exact confidence interval with
19 ## zeroes
20
21 ##
22 ## Wilcoxon signed rank test with continuity correction
23 ##
24 ## data:  subset(SSdataCompletes, intervention == "sham")$AHI.calculated and
25 subset(SSdataCompletes, intervention == "PrenaBelt")$AHI.calculated
26 ## V = 91, p-value = 0.5075
27 ## alternative hypothesis: true location shift is not equal to 0
28 ## 95 percent confidence interval:
29 ## -0.4367014  0.7981902
30 ## sample estimates:
31 ## (pseudo)median
32 ## 0.1385676
33
34
35 #between participants (grouped) comparison
36 summary(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
37
38 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
39 ##  0.0000  0.0000  0.5321  1.9720  1.4700 14.4300
40
41 sd(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
42
43 ## [1] 3.924224
44
45 length(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
46
47 ## [1] 20
48
49 qqnorm(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
50 qqline(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$AHI.calculated
## A = 3.8736, p-value = 4.736e-10

#non-normal

summary(subset(SSdata, intervention == "sham")$AHI.calculated)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.4765  2.3880  1.4770 19.5100

sd(subset(SSdata, intervention == "sham")$AHI.calculated)

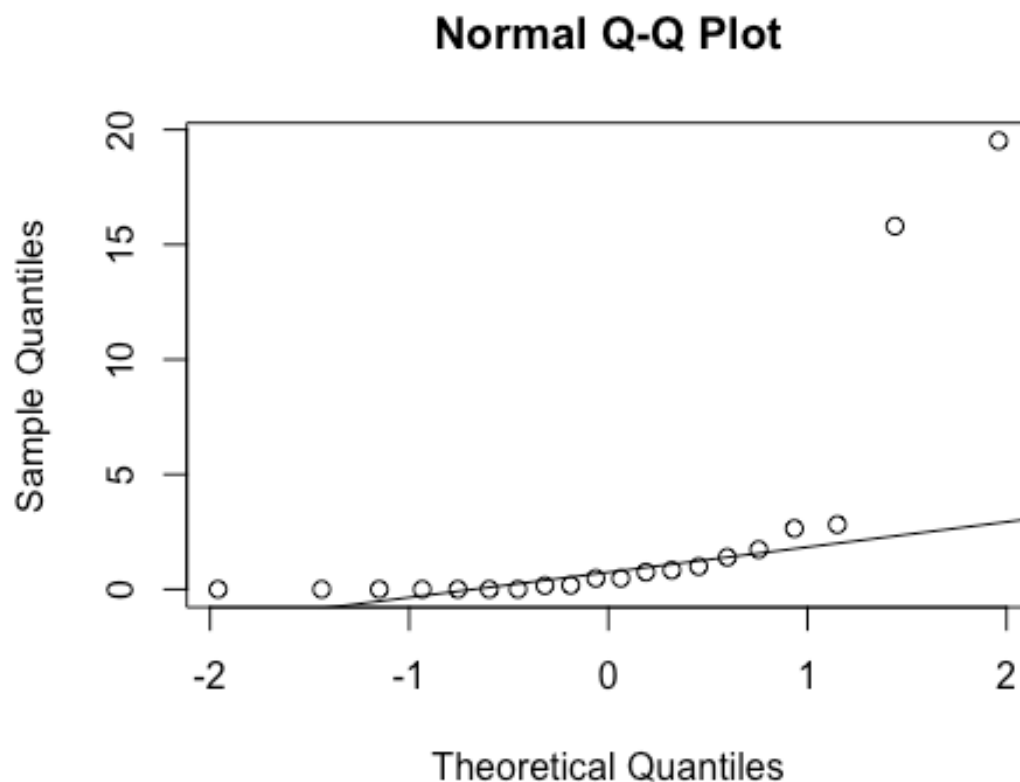
## [1] 5.326686

length(subset(SSdata, intervention == "sham")$AHI.calculated)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$AHI.calculated)
qqline(subset(SSdata, intervention == "sham")$AHI.calculated)

```



```

ad.test(subset(SSdata, intervention == "sham")$AHI.calculated)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$AHI.calculated
## A = 4.4571, p-value = 1.618e-11

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$AHI.calculated,
            subset(SSdata, intervention == "PrenaBelt")$AHI.calculated,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $AHI.calculated, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $AHI.calculated, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$AHI.calculated and subset(SS

```

```

1
2
3 data, intervention == "PrenaBelt")$AHI.calculated
4 ## W = 198.5, p-value = 0.9779
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -0.6092948 0.4774410
8 ## sample estimates:
9 ## difference in location
10 ## -1.726505e-05
11
12 ##### Central hypopneas Index #####
13 #Summary
14 summary(SSdata$central.hypopneas.index)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      0.000  0.000  0.000  0.015  0.000  0.600
18
19 sd(SSdata$central.hypopneas.index, na.rm = TRUE)
20
21 ## [1] 0.09486833
22
23 length(SSdata$central.hypopneas.index)
24
25 ## [1] 40
26
27 #ANOVA
28 night_tx_difference <- anova(lm(central.hypopneas.index ~ intervention + night,
29                               data = SSdata))
30
31 night_tx_difference
32
33 ## Analysis of Variance Table
34 ##
35 ## Response: central.hypopneas.index
36 ##
37 ##           Df Sum Sq Mean Sq F value Pr(>F)
38 ## intervention  1  0.009   0.009      1 0.3238
39 ## night         1  0.009   0.009      1 0.3238
40 ## Residuals    37  0.333   0.009
41
42 #within-participants (paired) comparison
43 #Paired Wilcoxon
44 wilcox.test(subset(SSdataCompletes, intervention == "sham")$central.hypopneas
45             .index,
46             subset(SSdataCompletes, intervention == "PrenaBelt")$central.hypopneas
47             .index,
48             paired = TRUE)
49
50 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
51 ## "sham")$central.hypopneas.index, : cannot compute exact p-value with zeroes
52
53
54 ##
55 ## Wilcoxon signed rank test with continuity correction
56
57
58
59
60

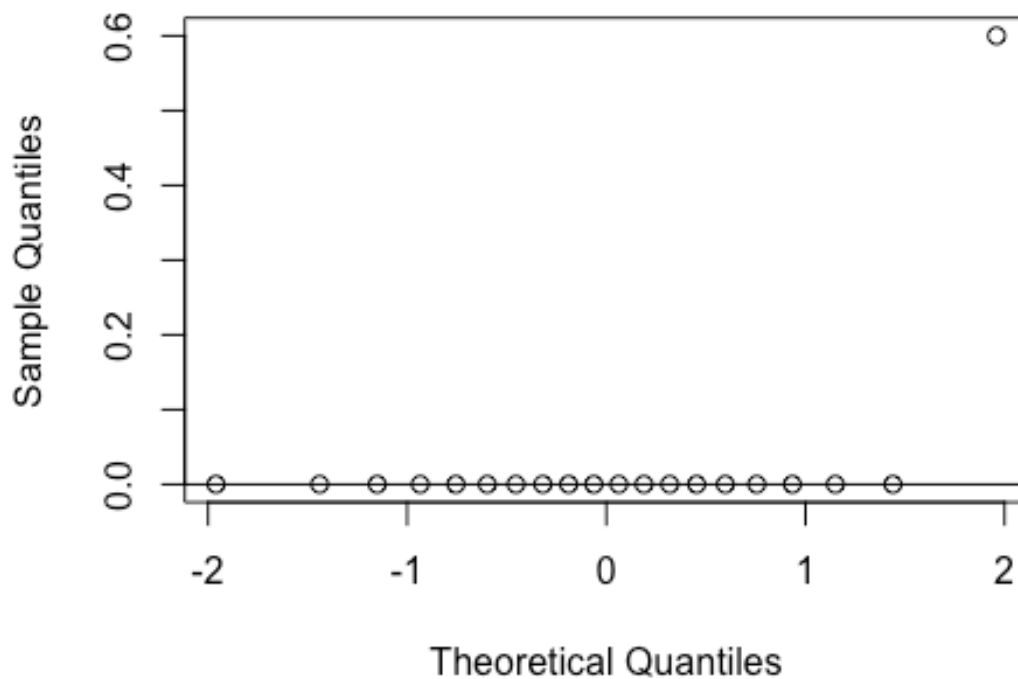
```

```

1  ##
2
3  ## data: subset(SSdataCompletes, intervention == "sham")$central.hypopneas.i
4  ndex and subset(SSdataCompletes, intervention == "PrenaBelt")$central.hypopne
5  as.index
6
7  ## V = 0, p-value = 1
8  ## alternative hypothesis: true location shift is not equal to 0
9
10
11  #between participants (grouped) comparison
12  summary(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
13
14  ##      Min. 1st Qu.  Median      Mean 3rd Qu.      Max.
15  ##      0.00   0.00   0.00   0.03   0.00   0.60
16
17  sd(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
18
19  ## [1] 0.1341641
20
21  length(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
22
23  ## [1] 20
24
25  qqnorm(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
26  qqline(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)

```

Normal Q-Q Plot



```

56  ad.test(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)

```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index
## A = 7.1762, p-value < 2.2e-16

#non-normal

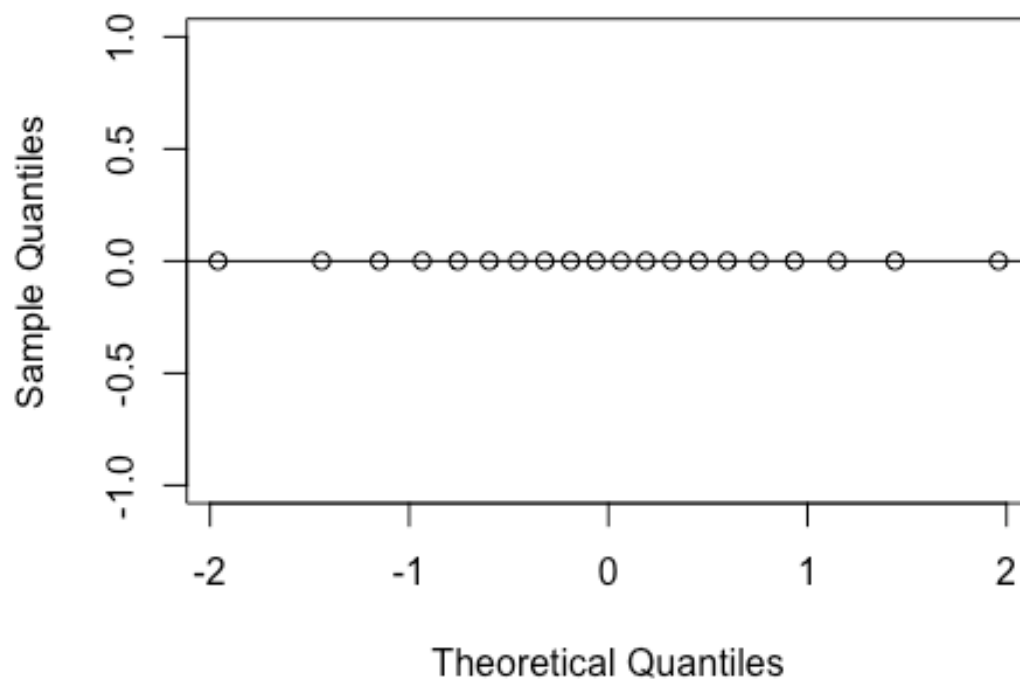
summary(subset(SSdata, intervention == "sham")$central.hypopneas.index)
##      Min. 1st Qu.  Median      Mean 3rd Qu.     Max.
##      0      0      0      0      0      0

sd(subset(SSdata, intervention == "sham")$central.hypopneas.index)
## [1] 0

length(subset(SSdata, intervention == "sham")$central.hypopneas.index)
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$central.hypopneas.index)
qqline(subset(SSdata, intervention == "sham")$central.hypopneas.index)
```

Normal Q-Q Plot

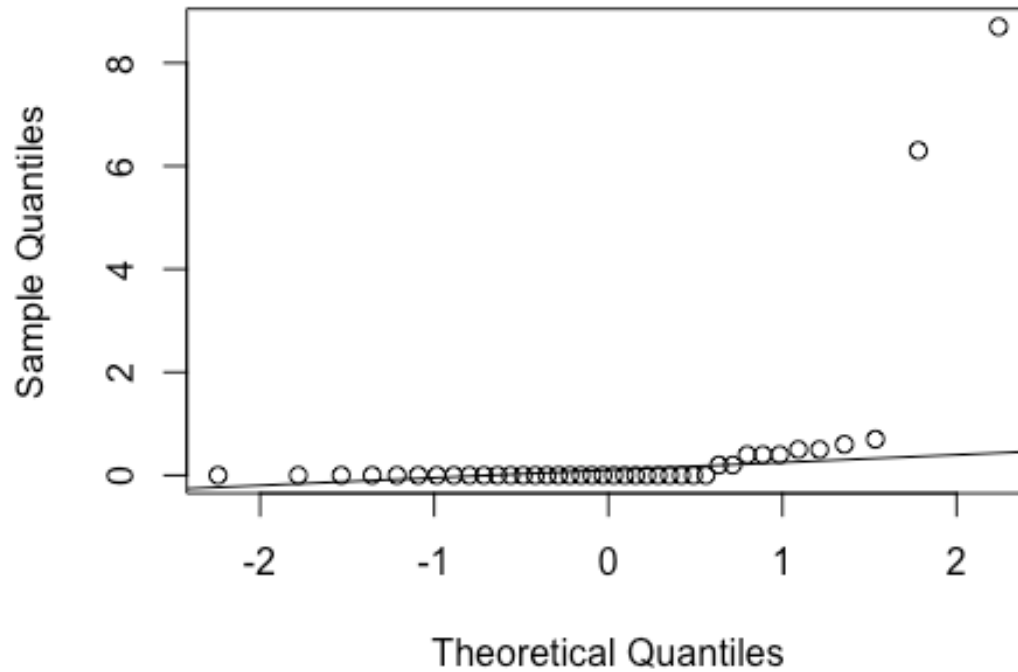


```

1
2
3 #ad.test(subset(SSdata, intervention == "sham")$central.hypopneas.index)
4 #distribution is made entirely of zeroes
5
6 wilcox.test(subset(SSdata, intervention == "sham")$central.hypopneas.index,
7             subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index,
8             ex,
9             conf.int = TRUE)
10
11 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
12 ## $central.hypopneas.index, : cannot compute exact p-value with ties
13
14 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
15 ## $central.hypopneas.index, : cannot compute exact confidence intervals with
16 ## ties
17
18 ##
19 ## Wilcoxon rank sum test with continuity correction
20 ##
21 ## data: subset(SSdata, intervention == "sham")$central.hypopneas.index and
22 ## subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index
23 ## W = 190, p-value = 0.3421
24 ## alternative hypothesis: true location shift is not equal to 0
25 ## 95 percent confidence interval:
26 ## 0 0
27 ## sample estimates:
28 ## difference in location
29 ## 0
30
31 ##### RERAs Index #####
32 #Summary
33 summary(SSdata$reras.index)
34
35 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
36 ## 0.0000  0.0000  0.0000  0.4725  0.2000  8.7000
37
38 sd(SSdata$reras.index, na.rm = TRUE)
39
40 ## [1] 1.66687
41
42 length(SSdata$reras.index)
43
44 ## [1] 40
45
46 qqnorm(SSdata$reras.index)
47 qqline(SSdata$reras.index)
48
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(SSdata$reras.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$reras.index
## A = 11.649, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(reras.index ~ intervention * night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: reras.index
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1  4.422   4.4223   1.7011 0.2004
## night           1  4.032   4.0322   1.5511 0.2210
## intervention:night 1  6.320   6.3203   2.4313 0.1277
## Residuals      36 93.585   2.5996
```

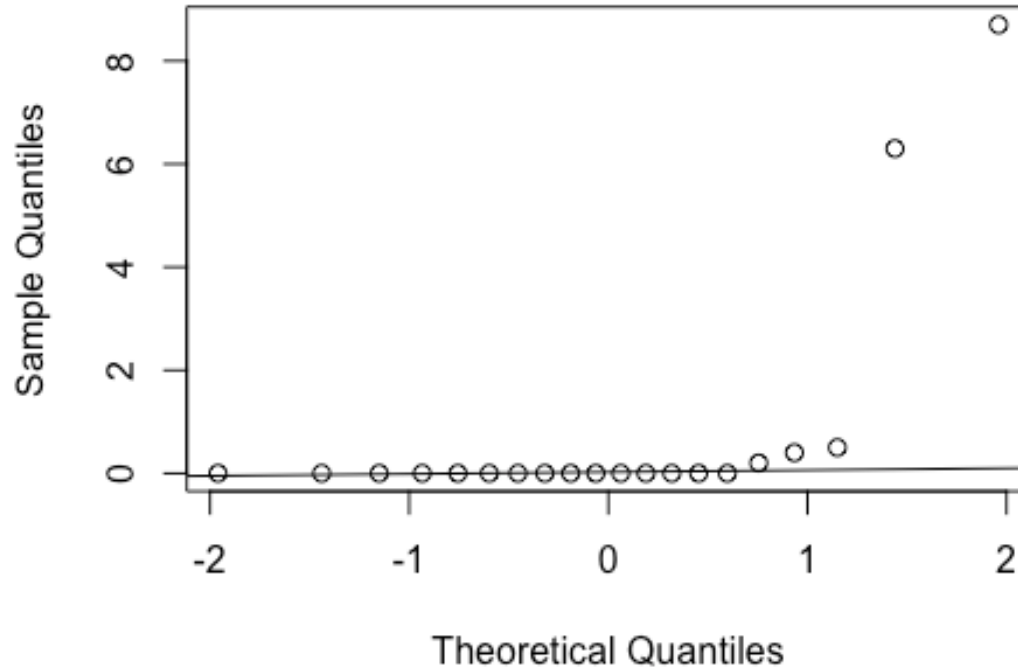


```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$reras.index,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$reras.index,
7             paired = TRUE, conf.int = TRUE)
8
9 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
10 ## "sham")$reras.index, : cannot compute exact p-value with ties
11
12 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13 ## "sham")$reras.index, : cannot compute exact confidence interval with ties
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$reras.index, : cannot compute exact p-value with zeroes
17
18 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
19 ## "sham")$reras.index, : cannot compute exact confidence interval with zeroes
20 s
21
22 ##
23 ## Wilcoxon signed rank test with continuity correction
24 ##
25 ## data: subset(SSdataCompletes, intervention == "sham")$reras.index and sub
26 set(SSdataCompletes, intervention == "PrenaBelt")$reras.index
27 ## V = 15.5, p-value = 0.7789
28 ## alternative hypothesis: true location shift is not equal to 0
29 ## 95 percent confidence interval:
30 ## -4.5999963 0.3500676
31 ## sample estimates:
32 ## (pseudo)median
33 ## -0.1499727
34
35
36 #between participants (grouped) comparison
37 summary(subset(SSdata, intervention == "PrenaBelt")$reras.index)
38
39 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
40 ##      0.000  0.000  0.000  0.805  0.050  8.700
41
42 sd(subset(SSdata, intervention == "PrenaBelt")$reras.index)
43
44 ## [1] 2.32684
45
46 length(subset(SSdata, intervention == "PrenaBelt")$reras.index)
47
48 ## [1] 20
49
50 qqnorm(subset(SSdata, intervention == "PrenaBelt")$reras.index)
51 qqline(subset(SSdata, intervention == "PrenaBelt")$reras.index)
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$reras.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$reras.index
## A = 5.7736, p-value = 8.367e-15

#non-normal

summary(subset(SSdata, intervention == "sham")$reras.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   0.00   0.14   0.25   0.70

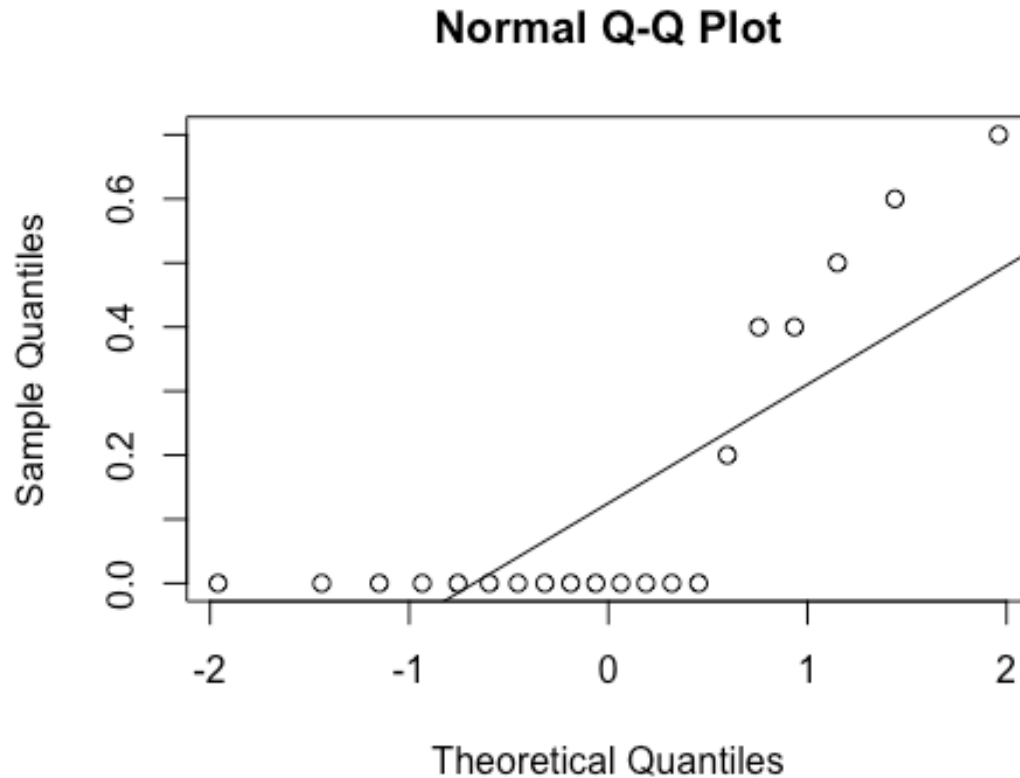
sd(subset(SSdata, intervention == "sham")$reras.index)

## [1] 0.2370876

length(subset(SSdata, intervention == "sham")$reras.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$reras.index)
qqline(subset(SSdata, intervention == "sham")$reras.index)
```



```

ad.test(subset(SSdata, intervention == "sham")$reras.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$reras.index
## A = 3.4375, p-value = 5.959e-09

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$reras.index,
            subset(SSdata, intervention == "PrenaBelt")$reras.index,
            conf.int = TRUE)

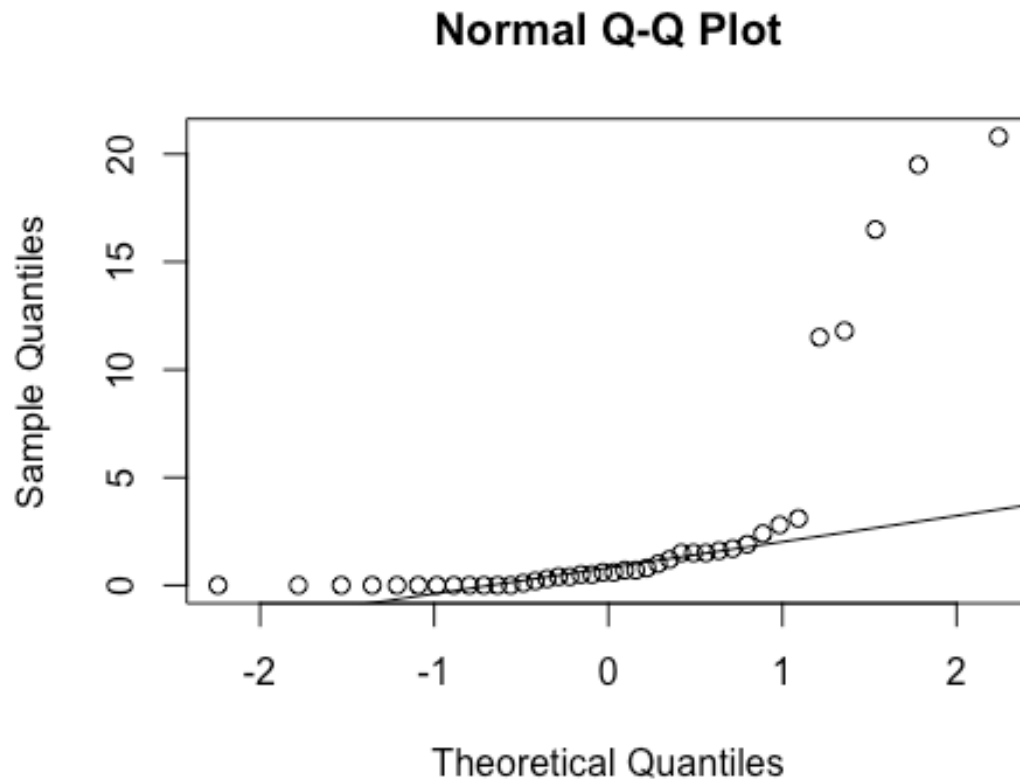
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $reras.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $reras.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$reras.index and subset(SSdat

```

```
1
2
3 a, intervention == "PrenaBelt")$reras.index
4 ## W = 207, p-value = 0.8231
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -3.950633e-05 5.862469e-06
8 ## sample estimates:
9 ## difference in location
10 ## 4.901185e-05
11
12 ##### Respiratory Disturbance Index #####
13 #Summary
14 summary(SSdata$rdi.index)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      0.000   0.000   0.600   2.652   1.625   20.800
18
19 sd(SSdata$rdi.index, na.rm = TRUE)
20
21 ## [1] 5.358817
22
23 length(SSdata$rdi.index)
24
25 ## [1] 40
26
27 qqnorm(SSdata$rdi.index)
28 qqline(SSdata$rdi.index)
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(SSdata$rdi.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$rdi.index
## A = 8.0555, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(rdi.index ~ intervention * night,
                               data = SSdata))
night_tx_difference

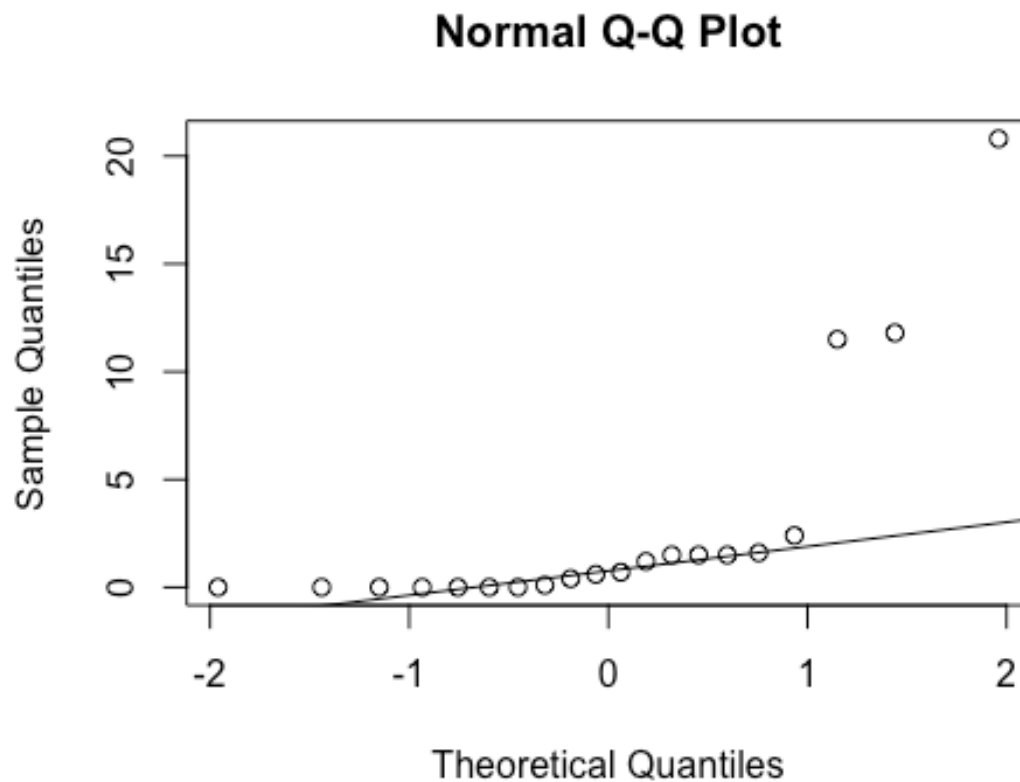
## Analysis of Variance Table
##
## Response: rdi.index
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    0.65    0.650   0.0245 0.87646
## night           1    0.01    0.012   0.0005 0.98297
## intervention:night  1 164.43 164.430   6.1993 0.01754 *
## Residuals      36 954.87  26.524

```

```

1
2
3  ## ---
4  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
5
6  #within-participants (paired) comparison
7  #non-normal - do Wilcoxon
8  wilcox.test(subset(SSdataCompletes, intervention == "sham")$rdi.index,
9             subset(SSdataCompletes, intervention == "PrenaBelt")$rdi.index,
10            paired = TRUE, conf.int = TRUE)
11
12  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13  ## "sham")$rdi.index, : cannot compute exact p-value with ties
14
15  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16  ## "sham")$rdi.index, : cannot compute exact confidence interval with ties
17
18  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
19  ## "sham")$rdi.index, : cannot compute exact p-value with zeroes
20
21  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
22  ## "sham")$rdi.index, : cannot compute exact confidence interval with zeroes
23
24  ##
25  ##  Wilcoxon signed rank test with continuity correction
26  ##
27  ## data:  subset(SSdataCompletes, intervention == "sham")$rdi.index and subse
28  ## t(SSdataCompletes, intervention == "PrenaBelt")$rdi.index
29  ## V = 67, p-value = 0.6699
30  ## alternative hypothesis: true location shift is not equal to 0
31  ## 95 percent confidence interval:
32  ##  -1.1999821  0.6499711
33  ## sample estimates:
34  ## (pseudo)median
35  ##      -0.199951
36
37
38  #between participants (grouped) comparison
39  summary(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
40
41  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
42  ##  0.000  0.000  0.650  2.780  1.525  20.800
43
44  sd(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
45
46  ## [1] 5.463236
47
48  length(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
49
50  ## [1] 20
51
52  qqnorm(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
53  qqline(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
54
55
56
57
58
59
60

```



```

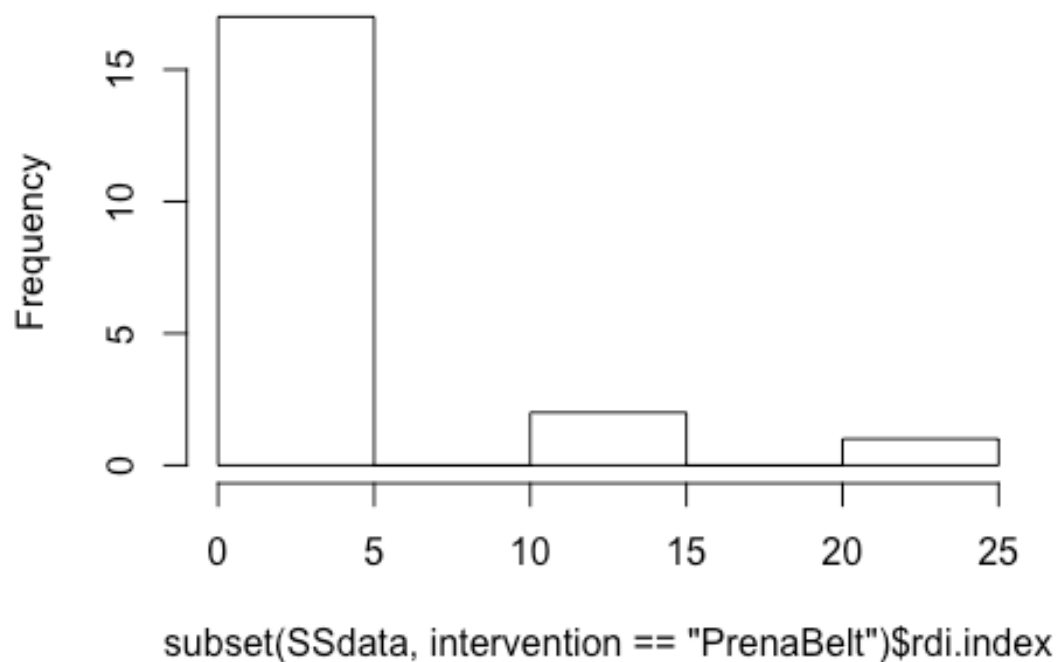
ad.test(subset(SSdata, intervention == "PrenaBelt")$rdi.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$rdi.index
## A = 3.8067, p-value = 6.979e-10

hist(subset(SSdata, intervention == "PrenaBelt")$rdi.index)

```

gram of subset(SSdata, intervention == "PrenaBelt");



#non-normal

```
summary(subset(SSdata, intervention == "sham")$rdi.index)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.150   0.550   2.525  1.750  19.500
```

```
sd(subset(SSdata, intervention == "sham")$rdi.index)
```

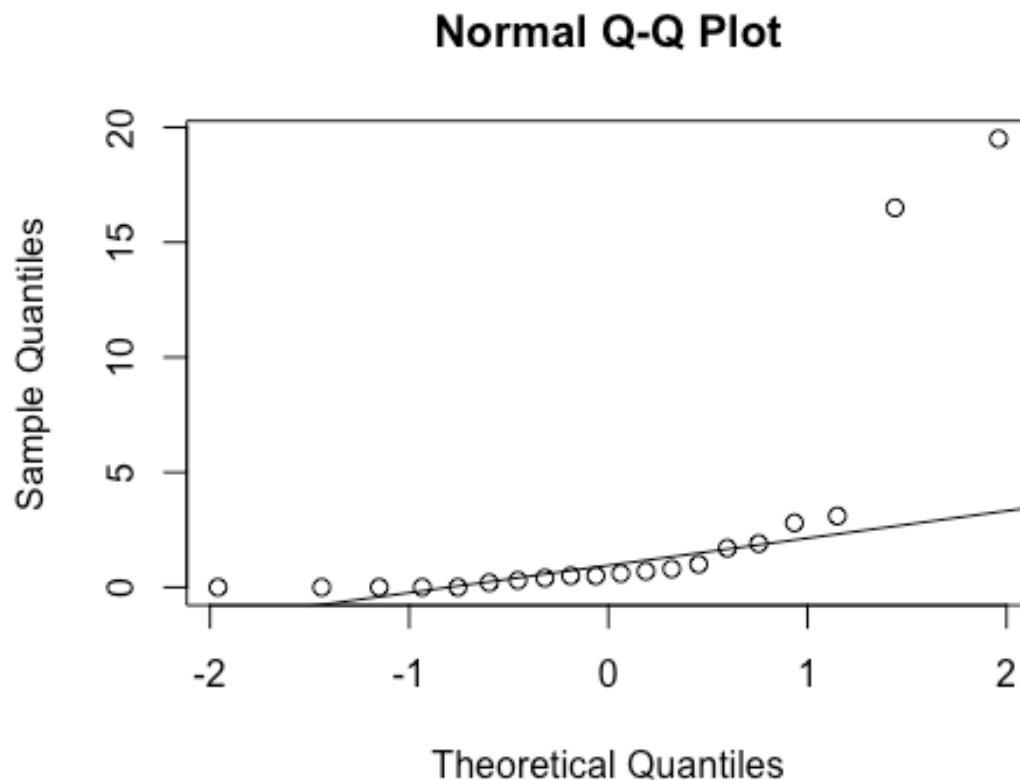
```
## [1] 5.391111
```

```
length(subset(SSdata, intervention == "sham")$rdi.index)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$rdi.index)
```

```
qqline(subset(SSdata, intervention == "sham")$rdi.index)
```

```

ad.test(subset(SSdata, intervention == "sham")$rdi.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$rdi.index
## A = 4.397, p-value = 2.29e-11

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$rdi.index,
            subset(SSdata, intervention == "PrenaBelt")$rdi.index,
            conf.int = TRUE)

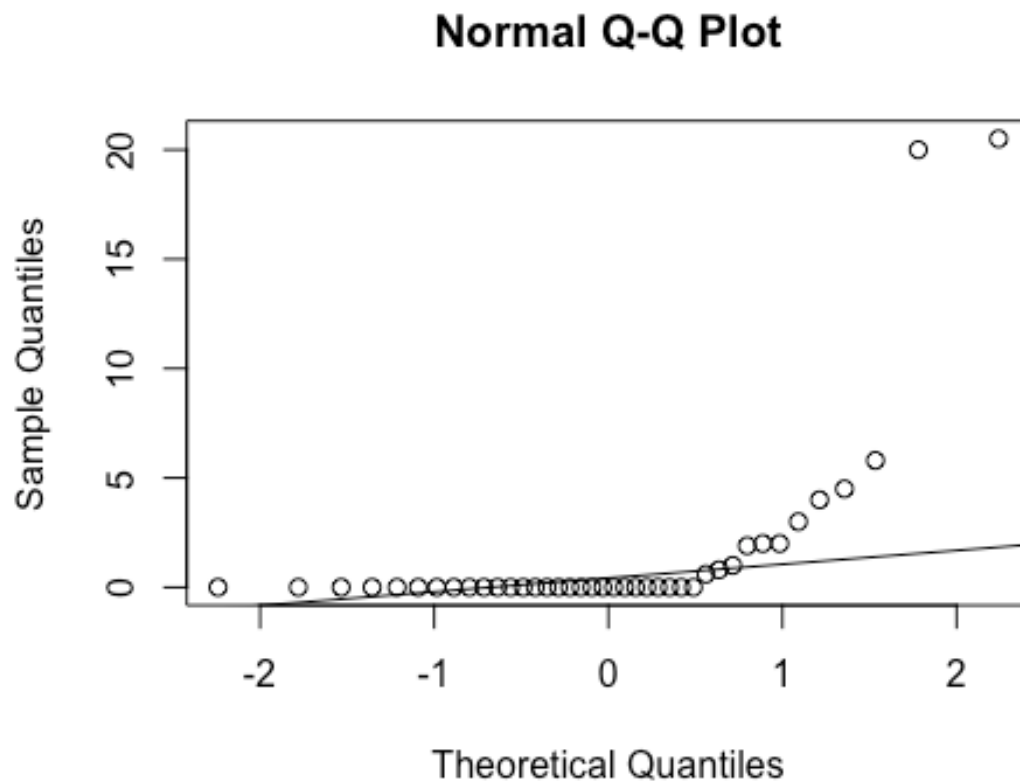
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $rdi.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $rdi.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$rdi.index and subset(SSdata,

```

```
1
2
3 intervention == "PrenaBelt")$rdi.index
4 ## W = 206, p-value = 0.8801
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -0.7000762 0.5000008
8 ## sample estimates:
9 ## difference in location
10 ## 8.805182e-05
11
12 ##### Supine Event Index #####
13 #Summary
14 summary(SSdata$index.of.supine.events)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      0.000  0.000  0.000   1.652  0.850  20.500
18
19 sd(SSdata$index.of.supine.events, na.rm = TRUE)
20
21 ## [1] 4.539061
22
23 length(SSdata$index.of.supine.events)
24
25 ## [1] 40
26
27 qqnorm(SSdata$index.of.supine.events)
28 qqline(SSdata$index.of.supine.events)
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(SSdata$index.of.supine.events)

##
## Anderson-Darling normality test
##
## data:  SSdata$index.of.supine.events
## A = 9.3271, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(index.of.supine.events ~ intervention * night
,
                             data = SSdata))
night_tx_difference

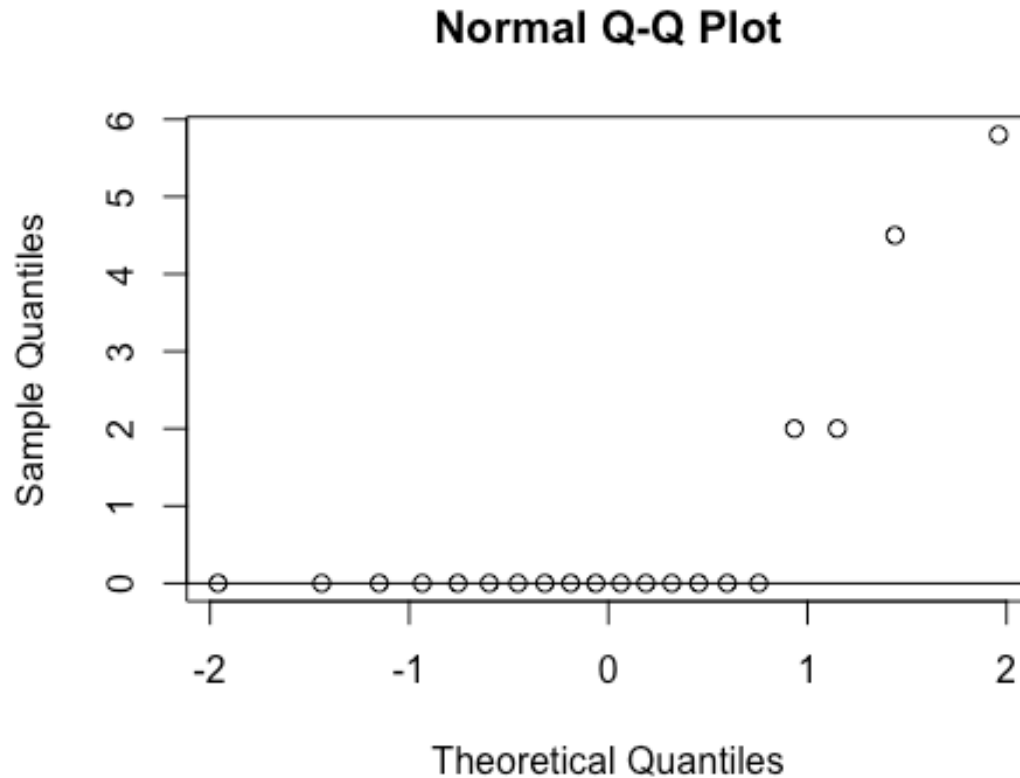
## Analysis of Variance Table
##
## Response: index.of.supine.events
##
##          Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1  35.16   35.156   1.8529 0.18191
## night           1  63.25   63.252   3.3337 0.07618 .
## intervention:night  1  22.05   22.052   1.1622 0.28817
## Residuals      36 683.06   18.974

```

```

1
2
3
4  ## ---
5  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
6
7  #within-participants (paired) comparison
8  #Paired Wilcoxon
9  wilcox.test(subset(SSdataCompletes, intervention == "sham")$index.of.supine.e
10 events,
11           subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.supine.e
12 events,
13           paired = TRUE)
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$index.of.supine.events, : cannot compute exact p-value with zeroes
17
18 ##
19 ## Wilcoxon signed rank test with continuity correction
20 ##
21 ## data:  subset(SSdataCompletes, intervention == "sham")$index.of.supine.eve
22 nts and subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.supine.
23 events
24 ## V = 35, p-value = 0.4755
25 ## alternative hypothesis: true location shift is not equal to 0
26
27 #between participants (grouped) comparison
28 summary(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
29
30 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
31 ##  0.000  0.000  0.000  0.715  0.000  5.800
32
33 sd(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
34
35 ## [1] 1.649011
36
37 length(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
38
39 ## [1] 20
40
41 qqnorm(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
42 qqline(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events
## A = 4.652, p-value = 5.253e-12

#non-normal

summary(subset(SSdata, intervention == "sham")$index.of.supine.events)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  2.590  1.225  20.500

sd(subset(SSdata, intervention == "sham")$index.of.supine.events)

## [1] 6.141738

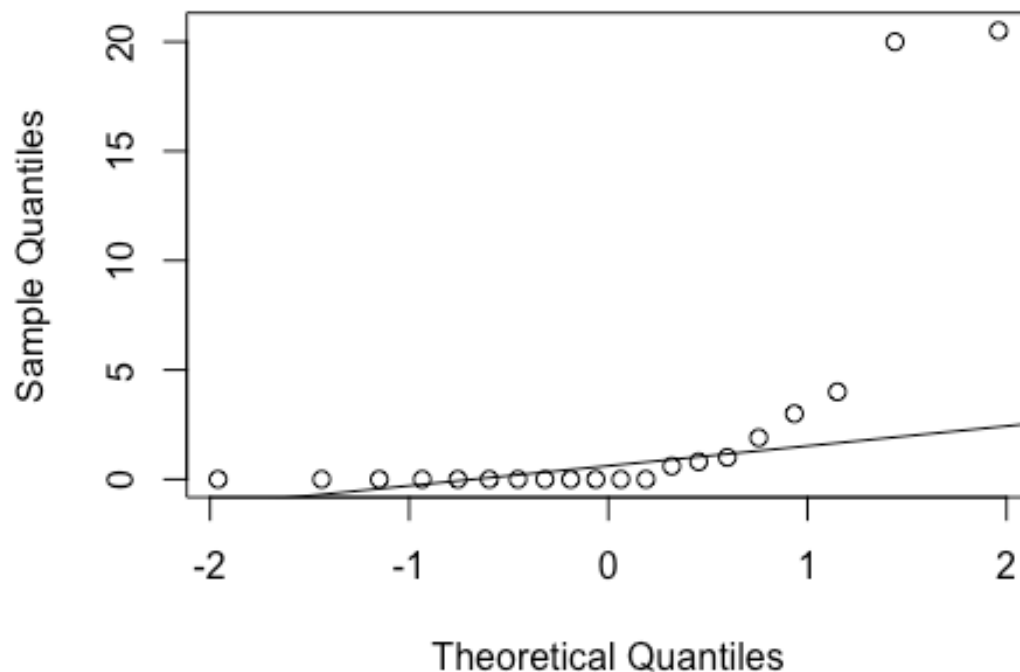
length(subset(SSdata, intervention == "sham")$index.of.supine.events)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$index.of.supine.events)
qqline(subset(SSdata, intervention == "sham")$index.of.supine.events)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$index.of.supine.events)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$index.of.supine.events
## A = 4.7296, p-value = 3.359e-12

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$index.of.supine.events,
            subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $index.of.supine.events, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $index.of.supine.events, : cannot compute exact confidence intervals with
## ties

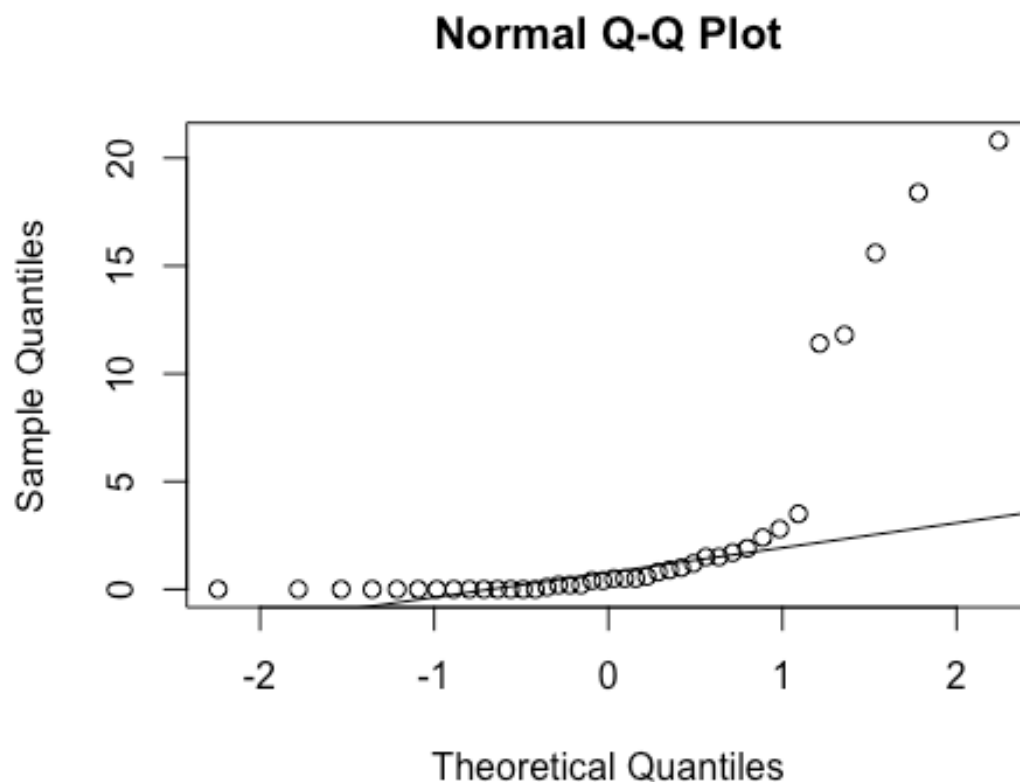
##
## Wilcoxon rank sum test with continuity correction

```

```

1
2
3
4  ##
5  ## data: subset(SSdata, intervention == "sham")$index.of.supine.events and s
6  ubset(SSdata, intervention == "PrenaBelt")$index.of.supine.events
7  ## W = 236, p-value = 0.2362
8  ## alternative hypothesis: true location shift is not equal to 0
9  ## 95 percent confidence interval:
10 ## -0.0000813554  0.6000459383
11 ## sample estimates:
12 ## difference in location
13 ##          7.189321e-06
14
15 ##### Non-Supine Event Index #####
16 #Summary
17 summary(SSdata$index.of.non.supine.events)
18
19 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
20 ##      0.00   0.00   0.45   2.52   1.55   20.80
21
22 sd(SSdata$index.of.non.supine.events, na.rm = TRUE)
23
24 ## [1] 5.242929
25
26 length(SSdata$index.of.non.supine.events)
27
28 ## [1] 40
29
30 qqnorm(SSdata$index.of.non.supine.events)
31 qqline(SSdata$index.of.non.supine.events)
32
33
34
35
36
37
38
39
40
41
42
43
44
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57
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59
60

```



```

ad.test(SSdata$index.of.non.supine.events)

##
## Anderson-Darling normality test
##
## data:  SSdata$index.of.non.supine.events
## A = 8.126, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(index.of.non.supine.events ~ intervention * n
ight,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: index.of.non.supine.events
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    0.40    0.400   0.0159 0.90038
## night           1    0.00    0.001   0.0000 0.99501
## intervention:night 1 165.65 165.649   6.5821 0.01461 *
## Residuals      36 905.99   25.166

```



```

1
2
3  ## ---
4  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
5
6  #within-participants (paired) comparison
7  #non-normal - use Wilcoxon
8  wilcox.test(subset(SSdataCompletes, intervention == "sham")$index.of.non.supine.events,
9             subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.non.supine.events,
10             paired = TRUE, conf.int = TRUE)
11
12
13
14  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
15  ## "sham")$index.of.non.supine.events, : cannot compute exact p-value with
16  ## ties
17
18  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
19  ## "sham")$index.of.non.supine.events, : cannot compute exact confidence
20  ## interval with ties
21
22  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
23  ## "sham")$index.of.non.supine.events, : cannot compute exact p-value with
24  ## zeroes
25
26  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
27  ## "sham")$index.of.non.supine.events, : cannot compute exact confidence
28  ## interval with zeroes
29
30
31  ##
32  ## Wilcoxon signed rank test with continuity correction
33  ##
34  ## data:  subset(SSdataCompletes, intervention == "sham")$index.of.non.supine
35  ## .events and subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.non
36  ## .supine.events
37  ## V = 70.5, p-value = 0.9176
38  ## alternative hypothesis: true location shift is not equal to 0
39  ## 95 percent confidence interval:
40  ## -1.0000733  0.8499829
41  ## sample estimates:
42  ## (pseudo)median
43  ## 0.04999832
44
45  #between participants (grouped) comparison
46  summary(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events)
47
48
49  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50  ##      0.00   0.00   0.20   2.62   1.50   20.80
51
52  sd(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events)
53
54  ## [1] 5.512245
55
56
57
58
59
60

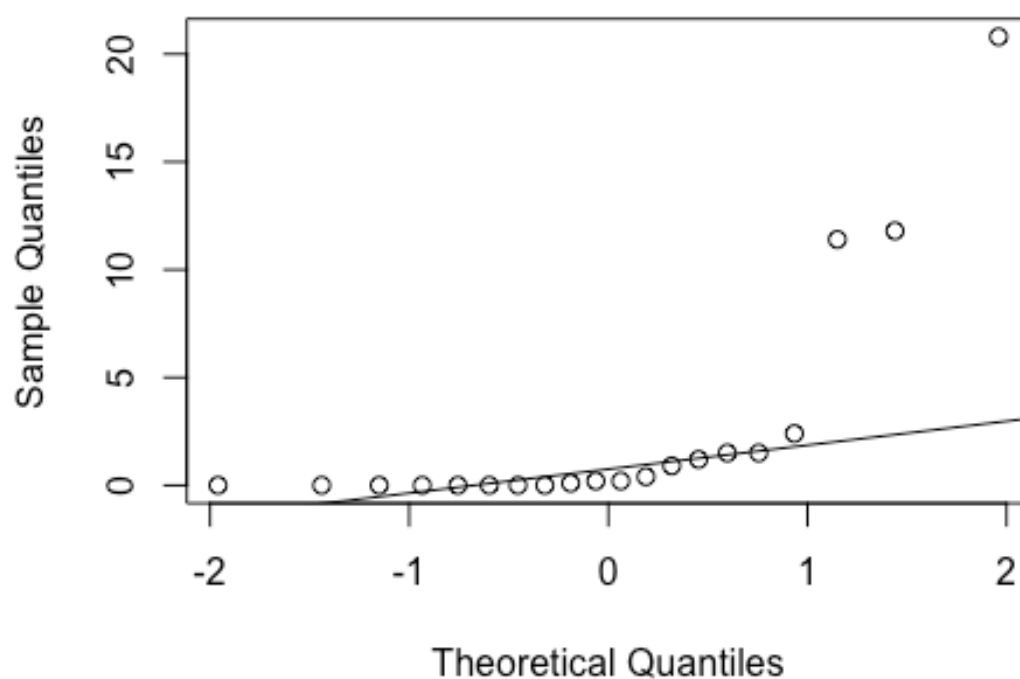
```

```

length(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
)
## [1] 20
qqnorm(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
)
qqline(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
## A = 4.0472, p-value = 1.731e-10
##non-normal
summary(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

```

```

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   0.50   2.42   1.75   18.40

sd(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

## [1] 5.100733

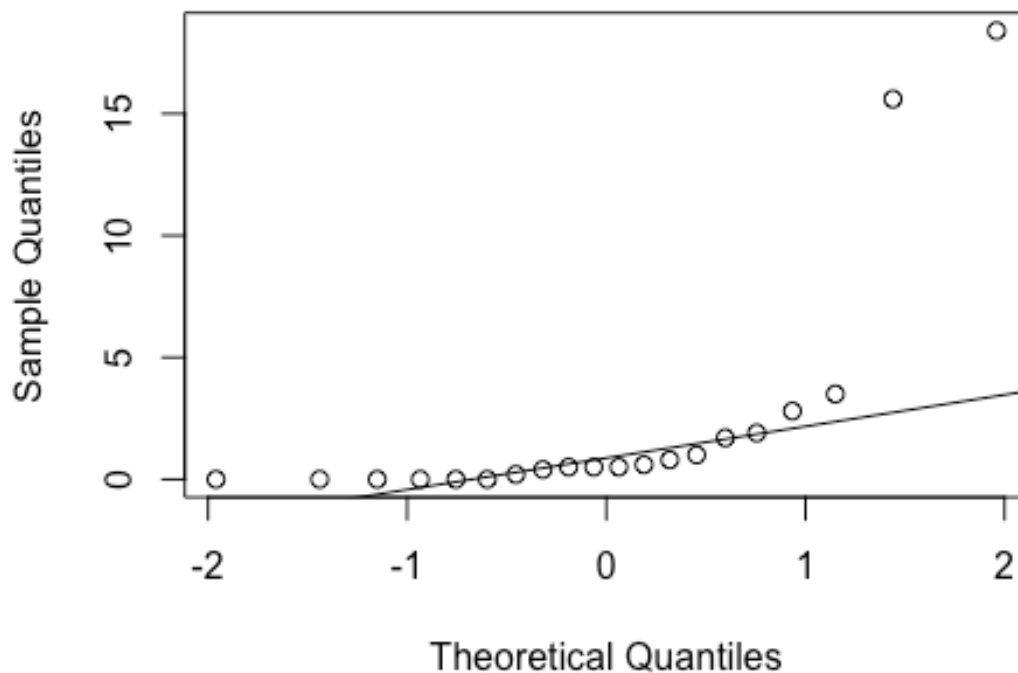
length(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$index.of.non.supine.events)
qqline(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$index.of.non.supine.events
## A = 4.229, p-value = 6.047e-11

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

```

```

1
2
3
4     subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.e
5 vents,
6     conf.int = TRUE)
7
8 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
9 ## $index.of.non.supine.events, : cannot compute exact p-value with ties
10
11 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
12 ## $index.of.non.supine.events, : cannot compute exact confidence intervals
13 ## with ties
14
15 ##
16 ## Wilcoxon rank sum test with continuity correction
17 ##
18 ## data: subset(SSdata, intervention == "sham")$index.of.non.supine.events a
19 nd subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
20 ## W = 222.5, p-value = 0.5428
21 ## alternative hypothesis: true location shift is not equal to 0
22 ## 95 percent confidence interval:
23 ## -0.3999612  0.5999875
24 ## sample estimates:
25 ## difference in location
26 ##          5.005918e-06
27
28 ##### Mean SaO2 AWAKE #####
29 #Summary
30 summary(SSdata$mean.sao2.awake)
31
32 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
33 ##    95.20  96.00   96.70   96.76   97.20   99.40
34
35 sd(SSdata$mean.sao2.awake, na.rm = TRUE)
36
37 ## [1] 0.99242
38
39 length(SSdata$mean.sao2.awake)
40
41 ## [1] 40
42
43 #ANOVA
44 night_tx_difference <- anova(lm(mean.sao2.awake ~ intervention * night,
45                               data = SSdata))
46
47 night_tx_difference
48
49 ## Analysis of Variance Table
50 ##
51 ## Response: mean.sao2.awake
52 ##
53 ##      Df Sum Sq Mean Sq F value Pr(>F)
54 ## intervention    1  0.049   0.0490   0.0464 0.8306
55 ## night           1  0.256   0.2560   0.2425 0.6254
56
57
58
59
60

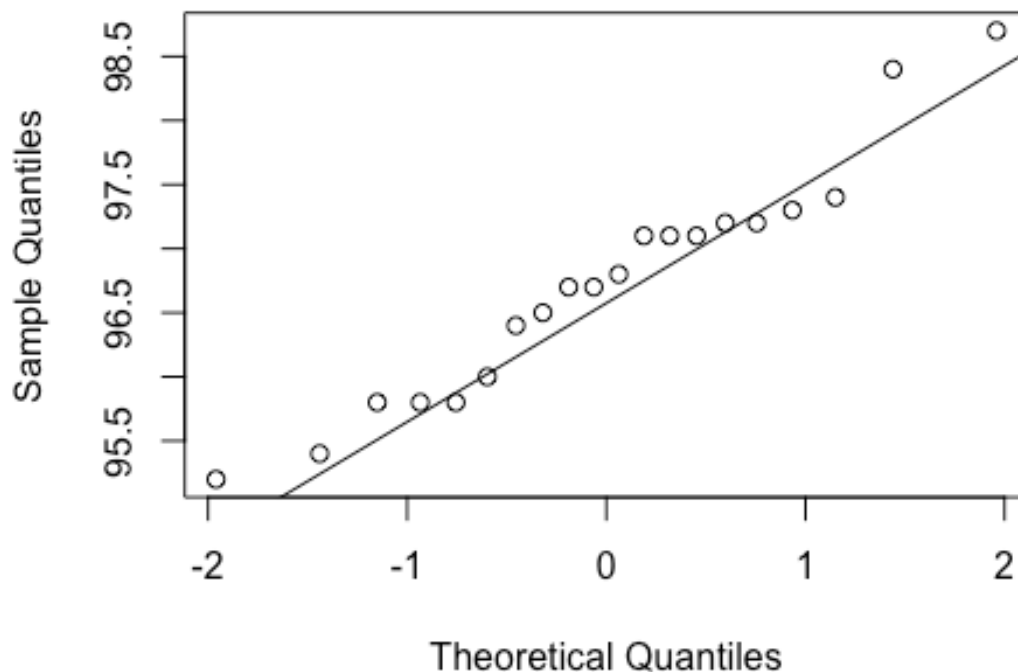
```

```

1
2
3  ## intervention:night  1  0.100  0.1000  0.0947  0.7600
4  ## Residuals          36 38.006  1.0557
5
6  #within-participants (paired) comparison
7  #Paired t-test
8  t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.awake,
9         subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.awake,
10        paired = TRUE)
11
12  ##
13  ## Paired t-test
14  ##
15  ## data: subset(SSdataCompletes, intervention == "sham")$mean.sao2.awake and
16  subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.awake
17  ## t = 0.53846, df = 19, p-value = 0.5965
18  ## alternative hypothesis: true difference in means is not equal to 0
19  ## 95 percent confidence interval:
20  ## -0.2020931  0.3420931
21  ## sample estimates:
22  ## mean of the differences
23  ##
24  ##          0.07
25
26  #between participants (grouped) comparison
27  summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
28
29  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
30  ##   95.20  95.95   96.75   96.73  97.20   98.70
31
32  sd(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
33
34  ## [1] 0.909077
35
36  length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
37
38  ## [1] 20
39
40  qqnorm(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
41  qqline(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake
## A = 0.38206, p-value = 0.3654

#normal

summary(subset(SSdata, intervention == "sham")$mean.sao2.awake)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  95.30  96.15   96.65   96.80  97.05   99.40

sd(subset(SSdata, intervention == "sham")$mean.sao2.awake)

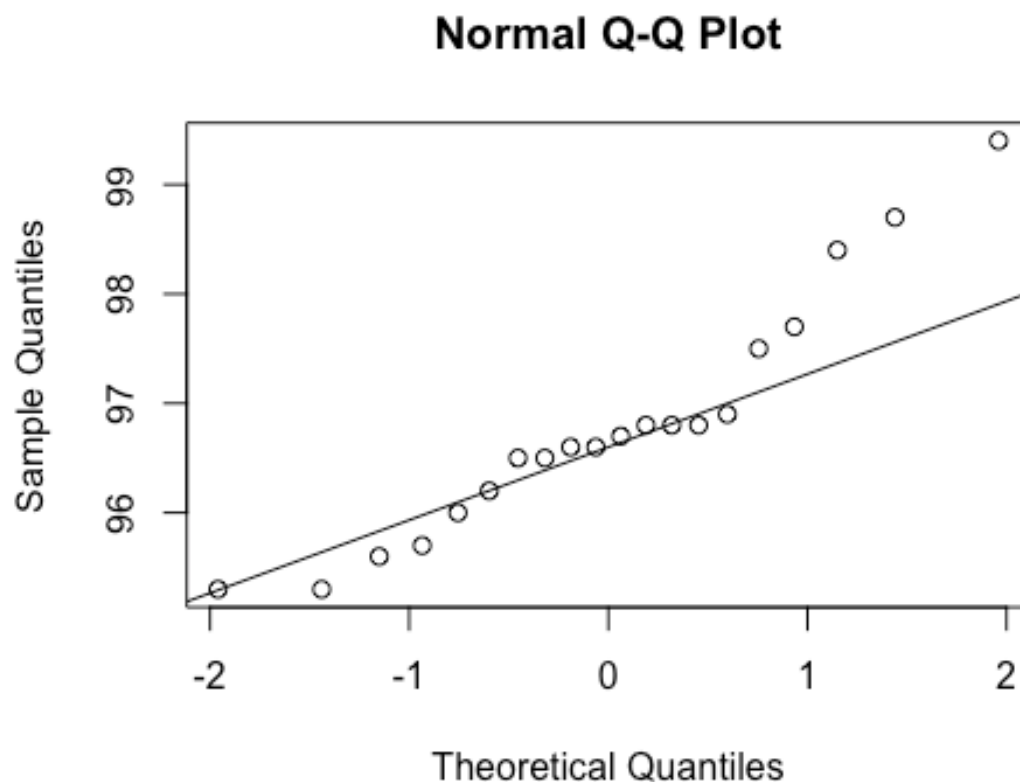
## [1] 1.092077

length(subset(SSdata, intervention == "sham")$mean.sao2.awake)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$mean.sao2.awake)
qqline(subset(SSdata, intervention == "sham")$mean.sao2.awake)

```



```

ad.test(subset(SSdata, intervention == "sham")$mean.sao2.awake)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.awake
## A = 0.61087, p-value = 0.09665

#normal

t.test(subset(SSdata, intervention == "sham")$mean.sao2.awake,
       subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.awake and subset(S
Sdata, intervention == "PrenaBelt")$mean.sao2.awake
## t = 0.22031, df = 36.79, p-value = 0.8268
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -0.5739073 0.7139073
## sample estimates:

```

```
## mean of x mean of y
##      96.80      96.73

##### Mean SaO2 NREM #####
#Summary
summary(SSdata$mean.sao2.nrem)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      94.40  95.60   96.15   96.23  96.93   99.10

sd(SSdata$mean.sao2.nrem, na.rm = TRUE)

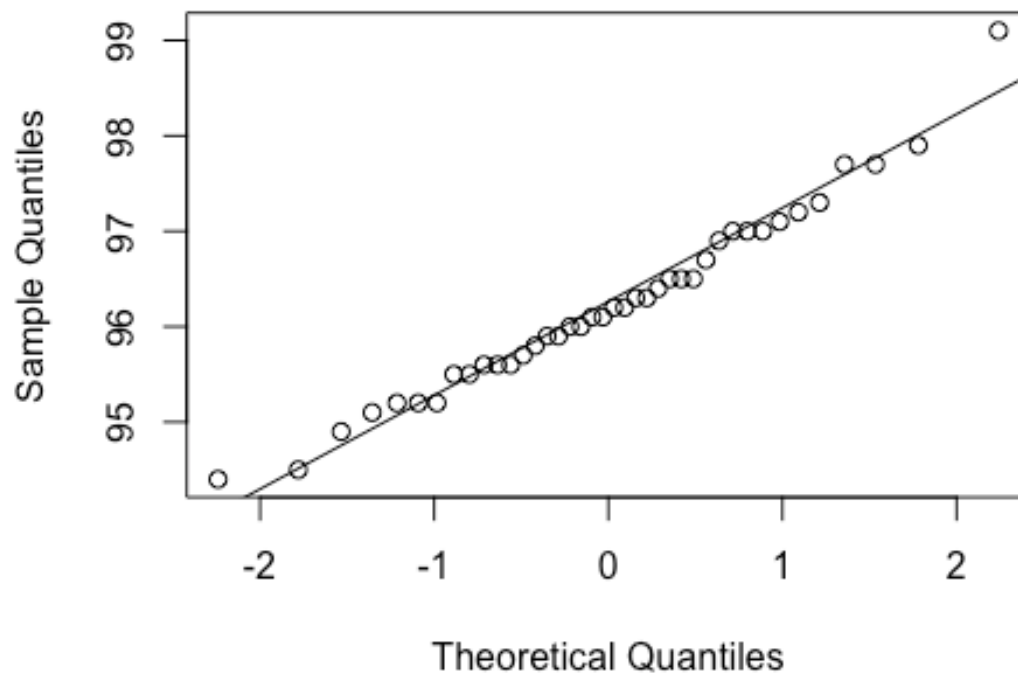
## [1] 0.9680505

length(SSdata$mean.sao2.nrem)

## [1] 40

qqnorm(SSdata$mean.sao2.nrem)
qqline(SSdata$mean.sao2.nrem)
```

Normal Q-Q Plot



```
ad.test(SSdata$mean.sao2.nrem)

##
## Anderson-Darling normality test
```

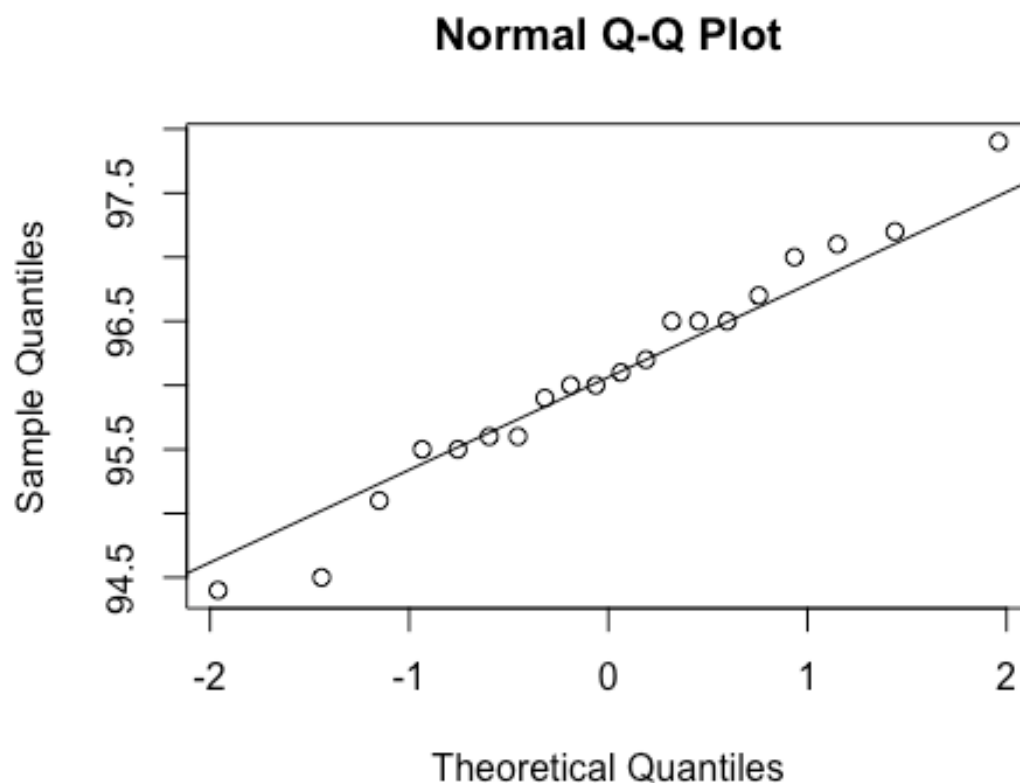


```

1
2
3 ##
4 ## data:  SSdata$mean.sao2.nrem
5 ## A = 0.24673, p-value = 0.7391
6
7 #normal
8
9 #ANOVA
10 night_tx_difference <- anova(lm(mean.sao2.nrem ~ intervention * night,
11                               data = SSdata))
12
13 night_tx_difference
14
15 ## Analysis of Variance Table
16 ##
17 ## Response: mean.sao2.nrem
18 ##           Df Sum Sq Mean Sq F value Pr(>F)
19 ## intervention      1  0.812  0.81225   0.8438 0.3644
20 ## night              1  0.992  0.99225   1.0308 0.3167
21 ## intervention:night  1  0.090  0.09025   0.0938 0.7612
22 ## Residuals        36 34.653  0.96258
23
24 #within-participants (paired) comparison
25 #Paired t-test
26 t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.nrem,
27         subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.nrem,
28         paired = TRUE)
29
30 ##
31 ## Paired t-test
32 ##
33 ## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.nrem and
34 subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.nrem
35 ## t = 1.4182, df = 19, p-value = 0.1723
36 ## alternative hypothesis: true difference in means is not equal to 0
37 ## 95 percent confidence interval:
38 ##  -0.1356036  0.7056036
39 ## sample estimates:
40 ## mean of the differences
41 ##           0.285
42
43 #between participants (grouped) comparison
44 summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
45
46 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
47 ##  94.40  95.57   96.05   96.09  96.55   97.90
48
49 sd(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
50
51 ## [1] 0.8837123
52
53 length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
54
55 ## [1] 20
56
57
58
59
60

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
qqline(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem
## A = 0.18102, p-value = 0.9013

#normal

summary(subset(SSdata, intervention == "sham")$mean.sao2.nrem)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  94.90  95.68   96.25   96.38  97.00   99.10

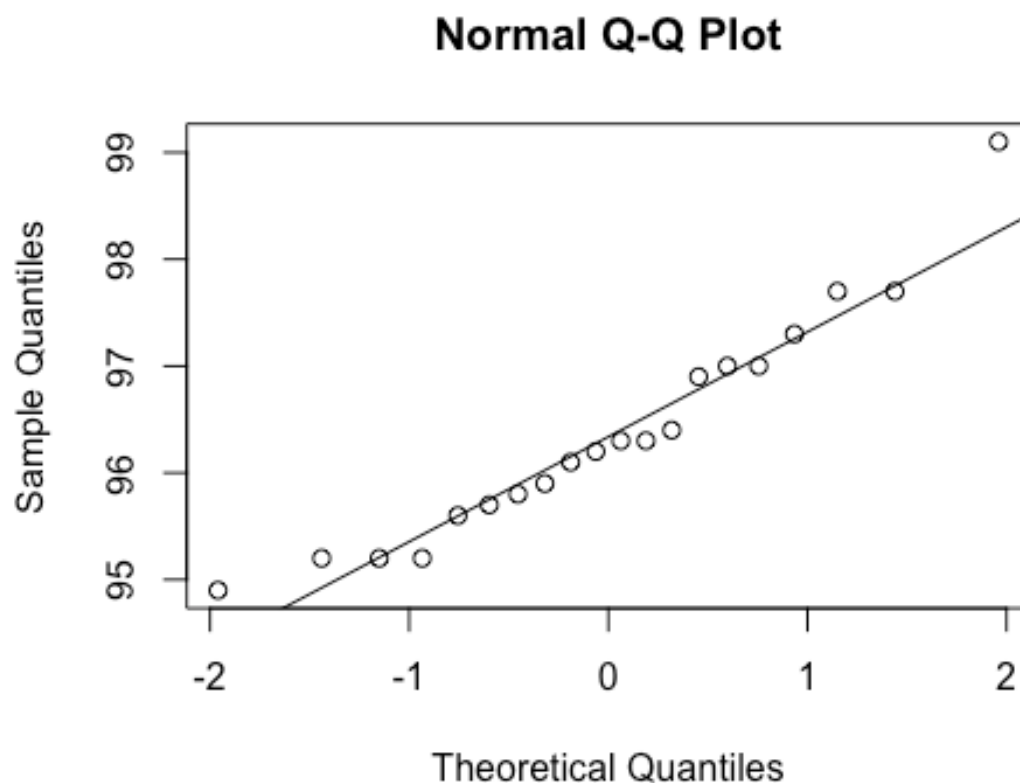
sd(subset(SSdata, intervention == "sham")$mean.sao2.nrem)

## [1] 1.048746

length(subset(SSdata, intervention == "sham")$mean.sao2.nrem)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$mean.sao2.nrem)
qqline(subset(SSdata, intervention == "sham")$mean.sao2.nrem)
```



```
ad.test(subset(SSdata, intervention == "sham")$mean.sao2.nrem)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.nrem
## A = 0.35668, p-value = 0.4209
```

```
#normal
```

```
t.test(subset(SSdata, intervention == "sham")$mean.sao2.nrem,
       subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
```

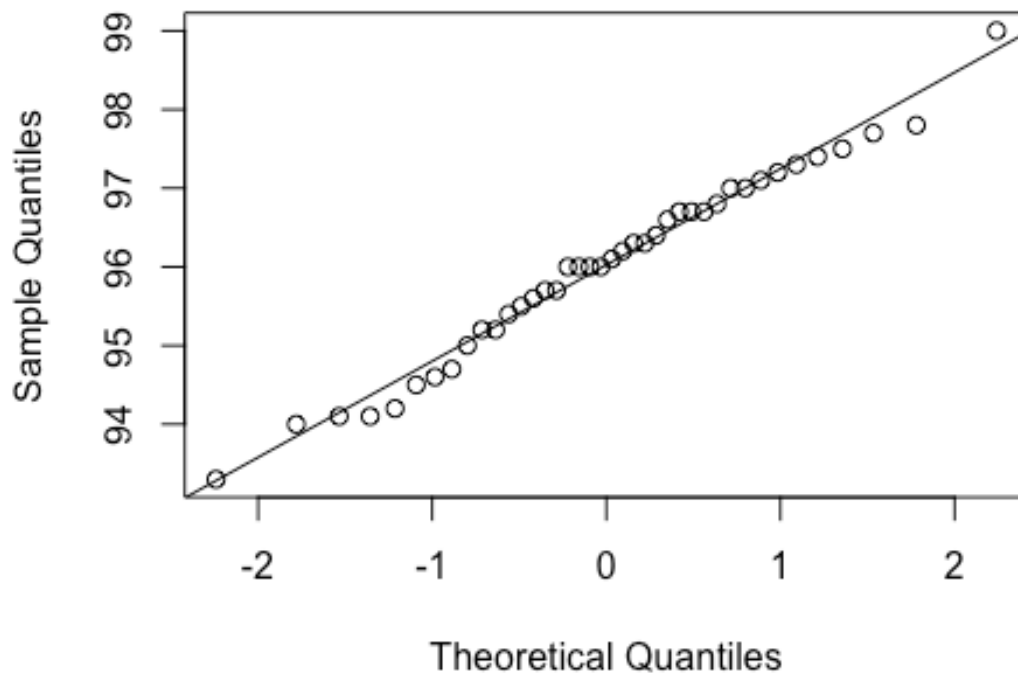
```
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.nrem and subset(SS
data, intervention == "PrenaBelt")$mean.sao2.nrem
## t = 0.92937, df = 36.938, p-value = 0.3587
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
```

```

1
2
3 ## -0.3363889  0.9063889
4 ## sample estimates:
5 ## mean of x mean of y
6 ##    96.375    96.090
7
8 ##### Mean SaO2 REM #####
9
10 #Summary
11 summary(SSdata$mean.sao2.rem)
12
13 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14 ##   93.30   95.20   96.05   96.02   96.85   99.00
15
16 sd(SSdata$mean.sao2.rem, na.rm = TRUE)
17
18 ## [1] 1.234244
19
20 length(SSdata$mean.sao2.rem)
21
22 ## [1] 40
23
24 qqnorm(SSdata$mean.sao2.rem)
25 qqline(SSdata$mean.sao2.rem)

```

Normal Q-Q Plot



```

54 ad.test(SSdata$mean.sao2.rem)
55
56
57
58
59
60

```

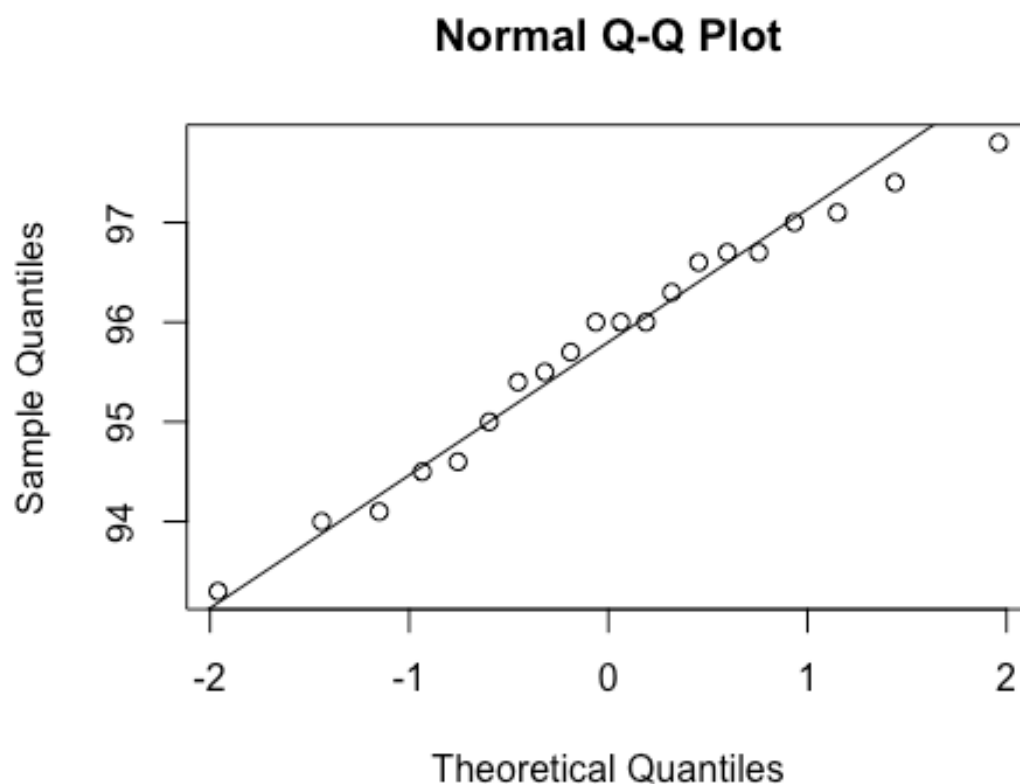
```

1
2
3
4  ## Anderson-Darling normality test
5  ##
6  ## data:  SSdata$mean.sao2.rem
7  ## A = 0.23901, p-value = 0.7646
8
9  #normal
10
11  #ANOVA
12  night_tx_difference <- anova(lm(mean.sao2.rem ~ intervention * night,
13                               data = SSdata))
14
15  night_tx_difference
16
17  ## Analysis of Variance Table
18  ##
19  ## Response: mean.sao2.rem
20  ##
21  ##           Df Sum Sq Mean Sq F value Pr(>F)
22  ## intervention      1  2.116   2.1160   1.4834 0.2312
23  ## night              1  3.025   3.0250   2.1206 0.1540
24  ## intervention:night  1  2.916   2.9160   2.0442 0.1614
25  ## Residuals         36 51.354   1.4265
26
27  #within-participants (paired) comparison
28  #Paired t-test
29  t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.rem,
30         subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.rem,
31         paired = TRUE)
32
33  ##
34  ## Paired t-test
35  ##
36  ## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.rem and s
37  subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.rem
38  ## t = 1.5919, df = 19, p-value = 0.1279
39  ## alternative hypothesis: true difference in means is not equal to 0
40  ## 95 percent confidence interval:
41  ## -0.1447888  1.0647888
42  ## sample estimates:
43  ## mean of the differences
44  ##           0.46
45
46  #between participants (grouped) comparison
47  summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
48
49  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50  ##  93.30  94.90   96.00   95.78  96.70   97.80
51
52  sd(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
53
54  ## [1] 1.229581
55
56  length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
57
58
59
60

```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
qqline(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem
## A = 0.22902, p-value = 0.7802
```

```
#normal
```

```
summary(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  94.10  95.50   96.25   96.24  97.05   99.00
```

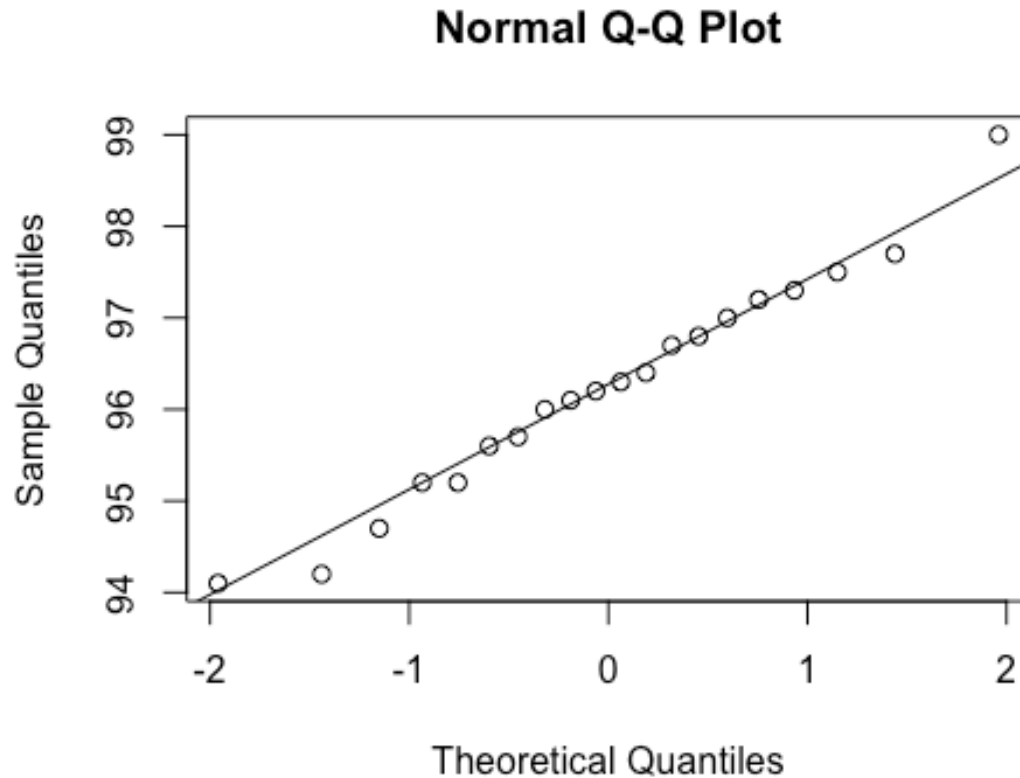
```
sd(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```

```
## [1] 1.226237
```

```
length(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$mean.sao2.rem)
qqline(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```



```
ad.test(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.rem
## A = 0.13652, p-value = 0.9718
```

```
#normal
```

```
t.test(subset(SSdata, intervention == "sham")$mean.sao2.rem,
       subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
```

```
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.rem and subset(SS
ata, intervention == "PrenaBelt")$mean.sao2.rem
## t = 1.1847, df = 38, p-value = 0.2435
```

```

1
2
3  ## alternative hypothesis: true difference in means is not equal to 0
4  ## 95 percent confidence interval:
5  ## -0.3260709  1.2460709
6  ## sample estimates:
7  ## mean of x mean of y
8  ##    96.245    95.785
9
10 ##### Mean SaO2 TST #####
11 #Summary
12 summary(SSdata$mean.sao2.tst)
13
14 ##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
15 ##   94.60  95.70   96.30   96.33   96.93   99.10
16
17 sd(SSdata$mean.sao2.tst, na.rm = TRUE)
18
19 ## [1] 0.9626319
20
21 length(SSdata$mean.sao2.tst)
22
23 ## [1] 40
24
25 #ANOVA
26 night_tx_difference <- anova(lm(mean.sao2.tst ~ intervention * night,
27                                data = SSdata))
28
29 night_tx_difference
30
31 ## Analysis of Variance Table
32 ##
33 ## Response: mean.sao2.tst
34 ##
35 ##           Df Sum Sq Mean Sq F value Pr(>F)
36 ## intervention      1  0.600  0.60025  0.6241 0.4347
37 ## night              1  0.870  0.87025  0.9048 0.3479
38 ## intervention:night  1  0.042  0.04225  0.0439 0.8352
39 ## Residuals        36 34.627  0.96186
40
41 #within-participants (paired) comparison
42 #Paired t-test
43 t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.tst,
44         subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.tst,
45         paired = TRUE)
46
47 ##
48 ## Paired t-test
49 ##
50 ## data: subset(SSdataCompletes, intervention == "sham")$mean.sao2.tst and s
51 ubset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.tst
52 ## t = 1.3161, df = 19, p-value = 0.2038
53 ## alternative hypothesis: true difference in means is not equal to 0
54 ## 95 percent confidence interval:
55 ## -0.1446432  0.6346432
56 ## sample estimates:
57
58
59
60

```

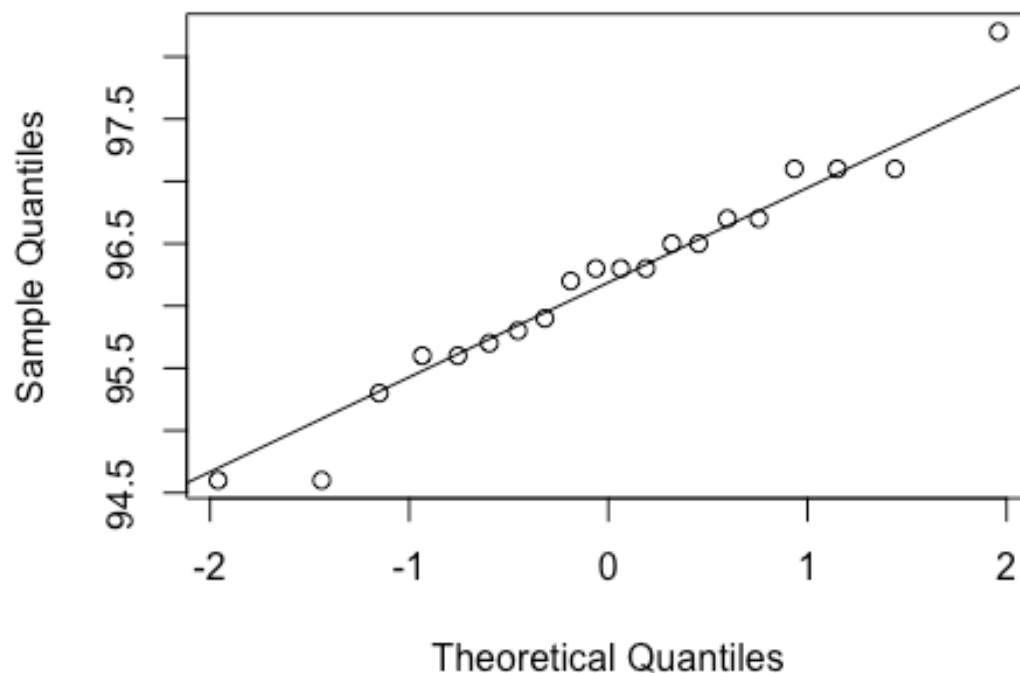


```

1
2
3 ## mean of the differences
4 ##           0.245
5
6 #between participants (grouped) comparison
7 summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
8
9 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
10 ##   94.60  95.68   96.30   96.20  96.70   98.20
11
12 sd(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
13
14 ## [1] 0.8672249
15
16 length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
17
18 ## [1] 20
19
20 qqnorm(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
21 qqline(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
22

```

Normal Q-Q Plot



```

51 ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
52
53 ##
54 ## Anderson-Darling normality test
55 ##
56

```

```
## data: subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst
## A = 0.2726, p-value = 0.6304
```

```
#normal
```

```
summary(subset(SSdata, intervention == "sham")$mean.sao2.tst)
```

```
##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  94.90  95.85  96.30  96.45  97.02  99.10
```

```
sd(subset(SSdata, intervention == "sham")$mean.sao2.tst)
```

```
## [1] 1.057554
```

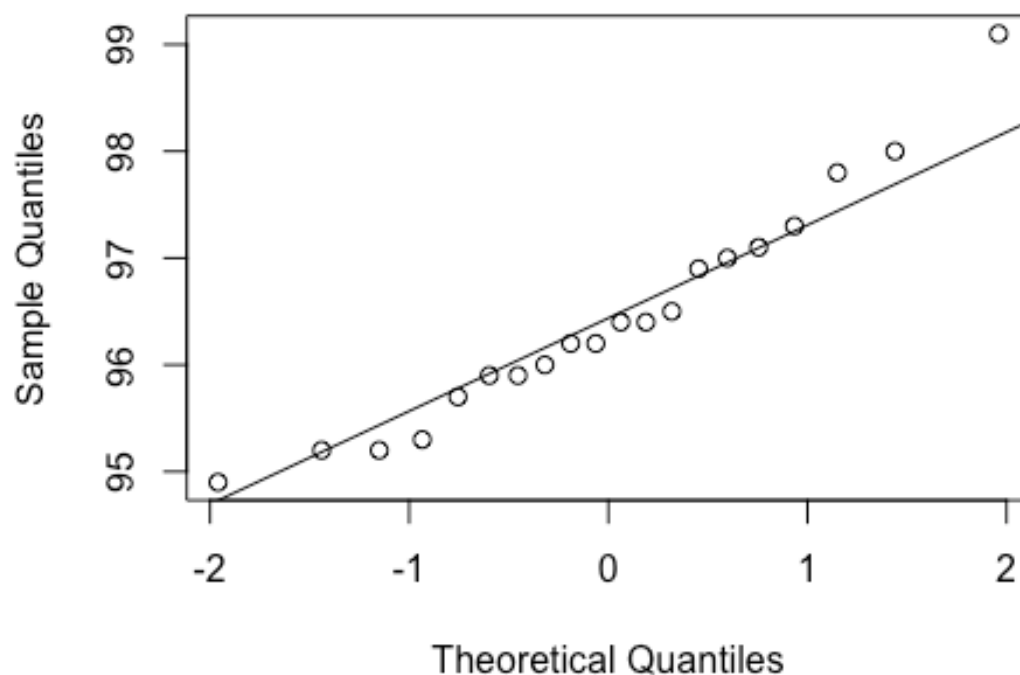
```
length(subset(SSdata, intervention == "sham")$mean.sao2.tst)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$mean.sao2.tst)
```

```
qqline(subset(SSdata, intervention == "sham")$mean.sao2.tst)
```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "sham")$mean.sao2.tst)
```

```
##
## Anderson-Darling normality test
```

```

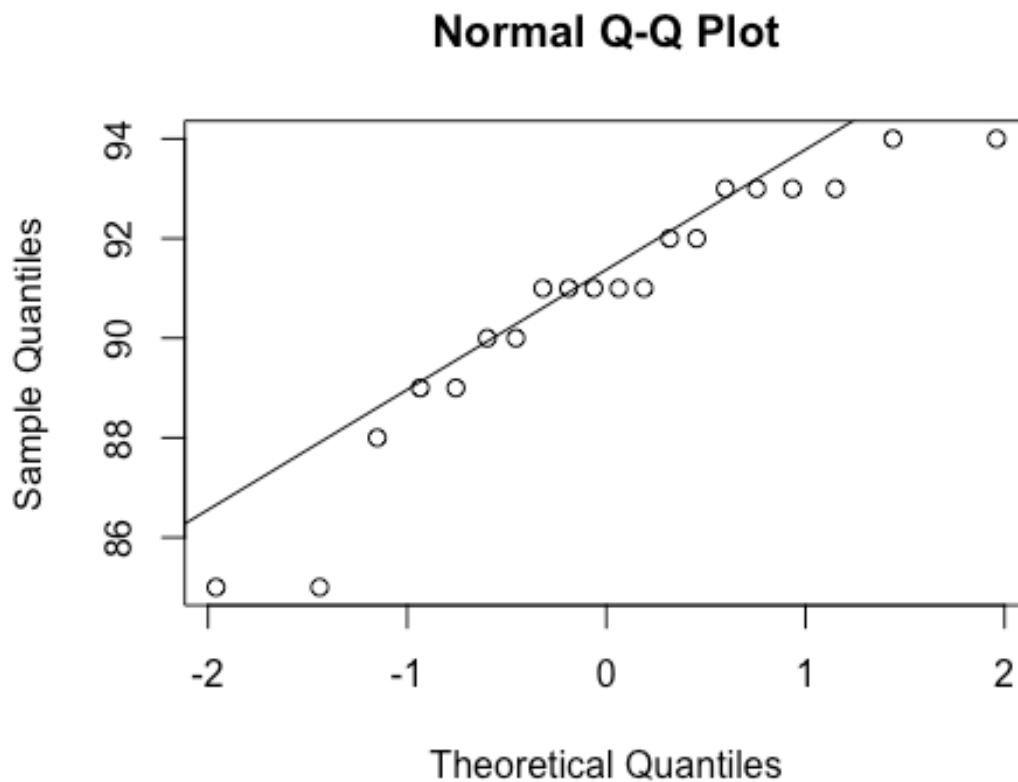
1
2
3  ##
4  ## data: subset(SSdata, intervention == "sham")$mean.sao2.tst
5  ## A = 0.30299, p-value = 0.5413
6
7  #normal
8
9  t.test(subset(SSdata, intervention == "sham")$mean.sao2.tst,
10         subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
11
12  ##
13  ## Welch Two Sample t-test
14  ##
15  ## data: subset(SSdata, intervention == "sham")$mean.sao2.tst and subset(SSd
16  ata, intervention == "PrenaBelt")$mean.sao2.tst
17  ## t = 0.80113, df = 36.596, p-value = 0.4282
18  ## alternative hypothesis: true difference in means is not equal to 0
19  ## 95 percent confidence interval:
20  ## -0.3748781  0.8648781
21  ## sample estimates:
22  ## mean of x mean of y
23  ## 96.450 96.205
24
25  ##### Min SaO2 AWAKE #####
26  #Summary
27  summary(SSdata$min.sao2.awake)
28
29  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
30  ## 70.00  88.75   91.00   89.75   93.00   94.00
31
32  sd(SSdata$min.sao2.awake, na.rm = TRUE)
33
34  ## [1] 5.026851
35
36  length(SSdata$min.sao2.awake)
37
38  ## [1] 40
39
40  #ANOVA
41  night_tx_difference <- anova(lm(min.sao2.awake ~ intervention * night,
42                                data = SSdata))
43
44  night_tx_difference
45
46  ## Analysis of Variance Table
47  ##
48  ## Response: min.sao2.awake
49  ##
50  ##           Df Sum Sq Mean Sq F value Pr(>F)
51  ## intervention      1  40.0   40.00  1.8391 0.18350
52  ## night              1  25.6   25.60  1.1770 0.28518
53  ## intervention:night  1 136.9  136.90  6.2943 0.01676 *
54  ## Residuals        36  783.0   21.75
55  ## ---
56  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
57
58
59

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.awake,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.awake,
7             paired = TRUE, conf.int = TRUE)
8
9
10 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
11 ## "sham")$min.sao2.awake, : cannot compute exact p-value with ties
12
13 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
14 ## "sham")$min.sao2.awake, : cannot compute exact confidence interval with
15 ## ties
16
17 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
18 ## "sham")$min.sao2.awake, : cannot compute exact p-value with zeroes
19
20 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21 ## "sham")$min.sao2.awake, : cannot compute exact confidence interval with
22 ## zeroes
23
24 ##
25 ## Wilcoxon signed rank test with continuity correction
26 ##
27 ## data: subset(SSdataCompletes, intervention == "sham")$min.sao2.awake and
28 subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.awake
29 ## V = 53, p-value = 0.1609
30 ## alternative hypothesis: true location shift is not equal to 0
31 ## 95 percent confidence interval:
32 ## -3.9999632 0.5000467
33 ## sample estimates:
34 ## (pseudo)median
35 ## -1.49991
36
37 #between participants (grouped) comparison
38 summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
39
40 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
41 ## 85.00  89.75   91.00   90.75   93.00   94.00
42
43 sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
44
45 ## [1] 2.572629
46
47 length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
48
49 ## [1] 20
50
51 qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
52 qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake
## A = 0.68841, p-value = 0.06104

#normal

summary(subset(SSdata, intervention == "sham")$min.sao2.awake)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  70.00  88.00   90.00  88.75  93.25   94.00

sd(subset(SSdata, intervention == "sham")$min.sao2.awake)

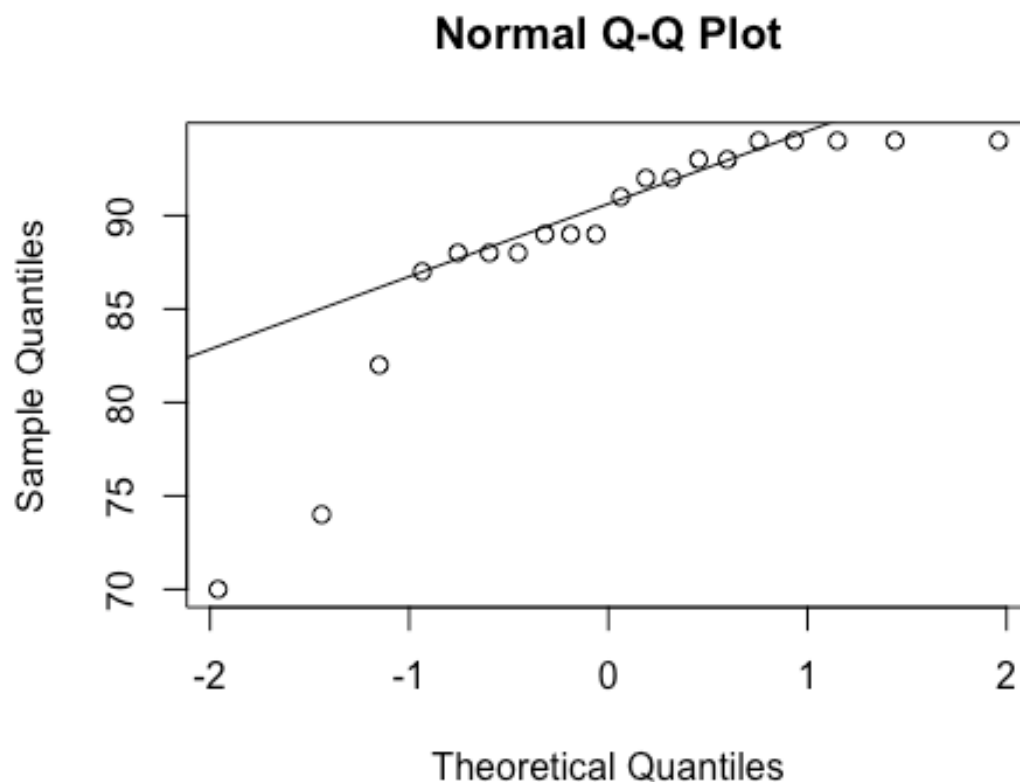
## [1] 6.568465

length(subset(SSdata, intervention == "sham")$min.sao2.awake)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$min.sao2.awake)
qqline(subset(SSdata, intervention == "sham")$min.sao2.awake)

```



```

ad.test(subset(SSdata, intervention == "sham")$min.sao2.awake)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$min.sao2.awake
## A = 1.7154, p-value = 0.0001417

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$min.sao2.awake,
            subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.awake, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.awake, : cannot compute exact confidence intervals with ties

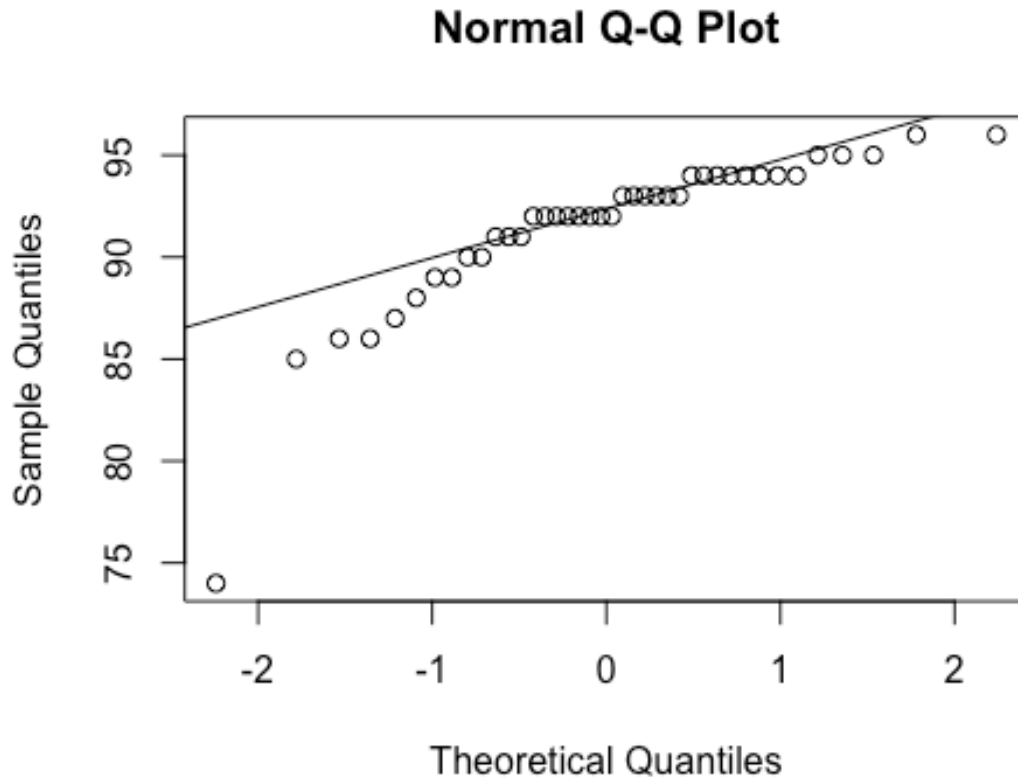
##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$min.sao2.awake and subset(SS

```

```

1
2
3 data, intervention == "PrenaBelt")$min.sao2.awake
4 ## W = 184, p-value = 0.6726
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -2.999945 1.000048
8 ## sample estimates:
9 ## difference in location
10 ## -7.483333e-05
11
12 ##### Min SaO2 NREM #####
13 #Summary
14 summary(SSdata$min.sao2.nrem)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##  74.00  90.75   92.00   91.50  94.00   96.00
18
19 sd(SSdata$min.sao2.nrem, na.rm = TRUE)
20
21 ## [1] 3.928854
22
23 length(SSdata$min.sao2.nrem)
24
25 ## [1] 40
26
27 qqnorm(SSdata$min.sao2.nrem)
28 qqline(SSdata$min.sao2.nrem)
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```
ad.test(SSdata$min.sao2.nrem)

##
## Anderson-Darling normality test
##
## data:  SSdata$min.sao2.nrem
## A = 2.2647, p-value = 7.529e-06

#non-normal

#ANOVA
night_tx_difference <- anova(lm(min.sao2.nrem ~ intervention * night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: min.sao2.nrem
##
```

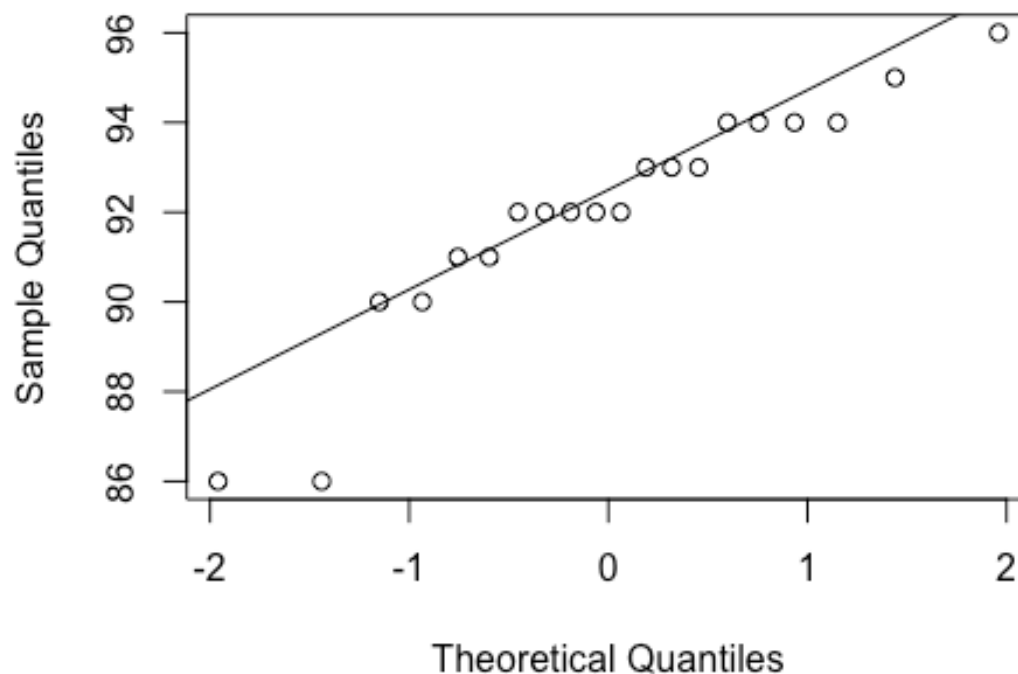
	Df	Sum Sq	Mean Sq	F value	Pr(>F)
## intervention	1	10.0	10.000	0.6475	0.4263
## night	1	3.6	3.600	0.2331	0.6322
## intervention:night	1	32.4	32.400	2.0978	0.1562
## Residuals	36	556.0	15.444		


```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.nrem,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.nrem,
7             paired = TRUE, conf.int = TRUE)
8
9 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
10 ## "sham")$min.sao2.nrem, : cannot compute exact p-value with ties
11
12 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13 ## "sham")$min.sao2.nrem, : cannot compute exact confidence interval with tie
14 s
15
16 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
17 ## "sham")$min.sao2.nrem, : cannot compute exact p-value with zeroes
18
19 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
20 ## "sham")$min.sao2.nrem, : cannot compute exact confidence interval with
21 ## zeroes
22
23 ##
24 ## Wilcoxon signed rank test with continuity correction
25 ##
26 ## data: subset(SSdataCompletes, intervention == "sham")$min.sao2.nrem and s
27 ubset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.nrem
28 ## V = 46, p-value = 0.26
29 ## alternative hypothesis: true location shift is not equal to 0
30 ## 95 percent confidence interval:
31 ## -2.4999583 0.5000763
32 ## sample estimates:
33 ## (pseudo)median
34 ## -0.500039
35
36
37 #between participants (grouped) comparison
38 summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
39
40 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
41 ##      86      91      92      92      94      96
42
43 sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
44
45 ## [1] 2.575185
46
47 length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
48
49 ## [1] 20
50
51 qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
52 qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem
## A = 0.79126, p-value = 0.03318

#non-normal

summary(subset(SSdata, intervention == "sham")$min.sao2.nrem)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      74.0   89.0   92.5   91.0   94.0   96.0

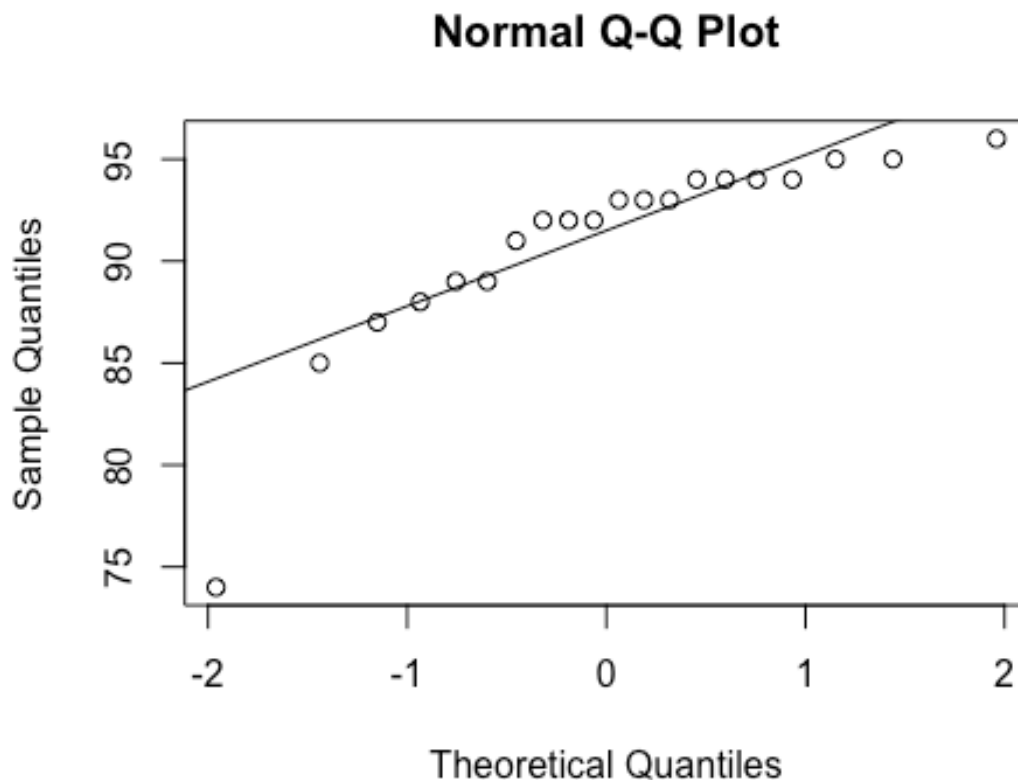
sd(subset(SSdata, intervention == "sham")$min.sao2.nrem)

## [1] 4.952405

length(subset(SSdata, intervention == "sham")$min.sao2.nrem)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$min.sao2.nrem)
qqline(subset(SSdata, intervention == "sham")$min.sao2.nrem)
```



```

ad.test(subset(SSdata, intervention == "sham")$min.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$min.sao2.nrem
## A = 1.4186, p-value = 0.0008139

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$min.sao2.nrem,
            subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem,
            conf.int = TRUE)

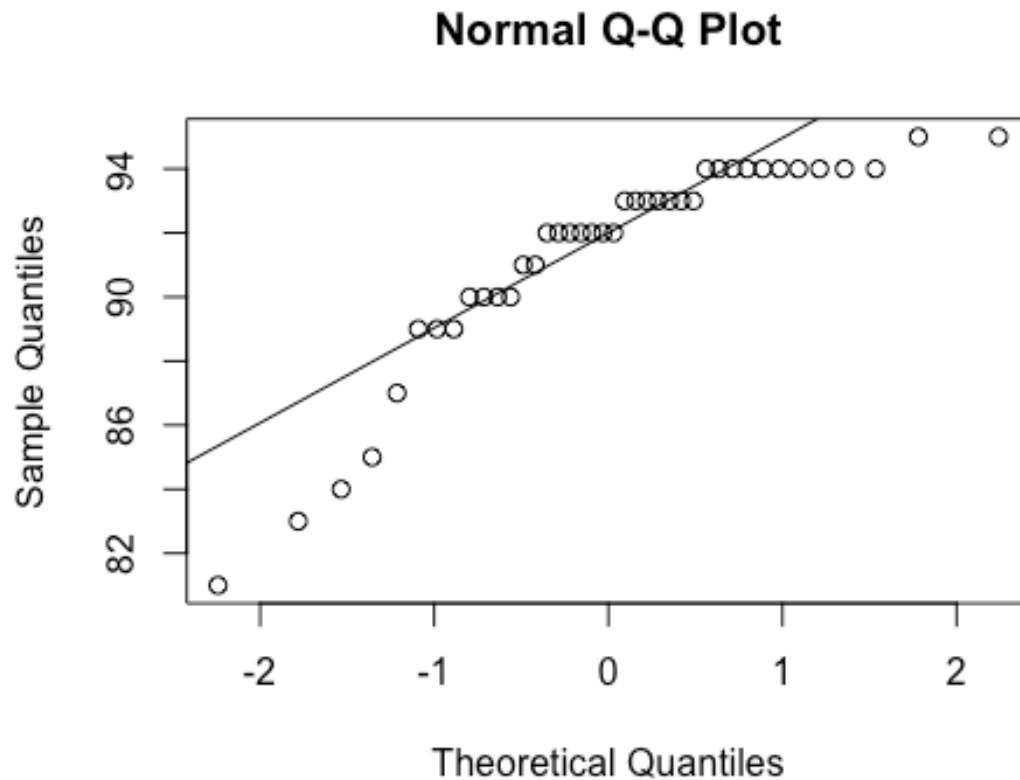
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.nrem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.nrem, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$min.sao2.nrem and subset(SSd

```

```
1
2
3 ata, intervention == "PrenaBelt")$min.sao2.nrem
4 ## W = 196.5, p-value = 0.9347
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -2.000016 1.999967
8 ## sample estimates:
9 ## difference in location
10 ## -3.487271e-05
11
12 ##### Min SaO2 REM #####
13 #Summary
14 summary(SSdata$min.sao2.rem)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      81.00   90.00   92.00   91.35   94.00   95.00
18
19 sd(SSdata$min.sao2.rem, na.rm = TRUE)
20
21 ## [1] 3.332436
22
23 length(SSdata$min.sao2.rem)
24
25 ## [1] 40
26
27 qqnorm(SSdata$min.sao2.rem)
28 qqline(SSdata$min.sao2.rem)
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(SSdata$min.sao2.rem)

##
## Anderson-Darling normality test
##
## data:  SSdata$min.sao2.rem
## A = 2.4334, p-value = 2.861e-06

#non-normal

#ANOVA
night_tx_difference <- anova(lm(min.sao2.rem ~ intervention * night,
                               data = SSdata))
night_tx_difference

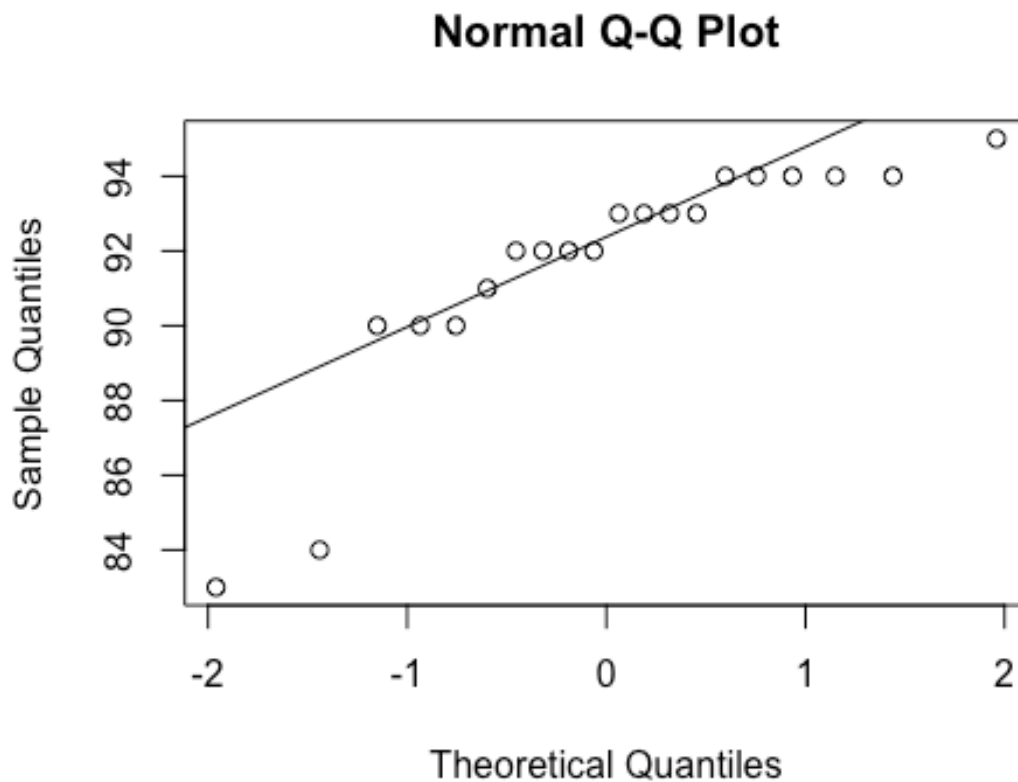
## Analysis of Variance Table
##
## Response: min.sao2.rem
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1     3.6   3.600   0.3264 0.57131
## night           1     0.1   0.100   0.0091 0.92466
## intervention:night 1    32.4  32.400   2.9380 0.09512 .
## Residuals      36   397.0  11.028

```

```

1
2
3
4  ## ---
5  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
6
7  #within-participants (paired) comparison
8  #Paired Wilcoxon
9  wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.rem,
10             subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.rem
11             ,
12             paired = TRUE, conf.int = TRUE)
13
14  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
15  ## "sham")$min.sao2.rem, : cannot compute exact p-value with ties
16
17  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
18  ## "sham")$min.sao2.rem, : cannot compute exact confidence interval with ties
19
20  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21  ## "sham")$min.sao2.rem, : cannot compute exact p-value with zeroes
22
23  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24  ## "sham")$min.sao2.rem, : cannot compute exact confidence interval with
25  ## zeroes
26
27  ##
28  ## Wilcoxon signed rank test with continuity correction
29  ##
30  ## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.rem and su
31  bset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.rem
32  ## V = 45, p-value = 0.4029
33  ## alternative hypothesis: true location shift is not equal to 0
34  ## 95 percent confidence interval:
35  ## -2.4999536  0.9999402
36  ## sample estimates:
37  ## (pseudo)median
38  ## -0.4999916
39
40  #between participants (grouped) comparison
41  summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
42
43  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
44  ##  83.00  90.75   92.50   91.65   94.00   95.00
45
46  sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
47
48  ## [1] 3.150188
49
50  length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
51
52  ## [1] 20
53
54  qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
55  qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem
## A = 1.6375, p-value = 0.000224

#non-normal

summary(subset(SSdata, intervention == "sham")$min.sao2.rem)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  81.00  89.00   92.00   91.05  94.00   95.00

sd(subset(SSdata, intervention == "sham")$min.sao2.rem)

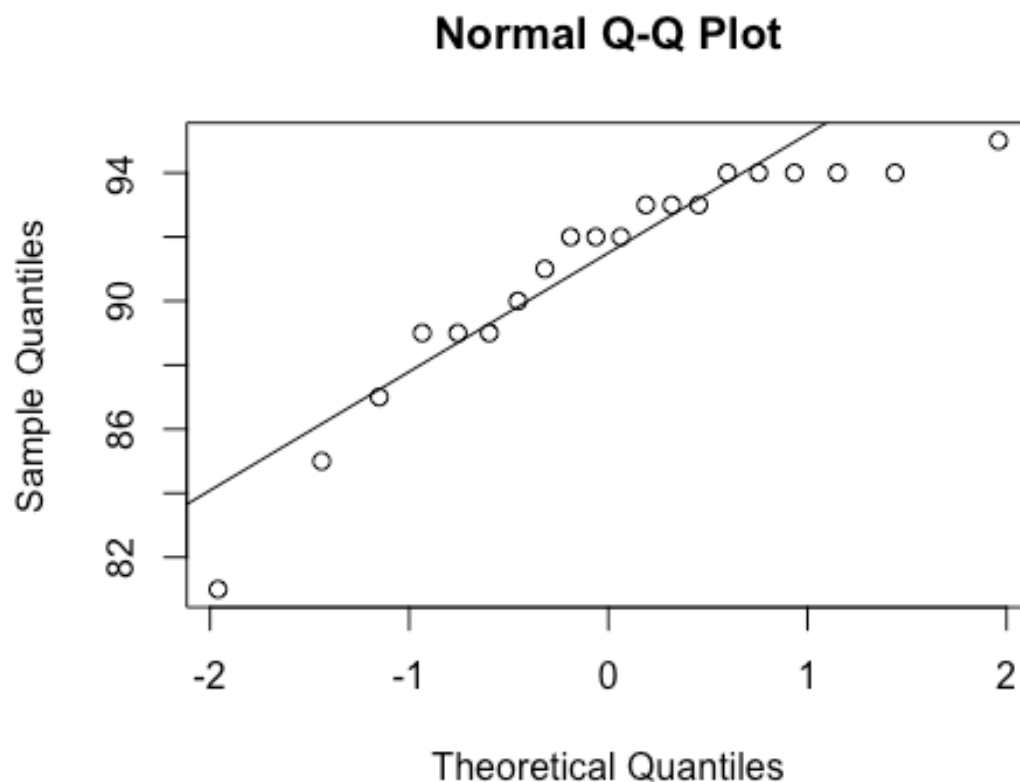
## [1] 3.56112

length(subset(SSdata, intervention == "sham")$min.sao2.rem)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$min.sao2.rem)
qqline(subset(SSdata, intervention == "sham")$min.sao2.rem)

```



```

ad.test(subset(SSdata, intervention == "sham")$min.sao2.rem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$min.sao2.rem
## A = 0.98564, p-value = 0.0105

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$min.sao2.rem,
            subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.rem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.rem, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$min.sao2.rem and subset(SSda

```



```

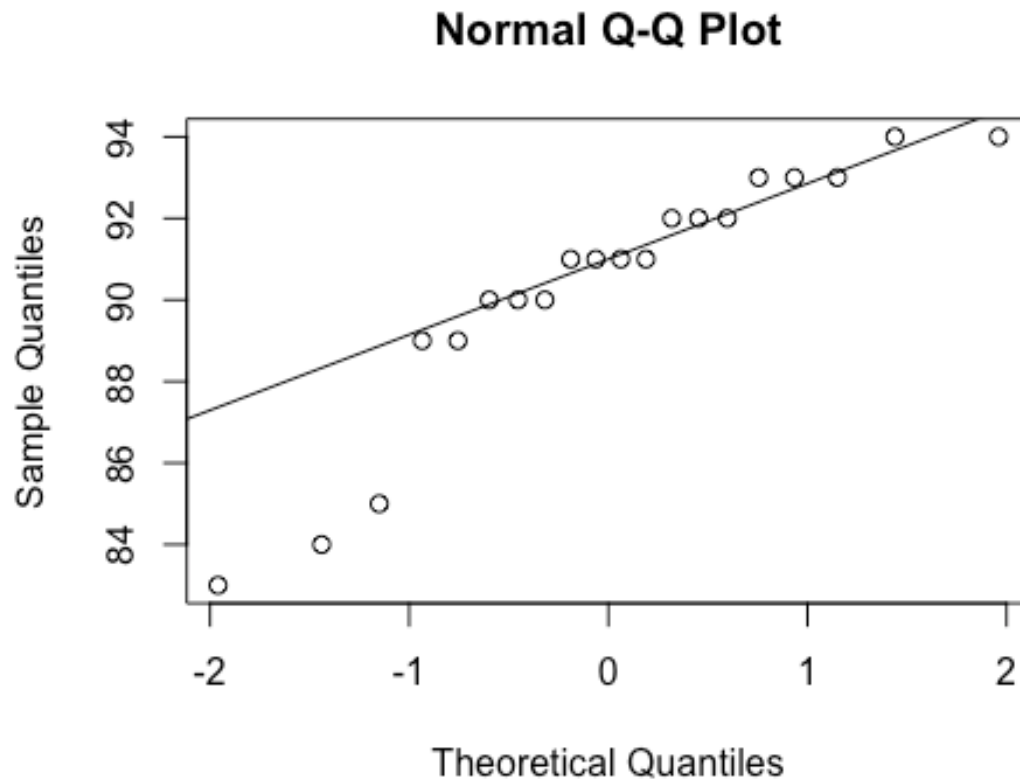
1
2
3 ta, intervention == "PrenaBelt")$min.sao2.rem
4 ## W = 181, p-value = 0.6118
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -2.000020 1.000041
8 ## sample estimates:
9 ## difference in location
10 ## -6.982535e-05
11
12 ##### Min SaO2 TST #####
13 #Summary
14 summary(SSdata$min.sao2.tst)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      70.00   88.00   91.00   89.28   93.00   94.00
18
19 sd(SSdata$min.sao2.tst, na.rm = TRUE)
20
21 ## [1] 5.11402
22
23 length(SSdata$min.sao2.tst)
24
25 ## [1] 40
26
27 #ANOVA
28 night_tx_difference <- anova(lm(min.sao2.tst ~ intervention * night,
29                               data = SSdata))
30
31 night_tx_difference
32
33 ## Analysis of Variance Table
34 ##
35 ## Response: min.sao2.tst
36 ##
37 ##           Df Sum Sq Mean Sq F value Pr(>F)
38 ## intervention      1  46.22  46.225  2.0356 0.16227
39 ## night              1  15.63  15.625  0.6881 0.41229
40 ## intervention:night  1 140.62 140.625  6.1927 0.01759 *
41 ## Residuals        36 817.50  22.708
42 ## ---
43 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
44
45 #within-participants (paired) comparison
46 #Paired Wilcoxon
47 wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.tst,
48             subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.tst,
49             paired = TRUE, conf.int = TRUE)
50
51 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
52 ## "sham")$min.sao2.tst, : cannot compute exact p-value with ties
53
54 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
55 ## "sham")$min.sao2.tst, : cannot compute exact confidence interval with ties
56
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$min.sao2.tst, : cannot compute exact p-value with zeroes
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7  ## "sham")$min.sao2.tst, : cannot compute exact confidence interval with
8  ## zeroes
9
10 ##
11 ## Wilcoxon signed rank test with continuity correction
12 ##
13 ## data: subset(SSdataCompletes, intervention == "sham")$min.sao2.tst and su
14 bset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.tst
15 ## V = 45, p-value = 0.07952
16 ## alternative hypothesis: true location shift is not equal to 0
17 ## 95 percent confidence interval:
18 ## -3.999980e+00 6.891261e-05
19 ## sample estimates:
20 ## (pseudo)median
21 ## -1.500056
22
23
24 #between participants (grouped) comparison
25 summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
26
27 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28 ##      83.00  89.75   91.00   90.35   92.25   94.00
29
30 sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
31
32 ## [1] 3.116594
33
34 length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
35
36 ## [1] 20
37
38 qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
39 qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst
## A = 1.0583, p-value = 0.006831

#non-normal

summary(subset(SSdata, intervention == "sham")$min.sao2.tst)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   70.00  87.75   89.00   88.20  93.00   94.00

sd(subset(SSdata, intervention == "sham")$min.sao2.tst)

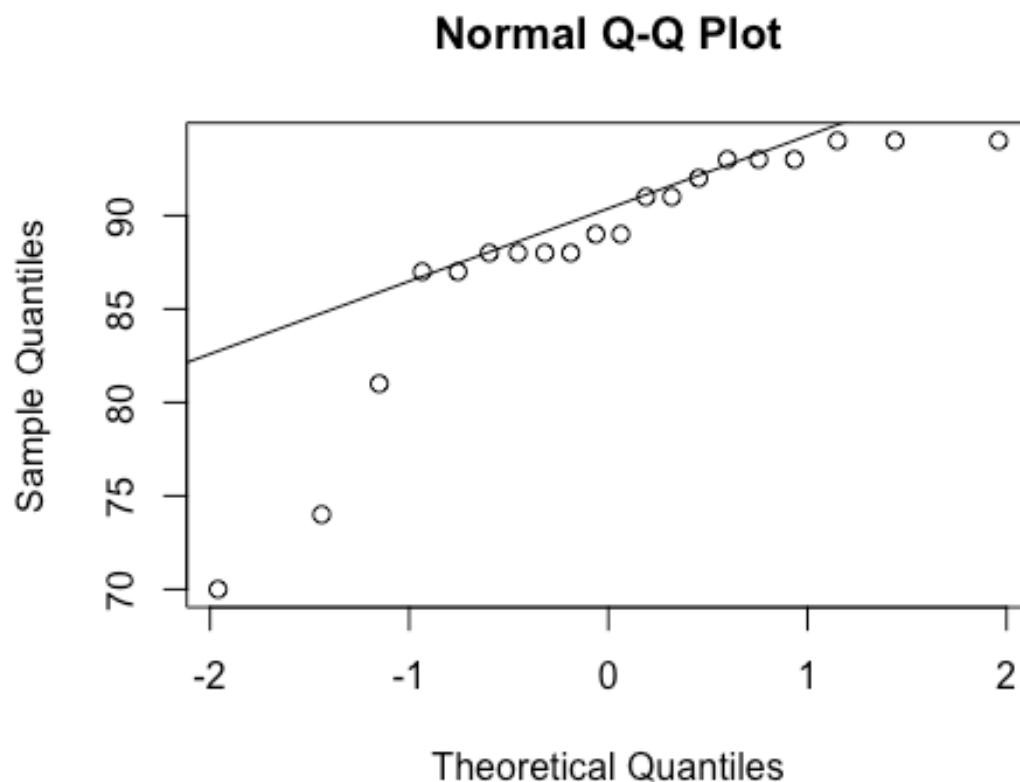
## [1] 6.444908

length(subset(SSdata, intervention == "sham")$min.sao2.tst)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$min.sao2.tst)
qqline(subset(SSdata, intervention == "sham")$min.sao2.tst)

```



```

ad.test(subset(SSdata, intervention == "sham")$min.sao2.tst)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$min.sao2.tst
## A = 1.5634, p-value = 0.0003467

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$min.sao2.tst,
            subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.tst, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.tst, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$min.sao2.tst and subset(SSda

```

```

1
2
3 ta, intervention == "PrenaBelt")$min.sao2.tst
4 ## W = 166, p-value = 0.362
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -3.000006 1.000035
8 ## sample estimates:
9 ## difference in location
10 ## -1.000019
11
12 ##### Max SaO2 AWAKE #####
13 #Summary
14 summary(SSdata$max.sao2.awake)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      98.00   99.00  100.00   99.68  100.00  100.00
18
19 sd(SSdata$max.sao2.awake, na.rm = TRUE)
20
21 ## [1] 0.5256254
22
23 length(SSdata$max.sao2.awake)
24
25 ## [1] 40
26
27 #ANOVA
28 night_tx_difference <- anova(lm(max.sao2.awake ~ intervention * night,
29                               data = SSdata))
30
31 night_tx_difference
32
33 ## Analysis of Variance Table
34 ##
35 ## Response: max.sao2.awake
36 ##
37 ##           Df Sum Sq Mean Sq F value Pr(>F)
38 ## intervention      1  0.625    0.625  2.2727 0.1404
39 ## night              1  0.025    0.025  0.0909 0.7648
40 ## intervention:night  1  0.225    0.225  0.8182 0.3717
41 ## Residuals        36  9.900    0.275
42
43 #within-participants (paired) comparison
44 #Paired Wilcoxon
45 wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.awake,
46             subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.awake,
47             paired = TRUE)
48
49 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
50 ## "sham")$max.sao2.awake, : cannot compute exact p-value with ties
51
52 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
53 ## "sham")$max.sao2.awake, : cannot compute exact p-value with zeroes
54
55 ##
56 ## Wilcoxon signed rank test with continuity correction

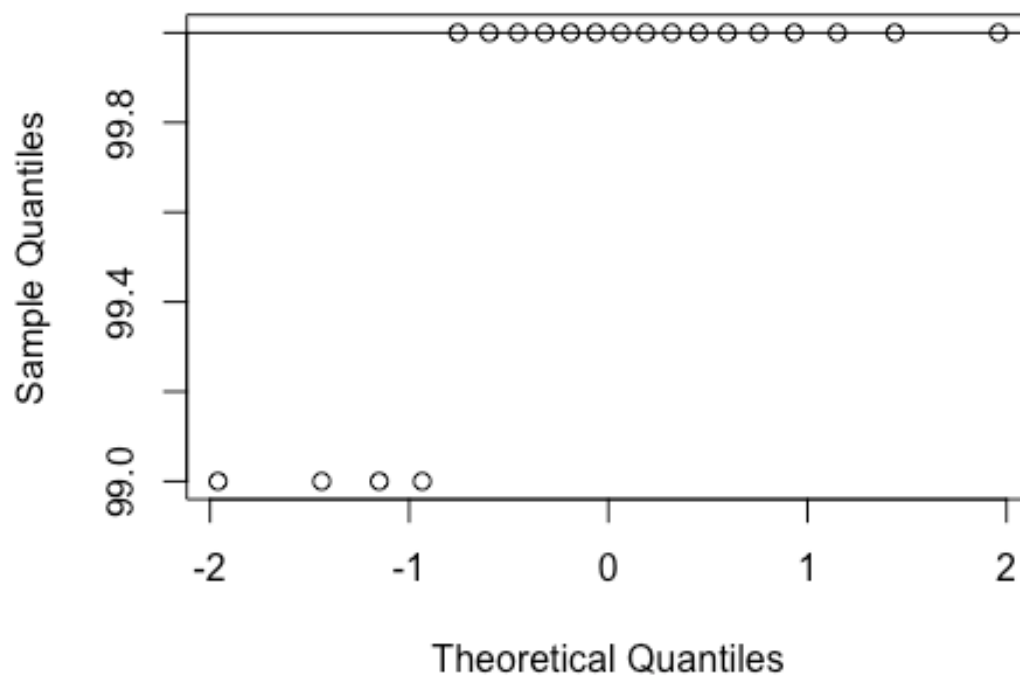
```

```

1  ##
2  ## data: subset(SSdataCompletes, intervention == "sham")$max.sao2.awake and
3  subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.awake
4  ## V = 4, p-value = 0.0726
5  ## alternative hypothesis: true location shift is not equal to 0
6
7  #between participants (grouped) comparison
8  summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
9
10  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11  ##      99.0  100.0  100.0   99.8  100.0  100.0
12
13  sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
14
15  ## [1] 0.4103913
16
17  length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
18
19  ## [1] 20
20
21  qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
22  qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)

```

Normal Q-Q Plot



```

55  ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)

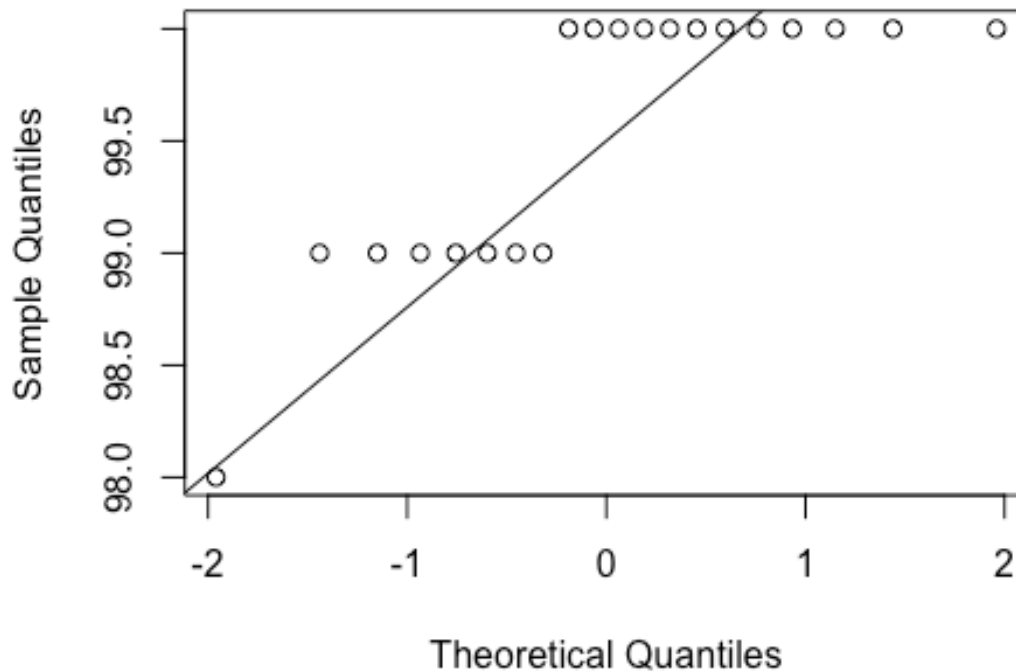
```

```

1
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data: subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake
7  ## A = 5.1941, p-value = 2.32e-13
8
9  #non-normal
10
11 summary(subset(SSdata, intervention == "sham")$max.sao2.awake)
12
13 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14 ##      98.00  99.00  100.00   99.55  100.00  100.00
15
16 sd(subset(SSdata, intervention == "sham")$max.sao2.awake)
17
18 ## [1] 0.6048053
19
20 length(subset(SSdata, intervention == "sham")$max.sao2.awake)
21
22 ## [1] 20
23
24 qqnorm(subset(SSdata, intervention == "sham")$max.sao2.awake)
25 qqline(subset(SSdata, intervention == "sham")$max.sao2.awake)
26
27
28
29
30
31

```

Normal Q-Q Plot



```

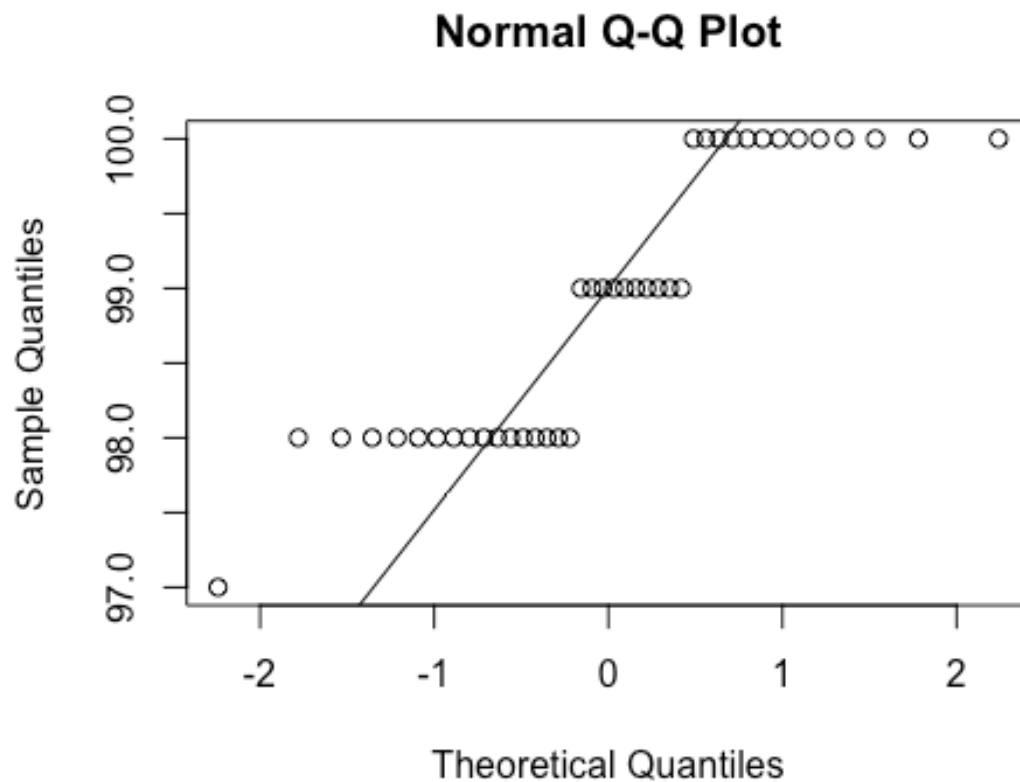
56 ad.test(subset(SSdata, intervention == "sham")$max.sao2.awake)
57
58
59
60

```

```

1
2
3
4  ## Anderson-Darling normality test
5  ##
6  ## data: subset(SSdata, intervention == "sham")$max.sao2.awake
7  ## A = 2.8091, p-value = 2.322e-07
8
9  #non-normal
10
11
12  wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.awake,
13             subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake,
14             conf.int = TRUE)
15
16  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
17  ## $max.sao2.awake, : cannot compute exact p-value with ties
18
19  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
20  ## $max.sao2.awake, : cannot compute exact confidence intervals with ties
21
22  ##
23  ## Wilcoxon rank sum test with continuity correction
24  ##
25  ## data: subset(SSdata, intervention == "sham")$max.sao2.awake and subset(SS
26  data, intervention == "PrenaBelt")$max.sao2.awake
27  ## W = 158, p-value = 0.1594
28  ## alternative hypothesis: true location shift is not equal to 0
29  ## 95 percent confidence interval:
30  ## -9.999288e-01  1.199059e-06
31  ## sample estimates:
32  ## difference in location
33  ## -1.027475e-05
34
35  ##### Max SaO2 NREM #####
36  #Summary
37  summary(SSdata$max.sao2.nrem)
38
39  ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
40  ##  97.00  98.00   99.00  98.88 100.00  100.00
41
42  sd(SSdata$max.sao2.nrem, na.rm = TRUE)
43
44  ## [1] 0.9111137
45
46  length(SSdata$max.sao2.nrem)
47
48  ## [1] 40
49
50  qqnorm(SSdata$max.sao2.nrem)
51  qqline(SSdata$max.sao2.nrem)
52
53
54
55
56
57
58
59
60

```

```

ad.test(SSdata$max.sao2.nrem)

##
## Anderson-Darling normality test
##
## data:  SSdata$max.sao2.nrem
## A = 3.1852, p-value = 3.895e-08

#non-normal

#ANOVA
night_tx_difference <- anova(lm(max.sao2.nrem ~ intervention * night,
                               data = SSdata))
night_tx_difference

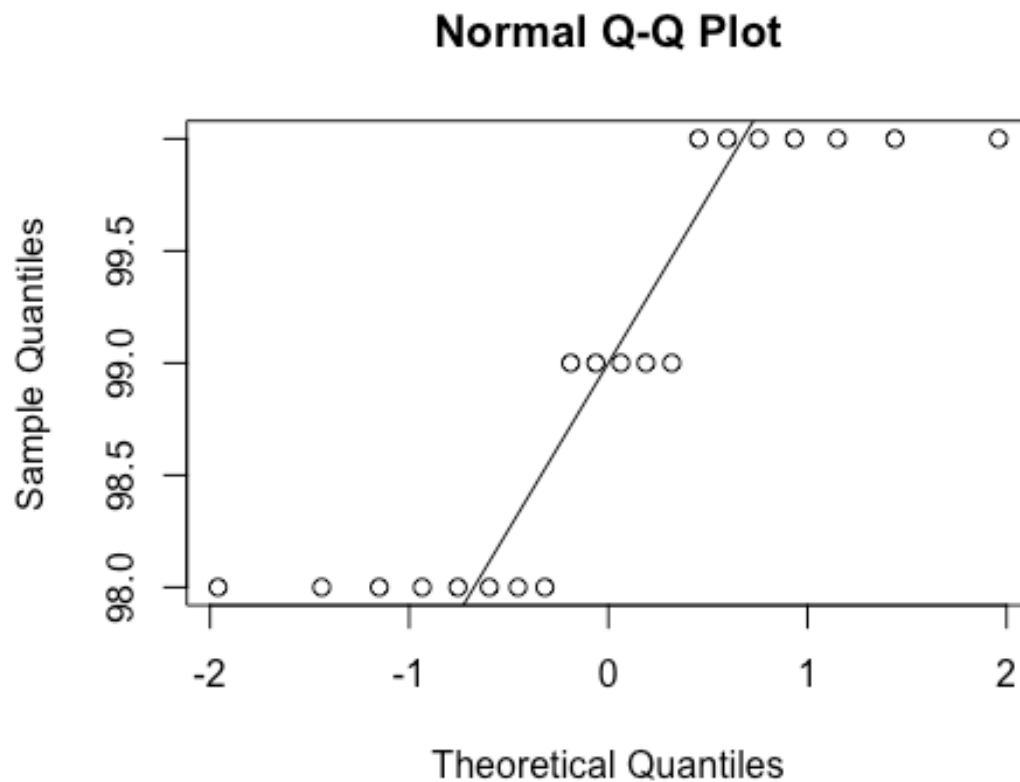
## Analysis of Variance Table
##
## Response: max.sao2.nrem
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1  0.225    0.225   0.2571 0.6152
## night           1  0.625    0.625   0.7143 0.4036
## intervention:night 1  0.025    0.025   0.0286 0.8667
## Residuals      36 31.500    0.875

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.nrem,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.nrem,
7             paired = TRUE, conf.int = TRUE)
8
9
10 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
11 ## "sham")$max.sao2.nrem, : requested conf.level not achievable
12
13 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
14 ## "sham")$max.sao2.nrem, : cannot compute exact p-value with ties
15
16 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
17 ## "sham")$max.sao2.nrem, : cannot compute exact confidence interval with ties
18
19
20 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21 ## "sham")$max.sao2.nrem, : cannot compute exact p-value with zeroes
22
23 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24 ## "sham")$max.sao2.nrem, : cannot compute exact confidence interval with zeroes
25
26 ## zeroes
27
28 ##
29 ## Wilcoxon signed rank test with continuity correction
30 ##
31 ## data: subset(SSdataCompletes, intervention == "sham")$max.sao2.nrem and subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.nrem
32 ## V = 20, p-value = 0.4575
33 ## alternative hypothesis: true location shift is not equal to 0
34 ## 90 percent confidence interval:
35 ## -1.499922 1.000000
36 ## sample estimates:
37 ## (pseudo)median
38 ## -0.4999789
39
40
41 #between participants (grouped) comparison
42 summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
43
44 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
45 ##  98.00  98.00   99.00  98.95 100.00 100.00
46
47 sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
48
49 ## [1] 0.8870412
50
51 length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
52
53 ## [1] 20
54
55 qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
56 qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem
## A = 1.809, p-value = 8.166e-05

#non-normal

summary(subset(SSdata, intervention == "sham")$max.sao2.nrem)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      97.0   98.0   99.0   98.8  100.0  100.0

sd(subset(SSdata, intervention == "sham")$max.sao2.nrem)

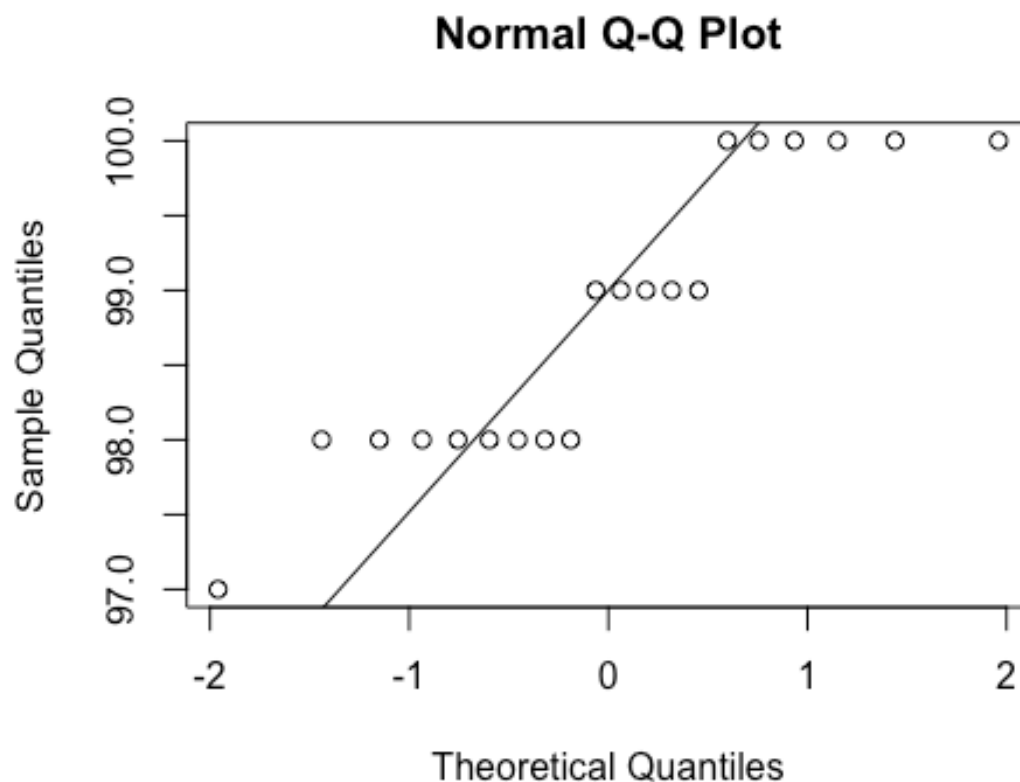
## [1] 0.9514532

length(subset(SSdata, intervention == "sham")$max.sao2.nrem)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$max.sao2.nrem)
qqline(subset(SSdata, intervention == "sham")$max.sao2.nrem)

```



```

ad.test(subset(SSdata, intervention == "sham")$max.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$max.sao2.nrem
## A = 1.3653, p-value = 0.001115

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.nrem,
            subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.nrem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.nrem, : cannot compute exact confidence intervals with ties

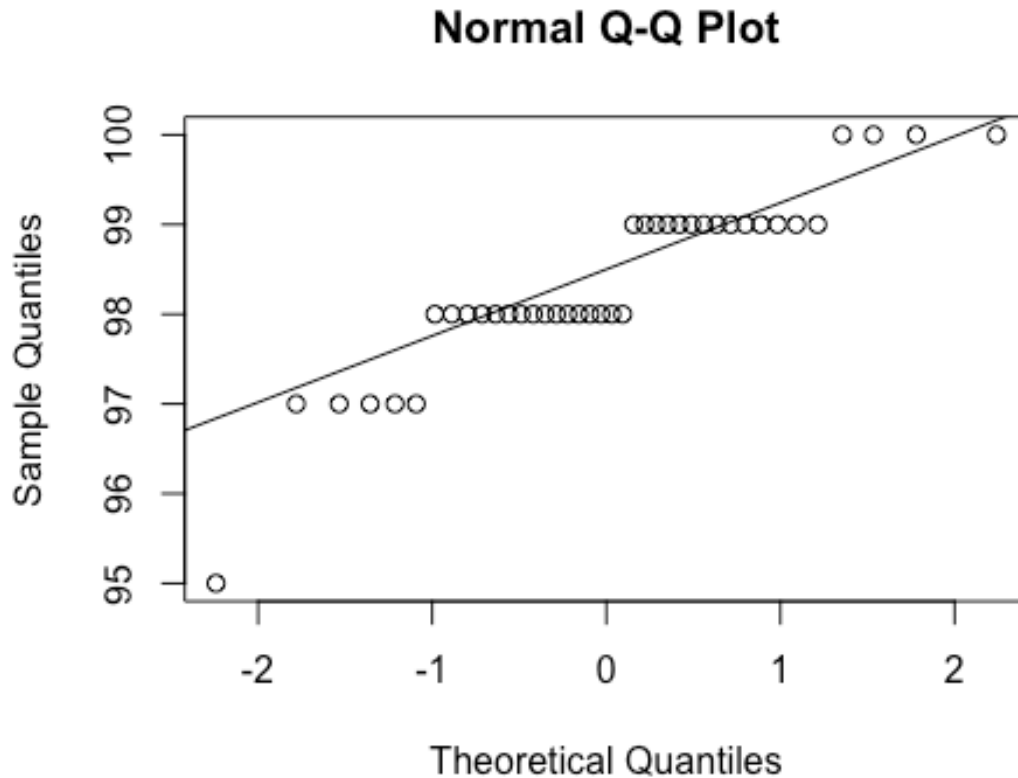
##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$max.sao2.nrem and subset(SSd

```

```

1
2
3   ata, intervention == "PrenaBelt")$max.sao2.nrem
4   ## W = 183.5, p-value = 0.6458
5   ## alternative hypothesis: true location shift is not equal to 0
6   ## 95 percent confidence interval:
7   ## -9.999960e-01  6.876513e-05
8   ## sample estimates:
9   ## difference in location
10  ##          -7.969806e-05
11
12  ##### Max SaO2 REM #####
13  #Summary
14  summary(SSdata$max.sao2.rem)
15
16  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17  ##    95.00  98.00   98.00   98.35  99.00  100.00
18
19  sd(SSdata$max.sao2.rem, na.rm = TRUE)
20
21  ## [1] 1.001281
22
23  length(SSdata$max.sao2.rem)
24
25  ## [1] 40
26
27  qqnorm(SSdata$max.sao2.rem)
28  qqline(SSdata$max.sao2.rem)
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(SSdata$max.sao2.rem)

##
## Anderson-Darling normality test
##
## data:  SSdata$max.sao2.rem
## A = 1.9711, p-value = 4.063e-05

#non-normal

#ANOVA
night_tx_difference <- anova(lm(max.sao2.rem ~ intervention * night,
                               data = SSdata))
night_tx_difference

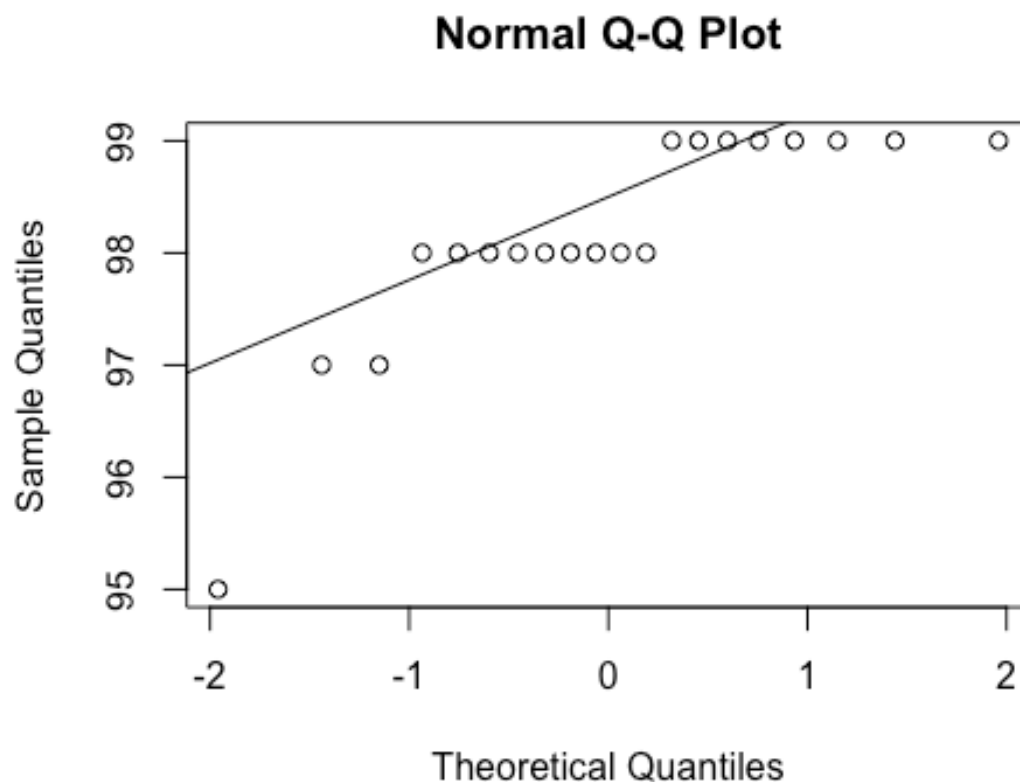
## Analysis of Variance Table
##
## Response: max.sao2.rem
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1     1.6  1.6000   1.7041  0.200
## night           1     3.6  3.6000   3.8343  0.058 .
## intervention:night 1     0.1  0.1000   0.1065  0.746
## Residuals      36    33.8  0.9389

```

```

1
2
3  ## ---
4  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
5
6  #within-participants (paired) comparison
7  #Paired Wilcoxon
8  wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.rem,
9             subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.rem
10             ,
11             paired = TRUE, conf.int = TRUE)
12
13  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
14  ## "sham")$max.sao2.rem, : cannot compute exact p-value with ties
15
16  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
17  ## "sham")$max.sao2.rem, : cannot compute exact confidence interval with ties
18
19  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
20  ## "sham")$max.sao2.rem, : cannot compute exact p-value with zeroes
21
22  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
23  ## "sham")$max.sao2.rem, : cannot compute exact confidence interval with
24  ## zeroes
25
26  ##
27  ## Wilcoxon signed rank test with continuity correction
28  ##
29  ## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.rem and su
30  bset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.rem
31  ## V = 78, p-value = 0.2819
32  ## alternative hypothesis: true location shift is not equal to 0
33  ## 95 percent confidence interval:
34  ##  -5.341455e-06  1.000049e+00
35  ## sample estimates:
36  ## (pseudo)median
37  ##  4.140595e-05
38
39
40  #between participants (grouped) comparison
41  summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
42
43  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
44  ##  95.00  98.00   98.00   98.15  99.00   99.00
45
46  sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
47
48  ## [1] 0.9880869
49
50  length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
51
52  ## [1] 20
53
54  qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
55  qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
56
57
58
59

```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem
## A = 1.7444, p-value = 0.0001194

#non-normal

summary(subset(SSdata, intervention == "sham")$max.sao2.rem)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  97.00  98.00  98.50  98.55  99.00 100.00

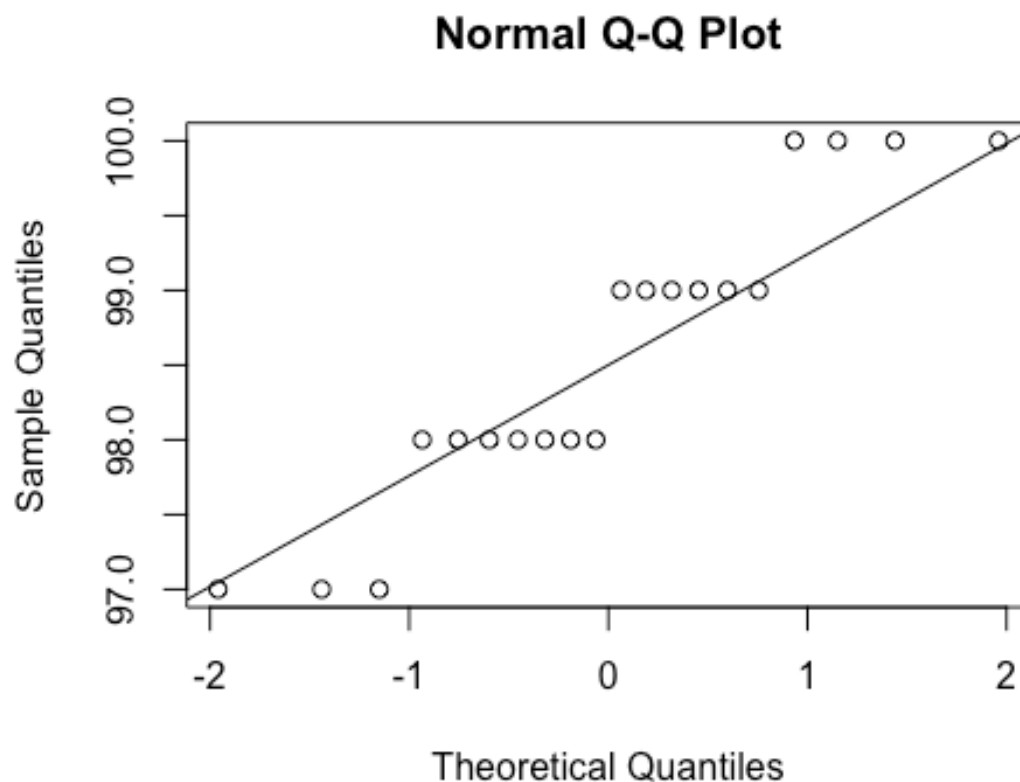
sd(subset(SSdata, intervention == "sham")$max.sao2.rem)

## [1] 0.9986833

length(subset(SSdata, intervention == "sham")$max.sao2.rem)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$max.sao2.rem)
qqline(subset(SSdata, intervention == "sham")$max.sao2.rem)
```

```

ad.test(subset(SSdata, intervention == "sham")$max.sao2.rem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$max.sao2.rem
## A = 0.89914, p-value = 0.01752

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.rem,
            subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.rem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.rem, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$max.sao2.rem and subset(SSda

```

```

1
2
3 ta, intervention == "PrenaBelt")$max.sao2.rem
4 ## W = 234.5, p-value = 0.3298
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -5.707564e-05 9.999595e-01
8 ## sample estimates:
9 ## difference in location
10 ## 5.182881e-05
11
12 ##### Max SaO2 TST #####
13 #Summary
14 summary(SSdata$max.sao2.tst)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      98.00   99.00   100.00   99.68  100.00   100.00
18
19 sd(SSdata$max.sao2.tst, na.rm = TRUE)
20
21 ## [1] 0.5256254
22
23 length(SSdata$max.sao2.tst)
24
25 ## [1] 40
26
27 #ANOVA
28 night_tx_difference <- anova(lm(max.sao2.tst ~ intervention * night,
29                               data = SSdata))
30
31 night_tx_difference
32
33 ## Analysis of Variance Table
34 ##
35 ## Response: max.sao2.tst
36 ##
37 ##           Df Sum Sq Mean Sq F value Pr(>F)
38 ## intervention      1  0.625    0.625   2.2727 0.1404
39 ## night              1  0.025    0.025   0.0909 0.7648
40 ## intervention:night  1  0.225    0.225   0.8182 0.3717
41 ## Residuals        36  9.900    0.275
42
43 #within-participants (paired) comparison
44 #Paired Wilcoxon
45 wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.tst,
46             subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.tst
47             ,
48             paired = TRUE)
49
50 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
51 ## "sham")$max.sao2.tst, : cannot compute exact p-value with ties
52
53 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
54 ## "sham")$max.sao2.tst, : cannot compute exact p-value with zeroes
55
56
57
58
59
60

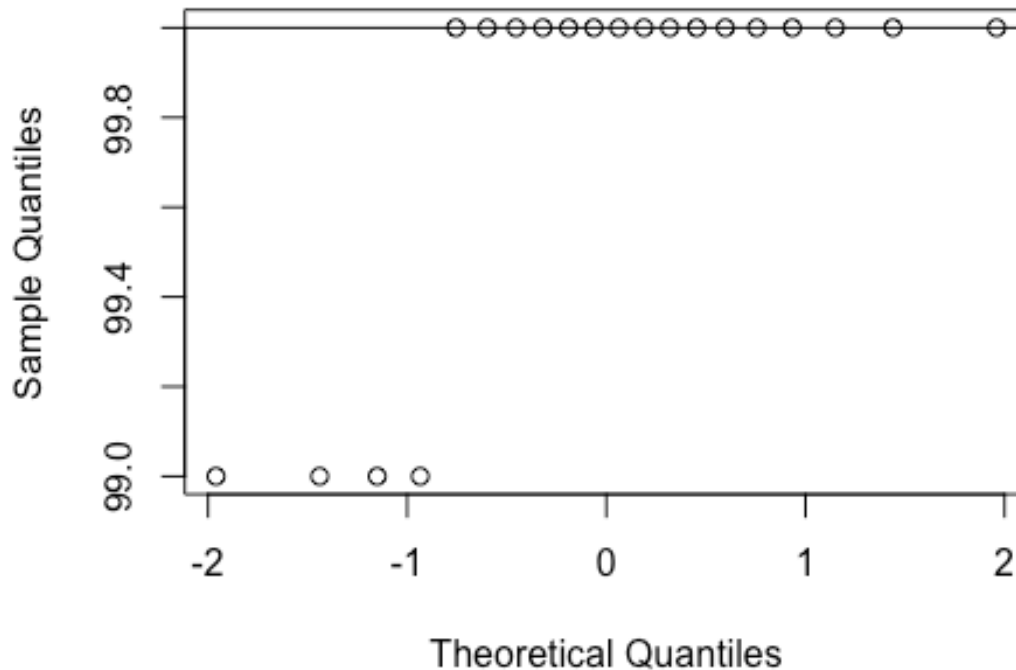
```

```

1
2
3
4 ## Wilcoxon signed rank test with continuity correction
5 ##
6 ## data: subset(SSdataCompletes, intervention == "sham")$max.sao2.tst and su
7 bset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.tst
8 ## V = 4, p-value = 0.0726
9 ## alternative hypothesis: true location shift is not equal to 0
10
11 #between participants (grouped) comparison
12 summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
13
14 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
15 ##      99.0  100.0  100.0   99.8  100.0  100.0
16
17 sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
18
19 ## [1] 0.4103913
20
21 length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
22
23 ## [1] 20
24
25 qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
26 qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
27

```

Normal Q-Q Plot

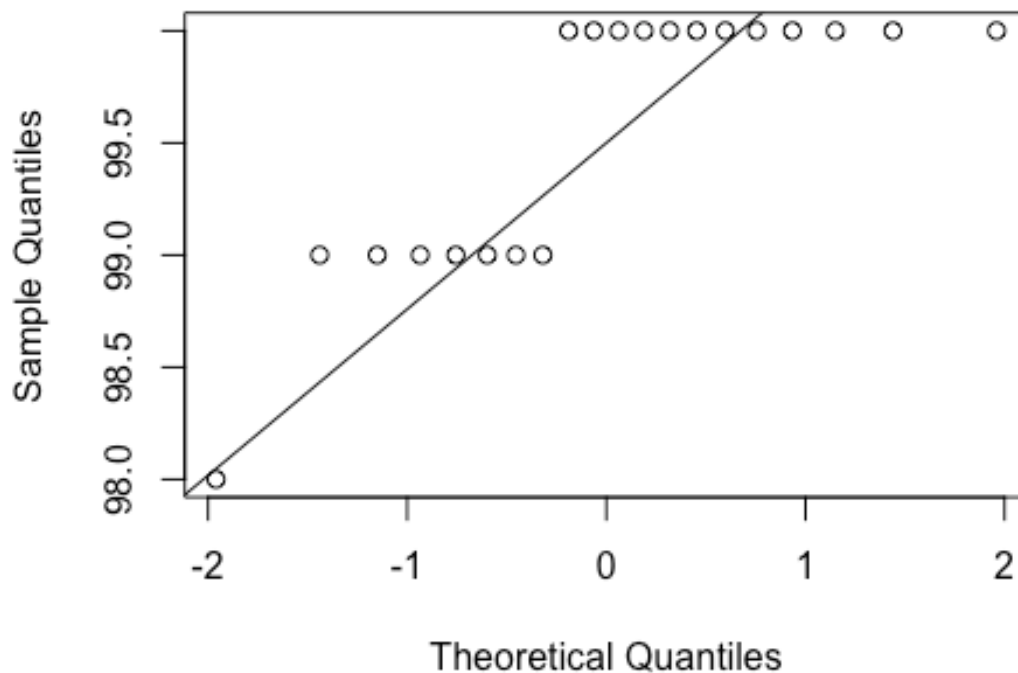


```

1 ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
2
3
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst
9 ## A = 5.1941, p-value = 2.32e-13
10
11 #non-normal
12
13 summary(subset(SSdata, intervention == "sham")$max.sao2.tst)
14
15 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
16 ##  98.00  99.00  100.00   99.55  100.00  100.00
17
18 sd(subset(SSdata, intervention == "sham")$max.sao2.tst)
19
20 ## [1] 0.6048053
21
22 length(subset(SSdata, intervention == "sham")$max.sao2.tst)
23
24 ## [1] 20
25
26 qqnorm(subset(SSdata, intervention == "sham")$max.sao2.tst)
27 qqline(subset(SSdata, intervention == "sham")$max.sao2.tst)
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```

1
2
3  ad.test(subset(SSdata, intervention == "sham")$max.sao2.tst)
4
5  ##
6  ## Anderson-Darling normality test
7  ##
8  ## data: subset(SSdata, intervention == "sham")$max.sao2.tst
9  ## A = 2.8091, p-value = 2.322e-07
10
11 #non-normal
12
13 wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.tst,
14             subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst,
15             conf.int = TRUE)
16
17 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
18 ## $max.sao2.tst, : cannot compute exact p-value with ties
19
20 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
21 ## $max.sao2.tst, : cannot compute exact confidence intervals with ties
22
23 ##
24 ## Wilcoxon rank sum test with continuity correction
25 ##
26 ## data: subset(SSdata, intervention == "sham")$max.sao2.tst and subset(SSda
27 ta, intervention == "PrenaBelt")$max.sao2.tst
28 ## W = 158, p-value = 0.1594
29 ## alternative hypothesis: true location shift is not equal to 0
30 ## 95 percent confidence interval:
31 ## -9.999288e-01 1.199059e-06
32 ## sample estimates:
33 ## difference in location
34 ## -1.027475e-05
35
36 ##### %TST with SaO2 90-100% #####
37 #Summary
38 summary(SSdata$sao2.Ptst.100to90)
39
40 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
41 ##  30.60  96.48   98.40   96.47  99.60  100.00
42
43 sd(SSdata$sao2.Ptst.100to90, na.rm = TRUE)
44
45 ## [1] 10.81533
46
47 length(SSdata$sao2.Ptst.100to90)
48
49 ## [1] 40
50
51 #ANOVA
52 night_tx_difference <- anova(lm(sao2.Ptst.100to90 ~ intervention * night,
53                               data = SSdata))
54
55 night_tx_difference
56
57
58
59
60

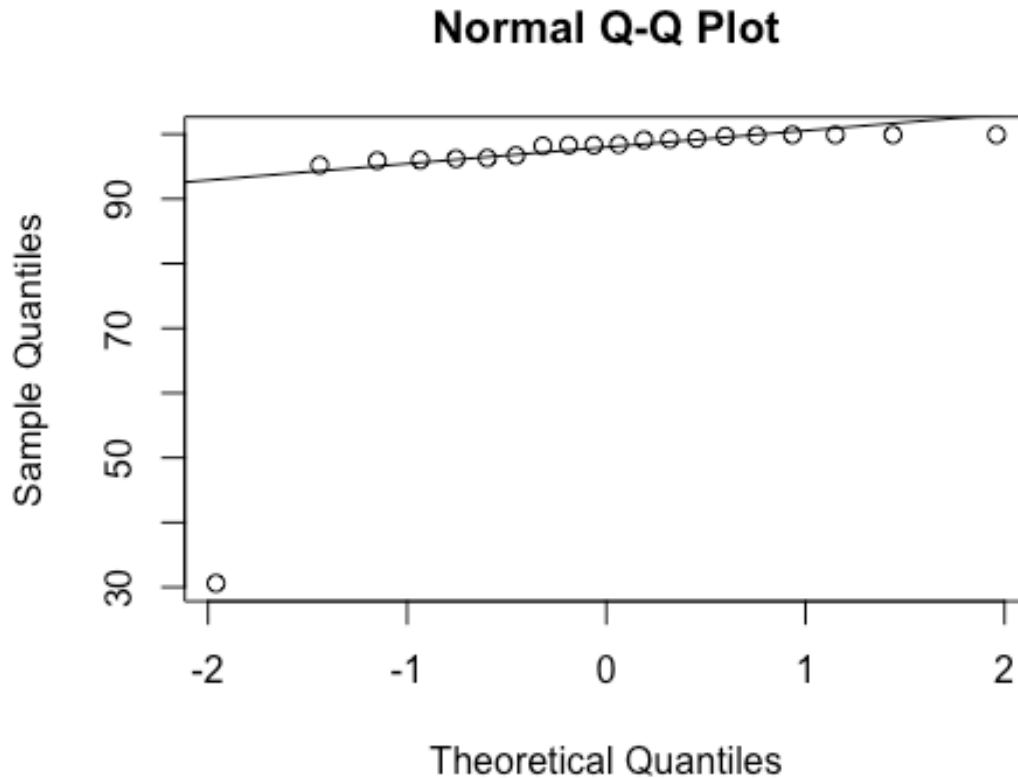
```

```

1
2
3  ## Analysis of Variance Table
4  ##
5  ## Response: sao2.Ptst.100to90
6  ##
7  ##           Df Sum Sq Mean Sq F value Pr(>F)
8  ## intervention      1  106.6   106.60   0.9253  0.3425
9  ## night              1  130.0   129.96   1.1280  0.2953
10 ## intervention:night  1  177.7   177.66   1.5420  0.2223
11 ## Residuals         36 4147.7   115.21
12
13 #within-participants (paired) comparison
14 #Paired Wilcoxon
15 wilcox.test(subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.100to90
16 ,
17           subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.100to90
18 ,
19           paired = TRUE, conf.int = TRUE)
20
21 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
22 ## "sham")$sao2.Ptst.100to90, : cannot compute exact p-value with ties
23
24 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
25 ## "sham")$sao2.Ptst.100to90, : cannot compute exact confidence interval with
26 ## ties
27
28 ##
29 ## Wilcoxon signed rank test with continuity correction
30 ##
31 ## data: subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.100to90 a
32 nd subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.100to90
33 ## V = 108, p-value = 0.9256
34 ## alternative hypothesis: true location shift is not equal to 0
35 ## 95 percent confidence interval:
36 ## -0.7499482  1.2500240
37 ## sample estimates:
38 ## (pseudo)median
39 ##      0.02366365
40
41 #between participants (grouped) comparison
42 summary(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
43
44 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
45 ##      30.60  96.28   98.35   94.84   99.72   99.90
46
47 sd(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
48
49 ## [1] 15.20458
50
51 length(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
52
53 ## [1] 20
54
55
56
57
58
59
60

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
qqline(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90
## A = 5.6171, p-value = 2.05e-14

#non-normal

summary(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  92.90  97.55   98.60   98.10  99.38  100.00

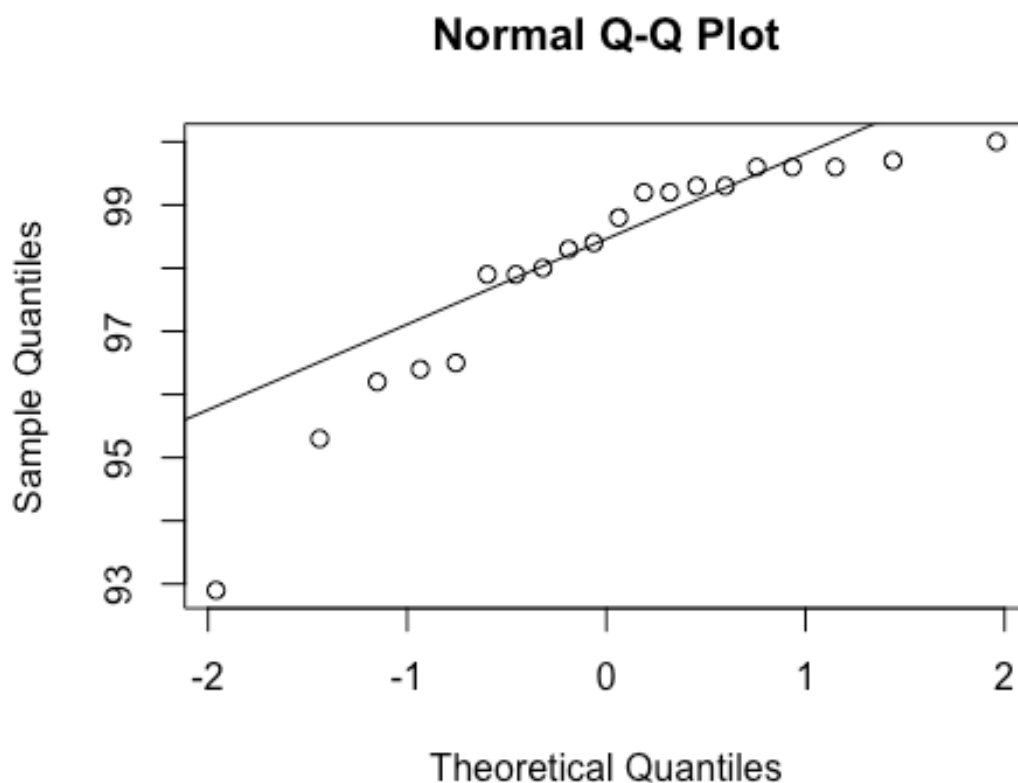
sd(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

## [1] 1.819044

length(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)
qqline(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)
```



```
ad.test(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$sao2.Ptst.100to90
## A = 1.0547, p-value = 0.006979

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90,
            subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sao2.Ptst.100to90, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sao2.Ptst.100to90, : cannot compute exact confidence intervals with ties
```



```

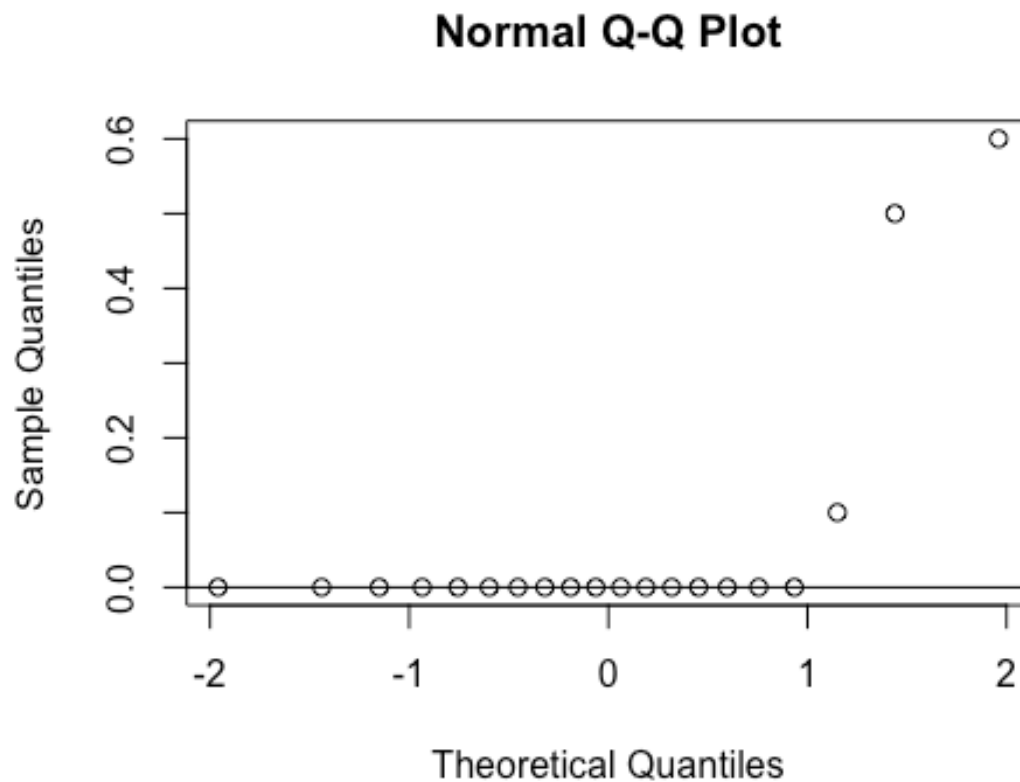
1
2
3  ##
4  ## Wilcoxon rank sum test with continuity correction
5  ##
6  ## data: subset(SSdata, intervention == "sham")$sao2.Ptst.100to90 and subset
7  (SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90
8  ## W = 199.5, p-value = 1
9  ## alternative hypothesis: true location shift is not equal to 0
10 ## 95 percent confidence interval:
11 ## -0.7000278  1.2000028
12 ## sample estimates:
13 ## difference in location
14 ## -3.177747e-05
15
16
17 ##### %TST with SaO2 85-89.9% #####
18 #Summary
19 summary(SSdata$sao2.Ptst.89.9to85)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##  0.0000  0.0000  0.0000  0.0775  0.0000  1.0000
23
24 sd(SSdata$sao2.Ptst.89.9to85, na.rm = TRUE)
25
26 ## [1] 0.2069157
27
28 length(SSdata$sao2.Ptst.89.9to85)
29
30 ## [1] 40
31
32 #ANOVA
33 night_tx_difference <- anova(lm(sao2.Ptst.89.9to85 ~ intervention * night,
34                               data = SSdata))
35
36 night_tx_difference
37
38 ## Analysis of Variance Table
39 ##
40 ## Response: sao2.Ptst.89.9to85
41 ##
42 ##           Df Sum Sq Mean Sq F value Pr(>F)
43 ## intervention      1  0.01225  0.012250   0.2994 0.58764
44 ## night              1  0.00225  0.002250   0.0550 0.81593
45 ## intervention:night  1  0.18225  0.182250   4.4542 0.04183 *
46 ## Residuals        36  1.47300  0.040917
47 ## ---
48 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
49
50 #within-participants (paired) comparison
51 #Paired Wilcoxon
52 wilcox.test(subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.89.9to8
53 5,
54               subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.89.9to8
55 5,
56               paired = TRUE, conf.int = TRUE)
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$sao2.Ptst.89.9to85, : cannot compute exact p-value with ties
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7  ## "sham")$sao2.Ptst.89.9to85, : cannot compute exact confidence interval wit
8  h
9  ## ties
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$sao2.Ptst.89.9to85, : cannot compute exact p-value with zeroes
13
14 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
15 ## "sham")$sao2.Ptst.89.9to85, : cannot compute exact confidence interval wit
16  h
17 ## zeroes
18
19 ##
20 ## Wilcoxon signed rank test with continuity correction
21 ##
22 ## data: subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.89.9to85
23 and subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
24 ## V = 18, p-value = 0.1198
25 ## alternative hypothesis: true location shift is not equal to 0
26 ## 95 percent confidence interval:
27 ## -0.0999194 0.3999194
28 ## sample estimates:
29 ## (pseudo)median
30 ## 0.1000482
31
32
33 #between participants (grouped) comparison
34 summary(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
35
36 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
37 ##      0.00   0.00   0.00   0.06   0.00   0.60
38
39 sd(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
40
41 ## [1] 0.1698296
42
43 length(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
44
45 ## [1] 20
46
47 qqnorm(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
48 qqline(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
## A = 5.7807, p-value = 8.032e-15

#non-normal

summary(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  0.095  0.100  1.000

sd(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

## [1] 0.24165

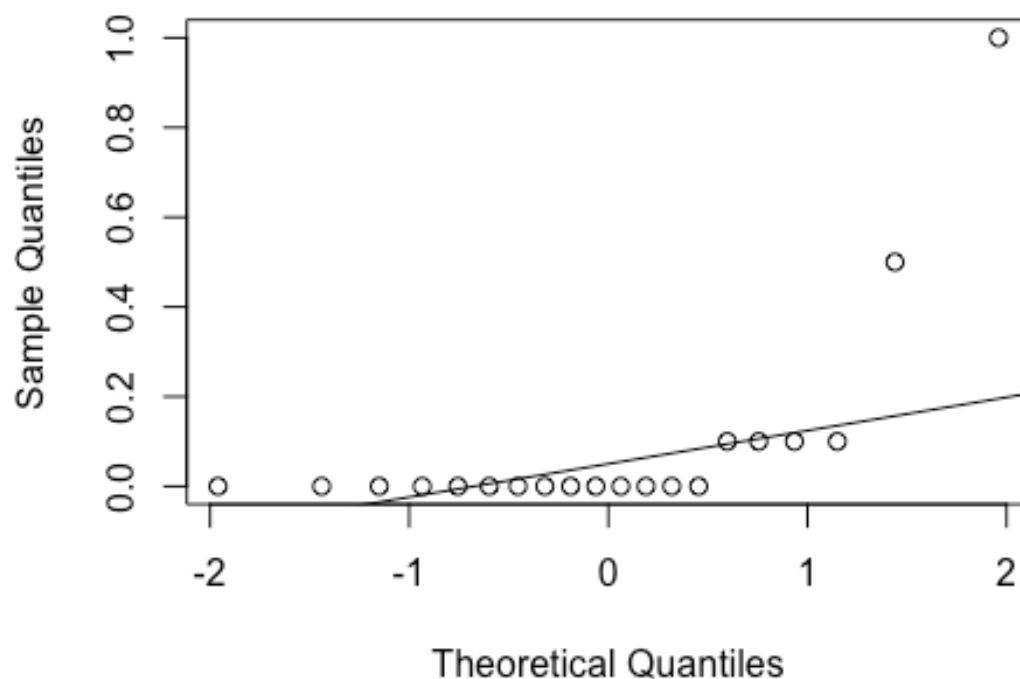
length(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)
qqline(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85
## A = 4.6098, p-value = 6.704e-12

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85,
            subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sao2.Ptst.89.9to85, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sao2.Ptst.89.9to85, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85 and subse

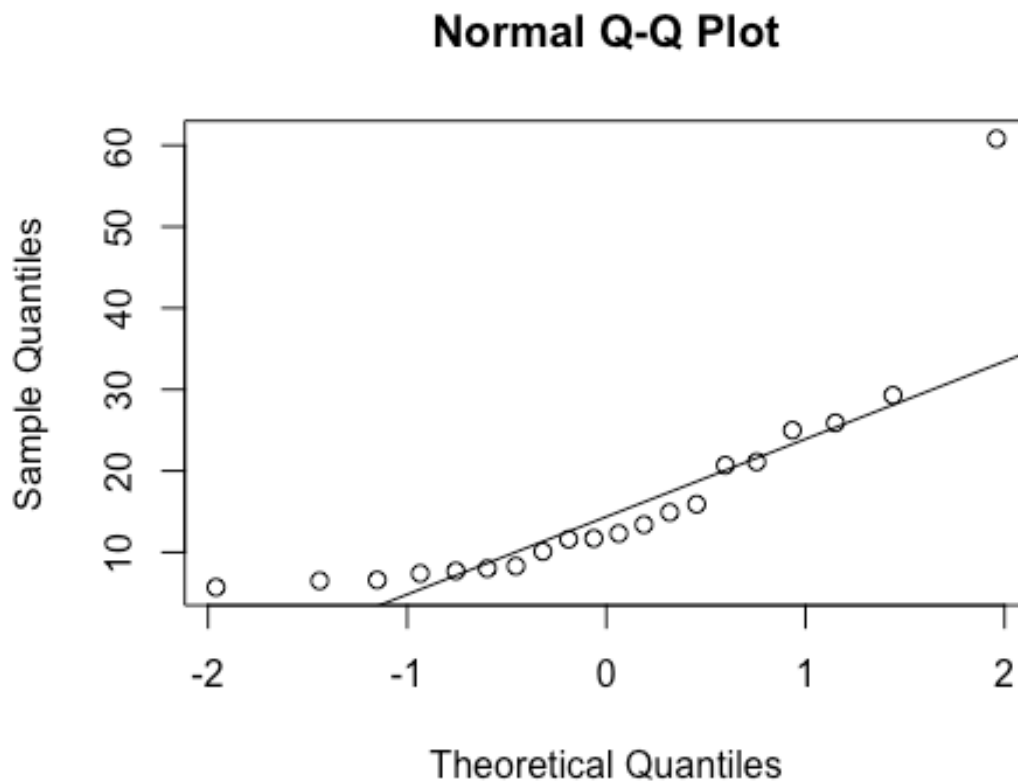
```

```

1
2
3 t(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
4 ## W = 227.5, p-value = 0.317
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -1.534144e-05 1.959457e-05
8 ## sample estimates:
9 ## difference in location
10 ## 3.556854e-06
11
12 ##### Total Arousal Index in NREM #####
13 #Summary
14 summary(SSdata$total.arousals.nrem.index)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      5.20   8.30   12.05   14.89   17.62   60.80
18
19 sd(SSdata$total.arousals.nrem.index, na.rm = TRUE)
20
21 ## [1] 10.14672
22
23 length(SSdata$total.arousals.nrem.index)
24
25 ## [1] 40
26
27 #ANOVA
28 night_tx_difference <- anova(lm(total.arousals.nrem.index ~ intervention * ni
29 ght,
30                               data = SSdata))
31
32 night_tx_difference
33
34 ## Analysis of Variance Table
35 ##
36 ## Response: total.arousals.nrem.index
37 ##
38 ##           Df Sum Sq Mean Sq F value Pr(>F)
39 ## intervention      1    63.3   63.252   0.6102 0.4398
40 ## night              1   190.5  190.532   1.8381 0.1836
41 ## intervention:night 1    29.8   29.756   0.2871 0.5954
42 ## Residuals        36  3731.7  103.660
43
44 #within-participants (paired) comparison
45 #Paired Wilcoxon
46 wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.nr
47 em.index,
48             subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals.nr
49 em.index,
50             paired = TRUE, conf.int = TRUE)
51
52 ##
53 ## Wilcoxon signed rank test
54 ##
55 ## data: subset(SSdataCompletes, intervention == "sham")$total.arousals.nrem
56 .index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousal
57
58
59
60

```

```
1
2
3 s.nrem.index
4 ## V = 100, p-value = 0.8695
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -4.70 1.65
8 ## sample estimates:
9 ## (pseudo)median
10 ## -0.2
11
12 #between participants (grouped) comparison
13 summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
14 )
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##  5.700  7.925  12.000  16.140  20.800  60.800
18
19 sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
20
21 ## [1] 12.68192
22
23 length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
24
25 ## [1] 20
26
27 qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
28 qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
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```

ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
## A = 1.5656, p-value = 0.0003422

#non-normal

summary(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   5.20   9.20   12.05   13.63   16.52   30.10

sd(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)

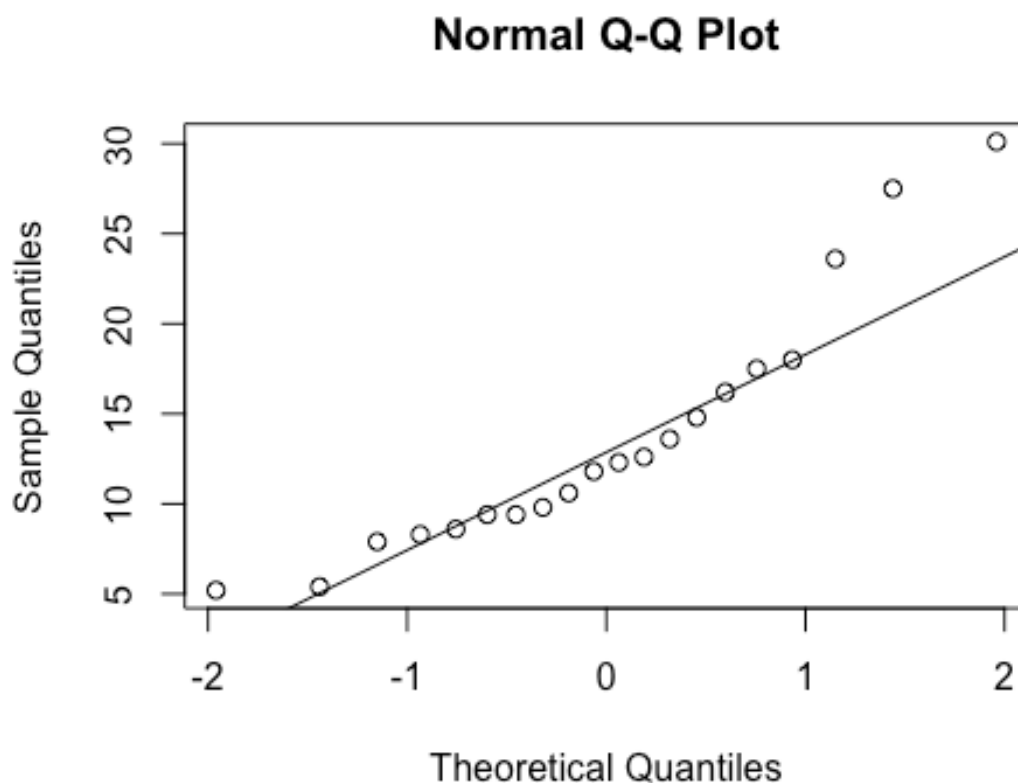
## [1] 6.868088

length(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
qqline(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$total.arousals.nrem.index
## A = 0.79128, p-value = 0.03318

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$total.arousals.nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.i
            ndex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $total.arousals.nrem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $total.arousals.nrem.index, : cannot compute exact confidence intervals
## with ties
```



```

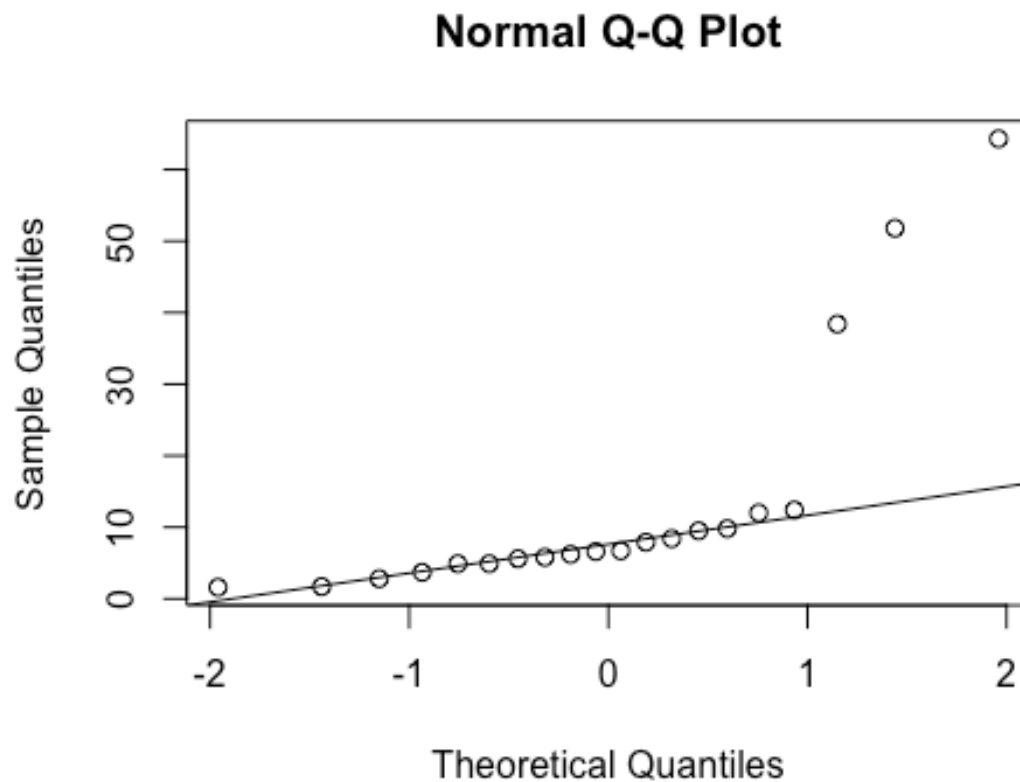
1
2
3  ##
4  ## Wilcoxon rank sum test with continuity correction
5  ##
6  ## data: subset(SSdata, intervention == "sham")$total.arousals.nrem.index an
7  d subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
8  ## W = 198, p-value = 0.9676
9  ## alternative hypothesis: true location shift is not equal to 0
10 ## 95 percent confidence interval:
11 ## -4.900032  3.200041
12 ## sample estimates:
13 ## difference in location
14 ## -0.09996643
15
16
17 ##### Total Arousal Index in REM #####
18 #Summary
19 summary(SSdata$total.arousals.rem.index)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      0.00   4.15   7.30  12.68  10.35   84.00
23
24 sd(SSdata$total.arousals.rem.index, na.rm = TRUE)
25
26 ## [1] 17.59224
27
28 length(SSdata$total.arousals.rem.index)
29
30 ## [1] 40
31
32 #ANOVA
33 night_tx_difference <- anova(lm(total.arousals.rem.index ~ intervention * nig
34 ht,
35                               data = SSdata))
36
37 night_tx_difference
38
39 ## Analysis of Variance Table
40 ##
41 ## Response: total.arousals.rem.index
42 ##
43 ##      Df Sum Sq Mean Sq F value Pr(>F)
44 ## intervention      1    13.1   13.11  0.0447 0.83377
45 ## night              1    10.3   10.30  0.0351 0.85241
46 ## intervention:night  1 1484.7 1484.74  5.0607 0.03068 *
47 ## Residuals        36 10561.8  293.38
48 ## ---
49 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
50
51 #within-participants (paired) comparison
52 #Paired t-test
53 wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.re
54 m.index,
55 subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals.re
56 m.index,
57 paired = TRUE, conf.int = TRUE)
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$total.arousals.rem.index, : cannot compute exact p-value with ties
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention
7  ## == "sham")$total.arousals.rem.index, : cannot compute exact confidence
8  ## interval with ties
9
10 ##
11 ## Wilcoxon signed rank test with continuity correction
12 ##
13 ## data: subset(SSdataCompletes, intervention == "sham")$total.arousals.rem.
14 index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals
15 .rem.index
16 ## V = 91, p-value = 0.6142
17 ## alternative hypothesis: true location shift is not equal to 0
18 ## 95 percent confidence interval:
19 ## -3.350040  2.100039
20 ## sample estimates:
21 ## (pseudo)median
22 ## -0.4334441
23
24
25 #between participants (grouped) comparison
26 summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
27
28 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
29 ##      1.60   4.90   6.65  13.25  10.35   64.30
30
31 sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
32
33 ## [1] 17.26717
34
35 length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
36
37 ## [1] 20
38
39 qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
40 qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
41
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```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index
## A = 3.3345, p-value = 1.085e-08

#non-normal

summary(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  3.975   8.000  12.100  10.220  84.000

sd(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

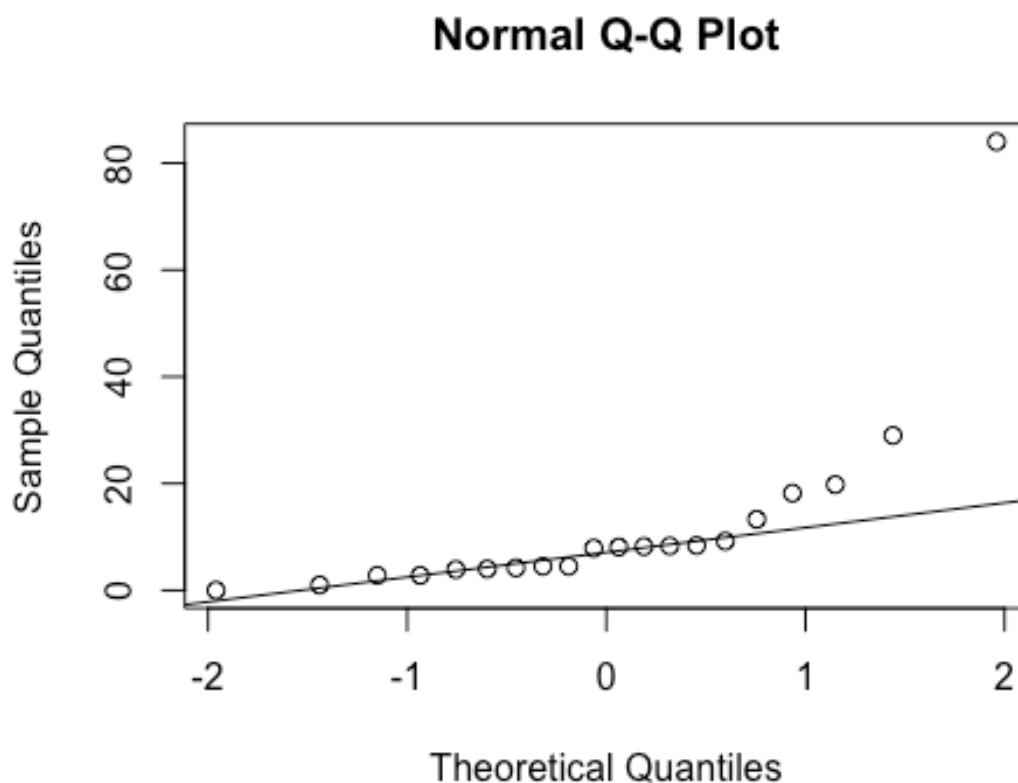
## [1] 18.34168

length(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "sham")$total.arousals.rem.index)
qqline(subset(SSdata, intervention == "sham")$total.arousals.rem.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$total.arousals.rem.index
## A = 3.0671, p-value = 5.152e-08

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$total.arousals.rem.index,
            subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.in
dex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $total.arousals.rem.index, : cannot compute exact p-value with ties

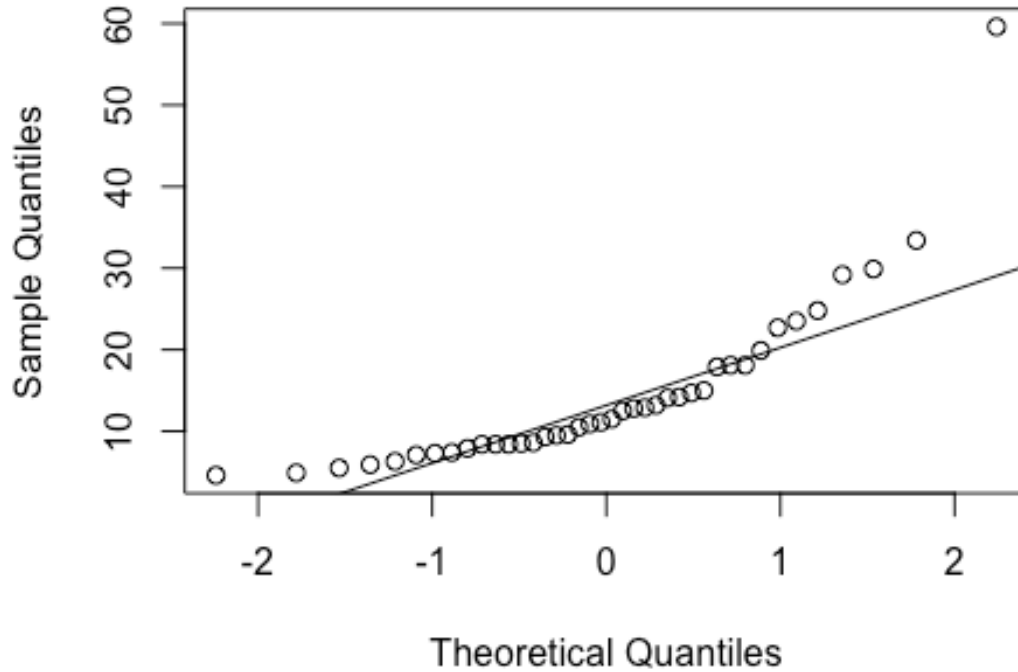
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $total.arousals.rem.index, : cannot compute exact confidence intervals wit
```

```

1
2
3 h
4 ## ties
5
6 ##
7 ## Wilcoxon rank sum test with continuity correction
8 ##
9 ## data: subset(SSdata, intervention == "sham")$total.arousals.rem.index and
10 subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index
11 ## W = 186, p-value = 0.7149
12 ## alternative hypothesis: true location shift is not equal to 0
13 ## 95 percent confidence interval:
14 ## -3.899974 2.800023
15 ## sample estimates:
16 ## difference in location
17 ## -0.6999841
18
19
20 ##### Total Arousal Index (TST = NREM + REM) #####
21 #####
22 #Summary
23 summary(SSdata$total.arousals.total.index)
24
25 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
26 ##      4.60   8.40   11.30   14.45   17.95   59.60
27
28 sd(SSdata$total.arousals.total.index, na.rm = TRUE)
29
30 ## [1] 10.25068
31
32 length(SSdata$total.arousals.total.index)
33
34 ## [1] 40
35
36 qqnorm(SSdata$total.arousals.total.index)
37 qqline(SSdata$total.arousals.total.index)
38
39
40
41
42
43
44
45
46
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```

Normal Q-Q Plot



```
ad.test(SSdata$total.arousals.total.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$total.arousals.total.index
## A = 2.5308, p-value = 1.638e-06

#non-normal

#ANOVA
night_tx_difference <- anova(lm(total.arousals.total.index ~ intervention * n
ight,
                               data = SSdata))
night_tx_difference

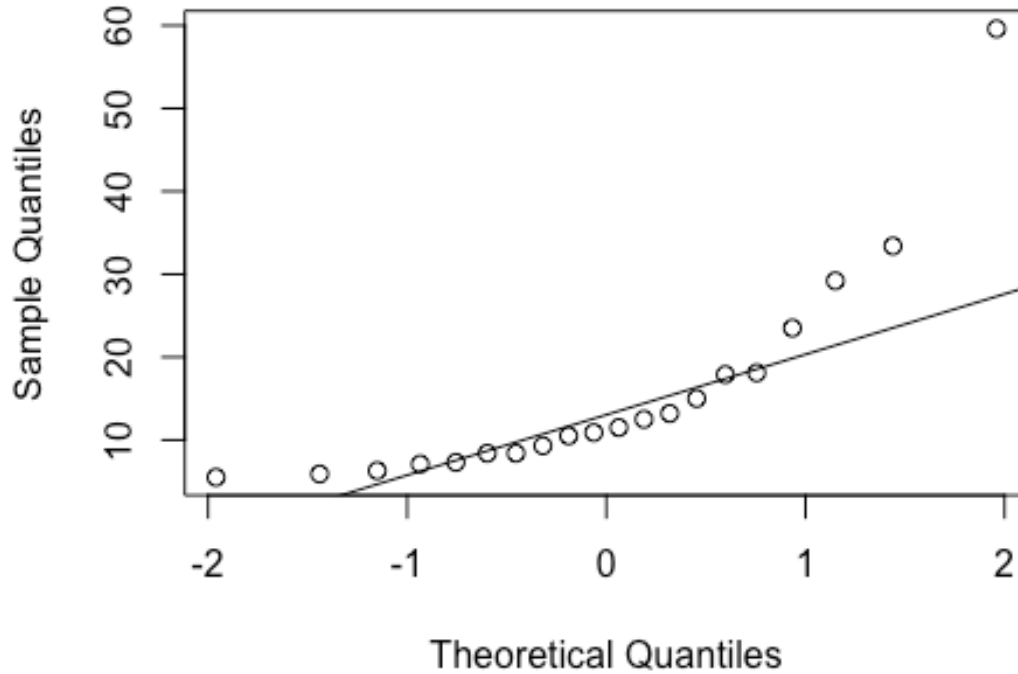
## Analysis of Variance Table
##
## Response: total.arousals.total.index
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention      1    59.8   59.78   0.5720  0.4544
## night              1   158.0  158.01   1.5119  0.2268
## intervention:night 1   118.0  117.99   1.1291  0.2951
## Residuals        36 3762.2  104.51
```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.to
6 tal.index,
7             subset(SSdataCompletes, intervention == "PrenaBelt")$total.
8 arousal.s.total.index,
9             paired = TRUE, conf.int = TRUE)
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$total.arousals.total.index, : cannot compute exact p-value with
13 ## ties
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$total.arousals.total.index, : cannot compute exact confidence
17 ## interval with ties
18
19 ##
20 ## Wilcoxon signed rank test with continuity correction
21 ##
22 ## data: subset(SSdataCompletes, intervention == "sham")$total.arousals.tota
23 l.index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousa
24 ls.total.index
25 ## V = 90, p-value = 0.5883
26 ## alternative hypothesis: true location shift is not equal to 0
27 ## 95 percent confidence interval:
28 ## -3.499935  1.499994
29 ## sample estimates:
30 ## (pseudo)median
31 ## -0.5984439
32
33 #between participants (grouped) comparison
34 summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.inde
35 x)
36
37 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
38 ##  5.500  8.125  11.200  15.680  17.950  59.600
39
40 sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index)
41
42 ## [1] 12.89508
43
44 length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
45 )
46
47 ## [1] 20
48
49 qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
50 )
51
52 qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
53 )
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
## A = 1.7931, p-value = 8.964e-05
##non-normal

summary(subset(SSdata, intervention == "sham")$total.arousals.total.index)
##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  4.600  8.475 11.950 13.230 15.550 29.900

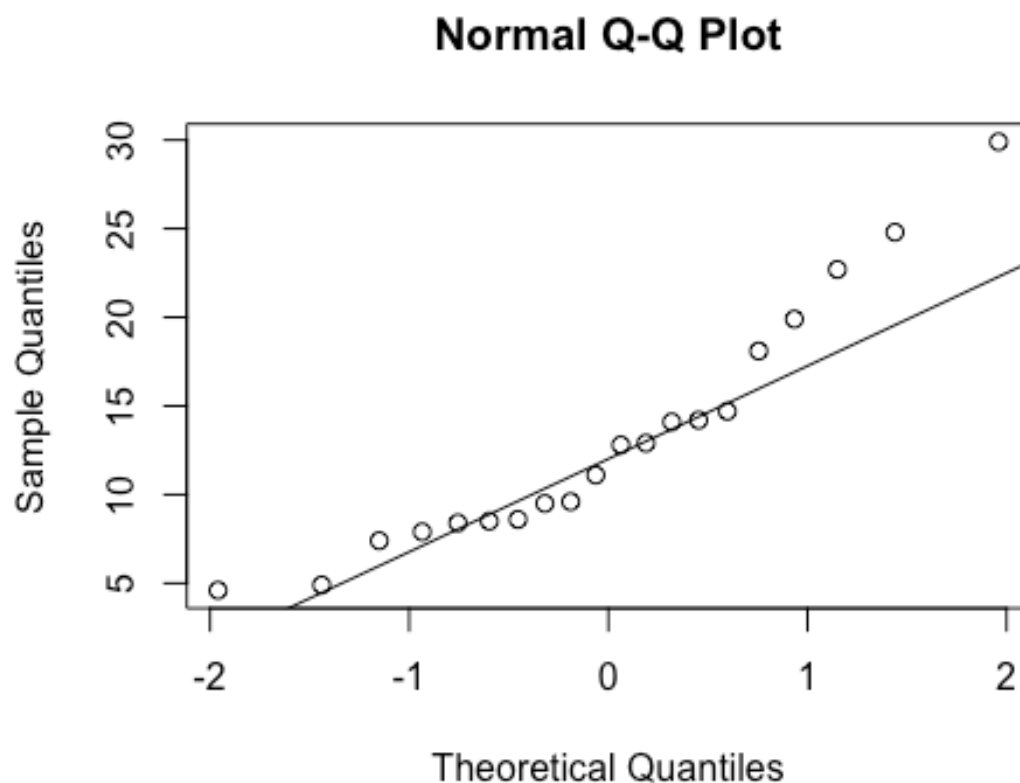
sd(subset(SSdata, intervention == "sham")$total.arousals.total.index)
## [1] 6.801014

length(subset(SSdata, intervention == "sham")$total.arousals.total.index)
## [1] 20

```



```
qqnorm(subset(SSdata, intervention == "sham")$total.arousals.total.index)
qqline(subset(SSdata, intervention == "sham")$total.arousals.total.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$total.arousals.total.index
## A = 0.65641, p-value = 0.07378

#normal

t.test(subset(SSdata, intervention == "sham")$total.arousals.total.index,
       subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$total.arousals.total.index and
subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
## t = -0.75003, df = 28.811, p-value = 0.4593
## alternative hypothesis: true difference in means is not equal to 0
```

```

1
2
3  ## 95 percent confidence interval:
4  ## -9.11411  4.22411
5  ## sample estimates:
6  ## mean of x mean of y
7  ##    13.230    15.675
8
9  wilcox.test(subset(SSdata, intervention == "sham")$total.arousals.total.index
10 ,
11             subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.
12 index,
13             conf.int = TRUE)
14
15  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
16  ## $total.arousals.total.index, : cannot compute exact p-value with ties
17
18  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
19  ## $total.arousals.total.index, : cannot compute exact confidence intervals
20  ## with ties
21
22  ##
23  ## Wilcoxon rank sum test with continuity correction
24  ##
25  ## data: subset(SSdata, intervention == "sham")$total.arousals.total.index a
26  nd subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
27  ## W = 201.5, p-value = 0.9784
28  ## alternative hypothesis: true location shift is not equal to 0
29  ## 95 percent confidence interval:
30  ## -4.099936  3.599950
31  ## sample estimates:
32  ## difference in location
33  ##             0.04235554
34
35  ##### Spontaneous Arousal Index in NREM #####
36  #
37  #Summary
38  summary(SSdata$spontaneous.arousals.nrem.index)
39
40  ##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
41  ##  0.800  7.475  10.550  11.490  13.180  26.500
42
43  sd(SSdata$spontaneous.arousals.nrem.index, na.rm = TRUE)
44
45  ## [1] 6.188624
46
47  length(SSdata$spontaneous.arousals.nrem.index)
48
49  ## [1] 40
50
51  #ANOVA
52  night_tx_difference <- anova(lm(spontaneous.arousals.nrem.index ~ interventio
53  n * night,
54
55
56
57
58
59
60

```

```

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```

```

                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: spontaneous.arousals.nrem.index
##
##           Df  Sum Sq Mean Sq F value Pr(>F)
## intervention    1    0.03   0.030  0.0007 0.9784
## night           1   26.73  26.732  0.6565 0.4231
## intervention:night 1    1.06   1.056  0.0259 0.8729
## Residuals      36 1465.84  40.718

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arousals.nrem.index,
            subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arousals.nrem.index,
            paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$spontaneous.arousals.nrem.index, : cannot compute exact p-value
## with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$spontaneous.arousals.nrem.index, : cannot compute exact confidence
## interval with ties

##
## Wilcoxon signed rank test with continuity correction
##
## data: subset(SSdataCompletes, intervention == "sham")$spontaneous.arousals.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arousals.nrem.index
## V = 116.5, p-value = 0.6813
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
## -2.650033  1.900025
## sample estimates:
## (pseudo)median
##      0.3000532

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      2.000   7.375  10.750  11.520  13.850  25.000

sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.index)

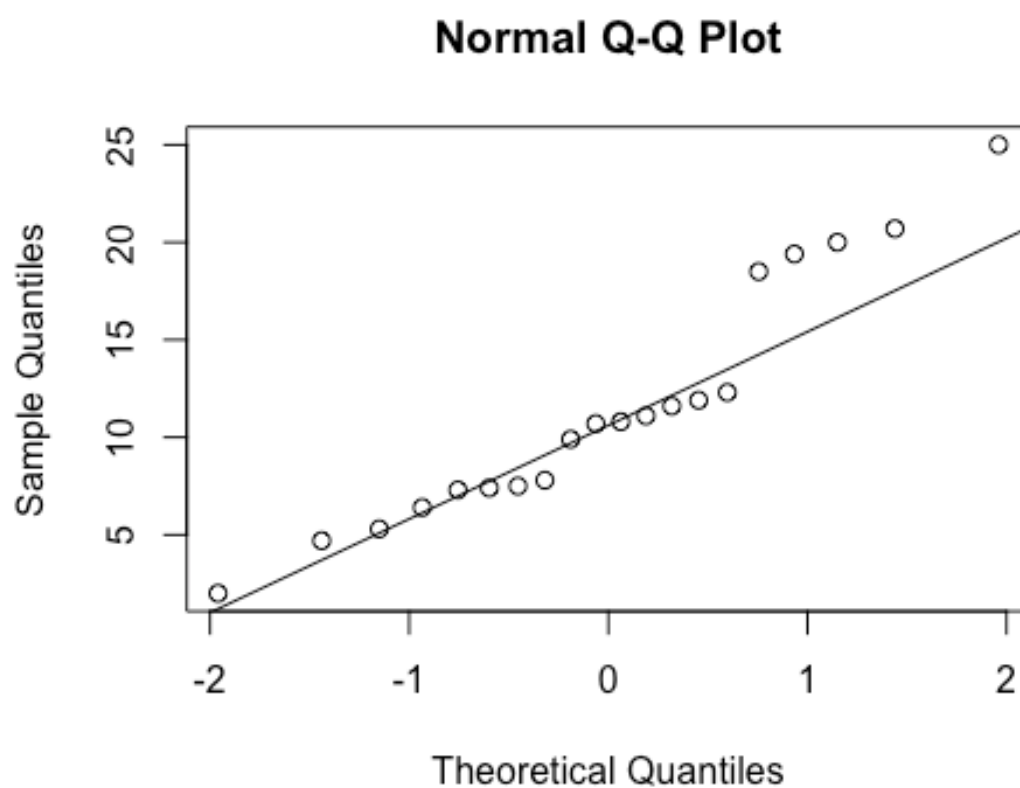
```

```
## [1] 6.15709

length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
index)
qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
index
## A = 0.69502, p-value = 0.05869

#normal
```

```

summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.80   7.85   10.15   11.46   13.18   26.50

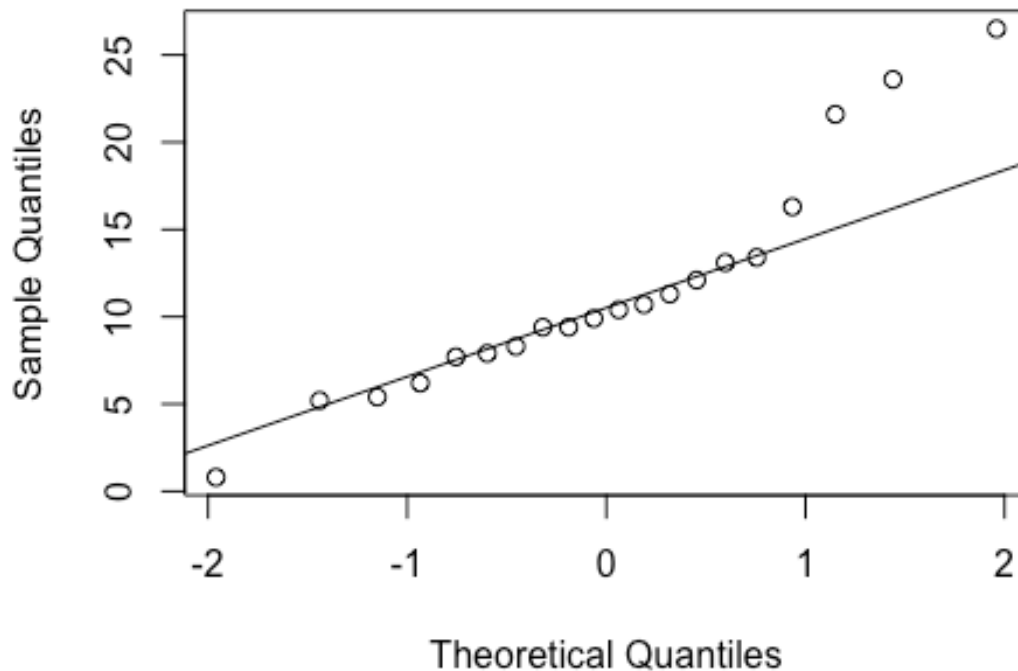
sd(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
## [1] 6.379853

length(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
qqline(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
##
## Anderson-Darling normality test

```

```
1
2
3 ##
4 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
5 dex
6 ## A = 0.77235, p-value = 0.03712
7
8 #non-normal
9
10 t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index
11 ,
12         subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
13 index)
14
15 ##
16 ## Welch Two Sample t-test
17 ##
18 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
19 dex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
20 .index
21 ## t = -0.027742, df = 37.952, p-value = 0.978
22 ## alternative hypothesis: true difference in means is not equal to 0
23 ## 95 percent confidence interval:
24 ## -4.068685  3.958685
25 ## sample estimates:
26 ## mean of x mean of y
27 ## 11.460 11.515
28
29 wilcox.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.
30 index,
31             subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.
32 nrem.index,
33             conf.int = TRUE)
34
35 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
36 ## $spontaneous.arousals.nrem.index, : cannot compute exact p-value with ties
37
38 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
39 ## $spontaneous.arousals.nrem.index, : cannot compute exact confidence
40 ## intervals with ties
41
42 ##
43 ## Wilcoxon rank sum test with continuity correction
44 ##
45 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
46 dex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
47 .index
48 ## W = 203, p-value = 0.9461
49 ## alternative hypothesis: true location shift is not equal to 0
50 ## 95 percent confidence interval:
51 ## -3.399998  3.200034
52 ## sample estimates:
```

```

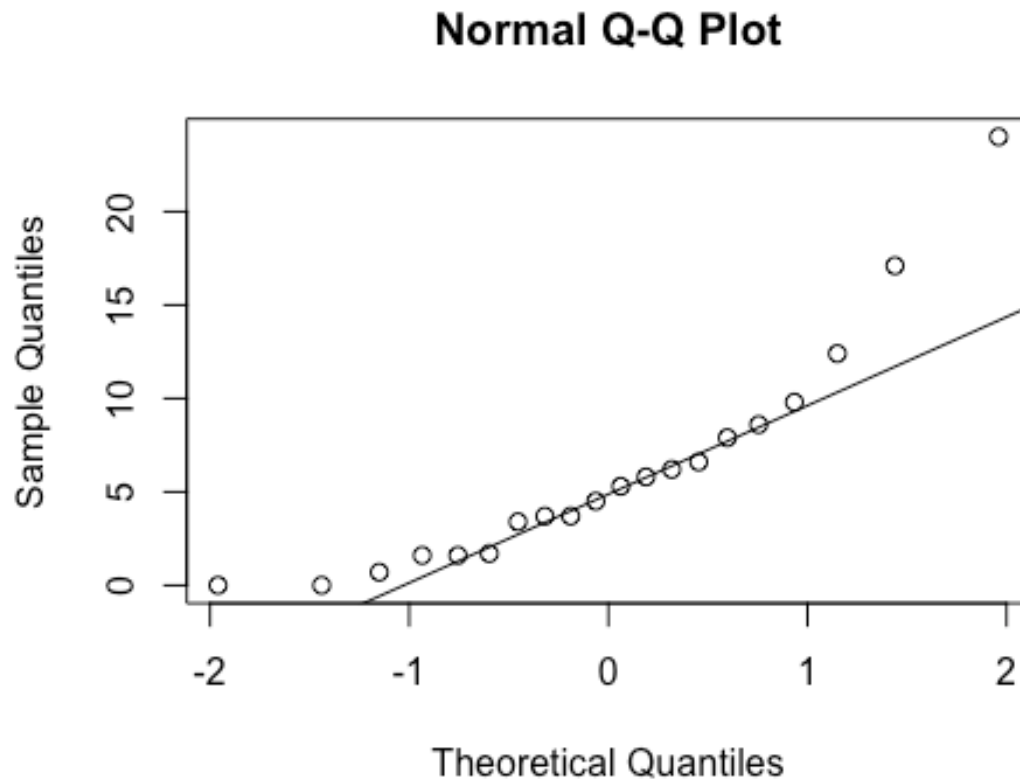
1
2
3  ## difference in location
4  ##           0.15
5
6  ##### Spontaneous Arousal Index in REM #####
7  #Summary
8  summary(SSdata$spontaneous.arousals.rem.index)
9
10 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11 ##  0.000  2.000  4.250   5.612  7.950  24.000
12
13 sd(SSdata$spontaneous.arousals.rem.index, na.rm = TRUE)
14
15 ## [1] 4.976312
16
17 length(SSdata$spontaneous.arousals.rem.index)
18
19 ## [1] 40
20
21 #ANOVA
22 night_tx_difference <- anova(lm(spontaneous.arousals.rem.index ~ intervention
23 * night,
24                               data = SSdata))
25
26 night_tx_difference
27
28 ## Analysis of Variance Table
29 ##
30 ## Response: spontaneous.arousals.rem.index
31 ##           Df Sum Sq Mean Sq F value Pr(>F)
32 ## intervention     1  15.25   15.252   0.6246 0.4345
33 ## night             1  37.44   37.442   1.5334 0.2236
34 ## intervention:night 1  34.04   34.040   1.3941 0.2455
35 ## Residuals       36 879.05   24.418
36
37 #within-participants (paired) comparison
38 #Paired Wilcoxon
39 wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
40 als.rem.index,
41             subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
42 als.rem.index,
43             paired = TRUE, conf.int = TRUE)
44
45 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
46 ## "sham")$spontaneous.arousals.rem.index, : cannot compute exact p-value wit
47 h
48 ## ties
49
50 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
51 ## "sham")$spontaneous.arousals.rem.index, : cannot compute exact confidence
52 ## interval with ties
53
54 ##
55 ## Wilcoxon signed rank test with continuity correction

```

```

1
2
3
4  ##
5  ## data: subset(SSdataCompletes, intervention == "sham")$spontaneous.arousals.rem.index
6  ## and subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arousals.rem.index
7  ## V = 93, p-value = 0.6676
8  ## alternative hypothesis: true location shift is not equal to 0
9  ## 95 percent confidence interval:
10 ## -2.950065  1.549957
11 ## sample estimates:
12 ## (pseudo)median
13 ## -0.3500398
14
15
16  #between participants (grouped) comparison
17  summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index)
18
19
20  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
21  ##  0.000  1.675   4.900   6.230  8.075  24.000
22
23  sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index)
24
25
26  ## [1] 6.025132
27
28  length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index)
29
30
31  ## [1] 20
32
33  qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index)
34
35  qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index)
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

```

ad.test(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.
index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.re
m.index
## A = 0.94606, p-value = 0.01327

#non-normal

summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index
)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  2.400  3.800  4.995  7.800 14.000

sd(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)

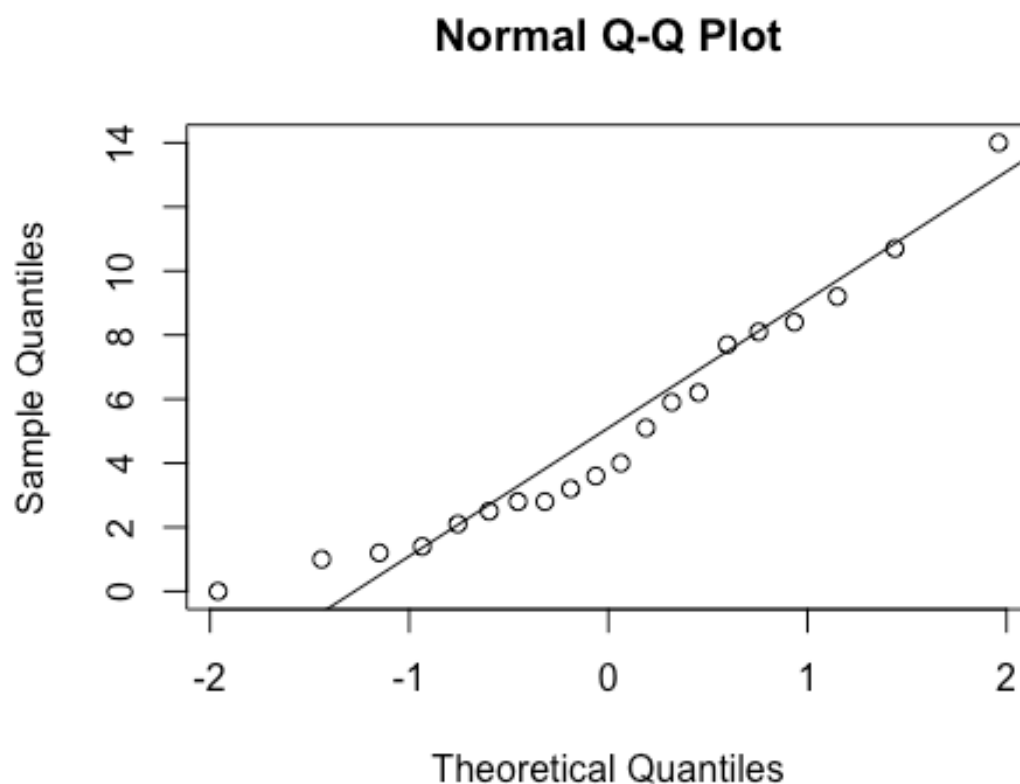
## [1] 3.70483

length(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)

```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)
qqline(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index
## A = 0.47886, p-value = 0.2093
```

```
#normal
```

```
t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index,
       subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index)
```

```
##
## Welch Two Sample t-test
##
```

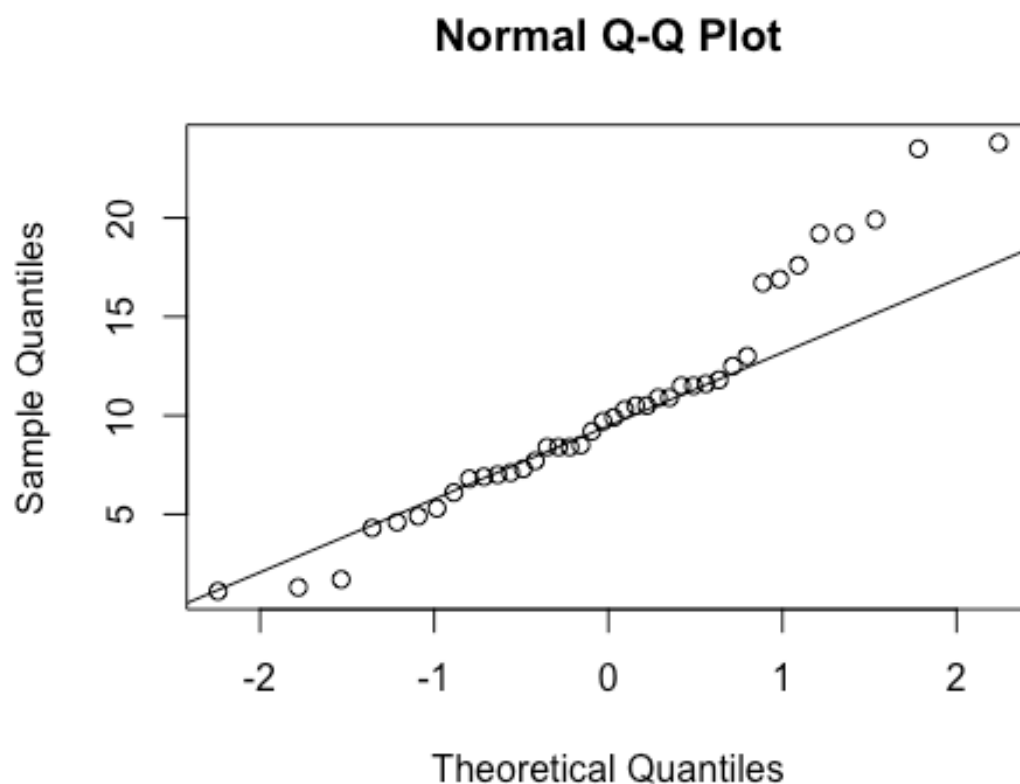
```

1
2
3  ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.ind
4  ex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
5  ndex
6  ## t = -0.78086, df = 31.571, p-value = 0.4407
7  ## alternative hypothesis: true difference in means is not equal to 0
8  ## 95 percent confidence interval:
9  ## -4.458294  1.988294
10 ## sample estimates:
11 ## mean of x mean of y
12 ##      4.995      6.230
13
14 wilcox.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.i
15 ndex,
16           subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.
17 rem.index,
18           conf.int = TRUE)
19
20
21 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
22 ## $spontaneous.arousals.rem.index, : cannot compute exact p-value with ties
23
24 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
25 ## $spontaneous.arousals.rem.index, : cannot compute exact confidence
26 ## intervals with ties
27
28 ##
29 ## Wilcoxon rank sum test with continuity correction
30 ##
31 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.ind
32 ex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
33 ndex
34 ## W = 185.5, p-value = 0.7048
35 ## alternative hypothesis: true location shift is not equal to 0
36 ## 95 percent confidence interval:
37 ## -3.199951  2.099934
38 ## sample estimates:
39 ## difference in location
40 ##      -0.4476729
41
42 ##### Spontaneous Arousal Index (TST = NREM + REM) #####
43 #####
44 #Summary
45 summary(SSdata$spontaneous.arousals.total.index)
46
47 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
48 ##   1.100   6.975   9.800  10.410  11.980  23.800
49
50 sd(SSdata$spontaneous.arousals.total.index, na.rm = TRUE)
51
52 ## [1] 5.594264
53
54 length(SSdata$spontaneous.arousals.total.index)
55
56
57
58
59
60

```

```
## [1] 40
```

```
qqnorm(SSdata$spontaneous.arousals.total.index)
qqline(SSdata$spontaneous.arousals.total.index)
```



```
ad.test(SSdata$spontaneous.arousals.total.index)
```

```
##
## Anderson-Darling normality test
##
## data:  SSdata$spontaneous.arousals.total.index
## A = 0.84189, p-value = 0.02744
```

```
#non-normal
```

```
#ANOVA
```

```
night_tx_difference <- anova(lm(spontaneous.arousals.total.index ~ interventi
on * night,
                                data = SSdata))
night_tx_difference
```

```
## Analysis of Variance Table
```

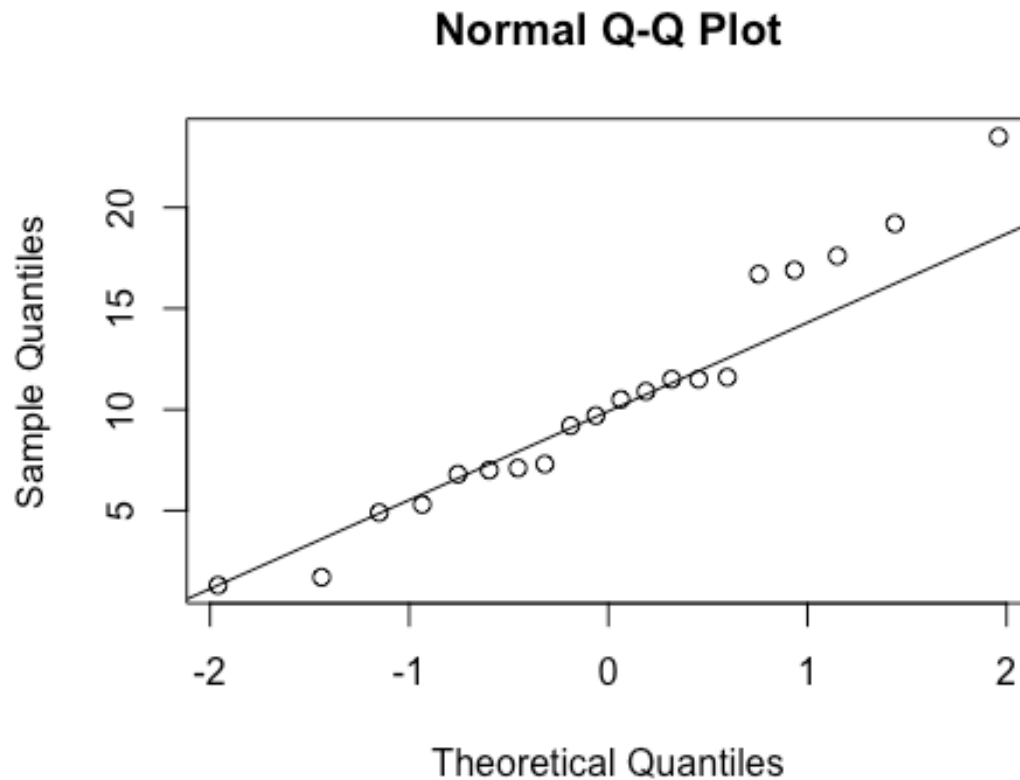
```
##
## Response: spontaneous.arousals.total.index
```

```

1
2
3      ##                Df   Sum Sq Mean Sq F value Pr(>F)
4      ## intervention      1    0.40   0.400  0.0120 0.9132
5      ## night            1   23.72  23.716  0.7138 0.4038
6      ## intervention:night 1    0.26   0.256  0.0077 0.9305
7      ## Residuals       36 1196.16  33.227
8
9      #within-participants (paired) comparison
10     #Paired t-test
11     t.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arousals.t
12     otal.index,
13           subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
14     als.total.index,
15           paired = TRUE)
16
17
18     ##
19     ## Paired t-test
20     ##
21     ## data: subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
22     s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$sponta
23     neous.arousals.total.index
24     ## t = -0.17543, df = 19, p-value = 0.8626
25     ## alternative hypothesis: true difference in means is not equal to 0
26     ## 95 percent confidence interval:
27     ## -2.586125  2.186125
28     ## sample estimates:
29     ## mean of the differences
30     ## -0.2
31
32     #Double check with Wilcoxon (borderline normal)
33     wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
34     als.total.index,
35               subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
36     als.total.index,
37               paired = TRUE, conf.int = TRUE)
38
39     ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
40     ## "sham")$spontaneous.arousals.total.index, : cannot compute exact p-value
41     ## with ties
42
43     ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
44     ## "sham")$spontaneous.arousals.total.index, : cannot compute exact confidenc
45     e
46     ## interval with ties
47
48     ##
49     ## Wilcoxon signed rank test with continuity correction
50     ##
51     ## data: subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
52     s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$sponta
53     neous.arousals.total.index
54     ## V = 114.5, p-value = 0.7368
55
56
57
58
59
60

```

```
1
2
3 ## alternative hypothesis: true location shift is not equal to 0
4 ## 95 percent confidence interval:
5 ## -2.500005 1.850093
6 ## sample estimates:
7 ## (pseudo)median
8 ## 0.25
9
10 #between participants (grouped) comparison
11 summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
12
13
14 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
15 ##      1.30   6.95   10.10   10.51   12.88   23.50
16
17 sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
18
19
20 ## [1] 5.841854
21
22 length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
23
24
25 ## [1] 20
26
27 qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
28
29 qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index
## A = 0.37989, p-value = 0.3699

#normal

summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      1.10   7.50   9.20  10.31  11.98  23.80

sd(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)

## [1] 5.485474

length(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)

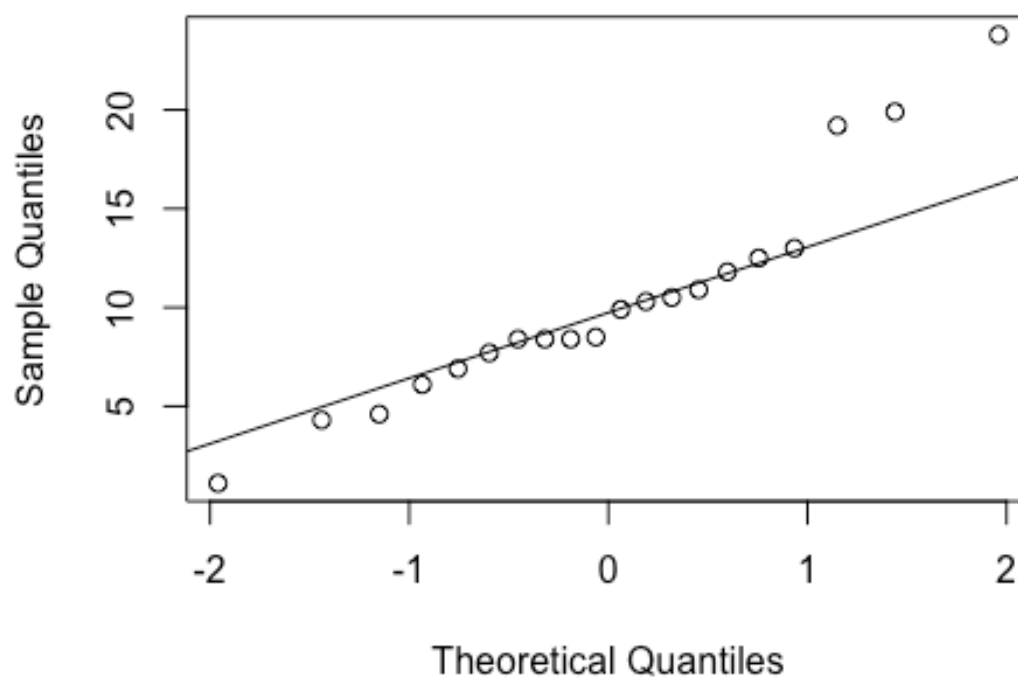
```

```

1
2
3  ## [1] 20
4
5 qqnorm(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
6 x)
7 qqline(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
8 x)
9

```

Normal Q-Q Plot



```

39 ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.ind
40 ex)
41
42 ##
43 ## Anderson-Darling normality test
44 ##
45 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.total.i
46 ndex
47 ## A = 0.71308, p-value = 0.05273
48
49 #normal
50
51 t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
52 x,
53 subset(SSdata, intervention == "PrenaBeIt")$spontaneous.arousals.total
54 .index)
55

```



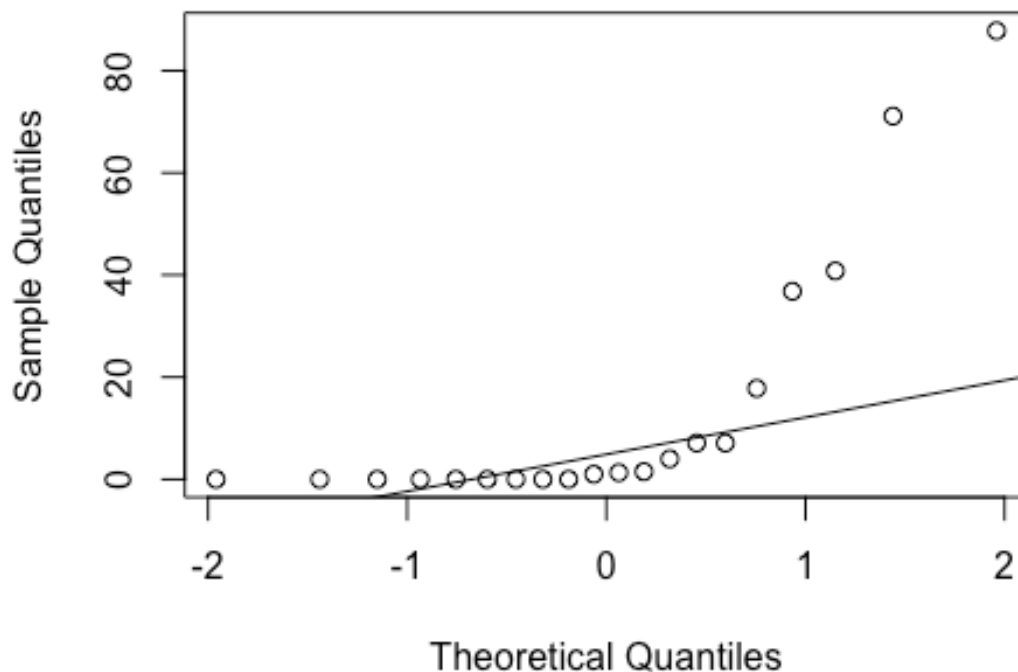
```

1
2
3
4  ## Welch Two Sample t-test
5  ##
6  ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.total.i
7  ndex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.tot
8  al.index
9
10 ## t = -0.11161, df = 37.85, p-value = 0.9117
11 ## alternative hypothesis: true difference in means is not equal to 0
12 ## 95 percent confidence interval:
13 ## -3.827971  3.427971
14 ## sample estimates:
15 ## mean of x mean of y
16 ##      10.31      10.51
17
18 ##### PLMs Index in NREM #####
19 #Summary
20 summary(SSdata$plms.nrem.index)
21
22 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
23 ##      0.000   0.000   0.850  13.280   9.775  87.800
24
25 sd(SSdata$plms.nrem.index, na.rm = TRUE)
26
27 ## [1] 24.58884
28
29 length(SSdata$plms.nrem.index)
30
31 ## [1] 40
32
33 #ANOVA
34 night_tx_difference <- anova(lm(plms.nrem.index ~ intervention * night,
35                               data = SSdata))
36
37 night_tx_difference
38
39 ## Analysis of Variance Table
40 ##
41 ## Response: plms.nrem.index
42 ##
43 ##      Df Sum Sq Mean Sq F value Pr(>F)
44 ## intervention      1    11.6   11.56  0.0178 0.8945
45 ## night              1   213.9  213.91  0.3303 0.5691
46 ## intervention:night  1    40.6   40.60  0.0627 0.8037
47 ## Residuals        36 23313.8  647.60
48
49 #within-participants (paired) comparison
50 #Paired Wilcoxon
51 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.nrem.index,
52             subset(SSdataCompletes, intervention == "PrenaBelt")$plms.nrem.index,
53             paired = TRUE, conf.int = TRUE)
54
55 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
56 ## "sham")$plms.nrem.index, : cannot compute exact p-value with zeroes

```

```
1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$plms.nrem.index, : cannot compute exact confidence interval with
5  ## zeroes
6
7  ##
8  ## Wilcoxon signed rank test with continuity correction
9  ##
10 ## data: subset(SSdataCompletes, intervention == "sham")$plms.nrem.index and
11 subset(SSdataCompletes, intervention == "PrenaBelt")$plms.nrem.index
12 ## V = 29, p-value = 0.4561
13 ## alternative hypothesis: true location shift is not equal to 0
14 ## 95 percent confidence interval:
15 ## -18.84993 13.74994
16 ## sample estimates:
17 ## (pseudo)median
18 ## -0.8327795
19
20
21 #between participants (grouped) comparison
22 summary(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
23
24 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
25 ##  0.000  0.000   1.150  13.820   9.775  87.800
26
27 sd(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
28
29 ## [1] 25.55123
30
31 length(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
32
33 ## [1] 20
34
35 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
36 qqline(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index
## A = 3.3293, p-value = 1.119e-08

#non-normal

summary(subset(SSdata, intervention == "sham")$plms.nrem.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   0.35   12.74   8.65   75.10

sd(subset(SSdata, intervention == "sham")$plms.nrem.index)

## [1] 24.23984

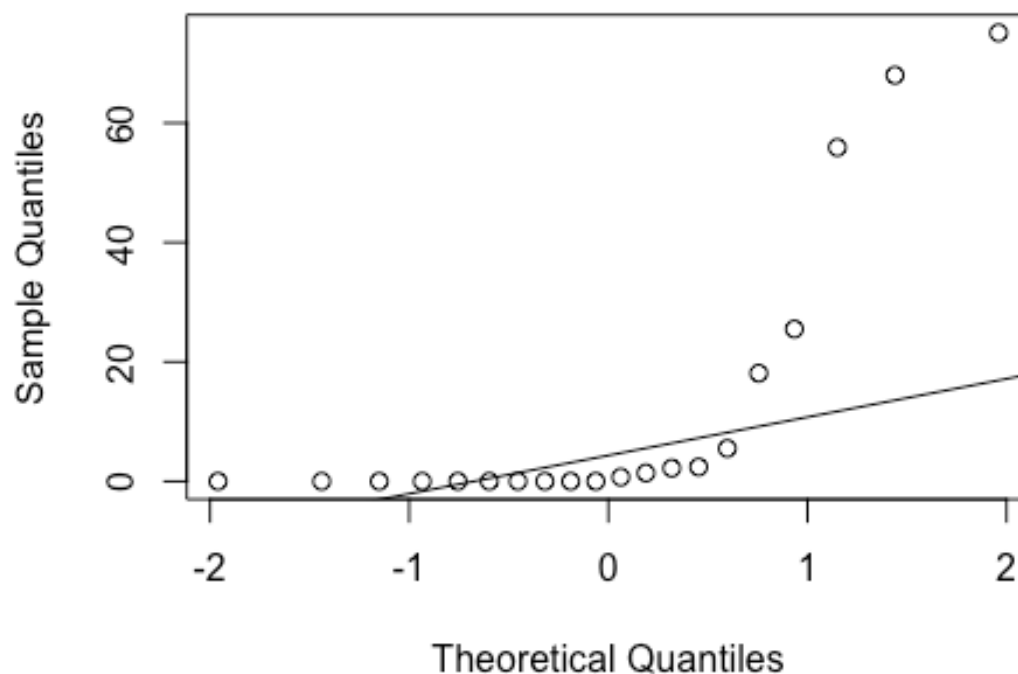
length(subset(SSdata, intervention == "sham")$plms.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plms.nrem.index)
qqline(subset(SSdata, intervention == "sham")$plms.nrem.index)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$plms.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plms.nrem.index
## A = 3.7582, p-value = 9.247e-10

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$plms.nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.nrem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.nrem.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$plms.nrem.index and subset(S

```

```

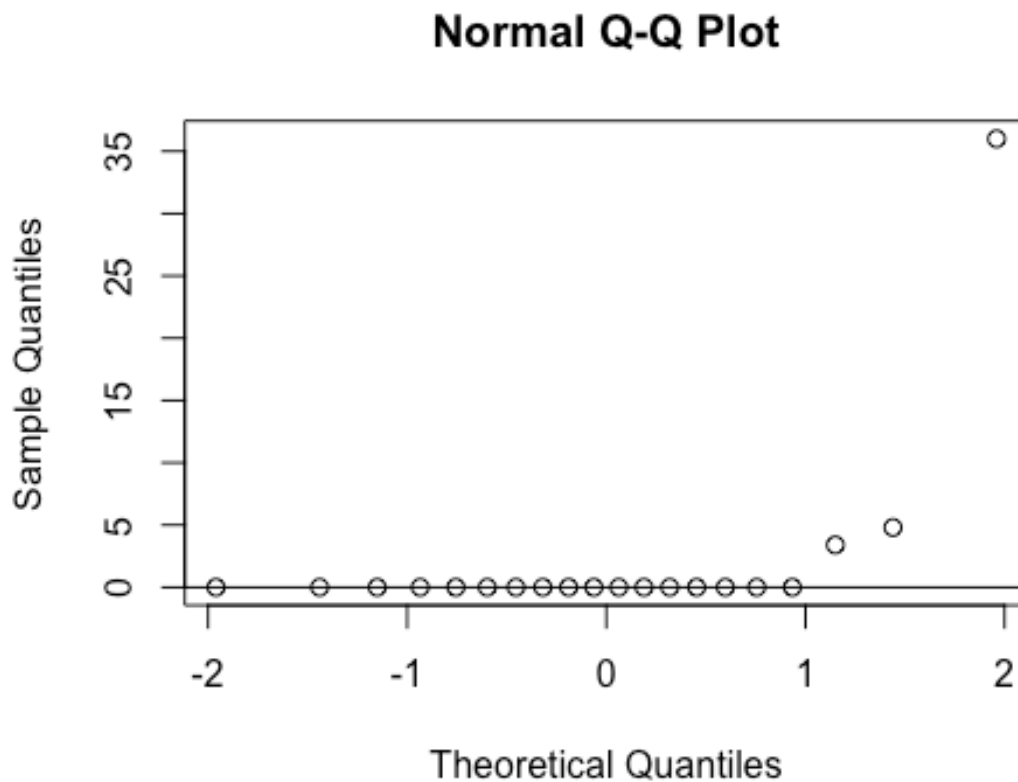
1
2
3 Sdata, intervention == "PrenaBelt")$plms.nrem.index
4 ## W = 189, p-value = 0.7637
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -1.800001 1.100068
8 ## sample estimates:
9 ## difference in location
10 ## -3.550462e-05
11
12 ##### PLMs Index in REM #####
13 #Summary
14 summary(SSdata$plms.rem.index)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      0.00   0.00   0.00   2.43   0.00   37.80
18
19 sd(SSdata$plms.rem.index, na.rm = TRUE)
20
21 ## [1] 8.281682
22
23 length(SSdata$plms.rem.index)
24
25 ## [1] 40
26
27 #ANOVA
28 night_tx_difference <- anova(lm(plms.rem.index ~ intervention * night,
29                               data = SSdata))
30
31 night_tx_difference
32
33 ## Analysis of Variance Table
34 ##
35 ## Response: plms.rem.index
36 ##
37 ##           Df Sum Sq Mean Sq F value Pr(>F)
38 ## intervention      1    1.94    1.936  0.0268 0.8708
39 ## night              1    0.04    0.036  0.0005 0.9823
40 ## intervention:night  1   73.98   73.984  1.0248 0.3181
41 ## Residuals        36 2598.91   72.192
42
43 #within-participants (paired) comparison
44 #Paired Wilcoxon
45 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.rem.index,
46             subset(SSdataCompletes, intervention == "PrenaBelt")$plms.rem.index,
47             paired = TRUE, conf.int = TRUE)
48
49 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
50 ## "sham")$plms.rem.index, : requested conf.level not achievable
51
52 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
53 ## "sham")$plms.rem.index, : cannot compute exact p-value with zeroes
54
55
56
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$plms.rem.index, : cannot compute exact confidence interval with
5  ## zeroes
6
7  ##
8  ## Wilcoxon signed rank test with continuity correction
9  ##
10 ## data: subset(SSdataCompletes, intervention == "sham")$plms.rem.index and
11 subset(SSdataCompletes, intervention == "PrenaBelt")$plms.rem.index
12 ## V = 11, p-value = 0.4185
13 ## alternative hypothesis: true location shift is not equal to 0
14 ## 80 percent confidence interval:
15 ## -0.8000532  4.5500270
16 ## sample estimates:
17 ## (pseudo)median
18 ##      1.799949
19
20
21 #between participants (grouped) comparison
22 summary(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
23
24 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
25 ##      0.00   0.00   0.00   2.21   0.00   36.00
26
27 sd(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
28
29 ## [1] 8.055459
30
31 length(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
32
33 ## [1] 20
34
35 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
36 qqline(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
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```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plms.rem.index
## A = 6.0576, p-value = 1.651e-15

#non-normal

summary(subset(SSdata, intervention == "sham")$plms.rem.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   0.00   2.65   0.00   37.80

sd(subset(SSdata, intervention == "sham")$plms.rem.index)

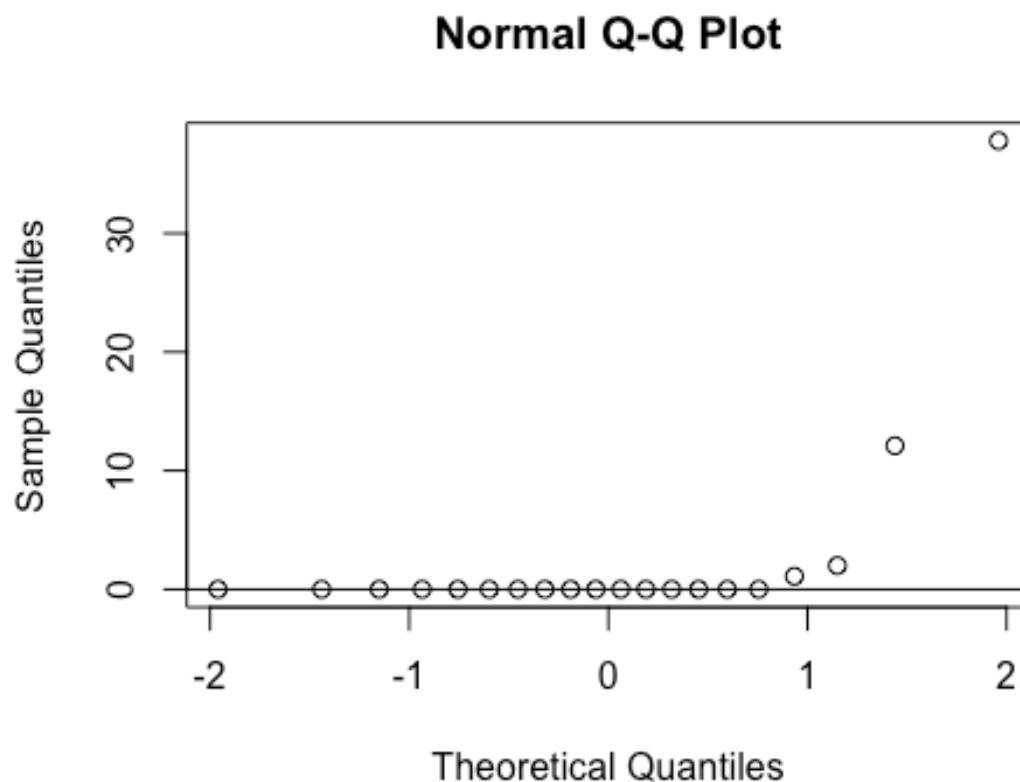
## [1] 8.705745

length(subset(SSdata, intervention == "sham")$plms.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plms.rem.index)
qqline(subset(SSdata, intervention == "sham")$plms.rem.index)

```



```

ad.test(subset(SSdata, intervention == "sham")$plms.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plms.rem.index
## A = 5.7316, p-value = 1.064e-14

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$plms.rem.index,
            subset(SSdata, intervention == "PrenaBelt")$plms.rem.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.rem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.rem.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$plms.rem.index and subset(SS

```



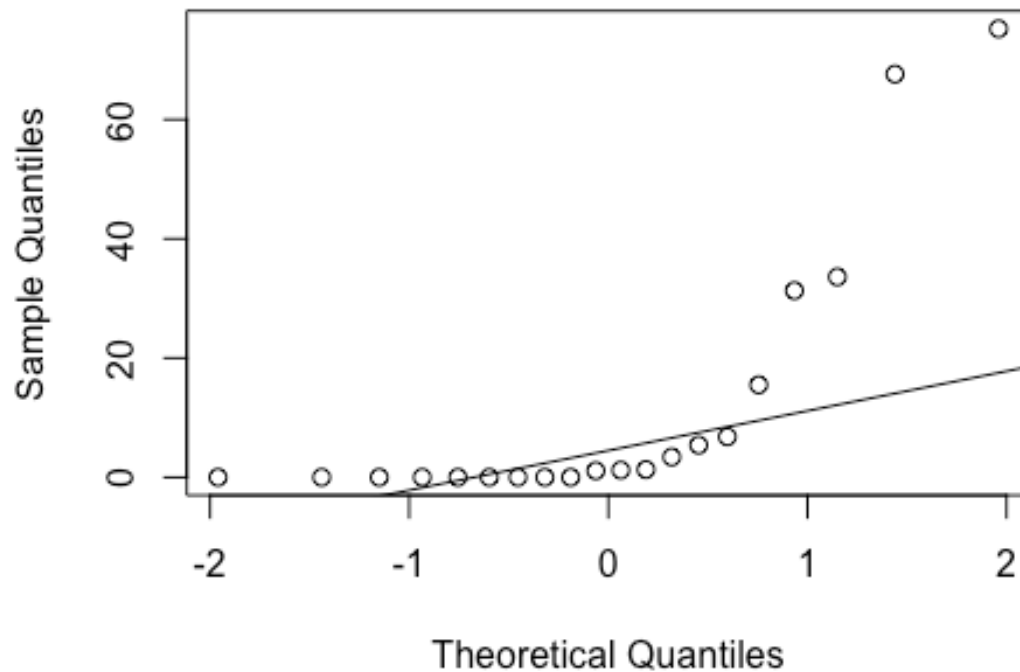
```

1
2
3 data, intervention == "PrenaBelt")$plms.rem.index
4 ## W = 209, p-value = 0.7285
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -2.226857e-05 1.825006e-06
8 ## sample estimates:
9 ## difference in location
10 ## 4.496583e-05
11
12 ##### PLMs Total Index (TST = NREM + REM) #####
13 ###
14 #Summary
15 summary(SSdata$plms.total.index)
16
17 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
18 ## 0.000 0.000 0.850 11.360 8.775 75.200
19
20 sd(SSdata$plms.total.index, na.rm = TRUE)
21
22 ## [1] 21.15996
23
24 length(SSdata$plms.total.index)
25
26 ## [1] 40
27
28 #ANOVA
29 night_tx_difference <- anova(lm(plms.total.index ~ intervention * night,
30 data = SSdata))
31
32 night_tx_difference
33
34 ## Analysis of Variance Table
35 ##
36 ## Response: plms.total.index
37 ##
38 ## Df Sum Sq Mean Sq F value Pr(>F)
39 ## intervention 1 23.3 23.26 0.0487 0.8265
40 ## night 1 219.5 219.49 0.4599 0.5020
41 ## intervention:night 1 37.1 37.06 0.0776 0.7821
42 ## Residuals 36 17182.2 477.28
43
44 #within-participants (paired) comparison
45 #Paired Wilcoxon
46 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.total.index,
47 subset(SSdataCompletes, intervention == "PrenaBelt")$plms.total.index,
48 paired = TRUE, conf.int = TRUE)
49
50 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
51 ## "sham")$plms.total.index, : cannot compute exact p-value with zeroes
52
53 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
54 ## "sham")$plms.total.index, : cannot compute exact confidence interval with
55 ## zeroes
56
57
58
59
60

```

```
1
2
3 ##
4 ## Wilcoxon signed rank test with continuity correction
5 ##
6 ## data: subset(SSdataCompletes, intervention == "sham")$plms.total.index an
7 d subset(SSdataCompletes, intervention == "PrenaBelt")$plms.total.index
8 ## V = 25, p-value = 0.2896
9 ## alternative hypothesis: true location shift is not equal to 0
10 ## 95 percent confidence interval:
11 ## -17.249992  8.399971
12 ## sample estimates:
13 ## (pseudo)median
14 ## -1.298512
15
16
17 #between participants (grouped) comparison
18 summary(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
19
20 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
21 ##  0.000  0.000  1.150  12.120  8.975  75.200
22
23 sd(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
24
25 ## [1] 22.62638
26
27 length(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
28
29 ## [1] 20
30
31 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
32 qqline(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plms.total.index
## A = 3.4069, p-value = 7.121e-09

#non-normal

summary(subset(SSdata, intervention == "sham")$plms.total.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.300  10.600  7.425  68.000

sd(subset(SSdata, intervention == "sham")$plms.total.index)

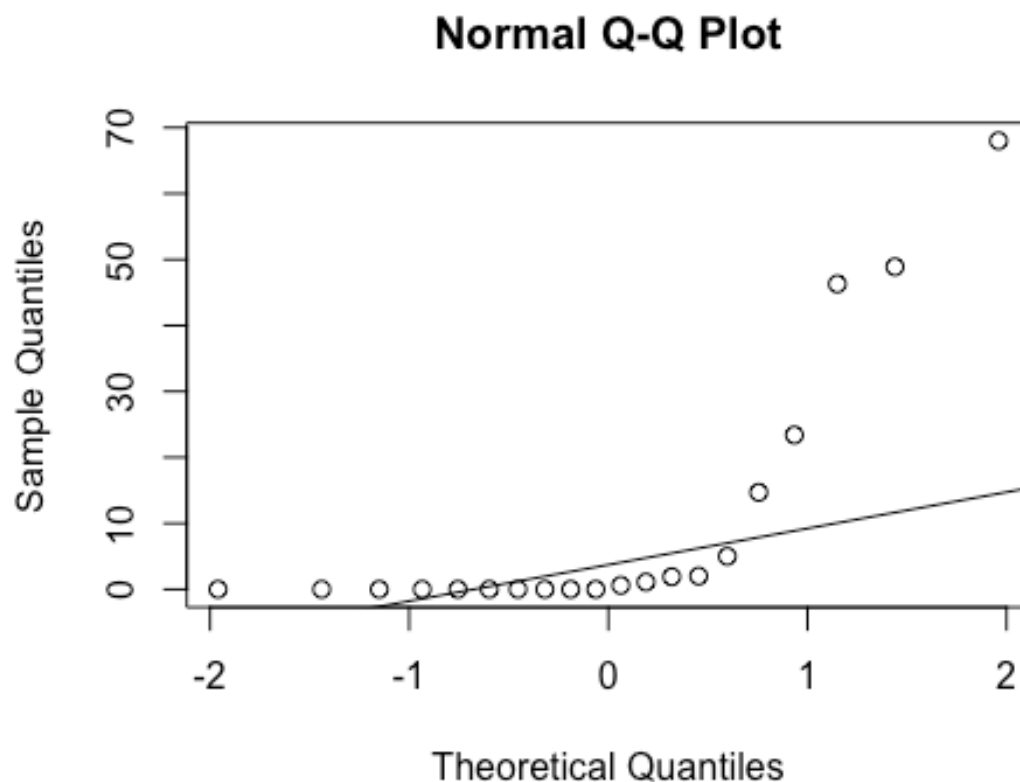
## [1] 20.14637

length(subset(SSdata, intervention == "sham")$plms.total.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plms.total.index)
qqline(subset(SSdata, intervention == "sham")$plms.total.index)

```



```

ad.test(subset(SSdata, intervention == "sham")$plms.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plms.total.index
## A = 3.6327, p-value = 1.917e-09

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$plms.total.index,
            subset(SSdata, intervention == "PrenaBelt")$plms.total.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.total.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.total.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$plms.total.index and subset(

```

```

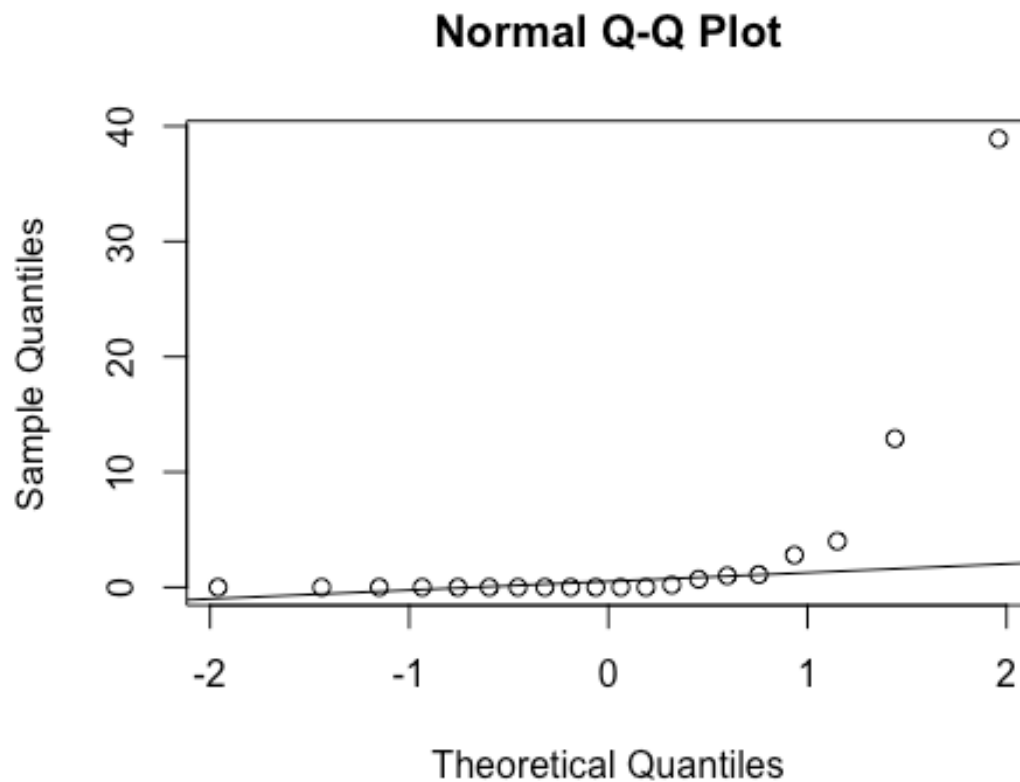
1
2
3 SSdata, intervention == "PrenaBelt")$plms.total.index
4 ## W = 186.5, p-value = 0.7098
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -1.8000395 0.7000302
8 ## sample estimates:
9 ## difference in location
10 ## -4.60136e-05
11
12 ##### PLM Arousals Index in NREM #####
13 #Summary
14 summary(SSdata$plm.arousals.nrem.index)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      0.000  0.000  0.000   2.245  0.850  38.900
18
19 sd(SSdata$plm.arousals.nrem.index, na.rm = TRUE)
20
21 ## [1] 6.766886
22
23 length(SSdata$plm.arousals.nrem.index)
24
25 ## [1] 40
26
27 #ANOVA
28 night_tx_difference <- anova(lm(plm.arousals.nrem.index ~ intervention * night,
29                                data = SSdata))
30
31 night_tx_difference
32
33 ## Analysis of Variance Table
34 ##
35 ## Response: plm.arousals.nrem.index
36 ##
37 ##           Df Sum Sq Mean Sq F value Pr(>F)
38 ## intervention      1   27.89   27.889   0.5852 0.4493
39 ## night              1   40.80   40.804   0.8563 0.3610
40 ## intervention:night 1    1.60    1.600   0.0336 0.8556
41 ## Residuals        36 1715.55   47.654
42
43 #within-participants (paired) comparison
44 #Paired Wilcoxon
45 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.nrem
46 .index,
47              subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nrem
48 .index,
49              paired = TRUE, conf.int = TRUE)
50
51 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
52 ## "sham")$plm.arousals.nrem.index, : cannot compute exact p-value with ties
53
54 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
55 ## "sham")$plm.arousals.nrem.index, : cannot compute exact confidence interval
56
57
58
59
60

```

```

1
2
3 l
4 ## with ties
5
6 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7 ## "sham")$plm.arousals.nrem.index, : cannot compute exact p-value with zeroes
8 s
9
10 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
11 ## "sham")$plm.arousals.nrem.index, : cannot compute exact confidence interval
12 l
13 ## with zeroes
14
15 ##
16 ## Wilcoxon signed rank test with continuity correction
17 ##
18 ## data: subset(SSdataCompletes, intervention == "sham")$plm.arousals.nrem.i
19 ndex and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nrem.index
20 em.index
21 ## V = 24.5, p-value = 0.4767
22 ## alternative hypothesis: true location shift is not equal to 0
23 ## 95 percent confidence interval:
24 ## -15.000023 1.300048
25 ## sample estimates:
26 ## (pseudo)median
27 ## -0.2999436
28
29
30 #between participants (grouped) comparison
31 summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
32
33 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
34 ##      0.000  0.000  0.000   3.080  1.025  38.900
35
36 sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
37
38 ## [1] 8.933886
39
40 length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
41
42 ## [1] 20
43
44 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
45 qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index
## A = 5.0288, p-value = 5.999e-13

#non-normal

summary(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  1.410  0.725  15.400

sd(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

## [1] 3.56502

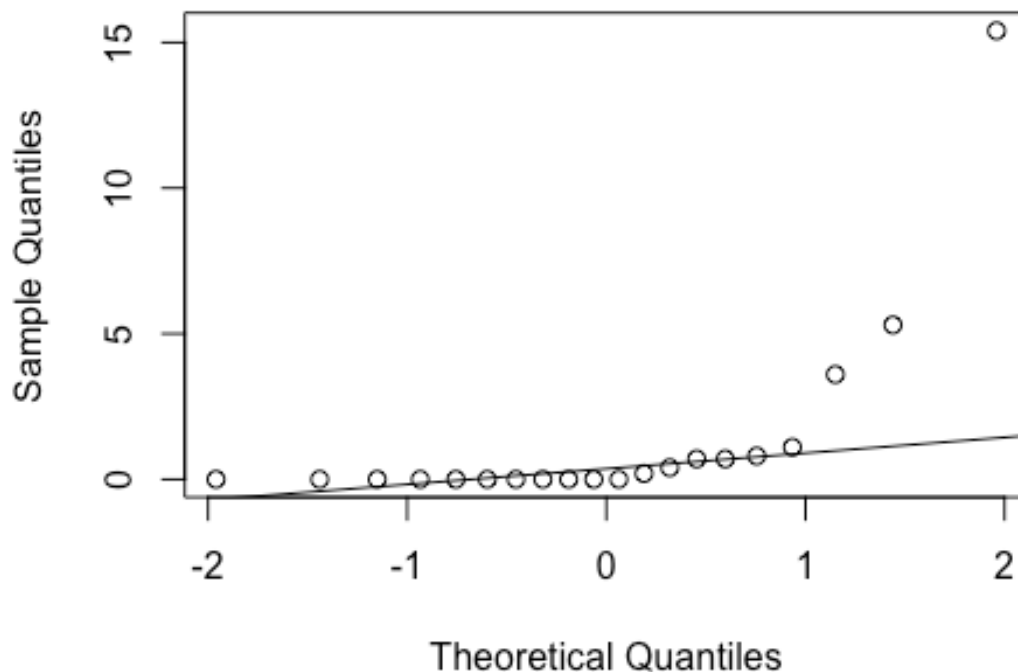
length(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)
qqline(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plm.arousals.nrem.index
## A = 4.353, p-value = 2.952e-11

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.nrem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.nrem.index, : cannot compute exact confidence intervals with
## ties

##
## Wilcoxon rank sum test with continuity correction

```



```

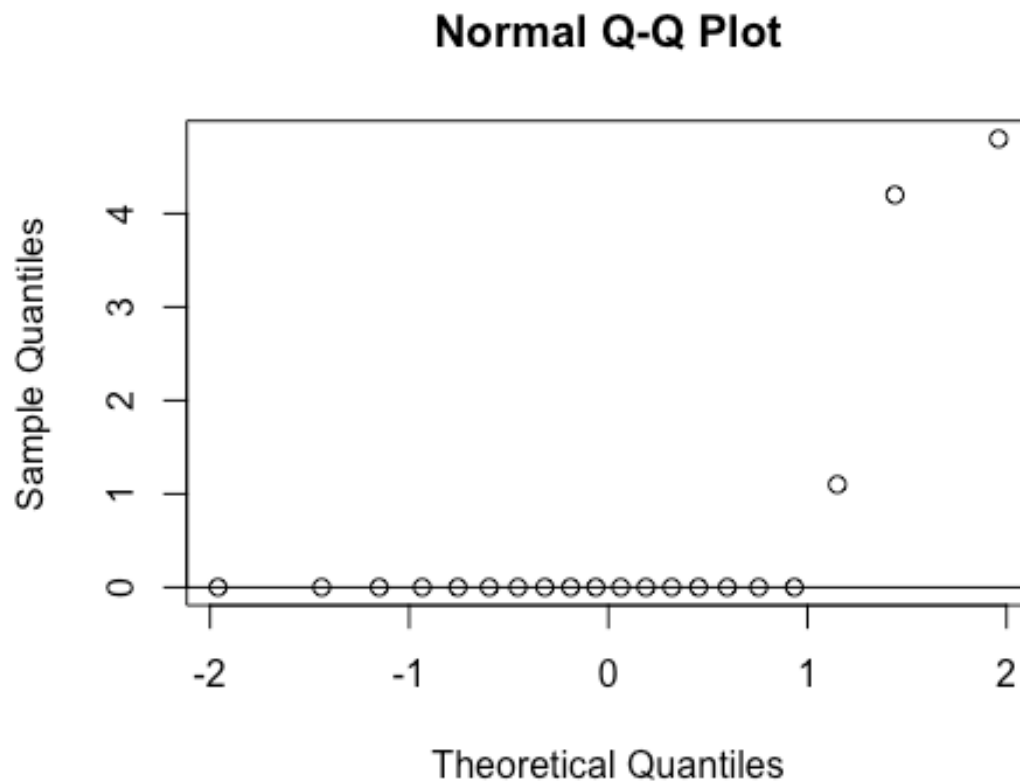
1
2
3
4  ##
5  ## data: subset(SSdata, intervention == "sham")$plm.arousals.nrem.index and
6  subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index
7  ## W = 202, p-value = 0.964
8  ## alternative hypothesis: true location shift is not equal to 0
9  ## 95 percent confidence interval:
10 ## -0.1999861  0.1999049
11 ## sample estimates:
12 ## difference in location
13 ##          4.324873e-05
14
15 ##### PLM Arousals Index in REM #####
16 #Summary
17 summary(SSdata$plm.arousals.rem.index)
18
19 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
20 ##      0.00   0.00   0.00   0.44   0.00   5.90
21
22 sd(SSdata$plm.arousals.rem.index, na.rm = TRUE)
23
24 ## [1] 1.342749
25
26 length(SSdata$plm.arousals.rem.index)
27
28 ## [1] 40
29
30 #ANOVA
31 night_tx_difference <- anova(lm(plm.arousals.rem.index ~ intervention * night
32 ,
33                               data = SSdata))
34
35 night_tx_difference
36
37 ## Analysis of Variance Table
38 ##
39 ## Response: plm.arousals.rem.index
40 ##
41 ##           Df Sum Sq Mean Sq F value Pr(>F)
42 ## intervention      1  0.169   0.1690   0.0894 0.7666
43 ## night              1  1.600   1.6000   0.8468 0.3636
44 ## intervention:night 1  0.529   0.5290   0.2800 0.6000
45 ## Residuals        36 68.018   1.8894
46
47 #within-participants (paired) comparison
48 #Paired Wilcoxon
49 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.rem.
50 index,
51           subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.rem.
52 index,
53           paired = TRUE, conf.int = TRUE)
54
55 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
56 ## "sham")$plm.arousals.rem.index, : requested conf.level not achievable

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$plm.arousals.rem.index, : cannot compute exact p-value with zeroes
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7  ## "sham")$plm.arousals.rem.index, : cannot compute exact confidence interval
8  ## with zeroes
9
10 ##
11 ## Wilcoxon signed rank test with continuity correction
12 ##
13 ## data: subset(SSdataCompletes, intervention == "sham")$plm.arousals.rem.in
14 ## dex and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.rem
15 ## .index
16 ## V = 7, p-value = 1
17 ## alternative hypothesis: true location shift is not equal to 0
18 ## 80 percent confidence interval:
19 ## -2.10052 1.15009
20 ## sample estimates:
21 ## (pseudo)median
22 ## -0.05003072
23
24
25 ##between participants (grouped) comparison
26 summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
27
28 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
29 ##  0.000  0.000  0.000  0.505  0.000  4.800
30
31 sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
32
33 ## [1] 1.391506
34
35 length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
36
37 ## [1] 20
38
39 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
40 qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index
## A = 5.6741, p-value = 1.478e-14

#non-normal

summary(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  0.375  0.000  5.900

sd(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

## [1] 1.325012

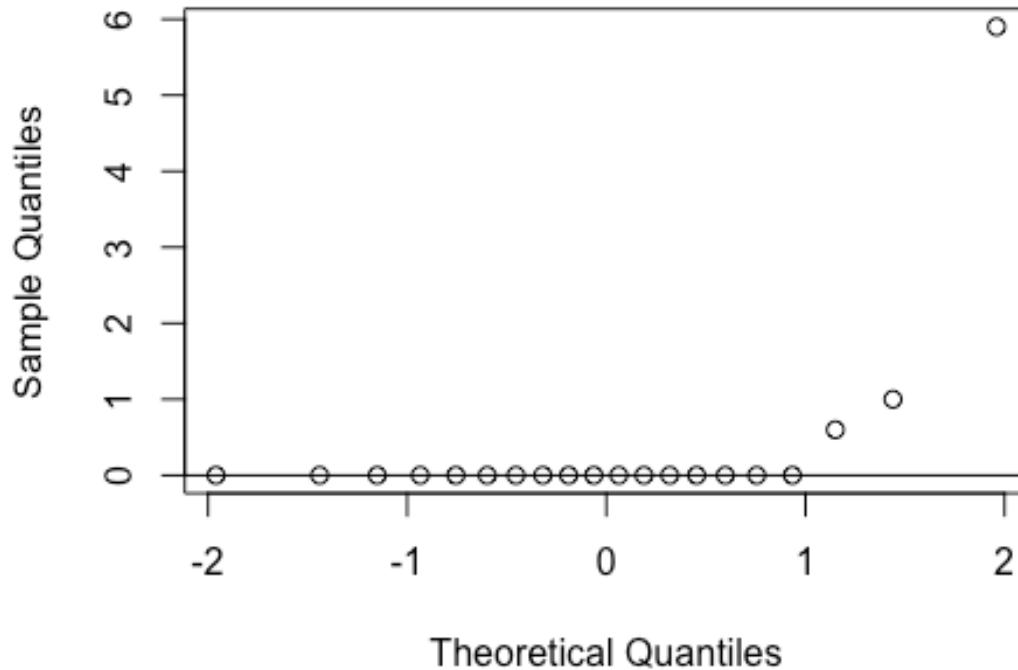
length(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)
qqline(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plm.arousals.rem.index
## A = 5.9139, p-value = 3.75e-15

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$plm.arousals.rem.index,
            subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.rem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.rem.index, : cannot compute exact confidence intervals with
## ties

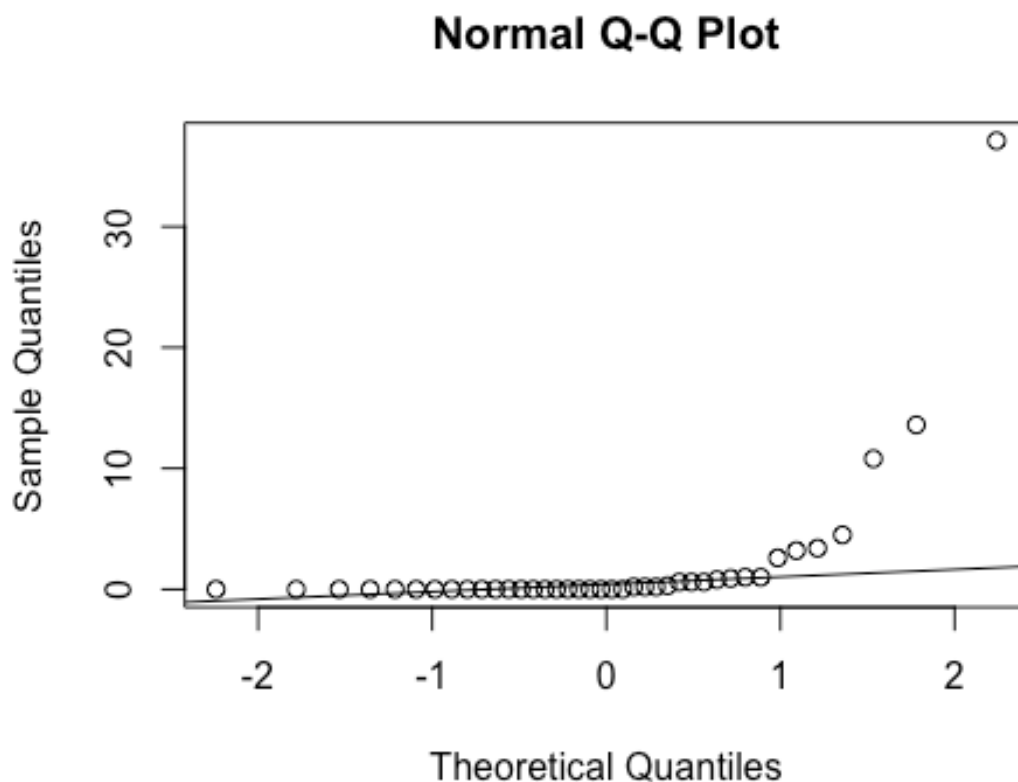
##
## Wilcoxon rank sum test with continuity correction

```

```

1
2
3
4  ##
5  ## data: subset(SSdata, intervention == "sham")$plm.arousals.rem.index and s
6  ubset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index
7  ## W = 198.5, p-value = 0.9653
8  ## alternative hypothesis: true location shift is not equal to 0
9  ## 95 percent confidence interval:
10 ## -1.538669e-05  6.131588e-05
11 ## sample estimates:
12 ## difference in location
13 ## -3.635924e-05
14
15 ##### PLM Arousals Total Index (TST = NREM + REM) #####
16 #####
17 #Summary
18 summary(SSdata$plm.arousals.total.index)
19
20 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
21 ##  0.000  0.000  0.000  2.040  0.825  37.100
22
23 sd(SSdata$plm.arousals.total.index, na.rm = TRUE)
24
25 ## [1] 6.334877
26
27 length(SSdata$plm.arousals.total.index)
28
29 ## [1] 40
30
31 qqnorm(SSdata$plm.arousals.total.index)
32 qqline(SSdata$plm.arousals.total.index)
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```
ad.test(SSdata$plm.arousals.total.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$plm.arousals.total.index
## A = 9.7136, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(plm.arousals.total.index ~ intervention * nig
ht,
                             data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: plm.arousals.total.index
##
```

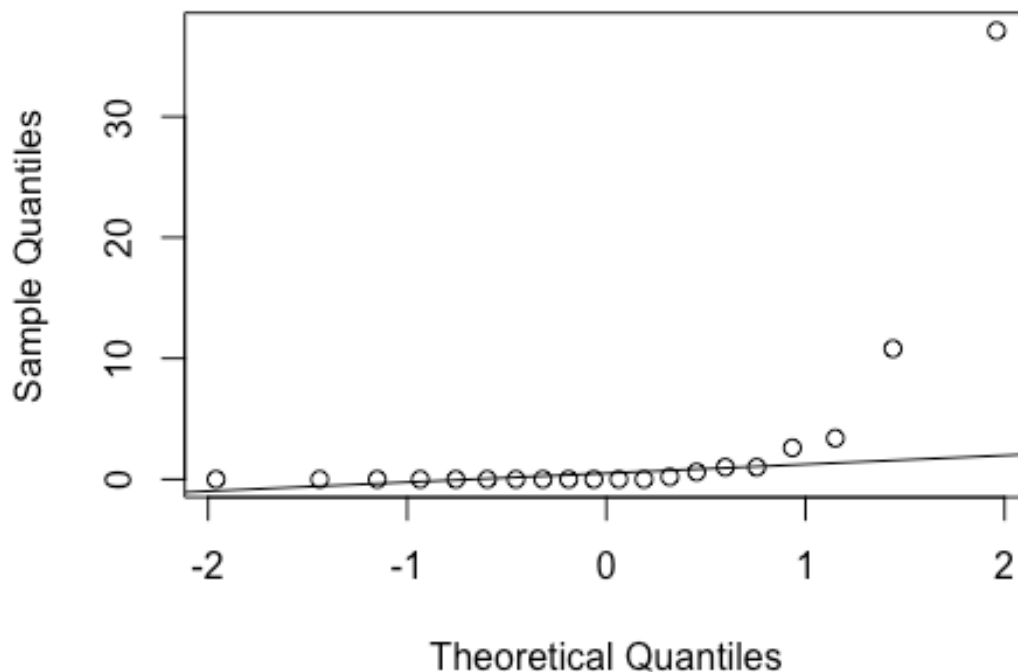
	Df	Sum Sq	Mean Sq	F value	Pr(>F)
## intervention	1	25.28	25.281	0.6075	0.4408
## night	1	38.81	38.809	0.9326	0.3406
## intervention:night	1	2.92	2.916	0.0701	0.7927
## Residuals	36	1498.09	41.614		

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.tota
6 l.index,
7             subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals
8 .total.index,
9             paired = TRUE, conf.int = TRUE)
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$plm.arousals.total.index, : cannot compute exact p-value with
13 ## zeroes
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention
16 ## == "sham")$plm.arousals.total.index, : cannot compute exact confidence
17 ## interval with zeroes
18
19 ##
20 ## Wilcoxon signed rank test with continuity correction
21 ##
22 ## data: subset(SSdataCompletes, intervention == "sham")$plm.arousals.total.
23 index and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.t
24 otal.index
25 ## V = 23, p-value = 0.6835
26 ## alternative hypothesis: true location shift is not equal to 0
27 ## 95 percent confidence interval:
28 ## -15.999946  1.499952
29 ## sample estimates:
30 ## (pseudo)median
31 ## -0.2999886
32
33 #between participants (grouped) comparison
34 summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
35
36 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
37 ##  0.000  0.000  0.000  2.835  1.000  37.100
38
39 sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
40
41 ## [1] 8.438712
42
43 length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
44
45 ## [1] 20
46
47 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
48 qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index
## A = 5.1126, p-value = 3.705e-13

#non-normal

summary(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.100  1.245  0.650  13.600

sd(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

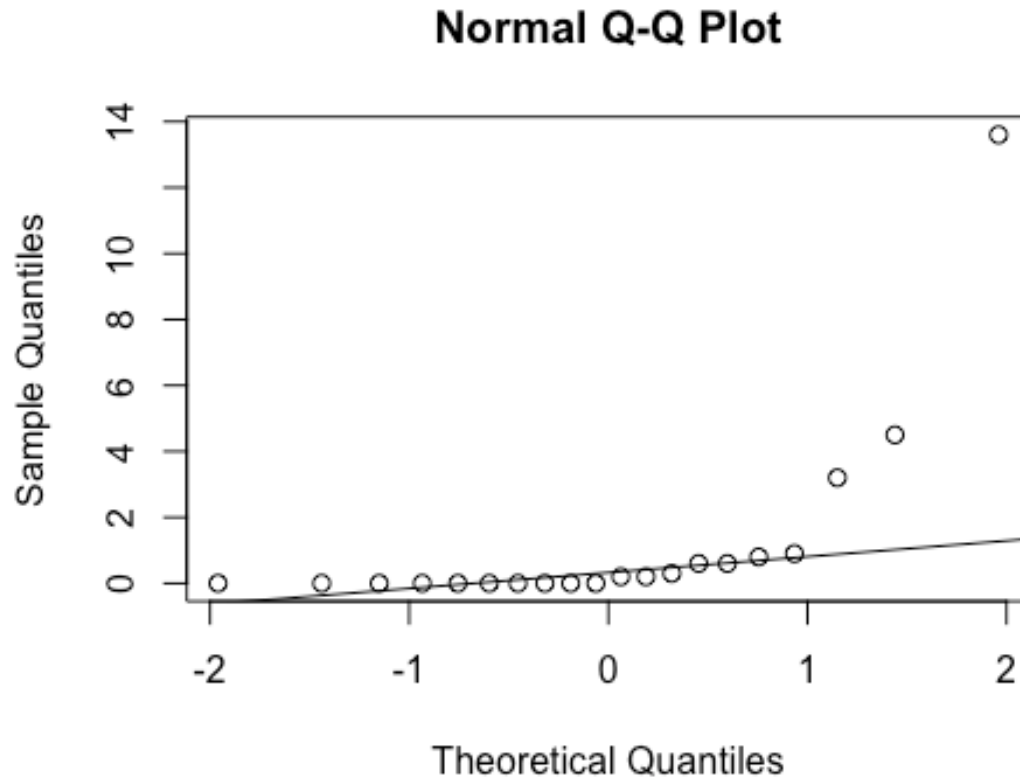
## [1] 3.135447

length(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

## [1] 20
```



```
qqnorm(subset(SSdata, intervention == "sham")$plm.arousals.total.index)
qqline(subset(SSdata, intervention == "sham")$plm.arousals.total.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plm.arousals.total.index
## A = 4.3437, p-value = 3.116e-11

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$plm.arousals.total.index,
            subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.in
dex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.total.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.total.index, : cannot compute exact confidence intervals wit
```

```

1
2
3 h
4 ## ties
5
6 ##
7 ## Wilcoxon rank sum test with continuity correction
8 ##
9 ## data: subset(SSdata, intervention == "sham")$plm.arousals.total.index and
10 subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index
11 ## W = 207, p-value = 0.8472
12 ## alternative hypothesis: true location shift is not equal to 0
13 ## 95 percent confidence interval:
14 ## -0.1999686 0.2000065
15 ## sample estimates:
16 ## difference in location
17 ## 4.063208e-05
18
19
20 ##### Respiratory Arousals Index in NREM #####
21 ##
22 #Summary
23 summary(SSdata$respiratory.arousals.nrem.index)
24
25 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
26 ##      0.00   0.00   0.20   1.11   0.80   11.10
27
28 sd(SSdata$respiratory.arousals.nrem.index, na.rm = TRUE)
29
30 ## [1] 2.639716
31
32 length(SSdata$respiratory.arousals.nrem.index)
33
34 ## [1] 40
35
36 #ANOVA
37 night_tx_difference <- anova(lm(respiratory.arousals.nrem.index ~ interventio
38 n * night,
39                               data = SSdata))
40
41 night_tx_difference
42
43 ## Analysis of Variance Table
44 ##
45 ## Response: respiratory.arousals.nrem.index
46 ##           Df Sum Sq Mean Sq F value Pr(>F)
47 ## intervention      1  6.084  6.0840  0.9328 0.34058
48 ## night              1  4.624  4.6240  0.7089 0.40535
49 ## intervention:night  1 26.244 26.2440  4.0237 0.05242 .
50 ## Residuals        36 234.804  6.5223
51 ## ---
52 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
53
54 #within-participants (paired) comparison
55 #Paired Wilcoxon
56 wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arous
57
58
59
60

```

```

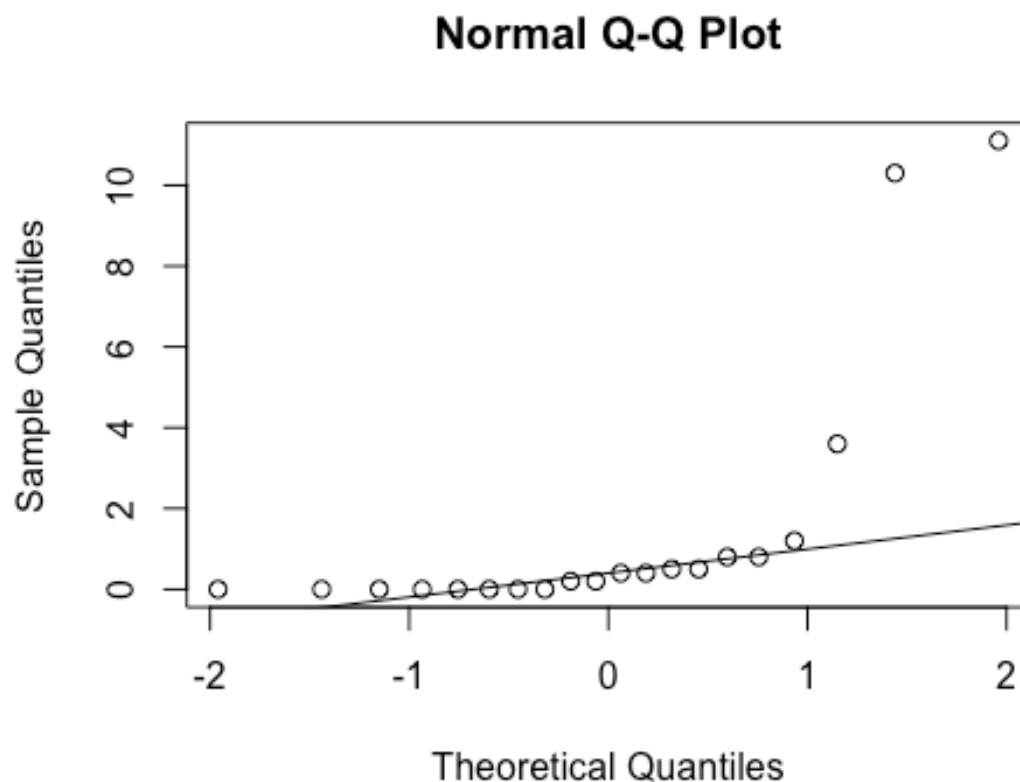
1
2
3 als.nrem.index,
4     subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arous
5 als.nrem.index,
6     paired = TRUE, conf.int = TRUE)
7
8 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
9 ## "sham")$respiratory.arousals.nrem.index, : cannot compute exact p-value
10 ## with ties
11
12 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13 ## "sham")$respiratory.arousals.nrem.index, : cannot compute exact confidence
14 ## interval with ties
15
16 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
17 ## "sham")$respiratory.arousals.nrem.index, : cannot compute exact p-value
18 ## with zeroes
19
20 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21 ## "sham")$respiratory.arousals.nrem.index, : cannot compute exact confidence
22 ## interval with zeroes
23
24 ##
25 ## Wilcoxon signed rank test with continuity correction
26 ##
27 ## data: subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
28 s.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respira
29 tory.arousals.nrem.index
30 ## V = 30, p-value = 0.09338
31 ## alternative hypothesis: true location shift is not equal to 0
32 ## 95 percent confidence interval:
33 ## -1.15001291 0.05002172
34 ## sample estimates:
35 ## (pseudo)median
36 ## -0.3500664
37
38
39 #between participants (grouped) comparison
40 summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
41 .index)
42
43 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
44 ##      0.0     0.0     0.3     1.5     0.8     11.1
45
46 sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.inde
47 x)
48
49 ## [1] 3.251558
50
51 length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
52 index)
53
54 ## [1] 20
55
56
57
58
59
60

```

```

1 qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
2 index)
3 qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
4 index)
5
6
7
8
9

```



```

37 ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
38 .index)
39
40 ##
41 ## Anderson-Darling normality test
42 ##
43 ## data: subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nr
44 em.index
45 ## A = 4.3757, p-value = 2.59e-11
46
47 ##non-normal
48
49 summary(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.inde
50 x)
51
52 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
53 ##      0.00   0.00   0.00   0.72   0.80   8.30
54
55 sd(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index)
56
57
58
59
60

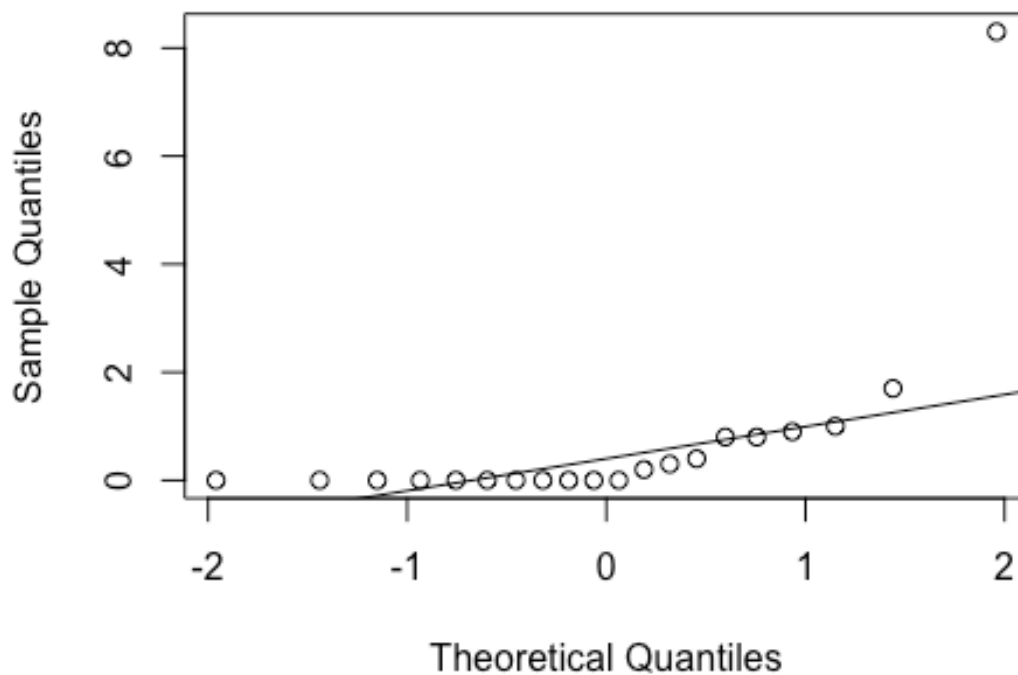
```

```

1
2
3 ## [1] 1.846647
4
5 length(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
6 )
7
8 ## [1] 20
9
10 qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
11 )
12 qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
13 )
14
15
16
17
18
19
20

```

Normal Q-Q Plot



```

44 ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.inde
45 x)
46
47 ##
48 ## Anderson-Darling normality test
49 ##
50 ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.in
51 dex
52 ## A = 4.3196, p-value = 3.581e-11
53
54 #non-normal
55
56
57
58
59
60

```

```

1
2
3 wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.
4 index,
5           subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.
6 nrem.index,
7           conf.int = TRUE)
8
9 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
10 ## $respiratory.arousals.nrem.index, : cannot compute exact p-value with ties
11
12 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
13 ## $respiratory.arousals.nrem.index, : cannot compute exact confidence
14 ## intervals with ties
15
16 ##
17 ## Wilcoxon rank sum test with continuity correction
18 ##
19 ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.in
20 dex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
21 .index
22 ## W = 171, p-value = 0.4142
23 ## alternative hypothesis: true location shift is not equal to 0
24 ## 95 percent confidence interval:
25 ## -4.000240e-01 3.702807e-05
26 ## sample estimates:
27 ## difference in location
28 ## -5.97387e-05
29
30 ##### Respiratory Arousals Index in REM #####
31 #
32 #Summary
33 summary(SSdata$respiratory.arousals.rem.index)
34
35 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
36 ##  0.000  0.000  0.950  6.612  4.225  70.000
37
38 sd(SSdata$respiratory.arousals.rem.index, na.rm = TRUE)
39
40 ## [1] 14.61077
41
42 length(SSdata$respiratory.arousals.rem.index)
43
44 ## [1] 40
45
46 #ANOVA
47 night_tx_difference <- anova(lm(respiratory.arousals.rem.index ~ intervention
48 * night,
49                               data = SSdata))
50
51 night_tx_difference
52
53 ## Analysis of Variance Table
54 ##
55 ## Response: respiratory.arousals.rem.index
56
57
58
59
60

```

```

1
2
3      ##                Df Sum Sq Mean Sq F value Pr(>F)
4      ## intervention      1    0.4    0.42  0.0021 0.96365
5      ## night            1   18.6   18.63  0.0934 0.76166
6      ## intervention:night 1 1124.7 1124.66  5.6376 0.02303 *
7      ## Residuals       36 7181.8  199.49
8      ## ---
9      ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
10
11      #within-participants (paired) comparison
12      #Paired Wilcoxon
13      wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arous
14      als.rem.index,
15      subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arous
16      als.rem.index,
17      paired = TRUE, conf.int = TRUE)
18
19
20      ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21      ## "sham")$respiratory.arousals.rem.index, : cannot compute exact p-value wit
22      h
23      ## ties
24
25      ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
26      ## "sham")$respiratory.arousals.rem.index, : cannot compute exact confidence
27      ## interval with ties
28
29      ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
30      ## "sham")$respiratory.arousals.rem.index, : cannot compute exact p-value wit
31      h
32      ## zeroes
33
34      ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
35      ## "sham")$respiratory.arousals.rem.index, : cannot compute exact confidence
36      ## interval with zeroes
37
38      ##
39      ## Wilcoxon signed rank test with continuity correction
40      ##
41      ## data: subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
42      s.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respirat
43      ory.arousals.rem.index
44      ## V = 67, p-value = 0.7119
45      ## alternative hypothesis: true location shift is not equal to 0
46      ## 95 percent confidence interval:
47      ## -3.249966  3.599990
48      ## sample estimates:
49      ## (pseudo)median
50      ## 0.3582702
51
52
53      #between participants (grouped) comparison
54      summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.
55      index)
56
57
58
59
60

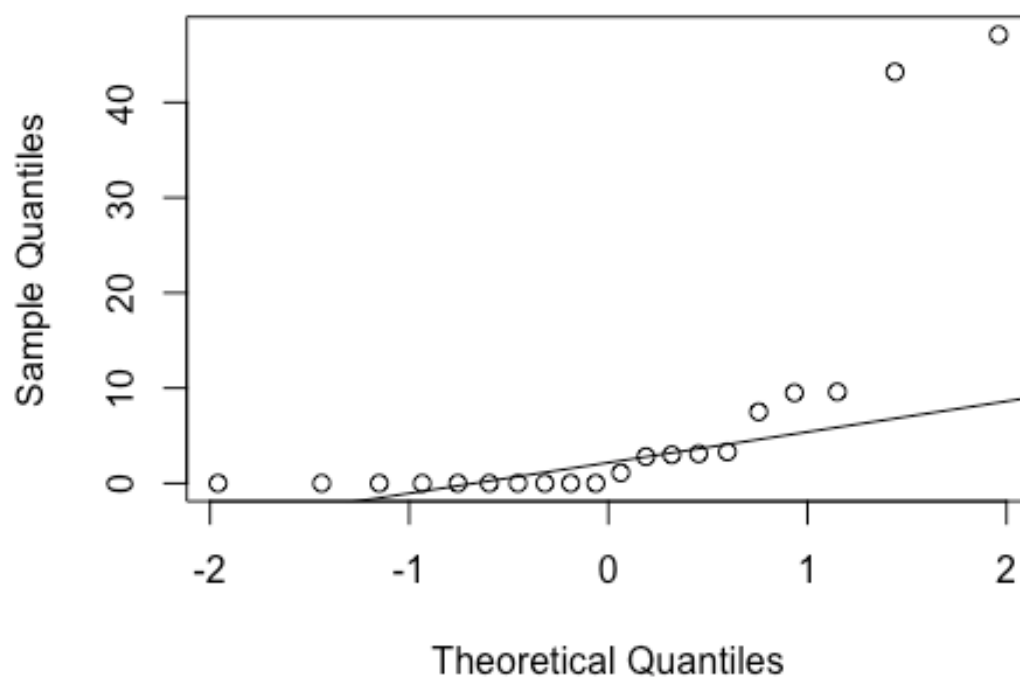
```

```

1
2
3  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4  ##      0.00   0.00   0.55   6.51   4.35   47.10
5
6  sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.index
7  )
8
9  ## [1] 13.60003
10
11 length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
12 ndex)
13
14 ## [1] 20
15
16 qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
17 ndex)
18 qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
19 ndex)
20

```

Normal Q-Q Plot



```

50 ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.
51 index)
52
53 ##
54 ## Anderson-Darling normality test
55 ##
56 ## data: subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.re
57
58
59

```

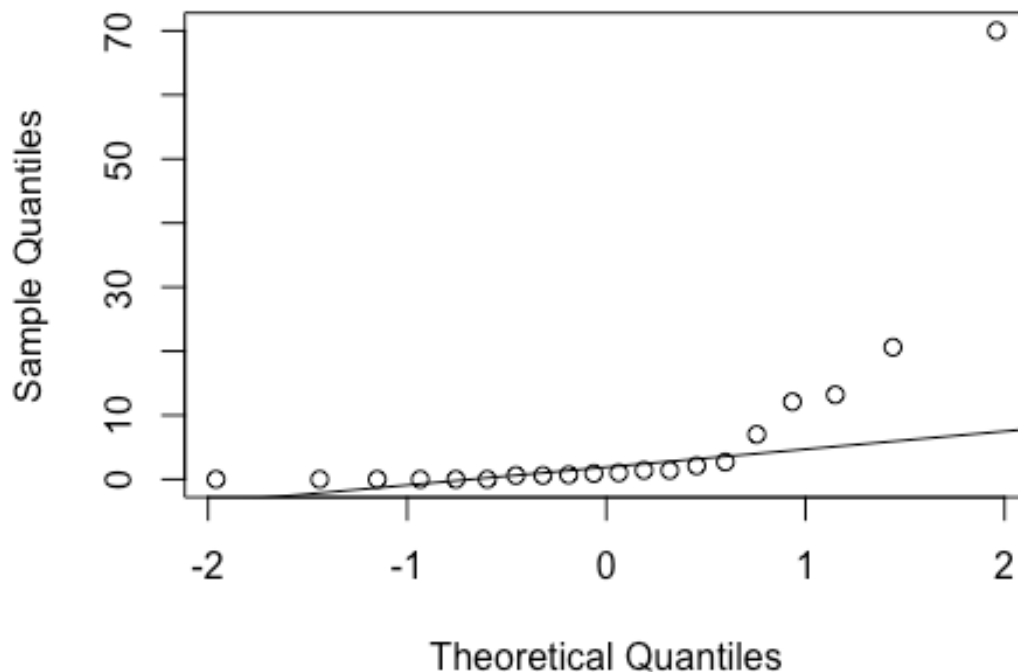


```

1
2
3 m.index
4 ## A = 4.0123, p-value = 2.119e-10
5
6 #non-normal
7
8 summary(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
9 )
10
11 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
12 ##  0.000  0.000  0.950  6.715  3.775  70.000
13
14 sd(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
15
16 ## [1] 15.9123
17
18 length(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
19
20 ## [1] 20
21
22 qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
23 qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54 ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
55 )
56
57
58
59
60

```

Normal Q-Q Plot



```

54 ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
55 )
56
57
58
59
60

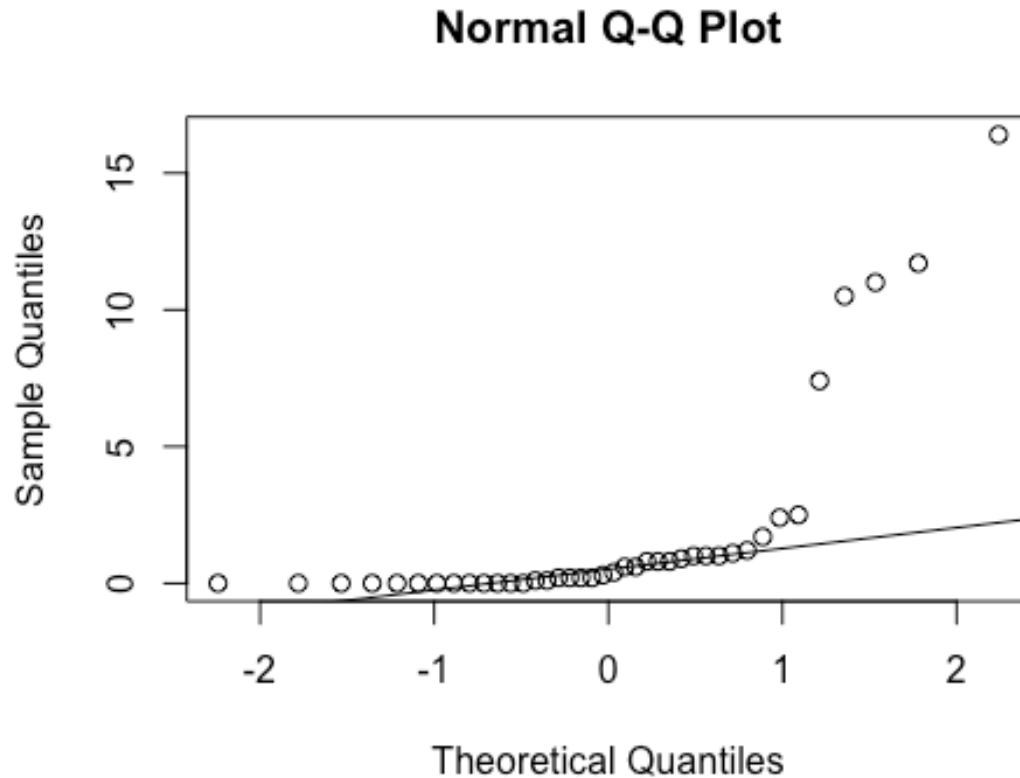
```

```

1
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
7  ## A = 4.0308, p-value = 1.904e-10
9
10 #non-normal
11
12 wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index,
13             subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.
14             rem.index,
15             conf.int = TRUE)
16
17 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
18 ## $respiratory.arousals.rem.index, : cannot compute exact p-value with ties
19
20 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
21 ## $respiratory.arousals.rem.index, : cannot compute exact confidence
22 ## intervals with ties
23
24 ##
25 ## Wilcoxon rank sum test with continuity correction
26 ##
27 ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
28 ## and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.index
29 ## W = 213, p-value = 0.7267
30 ## alternative hypothesis: true location shift is not equal to 0
31 ## 95 percent confidence interval:
32 ## -1.900003  1.399993
33 ## sample estimates:
34 ## difference in location
35 ##          5.850022e-05
36
37 ##### Respiratory Arousals Total Index (TST = NREM + REM) #####
38 #####
39 #Summary
40 summary(SSdata$respiratory.arousals.total.index)
41
42 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
43 ##      0.000  0.000  0.350  1.878  1.025  16.400
44
45 sd(SSdata$respiratory.arousals.total.index, na.rm = TRUE)
46
47 ## [1] 3.840706
48
49 length(SSdata$respiratory.arousals.total.index)
50
51 ## [1] 40

```

```
qqnorm(SSdata$respiratory.arousals.total.index)
qqline(SSdata$respiratory.arousals.total.index)
```



```
ad.test(SSdata$respiratory.arousals.total.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$respiratory.arousals.total.index
## A = 7.9786, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(respiratory.arousals.total.index ~ interventi
on * night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: respiratory.arousals.total.index
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    2.35    2.352   0.1732 0.67973
```

```

1
2
3  ## night          1  0.87  0.870  0.0641 0.80159
4  ## intervention:night 1 83.23 83.232 6.1296 0.01813 *
5  ## Residuals      36 488.83 13.579
6  ## ---
7  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
8
9  #within-participants (paired) comparison
10 #Paired Wilcoxon
11 wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arousals.total.index,
12             subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arousals.total.index,
13             paired = TRUE, conf.int = TRUE)
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$respiratory.arousals.total.index, : cannot compute exact p-value
17 ## with ties
18
19 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
20 ## "sham")$respiratory.arousals.total.index, : cannot compute exact confidence
21 ## interval with ties
22
23 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24 ## "sham")$respiratory.arousals.total.index, : cannot compute exact p-value
25 ## with zeroes
26
27 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
28 ## "sham")$respiratory.arousals.total.index, : cannot compute exact confidence
29 ## interval with zeroes
30
31 ##
32 ## Wilcoxon signed rank test with continuity correction
33 ##
34 ## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousals.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arousals.total.index
35 ## V = 62, p-value = 0.776
36 ## alternative hypothesis: true location shift is not equal to 0
37 ## 95 percent confidence interval:
38 ## -2.0999697  0.5000137
39 ## sample estimates:
40 ## (pseudo)median
41 ## -0.1000365
42
43 #between participants (grouped) comparison
44 summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.index)
45
46 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
47 ##      0.00   0.00   0.40   2.12   1.05   16.40

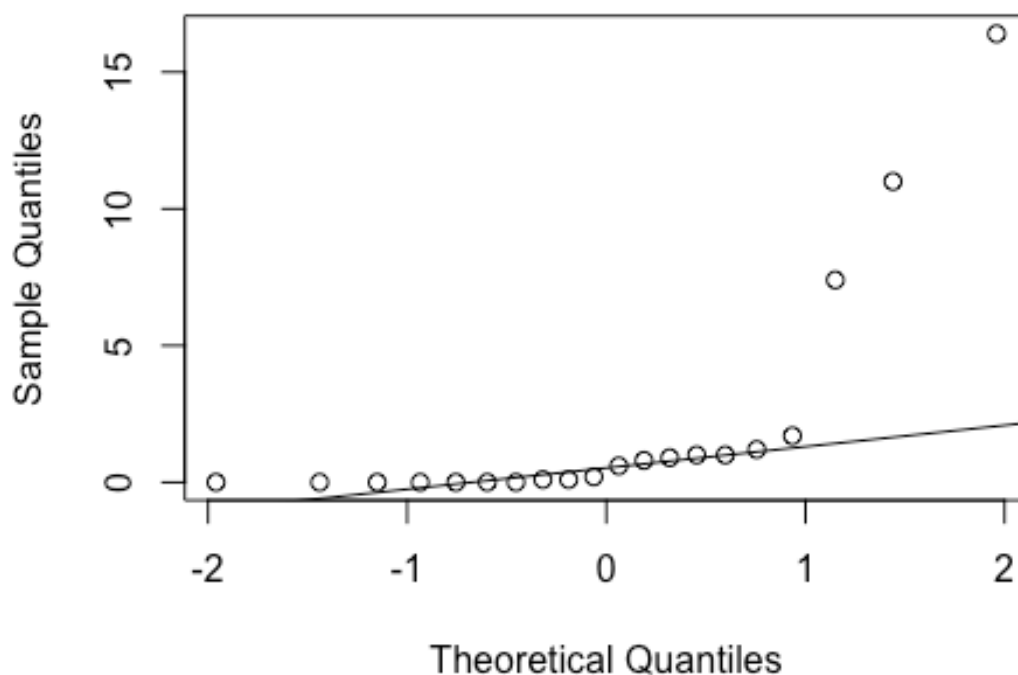
```

```

1
2
3 sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.index)
4
5
6 ## [1] 4.371149
7
8 length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.index)
9
10
11 ## [1] 20
12
13 qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.index)
14
15 qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.index)
16
17
18
19
20
21
22

```

Normal Q-Q Plot



```

23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47 ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.index)
48
49
50 ##
51 ## Anderson-Darling normality test
52 ##
53 ## data: subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.index
54
55 ## A = 3.9897, p-value = 2.416e-10
56
57
58
59
60

```

```
#non-normal
```

```
summary(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000   0.350   1.635   1.025  11.700
```

```
sd(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
```

```
## [1] 3.323802
```

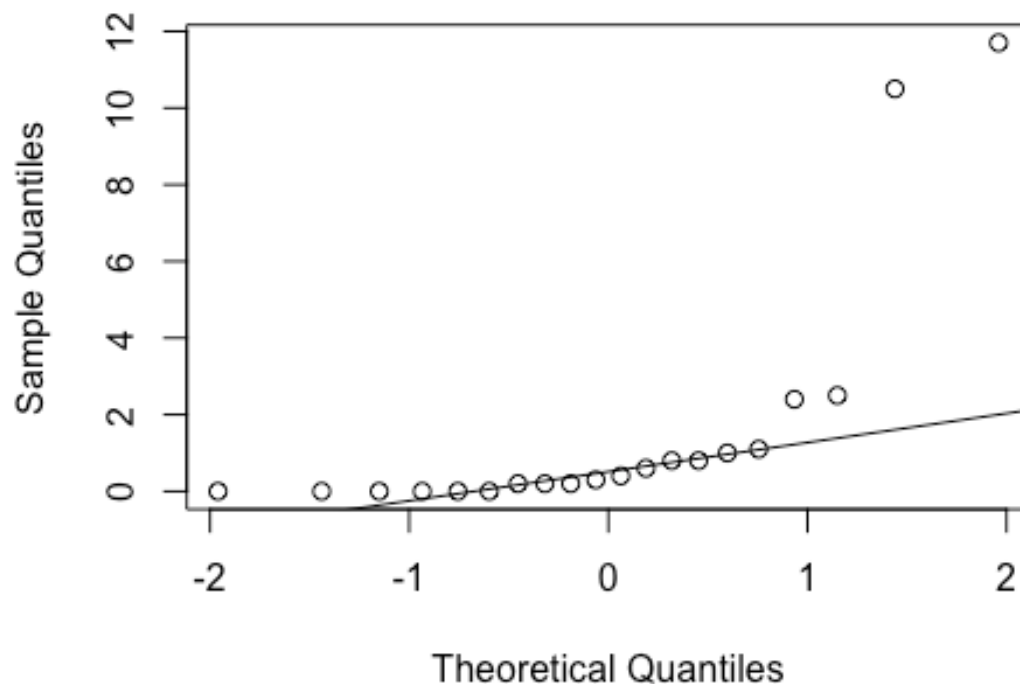
```
length(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
```

```
qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
```

```

1
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.total.i
7  ndex
8  ## A = 4.0437, p-value = 1.767e-10
9
10 #non-normal
11
12 wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.total
13 .index,
14             subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.
15 total.index,
16             conf.int = TRUE)
17
18 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
19 ## $respiratory.arousals.total.index, : cannot compute exact p-value with tie
20 s
21
22 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
23 ## $respiratory.arousals.total.index, : cannot compute exact confidence
24 ## intervals with ties
25
26 ##
27 ## Wilcoxon rank sum test with continuity correction
28 ##
29 ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.total.i
30 ndex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tot
31 al.index
32 ## W = 203, p-value = 0.9451
33 ## alternative hypothesis: true location shift is not equal to 0
34 ## 95 percent confidence interval:
35 ## -0.5999724  0.3999323
36 ## sample estimates:
37 ## difference in location
38 ##          9.000537e-06
39
40 ##### Arousing events NOT meeting respiratory criteria Index in NREM ##
41 #####
42 #Summary
43 summary(SSdata$arousals.with.respiratory.nrem.index)
44
45 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
46 ##      0.000  0.000  0.000  0.045  0.000  0.400
47
48 sd(SSdata$arousals.with.respiratory.nrem.index, na.rm = TRUE)
49
50 ## [1] 0.09594336
51
52 length(SSdata$arousals.with.respiratory.nrem.index)
53
54 ## [1] 40

```

```

1
2
3
4 #ANOVA
5 night_tx_difference <- anova(lm(arousals.with.respiratory.nrem.index ~ interv
6 ention * night,
7                               data = SSdata))
8
9 night_tx_difference
10
11 ## Analysis of Variance Table
12 ##
13 ## Response: arousals.with.respiratory.nrem.index
14 ##           Df Sum Sq   Mean Sq F value Pr(>F)
15 ## intervention      1  0.001 0.0010000   0.1034 0.7496
16 ## night              1  0.001 0.0010000   0.1034 0.7496
17 ## intervention:night  1  0.009 0.0090000   0.9310 0.3410
18 ## Residuals         36  0.348 0.0096667
19
20 #within-participants (paired) comparison
21 #Paired Wilcoxon
22 wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
23 piratory.nrem.index,
24             subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
25 piratory.nrem.index,
26             paired = TRUE)
27
28 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
29 ## "sham")$arousals.with.respiratory.nrem.index, : cannot compute exact p-
30 ## value with ties
31
32 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
33 ## "sham")$arousals.with.respiratory.nrem.index, : cannot compute exact p-
34 ## value with zeroes
35
36 ##
37 ## Wilcoxon signed rank test with continuity correction
38 ##
39 ## data: subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
40 ratory.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$ar
41 ousals.with.respiratory.nrem.index
42 ## V = 2, p-value = 0.7728
43 ## alternative hypothesis: true location shift is not equal to 0
44
45 #between participants (grouped) comparison
46 summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
47 .nrem.index)
48
49 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50 ##      0.00   0.00   0.00   0.05   0.00   0.40
51
52 sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.nrem
53 .index)
54
55 ## [1] 0.1100239

```



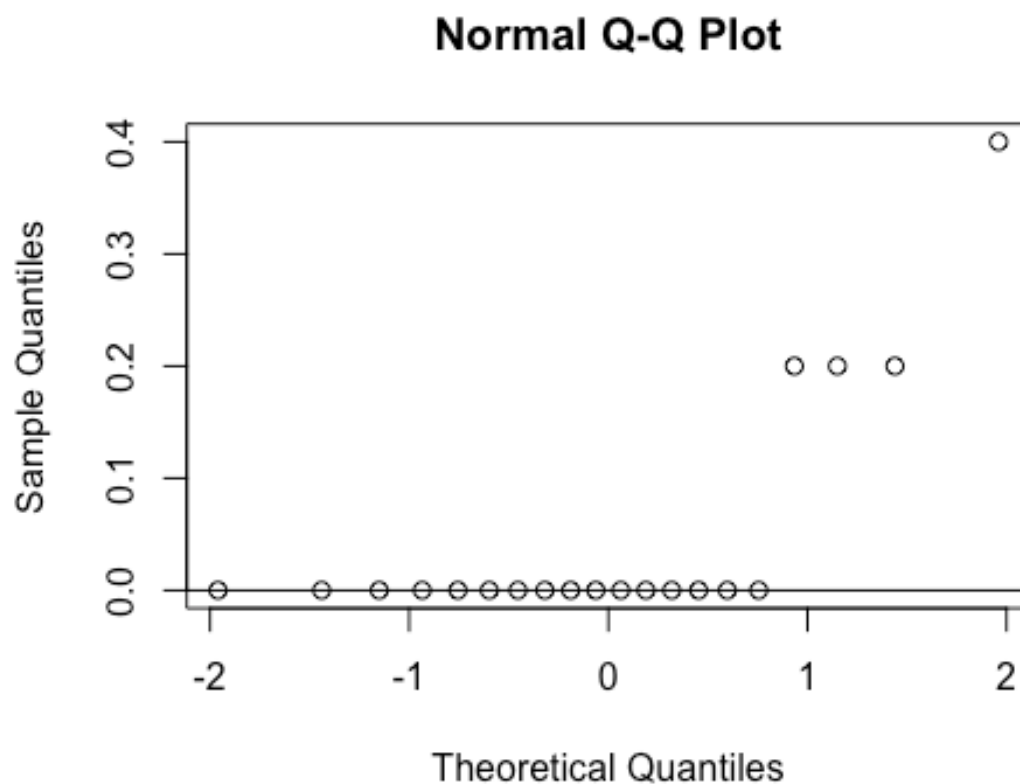
```

length(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
nrem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
nrem.index)

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$arousals.with.respirato
ry.nrem.index
## A = 4.6088, p-value = 6.743e-12

#non-normal

summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem
.index)

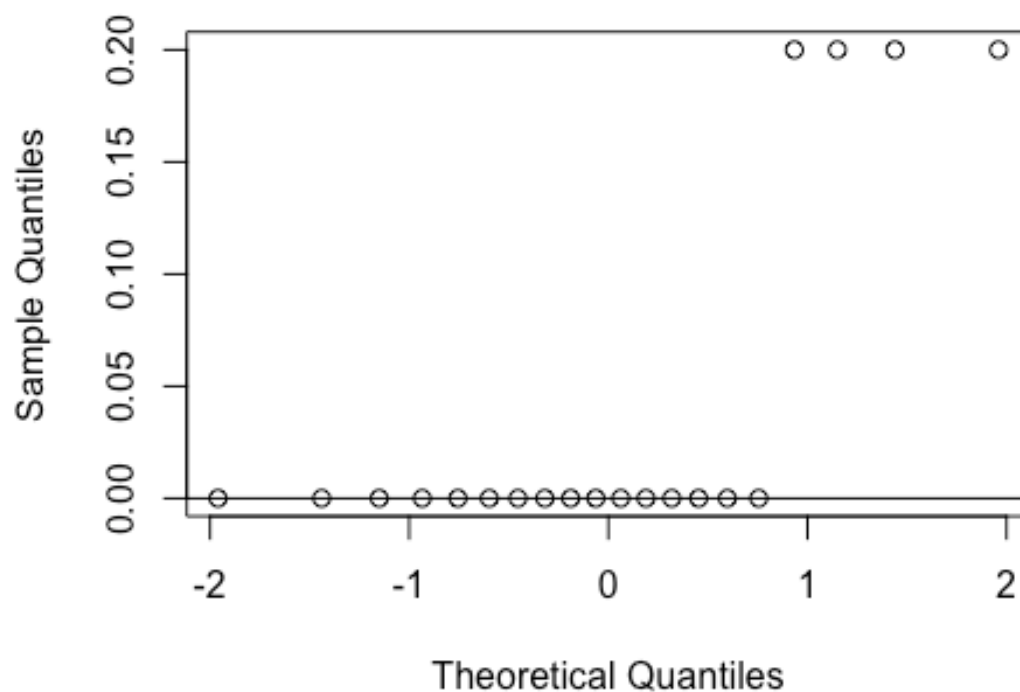
```

```

1
2
3  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4  ##      0.00   0.00   0.00   0.04   0.00   0.20
5
6  sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.inde
7  x)
8
9  ## [1] 0.08207827
10
11 length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.
12 index)
13
14 ## [1] 20
15
16 qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.
17 index)
18 qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.
19 index)
20

```

Normal Q-Q Plot



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44
45
46
47
48
49
50 ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem
51 .index)
52
53 ##
54 ## Anderson-Darling normality test
55 ##
56 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.nr
57
58
59
60

```

```

1
2
3 em.index
4 ## A = 5.1941, p-value = 2.32e-13
5
6 #non-normal
7
8 wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
9 nrem.index,
10 subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
11 tory.nrem.index,
12 conf.int = TRUE)
13
14 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
15 ## $arousals.with.respiratory.nrem.index, : cannot compute exact p-value with
16 ## ties
17
18 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
19 ## $arousals.with.respiratory.nrem.index, : cannot compute exact confidence
20 ## intervals with ties
21
22 ##
23 ## Wilcoxon rank sum test with continuity correction
24 ##
25 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.nr
26 em.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respir
27 atory.nrem.index
28 ## W = 198, p-value = 0.9534
29 ## alternative hypothesis: true location shift is not equal to 0
30 ## 95 percent confidence interval:
31 ## -1.407869e-05 9.852765e-06
32 ## sample estimates:
33 ## difference in location
34 ## -3.692335e-06
35
36 ##### Arousing events NOT meeting respiratory criteria Index in REM #####
37 ##
38 #Summary
39 summary(SSdata$arousals.with.respiratory.rem.index)
40
41 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
42 ## 0.000 0.000 0.000 0.015 0.000 0.600
43
44 sd(SSdata$arousals.with.respiratory.rem.index, na.rm = TRUE)
45
46 ## [1] 0.09486833
47
48 length(SSdata$arousals.with.respiratory.rem.index)
49
50 ## [1] 40
51
52 #ANOVA
53 night_tx_difference <- anova(lm(arousals.with.respiratory.rem.index ~ interve
54 ntion * night,
55
56
57
58
59
60

```

```

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```

```

                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: arousals.with.respiratory.rem.index
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention      1  0.009   0.009      1  0.324
## night              1  0.009   0.009      1  0.324
## intervention:night 1  0.009   0.009      1  0.324
## Residuals        36  0.324   0.009

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.respiratory.rem.index,
            subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.respiratory.rem.index,
            paired = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$arousals.with.respiratory.rem.index, : cannot compute exact p-value
## with zeroes

##
## Wilcoxon signed rank test with continuity correction
##
## data: subset(SSdataCompletes, intervention == "sham")$arousals.with.respiratory.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.respiratory.rem.index
## V = 1, p-value = 1
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.rem.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##         0         0         0         0         0         0

sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.rem.index)

## [1] 0

length(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.rem.index)

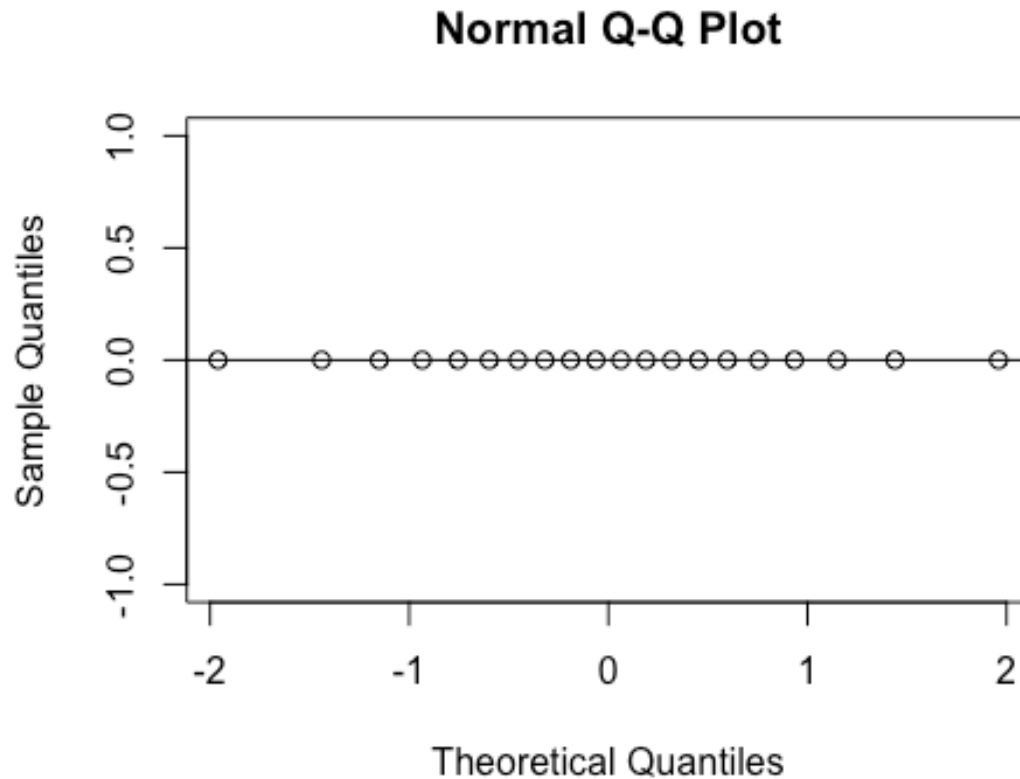
## [1] 20

```

```

1
2
3 qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
4 rem.index)
5 qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
6 rem.index)
7
8
9
10

```



```

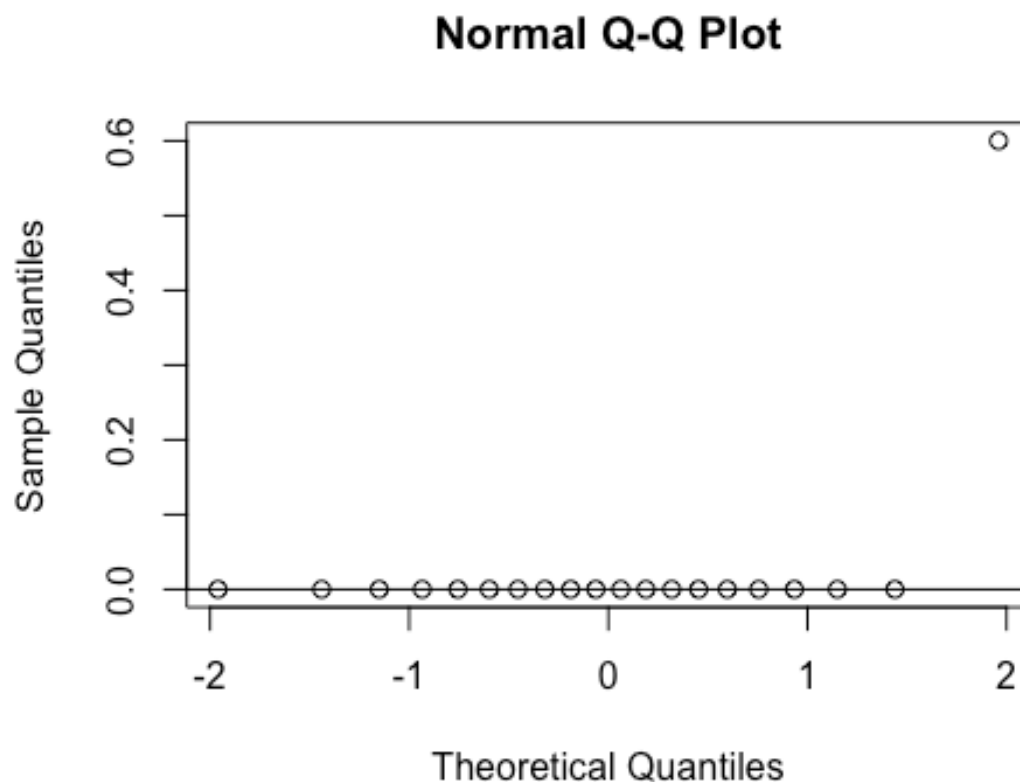
37 #ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respirator
38 y.rem.index)
39 #distribution is entirely zeroes
40
41 summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.
42 index)
43
44 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
45 ##      0.00   0.00   0.00   0.03   0.00   0.60
46
47 sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.index
48 )
49
50 ## [1] 0.1341641
51
52 length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
53 ndex)
54
55 ## [1] 20
56
57
58
59
60

```

```

1 qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
2 ndex)
3 qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
4 ndex)
5
6
7
8
9

```



```

37 ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.
38 index)
39
40 ##
41 ## Anderson-Darling normality test
42 ##
43 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.re
44 m.index
45 ## A = 7.1762, p-value < 2.2e-16
46
47 #non-normal
48
49 wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
50 rem.index,
51             subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
52 tory.rem.index,
53             conf.int = TRUE)
54
55
56
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
4  ## $arousals.with.respiratory.rem.index, : cannot compute exact p-value with
5  ## ties
6
7  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
8  ## $arousals.with.respiratory.rem.index, : cannot compute exact confidence
9  ## intervals with ties
10
11  ##
12  ## Wilcoxon rank sum test with continuity correction
13  ##
14  ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.re
15  m.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
16  tory.rem.index
17  ## W = 210, p-value = 0.3421
18  ## alternative hypothesis: true location shift is not equal to 0
19  ## 95 percent confidence interval:
20  ## 0 0
21  ## sample estimates:
22  ## difference in location
23  ## 0
24
25  ##### Arousing events NOT meeting respiratory criteria Index (TST = NREM +
26  REM) #####
27  #Summary
28  summary(SSdata$arousals.with.respiratory.total.index)
29
30  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
31  ## 0.0000 0.0000 0.0000 0.0425 0.0000 0.4000
32
33  sd(SSdata$arousals.with.respiratory.total.index, na.rm = TRUE)
34
35  ## [1] 0.09577618
36
37  length(SSdata$arousals.with.respiratory.total.index)
38
39  ## [1] 40
40
41  #ANOVA
42  night_tx_difference <- anova(lm(arousals.with.respiratory.total.index ~ inter
43  vention * night,
44                                data = SSdata))
45
46  night_tx_difference
47
48  ## Analysis of Variance Table
49  ##
50  ## Response: arousals.with.respiratory.total.index
51  ##
52  ##      Df Sum Sq Mean Sq F value Pr(>F)
53  ## intervention      1 0.00025 0.00025  0.0256 0.8737
54  ## night              1 0.00025 0.00025  0.0256 0.8737
55  ## intervention:night  1 0.00625 0.00625  0.6410 0.4286
56  ## Residuals         36 0.35100 0.00975

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
6 piratory.total.index,
7     subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
8 piratory.total.index,
9     paired = TRUE, conf.int = TRUE)
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$arousals.with.respiratory.total.index, : requested conf.level not
13 ## achievable
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$arousals.with.respiratory.total.index, : cannot compute exact p-
17 ## value with ties
18
19 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
20 ## "sham")$arousals.with.respiratory.total.index, : cannot compute exact
21 ## confidence interval with ties
22
23 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24 ## "sham")$arousals.with.respiratory.total.index, : cannot compute exact p-
25 ## value with zeroes
26
27 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
28 ## "sham")$arousals.with.respiratory.total.index, : cannot compute exact
29 ## confidence interval with zeroes
30
31 ##
32 ## Wilcoxon signed rank test with continuity correction
33 ##
34 ## data: subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
35 ratory.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$a
36 rousals.with.respiratory.total.index
37 ## V = 5.5, p-value = 0.6831
38 ## alternative hypothesis: true location shift is not equal to 0
39 ## 90 percent confidence interval:
40 ## -0.2 0.2
41 ## sample estimates:
42 ## (pseudo)median
43 ## -5.079939e-05
44
45 #between participants (grouped) comparison
46 summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
47 .total.index)
48
49 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50 ##      0.000  0.000  0.000  0.045  0.000  0.400
51
52 sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.tota
53 l.index)
54
55
56
57
58
59
60

```

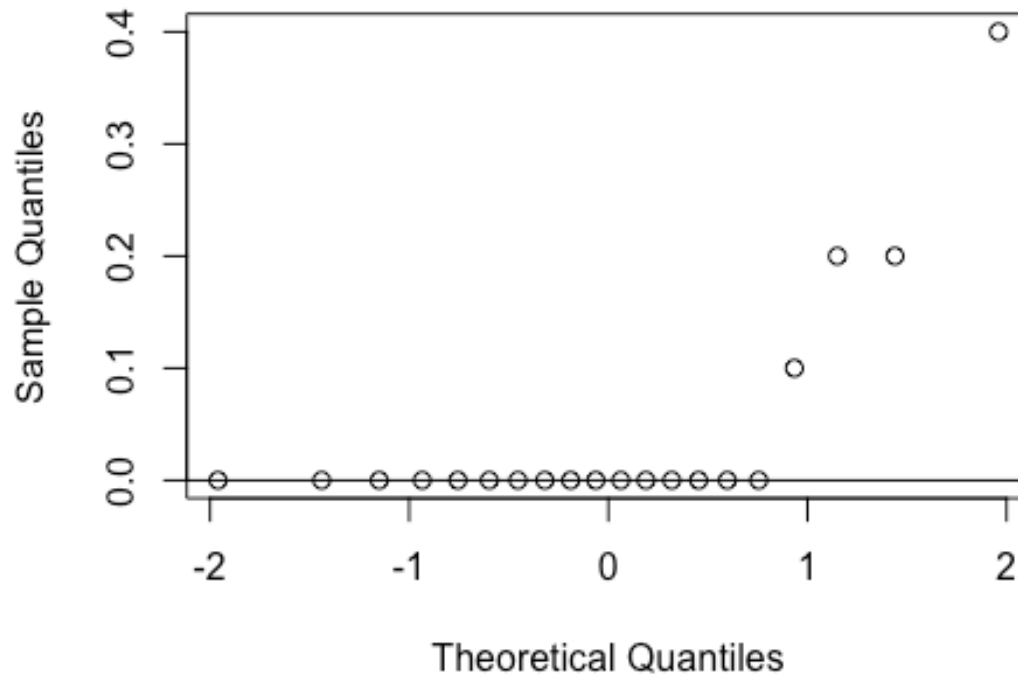


```

1
2
3 ## [1] 0.1050063
4
5 length(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
6 total.index)
7
8 ## [1] 20
9
10 qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
11 total.index)
12 qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
13 total.index)
14
15
16
17
18

```

Normal Q-Q Plot



```

44 ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
45 .total.index)
46
47 ##
48 ## Anderson-Darling normality test
49 ##
50 ## data: subset(SSdata, intervention == "PrenaBelt")$arousals.with.respirato
51 ry.total.index
52 ## A = 4.5718, p-value = 8.347e-12
53
54 #non-normal
55
56
57
58

```

```

1
2
3 summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.tota
4 l.index)
5
6 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
7 ##      0.00   0.00   0.00   0.04   0.00   0.30
8
9 sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total.ind
10 ex)
11
12 ## [1] 0.088258
13
14 length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
15 .index)
16
17 ## [1] 20
18
19 qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
20 .index)
21 qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
22 .index)
23 ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.tota
24 l.index)
25
26 ##
27 ## Anderson-Darling normality test
28 ##
29 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.to
30 tal.index
31 ## A = 4.6836, p-value = 4.379e-12
32
33 #non-normal
34
35 wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
36 total.index,
37             subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
38 tory.total.index,
39             conf.int = TRUE)
40
41 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
42 ## $arousals.with.respiratory.total.index, : cannot compute exact p-value wit
43 h
44 ## ties
45
46 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
47 ## $arousals.with.respiratory.total.index, : cannot compute exact confidence
48 ## intervals with ties
49
50 ##
51 ## Wilcoxon rank sum test with continuity correction
52 ##
53 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.to
54 tal.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respi
55
56
57
58
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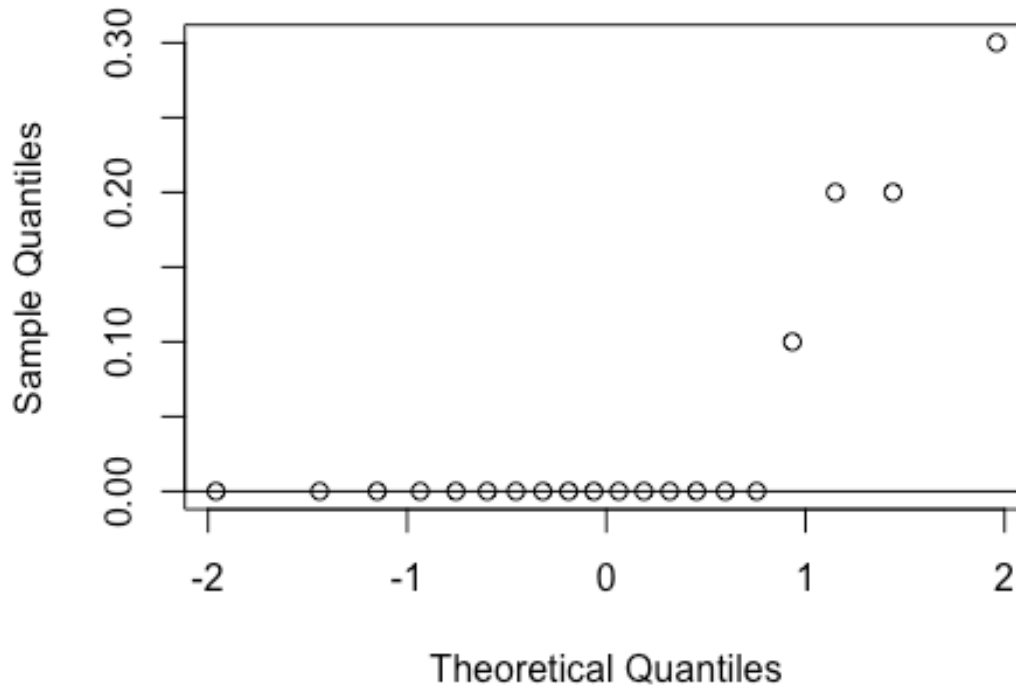
```

```

1
2
3 ratory.total.index
4 ## W = 199.5, p-value = 1
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -5.011195e-06 5.395622e-05
8 ## sample estimates:
9 ## difference in location
10 ## -6.56778e-05
11
12 ##### Linear Mixed Effects Model #####
13 library(epiDisplay)
14
15 ## Loading required package: foreign
16
17 ## Loading required package: survival
18
19 ## Loading required package: MASS
20
21 ## Loading required package: nnet
22
23 #linear mixed effects model
24 library(lme4)
25
26 ## Loading required package: Matrix

```

Normal Q-Q Plot



```

1
2
3 #PERCENTAGE sleep time supine:
4 #response variable: PtstSupine
5 #fixed effects: intervention (PrenaBelt, sham)
6 #random effects: participant, night
7
8
9 #Specify that the sham intervention is the reference
10 SSdata$intervention <- relevel(SSdata$intervention,
11                               ref = "sham")
12
13 #Specify model
14 intervention.lme <- lmer(PtstSupine ~ intervention + (1 | participant.s.code)
15 +
16                       (1 | night),
17                       data = SSdata)
18
19 #Print out results
20 intervention.lme
21
22 ## Linear mixed model fit by REML ['lmerMod']
23 ## Formula:
24 ## PtstSupine ~ intervention + (1 | participant.s.code) + (1 | night)
25 ## Data: SSdata
26 ## REML criterion at convergence: 321.3263
27 ## Random effects:
28 ## Groups Name Std.Dev.
29 ## participant.s.code (Intercept) 14.44
30 ## night (Intercept) 0.00
31 ## Residual 10.29
32 ## Number of obs: 40, groups: participant.s.code, 20; night, 2
33 ## Fixed Effects:
34 ## (Intercept) interventionPrenaBelt
35 ## 18.505 -6.825
36
37 summary(intervention.lme)
38
39 ## Linear mixed model fit by REML ['lmerMod']
40 ## Formula:
41 ## PtstSupine ~ intervention + (1 | participant.s.code) + (1 | night)
42 ## Data: SSdata
43 ##
44 ## REML criterion at convergence: 321.3
45 ##
46 ## Scaled residuals:
47 ## Min 1Q Median 3Q Max
48 ## -1.62094 -0.60673 -0.00144 0.39109 1.86710
49 ##
50 ## Random effects:
51 ## Groups Name Variance Std.Dev.
52 ## participant.s.code (Intercept) 208.6 14.44
53 ## night (Intercept) 0.0 0.00
54
55
56
57
58
59
60

```

```

1
2
3  ## Residual                105.8    10.29
4  ## Number of obs: 40, groups: participant.s.code, 20; night, 2
5  ##
6  ## Fixed effects:
7  ##
8  ##           Estimate Std. Error t value
9  ## (Intercept)      18.505      3.965   4.668
10 ## interventionPrenaBelt  -6.825      3.252  -2.098
11 ##
12 ## Correlation of Fixed Effects:
13 ##           (Intr)
14 ## intrvntnPrB -0.410
15
16 #compute 95% CI (two-sided)
17 confint(intervention.lme)
18
19 ## Computing profile confidence intervals ...
20
21 ##           2.5 %    97.5 %
22 ## .sig01      9.058653 21.1339282
23 ## .sig02      0.000000  9.4829922
24 ## .sigma      7.569426 14.1618877
25 ## (Intercept) 10.639735 26.3703919
26 ## interventionPrenaBelt -13.348929 -0.3010706
27
28 #compute p-value using formula p = 2*pt(t-value, dof=length(SSdata)-1)
29 p=2*pt(-2.098, 39)
30 p
31
32 ## [1] 0.04243394
33
34 #p<0.05, statistically significant: 6.8% absolute reduction in PtstSupine with PrenaBelt
35 h PrenaBelt
36  #(18.5% down to 11.5%), which is a 38% relative reduction.
37
38 #MINUTES sleep time supine:
39 #response variable: MinutesTSTSupine
40 #fixed effects: intervention (treatment, sham)
41 #random effects: participant, night
42
43 #Specify that the sham intervention is the reference
44 SSdata$intervention <- relevel(SSdata$intervention,ref = "sham")
45
46
47 #Specify model
48 intervention.lme <- lmer(minutesTSTSupine ~ intervention + (1 | participant.s
49 .code) +
50                 (1 | night),
51                 data = SSdata)
52
53 #Print out results
54 intervention.lme
55
56
57
58
59
60

```

```

1
2
3  ## Linear mixed model fit by REML ['lmerMod']
4  ## Formula: minutesTSTSupine ~ intervention + (1 | participant.s.code) +
5  ##   (1 | night)
6  ##   Data: SSdata
7  ## REML criterion at convergence: 414.0174
8  ## Random effects:
9  ##   Groups          Name          Std.Dev.
10  ## participant.s.code (Intercept) 54.66
11  ## night              (Intercept)  0.00
12  ## Residual                                32.20
13  ## Number of obs: 40, groups: participant.s.code, 20; night, 2
14  ## Fixed Effects:
15  ##           (Intercept) interventionPrenaBelt
16  ##           62.30          -24.35

```

```

17
18
19 summary(intervention.lme)

```

```

20
21  ## Linear mixed model fit by REML ['lmerMod']
22  ## Formula: minutesTSTSupine ~ intervention + (1 | participant.s.code) +
23  ##   (1 | night)
24  ##   Data: SSdata
25  ##
26  ## REML criterion at convergence: 414
27  ##
28  ## Scaled residuals:
29  ##   Min      1Q   Median      3Q      Max
30  ## -1.32084 -0.61087  0.05957  0.57539  1.44671
31  ##
32  ## Random effects:
33  ##   Groups          Name          Variance Std.Dev.
34  ## participant.s.code (Intercept) 2988      54.66
35  ## night              (Intercept)   0         0.00
36  ## Residual                                1037      32.20
37  ## Number of obs: 40, groups: participant.s.code, 20; night, 2
38  ##
39  ## Fixed effects:
40  ##           Estimate Std. Error t value
41  ## (Intercept)      62.30     14.19   4.392
42  ## interventionPrenaBelt -24.35     10.18  -2.391
43  ##
44  ## Correlation of Fixed Effects:
45  ##           (Intr)
46  ## intrvntnPrB -0.359

```

```

47
48  #compute 95% CI (two-sided)

```

```

49  confint(intervention.lme)

```

```

50  ## Computing profile confidence intervals ...

```

```

51
52  ##           2.5 %    97.5 %
53  ## .sig01      36.66838 78.512673

```

```
1
2
3 ## .sig02          0.00000 30.670482
4 ## .sigma         23.69611 44.333544
5 ## (Intercept)    34.21546 90.383559
6 ## interventionPrenaBelt -44.76840 -3.922302
7
8 #compute p-value using formula  $p = 2*pt(t-value, dof=length(SSdata)-1)$ 
9 p=2*pt(-2.697, 39)
10 p
11
12 ## [1] 0.01027937
13
14 #p<0.05, statistically significant: 24.4 minute reduction in number of minute
15 s spent
16 #supine with the PrenaBelt.
17
18
19 #####END#####
```

peer review only

1
2
3 **Supplementary file 3: Code and output – feedback analysis**
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For peer review only

Feedback_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 16:14:40 2018

```

#Description of code: this code processes the PUFQs Looking at summary of the
#se data,
#within-participant comparison of PUFQ data ("before/after"), and between-par
#ticipants
#comparison of PUFQ data (bulk test for differences btw all treatment nights
#vs all
#sham nights)

#Summary/Status:
#08APR: No difference on within-participant or between-participant compariso
#n (treatment
#vs. sham) for all variables.

#setting the workspace directory
setwd("/Users/Allan/Desktop/HPTStats/08APR2017")

#importing the PrenaBelt User Feedback (PBUF) Data
PBUFdata=read.csv("PUFD Data Halifax - 08APR2017.csv")

#Loading the functions (ad.test, etc.) into your workspace
library(nortest)

#Exclude drop outs
#How many drop outs?
summary(PBUFdata$drop.out)

## N Y
## 40 6

#6 dropout nights = 3 participants
#Remove the drop outs ("Y")
PBUFdata <- PBUFdata[!(PBUFdata$drop.out=="Y"),]
nrow(PBUFdata)

## [1] 40

#Separate into sham and treat group for within-participant comparisons
PBUF_sham <- subset(PBUFdata, Intervention == "sham")
PBUF_treat <- subset(PBUFdata, Intervention == "treatment")

#####SR POSITION ADOPTED#####

```

```

1
2
3 #summary data
4 summary(PBUFdata$SR.position.adopted)
5
6 ##           left left and right left and supine
7 ##           0           27           5           1
8 ##      right           supine
9 ##           5           2
10
11 length(PBUFdata$SR.position.adopted)
12
13 ## [1] 40
14
15 #between participants (grouped) comparison
16 xtabs(~SR.position.adopted + Intervention, data = PBUFdata)
17
18 ##           Intervention
19 ## SR.position.adopted sham treatment
20 ##           0           0
21 ## left           13           14
22 ## left and right  2           3
23 ## left and supine 1           0
24 ## right           3           2
25 ## supine          1           1
26
27 #build 2-row table for fisher test: sham vs treatment
28 SR.position.adopted_table <- matrix(c(16,17,5,5,2,1),
29                                     nrow = 2)
30
31 colnames(SR.position.adopted_table) <- c("left", "right", "supine")
32 rownames(SR.position.adopted_table) <- c("Sham",
33                                           "Treatment")
34
35 SR.position.adopted_table
36
37 ##           left right supine
38 ## Sham           16    5    2
39 ## Treatment      17    5    1
40
41 t(SR.position.adopted_table)
42
43 ##           Sham Treatment
44 ## left           16    17
45 ## right          5     5
46 ## supine         2     1
47
48 #Perform Fisher's Exact Tests
49
50 temp_table <- t(SR.position.adopted_table)
51 j=nrow(temp_table)
52 ControlCsum=colSums(temp_table)[1]
53 TreatmentCsum=colSums(temp_table)[2]
54 for(i in 1:j) {
55   a=temp_table[i,1]
56   b=temp_table[i,2]

```

```

1
2
3   c=ControlCsum-a
4   d=TreatmentCsum-b
5   ORtable <- matrix(c(a,c,b,d),nrow = 2)
6   colnames(ORtable) <- c("Sham","Treatment")
7   rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
8   print(row.names(temp_table)[i])
9   print(ORtable)
10  print(fisher.test(ORtable))
11
12 }
13
14 ## [1] "left"
15 ##      Sham Treatment
16 ## left   16         17
17 ## Other   7          6
18 ##
19 ## Fisher's Exact Test for Count Data
20 ##
21 ## data:  ORtable
22 ## p-value = 1
23 ## alternative hypothesis: true odds ratio is not equal to 1
24 ## 95 percent confidence interval:
25 ##  0.181121 3.522335
26 ## sample estimates:
27 ## odds ratio
28 ##  0.810505
29 ##
30 ## [1] "right"
31 ##      Sham Treatment
32 ## right   5          5
33 ## Other  18         18
34 ##
35 ## Fisher's Exact Test for Count Data
36 ##
37 ## data:  ORtable
38 ## p-value = 1
39 ## alternative hypothesis: true odds ratio is not equal to 1
40 ## 95 percent confidence interval:
41 ##  0.1927805 5.1872475
42 ## sample estimates:
43 ## odds ratio
44 ##          1
45 ##
46 ## [1] "supine"
47 ##      Sham Treatment
48 ## supine   2          1
49 ## Other   21         22
50 ##
51 ## Fisher's Exact Test for Count Data
52 ##
53 ## data:  ORtable

```

```

1
2
3  ## p-value = 1
4  ## alternative hypothesis: true odds ratio is not equal to 1
5  ## 95 percent confidence interval:
6  ##    0.1003416 129.0322645
7  ## sample estimates:
8  ## odds ratio
9  ##    2.062812
10
11 #####SR POSITION FELL ASLEEP#####
12 #####
13 #summary data
14 summary(PBUFdata$SR.position.fell.asleep)
15
16 ##                left          left and right
17 ##                0             27             5
18 ## left, right and back      right          supine
19 ##                1             5             2
20
21 length(PBUFdata$SR.position.fell.asleep)
22
23 ## [1] 40
24
25 #between participants (grouped) comparison
26 xtabs(~SR.position.fell.asleep + Intervention, data = PBUFdata)
27
28 ##                Intervention
29 ## SR.position.fell.asleep sham treatment
30 ##                0             0
31 ## left            13            14
32 ## left and right  2             3
33 ## left, right and back  1             0
34 ## right           3             2
35 ## supine          1             1
36
37 #build 2-row table for fisher test: sham vs treatment
38 SR.position.fell.asleep_table <- matrix(c(16,17,6,5,2,1),
39                                         nrow = 2)
40 colnames(SR.position.fell.asleep_table) <- c("left", "right", "supine")
41 rownames(SR.position.fell.asleep_table) <- c("Sham",
42                                             "Treatment")
43
44 t(SR.position.fell.asleep_table)
45
46 ##          Sham Treatment
47 ## left     16          17
48 ## right    6           5
49 ## supine   2           1
50
51 #Perform Fisher's Exact Tests
52
53 temp_table <- t(SR.position.fell.asleep_table)
54 j=nrow(temp_table)
55 ControlCsum=colSums(temp_table)[1]

```

```

1
2
3 TreatmentCsum=colSums(temp_table)[2]
4 for(i in 1:j) {
5   a=temp_table[i,1]
6   b=temp_table[i,2]
7   c=ControlCsum-a
8   d=TreatmentCsum-b
9
10  ORtable <- matrix(c(a,c,b,d),nrow = 2)
11  colnames(ORtable) <- c("Sham","Treatment")
12  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
13  print(row.names(temp_table)[i])
14  print(ORtable)
15  print(fisher.test(ORtable))
16 }
17
18 ## [1] "left"
19 ##      Sham Treatment
20 ## left   16      17
21 ## Other   8      6
22 ##
23 ## Fisher's Exact Test for Count Data
24 ##
25 ## data:  ORtable
26 ## p-value = 0.7516
27 ## alternative hypothesis: true odds ratio is not equal to 1
28 ## 95 percent confidence interval:
29 ##  0.1630989 2.9521011
30 ## sample estimates:
31 ## odds ratio
32 ##  0.7111464
33 ##
34 ## [1] "right"
35 ##      Sham Treatment
36 ## right   6      5
37 ## Other  18     18
38 ##
39 ## Fisher's Exact Test for Count Data
40 ##
41 ## data:  ORtable
42 ## p-value = 1
43 ## alternative hypothesis: true odds ratio is not equal to 1
44 ## 95 percent confidence interval:
45 ##  0.2513307 5.9379379
46 ## sample estimates:
47 ## odds ratio
48 ##  1.195355
49 ##
50 ## [1] "supine"
51 ##      Sham Treatment
52 ## supine   2      1
53 ## Other   22     22

```

```

1
2
3
4  ## Fisher's Exact Test for Count Data
5  ##
6  ## data: ORtable
7  ## p-value = 1
8  ## alternative hypothesis: true odds ratio is not equal to 1
9  ## 95 percent confidence interval:
10 ## 0.09605226 123.17436447
11 ## sample estimates:
12 ## odds ratio
13 ## 1.971677
14
15
16 #####SR SNORING#####
17 #summary data
18 summary(PBUFdata$SR.snored.last.night)
19
20 ##           don't know           no           yes
21 ##           3             26             8             3
22
23 length(PBUFdata$SR.snored.last.night)
24
25 ## [1] 40
26
27 #between participants (grouped) comparison
28 xtabs(~SR.snored.last.night + Intervention, data = PBUFdata)[-1,]
29
30 ##           Intervention
31 ## SR.snored.last.night sham treatment
32 ##           don't know    13         13
33 ##           no            4         4
34 ##           yes           1         2
35
36 #Perform Fisher's Exact Tests
37 temp_table <- xtabs(~SR.snored.last.night + Intervention, data = PBUFdata)[-1
38 ,]
39 j=nrow(temp_table)
40 ControlCsum=colSums(temp_table)[1]
41 TreatmentCsum=colSums(temp_table)[2]
42 for(i in 1:j) {
43   a=temp_table[i,1]
44   b=temp_table[i,2]
45   c=ControlCsum-a
46   d=TreatmentCsum-b
47   ORtable <- matrix(c(a,c,b,d),nrow = 2)
48   colnames(ORtable) <- c("Sham","Treatment")
49   rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
50   print(row.names(temp_table)[i])
51   print(ORtable)
52   print(fisher.test(ORtable))
53 }
54
55
56
57
58
59
60

```

```

1
2
3   ## [1] "don't know"
4   ##           Sham Treatment
5   ## don't know   13         13
6   ## Other       5         6
7   ##
8   ## Fisher's Exact Test for Count Data
9   ##
10  ## data: ORtable
11  ## p-value = 1
12  ## alternative hypothesis: true odds ratio is not equal to 1
13  ## 95 percent confidence interval:
14  ##  0.2341604 6.3402606
15  ## sample estimates:
16  ## odds ratio
17  ##    1.1941
18  ##
19  ## [1] "no"
20  ##           Sham Treatment
21  ## no         4         4
22  ## Other     14        15
23  ##
24  ## Fisher's Exact Test for Count Data
25  ##
26  ## data: ORtable
27  ## p-value = 1
28  ## alternative hypothesis: true odds ratio is not equal to 1
29  ## 95 percent confidence interval:
30  ##  0.1643428 6.9643241
31  ## sample estimates:
32  ## odds ratio
33  ##    1.06941
34  ##
35  ## [1] "yes"
36  ##           Sham Treatment
37  ## yes        1         2
38  ## Other     17        17
39  ##
40  ## Fisher's Exact Test for Count Data
41  ##
42  ## data: ORtable
43  ## p-value = 1
44  ## alternative hypothesis: true odds ratio is not equal to 1
45  ## 95 percent confidence interval:
46  ##  0.008017856 10.654170427
47  ## sample estimates:
48  ## odds ratio
49  ##    0.509154
50
51
52
53
54
55
56
57
58
59
60

```

```

#####SR LEGS TWITCH/JERK#####
#summary data
summary(PBUFdata$SR.legs.twitch.jerk)

##           don't know           no           yes
##           3             19           14           4

length(PBUFdata$SR.legs.twitch.jerk)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.legs.twitch.jerk + Intervention, data = PBUFdata)[-1,]

##           Intervention
## SR.legs.twitch.jerk sham treatment
##           don't know           9           10
##           no                 8           6
##           yes                 2           2

#Perform Fisher's Exact Tests
temp_table <- xtabs(~SR.legs.twitch.jerk + Intervention, data = PBUFdata)[-1,
]
j=nrow(temp_table)
ControlCsum=colSums(temp_table)[1]
TreatmentCsum=colSums(temp_table)[2]
for(i in 1:j) {
  a=temp_table[i,1]
  b=temp_table[i,2]
  c=ControlCsum-a
  d=TreatmentCsum-b
  ORtable <- matrix(c(a,c,b,d),nrow = 2)
  colnames(ORtable) <- c("Sham", "Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "don't know"
##           Sham Treatment
## don't know           9           10
## Other                 10           8
##
## Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7459
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1631369 3.1478545

```



```

1
2
3  ## sample estimates:
4  ## odds ratio
5  ## 0.7264619
6  ##
7  ## [1] "no"
8  ##      Sham Treatment
9  ## no      8          6
10 ## Other  11         12
11 ##
12 ## Fisher's Exact Test for Count Data
13 ##
14 ## data: ORtable
15 ## p-value = 0.7374
16 ## alternative hypothesis: true odds ratio is not equal to 1
17 ## 95 percent confidence interval:
18 ## 0.3156971 6.8777204
19 ## sample estimates:
20 ## odds ratio
21 ## 1.439815
22 ##
23 ## [1] "yes"
24 ##      Sham Treatment
25 ## yes      2          2
26 ## Other  17         16
27 ##
28 ## Fisher's Exact Test for Count Data
29 ##
30 ## data: ORtable
31 ## p-value = 1
32 ## alternative hypothesis: true odds ratio is not equal to 1
33 ## 95 percent confidence interval:
34 ## 0.06145761 14.45806216
35 ## sample estimates:
36 ## odds ratio
37 ## 0.9426919
38
39 #####SR WAKE POSITION#####
40 #summary data
41 summary(PBUFdata$SR.position.woke.up)
42
43 ##      left right
44 ##      0      28      12
45
46 length(PBUFdata$SR.position.woke.up)
47
48 ## [1] 40
49
50 #between participants (grouped) comparison
51 xtabs(~SR.position.woke.up + Intervention, data = PBUFdata)[-1,]
52
53
54
55
56
57
58
59
60

```

```

1
2
3      ##              Intervention
4      ## SR.position.woke.up sham treatment
5      ##           left      13      15
6      ##           right     7       5
7
8      fisher.test(xtabs(~SR.position.woke.up + Intervention, data = PBUFdata)[-1,])
9
10     ##
11     ## Fisher's Exact Test for Count Data
12     ##
13     ## data:
14     ## p-value = 0.7311
15     ## alternative hypothesis: true odds ratio is not equal to 1
16     ## 95 percent confidence interval:
17     ##  0.1235598 2.9574108
18     ## sample estimates:
19     ## odds ratio
20     ##  0.6265621
21
22
23     #####SR - did you change positions?#####
24     #####
25     #summary data
26     summary(PBUFdata$SR.position.changed)
27
28     ##           don\xcdt know           no           yes
29     ##           1             1             3             35
30
31     length(PBUFdata$SR.position.changed)
32
33     ## [1] 40
34
35     #between participants (grouped) comparison
36     xtabs(~SR.position.changed + Intervention, data = PBUFdata)[-1,]
37
38     ##              Intervention
39     ## SR.position.changed sham treatment
40     ## don\xcdt know      1      0
41     ## no                 1      2
42     ## yes                18     17
43
44     #Perform Fisher's Exact Tests
45     temp_table <- xtabs(~SR.position.changed + Intervention, data = PBUFdata)[-1,
46 ]
47     j=nrow(temp_table)
48     ControlCsum=colSums(temp_table)[1]
49     TreatmentCsum=colSums(temp_table)[2]
50     for(i in 1:j) {
51       a=temp_table[i,1]
52       b=temp_table[i,2]
53       c=ControlCsum-a
54       d=TreatmentCsum-b
55       ORtable <- matrix(c(a,c,b,d),nrow = 2)
56
57
58
59
60

```

```

1
2
3   colnames(ORtable) <- c("Sham", "Treatment")
4   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
5   print(row.names(temp_table)[i])
6   print(ORtable)
7   print(fisher.test(ORtable))
8
9 }
10
11 ## [1] "don\xcdt know"
12 ##           Sham Treatment
13 ## don\xcdt know   1         0
14 ## Other           19        19
15 ##
16 ## Fisher's Exact Test for Count Data
17 ##
18 ## data:  ORtable
19 ## p-value = 1
20 ## alternative hypothesis: true odds ratio is not equal to 1
21 ## 95 percent confidence interval:
22 ##  0.02435859      Inf
23 ## sample estimates:
24 ## odds ratio
25 ##           Inf
26 ##
27 ## [1] "no"
28 ##           Sham Treatment
29 ## no           1         2
30 ## Other       19        17
31 ##
32 ## Fisher's Exact Test for Count Data
33 ##
34 ## data:  ORtable
35 ## p-value = 0.605
36 ## alternative hypothesis: true odds ratio is not equal to 1
37 ## 95 percent confidence interval:
38 ##  0.007216433  9.507277143
39 ## sample estimates:
40 ## odds ratio
41 ##  0.456456
42 ##
43 ## [1] "yes"
44 ##           Sham Treatment
45 ## yes          18        17
46 ## Other         2         2
47 ##
48 ## Fisher's Exact Test for Count Data
49 ##
50 ## data:  ORtable
51 ## p-value = 1
52 ## alternative hypothesis: true odds ratio is not equal to 1
53 ## 95 percent confidence interval:

```

```

1
2
3 ## 0.0693477 16.1216542
4 ## sample estimates:
5 ## odds ratio
6 ## 1.057301
7
8 #Take out the pts that we don't have complete data on (these participants' st
9 udies were
10 #before the PUFQ was revised to ask about the participant's estimate of how m
11 uch time
12 #she spent in each position)
13 PBUF_shamSRpos <- PBUF_sham[-c(1,2,3),]
14 PBUF_treatSRpos <- PBUF_treat[-c(1,2,3),]
15
16 #####SR PROPORTION OF TIME ON LEFT#####
17 #####
18 #summary data
19 summary(PBUFdata$SR.Ptime.left)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
22 ##      0.00  41.50   66.00   59.91  84.00  100.00     5
23
24 sd(PBUFdata$SR.Ptime.left, na.rm = TRUE)
25
26 ## [1] 28.14915
27
28 length(na.omit(PBUFdata$SR.Ptime.left))
29
30 ## [1] 35
31
32 #within-participants (paired) comparison
33 #Paired t-test
34 t.test(PBUF_shamSRpos$SR.Ptime.left, PBUF_treatSRpos$SR.Ptime.left, paired =
35 TRUE)
36
37 ##
38 ## Paired t-test
39 ##
40 ## data: PBUF_shamSRpos$SR.Ptime.left and PBUF_treatSRpos$SR.Ptime.left
41 ## t = 0.38979, df = 16, p-value = 0.7018
42 ## alternative hypothesis: true difference in means is not equal to 0
43 ## 95 percent confidence interval:
44 ## -6.266297  9.089826
45 ## sample estimates:
46 ## mean of the differences
47 ##
48 ##          1.411765
49
50 #between participants (grouped) comparison
51 summary(PBUF_treatSRpos$SR.Ptime.left)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##      10.00  36.00   60.00   58.76  85.00   95.00
55
56
57
58
59
60

```

```

sd(PBUF_treatSRpos$SR.Ptime.left)

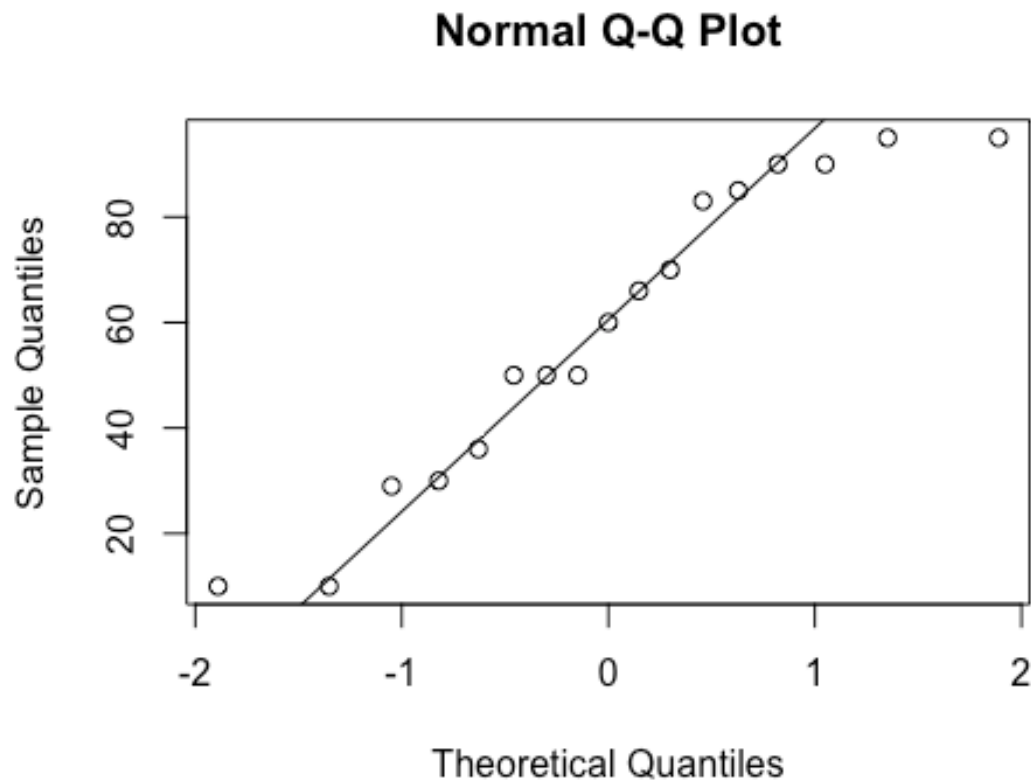
## [1] 28.77831

length(PBUF_treatSRpos$SR.Ptime.left)

## [1] 17

qqnorm(PBUF_treatSRpos$SR.Ptime.left)
qqline(PBUF_treatSRpos$SR.Ptime.left)

```



```

ad.test(PBUF_treatSRpos$SR.Ptime.left)

##
## Anderson-Darling normality test
##
## data: PBUF_treatSRpos$SR.Ptime.left
## A = 0.40809, p-value = 0.3093

#normal

summary(PBUF_shamSRpos$SR.Ptime.left)

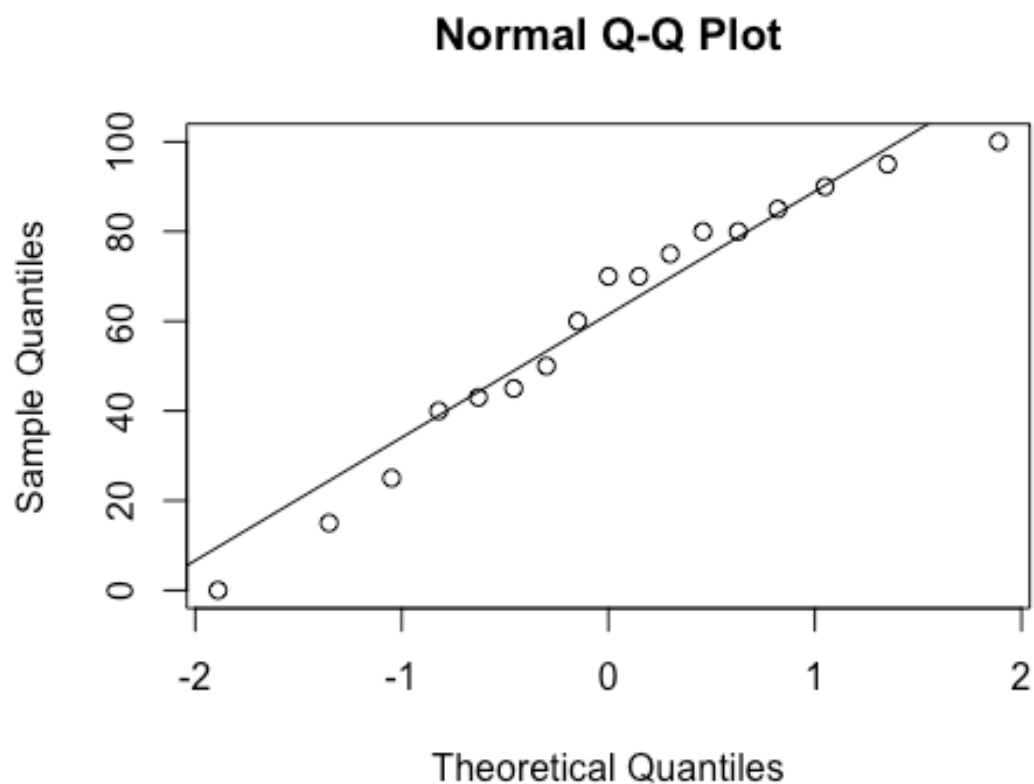
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00  43.00   70.00   60.18  80.00  100.00

```

```
sd(PBUF_shamSRpos$SR.Ptime.left)
## [1] 28.9811

length(PBUF_shamSRpos$SR.Ptime.left)
## [1] 17

qqnorm(PBUF_shamSRpos$SR.Ptime.left)
qqline(PBUF_shamSRpos$SR.Ptime.left)
```



```
ad.test(PBUF_shamSRpos$SR.Ptime.left)
##
## Anderson-Darling normality test
##
## data: PBUF_shamSRpos$SR.Ptime.left
## A = 0.31945, p-value = 0.506

#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_shamSRpos$SR.Ptime.left, PBUF_treatSRpos$SR.Ptime.left)
```

```

1
2
3
4  ## Welch Two Sample t-test
5  ##
6  ## data: PBUF_shamSRpos$SR.Ptime.left and PBUF_treatSRpos$SR.Ptime.left
7  ## t = 0.14252, df = 31.998, p-value = 0.8876
8  ## alternative hypothesis: true difference in means is not equal to 0
9  ## 95 percent confidence interval:
10 ## -18.76556 21.58909
11 ## sample estimates:
12 ## mean of x mean of y
13 ## 60.17647 58.76471
14
15
16 #####SR PROPORTION OF TIME ON RIGHT#####
17 #####
18 #summary data
19 summary(PBUFdata$SR.Ptime.right)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.     NA's
22 ##      0.00   2.50   30.00   31.29   50.00   90.00      5
23
24 sd(PBUFdata$SR.Ptime.right, na.rm = TRUE)
25
26 ## [1] 27.30177
27
28 length(na.omit(PBUFdata$SR.Ptime.right))
29
30 ## [1] 35
31
32 #within-participants (paired) comparison
33 #Paired t-test
34 t.test(PBUF_shamSRpos$SR.Ptime.right, PBUF_treatSRpos$SR.Ptime.right, paired
35 = TRUE)
36
37 ##
38 ## Paired t-test
39 ##
40 ## data: PBUF_shamSRpos$SR.Ptime.right and PBUF_treatSRpos$SR.Ptime.right
41 ## t = -0.10277, df = 16, p-value = 0.9194
42 ## alternative hypothesis: true difference in means is not equal to 0
43 ## 95 percent confidence interval:
44 ## -7.633106 6.927224
45 ## sample estimates:
46 ## mean of the differences
47 ##                -0.3529412
48
49 #between participants (grouped) comparison
50 summary(PBUF_treatSRpos$SR.Ptime.right)
51
52 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
53 ##      0.00   0.00   34.00   31.65   50.00   88.00
54
55 sd(PBUF_treatSRpos$SR.Ptime.right)
56
57
58
59
60

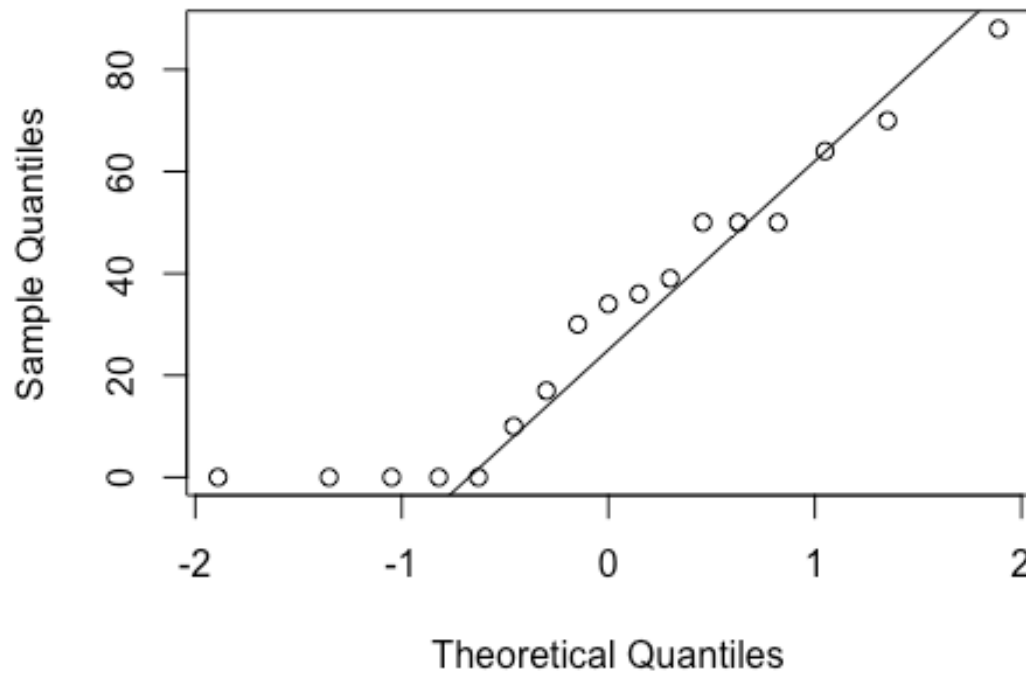
```

```

1
2
3 ## [1] 27.92387
4
5 length(PBUF_treatSRpos$SR.Ptime.right)
6
7 ## [1] 17
8
9 qqnorm(PBUF_treatSRpos$SR.Ptime.right)
10 qqline(PBUF_treatSRpos$SR.Ptime.right)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

```

Normal Q-Q Plot



```

41 ad.test(PBUF_treatSRpos$SR.Ptime.right)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: PBUF_treatSRpos$SR.Ptime.right
47 ## A = 0.51449, p-value = 0.1649
48
49 #normal
50
51 summary(PBUF_shamSRpos$SR.Ptime.right)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##      0.00   5.00   30.00   31.29   50.00   90.00
55
56 sd(PBUF_shamSRpos$SR.Ptime.right)
57
58
59
60

```

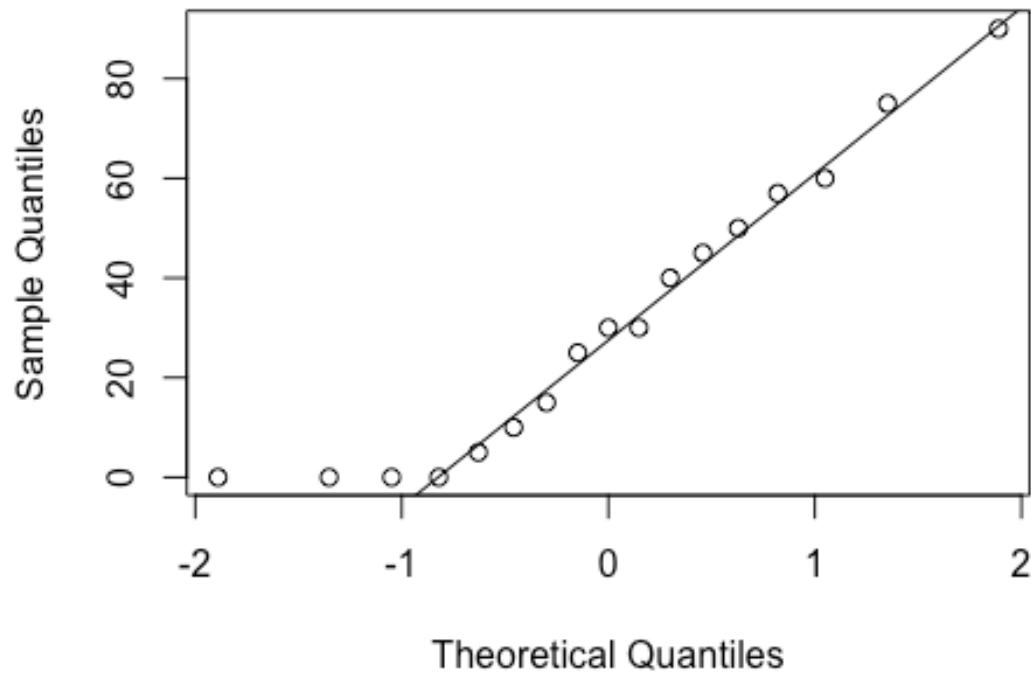


```

1
2
3 ## [1] 28.31246
4
5 length(PBUF_shamSRpos$SR.Ptime.right)
6
7 ## [1] 17
8
9 qqnorm(PBUF_shamSRpos$SR.Ptime.right)
10 qqline(PBUF_shamSRpos$SR.Ptime.right)
11
12
13
14
15
16

```

Normal Q-Q Plot



```

36
37
38
39
40
41 ad.test(PBUF_shamSRpos$SR.Ptime.right)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: PBUF_shamSRpos$SR.Ptime.right
47 ## A = 0.43793, p-value = 0.2602
48
49 #normal
50
51 #Perform 2-sample t-test (Welch's t-test)
52 t.test(PBUF_shamSRpos$SR.Ptime.right, PBUF_treatSRpos$SR.Ptime.right)
53
54 ##
55 ## Welch Two Sample t-test
56
57
58
59
60

```

```

1
2
3
4  ##
5  ## data: PBUF_shamSRpos$SR.Ptime.right and PBUF_treatSRpos$SR.Ptime.right
6  ## t = -0.036594, df = 31.994, p-value = 0.971
7  ## alternative hypothesis: true difference in means is not equal to 0
8  ## 95 percent confidence interval:
9  ## -19.99866 19.29278
10 ## sample estimates:
11 ## mean of x mean of y
12 ## 31.29412 31.64706
13
14 #####SR PROPORTION OF TIME ON BACK#####
15 #####
16 #summary data
17 summary(PBUFdata$SR.Ptime.back)
18
19 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
20 ##      0.0     0.0     0.0     7.8     5.0    90.0     5
21
22 sd(PBUFdata$SR.Ptime.back, na.rm = TRUE)
23
24 ## [1] 19.98205
25
26 length(na.omit(PBUFdata$SR.Ptime.back))
27
28 ## [1] 35
29
30 #within-participants (paired) comparison - non-normal, use parametric test (W
31 ilcoxon)
32 wilcox.test(PBUF_shamSRpos$SR.Ptime.back, PBUF_treatSRpos$SR.Ptime.back,
33             paired = TRUE, conf.int = TRUE)
34
35 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
36 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with ties
37
38 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
39 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence interval
40 ## with ties
41
42 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
43 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with zeroes
44
45 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
46 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence interval
47 ## with zeroes
48
49 ##
50 ## Wilcoxon signed rank test with continuity correction
51 ##
52 ## data: PBUF_shamSRpos$SR.Ptime.back and PBUF_treatSRpos$SR.Ptime.back
53 ## V = 18.5, p-value = 0.4951
54 ## alternative hypothesis: true location shift is not equal to 0
55 ## 95 percent confidence interval:
56
57
58
59
60

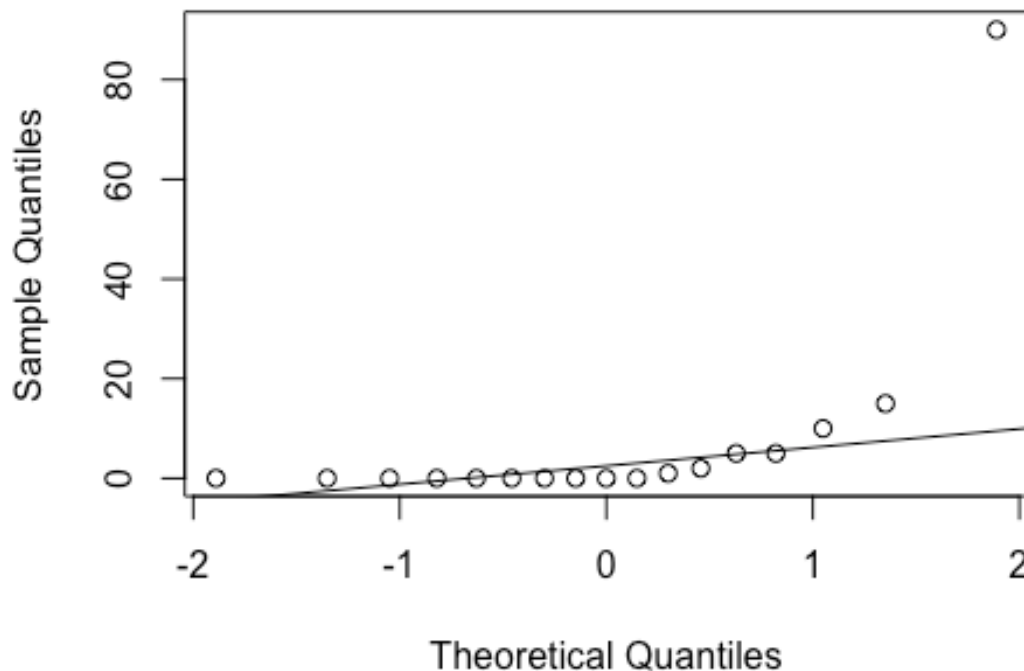
```

```

1
2
3 ## -7.499958  8.999966
4 ## sample estimates:
5 ## (pseudo)median
6 ##      4.090518
7
8 #between participants (grouped) comparison
9 summary(PBUF_treatSRpos$SR.Ptime.back)
10
11 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
12 ##      0.000   0.000   0.000   7.529   5.000   90.000
13
14 sd(PBUF_treatSRpos$SR.Ptime.back)
15
16 ## [1] 21.67406
17
18 length(PBUF_treatSRpos$SR.Ptime.back)
19
20 ## [1] 17
21
22 qqnorm(PBUF_treatSRpos$SR.Ptime.back)
23 qqline(PBUF_treatSRpos$SR.Ptime.back)

```

Normal Q-Q Plot



```

53
54 ad.test(PBUF_treatSRpos$SR.Ptime.back)
55
56
57
58
59
60

```

```
##
## Anderson-Darling normality test
##
## data: PBUF_treatSRpos$SR.Ptime.back
## A = 4.2859, p-value = 3.533e-11

#non-normal

summary(PBUF_shamSRpos$SR.Ptime.back)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.000  0.000  0.000   8.529  5.000  80.000

sd(PBUF_shamSRpos$SR.Ptime.back)

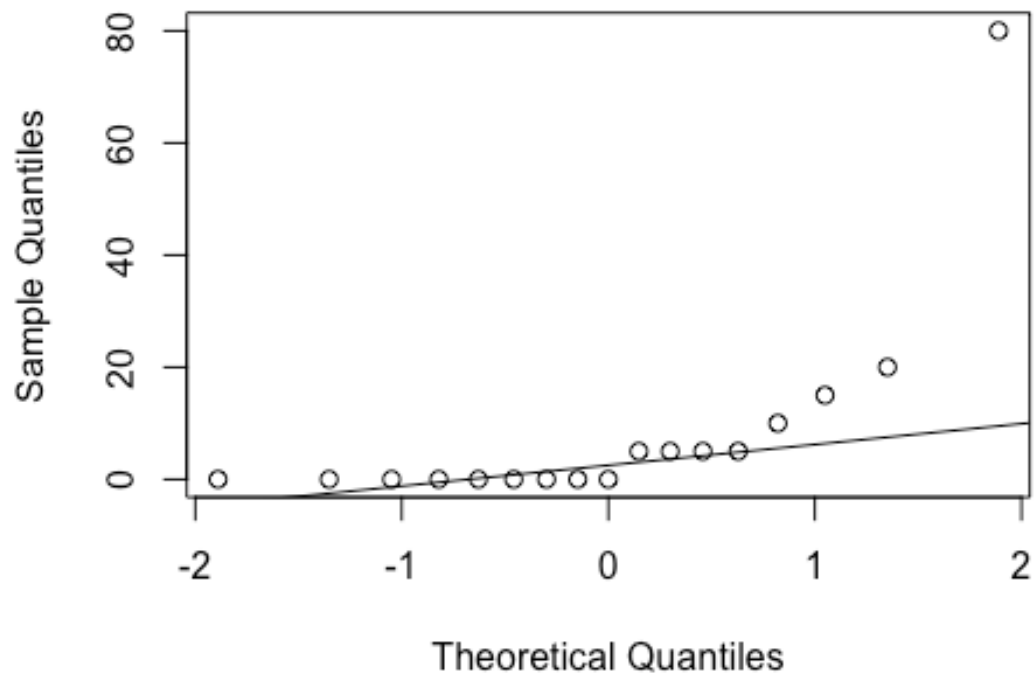
## [1] 19.34592

length(PBUF_shamSRpos$SR.Ptime.back)

## [1] 17

qqnorm(PBUF_shamSRpos$SR.Ptime.back)
qqline(PBUF_shamSRpos$SR.Ptime.back)
```

Normal Q-Q Plot



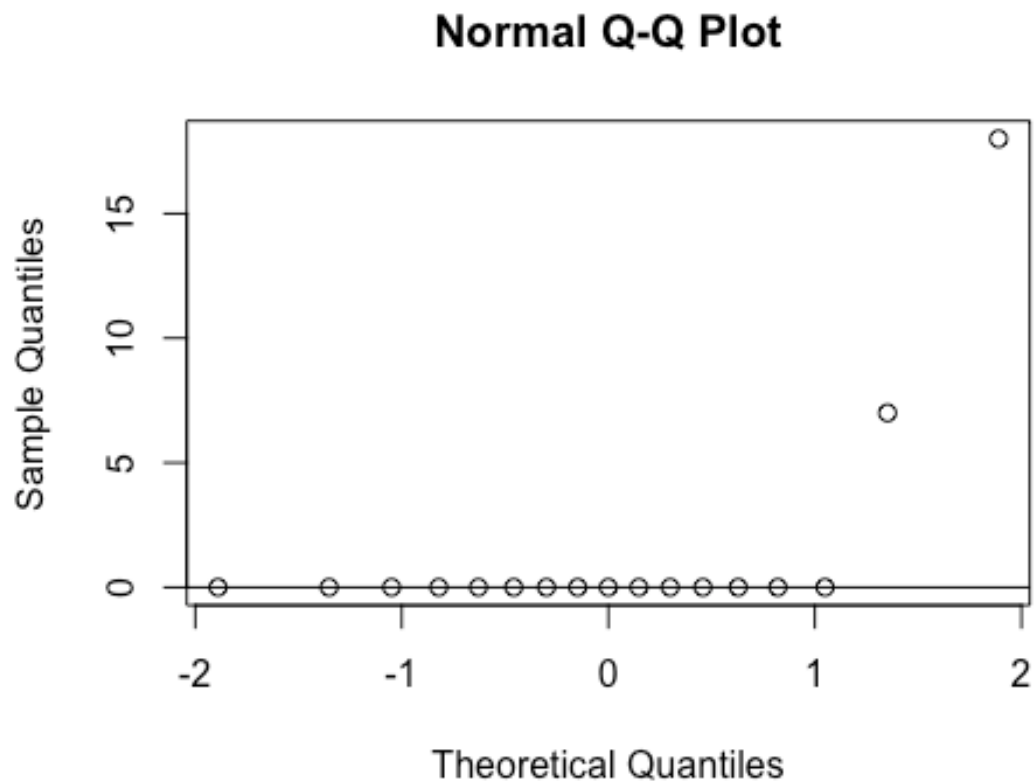
```
ad.test(PBUF_shamSRpos$SR.Ptime.back)
```

```

1
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data: PBUF_shamSRpos$SR.Ptime.back
7  ## A = 3.3048, p-value = 1.097e-08
8
9  #non-normal
10
11
12 #Perform non-parametric test (Wilcoxon)
13 wilcox.test(PBUF_shamSRpos$SR.Ptime.back, PBUF_treatSRpos$SR.Ptime.back, conf
14 .int = TRUE)
15
16 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
17 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with ties
18
19 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
20 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence intervals
21 ## with ties
22
23 ##
24 ## Wilcoxon rank sum test with continuity correction
25 ##
26 ## data: PBUF_shamSRpos$SR.Ptime.back and PBUF_treatSRpos$SR.Ptime.back
27 ## W = 159, p-value = 0.5944
28 ## alternative hypothesis: true location shift is not equal to 0
29 ## 95 percent confidence interval:
30 ## -3.745025e-05 4.999982e+00
31 ## sample estimates:
32 ## difference in location
33 ## 3.7504e-05
34
35 #####SR PROPORTION OF TIME ON STOMACH#####
36 #####
37 #summary data
38 summary(PBUFdata$SR.Ptime.stomach)
39
40 ## Min. 1st Qu. Median Mean 3rd Qu. Max. NA's
41 ## 0.0000 0.0000 0.0000 0.7143 0.0000 18.0000 5
42
43 sd(PBUFdata$SR.Ptime.stomach, na.rm = TRUE)
44
45 ## [1] 3.231931
46
47 length(na.omit(PBUFdata$SR.Ptime.stomach))
48
49 ## [1] 35
50
51 #within-participants (paired) comparison - non-normal, use parametric test (W
52 ilcoxon)
53 wilcox.test(PBUF_shamSRpos$SR.Ptime.stomach, PBUF_treatSRpos$SR.Ptime.stomach
54 ,
55 paired = TRUE)
56
57
58
59
60

```

```
1
2
3 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.stomach,
4 ## PBUF_treatSRpos$SR.Ptime.stomach, : cannot compute exact p-value with
5 ## zeroes
6
7 ##
8 ## Wilcoxon signed rank test with continuity correction
9 ##
10 ## data: PBUF_shamSRpos$SR.Ptime.stomach and PBUF_treatSRpos$SR.Ptime.stomac
11 h
12 ## V = 0, p-value = 0.3711
13 ## alternative hypothesis: true location shift is not equal to 0
14
15 #between participants (grouped) comparison
16 summary(PBUF_treatSRpos$SR.Ptime.stomach)
17
18 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
19 ##      0.000  0.000  0.000   1.471  0.000  18.000
20
21 sd(PBUF_treatSRpos$SR.Ptime.stomach)
22
23 ## [1] 4.58418
24
25 length(PBUF_treatSRpos$SR.Ptime.stomach)
26
27 ## [1] 17
28
29 qqnorm(PBUF_treatSRpos$SR.Ptime.stomach)
30 qqline(PBUF_treatSRpos$SR.Ptime.stomach)
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(PBUF_treatSRpos$SR.Ptime.stomach)

##
## Anderson-Darling normality test
##
## data: PBUF_treatSRpos$SR.Ptime.stomach
## A = 4.9879, p-value = 5.961e-13
##
#non-normal

summary(PBUF_shamSRpos$SR.Ptime.stomach)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0         0         0         0         0         0

sd(PBUF_shamSRpos$SR.Ptime.stomach)

## [1] 0

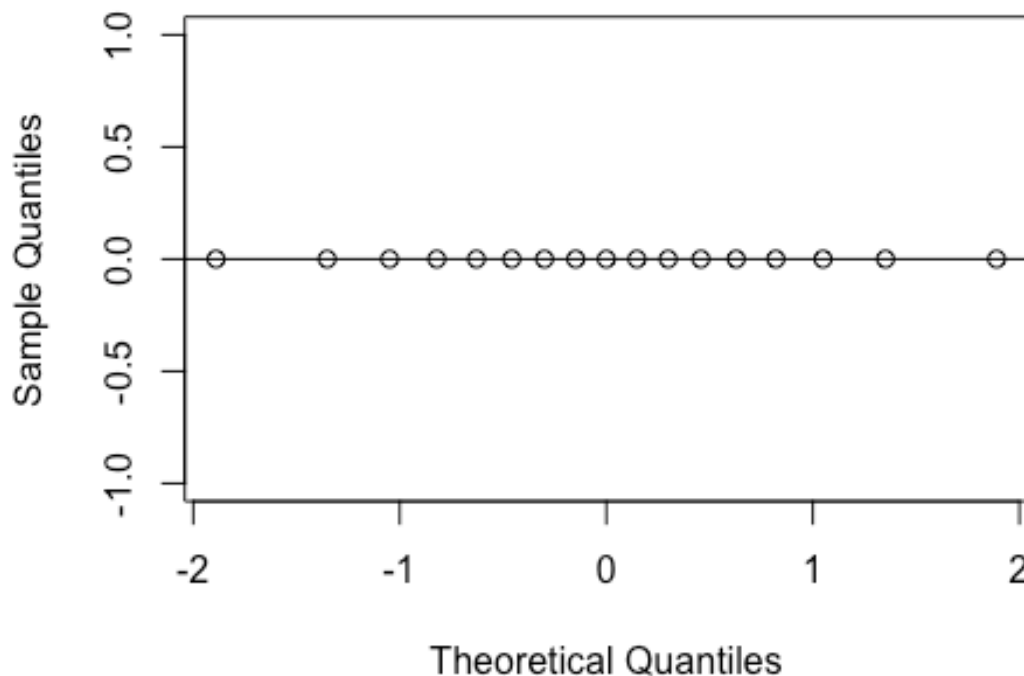
length(PBUF_shamSRpos$SR.Ptime.stomach)

## [1] 17

qqnorm(PBUF_shamSRpos$SR.Ptime.stomach)
qqline(PBUF_shamSRpos$SR.Ptime.stomach)

```

Normal Q-Q Plot



```

#ad.test(PBUF_shamSRpos$SR.Ptime.stomach)
#distribution is entirely zeroes

#Perform non-parametric test (Wilcoxon)
wilcox.test(PBUF_shamSRpos$SR.Ptime.stomach, PBUF_treatSRpos$SR.Ptime.stomach
, conf.int = TRUE)

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.stomach,
## PBUF_treatSRpos$SR.Ptime.stomach, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.stomach,
## PBUF_treatSRpos$SR.Ptime.stomach, : cannot compute exact confidence
## intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: PBUF_shamSRpos$SR.Ptime.stomach and PBUF_treatSRpos$SR.Ptime.stomach
## W = 127.5, p-value = 0.1635
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
## -7.272004e-05 0.000000e+00
## sample estimates:

```



```

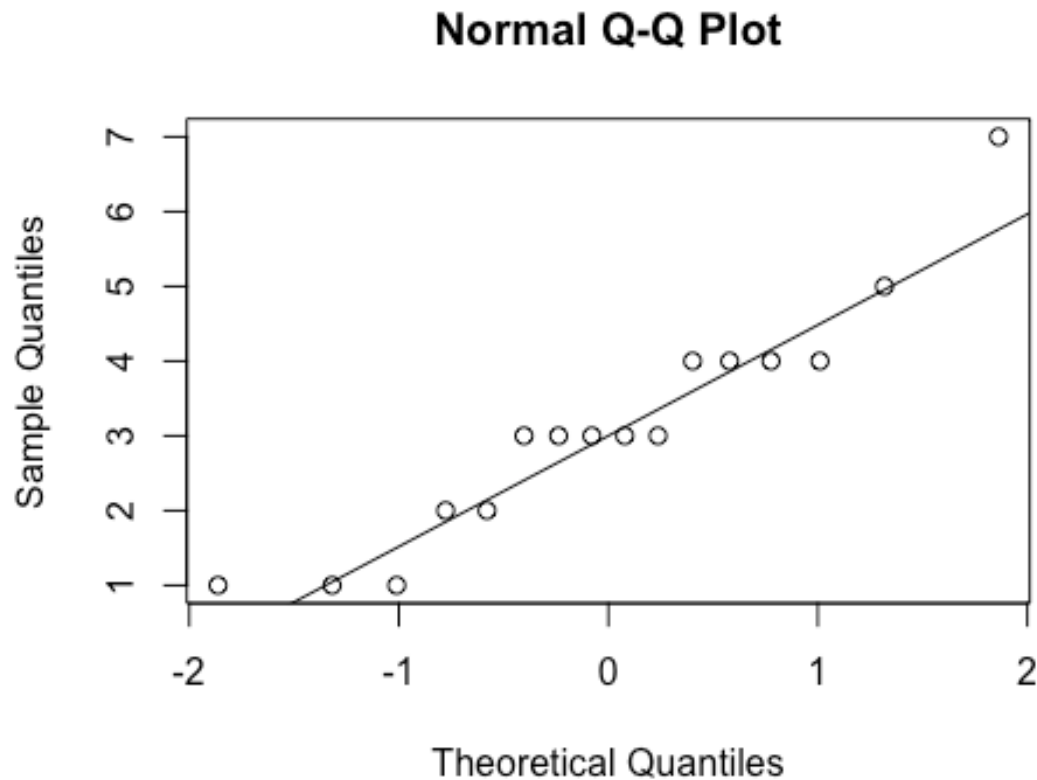
1
2
3  ## difference in location
4  ##           0
5
6  #####REMEMBER CHANGING POSITIONS#####
7  #####
8  #summary data
9  summary(PBUFdata$remember.changing.positions)
10
11  ##      no yes
12  ##    0  7 33
13
14  length(PBUFdata$remember.changing.positions)
15
16  ## [1] 40
17
18  #between participants (grouped) comparison
19  xtabs(~remember.changing.positions + Intervention, data = PBUFdata)[-1,]
20
21  ##
22  ##           Intervention
23  ## remember.changing.positions sham treatment
24  ##                no      4      3
25  ##                yes     16     17
26
27  fisher.test(xtabs(~remember.changing.positions + Intervention, data = PBUFdata)[-1,])
28
29  ##
30  ## Fisher's Exact Test for Count Data
31  ##
32  ## data:
33  ## p-value = 1
34  ## alternative hypothesis: true odds ratio is not equal to 1
35  ## 95 percent confidence interval:
36  ##  0.2020801 11.1277720
37  ## sample estimates:
38  ## odds ratio
39  ##  1.404393
40
41  #Remove rows with missing data or with participants who did not change position or did
42  #not remember changing positions
43  PBUF_shamSRchangeupos <- PBUF_sham[-c(1,5,6,7,14,19),]
44  PBUF_treatSRchangeupos <- PBUF_treat[-c(1,5,6,7,14,19),]
45
46  #####SR NUMBER OF TIMES CHANGED POSITION#####
47  #####
48  #summary data
49  summary(PBUFdata$SR.how.many.times.changed.positions)
50
51  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
52  ##    0.000  2.000   3.000   3.194  4.000   7.000     9
53
54
55
56
57
58
59
60

```

```

1
2
3 sd(PBUFdata$SR.how.many.times.changed.positions, na.rm = TRUE)
4
5 ## [1] 1.740103
6
7 length(na.omit(PBUFdata$SR.how.many.times.changed.positions))
8
9 ## [1] 31
10
11 #within-participants (paired) comparison
12 #Paired t-test
13 t.test(PBUF_shamSRchange$SR.how.many.times.changed.positions,
14        PBUF_treatSRchange$SR.how.many.times.changed.positions,
15        paired = TRUE)
16
17 ##
18 ## Paired t-test
19 ##
20 ## data: PBUF_shamSRchange$SR.how.many.times.changed.positions and PBUF_treatSRchange$SR.how.many.times.changed.positions
21 ## t = 0.31382, df = 13, p-value = 0.7586
22 ## alternative hypothesis: true difference in means is not equal to 0
23 ## 95 percent confidence interval:
24 ## -0.8405766 1.1262909
25 ## sample estimates:
26 ## mean of the differences
27 ## 0.1428571
28
29
30 #between participants (grouped) comparison
31 summary(PBUF_treat$SR.how.many.times.changed.positions)
32
33 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.     NA's
34 ##  1.000  2.000  3.000  3.125  4.000  7.000      4
35
36 sd(PBUF_treat$SR.how.many.times.changed.positions, na.rm = TRUE)
37
38 ## [1] 1.586401
39
40 length(na.omit(PBUF_treat$SR.how.many.times.changed.positions))
41
42 ## [1] 16
43
44 qqnorm(PBUF_treat$SR.how.many.times.changed.positions)
45 qqline(PBUF_treat$SR.how.many.times.changed.positions)
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(PBUF_treat$SR.how.many.times.changed.positions)

##
## Anderson-Darling normality test
##
## data:  PBUF_treat$SR.how.many.times.changed.positions
## A = 0.51178, p-value = 0.1658

#normal

summary(PBUF_sham$SR.how.many.times.changed.positions)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##  0.000  1.500   4.000   3.267  4.500   7.000     5

sd(PBUF_sham$SR.how.many.times.changed.positions, na.rm = TRUE)

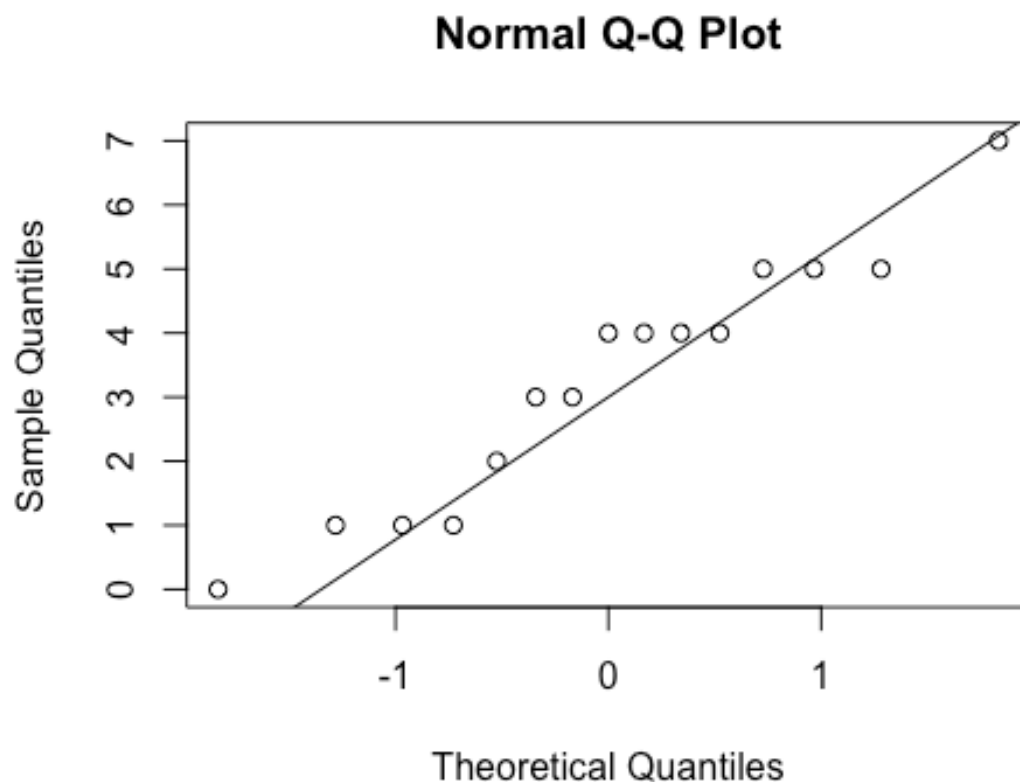
## [1] 1.944467

length(na.omit(PBUF_sham$SR.how.many.times.changed.positions))

## [1] 15

qqnorm(PBUF_sham$SR.how.many.times.changed.positions)
qqline(PBUF_sham$SR.how.many.times.changed.positions)

```



```

ad.test(PBUF_sham$SR.how.many.times.changed.positions)

##
## Anderson-Darling normality test
##
## data: PBUF_sham$SR.how.many.times.changed.positions
## A = 0.41783, p-value = 0.287

#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_sham$SR.how.many.times.changed.positions,
       PBUF_treat$SR.how.many.times.changed.positions)

##
## Welch Two Sample t-test
##
## data: PBUF_sham$SR.how.many.times.changed.positions and PBUF_treat$SR.how
## .many.times.changed.positions
## t = 0.22142, df = 27.082, p-value = 0.8264
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -1.170927 1.454261
## sample estimates:

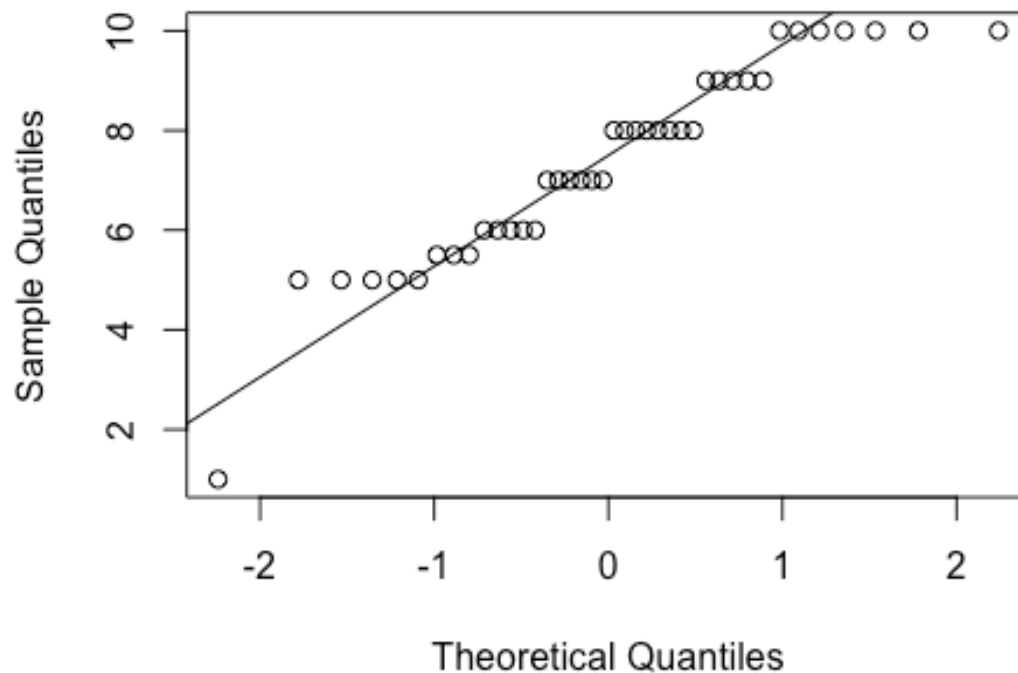
```

```

1
2
3 ## mean of x mean of y
4 ## 3.266667 3.125000
5
6 #####SATISFACTION LEVEL#####
7 #summary data
8 summary(PBUFdata$satisfaction.level)
9
10 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11 ##  1.000  6.000  7.500  7.338  9.000 10.000
12
13 sd(PBUFdata$satisfaction.level)
14
15 ## [1] 1.988388
16
17 length(PBUFdata$satisfaction.level)
18
19 ## [1] 40
20
21 qqnorm(PBUFdata$satisfaction.level)
22 qqline(PBUFdata$satisfaction.level)

```

Normal Q-Q Plot



```

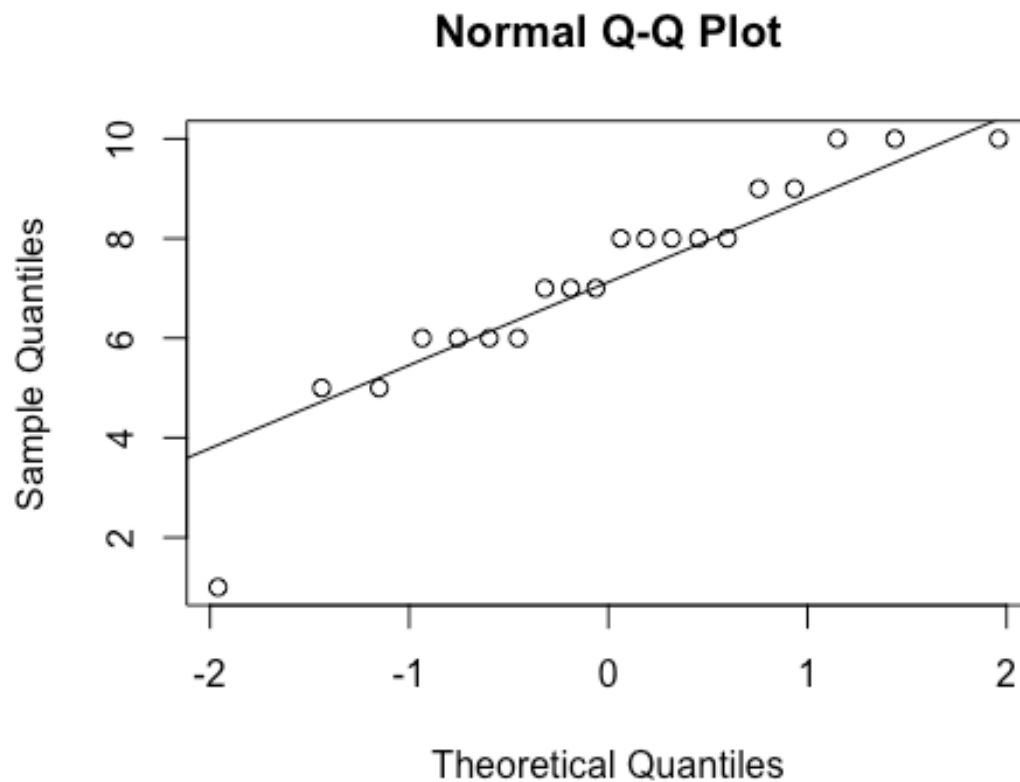
52 ad.test(PBUFdata$satisfaction.level)
53
54 ##
55 ## Anderson-Darling normality test
56
57
58
59
60

```

```

1
2
3 ##
4 ## data: PBUFdata$satisfaction.level
5 ## A = 0.79381, p-value = 0.03625
6
7 #within-participants (paired) comparison
8 #t-test (individual distributions are normal)
9 t.test(PBUF_sham$satisfaction.level,PBUF_treat$satisfaction.level, paired = T
10 RUE)
11
12 ##
13 ## Paired t-test
14 ##
15 ## data: PBUF_sham$satisfaction.level and PBUF_treat$satisfaction.level
16 ## t = 0.74891, df = 19, p-value = 0.4631
17 ## alternative hypothesis: true difference in means is not equal to 0
18 ## 95 percent confidence interval:
19 ## -0.4935575 1.0435575
20 ## sample estimates:
21 ## mean of the differences
22 ## 0.275
23
24 #between participants (grouped) comparison
25 summary(PBUF_treat$satisfaction.level)
26
27 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28 ##      1.00   6.00   7.50   7.20   8.25   10.00
29
30 sd(PBUF_treat$satisfaction.level, na.rm = TRUE)
31
32 ## [1] 2.142306
33
34 length(na.omit(PBUF_treat$satisfaction.level))
35
36 ## [1] 20
37
38 qqnorm(PBUF_treat$satisfaction.level)
39 qqline(PBUF_treat$satisfaction.level)
40
41
42
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```



```

ad.test(PBUF_treat$satisfaction.level)

##
## Anderson-Darling normality test
##
## data: PBUF_treat$satisfaction.level
## A = 0.54062, p-value = 0.1445

#normal

summary(PBUF_sham$satisfaction.level)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  5.000  5.500   7.500   7.475  9.000  10.000

sd(PBUF_sham$satisfaction.level, na.rm = TRUE)

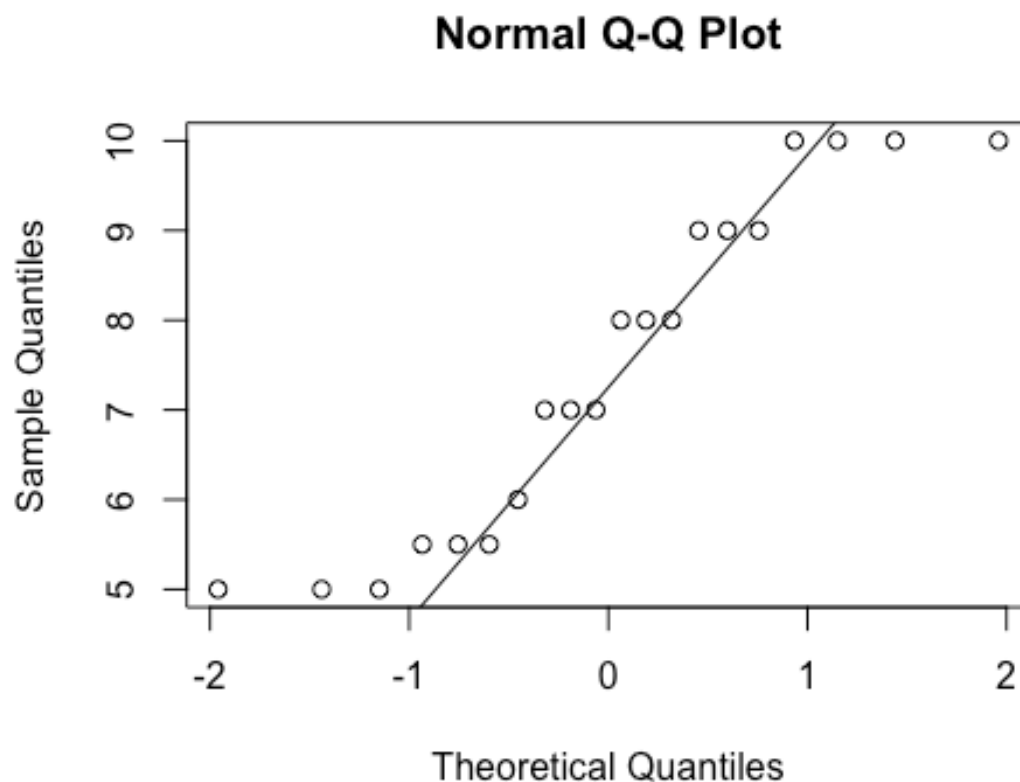
## [1] 1.867133

length(na.omit(PBUF_sham$satisfaction.level))

## [1] 20

qqnorm(PBUF_sham$satisfaction.level)
qqline(PBUF_sham$satisfaction.level)

```



```

ad.test(PBUF_sham$satisfaction.level)

##
## Anderson-Darling normality test
##
## data: PBUF_sham$satisfaction.level
## A = 0.69241, p-value = 0.0596

#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_sham$satisfaction.level,
       PBUF_treat$satisfaction.level)

##
## Welch Two Sample t-test
##
## data: PBUF_sham$satisfaction.level and PBUF_treat$satisfaction.level
## t = 0.43277, df = 37.304, p-value = 0.6677
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -1.012168 1.562168
## sample estimates:

```

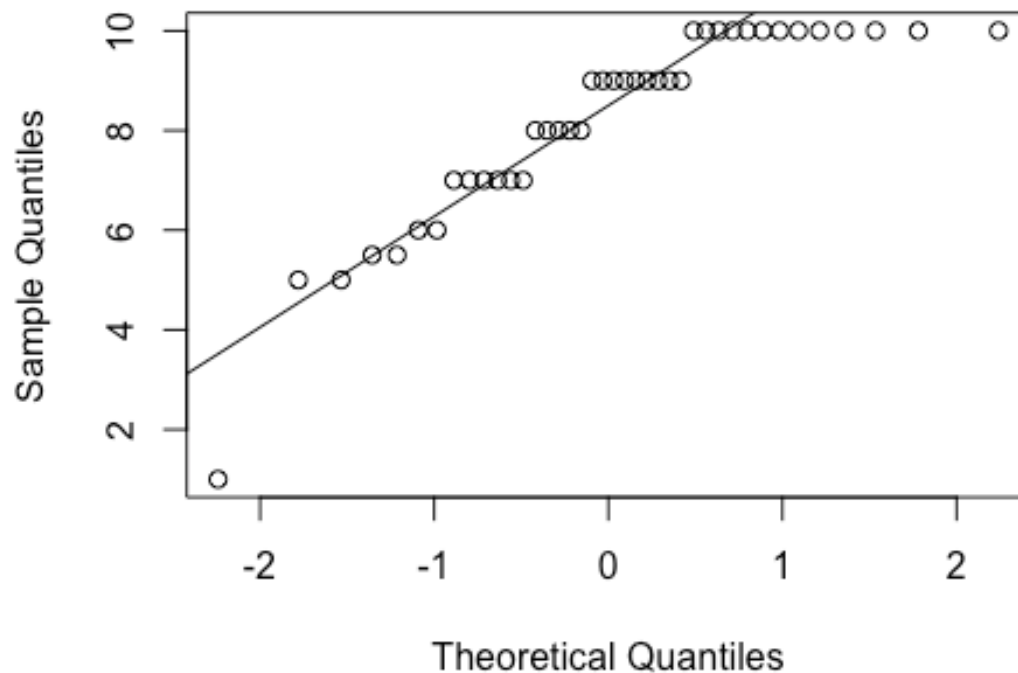


```

1
2
3  ## mean of x mean of y
4  ##      7.475      7.200
5
6  #####COMFORT LEVEL#####
7  #summary data
8  summary(PBUFdata$comfort.level)
9
10 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11 ##      1.000   7.000   9.000   8.175  10.000  10.000
12
13 sd(PBUFdata$comfort.level)
14
15 ## [1] 1.982455
16
17 length(PBUFdata$comfort.level)
18
19 ## [1] 40
20
21 qqnorm(PBUFdata$comfort.level)
22 qqline(PBUFdata$comfort.level)

```

Normal Q-Q Plot



```

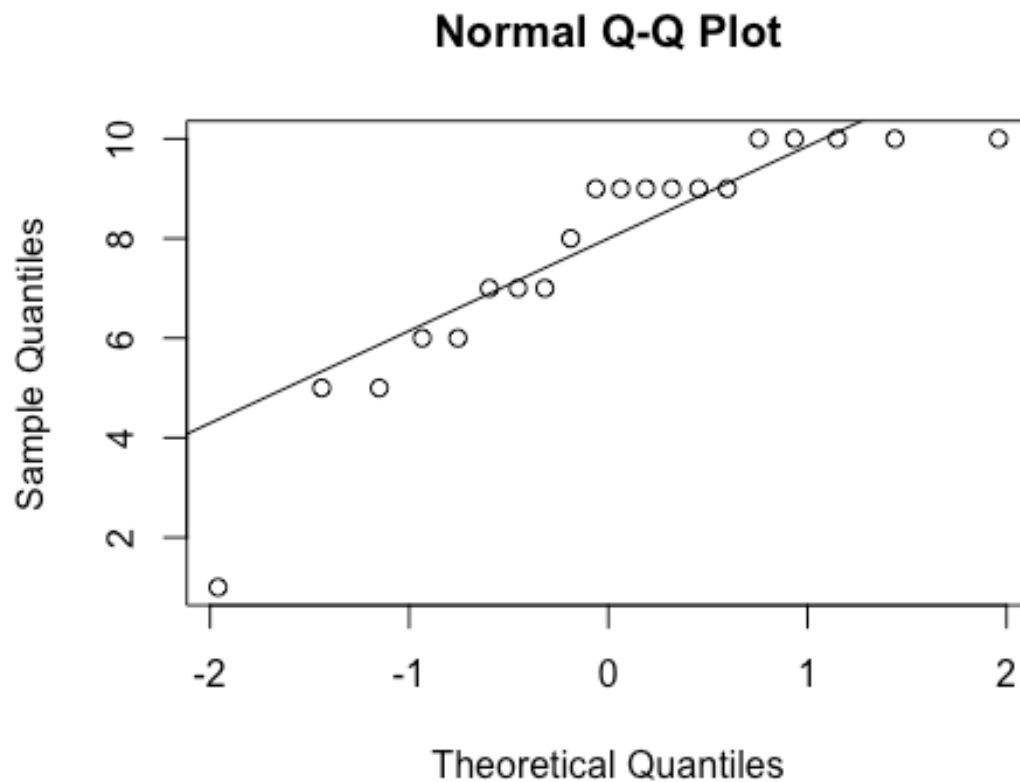
53 ad.test(PBUFdata$comfort.level)
54
55 ##
56 ## Anderson-Darling normality test

```

```

1
2
3
4  ##
5  ## data: PBUFdata$comfort.level
6  ## A = 1.8563, p-value = 7.865e-05
7
8  #within-participants (paired) comparison
9  #non-normal - perform Wilcoxon
10 wilcox.test(PBUF_sham$comfort.level,PBUF_treat$comfort.level,
11              paired = TRUE, conf.int = TRUE)
12
13 ## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
14 ## $comfort.level, : cannot compute exact p-value with ties
15
16 ## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
17 ## $comfort.level, : cannot compute exact confidence interval with ties
18
19 ## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
20 ## $comfort.level, : cannot compute exact p-value with zeroes
21
22 ## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
23 ## $comfort.level, : cannot compute exact confidence interval with zeroes
24
25 ##
26 ## Wilcoxon signed rank test with continuity correction
27 ##
28 ## data: PBUF_sham$comfort.level and PBUF_treat$comfort.level
29 ## V = 54.5, p-value = 0.0574
30 ## alternative hypothesis: true location shift is not equal to 0
31 ## 95 percent confidence interval:
32 ## -0.0000318032  2.7499508366
33 ## sample estimates:
34 ## (pseudo)median
35 ##      1.000052
36
37 #between participants (grouped) comparison
38 summary(PBUF_treat$comfort.level)
39
40 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
41 ##      1.00   6.75   9.00   7.80   9.25   10.00
42
43 sd(PBUF_treat$comfort.level, na.rm = TRUE)
44
45 ## [1] 2.330575
46
47 length(na.omit(PBUF_treat$comfort.level))
48
49 ## [1] 20
50
51 qqnorm(PBUF_treat$comfort.level)
52 qqline(PBUF_treat$comfort.level)
53
54
55
56
57
58
59
60

```



```

ad.test(PBUF_treat$comfort.level)

##
## Anderson-Darling normality test
##
## data: PBUF_treat$comfort.level
## A = 1.0308, p-value = 0.008039

#non-normal

summary(PBUF_sham$comfort.level)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      5.50   7.75   9.00   8.55  10.00  10.00

sd(PBUF_sham$comfort.level, na.rm = TRUE)

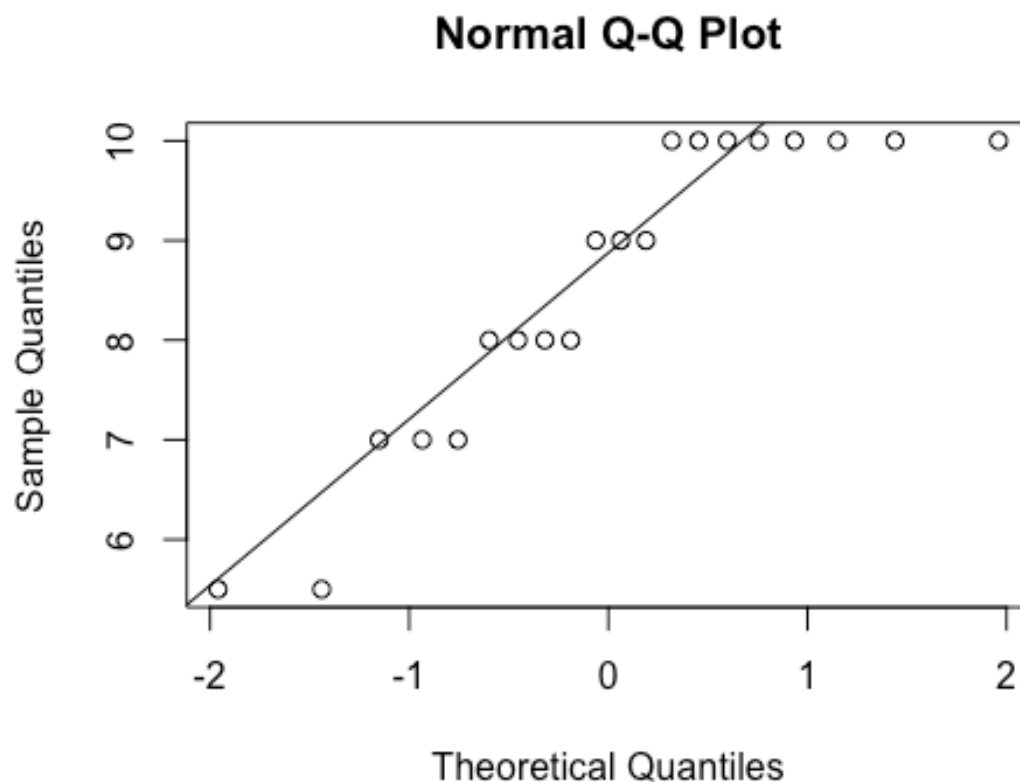
## [1] 1.529534

length(na.omit(PBUF_sham$comfort.level))

## [1] 20

qqnorm(PBUF_sham$comfort.level)
qqline(PBUF_sham$comfort.level)

```



```

ad.test(PBUF_sham$comfort.level)

##
## Anderson-Darling normality test
##
## data: PBUF_sham$comfort.level
## A = 1.1179, p-value = 0.004803

#non-normal

#Perform non-parametric test (Wilcoxon)
wilcox.test(PBUF_sham$comfort.level, PBUF_treat$comfort.level, conf.int = TRUE)

## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
## $comfort.level, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
## $comfort.level, : cannot compute exact confidence intervals with ties

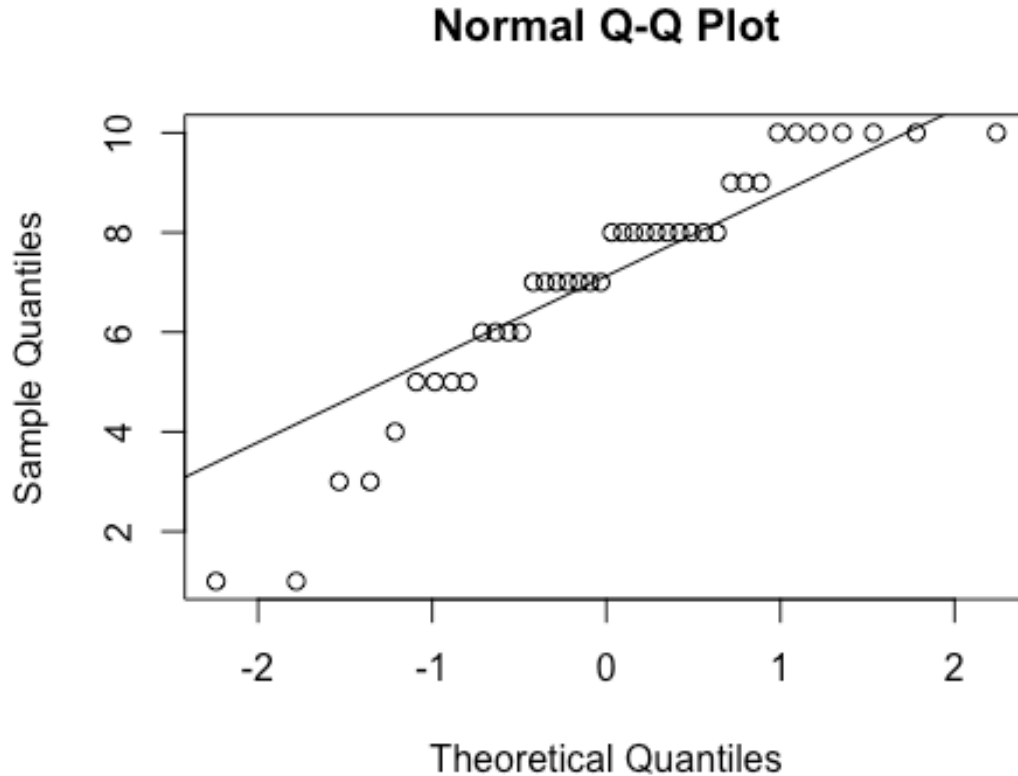
##
## Wilcoxon rank sum test with continuity correction
##
## data: PBUF_sham$comfort.level and PBUF_treat$comfort.level

```

```

1
2
3  ## W = 235.5, p-value = 0.3312
4  ## alternative hypothesis: true location shift is not equal to 0
5  ## 95 percent confidence interval:
6  ## -0.4999358  1.0000188
7  ## sample estimates:
8  ## difference in location
9  ##           0.3425784
10
11 #####INTENTION TO USE IN FUTURE PREGNANCY LEVEL#####
12 ####
13 #summary data
14 summary(PBUFdata$intention.to.use)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      1.00   6.00   7.50   7.05   8.25   10.00
18
19 sd(PBUFdata$intention.to.use)
20
21 ## [1] 2.363722
22
23 length(PBUFdata$intention.to.use)
24
25 ## [1] 40
26
27 qqnorm(PBUFdata$intention.to.use)
28 qqline(PBUFdata$intention.to.use)
29
30
31
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33
34
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```



```

ad.test(PBUFdata$intention.to.use)

##
## Anderson-Darling normality test
##
## data: PBUFdata$intention.to.use
## A = 1.0575, p-value = 0.00788

#within-participants (paired) comparison
#t-test (individual distributions are normal)
t.test(PBUF_sham$intention.to.use,PBUF_treat$intention.to.use, paired = TRUE)

##
## Paired t-test
##
## data: PBUF_sham$intention.to.use and PBUF_treat$intention.to.use
## t = 0.24031, df = 19, p-value = 0.8127
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -0.7709543 0.9709543
## sample estimates:
## mean of the differences
## 0.1

```

```

#between participants (grouped) comparison
summary(PBUF_treat$intention.to.use)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      1.00   5.75   8.00   7.00   8.00  10.00

sd(PBUF_treat$intention.to.use, na.rm = TRUE)

## [1] 2.339591

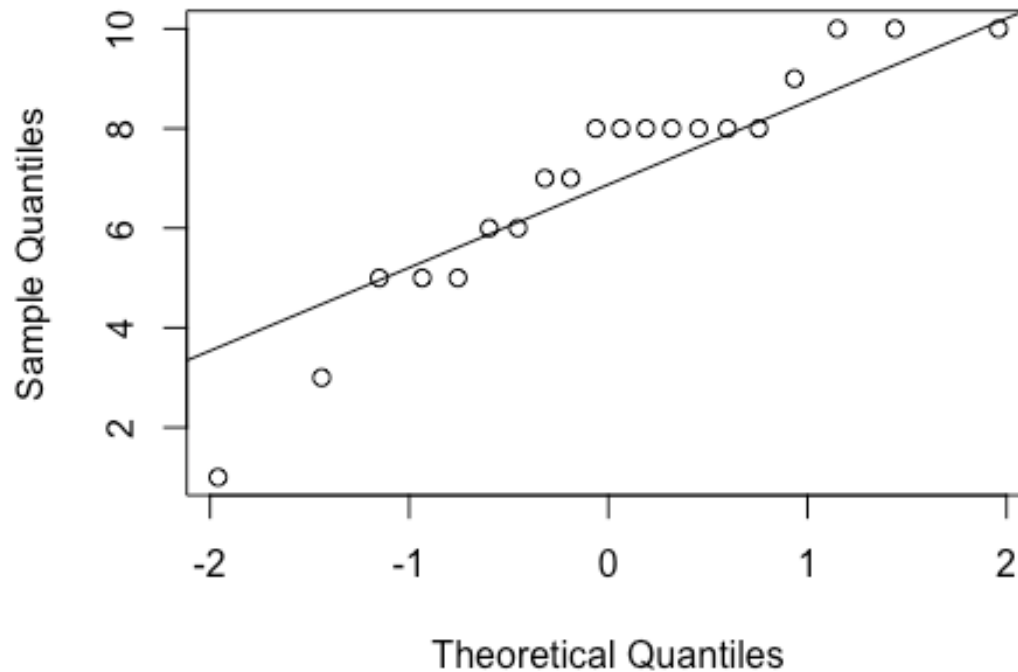
length(na.omit(PBUF_treat$intention.to.use))

## [1] 20

qqnorm(PBUF_treat$intention.to.use)
qqline(PBUF_treat$intention.to.use)

```

Normal Q-Q Plot



```

ad.test(PBUF_treat$intention.to.use)

##
## Anderson-Darling normality test
##
## data: PBUF_treat$intention.to.use
## A = 0.70743, p-value = 0.05453

```

```
#normal
```

```
summary(PBUF_sham$intention.to.use)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      1.0     6.0     7.0     7.1     9.0    10.0
```

```
sd(PBUF_sham$intention.to.use, na.rm = TRUE)
```

```
## [1] 2.44734
```

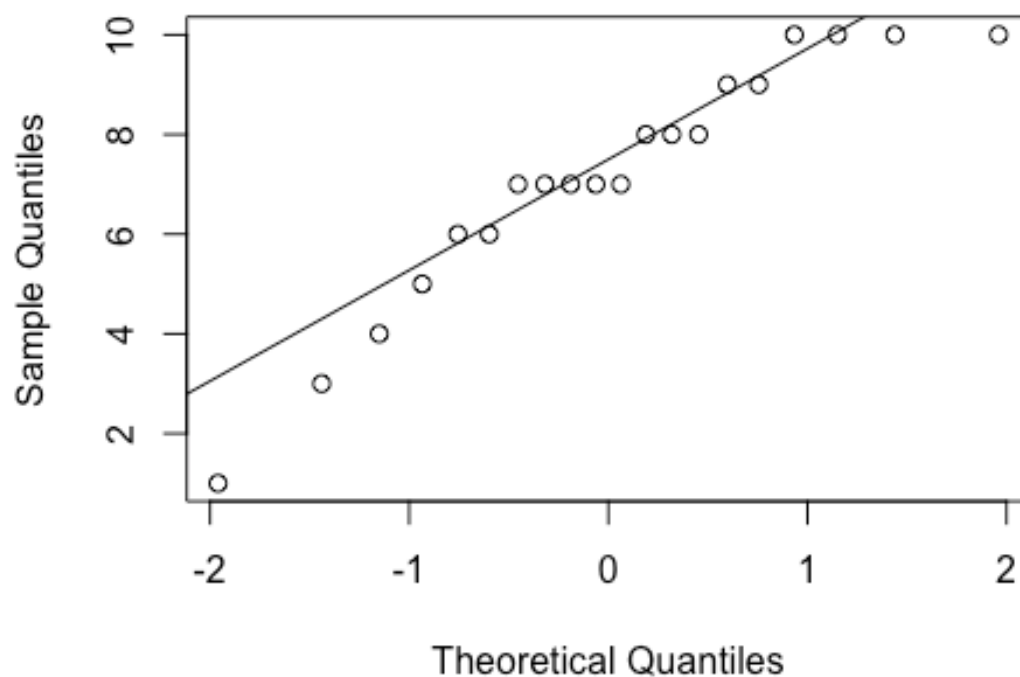
```
length(na.omit(PBUF_sham$intention.to.use))
```

```
## [1] 20
```

```
qqnorm(PBUF_sham$intention.to.use)
```

```
qqline(PBUF_sham$intention.to.use)
```

Normal Q-Q Plot



```
ad.test(PBUF_sham$intention.to.use)
```

```
##
## Anderson-Darling normality test
##
## data:  PBUF_sham$intention.to.use
## A = 0.54305, p-value = 0.1424
```



```

1
2
3 #normal
4
5 #Perform 2-sample t-test (Welch's t-test)
6 t.test(PBUF_sham$intention.to.use,
7         PBUF_treat$intention.to.use)
8
9
10 ##
11 ## Welch Two Sample t-test
12 ##
13 ## data: PBUF_sham$intention.to.use and PBUF_treat$intention.to.use
14 ## t = 0.13209, df = 37.923, p-value = 0.8956
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -1.432714 1.632714
18 ## sample estimates:
19 ## mean of x mean of y
20 ##      7.1      7.0
21
22 #####WOULD MAKE CHANGES#####
23 #summary data
24 summary(PBUFdata$would.make.changes)
25
26 ##      no yes
27 ## 2 31 7
28
29 length(PBUFdata$would.make.changes)
30
31 ## [1] 40
32
33 #7 nights, but only 6 participants of 20 (30%)
34
35 #between participants (grouped) comparison
36 xtabs(~would.make.changes + Intervention, data = PBUFdata)[-1,]
37
38 ##
39 ## Intervention
40 ## would.make.changes sham treatment
41 ##      no      16      15
42 ##      yes     3       4
43
44 fisher.test(xtabs(~would.make.changes + Intervention, data = PBUFdata)[-1,])
45
46 ##
47 ## Fisher's Exact Test for Count Data
48 ##
49 ## data:
50 ## p-value = 1
51 ## alternative hypothesis: true odds ratio is not equal to 1
52 ## 95 percent confidence interval:
53 ## 0.2007118 11.2700012
54 ## sample estimates:
55 ## odds ratio
56 ## 1.409106
57
58
59
60

```

#END

For peer review only

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Supplementary file 4: Code and output – self-report accuracy analysis

For peer review only

Self-Report_Accuracy_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 16:09:42 2018

#Description of code: Self-reported sleep behaviour accuracy analysis. This code compares the participants' perception of their sleep behaviours (as recorded on the PrenaBelt User Feedback Questionnaires) to the polysomnography-determined sleep behaviours.

#Summary: Participants recalled their sleep onset position accurately for 34 of 40 nights (85%, κ 0.62, moderate agreement). Participants recalled their waking position accurately for 28 of 40 nights (70%, κ 0.42, weak agreement). There was a weak relationship between sleep onset and waking position (κ 0.24). There was no agreement between the self-reported and PSG-reported number of position changes (κ 0.17). Percentage of time in each position, left, supine, and right, as estimated per self-report and measured per PSG had Spearman's ρ of 0.76 (good correlation, $p < 0.01$), 0.27 (poor correlation, $p = 0.11$), and 0.93 (excellent correlation, $p < 0.01$), respectively.

#Notes:

*#Spearman's rho - use for continuous variables
#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00*

#Cohen's kappa - use for categorical variables

#If the data is ordinal, then it may be appropriate to use a weighted Kappa (squared

or equal/linear). Unweighted calculation (used in the tests for non-ordinal data) treats

all differences as the same.

#values ≤ 0 as indicating no agreement

#0.01-0.20 no agreement

#0.21-0.39 minimal

#0.40- 0.59 weak

#0.60-0.79 moderate

#0.80-0.90 strong

#0.91-1.00 near perfect

#<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3900052/>

```

1
2
3
4 #Bland-Altman's plots - recall of continuous variables
5 #https://cran.r-project.org/web/packages/BlandAltmanLeh/vignettes/Intro.html
6
7
8 #setting the workspace directory
9 setwd("/Users/Allan/Desktop/HPTStats/08APR2017")
10
11 #importing the SR accuracy data
12 SRdatafull=read.csv("Self Reported vs Recorded Sleep Postions.csv")
13
14 #Exclude drop outs
15 #How many drop outs?
16 summary(SRdatafull$drop.out)
17
18 ## N Y
19 ## 40 6
20
21 #6 nights = 3 participants
22 #Remove the drop outs ("Y")
23 SRdata <- SRdatafull[!(SRdatafull$drop.out=="Y"),]
24 nrow(SRdata)
25
26 ## [1] 40
27
28 #Loading the functions into the workspace
29 library(nortest)
30 library(irr)
31
32 ## Loading required package: lpSolve
33
34 library(ggplot2)
35
36 ## Warning: package 'ggplot2' was built under R version 3.2.5
37
38 library(BlandAltmanLeh)
39
40 #####Fall asleep position#####
41 #droplevels to remove empty levels from the list of levels
42 SRdata$PSG.fall.asleep.position <- droplevels(SRdata$PSG.fall.asleep.position
43 )
44 SRdata$SR.fall.asleep.position <- droplevels(SRdata$SR.fall.asleep.position)
45 #Summary
46 #Polysomnography (PSG)
47 summary(SRdata$PSG.fall.asleep.position)
48
49 ## left right supine
50 ## 29 8 3
51
52 length(SRdata$PSG.fall.asleep.position)
53
54 ## [1] 40
55
56
57
58
59
60

```

```

1
2
3 #Self-Report (SR)
4 summary(SRdata$SR.fall.asleep.position)
5
6 ## left right supine
7 ## 31 7 2
8
9 length(SRdata$SR.fall.asleep.position)
10
11 ## [1] 40
12
13 #Cohen's Kappa
14 item1<-as.matrix(cbind(SRdata$PSG.fall.asleep.position, SRdata$SR.fall.asleep
15 .position))
16 kappa2(item1[,c(1,2)])
17
18 ## Cohen's Kappa for 2 Raters (Weights: unweighted)
19 ##
20 ## Subjects = 40
21 ## Raters = 2
22 ## Kappa = 0.624
23 ##
24 ## z = 4.87
25 ## p-value = 1.13e-06
26
27 #####Wake up position#####
28 #droplevels to remove empty levels from the list of levels
29 SRdata$PSG.wake.position <- droplevels(SRdata$PSG.wake.position)
30 SRdata$SR.wake.position <- droplevels(SRdata$SR.wake.position)
31 #Summary
32 #PSG
33 summary(SRdata$PSG.wake.position)
34
35 ## left right supine
36 ## 22 13 5
37
38 length(SRdata$PSG.wake.position)
39
40 ## [1] 40
41
42 #SR
43 summary(SRdata$SR.wake.position)
44
45 ## left right
46 ## 28 12
47
48 length(SRdata$SR.wake.position)
49
50 ## [1] 40
51
52 #Cohen's Kappa
53 item1<-as.matrix(cbind(SRdata$PSG.wake.position, SRdata$SR.wake.position))
54 kappa2(item1[,c(1,2)])
55
56
57
58
59
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```

```

1
2
3  ## Cohen's Kappa for 2 Raters (Weights: unweighted)
4  ##
5  ## Subjects = 40
6  ## Raters = 2
7  ## Kappa = 0.42
8  ##
9  ## z = 3.31
10 ## p-value = 0.000946
11
12 #####Look at relationship btw fall asleep and wake position###
13 #####
14 #Cohen's Kappa
15 #PSG
16 item1<-as.matrix(cbind(SRdata$PSG.fall.asleep.position, SRdata$PSG.wake.position))
17 kappa2(item1[,c(1,2)])
18
19 ## Cohen's Kappa for 2 Raters (Weights: unweighted)
20 ##
21 ## Subjects = 40
22 ## Raters = 2
23 ## Kappa = 0.241
24 ##
25 ## z = 2.05
26 ## p-value = 0.0399
27
28 #####Number of position changes#####
29 #Before running the number of position changes analyses below, we need to remove the rows
30 #corresponding to the 10 nights when participants did not give a self-report of the number
31 #of position changes because if these rows remain, they will make the summary statistics
32 inaccurate for the PSG data (n=40 instead of n=30).... note that
33 #the Cohens, ICC, and bland-altman will automatically drop these from their respective
34 analyses if the data point is continuous or ordinal (not if text! e.g., snoring analysis).
35
36 #Remove CDD night 1, LOH night 1, TBW night 1, WVE night1, YOG night 1 and 2, PBY night 1
37 #and 2, and KEQ night 1 and 2.
38 SRdata1 = SRdata[-c(3,7,19,23,25,26,27,28,37,38),]
39 nrow(SRdata1)
40
41 ## [1] 30

```

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```

1
2
3 #Summary
4 #PSG
5 summary(SRdata1$PSG.number.position.changes)
6
7 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
8 ##  1.000  3.250   6.000   6.833 10.000  15.000
9
10 length(SRdata1$PSG.number.position.changes)
11
12 ## [1] 30
13
14 #SR
15 summary(SRdata1$SR.number.position.changes)
16
17 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##   1.0    2.0    3.0    3.3    4.0    7.0
19
20 length(SRdata1$SR.number.position.changes)
21
22 ## [1] 30
23
24 #Cohen's Kappa
25 item1<-as.matrix(cbind(SRdata$PSG.number.position.changes,
26                        SRdata$SR.number.position.changes))
27 kappa2(item1[,c(1,2)], weight="equal")
28
29 ## Cohen's Kappa for 2 Raters (Weights: equal)
30 ##
31 ## Subjects = 30
32 ## Raters = 2
33 ## Kappa = 0.169
34 ##
35 ## z = 1.61
36 ## p-value = 0.107
37
38 #####Snoring#####
39 #droplevels to remove empty levels from the list of levels
40 SRdata$PSG.snore <- droplevels(SRdata$PSG.snore)
41 SRdata$SRSnore <- droplevels(SRdata$SRSnore)
42 #Summary
43 #PSG
44 summary(SRdata$PSG.snore)
45
46 ## N Y
47 ## 14 26
48
49 length(SRdata$PSG.snore)
50
51 ## [1] 40
52
53 summary(subset(SRdata, intervention == "treatment")$PSG.snore)
54
55
56
57
58
59
60

```



```

1
2
3 ## N Y
4 ## 5 15
5
6 summary(subset(SRdata, intervention == "sham")$PSG.snore)
7
8 ## N Y
9 ## 9 11
10
11 xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.levels = TRUE)
12
13 ##          intervention
14 ## PSG.snore sham treatment
15 ##          N      9      5
16 ##          Y     11     15
17
18 fisher.test(xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.level
19 s = TRUE))
20
21 ##
22 ## Fisher's Exact Test for Count Data
23 ##
24 ## data:  xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.levels
25 = TRUE)
26 ## p-value = 0.3203
27 ## alternative hypothesis: true odds ratio is not equal to 1
28 ## 95 percent confidence interval:
29 ##  0.5373446 11.9301555
30 ## sample estimates:
31 ## odds ratio
32 ##  2.398796
33
34 #SR
35 summary(SRdata$SRSnore)
36
37 ##          don't know          N          Y
38 ##          3          26          8          3
39
40 length(SRdata$SRSnore)
41
42 ## [1] 40
43
44 #Take a quick Look at the data
45 data.frame(SRdata$PSG.snore, SRdata$SRSnore)
46
47 ##      SRdata.PSG.snore SRdata.SRSnore
48 ## 1                Y     don't know
49 ## 2                Y     don't know
50 ## 3                N     don't know
51 ## 4                Y              N
52 ## 5                N              N
53 ## 6                Y     don't know
54 ## 7                Y

```

```

1
2
3      ## 8          Y
4      ## 9          N      don't know
5      ## 10         Y      don't know
6      ## 11         Y          Y
7      ## 12         Y          Y
8      ## 13         Y      don't know
9      ## 14         Y          N
10     ## 15         Y      don't know
11     ## 16         Y      don't know
12     ## 17         N      don't know
13     ## 18         N          N
14     ## 19         Y      don't know
15     ## 20         Y          Y
16     ## 21         N      don't know
17     ## 22         N      don't know
18     ## 23         Y      don't know
19     ## 24         Y      don't know
20     ## 25         N          N
21     ## 26         N          N
22     ## 27         Y      don't know
23     ## 28         Y      don't know
24     ## 29         Y      don't know
25     ## 30         Y      don't know
26     ## 31         N      don't know
27     ## 32         N          N
28     ## 33         Y      don't know
29     ## 34         N      don't know
30     ## 35         N          N
31     ## 36         N
32     ## 37         Y      don't know
33     ## 38         Y      don't know
34     ## 39         Y      don't know
35     ## 40         Y      don't know

```

#Drop the "" (blank) levels... for some reason, R includes them in the Kappa2 if the

#variable is text and blank

```
SRdataSnore <- SRdata[!(SRdata$SRsnore==""),]
```

```
nrow(SRdataSnore)
```

```
## [1] 37
```

#Drop the "don't know" levels because the PSG cannot answer "don't know", so these ratings

#should be excluded from the agreement analysis

```
SRdataSnore <- SRdataSnore[!(SRdataSnore$SRsnore=="don't know"),]
```

```
nrow(SRdataSnore)
```

```
## [1] 11
```

```

1
2
3 #Take a quick Look at the data
4 data.frame(SRdataSnore$PSG.snore, SRdataSnore$SRsnore)
5
6 ##      SRdataSnore.PSG.snore SRdataSnore.SRsnore
7 ## 1                Y                N
8 ## 2                N                N
9 ## 3                Y                Y
10 ## 4                Y                Y
11 ## 5                Y                N
12 ## 6                N                N
13 ## 7                Y                Y
14 ## 8                N                N
15 ## 9                N                N
16 ## 10               N                N
17 ## 11               N                N
18
19
20 #Cohen's Kappa
21 item1 <- data.frame(SRdataSnore$PSG.snore, SRdataSnore$SRsnore)
22 kappa2(item1[,c(1,2)])
23
24 ## Cohen's Kappa for 2 Raters (Weights: unweighted)
25 ##
26 ## Subjects = 11
27 ## Raters = 2
28 ## Kappa = 0.621
29 ##
30 ## z = 2.22
31 ## p-value = 0.0261
32
33 #####Body Position - Supine#####
34 #Before running the position analyses below, we need to remove the rows corre
35 sponding to
36 #the 5 nights when participants did not give a self-report of proportion of t
37 ime in each
38 #position (these five nights occurred before the REB approved the change to ou
39 r PrenaBelt
40 #User Feedback Questionnaire) because if these rows remain, they will make th
41 e summary
42 #statistics (summary, #SD, Length) inaccurate for the PSG data (n=40 instead
43 of n=35)....
44 #note that the Cohens, #ICC, and bland-altman will automatically drop these f
45 rom their
46 #respective analyses if #the data point is continuous or ordinal (not if text
47 ! e.g.,
48 #snoring analysis).
49
50
51 #Remove LIQ nights 1 and 2, LOH nights 1 and 2, and LQI night 1:
52 SRdata1 = SRdata[-c(5,6,7,8,9),]
53 nrow(SRdata1)
54
55 ## [1] 35

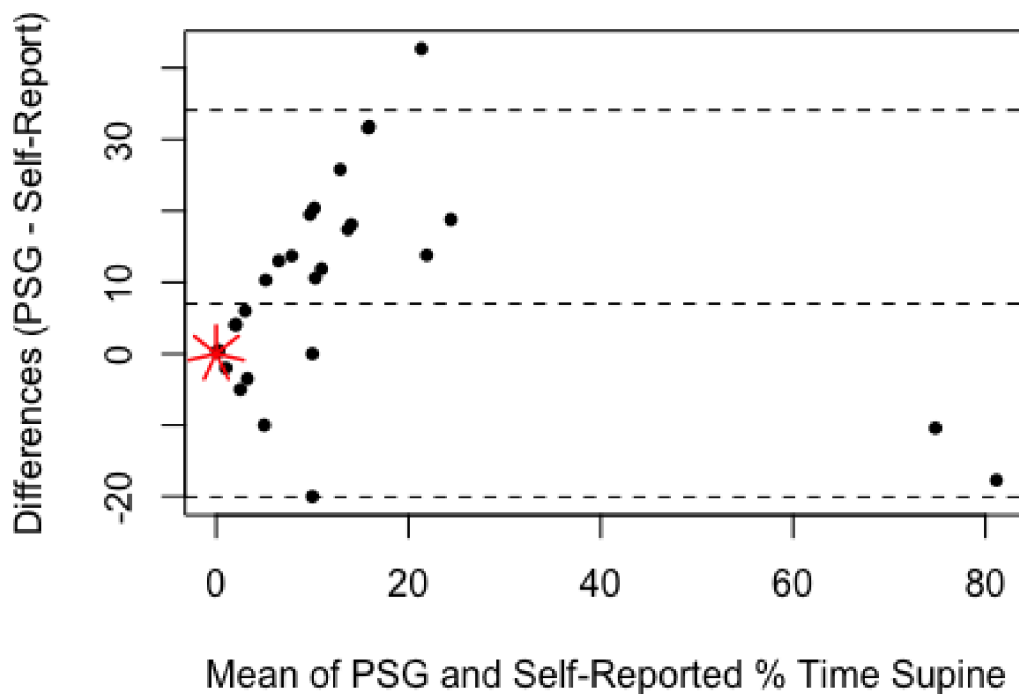
```

```

1
2
3 #Summary
4 #PSG
5 summary(SRdata1$PtstSupine)
6
7 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
8 ##      0.00   0.00   10.00   14.82  22.75   72.30
9
10 sd(SRdata1$PtstSupine)
11
12 ## [1] 18.69348
13
14 length(SRdata1$PtstSupine)
15
16 ## [1] 35
17
18 #SR
19 summary(SRdata1$SRSupine)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      0.0    0.0    0.0    7.8    5.0    90.0
23
24 sd(SRdata1$SRSupine)
25
26 ## [1] 19.98205
27
28 length(SRdata1$SRSupine)
29
30 ## [1] 35
31
32 #Test of association btw paired samples
33 cor.test(SRdata$PtstSupine, SRdata$SRSupine, method = "spearman")
34
35 ## Warning in cor.test.default(SRdata$PtstSupine, SRdata$SRSupine, method =
36 ## "spearman"): Cannot compute exact p-value with ties
37
38 ##
39 ## Spearman's rank correlation rho
40 ##
41 ## data: SRdata$PtstSupine and SRdata$SRSupine
42 ## S = 5190.2, p-value = 0.1125
43 ## alternative hypothesis: true rho is not equal to 0
44 ## sample estimates:
45 ##      rho
46 ## 0.2730782
47
48 #fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00
49
50 bland.altman.plot(SRdata$PtstSupine, SRdata$SRSupine,
51                   two = 1.96, mode = 1, graph.sys = "base", conf.int = 0, sil
52 ent = FALSE,
53                   sunflower = TRUE,
54                   main="",
55
56
57
58
59
60

```

```
xlab="Mean of PSG and Self-Reported % Time Supine",
ylab="Differences (PSG - Self-Report)")
```



```
## $means
## [1] 0.00 0.10 15.90 13.70 2.00 0.00 10.20 3.00 0.00 12.90 6.50
## [12] 10.95 5.15 9.75 15.80 24.40 21.90 3.25 7.85 10.30 2.50 10.00
## [23] 5.00 0.00 2.05 0.00 0.25 0.00 14.05 81.15 74.80 0.00 21.35
## [34] 1.00 10.00
##
## $diffs
## [1] 0.0 0.2 31.8 17.4 4.0 0.0 20.4 6.0 0.0 25.8 13.0
## [12] 11.9 10.3 19.5 31.6 18.8 13.8 -3.5 13.7 10.6 -5.0 -20.0
## [23] -10.0 0.0 4.1 0.0 0.5 0.0 18.1 -17.7 -10.4 0.0 42.7
## [34] -2.0 0.0
##
## $groups
## group1 group2
## 1 0.0 0
## 2 0.2 0
## 3 31.8 0
## 4 22.4 5
## 10 4.0 0
## 11 0.0 0
```

```

1
2
3    ## 12    20.4    0
4    ## 13     6.0    0
5    ## 14     0.0    0
6    ## 15    25.8    0
7    ## 16    13.0    0
8    ## 17    16.9    5
9    ## 18    10.3    0
10   ## 19    19.5    0
11   ## 20    31.6    0
12   ## 21    33.8    15
13   ## 22    28.8    15
14   ## 23     1.5     5
15   ## 24    14.7     1
16   ## 25    15.6     5
17   ## 26     0.0     5
18   ## 27     0.0    20
19   ## 28     0.0    10
20   ## 29     0.0     0
21   ## 30     4.1     0
22   ## 31     0.0     0
23   ## 32     0.5     0
24   ## 33     0.0     0
25   ## 34    23.1     5
26   ## 35    72.3    90
27   ## 36    69.6    80
28   ## 37     0.0     0
29   ## 38    42.7     0
30   ## 39     0.0     2
31   ## 40    10.0    10
32   ##
33   ## $based.on
34   ## [1] 35
35   ##
36   ## $lower.limit
37   ## [1] -20.0717
38   ##
39   ## $mean.diffs
40   ## [1] 7.017143
41   ##
42   ## $upper.limit
43   ## [1] 34.10599
44   ##
45   ## $lines
46   ## lower.limit mean.diffs upper.limit
47   ## -20.071701    7.017143    34.105987
48   ##
49   ## $CI.lines
50   ## lower.limit.ci.lower lower.limit.ci.upper mean.diff.ci.lower
51   ## -20.071701          -20.071701          7.017143
52   ## mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper

```

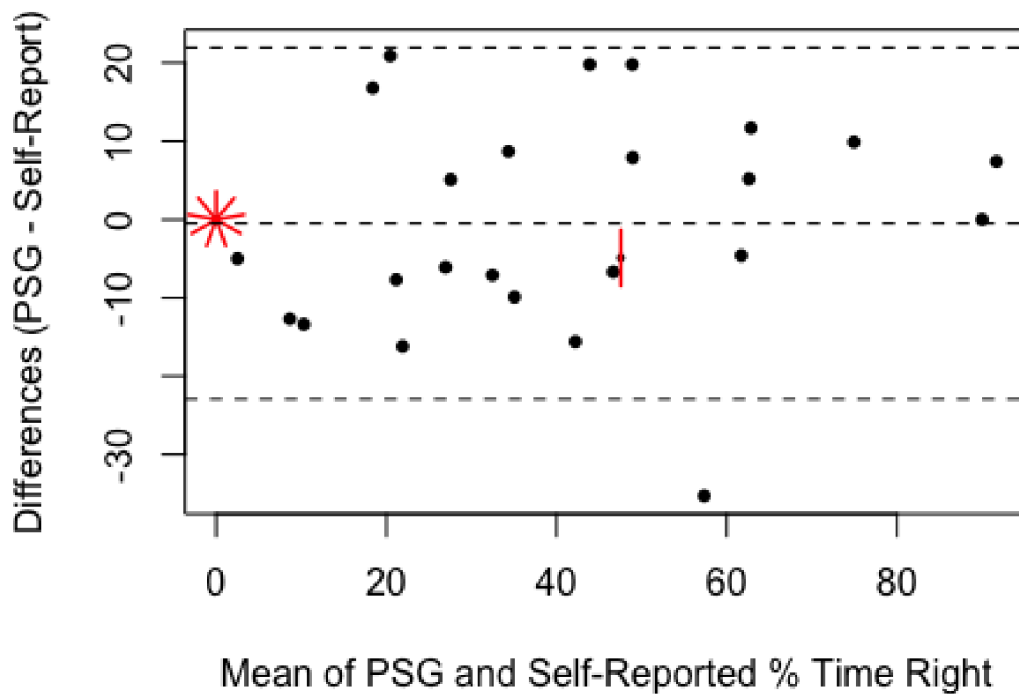
```

1
2
3      ##                7.017143                34.105987                34.105987
4      ##
5      ## $two
6      ## [1] 1.96
7      ##
8      ## $critical.diff
9      ## [1] 27.08884
10
11     #####Body Position - Right#####
12     #Summary
13     #PSG
14     summary(SRdata1$PtstRight)
15
16     ##      Min. 1st Qu.  Median      Mean 3rd Qu.      Max.
17     ##      0.0      0.0     30.1     30.8   49.0     95.4
18
19     sd(SRdata1$PtstRight)
20
21     ## [1] 28.50465
22
23     length(SRdata1$PtstRight)
24
25     ## [1] 35
26
27     #SR
28     summary(SRdata1$SRRight)
29
30     ##      Min. 1st Qu.  Median      Mean 3rd Qu.      Max.
31     ##      0.00      2.50   30.00   31.29   50.00   90.00
32
33     sd(SRdata1$SRRight)
34
35     ## [1] 27.30177
36
37     length(SRdata1$SRRight)
38
39     ## [1] 35
40
41     #Test of association btw paired samples
42     cor.test(SRdata$PtstRight, SRdata$SRRight, method = "spearman")
43
44     ## Warning in cor.test.default(SRdata$PtstRight, SRdata$SRRight, method =
45     ## "spearman"): Cannot compute exact p-value with ties
46
47     ##
48     ## Spearman's rank correlation rho
49     ##
50     ## data:  SRdata$PtstRight and SRdata$SRRight
51     ## S = 505.71, p-value = 8.061e-16
52     ## alternative hypothesis: true rho is not equal to 0
53     ## sample estimates:
54     ##      rho
55     ## 0.9291716
56
57
58
59
60

```

```
#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00

bland.altman.plot(SRdata$PtstRight, SRdata$SRRight,
                 two = 1.96, mode = 1, graph.sys = "base", conf.int = 0, sil
ent = FALSE,
                 sunflower = TRUE,
                 main="",
                 xlab="Mean of PSG and Self-Reported % Time Right",
                 ylab="Differences (PSG - Self-Report)")
```



```
## $means
## [1] 34.35 26.95 21.90 0.00 27.55 74.95 62.60 61.70 62.85 10.30 20.45
## [12] 47.55 42.20 0.00 18.40 0.00 0.00 48.95 48.90 0.00 0.00 0.00
## [23] 0.00 46.65 57.35 43.90 21.15 47.55 8.65 0.00 2.50 32.45 35.05
## [34] 91.70 90.00
##
## $diffs
## [1] 8.7 -6.1 -16.2 0.0 5.1 9.9 5.2 -4.6 11.7 -13.4 20.9
## [12] -4.9 -15.6 0.0 16.8 0.0 0.0 7.9 19.8 0.0 0.0 0.0
## [23] 0.0 -6.7 -35.3 19.8 -7.7 -4.9 -12.7 0.0 -5.0 -7.1 -9.9
## [34] 7.4 0.0
##
## $groups
```



```

1
2
3      ##      group1 group2
4      ## 1      38.7    30
5      ## 2      23.9    30
6      ## 3      13.8    30
7      ## 4       0.0     0
8      ## 10     30.1    25
9      ## 11     79.9    70
10     ## 12     65.2    60
11     ## 13     59.4    64
12     ## 14     68.7    57
13     ## 15      3.6    17
14     ## 16     30.9    10
15     ## 17     45.1    50
16     ## 18     34.4    50
17     ## 19      0.0     0
18     ## 20     26.8    10
19     ## 21      0.0     0
20     ## 22      0.0     0
21     ## 23     52.9    45
22     ## 24     58.8    39
23     ## 25      0.0     0
24     ## 26      0.0     0
25     ## 27      0.0     0
26     ## 28      0.0     0
27     ## 29     43.3    50
28     ## 30     39.7    75
29     ## 31     53.8    34
30     ## 32     17.3    25
31     ## 33     45.1    50
32     ## 34      2.3    15
33     ## 35      0.0     0
34     ## 36      0.0     5
35     ## 37     28.9    36
36     ## 38     30.1    40
37     ## 39     95.4    88
38     ## 40     90.0    90
39
40
41     ##
42     ## $based.on
43     ## [1] 35
44     ##
45     ## $lower.limit
46     ## [1] -22.91233
47     ##
48     ## $mean.diffs
49     ## [1] -0.4828571
50     ##
51     ## $upper.limit
52     ## [1] 21.94661
53     ##
54     ## $lines
55
56
57
58
59
60

```

```

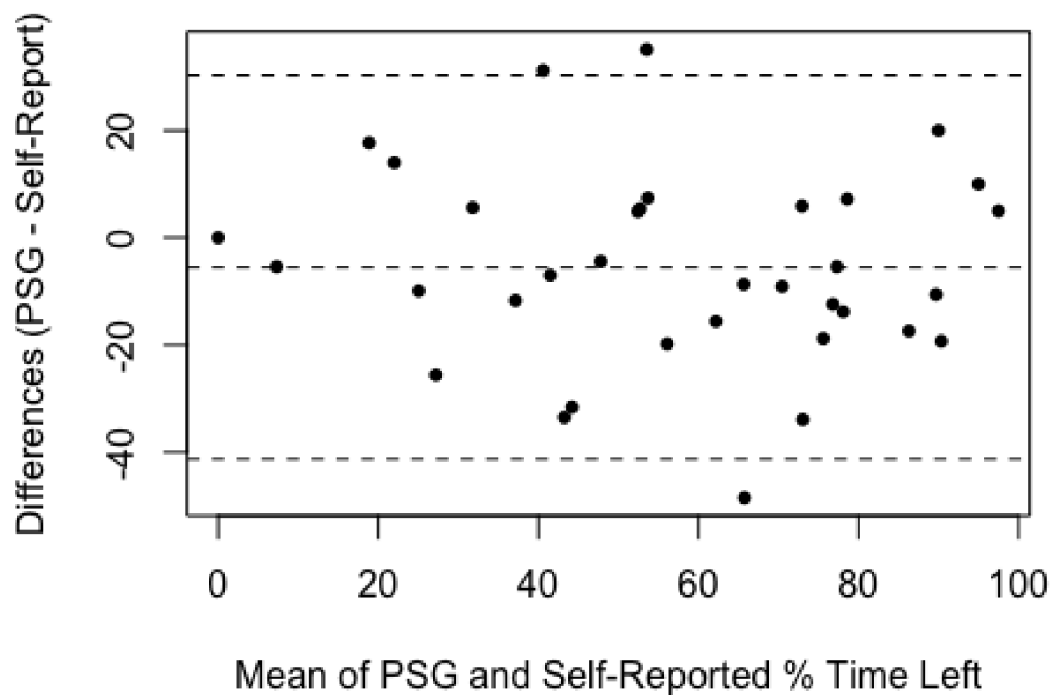
1
2
3  ## lower.limit mean.diff upper.limit
4  ## -22.9123292 -0.4828571 21.9466149
5  ##
6  ## $CI.lines
7  ## lower.limit.ci.lower lower.limit.ci.upper mean.diff.ci.lower
8  ## -22.9123292 -22.9123292 -0.4828571
9  ## mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
10 ## -0.4828571 21.9466149 21.9466149
11 ##
12 ## $two
13 ## [1] 1.96
14 ##
15 ## $critical.diff
16 ## [1] 22.42947
17
18 #####Body Position - Left#####
19 #Summary
20 #PSG
21 summary(SRdata1$PtstLeft)
22
23 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
24 ## 0.00 32.95 56.10 54.40 72.90 100.00
25
26 sd(SRdata1$PtstLeft)
27
28 ## [1] 26.40423
29
30 length(SRdata1$PtstLeft)
31
32 ## [1] 35
33
34 #SR
35 summary(SRdata1$SRLeft)
36
37 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
38 ## 0.00 41.50 66.00 59.91 84.00 100.00
39
40 sd(SRdata1$SRLeft)
41
42 ## [1] 28.14915
43
44 length(SRdata1$SRLeft)
45
46 ## [1] 35
47
48 #Test of association btw paired samples
49 cor.test(SRdata$PtstLeft, SRdata$SRLeft, method = "spearman")
50
51 ## Warning in cor.test.default(SRdata$PtstLeft, SRdata$SRLeft, method =
52 ## "spearman"): Cannot compute exact p-value with ties
53
54 ##
55 ## Spearman's rank correlation rho

```

```

1  ##
2
3  ##
4  ## data: SRdata$PtstLeft and SRdata$SRLeft
5  ## S = 1691.2, p-value = 9.796e-08
6  ## alternative hypothesis: true rho is not equal to 0
7  ## sample estimates:
8  ##      rho
9  ## 0.7631423
10
11  #fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00
12
13
14  bland.altman.plot(SRdata$PtstLeft, SRdata$SRLeft,
15                    two = 1.96, mode = 1, graph.sys = "base", conf.int = 0, sil
16  ent = FALSE,
17                    sunflower = TRUE,
18                    main="",
19                    xlab="Mean of PSG and Self-Reported % Time Left",
20                    ylab="Differences (PSG - Self-Report)")
21
22
23
24
25
26
27

```



```

51  ## $means
52  ## [1] 65.65 72.95 62.20 86.30 70.45 25.05 27.20 31.80 37.15 76.80 73.05
53  ## [12] 41.50 52.70 90.35 65.75 75.60 78.10 47.80 43.25 89.70 97.50 90.00
54  ## [23] 95.00 53.70 40.60 56.10 78.60 52.45 77.30 18.85 22.00 53.55 44.20
55  ## [34]  7.30  0.00
56
57
58
59
60

```

```

1
2
3 ##
4 ## $diffs
5 ## [1] -8.7 5.9 -15.6 -17.4 -9.1 -9.9 -25.6 5.6 -11.7 -12.4 -33.9
6 ## [12] -7.0 5.4 -19.3 -48.5 -18.8 -13.8 -4.4 -33.5 -10.6 5.0 20.0
7 ## [23] 10.0 7.4 31.2 -19.8 7.2 4.9 -5.4 17.7 14.0 35.1 -31.6
8 ## [34] -5.4 0.0
9 ##
10 ## $groups
11 ## group1 group2
12 ## 1 61.3 70
13 ## 2 75.9 70
14 ## 3 54.4 70
15 ## 4 77.6 95
16 ## 10 65.9 75
17 ## 11 20.1 30
18 ## 12 14.4 40
19 ## 13 34.6 29
20 ## 14 31.3 43
21 ## 15 70.6 83
22 ## 16 56.1 90
23 ## 17 38.0 45
24 ## 18 55.4 50
25 ## 19 80.7 100
26 ## 20 41.5 90
27 ## 21 66.2 85
28 ## 22 71.2 85
29 ## 23 45.6 50
30 ## 24 26.5 60
31 ## 25 84.4 95
32 ## 26 100.0 95
33 ## 27 100.0 80
34 ## 28 100.0 90
35 ## 29 57.4 50
36 ## 30 56.2 25
37 ## 31 46.2 66
38 ## 32 82.2 75
39 ## 33 54.9 50
40 ## 34 74.6 80
41 ## 35 27.7 10
42 ## 36 29.0 15
43 ## 37 71.1 36
44 ## 38 28.4 60
45 ## 39 4.6 10
46 ## 40 0.0 0
47 ##
48 ## $based.on
49 ## [1] 35
50 ##
51 ## $lower.limit
52 ## [1] -41.27743
53
54
55
56
57
58
59
60

```

```

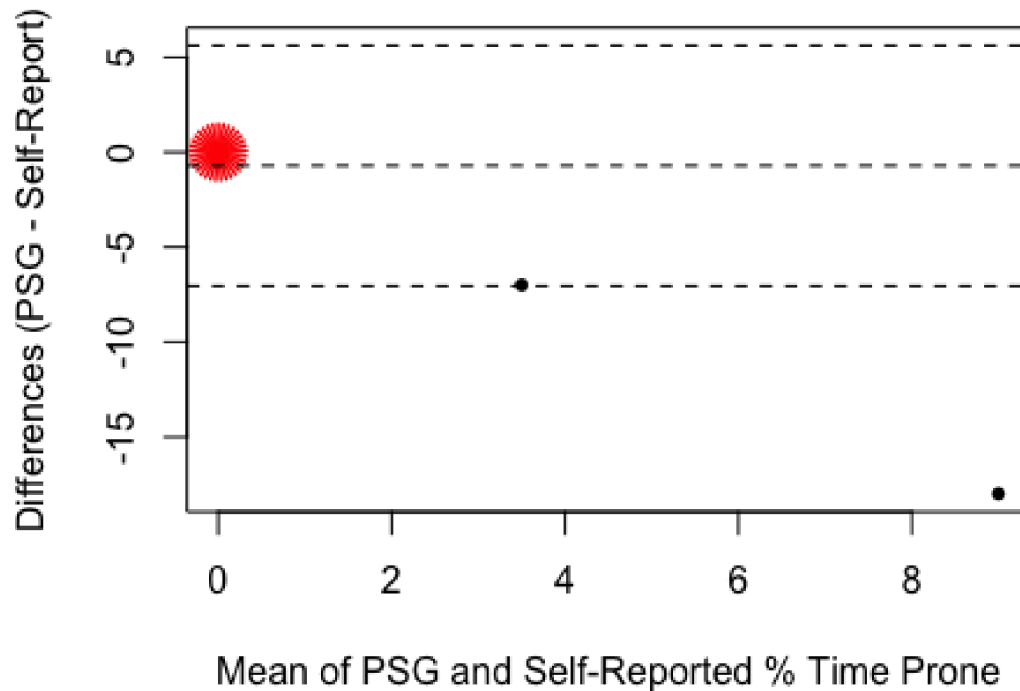
1
2
3 ##
4 ## $mean.diffs
5 ## [1] -5.514286
6 ##
7 ## $upper.limit
8 ## [1] 30.24886
9 ##
10 ## $lines
11 ## lower.limit mean.diffs upper.limit
12 ## -41.277427 -5.514286 30.248856
13 ##
14 ## $CI.lines
15 ## lower.limit.ci.lower lower.limit.ci.upper mean.diff.ci.lower
16 ## -41.277427 -41.277427 -5.514286
17 ## mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
18 ## -5.514286 30.248856 30.248856
19 ##
20 ## $two
21 ## [1] 1.96
22 ##
23 ## $critical.diff
24 ## [1] 35.76314
25
26 #####Body Position - Prone#####
27
28 #Summary
29 #PSG
30 summary(SRdata$PtstProne)
31
32 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
33 ## 0 0 0 0 0 0
34
35 length(SRdata$PtstProne)
36
37 ## [1] 40
38
39 #SR
40 summary(SRdata$SRProne)
41
42 ## Min. 1st Qu. Median Mean 3rd Qu. Max. NA's
43 ## 0.0000 0.0000 0.0000 0.7143 0.0000 18.0000 5
44
45 length(SRdata$SRProne)
46
47 ## [1] 40
48
49 #Test of association btw paired samples
50 cor.test(SRdata$PtstProne, SRdata$SRProne, method = "spearman")
51
52 ## Warning in cor(rank(x), rank(y)): the standard deviation is zero
53
54 ##
55 ## Spearman's rank correlation rho
56
57
58
59
60

```

```

1  ##
2  ## data: SRdata$PtstProne and SRdata$SRProne
3  ## S = NA, p-value = NA
4  ## alternative hypothesis: true rho is not equal to 0
5  ## sample estimates:
6  ## rho
7  ## NA
8
9  #fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00
10
11 bland.altman.plot(SRdata$PtstProne, SRdata$SRProne,
12                   two = 1.96, mode = 1, graph.sys = "base", conf.int = 0, sil
13 ent = FALSE,
14                   sunflower = TRUE,
15                   main="",
16                   xlab="Mean of PSG and Self-Reported % Time Prone",
17                   ylab="Differences (PSG - Self-Report)")
18
19
20
21
22
23
24
25
26
27

```



```

28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51 ## $means
52 ## [1] 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 3.5 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0
53 ## [18] 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 9.0 0.0 0.0
54 ## [35] 0.0
55 ##
56
57
58
59
60

```

```

1
2
3      ## $diffs
4      ## [1]  0  0  0  0  0  0  0  0 -7  0  0  0  0  0  0  0  0
5      ## [18]  0  0  0  0  0  0  0  0  0  0  0  0  0  0  0 -18  0  0
6      ## [35]  0
7      ##
8      ## $groups
9      ##   group1 group2
10     ## 1      0      0
11     ## 2      0      0
12     ## 3      0      0
13     ## 4      0      0
14     ## 10     0      0
15     ## 11     0      0
16     ## 12     0      0
17     ## 13     0      7
18     ## 14     0      0
19     ## 15     0      0
20     ## 16     0      0
21     ## 17     0      0
22     ## 18     0      0
23     ## 19     0      0
24     ## 20     0      0
25     ## 21     0      0
26     ## 22     0      0
27     ## 23     0      0
28     ## 24     0      0
29     ## 25     0      0
30     ## 26     0      0
31     ## 27     0      0
32     ## 28     0      0
33     ## 29     0      0
34     ## 30     0      0
35     ## 31     0      0
36     ## 32     0      0
37     ## 33     0      0
38     ## 34     0      0
39     ## 35     0      0
40     ## 36     0      0
41     ## 37     0     18
42     ## 38     0      0
43     ## 39     0      0
44     ## 40     0      0
45     ##
46     ## $based.on
47     ## [1] 35
48     ##
49     ## $lower.limit
50     ## [1] -7.048871
51     ##
52     ## $mean.diffs

```

```

1
2
3 ## [1] -0.7142857
4 ##
5 ## $upper.limit
6 ## [1] 5.620299
7 ##
8 ## $lines
9 ## lower.limit mean.diffs upper.limit
10 ## -7.0488705 -0.7142857 5.6202991
11 ##
12 ## $CI.lines
13 ## lower.limit.ci.lower lower.limit.ci.upper mean.diff.ci.lower
14 ## -7.0488705 -7.0488705 -0.7142857
15 ## mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
16 ## -0.7142857 5.6202991 5.6202991
17 ##
18 ## $two
19 ## [1] 1.96
20 ##
21 ## $critical.diff
22 ## [1] 6.334585
23
24 #####PLMs/Restless Legs#####
25 #droplevels to remove empty levels from the list of levels
26 SRdata$PSG.legs.restless <- droplevels(SRdata$PSG.legs.restless)
27 SRdata$SR.legs.restless <- droplevels(SRdata$SR.legs.restless)
28 #Summary
29 #PSG
30 summary(SRdata$PSG.legs.restless)
31
32 ## N Y
33 ## 26 14
34
35 length(SRdata$PSG.legs.restless)
36
37 ## [1] 40
38
39 #SR
40 summary(SRdata$SR.legs.restless)
41
42 ## don't know N Y
43 ## 3 19 14 4
44
45 length(SRdata$SR.legs.restless)
46
47 ## [1] 40
48
49 #Take a quick look at the data
50 data.frame(SRdata$PSG.legs.restless, SRdata$SR.legs.restless)
51
52 ## SRdata.PSG.legs.restless SRdata.SR.legs.restless
53 ## 1 N don't know
54 ## 2 N don't know
55
56
57
58
59
60

```



```

1
2
3      ## 3          N          N
4      ## 4          N          N
5      ## 5          Y          N
6      ## 6          Y          Y
7      ## 7          N
8      ## 8          N
9      ## 9          N          N
10     ## 10         N          don't know
11     ## 11         N          N
12     ## 12         N          N
13     ## 13         Y          don't know
14     ## 14         Y          Y
15     ## 15         N          don't know
16     ## 16         N          don't know
17     ## 17         N          don't know
18     ## 18         N          don't know
19     ## 19         N          N
20     ## 20         Y          N
21     ## 21         Y          don't know
22     ## 22         Y          don't know
23     ## 23         N          don't know
24     ## 24         N          don't know
25     ## 25         Y          Y
26     ## 26         Y          N
27     ## 27         Y          N
28     ## 28         Y          N
29     ## 29         Y          don't know
30     ## 30         Y          don't know
31     ## 31         N          don't know
32     ## 32         N          don't know
33     ## 33         N
34     ## 34         N          don't know
35     ## 35         N          don't know
36     ## 36         N          N
37     ## 37         Y          Y
38     ## 38         N          don't know
39     ## 39         N          N
40     ## 40         N          N

```

#Drop the "" (blank) Levels... for some reason, R includes them in the Kappa2 if the

#variable is text and blank

```
SRdataLegs <- SRdata[!(SRdata$SR.legs.restless==""),]
```

```
nrow(SRdataLegs)
```

```
## [1] 37
```

#Drop the "don't know" Levels because the PSG cannot answer "don't know", so these ratings

#should be excluded from the agreement analysis

```

1
2
3 SRdataLegs <- SRdataLegs[!(SRdataLegs$SR.legs.restless=="don't know"),]
4 nrow(SRdataLegs)
5
6 ## [1] 18
7
8 #Take a quick look at the data
9 data.frame(SRdataLegs$PSG.legs.restless, SRdataLegs$SR.legs.restless)
10
11 ##      SRdataLegs.PSG.legs.restless  SRdataLegs.SR.legs.restless
12 ## 1                N                N
13 ## 2                N                N
14 ## 3                Y                N
15 ## 4                Y                Y
16 ## 5                N                N
17 ## 6                N                N
18 ## 7                N                N
19 ## 8                Y                Y
20 ## 9                N                N
21 ## 10               Y                N
22 ## 11               Y                Y
23 ## 12               Y                N
24 ## 13               Y                N
25 ## 14               Y                N
26 ## 15               N                N
27 ## 16               Y                Y
28 ## 17               N                N
29 ## 18               N                N
30
31
32 #Cohen's Kappa
33 item1 <- data.frame(SRdataLegs$PSG.legs.restless, SRdataLegs$SR.legs.restless
34 )
35 kappa2(item1[,c(1,2)])
36
37 ## Cohen's Kappa for 2 Raters (Weights: unweighted)
38 ##
39 ## Subjects = 18
40 ## Raters = 2
41 ## Kappa = 0.444
42 ##
43 ## z = 2.27
44 ## p-value = 0.0233
45
46 #End
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

1
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4
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Supplementary file 5: Research protocol

For peer review only

1
2
3 March 15th, 2016
4

5 **To:** The IWK Health Centre – Research Ethics Board
6 Research Services, Richard Goldbloom Gallery, Main Floor
7 5850/5980 University Avenue, Halifax, NS, B3K 6R8
8

9
10 **From:** Allan Kember
11 Research Administrator, Global Innovations for Reproductive Health and Life
12 Project Lead, Grand Challenges Canada Grant #S7 0629-01-10
13 17 Oceanview Dr.
14 Halifax, NS, B3P 2H4
15

16
17 **Subject:** Research Protocol
18

19 **Project Title:** A Maternal Device for the Prevention of Stillbirth and Low Birthweight
20
21

22 **Foreword**

23 This project, entitled A Maternal Device for the Prevention of Stillbirth and Low Birthweight, was
24 originally submitted on March 10th, 2014 to Grand Challenges Canada in response to their Request for
25 Proposals: Stars in Global Health – Round 7 Phase I. Grand Challenges Canada's peer review of this
26 proposal was led by the Canadian Institutes of Health Research. This proposal was recommended to
27 proceed to the next stage of the *Stars in Global Health* grant process, which involved due diligence and
28 grant agreement negotiations between the primary organization for this project, Innovative Canadians
29 for Change Foundation (ICChange – Edmonton, AB), and Grand Challenges Canada, which were
30 completed on December 19th, 2014. Funding for this project was approved on December 19th, 2014.
31

32 Note that this proposal includes two feasibility studies – one in Halifax, Canada, and one in Accra,
33 Ghana. Both studies include human participants; therefore, both studies will require ethics approval. For
34 the study in Halifax, ethics approval was received on June 16th, 2015 (Project #1018753) from The IWK
35 Health Centre Review Ethics Board (REB). For the study in Accra, ethics approval was received from The
36 IWK-REB on June 16th, 2015 (Project #1019318) and from the Noguchi Memorial Institute for Medical
37 Research Institutional Review Board (local ethics board) on March 4th, 2015 (CPN 069/14-15).
38

39 The purpose of this document is to set forth the research protocol for the study related to The IWK
40 Health Centre in Halifax, Canada as per the guidelines given in the document Protocol Components
41 provided under the New Submissions – Guidelines and Templates section of the IWK Health Centre
42 Research website:
43

44 <http://www.iwk.nshealth.ca/research/application-materials-forms>
45

46 This research protocol is submitted for review by The IWK Health Centre's Review Ethics Board as part of
47 the requirements in the document Researcher's Checklist for Submissions: Delegated Review.
48
49

This document is divided into two main sections. The first section – “Scientific” – describes the scientific aspect of the study. The second section – “Ethical” – describes the ethical aspect of the study.

Sincerely,



Allan Kember

For peer review only

1 Scientific

1.1 Introduction

According to the WHO, stillbirth (SB) is defined as fetal death at gestation ≥ 28 weeks or weight ≥ 1000 g [1]. In Canada, the definition of SB is wider, including fetal death at gestation ≥ 20 weeks or weight ≥ 500 g [2]. In addition to the loss of life for the stillborn baby, SB assails parents with psychological grief of losing their baby and results in markedly increased mortality when compared with non-bereaved parents [3]. Current risk factors for SB in high-income countries are well established and documented. In a recent systematic review with meta-analysis [4], the three most important modifiable risk factors for SB were found to be obesity (population attributable risk (PAR) 8-18%), advanced maternal age (PAR 6-8%), and smoking (PAR 4-7%). Of these, smoking is the only modifiable risk factor that can be realistically addressed during the course of a pregnancy.

Low birthweight (LBW) is defined as a weight less than 2500g at birth [5]. LBW is a significant contributor to SB [4], and infants with LBW are 20 times more likely to die in the first year than heavier babies [5]. Although LBW babies constitute only about 15% of live births, they account for 60-80% of neonatal deaths [6] [7] [8] [9]. Neonatal deaths (death within the first year of life) account for 40% of all deaths under the age of five years [10]. LBW also accounts for significant morbidity such as cognitive impairment [11], and chronic diseases later in life [5] [12]. LBW arises through short gestation (preterm birth) or in-utero growth restriction, or both [13].

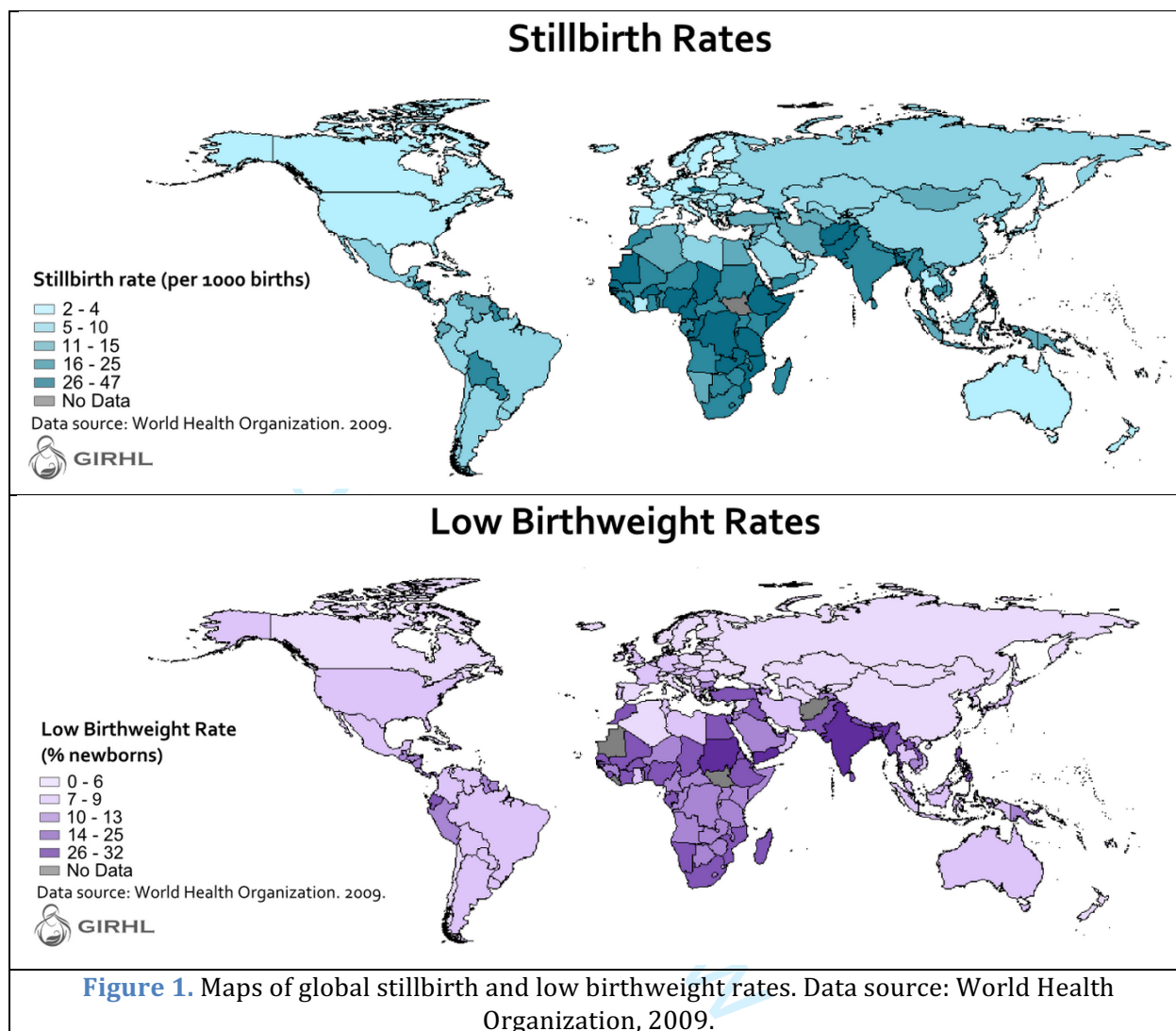
Maternal sleep position during pregnancy has recently emerged as a risk factor for LBW and SB [14] [15] [16]. A device to modify maternal sleep position and mitigate this risk factor has been developed (see section 1.1.3). The purpose of this *Stars in Global Health* project is to test the effectiveness of this device and assess the feasibility of incorporating this device into an antenatal care clinic in Ghana. Data will be used in effect size calculations for large-scale trials targeted at reducing poor pregnancy outcomes in Canada and worldwide.

1.1.1 Research Problem

In 2009, the World Health Organization reported the global prevalence of stillbirth (SB) to be 2.6 million (uncertainty range: 2.1-3.8 million), of which 98% occur in countries of low and middle income [1] – see Figure 1. Sub-Saharan Africa has the highest rate of SB worldwide and has made the least progress in SB reduction [1]. Little is known about effective interventions for SB, especially those that can be implemented in resource-limited settings.

In addition to the global burden of SB, the global incidence of LBW infants remains a significant public health challenge. Each year, there are over 20 million infants born with LBW, of which 96% occur in developing countries with the highest concentrations in Asia and Africa [5] – see Figure 1. Efforts to reduce the incidence of LBW have not been successful in these regions, and thus the incidence has remained largely unchanged [5].

Low- and middle-income countries urgently require simple, inexpensive, and effective interventions to reduce the rates of SB and LBW.



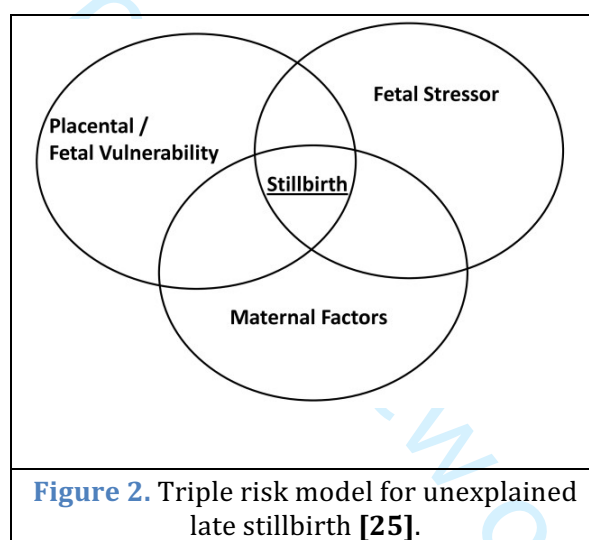
1.1.2 Background – Maternal Position

In obstetrics, it is well-known that when a pregnant woman assumes the supine position during the day, maternal cardiovascular parameters [17] [18] [19] and/or fetal oxygenation [20] are altered, often causing fetal distress, particularly during labour [21]. However, until recently, there has been little evidence on the effect of supine position during sleep in pregnancy. Recently, three studies have suggested that maternal sleep position may be a risk factor for SB [14] [15] [16] and LBW [16]. This is significant given that the majority of third trimester pregnant women spend up to 25% of their sleep time supine [22]. In the Auckland Stillbirth Study [15], the population attributable risk (PAR) for non-left sleep position was found to be 37%, which is greater than the PARs of the three most important modifiable risk factors for stillbirth (obesity, advanced maternal age, and smoking) combined [4]. In an African population [16], the newborns of women who reported supine sleep during pregnancy were at increased risk of low birth weight (OR, 5.0; 95% CI, 1.2–20.2; P=0.025) and stillbirth (OR, 8.0; 95% CI, 1.5–43.2; P=0.016) with a logistic regression that controlled for the covariates maternal age, gestational age, parity, and the presence of pre-eclampsia. Notably, low birth weight was found to mediate the relationship between supine sleep and stillbirth [16]. Currently, there is much interest [23] and follow up

research occurring worldwide, with a growing body of evidence regarding the detrimental effects of supine sleep position on pregnancy outcomes [24].

One proposed hypothesis is that the maternal supine position during sleep plays a causative role in LBW and SB via compression of the abdominal aorta and inferior vena cava ('aortocaval compression'), resulting in negative sequelae. In 2014, drawing on the triple risk model that has been useful in understanding the pathogenesis of sudden infant death syndrome, Warland and Mitchell [25] proposed a similar triple risk model (see Figure 2) to explain the inter-relationship between risk factors and stressors that may result in SB. Although any one risk factor may be insufficient to cause death, together they may produce a lethal combination (as represented by the intersection of the circles), particularly if the fetus is vulnerable [25]. Examples of factors and stressors for each circle are:

- Placental and Fetal vulnerability – e.g., intrauterine growth restriction, placental insufficiency.
- Maternal factors – e.g., obesity, advanced maternal age, smoking
- Fetal stressors – e.g., maternal aortocaval compression, umbilical cord compression



We consider that by addressing these factors and preventing their intersection, we may protect the vulnerable fetus from LBW or SB and thereby effect a significant reduction in the global rates of LBW and SB. In this *Stars in Global Health* project, we focus on how we may intervene to reduce the likelihood of a fetal stressor occurring, in particular maternal aortocaval compression caused via the maternal supine sleeping position.

1.1.3 Background – Maternal Device

Some pregnant women sleep with many pillows supporting their body, including a pillow behind their back to avoid the supine position. Asking women to sleep on their left increases the percentage of left sided sleep to approximately 60% of the night; however, this may come at a cost of a slightly reduced sleep duration, perhaps due to the women feeling they need to make a conscious effort to maintain sleep position [26].

1
2
3 Maternal sleep position has recently been implicated as a potential modifiable risk factor for LBW and
4 SB [14] [15] [16]. Hence, a simple, low-cost, and easily-implemented device has been developed for use
5 by pregnant women to mitigate this risk factor. We anticipate that using this device will remove the
6 need for the woman to make a conscious effort to avoid the supine sleeping position. The device name
7 is 'PrenaBelt'. The PrenaBelt is currently at the prototype stage of development, and as such, this
8 proposal is a proof-of-concept/feasibility project.
9
10

11 The PrenaBelt is a belt-like, positional therapy device designed specifically for pregnant women. While
12 the PrenaBelt does not prevent the user from lying on her back or right side during sleep, it is expected
13 to significantly decrease the amount of time she spends in these two positions via the mechanism of
14 positional therapy. Positional therapy is a simple, non-invasive, inexpensive, long-established, safe, and
15 effective intervention for preventing people with positional-dependent snoring or mild to moderate
16 obstructive sleep apnea from sleeping on their back [27] [28] – a position that exacerbates their
17 condition [29] [30] [31] [32].
18
19
20

21 The PrenaBelt is worn at the level of the waist. By virtue of its design and position on the user's body,
22 the PrenaBelt affects subtle pressure points around the midriff (back and right side) of the user when
23 she lies on her back or right side, respectively. These subtle pressure points activate her body's natural
24 mechanism to spontaneously reposition itself to relieve discomfort [33] [34] [35], thereby reducing the
25 amount of time she remains on her back or right side. Alternatively, the PrenaBelt can be worn at the
26 level of the thorax with the back of the device centered at the mid-back, in which case the front of the
27 device would sit just below the breasts at the level of the fundus (upper abdomen).
28
29
30

31 The PrenaBelt is also designed for adjustability and comfort. As such, its configuration can be easily
32 adapted by the user to only help her avoid sleeping on her back if she requires the option of sleeping on
33 her right side as well as her left for comfort reasons.
34
35

36 Members of our team at Global Innovations for Reproductive Health and Life (GIRHL, Cleveland) have
37 developed a Body Position Sensor (BPS) to be integrated into the PrenaBelt. The BPS is a small,
38 electronic data acquisition device developed for research purposes only and in accordance with the
39 original proposal to our funder, Grand Challenges Canada. The BPS fits into a pocket on the PrenaBelt
40 and uses a three axes accelerometer to detect orientation of the PrenaBelt, and thus the user, in three-
41 dimensional space. The accelerometer data is collected and stored on the BPS hard drive and can be
42 accessed via connecting it to a computer.
43
44
45

46 The PrenaBelt only comes into contact with intact skin and, as such, is a non-invasive medical device. As
47 per Rule 7, subrule (1) in the Government of Canada's Medical Devices Regulation – Classification Rules
48 For Medical Devices, the PrenaBelt is classified as a Class I medical device [36]. The BPS is a research-use
49 only device and, as such, does not fall under medical device regulation.
50
51

52 Per the Government of Canada's Medical Devices Regulation – Part 3: Medical Devices For
53 Investigational Testing Involving Human Subjects, Section 80, Subsection (3), "A manufacturer or
54 importer of a Class I medical device may sell the device to a qualified investigator for the purpose of
55 conducting investigational testing if the manufacturer or importer possesses records that contain all the
56
57

information and documents required by Section 81” [36]. Note that the information and documents required by Section 81 can be found in the [Product Information](#) document.

To date, no studies have investigated positional therapy in the pregnant population, and no positional therapy devices have been designed specifically for pregnant women (see Attachment 1). This is likely because the association between maternal sleeping position and adverse pregnancy outcomes has only recently been discovered and published in the literature [14] [15] [16]. The only FDA-approved product for treatment of positional dependent snoring and mild obstructive sleep apnea is the Zzoma Positional Sleeper by Sleep Specialists, LLC (Abington, PA) [37]. However, the Zzoma device was designed specifically for patients with positional-dependent snoring and mild obstructive sleep apnea and not for pregnant women, who are notably different in many aspects including anatomy (e.g., the gravid uterus) and nocturnal behaviour (e.g., rising up more often during the night).

1.1.4 Hypotheses

The following are hypotheses for the study proposed for Halifax:

1. When compared to one night of sleep with no positional therapy (PT) treatment, treatment with a PT intervention (PrenaBelt) during one night of sleep in the third trimester of pregnancy will significantly reduce the percentage of time spent in the supine and right-lateral positions and, thereby, have a favourable effect on maternal respiratory and cardiovascular parameters.
2. Maternal satisfaction, comfort, and desire to continue use of the PrenaBelt during third trimester sleep will be acceptable¹ after one night of use.

1.2 Relevant Literature

Below, is a list of additional relevant literature that has not been discussed in this research protocol.

1.2.1 Maternal Sleep Practices as Risk Factors for Adverse Pregnancy Outcomes

Romero R and Badr MS. *A role for sleep disorders in pregnancy complications: challenges and opportunities.* American Journal of Obstetrics & Gynecology, 2014; DOI: <http://dx.doi.org/10.1016/j.ajog.2013.11.020>

O’Brien LM, Bullough AS, Owusu JT, Tremblay KA, Brincat CA, Chames MC, Kalbfleisch JD, and Chervin RD. *Snoring during Pregnancy and Delivery Outcomes: A Cohort Study.* Sleep, 2013; 36(11):1625-1632.

1.2.2 Sleep Position and Polysomnography During Pregnancy

O’Brien LM, Bullough AS, Shelgikar AV, Chames MC, Armitage R, and Chervin RD. *Validation of Watch-PAT-200 Against Polysomnography During Pregnancy.* Journal of Clinical Sleep Medicine, 2012; 8(3):287-294

¹ “Acceptable” for each of these measures (satisfaction, comfort, intention to use) is defined independently for each measure as being rated 5 out of 10 or higher on a scale from 1 to 10 on the [PrenaBelt User Feedback Questionnaire](#). Each measure has a note indicating the user’s subjective evaluation correlated with various numbers on the scale.

1.2.3 Stillbirth and Low Birthweight

Bukowski R, et al. *Fetal Growth and Risk of Stillbirth: A Population-Based Case-Control Study.* PLOS Medicine, 2014; 11(4)e1001633

1.2.4 Positional Therapy (as a Treatment Option for Sleep Disordered Breathing)

Jokic R, Klimaszewski A, Crossley M, Sridhar G, and Fitzpatrick MF. *Positional treatment vs continuous positive airway pressure in patients with positional obstructive sleep apnea syndrome.* Chest, 1999; 115(3):771-781

Skinner MA, Kingshott RN, Filsell S, and Taylor DR. *Efficacy of the 'tennis ball technique' versus nCPAP in the management of position-dependent obstructive sleep apnoea syndrome.* Respirology, 2008; 13(5)708-715

Permut I, et al. *Comparison of positional therapy to CPAP in patients with positional obstructive sleep apnea.* Journal of Clinical Sleep Medicine, 2010; 6(3):238-243

1.3 Feasibility Study Objectives

The following are objectives for the study proposed for Halifax:

1. Compare maternal sleep position in third trimester pregnant women between a night with and a night without a positional therapy (PT) intervention (PrenaBelt).
2. Obtain PrenaBelt user experience feedback to evaluate PrenaBelt feasibility and acceptability and optimize PrenaBelt design for future research.

1.4 Research Design and Methodology

In Halifax, the utility of the PrenaBelt in modifying maternal sleeping position and the effect of the PrenaBelt on maternal respiratory and cardiovascular parameters during sleep and sleep staging in the third trimester of pregnancy will be evaluated via a two-night, randomized, cross-over, sham-controlled, triple-blind, sleep study in third trimester pregnant women.

- **Two Nights:** one night with positional therapy (PT) and one night with sham-PT to determine treatment effect on outcomes².
- **Randomized:** participants will be randomized to treatment order: sham-PT on first night, then true PT on second night, or vice versa. This will avoid the potential impact of changes to sleep across the two nights resulting from familiarization with the equipment, which could bias the results.
- **Cross-over:** on the second night, each participant will be crossed over from PT to sham-PT (or vice versa, depending on randomization order) to allow each participant to act as her own control for comparison of treatment effect on outcomes.
- **Sham-controlled:** a sham-PT device that has the same feel, fit, and form of the true PT device but without the ability of function (pressure points) will be used as a control. The purpose of a

² These nights need not be consecutive as this may be onerous on some participants who may have children at home; therefore, we will accommodate the schedule and wishes of the participants in the sleep test booking.

sham-PT device is to identify any specific benefit of one element of a PT device (e.g., fit or form) above and beyond all benefits that might be attributed to everything else about a that device (e.g., function). Note that there is no established effective therapy for the population for the indication under study.

- **Triple-blind:** participants, research assistants monitoring and sleep technologists scoring the sleep tests, and the specialized sleep physician reviewing and reporting the sleep test results will be blinded to the intervention – PrenaBelt or sham-PrenaBelt – received each night.
- **Laboratory:** conducting this study in a controlled lab setting will allow for continual, real time monitoring of various cardiovascular, respiratory, uterine, and sleep parameters of each participant by the research assistant. This contributes to a more controlled and safer study overall.
- **Sleep Test:** body position, various cardiovascular and respiratory parameters, uterine contractions, and sleep staging will be continuously recorded while the participants are sleeping. Sleep lab procedures will be followed by the personnel conducting, scoring, reviewing, and reporting the sleep tests from participant preparation through discharge.

1.4.1.1 Methods

After the recruitment, consent, and enrolment processes (see Section 2.5), each participant will be contacted by a researcher and booked for two overnight sleep tests at the Capital Health Sleep Disorders Clinic (4th floor, Abbie J Lane Building, QEII Hospital, 5909 Veterans Memorial Lane, Halifax, NS). These sleep tests will be booked to take place late in her pregnancy (28-37 weeks) but not beyond 37 weeks unless she is comfortable doing so. These two tests need not be consecutive nights as this may be onerous on the participants, who may have children at home; we will accommodate the schedules and wishes of the participants. The sleep clinic has two beds that can be dedicated to research; therefore, two participants should be booked into the clinic per night for budgetary reasons: two participants can be monitored by one research assistant in a twelve hour shift (see section 1.7).

Each participant will be told that she will be randomized by the researchers to which intervention – PrenaBelt device or sham-PrenaBelt – she will receive on the first night and not informed of the treatment order. On the second night, each participant will be switched over to the alternate intervention. Since the PrenaBelt and sham-PrenaBelt will be virtually identical (except for functional PT capability), each participant will be essentially blinded to the intervention received on each night. The PrenaBelt and sham-PrenaBelt will be randomly labeled as either “Device A” or “Device B” by one of the researchers not directly involved in sleep test monitoring, scoring, interpretation, or reporting. The research assistant monitoring and sleep technologist scoring the sleep tests and the sleep specialist physician interpreting and reporting the results will be blind to the intervention used on each night because they will not be told the true identification of “Device A” and “Device B”. As such, this triple-blind, cross-over, sham-controlled design enables each participant to serve as her own control and measurements/results can be compared between her sleep tests.

In preparing for the sleep tests, each participant will be directed to follow the instructions within the Information and Consent Form, which are standard instructions that the sleep clinic has published on its website:

- Participants will be asked to not drink alcohol on the days of their sleep tests.
- Participants will be asked to not drink or eat caffeine after 5:00pm on the days of their sleep tests.
- Participants will be informed that there will be healthy snacks and beverages available at the sleep clinic at no cost to them.
- If a participant becomes sick with a cold, flu, chest infection or any other physical/medical disorder that could interfere with her sleep, she will be asked to contact a member of the study team as soon as possible as her sleep tests may need to be rebooked.
- Participants will be asked to try to maintain their regular daytime schedule and, if at all possible, avoid napping on the days of their sleep tests.
- Participants will be asked to bring all of their regular medication to the sleep clinic. Unless otherwise instructed beforehand, participants should continue to take their medication as usual.
- Participants will be required to wear sleep attire and will be asked to try to avoid silky material. Pajamas, or walking shorts and a t-shirt are ideal. Participants can bring their own pillow and/or favorite blanket if they wish.
- To ensure the paste and tape for the various monitors adhere to the participant's skin, participants will be discouraged from using body and facial moisturizers. Participants will be asked to remove artificial fingernails and nail polish from at least one finger before the test as they prevent the function of the pulse oximeter.
- Presently, the sleep clinic does not have shower facilities but is able to provide participants with face cloths and towels. If participants wish to have access to shampoo, soap and combs/brushes, they will be asked to bring their own.
- Participants will be encouraged to bring reading material, puzzles, a movie (on DVD) or some other interest to help them relax before Lights Out. The sleep clinic has portable DVD players that participants can borrow.
- Onsite underground parking is available and presently costs \$4.00 for an overnight stay (in after 4:30pm, out before 8:00am). Participants will be reimbursed for this if they choose overnight parking.

The following are the specific details about how the sleep test will proceed:

- Sleep tests will be done in a private clinical/research room with continuous monitoring by a research assistant (in a separate room) through audio-visual and Sandman sleep software.
- Participants (1-4 per night) will be asked to arrive at the sleep clinic waiting room between 7:00pm and 8:00pm on the evenings of their sleep tests. The research assistant and/or study personnel will meet the participants in the waiting room, provide them with two forms to complete (below, first sleep test night only), and bring them to their respective rooms.
 - Participants will be asked to complete the Unexpected Events Contact Form and give it to the research assistant. This will only takes a few minutes to complete.
 - Participants will be asked to complete the Data Collection Form. This form will take about 5-10 minutes to complete. This form will be placed in a sealed envelope for the researchers.

- The forms can be completed before or after hook up.
- The research assistant will hook up one participant at a time. Several monitors (explained below) will be attached to each participant. Hook up will be according to the American Academy of Sleep Medicine 2014 guidelines. Monitors and software will be used to measure, record, and process the following information during the sleep tests:
 - Body position will be measured by direct observation by the research assistant through audio/video recording and by an electronic Body Position Sensor incorporated into the PrenaBelt.
 - Apnea-hypopnea index, which is a standardized measurement of how many times the breathing pauses or slows during sleep, will be calculated by measuring:
 - Chest and abdominal movement (respiratory effort) by having the participant wear two soft, stretchy belts with sensors (respiratory inductance plethysmography). One belt will be positioned around the rib cage just below the breasts, and one belt will be positioned near the umbilicus.
 - The airflow through the participant's mouth and nose by a soft, rubber tube placed just under the nares at its opening, which measures inspiration and expiration. This tube will also detect if snoring is present and how much.
 - The arterial oxygen saturation will be measured by a pulse oximeter placed on one of the participant's fingers.
 - Heart rate and regularity will be measured by electrocardiography (EKG), which involves attaching two electrodes to the skin on the chest and using wires and tape to connect the electrodes to the central box for signal processing.
 - Sleep staging (wake, stage 1, 2, 3, and REM) will be measured by a combination of EEG, EOG, and EMG, which involves attaching electrodes, tape, and wires (similar to above) to the skin on the head, face, chin, neck, arms, and legs.
- The research assistant and/or study personnel will use a demonstration PrenaBelt to show the participant how to don and doff the PrenaBelt. The participants will be informed that they can remove the PrenaBelt and/or sleep test equipment at any point of the sleep test if they become too uncomfortable.
- Bathroom visits during sleep tests are always possible. The research assistant and/or study personnel will discuss the bathroom visit process with participants before their sleep test. Bathroom breaks during sleep tests are part of routine practice at the sleep clinic. The research assistant will assist the participants when bathroom breaks are required and ensure privacy.
- The research assistant will not be apprised of whether the participant has been assigned the PrenaBelt or sham-PrenaBelt. The study personnel will place the appropriate device in a box in the participant's room. The participant will open the box and put on the PrenaBelt before lights out.
- The PrenaBelt will be preconfigured for the participant by the study personnel based on whether the participant indicated to the IWK Research Assistant that she would like the option of sleeping on her right side. If the right side sleeping position is requested, the balls will be removed from the pockets on the right side of the PrenaBelt. When the balls are removed from

the right side pockets, the configuration of the PrenaBelt as such will then only help the user avoid sleeping on her back.

- Lights Out is usually between 10:30pm to 11:00pm. Just before lights out, the research assistant will run calibration testing, which requires participation from the participants (e.g., “close your eyes, open your eyes, roll your eyes, look left, look right, clench your teeth, breath through your mouth, breath through your nose, hold your breath and move your belly in and out,...”). The research assistant will monitor the incoming sleep data in real time throughout the night for quality assurance.
- If a channel faults, the research assistant may fix it if the participant is still awake or wakes up for a bathroom break. If the research assistant cannot solve the fault, he/she may consult with the sleep technician (if present) or call the on-call sleep technician (Friday and Saturday evenings). Throughout the night, the research assistant may also add notes to the data that may assist with subsequent scoring of the data.
- If the device (PrenaBelt or Sham-PrenaBelt) cannot be tolerated by the participant and is removed during the sleep test (note that the Information and Consent Form clearly informs the participants that they are free to remove the device at any time at no penalty if it becomes too uncomfortable), this will be noted by the research assistant via the Sandman software. The sleep test data recording will continue until morning. Study personnel will follow up with the participant to determine whether or not she wishes to withdraw from participating in the study.
- The sleep tests will be finished between 6:00am and 6:30am. When the participant awakes, the research assistant will enter the room and unhook the participant from the sleep test equipment. It is expected that participants will be out of the sleep clinic bedrooms by 7:00am whenever possible.
- After participants are unhooked and before they leave the sleep clinic, they will be asked to complete the PrenaBelt User Feedback Questionnaire, which will take 5-10 minutes and will be sealed in an envelope for the researchers.

1.4.1.2 Measures

The information collected from her on the Data Collection Form is collectively referred to as “demographic and sleep habits information” in Section 1.4.1.6:

- Gestational age at time of sleep test
- Parity
- Maternal age
- Ethnicity/race
- BMI (weight, height) at time of sleep test and BMI at conception or early pregnancy
- Typical bed and rise times, usual sleep duration, habitual snoring (3 or more nights per week; if present, for how long this has been the case), typical position she goes to sleep in and wakes up in currently and when she is not pregnant, what part of the bed she sleeps on, if she has a bed partner, and if she uses pillows when she sleeps (if so, how)
- Presence of new pregnancy-related conditions since signing the consent form for this study

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3 For each participant, identical measurements (below, collectively referred to as “sleep variables” in
4 Section 1.4.1.6) will be recorded on both nights using the same methods, equipment, and software. The
5 sleep tests will be set up and monitored by a research assistant trained in polysomnography and under
6 the supervision of a sleep technologist except on Friday and Saturday evenings. On Friday and Saturday
7 evenings, either two research assistants will be present or one research assistant and one authorized
8 study personnel will be present and a sleep technician will be on call. The sleep tests will be scored by a
9 sleep technologist holding board certification in sleep technology (RPSGT). Scoring will be according to
10 the current American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated
11 Events. The sleep tests and scores will be interpreted and reported by a sleep specialist physician. Note
12 that the measurements, methods, equipment, and software employed will be non-invasive:
13
14
15

- 16 a. Maternal position: direct observation by the sleep technologist through real-time or
17 recorded audio/video and by an electronic Body Position Sensor incorporated into the
18 PrenaBelt
- 19 b. Chest and abdominal respiratory movement: respiratory inductance plethysmography
20 (RIP) via Pro-Tech zRIP DuraBelt with Sandman PSG software
- 21 c. Nasal and oral airflow and presence of snoring: Braebon nasal pressure transducer. If
22 the participant is a total mouth breather, Braebon thermistor will be available as a back-
23 up.
- 24 d. Arterial blood oxygenation: pulse oximetry (SpO₂) via Embla Sandman
- 25 e. Heartbeat rate and regularity: via electrocardiography (EKG)
- 26 f. Sleep staging: via electroencephalography (EEG), electromyography (EMG), and
27 electrooculography (EOG). Note that if a participant is uncomfortable or cannot tolerate
28 some of the EEG, EMG, or EOG electrodes/leads, e.g., EMG electrodes/leads on arms
29 and legs, these electrodes/leads may be removed.

30
31 In the morning following each sleep test, before each participant is discharged home, she will be asked
32 to complete the approved PrenaBelt User Feedback Questionnaire and seal it in a provided envelope for
33 the researchers. Participants will be asked:
34
35

- 36 a. What position she adopted upon settling down last night
- 37 b. What position she fell asleep in last night
- 38 c. What position she woke up in this morning
- 39 d. If she changed position during night
- 40 e. If she remembers changing positions
- 41 f. Her level of satisfaction with the PrenaBelt as it relates to the quantity and quality of her
42 sleep last night
- 43 g. Her level of comfort while wearing and sleeping with the PrenaBelt
- 44 h. Her intention to use the PrenaBelt for the remainder of her pregnancy if it was available
45 to her
- 46 i. Any suggestions of changes/ modifications/ improvements she may have for the
47 PrenaBelt

1.4.1.3 Outcomes

Primary Outcomes: For both sleep tests, the following are the primary outcomes for each participant:

- % of time spent in the supine and right-lateral positions with each intervention
- PrenaBelt User Feedback Questionnaires

The following data will be collected from each participant across each intervention and serve as pilot data to inform effect size calculations for future research.

- Apnea Hypopnea Index (AHI)
- Arterial blood oxygenation (SpO₂)
- Maternal heart rate (ECG)
- Sleep parameters (total sleep time, presence of snoring, RDI, sleep onset latency, sleep efficiency, sleep quality, number of arousals, number of position changes, mean AHI while supine, mean SpO₂ while supine)

When the two sleep tests are complete (interpreted and reported by the sleep specialist physician), the results will be provided to the participant's maternity care physician who will discuss her results with her at her next antenatal care visit. If warranted by the results of the sleep tests for a given participant (e.g., severe obstructive sleep apnea is discovered), contact will be made with the participant and her maternity care physician by a researcher to allow for proper management and care at the earliest opportunity. If her maternity care physician has any concerns about the sleep test results and plan for further investigation/management, he/she may consult with Dr. Debra Morrison (Site-Investigator, Respiriologist, Sleep Specialist Physician) who will be available to address these concerns.

1.4.1.4 Inclusion/Exclusion Criteria

Inclusion criteria: ≥18 years old, low-risk singleton pregnancy, in the last trimester of pregnancy (≥28 weeks of gestation), and residing in the Halifax Regional Municipality.

Exclusion criteria: BMI ≥ 35 at booking (first antenatal appointment for current pregnancy), pregnancy complicated by obstetric complications (hypertension [pre-eclampsia, gestational hypertension, chronic hypertension], diabetes [gestational or not], or intra-uterine growth restriction [<10th %ile for growth]), sleep complicated by medical conditions (known obstructive sleep apnea, known to get <4 hours of sleep per night due to insomnia, or musculoskeletal disorder that prevents sleeping on a certain side [e.g., arthritic shoulder]), multiple pregnancy, known fetal abnormality, non-English speaking and reading.

1.4.1.5 Sample size

To date, there has never been a positional therapy study performed on pregnant women [38]; therefore, there is little-to-no relevant data on which to base a proper sample size analysis. As a feasibility study, this study will be used to generate preliminary data to be used in effect size calculations for future clinical trials targeted at reducing poor pregnancy outcomes in Canada and globally.

A sample size of twenty-five³ (n=25) pregnant volunteers is selected for this feasibility study.

Rationale:

- For a one-sided paired t-test with power (β) of 0.80, significance level (α) of 0.05, n=25 pairs enable a detectable effect (d) of -0.5, which is a medium effect size per the literature regarding Cohen.
- Based on expert opinion (Dr. Louise O'Brien, Scientific Mentor on *Stars In Global Health* project, University of Michigan), n=25 was originally budgeted and proposed to Grand Challenges Canada, which was subsequently approved by Grand Challenges Canada and the Canadian Institute for Health Research.

1.4.1.6 Justification of Statistical Methods

Cross-over study design: each participant is her own control for comparison.

Descriptive statistics (mean, median, standard deviation, maximum, minimum) for demographic and sleep habits information and sleep variables (Section **Error! Reference source not found.**) will be reported.

For continuous variables, the assumption of normality will be assessed using Q-Q plots and the Anderson-Darling test. If normal, paired t-test will be used for evaluating differences. If non-normal, Wilcoxon signed rank test will be used for evaluating differences. For dichotomous data, we will evaluate for differences using McNemar's test for repeated measurements.

1.5 Timeline

November 2014 to May 2015: Halifax study preparation, PrenaBelt development and production of test samples, obtain ethical and research protocol approval from the IWK Health Centre REB.

November 2015 to July 2016: Training, recruitment, consent, enrolment, and data collection in Halifax.

July 2016 to August 2016: Data analysis, report writing, dissemination of findings from Halifax.

November 2014 to May 2015: Ghana study preparation, obtain ethical and research protocol approval from Noguchi Memorial Institute for Medical Research IRB, IWK Health Centre REB, and the Ghana FDA.

April 2015 to July 2015: Production of PrenaBelt test samples for Ghana study.

July 2015 to January 2016: Training, recruitment, consent, enrolment, and data collection in Ghana.

January 2016 to May 2016: Data analysis, report writing, dissemination of findings from Ghana.

1.6 Definition of Adverse Events

Labour is a natural process, so it will be classified as an unexpected event (not an adverse event) in this study should it begin to occur during a sleep test.

³ Note: the EAS Form submitted to the IWK states that a maximum number of thirty (n=30) participants will be recruited. The discrepancy of five (n=5) participants is a buffer to account for an approximate drop-out rate of 20%.

Participants may experience minor irritation of skin in areas in contact with the stickers that hold the sleep electrodes on their body.

The sleep tests for a given participant may reveal that an adverse event has been occurring in her pregnancy without prior knowledge. The sleep test may reveal the presence of maternal obstructive sleep apnea (OSA). We do anticipate that OSA will be discovered in some participants – especially since OSA is common yet often undiagnosed in pregnant women [39] [40] [41] [38] [42] [43] [44]. This adverse event is not related to this study, rather it is related to other obstetric and medical factors and only discovered by this study. It should also be noted that any events (e.g., OSA) that we do observe would be already occurring without anyone's knowledge. If severe OSA is discovered during any of the sleep tests, we will notify the participant and her maternity care physician, give them the test results, and ask them to speak with one another at earliest opportunity to ensure proper management and care. Her maternity care physician will also be informed that if he/she has any concerns about the sleep test results and plan for further investigation/management, he/she may consult with Dr. Debra Morrison (Site-Investigator, Respiriologist, Sleep Specialist Physician) who will be available to address these concerns.

Should a medical emergency occur, the sleep technologists at the Capital Health Sleep Disorders Clinic have been trained according to internal policies and procedures for handling emergencies and unexpected events during sleep tests. The sleep technologists will call EMS and provide basic life support (if needed) until EMS arrives. The sleep technologists are trained in CPR.

Although the risk is low, a participant may go into labour during the sleep study; therefore, our exclusion criteria excludes women at risk of pre-term labour, and we will not book any participants for a sleep test beyond 37 weeks gestation unless the participant is comfortable in doing so. The research assistant will follow a basic plan of action should the participant go into labour during a sleep test:

1. If a participant begins labour during a sleep test, stop the test immediately.
2. Urgent: if onset of labour is sudden and participant is in distress, call EHS to transport the participant to the IWK. Otherwise proceed to 3.
3. Non-urgent: if onset of labour is slow and participant is stable, use the information from the Unexpected Events Contact Form and assist the participant in reaching her contact to transport her to the IWK.

Pregnancy is associated with many risks for the mother and fetus, yet sleep tests are non-invasive and safe for pregnant women and their developing baby to undergo. Although the risks that this study poses to the pregnancy are minimal, all adverse events will be reported to the CDHA Patient Safety Reporting System as per hospital standard operating procedures.

1.7 Budget

For the budget related to research activities in the study in Halifax, see lines 77, 113, and 225 in the Project Budget (submitted as a component of the Researcher's Checklist for Submissions: Delegated Review).

1.8 Resources

Letters of support will be obtained from the applicable institutions (denoted by †) listed in Table 1 and submitted as a component of the Researcher's Checklist for Submissions: Delegated Review.

Table 1. Resources for Halifax Study

Study Component	Institution (Department)	Key Personnel (Position)	Lab/Facility	Equipment
Grant fund administration, Project Monitoring, and Advisory Board	Innovative Canadians for Change Foundation	Dr. Andre Isaac (Project Manager)	n/a	n/a
Ethics Process	IWK Health Centre (Review Ethics Board)	Bev White (REB Manager/ Information Officer)	n/a	n/a
Participant recruitment, consent, enrolment	IWK Health Centre† (Women's and Newborn Health)	Dr. Heather Scott (Obstetrical Co-Director) Ms. Darlene Baxendale (RN, Research Assistant)	Perinatal Centre	n/a
Sleep tests	Capital Health† (Sleep Disorders Clinic)	Dr. Debra Morrison (Clinical Director, Staff Respiriologist) TBD (Certified Sleep Technologist) TBD (Polysomnography Research Assistant)	Two sleep rooms in the sleep laboratory	A/V equipment, Braebon nasal pressure transducer, Braebon thermistor, Pro-Tech zRIP DuraBelt, Embla Sandman, Sandman PSG software, EKG, EEG, EMG, EOG, consumables
PrenaBelt engineering, liaison with Kaishin Design	Global Innovations for Reproductive Health and Life	Ali Borazjani (President, Co-Founder, Biomedical Engineer)	n/a	n/a
PrenaBelt samples: design, production	Kaishin Design	Kaishin Chu (Apparel Design and Development Strategist/Consultant)	n/a	n/a
Scientific Innovation	University of Michigan	Dr. Louise O'Brien	n/a	n/a
Business Innovation	Harvard Business School	Dr. John McArthur	n/a	n/a

n/a – 'not applicable'

2 Ethical

2.1 Potential Benefits to Participants and Others

2.1.1 Participants in Halifax

Undergoing a sleep test may benefit a participant and her developing baby. Due to physiological and anatomical changes in pregnancy, pregnant women have been found to be more susceptible to sleep-disordered breathing – e.g., snoring, obstructive sleep apnea (OSA) – than non-pregnant women [38]. Possible association between OSA and complications in pregnancy (gestational diabetes, gestational hypertension, pre-eclampsia, intra-uterine growth restriction) have been shown [45] [39] [40] [46] [47], and OSA is common yet often undiagnosed in pregnant women [39] [40] [41] [38] [42] [43] [44]. After the sleep tests are scored for a given participant, a researcher will follow up with her maternity care physician if she requests this in the Information and Consent Form. Her maternity care physician will

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2
3 discuss her results with her at her next antenatal care appointment. We have found in previous studies
4 that most women appreciate this.
5

6 If severe OSA is identified for a given participant, she and her maternity care physician will be notified
7 immediately, given the sleep test results, and advised to discuss this issue together at earliest
8 opportunity to ensure proper management and care. Proper management of her OSA may result in
9 instant and long-term benefits for her and her baby.
10
11

12 In addition, the opportunity to assist in the advancement of sleep-in-pregnancy knowledge and the
13 possibility of benefiting other pregnant women globally in the future may be a source of immediate
14 satisfaction to participants.
15

16 **2.1.2 Others**

17 Note: the following section refers to the WHO definition of stillbirth and not the definition used by
18 Statistics Canada (see Section 1.1).
19

20 In Canada, three babies are stillborn every day ($\geq 1000\text{g}$ birthweight or ≥ 28 weeks completed gestation)
21 [1]. This is a largely unrecognized national tragedy yet pales in comparison to Ghana, where 47 babies
22 are stillborn every day [1] (Note: in Ghana, the birth rate is 2 times greater than that in Canada, but the
23 stillbirth rate is more than 15 times greater). In addition, every day, 61 Canadian babies are born with
24 low birthweight ($\leq 2500\text{g}$) [48], and 232 Ghanaian babies are born with low birthweight [49] – many of
25 whom will die in infancy or suffer lifelong consequences. These statistics and disparities are
26 unconscionable, yet even they pale when compared to regions of further impoverishment where the
27 state of affairs has been aptly described by one author as ‘obstetric carnage’ [50].
28
29

30 Maternal supine sleep has recently emerged as a potential risk factor for SB and LBW [14] [15] [16]. If
31 supine sleep has a causative role in LBW and subsequently SB, the population attributable risk (PAR%)
32 suggests that up to 17% of LBW, and consequently 26% of SB, might be averted by changing maternal
33 sleep position [16] – this translates to the aversion of 3.7 million LBW and 676,000 SB annually [1] [5].
34 Since LBW is a major contributor to stillbirth [4], morbidity [5] [11] [12], and neonatal mortality (60-80%)
35 [6] [7] [8] [9], further benefit may be realized.
36

37 This study will test a novel approach to reducing the global incidence of SB and LBW by determining
38 whether this potential risk factor can be mitigated via treatment with a simple, positional therapy
39 device. Demonstrating that maternal sleep position is, in fact, amenable to positional therapy will be a
40 valuable contribution to existing knowledge and may be a key component to reducing the rates of SB
41 and LBW in Canada and worldwide.
42

43 Currently, research is underway to determine whether a causal relationship between maternal sleep
44 position and SB and LBW exists and collect a robust evidence base from which to advise whether a
45 public health intervention should be considered (dissemination of research findings expected by August
46 2016) [24]. If a public health intervention is advised, our study will be at the forefront of scientific
47 investigation into one possible intervention, i.e., positional therapy.
48

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3 Following successful completion of this proof-of-concept (Phase I) study, there is potential for transition-
4 to-scale (Phase II) funding from Grand Challenges Canada (contingent on 50% matching through
5 partnerships) of up to \$1,000,000 CAD for up to 2-3 years. In addition to this funding, other grant
6 options in the area of maternal, newborn, and child health (MNCH) are available, e.g., Bill and Melinda
7 Gates Foundation, Saving Lives at Birth. Such grants would enable exploration of the effectiveness of
8 this intervention in populations that have very high perinatal mortality rates.
9

10
11 Finally, this project may bring beneficial opportunities to members of the research team. For example, it
12 may cultivate future research collaboration with other teams worldwide through publication in journals
13 and presentations/networking at global health conventions. Another example is that the inventors of
14 the PrenaBelt (Mr. Borazjani, Mr. Kember) plan to establish or partner with a social enterprise
15 organization to ensure sustainability and maximum benefit to mothers and their babies globally.
16
17

18 **2.2 Potential Harms to Participants and Others**

19 This study is minimal risk. Participants in this study are at no greater risk of harms when completing the
20 activities of this study than those risks they encounter in their everyday life.
21
22

23
24 The PrenaBelt device is a non-invasive medical device of Class I designation (see section 1.1.3). Pregnant
25 women typically sleep with many pillows supporting their body, including a pillow behind their back to
26 avoid the supine position. The PrenaBelt is a positional therapy device that may assist pregnant women
27 to avoid supine sleep. Positional therapy devices have been shown to be safe and approved for use by
28 humans by the US Food and Drug Administration [37]. In addition, maternal body pillows, regular
29 pillows, and pelvic belts (lumbar support) have been used by pregnant women during sleep without
30 reports of serious adverse effects for the mother or neonate [51].
31
32

33
34 In Halifax, wearing the PrenaBelt and sleep monitoring equipment may be uncomfortable for a
35 participant and disturb her sleep. Each participant will be told that she can remove these devices at any
36 time overnight if she becomes too uncomfortable.
37

38
39 In order to ensure the monitor electrodes remain adhered to participant's skin, the research assistant
40 will need to prepare the area of skin, which involves cleaning and slight abrasion with an abrasive skin
41 preparation gel. In the morning, after the monitors are removed, participants may experience slight
42 discomfort and redness on the regions of their skin that were in contact with the electrodes. Rarely, a
43 person will have a minor skin reaction on the area of his/her skin that was in contact with the
44 electrodes. This reaction is not dangerous and usually goes away on its own within 24 hours to a few
45 days.
46
47

48 Since personal information will be collected from participants, there always exists the potential harm
49 should breach of confidentiality inadvertently occur.
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2.3 Alternative Treatments or Procedures

2.3.1 Positional Therapy

There are several techniques used for positional therapy such as positional alarms, verbal instructions, special pillows, tennis balls, vests, and “shark fins”. The latter three techniques prevent the wearer from lying supine in a passive manner by applying pressure points to the wearer’s back when lying supine, which is similar to the mechanism of the PrenaBelt.

To date, no studies have investigated positional therapy in the pregnant population, and no positional therapy devices have been designed specifically for pregnant women (see Attachment 1). This is likely because the association between maternal sleeping position and pregnancy outcome has only recently been published in the literature [14] [15] [16] [25].

There are several positional therapy products for persons with positional-dependent obstructive sleep apnea (POSA) (see Attachment 1). However, these devices are designed specifically for persons with POSA, not pregnant women, who may also have POSA but are notably different in aspects such as anatomy (e.g., the gravid uterus) and nocturnal behaviour (e.g., rising up more often during the night). Of these products, only the Zzoma Thoracic Anti-Supine Band is FDA-approved for the treatment of OSA. In addition, these devices are characteristically limited in that they are designed to only prevent supine sleep. Some of these devices involve expensive electronic components and, therefore, are not feasible for widespread deployment in low-resource areas.

2.3.2 Sleep Study

Sleep studies can be performed at home or in a sleep lab setting. Sleep studies for diagnosis of sleep disordered breathing in adults can vary in complexity. A Level I sleep study includes full polysomnography, is conducted in a sleep lab setting, and is considered the gold standard in sleep testing. A Level III sleep study is less complex and is generally performed in the home setting. In Halifax, we are proposing a Level I study.

2.4 Minimization of Potential Harms

While the risks of this study to the participants and their developing babies are minimal, all adverse events will be reported to the CDHA Patient safety Reporting System as per hospital standard operating procedures

Wearing the PrenaBelt and sleep monitoring equipment may be uncomfortable for a participant and disturb her sleep. Each participant will be instructed how to, and told that she can, remove these devices and discontinue use at any time if she becomes too uncomfortable. If bothersome skin irritation occurs for a given participant as a result of contact with the electrodes, we will limit the contact of sleep electrodes to one overnight study.

Personal health information (PHI) used to identify potential participants will not be accessed by anyone other than the researchers within their circle of care.

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2
3 Upon enrolment in the study, each participant will be assigned a random, six-digit, alphanumeric code.
4 All data collected from participants during the studies will be collected only in association with this code,
5 thus automatically de-identifying the data and minimizing the risk of identification. The key to the code,
6 which links the codes to patient names and contact information, will be kept in a secure location away
7 from the de-identified study data, thus minimizing the risk of re-identification. The de-identified data in
8 forms (paper) and files (electronic) will be secured in a locked filing cabinet and in password-protected
9 files on a password-protected computer, respectively, in a locked office with limited access.
10
11

12
13 For all study activities, all data collected from participants will be protected from unauthorized access to
14 safeguard participant privacy and confidentiality in accordance with TCPS2, PHIPA, and PIPEDA and
15 personal information policies at the IWK Health Centre.
16

17
18 There is a reasonable foreseeable risk that the Unexpected Events Contact Form for a given participant
19 (contains participant's first name, name of contact, phone numbers of contact, and relationship of
20 contact) could be matched with her Data Collection Form, PrenaBelt User Feedback Questionnaires, or
21 sleep recording files (which contain her alphanumeric code) and be used to re-identify her de-identified
22 information. To mitigate this risk of re-identification, the research assistant will be the only person who
23 will have access to the Unexpected Events Contact Form and will be instructed to keep it in a separate
24 secure location and shred it in a cross-cut shredder after the second sleep test is complete. In addition,
25 the research assistant will not have access to the Data Collection Form or PrenaBelt User Feedback
26 Questionnaires, which will be delivered and retrieved from each participant in a sealed envelope.
27
28
29

30 Study data will only be exchanged in de-identified form and between authorized research team
31 members per the approved EAS Form. Data will be protected in electronic transfers through password
32 protection and encryption if deemed necessary.
33
34

35 After study closure, study data will be stored securely (locked cabinets, password-protected files,
36 password-protected computers, locked offices) in de-identified form for five years, after which it will be
37 destroyed in a secure manner (e.g., incineration and cross-cut shredding).
38
39

40 2.5 Process for Seeking Consent

- 41 1. **Ethical Approval and Training:** The study requires approval from the Review Ethics Board at the
42 IWK Health Centre (Halifax, Canada). All study personnel will be trained to the approved
43 Research Protocol by Mr. Allan Kember (Sub-investigator, Project Lead).
44
45
- 46 2. **Recruitment:**
 - 47 • The IWK OB/GYN will review charts of her/his patients scheduled for their routine antenatal
48 visit at the clinic to identify potential participants. These patients will then be screened by
49 the OB/GYN within their circle of care using the Screening Inclusion Form to determine if they
50 meet the inclusion/exclusion criteria for this study.
 - 51 • Patients who meet the inclusion/exclusion criteria will be invited to participate in the study
52 by their OB/GYN at the end of their antenatal care visit via the approved Flyer. The Flyer will
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also be posted in the clinic rooms and waiting areas. A patient who expresses interest in participating in the study will be asked if she is agreeable to speak to the IWK Research Assistant about the study.

- If she is agreeable, the IWK Research Assistant will then come to the clinic, confirm the inclusion/exclusion criteria by reviewing the patient's chart, and conduct the formal consent process using the approved Information and Consent Form.
- If she does not wish to speak with the IWK Research Assistant immediately but is still interested in participating in the study, she will be given the Information and Consent Form to take home and read and asked whether she would agree to be contacted by the IWK Research Assistant in one week's time.
 - If she agrees, her name and contact information will be given to the IWK Research Assistant who will contact her in one week's time to see if she is still interested in participating in the study.
 - If she does not agree, she will be informed that she is free to contact the IWK Research Assistant whenever she wishes to do so.
- Snowball sampling may be used as well, i.e., potential participants who are interested may tell their friends about the study (share the Flyer and Information and Consent Form with them) and direct them to contact the IWK Research Assistant.

3. **Consent and Enrolment:**

- Potential participants, having
 - met the study inclusion/exclusion criteria,
 - been invited to participate in the study,
 - shown express interest in participating in the study, and
 - given verbal consent to speak with the IWK Research Assistant,
 will meet with the IWK Research Assistant to complete the consent process.
- In the meeting, the IWK Research Assistant will go through the approved Information and Consent Form with the potential participant, ensuring full and accurate disclosure of the,
 - nature of the study (what is involved, who will be conducting it, how the results will be used, how confidentiality and privacy will be protected),
 - the risks and benefits involved in participating in the study, and
 - the free choice to decline participation in or withdraw from the study at any time without consequence (no adverse or negative effect on her or her family's care in any way)
 to each potential participant.
- The capacity of each potential participant to provide consent will be assessed by the IWK Research Assistant by asking the potential participant questions to verify she understands the information relevant to giving or refusing consent and appreciates the outcomes of both choices:

- What is this study about?
- Why is this study important?
- What will you need to do in this study?
- What are the risks to you from being involved in this study?
- What are the benefits to you from being involved in this study?
- What happens if you choose to not participate today?
- What happens if you choose to participate today and then change your mind at another time either before the study starts or during the study?
- The IWK Research Assistant will give each potential participant an opportunity to ask any questions she may have.
- Voluntary, written, informed consent (form) will be obtained by the IWK Research Assistant from a potential participant who has demonstrated capacity and maintains an interest in enrolling in the study. Authorization or refusal of consent by a potential participant will be accepted by the IWK Research Assistant.

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Attachment 1: Treatment and Device Search

PrenaBelt Patent Search

Positional Therapy for Positional-dependent Obstructive Sleep Apnea (POSA) – Product Search

Pregnancy Sleep Product Search

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Table 1. PrenaBelt Patent Search

Publication Number	Application Number	Publication Date	Title	Potential Similarity to PrenaBelt [†]
US4471767 A	US 06/558,335	09/18/84	Therapeutic device for positional treatment for gastroesophageal reflux	1
US20110132378 A1	US 12/794,498	06/09/11	Systems and methods for controlling position	2
US 20110179573 A1	US 12/975,144	07/28/11	Suspended back pillow for sustaining a side sleeping position	1
US 20130043999 A1	US 13/695,209	02/21/13	Method and device for sleep posture correction	3
US 20120197340 A1	US 13/251,856	08/02/12	Screening devices and methods for obstructive sleep apnea therapy	1
US 20130108995 A1	US 13/286,037	05/02/13	System and method for monitoring and influencing body position	1
US 20100319131 A1	US 12/581,732	12/23/10	Suspended Back Pillow for Sustaining a Side Sleeping Position	1
US4506396 A	US 06/480,943	03/26/85	Comfort pillow for pregnant females	1
US 5359739 A	US 08/113,076	11/01/94	Patient repositioning and position maintenance device	1
US6886201 B1	US 10/698,244	05/03/05	Maternity pillow	1
USD547586 S1	US 29/192,913	07/31/07	Maternity pillow	1
WO 2008120897 A1	PCT/KR2008/001712	10/09/08	A maternity belt with vibration speaker	1
US20130067642 A1	US 13/239,179	03/21/13	Maternity belt structure	2
US20130072087 A1	US 13/239,164	03/21/13	Adjustable protective maternity belt	2
US 8396229 B2	US 11/834,085	03/12/13	Musical maternity belt	1
USD560328 S1	US 29/261,923	01/29/08	Maternity belt	1
US3315670	---	04/25/67	Maternity belt	1
US2765470	---	10/09/56	Maternity belt	2
US 20070037483 A1	US 11/271,892	02/15/07	Maternity belt	1
US2486211	---	10/25/49	Maternity belt	2
US6537132 B1	US 09/696,873	03/25/03	Maternity brace	1
US 20090142988 A1	US 11/998,477	06/04/09	Lower uterine segment maternity support belt	2
USD658350 S1	US 29/370,112	05/01/12	Asymmetric maternity support belt	1
US 3623488	---	11/30/71	Belly-band	2

Notes: [†]Subjective scoring: 1=minimal to no similarity → 5=highly similar

Table 2. Positional Therapy for Positional-dependent Obstructive Sleep Apnea (POSA) – Product Search

Company	Device(s)	Description	Cons
NightBalance B.V. (Delft, The Netherlands)	NightBalance Sleep Position Trainer	For light and moderate POSAS. Electronic sensor worn on an ergonomic strap around the chest. Vibrates when in supine position. Comfortable and user friendly. Trains user not to sleep supine. Can monitor sleep data on computer.	Expensive. Requires batteries. High-tech. Only prevents supine sleep. Available by prescription only (requires sleep examination).
Advanced Brain Monitoring(CA, USA)	Sleeptech Night Shift Sleep Positioner	For POSAS and snoring. Electronic sensor worn around the neck. Vibrates when wearer is supine and increases in intensity until wearer shifts. Can monitor sleep data on computer.	Price (\$270). Rechargeable battery lasts three nights. High-tech. Only prevents supine sleep.
N/A	Tennis ball technique	For POSAS. Simple. No electric components. A belt or shirt with pockets large enough to put a tennis ball inside. Also in the form of a pouch with straps.	Back discomfort. Low compliance long term. Only prevents supine sleep. Tennis balls can move around or fall out while sleeping.
Zzoma (PA, USA)	Zzoma Thoracic Anti-Supine Band	For POSAS. No electric components. A belt with a large piece of foam mounted on the area that covers the wearer's back. Prevents the wearer from rolling onto back while sleeping. Side elastics for comfortable breathing.	Bulky. Worn around the upper torso. If wearer wants to switch from left to right side, they must do so via the stomach. Only prevents supine sleep. Available by prescription only.

Table 3. Pregnancy Sleep Product Search

Company	Device(s)	Description	Cons
Utterly Yours (VA, USA)	Pregnancy Pillow	For maternal sleep. Simple, full-length, wedge, or U-shaped pillows to support and align the back and hips, and support the belly, knees, and/or body to help reduce pain and provide a good night sleep. Claim to benefit a pregnant mother's comfort, rest, and health.	Expensive. Bulky. Emphasizes comfort, not optimal position. Encourages lateral sleep, but does not prevent supine sleep or lateral-right sleep.
Boppy (CO, USA)	Cuddle Pillow, Custom Fit Total Body Pillow, Pregnancy Wedge		
Leachco (OK, USA)	Snoogle Total Body Pillow		
Today's Mom (CO, USA)	Coolmax, Cozy Cuddler, Cozy comfort		
Oggi (USA)	Elevation		
Yaz Design (USA)	Pillowband		
Peachy Products (South Africa)	Stress Nest		
Motherhood Maternity (USA, Canada)	Tummy Sleeve, Ultimate Maternity Belt, Maternity Support Belt	Wide pieces of stretchy fabric in a tube configuration designed to discreetly offer back support and lower belly support during pregnancy. Some have additional suspender-like straps to provide further fixation and support.	Does not affect sleeping position.
Mama Band (USA)	Belly Band		
Ingrid & Isabel (CA, USA)	Bellaband, BeBand		
Cabea, LLC (CT, USA)	BabyBellyBand		



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	8
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	9
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9-10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9, 5, 9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7-10

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2		assessing outcomes) and how	
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4		11b If relevant, description of the similarity of interventions	6-7
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	10
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
7			
8	Results		
9	Participant flow (a diagram is strongly recommended)	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig. 2, pages 10-11
10		13b For each group, losses and exclusions after randomisation, together with reasons	10-11
11	Recruitment	14a Dates defining the periods of recruitment and follow-up	10
12		14b Why the trial ended or was stopped	11
13	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	12-13
14	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11
15			
16	Outcomes and estimation	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13-17
17		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
18	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
19			
20	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	17
21			
22	Discussion		
23	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-20, 22-23
24	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	20-22
25	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17-22
26			
27	Other information		
28	Registration	23 Registration number and name of trial registry	2, 24
29	Protocol	24 Where the full trial protocol can be accessed, if available	24
30	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	26
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*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with Positional Therapy: A Randomized Pilot Trial

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Primary Subject Heading:	Obstetrics and gynaecology
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Keywords:	SLEEP MEDICINE, STILLBIRTH, Maternal medicine < OBSTETRICS, Respiratory physiology < THORACIC MEDICINE, Fetal medicine < OBSTETRICS

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Manuscripts

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3 **Title:** Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with
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5 Positional Therapy: A Randomized Pilot Trial
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ABSTRACT:

OBJECTIVE: To evaluate whether the percentage of time spent supine during sleep in the third trimester of pregnancy could be reduced using a positional therapy device (PrenaBelt) compared with a sham device.

DESIGN: A double-blind, randomized, sham-controlled, crossover pilot trial.

SETTING: Conducted between March 2016 and January 2017, at a single, tertiary-level center in Canada.

PARTICIPANTS: Twenty-three participants entered the study. Twenty participants completed the study. Participants were low-risk, singleton, third-trimester pregnant women aged 18 years and older with BMI <35 at the first antenatal appointment for the index pregnancy and without known fetal abnormalities, pregnancy complications, or medical conditions complicating sleep.

INTERVENTIONS: A two-night, polysomnography study in a sleep laboratory. Participants were randomized by computer-generated, one-to-one, simple randomization to receive either a the PrenaBelt or a sham-PrenaBelt on the 1st night and were crossed over to the alternate device on the 2nd night. Allocation concealment was by unmarked, security-tinted, sealed envelopes. Participants, the recruiter, and personnel involved in setting up, conducting, scoring, and interpreting the polysomnogram were blinded to allocation.

PRIMARY AND SECONDARY OUTCOME MEASURES: The primary outcome was the percentage of time spent supine during sleep. Secondary outcomes included maternal sleep architecture, respiration, self-reported sleep position, and feedback.

RESULTS: The median percentage of sleep time supine was reduced from 16.4% on the sham night to 3.5% on the PrenaBelt night (pseudomedian=5.8, p=0.03). We were unable to demonstrate differences in sleep architecture or respiration. Participants underestimated the time they spent sleeping supine by 7.0%, and six (30%) participants indicated they would make changes to the PrenaBelt. There were no harms in this study.

CONCLUSIONS: This study demonstrates that the percentage of sleep time supine during late pregnancy can be significantly reduced via positional therapy.

TRIAL REGISTRATION: ClinicalTrials.gov NCT02377817

Strengths and limitations of this study:

- A double-blind, randomized, sham-controlled, cross-over pilot trial.
- Employed polysomnography, the gold-standard test for investigating sleep physiology and pathophysiology.
- The first to investigate positional therapy during sleep in pregnancy.
- Performed in a controlled sleep laboratory setting over two nights; therefore, caution should be taken when extrapolating the results to the home setting and across the third trimester.
- Due to the small sample, may have been underpowered.

INTRODUCTION

Background

Stillbirth (SB) and low birth weight (LBW) are devastating complications of pregnancy. Recently, five studies have demonstrated an association between maternal supine sleep position in late pregnancy and the risk of late term SB (1–5) and LBW.(1) The population attributable risk of supine sleep for SB has been reported as being between 3.7% and 37%,(1–5) suggesting that a significant proportion of late term SB could be averted if supine sleep was avoided. A number of major risk factors for SB and LBW are not modifiable in the course of the pregnancy (e.g., elevated BMI, advanced maternal age); however, maternal supine sleep is potentially modifiable with the majority of third-trimester pregnant women spending up to 25% of their sleep time supine.(6–8)

The contribution of supine sleep to LBW and SB is biologically plausible due to inferior vena cava compression by the gravid uterus, affecting maternal hemodynamics (9–22) and fetal oxygenation.(14,23–25) The supine position also exacerbates sleep disordered breathing (SDB),(26,27) which has been linked to adverse pregnancy outcomes.(28–30) In persons with mild to moderate SDB, the majority experience most of their breathing abnormalities while sleeping supine.(31) Positional therapy (PT) is a simple, safe, and effective treatment that helps individuals with SDB maintain a lateral position while sleeping, thus significantly reducing or eliminating their breathing abnormalities.(31,32) Drawing on the concept of PT for SDB, the authors (AK, AB, KC) designed a PT device for pregnant women called “PrenaBelt” to minimize supine sleep (**Fig. 1.**). This study is a randomized pilot trial because it *trialed* a new intervention on a

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3 smaller scale (*pilot*) to evaluate it for use in a full-scale randomized controlled trial.(33)
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8 **Objectives**

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10 The primary objective was to evaluate whether the percentage of time spent supine
11 during sleep in the third trimester of pregnancy could be reduced using the PrenaBelt
12 when compared with a sham. Secondary objectives were to evaluate the effect of the
13 PrenaBelt on maternal sleep architecture and respiration in comparison with a sham,
14 evaluate the accuracy of maternal self-reported sleep position, and collect feedback
15 from the participants regarding the PrenaBelt.
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26 **METHODS**

27 **Randomized Pilot Trial Design**

28 A single-center, double-blind, randomized (one-to-one), sham-controlled, crossover trial.
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30 No methodological changes were made after trial commencement.
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38 **Patient and Public Involvement**

39 Patients and the public were not involved in the development of the research question
40 or outcome measures, design of the study, recruitment process, or conduct of the study.
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42 During the consent process, participants indicated whether they wished to receive a
43 copy of their personal study results and/or a summary of the overall study results (to be
44 shared by email).
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54 **Participants**

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3 Participants were recruited by a trained nurse at the IWK Health Centre – a tertiary and
4 primary care center for women and children with approximately 5000 newborns
5 delivered per year. Overnight polysomnograms (PSGs) were conducted at the Queen
6 Elizabeth II (QEII) Health Sciences Centre Sleep Disorders Clinic. The IWK and QEII
7 are teaching hospitals associated with Dalhousie University in Halifax, Canada. Halifax
8 has a population of approximately 400,000. Participants expressing interest in the study
9 (paper flyer, online advertisement) were screened.
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21 Participants were eligible if they had a low-risk singleton pregnancy and were 18 years
22 of age or older, more than 20 weeks gestation at screening, and residing in the Halifax
23 Regional Municipality. Exclusion criteria included BMI ≥ 35 at the first antenatal
24 appointment for the current pregnancy, pregnancy complicated by obstetric conditions
25 (e.g., hypertension, diabetes, intra-uterine growth restriction), sleep complicated by any
26 medical conditions (e.g., known obstructive sleep apnea, insomnia, musculoskeletal
27 deformity affecting sleep position), multiple pregnancy, known fetal-abnormality, and
28 non-English speaking and reading.
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42 All participants in the trial gave written informed consent. This trial was approved by the
43 IWK Health Centre Research Ethics Board in June 2015 (Project No. 1018753). There
44 was no independent data monitoring committee.
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51 Interventions

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3 There was no run-in measurement of baseline sleep habits. Each participant underwent
4 two overnight PSG studies between 28-37 weeks gestation. The study nights were not
5 required to be consecutive dates, and we did not specify a defined washout period. The
6 only difference between the two nights was the intervention (PrenaBelt or sham) and
7 that participants completed a demographic questionnaire on the 1st PSG night only. The
8 PrenaBelt is worn at the level of the waist and has four firm plastic balls embedded into
9 foam inserts within the pockets posteriorly (**Fig.1**). The mechanism of action of the
10 PrenaBelt is theoretical and based on the tennis-ball technique of PT:(34–36) when
11 supine, the balls apply pressure points across the user's lower back, prompting her to
12 reposition herself in a lateral position to maintain comfort. The sham was identical in
13 appearance, materials, and construction to the PrenaBelt, but had soft foam balls
14 instead of firm plastic balls and did not have foam inserts; as such, the sham did not
15 provide pressure points. Participants crossed over to the alternative intervention on the
16 2nd PSG night.

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38 PSG set-up, including Pro-Tech zRIP Durabelts (Philips Respironics, Murrysville, USA)
39 for respiration, PT1 pressure transducers (BRAEBON Medical Corporation, Kanata,
40 Canada) for airflow and snoring, electrodes (Natus Medical Incorporated, Pleasanton,
41 USA) for ECG/EEG/EOG/EMG, and finger-tip pulse oximetry, was by trained research
42 assistants (RAs), in accordance with the American Academy of Sleep Medicine 2014
43 guidelines,(37) and in a private clinical room with continuous monitoring by an RA in a
44 separate room through audio/visual and Embla Sandman Elite sleep diagnostic
45 software (Natus Medical Incorporated, Pleasanton, USA).

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6 Immediately before the participant settled to sleep, the unblinded research personnel
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8 (co-PI [AK] or study coordinator [JW]) entered the room to assist her in donning the
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10 assigned intervention (PrenaBelt/sham) without disclosing the identity of the intervention
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12 to the participant or the RA in order to maintain blinding. Upon waking for the day, the
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14 participants immediately removed the intervention and placed it in an opaque closed
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16 box for collection by the unblinded personnel in order to keep it concealed from the RA.
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18 The RA subsequently entered the room and unhooked the PSG equipment. The
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20 participant completed a feedback questionnaire and placed it in a sealed envelope for
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22 the unblinded personnel. Participants were permitted bathroom breaks and to remove
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24 the intervention and/or PSG equipment at any point if they became uncomfortable.
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31 Scoring of PSG's was performed by blinded Registered PSG Technicians, and
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33 interpretation was by a blinded sleep medicine physician (DM).
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38 **Outcomes**

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40 The pre-specified primary outcomes per protocol were the percent of time spent in the
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42 supine and right-lateral positions (we originally intended to minimize both) and the
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44 feedback questionnaire; however, for reporting clarity and participant comfort, the
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46 PrenaBelt was configured to provide pressure points only when the user was supine,
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48 the primary outcome was further specified to be the percentage of time spent supine
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50 during sleep only, and the other pre-specified primary outcomes were instead reported
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3 as secondary outcomes. The primary outcome was documented continuously by an RA
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5 via video feed.
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10 Secondary outcomes were total sleep time, sleep time in each position (left-lateral,
11 right-lateral, supine, prone), percentage of sleep left and right, sleep latency, sleep
12 efficiency, sleep indices (total arousal, spontaneous arousal, periodic limb movement,
13 respiratory arousal, apnea-hypopnea, respiratory effort-related arousal), percentage of
14 sleep stage (1, 2, 3, and rapid eye movement (REM)), peripheral oxygen saturation
15 (SpO₂) during sleep, snoring, and feedback questionnaire. The questionnaire elicited
16 participants' perceptions of body position at sleep onset and waking, number of
17 changes in position, and estimates of percentage/time spent in each position during
18 sleep. Participants also ranked their satisfaction, comfort level, and intention to continue
19 using the PrenaBelt (if it were available) on a 10-point Likert scale (with 10 out of 10
20 reflecting the highest satisfaction, comfort, and intention to use, and 1 out of 10 the
21 lowest).
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40 Per our research protocol and trial registry, supine and non-supine apnea-hypopnea
41 index (AHI), min/mean/max SpO₂ while awake, and min/mean/max maternal heart rate
42 during wake, REM, and non-REM states, were also specified as secondary outcomes;
43 however, we were unable to report the supine and non-supine AHI and heart rate data
44 due a software configuration issue nor the awake SpO₂ values due to data artifact.
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54 **Sample Size**

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3 This is the first trial investigating PT in pregnant women to reduce supine sleep time.
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5 For a one-sided paired t-test with power (β) of 0.80, significance level (α) of 0.05, and
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7 detectable effect (d) of -0.5 (difference in mean percentage of time spent sleeping
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9 supine by half a standard deviation), which is a medium effect size per the literature
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11 regarding Cohen,(38) a sample size of twenty-five (n=25) participants was required. All
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13 statistical analyses were conducted using the R Statistical Software package (version
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15 3.2.4 (2016-03-10)).(39) There was no planned interim analysis or stopping guidelines.
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21 **Randomization**

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23 Participants were allocated by computer-generated (R), one-to-one, simple
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25 randomization into one of two possible crossover schemes: PrenaBelt on the 1st PSG
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27 night followed by sham on the 2nd PSG night, and vice versa (**Fig. 2.**). Allocation
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29 sequence was concealed via unmarked, security-tinted, sealed envelopes by an
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31 independent statistician (MB). An envelope was drawn in sequence, opened, and the
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33 participant's name and birth date were recorded on the enclosed allocation sheet by the
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35 unblinded personnel (AK, JW) on the participant's first PSG night.
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42 **Blinding**

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44 Participants, the recruiter, and personnel involved in setting up, conducting, scoring,
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46 and interpreting the PSG were blinded to allocation. The only research personnel
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48 unblinded to the allocation were the co-PI (AK) and the study coordinator (JW), which
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50 was required in order to provide the appropriate intervention to the participant before
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3 she went to sleep. It was not feasible to blind the researchers analyzing the study data
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5 (AK, JW, MB) to the allocation.
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10 **Statistical Methods**

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12 Primary and secondary outcomes were compared between interventions by paired t-
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14 tests (normal) and Wilcoxon signed rank tests (non-normal). Cohen's Kappa (κ) was
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16 used to assess agreement between categorical variables. Spearman's Rho (ρ) and
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18 Bland-Altman plots were used for continuous variables.
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24 For continuous variables, normality was assessed using Q-Q plots and Anderson-
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26 Darling test. All testing was performed at a 0.05 significance level. Treatment effects
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28 (differences in means and odds ratio) and associated confidence intervals were
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30 presented at a 95% confidence level with p-values.
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35 **RESULTS**

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37 Between March 2016 and January 2017, 28 participants were assessed for eligibility
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39 (**Fig. 2.**). Following exclusion of three (11%) who declined participation and two (7%)
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41 who failed to meet eligibility criteria, 23 were randomized. After randomization, there
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43 were three (13%) dropouts – all from the PrenaBelt-then-sham group and after
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45 completing the 1st PSG night. Two were due to transportation/childcare reasons, and
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47 one was due to an unrelated injury preventing her from sleeping in a horizontal position.
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49 Thus, twenty participants – ten from each group – were included in the primary analysis,
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52 which was by original assigned groups and on a complete-case basis (drop-outs
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3 excluded). The originally planned sample size of 25 participants was not reached due to
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5 unforeseen budget restrictions preventing recruitment beyond 20 participants. The
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7 length of time between studies for the same participant (washout period) was a median
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9 of 1 day (IQR 1 – 3.25 days; maximum 13 days).

14 **Sample Characteristics**

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16 Baseline demographic, obstetric, and sleep habit characteristics (see **Supplementary**
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18 **File 1**) of the 20 participants who completed the study are shown in **Table 1** per
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20 randomized group (n=10 each). The two randomized groups were well balanced with
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22 respect to the sample characteristics – there were no statistically significant differences
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24 in baseline characteristics between groups ($\alpha=0.05$). The mean (SD) age was 30.9 (5.0)
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26 years. The majority (80%) were Caucasian. The mean (SD) pre-pregnancy BMI was
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28 26.6 kg/m² (3.3) and rose to a mean of 30.4 kg/m² (3.6) at the time of the 1st PSG,
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30 which took place at a median (IQR) gestational age of 30.0 weeks (28-33.1). Half (50%)
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32 of the participants were nulliparous.

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40 The median (IQR) self-reported overnight sleep duration at the time of the 1st PSG was
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42 8 (7-8) hours. In the week previous to the 1st PSG (when pregnant), left was the most
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44 common position at sleep onset (85%) and waking (60%), although a large proportion of
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46 women also reported the supine position at sleep onset and waking (25% and 40%,
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48 respectively). When not pregnant, prone was the most common position at sleep onset
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50 (65%), and supine was the most common at waking (55%). Most participants used a
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52 pillow under their head (90%) and between their knees (70%).
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In comparing baseline demographic, obstetric, and sleep habit characteristics between the participants who completed the study (n=20) and those who did not (n=3), the groups were similar; however, participants who did not complete the study were younger (mean 26.7 years), had a higher current BMI (mean 32.5 kg/m²), and had less self-reported overnight sleep duration (mean 6.8 hours).

Table 1 | Baseline demographic, obstetric, and sleep habit characteristics*

	PrenaBelt-then-sham (n=10)	sham-then-PrenaBelt (n=10)
Age (years)	31.1 (6.0)	30.7 (4.1)
Caucasian ethnicity	6 (60%)	10 (100%)
Pre-pregnancy BMI (kg/m ²)	27.0 (3.3)	26.2 (3.5)
Current BMI (kg/m ²)	30.9 (3.7)	29.9 (3.6)
Gestational age (weeks)	30.9 (3.0)	30.8 (2.8)
Gravida		
1	4 (40%)	6 (60%)
≥2	6 (60%)	4 (40%)
Sleep duration (hours)	8.0 (7.5-8.0)	7.8 (7.0-8.0)
In the last week:		
Sleep onset positions:		
Left	7 (70%)	10 (100%)
Supine	3 (30%)	2 (20%)
Right	8 (80%)	3 (30%)
Prone	1 (10%)	0 (0%)
Waking positions:		
Left	8 (80%)	4 (40%)
Supine	4 (40%)	4 (40%)
Right	5 (50%)	6 (60%)
Prone	0 (0%)	0 (0%)
When not pregnant:		
Sleep onset positions:		
Left	2 (20%)	3 (30%)
Supine	3 (30%)	3 (30%)
Right	2 (20%)	4 (40%)
Prone	7 (70%)	6 (60%)
Waking positions:		
Left	5 (50%)	4 (40%)
Supine	4 (40%)	7 (70%)
Right	5 (50%)	2 (20%)
Prone	5 (50%)	4 (40%)
Snores ≥3 nights per week	4 (40%)	3 (30%)
Sleeps with bed partner	7 (70%)	10 (100%)
Pillow use		

Under head	9 (90%)	9 (90%)
Between knees	8 (80%)	6 (60%)
Behind back	3 (30%)	5 (50%)
Under tummy	3 (30%)	4 (40%)
Pregnancy pillow	4 (40%)	1 (10%)

Normally distributed continuous variables are reported as mean (SD). Non-normally distributed continuous variables are presented as median (IQR). Count data are presented as frequency (%). Percentages for responses to some questions may add to greater than 100% because some participants checked more than one box in response to a question, e.g., for sleep onset position in the last week, some responded "left" and "right".

Primary Outcome

The primary outcome (see **Supplementary File 2**) was not normally distributed. The median (IQR) percentage of sleep time supine on the PrenaBelt night (n=20) and sham night (n=20) was 3.5% (0-16.6) and 16.4% (3.5-25.3), respectively (**Table 2, Fig. 3**). On a one-sided paired Wilcoxon signed rank test, the median of the pairwise differences (pseudomedian) in percentage of sleep time supine between the sham night versus the PrenaBelt night was significantly greater than zero (pseudomedian=5.8; 95%CI 0.70 to Inf; p=0.03).

Table 2 | Primary outcome: percentage (%) of sleep time supine

	PrenaBelt night (n=20)	sham night (n=20)	p-value
Median (IQR)	3.5 (0-16.6)	16.4 (3.5-25.3)	0.03*

*One-sided paired Wilcoxon signed rank test

Secondary Outcomes

The estimates, 95% confidence intervals (CI), and p-values for the intervention-associated differences, PrenaBelt versus sham, in the sleep and respiratory variables (see **Supplementary File 2**) and user feedback (see **Supplementary File 3**) are shown in **Table 3**. The median (IQR) number of minutes spent sleeping supine and right-lateral was 38.9 (0-72.7) and 90.8 (0-166.1), respectively. The mean (SD) number of minutes

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3 spent sleeping left-lateral was 180.9 (97.7). The mean (SD) percentage of time spent
4 sleeping in the left-lateral and right-lateral positions was 54.6% (26.7) and 30.3% (27.8),
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6 respectively. No time was spent sleeping prone.
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11 Regarding sleep architecture for the complete sample (n=40 nights), the median (IQR)
12 sleep time was 352 minutes (318-374), sleep efficiency 82% (76-89), and sleep latency
13 12.8 minutes (6.7-23.9). The median (IQR) total arousal index was 11.3 (8.4-18.0),
14 spontaneous arousal index 9.8 (7.0-12.0), periodic leg movement arousal index 0 (0-
15 0.8), and respiratory arousal index 0.4 (0-1.0). The mean (SD) percentage of stage 1
16 sleep was 9.4% (5.6), stage 2 sleep 62.7% (7.9), stage 3 sleep 11.2% (8.3), and REM
17 sleep 16.7% (5.6). For respiratory variables, the median (IQR) apnea-hypopnea index
18 was 0.5 (0-1.5), respiratory effort-related arousal index 0 (0-0.2), respiratory disturbance
19 index (RDI) 0.6 (0-1.6), RDI supine 0 (0-0.9), RDI non-supine 0.5 (0-1.6), peripheral
20 oxygen saturation (SpO₂) maximum and minimum during REM sleep were 98% (98-99)
21 and 92% (90-94), respectively, and SpO₂ maximum and minimum during NREM sleep
22 were 99% (98-100) and 92% (91-94), respectively. The mean (SD) SpO₂ during REM
23 and NREM sleep was 96.0 (1.2) and 96.2 (1.0), respectively. Presence of snoring was
24 detected on 26 of 40 (65%) nights. Six participants (30%) indicated that they would
25 make changes to the PrenaBelt – of these, five were with regard to comfort and one
26 was with regard to sizing. There were no statistically significant differences in sleep
27 architecture, respiration, or user feedback between the PrenaBelt and sham nights on
28 paired testing (n=20 pairs) (**Table 3**).
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56 **Table 3 | Secondary outcomes: time supine, sleep architecture, respiration, user feedback**
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	PrenaBelt (n=20)	sham (n=20)	PrenaBelt minus sham Difference (95%CI)	p-value
Total sleep time (minutes)	353 (318-376)	350 (318-374)	-3.6 [†] (-33.8 to 21.8)	0.81
Supine sleep (minutes)	12.3 (0-53.5)	56.8 (12.4-79.1)	-26.4 [†] (-49.9 to -2.6)	0.03
Left-lateral sleep (minutes)	185.6 (102.5)	176.1 (95.2)	9.5 [‡] (-24.3 to 43.3)	0.56
Right-lateral sleep (minutes)	108.9 (110.1)	101.9 (100.9)	6.9 [‡] (-22.9 to 36.7)	0.63
Percentage sleep left (%)	57.0 (26.9)	52.2 (27.0)	4.8 [‡] (-5.1 to 14.8)	0.32
Percentage sleep right (%)	31.3 (28.8)	29.3 (27.5)	2.0 [‡] (-6.0 to 10.1)	0.60
Sleep latency (minutes)	11.7 (6.7-21.9)	14.5 (7.2-26.2)	2.0 [†] (-7.2 to 9.4)	0.65
Sleep efficiency (%)	81 (76-89)	83 (79-88)	-1.4 [†] (-5.9 to 3.0)	0.46
Total arousal index	11.2 (8.1-18.0)	12.0 (8.5-15.6)	0.60 [†] (-1.5 to 3.5)	0.59
Spontaneous arousal index	10.5 (5.8)	10.3 (5.5)	0.20 [‡] (-2.2 to 2.6)	0.86
PLM arousal index	0 (0-1.0)	0.1 (0-0.7)	0.3 [†] (-1.5 to 16.0)	0.68
Respiratory arousal index	0.4 (0-1.1)	0.4 (0-1.0)	0.1 [†] (-0.5 to 2.1)	0.78
Percent stage 1 sleep (%)	9.1 (5.2)	9.6 (6.0)	-0.50 [‡] (-2.3 to 1.3)	0.56
Percent stage 2 sleep (%)	64.5 (7.4)	61.0 (8.1)	3.5 [‡] (-0.3 to 7.3)	0.07
Percent stage 3 sleep (%)	10.9 (8.0)	11.5 (8.8)	-0.63 [‡] (-2.6 to 1.4)	0.52
Percent REM sleep (%)	15.5 (6.4)	18 (4.6)	-2.5 [‡] (-5.1 to 0.05)	0.05
Apnea Hypopnea Index	0.5 (0-1.5)	0.5 (0-1.5)	-0.14 [†] (-0.8 to 0.4)	0.51
RERA index	0 (0-0.1)	0 (0-0.3)	0.15 [†] (-0.4 to 4.6)	0.78
Respiratory disturbance Index	0.65 (0-1.5)	0.55 (0.15-1.75)	0.2 [†] (-0.6 to 1.2)	0.67
RDI while supine	0 (0-0)	0 (0-1.2)	-1.3 [†] (-11.2 to 2.4)	0.48
RDI while non-supine	0.2 (0-1.5)	0.5 (0-1.75)	-0.05 [†] (-0.85 to 1.0)	0.92
SpO2 during REM (%)				
Maximum	98 (98-99)	98.5 (98-99)	0.0 [†] (-1.0 to 0)	0.28
Mean	95.8 (1.2)	96.2 (1.2)	-0.46 [‡] (-1.1 to 0.15)	0.13
Minimum	92.5 (90.8-94)	92 (89-94)	0.5 [†] (-1.0 to 2.5)	0.40
SpO2 during NREM (%)				
Maximum	99.0 (98-100)	99 (98-100)	0.5 [†] (-1.0 to 1.5)	0.46
Mean	96.1 (0.88)	96.4 (1.0)	-0.29 [‡] (-0.71 to 0.14)	0.17
Minimum	92 (91-94)	92.5 (89-94)	0.5 [†] (-0.5 to 2.5)	0.26
Presence of snoring	15 (75%)	11 (55%)	2.4* (0.54 to 11.9)	0.32
Satisfaction (out of 10)	7.5 (6.0-8.3)	7.5 (5.5-9.0)	-0.28 [‡] (-1.0 to 0.5)	0.46
Comfort (out of 10)	9.0 (6.8-9.3)	9.0 (7.8-10)	-1 [†] (-2.8 to 0)	0.06
Intention to use (out of 10)	8.0 (5.8-8.0)	7.0 (6.0-9.0)	-0.1 [‡] (-1.0 to 0.8)	0.81

Normally distributed continuous variables are reported as mean (SD), and paired t-test is used to test for difference and indicated by [†].

Non-normally distributed continuous variables and discrete data (Satisfaction, Comfort, and Intention to use) are presented as median (IQR), and two-sided paired Wilcoxon signed rank test is used to test for difference ("Difference (95%CI)" is the median of the pairwise differences (pseudomedian) and 95% confidence interval for the pseudomedian) and indicated by [‡].

Count data (Presence of snoring) are presented as frequency (%).

Units for "index" variables are events per hour.

*Fisher's Exact Test ("difference" is odds ratio)

PLM = Periodic Leg Movement

REM = Rapid Eye Movement

NREM = Non-Rapid Eye Movement

RERA = Respiratory Effort-Related Arousal

RDI = Respiratory Disturbance Index

SpO2 = peripheral oxygen saturation

The self-reported sleep data (see **Supplementary File 4**) are presented in **Table 4** with the PSG recorded correlates and the statistical analysis of agreement. Participants recalled their sleep onset position accurately for 34 of 40 nights (85%, κ 0.62, moderate agreement). Participants recalled their waking position accurately for 28 of 40 nights (70%, κ 0.42, weak agreement). There was a weak relationship between sleep onset and waking position (κ 0.24). There was no agreement between the self-reported and PSG-reported number of position changes (κ 0.17). Percentage of time in each position, left, supine, and right, as estimated per self-report and measured per PSG had Spearman's ρ of 0.76 (good correlation, $p < 0.01$), 0.27 (poor correlation, $p = 0.11$), and 0.93 (excellent correlation, $p < 0.01$), respectively. Bland-Altman plots (**Fig. 4.**, **Fig. 5.**, **Fig. 6.**) demonstrated that, on average, participants' self-reports tended to overestimate the percentage of left-side and right-side sleep by 5.5% (95%CI -30.2 to 41.2) and 0.5% (95%CI -21.9 to 22.9), respectively, and underestimate the percentage of supine sleep by 7.0% (95%CI -20.1 to 34.1) when compared to the PSG-determined position.

Table 4 | Secondary outcomes: self-reported versus PSG-recorded sleep behaviors

	Self-Report	PSG	Agreement
Sleep onset position (n=40)*			
Left	31 (78%)	29 (73%)	Cohen's κ † 0.62
Supine	2 (5%)	3 (7%)	
Right	7 (17%)	8 (20%)	
Waking position (n=40)*			
Left	28 (70%)	22 (55%)	Cohen's κ † 0.42
Supine	0 (0%)	5 (13%)	
Right	12 (30%)	13 (32%)	
Number of position changes (n=30)**	3 (2-4)	6 (3.3-10)	Cohen's κ ‡ 0.17
% of total sleep time in position (n=35)***:			
Left	59.9 (28.1)	54.4 (26.4)	Spearman's ρ 0.76
Supine	7.8 (20.0)	14.8 (18.7)	Spearman's ρ 0.27
Right	31.3 (27.3)	30.8 (28.5)	Spearman's ρ 0.93

* Count data are presented as: frequency (%). **Ordinal data presented as: median (IQR).

***Continuous data presented as: mean (SD). †Linear/equal weighted Cohen's κ . ‡Unweighted Cohen's κ .

Harms

No participants (including the dropouts) requested to remove the intervention or PSG equipment. There were no known harms related to the interventions or procedures in this study.

DISCUSSION

Principal Findings

Use of the PrenaBelt resulted in a reduction in the percentage of sleep time supine in comparison with the sham, and we were unable to demonstrate an effect on maternal sleep architecture or respiration.

Strengths and Weaknesses in Relation to Other Studies

Our study only included two nights for each participant and was a randomized pilot trial; therefore, caution should be taken when extrapolating our results across the third trimester with regard to efficacy and compliance – PT in non-pregnant individuals with positional obstructive sleep apnea (OSA) has sustained efficacy in the long term but decreasing compliance from 93% at 1 month,(40) 74% at three months,(41) and 60% at six months.(42)

In recent studies of PT in non-pregnant individuals with positional OSA, PT devices incorporating active supine sensing technology and vibration mechanisms have been shown to be more effective in reducing supine sleep than inactive pressure-point PT

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3 devices like the PrenaBelt.(41,43) In comparison to a study of pressure-point PT in non-
4 pregnant individuals with positional OSA by Heinzer et al.,(41) the PrenaBelt resulted in
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6 a lesser reduction in mean percentage of sleep time supine; however, in contrast, we
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8 did not have a non-intervention night as Heinzer et al. did. The sham, by intrinsic
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10 characteristics, may have caused a reduction in supine sleep in comparison to a non-
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12 intervention night. O'Brien and Warland (6) reported a non-interventional, one-night, in-
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14 home study of 51 healthy women in their 2nd and 3rd trimester using ambulatory PSG; in
15
16 a subgroup of participants in their 3rd trimester (n=33), the median percentage of overall
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18 sleep time spent supine was 26.5%. McIntyre et al.,(7) in a similar non-interventional,
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20 one-night, in-home, ambulatory PSG study in 30 healthy women in the 3rd trimester,
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22 reported the median percentage of overall sleep time spent supine to be 19%.

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24 Participants were not asked to adopt or try to maintain any sleep position in either study.
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26 Both of these studies reported a greater median percentage of overall sleep time spent
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28 supine than that in the current study (16.4%), which indicates that the sham device may
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30 have affected position. This, along with differences inherent to pregnancy (e.g., body
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32 habitus, increased sleep disruption) may account for the lesser reduction in mean
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34 percentage of sleep time supine achieved by the PrenaBelt in comparison Heinzer et al.

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47 Zaremba et al. undertook a randomized, cross-over, PSG study in 30 post-partum
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49 women sleeping in non-elevated and 45° elevated body position and reported moderate
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51 to severe OSA in 20% of the participants.(44) The minimum SpO₂ was higher (p 0.03)
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53 and AHI was reduced (p 0.03) in the 45° elevated body position in comparison to non-
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3 elevated without affecting sleep quantity or quality. In our analysis, we were unable to
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5 demonstrate any differences in sleep architecture or duration despite a significant
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7 difference in body position (less supine time).
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12 Seventy-three percent of participants in the study by McIntyre et al.(7) recalled their
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14 sleep onset position accurately (κ 0.52), which is a lower accuracy than our results
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16 (85% accurate, κ 0.62) possibly because each of our participants underwent two PSG
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18 nights and, after being asked to recall various details about their sleep after their 1st
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20 PSG night, may have anticipated these questions again after their 2nd PSG night. Forty
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22 percent of McIntyre et al.'s participants recalled their waking position accurately (κ
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24 0.24), which is a lower accuracy than our results (70% accurate, κ 0.42). Being an
25
26 ambulatory PSG, McIntyre et al.'s study did not include electroencephalography (EEG)
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28 – they estimated sleep and wake times by pre-defined video criteria (i.e., lack of
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30 movement) and not by brain activity and noted that this may have introduced
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32 discrepancy between their participants' self-reports and the video assessment criteria,
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34 thus reducing their calculated accuracy. We reported a weak relationship (κ 0.24)
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36 between sleep onset and waking position via PSG-determination, whereas previous
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38 studies have reported discrepant results – McIntyre et al. reported no relationship (κ -
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40 0.13) via video-determination, and the Auckland Stillbirth Study reported a strong
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42 relationship (Pearson r 0.72) via self-reports;(2), however, our study has shown self-
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44 reports of sleep onset and waking position to have only moderate and weak agreement
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46 with the gold standard (PSG), respectively, which points to reliance on non-PSG
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48 methods (e.g., self-reports) as a potential source of this discrepancy.
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5 Warland and Dorrian reported a three-night observational study of 30 healthy women in
6 late pregnancy and found moderate basic correlation between self-reported and video-
7 determined time on the left ($r=0.418$);(8) however, they did not report correlations for
8 right or supine sleep. We report a good correlation between self-reported and PSG-
9 determined time on the left (Spearman's ρ 0.76, $p<0.01$). Notably, we found poor
10 correlation between self-reports and PSG-determined supine time and that pregnant
11 women tend to underestimate this value. There are only two other studies investigating
12 reliability of adults' self-reports of sleep position;(45,46) both consist of non-pregnant
13 adults, have conflicting results with each other, and are not reported in adequate detail
14 for comparison to our results.
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31 In the non-pregnant population, approximately 20% of a typical night's sleep is spent in
32 the REM state and 80% is spent in the NREM state. The sleep architecture in the
33 current study is consistent with previously reported patterns during pregnancy, that is,
34 reduced slow-wave sleep (SWS), REM sleep, and sleep efficiency.(47–51)
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42 **Meaning of the Study**

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44 The previous studies by Owusu et al.(1) and O'Brien and Warland (6) recommended the
45 development and testing of a PT device for pregnant women. In our study, a PT
46 intervention was implemented in a population of healthy, third-trimester, pregnant
47 women during sleep in a clinical sleep laboratory environment over two nights. This
48 study extends the work of Stacey et al.,(2) Gordon et al.,(3) McCowan et al.,(4) and
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3 Warland and Mitchell (52) by finding that supine sleep position in late pregnancy can be
4 reduced with PT.
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10 Left side sleeping is common among pregnant women. This may be a more comfortable
11 position but also may be related to the “sleep-on-side” messages prevalent on the
12 internet and among maternity care providers. Women in our study preferentially settled
13 to sleep on their left for 73% of the nights and right for 20% of the nights. This is
14 corroborated by McCowan et al.(4) who reported a significant increase in left-sided
15 going-to-sleep position (43% to 58%) and small decrease in supine going-to-sleep
16 position (5% to 3.8%) in New Zealand over an approximate 5 year period following
17 publicity of The Auckland Stillbirth Study by Stacey et al.(2) If the supine sleeper is to be
18 identified by history-taking and stratified for targeted education or intervention,
19 obstetricians, midwives, and nurses should be aware that despite sleep-on-side
20 knowledge and high rates of lateral going-to-sleep position, most pregnant women
21 continue to spend a significant amount of time supine during sleep in late pregnancy per
22 our study and previous studies.(6–8) Also, per our study, pregnant women’s estimates
23 of time in each sleep position, while relatively accurate for lateral sleeping positions,
24 underestimate the time they spend supine. Together, this suggests that healthcare
25 providers may need to recommend interventions to prevent unintentional supine
26 positioning during sleep.
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51 Strengths

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3 Strengths of this study include its rigorous methodology and use of the gold-standard
4 sleep diagnostic test in a controlled laboratory setting. The sham intervention ensured
5 that on the sham PSG night, participants received any specific benefit of any element of
6 the PrenaBelt above and beyond all benefits that might be attributed to its ability to
7 cause pressure points and, thus, reduced treatment bias. The cross-over allowed each
8 participant to serve as her own control for comparison of intervention effect on
9 outcomes. Allocation concealment and randomization of participants to intervention
10 order helped avoid allocation bias and the potential impact of changes to sleep across
11 the two PSG nights that could have resulted from familiarization with the equipment and
12 environment. Blinding of the participants, RAs, Registered PSG Technicians, and the
13 sleep specialist physician further reduced potential sources of bias and strengthened
14 data integrity.

33 **Weaknesses**

34 Weaknesses of this study included that we had no baseline sleep data (run-in
35 measurement) to which we could compare the PrenaBelt and sham nights; therefore,
36 conclusions cannot be made regarding the effect, if any, of the PrenaBelt on sleep
37 architecture and respiration in relation to no intervention. Participants' unfamiliarity with
38 the sleep environment also may have affected sleep quantity and quality; however, we
39 were unaware of any impact reported by participants. Period effects and carryover may
40 have occurred due to advancing gestation and familiarization with the sleep
41 environment/equipment; however, given the median washout period (1 day) was
42 negligible in the context of a 12-week third trimester, period effects from the washout
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3 were, at most, minimal. On the 2nd PSG night, participants were exposed to the
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5 alternate intervention and could have unblinded themselves if they remembered what
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7 the intervention felt like on the 1st PSG night; however, we are unaware of what effect
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9 this may have had. The current study was conducted in a cohort of healthy, non-obese,
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11 and majority Caucasian pregnant women. Due to the small sample size, this study may
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13 be underpowered and potentially overstate the true reduction in percentage of supine
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15 sleep; however, the sleep time in our study was relatively short (median 5.87 hours).
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17 Our participants reported a median of 8 hours overnight sleep duration at home;
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19 therefore, even if the reduction in supine sleep is lower than we observed, over a longer
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21 sleep duration, the PrenaBelt is still likely to result in a significant amount of supine
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23 sleep avoided. The power analysis was performed using the one-sided t-test, which
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25 could be a source of systemic confounding. Because of the fragility of our primary
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27 outcome (p 0.03), a confounding could shift our conclusions into statistical non-
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29 significance. This stresses the importance of future research to ascertain if our
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31 observed effects persist.
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40 **Future Research**

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42 To date, it is unclear whether formal advice, given by a maternity care provider to a
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44 pregnant woman, about sleeping position in late pregnancy is less, as, or more effective
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46 in reducing supine sleep in comparison to a PT device such as the PrenaBelt. Future
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48 research comparing advice versus a PT intervention in the home setting is imperative. If
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50 sleeping supine is potentially harmful to the fetus, the amount of supine time that is
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52 harmful needs quantification in order to target interventions to avoid this. Given that
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3 estimations of time in each body position during sleep are based on the recollection of
4 an unconscious state and thus inherently inaccurate, future research should not rely on
5 self-reports but should incorporate an objective measure of body position during sleep
6 throughout the third trimester allowing body position to be directly linked to pregnancy
7 outcomes. The results of our randomized pilot trial warrant future, large, multi-ethnic
8 studies that include women with a range of pregnancy and health conditions to
9 ascertain if the observed effects persist.
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21 **OTHER INFORMATION**

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24 **Registration:** This trial was registered at ClinicalTrials.gov, NCT02377817, on 17
25 February 2015 (<https://clinicaltrials.gov/ct2/show/NCT02377817>).
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31 **Protocol:** Full details of the trial protocol are available with the full text of this article
32 (see **Supplementary File 5**).
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39 who gave up their time and the comfort of home to spend two nights in our study.
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43 technical expertise in polysomnography setup and scoring. There were no patient
44 advisers.
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3 **Contributors:** AK designed the protocol, secured funding, ethics approval, and the
4 research contract, trained the study personnel, maintained the study master record,
5 facilitated PSG studies as an unblinded personnel, monitored data collection, cleaned
6 and analyzed the data, and drafted and revised the paper. He is guarantor. AK and AB
7 conceptualized the PrenaBelt. KC designed and manufactured the PrenaBelt research
8 samples. DM, HS, LMO, AB, JC, MB, KC, and AI designed the protocol. HS oversaw
9 participant recruitment and was the Principal Investigator responsible for all aspects of
10 the trial. DM was the Supervising Investigator, oversaw the PSG studies at the trial site,
11 and interpreted the PSG studies. MB wrote the statistical plan and oversaw the
12 statistical analysis. JW maintained the study master record, facilitated PSG studies as
13 an unblinded personnel, monitored data collection, and cleaned and analyzed the data.
14 AI negotiated the research contract and managed the trial funds. DM, HS, LMO, AB, JC,
15 JW, MB, KC, and AI made intellectual contributions to the paper.

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35 **Competing Interests:** All authors have completed the ICMJE uniform disclosure form
36 at www.icmje.org/coi_disclosure.pdf and declare: Mr. Kember and Dr. Borazjani, are
37 officers at GIRHL, which has a patent application for the PrenaBelt
38 (#WO2016176632A1) on which Mr. Kember, Dr. Borazjani, and Ms. Chu are listed as
39 Inventors. Dr. Morrison reports grants from Bresotec and grants from CIHR/Industry
40 Grant (Phillips) outside the submitted work. Dr. Scott, Dr. Coleman, Mr. Wells, Mr.
41 Butler, Dr. Isaac, and Dr. O'Brien have declared no support from any organization for
42 the submitted work, no financial relationships with any organizations that might have an
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3 interest in the submitted work in the previous three years, and no other relationships or
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5 activities that could appear to have influenced the submitted work.
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13
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15
16 Canada.
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21 **Data Sharing:** Data analysis scripts and output are attached as supplementary files.
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17 **SUPPLEMENTARY APPENDIX**

18
19 Supplementary File 1: Code and output – demographic analysis
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21 Supplementary File 2: Code and output – PSG analysis
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23 Supplementary File 3: Code and output – feedback analysis
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25 Supplementary File 4: Code and output – self-report accuracy analysis
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28 Supplementary File 5: Research protocol
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Figures and Tables:

Fig. 1. PrenaBelt; BPS = Body Position Sensor.

Fig 2. Enrollment, allocation, and analysis of trial participants.

Fig. 3. Scatter plot of percentage of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

Table 1. Baseline demographic, obstetric, and sleep habit characteristics

Table 2. Primary outcome: percentage of sleep time supine

Table 3. Secondary outcomes: time supine, sleep architecture, respiration, user feedback

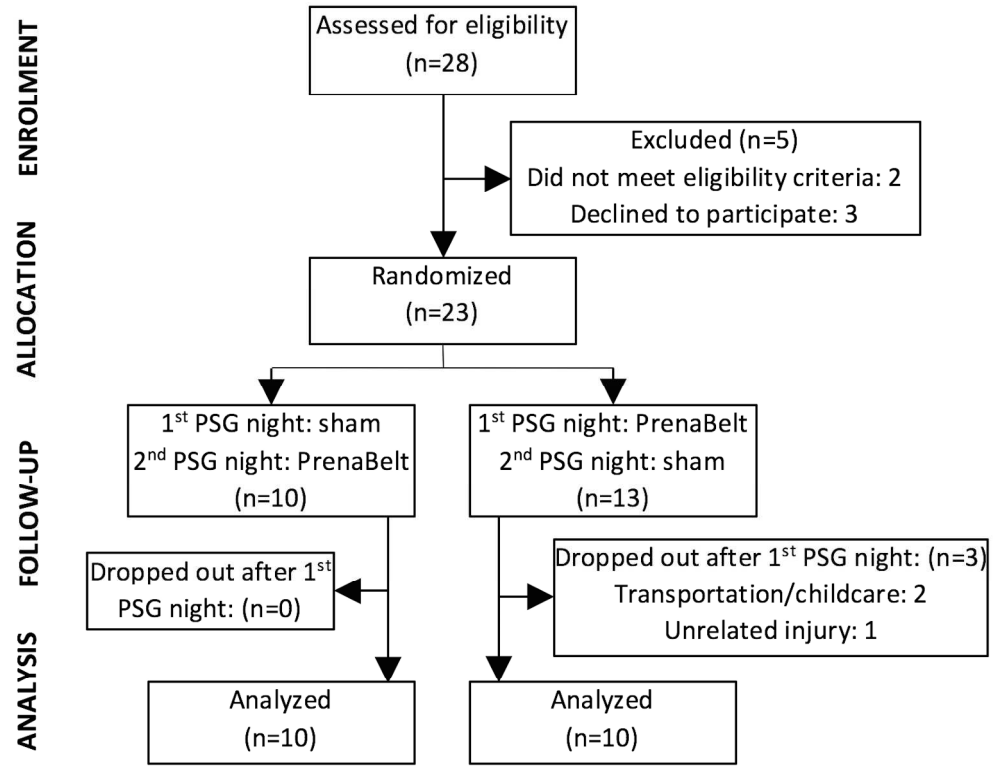
Table 4. Secondary outcomes: self-reported versus PSG-recorded sleep behaviors



Fig. 1. PrenaBelt; BPS = Body Position Sensor.

108x63mm (300 x 300 DPI)

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Enrollment, allocation, and analysis of trial participants.

293x227mm (300 x 300 DPI)

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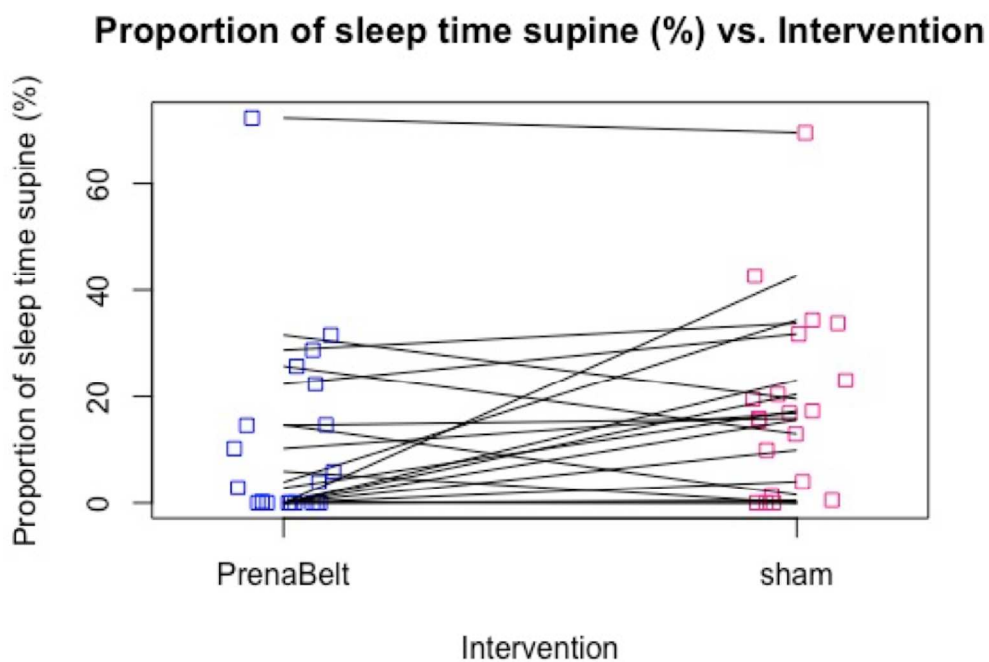


Fig. 3. Scatter plot of percentage of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

216x162mm (300 x 300 DPI)

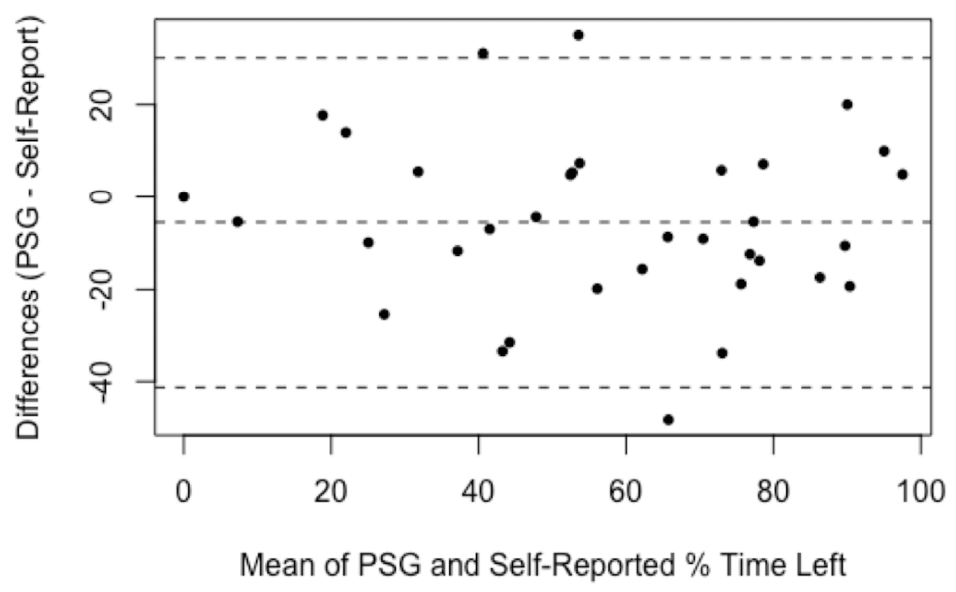


Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

216x162mm (300 x 300 DPI)

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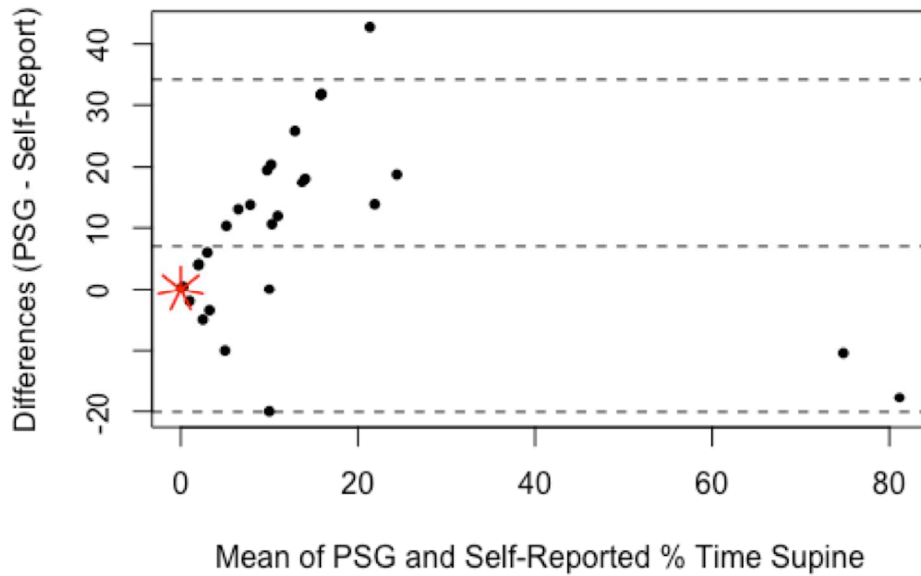


Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

216x162mm (300 x 300 DPI)

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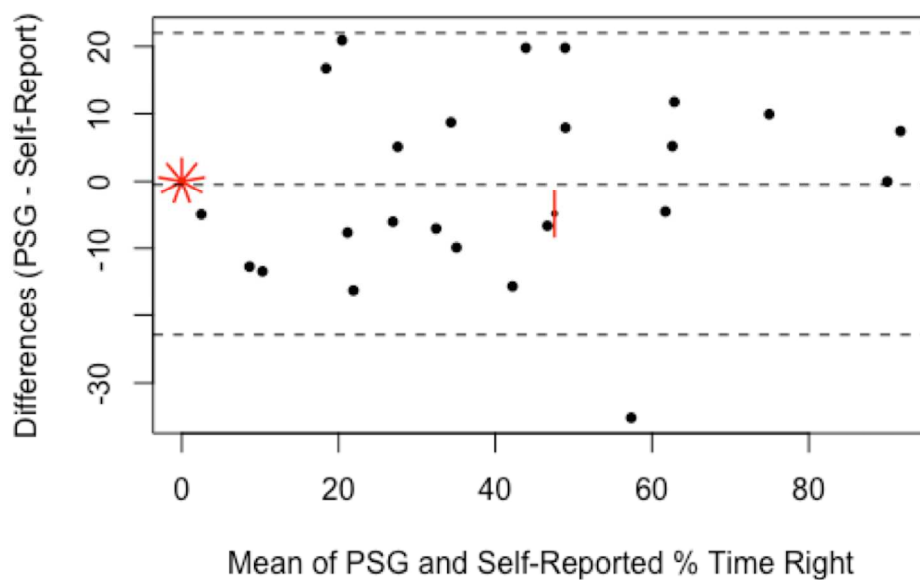


Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point at that location (sunflower plot).

216x162mm (300 x 300 DPI)

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3 **Supplementary file 1: Code and output – demographic analysis**
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For peer review only

Demographic_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 15:54:34 2018

```
#Description of code:
#This code summarizes the demographic, obstetric, and sleep behaviour of the
participants
#and compares these data between all participants whose first sleep test was
PrenaBelt
#versus all participants whose first sleep test was sham-PrenaBelt.

#Summary:
#08APR2017: There is no difference between groups for any characteristic (ran
domization took
care of it).

#setting the workspace directory
setwd("/Users/Allan/Desktop/HPTStats/08APR2017")

#importing the Data Collection Form (DCF) data
DCFdata=read.csv("DCF Data Halifax - 08APR2017.csv")

#Loading the functions (ad.test, etc.) into your workspace
library(nortest)

#Exclude drop outs
#How many drop outs?
summary(DCFdata$drop.out)

## N Y
## 20 3

#Define drop out group so that differences can be tested for
DropOutdata <- DCFdata[!(DCFdata$drop.out=="N"),]
nrow(DropOutdata)

## [1] 3

#Remove the drop outs ("Y") from DCFdata file
DCFdata <- DCFdata[!(DCFdata$drop.out=="Y"),]
nrow(DCFdata)

## [1] 20
```

```
#####AGES#####
#ages summary
summary(DCFdata$age)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  22.00  27.25  31.50  30.90  35.00  39.00

sd(DCFdata$age, na.rm = TRUE)

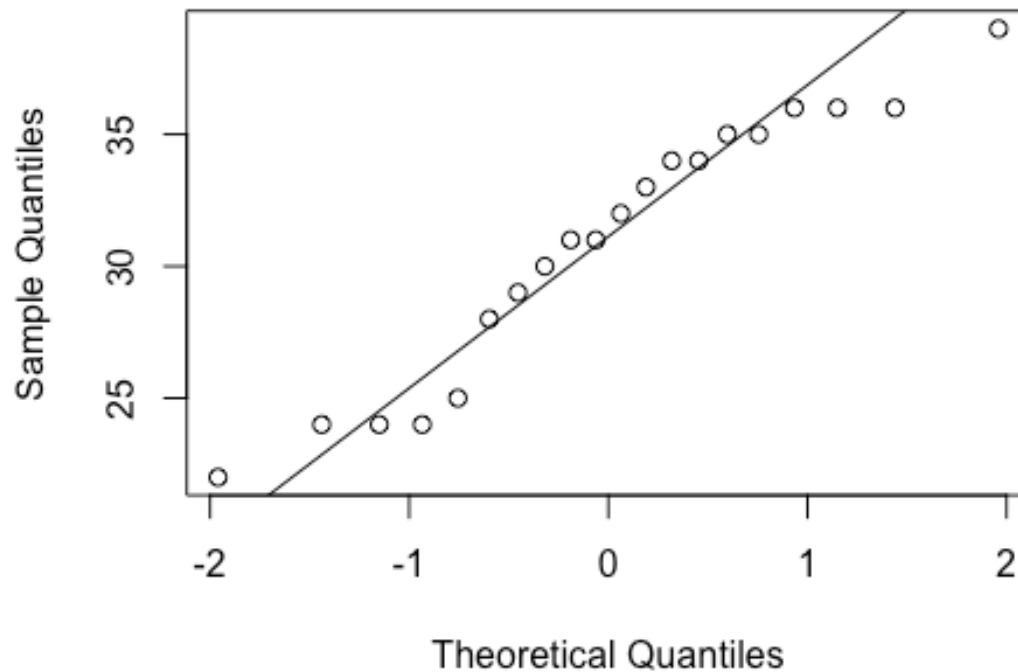
## [1] 4.983129

length(DCFdata$age)

## [1] 20

qqnorm(DCFdata$age)
qqline(DCFdata$age)
```

Normal Q-Q Plot



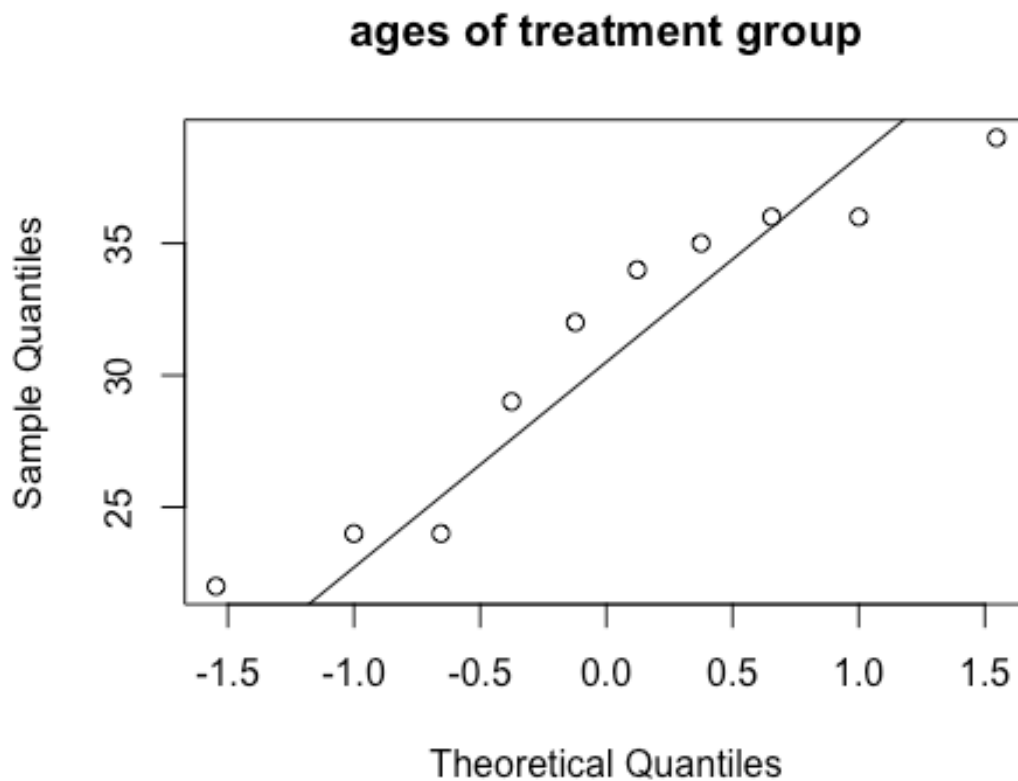
```
ad.test(DCFdata$age)

##
## Anderson-Darling normality test
##
## data: DCFdata$age
## A = 0.52863, p-value = 0.1554
```

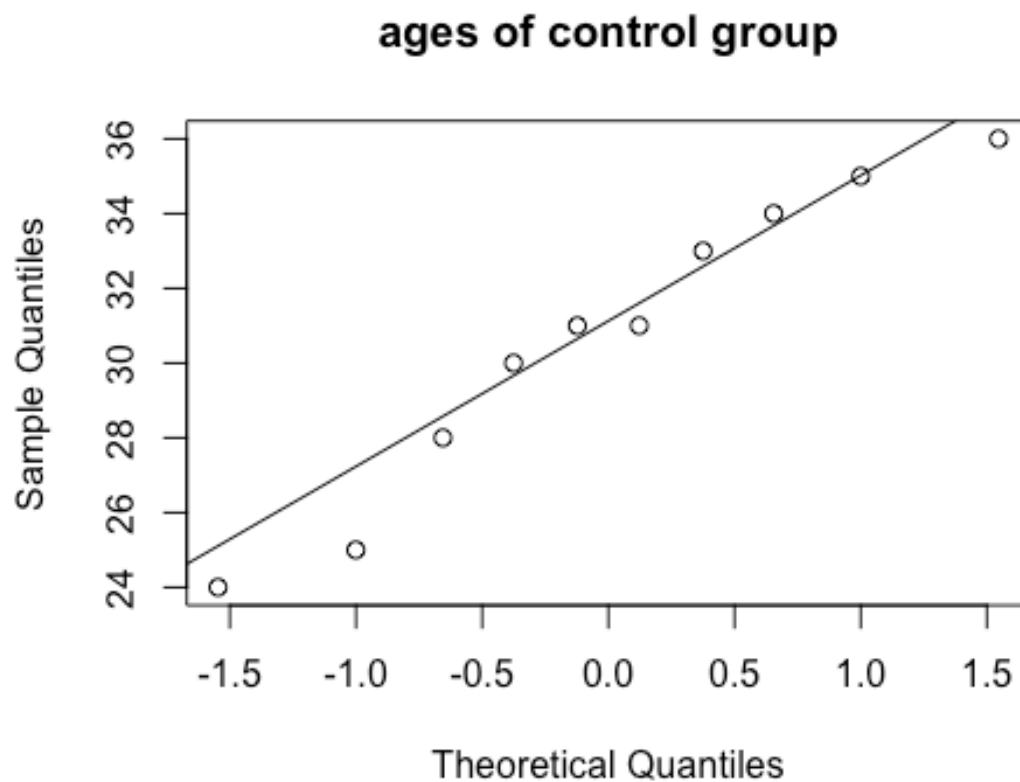
```

1
2
3 #Compare above with those who did not complete the study (n=3):
4 summary(DropOutdata$age)
5
6 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
7 ##  26.00  26.50   27.00   26.67  27.00   27.00
8
9 #Treatment ages
10 treatment.ages=na.omit(subset(DCFdata, intervention == "Treatment")$age)
11 length(treatment.ages)
12
13 ## [1] 10
14
15 summary(treatment.ages)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##  22.00  25.25   33.00   31.10  35.75   39.00
19
20 sd(treatment.ages)
21
22 ## [1] 5.989806
23
24 #check for normality
25 qqnorm(treatment.ages, main = "ages of treatment group")
26 qqline(treatment.ages)
27
28
29
30
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```
1
2
3 ad.test(treatment.ages)
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: treatment.ages
9 ## A = 0.4521, p-value = 0.2133
10
11 #normal
12
13 #Control ages
14 control.ages=na.omit(subset(DCFdata, intervention == "Control")$age)
15 length(control.ages)
16
17 ## [1] 10
18
19 summary(control.ages)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##  24.00  28.50   31.00   30.70  33.75   36.00
23
24 sd(control.ages)
25
26 ## [1] 4.056545
27
28 #check for normality
29 qqnorm(control.ages, main = "ages of control group")
30 qqline(control.ages)
31
32
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```

ad.test(control.ages)

##
## Anderson-Darling normality test
##
## data: control.ages
## A = 0.24422, p-value = 0.6844

#normal

#Perform 2-sample t-test (Welch's t-test) on the ages
t.test(treatment.ages, control.ages)

##
## Welch Two Sample t-test
##
## data: treatment.ages and control.ages
## t = 0.17485, df = 15.821, p-value = 0.8634
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -4.454062 5.254062
## sample estimates:
## mean of x mean of y
## 31.1 30.7

```

```
#####GESTATIONAL AGE @ First Sleep Test#####
#summary of gestational age at first sleep test (gar)
summary(DCFdata$gar)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  28.00  28.00  30.00  30.86  33.11  36.00

sd(DCFdata$gar, na.rm = TRUE)

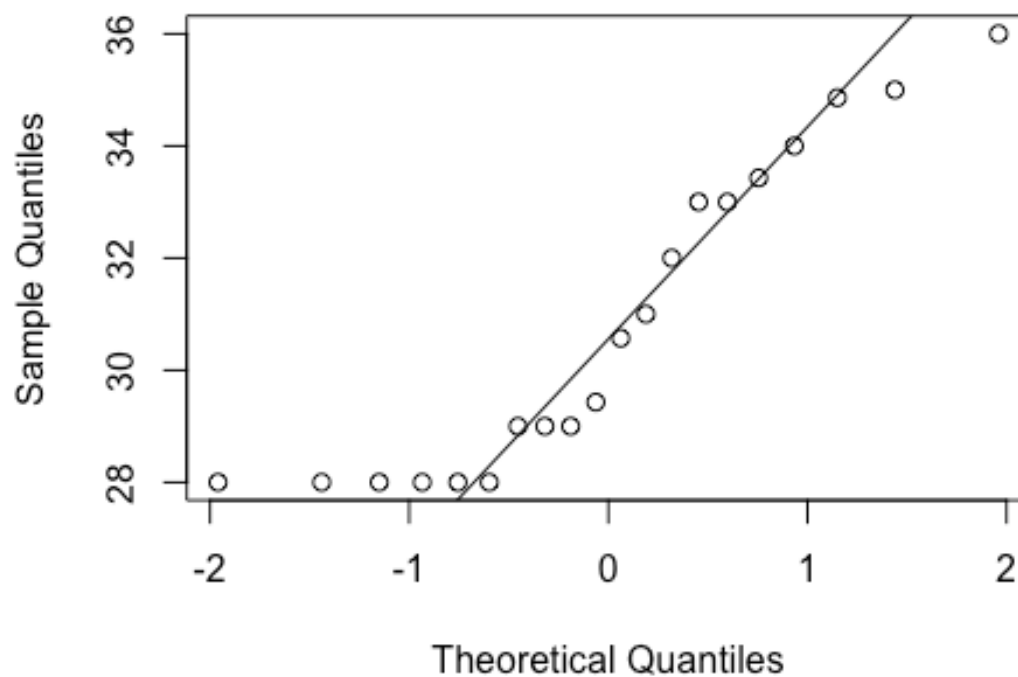
## [1] 2.791784

length(DCFdata$gar)

## [1] 20

qqnorm(DCFdata$gar)
qqline(DCFdata$gar)
```

Normal Q-Q Plot



```
ad.test(DCFdata$gar)

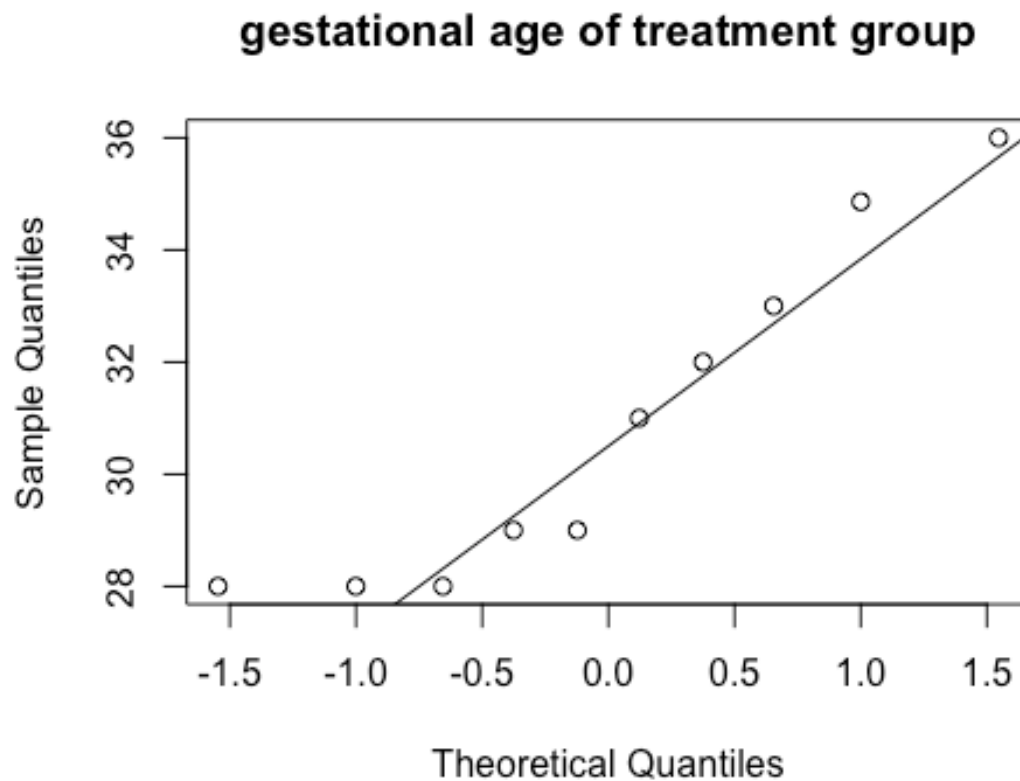
##
## Anderson-Darling normality test
##
## data: DCFdata$gar
## A = 0.96384, p-value = 0.01195
```



```

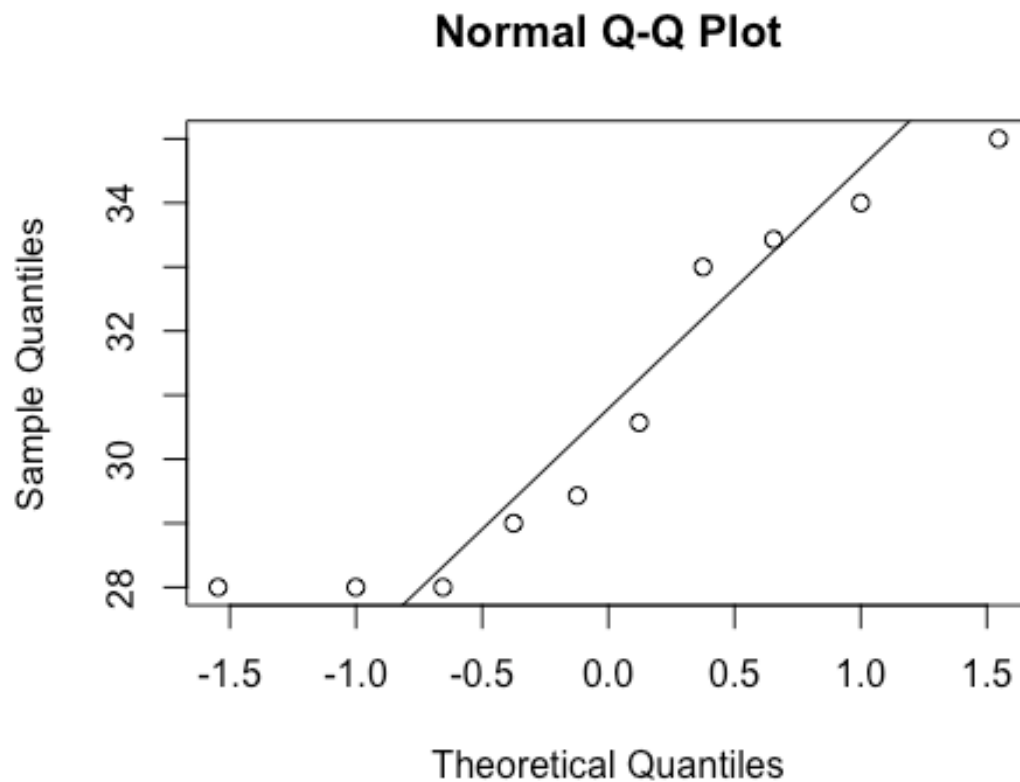
1
2
3 #Compare above with those who did not complete the study (n=3):
4 summary(DropOutdata$gar)
5
6 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
7 ##  29.00  29.50   30.00   30.62  31.43   32.86
8
9 #Treatment gestational age @ First Sleep Test
10 treatment.gar=na.omit(subset(DCFdata, intervention == "Treatment")$gar)
11 length(treatment.gar)
12
13 ## [1] 10
14
15 summary(treatment.gar)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##  28.00  28.25   30.00   30.89  32.75   36.00
19
20 sd(treatment.gar)
21
22 ## [1] 2.977128
23
24 #check for normality
25 qqnorm(treatment.gar, main = "gestational age of treatment group")
26 qqline(treatment.gar)
27
28
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```



```
1
2
3 ad.test(treatment.gar)
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: treatment.gar
9 ## A = 0.4918, p-value = 0.1663
10
11 #normal
12
13 #Control gestational age @ First Sleep Test
14 control.gar=na.omit(subset(DCFdata, intervention == "Control")$gar)
15 length(control.gar)
16
17 ## [1] 10
18
19 summary(control.gar)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##  28.00  28.25   30.00   30.84  33.32   35.00
23
24 sd(control.gar)
25
26 ## [1] 2.754959
27
28 #check for normality
29 qqnorm(control.gar)
30 qqline(control.gar)
31
32
33
34
35
36
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view only



```
ad.test(control.gar)
```

```
##
## Anderson-Darling normality test
##
## data: control.gar
## A = 0.55828, p-value = 0.1111
```

```
#normal
```

```
#Perform 2-sample t-test (Welch's t-test) on gestational age at First Sleep Test
```

```
t.test(treatment.gar, control.gar)
```

```
##
## Welch Two Sample t-test
##
## data: treatment.gar and control.gar
## t = 0.033523, df = 17.893, p-value = 0.9736
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -2.653002 2.739002
## sample estimates:
```

```

1
2
3 ## mean of x mean of y
4 ## 30.886 30.843
5
6 #####GRAVIDITY#####
7 summary(DCFdata$gravidity)
8
9 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
10 ## 1.0 1.0 1.5 1.5 2.0 2.0
11
12 sd(na.omit(DCFdata$gravidity))
13
14 ## [1] 0.5129892
15
16 length(DCFdata$gravidity)
17
18 ## [1] 20
19
20 #Compare above with those who did not complete the study (n=3):
21 summary(DropOutdata$gravidity)
22
23 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
24 ## 1 1 1 1 1 1
25
26 #Treatment gravidity
27 treatment.gravidity=na.omit(subset(DCFdata, intervention == "Treatment")$gravidity)
28
29 length(treatment.gravidity)
30
31 ## [1] 10
32
33 summary(treatment.gravidity)
34
35 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
36 ## 1.0 1.0 2.0 1.6 2.0 2.0
37
38 sd(treatment.gravidity)
39
40 ## [1] 0.5163978
41
42 #Control gravidity
43 control.gravidity=na.omit(subset(DCFdata, intervention == "Control")$gravidity)
44
45 length(control.gravidity)
46
47 ## [1] 10
48
49 summary(control.gravidity)
50
51 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
52 ## 1.0 1.0 1.0 1.4 2.0 2.0
53
54 sd(control.gravidity)
55
56 ## [1] 0.5163978

```

```

1
2
3 #Tabulate the data
4 xtabs(~gravity + intervention, data = DCFdata)
5
6 ##           intervention
7 ## gravity Control Treatment
8 ##           1         6         4
9 ##           2         4         6
10
11 #Perform Fisher's Exact Test
12 fisher.test(xtabs(~gravity + intervention, data = DCFdata))
13
14 ##
15 ## Fisher's Exact Test for Count Data
16 ##
17 ## data:  xtabs(~gravity + intervention, data = DCFdata)
18 ## p-value = 0.6563
19 ## alternative hypothesis: true odds ratio is not equal to 1
20 ## 95 percent confidence interval:
21 ##  0.2773893 19.1425577
22 ## sample estimates:
23 ## odds ratio
24 ##  2.158166
25
26 #####ETHNICITY#####
27 summary(DCFdata$ethnicity)
28
29 ##      caucasian      Filipino      Indian Middle Eastern
30 ##             16             1             1             2
31
32 length(DCFdata$ethnicity)
33
34 ## [1] 20
35
36 #Compare above with those who did not complete the study (n=3):
37 summary(DropOutdata$ethnicity)
38
39 ##      caucasian      Filipino      Indian Middle Eastern
40 ##             3             0             0             0
41
42 #Tabulate the data
43 xtabs(~ethnicity + intervention, data = DCFdata)
44
45 ##           intervention
46 ## ethnicity Control Treatment
47 ## caucasian      10         6
48 ## Filipino       0         1
49 ## Indian         0         1
50 ## Middle Eastern 0         2
51
52 #Perform Fisher's Exact Test
53 fisher.test(xtabs(~ethnicity + intervention, data = DCFdata))
54
55
56
57
58
59
60

```

```

1
2
3
4  ## Fisher's Exact Test for Count Data
5  ##
6  ## data:  xtabs(~ethnicity + intervention, data = DCFdata)
7  ## p-value = 0.08669
8  ## alternative hypothesis: two.sided
9
10 temp_table <- xtabs(~ethnicity + intervention, data = DCFdata)
11 j=nrow(temp_table)
12 ControlCsum=colSums(temp_table)[1]
13 TreatmentCsum=colSums(temp_table)[2]
14 for(i in 1:j) {
15   a=temp_table[i,1]
16   b=temp_table[i,2]
17   c=ControlCsum-a
18   d=TreatmentCsum-b
19   ORtable <- matrix(c(a,c,b,d),nrow = 2)
20   colnames(ORtable) <- c("Control", "Treatment")
21   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
22   print(row.names(temp_table)[i])
23   print(ORtable)
24   print(fisher.test(ORtable))
25 }
26
27
28 ## [1] "caucasian"
29 ##           Control Treatment
30 ## caucasian    10         6
31 ## Other        0         4
32 ##
33 ## Fisher's Exact Test for Count Data
34 ##
35 ## data:  ORtable
36 ## p-value = 0.08669
37 ## alternative hypothesis: true odds ratio is not equal to 1
38 ## 95 percent confidence interval:
39 ##  0.7703894      Inf
40 ## sample estimates:
41 ## odds ratio
42 ##           Inf
43 ##
44 ## [1] "Filipino"
45 ##           Control Treatment
46 ## Filipino     0         1
47 ## Other        10         9
48 ##
49 ## Fisher's Exact Test for Count Data
50 ##
51 ## data:  ORtable
52 ## p-value = 1
53 ## alternative hypothesis: true odds ratio is not equal to 1
54
55
56
57
58
59
60

```

```

1
2
3  ## 95 percent confidence interval:
4  ## 0.00000 39.00055
5  ## sample estimates:
6  ## odds ratio
7  ## 0
8  ##
9  ## [1] "Indian"
10 ## Control Treatment
11 ## Indian 0 1
12 ## Other 10 9
13 ##
14 ## Fisher's Exact Test for Count Data
15 ##
16 ## data: ORtable
17 ## p-value = 1
18 ## alternative hypothesis: true odds ratio is not equal to 1
19 ## 95 percent confidence interval:
20 ## 0.00000 39.00055
21 ## sample estimates:
22 ## odds ratio
23 ## 0
24 ##
25 ## [1] "Middle Eastern"
26 ## Control Treatment
27 ## Middle Eastern 0 2
28 ## Other 10 8
29 ##
30 ## Fisher's Exact Test for Count Data
31 ##
32 ## data: ORtable
33 ## p-value = 0.4737
34 ## alternative hypothesis: true odds ratio is not equal to 1
35 ## 95 percent confidence interval:
36 ## 0.00000 5.231968
37 ## sample estimates:
38 ## odds ratio
39 ## 0
40
41 #####HEIGHT.CURRENT#####
42 summary(DCFdata$height.current.inches)
43
44 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
45 ## 59.00 63.75 65.00 64.73 66.62 70.00
46
47 sd(DCFdata$height.current.inches, na.rm = TRUE)
48
49 ## [1] 2.955734
50
51 length(DCFdata$height.current.inches)
52
53 ## [1] 20
54
55
56
57
58
59
60

```

```

#####WEIGHT.CURRENT#####
summary(DCFdata$weight.current.lbs)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  140.0  169.5   177.0   181.2  194.8   252.0

sd(DCFdata$weight.current.lbs, na.rm = TRUE)

## [1] 27.51532

length(DCFdata$weight.current.lbs)

## [1] 20

#####BMI.CURRENT#####
summary(DCFdata$BMI.current)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  25.01  27.45   29.84   30.41  31.50   37.77

sd(DCFdata$BMI.current, na.rm = TRUE)

## [1] 3.592679

length(DCFdata$BMI.current)

## [1] 20

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$BMI.current)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  31.16  31.43   31.71   32.52  33.20   34.69

#Treatment current BMI (at first sleep study... 26-30 weeks)
treatment.current.BMI=na.omit((subset(DCFdata, intervention == "Treatment")$B
MI.current))
length(treatment.current.BMI)

## [1] 10

summary(treatment.current.BMI)

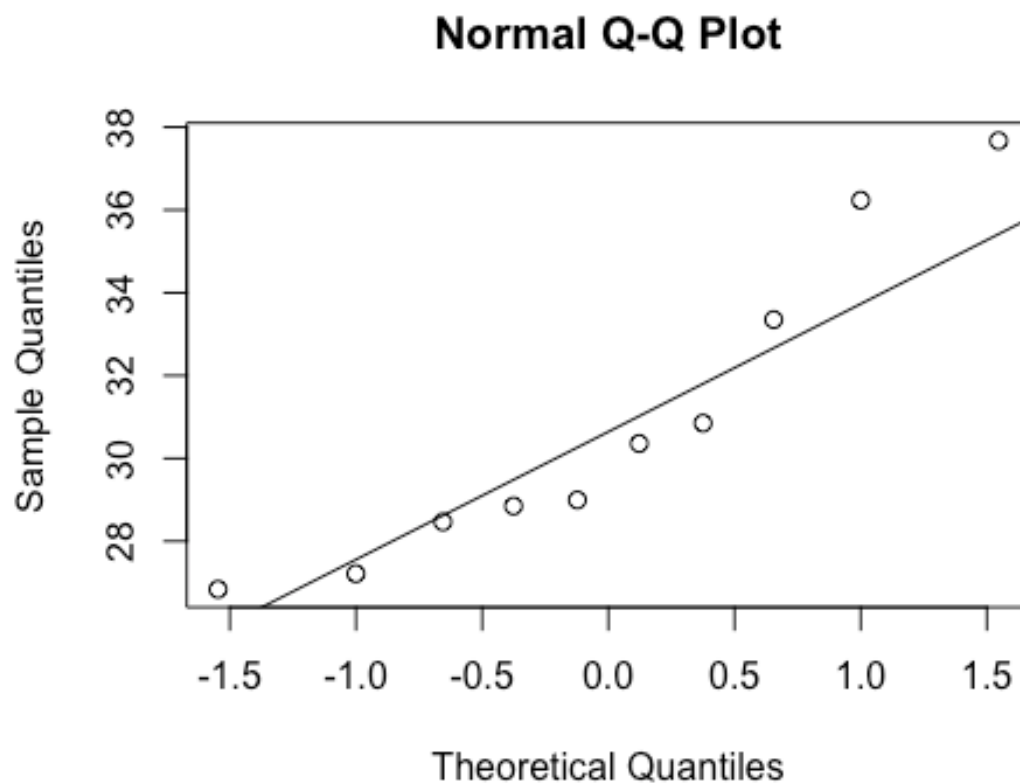
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  26.84  28.56   29.68   30.88  32.73   37.67

sd(treatment.current.BMI)

## [1] 3.717947

#normality check
qqnorm(treatment.current.BMI)
qqline(treatment.current.BMI)

```

```

ad.test(treatment.current.BMI)

##
## Anderson-Darling normality test
##
## data: treatment.current.BMI
## A = 0.48034, p-value = 0.1788

#normal

#Control current BMI (at first sleep study... 26-30 weeks)
control.current.BMI=na.omit((subset(DCFdata, intervention == "Control")$BMI.c
urrent))
length(control.current.BMI)

## [1] 10

summary(control.current.BMI)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 25.01  27.33  29.97  29.93  31.08  37.77

sd(control.current.BMI)

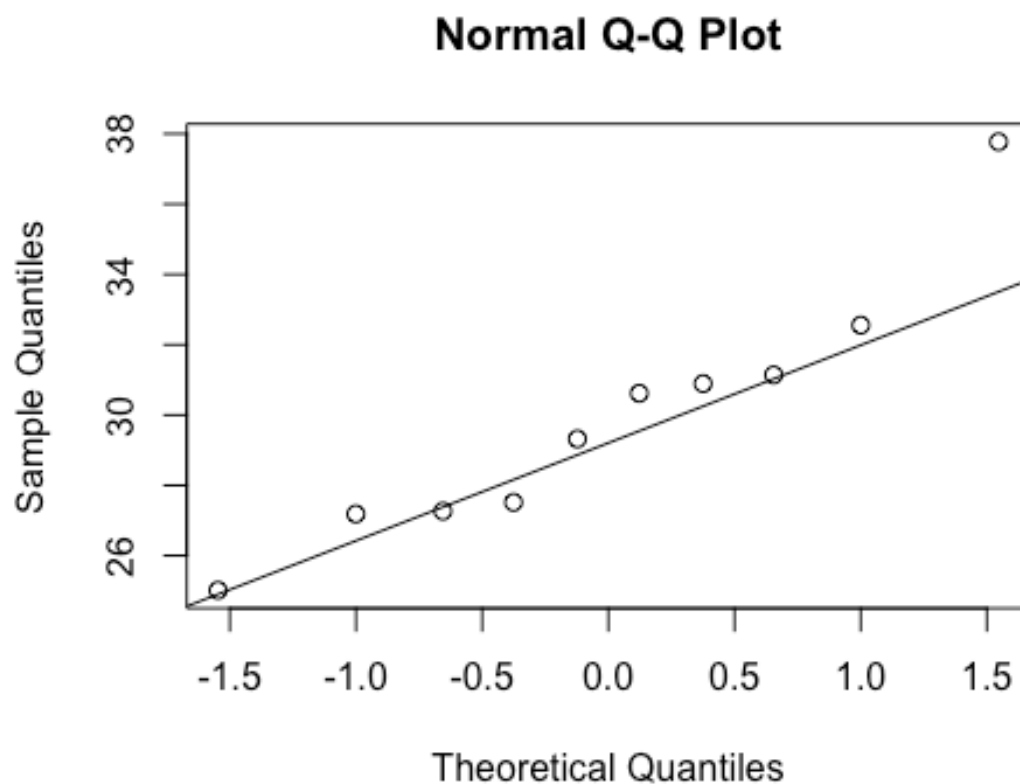
```

```
## [1] 3.594262
```

```
#normality check
```

```
qqnorm(control.current.BMI)
```

```
qqline(control.current.BMI)
```



```
ad.test(control.current.BMI)
```

```
##
```

```
## Anderson-Darling normality test
```

```
##
```

```
## data: control.current.BMI
```

```
## A = 0.35099, p-value = 0.3924
```

```
#normal
```

```
#Perform 2-sample t-test (Welch's t-test) on the current BMIs
```

```
t.test(treatment.current.BMI, control.current.BMI)
```

```
##
```

```
## Welch Two Sample t-test
```

```
##
```

```
## data: treatment.current.BMI and control.current.BMI
```

```
## t = 0.58417, df = 17.979, p-value = 0.5664
```

```

1
2
3  ## alternative hypothesis: true difference in means is not equal to 0
4  ## 95 percent confidence interval:
5  ## -2.480620  4.391192
6  ## sample estimates:
7  ## mean of x mean of y
8  ## 30.88316  29.92787
9

```

```

10 #####WEIGHT.BEFORE#####
11 summary(DCFdata$weight.before.lbs)
12

```

```

13 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14 ##    118.8  148.0   154.5   157.8   171.5   198.0
15

```

```

16 sd(DCFdata$weight.before.lbs, na.rm = TRUE)
17

```

```

18 ## [1] 20.45863
19

```

```

20 length(DCFdata$weight.before.lbs)
21

```

```

22 ## [1] 20
23

```

```

24 #####BMI.BEFORE#####
25 summary(DCFdata$BMI.before)
26

```

```

27 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28 ##     22.44  24.67   26.49   26.57   27.38   35.03
29

```

```

30 sd(DCFdata$BMI.before, na.rm = TRUE)
31

```

```

32 ## [1] 3.347304
33

```

```

34 length(DCFdata$BMI.before)
35

```

```

36 ## [1] 20
37

```

```

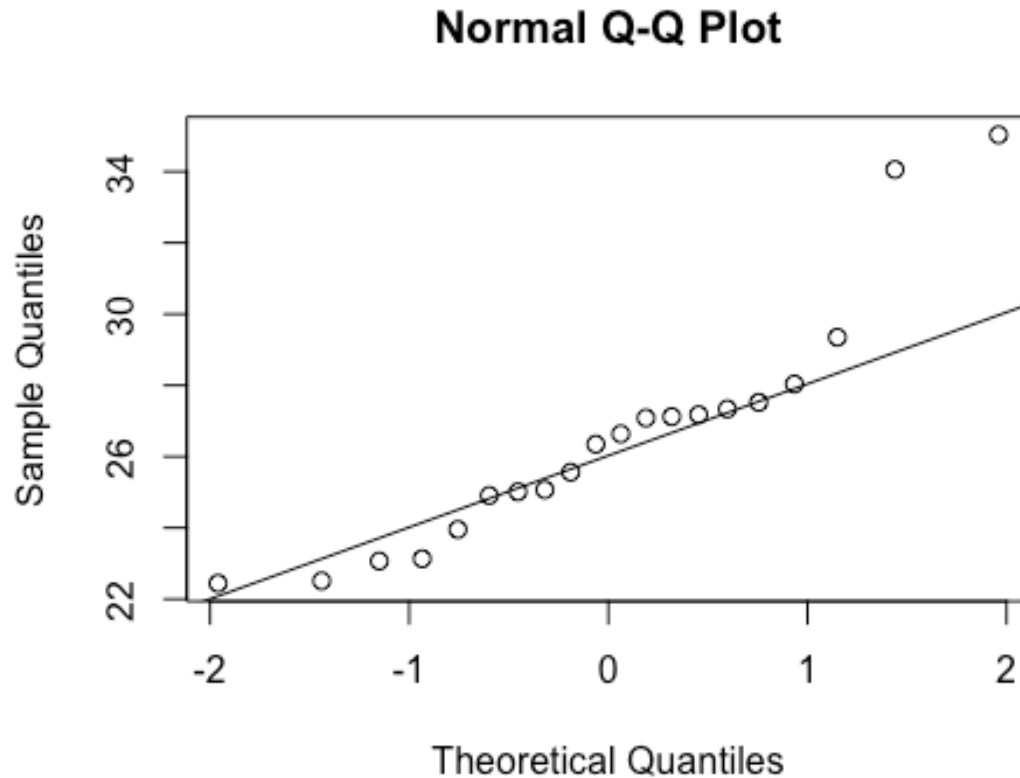
38 qqnorm(DCFdata$BMI.before)
39

```

```

40 qqline(DCFdata$BMI.before)
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```
ad.test(DCFdata$BMI.before)
```

```
##
## Anderson-Darling normality test
##
## data: DCFdata$BMI.before
## A = 0.80016, p-value = 0.03148
```

```
#Compare above with those who did not complete the study (n=3):
```

```
summary(DropOutdata$BMI.before)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 23.83  24.84  25.85  26.64  28.04  30.24
```

```
#Treatment BMI before pregnancy
```

```
treatment.before.BMI=na.omit((subset(DCFdata, intervention == "Treatment")$BMI.before))
```

```
length(treatment.before.BMI)
```

```
## [1] 10
```

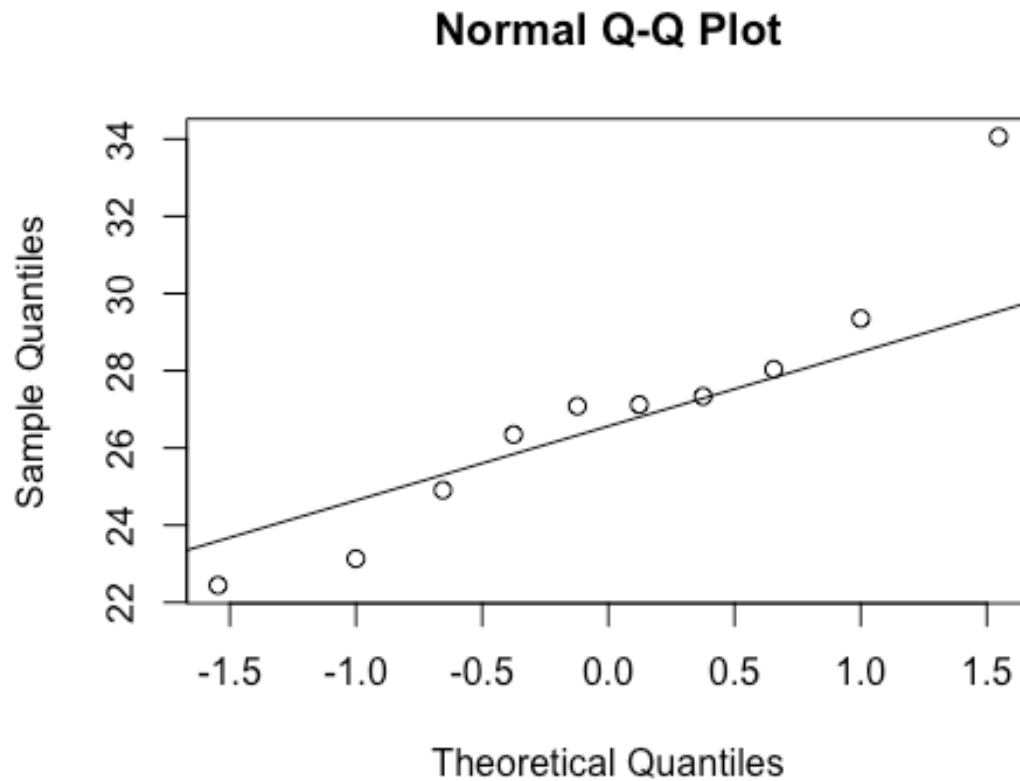
```
summary(treatment.before.BMI)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 22.44  25.27  27.10  26.98  27.86  34.06
```

```

1
2
3 sd(treatment.before.BMI)
4
5 ## [1] 3.283838
6
7 #normality check
8 qqnorm(treatment.before.BMI)
9 qqline(treatment.before.BMI)
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39

```



```

40 ad.test(treatment.before.BMI)
41
42 ##
43 ## Anderson-Darling normality test
44 ##
45 ## data: treatment.before.BMI
46 ## A = 0.35509, p-value = 0.3831
47
48 #normal
49
50 #Control BMI before pregnancy
51 control.before.BMI=na.omit((subset(DCFdata, intervention == "Control")$BMI.be
52 fore))
53 length(control.before.BMI)
54
55 ## [1] 10
56
57
58
59
60

```

```
summary(control.before.BMI)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 22.51  24.22  25.32  26.15  27.04  35.03
```

```
sd(control.before.BMI)
```

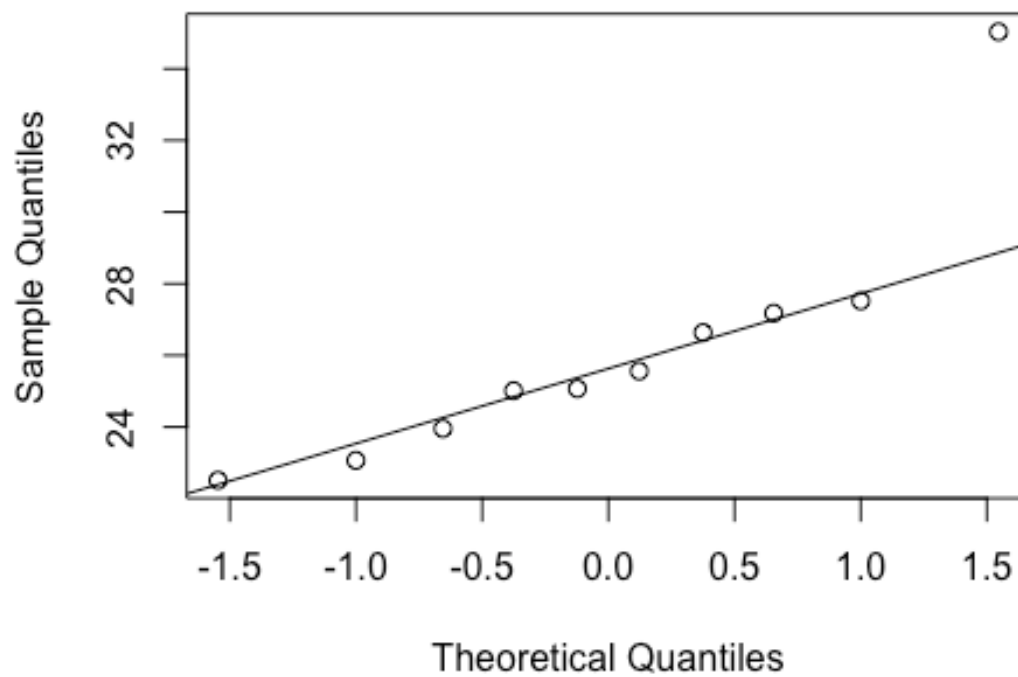
```
## [1] 3.534125
```

```
#normality check
```

```
qqnorm(control.before.BMI)
```

```
qqline(control.before.BMI)
```

Normal Q-Q Plot



```
ad.test(control.before.BMI)
```

```
##
## Anderson-Darling normality test
##
## data: control.before.BMI
## A = 0.71903, p-value = 0.04077
```

```
#non-normal
```

```

1
2
3 #Perform non-parametric method (Wilcoxon rank sum test)
4 wilcox.test(treatment.before.BMI, control.before.BMI, conf.int = TRUE)
5
6 ##
7 ## Wilcoxon rank sum test
8 ##
9 ## data: treatment.before.BMI and control.before.BMI
10 ## W = 60, p-value = 0.4813
11 ## alternative hypothesis: true location shift is not equal to 0
12 ## 95 percent confidence interval:
13 ## -1.728710 3.835403
14 ## sample estimates:
15 ## difference in location
16 ##
17 ## 1.115286
18
19 #####BED TIME#####
20 summary(DCFdata$bedtime.hrs)
21
22 ## 0:00 1:00 21:00 22:00 23:00
23 ## 4 1 1 6 8
24
25 #Tabulate the data
26 xtabs(~bedtime.hrs + intervention, data = DCFdata)
27
28 ## intervention
29 ## bedtime.hrs Control Treatment
30 ## 0:00 2 2
31 ## 1:00 0 1
32 ## 21:00 1 0
33 ## 22:00 3 3
34 ## 23:00 4 4
35
36 #Perform Fisher's Exact Test
37 fisher.test(xtabs(~bedtime.hrs + intervention, data = DCFdata))
38
39 ##
40 ## Fisher's Exact Test for Count Data
41 ##
42 ## data: xtabs(~bedtime.hrs + intervention, data = DCFdata)
43 ## p-value = 1
44 ## alternative hypothesis: two.sided
45
46 temp_table <- xtabs(~bedtime.hrs + intervention, data = DCFdata)
47 j=nrow(temp_table)
48 ControlCsum=colSums(temp_table)[1]
49 TreatmentCsum=colSums(temp_table)[2]
50 for(i in 1:j) {
51 a=temp_table[i,1]
52 b=temp_table[i,2]
53 c=ControlCsum-a
54 d=TreatmentCsum-b
55 ORtable <- matrix(c(a,c,b,d),nrow = 2)
56
57
58
59
60

```

```

1
2
3   colnames(ORtable) <- c("Control", "Treatment")
4   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
5   print(row.names(temp_table)[i])
6   print(ORtable)
7   print(fisher.test(ORtable))
8
9 }
10
11 ## [1] "0:00"
12 ##      Control Treatment
13 ## 0:00      2         2
14 ## Other      8         8
15 ##
16 ## Fisher's Exact Test for Count Data
17 ##
18 ## data:  ORtable
19 ## p-value = 1
20 ## alternative hypothesis: true odds ratio is not equal to 1
21 ## 95 percent confidence interval:
22 ##  0.0585532 17.0784861
23 ## sample estimates:
24 ## odds ratio
25 ##          1
26 ##
27 ## [1] "1:00"
28 ##      Control Treatment
29 ## 1:00      0         1
30 ## Other     10        9
31 ##
32 ## Fisher's Exact Test for Count Data
33 ##
34 ## data:  ORtable
35 ## p-value = 1
36 ## alternative hypothesis: true odds ratio is not equal to 1
37 ## 95 percent confidence interval:
38 ##  0.00000 39.00055
39 ## sample estimates:
40 ## odds ratio
41 ##          0
42 ##
43 ## [1] "21:00"
44 ##      Control Treatment
45 ## 21:00      1         0
46 ## Other      9         10
47 ##
48 ## Fisher's Exact Test for Count Data
49 ##
50 ## data:  ORtable
51 ## p-value = 1
52 ## alternative hypothesis: true odds ratio is not equal to 1
53 ## 95 percent confidence interval:
54
55
56
57
58
59
60

```



```

1
2
3      ## 0.02564066      Inf
4      ## sample estimates:
5      ## odds ratio
6      ##      Inf
7      ##
8      ## [1] "22:00"
9      ##      Control Treatment
10     ## 22:00      3      3
11     ## Other      7      7
12     ##
13     ## Fisher's Exact Test for Count Data
14     ##
15     ## data: ORtable
16     ## p-value = 1
17     ## alternative hypothesis: true odds ratio is not equal to 1
18     ## 95 percent confidence interval:
19     ## 0.09678719 10.33194569
20     ## sample estimates:
21     ## odds ratio
22     ##      1
23     ##
24     ## [1] "23:00"
25     ##      Control Treatment
26     ## 23:00      4      4
27     ## Other      6      6
28     ##
29     ## Fisher's Exact Test for Count Data
30     ##
31     ## data: ORtable
32     ## p-value = 1
33     ## alternative hypothesis: true odds ratio is not equal to 1
34     ## 95 percent confidence interval:
35     ## 0.118794 8.417935
36     ## sample estimates:
37     ## odds ratio
38     ##      1
39
40     #####WAKE TIME#####
41     summary(DCFdata$waketime.hrs)
42
43     ## 5:00 6:00 7:00 8:00 9:00
44     ## 0 5 8 4 3
45
46     #Tabulate the data
47     xtabs(~waketime.hrs + intervention, data = DCFdata)
48
49     ##      intervention
50     ## waketime.hrs Control Treatment
51     ##      5:00      0      0
52     ##      6:00      4      1
53     ##      7:00      2      6

```

```

1
2
3 ##           8:00           3           1
4 ##           9:00           1           2
5
6 #Perform Fisher's Exact Test
7 fisher.test(xtabs(~waketime.hrs + intervention, data = DCFdata))
8
9 ##
10 ## Fisher's Exact Test for Count Data
11 ##
12 ## data:  xtabs(~waketime.hrs + intervention, data = DCFdata)
13 ## p-value = 0.2044
14 ## alternative hypothesis: two.sided
15
16 temp_table <- xtabs(~waketime.hrs + intervention, data = DCFdata)
17 j=nrow(temp_table)
18 ControlCsum=colSums(temp_table)[1]
19 TreatmentCsum=colSums(temp_table)[2]
20 for(i in 1:j) {
21   a=temp_table[i,1]
22   b=temp_table[i,2]
23   c=ControlCsum-a
24   d=TreatmentCsum-b
25   ORtable <- matrix(c(a,c,b,d),nrow = 2)
26   colnames(ORtable) <- c("Control", "Treatment")
27   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
28   print(row.names(temp_table)[i])
29   print(ORtable)
30   print(fisher.test(ORtable))
31 }
32
33
34 ## [1] "5:00"
35 ##           Control Treatment
36 ## 5:00           0           0
37 ## Other           10          10
38 ##
39 ## Fisher's Exact Test for Count Data
40 ##
41 ## data:  ORtable
42 ## p-value = 1
43 ## alternative hypothesis: true odds ratio is not equal to 1
44 ## 95 percent confidence interval:
45 ##    0 Inf
46 ## sample estimates:
47 ## odds ratio
48 ##           0
49 ##
50 ## [1] "6:00"
51 ##           Control Treatment
52 ## 6:00           4           1
53 ## Other           6           9
54 ##
55 ##
56
57
58
59
60

```

```

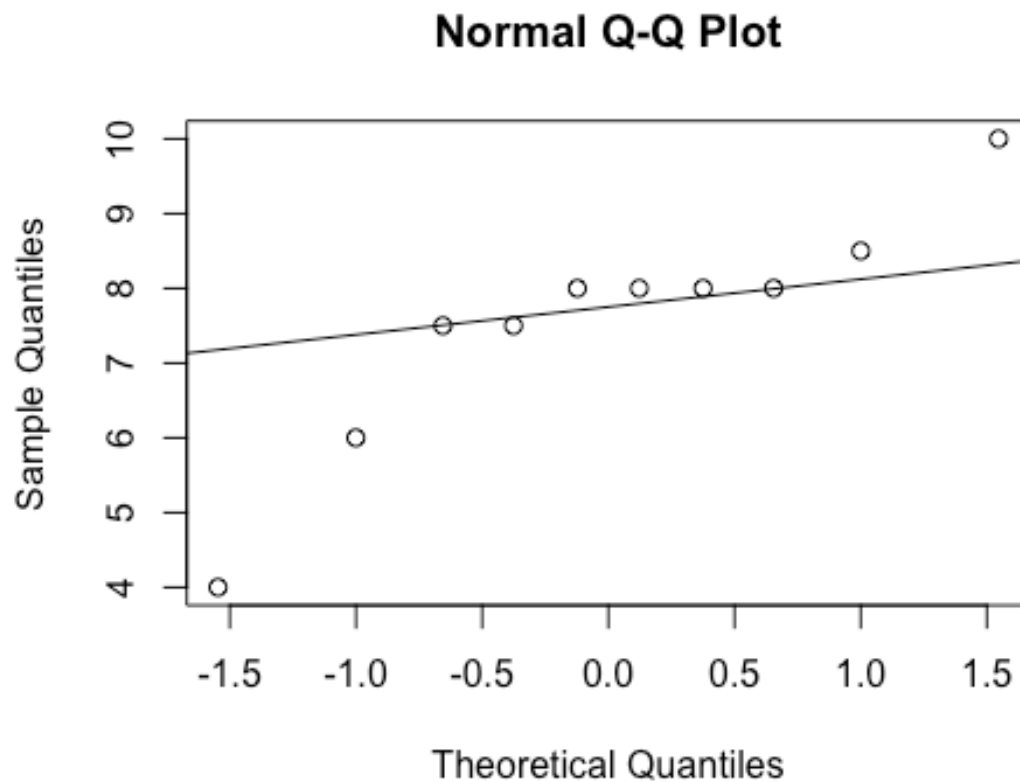
1
2
3   ## Fisher's Exact Test for Count Data
4   ##
5   ## data: ORtable
6   ## p-value = 0.3034
7   ## alternative hypothesis: true odds ratio is not equal to 1
8   ## 95 percent confidence interval:
9   ##    0.4075889 326.8267297
10  ## sample estimates:
11  ## odds ratio
12  ##    5.485861
13  ##
14  ## [1] "7:00"
15  ##      Control Treatment
16  ## 7:00      2      6
17  ## Other      8      4
18  ##
19  ## Fisher's Exact Test for Count Data
20  ##
21  ## data: ORtable
22  ## p-value = 0.1698
23  ## alternative hypothesis: true odds ratio is not equal to 1
24  ## 95 percent confidence interval:
25  ##    0.01252647 1.65925396
26  ## sample estimates:
27  ## odds ratio
28  ##    0.1841181
29  ##
30  ## [1] "8:00"
31  ##      Control Treatment
32  ## 8:00      3      1
33  ## Other      7      9
34  ##
35  ## Fisher's Exact Test for Count Data
36  ##
37  ## data: ORtable
38  ## p-value = 0.582
39  ## alternative hypothesis: true odds ratio is not equal to 1
40  ## 95 percent confidence interval:
41  ##    0.2301177 224.1916418
42  ## sample estimates:
43  ## odds ratio
44  ##    3.610815
45  ##
46  ## [1] "9:00"
47  ##      Control Treatment
48  ## 9:00      1      2
49  ## Other      9      8
50  ##
51  ## Fisher's Exact Test for Count Data
52  ##

```

```

1
2
3  ## data: ORtable
4  ## p-value = 1
5  ## alternative hypothesis: true odds ratio is not equal to 1
6  ## 95 percent confidence interval:
7  ## 0.0067986 10.5137419
8  ## sample estimates:
9  ## odds ratio
10 ## 0.4624944
11
12 #####SLEEP DURATION REPORTED#####
13 summary(DCFdata$sleep.reported.hrs)
14
15 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
16 ##      4.00   7.00   8.00   7.55   8.00   10.00
17
18 sd(DCFdata$sleep.reported.hrs, na.rm = TRUE)
19
20 ## [1] 1.145931
21
22 length(DCFdata$sleep.reported.hrs)
23
24 ## [1] 20
25
26 #Compare above with those who did not complete the study (n=3):
27 summary(DropOutdata$sleep.reported.hrs)
28
29 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
30 ##      5.500   6.250   7.000   6.833   7.500   8.000
31
32 #Treatment sleep duration reported
33 treatment.sleep.reported.hrs=na.omit((subset(DCFdata,
34                                     intervention == "Treatment")$sle
35 ep.reported.hrs))
36 length(treatment.sleep.reported.hrs)
37
38 ## [1] 10
39
40 summary(treatment.sleep.reported.hrs)
41
42 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
43 ##      4.00   7.50   8.00   7.55   8.00   10.00
44
45 sd(treatment.sleep.reported.hrs)
46
47 ## [1] 1.589025
48
49 #normality check
50 qqnorm(treatment.sleep.reported.hrs)
51 qqline(treatment.sleep.reported.hrs)
52
53
54
55
56
57
58
59
60

```



```

ad.test(treatment.sleep.reported.hrs)

##
## Anderson-Darling normality test
##
## data: treatment.sleep.reported.hrs
## A = 0.76112, p-value = 0.03136

#non-normal

#Control sleep duration reported
control.sleep.reported.hrs=na.omit((subset(DCFdata, intervention == "Control")
)$sleep.reported.hrs)
length(control.sleep.reported.hrs)

## [1] 10

summary(control.sleep.reported.hrs)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      7.00   7.00   7.75   7.55   8.00   8.00

sd(control.sleep.reported.hrs)

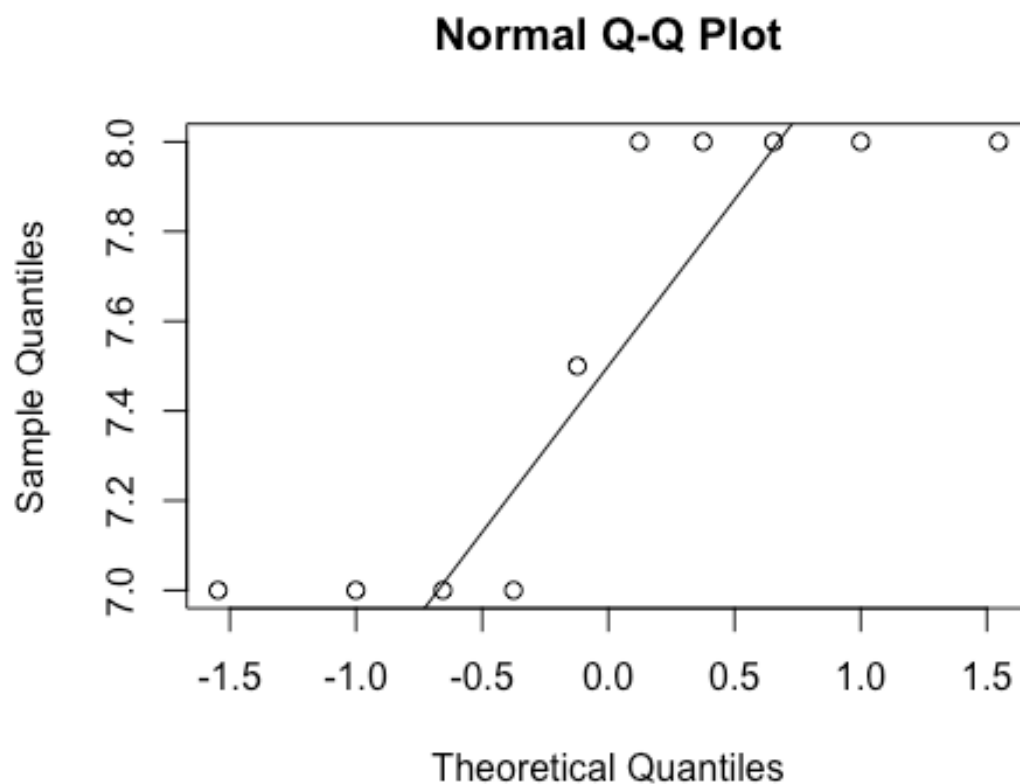
```

```
## [1] 0.4972145
```

```
#normality check
```

```
qqnorm(control.sleep.reported.hrs)
```

```
qqline(control.sleep.reported.hrs)
```



```
ad.test(control.sleep.reported.hrs)
```

```
##
```

```
## Anderson-Darling normality test
```

```
##
```

```
## data: control.sleep.reported.hrs
```

```
## A = 1.2746, p-value = 0.001286
```

```
#non-normal
```

```
#Perform non-parametric method (Wilcoxon rank sum test)
```

```
wilcox.test(treatment.sleep.reported.hrs, control.sleep.reported.hrs, conf.in  
t = TRUE)
```

```
## Warning in wilcox.test.default(treatment.sleep.reported.hrs,
```

```
## control.sleep.reported.hrs, : cannot compute exact p-value with ties
```

```

1
2
3  ## Warning in wilcox.test.default(treatment.sleep.reported.hrs,
4  ## control.sleep.reported.hrs, : cannot compute exact confidence intervals
5  ## with ties
6
7  ##
8  ##  Wilcoxon rank sum test with continuity correction
9  ##
10 ## data:  treatment.sleep.reported.hrs and control.sleep.reported.hrs
11 ## W = 59, p-value = 0.498
12 ## alternative hypothesis: true location shift is not equal to 0
13 ## 95 percent confidence interval:
14 ##  -0.5000247  0.9999945
15 ## sample estimates:
16 ## difference in location
17 ##           3.045828e-05
18
19
20 #####FALL ASLEEP POSITION IN PAST WEEK#####
21 summary(DCFdata$fell.asleep.in.past.week)
22
23 ##           left           left, right  left, right, prone
24 ##           7             4             1
25 ## left, right, supine   left, supine           right
26 ##           3             2             3
27 ##           right, supine
28 ##           0
29
30 length(DCFdata$fell.asleep.in.past.week)
31
32 ## [1] 20
33
34 #Tabulate the data
35 xtabs(~fell.asleep.in.past.week + intervention, data = DCFdata)
36
37 ##           intervention
38 ## fell.asleep.in.past.week Control Treatment
39 ## left           7           0
40 ## left, right    1           3
41 ## left, right, prone  0           1
42 ## left, right, supine  2           1
43 ## left, supine      0           2
44 ## right           0           3
45 ## right, supine     0           0
46
47 #Perform Fisher's Exact Test
48 #fisher.test(xtabs(~fell.asleep.in.past.week + intervention, data = DCFdata))
49 #build 2-row table for fisher test: control vs treatment
50 fell.asleep.in.past.week_table <- matrix(c(10,7,3,8,2,3,0,1),
51                                           nrow = 2)
52
53 colnames(fell.asleep.in.past.week_table) <- c("left", "right", "supine", "prone"
54 )
55 rownames(fell.asleep.in.past.week_table) <- c("Control",
56
57
58
59
60

```

```

1
2
3                                     "Treatment")
4 t(fell.asleep.in.past.week_table)
5
6 ##           Control Treatment
7 ## left           10         7
8 ## right          3         8
9 ## supine         2         3
10 ## prone         0         1
11
12 #Compare above with those who did not complete the study (n=3):
13 summary(DropOutdata$fell.asleep.in.past.week)
14
15 ##           left           left, right  left, right, prone
16 ##           0             1             0
17 ## left, right, supine   left, supine   right
18 ##           1             0             0
19 ##           right, supine
20 ##           1
21
22 #Perform Fisher's Exact Test
23 fisher.test(fell.asleep.in.past.week_table)
24
25 ##
26 ## Fisher's Exact Test for Count Data
27 ##
28 ## data:  fell.asleep.in.past.week_table
29 ## p-value = 0.3141
30 ## alternative hypothesis: two.sided
31
32 temp_table <- t(fell.asleep.in.past.week_table)
33 j=nrow(temp_table)
34 ControlCsum=colSums(temp_table)[1]
35 TreatmentCsum=colSums(temp_table)[2]
36 for(i in 1:j) {
37   a=temp_table[i,1]
38   b=temp_table[i,2]
39   c=ControlCsum-a
40   d=TreatmentCsum-b
41   ORtable <- matrix(c(a,c,b,d),nrow = 2)
42   colnames(ORtable) <- c("Control", "Treatment")
43   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
44   print(row.names(temp_table)[i])
45   print(ORtable)
46   print(fisher.test(ORtable))
47 }
48
49 ## [1] "left"
50
51 ##           Control Treatment
52 ## left           10         7
53 ## Other          5         12
54 ##
55
56
57
58
59
60

```



```

1
2
3   ## Fisher's Exact Test for Count Data
4   ##
5   ## data: ORtable
6   ## p-value = 0.1663
7   ## alternative hypothesis: true odds ratio is not equal to 1
8   ## 95 percent confidence interval:
9   ##  0.680546 18.170891
10  ## sample estimates:
11  ## odds ratio
12  ##  3.299199
13  ##
14  ## [1] "right"
15  ##      Control Treatment
16  ## right      3          8
17  ## Other     12         11
18  ##
19  ## Fisher's Exact Test for Count Data
20  ##
21  ## data: ORtable
22  ## p-value = 0.2714
23  ## alternative hypothesis: true odds ratio is not equal to 1
24  ## 95 percent confidence interval:
25  ##  0.04812652 1.98278653
26  ## sample estimates:
27  ## odds ratio
28  ##  0.3547015
29  ##
30  ## [1] "supine"
31  ##      Control Treatment
32  ## supine      2          3
33  ## Other     13         16
34  ##
35  ## Fisher's Exact Test for Count Data
36  ##
37  ## data: ORtable
38  ## p-value = 1
39  ## alternative hypothesis: true odds ratio is not equal to 1
40  ## 95 percent confidence interval:
41  ##  0.06037268 8.38423263
42  ## sample estimates:
43  ## odds ratio
44  ##  0.8252566
45  ##
46  ## [1] "prone"
47  ##      Control Treatment
48  ## prone       0          1
49  ## Other     15         18
50  ##
51  ## Fisher's Exact Test for Count Data
52  ##

```

```

1
2
3  ## data: ORtable
4  ## p-value = 1
5  ## alternative hypothesis: true odds ratio is not equal to 1
6  ## 95 percent confidence interval:
7  ## 0.00000 49.36267
8  ## sample estimates:
9  ## odds ratio
10 ## 0
11
12 #####FALL ASLEEP POSITION WHEN NOT PREGNANT#####
13 summary(DCFdata$fell.asleep.when.not.pregnant)
14
15 ##                left                left, prone
16 ##                1                    1
17 ##                left, right          left, right, supine
18 ##                1                    1
19 ## left, right, supine, prone          prone
20 ##                1                    8
21 ##                right                right, prone
22 ##                2                    1
23 ##                supine                supine, prone
24 ##                2                    2
25
26
27 length(DCFdata$fell.asleep.when.not.pregnant)
28
29 ## [1] 20
30
31 #Tabulate the data
32 xtabs(~fell.asleep.when.not.pregnant + intervention, data = DCFdata)
33
34 ##                intervention
35 ## fell.asleep.when.not.pregnant Control Treatment
36 ## left                1                0
37 ## left, prone          1                0
38 ## left, right          0                1
39 ## left, right, supine  0                1
40 ## left, right, supine, prone  1                0
41 ## prone                2                6
42 ## right                2                0
43 ## right, prone         1                0
44 ## supine               1                1
45 ## supine, prone        1                1
46
47
48 #Perform Fisher's Exact Test
49 #fisher.test(xtabs(~fell.asleep.when.not.pregnant + intervention, data = DCFdata))
50
51 #build 2-row table for fisher test: control vs treatment
52 fell.asleep.when.not.pregnant_table <- matrix(c(3,2,4,2,3,3,6,7),
53                nrow = 2)
54 colnames(fell.asleep.when.not.pregnant_table) <- c("left", "right", "supine", "prone")
55
56
57
58
59
60

```

```

1
2
3 rownames(fell.asleep.when.not.pregnant_table) <- c("Control",
4           "Treatment")
5
6 t(fell.asleep.when.not.pregnant_table)
7
8 ##           Control Treatment
9 ## left       3           2
10 ## right      4           2
11 ## supine     3           3
12 ## prone      6           7
13
14 #Compare above with those who did not complete the study (n=3):
15 summary(DropOutdata$fell.asleep.when.not.pregnant)
16
17 ##           left           left, prone
18 ##           0             0
19 ##           left, right     left, right, supine
20 ##           0             1
21 ## left, right, supine, prone prone
22 ##           0             0
23 ##           right          right, prone
24 ##           0             0
25 ##           supine         supine, prone
26 ##           2             0
27
28 #Perform Fisher's Exact Test
29 fisher.test(fell.asleep.when.not.pregnant_table)
30
31 ##
32 ## Fisher's Exact Test for Count Data
33 ##
34 ## data:  fell.asleep.when.not.pregnant_table
35 ## p-value = 0.9528
36 ## alternative hypothesis: two.sided
37
38 temp_table <- t(fell.asleep.when.not.pregnant_table)
39 j=nrow(temp_table)
40 ControlCsum=colSums(temp_table)[1]
41 TreatmentCsum=colSums(temp_table)[2]
42 for(i in 1:j) {
43   a=temp_table[i,1]
44   b=temp_table[i,2]
45   c=ControlCsum-a
46   d=TreatmentCsum-b
47   ORtable <- matrix(c(a,c,b,d),nrow = 2)
48   colnames(ORtable) <- c("Control", "Treatment")
49   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
50   print(row.names(temp_table)[i])
51   print(ORtable)
52   print(fisher.test(ORtable))
53 }
54
55
56
57
58
59
60

```

```

1
2
3  ## [1] "left"
4  ##      Control Treatment
5  ## left      3          2
6  ## Other     13         12
7  ##
8  ## Fisher's Exact Test for Count Data
9  ##
10 ## data: ORtable
11 ## p-value = 1
12 ## alternative hypothesis: true odds ratio is not equal to 1
13 ## 95 percent confidence interval:
14 ##  0.1319695 19.0880365
15 ## sample estimates:
16 ## odds ratio
17 ##  1.36981
18 ##
19 ## [1] "right"
20 ##      Control Treatment
21 ## right     4          2
22 ## Other     12         12
23 ##
24 ## Fisher's Exact Test for Count Data
25 ##
26 ## data: ORtable
27 ## p-value = 0.6567
28 ## alternative hypothesis: true odds ratio is not equal to 1
29 ## 95 percent confidence interval:
30 ##  0.2279875 25.5286215
31 ## sample estimates:
32 ## odds ratio
33 ##  1.95517
34 ##
35 ## [1] "supine"
36 ##      Control Treatment
37 ## supine    3          3
38 ## Other     13         11
39 ##
40 ## Fisher's Exact Test for Count Data
41 ##
42 ## data: ORtable
43 ## p-value = 1
44 ## alternative hypothesis: true odds ratio is not equal to 1
45 ## 95 percent confidence interval:
46 ##  0.09371084 7.70893039
47 ## sample estimates:
48 ## odds ratio
49 ##  0.8508967
50 ##
51 ## [1] "prone"
52 ##      Control Treatment

```

```

1
2
3     ## prone          6          7
4     ## Other         10          7
5     ##
6     ## Fisher's Exact Test for Count Data
7     ##
8     ## data: ORtable
9     ## p-value = 0.7131
10    ## alternative hypothesis: true odds ratio is not equal to 1
11    ## 95 percent confidence interval:
12    ##  0.1101751 3.2231312
13    ## sample estimates:
14    ## odds ratio
15    ##  0.6104211
16
17
18    #####WAKE UP POSITION IN PAST WEEK#####
19    summary(DCFdata$woke.up.in.past.week)
20
21    ##                left          left, right left, right, supine
22    ##                3                5                2
23    ##      left, supine          right          right, supine
24    ##                2                4                0
25    ##                supine
26    ##                4
27
28    length(DCFdata$woke.up.in.past.week)
29
30    ## [1] 20
31
32    #Tabulate the data
33    xtabs(~woke.up.in.past.week + intervention, data = DCFdata)
34
35    ##                intervention
36    ## woke.up.in.past.week Control Treatment
37    ## left                1                2
38    ## left, right        1                4
39    ## left, right, supine 1                1
40    ## left, supine        1                1
41    ## right               4                0
42    ## right, supine       0                0
43    ## supine              2                2
44
45    #Perform Fisher's Exact Test
46    #fisher.test(xtabs(~woke.up.in.past.week + intervention, data = DCFdata))
47    #build 2-row table for fisher test: control vs treatment
48    woke.up.in.past.week_table <- matrix(c(4,8,6,5,4,4),
49                                         nrow = 2)
50    colnames(woke.up.in.past.week_table) <- c("left", "right", "supine")
51    rownames(woke.up.in.past.week_table) <- c("Control",
52                                              "Treatment")
53
54    t(woke.up.in.past.week_table)
55
56
57
58
59
60

```

```

1
2
3     ##           Control Treatment
4     ## left           4           8
5     ## right          6           5
6     ## supine         4           4
7
8     #Compare above with those who did not complete the study (n=3):
9     summary(DropOutdata$woke.up.in.past.week)
10
11     ##           left           left, right left, right, supine
12     ##           0             2             0
13     ## left, supine          right           right, supine
14     ##           0             0             1
15     ##           supine
16     ##           0
17
18     #Perform Fisher's Exact Test
19     fisher.test(woke.up.in.past.week_table)
20
21     ##
22     ## Fisher's Exact Test for Count Data
23     ##
24     ## data:  woke.up.in.past.week_table
25     ## p-value = 0.6555
26     ## alternative hypothesis: two.sided
27
28     temp_table <- t(woke.up.in.past.week_table)
29     j=nrow(temp_table)
30     ControlCsum=colSums(temp_table)[1]
31     TreatmentCsum=colSums(temp_table)[2]
32     for(i in 1:j) {
33         a=temp_table[i,1]
34         b=temp_table[i,2]
35         c=ControlCsum-a
36         d=TreatmentCsum-b
37         ORtable <- matrix(c(a,c,b,d),nrow = 2)
38         colnames(ORtable) <- c("Control", "Treatment")
39         rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
40         print(row.names(temp_table)[i])
41         print(ORtable)
42         print(fisher.test(ORtable))
43     }
44
45     ## [1] "left"
46     ##           Control Treatment
47     ## left           4           8
48     ## Other          10           9
49     ##
50     ## Fisher's Exact Test for Count Data
51     ##
52     ## data:  ORtable
53     ## p-value = 0.4607
54
55
56
57
58
59
60

```

```

1
2
3  ## alternative hypothesis: true odds ratio is not equal to 1
4  ## 95 percent confidence interval:
5  ## 0.07417123 2.49180269
6  ## sample estimates:
7  ## odds ratio
8  ## 0.4618727
9  ##
10 ## [1] "right"
11 ##      Control Treatment
12 ## right      6          5
13 ## Other      8          12
14 ##
15 ## Fisher's Exact Test for Count Data
16 ##
17 ## data: ORtable
18 ## p-value = 0.4775
19 ## alternative hypothesis: true odds ratio is not equal to 1
20 ## 95 percent confidence interval:
21 ## 0.3207388 10.2754454
22 ## sample estimates:
23 ## odds ratio
24 ## 1.765584
25 ##
26 ## [1] "supine"
27 ##      Control Treatment
28 ## supine     4          4
29 ## Other      10         13
30 ##
31 ## Fisher's Exact Test for Count Data
32 ##
33 ## data: ORtable
34 ## p-value = 1
35 ## alternative hypothesis: true odds ratio is not equal to 1
36 ## 95 percent confidence interval:
37 ## 0.1885274 8.8685637
38 ## sample estimates:
39 ## odds ratio
40 ## 1.288954
41
42 #####WAKE UP POSITION WHEN NOT PREGNANT#####
43 summary(DCFdata$woke.up.when.not.pregnant)
44
45 ##                left                left, right
46 ##                3                  1
47 ##      left, right, prone      left, right, supine
48 ##                1                  1
49 ## left, right, supine, prone  left, supine, prone
50 ##                2                  1
51 ##                prone                right
52 ##                2                  2

```

```

1
2
3 ##           right, supine                supine
4 ##                   0                    4
5 ##           supine, prone
6 ##                   3
7
8 length(DCFdata$woke.up.when.not.pregnant)
9
10 ## [1] 20
11
12 #Tabulate the data
13 xtabs(~woke.up.when.not.pregnant + intervention, data = DCFdata)
14
15 ##           intervention
16 ## woke.up.when.not.pregnant  Control Treatment
17 ## left                       2           1
18 ## left, right                 0           1
19 ## left, right, prone          0           1
20 ## left, right, supine         0           1
21 ## left, right, supine, prone  1           1
22 ## left, supine, prone         1           0
23 ## prone                       0           2
24 ## right                       1           1
25 ## right, supine               0           0
26 ## supine                      3           1
27 ## supine, prone               2           1
28
29
30 #Perform Fisher's Exact Test
31 #fisher.test(xtabs(~woke.up.when.not.pregnant + intervention, data = DCFdata)
32 )
33 #build 2-row table for fisher test: control vs treatment
34 woke.up.when.not.pregnant_table <- matrix(c(4,5,2,5,7,4,4,5),
35                                           nrow = 2)
36 colnames(woke.up.when.not.pregnant_table) <- c("left", "right", "supine", "prone")
37 rownames(woke.up.when.not.pregnant_table) <- c("Control",
38                                                "Treatment")
39
40 t(woke.up.when.not.pregnant_table)
41
42 ##           Control Treatment
43 ## left           4           5
44 ## right          2           5
45 ## supine         7           4
46 ## prone          4           5
47
48
49 #Compare above with those who did not complete the study (n=3):
50 summary(DropOutdata$woke.up.when.not.pregnant)
51
52 ##           left                left, right
53 ##                   0                    0
54 ##           left, right, prone    left, right, supine
55 ##                   0                    1
56 ## left, right, supine, prone    left, supine, prone
57
58
59
60

```



```

1
2
3      ##                0                0
4      ##                prone            right
5      ##                1                0
6      ##                right, supine    supine
7      ##                1                0
8      ##                supine, prone
9      ##                0
10
11     #Perform Fisher's Exact Test
12     fisher.test(woke.up.when.not.pregnant_table)
13
14     ##
15     ## Fisher's Exact Test for Count Data
16     ##
17     ## data:  woke.up.when.not.pregnant_table
18     ## p-value = 0.56
19     ## alternative hypothesis: two.sided
20
21     temp_table <- t(woke.up.when.not.pregnant_table)
22     j=nrow(temp_table)
23     ControlCsum=colSums(temp_table)[1]
24     TreatmentCsum=colSums(temp_table)[2]
25     for(i in 1:j) {
26         a=temp_table[i,1]
27         b=temp_table[i,2]
28         c=ControlCsum-a
29         d=TreatmentCsum-b
30         ORtable <- matrix(c(a,c,b,d),nrow = 2)
31         colnames(ORtable) <- c("Control", "Treatment")
32         rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
33         print(row.names(temp_table)[i])
34         print(ORtable)
35         print(fisher.test(ORtable))
36     }
37
38     ## [1] "left"
39     ##      Control Treatment
40     ## left      4         5
41     ## Other    13        14
42     ##
43     ## Fisher's Exact Test for Count Data
44     ##
45     ## data:  ORtable
46     ## p-value = 1
47     ## alternative hypothesis: true odds ratio is not equal to 1
48     ## 95 percent confidence interval:
49     ##  0.13878 5.04642
50     ## sample estimates:
51     ## odds ratio
52     ##  0.8651067
53     ##
54
55
56
57
58
59
60

```

```

1
2
3  ## [1] "right"
4  ##      Control Treatment
5  ## right      2          5
6  ## Other      15         14
7  ##
8  ## Fisher's Exact Test for Count Data
9  ##
10 ## data: ORtable
11 ## p-value = 0.408
12 ## alternative hypothesis: true odds ratio is not equal to 1
13 ## 95 percent confidence interval:
14 ##  0.03161314 2.82646603
15 ## sample estimates:
16 ## odds ratio
17 ##  0.3834022
18 ##
19 ## [1] "supine"
20 ##      Control Treatment
21 ## supine      7          4
22 ## Other      10         15
23 ##
24 ## Fisher's Exact Test for Count Data
25 ##
26 ## data: ORtable
27 ## p-value = 0.2814
28 ## alternative hypothesis: true odds ratio is not equal to 1
29 ## 95 percent confidence interval:
30 ##  0.4917611 15.3003743
31 ## sample estimates:
32 ## odds ratio
33 ##  2.553445
34 ##
35 ## [1] "prone"
36 ##      Control Treatment
37 ## prone       4          5
38 ## Other      13         14
39 ##
40 ## Fisher's Exact Test for Count Data
41 ##
42 ## data: ORtable
43 ## p-value = 1
44 ## alternative hypothesis: true odds ratio is not equal to 1
45 ## 95 percent confidence interval:
46 ##  0.13878 5.04642
47 ## sample estimates:
48 ## odds ratio
49 ##  0.8651067
50
51 #####PART OF BED PARTICIPANT SLEEPS ON#####
52 summary(DCFdata$side.of.bed)
53
54
55
56
57
58
59
60

```

```

1
2
3      ##           center           left left, right, center
4      ##           2             8             1
5      ##           right        right, center
6      ##           9             0
7
8      length(DCFdata$side.of.bed)
9
10     ## [1] 20
11
12     #Tabulate the data
13     xtabs(~side.of.bed + intervention, data = DCFdata)
14
15     ##           intervention
16     ## side.of.bed      Control Treatment
17     ## center           0           2
18     ## left             5           3
19     ## left, right, center 0           1
20     ## right            5           4
21     ## right, center     0           0
22
23     #Perform Fisher's Exact Test
24     #fisher.test(xtabs(~side.of.bed + intervention, data = DCFdata))
25     #build 2-row table for fisher test: control vs treatment
26     side.of.bed_table <- matrix(c(5,4,5,5,0,3),
27                                 nrow = 2)
28
29     colnames(side.of.bed_table) <- c("left", "right", "center")
30     rownames(side.of.bed_table) <- c("Control",
31                                     "Treatment")
32     t(side.of.bed_table)
33
34     ##           Control Treatment
35     ## left           5           4
36     ## right          5           5
37     ## center         0           3
38
39     #Perform Fisher's Exact Test
40     fisher.test(side.of.bed_table)
41
42     ##
43     ## Fisher's Exact Test for Count Data
44     ##
45     ## data: side.of.bed_table
46     ## p-value = 0.357
47     ## alternative hypothesis: two.sided
48
49     temp_table <- t(side.of.bed_table)
50     j=nrow(temp_table)
51     ControlCsum=colSums(temp_table)[1]
52     TreatmentCsum=colSums(temp_table)[2]
53     for(i in 1:j) {
54         a=temp_table[i,1]
55         b=temp_table[i,2]

```

```

1
2
3   c=ControlCsum-a
4   d=TreatmentCsum-b
5   ORtable <- matrix(c(a,c,b,d),nrow = 2)
6   colnames(ORtable) <- c("Control","Treatment")
7   rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
8   print(row.names(temp_table)[i])
9   print(ORtable)
10  print(fisher.test(ORtable))
11
12 }
13
14 ## [1] "left"
15 ##      Control Treatment
16 ## left      5         4
17 ## Other     5         8
18 ##
19 ## Fisher's Exact Test for Count Data
20 ##
21 ## data:  ORtable
22 ## p-value = 0.6656
23 ## alternative hypothesis: true odds ratio is not equal to 1
24 ## 95 percent confidence interval:
25 ##  0.2637526 15.6036729
26 ## sample estimates:
27 ## odds ratio
28 ##  1.936521
29 ##
30 ## [1] "right"
31 ##      Control Treatment
32 ## right     5         5
33 ## Other     5         7
34 ##
35 ## Fisher's Exact Test for Count Data
36 ##
37 ## data:  ORtable
38 ## p-value = 1
39 ## alternative hypothesis: true odds ratio is not equal to 1
40 ## 95 percent confidence interval:
41 ##  0.1920501 10.2898393
42 ## sample estimates:
43 ## odds ratio
44 ##  1.378598
45 ##
46 ## [1] "center"
47 ##      Control Treatment
48 ## center    0         3
49 ## Other     10        9
50 ##
51 ## Fisher's Exact Test for Count Data
52 ##
53 ## data:  ORtable

```

```

1
2
3  ## p-value = 0.2208
4  ## alternative hypothesis: true odds ratio is not equal to 1
5  ## 95 percent confidence interval:
6  ## 0.000000 2.779036
7  ## sample estimates:
8  ## odds ratio
9  ##          0
10
11 #####BED PARTNER#####
12 summary(DCFdata$sleeps.with.without.partner)
13
14  ##      with without
15  ##      17      3
16
17 length(DCFdata$sleeps.with.without.partner)
18
19  ## [1] 20
20
21 #Compare above with those who did not complete the study (n=3):
22 summary(DropOutdata$sleeps.with.without.partner)
23
24  ##      with without
25  ##       3      0
26
27 #Tabulate the data
28 xtabs(~sleeps.with.without.partner + intervention, data = DCFdata)
29
30  ##
31  ##          intervention
32  ## sleeps.with.without.partner Control Treatment
33  ##                with      10      7
34  ##                without    0      3
35
36 #Perform Fisher's Exact Test
37 fisher.test(xtabs(~sleeps.with.without.partner + intervention, data = DCFdata
38 ))
39
40  ##
41  ## Fisher's Exact Test for Count Data
42  ##
43  ## data:  xtabs(~sleeps.with.without.partner + intervention, data = DCFdata)
44  ## p-value = 0.2105
45  ## alternative hypothesis: true odds ratio is not equal to 1
46  ## 95 percent confidence interval:
47  ## 0.443414      Inf
48  ## sample estimates:
49  ## odds ratio
50  ##          Inf
51
52 #####PILLOW USE#####
53 summary(DCFdata$pillow)
54
55
56
57
58
59
60

```

```

1
2
3     ##                pregnancy pillow
4     ##                2
5     ##                under head
6     ##                1
7     ##                under head and between knees
8     ##                4
9     ##                under head and pregnancy pillow
10    ##                1
11    ##                under head between knees
12    ##                1
13    ##                under head between knees and behind back
14    ##                2
15    ##                under head between knees and pregnancy pillow
16    ##                1
17    ##                under head between knees and under tummy
18    ##                1
19    ## under head between knees behind back and pregnany pillow
20    ##                1
21    ##                under head between knees under tummy
22    ##                1
23    ##                under head between knees under tummy and behind back
24    ##                3
25    ##                under head under tummy and behind back
26    ##                2
27
28
29
30 length(DCFdata$pillow)
31
32 ## [1] 20
33
34 #Tabulate the data
35 xtabs(~pillow + intervention, data = DCFdata)
36
37 ##                intervention
38 ## pillow                Control
39 ## pregnancy pillow                1
40 ## under head                1
41 ## under head and between knees                3
42 ## under head and pregnancy pillow                0
43 ## under head between knees                0
44 ## under head between knees and behind back                1
45 ## under head between knees and pregnancy pillow                0
46 ## under head between knees and under tummy                0
47 ## under head between knees behind back and pregnany pillow                0
48 ## under head between knees under tummy                0
49 ## under head between knees under tummy and behind back                2
50 ## under head under tummy and behind back                2
51
52 ##                intervention
53 ## pillow                Treatment
54 ## pregnancy pillow                1
55 ## under head                0
56 ## under head and between knees                1

```

```

1
2
3   ## under head and pregnancy pillow 1
4   ## under head between knees 1
5   ## under head between knees and behind back 1
6   ## under head between knees and pregnancy pillow 1
7   ## under head between knees and under tummy 1
8   ## under head between knees behind back and pregnancy pillow 1
9   ## under head between knees under tummy 1
10  ## under head between knees under tummy and behind back 1
11  ## under head under tummy and behind back 0
12
13
14  #Perform Fisher's Exact Test
15  fisher.test(xtabs(~pillow + intervention, data = DCFdata))
16
17  ##
18  ## Fisher's Exact Test for Count Data
19  ##
20  ## data: xtabs(~pillow + intervention, data = DCFdata)
21  ## p-value = 0.7563
22  ## alternative hypothesis: two.sided
23
24  #build 2-row table for fisher test: control vs treatment
25  pillow_table <- matrix(c(1,4,9,9,6,8,5,3,4,3),
26                          nrow = 2)
27  colnames(pillow_table) <- c("pregnancy pillow", "under head", "btw knees", "behind back", "under tummy")
28  rownames(pillow_table) <- c("Control",
29                              "Treatment")
30
31  t(pillow_table)
32
33  ##           Control Treatment
34  ## pregnancy pillow      1      4
35  ## under head           9      9
36  ## btw knees            6      8
37  ## behind back          5      3
38  ## under tummy          4      3
39
40  #Compare above with those who did not complete the study (n=3):
41  summary(DropOutdata$pillow)
42
43  ##           pregnancy pillow
44  ##                0
45  ##           under head
46  ##                0
47  ##           under head and between knees
48  ##                1
49  ##           under head and pregnancy pillow
50  ##                0
51  ##           under head between knees
52  ##                0
53  ##           under head between knees and behind back
54  ##                1
55  ##
56
57
58
59
60

```

```

1
2
3     ##           under head between knees and pregnancy pillow
4     ##                                           0
5     ##           under head between knees and under tummy
6     ##                                           1
7     ## under head between knees behind back and pregnany pillow
8     ##                                           0
9     ##           under head between knees under tummy
10    ##                                           0
11    ##           under head between knees under tummy and behind back
12    ##                                           0
13    ##           under head under tummy and behind back
14    ##                                           0
15    ##                                           0
16
17    #Perform Fisher's Exact Test
18    fisher.test(pillow_table)
19
20    ##
21    ## Fisher's Exact Test for Count Data
22    ##
23    ## data: pillow_table
24    ## p-value = 0.6624
25    ## alternative hypothesis: two.sided
26
27    temp_table <- t(pillow_table)
28    j=nrow(temp_table)
29    ControlCsum=colSums(temp_table)[1]
30    TreatmentCsum=colSums(temp_table)[2]
31    for(i in 1:j) {
32      a=temp_table[i,1]
33      b=temp_table[i,2]
34      c=ControlCsum-a
35      d=TreatmentCsum-b
36      ORtable <- matrix(c(a,c,b,d),nrow = 2)
37      colnames(ORtable) <- c("Control","Treatment")
38      rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
39      print(row.names(temp_table)[i])
40      print(ORtable)
41      print(fisher.test(ORtable))
42    }
43
44
45    ## [1] "pregnancy pillow"
46    ##           Control Treatment
47    ## pregnancy pillow      1      4
48    ## Other                 24     23
49    ##
50    ## Fisher's Exact Test for Count Data
51    ##
52    ## data: ORtable
53    ## p-value = 0.3517
54    ## alternative hypothesis: true odds ratio is not equal to 1
55    ## 95 percent confidence interval:

```



```

1
2
3      ## 0.004679473 2.727254390
4      ## sample estimates:
5      ## odds ratio
6      ## 0.2455393
7      ##
8      ## [1] "under head"
9      ##           Control Treatment
10     ## under head      9      9
11     ## Other          16     18
12     ##
13     ## Fisher's Exact Test for Count Data
14     ##
15     ## data: ORtable
16     ## p-value = 1
17     ## alternative hypothesis: true odds ratio is not equal to 1
18     ## 95 percent confidence interval:
19     ## 0.3077428 4.1067353
20     ## sample estimates:
21     ## odds ratio
22     ## 1.12245
23     ##
24     ## [1] "btw knees"
25     ##           Control Treatment
26     ## btw knees      6      8
27     ## Other          19     19
28     ##
29     ## Fisher's Exact Test for Count Data
30     ##
31     ## data: ORtable
32     ## p-value = 0.7587
33     ## alternative hypothesis: true odds ratio is not equal to 1
34     ## 95 percent confidence interval:
35     ## 0.1779795 3.0415532
36     ## sample estimates:
37     ## odds ratio
38     ## 0.7541601
39     ##
40     ## [1] "behind back"
41     ##           Control Treatment
42     ## behind back    5      3
43     ## Other          20     24
44     ##
45     ## Fisher's Exact Test for Count Data
46     ##
47     ## data: ORtable
48     ## p-value = 0.4583
49     ## alternative hypothesis: true odds ratio is not equal to 1
50     ## 95 percent confidence interval:
51     ## 0.3355811 14.3021716
52     ## sample estimates:

```

```

1
2
3 ## odds ratio
4 ## 1.973559
5 ##
6 ## [1] "under tummy"
7 ##           Control Treatment
8 ## under tummy      4          3
9 ## Other            21          24
10 ##
11 ## Fisher's Exact Test for Count Data
12 ##
13 ## data: ORtable
14 ## p-value = 0.6983
15 ## alternative hypothesis: true odds ratio is not equal to 1
16 ## 95 percent confidence interval:
17 ## 0.2268471 11.5245873
18 ## sample estimates:
19 ## odds ratio
20 ## 1.511484
21
22
23 #####SNORING#####
24 summary(DCFdata$snore.3.times.or.more.per.week.does.not.snore)
25
26 ## does not snore      snores
27 ##           13          7
28
29 length(DCFdata$snore.3.times.or.more.per.week.does.not.snore)
30
31 ## [1] 20
32
33 #Compare above with those who did not complete the study (n=3):
34 summary(DropOutdata$snore.3.times.or.more.per.week.does.not.snore)
35
36 ## does not snore      snores
37 ##           2          1
38
39 #Tabulate the data
40 xtabs(~snore.3.times.or.more.per.week.does.not.snore + intervention, data =
41 DCFdata)
42
43 ##                               intervention
44 ## snore.3.times.or.more.per.week.does.not.snore Control Treatment
45 ##                               does not snore      7          6
46 ##                               snores              3          4
47
48 #Perform Fisher's Exact Test
49 fisher.test(xtabs(~snore.3.times.or.more.per.week.does.not.snore + intervent
50 ion, data = DCFdata))
51
52 ##
53 ## Fisher's Exact Test for Count Data
54 ##
55 ## data:

```

```

1
2
3  ## p-value = 1
4  ## alternative hypothesis: true odds ratio is not equal to 1
5  ## 95 percent confidence interval:
6  ##   0.1731447 15.0151265
7  ## sample estimates:
8  ## odds ratio
9  ##   1.521346
10
11 summary(DCFdata$how.long.snores)
12
13 ##
14 ##
15 14
16 ##
17 2-3 months
18 ##
19 1
20 ##
21 7.5 months
22 ##
23 1
24 ## I think so, my husband informs me that I do + it gets worse the further al
25 ong in pregnancy (louder/same frequency)
26 ##
27 1
28 ##
29 lifetime
30 ##
31 1
32 ##
33 several years
34 ##
35 1
36 ##
37 Since before I was pregnant
38 ##
39 1
40 ##
41 Since being pregnant
42 ##
43 0
44
45 length(DCFdata$how.long.snores)
46
47 ## [1] 20
48
49 #####PREGNANCY HISTORY#####
50 summary(DCFdata$pregnancy.related.medical.conditions)
51
52 ## none
53 ##   20
54
55
56
57
58
59
60

```

```
1
2
3 length(DCFdata$pregnancy.related.medical.conditions)
4
5 ## [1] 20
6
7 temp <- matrix(c(10,0,10,0), nrow = 2)
8 temp
9
10 ##      [,1] [,2]
11 ## [1,]   10   10
12 ## [2,]    0    0
13
14 fisher.test(temp)
15
16 ##
17 ## Fisher's Exact Test for Count Data
18 ##
19 ## data: temp
20 ## p-value = 1
21 ## alternative hypothesis: true odds ratio is not equal to 1
22 ## 95 percent confidence interval:
23 ##    0 Inf
24 ## sample estimates:
25 ## odds ratio
26 ##          0
27
28 #The End
29
30
31
32
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```

Review only

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Supplementary file 2: Code and output – PSG analysis

For peer review only

PSG_Analysis_-_BMJSubmission2.R

Allan Kember

Mon May 21 22:49:35 2018

```
#Description of code: this code process the polysomnography (PSG) sleep reports in full.
#Within-participant (paired) comparisons are computed.
#Between-participant comparisons are computed FYI only.

#Summary: results reveal a statistically significant reduction in the percent age of time spent sleeping supine and in the number of minutes spent sleeping supine with the PrenaBelt versus the sham on testing via a paired Wilcoxon signed rank test.

#General Preamble and Notes:
#Regarding ANOVA:
#The result of this calculation is expressed in a test statistic called the F ratio
 #(designated simply as F), the ratio of how much variability there is between the groups
#relative to how much there is within the groups.

#If the null hypothesis is true (in other words, if no true difference exists between the groups), then the F ratio should be close to 1.

#The p value can be calculated from the values of F, df1, and df2, and the software will perform this calculation for you. If the p value from the ANOVA is significant
 #(less than 0.05 or your chosen alpha level), then you can conclude that the groups are not all the same (because the means varied from each other by too large an amount).

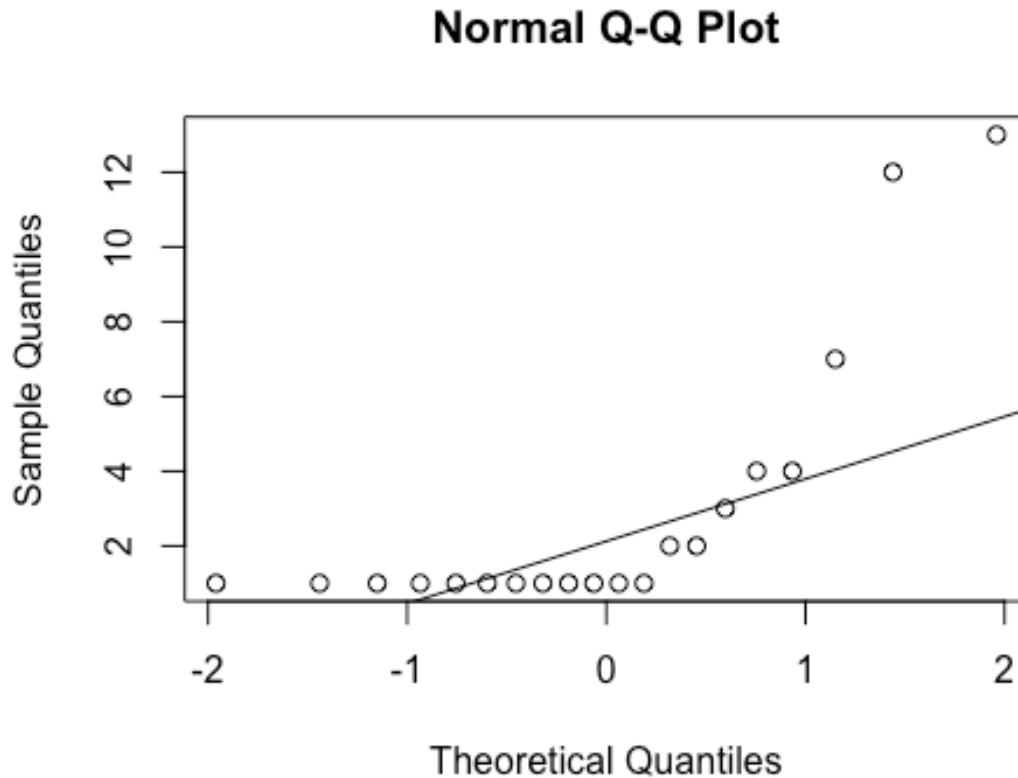
#setting the workspace directory
setwd("/Users/Allan/Desktop/HPTStats/08APR2017")

#importing the sleep study (SS) data
SSdatafull=read.csv("SS Data Halifax - 08APR2017.csv")
#Exclude drop outs
#How many drop outs?
summary(SSdatafull$drop.out)
```

```

1
2
3 ## N Y
4 ## 40 6
5
6 #6 nights = 3 participants
7 #Remove the drop outs ("Y")
8 SSdata <- SSdatafull[!(SSdatafull$drop.out=="Y"),]
9 nrow(SSdata)
10
11 ## [1] 40
12
13 #Loading the functions (ad.test, etc.) into your workspace
14 library(nortest)
15
16 ##### Time between studies (days) #####
17 #FYI: this data was not a pre-specified secondary outcome per the research pr
18 otocol or
19 #trial registry. FYI only for purposes of peer reviewer's questions/comments.
20 #Summary
21 summary(SSdata$time.between.studies..days.)
22
23 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.     NA's
24 ##      1.00   1.00   1.00   2.95   3.25   13.00     20
25
26 sd(SSdata$time.between.studies..days., na.rm = TRUE)
27
28 ## [1] 3.619756
29
30 length(SSdata$time.between.studies..days.)
31
32 ## [1] 40
33
34 #Check for normality
35 qqnorm(SSdata$time.between.studies..days.)
36 qqline(SSdata$time.between.studies..days.)
37
38
39
40
41
42
43
44
45
46
47
48
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```



```

ad.test(SSdata$time.between.studies..days.)

##
## Anderson-Darling normality test
##
## data:  SSdata$time.between.studies..days.
## A = 3.3009, p-value = 1.32e-08

#non-normal

#####Total sleep time#####
#Summary
summary(SSdata$total.sleep.time)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  154.5  317.6   351.6   336.4   373.5   431.0

sd(SSdata$total.sleep.time, na.rm = TRUE)

## [1] 63.95136

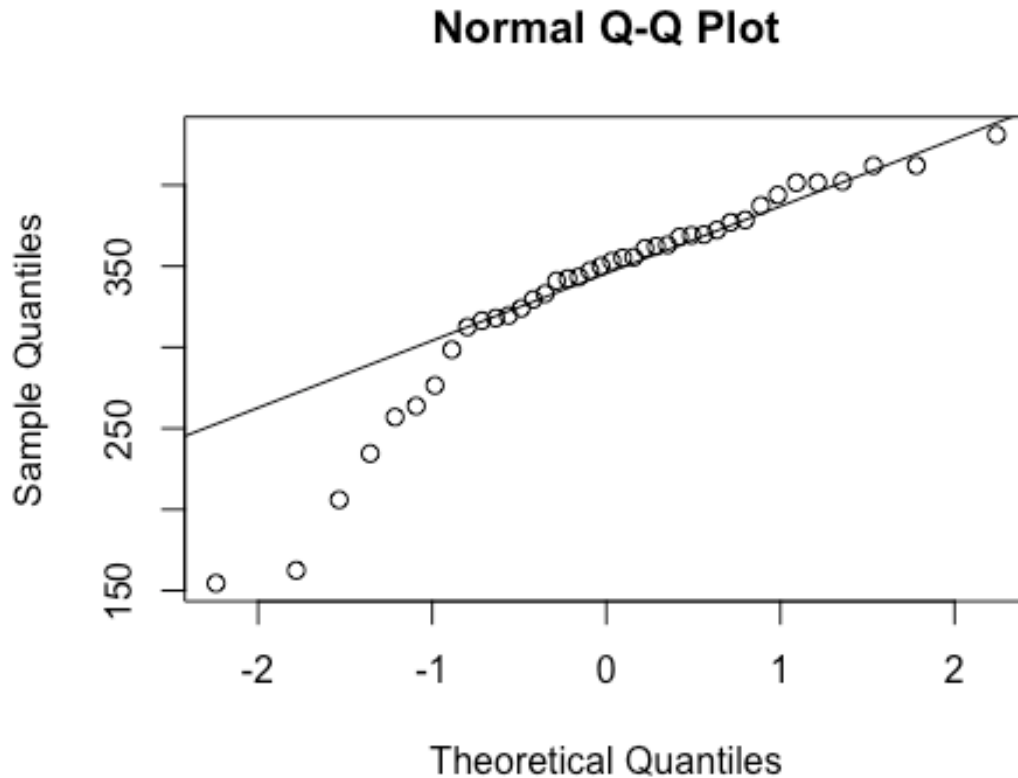
length(SSdata$total.sleep.time)

## [1] 40

```



```
qqnorm(SSdata$total.sleep.time)
qqline(SSdata$total.sleep.time)
```



```
ad.test(SSdata$total.sleep.time)

##
## Anderson-Darling normality test
##
## data:  SSdata$total.sleep.time
## A = 1.3949, p-value = 0.001122

#non-normal

#ANOVA
night_tx_difference <- anova(lm(total.sleep.time ~ intervention*night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: total.sleep.time
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1     659    658.5   0.1527 0.6983
## night           1    3574   3574.0   0.8287 0.3687
```

```

1
2
3 ## intervention:night 1      3      2.8  0.0006 0.9800
4 ## Residuals          36 155266  4312.9
5
6 #No association between intervention or night on sleeptime, even when account
7 ing for
8 #both factors at the same time. It does not matter whether they received the
9 PrenaBelt
10 #on night one or night two.
11
12 #within-participants (paired) comparison
13 #need to remove drop outs in order to have balanced pairs
14 #Exclude drop outs
15 #How many drop outs?
16 summary(SSdata$drop.out)
17
18
19 ## N Y
20 ## 40 0
21
22 #Remove the drop outs ("Y")
23 SSdataCompletes <- SSdata[!(SSdata$drop.out=="Y"),]
24 nrow(SSdataCompletes)
25
26 ## [1] 40
27
28 #Non-normal - perform non-parametric test (Wilcoxon)
29 wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.sleep.time,
30             subset(SSdataCompletes, intervention == "PrenaBelt")$total.sleep.time,
31             paired = TRUE, conf.int = TRUE)
32
33 ##
34 ## Wilcoxon signed rank test
35 ##
36 ## data: subset(SSdataCompletes, intervention == "sham")$total.sleep.time an
37 d subset(SSdataCompletes, intervention == "PrenaBelt")$total.sleep.time
38 ## V = 112, p-value = 0.8124
39 ## alternative hypothesis: true location shift is not equal to 0
40 ## 95 percent confidence interval:
41 ## -21.80  33.75
42 ## sample estimates:
43 ## (pseudo)median
44 ##          3.55
45
46 #between participants (grouped) comparison
47 summary(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
48
49 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50 ##      154.5  317.6   352.6   332.4  375.6   412.1
51
52 sd(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
53
54 ## [1] 75.04747
55
56
57
58
59
60

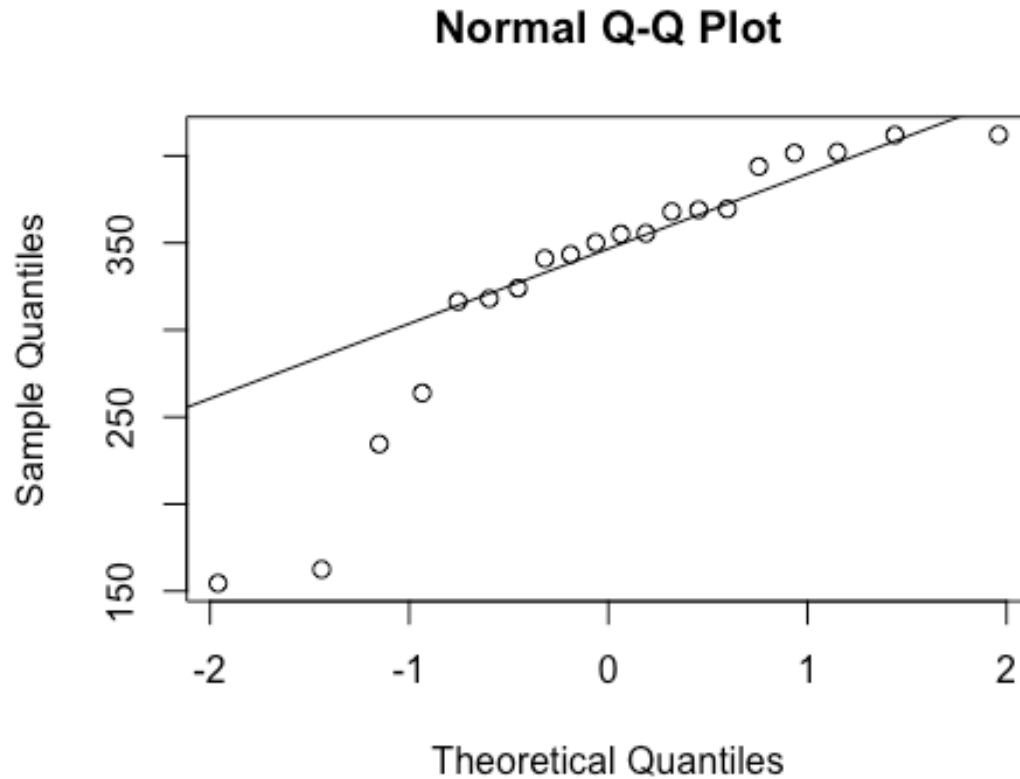
```

```

length(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
qqline(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$total.sleep.time
## A = 1.1032, p-value = 0.005239
##
## non-normal

summary(subset(SSdata, intervention == "sham")$total.sleep.time)
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      206.0  317.8   350.2   340.5   373.5   431.0

sd(subset(SSdata, intervention == "sham")$total.sleep.time)
## [1] 52.23046

```

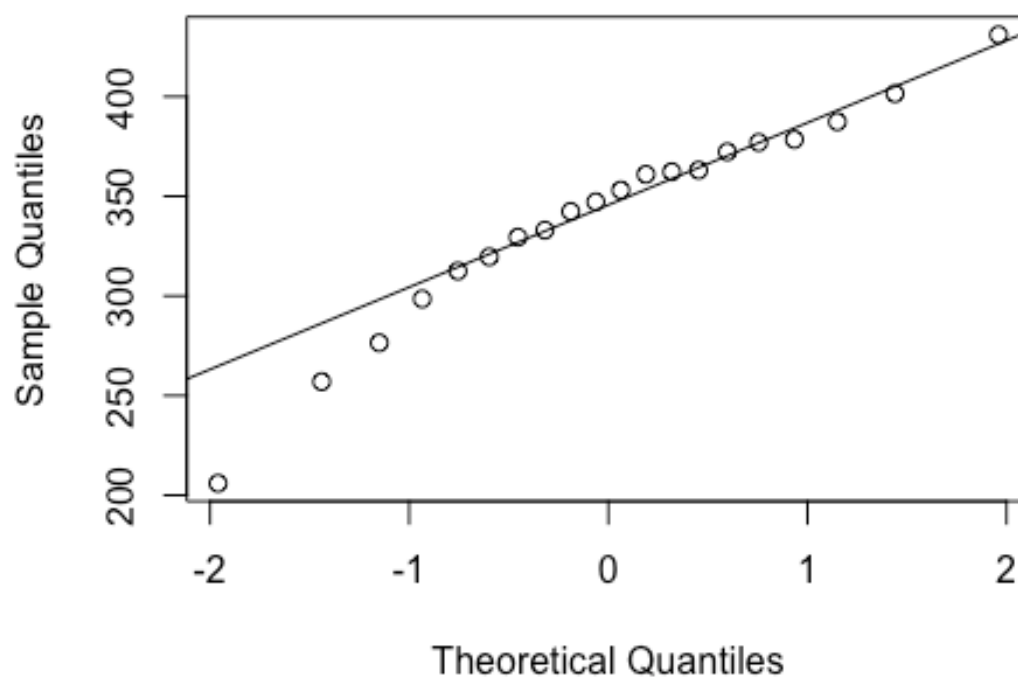
```

length(subset(SSdata, intervention == "sham")$total.sleep.time)
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$total.sleep.time)
qqline(subset(SSdata, intervention == "sham")$total.sleep.time)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$total.sleep.time)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$total.sleep.time
## A = 0.39153, p-value = 0.3464

#normal

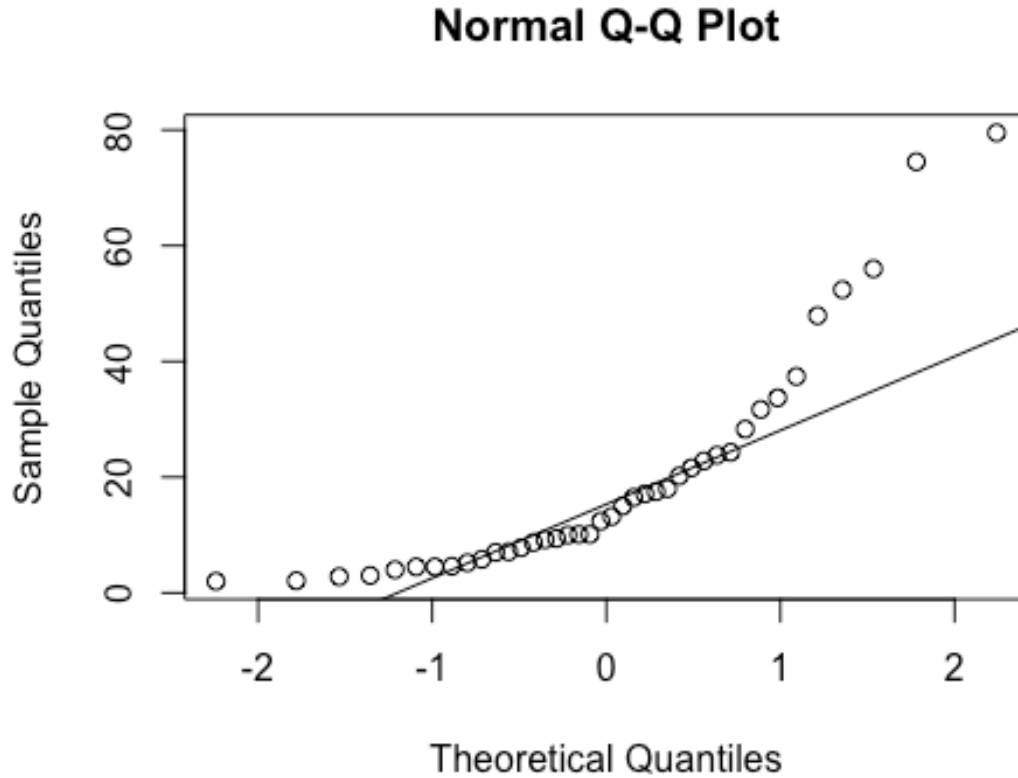
#Non-normal - perform non-parametric test (Wilcoxon)
#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$total.sleep.time,
            subset(SSdata, intervention == "PrenaBelt")$total.sleep.time,
            conf.int = TRUE)

```

```

1
2
3
4  ##
5  ## Wilcoxon rank sum test
6  ##
7  ## data: subset(SSdata, intervention == "sham")$total.sleep.time and subset(
8  SSdata, intervention == "PrenaBelt")$total.sleep.time
9  ## W = 196, p-value = 0.9254
10 ## alternative hypothesis: true location shift is not equal to 0
11 ## 95 percent confidence interval:
12 ## -35.1 32.3
13 ## sample estimates:
14 ## difference in location
15 ## -2.2
16
17 #####Sleep Latency#####
18 #Summary
19 summary(SSdata$sleep.latency)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      2.00   6.70   12.80   19.54   23.92   79.50
23
24 sd(SSdata$sleep.latency, na.rm = TRUE)
25
26 ## [1] 19.13941
27
28 length(SSdata$sleep.latency)
29
30 ## [1] 40
31
32 qqnorm(SSdata$sleep.latency)
33 qqline(SSdata$sleep.latency)

```



```

ad.test(SSdata$sleep.latency)

##
## Anderson-Darling normality test
##
## data:  SSdata$sleep.latency
## A = 2.6549, p-value = 8.053e-07

#non-normal

#ANOVA
night_tx_difference <- anova(lm(sleep.latency ~ intervention*night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: sleep.latency
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1     9.7    9.70  0.0247  0.8760
## night           1     1.0     0.99  0.0025  0.9602
## intervention:night 1    144.8  144.78  0.3688  0.5474
## Residuals      36 14130.9  392.52

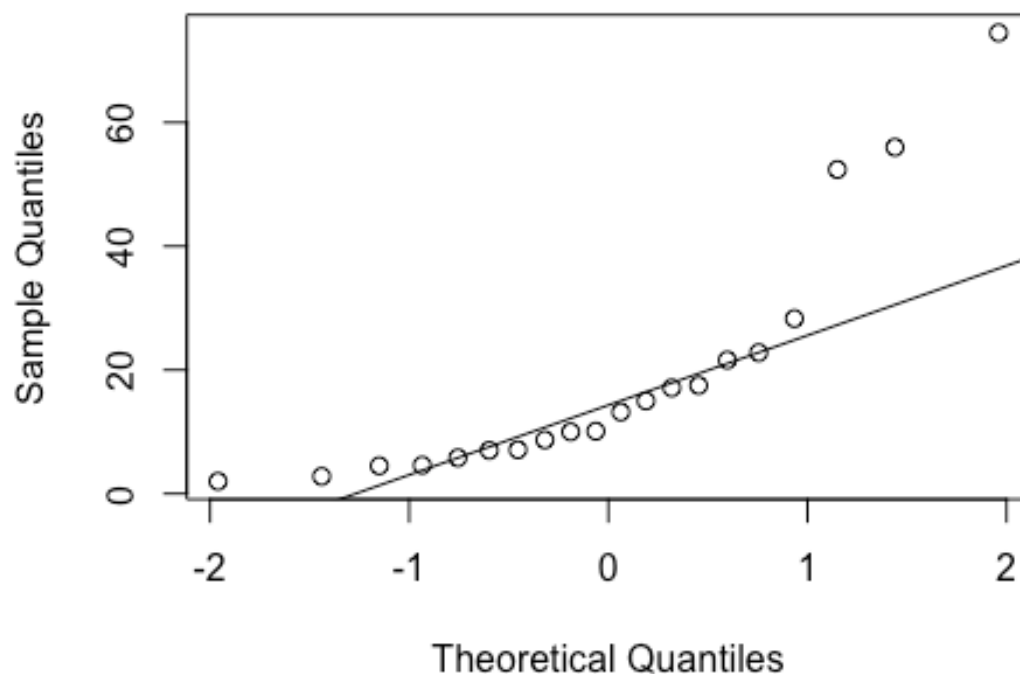
```

```

1
2
3 #within-participants (paired) comparison
4 wilcox.test(subset(SSdataCompletes, intervention == "sham")$sleep.latency,
5             subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.latency,
6             paired = TRUE, conf.int = TRUE)
7
8 ##
9 ## Wilcoxon signed rank test
10 ##
11 ## data: subset(SSdataCompletes, intervention == "sham")$sleep.latency and s
12 subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.latency
13 ## V = 92, p-value = 0.6477
14 ## alternative hypothesis: true location shift is not equal to 0
15 ## 95 percent confidence interval:
16 ## -9.40 7.15
17 ## sample estimates:
18 ## (pseudo)median
19 ## -2
20
21 #between participants (grouped) comparison
22 summary(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
23
24 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
25 ##      2.00   6.70   11.65   19.05   21.90   74.50
26
27 sd(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
28
29 ## [1] 19.76593
30
31 length(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
32
33 ## [1] 20
34
35 qqnorm(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
36 qqline(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)
37
38
39
40
41
42
43
44
45
46
47
48
49
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51
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53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$sleep.latency
## A = 1.8095, p-value = 8.14e-05

#Non-normal

summary(subset(SSdata, intervention == "sham")$sleep.latency)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      2.10   7.15   14.45   20.04   26.15   79.50

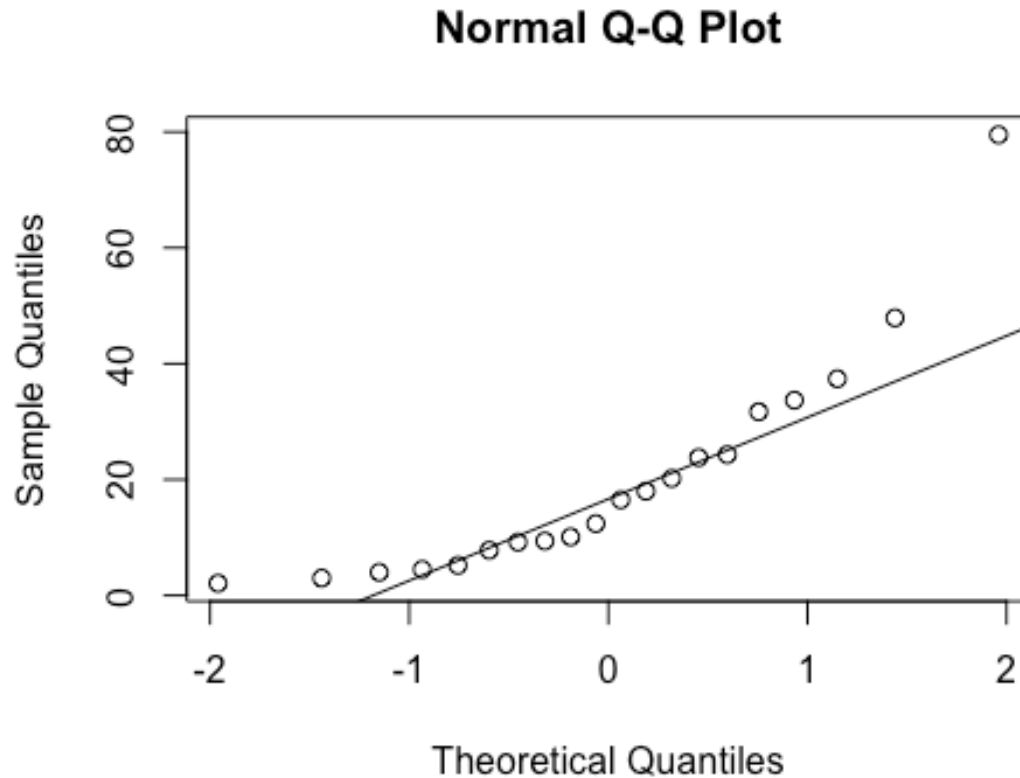
sd(subset(SSdata, intervention == "sham")$sleep.latency)

## [1] 18.99239

length(subset(SSdata, intervention == "sham")$sleep.latency)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$sleep.latency)
qqline(subset(SSdata, intervention == "sham")$sleep.latency)
```

```

ad.test(subset(SSdata, intervention == "sham")$sleep.latency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$sleep.latency
## A = 1.0478, p-value = 0.007272

#Non-normal - perform non-parametric test (Wilcoxon)
#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$sleep.latency,
            subset(SSdata, intervention == "PrenaBelt")$sleep.latency,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sleep.latency, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sleep.latency, : cannot compute exact confidence intervals with ties

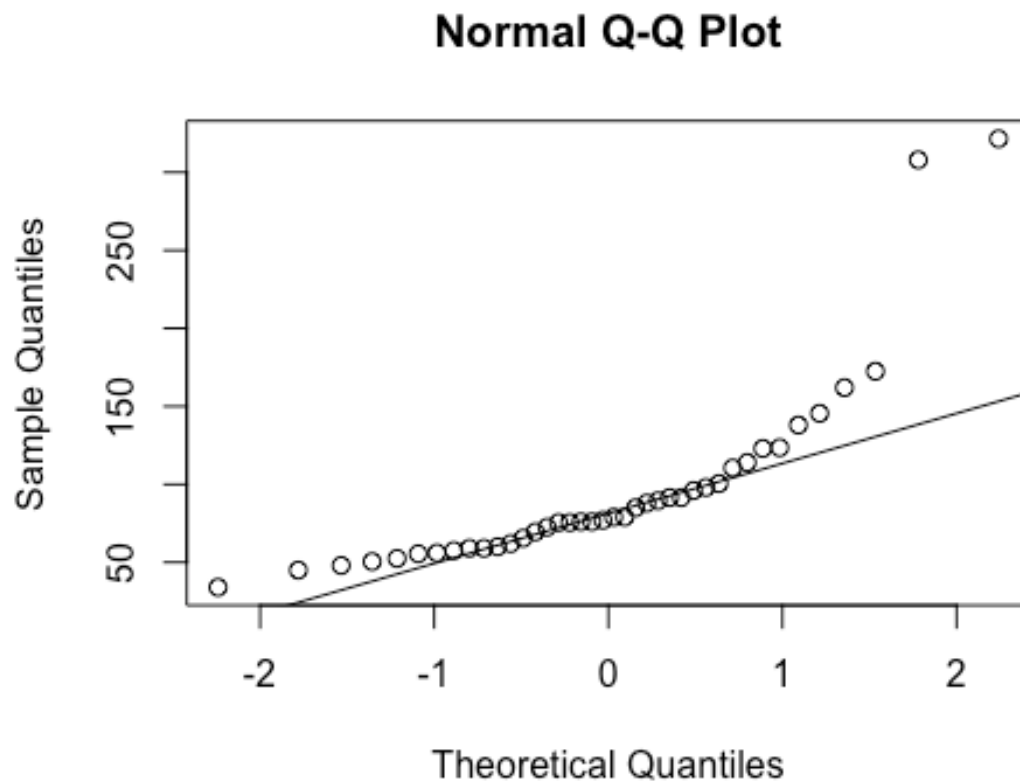
##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$sleep.latency and subset(SSd

```

```

1
2
3 ata, intervention == "PrenaBelt")$sleep.latency
4 ## W = 214, p-value = 0.715
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -5.700008 10.099985
8 ## sample estimates:
9 ## difference in location
10 ## 1.01358
11
12 #####REM Latency#####
13 #FYI: this data was generated in our PSG reports per default configuration but is not a
14 #pre-specified secondary outcome per the research protocol or trial registry.
15 FYI only.
16 #Summary
17 summary(SSdata$rem.latency)
18
19 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
20 ## 34.00  59.75   78.00   96.08 103.00  321.50
21
22 sd(SSdata$rem.latency, na.rm = TRUE)
23
24 ## [1] 59.89655
25
26 length(SSdata$rem.latency)
27
28 ## [1] 40
29
30 qqnorm(SSdata$rem.latency)
31 qqline(SSdata$rem.latency)
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(SSdata$rem.latency)

##
## Anderson-Darling normality test
##
## data:  SSdata$rem.latency
## A = 3.4165, p-value = 1.043e-08
##
#non-normal

#ANOVA
night_tx_difference <- anova(lm(rem.latency ~ intervention*night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: rem.latency
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1   4580   4579.6   1.2379  0.2732
## night           1   1974   1974.0   0.5336  0.4698
## intervention:night 1    185    184.9   0.0500  0.8244
## Residuals      36 133178   3699.4

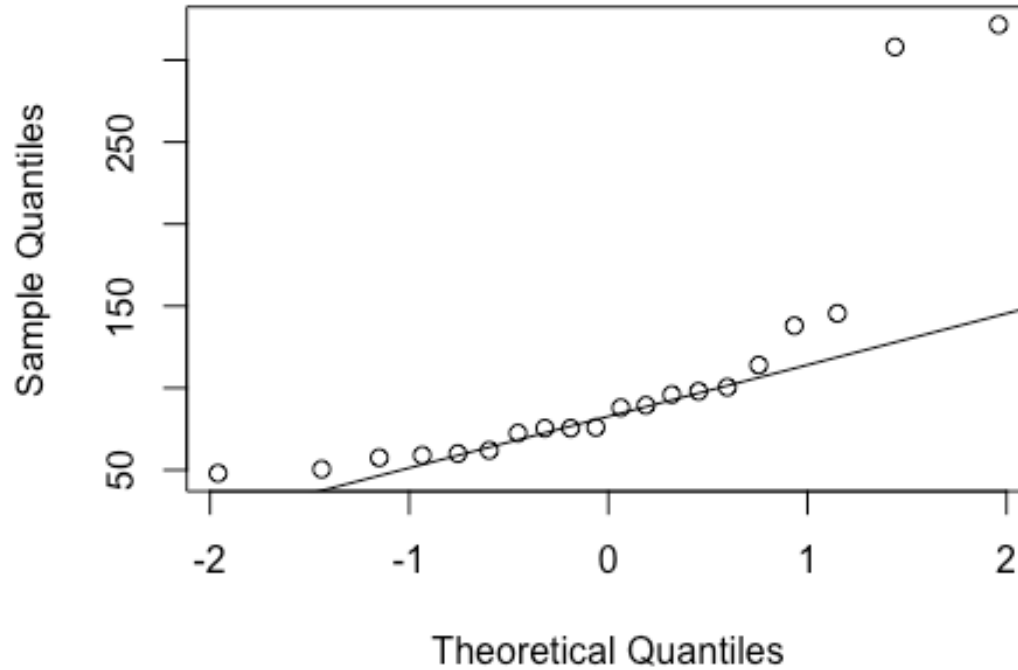
```

```

1
2
3
4 #within-participants (paired) comparison
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$rem.latency,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$rem.latency,
7             paired = TRUE, conf.int = TRUE)
8
9 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
10 ## "sham")$rem.latency, : cannot compute exact p-value with ties
11
12 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13 ## "sham")$rem.latency, : cannot compute exact confidence interval with ties
14
15 ##
16 ## Wilcoxon signed rank test with continuity correction
17 ##
18 ## data: subset(SSdataCompletes, intervention == "sham")$rem.latency and sub
19 ## set(SSdataCompletes, intervention == "PrenaBelt")$rem.latency
20 ## V = 80.5, p-value = 0.37
21 ## alternative hypothesis: true location shift is not equal to 0
22 ## 95 percent confidence interval:
23 ## -35.50005 17.50006
24 ## sample estimates:
25 ## (pseudo)median
26 ## -5.190503
27
28 #between participants (grouped) comparison
29 summary(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
30
31 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
32 ##      48.0   61.5   82.0   106.8  103.9   321.5
33
34 sd(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
35
36 ## [1] 75.95402
37
38 length(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
39
40 ## [1] 20
41
42 qqnorm(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
43 qqline(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$rem.latency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$rem.latency
## A = 2.5226, p-value = 1.24e-06

#non-normal

summary(subset(SSdata, intervention == "sham")$rem.latency)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  34.00  58.25   78.00   85.38  96.25  172.50

sd(subset(SSdata, intervention == "sham")$rem.latency)

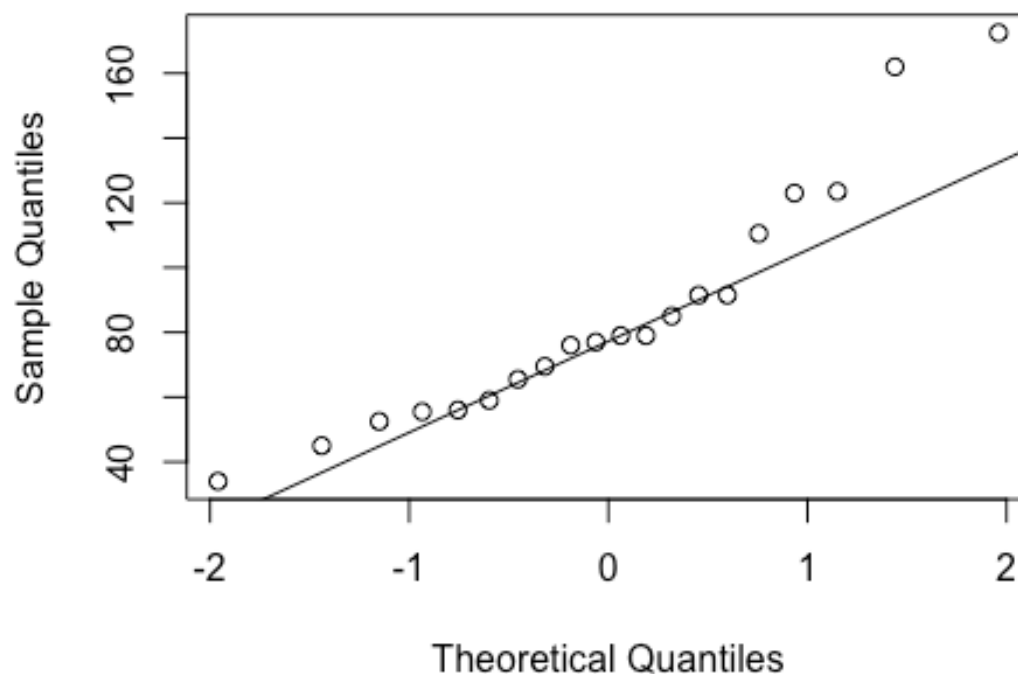
## [1] 36.79634

length(subset(SSdata, intervention == "sham")$rem.latency)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$rem.latency)
qqline(subset(SSdata, intervention == "sham")$rem.latency)
```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$rem.latency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$rem.latency
## A = 0.68703, p-value = 0.06153

#Non-normal - perform non-parametric test (Wilcoxon)
#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$rem.latency,
            subset(SSdata, intervention == "PrenaBelt")$rem.latency,
            conf.int = TRUE)

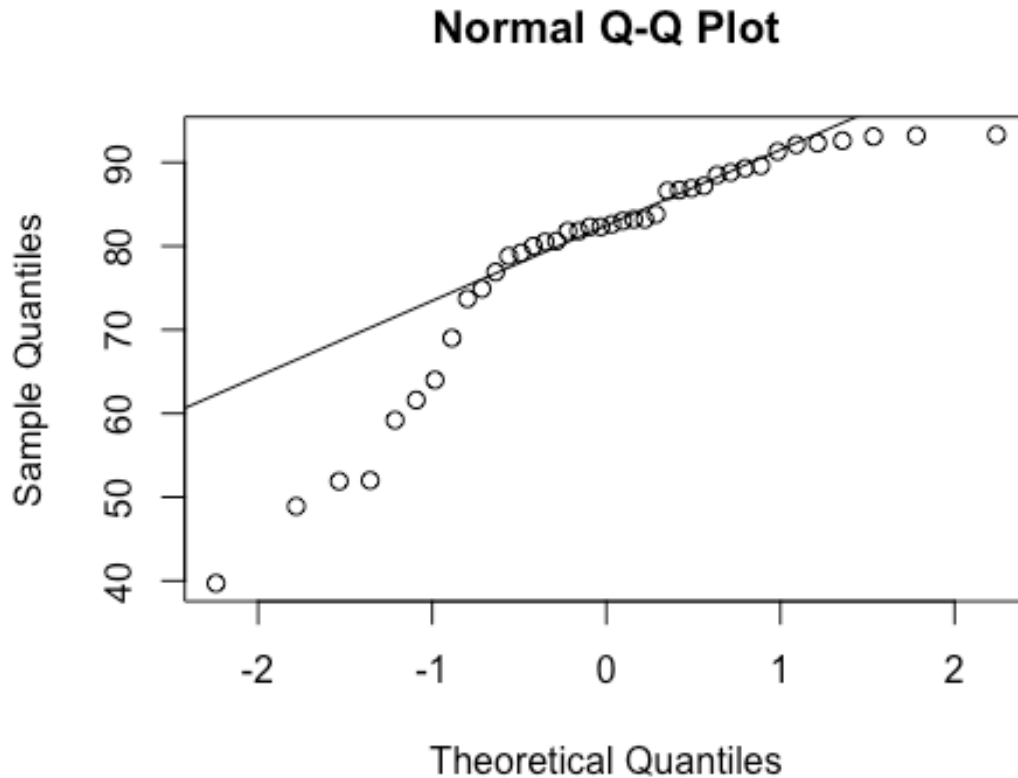
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $rem.latency, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $rem.latency, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$rem.latency and subset(SSdat

```

```
1
2
3 a, intervention == "PrenaBelt")$rem.latency
4 ## W = 178, p-value = 0.5608
5 ## alternative hypothesis: true location shift is not equal to 0
6 ## 95 percent confidence interval:
7 ## -27.50004 15.50003
8 ## sample estimates:
9 ## difference in location
10 ## -6.499973
11
12 #####Sleep Efficiency#####
13 #Summary
14 summary(SSdata$sleep.efficiency)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ## 39.70  76.40  82.45  79.16  88.58  93.30
18
19 sd(SSdata$sleep.efficiency, na.rm = TRUE)
20
21 ## [1] 13.44863
22
23 length(SSdata$sleep.efficiency)
24
25 ## [1] 40
26
27 qqnorm(SSdata$sleep.efficiency)
28 qqline(SSdata$sleep.efficiency)
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(SSdata$sleep. efficiency)

##
## Anderson-Darling normality test
##
## data:  SSdata$sleep. efficiency
## A = 2.2288, p-value = 9.251e-06

#non-normal

#ANOVA
night_tx_difference <- anova(lm(sleep. efficiency ~ intervention*night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: sleep. efficiency
##
##          Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1   42.0   42.025    0.2179  0.6435
## night           1   36.1   36.100    0.1872  0.6679
## intervention:night 1   32.0   32.041    0.1661  0.6860
## Residuals      36 6943.6  192.877

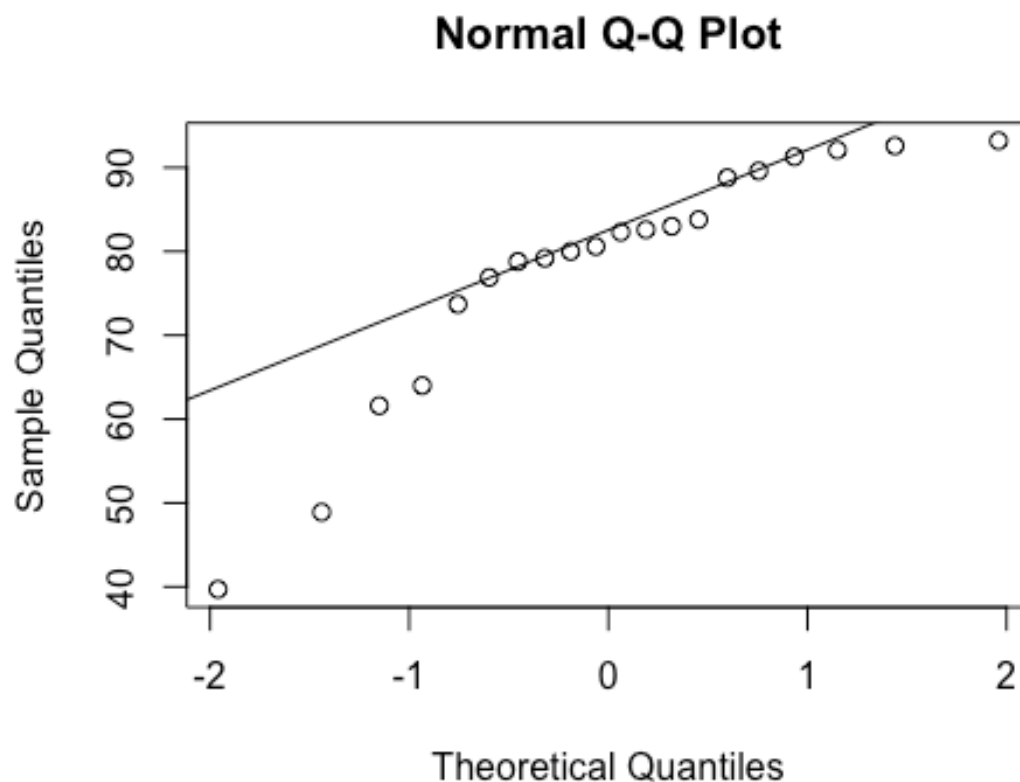
```



```

1
2
3 #within-participants (paired) comparison
4 wilcox.test(subset(SSdataCompletes, intervention == "sham")$sleep.efficiency,
5             subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.efficiency,
6             paired = TRUE, conf.int = TRUE)
7
8 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
9 ## "sham")$sleep.efficiency, : cannot compute exact p-value with ties
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$sleep.efficiency, : cannot compute exact confidence interval with
13 ## ties
14
15 ##
16 ## Wilcoxon signed rank test with continuity correction
17 ##
18 ## data: subset(SSdataCompletes, intervention == "sham")$sleep.efficiency an
19 d subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.efficiency
20 ## V = 125.5, p-value = 0.4552
21 ## alternative hypothesis: true location shift is not equal to 0
22 ## 95 percent confidence interval:
23 ## -3.000041 5.899953
24 ## sample estimates:
25 ## (pseudo)median
26 ## 1.444485
27
28 #between participants (grouped) comparison
29 summary(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
30
31 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
32 ## 39.70  76.10  81.45  78.14  89.00  93.20
33
34 sd(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
35
36 ## [1] 14.47362
37
38 length(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
39
40 ## [1] 20
41
42 qqnorm(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
43 qqline(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency
## A = 1.0955, p-value = 0.005485

#non-normal

summary(subset(SSdata, intervention == "sham")$sleep.efficiency)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  51.90   79.10   83.20   80.18   87.52   93.30

sd(subset(SSdata, intervention == "sham")$sleep.efficiency)

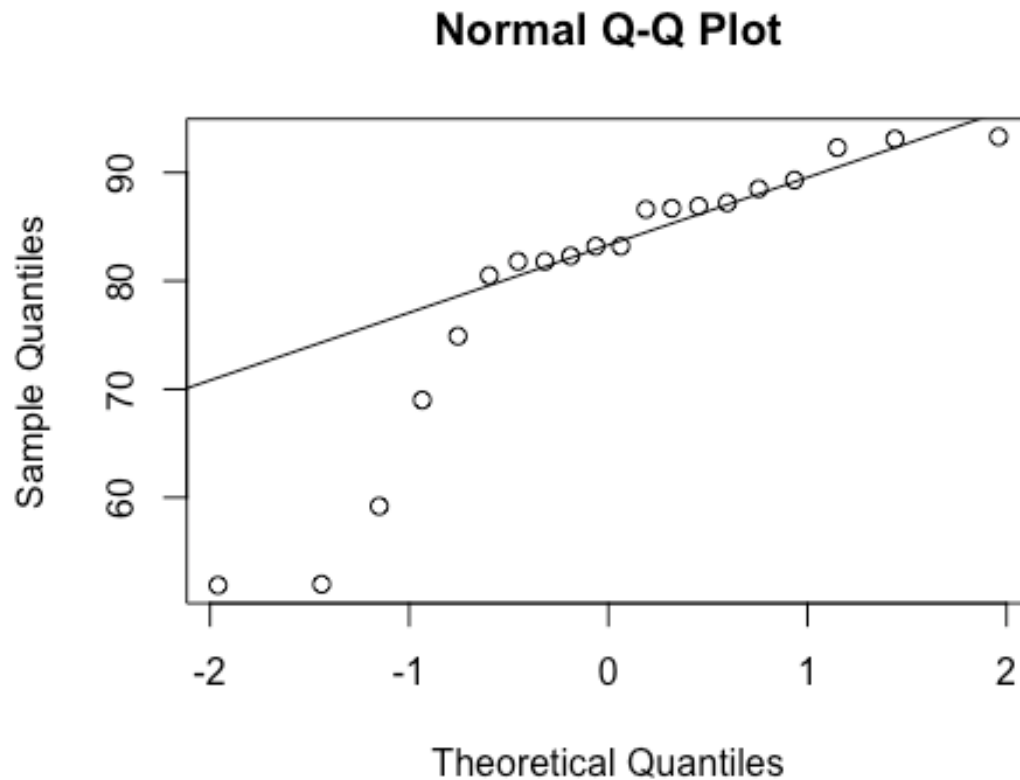
## [1] 12.63143

length(subset(SSdata, intervention == "sham")$sleep.efficiency)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$sleep.efficiency)
qqline(subset(SSdata, intervention == "sham")$sleep.efficiency)

```



```

ad.test(subset(SSdata, intervention == "sham")$sleep.efficiency)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$sleep.efficiency
## A = 1.4349, p-value = 0.0007392

#non-normal

#Non-normal - perform non-parametric test (Wilcoxon)
#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$sleep.efficiency,
            subset(SSdata, intervention == "PrenaBeIt")$sleep.efficiency,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sleep.efficiency, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sleep.efficiency, : cannot compute exact confidence intervals with ties

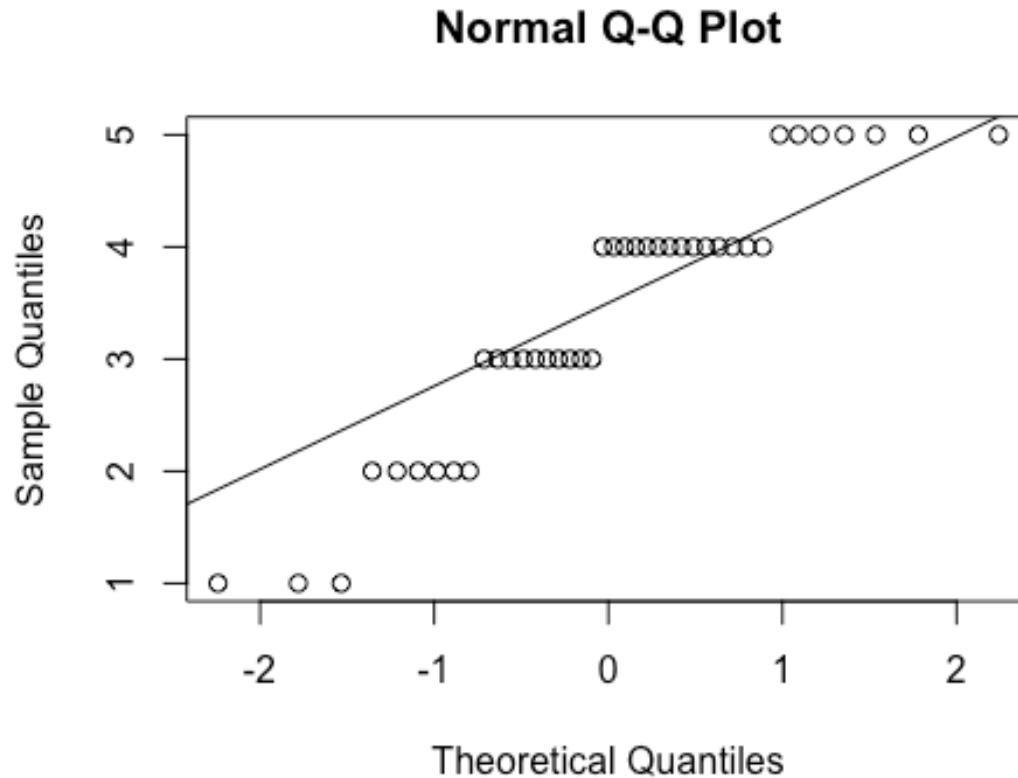
##
## Wilcoxon rank sum test with continuity correction

```

```

1
2
3
4  ##
5  ## data: subset(SSdata, intervention == "sham")$sleep.efficiency and subset(
6  SSdata, intervention == "PrenaBelt")$sleep.efficiency
7  ## W = 222.5, p-value = 0.5517
8  ## alternative hypothesis: true location shift is not equal to 0
9  ## 95 percent confidence interval:
10 ## -4.800018  7.900004
11 ## sample estimates:
12 ## difference in location
13 ##          1.799971
14
15 #####Number of REM Periods#####
16 #FYI: this data was generated in our PSG reports per default configuration but is not a
17 #pre-specified secondary outcome per the research protocol or trial registry.
18 FYI only.
19 #Summary
20 summary(SSdata$num.rem.periods)
21
22
23 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
24 ##      1.0     3.0     4.0     3.4     4.0     5.0
25
26 sd(SSdata$num.rem.periods, na.rm = TRUE)
27
28 ## [1] 1.172331
29
30 length(SSdata$num.rem.periods)
31
32 ## [1] 40
33
34 qqnorm(SSdata$num.rem.periods)
35 qqline(SSdata$num.rem.periods)
36
37
38
39
40
41
42
43
44
45
46
47
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52
53
54
55
56
57
58
59
60

```



```
ad.test(SSdata$num.rem.periods)

##
## Anderson-Darling normality test
##
## data:  SSdata$num.rem.periods
## A = 1.5069, p-value = 0.000588

#Looks non-normal, but it is ordinal data

#ANOVA
night_tx_difference <- anova(lm(num.rem.periods ~ intervention*night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: num.rem.periods
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    0.4  0.4000   0.2903 0.5933
## night           1    3.6  3.6000   2.6129 0.1147
## intervention:night 1    0.0  0.0000   0.0000 1.0000
## Residuals      36   49.6  1.3778
```

```

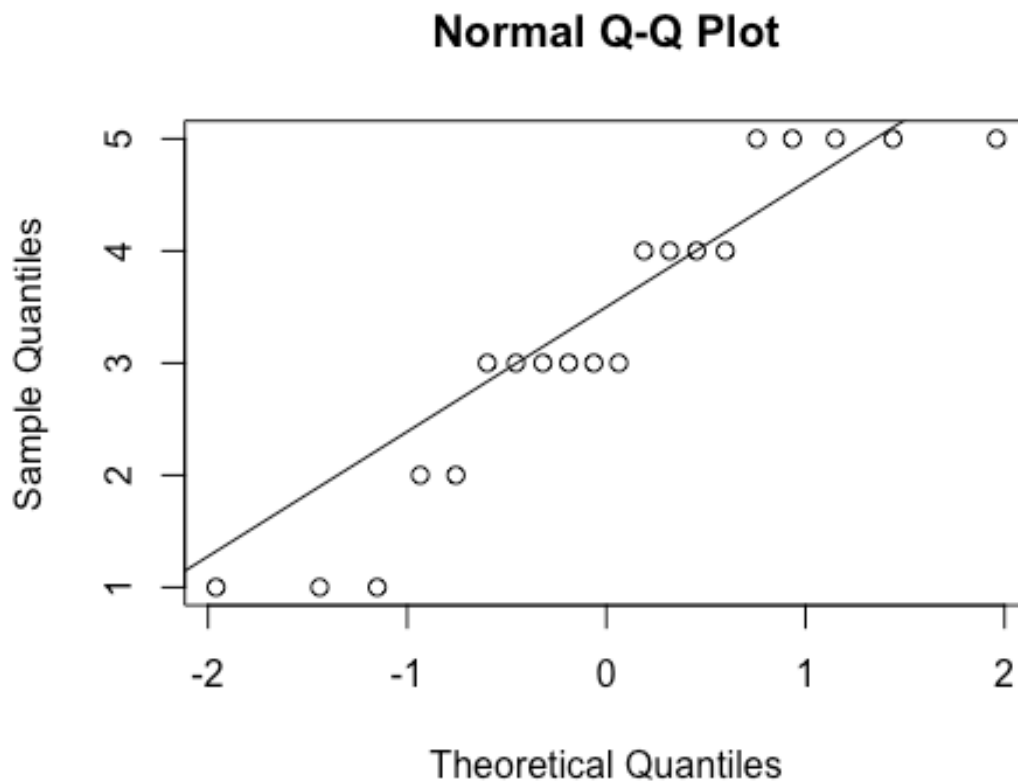
1
2
3 #within-participants (paired) comparison
4 t.test(subset(SSdataCompletes, intervention == "sham")$num.rem.periods,
5       subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods,
6       paired = TRUE)
7
8 ##
9 ## Paired t-test
10 ##
11 ## data: subset(SSdataCompletes, intervention == "sham")$num.rem.periods and
12 subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods
13 ## t = 0.80943, df = 19, p-value = 0.4283
14 ## alternative hypothesis: true difference in means is not equal to 0
15 ## 95 percent confidence interval:
16 ## -0.3171618  0.7171618
17 ## sample estimates:
18 ## mean of the differences
19 ##
20 ##          0.2
21
22 wilcox.test(subset(SSdataCompletes, intervention == "sham")$num.rem.periods,
23            subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods,
24            paired = TRUE, conf.int = TRUE)
25
26 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
27 ## "sham")$num.rem.periods, : cannot compute exact p-value with ties
28
29 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
30 ## "sham")$num.rem.periods, : cannot compute exact confidence interval with
31 ## ties
32
33 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
34 ## "sham")$num.rem.periods, : cannot compute exact p-value with zeroes
35
36 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
37 ## "sham")$num.rem.periods, : cannot compute exact confidence interval with
38 ## zeroes
39
40 ##
41 ## Wilcoxon signed rank test with continuity correction
42 ##
43 ## data: subset(SSdataCompletes, intervention == "sham")$num.rem.periods and
44 subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods
45 ## V = 73.5, p-value = 0.432
46 ## alternative hypothesis: true location shift is not equal to 0
47 ## 95 percent confidence interval:
48 ## -0.4999577  1.0000552
49 ## sample estimates:
50 ## (pseudo)median
51 ## 4.422455e-05
52
53 #between participants (grouped) comparison
54 summary(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
55
56
57
58
59
60

```

```

1
2
3  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4  ##      1.00   2.75   3.00   3.30   4.25   5.00
5
6  sd(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
7
8  ## [1] 1.380313
9
10 length(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
11
12 ## [1] 20
13
14 qqnorm(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
15 qqline(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
16
17
18
19
20
21

```



```

22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45  ad.test(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
46
47  ##
48  ## Anderson-Darling normality test
49  ##
50  ## data: subset(SSdata, intervention == "PrenaBelt")$num.rem.periods
51  ## A = 0.72773, p-value = 0.04835
52
53  #non-normal (ordinal data not held well by q-q plots)
54
55  summary(subset(SSdata, intervention == "sham")$num.rem.periods)
56
57
58
59
60

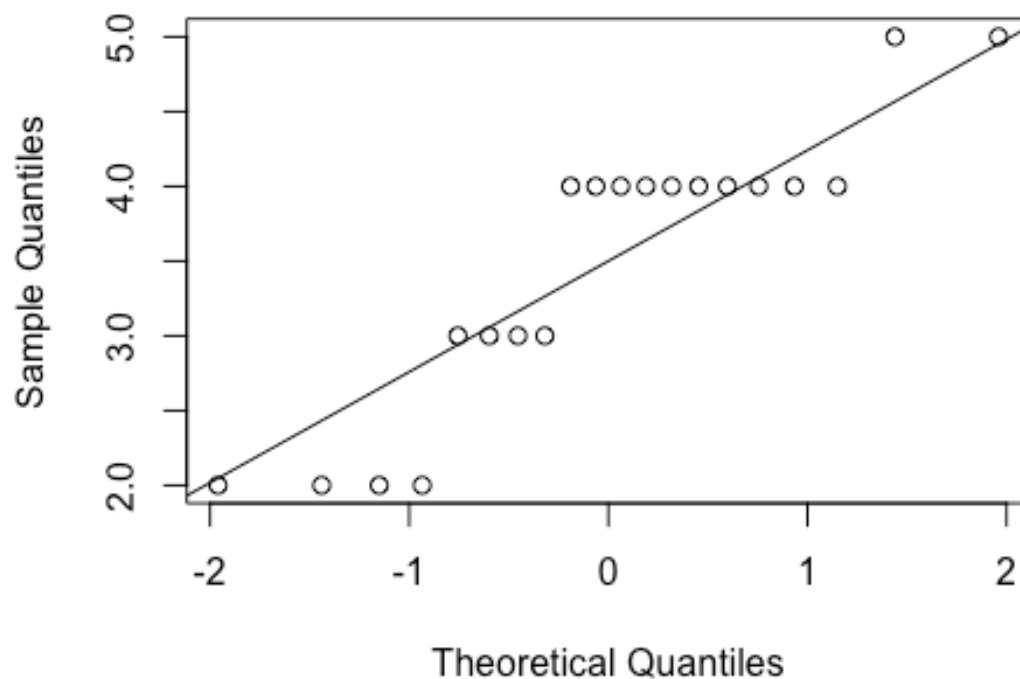
```

```

1
2
3  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4  ##      2.0    3.0    4.0    3.5    4.0    5.0
5
6  sd(subset(SSdata, intervention == "sham")$num.rem.periods)
7
8  ## [1] 0.9459053
9
10 length(subset(SSdata, intervention == "sham")$num.rem.periods)
11
12 ## [1] 20
13
14 qqnorm(subset(SSdata, intervention == "sham")$num.rem.periods)
15 qqline(subset(SSdata, intervention == "sham")$num.rem.periods)
16
17
18
19
20
21

```

Normal Q-Q Plot



```

22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45  ad.test(subset(SSdata, intervention == "sham")$num.rem.periods)
46
47  ##
48  ## Anderson-Darling normality test
49  ##
50  ## data: subset(SSdata, intervention == "sham")$num.rem.periods
51  ## A = 1.4725, p-value = 0.0005924
52
53  #non-normal (ordinal data not held well by q-q plots)
54
55  #FYI - unpaired test
56
57
58
59
60

```



```

1
2
3 t.test(subset(SSdata, intervention == "sham")$num.rem.periods,
4         subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
5
6 ##
7 ## Welch Two Sample t-test
8 ##
9 ## data: subset(SSdata, intervention == "sham")$num.rem.periods and subset(S
10 Sdata, intervention == "PrenaBelt")$num.rem.periods
11 ## t = 0.53452, df = 33.621, p-value = 0.5965
12 ## alternative hypothesis: true difference in means is not equal to 0
13 ## 95 percent confidence interval:
14 ## -0.5607122 0.9607122
15 ## sample estimates:
16 ## mean of x mean of y
17 ## 3.5 3.3
18
19
20 wilcox.test(subset(SSdata, intervention == "sham")$num.rem.periods,
21             subset(SSdata, intervention == "PrenaBelt")$num.rem.periods,
22             conf.int = TRUE)
23
24 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
25 ## $num.rem.periods, : cannot compute exact p-value with ties
26
27 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
28 ## $num.rem.periods, : cannot compute exact confidence intervals with ties
29
30 ##
31 ## Wilcoxon rank sum test with continuity correction
32 ##
33 ## data: subset(SSdata, intervention == "sham")$num.rem.periods and subset(S
34 Sdata, intervention == "PrenaBelt")$num.rem.periods
35 ## W = 213, p-value = 0.7263
36 ## alternative hypothesis: true location shift is not equal to 0
37 ## 95 percent confidence interval:
38 ## -0.9999963 1.0000309
39 ## sample estimates:
40 ## difference in location
41 ## 1.121393e-06
42
43 #####Number of Stage Shifts#####
44 #FYI: this data was generated in our PSG reports per default configuration bu
45 t is not a
46 #pre-specified secondary outcome per the research protocol or trial registry.
47 FYI only.
48 #Summary
49 summary(SSdata$num.stage.shifts)
50
51 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
52 ## 43.00 72.75 96.50 105.20 133.80 183.00
53
54
55 sd(SSdata$num.stage.shifts, na.rm = TRUE)
56
57
58
59
60

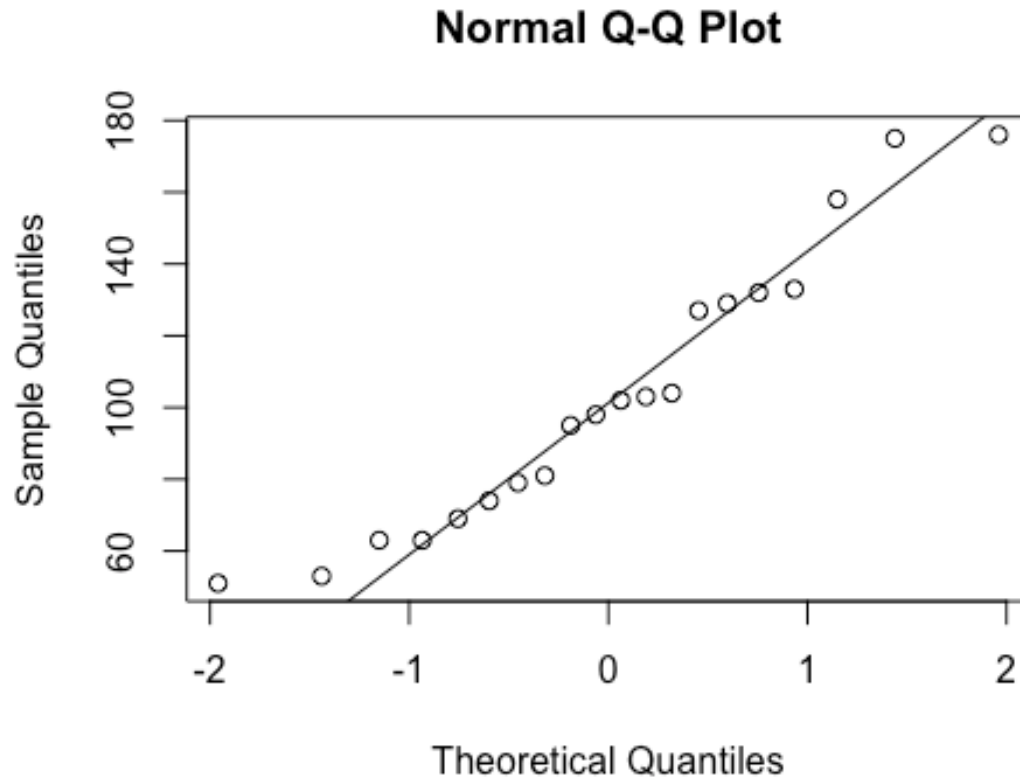
```

```

1
2
3 ## [1] 39.29043
4
5 length(SSdata$num.stage.shifts)
6
7 ## [1] 40
8
9 #ANOVA
10 night_tx_difference <- anova(lm(num.stage.shifts ~ intervention*night,
11                               data = SSdata))
12
13 night_tx_difference
14
15 ## Analysis of Variance Table
16 ##
17 ## Response: num.stage.shifts
18 ##           Df Sum Sq Mean Sq F value Pr(>F)
19 ## intervention      1    148   148.22   0.0912  0.7644
20 ## night              1     60    60.03   0.0369  0.8487
21 ## intervention:night  1   1501  1500.63   0.9235  0.3430
22 ## Residuals        36  58497  1624.91
23
24 #within-participants (paired) comparison
25 #Paired t-test
26 t.test(subset(SSdataCompletes, intervention == "sham")$num.stage.shifts,
27        subset(SSdataCompletes, intervention == "PrenaBelt")$num.stage.shifts,
28        paired = TRUE)
29
30 ##
31 ## Paired t-test
32 ##
33 ## data: subset(SSdataCompletes, intervention == "sham")$num.stage.shifts an
34 d subset(SSdataCompletes, intervention == "PrenaBelt")$num.stage.shifts
35 ## t = 0.77738, df = 19, p-value = 0.4465
36 ## alternative hypothesis: true difference in means is not equal to 0
37 ## 95 percent confidence interval:
38 ##  -6.515809 14.215809
39 ## sample estimates:
40 ## mean of the differences
41 ##           3.85
42
43 #between participants (grouped) comparison
44 summary(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
45
46 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
47 ##  51.00  72.75  100.00  103.20  129.80  176.00
48
49 sd(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
50
51 ## [1] 38.44459
52
53 length(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
54
55 ## [1] 20
56
57
58
59
60

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
qqline(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts
## A = 0.40309, p-value = 0.3245

#normal

summary(subset(SSdata, intervention == "sham")$num.stage.shifts)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  43.00   80.25   95.00  107.10  147.80  183.00

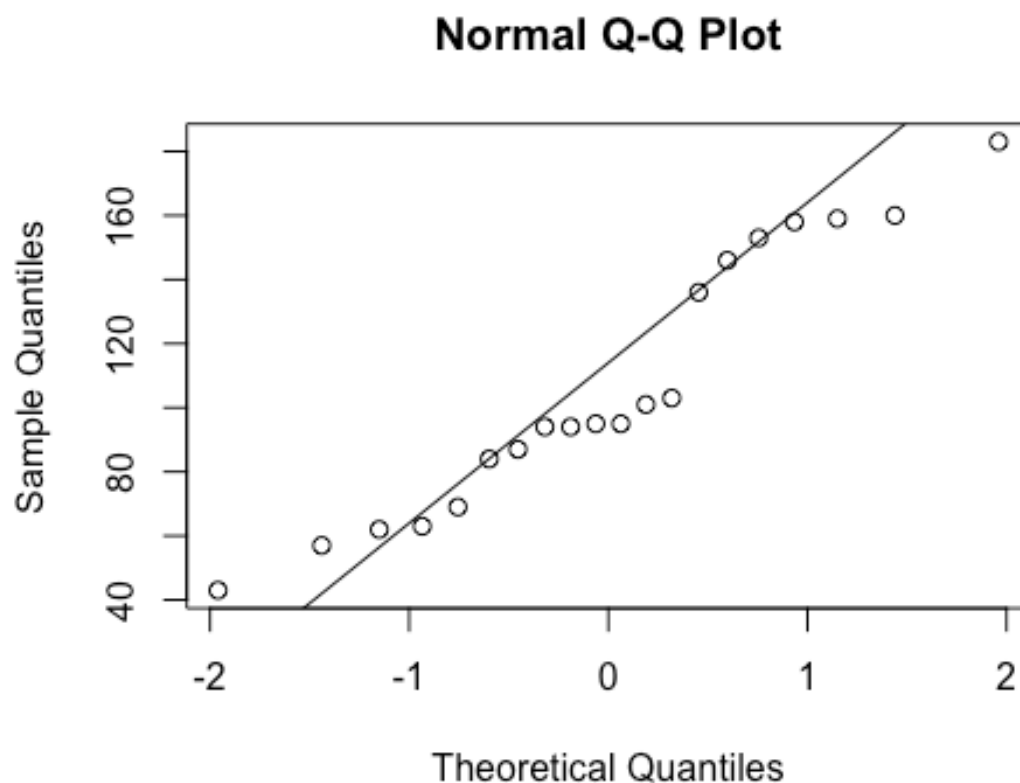
sd(subset(SSdata, intervention == "sham")$num.stage.shifts)

## [1] 41.02361

length(subset(SSdata, intervention == "sham")$num.stage.shifts)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$num.stage.shifts)
qqline(subset(SSdata, intervention == "sham")$num.stage.shifts)
```



```
ad.test(subset(SSdata, intervention == "sham")$num.stage.shifts)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$num.stage.shifts
## A = 0.64165, p-value = 0.08053

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$num.stage.shifts,
       subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$num.stage.shifts and subset(
SSdata, intervention == "PrenaBelt")$num.stage.shifts
## t = 0.30624, df = 37.841, p-value = 0.7611
## alternative hypothesis: true difference in means is not equal to 0
```

```

1
2
3 ## 95 percent confidence interval:
4 ## -21.60347 29.30347
5 ## sample estimates:
6 ## mean of x mean of y
7 ## 107.10 103.25
8
9 #####Awakenings#####
10 #FYI: this data was generated in our PSG reports per default configuration but is not a
11 #pre-specified secondary outcome per the research protocol or trial registry.
12 FYI only.
13 #Summary
14 summary(SSdata$awakenings)
15
16 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
17 ## 10.00 14.75 19.00 19.70 24.25 32.00
18
19 sd(SSdata$awakenings, na.rm = TRUE)
20
21 ## [1] 6.329418
22
23 length(SSdata$awakenings)
24
25 ## [1] 40
26
27 #ANOVA
28 night_tx_difference <- anova(lm(awakenings ~ intervention*night,
29 data = SSdata))
30
31 night_tx_difference
32
33 ## Analysis of Variance Table
34 ##
35 ## Response: awakenings
36 ##
37 ## Df Sum Sq Mean Sq F value Pr(>F)
38 ## intervention 1 2.5 2.50 0.0589 0.8096
39 ## night 1 19.6 19.60 0.4617 0.5012
40 ## intervention:night 1 12.1 12.10 0.2850 0.5967
41 ## Residuals 36 1528.2 42.45
42
43 #within-participants (paired) comparison
44 #Paired t-test
45 t.test(subset(SSdataCompletes, intervention == "sham")$awakenings,
46 subset(SSdataCompletes, intervention == "PrenaBelt")$awakenings,
47 paired = TRUE)
48
49 ##
50 ## Paired t-test
51 ##
52 ## data: subset(SSdataCompletes, intervention == "sham")$awakenings and subset(SSdataCompletes, intervention == "PrenaBelt")$awakenings
53 ## t = 0.38863, df = 19, p-value = 0.7019
54 ## alternative hypothesis: true difference in means is not equal to 0
55
56
57
58
59
60

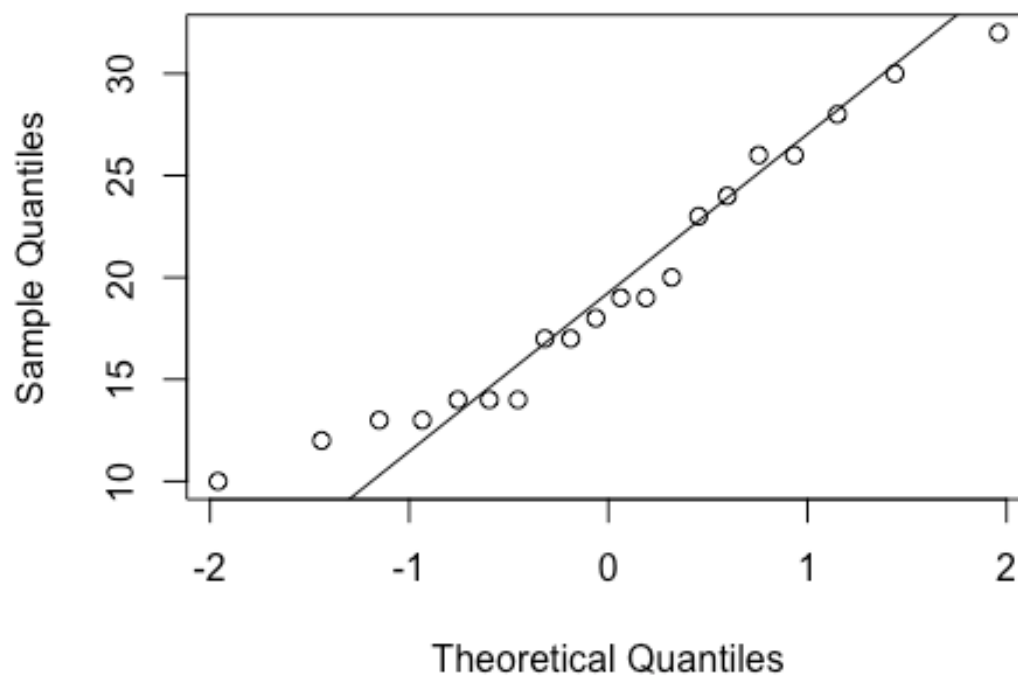
```

```

1
2
3  ## 95 percent confidence interval:
4  ## -2.192823  3.192823
5  ## sample estimates:
6  ## mean of the differences
7  ##           0.5
8
9  #between participants (grouped) comparison
10 summary(subset(SSdata, intervention == "PrenaBelt")$awakenings)
11
12  ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
13  ##  10.00  14.00  18.50  19.45  24.50  32.00
14
15 sd(subset(SSdata, intervention == "PrenaBelt")$awakenings)
16
17  ## [1] 6.460202
18
19 length(subset(SSdata, intervention == "PrenaBelt")$awakenings)
20
21  ## [1] 20
22
23 qqnorm(subset(SSdata, intervention == "PrenaBelt")$awakenings)
24 qqline(subset(SSdata, intervention == "PrenaBelt")$awakenings)
25

```

Normal Q-Q Plot



```

55 ad.test(subset(SSdata, intervention == "PrenaBelt")$awakenings)
56
57
58
59
60

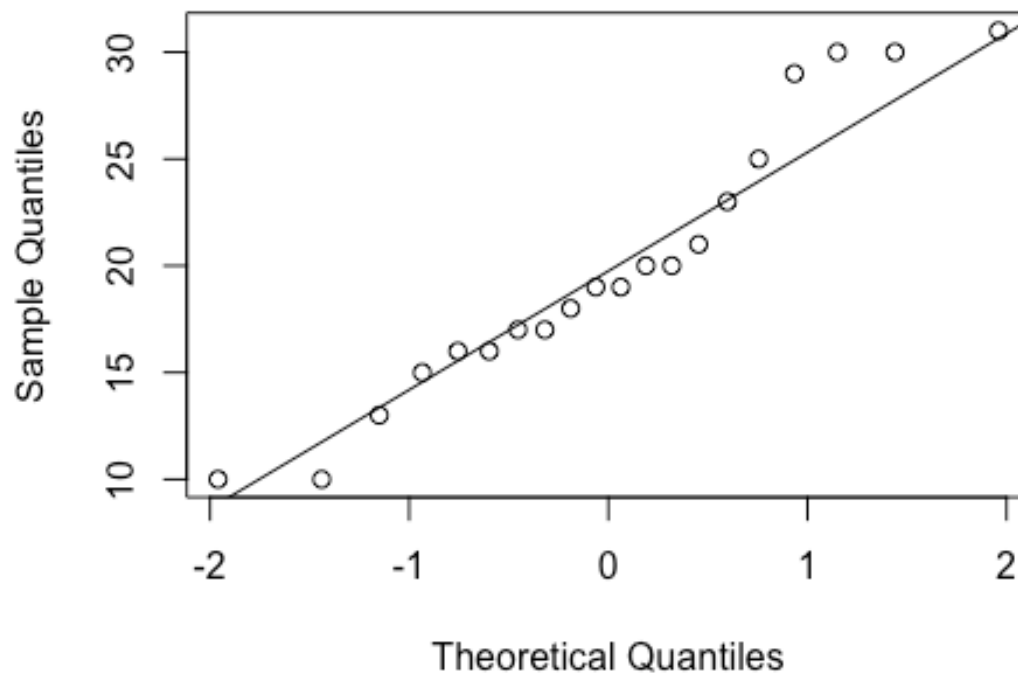
```

```

1
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data: subset(SSdata, intervention == "PrenaBelt")$awakenings
7  ## A = 0.44596, p-value = 0.2537
8
9  #normal
10
11 summary(subset(SSdata, intervention == "sham")$awakenings)
12
13 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14 ##      10.00  16.00   19.00   19.95  23.50   31.00
15
16 sd(subset(SSdata, intervention == "sham")$awakenings)
17
18 ## [1] 6.353408
19
20 length(subset(SSdata, intervention == "sham")$awakenings)
21
22 ## [1] 20
23
24 qqnorm(subset(SSdata, intervention == "sham")$awakenings)
25 qqline(subset(SSdata, intervention == "sham")$awakenings)
26
27
28
29
30
31
32

```

Normal Q-Q Plot



```

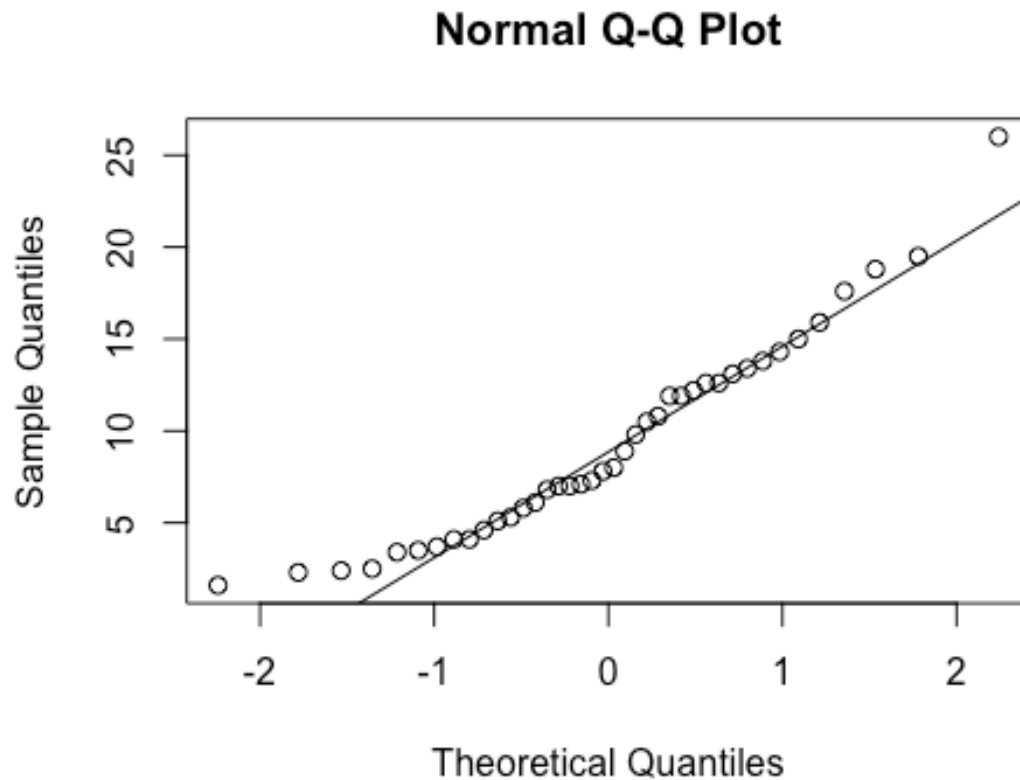
56 ad.test(subset(SSdata, intervention == "sham")$awakenings)
57
58
59
60

```

```

1
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data: subset(SSdata, intervention == "sham")$awakenings
7  ## A = 0.47198, p-value = 0.2179
8
9  #normal
10
11 #FYI - unpaired test
12 t.test(subset(SSdata, intervention == "sham")$awakenings,
13        subset(SSdata, intervention == "PrenaBelt")$awakenings)
14
15 ##
16 ## Welch Two Sample t-test
17 ##
18 ## data: subset(SSdata, intervention == "sham")$awakenings and subset(SSdata
19 , intervention == "PrenaBelt")$awakenings
20 ## t = 0.24678, df = 37.989, p-value = 0.8064
21 ## alternative hypothesis: true difference in means is not equal to 0
22 ## 95 percent confidence interval:
23 ## -3.601622  4.601622
24 ## sample estimates:
25 ## mean of x mean of y
26 ##      19.95      19.45
27
28 ##### % Stage 1 Sleep #####
29 #Summary
30 summary(SSdata$Pstage.1)
31
32 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
33 ##      1.600  4.975   7.900   9.353 12.720  26.000
34
35 sd(SSdata$Pstage.1, na.rm = TRUE)
36
37 ## [1] 5.561267
38
39 length(SSdata$Pstage.1)
40
41 ## [1] 40
42
43 qqnorm(SSdata$Pstage.1)
44 qqline(SSdata$Pstage.1)
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

```

ad.test(SSdata$Pstage.1)

##
## Anderson-Darling normality test
##
## data:  SSdata$Pstage.1
## A = 0.60276, p-value = 0.1097

#normal

#ANOVA
night_tx_difference <- anova(lm(Pstage.1 ~ intervention*night,
                               data = SSdata))
night_tx_difference

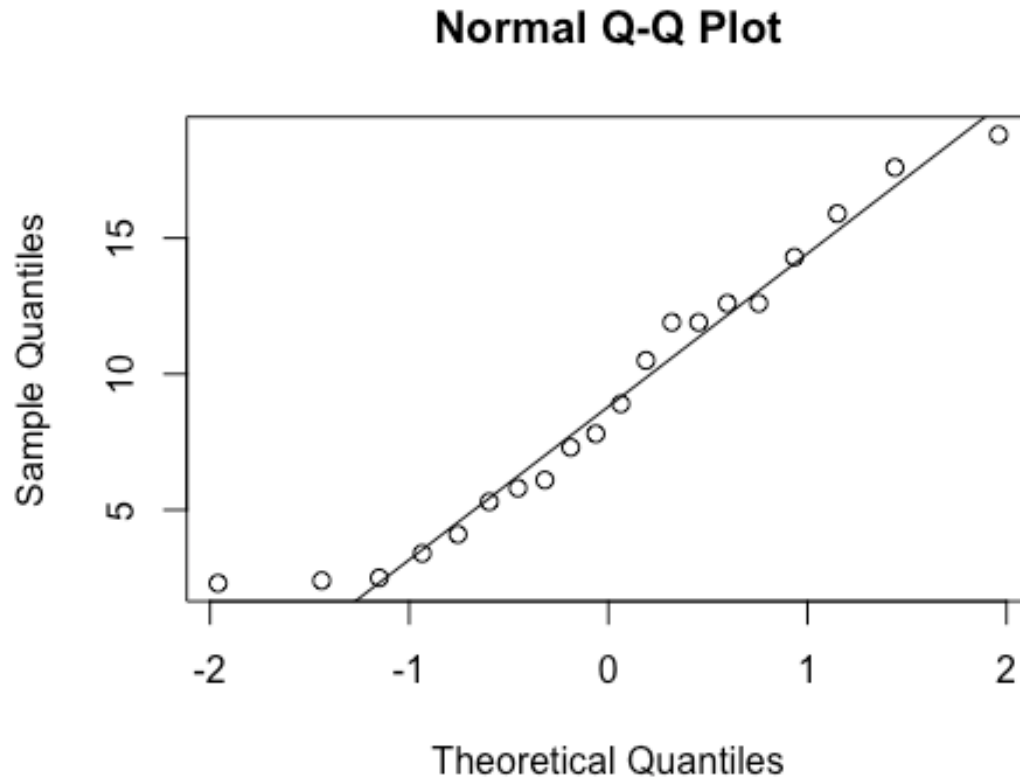
## Analysis of Variance Table
##
## Response: Pstage.1
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    2.55    2.550   0.0778 0.7819
## night           1   11.77   11.772   0.3593 0.5527
## intervention:night 1   12.21   12.210   0.3726 0.5454
## Residuals     36 1179.65   32.768

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired t-test
5 t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.1,
6        subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.1,
7        paired = TRUE)
8
9 ##
10 ## Paired t-test
11 ##
12 ## data: subset(SSdataCompletes, intervention == "sham")$Pstage.1 and subset
13 (SSdataCompletes, intervention == "PrenaBelt")$Pstage.1
14 ## t = 0.59457, df = 19, p-value = 0.5591
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -1.272708 2.282708
18 ## sample estimates:
19 ## mean of the differences
20 ## 0.505
21
22
23 #between participants (grouped) comparison
24 summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
25
26 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##      2.30   5.00   8.35   9.10  12.60  18.80
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
30
31 ## [1] 5.197368
32
33 length(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
34
35 ## [1] 20
36
37 qqnorm(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
38 qqline(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$Pstage.1
## A = 0.34971, p-value = 0.4374

#normal

summary(subset(SSdata, intervention == "sham")$Pstage.1)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  1.600  4.975   7.550   9.605 13.180  26.000

sd(subset(SSdata, intervention == "sham")$Pstage.1)

## [1] 6.027959

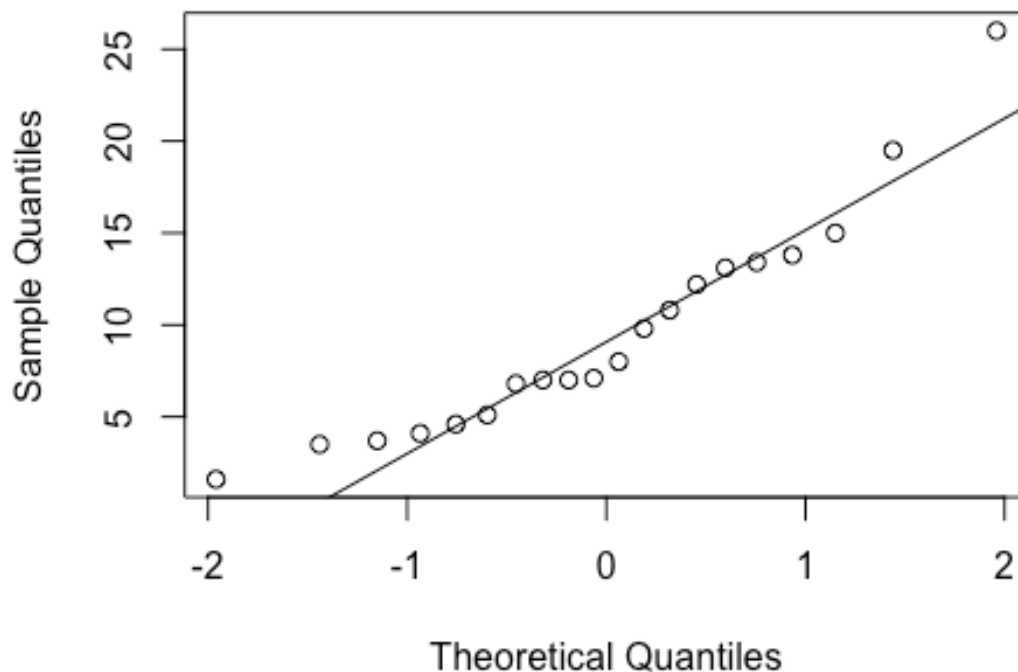
length(subset(SSdata, intervention == "sham")$Pstage.1)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$Pstage.1)
qqline(subset(SSdata, intervention == "sham")$Pstage.1)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$Pstage.1)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$Pstage.1
## A = 0.55353, p-value = 0.1336

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$Pstage.1,
       subset(SSdata, intervention == "PrenaBelt")$Pstage.1)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$Pstage.1 and subset(SSdata,
## intervention == "PrenaBelt")$Pstage.1
## t = 0.28375, df = 37.194, p-value = 0.7782
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -3.100444 4.110444
## sample estimates:

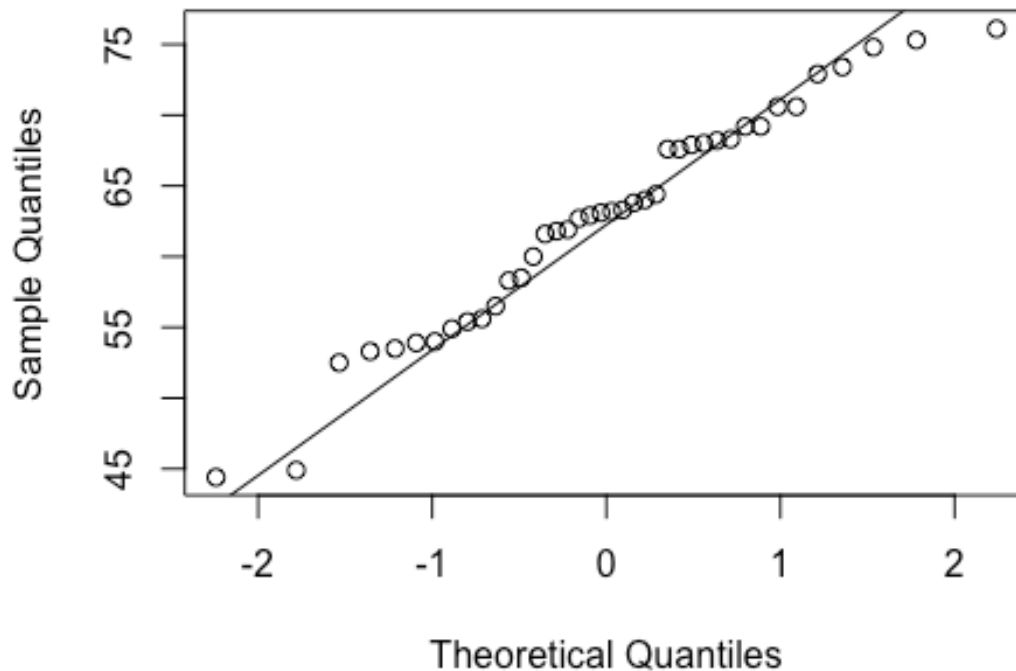
```

```

1
2
3 ## mean of x mean of y
4 ##      9.605      9.100
5
6 ##### % Stage 2 Sleep #####
7 #Summary
8 summary(SSdata$Pstage.2)
9
10 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11 ##      44.40  56.28   63.15   62.70  68.23   76.10
12
13 sd(SSdata$Pstage.2, na.rm = TRUE)
14
15 ## [1] 7.870376
16
17 length(SSdata$Pstage.2)
18
19 ## [1] 40
20
21 qqnorm(SSdata$Pstage.2)
22 qqline(SSdata$Pstage.2)

```

Normal Q-Q Plot



```

52 ad.test(SSdata$Pstage.2)
53
54 ##
55 ## Anderson-Darling normality test
56
57
58
59
60

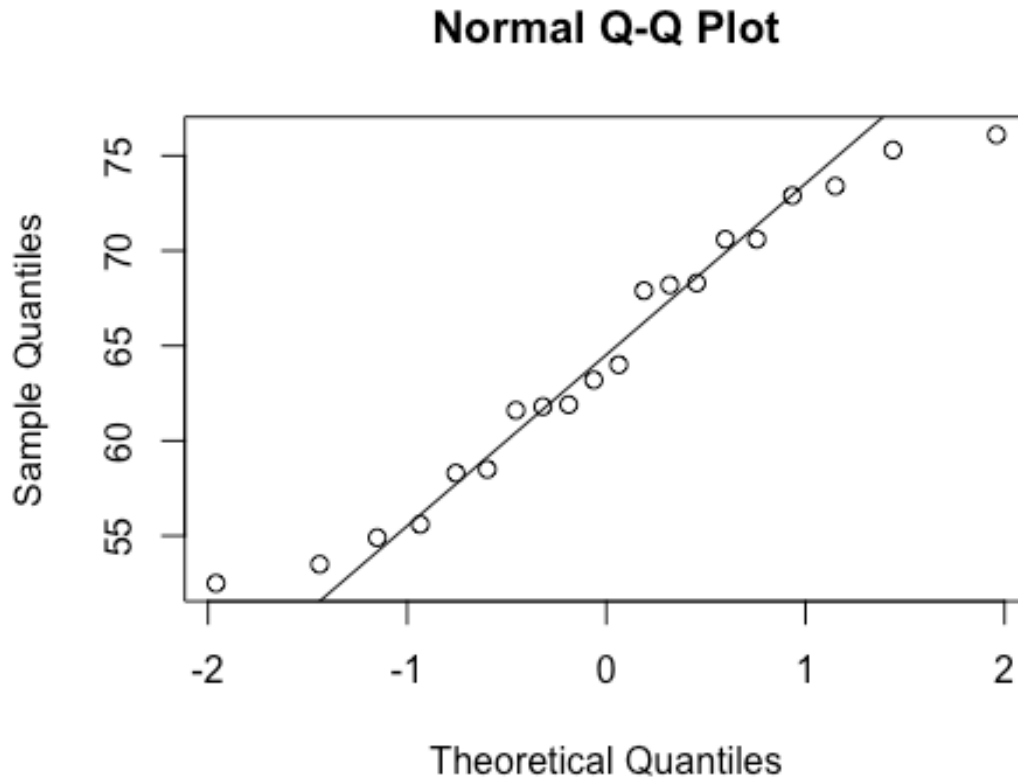
```

```

1
2
3
4  ##
5  ## data:  SSdata$Pstage.2
6  ## A = 0.37344, p-value = 0.4014
7
8  #normal
9
10 #ANOVA
11 night_tx_difference <- anova(lm(Pstage.2 ~ intervention*night,
12                               data = SSdata))
13
14 night_tx_difference
15
16 ## Analysis of Variance Table
17 ##
18 ## Response: Pstage.2
19 ##
20 ##           Df  Sum Sq Mean Sq F value Pr(>F)
21 ## intervention    1  122.85  122.850   2.0304 0.1628
22 ## night            1   58.32   58.322   0.9639 0.3328
23 ## intervention:night 1   56.41   56.406   0.9323 0.3407
24 ## Residuals      36 2178.19   60.505
25
26 #within-participants (paired) comparison
27 #Paired t-test
28 t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.2,
29         subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.2,
30         paired = TRUE)
31
32 ##
33 ## Paired t-test
34 ##
35 ## data:  subset(SSdataCompletes, intervention == "sham")$Pstage.2 and subset
36 (SSdataCompletes, intervention == "PrenaBelt")$Pstage.2
37 ## t = -1.9128, df = 19, p-value = 0.07097
38 ## alternative hypothesis: true difference in means is not equal to 0
39 ## 95 percent confidence interval:
40 ##  -7.3402984  0.3302984
41 ## sample estimates:
42 ## mean of the differences
43 ##           -3.505
44
45 #between participants (grouped) comparison
46 summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
47
48 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
49 ##      52.50  58.45   63.60   64.46   70.60   76.10
50
51 sd(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
52
53 ## [1] 7.434803
54
55 length(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
56
57 ## [1] 20
58
59
60

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
qqline(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$Pstage.2
## A = 0.30768, p-value = 0.5308

#normal

summary(subset(SSdata, intervention == "sham")$Pstage.2)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 44.40  55.05   63.00  60.95  67.60  74.80

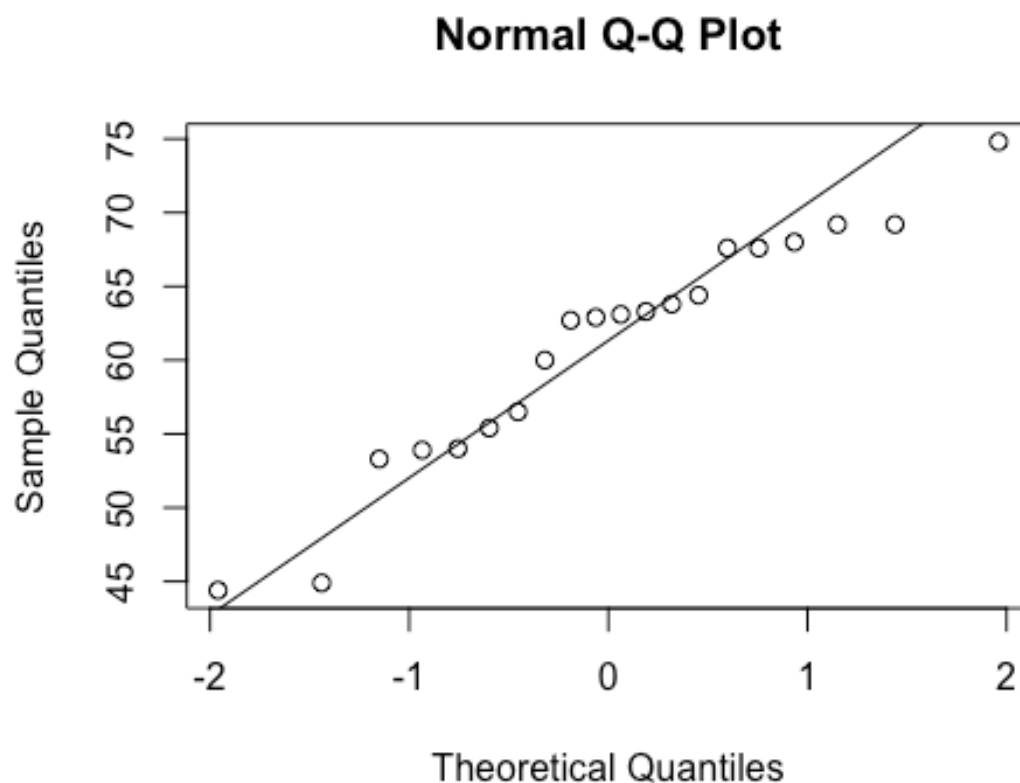
sd(subset(SSdata, intervention == "sham")$Pstage.2)

## [1] 8.087254

length(subset(SSdata, intervention == "sham")$Pstage.2)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$Pstage.2)
qqline(subset(SSdata, intervention == "sham")$Pstage.2)
```



```
ad.test(subset(SSdata, intervention == "sham")$Pstage.2)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$Pstage.2
## A = 0.47938, p-value = 0.2087

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$Pstage.2,
       subset(SSdata, intervention == "PrenaBelt")$Pstage.2)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$Pstage.2 and subset(SSdata,
## intervention == "PrenaBelt")$Pstage.2
## t = -1.4269, df = 37.734, p-value = 0.1618
## alternative hypothesis: true difference in means is not equal to 0
```

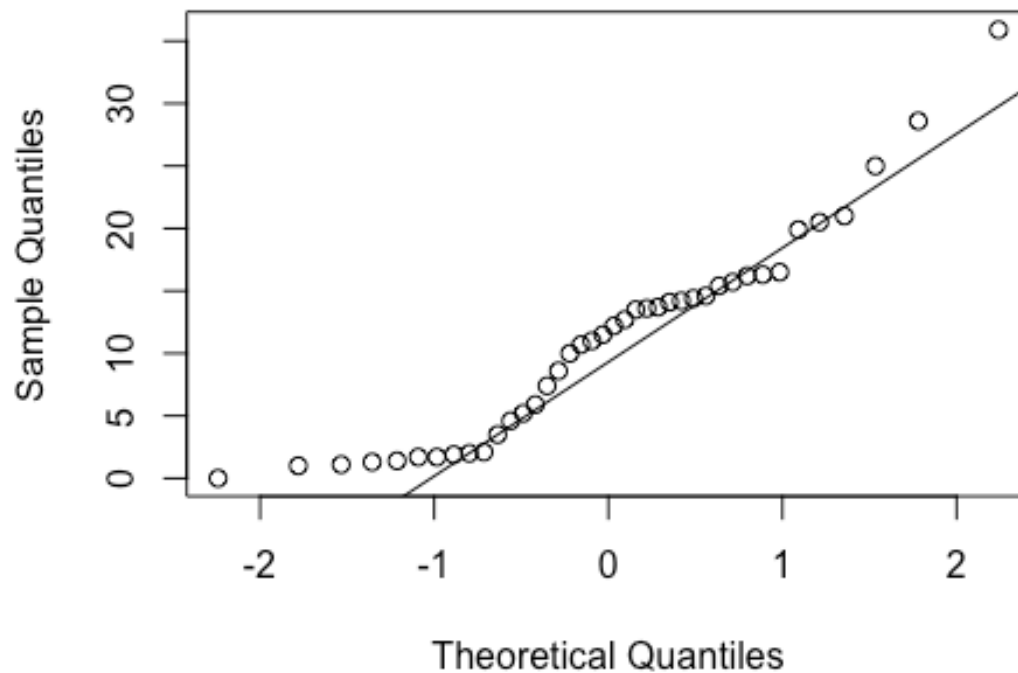


```

1
2
3  ## 95 percent confidence interval:
4  ## -8.478912  1.468912
5  ## sample estimates:
6  ## mean of x mean of y
7  ##    60.950    64.455
8
9  ##### % Stage 3 Sleep #####
10 #Summary
11 summary(SSdata$Pstage.3)
12
13 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14 ##      0.00   3.15   11.85   11.16   15.48   35.90
15
16 sd(SSdata$Pstage.3, na.rm = TRUE)
17
18 ## [1] 8.302226
19
20 length(SSdata$Pstage.3)
21
22 ## [1] 40
23
24 qqnorm(SSdata$Pstage.3)
25 qqline(SSdata$Pstage.3)

```

Normal Q-Q Plot



```

56 ad.test(SSdata$Pstage.3)
57
58
59
60

```

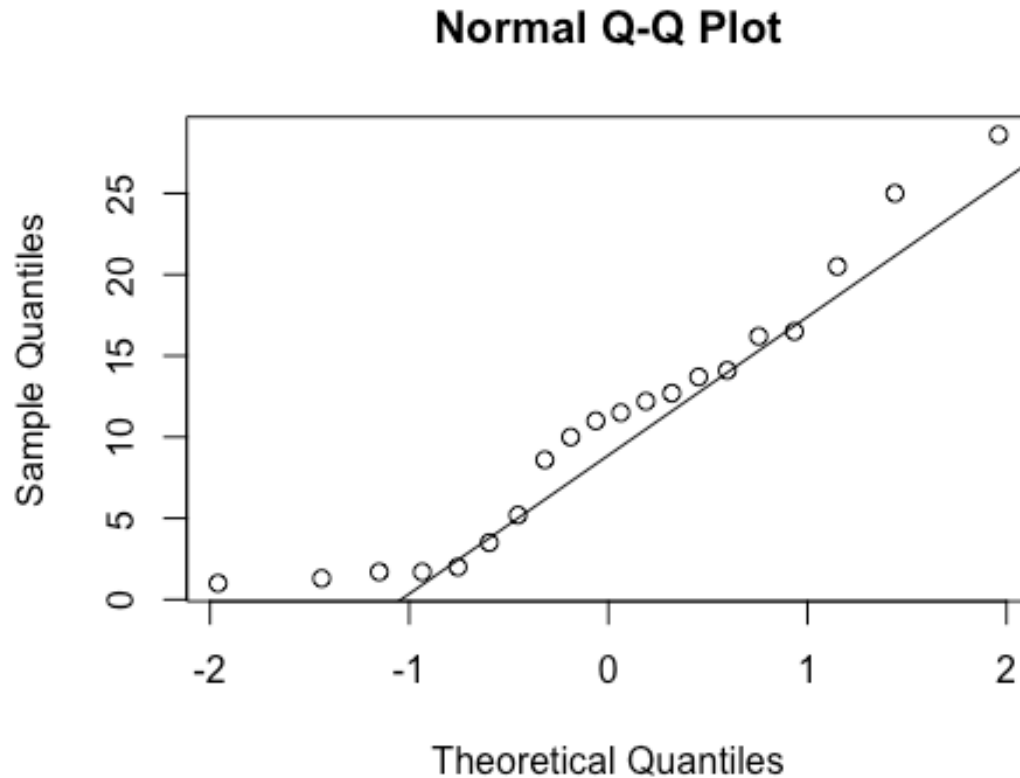
```

1
2
3
4  ## Anderson-Darling normality test
5  ##
6  ## data:  SSdata$Pstage.3
7  ## A = 0.79648, p-value = 0.03569
8
9  #non-normal
10
11
12  #ANOVA
13  night_tx_difference <- anova(lm(Pstage.3 ~ intervention * night,
14                               data = SSdata))
15  night_tx_difference
16
17  ## Analysis of Variance Table
18  ##
19  ## Response: Pstage.3
20  ##
21  ##           Df  Sum Sq Mean Sq F value Pr(>F)
22  ## intervention    1    3.97   3.969   0.0535 0.8184
23  ## night           1    3.60   3.600   0.0485 0.8269
24  ## intervention:night 1   10.40  10.404   0.1403 0.7102
25  ## Residuals      36 2670.18  74.172
26
27  #within-participants (paired) comparison
28  #Paired t-test (individual distributions are normal)
29  t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.3,
30         subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.3,
31         paired = TRUE)
32
33  ##
34  ## Paired t-test
35  ##
36  ## data: subset(SSdataCompletes, intervention == "sham")$Pstage.3 and subset
37  ## (SSdataCompletes, intervention == "PrenaBelt")$Pstage.3
38  ## t = 0.65795, df = 19, p-value = 0.5185
39  ## alternative hypothesis: true difference in means is not equal to 0
40  ## 95 percent confidence interval:
41  ## -1.374115  2.634115
42  ## sample estimates:
43  ## mean of the differences
44  ##           0.63
45
46  #between participants (grouped) comparison
47  summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
48
49  ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50  ##  1.000  3.125  11.250  10.850  14.620  28.600
51
52  sd(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
53
54  ## [1] 8.010027
55
56  length(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
57
58
59
60

```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
qqline(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$Pstage.3
## A = 0.44499, p-value = 0.2552
```

```
#normal
```

```
summary(subset(SSdata, intervention == "sham")$Pstage.3)
```

```
##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000  3.975  13.550  11.480  15.480  35.900
```

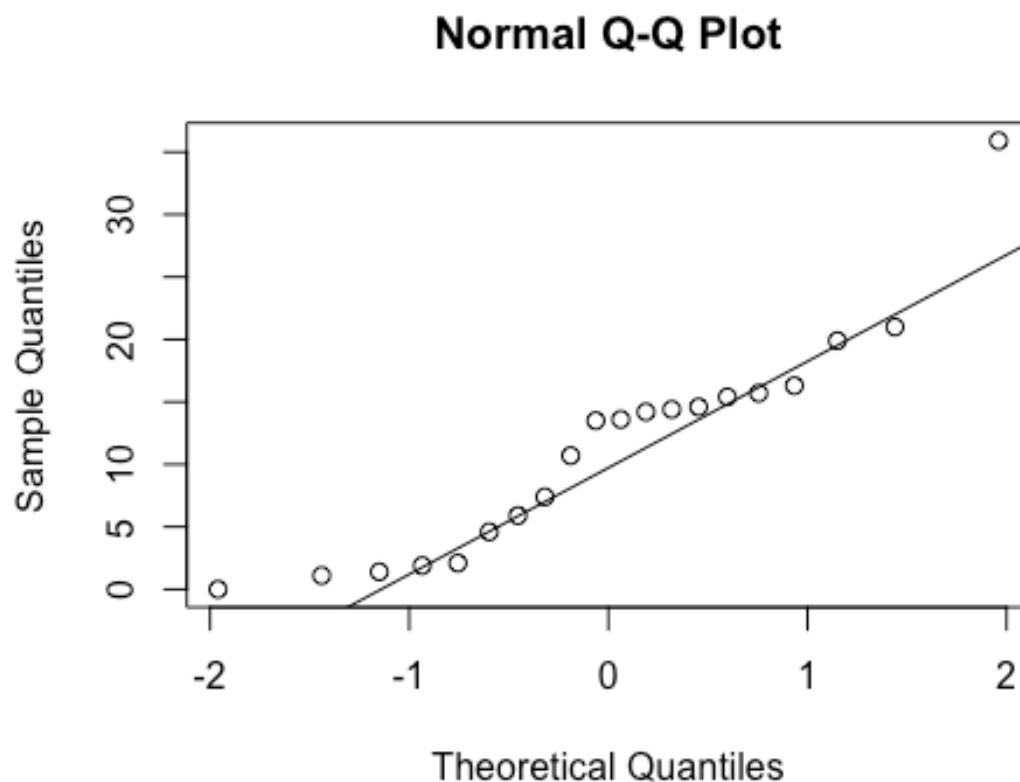
```
sd(subset(SSdata, intervention == "sham")$Pstage.3)
```

```
## [1] 8.781356
```

```
length(subset(SSdata, intervention == "sham")$Pstage.3)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$Pstage.3)
qqline(subset(SSdata, intervention == "sham")$Pstage.3)
```



```
ad.test(subset(SSdata, intervention == "sham")$Pstage.3)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$Pstage.3
## A = 0.5987, p-value = 0.1039
```

```
#normal
```

```
#FYI - unpaired test
```

```
t.test(subset(SSdata, intervention == "sham")$Pstage.3,
       subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
```

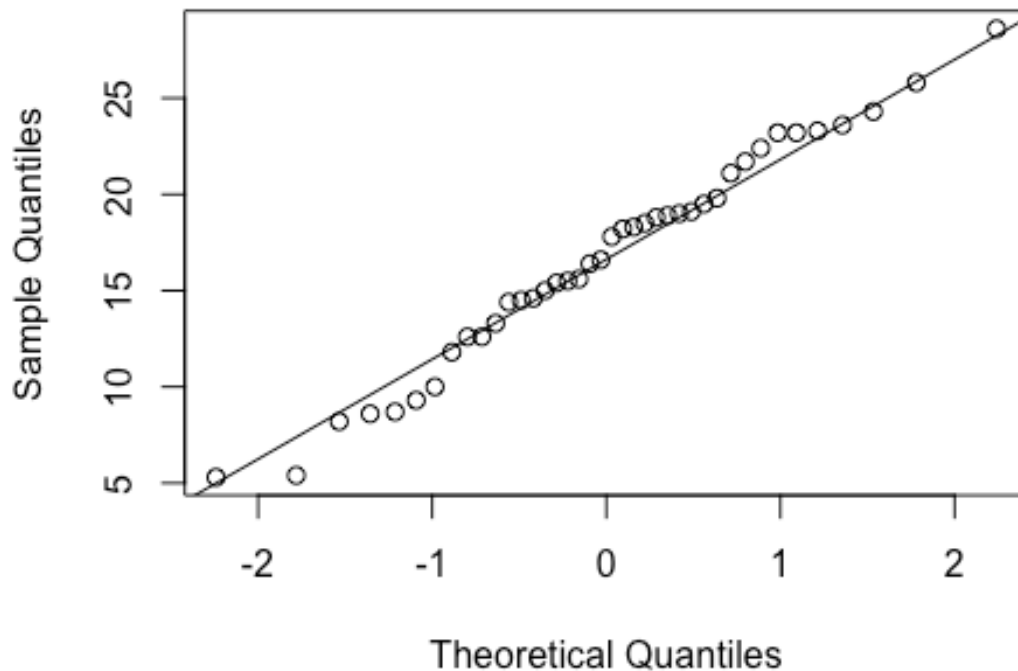
```
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$Pstage.3 and subset(SSdata,
intervention == "PrenaBelt")$Pstage.3
```

```

1
2
3  ## t = 0.23704, df = 37.683, p-value = 0.8139
4  ## alternative hypothesis: true difference in means is not equal to 0
5  ## 95 percent confidence interval:
6  ## -4.75182  6.01182
7  ## sample estimates:
8  ## mean of x mean of y
9  ##      11.48      10.85
10
11 ##### % Stage REM #####
12 #Summary
13 summary(SSdata$Prem)
14
15 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
16 ##      5.30  13.13   17.20   16.72   20.12   28.60
17
18 sd(SSdata$Prem, na.rm = TRUE)
19
20 ## [1] 5.62027
21
22 length(SSdata$Prem)
23
24 ## [1] 40
25
26 qqnorm(SSdata$Prem)
27 qqline(SSdata$Prem)

```

Normal Q-Q Plot



```

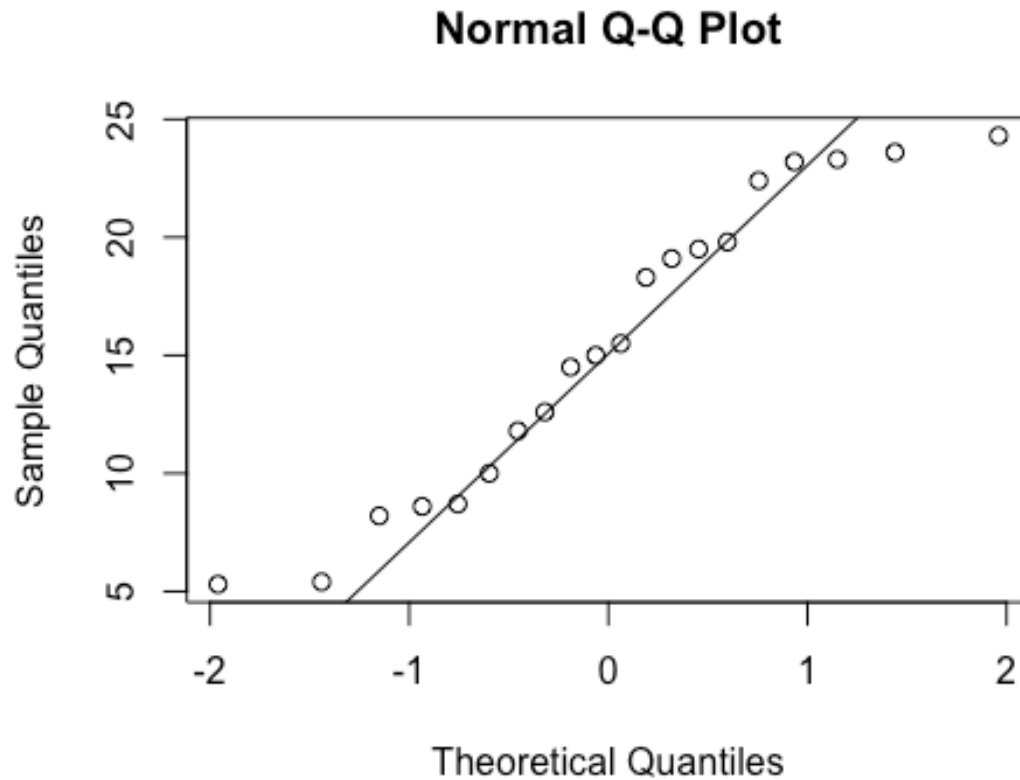
1
2
3 ad.test(SSdata$Prem)
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: SSdata$Prem
9 ## A = 0.23648, p-value = 0.7728
10
11 #normal
12
13 #ANOVA
14 night_tx_difference <- anova(lm(Prem ~ intervention * night,
15                               data = SSdata))
16
17 night_tx_difference
18
19 ## Analysis of Variance Table
20 ##
21 ## Response: Prem
22 ##
23 ##           Df Sum Sq Mean Sq F value Pr(>F)
24 ## intervention      1   64.26   64.262   2.2623 0.14128
25 ## night              1   89.10   89.102   3.1367 0.08501 .
26 ## intervention:night  1   55.93   55.932   1.9690 0.16912
27 ## Residuals        36 1022.61   28.406
28 ## ---
29 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
30
31 #within-participants (paired) comparison
32 #Paired t-test
33 t.test(subset(SSdataCompletes, intervention == "sham")$Prem,
34        subset(SSdataCompletes, intervention == "PrenaBelt")$Prem,
35        paired = TRUE)
36
37 ##
38 ## Paired t-test
39 ##
40 ## data: subset(SSdataCompletes, intervention == "sham")$Prem and subset(SSdataCompletes, intervention == "PrenaBelt")$Prem
41 ## t = 2.0564, df = 19, p-value = 0.05374
42 ## alternative hypothesis: true difference in means is not equal to 0
43 ## 95 percent confidence interval:
44 ## -0.04510822  5.11510822
45 ## sample estimates:
46 ## mean of the differences
47 ##
48 ##           2.535
49
50 #between participants (grouped) comparison
51 summary(subset(SSdata, intervention == "PrenaBelt")$Prem)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##  5.300   9.675  15.250  15.460  20.450  24.300
55
56 sd(subset(SSdata, intervention == "PrenaBelt")$Prem)
57
58
59
60

```

```

1
2
3 ## [1] 6.377714
4
5 length(subset(SSdata, intervention == "PrenaBelt")$Prem)
6
7 ## [1] 20
8
9 qqnorm(subset(SSdata, intervention == "PrenaBelt")$Prem)
10 qqline(subset(SSdata, intervention == "PrenaBelt")$Prem)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

```



```

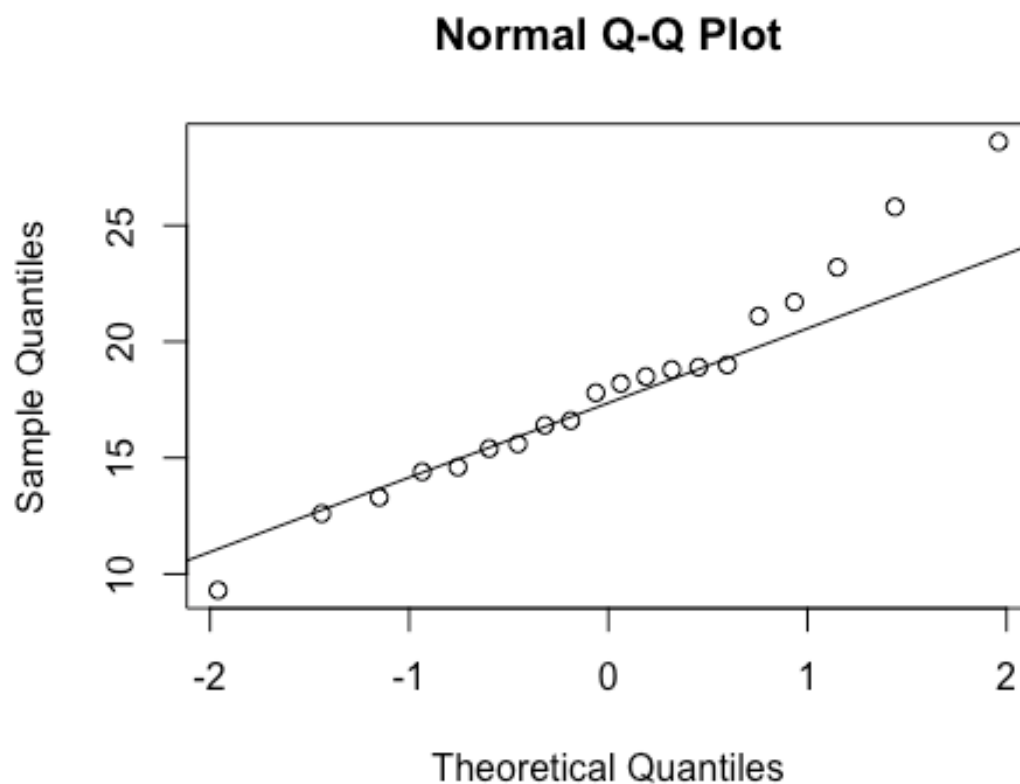
41 ad.test(subset(SSdata, intervention == "PrenaBelt")$Prem)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: subset(SSdata, intervention == "PrenaBelt")$Prem
47 ## A = 0.44545, p-value = 0.2545
48
49 #normal
50
51 summary(subset(SSdata, intervention == "sham")$Prem)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##      9.30  15.20  18.00  17.99  19.52  28.60
55
56 sd(subset(SSdata, intervention == "sham")$Prem)
57
58
59
60

```

```

1
2
3 ## [1] 4.558497
4
5 length(subset(SSdata, intervention == "sham")$Prem)
6
7 ## [1] 20
8
9 qqnorm(subset(SSdata, intervention == "sham")$Prem)
10 qqline(subset(SSdata, intervention == "sham")$Prem)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

```



```

41 ad.test(subset(SSdata, intervention == "sham")$Prem)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: subset(SSdata, intervention == "sham")$Prem
47 ## A = 0.27628, p-value = 0.6181
48
49 #normal
50
51 #FYI - unpaired test
52 t.test(subset(SSdata, intervention == "sham")$Prem,
53        subset(SSdata, intervention == "PrenaBeIt")$Prem)
54
55
56
57
58
59
60

```

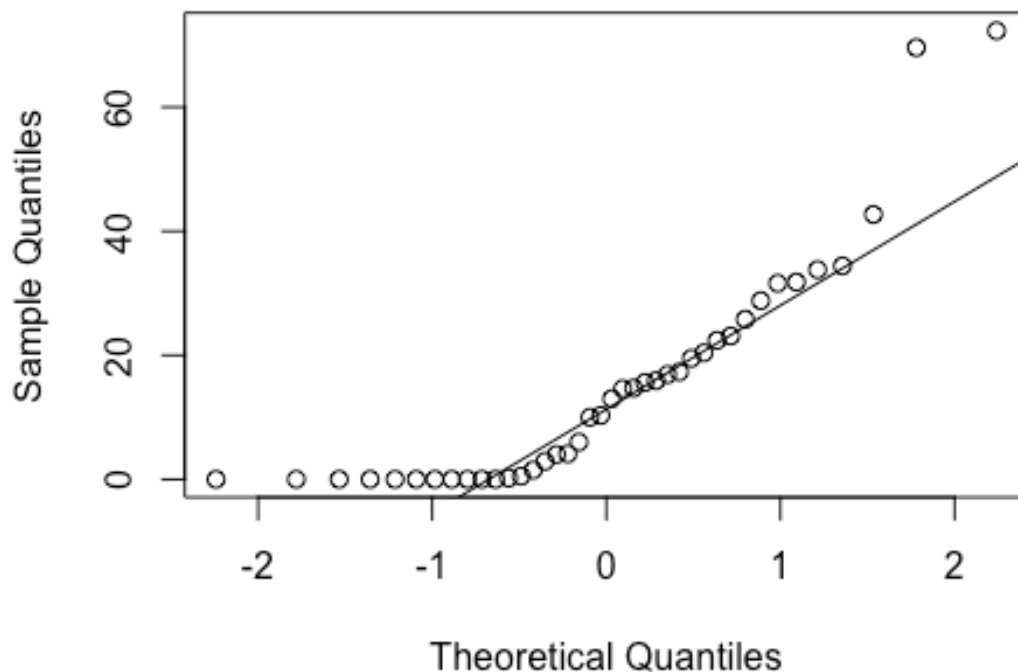


```

1
2
3
4  ## Welch Two Sample t-test
5  ##
6  ## data: subset(SSdata, intervention == "sham")$Prem and subset(SSdata, inte
7  rvention == "PrenaBelt")$Prem
8  ## t = 1.4462, df = 34.395, p-value = 0.1572
9  ## alternative hypothesis: true difference in means is not equal to 0
10 ## 95 percent confidence interval:
11 ## -1.025871  6.095871
12 ## sample estimates:
13 ## mean of x mean of y
14 ## 17.990 15.455
15
16
17 ##### %TST Supine #####
18 #Summary
19 summary(SSdata$PtstSupine)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      0.00   0.00   11.65   15.09   22.57   72.30
23
24 sd(SSdata$PtstSupine, na.rm = TRUE)
25
26 ## [1] 17.83904
27
28 length(SSdata$PtstSupine)
29
30 ## [1] 40
31
32 #ANOVA
33 night_tx_difference <- anova(lm(PtstSupine ~ intervention * night,
34                               data = SSdata))
35
36 night_tx_difference
37
38 ## Analysis of Variance Table
39 ##
40 ## Response: PtstSupine
41 ##
42 ##           Df Sum Sq Mean Sq F value Pr(>F)
43 ## intervention      1  465.8  465.81  1.4119 0.2425
44 ## night              1   64.8   64.77  0.1963 0.6604
45 ## intervention:night  1    3.4    3.42  0.0104 0.9194
46 ## Residuals        36 11877.0  329.92
47
48 qqnorm(SSdata$PtstSupine)
49 qqline(SSdata$PtstSupine)
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(SSdata$PtstSupine)

##
## Anderson-Darling normality test
##
## data:  SSdata$PtstSupine
## A = 2.1537, p-value = 1.423e-05

#data do not follow a normal distribution; perform paired Wilcoxon rank sum t
est

#within-participants (paired) comparison
#Paired Wilcoxon, one-tailed
wilcox.test(subset(SSdataCompletes, intervention == "sham")$PtstSupine,
            subset(SSdataCompletes, intervention == "PrenaBelt")$PtstSupine,
            paired = TRUE, conf.int = TRUE, alternative = "greater")

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$PtstSupine, : cannot compute exact p-value with zeroes

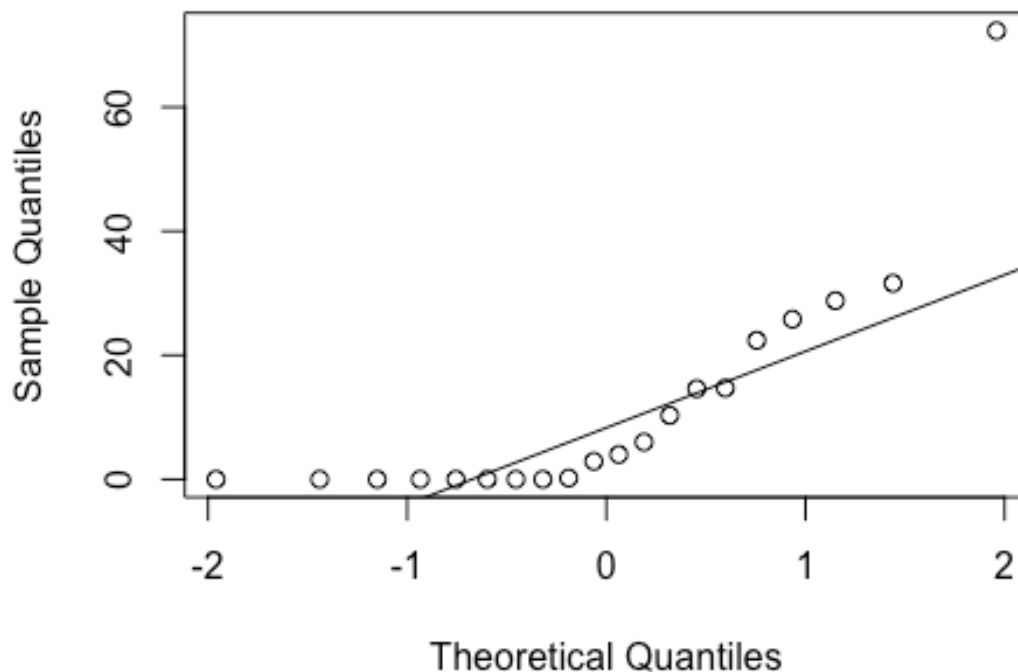
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$PtstSupine, : cannot compute exact confidence interval with zeroes
```

```

1
2
3  ##
4  ## Wilcoxon signed rank test with continuity correction
5  ##
6  ## data: subset(SSdataCompletes, intervention == "sham")$PtstSupine and subse
7  et(SSdataCompletes, intervention == "PrenaBelt")$PtstSupine
8  ## V = 142, p-value = 0.03065
9  ## alternative hypothesis: true location shift is greater than 0
10 ## 95 percent confidence interval:
11 ##  0.7000854      Inf
12 ## sample estimates:
13 ## (pseudo)median
14 ##      5.804603
15
16
17 #difference in medians = 16.4 - 3.5 = 12.9 (corresponds to Wilcoxon rank sum
18 test)
19 #median of differences = pseudomedian = 5.8 (corresponds to Wilcoxon signed r
20 ank test)
21
22 #between participants (grouped) comparison
23 summary(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
24
25 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
26 ##      0.00   0.00   3.45   11.68   16.62   72.30
27
28 sd(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
29
30 ## [1] 17.9033
31
32 length(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
33
34 ## [1] 20
35
36 qqnorm(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
37 qqline(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$PtstSupine
## A = 1.97, p-value = 3.17e-05

#non-normal

summary(subset(SSdata, intervention == "sham")$PtstSupine)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   3.45   16.40   18.50   25.28   69.60

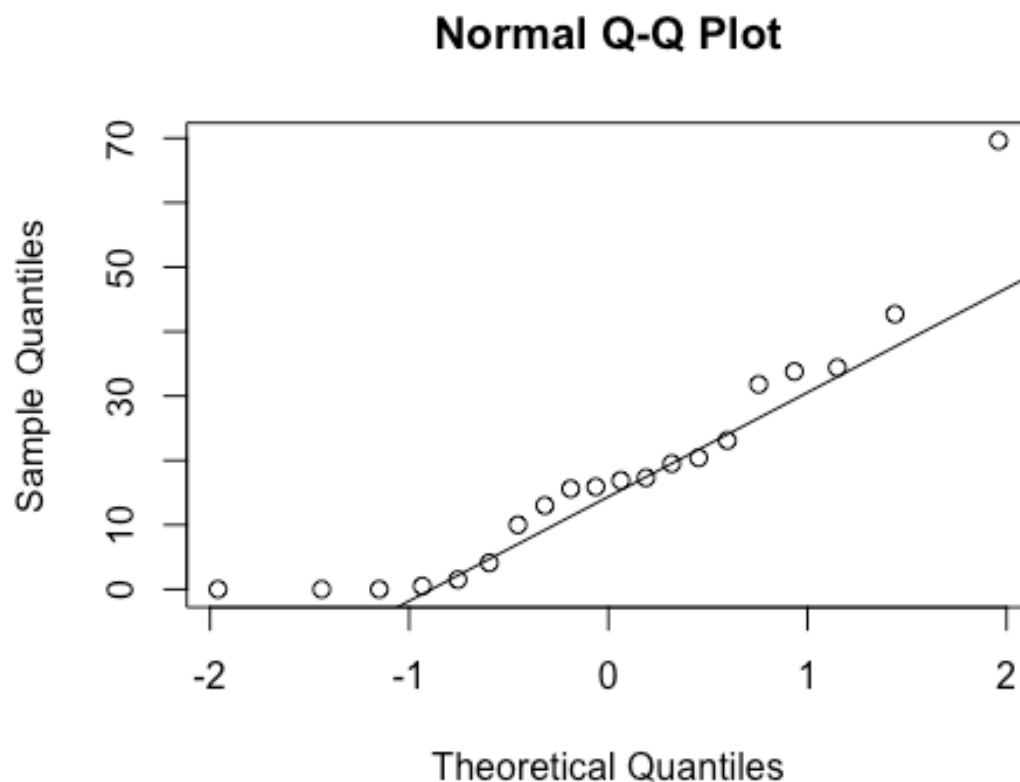
sd(subset(SSdata, intervention == "sham")$PtstSupine)

## [1] 17.55471

length(subset(SSdata, intervention == "sham")$PtstSupine)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$PtstSupine)
qqline(subset(SSdata, intervention == "sham")$PtstSupine)
```



```

ad.test(subset(SSdata, intervention == "sham")$PtstSupine)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$PtstSupine
## A = 0.67467, p-value = 0.06621

#normal

#FYI - unpaired test
#non-parametric test for differences (one-tailed Wilcoxon, unpaired)
wilcox.test(subset(SSdata, intervention == "sham")$PtstSupine,
            subset(SSdata, intervention == "PrenaBelt")$PtstSupine,
            conf.int = TRUE, alternative = "greater")

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $PtstSupine, : cannot compute exact p-value with ties

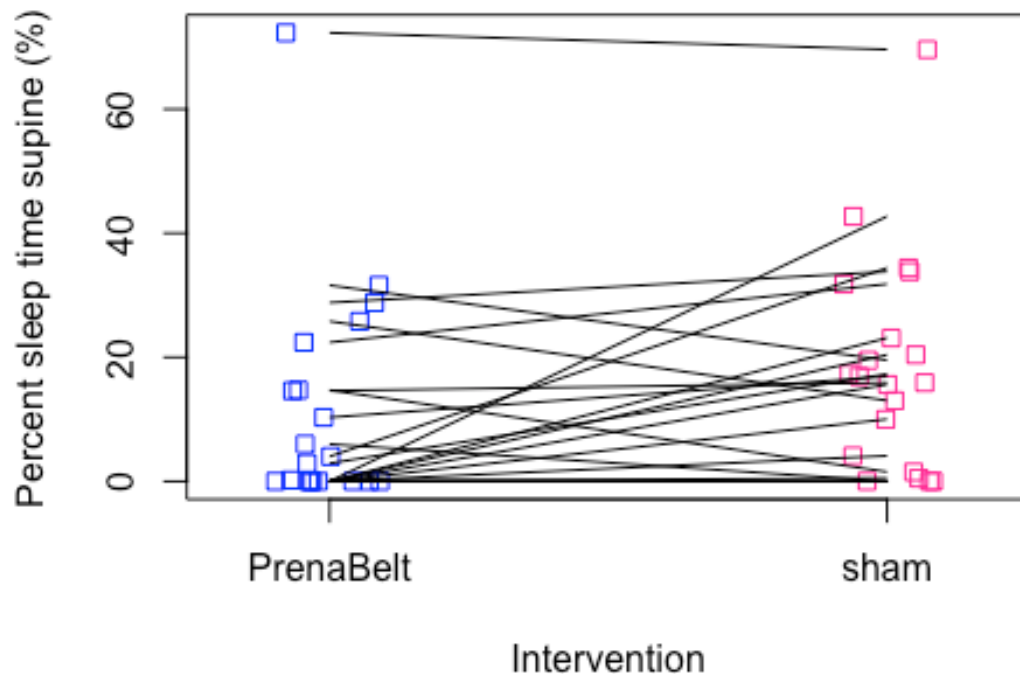
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $PtstSupine, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction

```

```
1
2
3 ##
4 ## data: subset(SSdata, intervention == "sham")$PtstSupine and subset(SSdata
5 , intervention == "PrenaBelt")$PtstSupine
6 ## W = 267, p-value = 0.03456
7 ## alternative hypothesis: true location shift is greater than 0
8 ## 95 percent confidence interval:
9 ## 2.150084e-05      Inf
10 ## sample estimates:
11 ## difference in location
12 ## 6.666346
13
14 # Use droplevels to remove the empty levels from the list of levels
15 SSdata$intervention <- droplevels(SSdata$intervention)
16 summary(SSdata$intervention)
17
18 ## PrenaBelt      sham
19 ##          20      20
20
21 stripchart(SSdata$PtstSupine~SSdata$intervention,
22             vertical = TRUE, method="jitter", col=c("blue","deeppink"),
23             ylab='Percent sleep time supine (%)', xlab='Intervention',
24             main='Percent sleep time supine vs. Intervention',)
25
26
27 for(participant.s.code in split(SSdata, SSdata$participant.s.code))
28   lines(PtstSupine ~ intervention, participant.s.code)
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

Percent sleep time supine vs. Intervention



```

32 boxplot(SSdata$PtstSupine~SSdata$intervention,
33         col=c("lightblue1","thistle1"),
34         ylab='Percent sleep time supine', xlab='Intervention',
35         main='Percent sleep time supine vs. intervention',
36         medcol="blue", boxwex = 0.25)
37
38 #Get the group means & medians
39 means <- by(SSdata$PtstSupine, SSdata$intervention, mean)
40 medians <- by(SSdata$PtstSupine, SSdata$intervention, median)
41
42 #Plot symbols for each mean, centered on x = 1 and x = 2, which are the default
43 #center values.
44 points(1:2, means, pch = 23, cex = 1.0, bg = "red")
45 #Now Label the means, formatting the values to one decimal place. Place the values
46 #to the left of each group plot.
47 text(1:2 - 0.1, means,
48      labels = formatC(means, format = "f", digits = 1),
49      pos = 2, cex = 0.9, col = "red")
50
51 ## Warning in formatC(means, format = "f", digits = 1): class of 'x' was
52 ## discarded

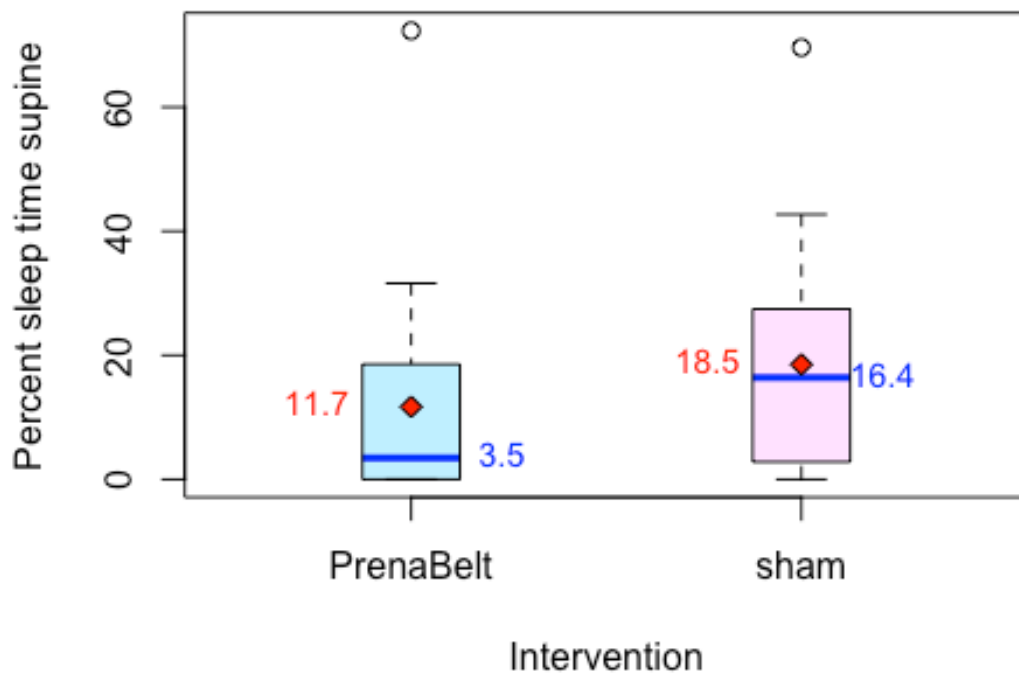
```

```

text(1:2 + 0.35, medians,
     labels = formatC(medians, format = "f", digits = 1),
     pos = 2, cex = 0.9, col = "blue")

## Warning in formatC(medians, format = "f", digits = 1): class of 'x' was
## discarded
    
```

Percent sleep time supine vs. intervention



```

##### %TST Right #####
#Summary
summary(SSdata$PtstRight)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   30.10   30.30   45.92   95.40

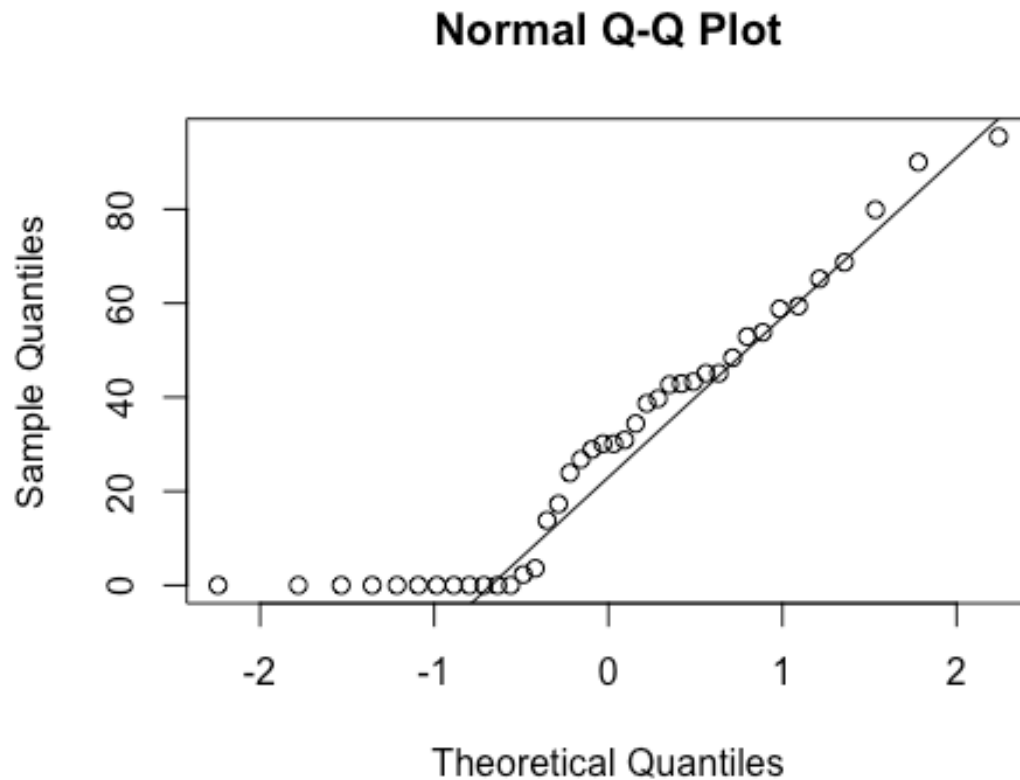
sd(SSdata$PtstRight, na.rm = TRUE)

## [1] 27.78612

length(SSdata$PtstRight)

## [1] 40

qqnorm(SSdata$PtstRight)
qqline(SSdata$PtstRight)
    
```

```
ad.test(SSdata$PtstRight)

##
## Anderson-Darling normality test
##
## data:  SSdata$PtstRight
## A = 1.2731, p-value = 0.002267

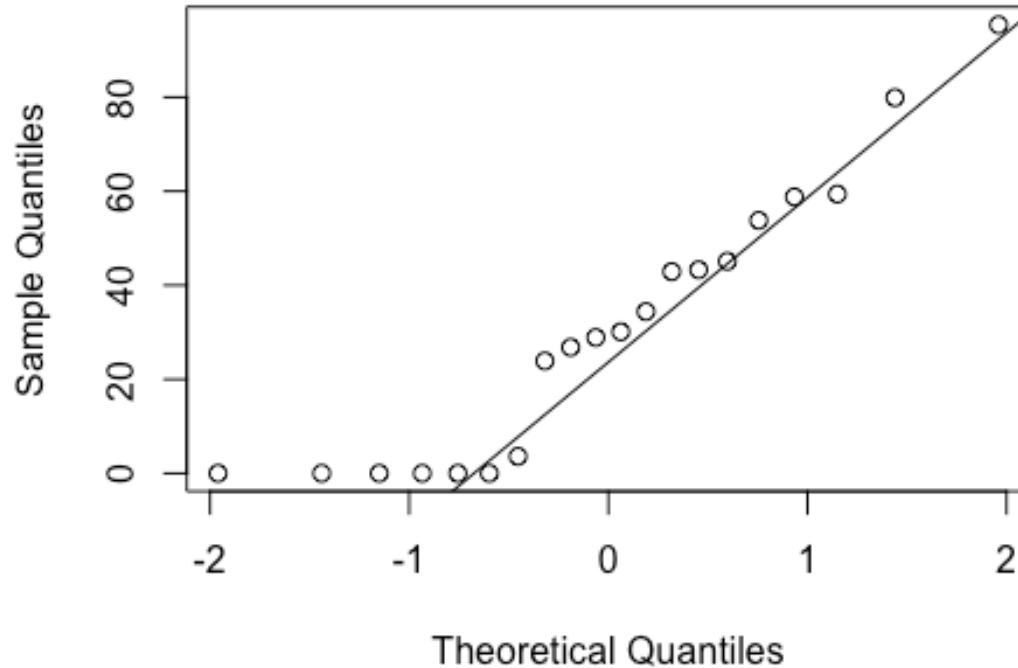
#non-normal

#ANOVA
night_tx_difference <- anova(lm(PtstRight ~ intervention + night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: PtstRight
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention  1    41.0   41.01  0.0508  0.8229
## night         1   202.1  202.05  0.2503  0.6198
## Residuals    37 29867.6  807.23
```

```
1
2
3 #within-participants (paired) comparison
4 #Paired t-test (individual distributions are normally distributed)
5 t.test(subset(SSdataCompletes, intervention == "sham")$PtstRight,
6        subset(SSdataCompletes, intervention == "PrenaBelt")$PtstRight,
7        paired = TRUE)
8
9 ##
10 ## Paired t-test
11 ##
12 ## data: subset(SSdataCompletes, intervention == "sham")$PtstRight and subse
13 t(SSdataCompletes, intervention == "PrenaBelt")$PtstRight
14 ## t = -0.52565, df = 19, p-value = 0.6052
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -10.088139  6.038139
18 ## sample estimates:
19 ## mean of the differences
20 ## -2.025
21
22
23 #between participants (grouped) comparison
24 summary(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
25
26 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##      0.00   0.00   29.50   31.32   47.28   95.40
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
30
31 ## [1] 28.77236
32
33 length(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
34
35 ## [1] 20
36
37 qqnorm(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
38 qqline(subset(SSdata, intervention == "PrenaBelt")$PtstRight)
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstRight)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$PtstRight
## A = 0.64629, p-value = 0.07835

#normal

summary(subset(SSdata, intervention == "sham")$PtstRight)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.00   0.00   30.50   29.29   45.92   90.00

sd(subset(SSdata, intervention == "sham")$PtstRight)

## [1] 27.47299

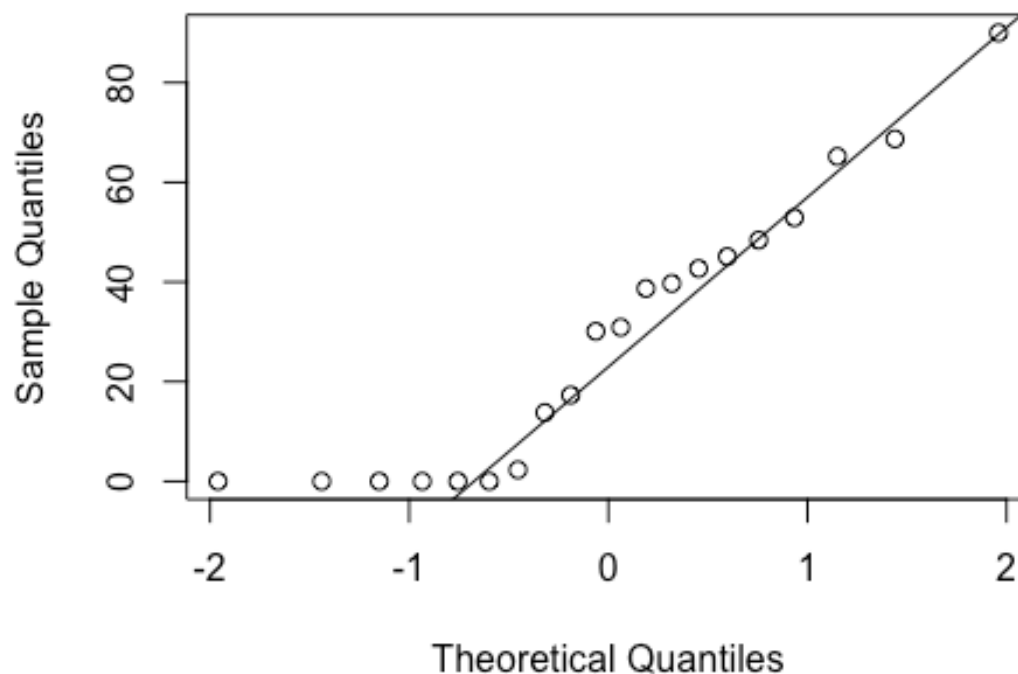
length(subset(SSdata, intervention == "sham")$PtstRight)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$PtstRight)
qqline(subset(SSdata, intervention == "sham")$PtstRight)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$PtstRight)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$PtstRight
## A = 0.70627, p-value = 0.0549

#borderline normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$PtstRight,
       subset(SSdata, intervention == "PrenaBelt")$PtstRight)

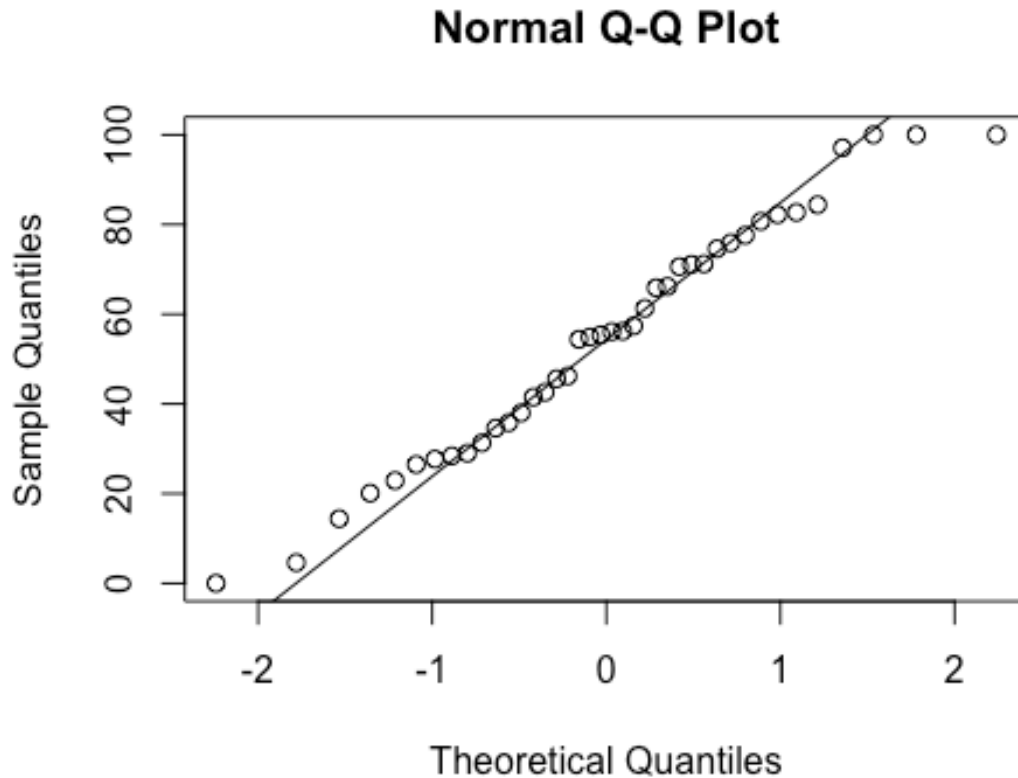
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$PtstRight and subset(SSdata,
intervention == "PrenaBelt")$PtstRight
## t = -0.22764, df = 37.919, p-value = 0.8211
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -20.03435 15.98435
## sample estimates:

```

```

1
2
3 ## mean of x mean of y
4 ##    29.290    31.315
5
6 wilcox.test(subset(SSdata, intervention == "sham")$PtstRight,
7             subset(SSdata, intervention == "PrenaBelt")$PtstRight,
8             conf.int = TRUE)
9
10 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
11 ## $PtstRight, : cannot compute exact p-value with ties
12
13 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
14 ## $PtstRight, : cannot compute exact confidence intervals with ties
15
16 ##
17 ## Wilcoxon rank sum test with continuity correction
18 ##
19 ## data: subset(SSdata, intervention == "sham")$PtstRight and subset(SSdata,
20 ## intervention == "PrenaBelt")$PtstRight
21 ## W = 195, p-value = 0.9018
22 ## alternative hypothesis: true location shift is not equal to 0
23 ## 95 percent confidence interval:
24 ## -23.89994  14.80004
25 ## sample estimates:
26 ## difference in location
27 ##          -3.997034e-06
28
29 ##### %TST Left #####
30 #Summary
31 summary(SSdata$PtstLeft)
32
33 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
34 ##      0.00  33.78   55.75   54.63   74.92  100.00
35
36 sd(SSdata$PtstLeft, na.rm = TRUE)
37
38 ## [1] 26.70052
39
40 length(SSdata$PtstLeft)
41
42 ## [1] 40
43
44 qqnorm(SSdata$PtstLeft)
45 qqline(SSdata$PtstLeft)
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(SSdata$PtstLeft)

##
## Anderson-Darling normality test
##
## data:  SSdata$PtstLeft
## A = 0.26013, p-value = 0.6934

#normal

#ANOVA
night_tx_difference <- anova(lm(PtstLeft ~ intervention + night,
                               data = SSdata))
night_tx_difference

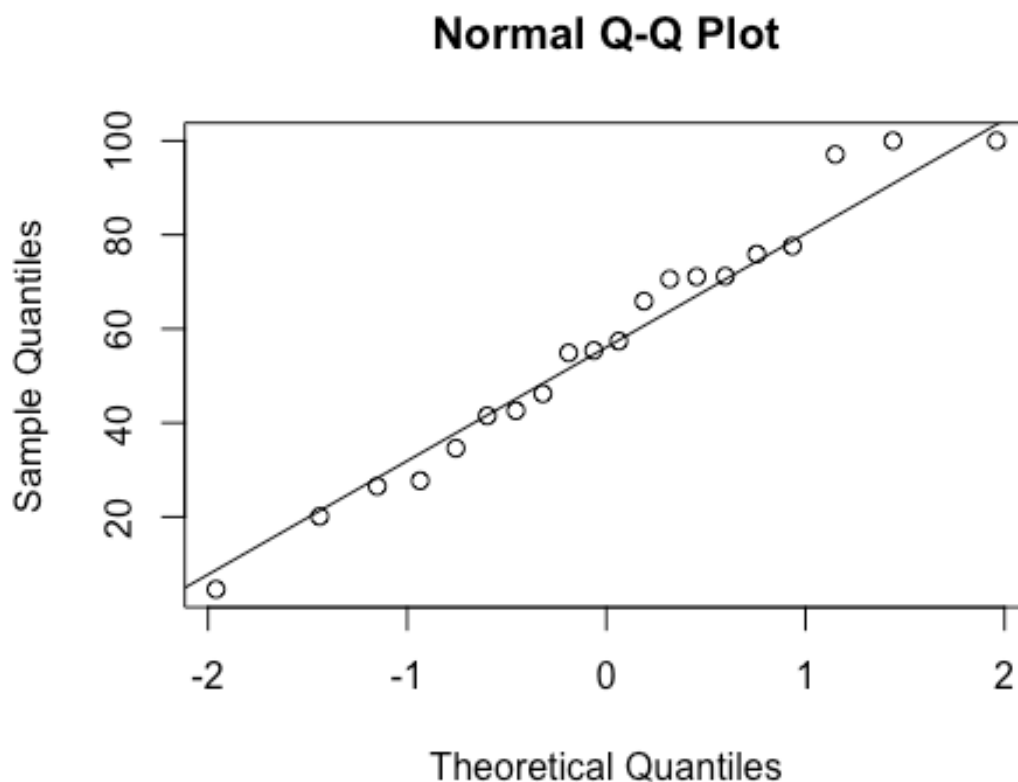
## Analysis of Variance Table
##
## Response: PtstLeft
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention  1   233.8   233.77   0.3141 0.5785
## night         1    35.9    35.91   0.0483 0.8273
## Residuals    37 27534.1   744.17

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired t-test
5 t.test(subset(SSdataCompletes, intervention == "sham")$PtstLeft,
6         subset(SSdataCompletes, intervention == "PrenaBelt")$PtstLeft,
7         paired = TRUE)
8
9 ##
10 ## Paired t-test
11 ##
12 ## data: subset(SSdataCompletes, intervention == "sham")$PtstLeft and subset
13 (SSdataCompletes, intervention == "PrenaBelt")$PtstLeft
14 ## t = -1.0137, df = 19, p-value = 0.3234
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -14.817699  5.147699
18 ## sample estimates:
19 ## mean of the differences
20 ## -4.835
21
22
23 #between participants (grouped) comparison
24 summary(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
25
26 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##      4.60  39.78   56.40   57.04   72.38  100.00
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
30
31 ## [1] 26.8734
32
33 length(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
34
35 ## [1] 20
36
37 qqnorm(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
38 qqline(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$PtstLeft
## A = 0.20177, p-value = 0.86

#normal

summary(subset(SSdata, intervention == "sham")$PtstLeft)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.00  30.72   55.25   52.21  76.12  100.00

sd(subset(SSdata, intervention == "sham")$PtstLeft)

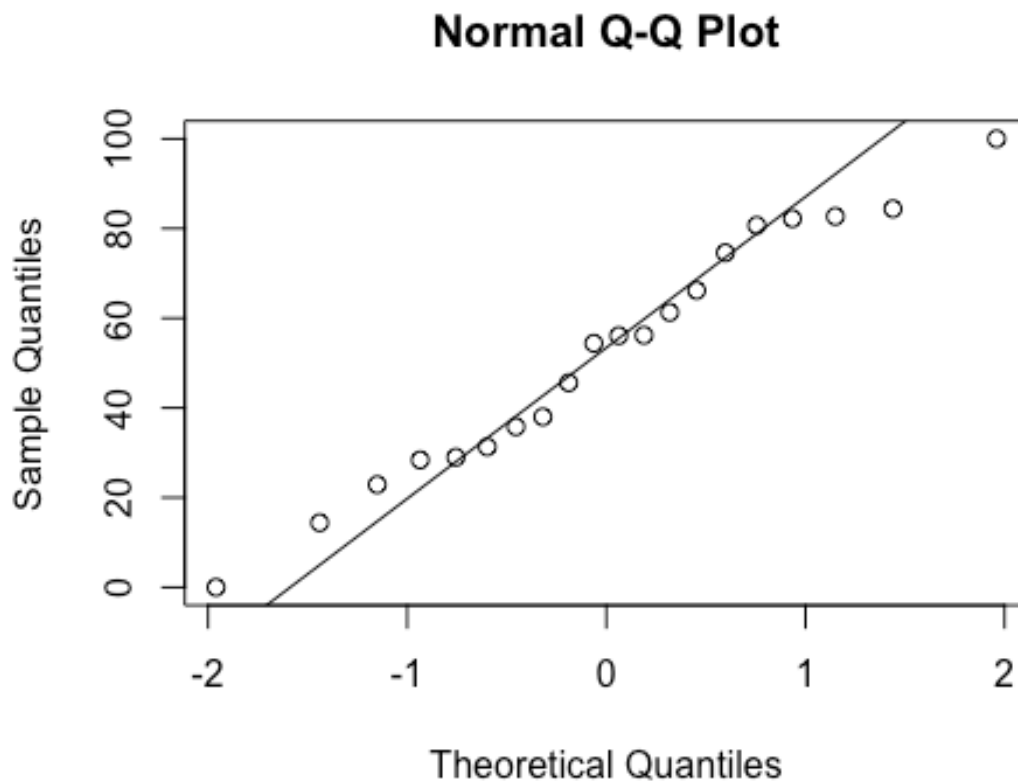
## [1] 26.99768

length(subset(SSdata, intervention == "sham")$PtstLeft)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$PtstLeft)
qqline(subset(SSdata, intervention == "sham")$PtstLeft)

```

```

ad.test(subset(SSdata, intervention == "sham")$PtstLeft)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$PtstLeft
## A = 0.24563, p-value = 0.7241

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$PtstLeft,
       subset(SSdata, intervention == "PrenaBelt")$PtstLeft)

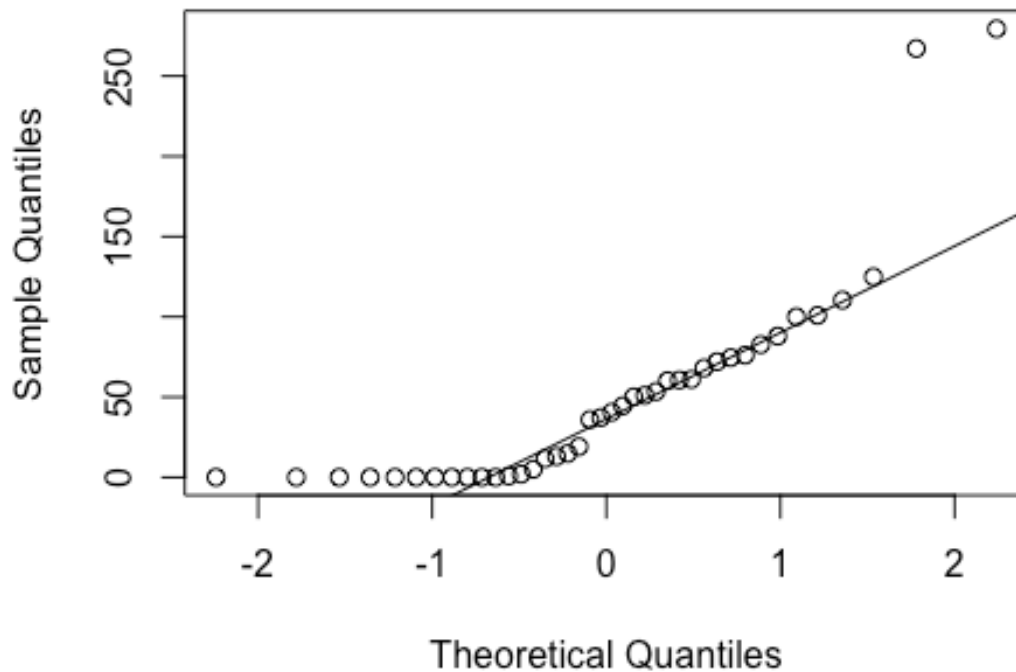
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$PtstLeft and subset(SSdata,
## intervention == "PrenaBelt")$PtstLeft
## t = -0.56764, df = 37.999, p-value = 0.5736
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -22.07837 12.40837
## sample estimates:

```

```
1
2
3 ## mean of x mean of y
4 ##    52.210    57.045
5
6 #no time was spent prone
7 summary(SSdata$PtstProne)
8
9 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
10 ##         0         0         0         0         0         0
11
12 sd(SSdata$PtstProne, na.rm = TRUE)
13
14 ## [1] 0
15
16 length(SSdata$PtstProne)
17
18 ## [1] 40
19
20 ##### Minutes Sleeping Supine #####
21 #Summary
22 summary(SSdata$minutesTSTSupine)
23
24 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
25 ##     0.00    0.00   38.90   50.13   72.67   279.40
26
27 sd(SSdata$minutesTSTSupine, na.rm = TRUE)
28
29 ## [1] 63.82465
30
31 length(SSdata$minutesTSTSupine)
32
33 ## [1] 40
34
35 qqnorm(SSdata$minutesTSTSupine)
36 qqline(SSdata$minutesTSTSupine)
```

Only

Normal Q-Q Plot



```
ad.test(SSdata$minutesTSTSupine)
```

```
##
## Anderson-Darling normality test
##
## data: SSdata$minutesTSTSupine
## A = 2.6888, p-value = 6.632e-07
```

```
#data do not follow a normal distribution; perform paired Wilcoxon rank sum t est
```

```
#ANOVA
```

```
night_tx_difference <- anova(lm(minutesTSTSupine ~ intervention * night,
                                data = SSdata))
```

```
night_tx_difference
```

```
## Analysis of Variance Table
```

```
##
```

```
## Response: minutesTSTSupine
```

	Df	Sum Sq	Mean Sq	F value	Pr(>F)
## intervention	1	5927	5927.0	1.4014	0.2442
## night	1	500	499.8	0.1182	0.7330
## intervention:night	1	189	188.9	0.0447	0.8338
## Residuals	36	152254	4229.3		

```

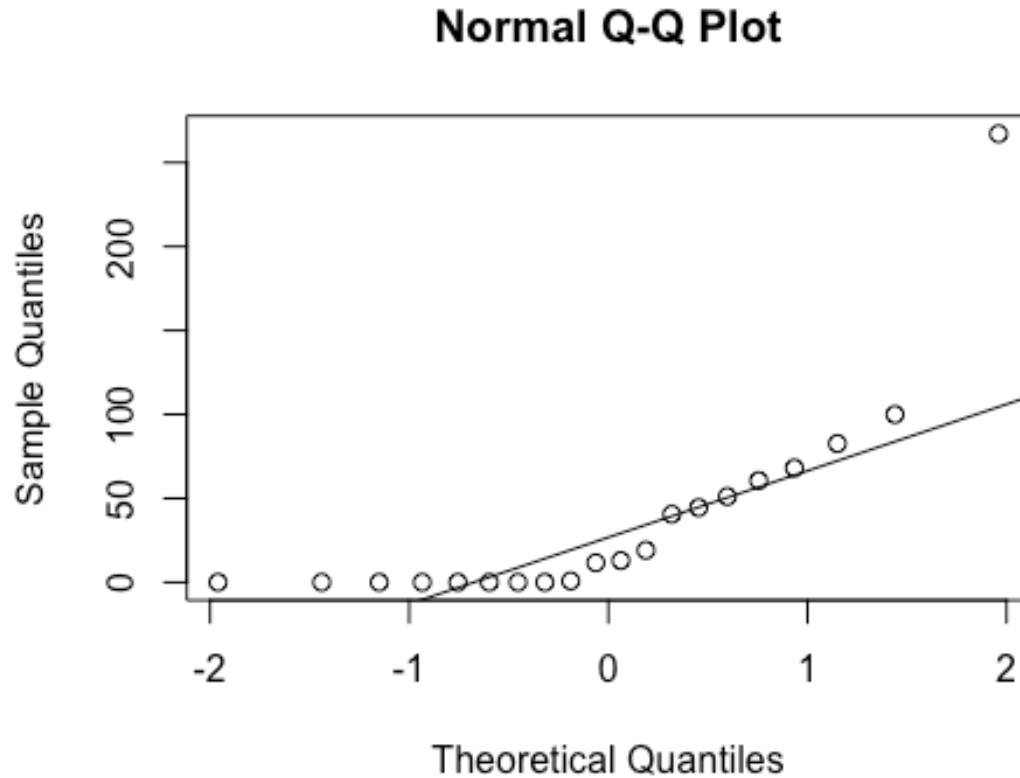
1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSu
7 pine,
8             paired = TRUE, conf.int = TRUE, alternative = "two.sided")
9
10 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
11 ## "sham")$minutesTSTSupine, : cannot compute exact p-value with zeroes
12
13 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
14 ## "sham")$minutesTSTSupine, : cannot compute exact confidence interval with
15 ## zeroes
16
17 ##
18 ## Wilcoxon signed rank test with continuity correction
19 ##
20 ## data: subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine an
21 d subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine
22 ## V = 150, p-value = 0.02829
23 ## alternative hypothesis: true location shift is not equal to 0
24 ## 95 percent confidence interval:
25 ## 2.557336 49.892997
26 ## sample estimates:
27 ## (pseudo)median
28 ## 26.37306
29
30
31 #Paired t-test to double check and confirm non-parametric results
32 t.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine,
33        subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine,
34        paired = TRUE)
35
36 ##
37 ## Paired t-test
38 ##
39 ## data: subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine an
40 d subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine
41 ## t = 2.3911, df = 19, p-value = 0.02731
42 ## alternative hypothesis: true difference in means is not equal to 0
43 ## 95 percent confidence interval:
44 ## 3.03469 45.65601
45 ## sample estimates:
46 ## mean of the differences
47 ## 24.34535
48
49
50 #between participants (grouped) comparison
51 summary(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
52
53 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
54 ## 0.00 0.00 12.30 37.95 53.48 267.10
55
56 sd(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
57
58
59
60

```

```

1
2
3 ## [1] 62.65788
4
5 length(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
6
7 ## [1] 20
8
9 qqnorm(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
10 qqline(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

```



```

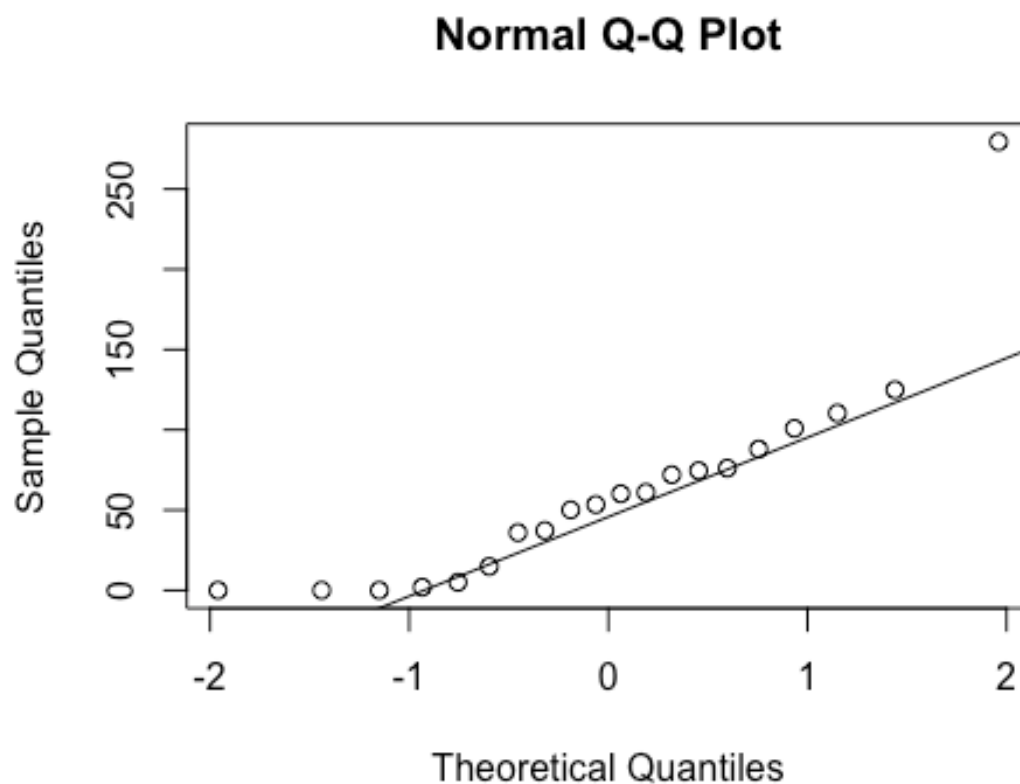
41 ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine
47 ## A = 2.2269, p-value = 7.014e-06
48
49 #non-normal
50
51 summary(subset(SSdata, intervention == "sham")$minutesTSTSupine)
52
53 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##   0.00  12.39   56.80   62.30   79.08  279.40
55
56 sd(subset(SSdata, intervention == "sham")$minutesTSTSupine)
57
58
59
60

```

```

1
2
3 ## [1] 64.21539
4
5 length(subset(SSdata, intervention == "sham")$minutesTSTSupine)
6
7 ## [1] 20
8
9 qqnorm(subset(SSdata, intervention == "sham")$minutesTSTSupine)
10 qqline(subset(SSdata, intervention == "sham")$minutesTSTSupine)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

```



```

41 ad.test(subset(SSdata, intervention == "sham")$minutesTSTSupine)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: subset(SSdata, intervention == "sham")$minutesTSTSupine
47 ## A = 0.96839, p-value = 0.01163
48
49 #non-normal
50
51 #FYI - unpaired test
52 wilcox.test(subset(SSdata, intervention == "sham")$minutesTSTSupine,
53             subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine,
54             conf.int = TRUE, alternative = "greater")
55
56
57
58
59
60

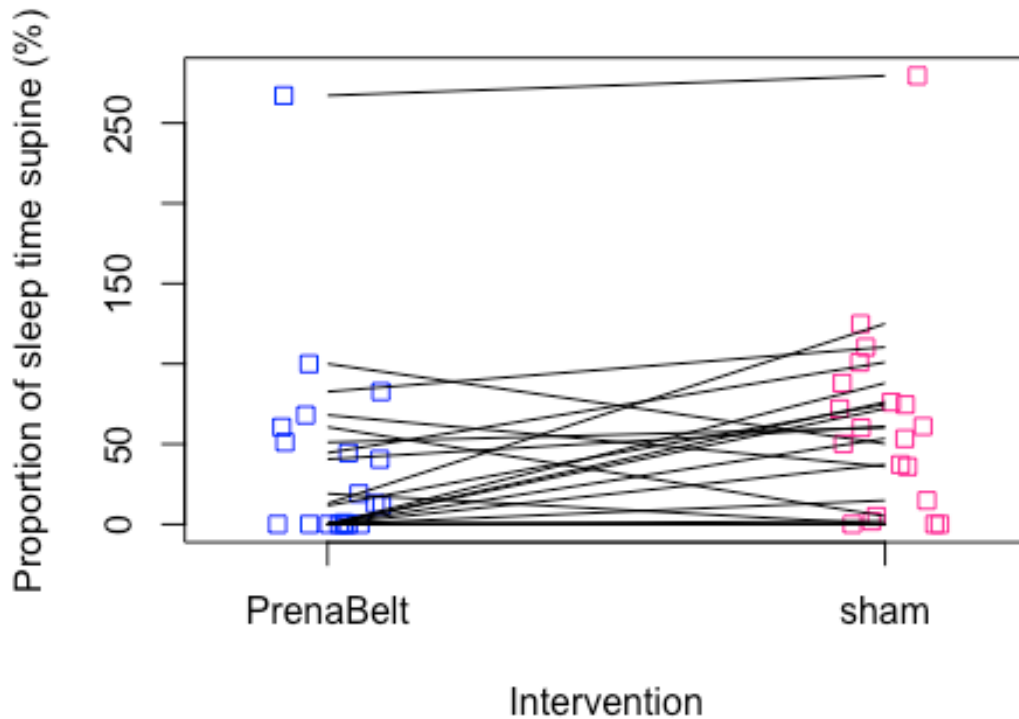
```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
4  ## $minutesTSTSupine, : cannot compute exact p-value with ties
5
6  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
7  ## $minutesTSTSupine, : cannot compute exact confidence intervals with ties
8
9  ##
10 ## Wilcoxon rank sum test with continuity correction
11 ##
12 ## data: subset(SSdata, intervention == "sham")$minutesTSTSupine and subset(
13 SSdata, intervention == "PrenaBelt")$minutesTSTSupine
14 ## W = 271, p-value = 0.02699
15 ## alternative hypothesis: true location shift is greater than 0
16 ## 95 percent confidence interval:
17 ##  6.926608e-05      Inf
18 ## sample estimates:
19 ## difference in location
20 ##                24.28712
21
22
23 # Use droplevels to remove the empty levels from the list of levels
24 SSdata$intervention <- droplevels(SSdata$intervention)
25 summary(SSdata$intervention)
26
27 ## PrenaBelt      sham
28 ##          20      20
29
30 stripchart(SSdata$minutesTSTSupine~SSdata$intervention,
31             vertical = TRUE, method="jitter", col=c("blue","deeppink"),
32             ylab='Proportion of sleep time supine (%)', xlab='Intervention',
33             main='Proportion of sleep time supine (%) vs. Intervention',)
34
35 for(participant.s.code in split(SSdata, SSdata$participant.s.code))
36   lines(minutesTSTSupine ~ intervention, participant.s.code)
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

Proportion of sleep time supine (%) vs. Interventio



```
##### Minutes Sleeping Left #####
#Summary
summary(SSdata$minutesTSTLeft)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.0  114.2   162.6   180.9   225.1   390.0

sd(SSdata$minutesTSTLeft, na.rm = TRUE)

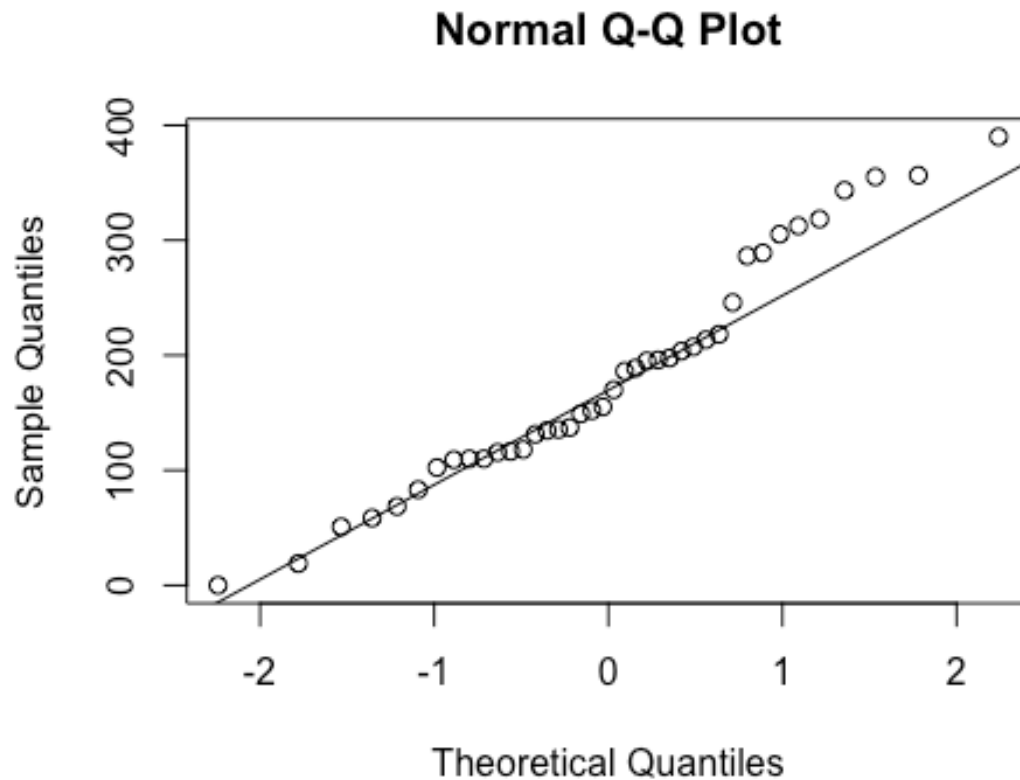
## [1] 97.72311

length(SSdata$minutesTSTLeft)

## [1] 40

qqnorm(SSdata$minutesTSTLeft)
qqline(SSdata$minutesTSTLeft)
```

BMJ Open: first published as 10.1136/bmjopen-2017-020256 on 29 August 2018. Downloaded from <http://bmjopen.bmj.com/> on April 20, 2024 by guest. Protected by copyright.



```
ad.test(SSdata$minutesTSTLeft)

##
## Anderson-Darling normality test
##
## data:  SSdata$minutesTSTLeft
## A = 0.60089, p-value = 0.1109

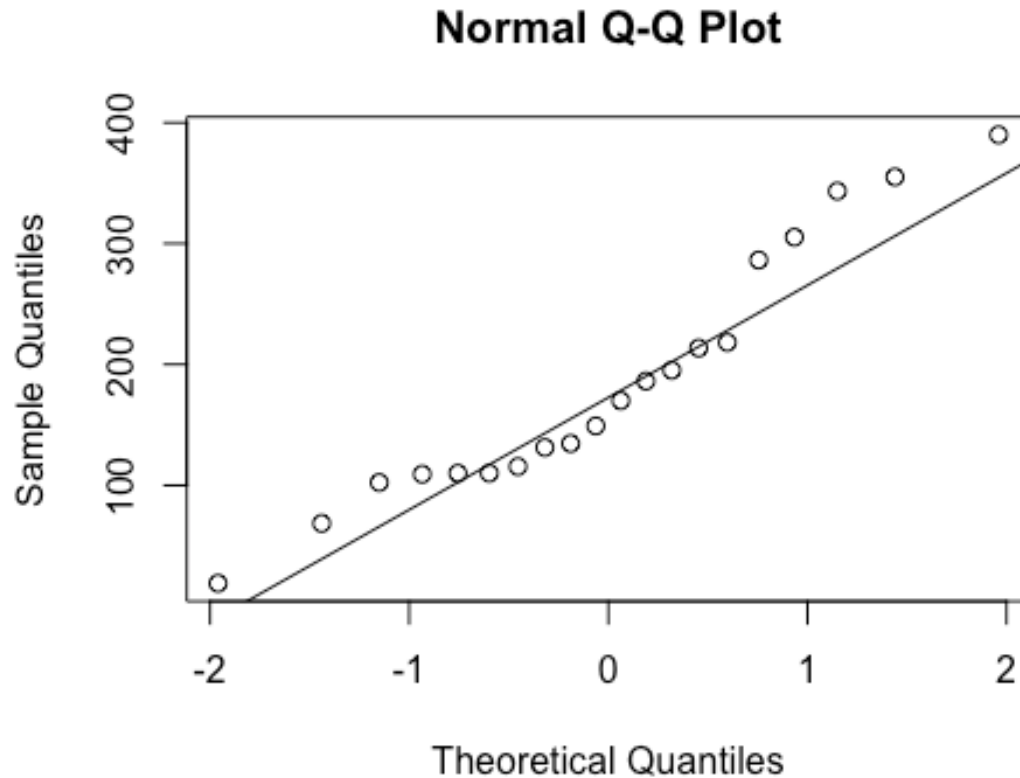
#normal

#ANOVA
night_tx_difference <- anova(lm(minutesTSTLeft ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: minutesTSTLeft
##
```

	Df	Sum Sq	Mean Sq	F value	Pr(>F)
## intervention	1	910	909.5	0.0960	0.7585
## night	1	5161	5160.9	0.5447	0.4653
## intervention:night	1	25295	25294.7	2.6698	0.1110
## Residuals	36	341077	9474.4		

```
1
2
3 #within-participants (paired) comparison
4 #Paired t-test
5 t.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTLeft,
6        subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTLeft,
7        paired = TRUE)
8
9 ##
10 ## Paired t-test
11 ##
12 ## data: subset(SSdataCompletes, intervention == "sham")$minutesTSTLeft and
13 subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTLeft
14 ## t = -0.59061, df = 19, p-value = 0.5617
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -43.33418 24.26038
18 ## sample estimates:
19 ## mean of the differences
20 ## -9.5369
21
22
23 #between participants (grouped) comparison
24 summary(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
25
26 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##  18.95  110.00  159.60  185.60  235.30  390.00
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
30
31 ## [1] 102.4677
32
33 length(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
34
35 ## [1] 20
36
37 qqnorm(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
38 qqline(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft
## A = 0.60013, p-value = 0.103

#normal

summary(subset(SSdata, intervention == "sham")$minutesTSTLeft)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.0  117.6   172.0   176.1  217.0   356.4

sd(subset(SSdata, intervention == "sham")$minutesTSTLeft)

## [1] 95.1564

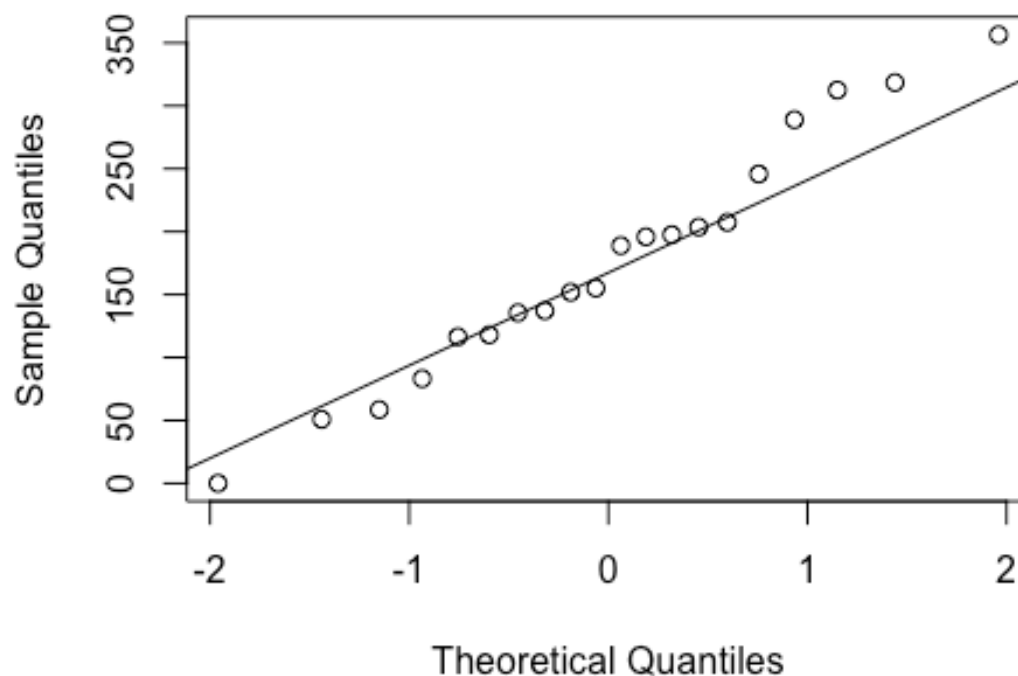
length(subset(SSdata, intervention == "sham")$minutesTSTLeft)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$minutesTSTLeft)
qqline(subset(SSdata, intervention == "sham")$minutesTSTLeft)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$minutesTSTLeft)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$minutesTSTLeft
## A = 0.21195, p-value = 0.8324

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$minutesTSTLeft,
       subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$minutesTSTLeft and subset(SS
data, intervention == "PrenaBelt")$minutesTSTLeft
## t = -0.305, df = 37.794, p-value = 0.762
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -72.84799 53.77419
## sample estimates:

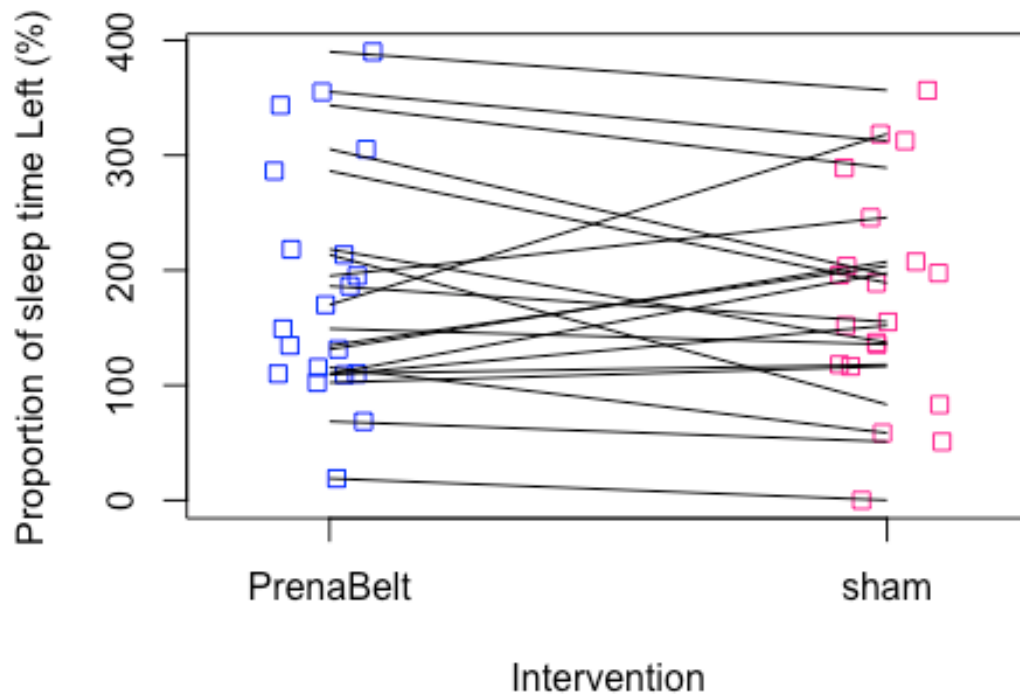
```

```

1
2
3  ## mean of x mean of y
4  ## 176.1083 185.6452
5
6  # Use droplevels to remove the empty Levels from the List of Levels
7  SSdata$intervention <- droplevels(SSdata$intervention)
8  summary(SSdata$intervention)
9
10 ## PrenaBelt      sham
11 ##          20      20
12
13 stripchart(SSdata$minutesTSTLeft~SSdata$intervention,
14            vertical = TRUE, method="jitter", col=c("blue","deeppink"),
15            ylab='Proportion of sleep time Left (%)', xlab='Intervention',
16            main='Proportion of sleep time Left (%) vs. Intervention',)
17
18 for(participant.s.code in split(SSdata, SSdata$participant.s.code))
19   lines(minutesTSTLeft ~ intervention, participant.s.code)
20
21
22
23
24
25
26

```

Proportion of sleep time Left (%) vs. Intervention



```

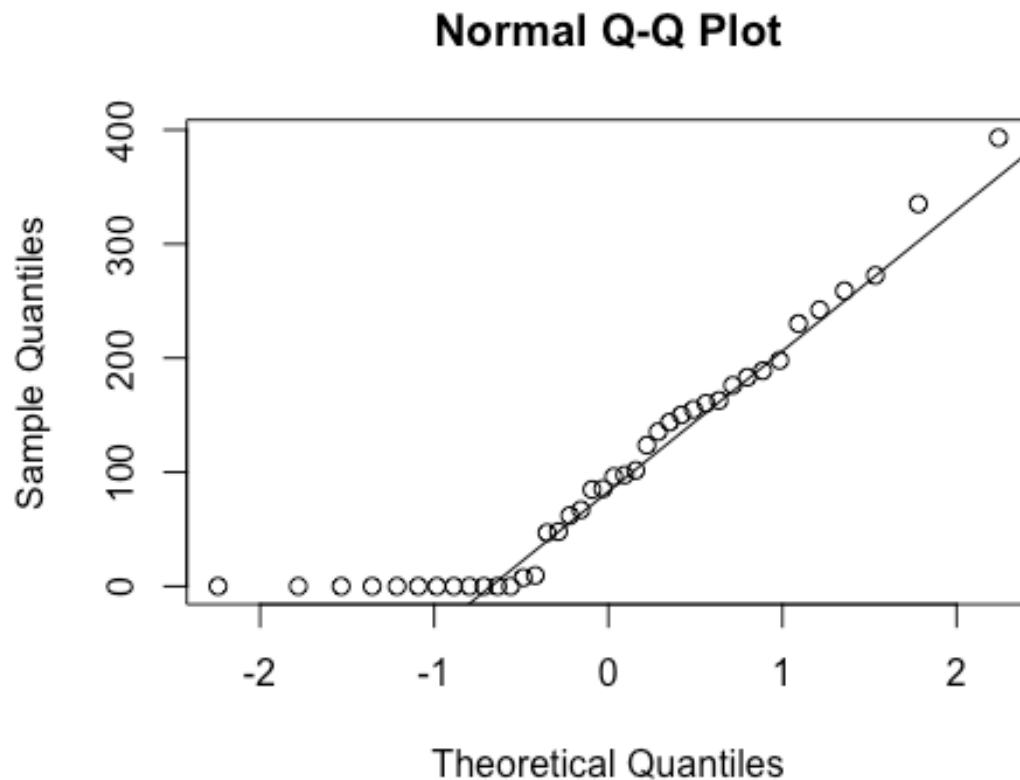
50 ##### Minutes Sleeping Right #####
51 #Summary
52 summary(SSdata$minutesTSTRight)
53
54 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
55 ##   0.00   0.00   90.78  105.40  166.10  393.00
56
57
58
59
60

```

```
sd(SSdata$minutesTSTRight, na.rm = TRUE)
## [1] 104.3365

length(SSdata$minutesTSTRight)
## [1] 40

qqnorm(SSdata$minutesTSTRight)
qqline(SSdata$minutesTSTRight)
```



```
ad.test(SSdata$minutesTSTRight)
##
## Anderson-Darling normality test
##
## data: SSdata$minutesTSTRight
## A = 1.3459, p-value = 0.001489

#non-normal

#ANOVA
night_tx_difference <- anova(lm(minutesTSTRight ~ intervention * night,
```

```

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```

```

                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: minutesTSTRight
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention      1    477   477.4    0.0427 0.8374
## night              1   1242  1242.1    0.1111 0.7408
## intervention:night  1  20504 20503.6    1.8346 0.1840
## Residuals         36 402335 11176.0

#within-participants (paired) comparison
#Paired Wilcoxon (non-normal)
wilcox.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTRight,
            subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTRight,
            ht,
            paired = TRUE, conf.int = TRUE, alternative = "greater")

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$minutesTSTRight, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$minutesTSTRight, : cannot compute exact confidence interval with
## zeroes

##
## Wilcoxon signed rank test with continuity correction
##
## data: subset(SSdataCompletes, intervention == "sham")$minutesTSTRight and
subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTRight
## V = 54, p-value = 0.644
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
## -47.61614      Inf
## sample estimates:
## (pseudo)median
##      -7.343686

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   96.82  108.90  167.50  393.00

sd(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

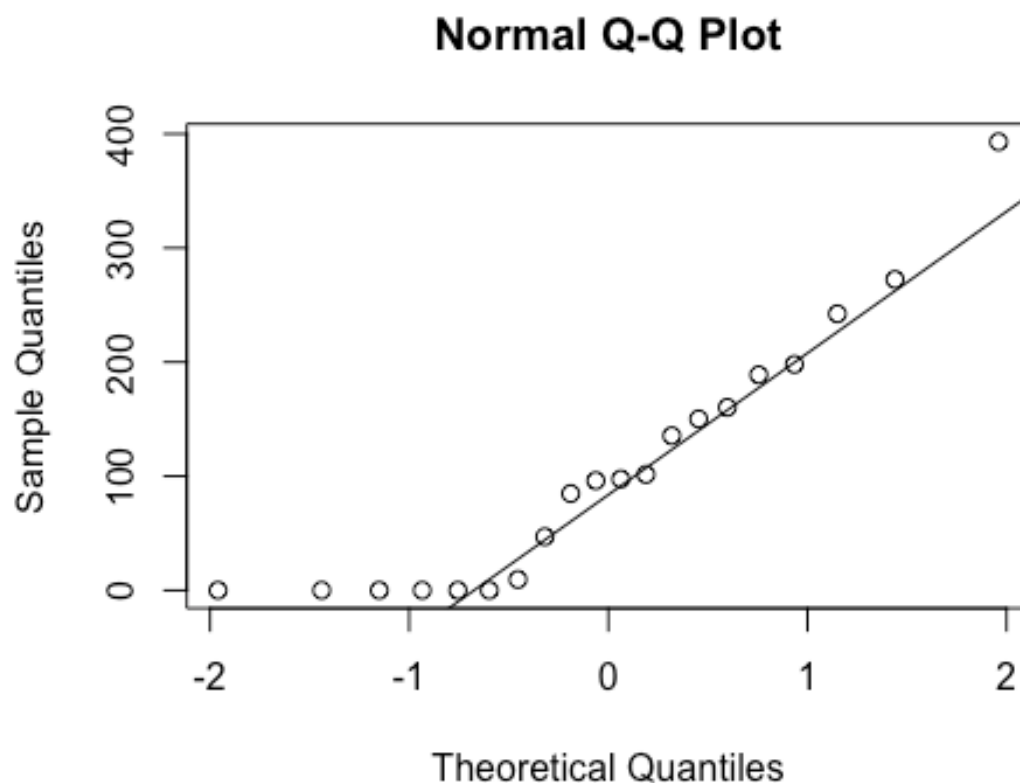
## [1] 110.1396

length(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)
qqline(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight
## A = 0.71202, p-value = 0.05306

#borderline normal

summary(subset(SSdata, intervention == "sham")$minutesTSTRight)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   76.23  101.90  166.10  335.10

sd(subset(SSdata, intervention == "sham")$minutesTSTRight)

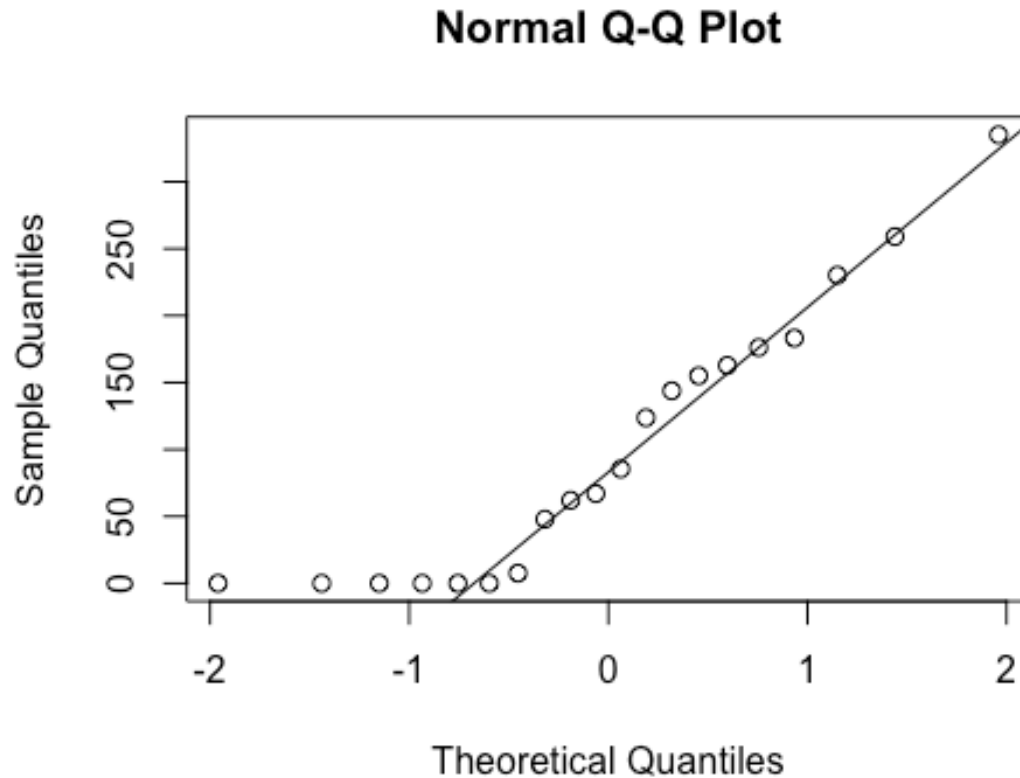
## [1] 100.9421

length(subset(SSdata, intervention == "sham")$minutesTSTRight)

## [1] 20
```



```
qqnorm(subset(SSdata, intervention == "sham")$minutesTSTRight)
qqline(subset(SSdata, intervention == "sham")$minutesTSTRight)
```



```
ad.test(subset(SSdata, intervention == "sham")$minutesTSTRight)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$minutesTSTRight
## A = 0.73955, p-value = 0.04508

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$minutesTSTRight,
            subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight,
            conf.int = TRUE, alternative = "greater")

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $minutesTSTRight, : cannot compute exact p-value with ties

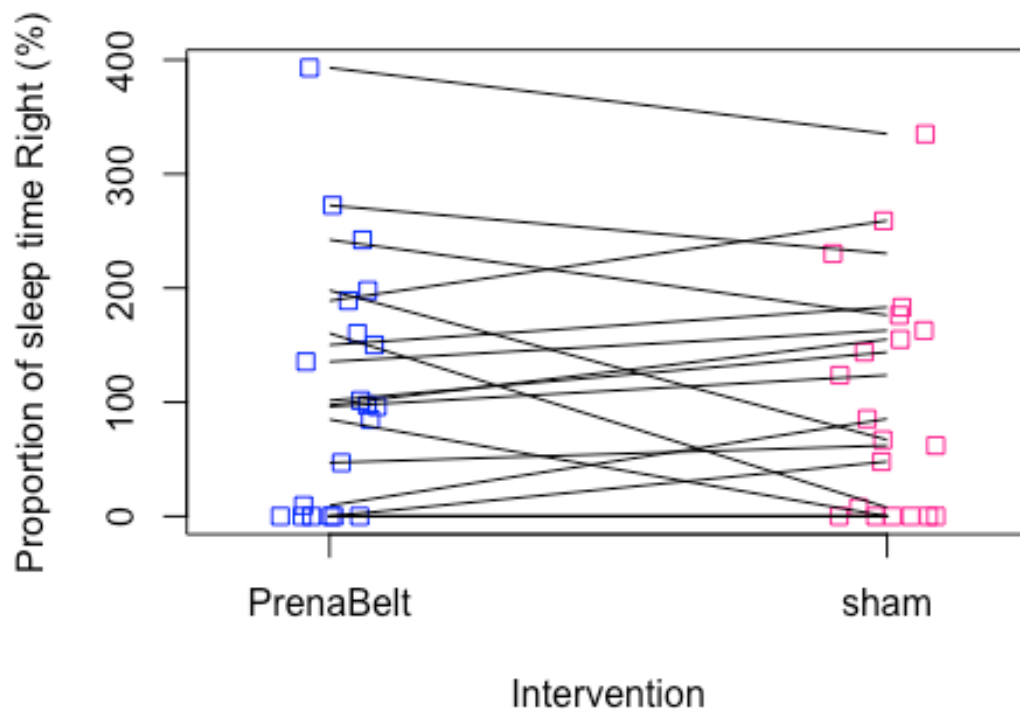
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $minutesTSTRight, : cannot compute exact confidence intervals with ties
```

```

1
2
3
4 ## Wilcoxon rank sum test with continuity correction
5 ##
6 ## data: subset(SSdata, intervention == "sham")$minutesTSTRight and subset(S
7 Sdata, intervention == "PrenaBelt")$minutesTSTRight
8 ## W = 195, p-value = 0.5599
9 ## alternative hypothesis: true location shift is greater than 0
10 ## 95 percent confidence interval:
11 ## -54.15088      Inf
12 ## sample estimates:
13 ## difference in location
14 ## -3.909212e-05
15
16
17 # Use droplevels to remove the empty levels from the list of levels
18 SSdata$intervention <- droplevels(SSdata$intervention)
19 summary(SSdata$intervention)
20
21 ## PrenaBelt      sham
22 ##          20          20
23
24 stripchart(SSdata$minutesTSTRight~SSdata$intervention,
25             vertical = TRUE, method="jitter", col=c("blue","deeppink"),
26             ylab='Proportion of sleep time Right (%)', xlab='Intervention',
27             main='Proportion of sleep time Right (%) vs. Intervention',)
28
29 for(participant.s.code in split(SSdata, SSdata$participant.s.code))
30   lines(minutesTSTRight ~ intervention, participant.s.code)
31
32
33
34
35
36
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```

Proportion of sleep time Right (%) vs. Intervention



```

32 #Considering index (events per hour) data now:
33 ##### Central Apnea Index #####
34 #FYI: this data was generated in our PSG reports per default configuration but
35 #is not a
36 #pre-specified secondary outcome per the research protocol or trial registry.
37 #FYI only.
38 #Summary
39 summary(SSdata$central.apneas.index)
40
41 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
42 ##  0.000  0.000  0.000  0.060  0.025  0.500
43
44 sd(SSdata$central.apneas.index, na.rm = TRUE)
45
46 ## [1] 0.1236206
47
48 length(SSdata$central.apneas.index)
49
50 ## [1] 40
51
52 #ANOVA
53 night_tx_difference <- anova(lm(central.apneas.index ~ intervention * night,
54                               data = SSdata))
55 night_tx_difference

```

```

1
2
3  ## Analysis of Variance Table
4  ##
5  ## Response: central.apneas.index
6  ##
7  ##           Df Sum Sq Mean Sq F value Pr(>F)
8  ## intervention      1  0.001  0.001000  0.0679 0.79587
9  ## night              1  0.001  0.001000  0.0679 0.79587
10 ## intervention:night  1  0.064  0.064000  4.3472 0.04422 *
11 ## Residuals         36  0.530  0.014722
12 ## ---
13 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
14
15 #within-participants (paired) comparison
16 #Paired Wilcoxon
17 wilcox.test(subset(SSdataCompletes, intervention == "sham")$central.apneas.in
18 dex,
19           subset(SSdataCompletes, intervention == "PrenaBelt")$central.apneas.in
20 dex,
21           paired = TRUE, conf.int = TRUE)
22
23 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24 ## "sham")$central.apneas.index, : cannot compute exact p-value with ties
25
26 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
27 ## "sham")$central.apneas.index, : cannot compute exact confidence interval
28 ## with ties
29
30 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
31 ## "sham")$central.apneas.index, : cannot compute exact p-value with zeroes
32
33 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
34 ## "sham")$central.apneas.index, : cannot compute exact confidence interval
35 ## with zeroes
36
37 ##
38 ## Wilcoxon signed rank test with continuity correction
39 ##
40 ## data:  subset(SSdataCompletes, intervention == "sham")$central.apneas.inde
41 x and subset(SSdataCompletes, intervention == "PrenaBelt")$central.apneas.ind
42 ex
43 ## V = 26.5, p-value = 0.6746
44 ## alternative hypothesis: true location shift is not equal to 0
45 ## 95 percent confidence interval:
46 ## -0.1500585  0.2000332
47 ## sample estimates:
48 ## (pseudo)median
49 ## 0.04999741
50
51 #between participants (grouped) comparison
52 summary(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
53
54 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
55 ##      0.000  0.000  0.000  0.055  0.000  0.500
56
57
58
59
60

```

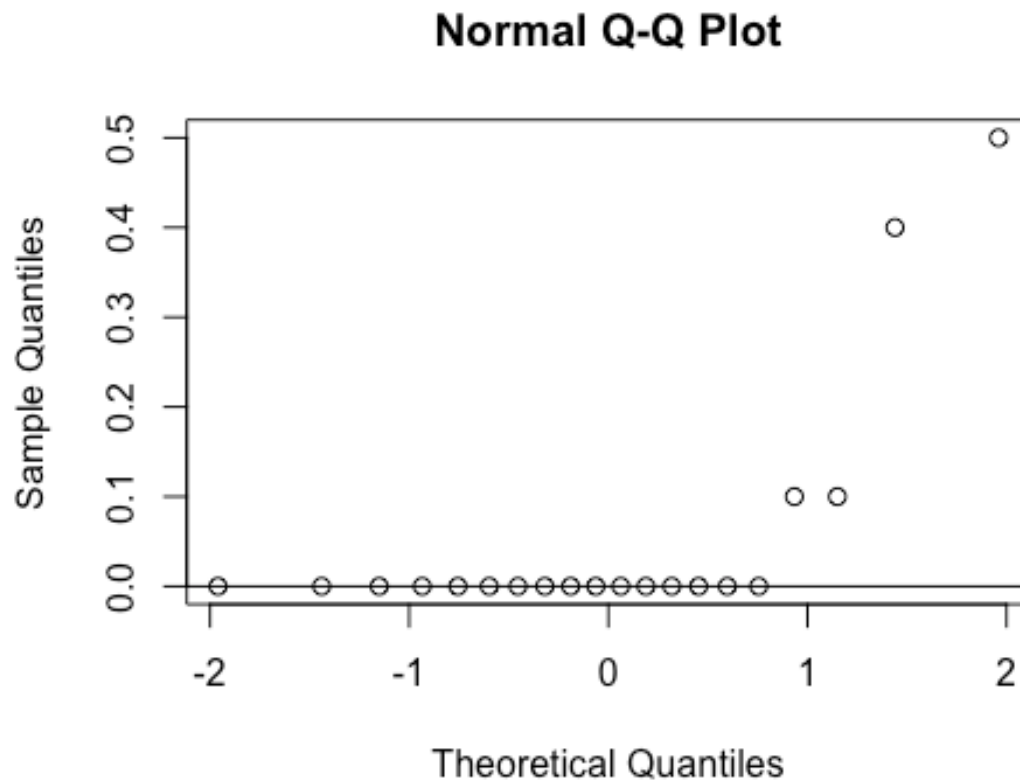
```

sd(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
## [1] 0.1394538

length(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$central.apneas.index
## A = 5.0415, p-value = 5.577e-13

#non-norma

summary(subset(SSdata, intervention == "sham")$central.apneas.index)
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 0.000  0.000  0.000  0.065  0.125  0.300

```

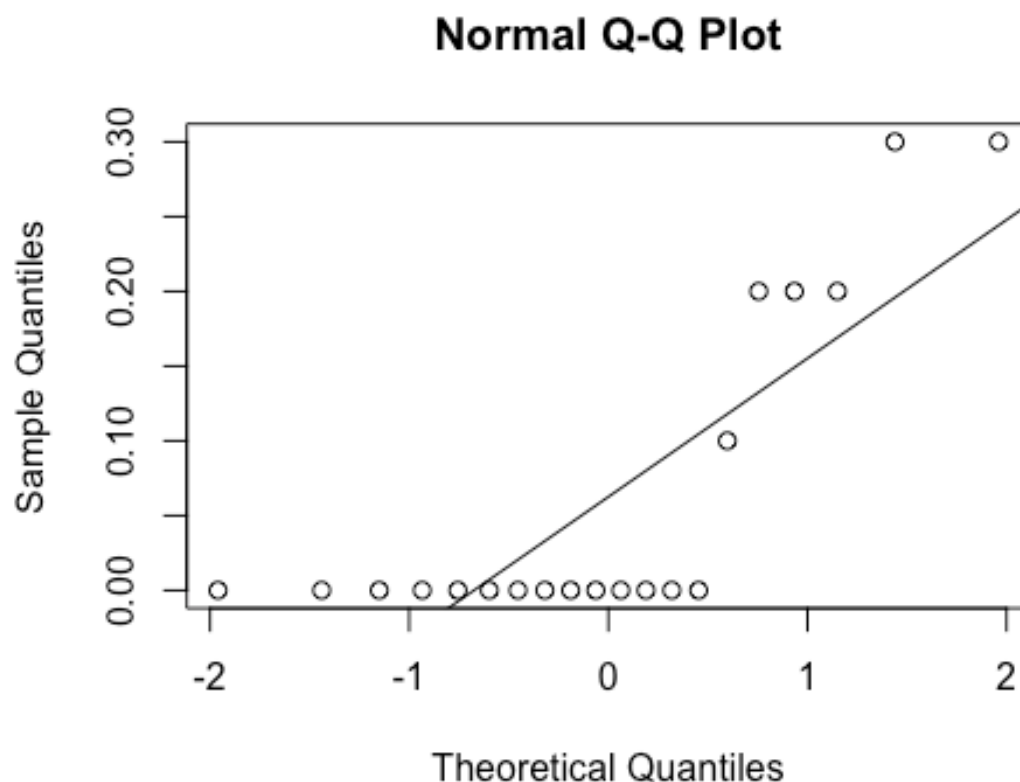
```

sd(subset(SSdata, intervention == "sham")$central.apneas.index)
## [1] 0.1089423

length(subset(SSdata, intervention == "sham")$central.apneas.index)
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$central.apneas.index)
qqline(subset(SSdata, intervention == "sham")$central.apneas.index)

```



```

ad.test(subset(SSdata, intervention == "sham")$central.apneas.index)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$central.apneas.index
## A = 3.5176, p-value = 3.741e-09

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$central.apneas.index,

```

```

subset(SSdata, intervention == "PrenaBelt")$central.apneas.index,
conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $central.apneas.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $central.apneas.index, : cannot compute exact confidence intervals with
## ties

##
## Wilcoxon rank sum test with continuity correction
##
## data: subset(SSdata, intervention == "sham")$central.apneas.index and sub
set(SSdata, intervention == "PrenaBelt")$central.apneas.index
## W = 219, p-value = 0.5102
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
## -6.326233e-05 3.161243e-05
## sample estimates:
## difference in location
## 5.5406e-05

##### Obstructive Apnea Index #####
#FYI: this data was generated in our PSG reports per default configuration bu
t is not a
#pre-specified secondary outcome per the research protocol or trial registry.
FYI only.
#Summary
summary(SSdata$obstructive.apneas.index)

## Min. 1st Qu. Median Mean 3rd Qu. Max.
## 0.000 0.000 0.000 0.730 0.225 11.400

sd(SSdata$obstructive.apneas.index, na.rm = TRUE)

## [1] 2.115171

length(SSdata$obstructive.apneas.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(obstructive.apneas.index ~ intervention + nig
ht,
data = SSdata))

night_tx_difference

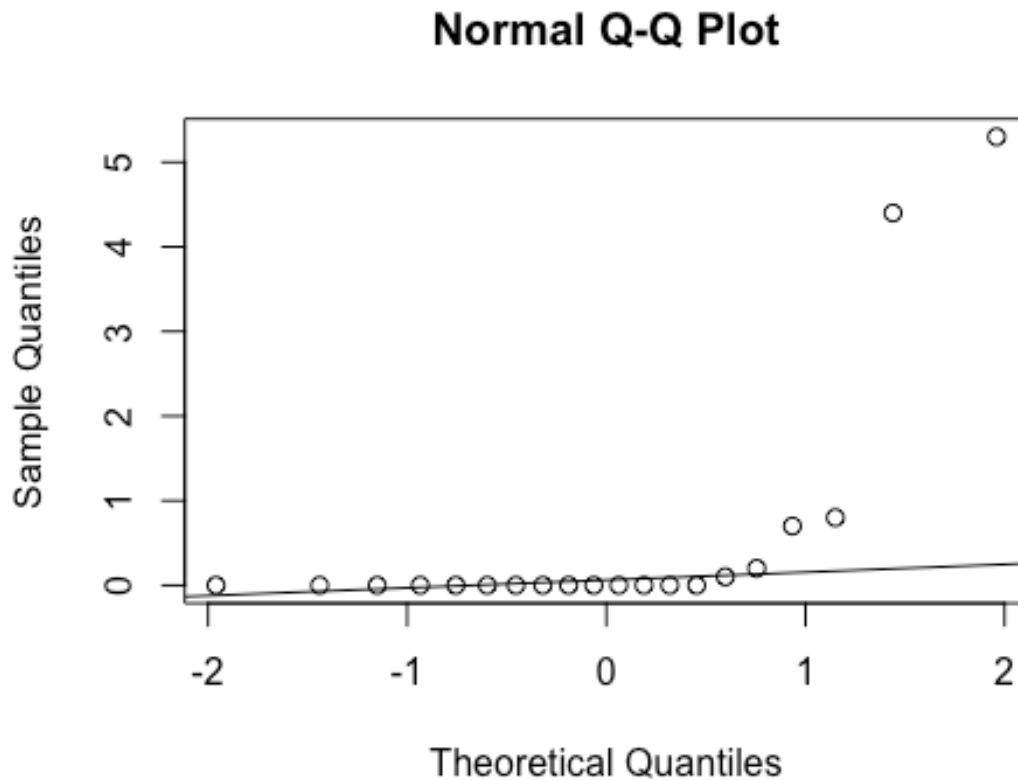
## Analysis of Variance Table
##
## Response: obstructive.apneas.index
## Df Sum Sq Mean Sq F value Pr(>F)

```

```

1
2
3 ## intervention  1  0.961  0.9610  0.2065  0.6521
4 ## night        1  1.369  1.3690  0.2942  0.5908
5 ## Residuals   37 172.154  4.6528
6
7 #within-participants (paired) comparison
8 #Paired Wilcoxon
9 wilcox.test(subset(SSdataCompletes, intervention == "sham")$obstructive.apnea
10 s.index,
11           subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.apnea
12 s.index,
13           paired = TRUE, conf.int = TRUE)
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$obstructive.apneas.index, : cannot compute exact p-value with
17 ## zeroes
18
19 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention
20 ## == "sham")$obstructive.apneas.index, : cannot compute exact confidence
21 ## interval with zeroes
22
23 ##
24 ## Wilcoxon signed rank test with continuity correction
25 ##
26 ## data: subset(SSdataCompletes, intervention == "sham")$obstructive.apneas.
27 index and subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.ap
28 neas.index
29 ## V = 18, p-value = 1
30 ## alternative hypothesis: true location shift is not equal to 0
31 ## 95 percent confidence interval:
32 ## -0.7499621  3.5499235
33 ## sample estimates:
34 ## (pseudo)median
35 ## 0.03901549
36
37 #between participants (grouped) comparison
38 summary(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
39
40 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
41 ##  0.000  0.000  0.000  0.575  0.125  5.300
42
43 sd(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
44
45 ## [1] 1.487094
46
47 length(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
48
49 ## [1] 20
50
51 qqnorm(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
52 qqline(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)
53
54
55
56
57
58
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```

```

ad.test(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index
## A = 5.1462, p-value = 3.055e-13

#non-normal

summary(subset(SSdata, intervention == "sham")$obstructive.apneas.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  0.885  0.300  11.400

sd(subset(SSdata, intervention == "sham")$obstructive.apneas.index)

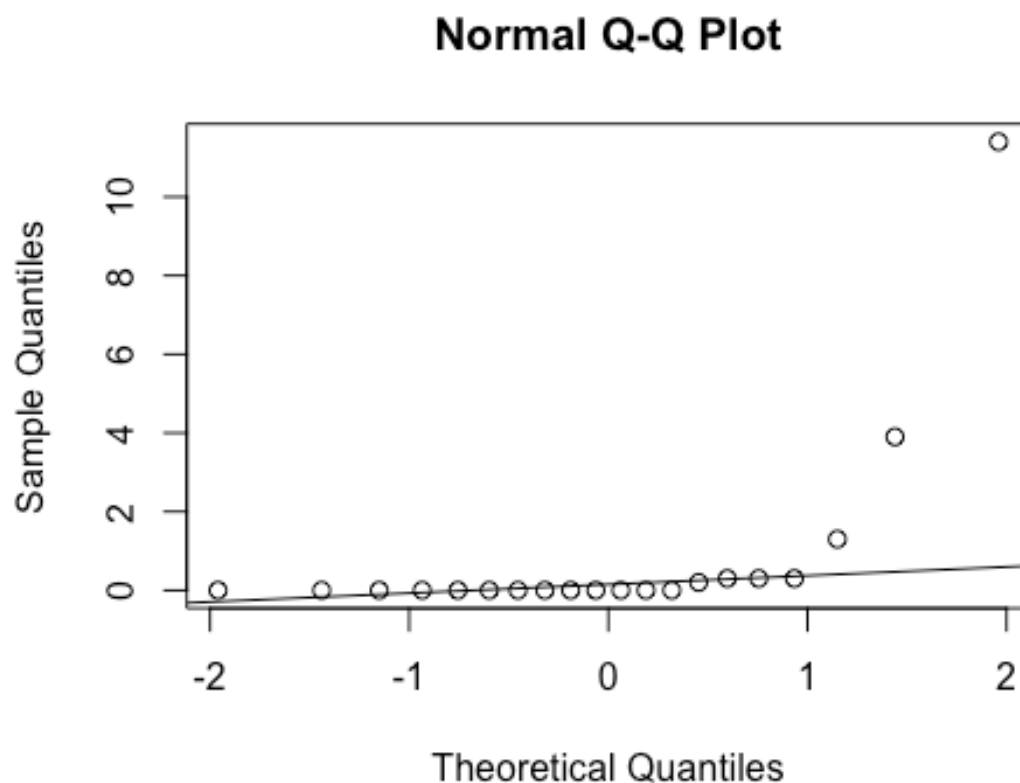
## [1] 2.630844

length(subset(SSdata, intervention == "sham")$obstructive.apneas.index)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "sham")$obstructive.apneas.index)
qqline(subset(SSdata, intervention == "sham")$obstructive.apneas.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$obstructive.apneas.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$obstructive.apneas.index
## A = 5.2073, p-value = 2.15e-13

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$obstructive.apneas.index,
            subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.in
dex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $obstructive.apneas.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $obstructive.apneas.index, : cannot compute exact confidence intervals wit
```

```

1
2
3 h
4 ## ties
5
6 ##
7 ## Wilcoxon rank sum test with continuity correction
8 ##
9 ## data: subset(SSdata, intervention == "sham")$obstructive.apneas.index and
10 subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index
11 ## W = 210.5, p-value = 0.7451
12 ## alternative hypothesis: true location shift is not equal to 0
13 ## 95 percent confidence interval:
14 ## -3.671494e-05 4.691508e-05
15 ## sample estimates:
16 ## difference in location
17 ## 2.019957e-05
18
19
20 ##### Mixed Apnea Index #####
21 #FYI: this data was generated in our PSG reports per default configuration but is not a
22 t is not a
23 #pre-specified secondary outcome per the research protocol or trial registry.
24 FYI only.
25 #Summary
26 summary(SSdata$mixed.apneas.index)
27
28 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
29 ##           0         0         0         0         0         0
30
31 sd(SSdata$mixed.apneas.index, na.rm = TRUE)
32
33 ## [1] 0
34
35 length(SSdata$mixed.apneas.index)
36
37 ## [1] 40
38
39 #ANOVA
40 night_tx_difference <- anova(lm(mixed.apneas.index ~ intervention + night,
41                               data = SSdata))
42
43 night_tx_difference
44
45 ## Analysis of Variance Table
46 ##
47 ## Response: mixed.apneas.index
48 ##           Df Sum Sq Mean Sq F value Pr(>F)
49 ## intervention  1      0      0
50 ## night         1      0      0
51 ## Residuals    37      0      0
52
53 #within-participants (paired) comparison
54 #distribution is made entirely of zeroes
55 #difference testing not applicable
56
57
58
59
60

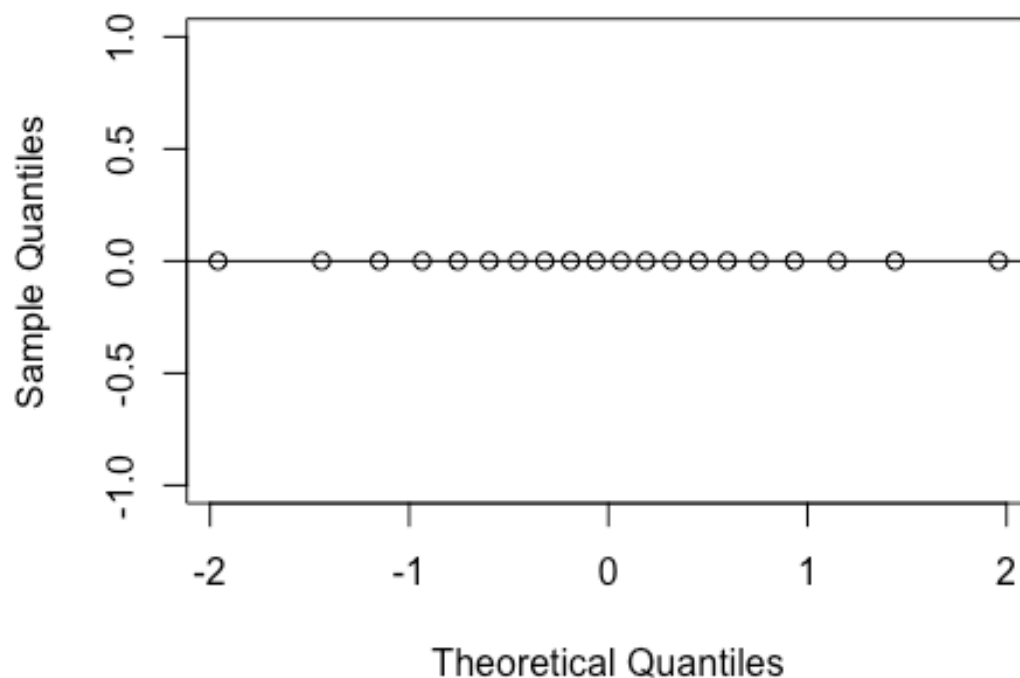
```

```

1
2
3 #between participants (grouped) comparison
4 summary(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
5
6 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
7 ##          0         0         0         0         0         0
8
9 sd(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
10
11 ## [1] 0
12
13 length(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
14
15 ## [1] 20
16
17 qqnorm(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
18 qqline(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
19

```

Normal Q-Q Plot



```

48 #ad.test(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
49 #distribution is made entirely of zeroes
50
51
52 summary(subset(SSdata, intervention == "sham")$mixed.apneas.index)
53
54 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
55 ##          0         0         0         0         0         0
56
57
58
59
60

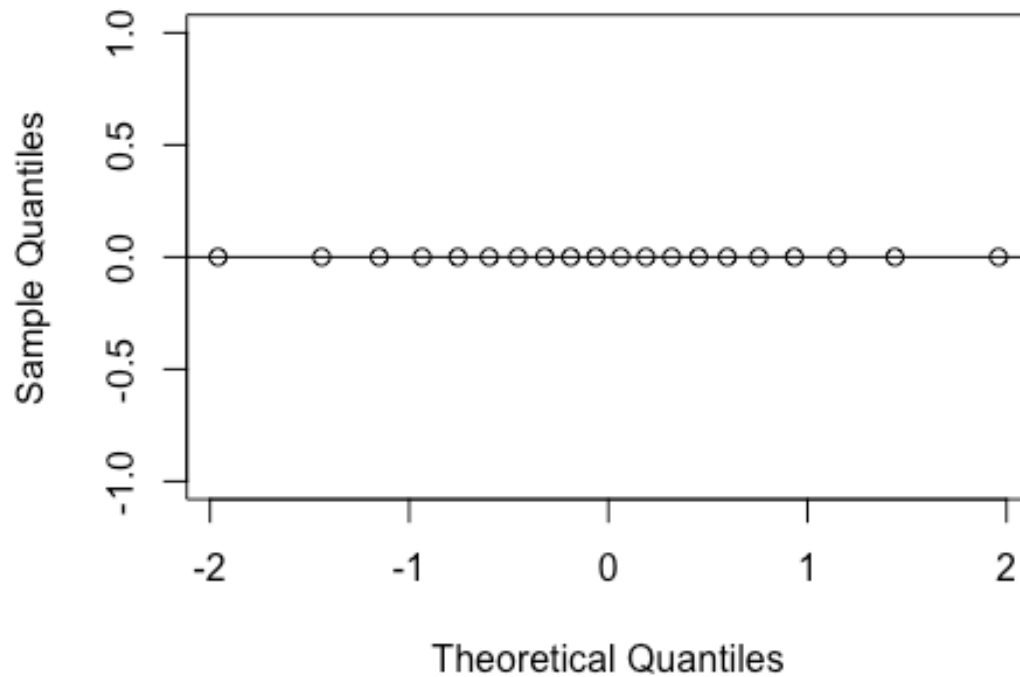
```

```

1
2
3 sd(subset(SSdata, intervention == "sham")$mixed.apneas.index)
4
5 ## [1] 0
6
7 length(subset(SSdata, intervention == "sham")$mixed.apneas.index)
8
9 ## [1] 20
10
11 qqnorm(subset(SSdata, intervention == "sham")$mixed.apneas.index)
12 qqline(subset(SSdata, intervention == "sham")$mixed.apneas.index)
13
14
15
16
17
18

```

Normal Q-Q Plot



```

42 #ad.test(subset(SSdata, intervention == "sham")$mixed.apneas.index)
43 #distribution is made entirely of zeroes
44 #difference testing not applicable
45
46
47 ##### Obstructive hypopneas Index #####
48 #FYI: this data was generated in our PSG reports per default configuration but is not a
49 #pre-specified secondary outcome per the research protocol or trial registry.
50 FYI only.
51 #Summary
52 summary(SSdata$obstructive.hypopneas.index)
53
54
55
56
57
58

```

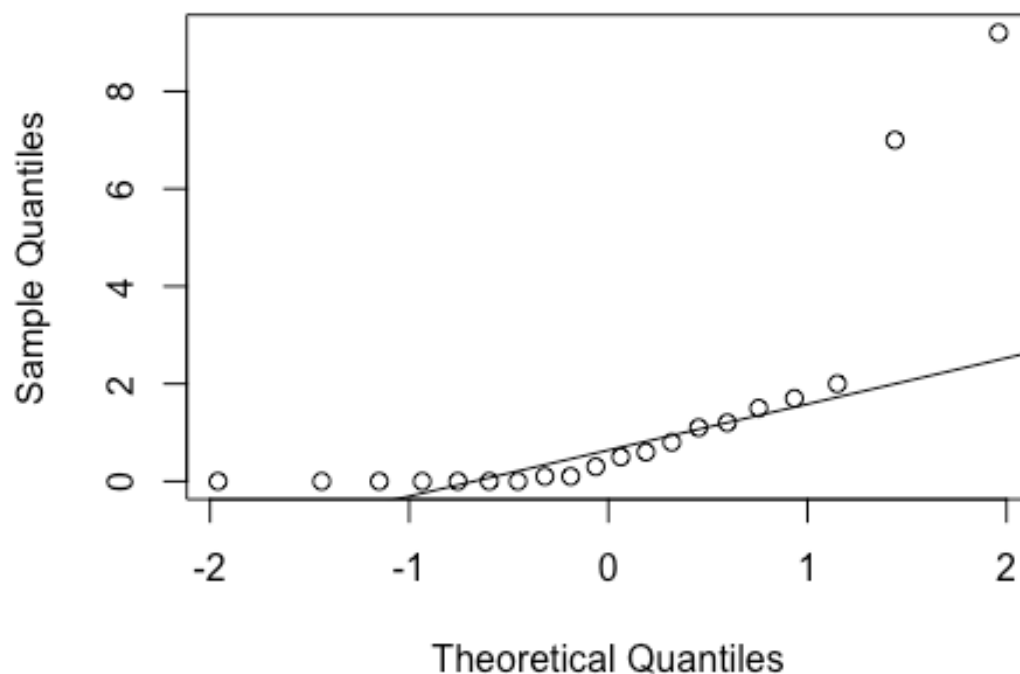
```

1
2
3   ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4   ##    0.000  0.000   0.250   1.378   1.225   11.900
5
6   sd(SSdata$obstructive.hypopneas.index, na.rm = TRUE)
7
8   ## [1] 2.738097
9
10  length(SSdata$obstructive.hypopneas.index)
11
12  ## [1] 40
13
14  #ANOVA
15  night_tx_difference <- anova(lm(obstructive.hypopneas.index ~ intervention +
16  night,
17                                data = SSdata))
18  night_tx_difference
19
20  ## Analysis of Variance Table
21  ##
22  ## Response: obstructive.hypopneas.index
23  ##           Df Sum Sq Mean Sq F value Pr(>F)
24  ## intervention  1  0.210  0.2103  0.0267 0.8711
25  ## night         1  0.702  0.7023  0.0891 0.7669
26  ## Residuals    37 291.477  7.8778
27
28  #within-participants (paired) comparison
29  #Paired Wilcoxon
30  wilcox.test(subset(SSdataCompletes, intervention == "sham")$obstructive.hypop
31  neas.index,
32              subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.hypop
33  neas.index,
34              paired = TRUE, conf.int = TRUE)
35
36  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
37  ## "sham")$obstructive.hypopneas.index, : cannot compute exact p-value with
38  ## ties
39
40  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
41  ## "sham")$obstructive.hypopneas.index, : cannot compute exact confidence
42  ## interval with ties
43
44  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
45  ## "sham")$obstructive.hypopneas.index, : cannot compute exact p-value with
46  ## zeroes
47
48  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
49  ## "sham")$obstructive.hypopneas.index, : cannot compute exact confidence
50  ## interval with zeroes
51
52  ##
53  ## Wilcoxon signed rank test with continuity correction
54  ##
55
56
57
58
59
60

```

```
1
2
3  ## data: subset(SSdataCompletes, intervention == "sham")$obstructive.hypopne
4  as.index and subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive
5  .hypopneas.index
6  ## V = 87, p-value = 0.6357
7  ## alternative hypothesis: true location shift is not equal to 0
8  ## 95 percent confidence interval:
9  ## -0.2999835  0.5499741
10 ## sample estimates:
11 ## (pseudo)median
12 ##      0.09999107
13
14 #between participants (grouped) comparison
15 summary(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.ind
16 ex)
17
18 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
19 ##      0.000   0.000   0.400   1.305   1.275   9.200
20
21 sd(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index)
22
23 ## [1] 2.435802
24
25 length(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
26 x)
27
28 ## [1] 20
29
30 qqnorm(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
31 x)
32 qqline(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
33 x)
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index
## A = 3.342, p-value = 1.039e-08
##non-normal

summary(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.00  0.00   0.20   1.45  1.00   11.90

sd(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

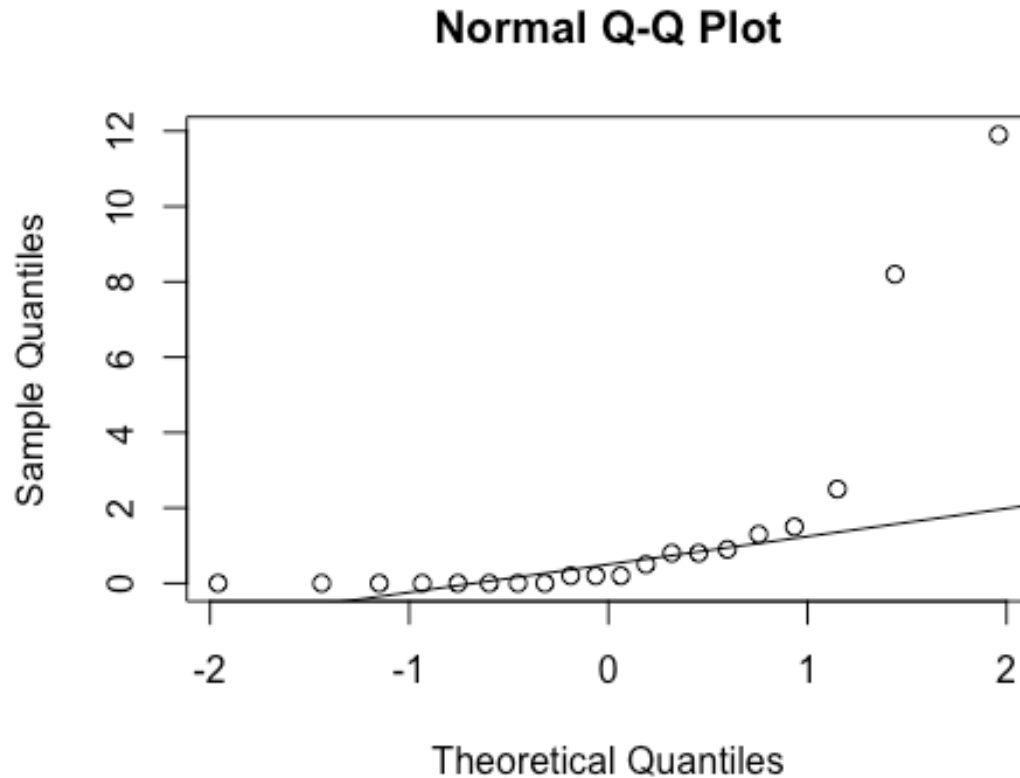
## [1] 3.073229

length(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

## [1] 20
```



```
qqnorm(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)
qqline(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$obstructive.hypopneas.index
## A = 3.9511, p-value = 3.022e-10

#non-normal

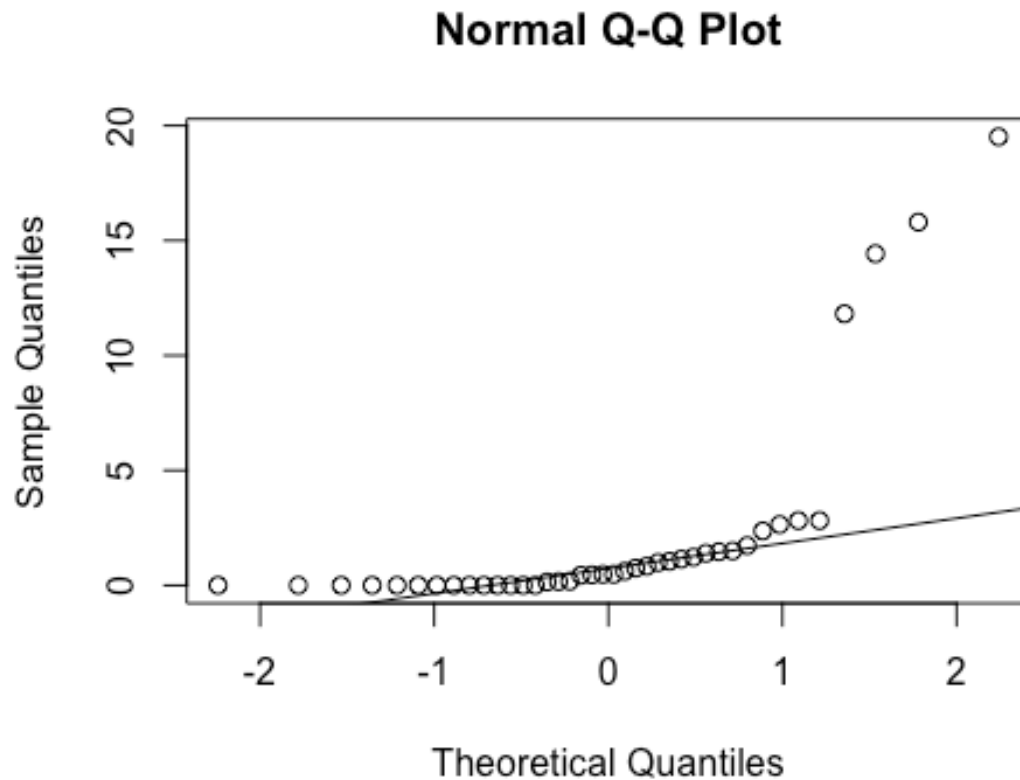
#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index,
            subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $obstructive.hypopneas.index, : cannot compute exact p-value with ties
```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
4  ## $obstructive.hypopneas.index, : cannot compute exact confidence intervals
5  ## with ties
6
7  ##
8  ##  Wilcoxon rank sum test with continuity correction
9  ##
10 ## data:  subset(SSdata, intervention == "sham")$obstructive.hypopneas.index
11 and subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index
12 ## W = 191, p-value = 0.8132
13 ## alternative hypothesis: true location shift is not equal to 0
14 ## 95 percent confidence interval:
15 ##  -0.5000080  0.2999871
16 ## sample estimates:
17 ## difference in location
18 ##          -1.817308e-06
19
20
21 ##### Apnea-Hypopnea Index #####
22 #Summary
23 summary(SSdata$AHI.calculated)
24
25 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
26 ##  0.0000  0.0000  0.4765  2.1800  1.4700 19.5100
27
28 sd(SSdata$AHI.calculated, na.rm = TRUE)
29
30 ## [1] 4.622751
31
32 length(SSdata$AHI.calculated)
33
34 ## [1] 40
35
36 qqnorm(SSdata$AHI.calculated)
37 qqline(SSdata$AHI.calculated)
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(SSdata$AHI.calculated)

##
## Anderson-Darling normality test
##
## data:  SSdata$AHI.calculated
## A = 8.242, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(AHI.calculated ~ intervention * night,
                               data = SSdata))
night_tx_difference

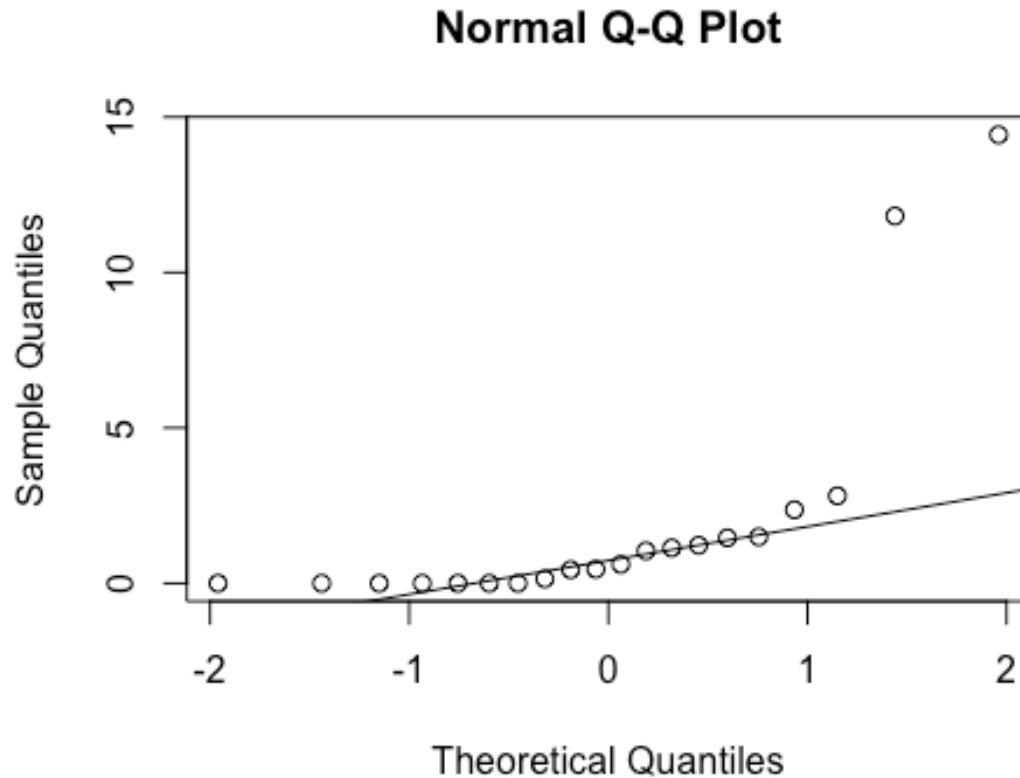
## Analysis of Variance Table
##
## Response: AHI.calculated
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    1.73    1.734   0.0866 0.77027
## night           1    4.60    4.596   0.2295 0.63478
## intervention:night  1 106.12 106.123   5.2990 0.02723 *
## Residuals      36 720.97   20.027

```

```

1
2
3  ## ---
4  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
5
6  #within-participants (paired) comparison
7  #Paired Wilcoxon
8  wilcox.test(subset(SSdataCompletes, intervention == "sham")$AHI.calculated,
9             subset(SSdataCompletes, intervention == "PrenaBelt")$AHI.calculated,
10            paired = TRUE, conf.int = TRUE)
11
12  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13  ## "sham")$AHI.calculated, : cannot compute exact p-value with zeroes
14
15  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16  ## "sham")$AHI.calculated, : cannot compute exact confidence interval with
17  ## zeroes
18
19  ##
20  ## Wilcoxon signed rank test with continuity correction
21  ##
22  ## data:  subset(SSdataCompletes, intervention == "sham")$AHI.calculated and
23  subset(SSdataCompletes, intervention == "PrenaBelt")$AHI.calculated
24  ## V = 91, p-value = 0.5075
25  ## alternative hypothesis: true location shift is not equal to 0
26  ## 95 percent confidence interval:
27  ## -0.4367014  0.7981902
28  ## sample estimates:
29  ## (pseudo)median
30  ##      0.1385676
31
32
33  #between participants (grouped) comparison
34  summary(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
35
36  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
37  ##  0.0000  0.0000  0.5321  1.9720  1.4700 14.4300
38
39  sd(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
40
41  ## [1] 3.924224
42
43  length(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
44
45  ## [1] 20
46
47  qqnorm(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
48  qqline(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$AHI.calculated
## A = 3.8736, p-value = 4.736e-10

#non-normal

summary(subset(SSdata, intervention == "sham")$AHI.calculated)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.4765  2.3880  1.4770 19.5100

sd(subset(SSdata, intervention == "sham")$AHI.calculated)

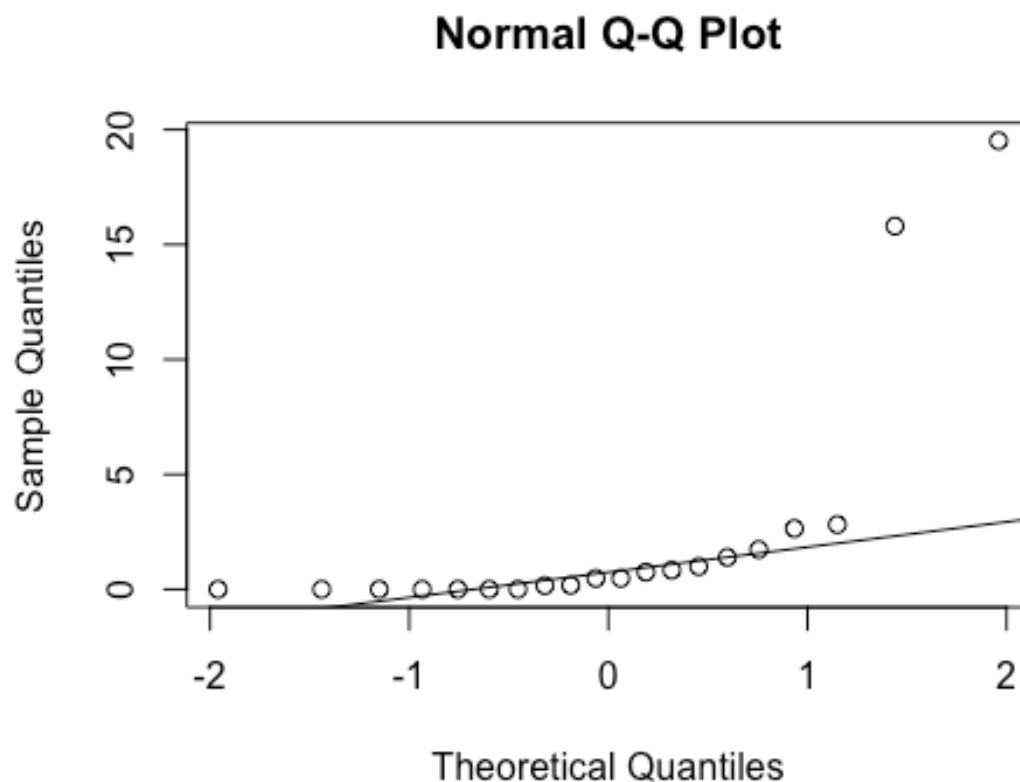
## [1] 5.326686

length(subset(SSdata, intervention == "sham")$AHI.calculated)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$AHI.calculated)
qqline(subset(SSdata, intervention == "sham")$AHI.calculated)

```



```

ad.test(subset(SSdata, intervention == "sham")$AHI.calculated)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$AHI.calculated
## A = 4.4571, p-value = 1.618e-11

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$AHI.calculated,
            subset(SSdata, intervention == "PrenaBelt")$AHI.calculated,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $AHI.calculated, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $AHI.calculated, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```

```

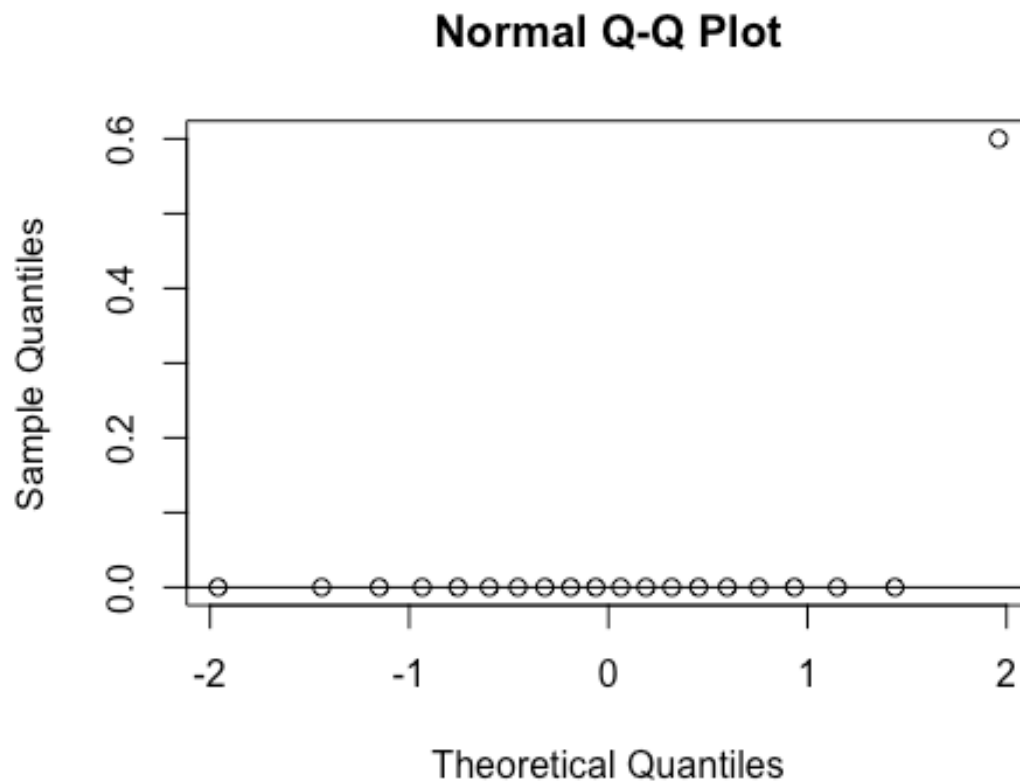
1
2
3  ## data: subset(SSdata, intervention == "sham")$AHI.calculated and subset(SS
4  data, intervention == "PrenaBelt")$AHI.calculated
5  ## W = 198.5, p-value = 0.9779
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -0.6092948  0.4774410
9  ## sample estimates:
10 ## difference in location
11 ## -1.726505e-05
12
13 ##### Central hypopneas Index #####
14 ##FYI: this data was generated in our PSG reports per default configuration bu
15 t is not a
16 ##pre-specified secondary outcome per the research protocol or trial registry.
17 FYI only.
18 ##Summary
19 summary(SSdata$central.hypopneas.index)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##    0.000  0.000  0.000  0.015  0.000  0.600
23
24 sd(SSdata$central.hypopneas.index, na.rm = TRUE)
25
26 ## [1] 0.09486833
27
28 length(SSdata$central.hypopneas.index)
29
30 ## [1] 40
31
32 ##ANOVA
33 night_tx_difference <- anova(lm(central.hypopneas.index ~ intervention + nigh
34 t,
35                               data = SSdata))
36
37 night_tx_difference
38
39 ## Analysis of Variance Table
40 ##
41 ## Response: central.hypopneas.index
42 ##           Df Sum Sq Mean Sq F value Pr(>F)
43 ## intervention  1  0.009  0.009      1 0.3238
44 ## night         1  0.009  0.009      1 0.3238
45 ## Residuals    37  0.333  0.009
46
47 ##within-participants (paired) comparison
48 ##Paired Wilcoxon
49 wilcox.test(subset(SSdataCompletes, intervention == "sham")$central.hypopneas
50 .index,
51              subset(SSdataCompletes, intervention == "PrenaBelt")$central.hypopneas
52 .index,
53              paired = TRUE)
54
55
56
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$central.hypopneas.index, : cannot compute exact p-value with zeroes
5  s
6
7  ##
8  ## Wilcoxon signed rank test with continuity correction
9  ##
10 ## data: subset(SSdataCompletes, intervention == "sham")$central.hypopneas.i
11 ndex and subset(SSdataCompletes, intervention == "PrenaBelt")$central.hypopne
12 as.index
13 ## V = 0, p-value = 1
14 ## alternative hypothesis: true location shift is not equal to 0
15
16 #between participants (grouped) comparison
17 summary(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
18
19 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
20 ##      0.00   0.00   0.00   0.03   0.00   0.60
21
22 sd(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
23
24 ## [1] 0.1341641
25
26 length(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
27
28 ## [1] 20
29
30 qqnorm(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
31 qqline(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

```

ad.test(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index
## A = 7.1762, p-value < 2.2e-16

#non-normal

summary(subset(SSdata, intervention == "sham")$central.hypopneas.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##         0         0         0         0         0         0

sd(subset(SSdata, intervention == "sham")$central.hypopneas.index)

## [1] 0

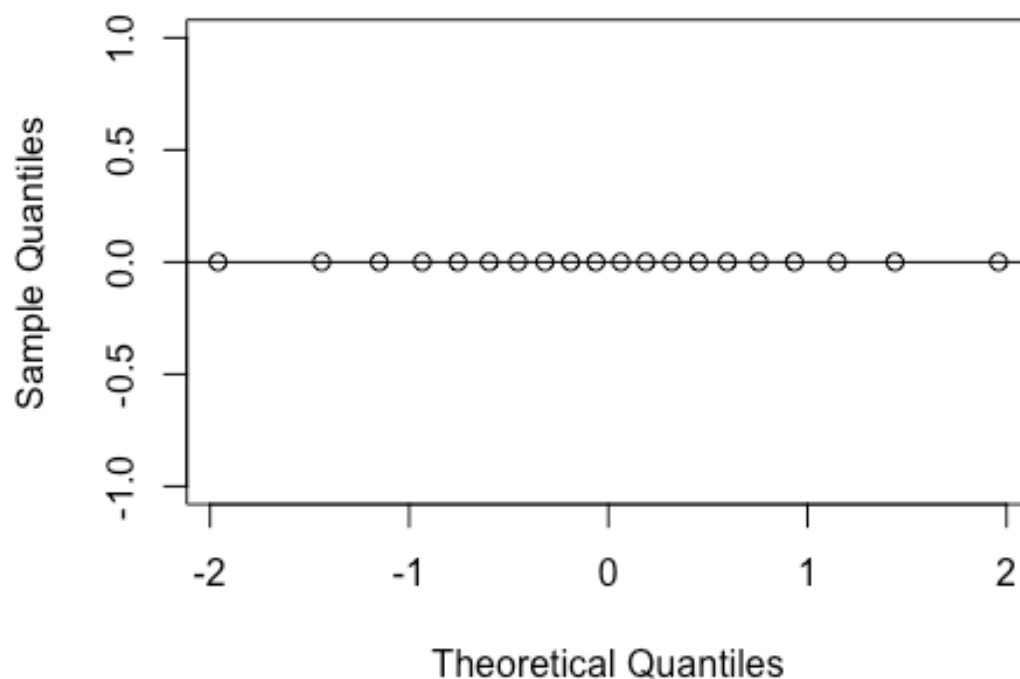
length(subset(SSdata, intervention == "sham")$central.hypopneas.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$central.hypopneas.index)
qqline(subset(SSdata, intervention == "sham")$central.hypopneas.index)

```

Normal Q-Q Plot



```

32 #ad.test(subset(SSdata, intervention == "sham")$central.hypopneas.index)
33 #distribution is made entirely of zeroes
34
35 #FYI - unpaired test
36 wilcox.test(subset(SSdata, intervention == "sham")$central.hypopneas.index,
37             subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index,
38             ex,
39             conf.int = TRUE)
40
41 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
42 ## $central.hypopneas.index, : cannot compute exact p-value with ties
43
44 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
45 ## $central.hypopneas.index, : cannot compute exact confidence intervals with
46 ## ties
47
48 ##
49 ## Wilcoxon rank sum test with continuity correction
50 ##
51 ## data: subset(SSdata, intervention == "sham")$central.hypopneas.index and
52 ## subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index
53 ## W = 190, p-value = 0.3421
54 ## alternative hypothesis: true location shift is not equal to 0
55 ## 95 percent confidence interval:

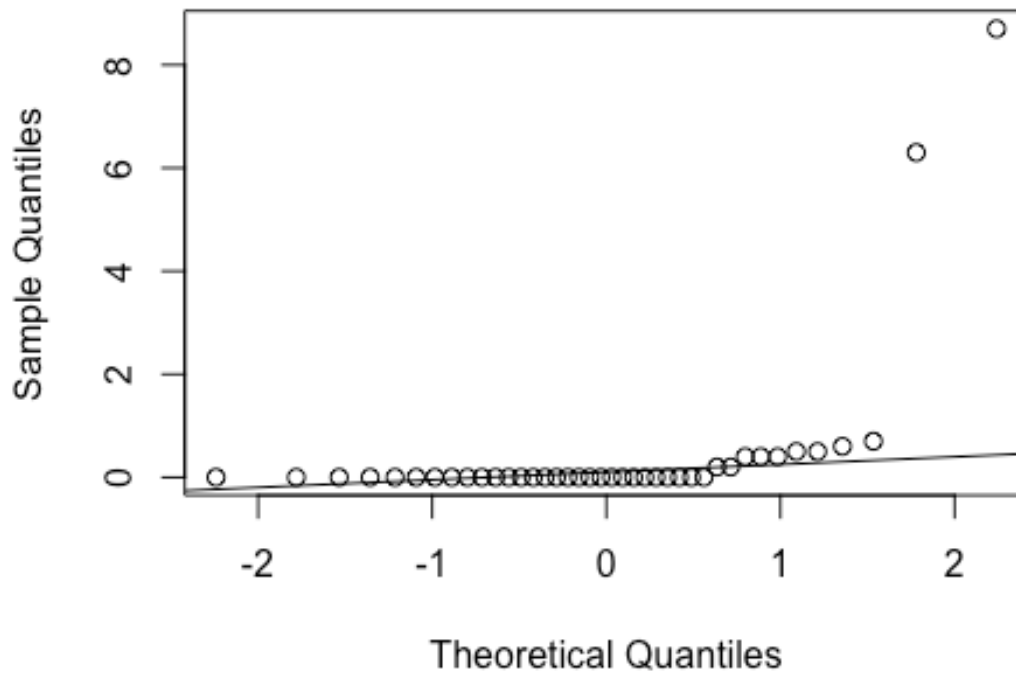
```

```

1
2
3 ## 0 0
4 ## sample estimates:
5 ## difference in location
6 ## 0
7
8 ##### RERAs Index #####
9
10 #Summary
11 summary(SSdata$reras.index)
12
13 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14 ## 0.0000  0.0000  0.0000  0.4725  0.2000  8.7000
15
16 sd(SSdata$reras.index, na.rm = TRUE)
17
18 ## [1] 1.66687
19
20 length(SSdata$reras.index)
21
22 ## [1] 40
23
24 qqnorm(SSdata$reras.index)
25 qqline(SSdata$reras.index)

```

Normal Q-Q Plot



```

54 ad.test(SSdata$reras.index)
55
56
57
58
59
60

```

```

1
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data:  SSdata$reras.index
7  ## A = 11.649, p-value < 2.2e-16
8
9  #non-normal
10
11  #ANOVA
12  night_tx_difference <- anova(lm(reras.index ~ intervention * night,
13                               data = SSdata))
14
15  night_tx_difference
16
17  ## Analysis of Variance Table
18  ##
19  ## Response: reras.index
20  ##
21  ##           Df Sum Sq Mean Sq F value Pr(>F)
22  ## intervention      1  4.422   4.4223   1.7011 0.2004
23  ## night              1  4.032   4.0322   1.5511 0.2210
24  ## intervention:night  1  6.320   6.3203   2.4313 0.1277
25  ## Residuals         36 93.585   2.5996
26
27  #within-participants (paired) comparison
28  #Paired Wilcoxon
29  wilcox.test(subset(SSdataCompletes, intervention == "sham")$reras.index,
30             subset(SSdataCompletes, intervention == "PrenaBelt")$reras.index,
31             paired = TRUE, conf.int = TRUE)
32
33  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
34  ## "sham")$reras.index, : cannot compute exact p-value with ties
35
36  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
37  ## "sham")$reras.index, : cannot compute exact confidence interval with ties
38
39  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
40  ## "sham")$reras.index, : cannot compute exact p-value with zeroes
41
42  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
43  ## "sham")$reras.index, : cannot compute exact confidence interval with zeroes
44
45  ##
46  ## Wilcoxon signed rank test with continuity correction
47  ##
48  ## data:  subset(SSdataCompletes, intervention == "sham")$reras.index and sub
49  ## set(SSdataCompletes, intervention == "PrenaBelt")$reras.index
50  ## V = 15.5, p-value = 0.7789
51  ## alternative hypothesis: true location shift is not equal to 0
52  ## 95 percent confidence interval:
53  ## -4.5999963  0.3500676
54  ## sample estimates:
55
56
57
58
59
60

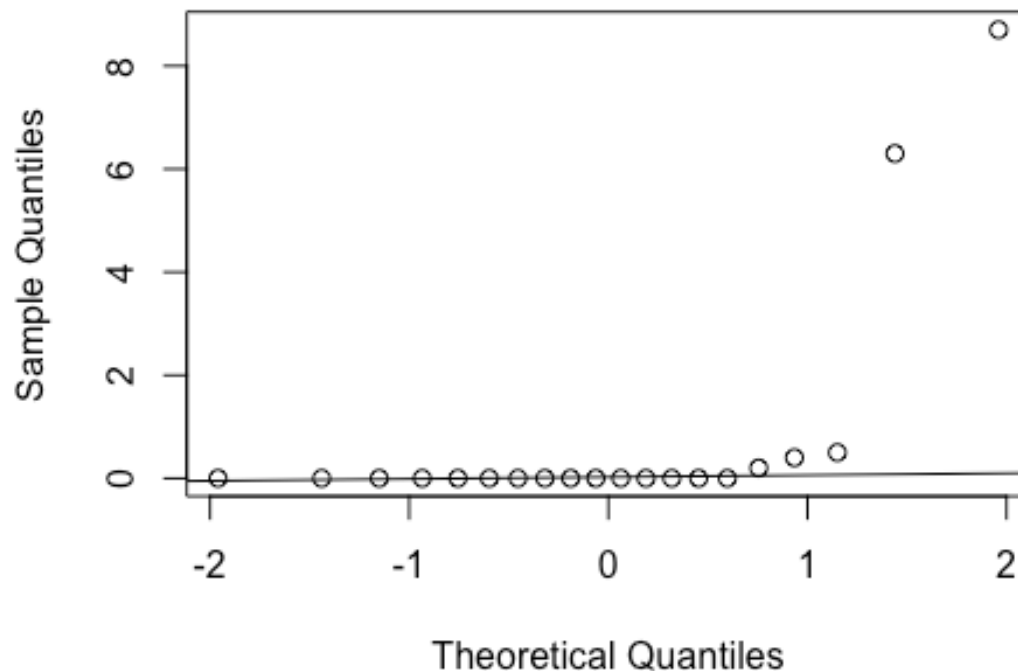
```

```

1
2
3  ## (pseudo)median
4  ##      -0.1499727
5
6  #between participants (grouped) comparison
7  summary(subset(SSdata, intervention == "PrenaBelt")$reras.index)
8
9  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
10 ##      0.000   0.000   0.000   0.805   0.050   8.700
11
12  sd(subset(SSdata, intervention == "PrenaBelt")$reras.index)
13
14  ## [1] 2.32684
15
16  length(subset(SSdata, intervention == "PrenaBelt")$reras.index)
17
18  ## [1] 20
19
20  qqnorm(subset(SSdata, intervention == "PrenaBelt")$reras.index)
21  qqline(subset(SSdata, intervention == "PrenaBelt")$reras.index)
22

```

Normal Q-Q Plot



```

51  ad.test(subset(SSdata, intervention == "PrenaBelt")$reras.index)
52
53  ##
54  ## Anderson-Darling normality test
55  ##
56

```

```
## data: subset(SSdata, intervention == "PrenaBelt")$reras.index
## A = 5.7736, p-value = 8.367e-15
```

```
#non-normal
```

```
summary(subset(SSdata, intervention == "sham")$reras.index)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   0.00   0.14   0.25   0.70
```

```
sd(subset(SSdata, intervention == "sham")$reras.index)
```

```
## [1] 0.2370876
```

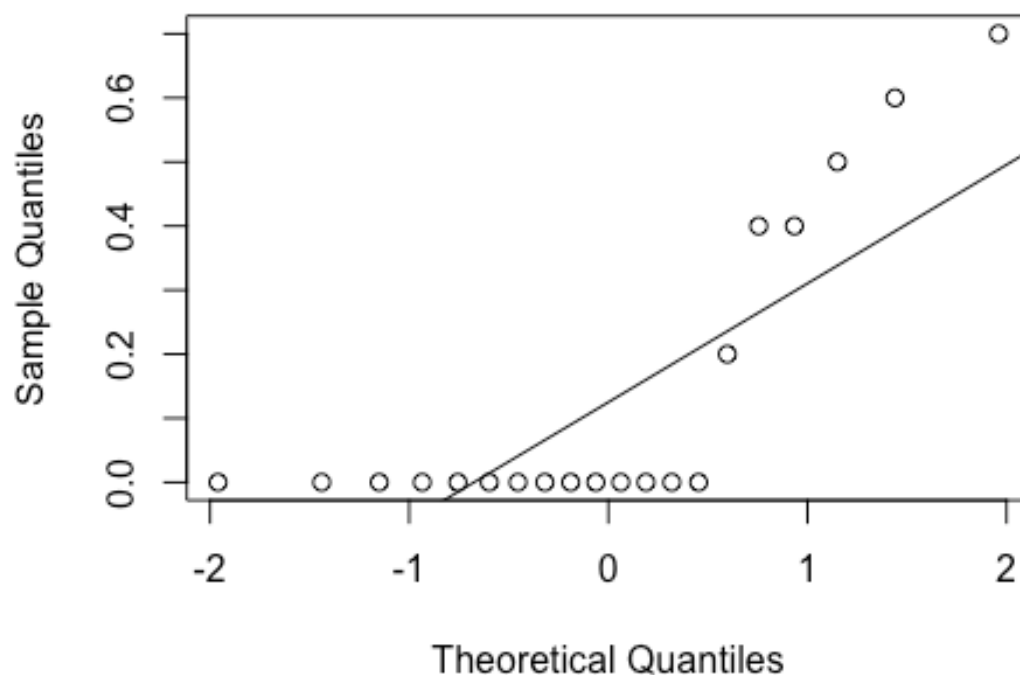
```
length(subset(SSdata, intervention == "sham")$reras.index)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$reras.index)
```

```
qqline(subset(SSdata, intervention == "sham")$reras.index)
```

Normal Q-Q Plot



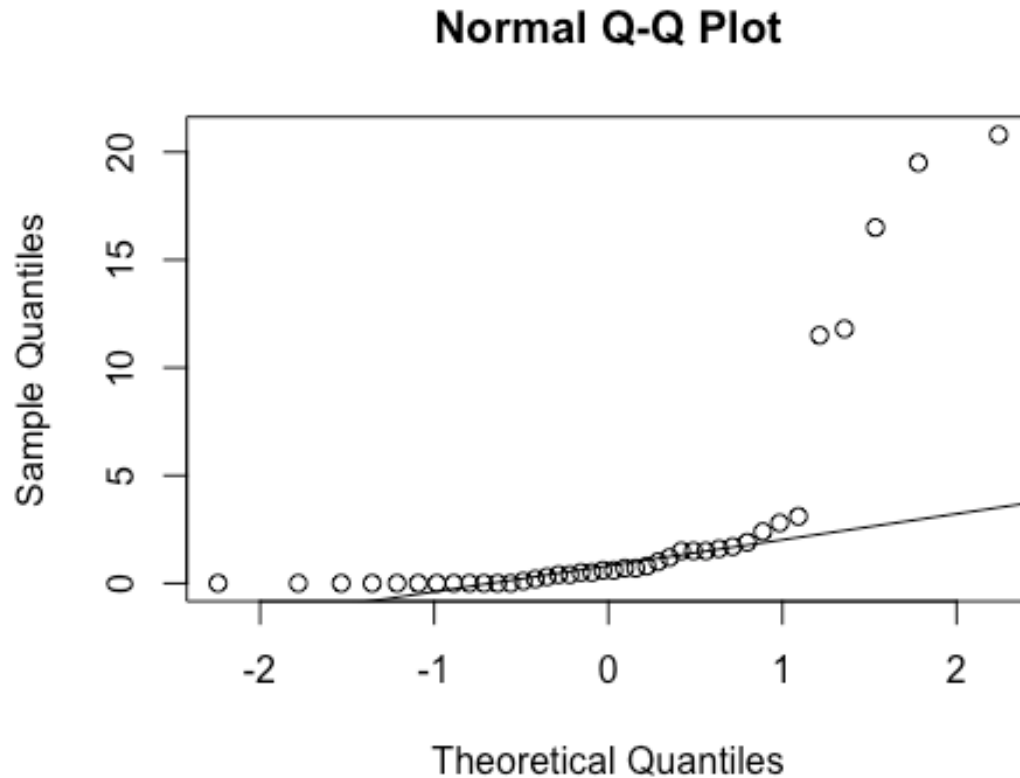
```
ad.test(subset(SSdata, intervention == "sham")$reras.index)
```

```
##
## Anderson-Darling normality test
```

```

1
2
3
4  ##
5  ## data: subset(SSdata, intervention == "sham")$reras.index
6  ## A = 3.4375, p-value = 5.959e-09
7
8  #non-normal
9
10 #FYI - unpaired test
11 wilcox.test(subset(SSdata, intervention == "sham")$reras.index,
12             subset(SSdata, intervention == "PrenaBelt")$reras.index,
13             conf.int = TRUE)
14
15 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
16 ## $reras.index, : cannot compute exact p-value with ties
17
18 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
19 ## $reras.index, : cannot compute exact confidence intervals with ties
20
21 ##
22 ## Wilcoxon rank sum test with continuity correction
23 ##
24 ## data: subset(SSdata, intervention == "sham")$reras.index and subset(SSdat
25 a, intervention == "PrenaBelt")$reras.index
26 ## W = 207, p-value = 0.8231
27 ## alternative hypothesis: true location shift is not equal to 0
28 ## 95 percent confidence interval:
29 ## -3.950633e-05 5.862469e-06
30 ## sample estimates:
31 ## difference in location
32 ## 4.901185e-05
33
34 ##### Respiratory Disturbance Index #####
35 #Summary
36 summary(SSdata$rdi.index)
37
38 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
39 ##  0.000  0.000   0.600   2.652  1.625   20.800
40
41 sd(SSdata$rdi.index, na.rm = TRUE)
42
43 ## [1] 5.358817
44
45 length(SSdata$rdi.index)
46
47 ## [1] 40
48
49 qqnorm(SSdata$rdi.index)
50 qqline(SSdata$rdi.index)
51
52
53
54
55
56
57
58
59
60

```



```
ad.test(SSdata$rdi.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$rdi.index
## A = 8.0555, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(rdi.index ~ intervention * night,
                               data = SSdata))
night_tx_difference

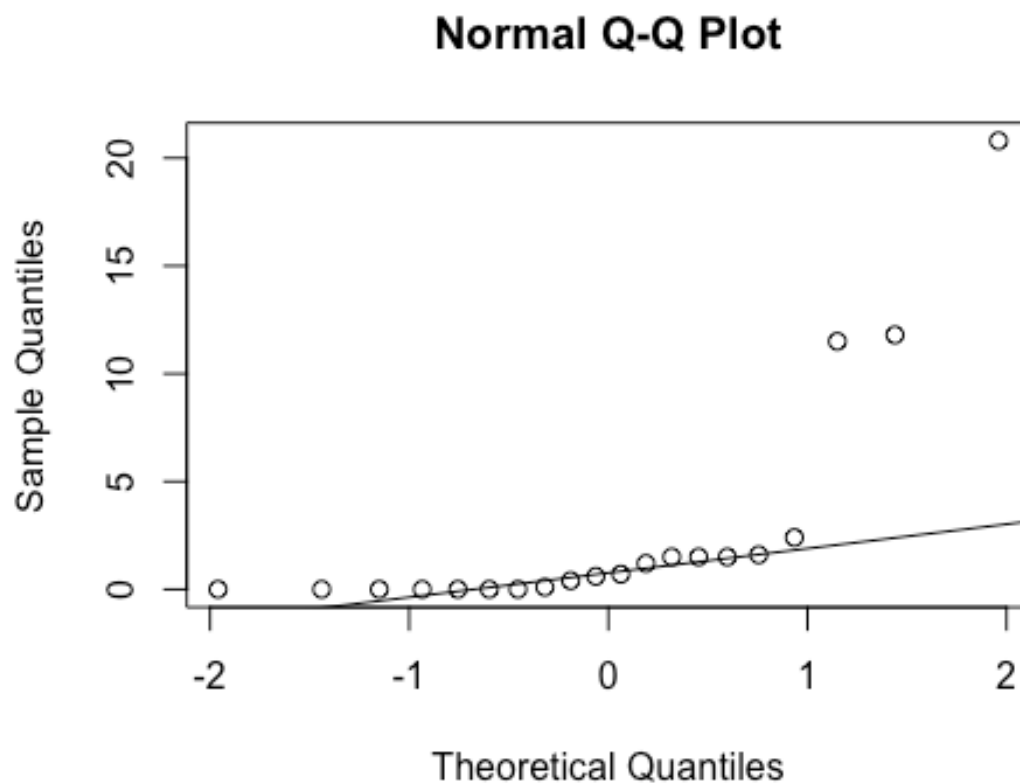
## Analysis of Variance Table
##
## Response: rdi.index
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    0.65    0.650   0.0245 0.87646
## night           1    0.01    0.012   0.0005 0.98297
## intervention:night  1 164.43 164.430   6.1993 0.01754 *
## Residuals      36 954.87  26.524
```



```

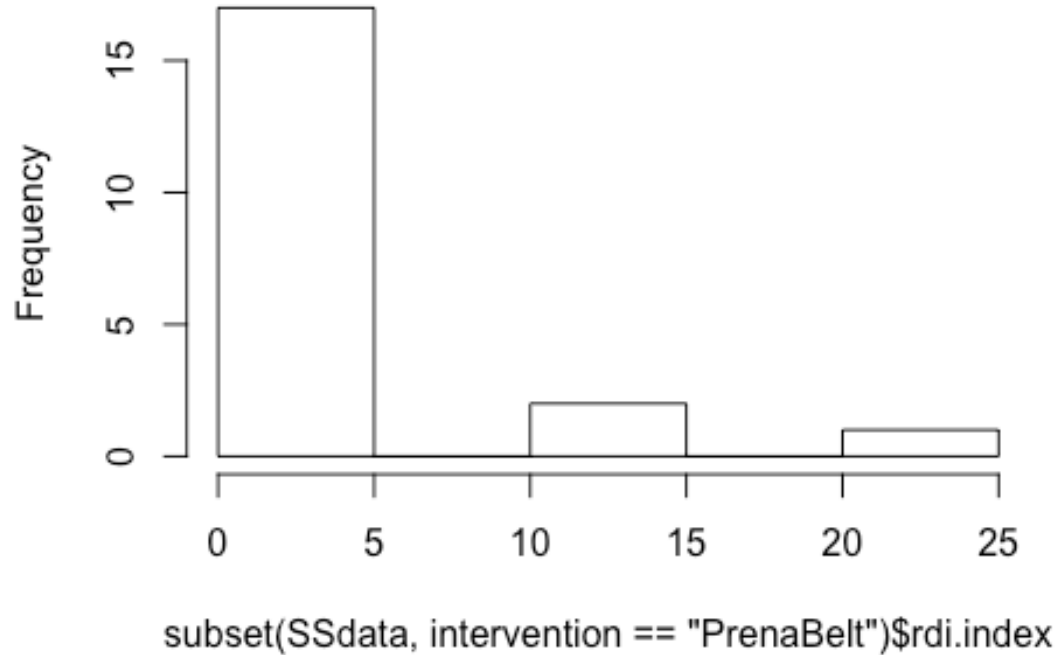
1
2
3  ## ---
4  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
5
6  #within-participants (paired) comparison
7  #non-normal - do Wilcoxon
8  wilcox.test(subset(SSdataCompletes, intervention == "sham")$rdi.index,
9             subset(SSdataCompletes, intervention == "PrenaBelt")$rdi.index,
10            paired = TRUE, conf.int = TRUE)
11
12  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13  ## "sham")$rdi.index, : cannot compute exact p-value with ties
14
15  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16  ## "sham")$rdi.index, : cannot compute exact confidence interval with ties
17
18  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
19  ## "sham")$rdi.index, : cannot compute exact p-value with zeroes
20
21  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
22  ## "sham")$rdi.index, : cannot compute exact confidence interval with zeroes
23
24  ##
25  ##  Wilcoxon signed rank test with continuity correction
26  ##
27  ## data:  subset(SSdataCompletes, intervention == "sham")$rdi.index and subse
28  ## t(SSdataCompletes, intervention == "PrenaBelt")$rdi.index
29  ## V = 67, p-value = 0.6699
30  ## alternative hypothesis: true location shift is not equal to 0
31  ## 95 percent confidence interval:
32  ##  -1.1999821  0.6499711
33  ## sample estimates:
34  ## (pseudo)median
35  ##      -0.199951
36
37
38  #between participants (grouped) comparison
39  summary(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
40
41  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
42  ##  0.000  0.000  0.650  2.780  1.525  20.800
43
44  sd(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
45
46  ## [1] 5.463236
47
48  length(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
49
50  ## [1] 20
51
52  qqnorm(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
53  qqline(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
54
55
56
57
58
59
60

```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$rdi.index
## A = 3.8067, p-value = 6.979e-10
hist(subset(SSdata, intervention == "PrenaBelt")$rdi.index)
```

gram of subset(SSdata, intervention == "PrenaBelt");



#non-normal

```
summary(subset(SSdata, intervention == "sham")$rdi.index)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.000  0.150  0.550  2.525  1.750  19.500
```

```
sd(subset(SSdata, intervention == "sham")$rdi.index)
```

```
## [1] 5.391111
```

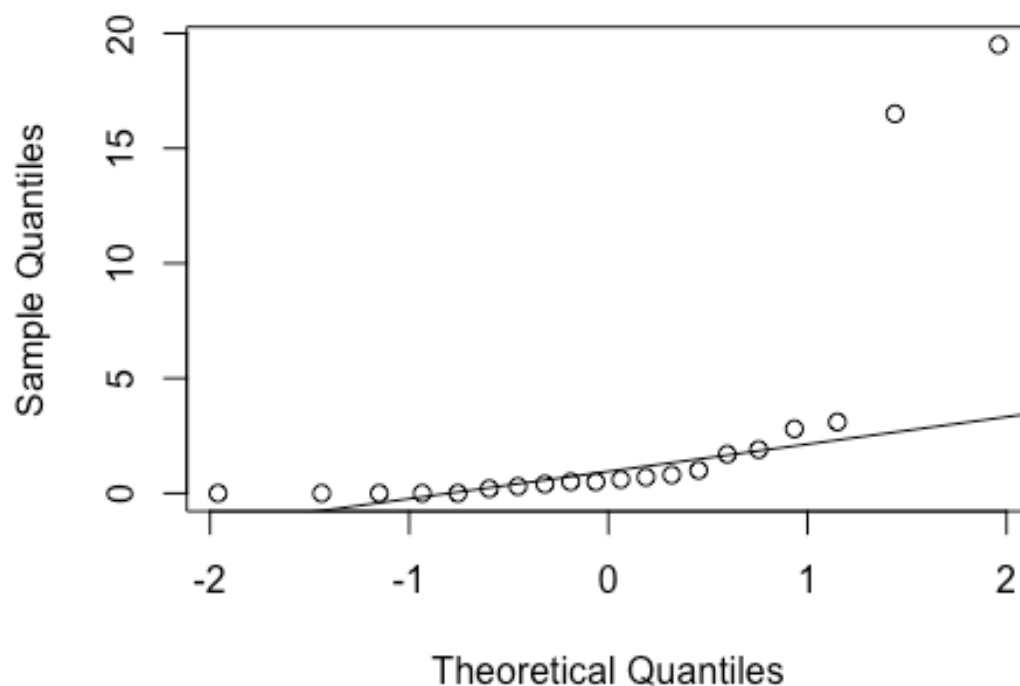
```
length(subset(SSdata, intervention == "sham")$rdi.index)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$rdi.index)
```

```
qqline(subset(SSdata, intervention == "sham")$rdi.index)
```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$rdi.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$rdi.index
## A = 4.397, p-value = 2.29e-11

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$rdi.index,
            subset(SSdata, intervention == "PrenaBelt")$rdi.index,
            conf.int = TRUE)

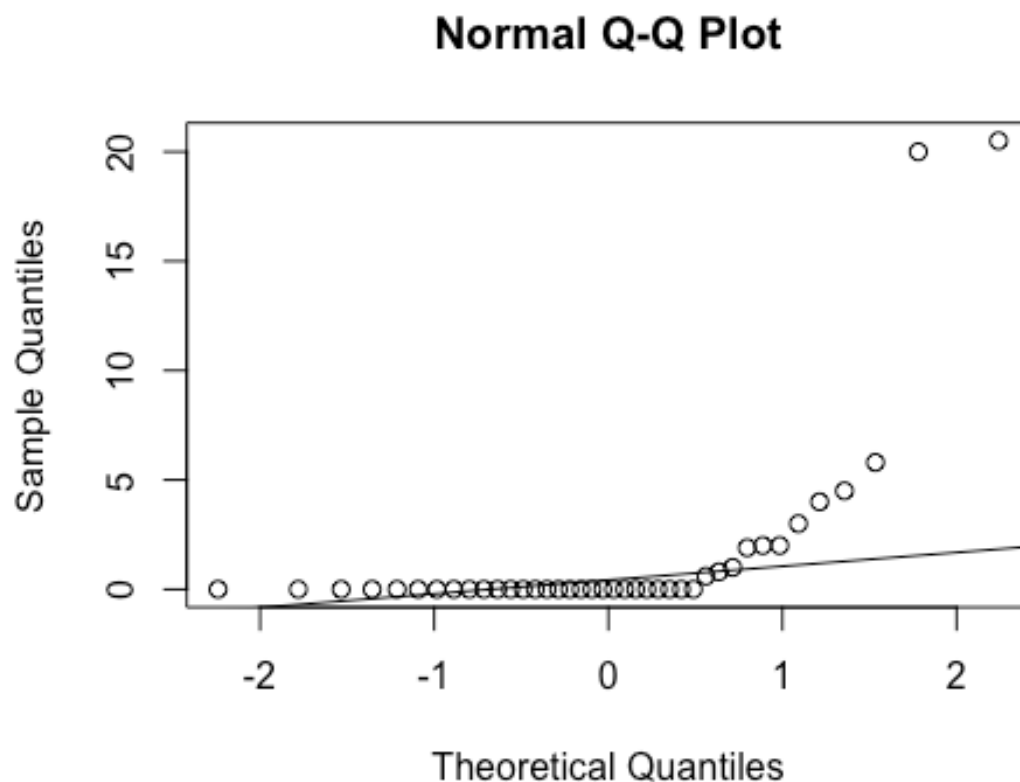
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $rdi.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $rdi.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```

```
1
2
3  ## data: subset(SSdata, intervention == "sham")$rdi.index and subset(SSdata,
4  intervention == "PrenaBelt")$rdi.index
5  ## W = 206, p-value = 0.8801
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -0.7000762  0.5000008
9  ## sample estimates:
10 ## difference in location
11 ##          8.805182e-05
12
13 ##### Supine Event Index #####
14 #Summary
15 summary(SSdata$index.of.supine.events)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##  0.000  0.000  0.000  1.652  0.850  20.500
19
20 sd(SSdata$index.of.supine.events, na.rm = TRUE)
21
22 ## [1] 4.539061
23
24 length(SSdata$index.of.supine.events)
25
26 ## [1] 40
27
28 qqnorm(SSdata$index.of.supine.events)
29 qqline(SSdata$index.of.supine.events)
```



```

ad.test(SSdata$index.of.supine.events)

##
## Anderson-Darling normality test
##
## data:  SSdata$index.of.supine.events
## A = 9.3271, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(index.of.supine.events ~ intervention * night
,
                             data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: index.of.supine.events
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1  35.16   35.156   1.8529  0.18191
## night            1  63.25   63.252   3.3337  0.07618 .
## intervention:night  1  22.05   22.052   1.1622  0.28817
## Residuals      36 683.06   18.974

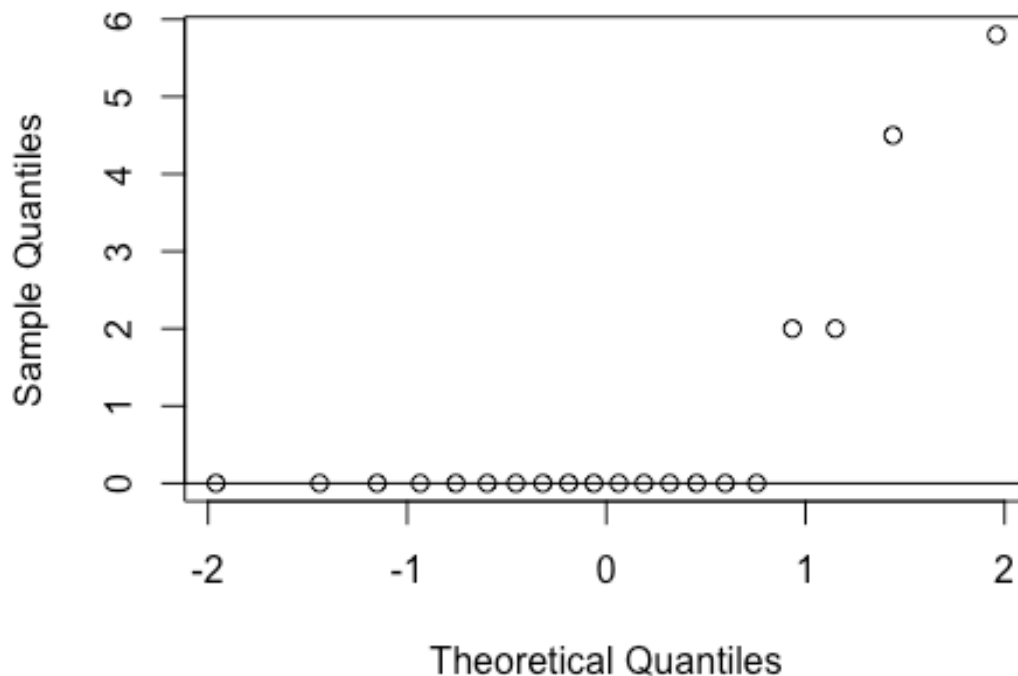
```

```

1
2
3
4  ## ---
5  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
6
7  #within-participants (paired) comparison
8  #Paired Wilcoxon
9  wilcox.test(subset(SSdataCompletes, intervention == "sham")$index.of.supine.e
10 events,
11             subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.supine.e
12 events,
13             paired = TRUE)
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$index.of.supine.events, : cannot compute exact p-value with zeroes
17
18 ##
19 ## Wilcoxon signed rank test with continuity correction
20 ##
21 ## data:  subset(SSdataCompletes, intervention == "sham")$index.of.supine.eve
22 nts and subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.supine.
23 events
24 ## V = 35, p-value = 0.4755
25 ## alternative hypothesis: true location shift is not equal to 0
26
27 #between participants (grouped) comparison
28 summary(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
29
30 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
31 ##  0.000  0.000  0.000  0.715  0.000  5.800
32
33 sd(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
34
35 ## [1] 1.649011
36
37 length(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
38
39 ## [1] 20
40
41 qqnorm(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
42 qqline(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events
## A = 4.652, p-value = 5.253e-12

#non-normal

summary(subset(SSdata, intervention == "sham")$index.of.supine.events)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  2.590  1.225  20.500

sd(subset(SSdata, intervention == "sham")$index.of.supine.events)

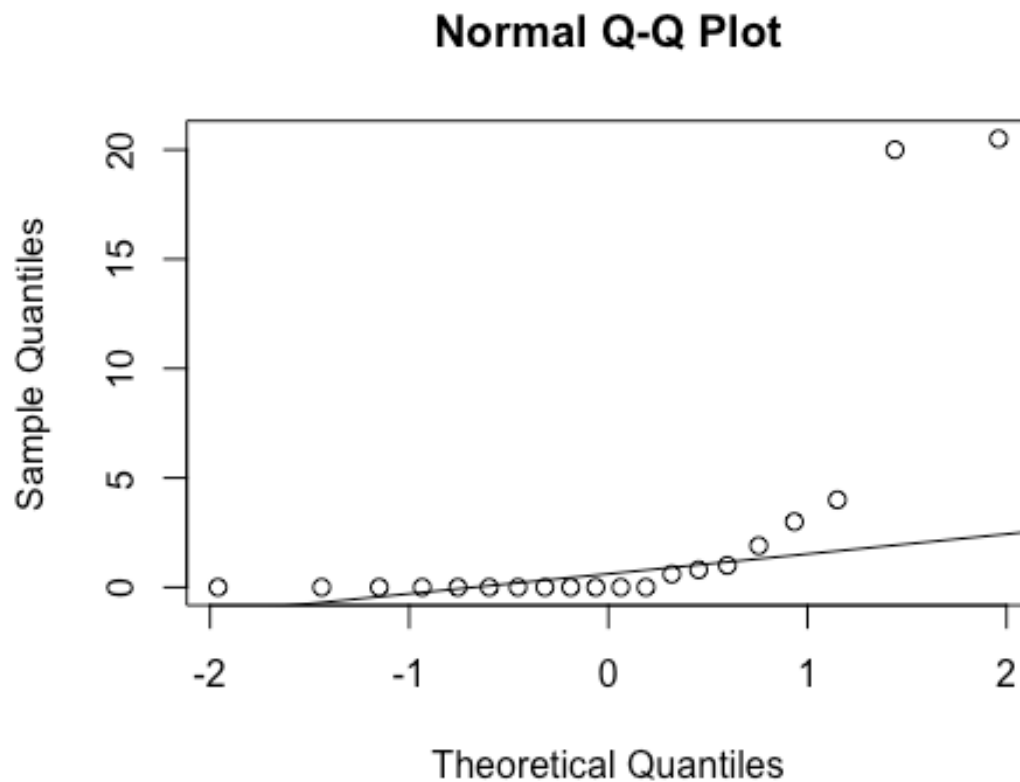
## [1] 6.141738

length(subset(SSdata, intervention == "sham")$index.of.supine.events)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$index.of.supine.events)
qqline(subset(SSdata, intervention == "sham")$index.of.supine.events)

```

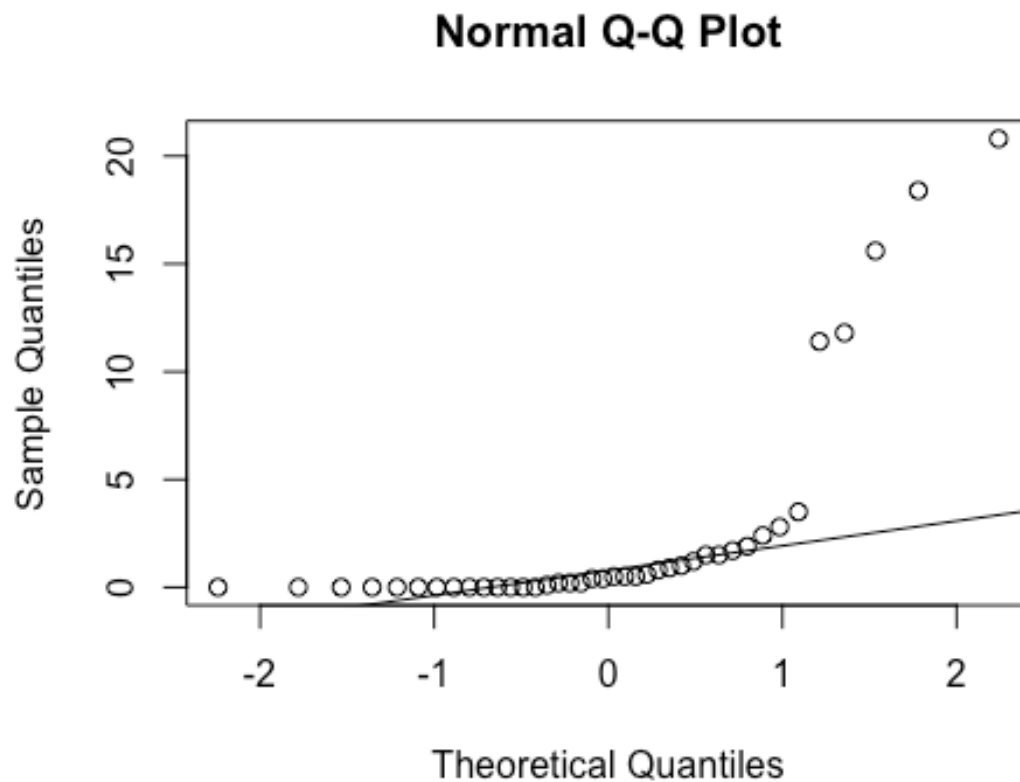



```

32 ad.test(subset(SSdata, intervention == "sham")$index.of.supine.events)
33
34 ##
35 ## Anderson-Darling normality test
36 ##
37 ## data: subset(SSdata, intervention == "sham")$index.of.supine.events
38 ## A = 4.7296, p-value = 3.359e-12
39
40 #non-normal
41
42 #FYI - unpaired test
43 wilcox.test(subset(SSdata, intervention == "sham")$index.of.supine.events,
44             subset(SSdata, intervention == "PrenaBelt")$index.of.supine.event
45 s,
46             conf.int = TRUE)
47
48 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
49 ## $index.of.supine.events, : cannot compute exact p-value with ties
50
51 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
52 ## $index.of.supine.events, : cannot compute exact confidence intervals with
53 ## ties

```

```
1
2
3 ##
4 ## Wilcoxon rank sum test with continuity correction
5 ##
6 ## data: subset(SSdata, intervention == "sham")$index.of.supine.events and s
7 ubset(SSdata, intervention == "PrenaBelt")$index.of.supine.events
8 ## W = 236, p-value = 0.2362
9 ## alternative hypothesis: true location shift is not equal to 0
10 ## 95 percent confidence interval:
11 ## -0.0000813554 0.6000459383
12 ## sample estimates:
13 ## difference in location
14 ## 7.189321e-06
15
16
17 ##### Non-Supine Event Index #####
18 #Summary
19 summary(SSdata$index.of.non.supine.events)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      0.00   0.00   0.45   2.52   1.55   20.80
23
24 sd(SSdata$index.of.non.supine.events, na.rm = TRUE)
25
26 ## [1] 5.242929
27
28 length(SSdata$index.of.non.supine.events)
29
30 ## [1] 40
31
32 qqnorm(SSdata$index.of.non.supine.events)
33 qqline(SSdata$index.of.non.supine.events)
34
35
36
37
38
39
40
41
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44
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46
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55
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57
58
59
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```



```

ad.test(SSdata$index.of.non.supine.events)

##
## Anderson-Darling normality test
##
## data:  SSdata$index.of.non.supine.events
## A = 8.126, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(index.of.non.supine.events ~ intervention * n
ight,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: index.of.non.supine.events
##          Df Sum Sq Mean Sq F value Pr(>F)
## intervention      1    0.40    0.400   0.0159 0.90038
## night              1    0.00    0.001   0.0000 0.99501
## intervention:night  1 165.65 165.649   6.5821 0.01461 *
## Residuals        36 905.99  25.166

```

```

1
2
3  ## ---
4  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
5
6  #within-participants (paired) comparison
7  #non-normal - use Wilcoxon
8  wilcox.test(subset(SSdataCompletes, intervention == "sham")$index.of.non.supine.events,
9             subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.non.supine.events,
10             paired = TRUE, conf.int = TRUE)
11
12  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13  ## "sham")$index.of.non.supine.events, : cannot compute exact p-value with
14  ## ties
15
16  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
17  ## "sham")$index.of.non.supine.events, : cannot compute exact confidence
18  ## interval with ties
19
20  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21  ## "sham")$index.of.non.supine.events, : cannot compute exact p-value with
22  ## zeroes
23
24  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
25  ## "sham")$index.of.non.supine.events, : cannot compute exact confidence
26  ## interval with zeroes
27
28  ##
29  ## Wilcoxon signed rank test with continuity correction
30  ##
31  ## data:  subset(SSdataCompletes, intervention == "sham")$index.of.non.supine
32  ## .events and subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.non
33  ## .supine.events
34  ## V = 70.5, p-value = 0.9176
35  ## alternative hypothesis: true location shift is not equal to 0
36  ## 95 percent confidence interval:
37  ## -1.0000733  0.8499829
38  ## sample estimates:
39  ## (pseudo)median
40  ## 0.04999832
41
42  #between participants (grouped) comparison
43  summary(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events)
44
45  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
46  ##      0.00   0.00   0.20   2.62   1.50   20.80
47
48  sd(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events)
49
50  ## [1] 5.512245
51
52
53
54
55
56
57
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60

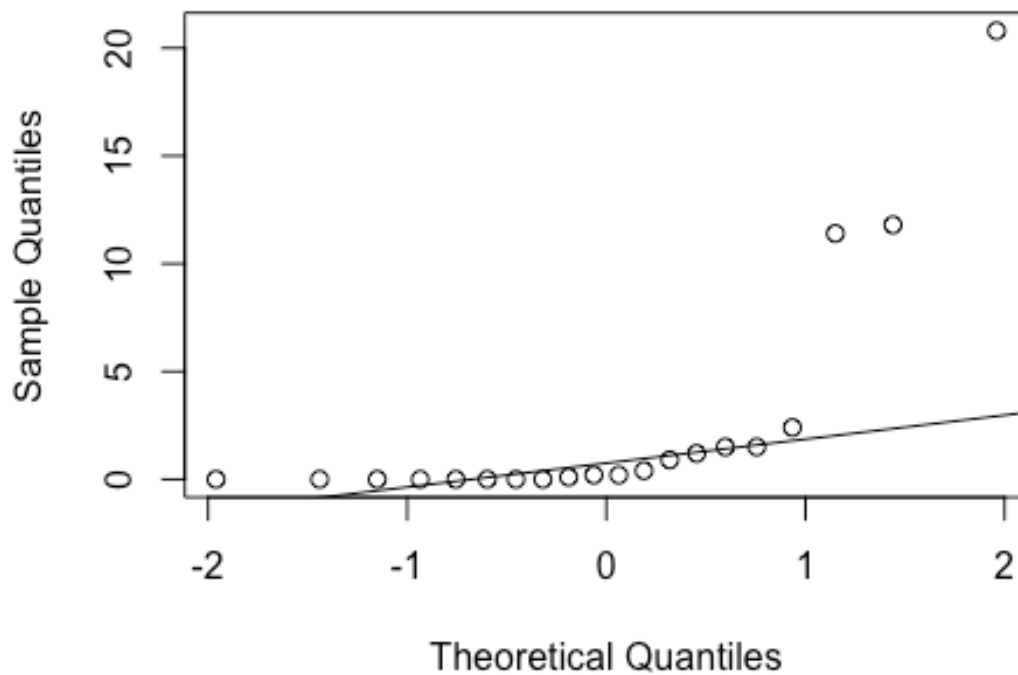
```

```

length(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
)
## [1] 20
qqnorm(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
)
qqline(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
## A = 4.0472, p-value = 1.731e-10
##non-normal
summary(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

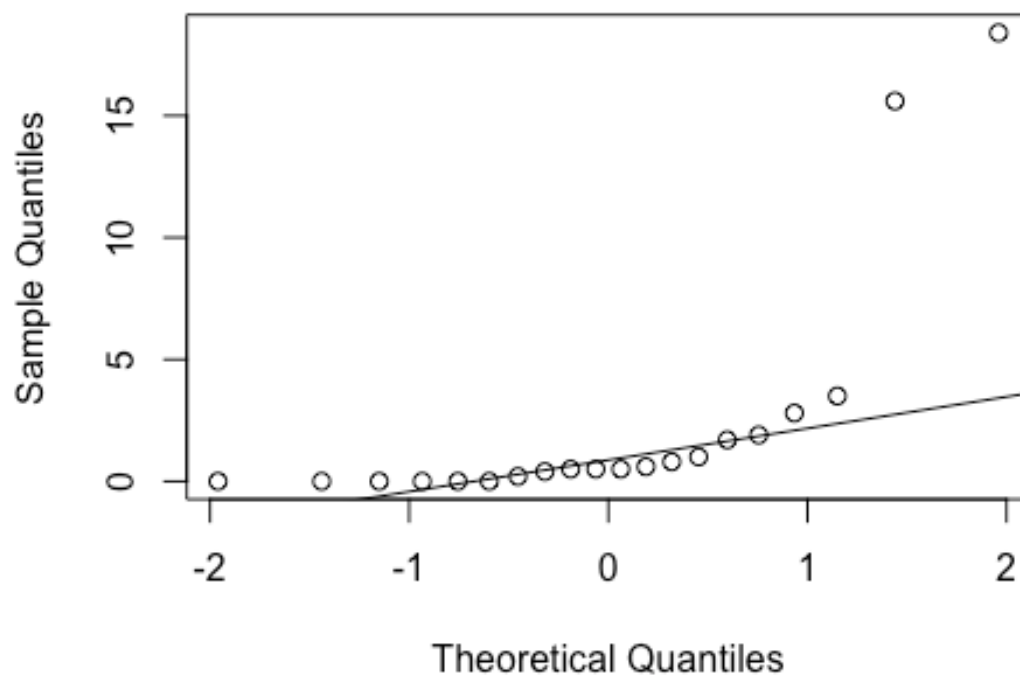
```

```

1
2
3  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4  ##      0.00   0.00   0.50    2.42   1.75   18.40
5
6  sd(subset(SSdata, intervention == "sham")$index.of.non.supine.events)
7
8  ## [1] 5.100733
9
10 length(subset(SSdata, intervention == "sham")$index.of.non.supine.events)
11
12 ## [1] 20
13
14 qqnorm(subset(SSdata, intervention == "sham")$index.of.non.supine.events)
15 qqline(subset(SSdata, intervention == "sham")$index.of.non.supine.events)
16
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24
25
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27
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60

```

Normal Q-Q Plot



```

45 ad.test(subset(SSdata, intervention == "sham")$index.of.non.supine.events)
46
47 ##
48 ## Anderson-Darling normality test
49 ##
50 ## data: subset(SSdata, intervention == "sham")$index.of.non.supine.events
51 ## A = 4.229, p-value = 6.047e-11
52
53 #non-normal
54
55 #FYI - unpaired test
56
57
58
59
60

```

```

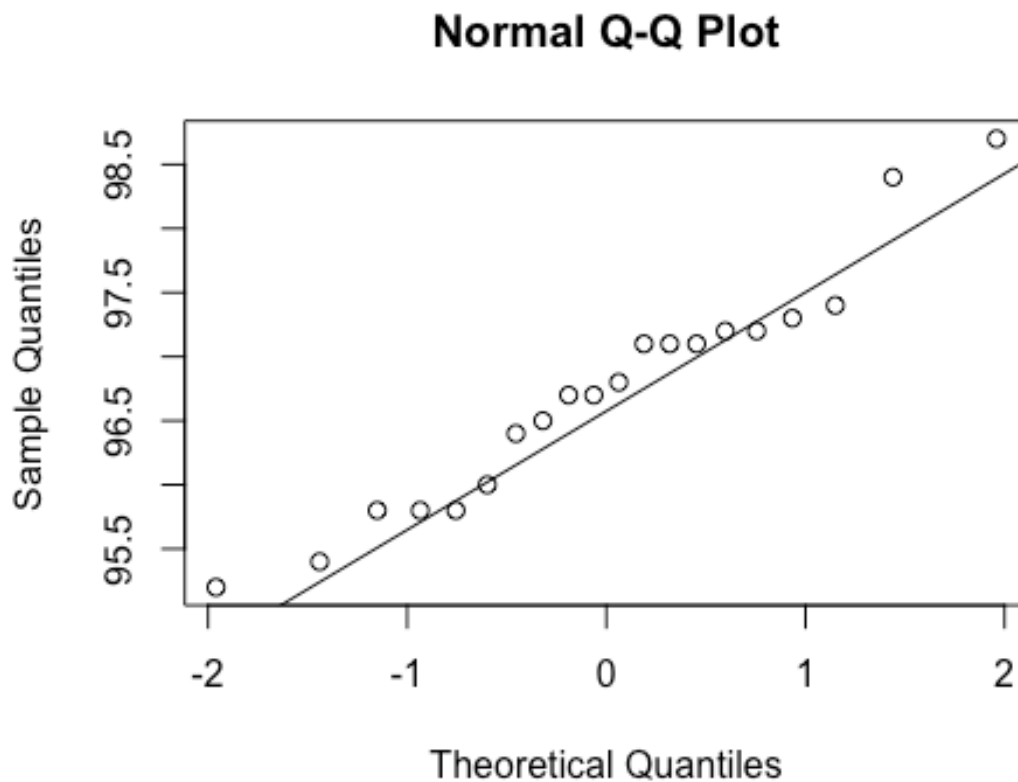
1
2
3 wilcox.test(subset(SSdata, intervention == "sham")$index.of.non.supine.events
4 ,
5           subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.e
6 vents,
7           conf.int = TRUE)
8
9 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
10 ## $index.of.non.supine.events, : cannot compute exact p-value with ties
11
12 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
13 ## $index.of.non.supine.events, : cannot compute exact confidence intervals
14 ## with ties
15
16 ##
17 ## Wilcoxon rank sum test with continuity correction
18 ##
19 ## data: subset(SSdata, intervention == "sham")$index.of.non.supine.events a
20 nd subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
21 ## W = 222.5, p-value = 0.5428
22 ## alternative hypothesis: true location shift is not equal to 0
23 ## 95 percent confidence interval:
24 ## -0.3999612 0.5999875
25 ## sample estimates:
26 ## difference in location
27 ## 5.005918e-06
28
29 ##### Mean SpO2 AWAKE #####
30 #Summary
31 summary(SSdata$mean.sao2.awake)
32
33 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
34 ## 95.20  96.00   96.70   96.76  97.20   99.40
35
36 sd(SSdata$mean.sao2.awake, na.rm = TRUE)
37
38 ## [1] 0.99242
39
40 length(SSdata$mean.sao2.awake)
41
42 ## [1] 40
43
44 #ANOVA
45 night_tx_difference <- anova(lm(mean.sao2.awake ~ intervention * night,
46                               data = SSdata))
47
48 night_tx_difference
49
50 ## Analysis of Variance Table
51 ##
52 ## Response: mean.sao2.awake
53 ##
54 ##      Df Sum Sq Mean Sq F value Pr(>F)
55 ## intervention      1  0.049  0.0490  0.0464 0.8306
56 ## night              1  0.256  0.2560  0.2425 0.6254
57
58
59
60

```

```

1
2
3  ## intervention:night  1  0.100  0.1000  0.0947  0.7600
4  ## Residuals          36 38.006  1.0557
5
6  #within-participants (paired) comparison
7  #Paired t-test
8  t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.awake,
9         subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.awake,
10        paired = TRUE)
11
12  ##
13  ## Paired t-test
14  ##
15  ## data: subset(SSdataCompletes, intervention == "sham")$mean.sao2.awake and
16  subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.awake
17  ## t = 0.53846, df = 19, p-value = 0.5965
18  ## alternative hypothesis: true difference in means is not equal to 0
19  ## 95 percent confidence interval:
20  ## -0.2020931  0.3420931
21  ## sample estimates:
22  ## mean of the differences
23  ##
24  ##          0.07
25
26  #between participants (grouped) comparison
27  summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
28
29  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
30  ##  95.20  95.95   96.75   96.73  97.20   98.70
31
32  sd(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
33
34  ## [1] 0.909077
35
36  length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
37
38  ## [1] 20
39
40  qqnorm(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
41  qqline(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)
42
43
44
45
46
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48
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51
52
53
54
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57
58
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60

```

```

ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake
## A = 0.38206, p-value = 0.3654

#normal

summary(subset(SSdata, intervention == "sham")$mean.sao2.awake)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
## 95.30  96.15   96.65   96.80  97.05   99.40

sd(subset(SSdata, intervention == "sham")$mean.sao2.awake)

## [1] 1.092077

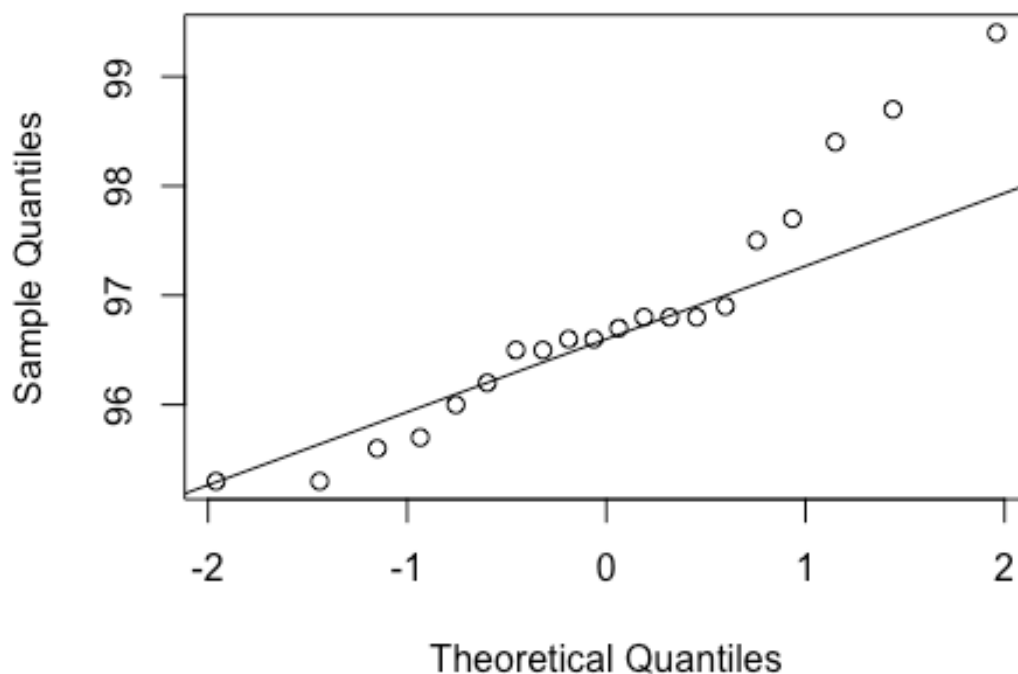
length(subset(SSdata, intervention == "sham")$mean.sao2.awake)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$mean.sao2.awake)
qqline(subset(SSdata, intervention == "sham")$mean.sao2.awake)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$mean.sao2.awake)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.awake
## A = 0.61087, p-value = 0.09665

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$mean.sao2.awake,
       subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.awake and subset(S
Sdata, intervention == "PrenaBelt")$mean.sao2.awake
## t = 0.22031, df = 36.79, p-value = 0.8268
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -0.5739073 0.7139073
## sample estimates:

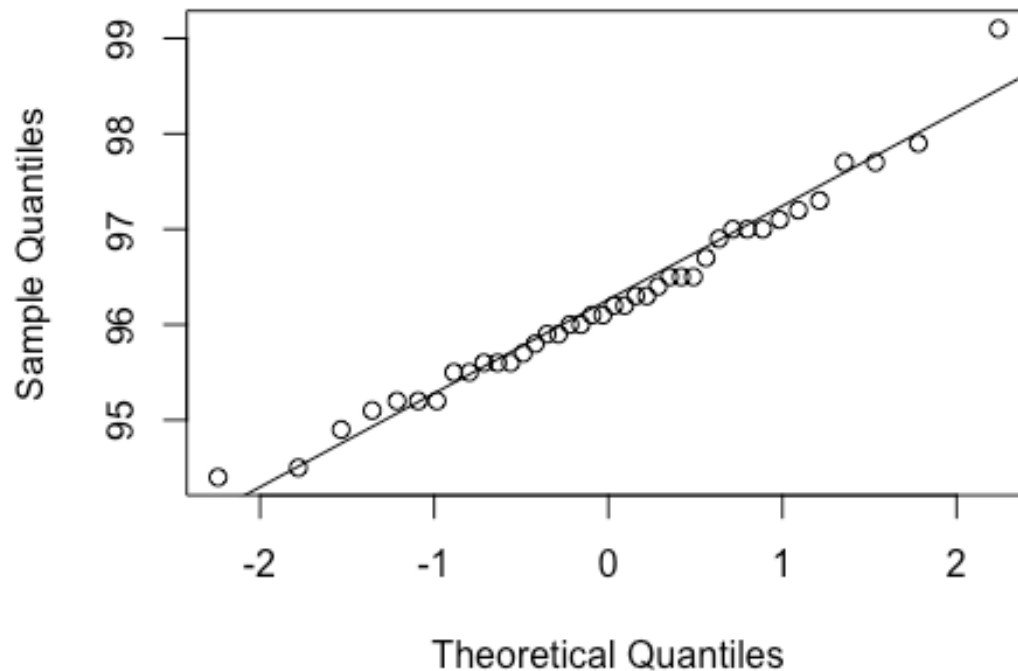
```

```

1
2
3  ## mean of x mean of y
4  ##    96.80    96.73
5
6  ##### Mean SpO2 NREM #####
7  #Summary
8  summary(SSdata$mean.sao2.nrem)
9
10 ##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11 ##   94.40  95.60   96.15   96.23  96.93   99.10
12
13 sd(SSdata$mean.sao2.nrem, na.rm = TRUE)
14
15 ## [1] 0.9680505
16
17 length(SSdata$mean.sao2.nrem)
18
19 ## [1] 40
20
21 qqnorm(SSdata$mean.sao2.nrem)
22 qqline(SSdata$mean.sao2.nrem)

```

Normal Q-Q Plot



```

53 ad.test(SSdata$mean.sao2.nrem)
54
55 ##
56 ## Anderson-Darling normality test

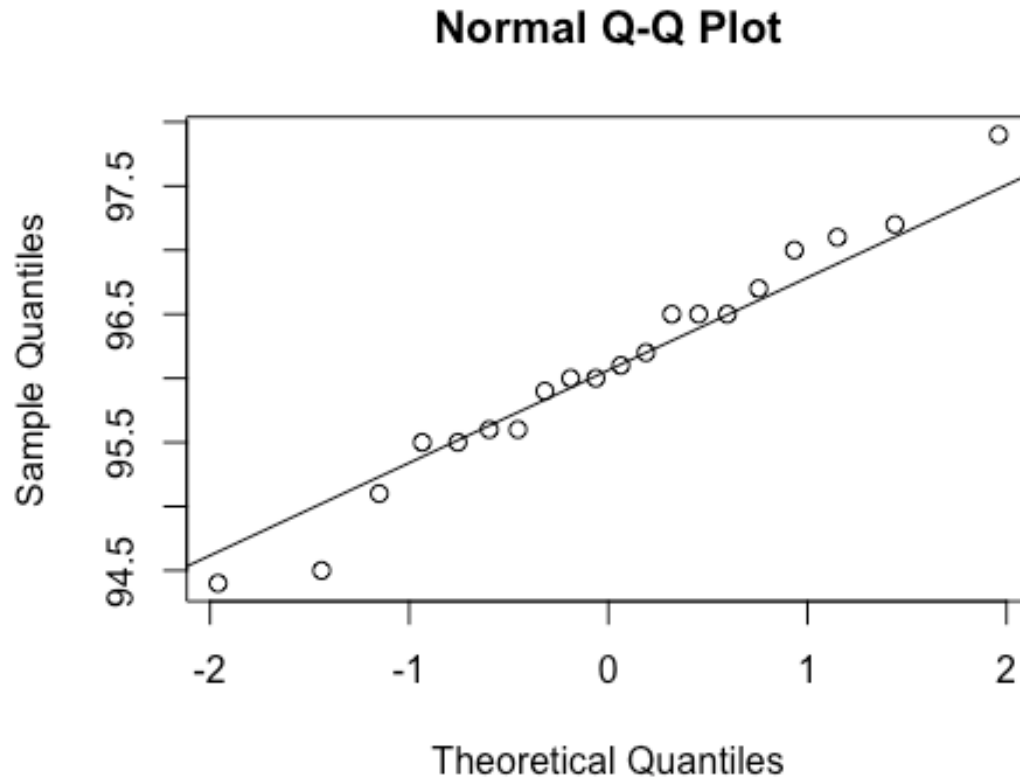
```

```

1
2
3
4  ##
5  ## data:  SSdata$mean.sao2.nrem
6  ## A = 0.24673, p-value = 0.7391
7
8  #normal
9
10 #ANOVA
11 night_tx_difference <- anova(lm(mean.sao2.nrem ~ intervention * night,
12                               data = SSdata))
13
14 night_tx_difference
15
16 ## Analysis of Variance Table
17 ##
18 ## Response: mean.sao2.nrem
19 ##
20 ##           Df Sum Sq Mean Sq F value Pr(>F)
21 ## intervention      1  0.812  0.81225   0.8438  0.3644
22 ## night              1  0.992  0.99225   1.0308  0.3167
23 ## intervention:night  1  0.090  0.09025   0.0938  0.7612
24 ## Residuals        36 34.653  0.96258
25
26 #within-participants (paired) comparison
27 #Paired t-test
28 t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.nrem,
29         subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.nrem,
30         paired = TRUE)
31
32 ##
33 ## Paired t-test
34 ##
35 ## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.nrem and
36 subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.nrem
37 ## t = 1.4182, df = 19, p-value = 0.1723
38 ## alternative hypothesis: true difference in means is not equal to 0
39 ## 95 percent confidence interval:
40 ## -0.1356036  0.7056036
41 ## sample estimates:
42 ## mean of the differences
43 ##           0.285
44
45 #between participants (grouped) comparison
46 summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
47
48 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
49 ##      94.40  95.57   96.05   96.09  96.55   97.90
50
51 sd(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
52
53 ## [1] 0.8837123
54
55 length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
56
57 ## [1] 20
58
59
60

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
qqline(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem
## A = 0.18102, p-value = 0.9013

#normal

summary(subset(SSdata, intervention == "sham")$mean.sao2.nrem)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  94.90  95.68   96.25   96.38  97.00   99.10

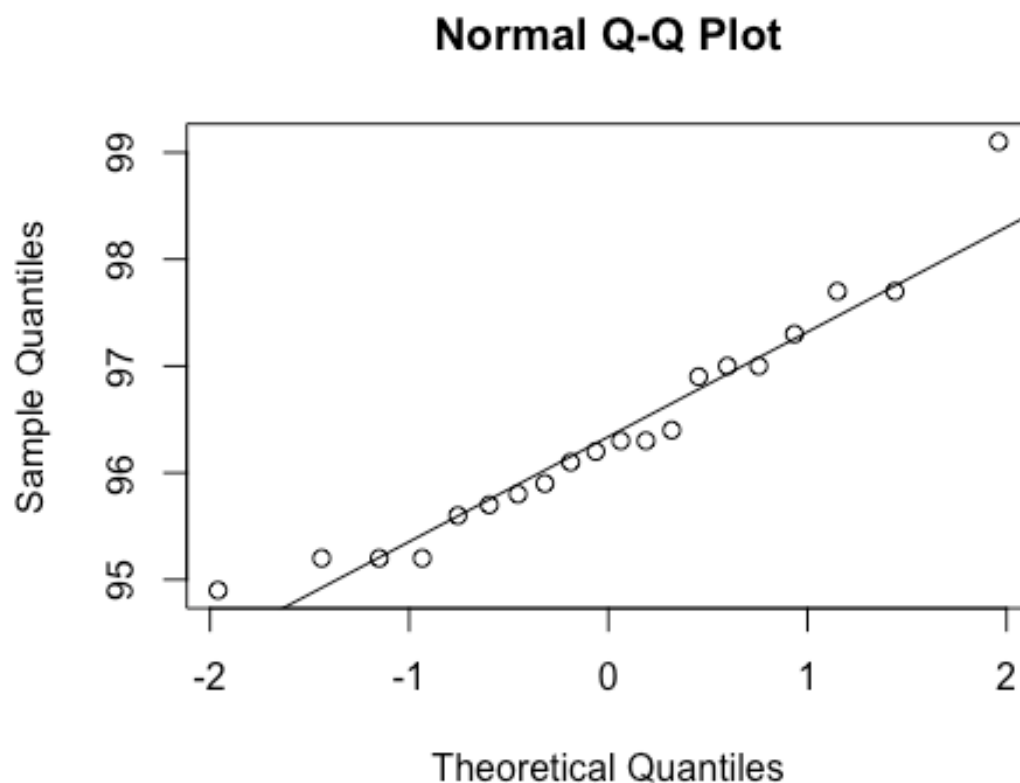
sd(subset(SSdata, intervention == "sham")$mean.sao2.nrem)

## [1] 1.048746

length(subset(SSdata, intervention == "sham")$mean.sao2.nrem)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$mean.sao2.nrem)
qqline(subset(SSdata, intervention == "sham")$mean.sao2.nrem)
```



```
ad.test(subset(SSdata, intervention == "sham")$mean.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.nrem
## A = 0.35668, p-value = 0.4209

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$mean.sao2.nrem,
       subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)

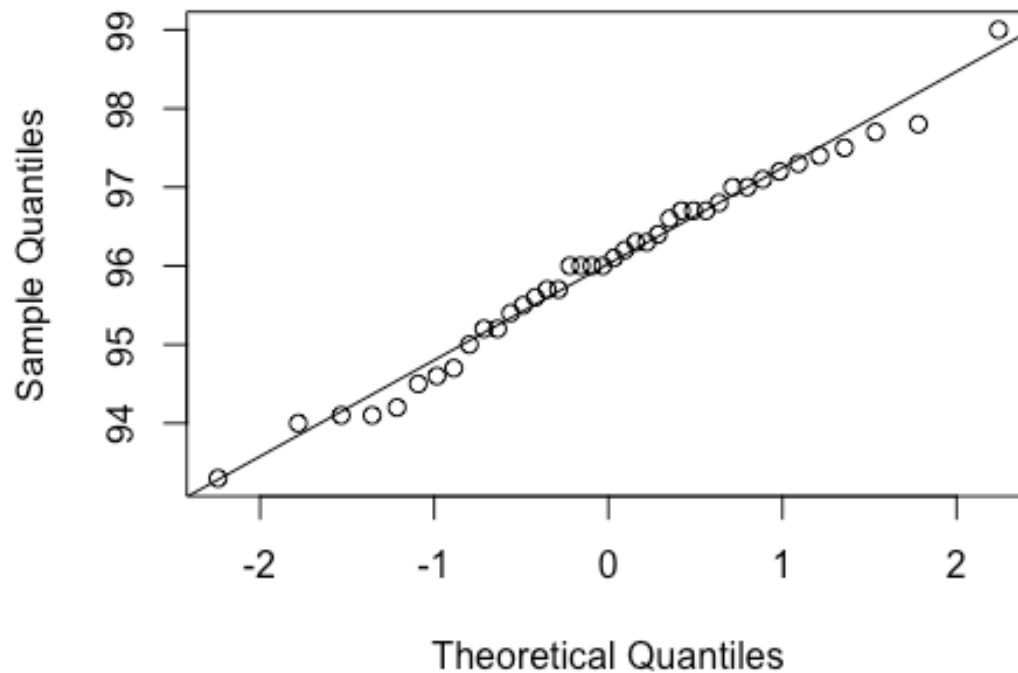
##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$mean.sao2.nrem and subset(SS
data, intervention == "PrenaBelt")$mean.sao2.nrem
## t = 0.92937, df = 36.938, p-value = 0.3587
## alternative hypothesis: true difference in means is not equal to 0
```

```

1
2
3  ## 95 percent confidence interval:
4  ## -0.3363889  0.9063889
5  ## sample estimates:
6  ## mean of x mean of y
7  ##    96.375    96.090
8
9  ##### Mean SpO2 REM #####
10 #Summary
11 summary(SSdata$mean.sao2.rem)
12
13 ##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14 ##   93.30  95.20   96.05   96.02  96.85   99.00
15
16 sd(SSdata$mean.sao2.rem, na.rm = TRUE)
17
18 ## [1] 1.234244
19
20 length(SSdata$mean.sao2.rem)
21
22 ## [1] 40
23
24 qqnorm(SSdata$mean.sao2.rem)
25 qqline(SSdata$mean.sao2.rem)

```

Normal Q-Q Plot



```

56 ad.test(SSdata$mean.sao2.rem)
57
58
59
60

```

```

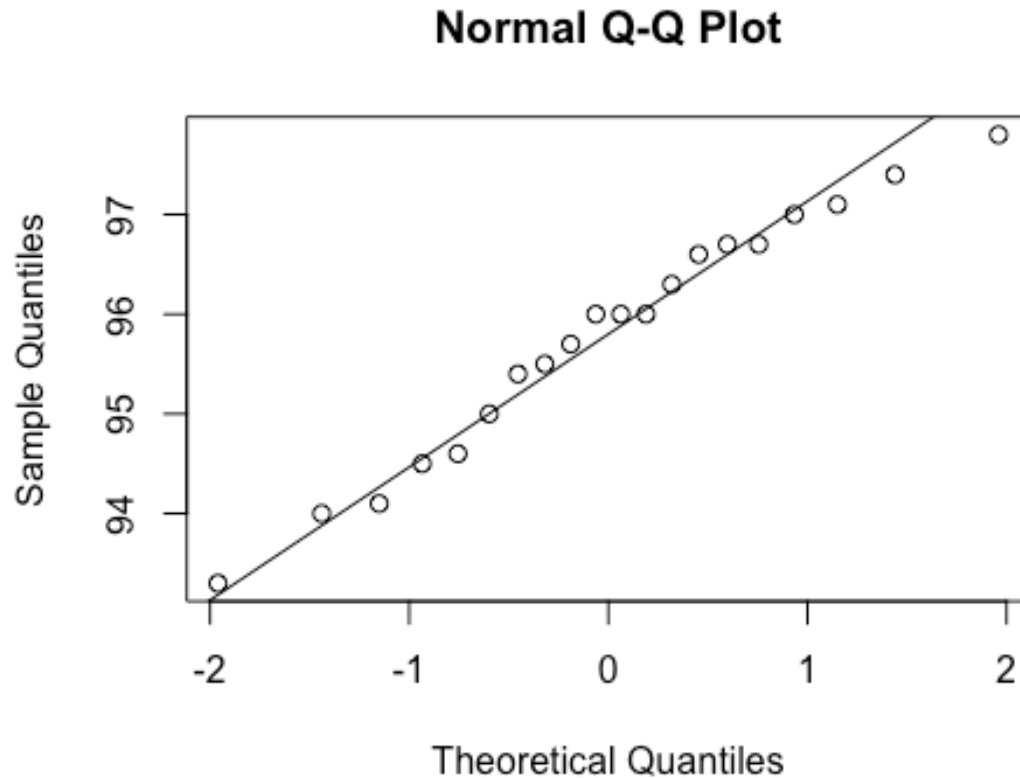
1
2
3
4  ## Anderson-Darling normality test
5  ##
6  ## data:  SSdata$mean.sao2.rem
7  ## A = 0.23901, p-value = 0.7646
8
9  #normal
10
11
12 #ANOVA
13 night_tx_difference <- anova(lm(mean.sao2.rem ~ intervention * night,
14                               data = SSdata))
15
16 night_tx_difference
17
18 ## Analysis of Variance Table
19 ##
20 ## Response: mean.sao2.rem
21 ##
22 ##           Df Sum Sq Mean Sq F value Pr(>F)
23 ## intervention      1  2.116   2.1160   1.4834 0.2312
24 ## night              1  3.025   3.0250   2.1206 0.1540
25 ## intervention:night  1  2.916   2.9160   2.0442 0.1614
26 ## Residuals        36 51.354   1.4265
27
28 #within-participants (paired) comparison
29 #Paired t-test
30 t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.rem,
31        subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.rem,
32        paired = TRUE)
33
34 ##
35 ## Paired t-test
36 ##
37 ## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.rem and s
38 subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.rem
39 ## t = 1.5919, df = 19, p-value = 0.1279
40 ## alternative hypothesis: true difference in means is not equal to 0
41 ## 95 percent confidence interval:
42 ##  -0.1447888  1.0647888
43 ## sample estimates:
44 ## mean of the differences
45 ##           0.46
46
47 #between participants (grouped) comparison
48 summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
49
50 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
51 ##      93.30  94.90   96.00   95.78  96.70   97.80
52
53 sd(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
54
55 ## [1] 1.229581
56
57 length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
58
59
60

```



```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
qqline(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem
## A = 0.22902, p-value = 0.7802
```

```
#normal
```

```
summary(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```

```
##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  94.10  95.50   96.25   96.24  97.05   99.00
```

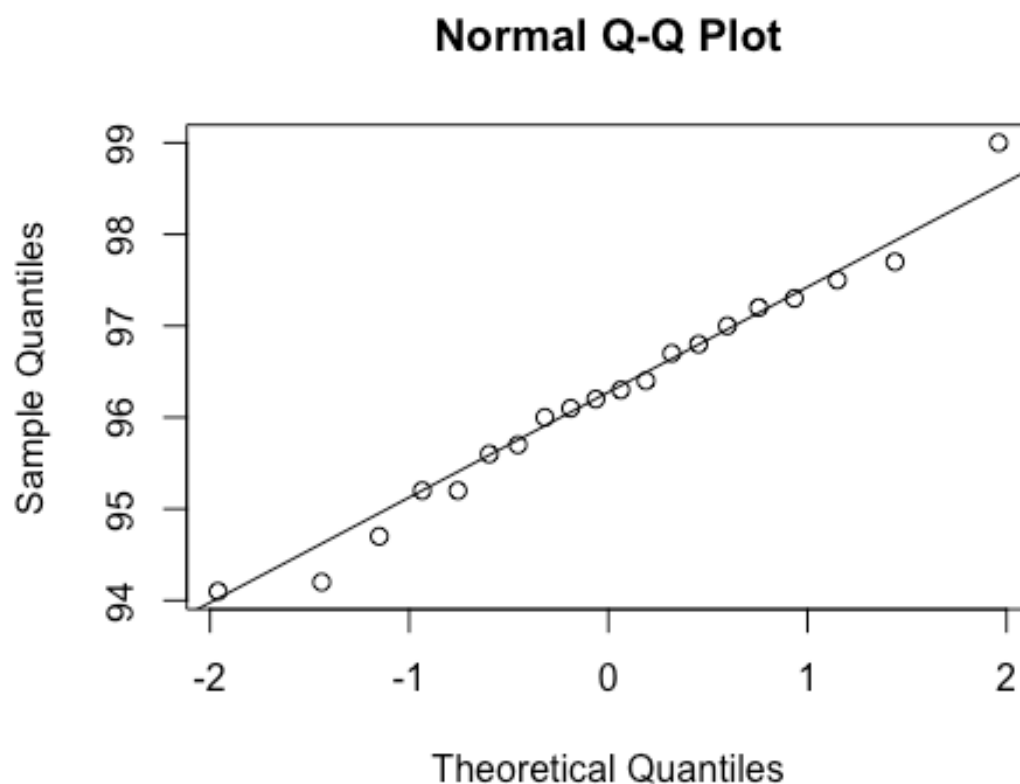
```
sd(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```

```
## [1] 1.226237
```

```
length(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$mean.sao2.rem)
qqline(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```



```
ad.test(subset(SSdata, intervention == "sham")$mean.sao2.rem)
```

```
##
## Anderson-Darling normality test
```

```
## data: subset(SSdata, intervention == "sham")$mean.sao2.rem
## A = 0.13652, p-value = 0.9718
```

```
#normal
```

```
#FYI - unpaired test
```

```
t.test(subset(SSdata, intervention == "sham")$mean.sao2.rem,
       subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
```

```
##
## Welch Two Sample t-test
```

```
## data: subset(SSdata, intervention == "sham")$mean.sao2.rem and subset(SSdata,
intervention == "PrenaBelt")$mean.sao2.rem
```

```

1
2
3  ## t = 1.1847, df = 38, p-value = 0.2435
4  ## alternative hypothesis: true difference in means is not equal to 0
5  ## 95 percent confidence interval:
6  ## -0.3260709  1.2460709
7  ## sample estimates:
8  ## mean of x mean of y
9  ##    96.245    95.785
10
11 ##### Mean SpO2 TST #####
12 #FYI: this data was generated in our PSG reports per default configuration bu
13 t is not a
14 #pre-specified secondary outcome per the research protocol or trial registry.
15 FYI only.
16 #Summary
17 summary(SSdata$mean.sao2.tst)
18
19
20 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
21 ##    94.60  95.70   96.30   96.33   96.93   99.10
22
23 sd(SSdata$mean.sao2.tst, na.rm = TRUE)
24
25 ## [1] 0.9626319
26
27 length(SSdata$mean.sao2.tst)
28
29 ## [1] 40
30
31 #ANOVA
32 night_tx_difference <- anova(lm(mean.sao2.tst ~ intervention * night,
33                                data = SSdata))
34
35 night_tx_difference
36
37 ## Analysis of Variance Table
38 ##
39 ## Response: mean.sao2.tst
40 ##
41 ##           Df Sum Sq Mean Sq F value Pr(>F)
42 ## intervention      1  0.600  0.60025   0.6241 0.4347
43 ## night              1  0.870  0.87025   0.9048 0.3479
44 ## intervention:night  1  0.042  0.04225   0.0439 0.8352
45 ## Residuals        36 34.627  0.96186
46
47 #within-participants (paired) comparison
48 #Paired t-test
49 t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.tst,
50         subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.tst,
51         paired = TRUE)
52
53 ##
54 ## Paired t-test
55 ##
56 ## data: subset(SSdataCompletes, intervention == "sham")$mean.sao2.tst and s
57 subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.tst
58
59
60

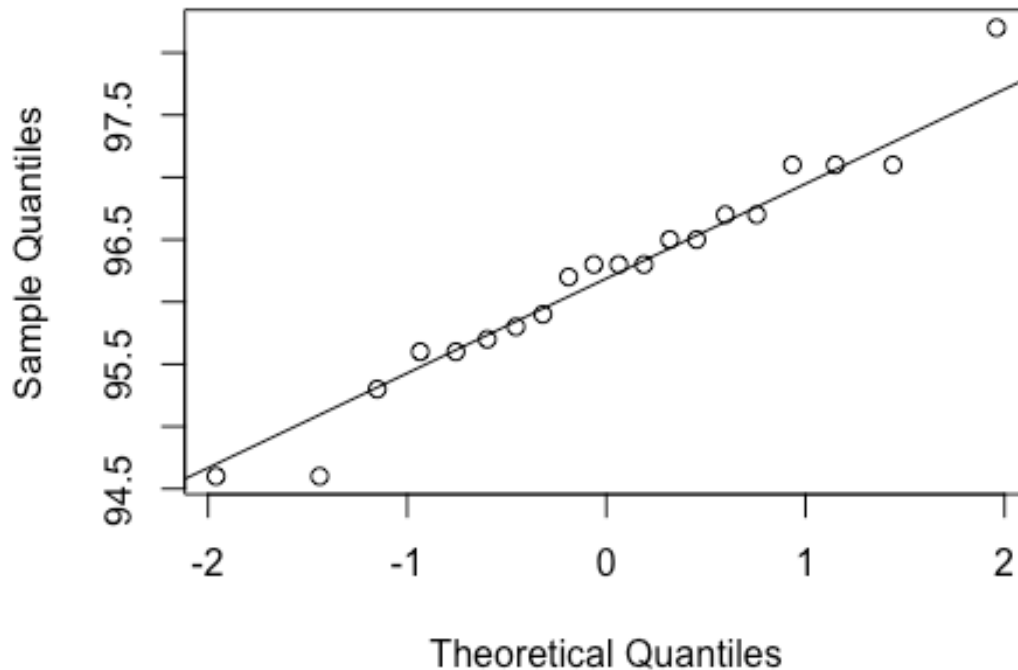
```

```

1
2
3  ## t = 1.3161, df = 19, p-value = 0.2038
4  ## alternative hypothesis: true difference in means is not equal to 0
5  ## 95 percent confidence interval:
6  ## -0.1446432  0.6346432
7  ## sample estimates:
8  ## mean of the differences
9  ##                0.245
10
11  #between participants (grouped) comparison
12  summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
13
14  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
15  ##   94.60  95.68   96.30   96.20  96.70   98.20
16
17  sd(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
18
19  ## [1] 0.8672249
20
21  length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
22
23  ## [1] 20
24
25  qqnorm(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
26  qqline(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
27

```

Normal Q-Q Plot

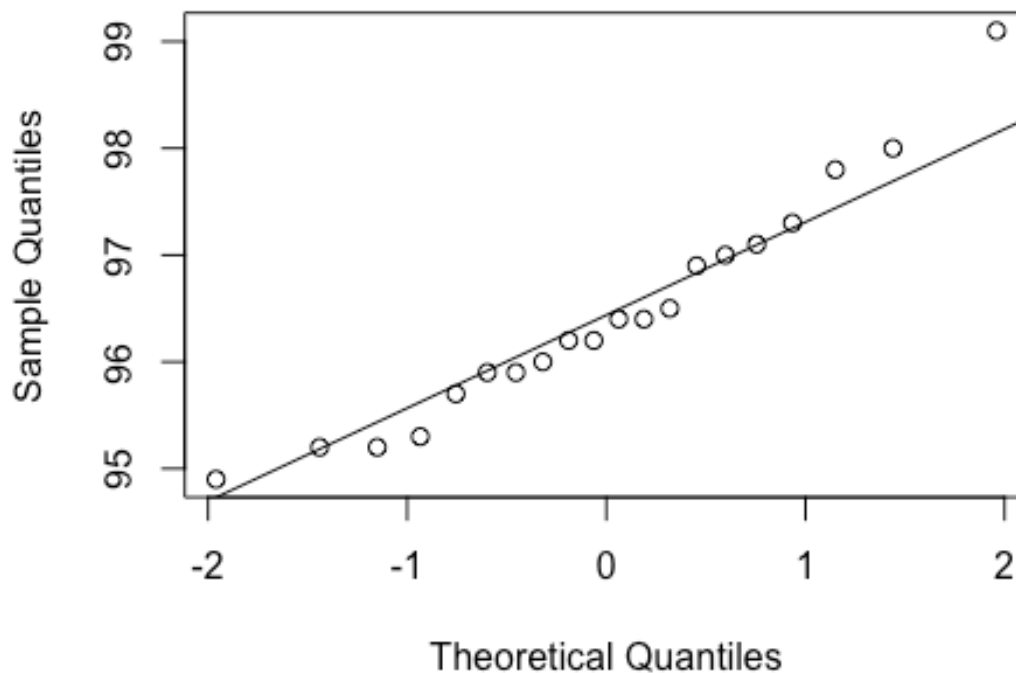


```

1  ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data: subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst
7  ## A = 0.2726, p-value = 0.6304
8
9  #normal
10
11  summary(subset(SSdata, intervention == "sham")$mean.sao2.tst)
12
13  ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
14  ##  94.90  95.85  96.30  96.45  97.02  99.10
15
16  sd(subset(SSdata, intervention == "sham")$mean.sao2.tst)
17
18  ## [1] 1.057554
19
20  length(subset(SSdata, intervention == "sham")$mean.sao2.tst)
21
22  ## [1] 20
23
24  qqnorm(subset(SSdata, intervention == "sham")$mean.sao2.tst)
25  qqline(subset(SSdata, intervention == "sham")$mean.sao2.tst)

```

Normal Q-Q Plot



```

1
2
3 ad.test(subset(SSdata, intervention == "sham")$mean.sao2.tst)
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: subset(SSdata, intervention == "sham")$mean.sao2.tst
9 ## A = 0.30299, p-value = 0.5413
10
11 #normal
12
13 #FYI - unpaired test
14 t.test(subset(SSdata, intervention == "sham")$mean.sao2.tst,
15        subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)
16
17 ##
18 ## Welch Two Sample t-test
19 ##
20 ## data: subset(SSdata, intervention == "sham")$mean.sao2.tst and subset(SSd
21 ata, intervention == "PrenaBelt")$mean.sao2.tst
22 ## t = 0.80113, df = 36.596, p-value = 0.4282
23 ## alternative hypothesis: true difference in means is not equal to 0
24 ## 95 percent confidence interval:
25 ## -0.3748781 0.8648781
26 ## sample estimates:
27 ## mean of x mean of y
28 ## 96.450 96.205
29
30 ##### Min SpO2 AWAKE #####
31 #Summary
32 summary(SSdata$min.sao2.awake)
33
34 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
35 ## 70.00 88.75 91.00 89.75 93.00 94.00
36
37 sd(SSdata$min.sao2.awake, na.rm = TRUE)
38
39 ## [1] 5.026851
40
41 length(SSdata$min.sao2.awake)
42
43 ## [1] 40
44
45 #ANOVA
46 night_tx_difference <- anova(lm(min.sao2.awake ~ intervention * night,
47                                data = SSdata))
48
49 night_tx_difference
50
51 ## Analysis of Variance Table
52 ##
53 ## Response: min.sao2.awake
54 ##
55 ## Df Sum Sq Mean Sq F value Pr(>F)
56 ## intervention 1 40.0 40.00 1.8391 0.18350
57
58
59
60

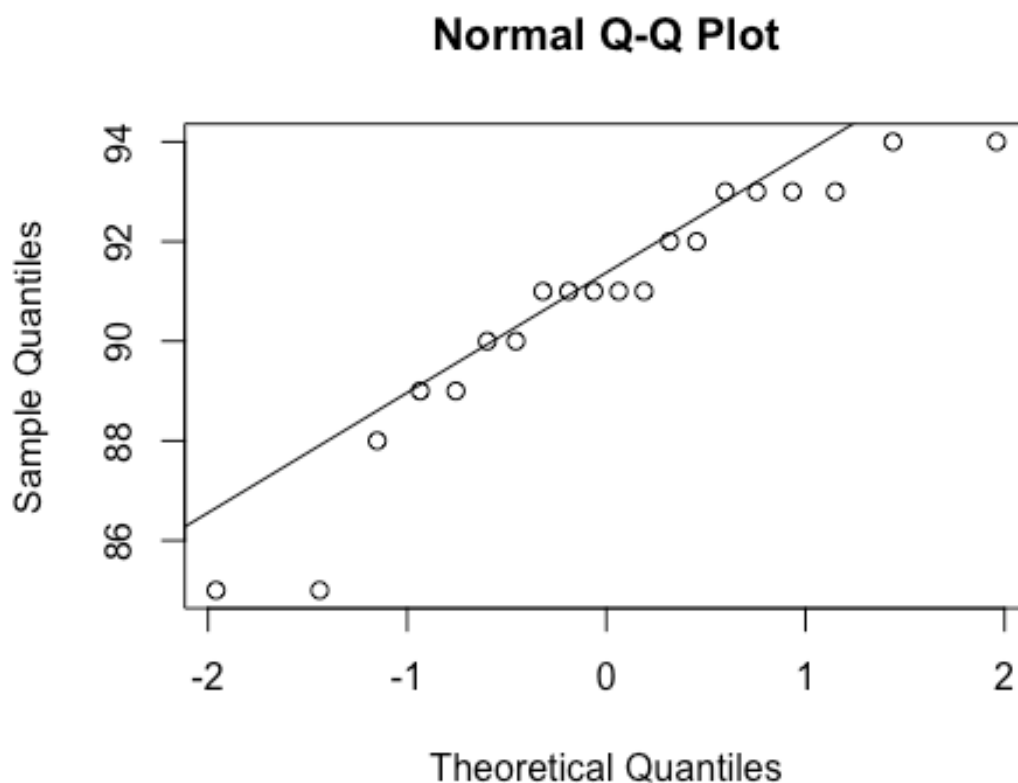
```

```

1
2
3  ## night          1  25.6   25.60  1.1770 0.28518
4  ## intervention:night 1 136.9 136.90 6.2943 0.01676 *
5  ## Residuals      36 783.0   21.75
6  ## ---
7  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
8
9  #within-participants (paired) comparison
10 #Paired Wilcoxon
11 wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.awake,
12             subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.awake,
13             paired = TRUE, conf.int = TRUE)
14
15  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16  ## "sham")$min.sao2.awake, : cannot compute exact p-value with ties
17
18  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
19  ## "sham")$min.sao2.awake, : cannot compute exact confidence interval with
20  ## ties
21
22  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
23  ## "sham")$min.sao2.awake, : cannot compute exact p-value with zeroes
24
25  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
26  ## "sham")$min.sao2.awake, : cannot compute exact confidence interval with
27  ## zeroes
28
29  ##
30  ## Wilcoxon signed rank test with continuity correction
31  ##
32  ## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.awake and
33  ## subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.awake
34  ## V = 53, p-value = 0.1609
35  ## alternative hypothesis: true location shift is not equal to 0
36  ## 95 percent confidence interval:
37  ## -3.9999632  0.5000467
38  ## sample estimates:
39  ## (pseudo)median
40  ## -1.49991
41
42  #between participants (grouped) comparison
43 summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
44
45  ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
46  ##  85.00  89.75   91.00   90.75   93.00   94.00
47
48  sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
49
50  ## [1] 2.572629
51
52  length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
53
54  ## [1] 20
55
56
57
58
59
60

```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake
## A = 0.68841, p-value = 0.06104

#normal

summary(subset(SSdata, intervention == "sham")$min.sao2.awake)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   70.00  88.00   90.00  88.75  93.25   94.00

sd(subset(SSdata, intervention == "sham")$min.sao2.awake)

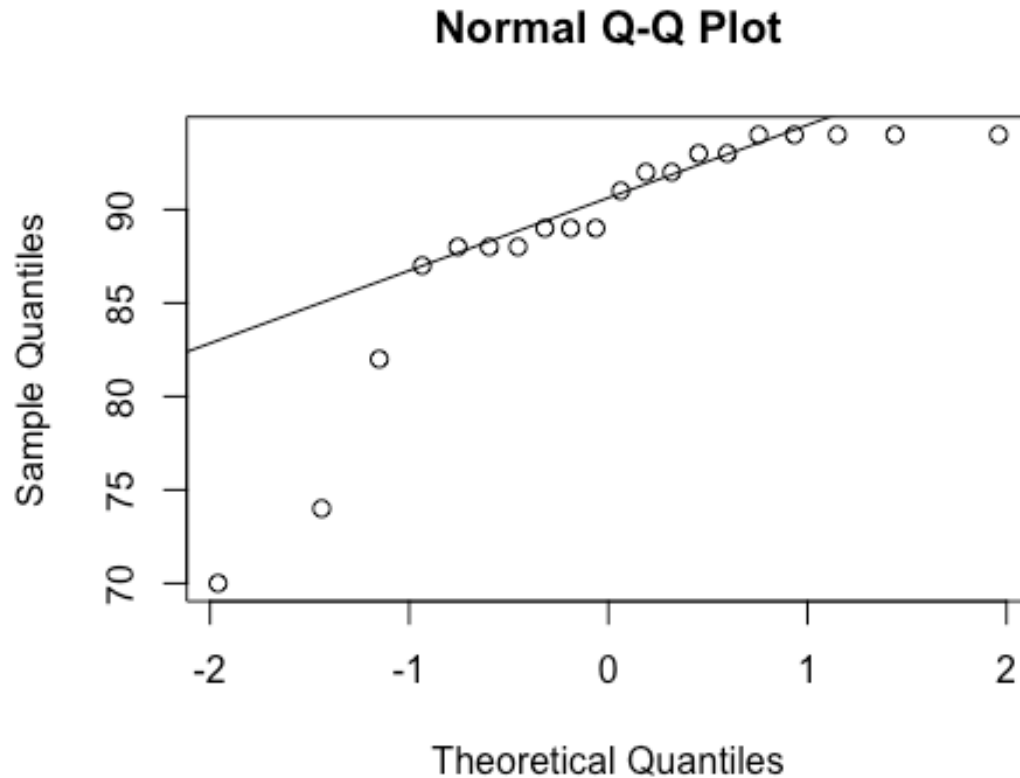
## [1] 6.568465

length(subset(SSdata, intervention == "sham")$min.sao2.awake)

## [1] 20
```



```
qqnorm(subset(SSdata, intervention == "sham")$min.sao2.awake)
qqline(subset(SSdata, intervention == "sham")$min.sao2.awake)
```



```
ad.test(subset(SSdata, intervention == "sham")$min.sao2.awake)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$min.sao2.awake
## A = 1.7154, p-value = 0.0001417

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$min.sao2.awake,
            subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake,
            conf.int = TRUE)

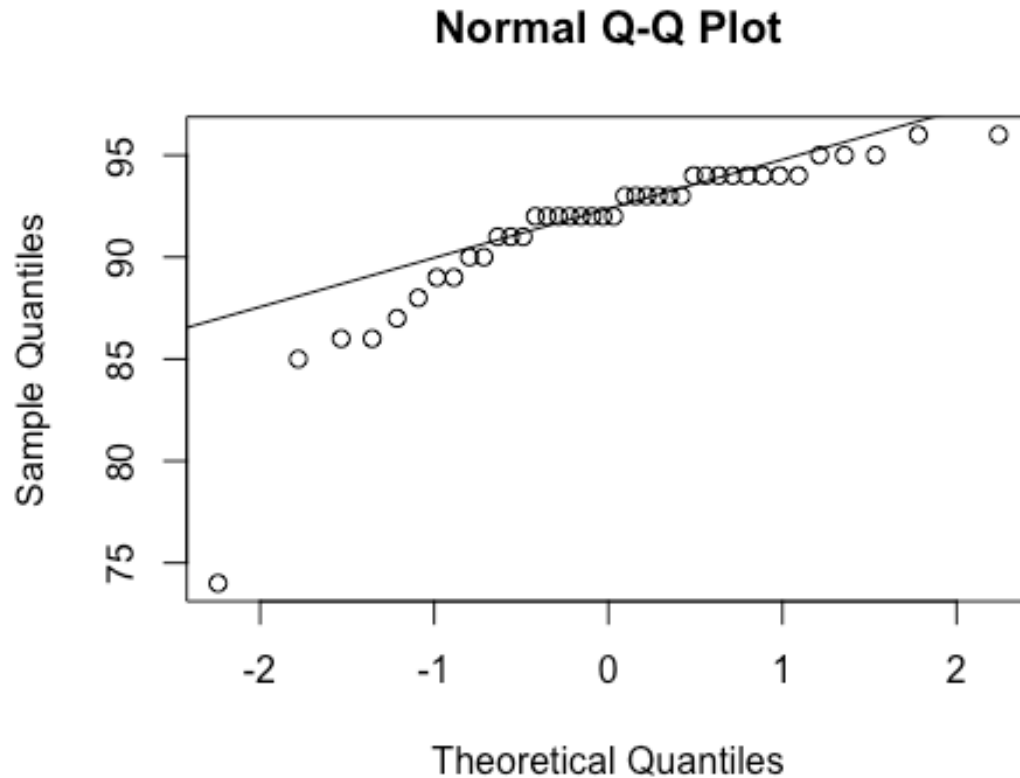
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.awake, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.awake, : cannot compute exact confidence intervals with ties
```

```

1
2
3 ##
4 ## Wilcoxon rank sum test with continuity correction
5 ##
6 ## data: subset(SSdata, intervention == "sham")$min.sao2.awake and subset(SS
7 data, intervention == "PrenaBelt")$min.sao2.awake
8 ## W = 184, p-value = 0.6726
9 ## alternative hypothesis: true location shift is not equal to 0
10 ## 95 percent confidence interval:
11 ## -2.999945 1.000048
12 ## sample estimates:
13 ## difference in location
14 ## -7.483333e-05
15
16
17 ##### Min SpO2 NREM #####
18 #Summary
19 summary(SSdata$min.sao2.nrem)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##  74.00  90.75   92.00   91.50   94.00   96.00
23
24 sd(SSdata$min.sao2.nrem, na.rm = TRUE)
25
26 ## [1] 3.928854
27
28 length(SSdata$min.sao2.nrem)
29
30 ## [1] 40
31
32 qqnorm(SSdata$min.sao2.nrem)
33 qqline(SSdata$min.sao2.nrem)
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
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```



```

ad.test(SSdata$min.sao2.nrem)

##
## Anderson-Darling normality test
##
## data:  SSdata$min.sao2.nrem
## A = 2.2647, p-value = 7.529e-06

#non-normal

#ANOVA
night_tx_difference <- anova(lm(min.sao2.nrem ~ intervention * night,
                                data = SSdata))
night_tx_difference

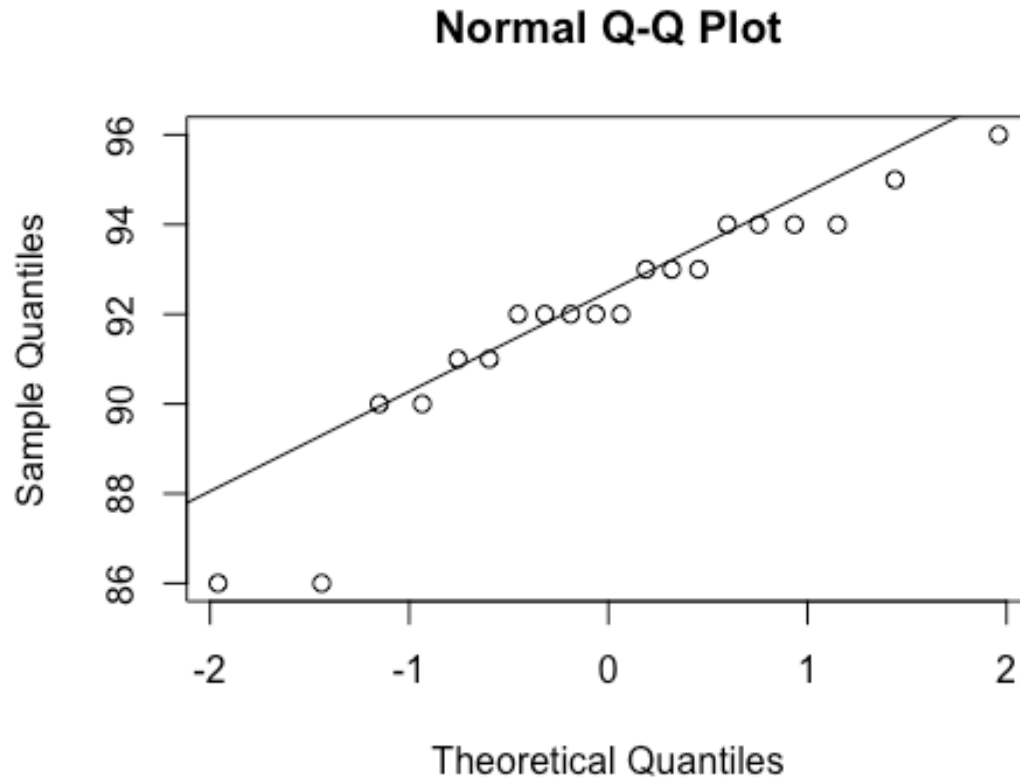
## Analysis of Variance Table
##
## Response: min.sao2.nrem
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    10.0   10.000    0.6475  0.4263
## night            1     3.6    3.600    0.2331  0.6322
## intervention:night  1    32.4   32.400    2.0978  0.1562
## Residuals      36   556.0   15.444

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.nrem,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.nrem,
7             paired = TRUE, conf.int = TRUE)
8
9
10 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
11 ## "sham")$min.sao2.nrem, : cannot compute exact p-value with ties
12
13 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
14 ## "sham")$min.sao2.nrem, : cannot compute exact confidence interval with tie
15 s
16
17 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
18 ## "sham")$min.sao2.nrem, : cannot compute exact p-value with zeroes
19
20 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21 ## "sham")$min.sao2.nrem, : cannot compute exact confidence interval with
22 ## zeroes
23
24 ##
25 ## Wilcoxon signed rank test with continuity correction
26 ##
27 ## data: subset(SSdataCompletes, intervention == "sham")$min.sao2.nrem and s
28 subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.nrem
29 ## V = 46, p-value = 0.26
30 ## alternative hypothesis: true location shift is not equal to 0
31 ## 95 percent confidence interval:
32 ## -2.4999583 0.5000763
33 ## sample estimates:
34 ## (pseudo)median
35 ## -0.500039
36
37 #between participants (grouped) comparison
38 summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
39
40 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
41 ##      86      91      92      92      94      96
42
43 sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
44
45 ## [1] 2.575185
46
47 length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
48
49 ## [1] 20
50
51 qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
52 qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem
## A = 0.79126, p-value = 0.03318

#non-normal

summary(subset(SSdata, intervention == "sham")$min.sao2.nrem)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      74.0   89.0   92.5   91.0   94.0   96.0

sd(subset(SSdata, intervention == "sham")$min.sao2.nrem)

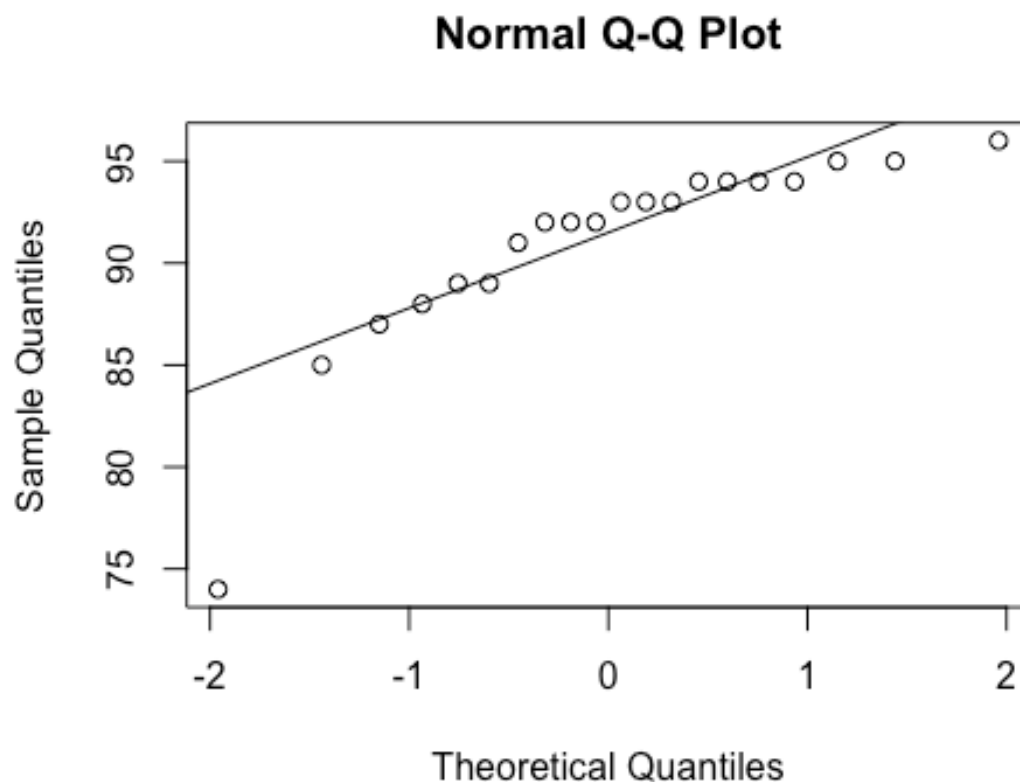
## [1] 4.952405

length(subset(SSdata, intervention == "sham")$min.sao2.nrem)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$min.sao2.nrem)
qqline(subset(SSdata, intervention == "sham")$min.sao2.nrem)

```



```

ad.test(subset(SSdata, intervention == "sham")$min.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$min.sao2.nrem
## A = 1.4186, p-value = 0.0008139

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$min.sao2.nrem,
            subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.nrem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.nrem, : cannot compute exact confidence intervals with ties

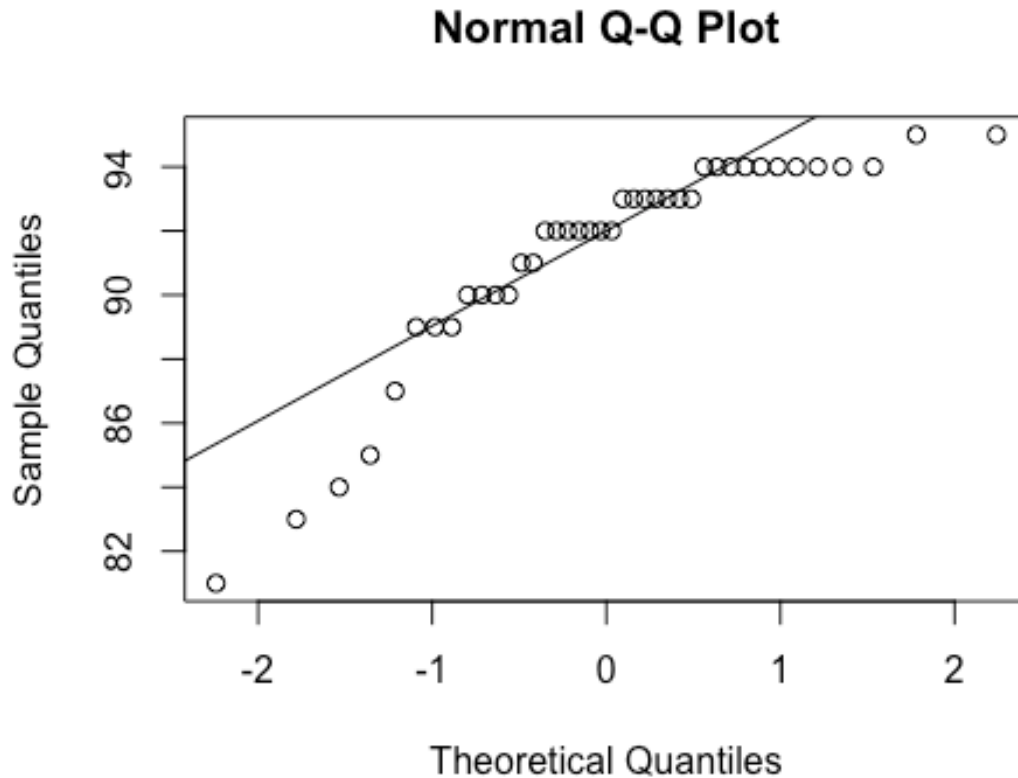
##
## Wilcoxon rank sum test with continuity correction
##

```

```

1
2
3  ## data: subset(SSdata, intervention == "sham")$min.sao2.nrem and subset(SSd
4  ata, intervention == "PrenaBelt")$min.sao2.nrem
5  ## W = 196.5, p-value = 0.9347
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -2.000016  1.999967
9  ## sample estimates:
10 ## difference in location
11 ## -3.487271e-05
12
13 ##### Min SpO2 REM #####
14 #Summary
15 summary(SSdata$min.sao2.rem)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##      81.00  90.00   92.00   91.35  94.00   95.00
19
20 sd(SSdata$min.sao2.rem, na.rm = TRUE)
21
22 ## [1] 3.332436
23
24 length(SSdata$min.sao2.rem)
25
26 ## [1] 40
27
28 qqnorm(SSdata$min.sao2.rem)
29 qqline(SSdata$min.sao2.rem)
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
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57
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60

```



```
ad.test(SSdata$min.sao2.rem)

##
## Anderson-Darling normality test
##
## data:  SSdata$min.sao2.rem
## A = 2.4334, p-value = 2.861e-06

#non-normal

#ANOVA
night_tx_difference <- anova(lm(min.sao2.rem ~ intervention * night,
                               data = SSdata))
night_tx_difference

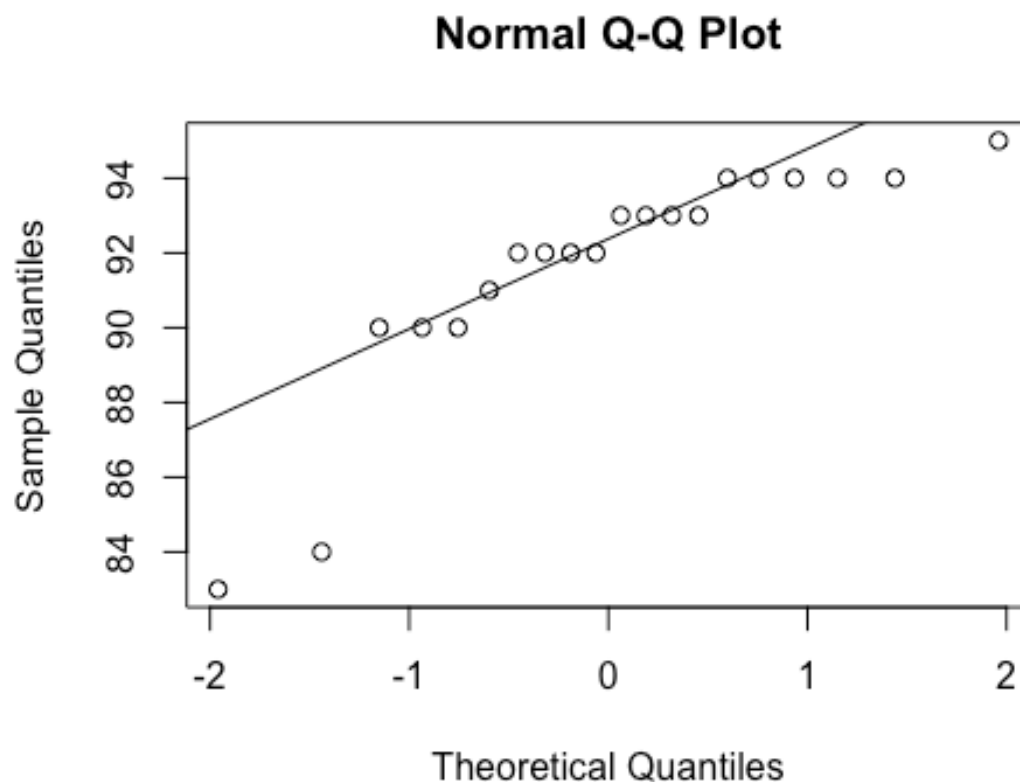
## Analysis of Variance Table
##
## Response: min.sao2.rem
##          Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1     3.6   3.600   0.3264 0.57131
## night           1     0.1   0.100   0.0091 0.92466
## intervention:night 1    32.4  32.400   2.9380 0.09512 .
## Residuals     36   397.0  11.028
```



```

1
2
3  ## ---
4  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
5
6  #within-participants (paired) comparison
7  #Paired Wilcoxon
8  wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.rem,
9              subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.rem
10             ,
11             paired = TRUE, conf.int = TRUE)
12
13  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
14  ## "sham")$min.sao2.rem, : cannot compute exact p-value with ties
15
16  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
17  ## "sham")$min.sao2.rem, : cannot compute exact confidence interval with ties
18
19  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
20  ## "sham")$min.sao2.rem, : cannot compute exact p-value with zeroes
21
22  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
23  ## "sham")$min.sao2.rem, : cannot compute exact confidence interval with
24  ## zeroes
25
26  ##
27  ## Wilcoxon signed rank test with continuity correction
28  ##
29  ## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.rem and su
30  bset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.rem
31  ## V = 45, p-value = 0.4029
32  ## alternative hypothesis: true location shift is not equal to 0
33  ## 95 percent confidence interval:
34  ## -2.4999536  0.9999402
35  ## sample estimates:
36  ## (pseudo)median
37  ## -0.4999916
38
39
40  #between participants (grouped) comparison
41  summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
42
43  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
44  ##  83.00  90.75   92.50   91.65   94.00   95.00
45
46  sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
47
48  ## [1] 3.150188
49
50  length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
51
52  ## [1] 20
53
54  qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
55  qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)
56
57
58
59

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem
## A = 1.6375, p-value = 0.000224

#non-normal

summary(subset(SSdata, intervention == "sham")$min.sao2.rem)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  81.00  89.00   92.00   91.05  94.00   95.00

sd(subset(SSdata, intervention == "sham")$min.sao2.rem)

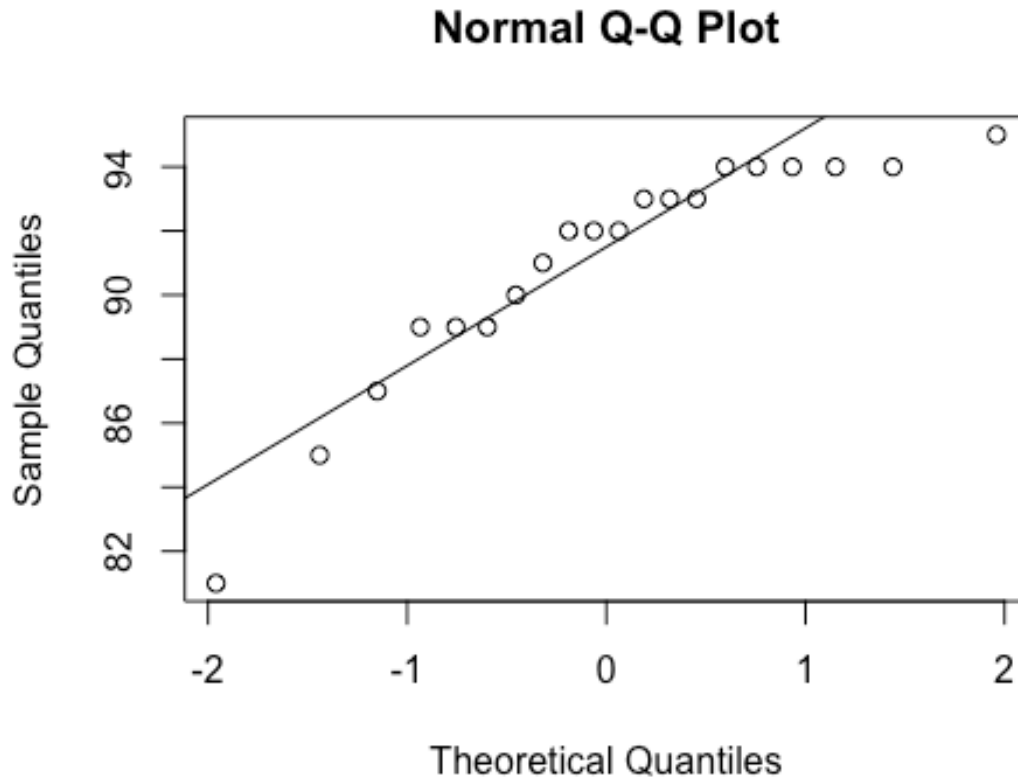
## [1] 3.56112

length(subset(SSdata, intervention == "sham")$min.sao2.rem)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$min.sao2.rem)
qqline(subset(SSdata, intervention == "sham")$min.sao2.rem)

```



```

ad.test(subset(SSdata, intervention == "sham")$min.sao2.rem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$min.sao2.rem
## A = 0.98564, p-value = 0.0105

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$min.sao2.rem,
            subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.rem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.rem, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```

```

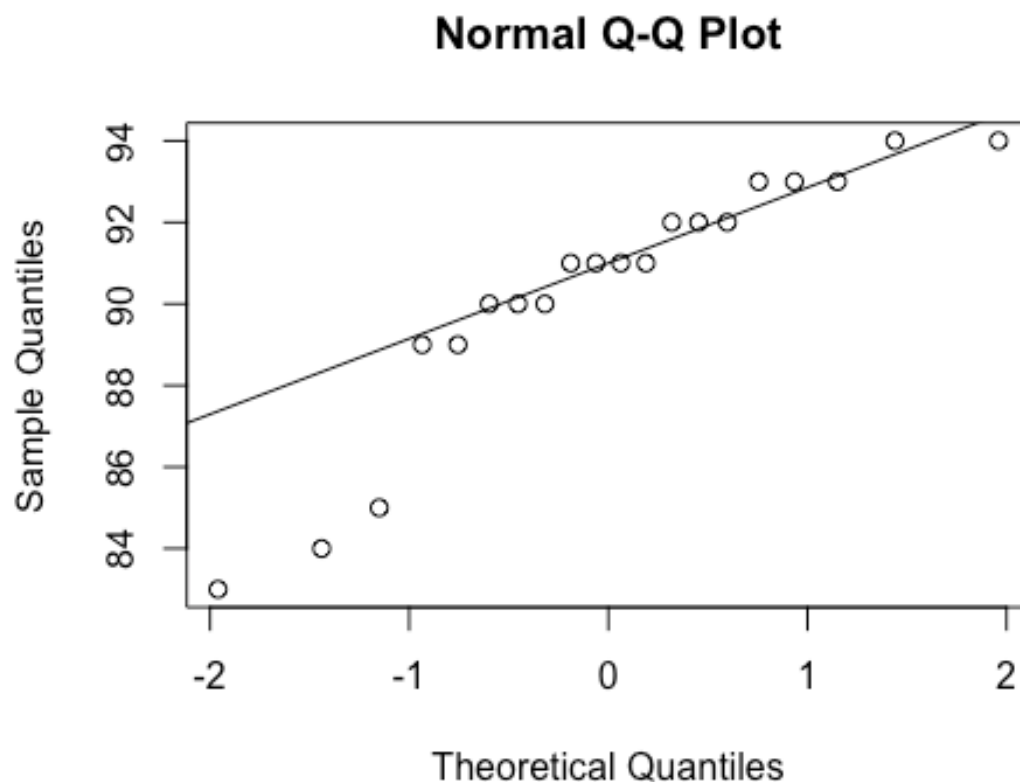
1
2
3 ## data: subset(SSdata, intervention == "sham")$min.sao2.rem and subset(SSda
4 ta, intervention == "PrenaBelt")$min.sao2.rem
5 ## W = 181, p-value = 0.6118
6 ## alternative hypothesis: true location shift is not equal to 0
7 ## 95 percent confidence interval:
8 ## -2.000020 1.000041
9 ## sample estimates:
10 ## difference in location
11 ## -6.982535e-05
12
13 ##### Min SpO2 TST #####
14 #FYI: this data was generated in our PSG reports per default configuration bu
15 t is not a
16 #pre-specified secondary outcome per the research protocol or trial registry.
17 FYI only.
18 #Summary
19 summary(SSdata$min.sao2.tst)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      70.00   88.00   91.00   89.28   93.00   94.00
23
24 sd(SSdata$min.sao2.tst, na.rm = TRUE)
25
26 ## [1] 5.11402
27
28 length(SSdata$min.sao2.tst)
29
30 ## [1] 40
31
32 #ANOVA
33 night_tx_difference <- anova(lm(min.sao2.tst ~ intervention * night,
34                               data = SSdata))
35
36 night_tx_difference
37
38 ## Analysis of Variance Table
39 ##
40 ## Response: min.sao2.tst
41 ##
42 ##           Df Sum Sq Mean Sq F value Pr(>F)
43 ## intervention      1  46.22  46.225  2.0356 0.16227
44 ## night              1  15.63  15.625  0.6881 0.41229
45 ## intervention:night  1 140.62 140.625  6.1927 0.01759 *
46 ## Residuals        36 817.50  22.708
47 ## ---
48 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
49
50 #within-participants (paired) comparison
51 #Paired Wilcoxon
52 wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.tst,
53             subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.tst,
54             paired = TRUE, conf.int = TRUE)
55
56
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$min.sao2.tst, : cannot compute exact p-value with ties
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7  ## "sham")$min.sao2.tst, : cannot compute exact confidence interval with ties
8
9  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
10 ## "sham")$min.sao2.tst, : cannot compute exact p-value with zeroes
11
12 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13 ## "sham")$min.sao2.tst, : cannot compute exact confidence interval with
14 ## zeroes
15
16 ##
17 ## Wilcoxon signed rank test with continuity correction
18 ##
19 ## data: subset(SSdataCompletes, intervention == "sham")$min.sao2.tst and su
20 bset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.tst
21 ## V = 45, p-value = 0.07952
22 ## alternative hypothesis: true location shift is not equal to 0
23 ## 95 percent confidence interval:
24 ## -3.999980e+00 6.891261e-05
25 ## sample estimates:
26 ## (pseudo)median
27 ## -1.500056
28
29
30 #between participants (grouped) comparison
31 summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
32
33 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
34 ##      83.00  89.75   91.00   90.35   92.25   94.00
35
36 sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
37
38 ## [1] 3.116594
39
40 length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
41
42 ## [1] 20
43
44 qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
45 qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst
## A = 1.0583, p-value = 0.006831

#non-normal

summary(subset(SSdata, intervention == "sham")$min.sao2.tst)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   70.00  87.75   89.00   88.20  93.00   94.00

sd(subset(SSdata, intervention == "sham")$min.sao2.tst)

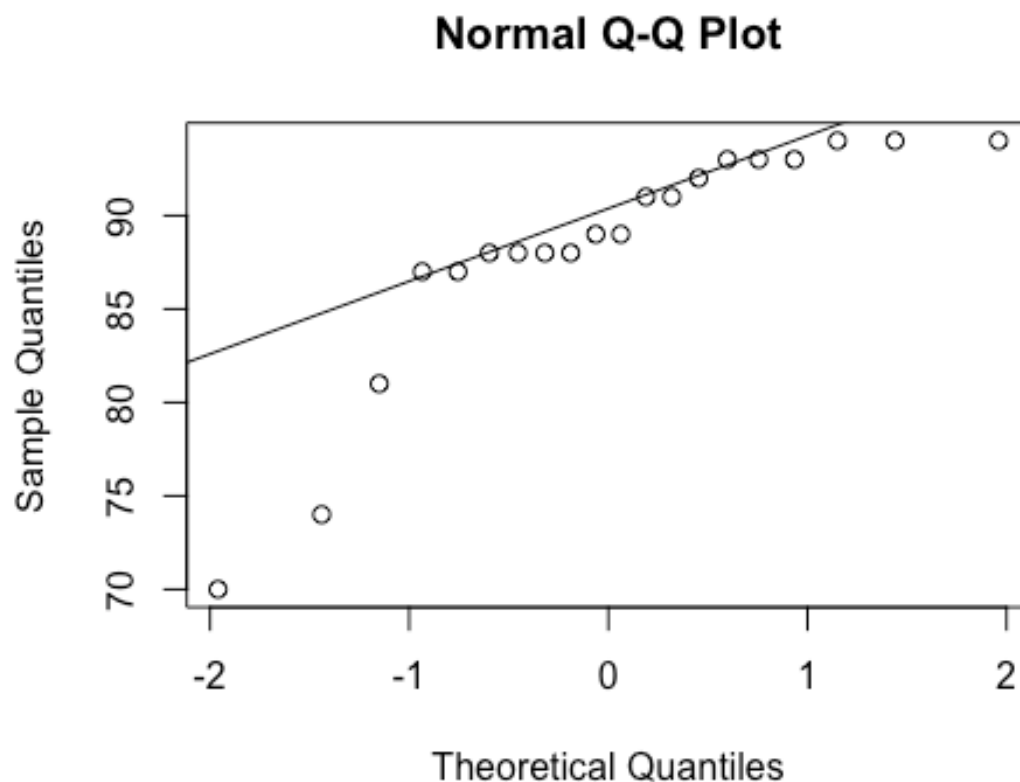
## [1] 6.444908

length(subset(SSdata, intervention == "sham")$min.sao2.tst)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$min.sao2.tst)
qqline(subset(SSdata, intervention == "sham")$min.sao2.tst)

```



```

ad.test(subset(SSdata, intervention == "sham")$min.sao2.tst)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$min.sao2.tst
## A = 1.5634, p-value = 0.0003467

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$min.sao2.tst,
            subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.tst, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $min.sao2.tst, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```

```

1
2
3  ## data: subset(SSdata, intervention == "sham")$min.sao2.tst and subset(SSda
4 ta, intervention == "PrenaBelt")$min.sao2.tst
5  ## W = 166, p-value = 0.362
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -3.000006  1.000035
9  ## sample estimates:
10 ## difference in location
11 ## -1.000019
12
13 ##### Max SpO2 AWAKE #####
14 #Summary
15 summary(SSdata$max.sao2.awake)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##      98.00   99.00   100.00   99.68  100.00   100.00
19
20 sd(SSdata$max.sao2.awake, na.rm = TRUE)
21
22 ## [1] 0.5256254
23
24 length(SSdata$max.sao2.awake)
25
26 ## [1] 40
27
28 #ANOVA
29 night_tx_difference <- anova(lm(max.sao2.awake ~ intervention * night,
30                               data = SSdata))
31
32 night_tx_difference
33
34 ## Analysis of Variance Table
35 ##
36 ## Response: max.sao2.awake
37 ##
38 ##      Df Sum Sq Mean Sq F value Pr(>F)
39 ## intervention      1  0.625    0.625  2.2727 0.1404
40 ## night              1  0.025    0.025  0.0909 0.7648
41 ## intervention:night  1  0.225    0.225  0.8182 0.3717
42 ## Residuals        36  9.900    0.275
43
44 #within-participants (paired) comparison
45 #Paired Wilcoxon
46 wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.awake,
47              subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.awake,
48              paired = TRUE)
49
50 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
51 ## "sham")$max.sao2.awake, : cannot compute exact p-value with ties
52
53 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
54 ## "sham")$max.sao2.awake, : cannot compute exact p-value with zeroes
55
56
57
58
59
60

```

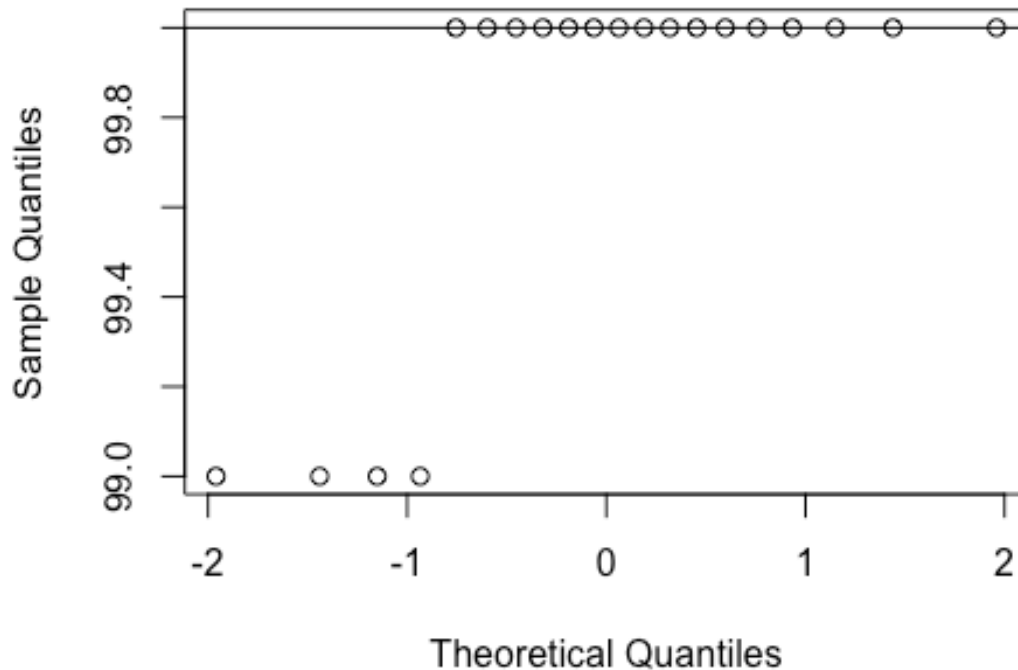


```

1
2
3
4 ## Wilcoxon signed rank test with continuity correction
5 ##
6 ## data: subset(SSdataCompletes, intervention == "sham")$max.sao2.awake and
7 subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.awake
8 ## V = 4, p-value = 0.0726
9 ## alternative hypothesis: true location shift is not equal to 0
10
11 #between participants (grouped) comparison
12 summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
13
14 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
15 ##      99.0  100.0  100.0   99.8  100.0  100.0
16
17 sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
18
19 ## [1] 0.4103913
20
21 length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
22
23 ## [1] 20
24
25 qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
26 qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
27
28
29
30
31
32
33

```

Normal Q-Q Plot

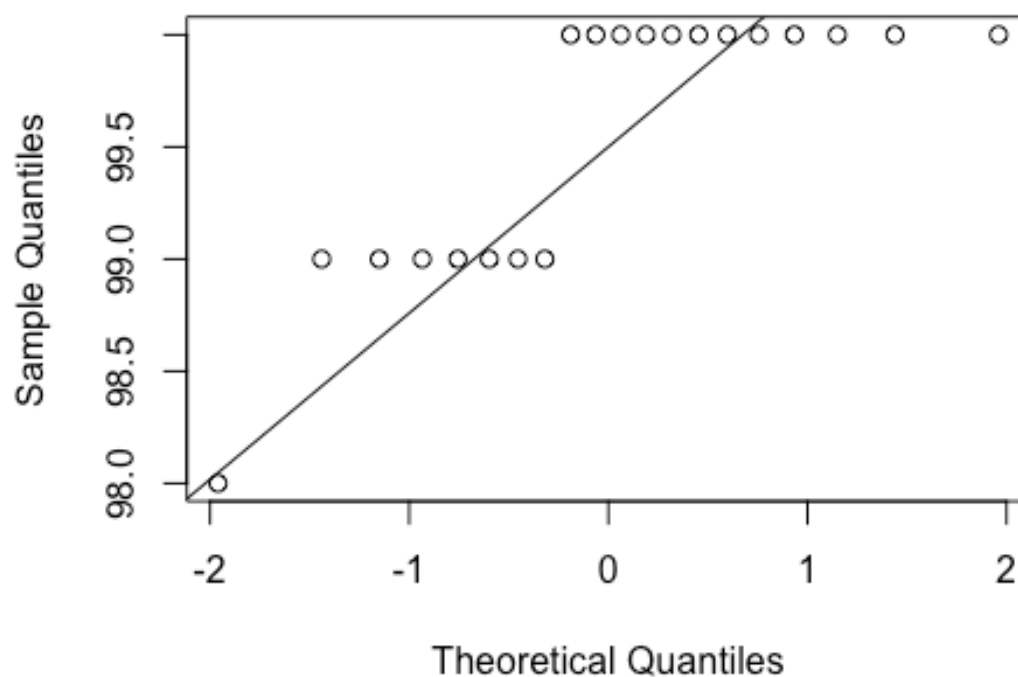


```

1 ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
2
3
4
5 ##
6 ## Anderson-Darling normality test
7 ##
8 ## data: subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake
9 ## A = 5.1941, p-value = 2.32e-13
10
11 #non-normal
12
13 summary(subset(SSdata, intervention == "sham")$max.sao2.awake)
14
15 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
16 ##  98.00  99.00  100.00   99.55  100.00  100.00
17
18 sd(subset(SSdata, intervention == "sham")$max.sao2.awake)
19
20 ## [1] 0.6048053
21
22 length(subset(SSdata, intervention == "sham")$max.sao2.awake)
23
24 ## [1] 20
25
26 qqnorm(subset(SSdata, intervention == "sham")$max.sao2.awake)
27 qqline(subset(SSdata, intervention == "sham")$max.sao2.awake)
28
29
30
31
32
33

```

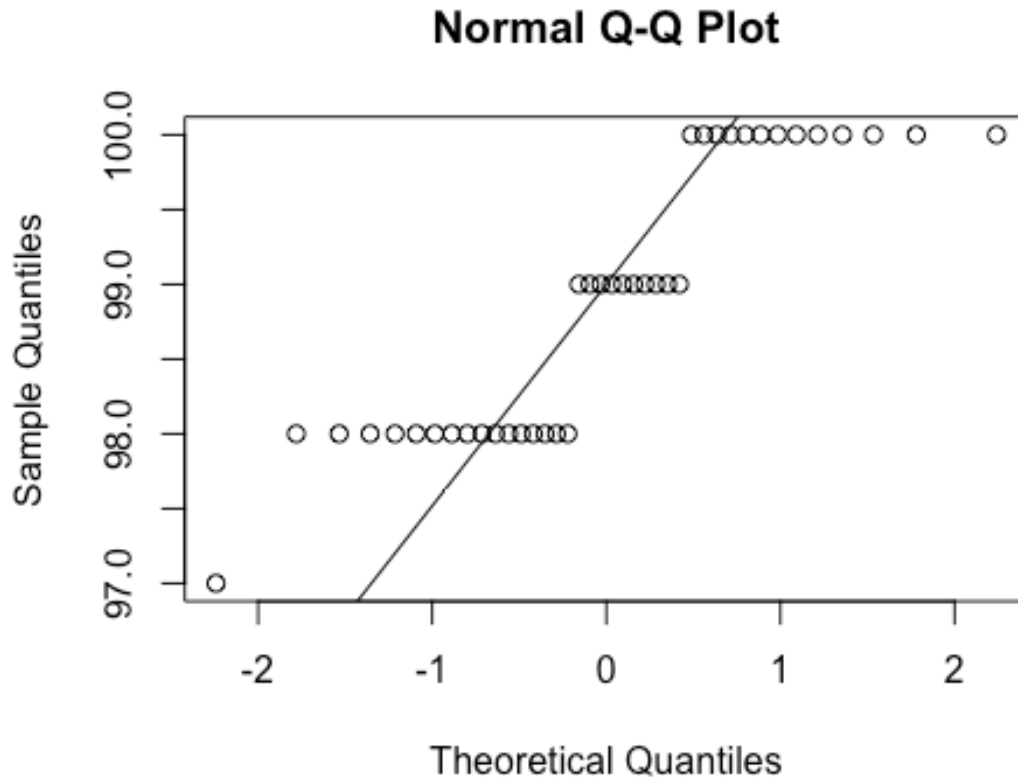
Normal Q-Q Plot



```

1
2
3  ad.test(subset(SSdata, intervention == "sham")$max.sao2.awake)
4
5  ##
6  ## Anderson-Darling normality test
7  ##
8  ## data: subset(SSdata, intervention == "sham")$max.sao2.awake
9  ## A = 2.8091, p-value = 2.322e-07
10
11  #non-normal
12
13  #FYI - unpaired test
14  wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.awake,
15             subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake,
16             conf.int = TRUE)
17
18  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
19  ## $max.sao2.awake, : cannot compute exact p-value with ties
20
21  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
22  ## $max.sao2.awake, : cannot compute exact confidence intervals with ties
23
24  ##
25  ## Wilcoxon rank sum test with continuity correction
26  ##
27  ## data: subset(SSdata, intervention == "sham")$max.sao2.awake and subset(SS
28  data, intervention == "PrenaBelt")$max.sao2.awake
29  ## W = 158, p-value = 0.1594
30  ## alternative hypothesis: true location shift is not equal to 0
31  ## 95 percent confidence interval:
32  ## -9.999288e-01  1.199059e-06
33  ## sample estimates:
34  ## difference in location
35  ## -1.027475e-05
36
37  ##### Max SpO2 NREM #####
38  #Summary
39  summary(SSdata$max.sao2.nrem)
40
41  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
42  ##  97.00  98.00   99.00   98.88 100.00  100.00
43
44  sd(SSdata$max.sao2.nrem, na.rm = TRUE)
45
46  ## [1] 0.9111137
47
48  length(SSdata$max.sao2.nrem)
49
50  ## [1] 40
51
52  qqnorm(SSdata$max.sao2.nrem)
53  qqline(SSdata$max.sao2.nrem)
54
55
56
57
58
59
60

```



```

ad.test(SSdata$max.sao2.nrem)

##
## Anderson-Darling normality test
##
## data:  SSdata$max.sao2.nrem
## A = 3.1852, p-value = 3.895e-08

#non-normal

#ANOVA
night_tx_difference <- anova(lm(max.sao2.nrem ~ intervention * night,
                               data = SSdata))
night_tx_difference

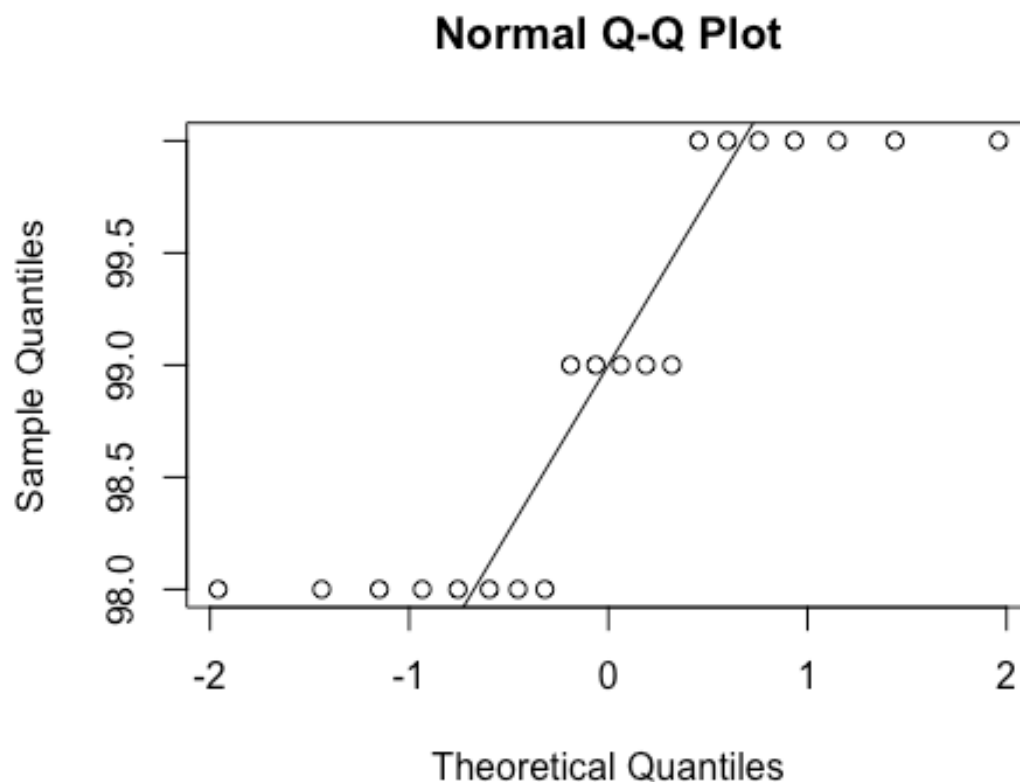
## Analysis of Variance Table
##
## Response: max.sao2.nrem
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1  0.225    0.225   0.2571 0.6152
## night           1  0.625    0.625   0.7143 0.4036
## intervention:night 1  0.025    0.025   0.0286 0.8667
## Residuals     36 31.500    0.875

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.nrem,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.nrem,
7             paired = TRUE, conf.int = TRUE)
8
9
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$max.sao2.nrem, : requested conf.level not achievable
13
14 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
15 ## "sham")$max.sao2.nrem, : cannot compute exact p-value with ties
16
17 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
18 ## "sham")$max.sao2.nrem, : cannot compute exact confidence interval with ties
19
20 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21 ## "sham")$max.sao2.nrem, : cannot compute exact p-value with zeroes
22
23 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24 ## "sham")$max.sao2.nrem, : cannot compute exact confidence interval with zeroes
25 ## zeroes
26
27 ##
28 ## Wilcoxon signed rank test with continuity correction
29 ##
30 ## data: subset(SSdataCompletes, intervention == "sham")$max.sao2.nrem and subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.nrem
31 ## V = 20, p-value = 0.4575
32 ## alternative hypothesis: true location shift is not equal to 0
33 ## 90 percent confidence interval:
34 ## -1.499922 1.000000
35 ## sample estimates:
36 ## (pseudo)median
37 ## -0.4999789
38
39
40
41 #between participants (grouped) comparison
42 summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
43
44 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
45 ##  98.00  98.00   99.00  98.95 100.00 100.00
46
47 sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
48
49 ## [1] 0.8870412
50
51 length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
52
53 ## [1] 20
54
55 qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
56 qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem
## A = 1.809, p-value = 8.166e-05

#non-normal

summary(subset(SSdata, intervention == "sham")$max.sao2.nrem)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      97.0   98.0   99.0   98.8   100.0   100.0

sd(subset(SSdata, intervention == "sham")$max.sao2.nrem)

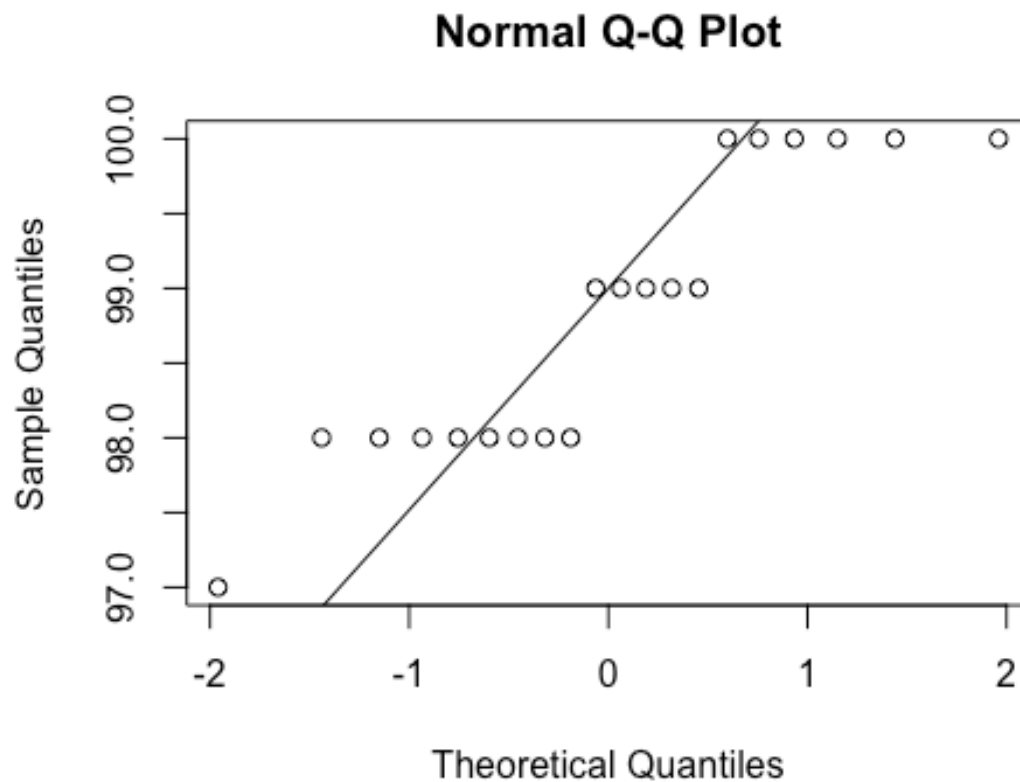
## [1] 0.9514532

length(subset(SSdata, intervention == "sham")$max.sao2.nrem)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$max.sao2.nrem)
qqline(subset(SSdata, intervention == "sham")$max.sao2.nrem)

```



```

ad.test(subset(SSdata, intervention == "sham")$max.sao2.nrem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$max.sao2.nrem
## A = 1.3653, p-value = 0.001115

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.nrem,
            subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem,
            conf.int = TRUE)

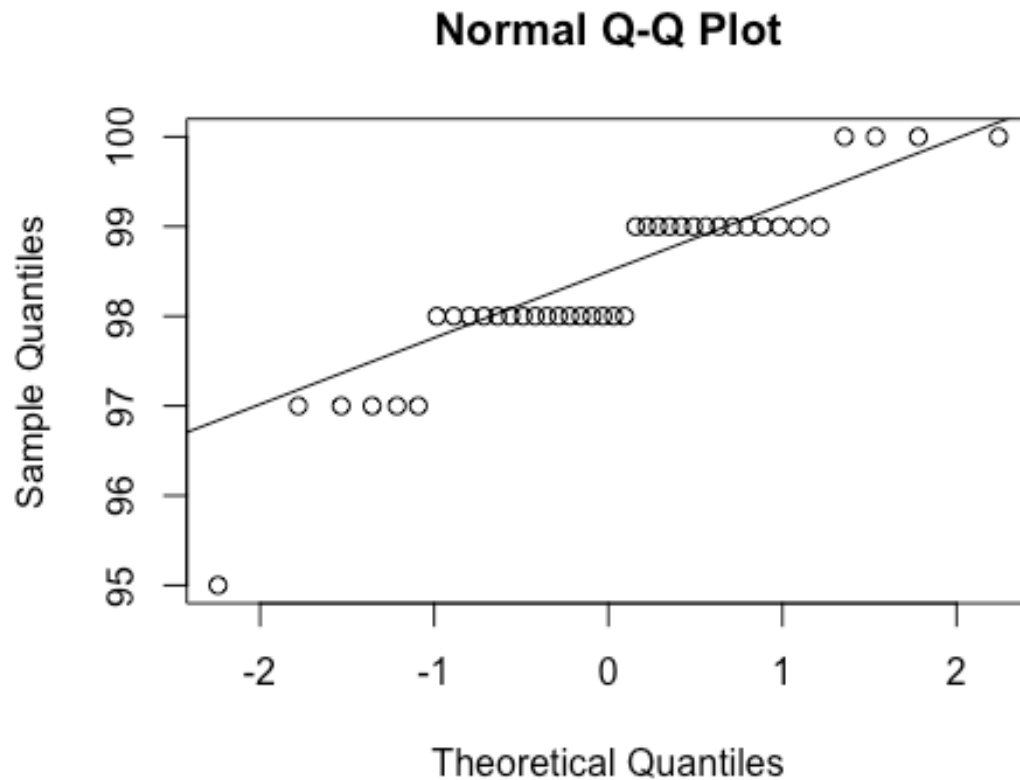
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.nrem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.nrem, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```

```
1
2
3 ## data: subset(SSdata, intervention == "sham")$max.sao2.nrem and subset(SSd
4 ata, intervention == "PrenaBelt")$max.sao2.nrem
5 ## W = 183.5, p-value = 0.6458
6 ## alternative hypothesis: true location shift is not equal to 0
7 ## 95 percent confidence interval:
8 ## -9.999960e-01 6.876513e-05
9 ## sample estimates:
10 ## difference in location
11 ## -7.969806e-05
12
13 ##### Max SpO2 REM #####
14 #Summary
15 summary(SSdata$max.sao2.rem)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##  95.00  98.00   98.00   98.35  99.00  100.00
19
20 sd(SSdata$max.sao2.rem, na.rm = TRUE)
21
22 ## [1] 1.001281
23
24 length(SSdata$max.sao2.rem)
25
26 ## [1] 40
27
28 qqnorm(SSdata$max.sao2.rem)
29 qqline(SSdata$max.sao2.rem)
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

```

ad.test(SSdata$max.sao2.rem)

##
## Anderson-Darling normality test
##
## data:  SSdata$max.sao2.rem
## A = 1.9711, p-value = 4.063e-05

#non-normal

#ANOVA
night_tx_difference <- anova(lm(max.sao2.rem ~ intervention * night,
                               data = SSdata))
night_tx_difference

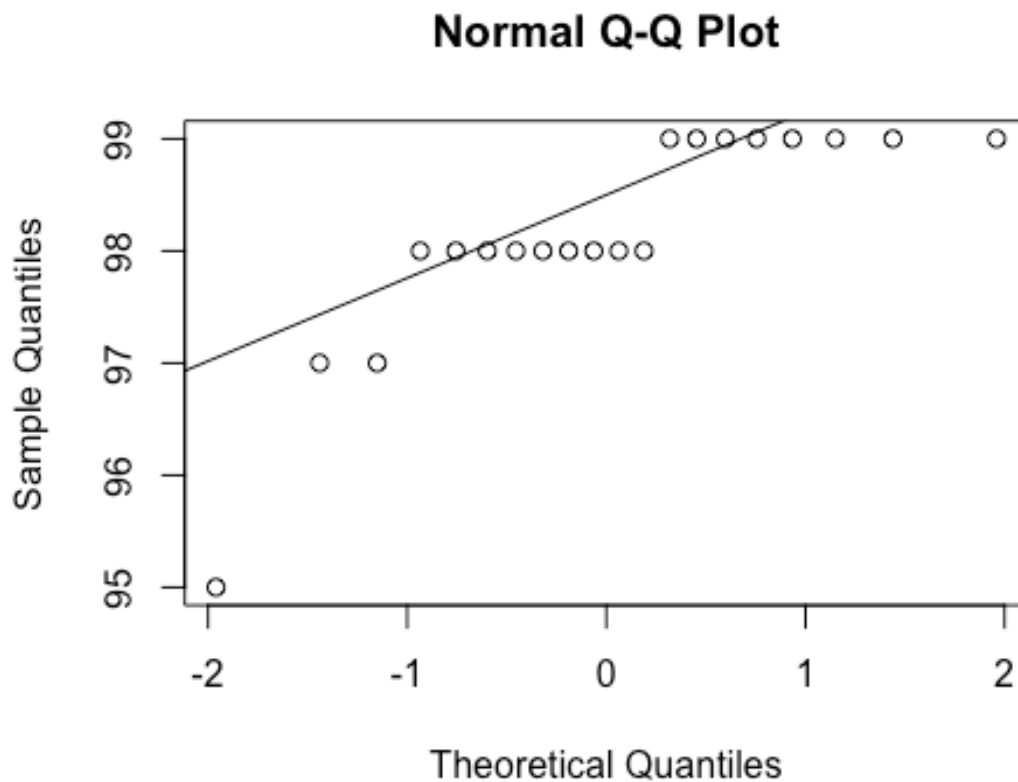
## Analysis of Variance Table
##
## Response: max.sao2.rem
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    1.6  1.6000   1.7041  0.200
## night           1    3.6  3.6000   3.8343  0.058 .
## intervention:night  1    0.1  0.1000   0.1065  0.746
## Residuals      36   33.8  0.9389

```

```

1
2
3
4  ## ---
5  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
6
7  #within-participants (paired) comparison
8  #Paired Wilcoxon
9  wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.rem,
10             subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.rem
11             ,
12             paired = TRUE, conf.int = TRUE)
13
14  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
15  ## "sham")$max.sao2.rem, : cannot compute exact p-value with ties
16
17  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
18  ## "sham")$max.sao2.rem, : cannot compute exact confidence interval with ties
19
20  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
21  ## "sham")$max.sao2.rem, : cannot compute exact p-value with zeroes
22
23  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24  ## "sham")$max.sao2.rem, : cannot compute exact confidence interval with
25  ## zeroes
26
27  ##
28  ## Wilcoxon signed rank test with continuity correction
29  ##
30  ## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.rem and su
31  bset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.rem
32  ## V = 78, p-value = 0.2819
33  ## alternative hypothesis: true location shift is not equal to 0
34  ## 95 percent confidence interval:
35  ## -5.341455e-06 1.000049e+00
36  ## sample estimates:
37  ## (pseudo)median
38  ## 4.140595e-05
39
40  #between participants (grouped) comparison
41  summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
42
43  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
44  ##  95.00  98.00   98.00   98.15  99.00   99.00
45
46  sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
47
48  ## [1] 0.9880869
49
50  length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
51
52  ## [1] 20
53
54  qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
55  qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem
## A = 1.7444, p-value = 0.0001194

#non-normal

summary(subset(SSdata, intervention == "sham")$max.sao2.rem)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  97.00  98.00  98.50  98.55  99.00  100.00

sd(subset(SSdata, intervention == "sham")$max.sao2.rem)

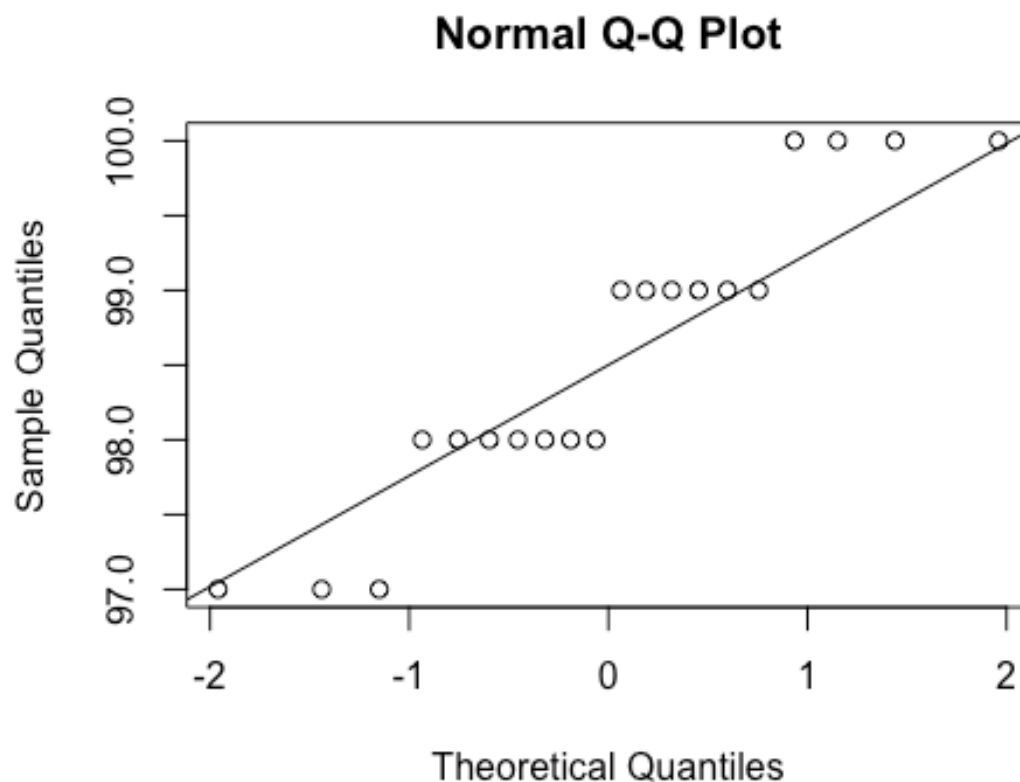
## [1] 0.9986833

length(subset(SSdata, intervention == "sham")$max.sao2.rem)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$max.sao2.rem)
qqline(subset(SSdata, intervention == "sham")$max.sao2.rem)

```



```

ad.test(subset(SSdata, intervention == "sham")$max.sao2.rem)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$max.sao2.rem
## A = 0.89914, p-value = 0.01752

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.rem,
            subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.rem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.rem, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

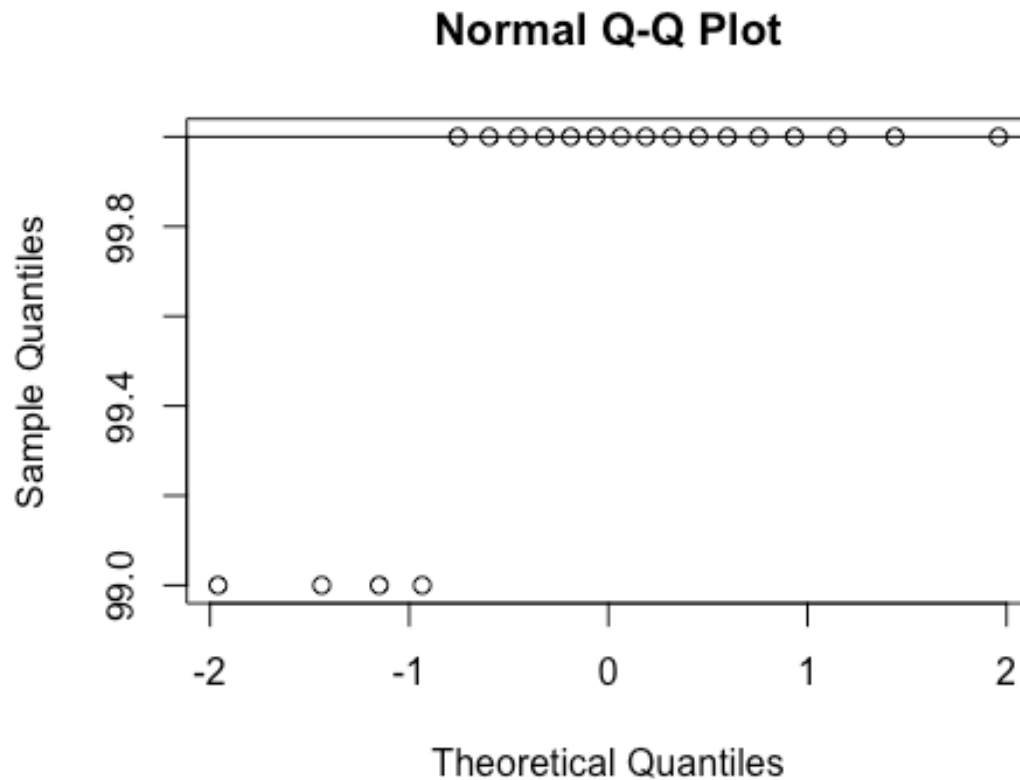
```

```

1
2
3  ## data: subset(SSdata, intervention == "sham")$max.sao2.rem and subset(SSda
4 ta, intervention == "PrenaBelt")$max.sao2.rem
5  ## W = 234.5, p-value = 0.3298
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -5.707564e-05  9.999595e-01
9  ## sample estimates:
10 ## difference in location
11 ##          5.182881e-05
12
13 ##### Max SpO2 TST #####
14 ##FYI: this data was generated in our PSG reports per default configuration bu
15 t is not a
16 ##pre-specified secondary outcome per the research protocol or trial registry.
17 FYI only.
18 ##Summary
19 summary(SSdata$max.sao2.tst)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##   98.00   99.00  100.00   99.68  100.00  100.00
23
24 sd(SSdata$max.sao2.tst, na.rm = TRUE)
25
26 ## [1] 0.5256254
27
28 length(SSdata$max.sao2.tst)
29
30 ## [1] 40
31
32 ##ANOVA
33 night_tx_difference <- anova(lm(max.sao2.tst ~ intervention * night,
34                               data = SSdata))
35
36 night_tx_difference
37
38 ## Analysis of Variance Table
39 ##
40 ## Response: max.sao2.tst
41 ##
42 ##           Df Sum Sq Mean Sq F value Pr(>F)
43 ## intervention      1  0.625    0.625   2.2727 0.1404
44 ## night              1  0.025    0.025   0.0909 0.7648
45 ## intervention:night  1  0.225    0.225   0.8182 0.3717
46 ## Residuals        36  9.900    0.275
47
48 ##within-participants (paired) comparison
49 ##Paired Wilcoxon
50 wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.tst,
51              subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.tst
52              ,
53              paired = TRUE)
54
55 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
56 ## "sham")$max.sao2.tst, : cannot compute exact p-value with ties

```

```
1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$max.sao2.tst, : cannot compute exact p-value with zeroes
5
6  ##
7  ## Wilcoxon signed rank test with continuity correction
8  ##
9  ## data: subset(SSdataCompletes, intervention == "sham")$max.sao2.tst and su
10 bset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.tst
11 ## V = 4, p-value = 0.0726
12 ## alternative hypothesis: true location shift is not equal to 0
13
14 #between participants (grouped) comparison
15 summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
16
17 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##      99.0  100.0   100.0   99.8  100.0   100.0
19
20 sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
21
22 ## [1] 0.4103913
23
24 length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
25
26 ## [1] 20
27
28 qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
29 qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst
## A = 5.1941, p-value = 2.32e-13

#non-normal

summary(subset(SSdata, intervention == "sham")$max.sao2.tst)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  98.00  99.00  100.00  99.55  100.00  100.00

sd(subset(SSdata, intervention == "sham")$max.sao2.tst)

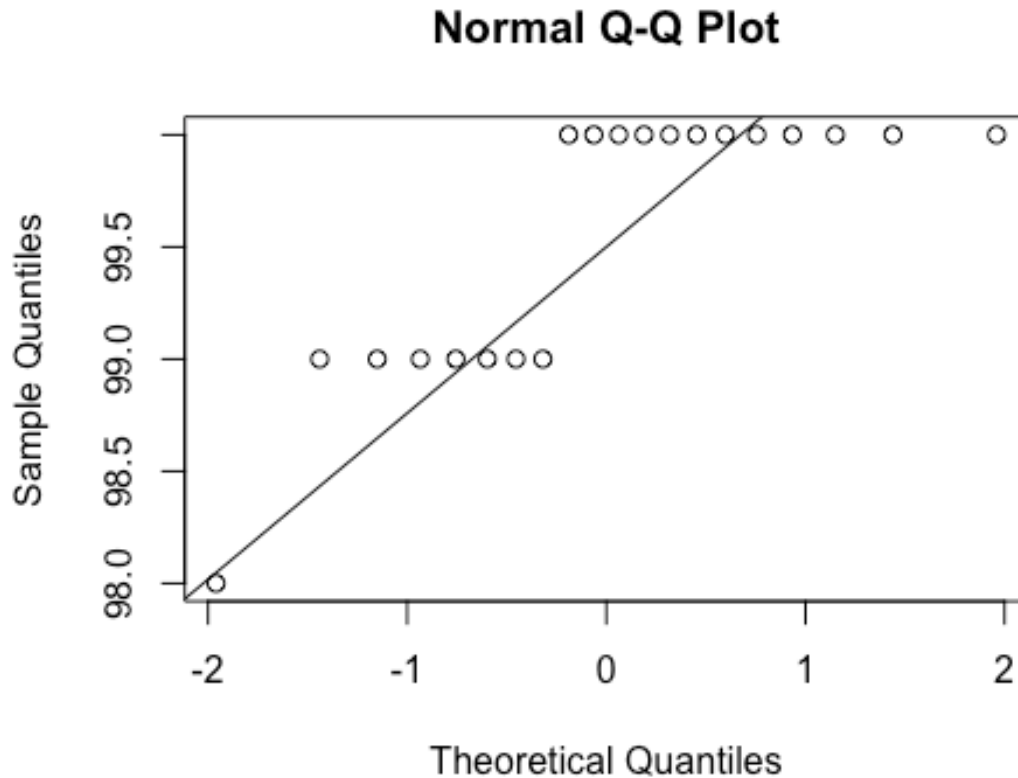
## [1] 0.6048053

length(subset(SSdata, intervention == "sham")$max.sao2.tst)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$max.sao2.tst)
qqline(subset(SSdata, intervention == "sham")$max.sao2.tst)

```



```

ad.test(subset(SSdata, intervention == "sham")$max.sao2.tst)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$max.sao2.tst
## A = 2.8091, p-value = 2.322e-07

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.tst,
            subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.tst, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.tst, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```



```

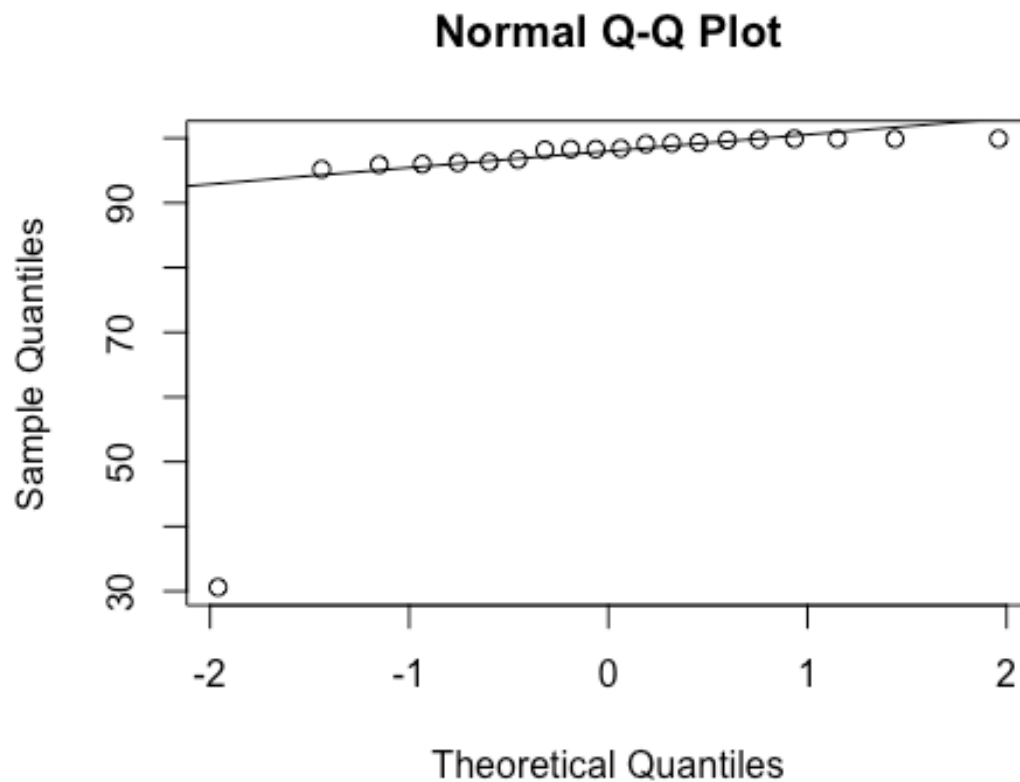
1
2
3  ## data: subset(SSdata, intervention == "sham")$max.sao2.tst and subset(SSda
4 ta, intervention == "PrenaBelt")$max.sao2.tst
5  ## W = 158, p-value = 0.1594
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -9.999288e-01  1.199059e-06
9  ## sample estimates:
10 ## difference in location
11 ##          -1.027475e-05
12
13
14 ##### %TST with SpO2 90-100% #####
15 #FYI: this data was generated in our PSG reports per default configuration bu
16 t is not a
17 #pre-specified secondary outcome per the research protocol or trial registry.
18 FYI only.
19 #Summary
20 summary(SSdata$sao2.Ptst.100to90)
21
22 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
23 ##  30.60   96.48   98.40   96.47   99.60  100.00
24
25 sd(SSdata$sao2.Ptst.100to90, na.rm = TRUE)
26
27 ## [1] 10.81533
28
29 length(SSdata$sao2.Ptst.100to90)
30
31 ## [1] 40
32
33 #ANOVA
34 night_tx_difference <- anova(lm(sao2.Ptst.100to90 ~ intervention * night,
35                               data = SSdata))
36
37 night_tx_difference
38
39 ## Analysis of Variance Table
40 ##
41 ## Response: sao2.Ptst.100to90
42 ##
43 ##      Df Sum Sq Mean Sq F value Pr(>F)
44 ## intervention      1  106.6   106.60   0.9253  0.3425
45 ## night              1  130.0   129.96   1.1280  0.2953
46 ## intervention:night  1  177.7   177.66   1.5420  0.2223
47 ## Residuals        36 4147.7   115.21
48
49 #within-participants (paired) comparison
50 #Paired Wilcoxon
51 wilcox.test(subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.100to90
52 ,
53             subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.100to90
54 ,
55             paired = TRUE, conf.int = TRUE)
56
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$sao2.Ptst.100to90, : cannot compute exact p-value with ties
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7  ## "sham")$sao2.Ptst.100to90, : cannot compute exact confidence interval with
8  ## ties
9
10 ##
11 ## Wilcoxon signed rank test with continuity correction
12 ##
13 ## data: subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.100to90 a
14 nd subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.100to90
15 ## V = 108, p-value = 0.9256
16 ## alternative hypothesis: true location shift is not equal to 0
17 ## 95 percent confidence interval:
18 ## -0.7499482 1.2500240
19 ## sample estimates:
20 ## (pseudo)median
21 ## 0.02366365
22
23
24 #between participants (grouped) comparison
25 summary(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
26
27 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28 ##      30.60  96.28   98.35   94.84   99.72   99.90
29
30 sd(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
31
32 ## [1] 15.20458
33
34 length(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
35
36 ## [1] 20
37
38 qqnorm(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
39 qqline(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90
## A = 5.6171, p-value = 2.05e-14

#non-normal

summary(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  92.90  97.55   98.60   98.10  99.38  100.00

sd(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

## [1] 1.819044

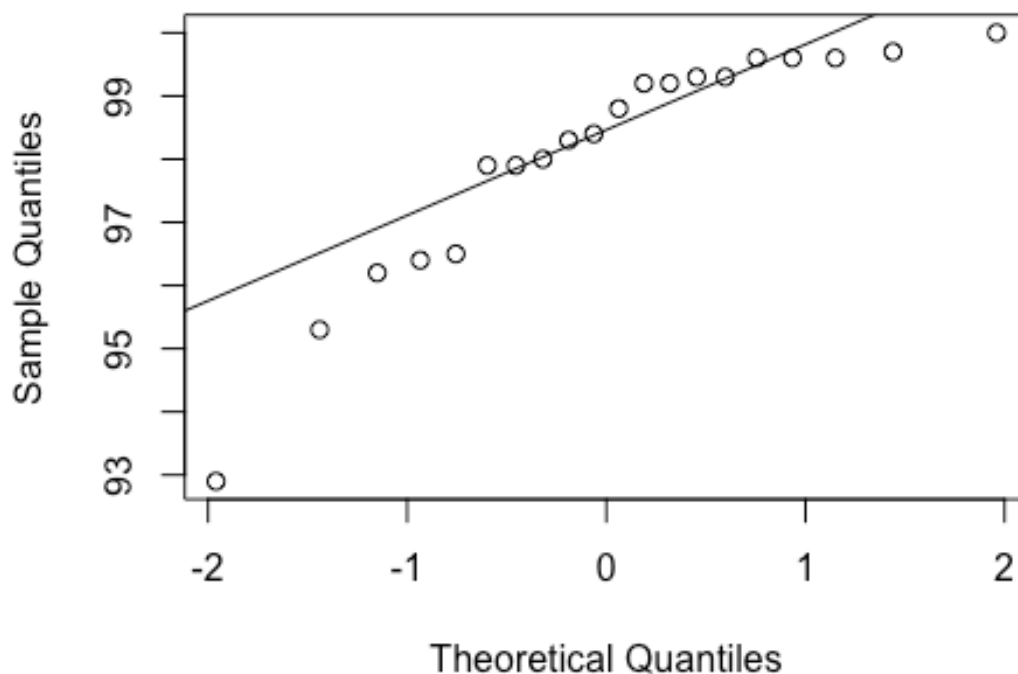
length(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)
qqline(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$sao2.Ptst.100to90
## A = 1.0547, p-value = 0.006979

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90,
            subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sao2.Ptst.100to90, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sao2.Ptst.100to90, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```

```

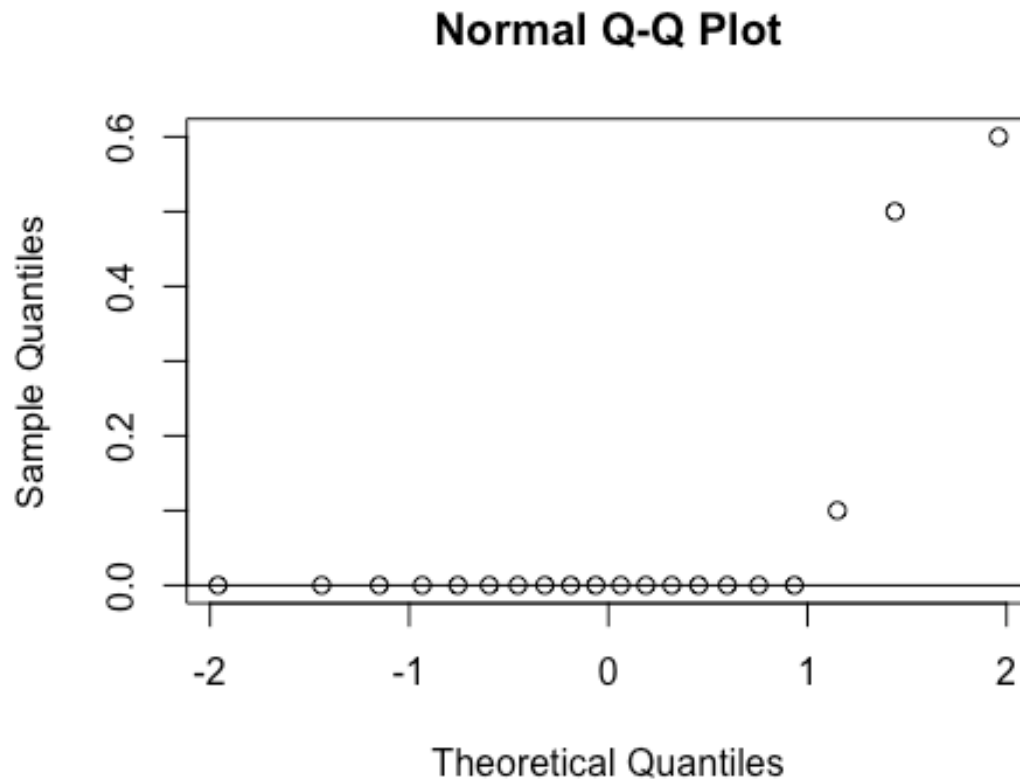
1
2
3  ## data: subset(SSdata, intervention == "sham")$sao2.Ptst.100to90 and subset
4  (SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90
5  ## W = 199.5, p-value = 1
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ##  -0.7000278  1.2000028
9  ## sample estimates:
10 ## difference in location
11 ##          -3.177747e-05
12
13
14 ##### %TST with SpO2 85-89.9% #####
15 #FYI: this data was generated in our PSG reports per default configuration bu
16 t is not a
17 #pre-specified secondary outcome per the research protocol or trial registry.
18 FYI only.
19 #Summary
20 summary(SSdata$sao2.Ptst.89.9to85)
21
22 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
23 ##  0.0000  0.0000  0.0000  0.0775  0.0000  1.0000
24
25 sd(SSdata$sao2.Ptst.89.9to85, na.rm = TRUE)
26
27 ## [1] 0.2069157
28
29 length(SSdata$sao2.Ptst.89.9to85)
30
31 ## [1] 40
32
33 #ANOVA
34 night_tx_difference <- anova(lm(sao2.Ptst.89.9to85 ~ intervention * night,
35                               data = SSdata))
36
37 night_tx_difference
38
39 ## Analysis of Variance Table
40 ##
41 ## Response: sao2.Ptst.89.9to85
42 ##
43 ##           Df Sum Sq Mean Sq F value Pr(>F)
44 ## intervention      1  0.01225  0.012250   0.2994 0.58764
45 ## night              1  0.00225  0.002250   0.0550 0.81593
46 ## intervention:night  1  0.18225  0.182250   4.4542 0.04183 *
47 ## Residuals        36  1.47300  0.040917
48 ## ---
49 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
50
51 #within-participants (paired) comparison
52 #Paired Wilcoxon
53 wilcox.test(subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.89.9to8
54 5,
55             subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.89.9to8
56 5,
57             paired = TRUE, conf.int = TRUE)
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$sao2.Ptst.89.9to85, : cannot compute exact p-value with ties
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7  ## "sham")$sao2.Ptst.89.9to85, : cannot compute exact confidence interval wit
8  h
9  ## ties
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$sao2.Ptst.89.9to85, : cannot compute exact p-value with zeroes
13
14 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
15 ## "sham")$sao2.Ptst.89.9to85, : cannot compute exact confidence interval wit
16 h
17 ## zeroes
18
19 ##
20 ## Wilcoxon signed rank test with continuity correction
21 ##
22 ## data: subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.89.9to85
23 and subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
24 ## V = 18, p-value = 0.1198
25 ## alternative hypothesis: true location shift is not equal to 0
26 ## 95 percent confidence interval:
27 ## -0.0999194 0.3999194
28 ## sample estimates:
29 ## (pseudo)median
30 ## 0.1000482
31
32
33 #between participants (grouped) comparison
34 summary(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
35
36 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
37 ##      0.00   0.00   0.00   0.06   0.00   0.60
38
39 sd(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
40
41 ## [1] 0.1698296
42
43 length(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
44
45 ## [1] 20
46
47 qqnorm(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
48 qqline(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
## A = 5.7807, p-value = 8.032e-15

#non-normal

summary(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  0.095  0.100  1.000

sd(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

## [1] 0.24165

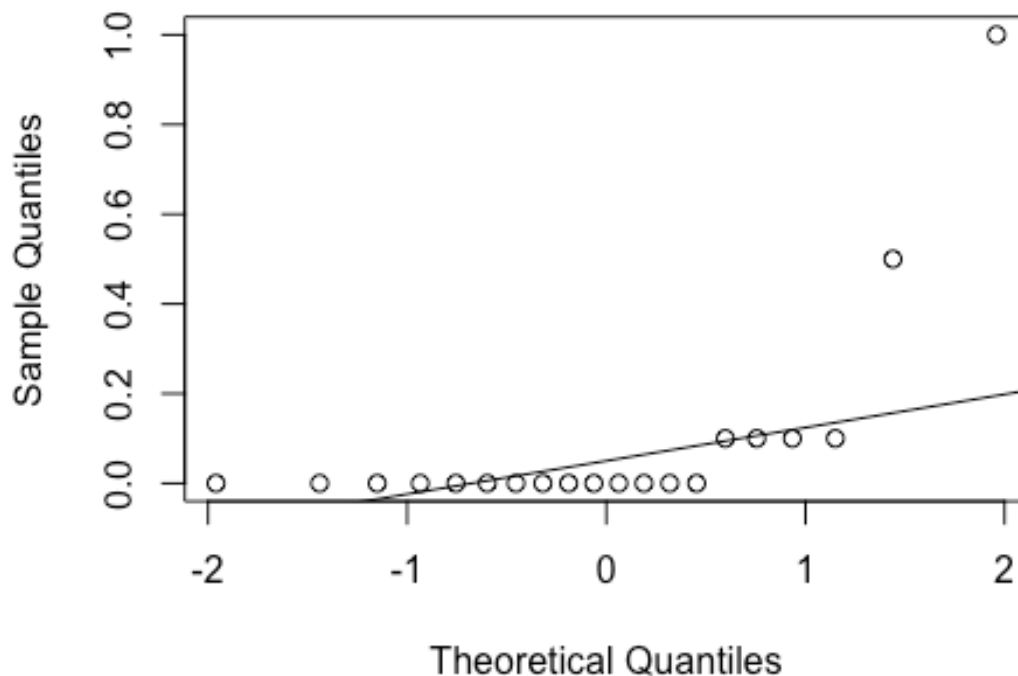
length(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)
qqline(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85
## A = 4.6098, p-value = 6.704e-12

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85,
            subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sao2.Ptst.89.9to85, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $sao2.Ptst.89.9to85, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```

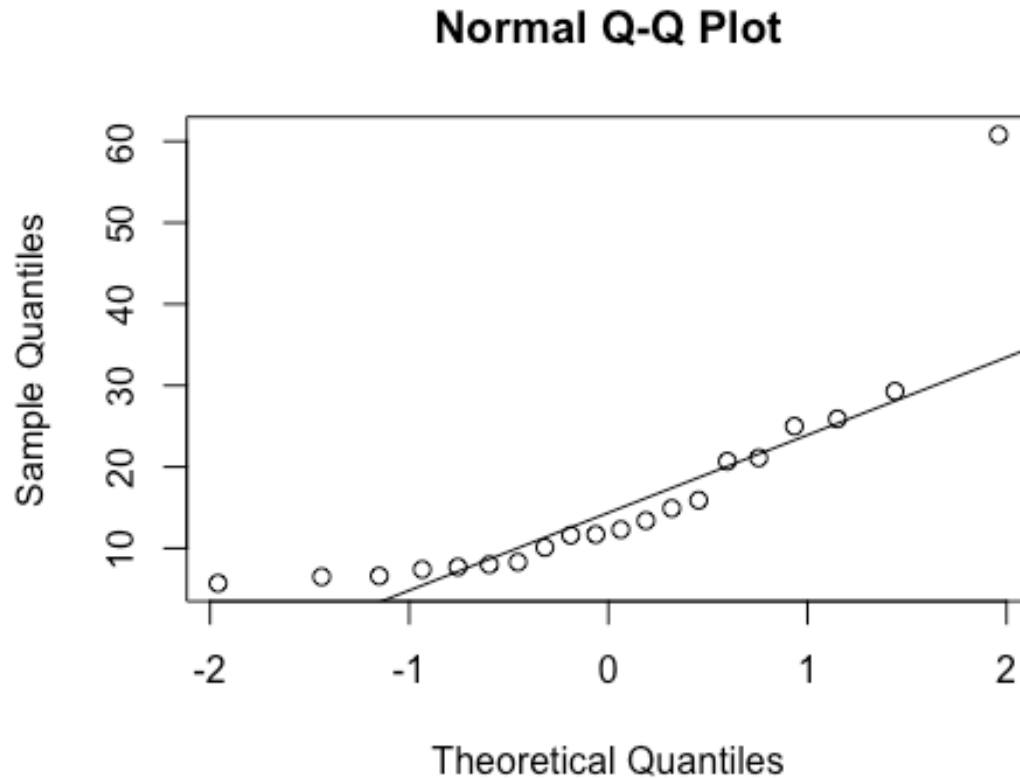


```

1
2
3  ## data: subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85 and subse
4 t(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
5  ## W = 227.5, p-value = 0.317
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -1.534144e-05  1.959457e-05
9  ## sample estimates:
10 ## difference in location
11 ##          3.556854e-06
12
13 ##### Total Arousal Index in NREM #####
14 #FYI: this data was generated in our PSG reports per default configuration bu
15 t is not a
16 #pre-specified secondary outcome per the research protocol or trial registry.
17 FYI only.
18 #Summary
19 summary(SSdata$total.arousals.nrem.index)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      5.20   8.30   12.05   14.89   17.62   60.80
23
24 sd(SSdata$total.arousals.nrem.index, na.rm = TRUE)
25
26 ## [1] 10.14672
27
28 length(SSdata$total.arousals.nrem.index)
29
30 ## [1] 40
31
32 #ANOVA
33 night_tx_difference <- anova(lm(total.arousals.nrem.index ~ intervention * ni
34 ght,
35                               data = SSdata))
36
37 night_tx_difference
38
39 ## Analysis of Variance Table
40 ##
41 ## Response: total.arousals.nrem.index
42 ##
43 ##      Df Sum Sq Mean Sq F value Pr(>F)
44 ## intervention      1   63.3   63.252   0.6102 0.4398
45 ## night              1  190.5  190.532   1.8381 0.1836
46 ## intervention:night  1   29.8   29.756   0.2871 0.5954
47 ## Residuals         36 3731.7  103.660
48
49 #within-participants (paired) comparison
50 #Paired Wilcoxon
51 wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.nr
52 em.index,
53             subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals.nr
54 em.index,
55             paired = TRUE, conf.int = TRUE)
56
57
58
59
60

```

```
1
2
3 ##
4 ## Wilcoxon signed rank test
5 ##
6 ## data: subset(SSdataCompletes, intervention == "sham")$total.arousals.nrem
7 .index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousal
8 s.nrem.index
9 ## V = 100, p-value = 0.8695
10 ## alternative hypothesis: true location shift is not equal to 0
11 ## 95 percent confidence interval:
12 ## -4.70 1.65
13 ## sample estimates:
14 ## (pseudo)median
15 ## -0.2
16
17
18 #between participants (grouped) comparison
19 summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
20 )
21
22 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
23 ##  5.700  7.925  12.000  16.140  20.800  60.800
24
25 sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
26
27 ## [1] 12.68192
28
29 length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
30
31 ## [1] 20
32
33 qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
34 qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
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51
52
53
54
55
56
57
58
59
60
```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
)
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
## A = 1.5656, p-value = 0.0003422
##non-normal

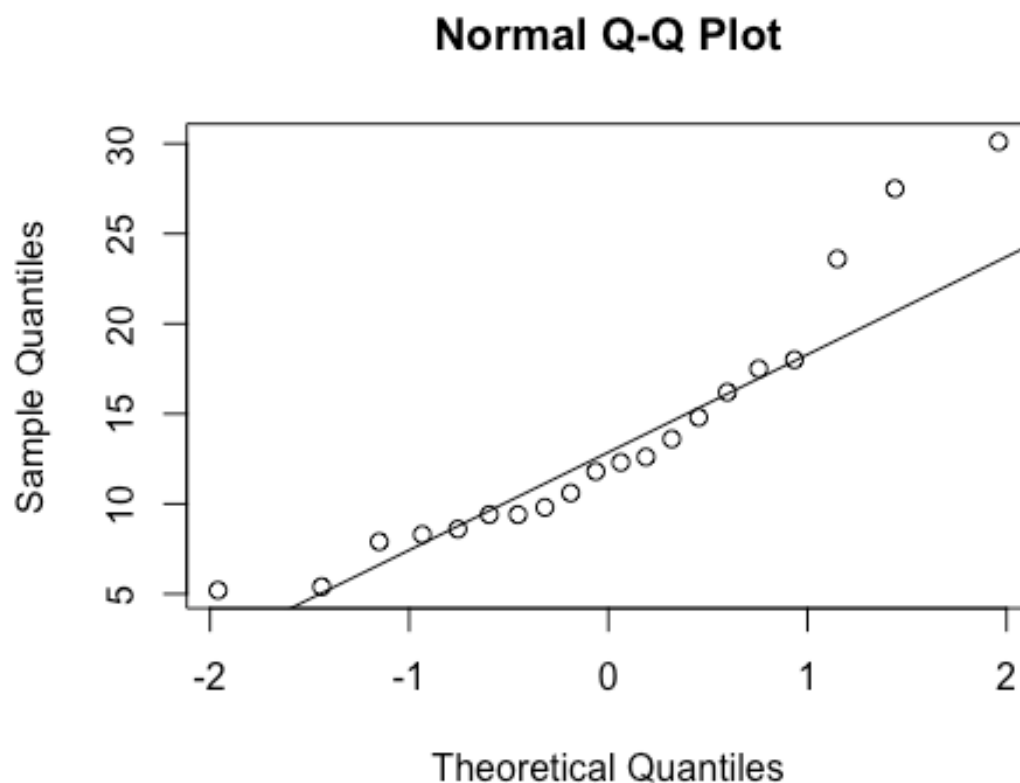
summary(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   5.20   9.20   12.05   13.63   16.52   30.10

sd(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
## [1] 6.868088

length(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
qqline(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$total.arousals.nrem.index
## A = 0.79128, p-value = 0.03318

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$total.arousals.nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.i
            ndex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $total.arousals.nrem.index, : cannot compute exact p-value with ties
```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
4  ## $total.arousals.nrem.index, : cannot compute exact confidence intervals
5  ## with ties
6
7  ##
8  ##  Wilcoxon rank sum test with continuity correction
9  ##
10 ## data:  subset(SSdata, intervention == "sham")$total.arousals.nrem.index an
11 d subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
12 ## W = 198, p-value = 0.9676
13 ## alternative hypothesis: true location shift is not equal to 0
14 ## 95 percent confidence interval:
15 ##  -4.900032  3.200041
16 ## sample estimates:
17 ## difference in location
18 ##                -0.09996643
19
20
21 ##### Total Arousal Index in REM #####
22 #FYI: this data was generated in our PSG reports per default configuration bu
23 t is not a
24 #pre-specified secondary outcome per the research protocol or trial registry.
25 FYI only.
26 #Summary
27 summary(SSdata$total.arousals.rem.index)
28
29 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
30 ##      0.00   4.15   7.30   12.68   10.35   84.00
31
32 sd(SSdata$total.arousals.rem.index, na.rm = TRUE)
33
34 ## [1] 17.59224
35
36 length(SSdata$total.arousals.rem.index)
37
38 ## [1] 40
39
40 #ANOVA
41 night_tx_difference <- anova(lm(total.arousals.rem.index ~ intervention * nig
42 ht,
43                               data = SSdata))
44
45 night_tx_difference
46
47 ## Analysis of Variance Table
48 ##
49 ## Response: total.arousals.rem.index
50 ##
51 ##           Df Sum Sq Mean Sq F value Pr(>F)
52 ## intervention      1    13.1   13.11  0.0447 0.83377
53 ## night              1    10.3   10.30  0.0351 0.85241
54 ## intervention:night  1 1484.7 1484.74  5.0607 0.03068 *
55 ## Residuals        36 10561.8  293.38
56 ## ---
57 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
58
59
60

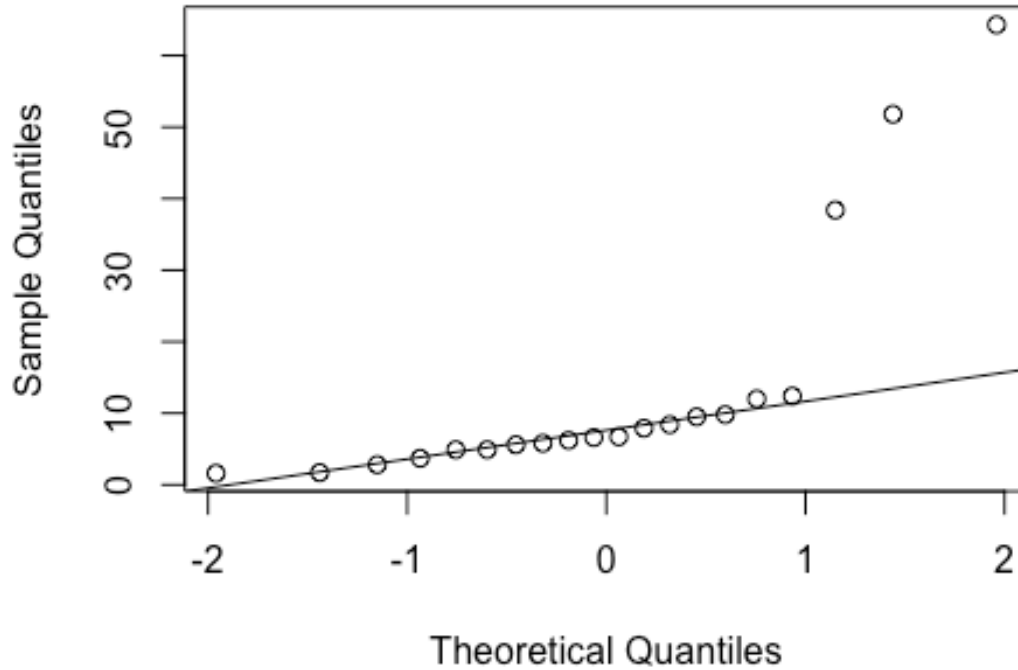
```

```

1
2
3 #within-participants (paired) comparison
4 #Paired t-test
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.re
6 m.index,
7     subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals.re
8 m.index,
9     paired = TRUE, conf.int = TRUE)
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$total.arousals.rem.index, : cannot compute exact p-value with ties
13
14 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention
15 ## == "sham")$total.arousals.rem.index, : cannot compute exact confidence
16 ## interval with ties
17
18 ##
19 ## Wilcoxon signed rank test with continuity correction
20 ##
21 ## data: subset(SSdataCompletes, intervention == "sham")$total.arousals.rem.
22 index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals
23 .rem.index
24 ## V = 91, p-value = 0.6142
25 ## alternative hypothesis: true location shift is not equal to 0
26 ## 95 percent confidence interval:
27 ## -3.350040 2.100039
28 ## sample estimates:
29 ## (pseudo)median
30 ## -0.4334441
31
32 #between participants (grouped) comparison
33
34 summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
35
36 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
37 ##   1.60   4.90   6.65  13.25  10.35   64.30
38
39 sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
40
41 ## [1] 17.26717
42
43 length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
44
45 ## [1] 20
46
47 qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
48 qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index
## A = 3.3345, p-value = 1.085e-08

#non-normal

summary(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  3.975   8.000  12.100  10.220  84.000

sd(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

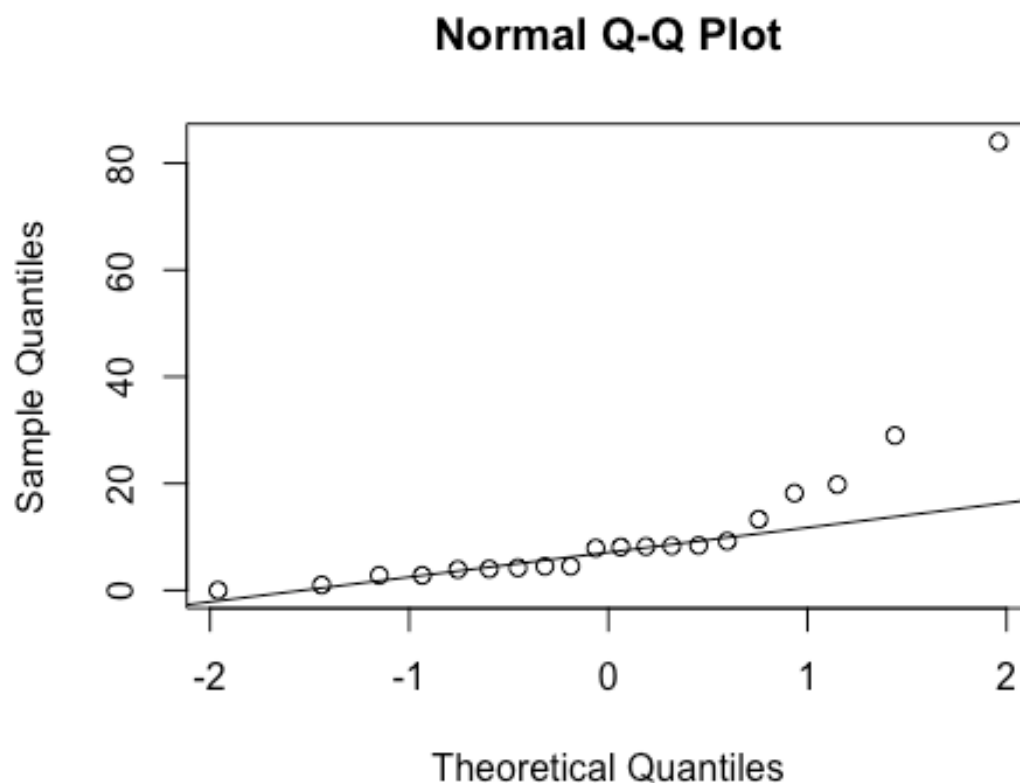
## [1] 18.34168

length(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "sham")$total.arousals.rem.index)
qqline(subset(SSdata, intervention == "sham")$total.arousals.rem.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$total.arousals.rem.index
## A = 3.0671, p-value = 5.152e-08

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$total.arousals.rem.index,
            subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.in
dex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $total.arousals.rem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $total.arousals.rem.index, : cannot compute exact confidence intervals wit
```

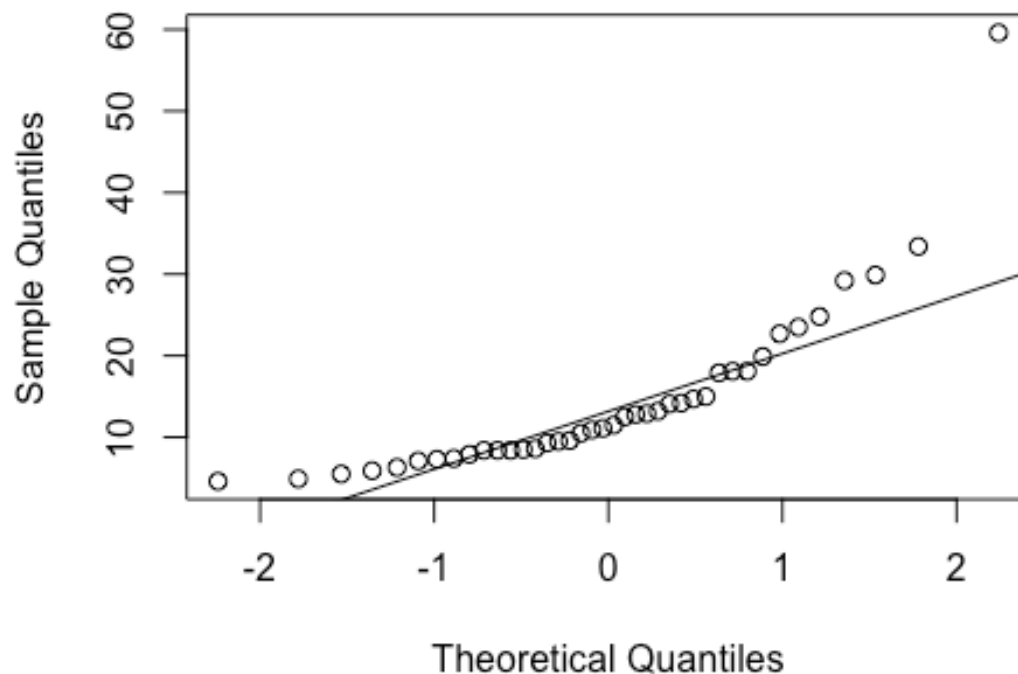


```

1
2
3 h
4 ## ties
5
6 ##
7 ## Wilcoxon rank sum test with continuity correction
8 ##
9 ## data: subset(SSdata, intervention == "sham")$total.arousals.rem.index and
10 subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index
11 ## W = 186, p-value = 0.7149
12 ## alternative hypothesis: true location shift is not equal to 0
13 ## 95 percent confidence interval:
14 ## -3.899974 2.800023
15 ## sample estimates:
16 ## difference in location
17 ## -0.6999841
18
19
20 ##### Total Arousal Index (TST = NREM + REM) #####
21 #####
22 #Summary
23 summary(SSdata$total.arousals.total.index)
24
25 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
26 ##      4.60   8.40   11.30   14.45   17.95   59.60
27
28 sd(SSdata$total.arousals.total.index, na.rm = TRUE)
29
30 ## [1] 10.25068
31
32 length(SSdata$total.arousals.total.index)
33
34 ## [1] 40
35
36 qqnorm(SSdata$total.arousals.total.index)
37 qqline(SSdata$total.arousals.total.index)
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```
ad.test(SSdata$total.arousals.total.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$total.arousals.total.index
## A = 2.5308, p-value = 1.638e-06

#non-normal

#ANOVA
night_tx_difference <- anova(lm(total.arousals.total.index ~ intervention * n
ight,
                               data = SSdata))
night_tx_difference

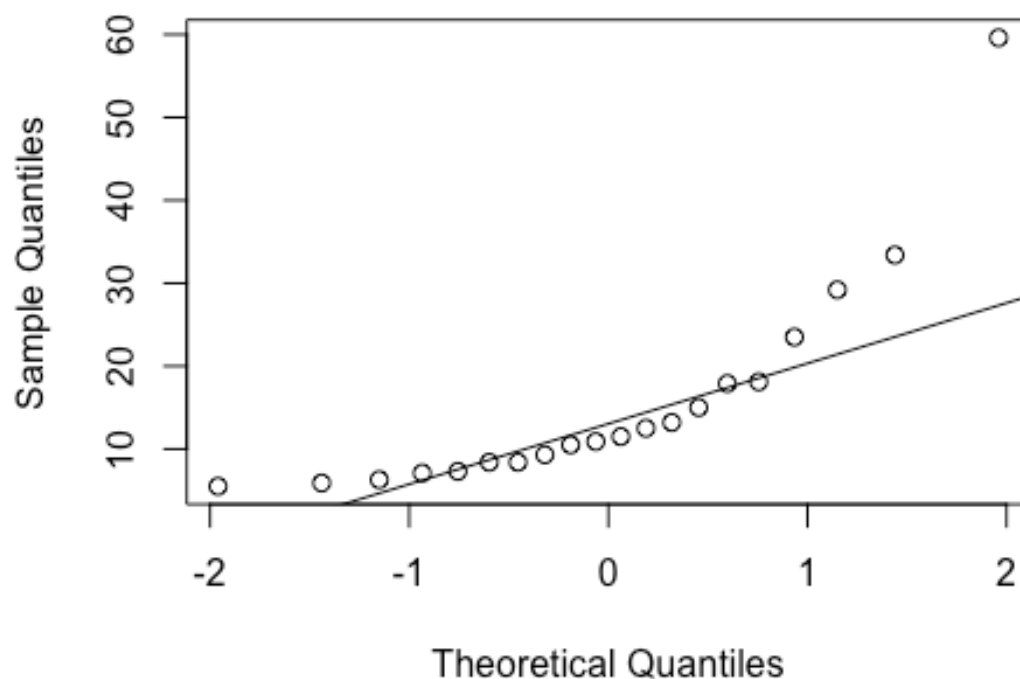
## Analysis of Variance Table
##
## Response: total.arousals.total.index
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    59.8   59.78   0.5720  0.4544
## night           1   158.0  158.01   1.5119  0.2268
## intervention:night 1   118.0  117.99   1.1291  0.2951
## Residuals      36 3762.2  104.51
```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.to
6 tal.index,
7             subset(SSdataCompletes, intervention == "PrenaBelt")$total.
8 arousal.s.total.index,
9             paired = TRUE, conf.int = TRUE)
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$total.arousals.total.index, : cannot compute exact p-value with
13 ## ties
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$total.arousals.total.index, : cannot compute exact confidence
17 ## interval with ties
18
19 ##
20 ## Wilcoxon signed rank test with continuity correction
21 ##
22 ## data: subset(SSdataCompletes, intervention == "sham")$total.arousals.tota
23 l.index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousa
24 ls.total.index
25 ## V = 90, p-value = 0.5883
26 ## alternative hypothesis: true location shift is not equal to 0
27 ## 95 percent confidence interval:
28 ## -3.499935  1.499994
29 ## sample estimates:
30 ## (pseudo)median
31 ## -0.5984439
32
33 #between participants (grouped) comparison
34
35 summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.inde
36 x)
37
38 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
39 ##  5.500  8.125  11.200  15.680  17.950  59.600
40
41 sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index)
42
43 ## [1] 12.89508
44
45 length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
46 )
47
48 ## [1] 20
49
50 qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
51 )
52 qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
53 )
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
## A = 1.7931, p-value = 8.964e-05
##
#non-normal

summary(subset(SSdata, intervention == "sham")$total.arousals.total.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  4.600  8.475 11.950 13.230 15.550 29.900

sd(subset(SSdata, intervention == "sham")$total.arousals.total.index)

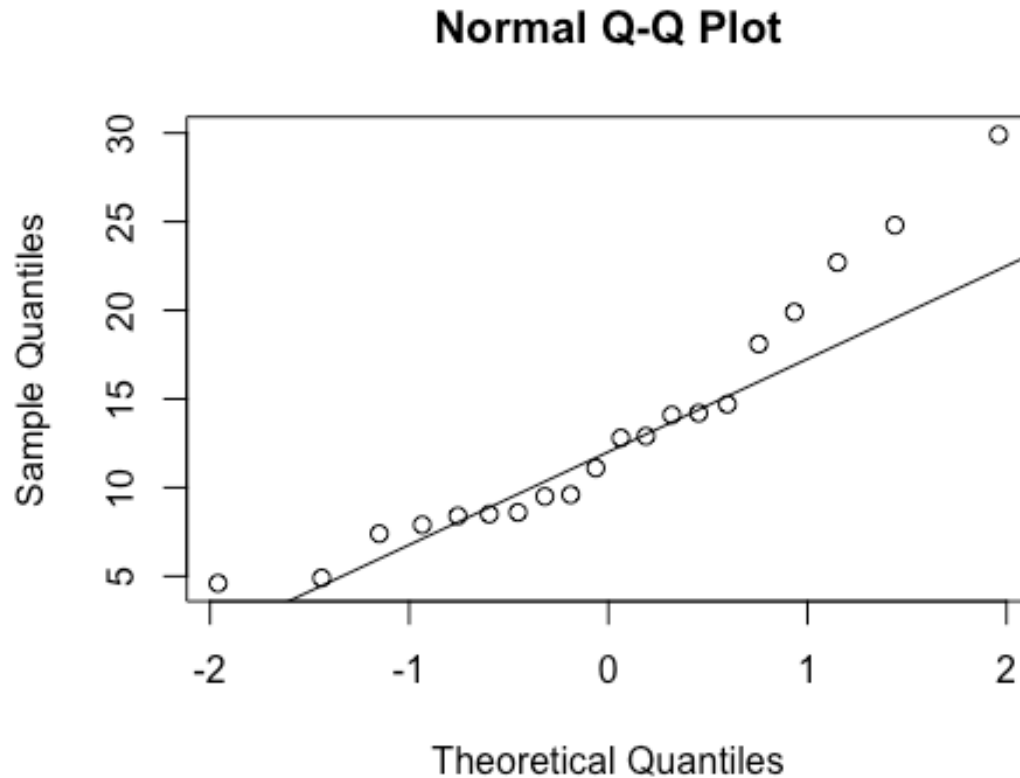
## [1] 6.801014

length(subset(SSdata, intervention == "sham")$total.arousals.total.index)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "sham")$total.arousals.total.index)
qqline(subset(SSdata, intervention == "sham")$total.arousals.total.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$total.arousals.total.index
## A = 0.65641, p-value = 0.07378

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$total.arousals.total.index,
       subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
)

##
## Welch Two Sample t-test
##
## data: subset(SSdata, intervention == "sham")$total.arousals.total.index and
subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
## t = -0.75003, df = 28.811, p-value = 0.4593
```

```

1
2
3  ## alternative hypothesis: true difference in means is not equal to 0
4  ## 95 percent confidence interval:
5  ## -9.11411  4.22411
6  ## sample estimates:
7  ## mean of x mean of y
8  ##    13.230    15.675
9
10 wilcox.test(subset(SSdata, intervention == "sham")$total.arousals.total.index
11 ,
12             subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.
13 index,
14             conf.int = TRUE)
15
16 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
17 ## $total.arousals.total.index, : cannot compute exact p-value with ties
18
19 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
20 ## $total.arousals.total.index, : cannot compute exact confidence intervals
21 ## with ties
22
23 ##
24 ## Wilcoxon rank sum test with continuity correction
25 ##
26 ## data: subset(SSdata, intervention == "sham")$total.arousals.total.index a
27 nd subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
28 ## W = 201.5, p-value = 0.9784
29 ## alternative hypothesis: true location shift is not equal to 0
30 ## 95 percent confidence interval:
31 ## -4.099936  3.599950
32 ## sample estimates:
33 ## difference in location
34 ##                0.04235554
35
36 ##### Spontaneous Arousal Index in NREM #####
37 #
38 #FYI: this data was generated in our PSG reports per default configuration bu
39 t is not a
40 #pre-specified secondary outcome per the research protocol or trial registry.
41 FYI only.
42 #Summary
43 summary(SSdata$spontaneous.arousals.nrem.index)
44
45 ##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
46 ##    0.800  7.475 10.550 11.490 13.180 26.500
47
48 sd(SSdata$spontaneous.arousals.nrem.index, na.rm = TRUE)
49
50 ## [1] 6.188624
51
52 length(SSdata$spontaneous.arousals.nrem.index)
53
54 ## [1] 40
55
56
57
58
59
60

```

```

1
2
3 #ANOVA
4 night_tx_difference <- anova(lm(spontaneous.arousals.nrem.index ~ interventio
5 n * night,
6                               data = SSdata))
7
8 night_tx_difference
9
10 ## Analysis of Variance Table
11 ##
12 ## Response: spontaneous.arousals.nrem.index
13 ##           Df  Sum Sq Mean Sq F value Pr(>F)
14 ## intervention    1    0.03   0.030   0.0007 0.9784
15 ## night           1   26.73  26.732   0.6565 0.4231
16 ## intervention:night 1    1.06   1.056   0.0259 0.8729
17 ## Residuals      36 1465.84  40.718
18
19 #within-participants (paired) comparison
20 #Paired Wilcoxon
21 wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
22 als.nrem.index,
23             subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
24 als.nrem.index,
25             paired = TRUE, conf.int = TRUE)
26
27 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
28 ## "sham")$spontaneous.arousals.nrem.index, : cannot compute exact p-value
29 ## with ties
30
31 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
32 ## "sham")$spontaneous.arousals.nrem.index, : cannot compute exact confidence
33 ## interval with ties
34
35 ##
36 ## Wilcoxon signed rank test with continuity correction
37 ##
38 ## data: subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
39 s.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$spontan
40 eous.arousals.nrem.index
41 ## V = 116.5, p-value = 0.6813
42 ## alternative hypothesis: true location shift is not equal to 0
43 ## 95 percent confidence interval:
44 ## -2.650033  1.900025
45 ## sample estimates:
46 ## (pseudo)median
47 ##      0.3000532
48
49 #between participants (grouped) comparison
50 summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
51 .index)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##      2.000   7.375  10.750  11.520  13.850  25.000
55
56
57
58
59
60

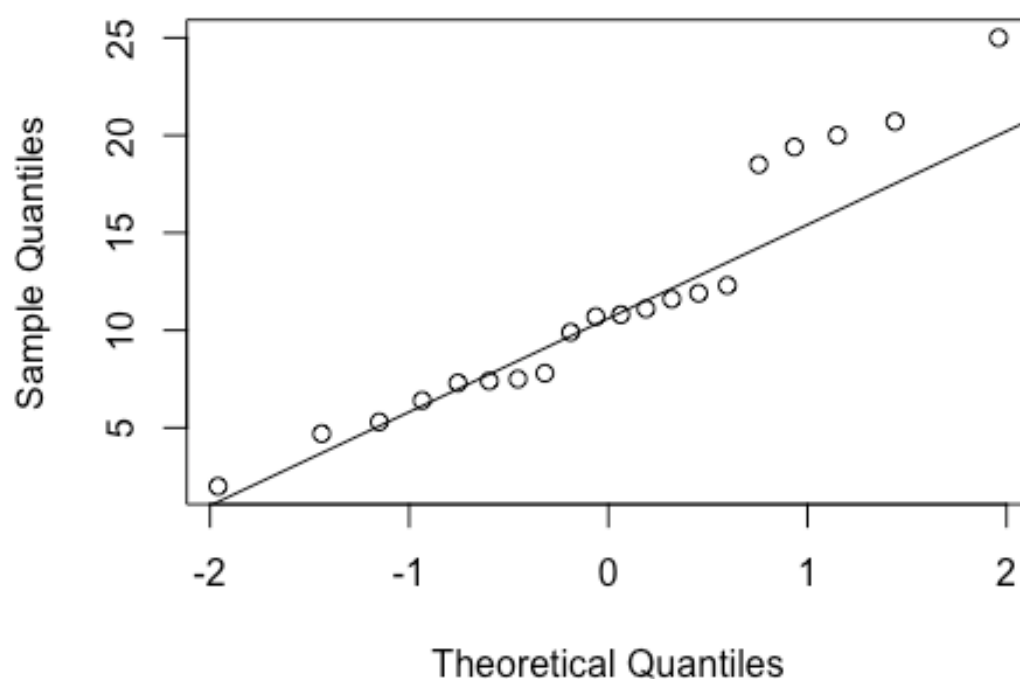
```

```

1
2
3 sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.inde
4 x)
5
6 ## [1] 6.15709
7
8 length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
9 index)
10
11 ## [1] 20
12
13 qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
14 index)
15 qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
16 index)
17

```

Normal Q-Q Plot



```

47 ad.test(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
48 .index)
49
50 ##
51 ## Anderson-Darling normality test
52 ##
53 ## data: subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nr
54 em.index
55 ## A = 0.69502, p-value = 0.05869
56
57
58
59
60

```



```
#normal
```

```
summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.80   7.85   10.15   11.46   13.18   26.50
```

```
sd(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
```

```
## [1] 6.379853
```

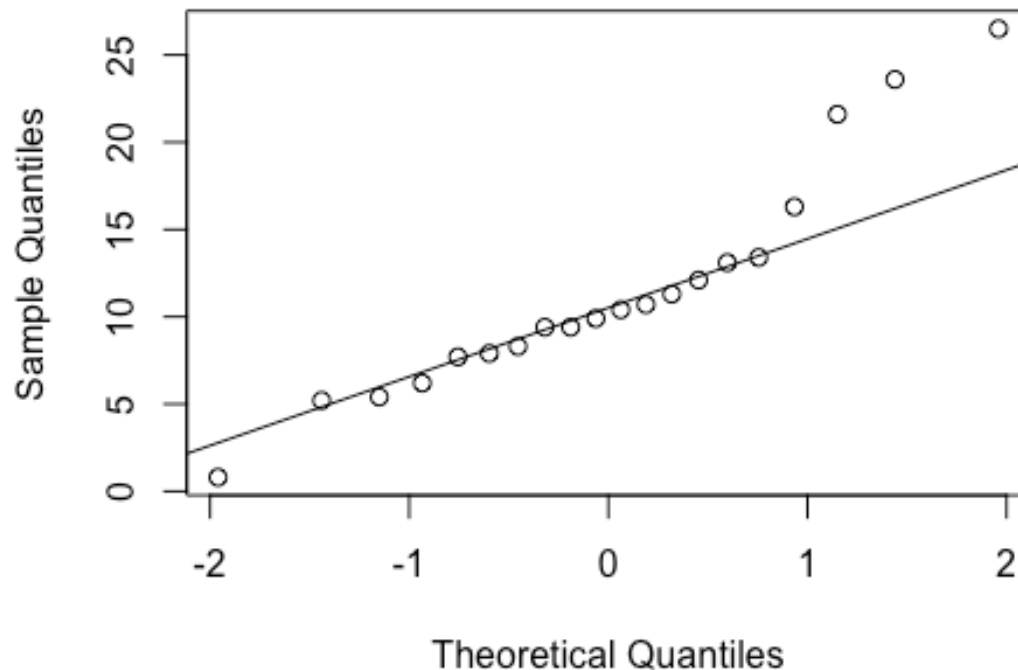
```
length(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
```

```
qqline(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
```

Normal Q-Q Plot



```
ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index)
```

```
1
2
3 ##
4 ## Anderson-Darling normality test
5 ##
6 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
7 dex
8 ## A = 0.77235, p-value = 0.03712
9
10 #non-normal
11
12 #FYI - unpaired test
13 t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index
14 ,
15         subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
16 index)
17
18 ##
19 ## Welch Two Sample t-test
20 ##
21 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
22 dex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
23 .index
24 ## t = -0.027742, df = 37.952, p-value = 0.978
25 ## alternative hypothesis: true difference in means is not equal to 0
26 ## 95 percent confidence interval:
27 ## -4.068685 3.958685
28 ## sample estimates:
29 ## mean of x mean of y
30 ## 11.460 11.515
31
32 wilcox.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.
33 index,
34             subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.
35 nrem.index,
36             conf.int = TRUE)
37
38 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
39 ## $spontaneous.arousals.nrem.index, : cannot compute exact p-value with ties
40
41 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
42 ## $spontaneous.arousals.nrem.index, : cannot compute exact confidence
43 ## intervals with ties
44
45 ##
46 ## Wilcoxon rank sum test with continuity correction
47 ##
48 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
49 dex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
50 .index
51 ## W = 203, p-value = 0.9461
52 ## alternative hypothesis: true location shift is not equal to 0
53 ## 95 percent confidence interval:
```

```

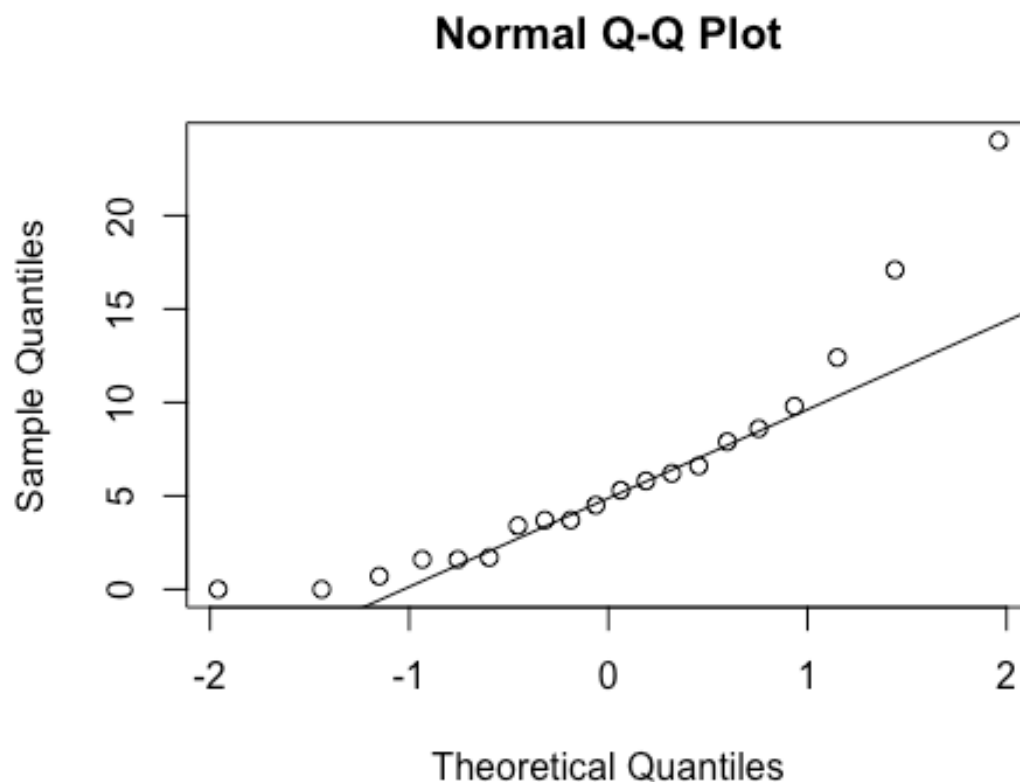
1
2
3      ## -3.399998  3.200034
4      ## sample estimates:
5      ## difference in location
6      ##                0.15
7
8      ##### Spontaneous Arousal Index in REM #####
9      #FYI: this data was generated in our PSG reports per default configuration bu
10     t is not a
11     #pre-specified secondary outcome per the research protocol or trial registry.
12     FYI only.
13     #Summary
14     summary(SSdata$spontaneous.arousals.rem.index)
15
16     ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17     ##      0.000   2.000   4.250   5.612   7.950  24.000
18
19     sd(SSdata$spontaneous.arousals.rem.index, na.rm = TRUE)
20
21     ## [1] 4.976312
22
23     length(SSdata$spontaneous.arousals.rem.index)
24
25     ## [1] 40
26
27     #ANOVA
28     night_tx_difference <- anova(lm(spontaneous.arousals.rem.index ~ intervention
29     * night,
30                                   data = SSdata))
31
32     night_tx_difference
33
34     ## Analysis of Variance Table
35     ##
36     ## Response: spontaneous.arousals.rem.index
37     ##
38     ##           Df Sum Sq Mean Sq F value Pr(>F)
39     ## intervention      1  15.25   15.252   0.6246  0.4345
40     ## night              1  37.44   37.442   1.5334  0.2236
41     ## intervention:night  1  34.04   34.040   1.3941  0.2455
42     ## Residuals        36 879.05   24.418
43
44     #within-participants (paired) comparison
45     #Paired Wilcoxon
46     wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
47     als.rem.index,
48                 subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
49     als.rem.index,
50                 paired = TRUE, conf.int = TRUE)
51
52     ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
53     ## "sham")$spontaneous.arousals.rem.index, : cannot compute exact p-value wit
54     h
55     ## ties

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$spontaneous.arousals.rem.index, : cannot compute exact confidence
5  ## interval with ties
6
7  ##
8  ## Wilcoxon signed rank test with continuity correction
9  ##
10 ## data: subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
11 s.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$spontane
12 ous.arousals.rem.index
13 ## V = 93, p-value = 0.6676
14 ## alternative hypothesis: true location shift is not equal to 0
15 ## 95 percent confidence interval:
16 ## -2.950065  1.549957
17 ## sample estimates:
18 ## (pseudo)median
19 ##      -0.3500398
20
21
22 #between participants (grouped) comparison
23 summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.
24 index)
25
26 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##      0.000  1.675   4.900   6.230   8.075  24.000
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index
30 )
31
32 ## [1] 6.025132
33
34 length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
35 ndex)
36
37 ## [1] 20
38
39 qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
40 ndex)
41 qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
42 ndex)
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.
index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.re
m.index
## A = 0.94606, p-value = 0.01327

#non-normal

summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index
)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  2.400  3.800  4.995  7.800 14.000

sd(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)

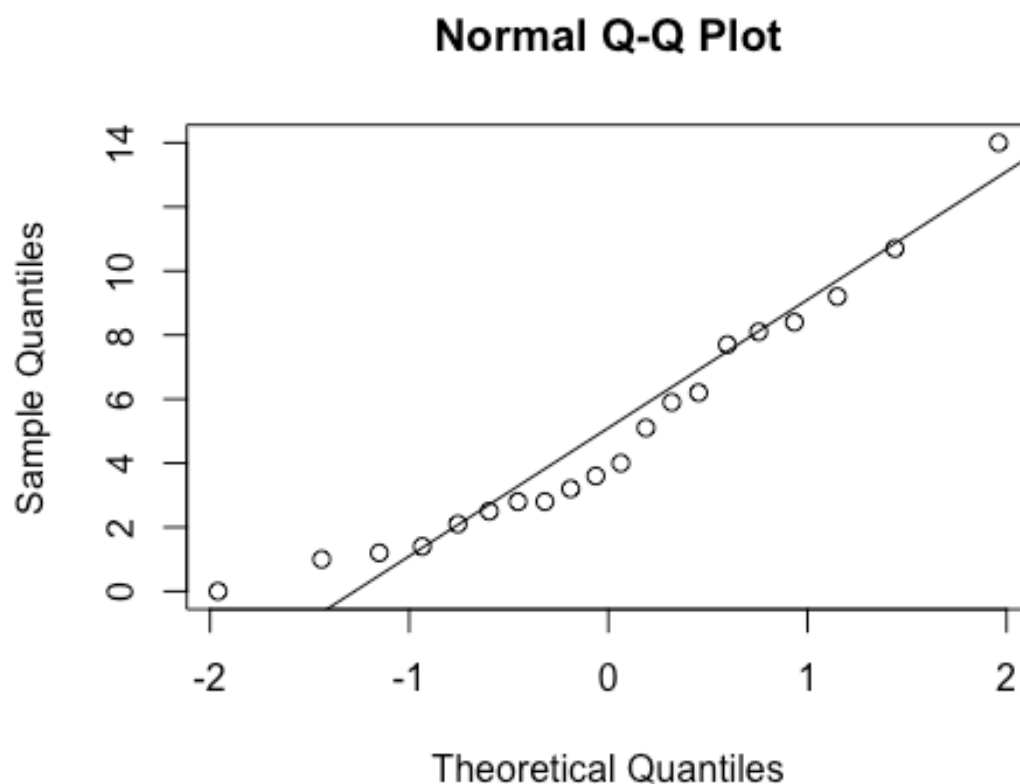
## [1] 3.70483

length(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)

```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)
qqline(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index)
```

```
##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index
## A = 0.47886, p-value = 0.2093
```

```
#normal
```

```
#FYI - unpaired test
```

```
t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index,
        subset(SSdata, intervention == "PrenaBeIt")$spontaneous.arousals.rem.index)
```

```
##
## Welch Two Sample t-test
```

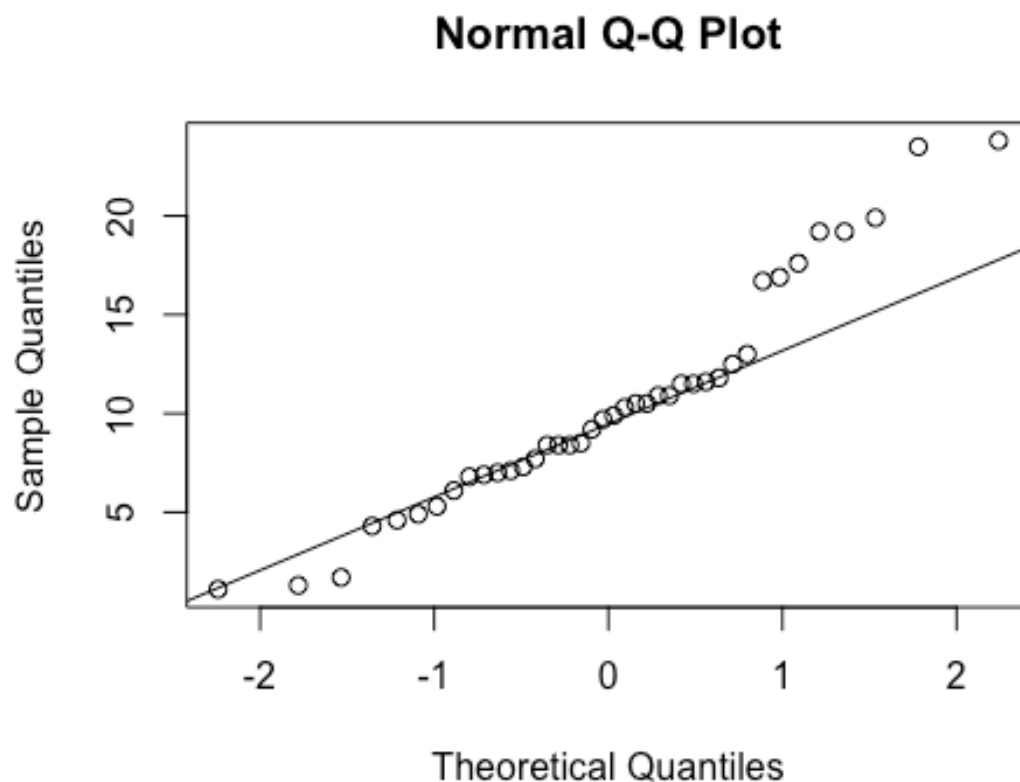
```

1
2
3
4  ##
5  ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index
6  and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index
7
8  ## t = -0.78086, df = 31.571, p-value = 0.4407
9  ## alternative hypothesis: true difference in means is not equal to 0
10 ## 95 percent confidence interval:
11 ## -4.458294  1.988294
12 ## sample estimates:
13 ## mean of x mean of y
14 ##      4.995      6.230
15
16 wilcox.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index,
17             subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.
18             rem.index,
19             conf.int = TRUE)
20
21
22 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
23 ## $spontaneous.arousals.rem.index, : cannot compute exact p-value with ties
24
25 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
26 ## $spontaneous.arousals.rem.index, : cannot compute exact confidence
27 ## intervals with ties
28
29 ##
30 ## Wilcoxon rank sum test with continuity correction
31 ##
32 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index
33 and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index
34
35 ## W = 185.5, p-value = 0.7048
36 ## alternative hypothesis: true location shift is not equal to 0
37 ## 95 percent confidence interval:
38 ## -3.199951  2.099934
39 ## sample estimates:
40 ## difference in location
41 ##      -0.4476729
42
43
44 ##### Spontaneous Arousal Index (TST = NREM + REM) #####
45 #####
46 #Summary
47 summary(SSdata$spontaneous.arousals.total.index)
48
49 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50 ##      1.100   6.975   9.800  10.410  11.980  23.800
51
52 sd(SSdata$spontaneous.arousals.total.index, na.rm = TRUE)
53
54 ## [1] 5.594264
55
56 length(SSdata$spontaneous.arousals.total.index)
57
58
59
60

```

```
## [1] 40
```

```
qqnorm(SSdata$spontaneous.arousals.total.index)
qqline(SSdata$spontaneous.arousals.total.index)
```



```
ad.test(SSdata$spontaneous.arousals.total.index)
```

```
##
## Anderson-Darling normality test
##
## data:  SSdata$spontaneous.arousals.total.index
## A = 0.84189, p-value = 0.02744
```

```
#non-normal
```

```
#ANOVA
```

```
night_tx_difference <- anova(lm(spontaneous.arousals.total.index ~ interventi
on * night,
                                data = SSdata))
night_tx_difference
```

```
## Analysis of Variance Table
```

```
##
## Response: spontaneous.arousals.total.index
```

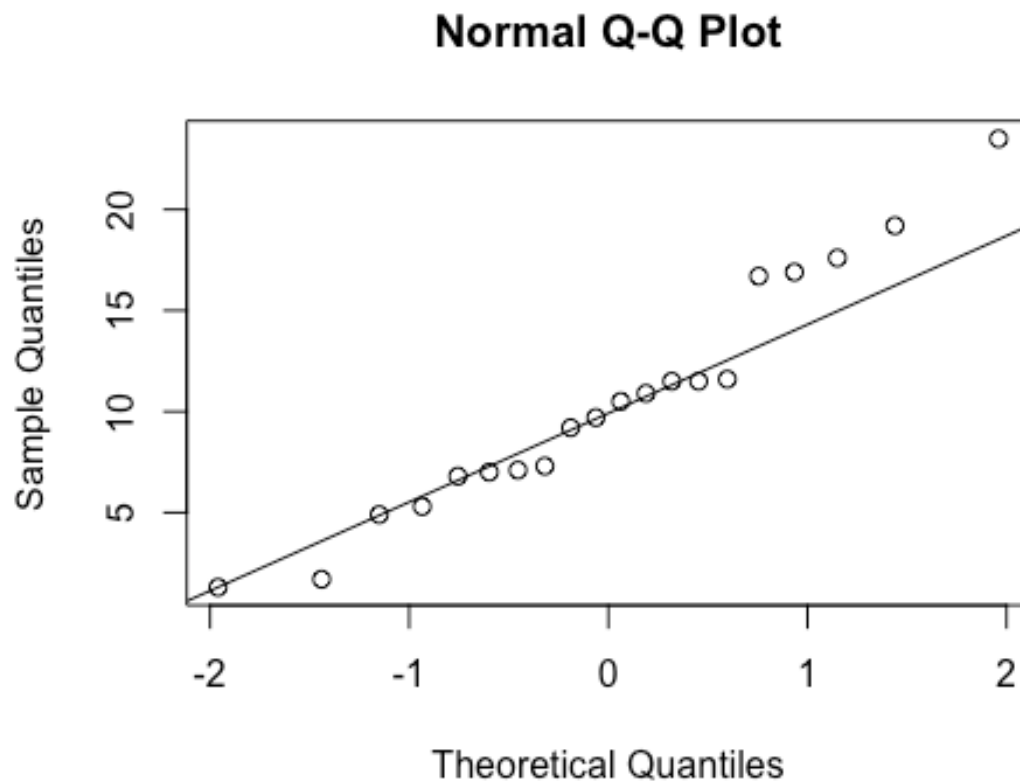


```

1
2
3      ##                Df  Sum Sq Mean Sq F value Pr(>F)
4      ## intervention      1    0.40   0.400  0.0120 0.9132
5      ## night            1   23.72  23.716  0.7138 0.4038
6      ## intervention:night 1    0.26   0.256  0.0077 0.9305
7      ## Residuals       36 1196.16  33.227
8
9      #within-participants (paired) comparison
10     #Paired t-test
11     t.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arousals.t
12     otal.index,
13           subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
14     als.total.index,
15           paired = TRUE)
16
17
18     ##
19     ## Paired t-test
20     ##
21     ## data: subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
22     s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$sponta
23     neous.arousals.total.index
24     ## t = -0.17543, df = 19, p-value = 0.8626
25     ## alternative hypothesis: true difference in means is not equal to 0
26     ## 95 percent confidence interval:
27     ## -2.586125  2.186125
28     ## sample estimates:
29     ## mean of the differences
30     ##                -0.2
31
32     #Double check with Wilcoxon (borderline normal)
33     wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
34     als.total.index,
35                 subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
36     als.total.index,
37                 paired = TRUE, conf.int = TRUE)
38
39     ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
40     ## "sham")$spontaneous.arousals.total.index, : cannot compute exact p-value
41     ## with ties
42
43     ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
44     ## "sham")$spontaneous.arousals.total.index, : cannot compute exact confidenc
45     e
46     ## interval with ties
47
48     ##
49     ## Wilcoxon signed rank test with continuity correction
50     ##
51     ## data: subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
52     s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$sponta
53     neous.arousals.total.index
54     ## V = 114.5, p-value = 0.7368
55
56
57
58
59
60

```

```
1
2
3  ## alternative hypothesis: true location shift is not equal to 0
4  ## 95 percent confidence interval:
5  ## -2.500005  1.850093
6  ## sample estimates:
7  ## (pseudo)median
8  ##          0.25
9
10 #between participants (grouped) comparison
11 summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
12
13
14  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
15  ##      1.30   6.95   10.10   10.51   12.88   23.50
16
17 sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
18
19
20  ## [1] 5.841854
21
22 length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
23
24
25  ## [1] 20
26
27 qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
28
29 qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
30
31
32
33
34
35
36
37
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39
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46
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60
```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index
## A = 0.37989, p-value = 0.3699

#normal

summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      1.10   7.50   9.20  10.31  11.98   23.80

sd(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)

## [1] 5.485474

length(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)

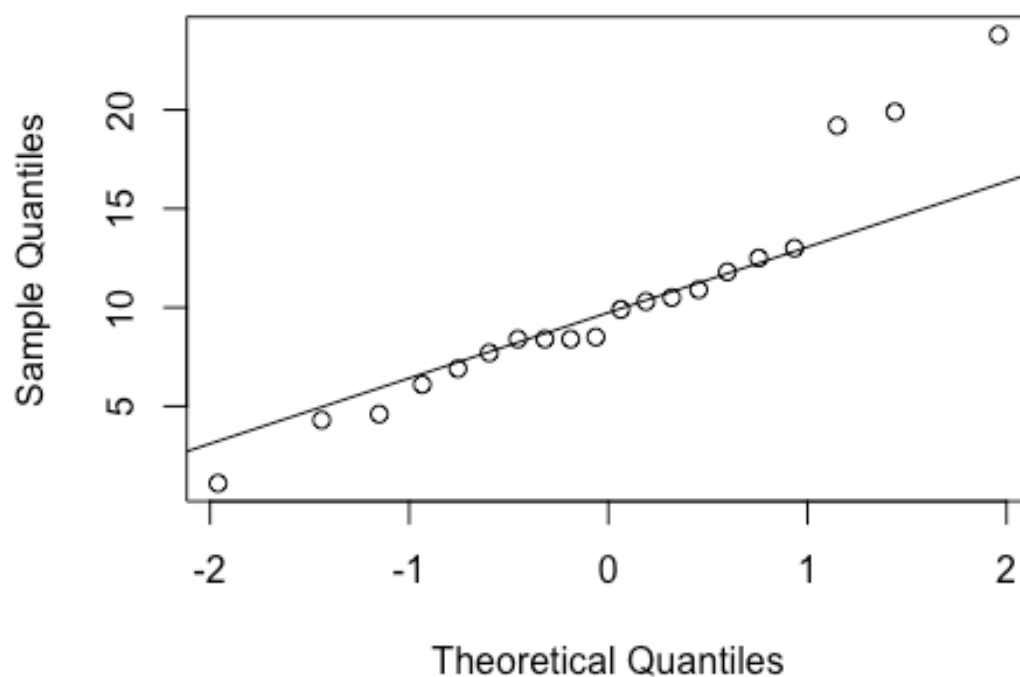
```

```

1
2
3 ## [1] 20
4
5 qqnorm(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)
6
7 qqline(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)
8
9

```

Normal Q-Q Plot



```

39 ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index)
40
41
42 ##
43 ## Anderson-Darling normality test
44 ##
45 ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index
46 ## A = 0.71308, p-value = 0.05273
47
48 #normal
49
50 #FYI - unpaired test
51 t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.index,
52        subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.index)
53
54
55
56
57
58
59
60

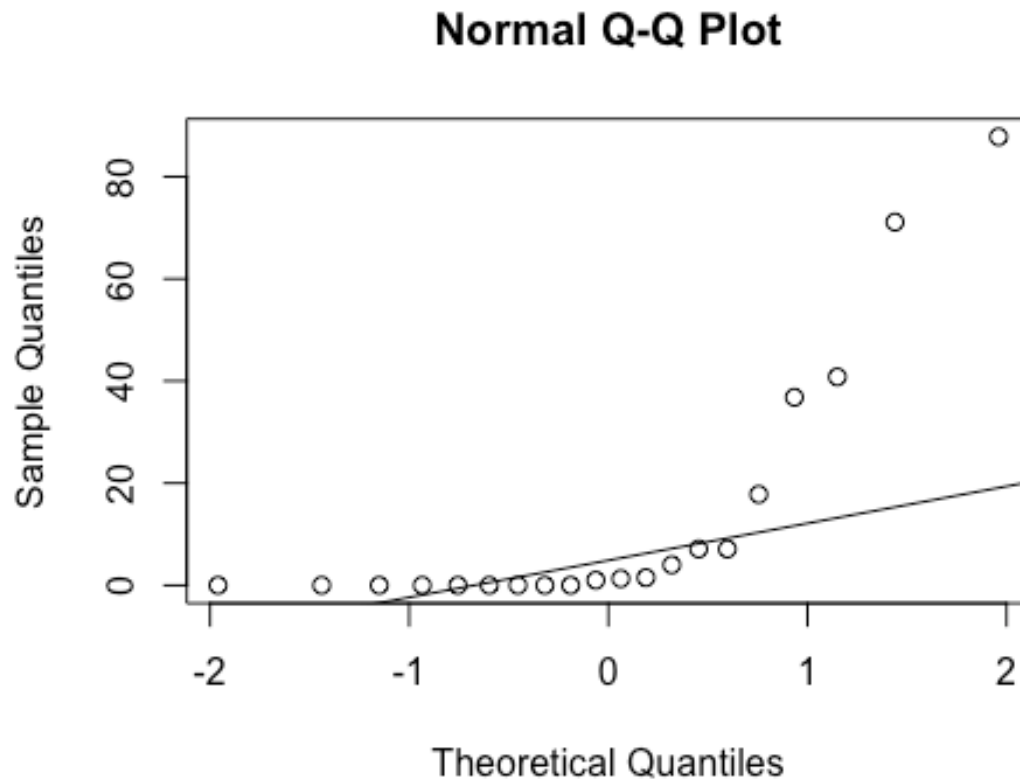
```

```

1
2
3  ##
4  ## Welch Two Sample t-test
5  ##
6  ## data: subset(SSdata, intervention == "sham")$spontaneous.arousals.total.i
7  ndex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.tot
8  al.index
9
10 ## t = -0.11161, df = 37.85, p-value = 0.9117
11 ## alternative hypothesis: true difference in means is not equal to 0
12 ## 95 percent confidence interval:
13 ## -3.827971  3.427971
14 ## sample estimates:
15 ## mean of x mean of y
16 ##      10.31      10.51
17
18 ##### PLMs Index in NREM #####
19 ##FYI: this data was generated in our PSG reports per default configuration bu
20 t is not a
21 ##pre-specified secondary outcome per the research protocol or trial registry.
22 FYI only.
23 ##Summary
24 summary(SSdata$plms.nrem.index)
25
26 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##      0.000   0.000   0.850  13.280   9.775  87.800
28
29 sd(SSdata$plms.nrem.index, na.rm = TRUE)
30
31 ## [1] 24.58884
32
33 length(SSdata$plms.nrem.index)
34
35 ## [1] 40
36
37 ##ANOVA
38 night_tx_difference <- anova(lm(plms.nrem.index ~ intervention * night,
39                               data = SSdata))
40
41 night_tx_difference
42
43 ## Analysis of Variance Table
44 ##
45 ## Response: plms.nrem.index
46 ##           Df Sum Sq Mean Sq F value Pr(>F)
47 ## intervention      1    11.6   11.56  0.0178 0.8945
48 ## night              1   213.9  213.91  0.3303 0.5691
49 ## intervention:night  1    40.6   40.60  0.0627 0.8037
50 ## Residuals        36 23313.8  647.60
51
52 ##within-participants (paired) comparison
53 ##Paired Wilcoxon
54 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.nrem.index,
55             subset(SSdataCompletes, intervention == "PrenaBelt")$plms.nrem.index,
56             paired = TRUE, conf.int = TRUE)

```

```
1
2
3 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4 ## "sham")$plms.nrem.index, : cannot compute exact p-value with zeroes
5
6 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7 ## "sham")$plms.nrem.index, : cannot compute exact confidence interval with
8 ## zeroes
9
10 ##
11 ## Wilcoxon signed rank test with continuity correction
12 ##
13 ## data: subset(SSdataCompletes, intervention == "sham")$plms.nrem.index and
14 subset(SSdataCompletes, intervention == "PrenaBelt")$plms.nrem.index
15 ## V = 29, p-value = 0.4561
16 ## alternative hypothesis: true location shift is not equal to 0
17 ## 95 percent confidence interval:
18 ## -18.84993 13.74994
19 ## sample estimates:
20 ## (pseudo)median
21 ## -0.8327795
22
23 #between participants (grouped) comparison
24 summary(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
25
26 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
27 ##      0.000  0.000   1.150  13.820   9.775  87.800
28
29 sd(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
30
31 ## [1] 25.55123
32
33 length(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
34
35 ## [1] 20
36
37 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
38 qqline(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
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57
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```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index
## A = 3.3293, p-value = 1.119e-08

#non-normal

summary(subset(SSdata, intervention == "sham")$plms.nrem.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   0.35   12.74   8.65   75.10

sd(subset(SSdata, intervention == "sham")$plms.nrem.index)

## [1] 24.23984

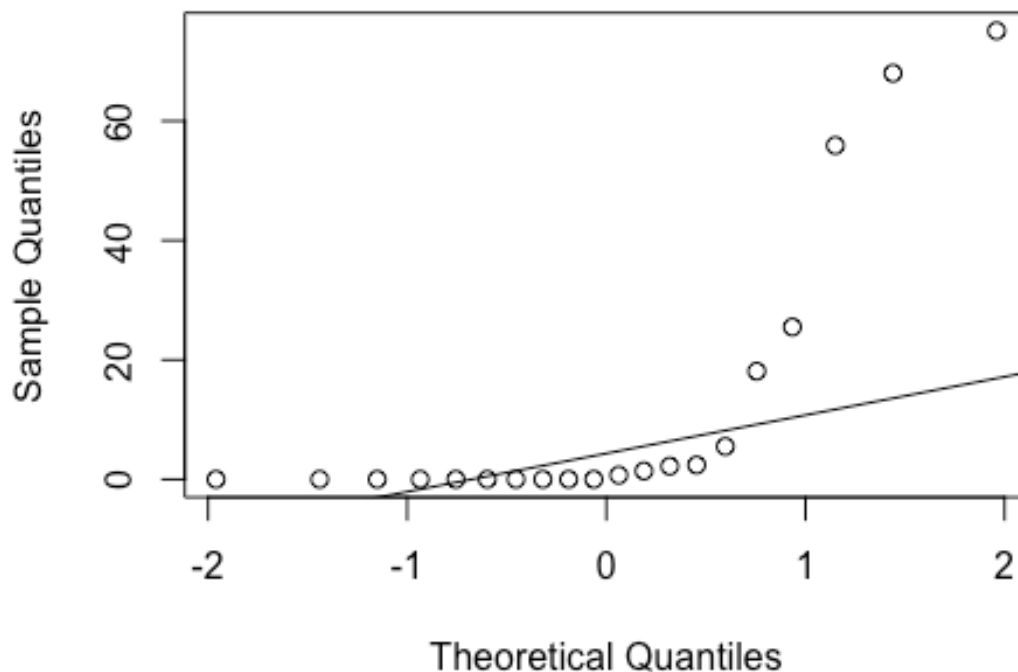
length(subset(SSdata, intervention == "sham")$plms.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plms.nrem.index)
qqline(subset(SSdata, intervention == "sham")$plms.nrem.index)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$plms.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plms.nrem.index
## A = 3.7582, p-value = 9.247e-10

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$plms.nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.nrem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.nrem.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```



```

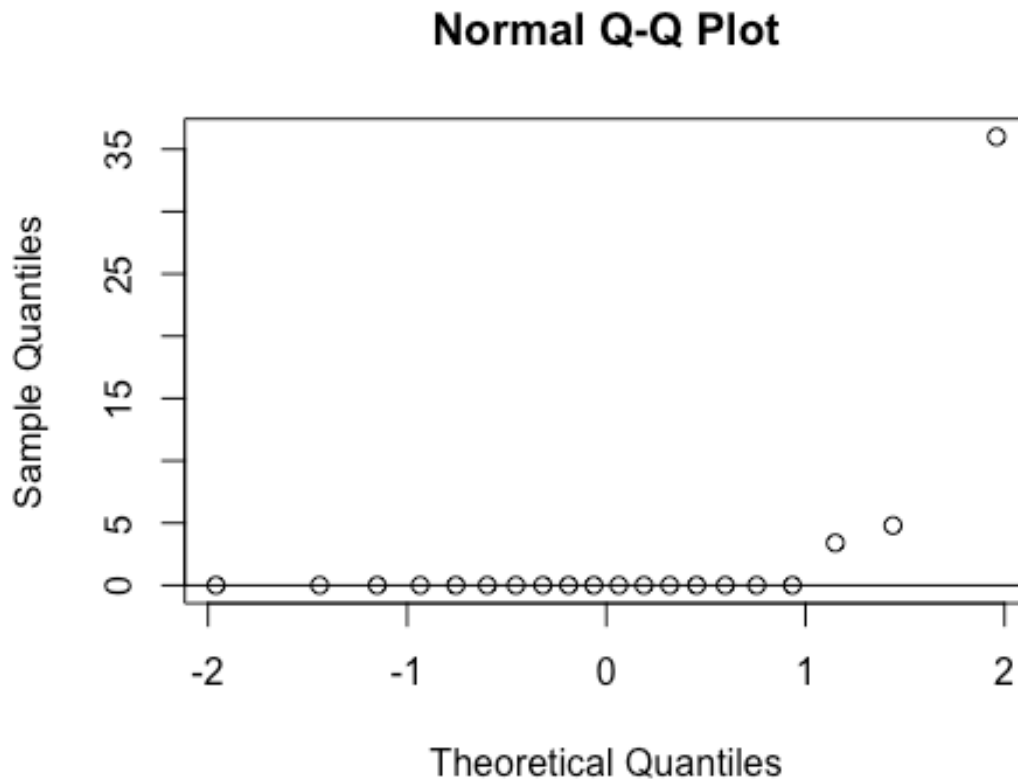
1
2
3  ## data: subset(SSdata, intervention == "sham")$plms.nrem.index and subset(S
4  Sdata, intervention == "PrenaBelt")$plms.nrem.index
5  ## W = 189, p-value = 0.7637
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -1.800001  1.100068
9  ## sample estimates:
10 ## difference in location
11 ## -3.550462e-05
12
13
14 ##### PLMs Index in REM #####
15 #FYI: this data was generated in our PSG reports per default configuration bu
16 t is not a
17 #pre-specified secondary outcome per the research protocol or trial registry.
18 FYI only.
19 #Summary
20 summary(SSdata$plms.rem.index)
21
22 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
23 ##      0.00   0.00   0.00   2.43   0.00   37.80
24
25 sd(SSdata$plms.rem.index, na.rm = TRUE)
26
27 ## [1] 8.281682
28
29 length(SSdata$plms.rem.index)
30
31 ## [1] 40
32
33 #ANOVA
34 night_tx_difference <- anova(lm(plms.rem.index ~ intervention * night,
35                               data = SSdata))
36
37 night_tx_difference
38
39 ## Analysis of Variance Table
40 ##
41 ## Response: plms.rem.index
42 ##
43 ##      Df Sum Sq Mean Sq F value Pr(>F)
44 ## intervention      1    1.94    1.936   0.0268 0.8708
45 ## night              1    0.04    0.036   0.0005 0.9823
46 ## intervention:night  1   73.98   73.984   1.0248 0.3181
47 ## Residuals        36 2598.91   72.192
48
49 #within-participants (paired) comparison
50 #Paired Wilcoxon
51 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.rem.index,
52             subset(SSdataCompletes, intervention == "PrenaBelt")$plms.rem.index,
53             paired = TRUE, conf.int = TRUE)
54
55 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
56 ## "sham")$plms.rem.index, : requested conf.level not achievable
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$plms.rem.index, : cannot compute exact p-value with zeroes
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7  ## "sham")$plms.rem.index, : cannot compute exact confidence interval with
8  ## zeroes
9
10 ##
11 ## Wilcoxon signed rank test with continuity correction
12 ##
13 ## data: subset(SSdataCompletes, intervention == "sham")$plms.rem.index and
14 subset(SSdataCompletes, intervention == "PrenaBelt")$plms.rem.index
15 ## V = 11, p-value = 0.4185
16 ## alternative hypothesis: true location shift is not equal to 0
17 ## 80 percent confidence interval:
18 ## -0.8000532 4.5500270
19 ## sample estimates:
20 ## (pseudo)median
21 ## 1.799949
22
23
24 #between participants (grouped) comparison
25 summary(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
26
27 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28 ##      0.00   0.00   0.00   2.21   0.00   36.00
29
30 sd(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
31
32 ## [1] 8.055459
33
34 length(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
35
36 ## [1] 20
37
38 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
39 qqline(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plms.rem.index
## A = 6.0576, p-value = 1.651e-15

#non-normal

summary(subset(SSdata, intervention == "sham")$plms.rem.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   0.00   2.65   0.00   37.80

sd(subset(SSdata, intervention == "sham")$plms.rem.index)

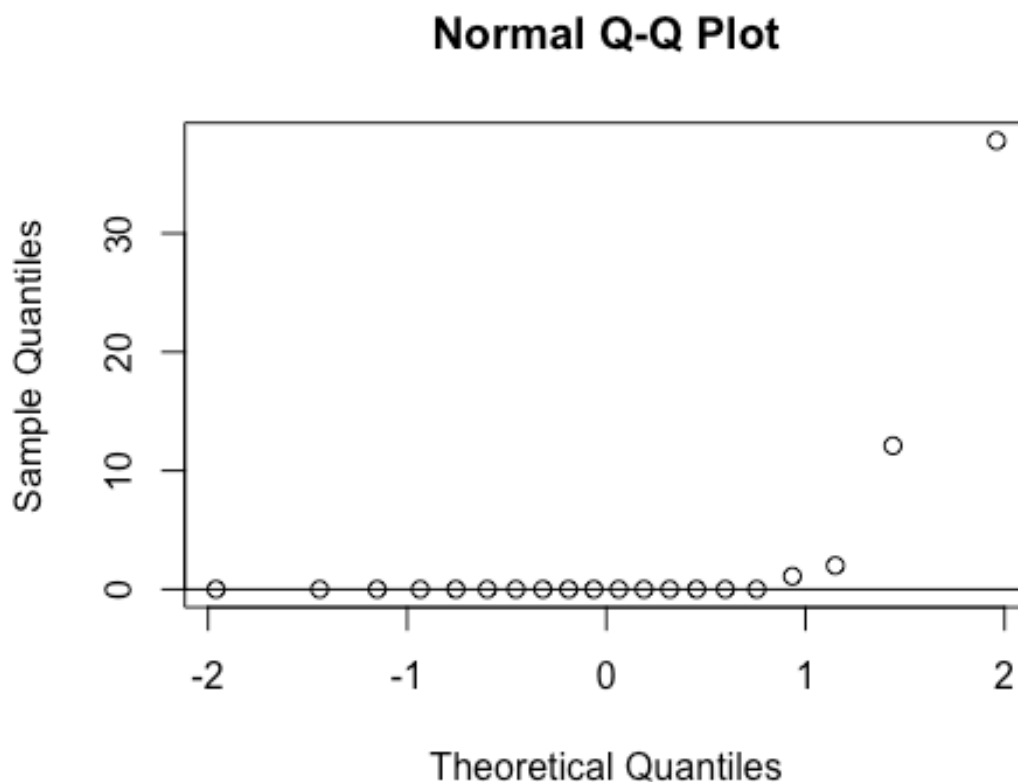
## [1] 8.705745

length(subset(SSdata, intervention == "sham")$plms.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plms.rem.index)
qqline(subset(SSdata, intervention == "sham")$plms.rem.index)

```



```

ad.test(subset(SSdata, intervention == "sham")$plms.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plms.rem.index
## A = 5.7316, p-value = 1.064e-14

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$plms.rem.index,
            subset(SSdata, intervention == "PrenaBelt")$plms.rem.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.rem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.rem.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```

```

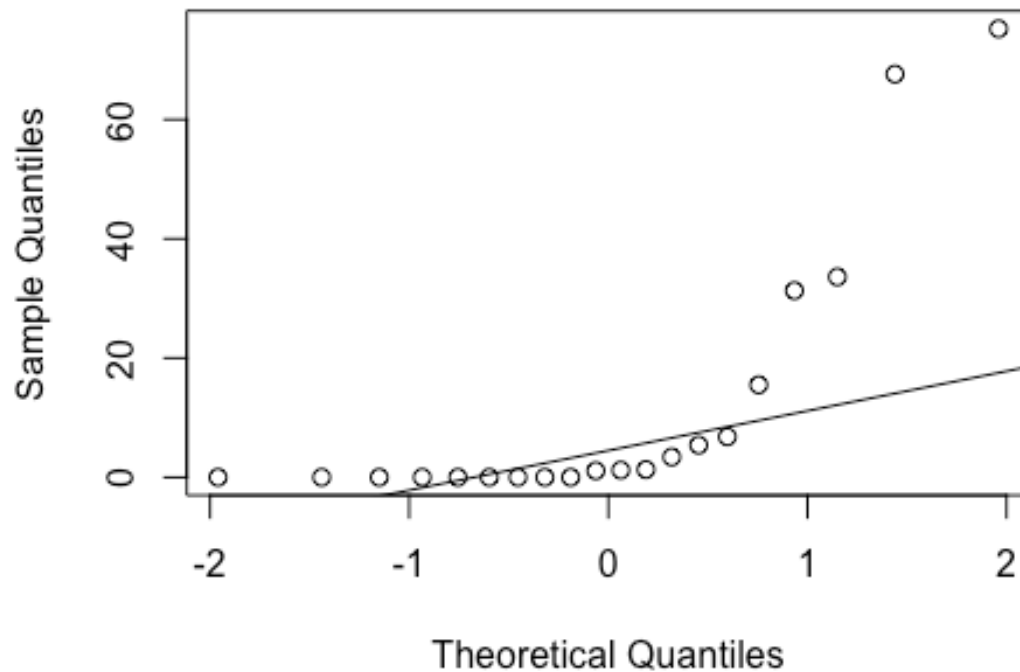
1
2
3  ## data: subset(SSdata, intervention == "sham")$plms.rem.index and subset(SS
4  data, intervention == "PrenaBelt")$plms.rem.index
5  ## W = 209, p-value = 0.7285
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -2.226857e-05  1.825006e-06
9  ## sample estimates:
10 ## difference in location
11 ##          4.496583e-05
12
13 ##### PLMs Total Index (TST = NREM + REM) #####
14 ###
15 #FYI: this data was generated in our PSG reports per default configuration bu
16 t is not a
17 #pre-specified secondary outcome per the research protocol or trial registry.
18 FYI only.
19 #Summary
20 summary(SSdata$plms.total.index)
21
22
23 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
24 ##    0.000   0.000   0.850  11.360   8.775  75.200
25
26 sd(SSdata$plms.total.index, na.rm = TRUE)
27
28 ## [1] 21.15996
29
30 length(SSdata$plms.total.index)
31
32 ## [1] 40
33
34 #ANOVA
35 night_tx_difference <- anova(lm(plms.total.index ~ intervention * night,
36                               data = SSdata))
37
38 night_tx_difference
39
40 ## Analysis of Variance Table
41 ##
42 ## Response: plms.total.index
43 ##
44 ##      Df Sum Sq Mean Sq F value Pr(>F)
45 ## intervention      1    23.3   23.26  0.0487 0.8265
46 ## night              1   219.5  219.49  0.4599 0.5020
47 ## intervention:night  1    37.1   37.06  0.0776 0.7821
48 ## Residuals        36 17182.2  477.28
49
50 #within-participants (paired) comparison
51 #Paired Wilcoxon
52 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.total.index,
53              subset(SSdataCompletes, intervention == "PrenaBelt")$plms.total.index,
54              paired = TRUE, conf.int = TRUE)
55
56 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
57 ## "sham")$plms.total.index, : cannot compute exact p-value with zeroes

```

```
1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$plms.total.index, : cannot compute exact confidence interval with
5  ## zeroes
6
7  ##
8  ## Wilcoxon signed rank test with continuity correction
9  ##
10 ## data: subset(SSdataCompletes, intervention == "sham")$plms.total.index an
11 d subset(SSdataCompletes, intervention == "PrenaBelt")$plms.total.index
12 ## V = 25, p-value = 0.2896
13 ## alternative hypothesis: true location shift is not equal to 0
14 ## 95 percent confidence interval:
15 ## -17.249992  8.399971
16 ## sample estimates:
17 ## (pseudo)median
18 ## -1.298512
19
20
21 #between participants (grouped) comparison
22 summary(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
23
24 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
25 ##  0.000  0.000   1.150  12.120   8.975  75.200
26
27 sd(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
28
29 ## [1] 22.62638
30
31 length(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
32
33 ## [1] 20
34
35 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
36 qqline(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
```

Only

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plms.total.index
## A = 3.4069, p-value = 7.121e-09

#non-normal

summary(subset(SSdata, intervention == "sham")$plms.total.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000   0.300  10.600   7.425  68.000

sd(subset(SSdata, intervention == "sham")$plms.total.index)

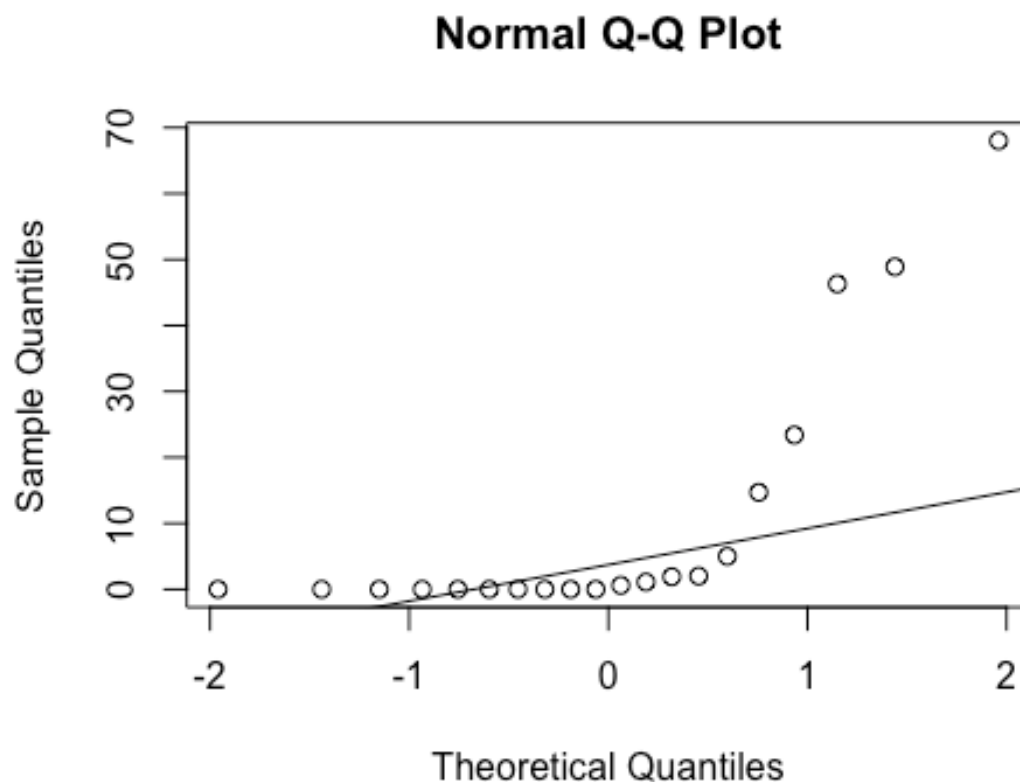
## [1] 20.14637

length(subset(SSdata, intervention == "sham")$plms.total.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plms.total.index)
qqline(subset(SSdata, intervention == "sham")$plms.total.index)

```



```

ad.test(subset(SSdata, intervention == "sham")$plms.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plms.total.index
## A = 3.6327, p-value = 1.917e-09

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$plms.total.index,
            subset(SSdata, intervention == "PrenaBelt")$plms.total.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.total.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plms.total.index, : cannot compute exact confidence intervals with ties

##
## Wilcoxon rank sum test with continuity correction
##

```



```

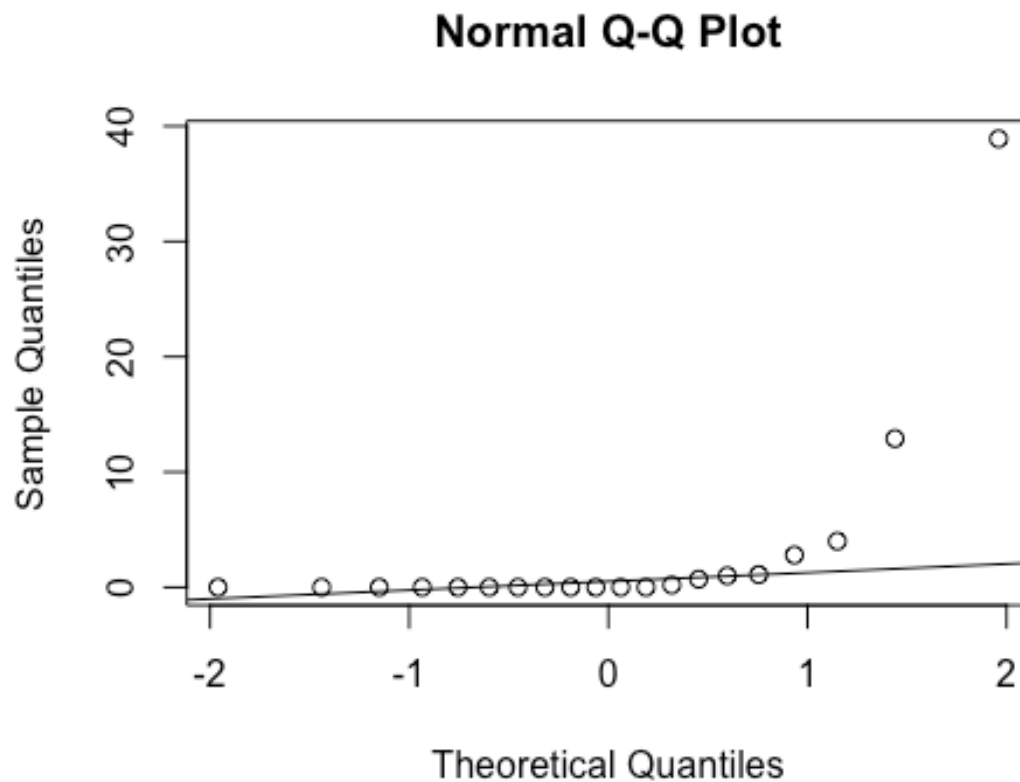
1
2
3  ## data: subset(SSdata, intervention == "sham")$plms.total.index and subset(
4  SSdata, intervention == "PrenaBelt")$plms.total.index
5  ## W = 186.5, p-value = 0.7098
6  ## alternative hypothesis: true location shift is not equal to 0
7  ## 95 percent confidence interval:
8  ## -1.8000395  0.7000302
9  ## sample estimates:
10 ## difference in location
11 ## -4.60136e-05
12
13 ##### PLM Arousals Index in NREM #####
14 ##FYI: this data was generated in our PSG reports per default configuration bu
15 t is not a
16 ##pre-specified secondary outcome per the research protocol or trial registry.
17 FYI only.
18 ##Summary
19 summary(SSdata$plm.arousals.nrem.index)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      0.000   0.000   0.000   2.245   0.850   38.900
23
24 sd(SSdata$plm.arousals.nrem.index, na.rm = TRUE)
25
26 ## [1] 6.766886
27
28 length(SSdata$plm.arousals.nrem.index)
29
30 ## [1] 40
31
32 ##ANOVA
33 night_tx_difference <- anova(lm(plm.arousals.nrem.index ~ intervention * nigh
34 t,
35                               data = SSdata))
36
37 night_tx_difference
38
39 ## Analysis of Variance Table
40 ##
41 ## Response: plm.arousals.nrem.index
42 ##
43 ##      Df  Sum Sq Mean Sq F value Pr(>F)
44 ## intervention    1   27.89   27.889   0.5852 0.4493
45 ## night            1   40.80   40.804   0.8563 0.3610
46 ## intervention:night  1    1.60    1.600   0.0336 0.8556
47 ## Residuals      36 1715.55   47.654
48
49 ##within-participants (paired) comparison
50 ##Paired Wilcoxon
51 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.nrem
52 .index,
53             subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nrem
54 .index,
55             paired = TRUE, conf.int = TRUE)
56
57
58
59
60

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
4  ## "sham")$plm.arousals.nrem.index, : cannot compute exact p-value with ties
5
6  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7  ## "sham")$plm.arousals.nrem.index, : cannot compute exact confidence interval
8  l
9  ## with ties
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$plm.arousals.nrem.index, : cannot compute exact p-value with zeroes
13 s
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$plm.arousals.nrem.index, : cannot compute exact confidence interval
17 l
18 ## with zeroes
19
20 ##
21 ## Wilcoxon signed rank test with continuity correction
22 ##
23 ## data: subset(SSdataCompletes, intervention == "sham")$plm.arousals.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nrem.index
24 ndex and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nrem.index
25 em.index
26 ## V = 24.5, p-value = 0.4767
27 ## alternative hypothesis: true location shift is not equal to 0
28 ## 95 percent confidence interval:
29 ## -15.000023  1.300048
30 ## sample estimates:
31 ## (pseudo)median
32 ## -0.2999436
33
34
35 #between participants (grouped) comparison
36 summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
37
38 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
39 ##      0.000  0.000  0.000  3.080  1.025  38.900
40
41 sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
42
43 ## [1] 8.933886
44
45 length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
46
47 ## [1] 20
48
49 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
50 qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index
## A = 5.0288, p-value = 5.999e-13

#non-normal

summary(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  1.410  0.725  15.400

sd(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

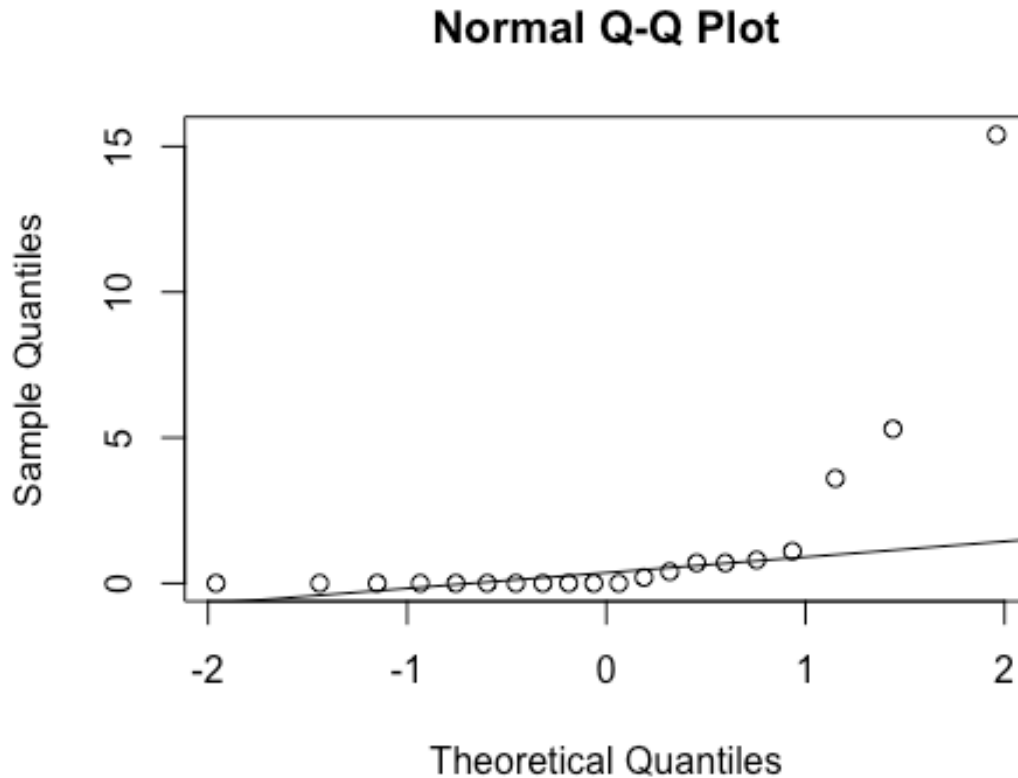
## [1] 3.56502

length(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)
qqline(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

```



```

ad.test(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plm.arousals.nrem.index
## A = 4.353, p-value = 2.952e-11

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index,
            subset(SSdata, intervention == "PrenaBeIt")$plm.arousals.nrem.in
ex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.nrem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.nrem.index, : cannot compute exact confidence intervals with
## ties

```

```

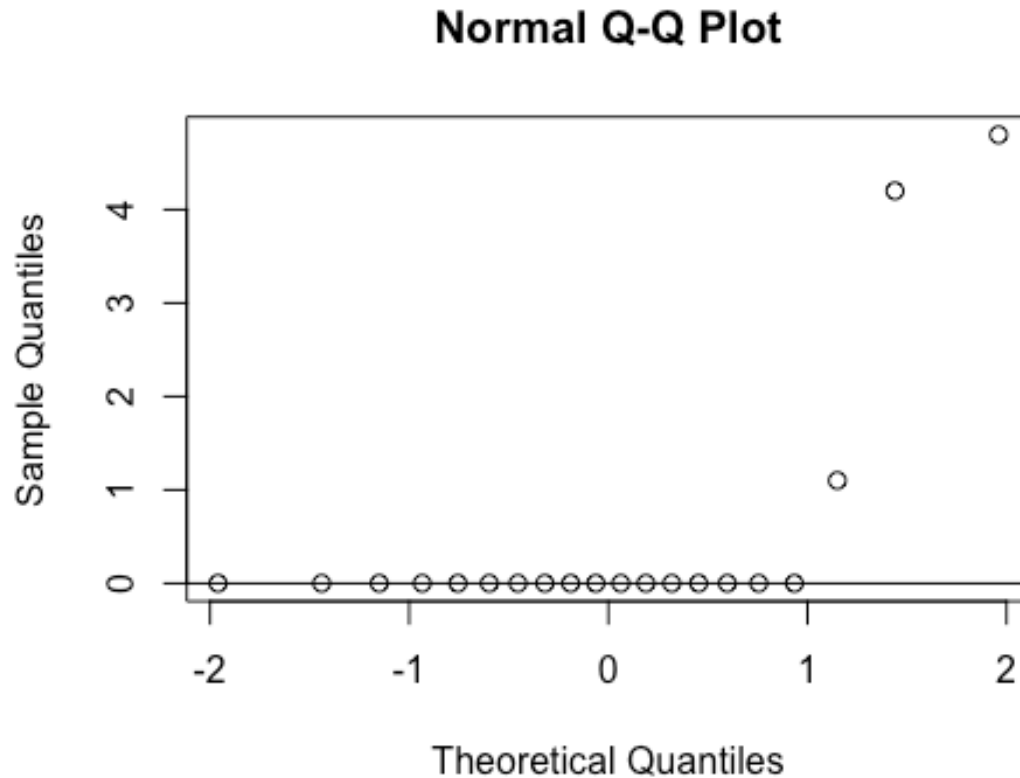
1
2
3  ##
4  ## Wilcoxon rank sum test with continuity correction
5  ##
6  ## data: subset(SSdata, intervention == "sham")$plm.arousals.nrem.index and
7  subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index
8  ## W = 202, p-value = 0.964
9  ## alternative hypothesis: true location shift is not equal to 0
10 ## 95 percent confidence interval:
11 ## -0.1999861  0.1999049
12 ## sample estimates:
13 ## difference in location
14 ##          4.324873e-05
15
16
17 ##### PLM Arousals Index in REM #####
18 #FYI: this data was generated in our PSG reports per default configuration bu
19 t is not a
20 #pre-specified secondary outcome per the research protocol or trial registry.
21 FYI only.
22 #Summary
23 summary(SSdata$plm.arousals.rem.index)
24
25 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
26 ##      0.00   0.00   0.00   0.44   0.00   5.90
27
28 sd(SSdata$plm.arousals.rem.index, na.rm = TRUE)
29
30 ## [1] 1.342749
31
32 length(SSdata$plm.arousals.rem.index)
33
34 ## [1] 40
35
36 #ANOVA
37 night_tx_difference <- anova(lm(plm.arousals.rem.index ~ intervention * night
38 ,
39                               data = SSdata))
40 night_tx_difference
41
42 ## Analysis of Variance Table
43 ##
44 ## Response: plm.arousals.rem.index
45 ##
46 ##           Df Sum Sq Mean Sq F value Pr(>F)
47 ## intervention      1  0.169  0.1690  0.0894 0.7666
48 ## night              1  1.600  1.6000  0.8468 0.3636
49 ## intervention:night  1  0.529  0.5290  0.2800 0.6000
50 ## Residuals        36 68.018  1.8894
51
52 #within-participants (paired) comparison
53 #Paired Wilcoxon
54 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.rem.
55 index,
56            subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.rem.

```

```

1
2
3 index,
4     paired = TRUE, conf.int = TRUE)
5
6 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
7 ## "sham")$plm.arousals.rem.index, : requested conf.level not achievable
8
9 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
10 ## "sham")$plm.arousals.rem.index, : cannot compute exact p-value with zeroes
11
12 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
13 ## "sham")$plm.arousals.rem.index, : cannot compute exact confidence interval
14 ## with zeroes
15
16 ##
17 ## Wilcoxon signed rank test with continuity correction
18 ##
19 ## data: subset(SSdataCompletes, intervention == "sham")$plm.arousals.rem.in
20 dex and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.rem
21 .index
22 ## V = 7, p-value = 1
23 ## alternative hypothesis: true location shift is not equal to 0
24 ## 80 percent confidence interval:
25 ## -2.10052 1.150009
26 ## sample estimates:
27 ## (pseudo)median
28 ## -0.05003072
29
30
31 #between participants (grouped) comparison
32 summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
33
34 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
35 ##  0.000  0.000  0.000  0.505  0.000  4.800
36
37 sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
38
39 ## [1] 1.391506
40
41 length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
42
43 ## [1] 20
44
45 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
46 qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index
## A = 5.6741, p-value = 1.478e-14

#non-normal

summary(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.000  0.375  0.000  5.900

sd(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

## [1] 1.325012

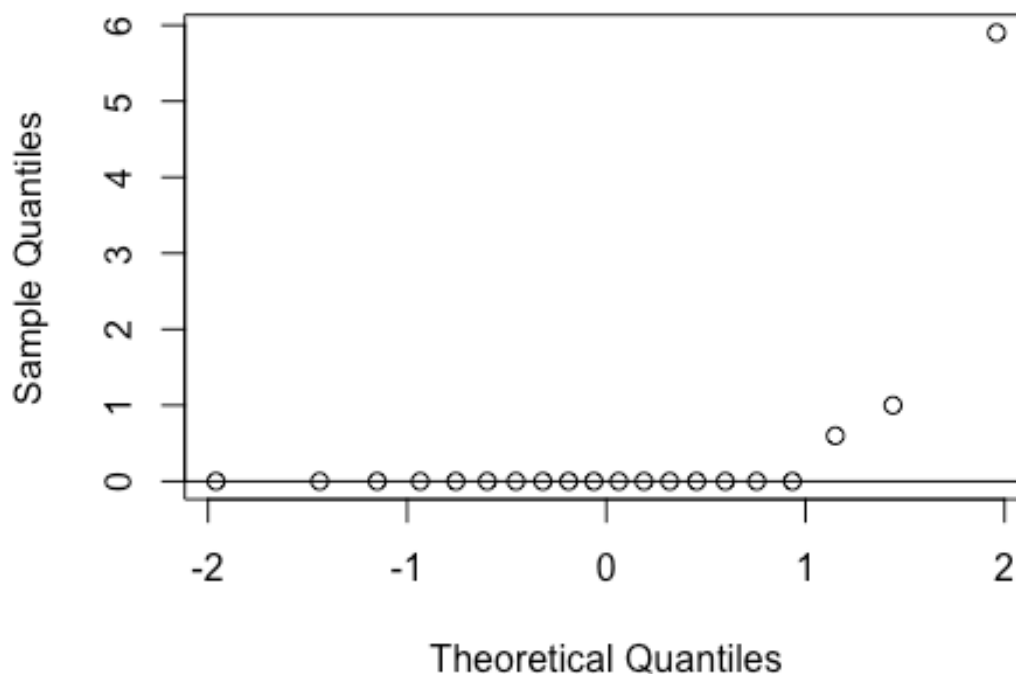
length(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)
qqline(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plm.arousals.rem.index
## A = 5.9139, p-value = 3.75e-15

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$plm.arousals.rem.index,
            subset(SSdata, intervention == "PrenaBeIt")$plm.arousals.rem.inde
x,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.rem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.rem.index, : cannot compute exact confidence intervals with
## ties

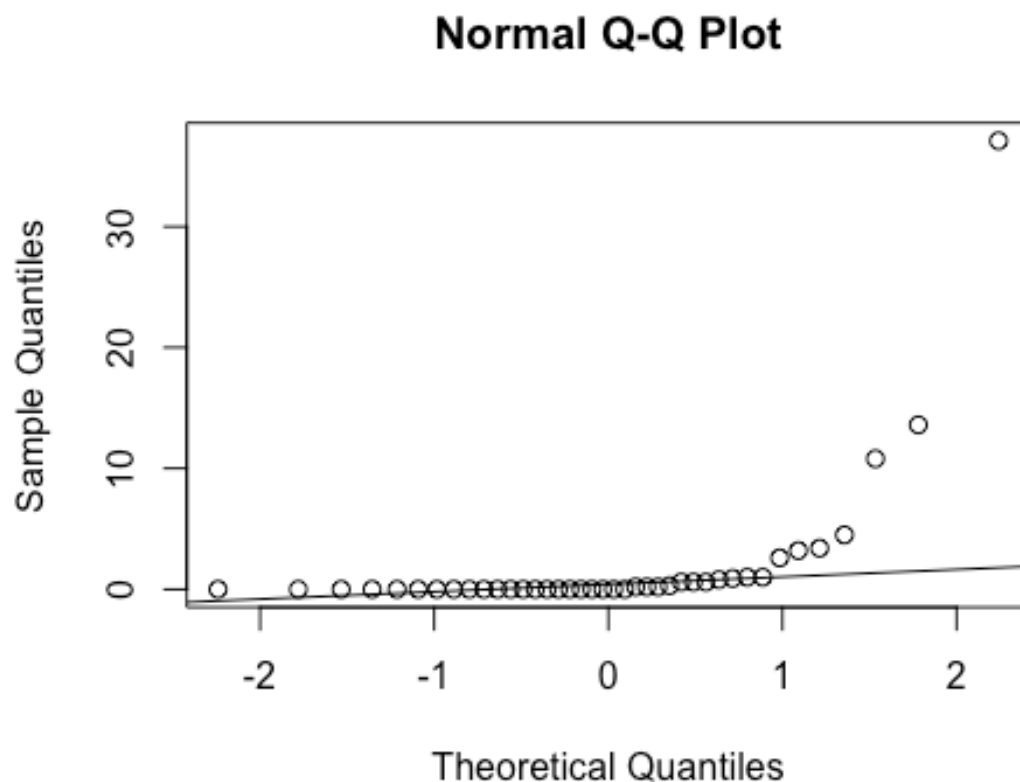
```



```

1
2
3
4  ##
5  ## Wilcoxon rank sum test with continuity correction
6  ##
7  ## data: subset(SSdata, intervention == "sham")$plm.arousals.rem.index and s
8  ubset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index
9  ## W = 198.5, p-value = 0.9653
10 ## alternative hypothesis: true location shift is not equal to 0
11 ## 95 percent confidence interval:
12 ## -1.538669e-05 6.131588e-05
13 ## sample estimates:
14 ## difference in location
15 ## -3.635924e-05
16
17 ##### PLM Arousals Total Index (TST = NREM + REM) #####
18 #####
19 #Summary
20 summary(SSdata$plm.arousals.total.index)
21
22 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
23 ## 0.000 0.000 0.000 2.040 0.825 37.100
24
25 sd(SSdata$plm.arousals.total.index, na.rm = TRUE)
26
27 ## [1] 6.334877
28
29 length(SSdata$plm.arousals.total.index)
30
31 ## [1] 40
32
33 qqnorm(SSdata$plm.arousals.total.index)
34 qqline(SSdata$plm.arousals.total.index)
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(SSdata$plm.arousals.total.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$plm.arousals.total.index
## A = 9.7136, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(plm.arousals.total.index ~ intervention * nig
ht,
                             data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: plm.arousals.total.index
##
##           Df Sum Sq Mean Sq F value Pr(>F)
## intervention    1    25.28   25.281    0.6075  0.4408
## night           1    38.81   38.809    0.9326  0.3406
## intervention:night 1     2.92    2.916    0.0701  0.7927
## Residuals      36 1498.09   41.614

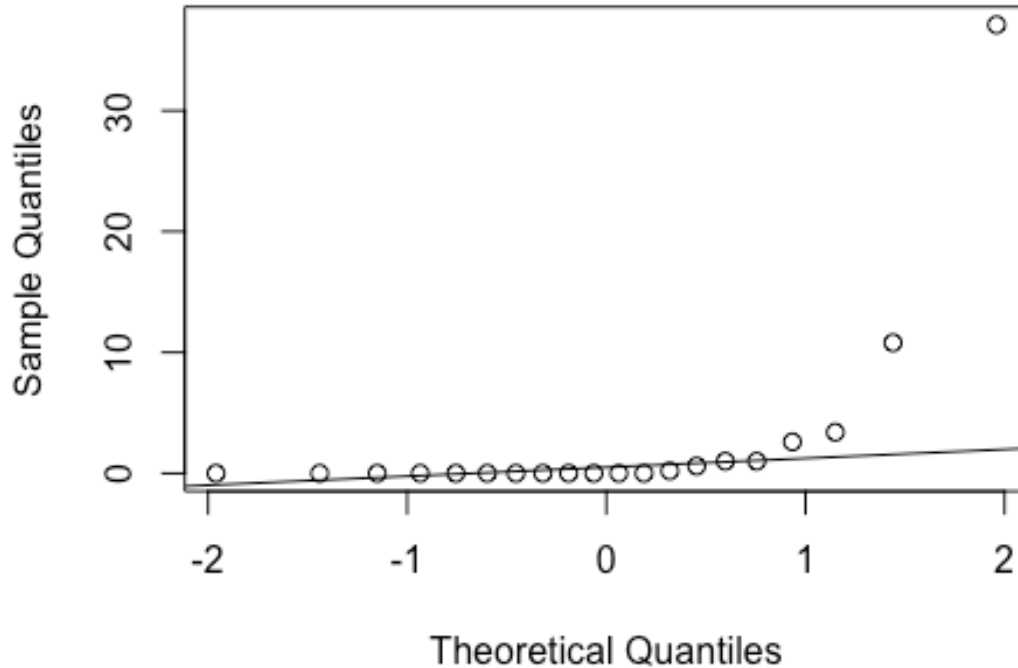
```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.total.index,
6             subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals
7             .total.index,
8             paired = TRUE, conf.int = TRUE)
9
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$plm.arousals.total.index, : cannot compute exact p-value with
13 ## zeroes
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention
16 ## == "sham")$plm.arousals.total.index, : cannot compute exact confidence
17 ## interval with zeroes
18
19 ##
20 ## Wilcoxon signed rank test with continuity correction
21 ##
22 ## data: subset(SSdataCompletes, intervention == "sham")$plm.arousals.total.
23 index and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.t
24 otal.index
25 ## V = 23, p-value = 0.6835
26 ## alternative hypothesis: true location shift is not equal to 0
27 ## 95 percent confidence interval:
28 ## -15.999946  1.499952
29 ## sample estimates:
30 ## (pseudo)median
31 ## -0.2999886
32
33 #between participants (grouped) comparison
34 summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
35
36 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
37 ##  0.000  0.000  0.000  2.835  1.000  37.100
38
39 sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
40
41 ## [1] 8.438712
42
43 length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
44
45 ## [1] 20
46
47 qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
48 qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
49
50
51
52
53
54
55
56
57
58
59
60

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index
## A = 5.1126, p-value = 3.705e-13

#non-normal

summary(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.000  0.000  0.100  1.245  0.650  13.600

sd(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

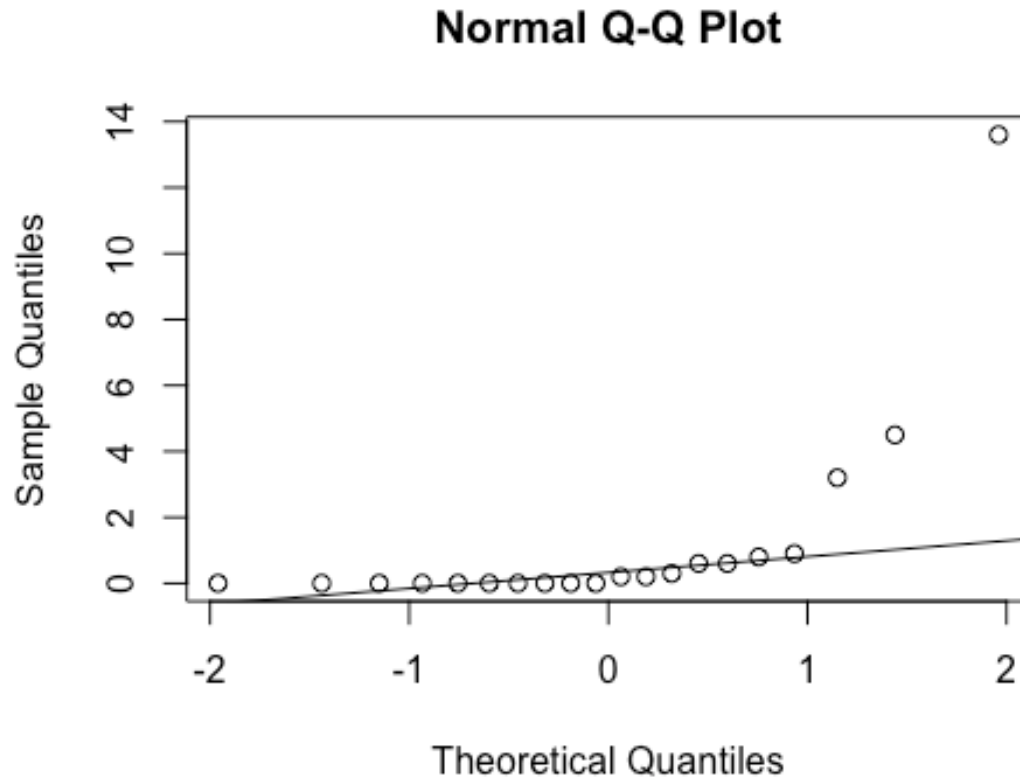
## [1] 3.135447

length(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

## [1] 20

```

```
qqnorm(subset(SSdata, intervention == "sham")$plm.arousals.total.index)
qqline(subset(SSdata, intervention == "sham")$plm.arousals.total.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$plm.arousals.total.index
## A = 4.3437, p-value = 3.116e-11

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$plm.arousals.total.index,
            subset(SSdata, intervention == "PrenaBeIt")$plm.arousals.total.in
dex,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.total.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $plm.arousals.total.index, : cannot compute exact confidence intervals wit
```

```

1
2
3 h
4 ## ties
5
6 ##
7 ## Wilcoxon rank sum test with continuity correction
8 ##
9 ## data: subset(SSdata, intervention == "sham")$plm.arousals.total.index and
10 subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index
11 ## W = 207, p-value = 0.8472
12 ## alternative hypothesis: true location shift is not equal to 0
13 ## 95 percent confidence interval:
14 ## -0.1999686 0.2000065
15 ## sample estimates:
16 ## difference in location
17 ## 4.063208e-05
18
19
20 ##### Respiratory Arousals Index in NREM #####
21 ##
22 ##FYI: this data was generated in our PSG reports per default configuration but is not a
23 pre-specified secondary outcome per the research protocol or trial registry. FYI only.
24 ##Summary
25 summary(SSdata$respiratory.arousals.nrem.index)
26
27 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
28 ## 0.00 0.00 0.20 1.11 0.80 11.10
29
30 sd(SSdata$respiratory.arousals.nrem.index, na.rm = TRUE)
31
32 ## [1] 2.639716
33
34 length(SSdata$respiratory.arousals.nrem.index)
35
36 ## [1] 40
37
38 ##ANOVA
39 night_tx_difference <- anova(lm(respiratory.arousals.nrem.index ~ intervention * night,
40 data = SSdata))
41
42 night_tx_difference
43
44 ## Analysis of Variance Table
45 ##
46 ## Response: respiratory.arousals.nrem.index
47 ##
48 ## Df Sum Sq Mean Sq F value Pr(>F)
49 ## intervention 1 6.084 6.0840 0.9328 0.34058
50 ## night 1 4.624 4.6240 0.7089 0.40535
51 ## intervention:night 1 26.244 26.2440 4.0237 0.05242 .
52 ## Residuals 36 234.804 6.5223
53 ## ---
54 ## Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
55
56
57
58
59
60

```

```

1
2
3 #within-participants (paired) comparison
4 #Paired Wilcoxon
5 wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.rous
6 als.nrem.index,
7         subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.rous
8 als.nrem.index,
9         paired = TRUE, conf.int = TRUE)
10
11 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
12 ## "sham")$respiratory.arousals.nrem.index, : cannot compute exact p-value
13 ## with ties
14
15 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
16 ## "sham")$respiratory.arousals.nrem.index, : cannot compute exact confidence
17 ## interval with ties
18
19 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
20 ## "sham")$respiratory.arousals.nrem.index, : cannot compute exact p-value
21 ## with zeroes
22
23 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24 ## "sham")$respiratory.arousals.nrem.index, : cannot compute exact confidence
25 ## interval with zeroes
26
27 ##
28 ## Wilcoxon signed rank test with continuity correction
29 ##
30 ## data: subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
31 s.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respira
32 tory.arousals.nrem.index
33 ## V = 30, p-value = 0.09338
34 ## alternative hypothesis: true location shift is not equal to 0
35 ## 95 percent confidence interval:
36 ## -1.15001291 0.05002172
37 ## sample estimates:
38 ## (pseudo)median
39 ## -0.3500664
40
41
42 #between participants (grouped) comparison
43 summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
44 .index)
45
46 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
47 ##      0.0     0.0     0.3     1.5     0.8     11.1
48
49 sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.inde
50 x)
51
52 ## [1] 3.251558
53
54 length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
55 index)
56
57
58
59
60

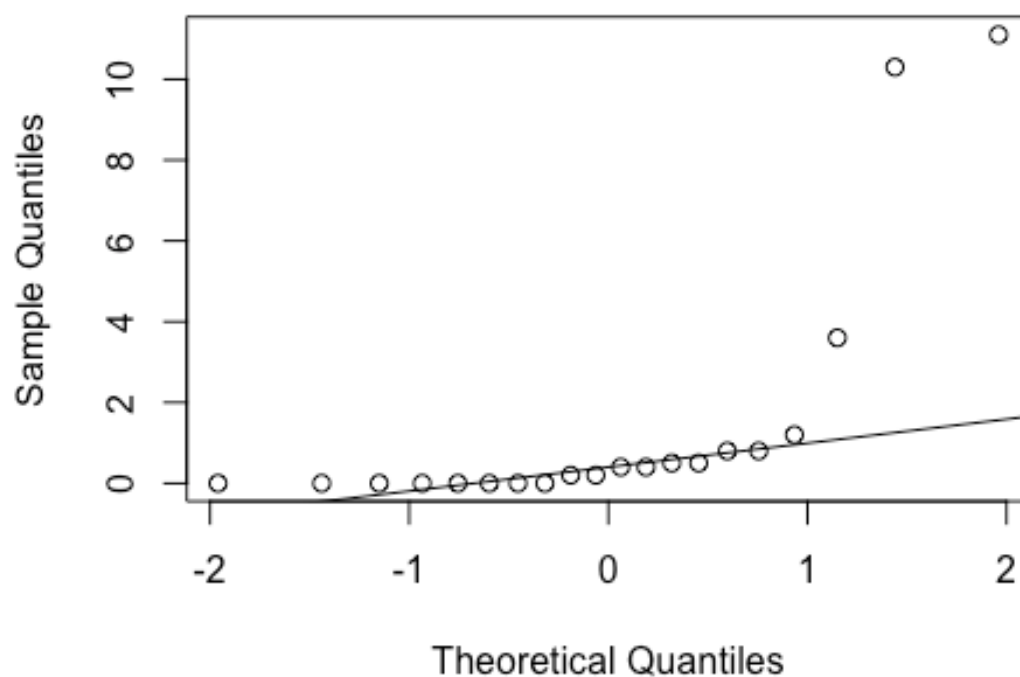
```

```

1
2
3 ## [1] 20
4
5 qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
6 index)
7 qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
8 index)
9

```

Normal Q-Q Plot



```

39 ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
40 .index)
41
42 ##
43 ## Anderson-Darling normality test
44 ##
45 ## data: subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nr
46 em.index
47 ## A = 4.3757, p-value = 2.59e-11
48
49 #non-normal
50
51 summary(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.inde
52 x)
53
54 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
55 ##      0.00   0.00   0.00   0.72   0.80   8.30
56

```

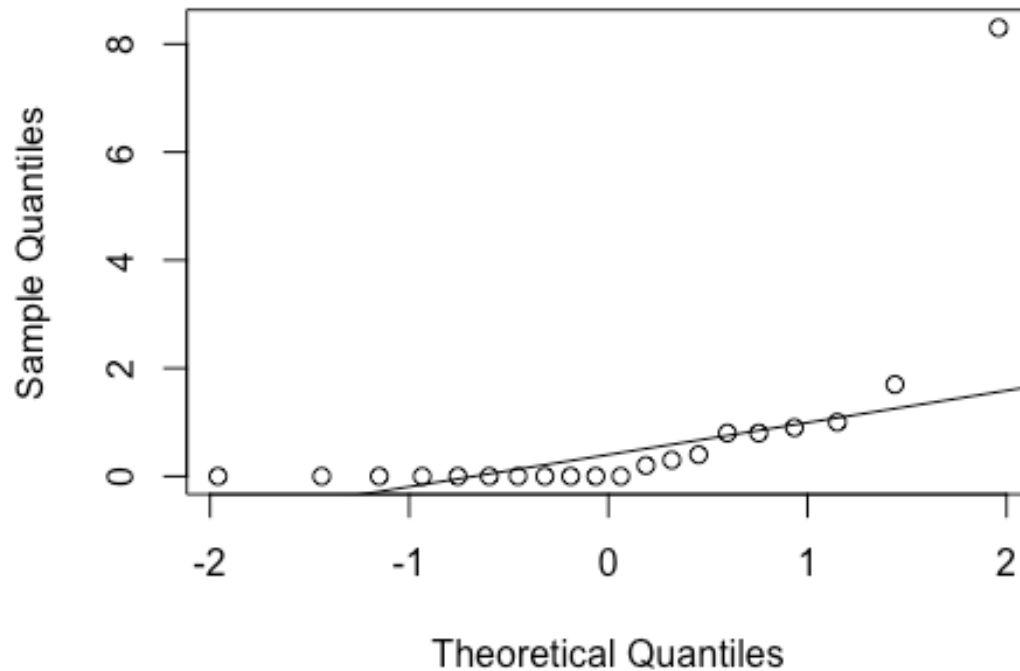


```

1
2
3 sd(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index)
4
5 ## [1] 1.846647
6
7 length(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
8 )
9
10 ## [1] 20
11
12 qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
13 )
14 qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
15 )

```

Normal Q-Q Plot



```

46 ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.inde
47 x)
48
49 ##
50 ## Anderson-Darling normality test
51 ##
52 ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.in
53 dex
54 ## A = 4.3196, p-value = 3.581e-11
55
56
57
58
59
60

```

```

1
2
3 #non-normal
4
5 #FYI - unpaired test
6 wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.
7 index,
8           subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.
9 nrem.index,
10          conf.int = TRUE)
11
12 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
13 ## $respiratory.arousals.nrem.index, : cannot compute exact p-value with ties
14
15 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
16 ## $respiratory.arousals.nrem.index, : cannot compute exact confidence
17 ## intervals with ties
18
19 ##
20 ## Wilcoxon rank sum test with continuity correction
21 ##
22 ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.in
23 dex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
24 .index
25 ## W = 171, p-value = 0.4142
26 ## alternative hypothesis: true location shift is not equal to 0
27 ## 95 percent confidence interval:
28 ## -4.000240e-01 3.702807e-05
29 ## sample estimates:
30 ## difference in location
31 ## -5.97387e-05
32
33 ##### Respiratory Arousals Index in REM #####
34 #
35 #FYI: this data was generated in our PSG reports per default configuration bu
36 t is not a
37 #pre-specified secondary outcome per the research protocol or trial registry.
38 FYI only.
39 #Summary
40 summary(SSdata$respiratory.arousals.rem.index)
41
42 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
43 ##  0.000  0.000  0.950  6.612  4.225  70.000
44
45 sd(SSdata$respiratory.arousals.rem.index, na.rm = TRUE)
46
47 ## [1] 14.61077
48
49 length(SSdata$respiratory.arousals.rem.index)
50
51 ## [1] 40
52
53 #ANOVA
54 night_tx_difference <- anova(lm(respiratory.arousals.rem.index ~ intervention
55
56
57
58
59
60

```

```

1
2
3 * night,
4                               data = SSdata))
5
6 night_tx_difference
7
8 ## Analysis of Variance Table
9 ##
10 ## Response: respiratory.arousals.rem.index
11 ##           Df Sum Sq Mean Sq F value Pr(>F)
12 ## intervention      1    0.4    0.42  0.0021 0.96365
13 ## night              1   18.6   18.63  0.0934 0.76166
14 ## intervention:night 1 1124.7 1124.66  5.6376 0.02303 *
15 ## Residuals        36 7181.8  199.49
16 ## ---
17 ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
18
19 #within-participants (paired) comparison
20 #Paired Wilcoxon
21 wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arousals.rem.index,
22             subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arousals.rem.index,
23             paired = TRUE, conf.int = TRUE)
24
25 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
26 ## "sham")$respiratory.arousals.rem.index, : cannot compute exact p-value with
27 ties
28
29 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
30 ## "sham")$respiratory.arousals.rem.index, : cannot compute exact confidence
31 ## interval with ties
32
33 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
34 ## "sham")$respiratory.arousals.rem.index, : cannot compute exact p-value with
35 zeroes
36
37 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
38 ## "sham")$respiratory.arousals.rem.index, : cannot compute exact confidence
39 ## interval with zeroes
40
41 ##
42 ## Wilcoxon signed rank test with continuity correction
43 ##
44 ## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousals.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arousals.rem.index
45 ## V = 67, p-value = 0.7119
46 ## alternative hypothesis: true location shift is not equal to 0
47 ## 95 percent confidence interval:
48 ## -3.249966  3.599990

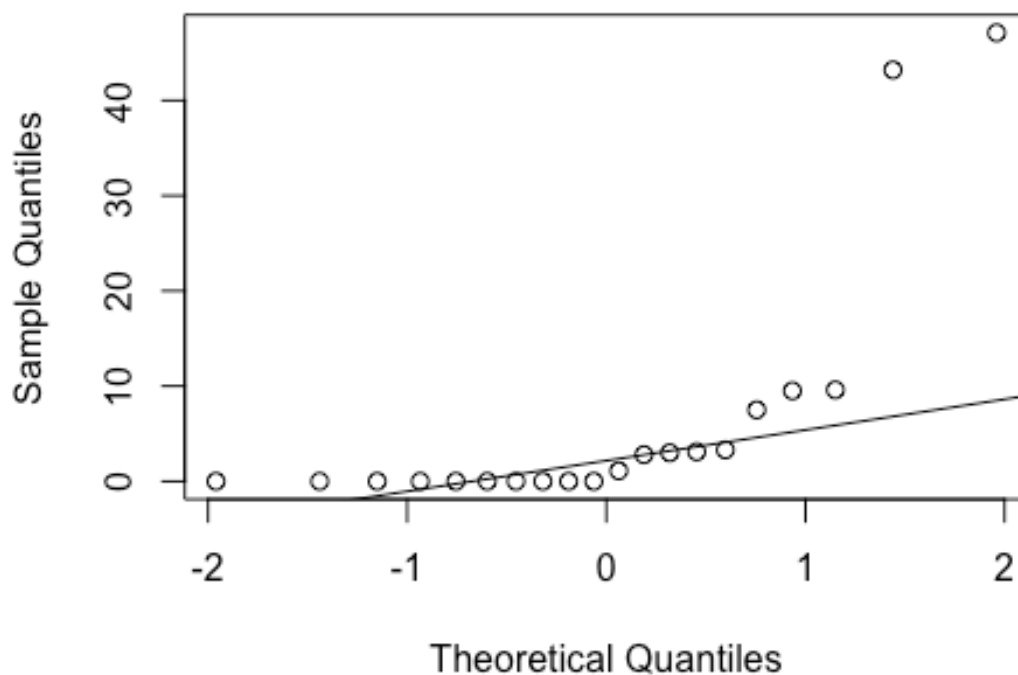
```

```

1
2
3  ## sample estimates:
4  ## (pseudo)median
5  ##      0.3582702
6
7  #between participants (grouped) comparison
8  summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.
9  index)
10
11  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
12  ##      0.00   0.00   0.55   6.51   4.35   47.10
13
14  sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.index
15  )
16
17  ## [1] 13.60003
18
19  length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
20  ndex)
21
22  ## [1] 20
23
24  qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
25  ndex)
26  qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
27  ndex)
28

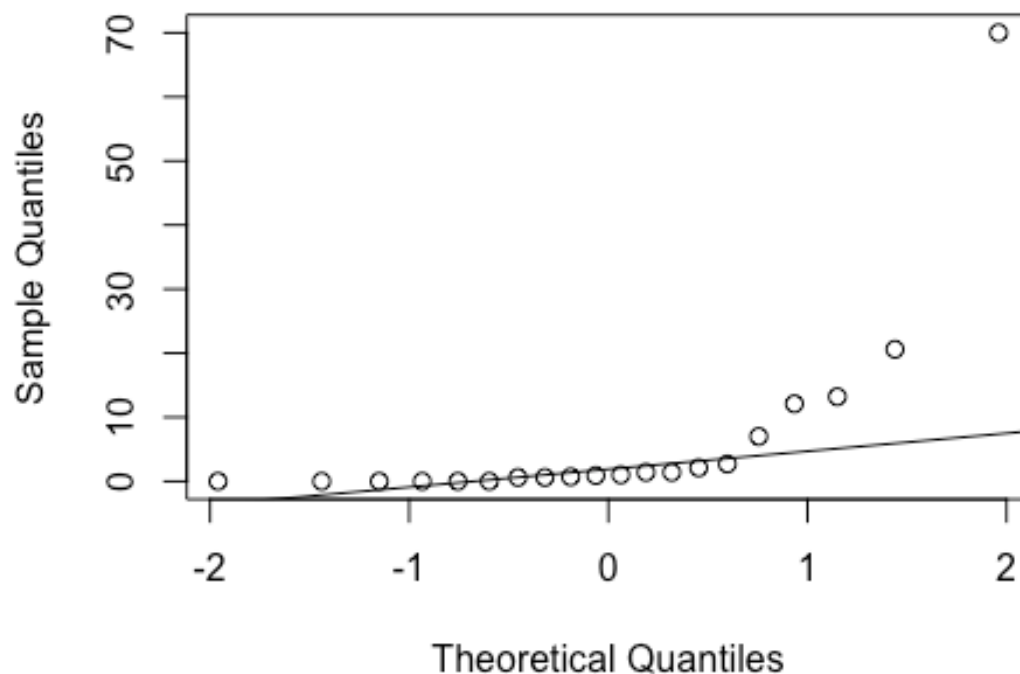
```

Normal Q-Q Plot



```
1
2
3 ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.
4 index)
5
6 ##
7 ## Anderson-Darling normality test
8 ##
9 ## data: subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.re
10 m.index
11 ## A = 4.0123, p-value = 2.119e-10
12
13 #non-normal
14
15 summary(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
16 )
17
18 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
19 ##      0.000  0.000  0.950   6.715  3.775  70.000
20
21 sd(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
22
23 ## [1] 15.9123
24
25 length(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
26
27 ## [1] 20
28
29 qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
30 qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
## A = 4.0308, p-value = 1.904e-10

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index,
            subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.index,
            conf.int = TRUE)

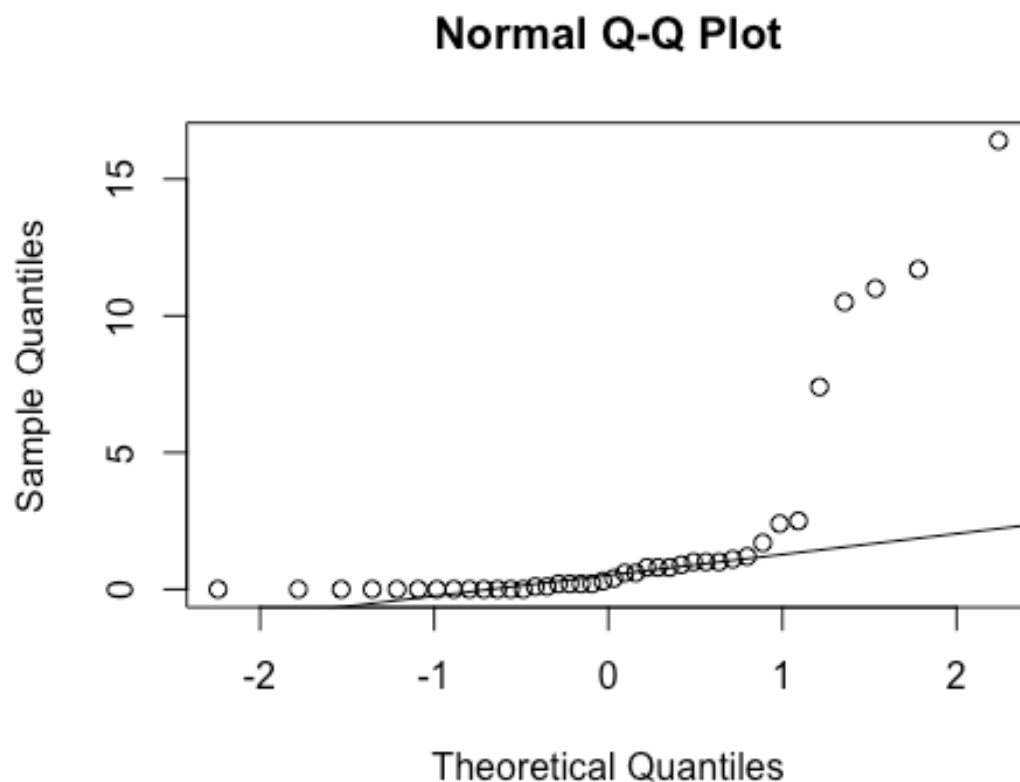
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $respiratory.arousals.rem.index, : cannot compute exact p-value with ties

```

```

1
2
3  ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
4  ## $respiratory.arousals.rem.index, : cannot compute exact confidence
5  ## intervals with ties
6
7  ##
8  ##  Wilcoxon rank sum test with continuity correction
9  ##
10 ## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.rem.ind
11 ex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
12 ndex
13 ## W = 213, p-value = 0.7267
14 ## alternative hypothesis: true location shift is not equal to 0
15 ## 95 percent confidence interval:
16 ##  -1.900003  1.399993
17 ## sample estimates:
18 ## difference in location
19 ##           5.850022e-05
20
21
22 ##### Respiratory Arousals Total Index (TST = NREM + REM) ####
23 #####
24 #Summary
25 summary(SSdata$respiratory.arousals.total.index)
26
27 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28 ##    0.000  0.000   0.350   1.878   1.025  16.400
29
30 sd(SSdata$respiratory.arousals.total.index, na.rm = TRUE)
31
32 ## [1] 3.840706
33
34 length(SSdata$respiratory.arousals.total.index)
35
36 ## [1] 40
37
38 qqnorm(SSdata$respiratory.arousals.total.index)
39 qqline(SSdata$respiratory.arousals.total.index)
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(SSdata$respiratory.arousals.total.index)

##
## Anderson-Darling normality test
##
## data:  SSdata$respiratory.arousals.total.index
## A = 7.9786, p-value < 2.2e-16

#non-normal

#ANOVA
night_tx_difference <- anova(lm(respiratory.arousals.total.index ~ interventi
on * night,
                               data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: respiratory.arousals.total.index
##
##          Df Sum Sq Mean Sq F value Pr(>F)
## intervention      1    2.35    2.352   0.1732 0.67973
## night              1    0.87    0.870   0.0641 0.80159
## intervention:night  1  83.23  83.232   6.1296 0.01813 *
## Residuals        36 488.83  13.579

```



```

1
2
3  ## ---
4  ## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
5
6  #within-participants (paired) comparison
7  #Paired Wilcoxon
8  wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.rousals.total.index,
9  als.total.index,
10                 subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.
11  arousals.total.index,
12                 paired = TRUE, conf.int = TRUE)
13
14  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
15  ## "sham")$respiratory.rousals.total.index, : cannot compute exact p-value
16  ## with ties
17
18  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
19  ## "sham")$respiratory.rousals.total.index, : cannot compute exact confidenc
20  e
21  ## interval with ties
22
23  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
24  ## "sham")$respiratory.rousals.total.index, : cannot compute exact p-value
25  ## with zeroes
26
27  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
28  ## "sham")$respiratory.rousals.total.index, : cannot compute exact confidenc
29  e
30  ## interval with zeroes
31
32
33  ##
34  ##  Wilcoxon signed rank test with continuity correction
35  ##
36  ## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousals.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.rousals.total.index
37  ## V = 62, p-value = 0.776
38  ## alternative hypothesis: true location shift is not equal to 0
39  ## 95 percent confidence interval:
40  ##  -2.0999697  0.5000137
41  ## sample estimates:
42  ## (pseudo)median
43  ##  -0.1000365
44
45  #between participants (grouped) comparison
46  summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.rousals.total.index)
47
48  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
49  ##      0.00  0.00   0.40   2.12  1.05   16.40
50
51  sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.rousals.total.index)
52
53
54
55
56
57
58
59
60

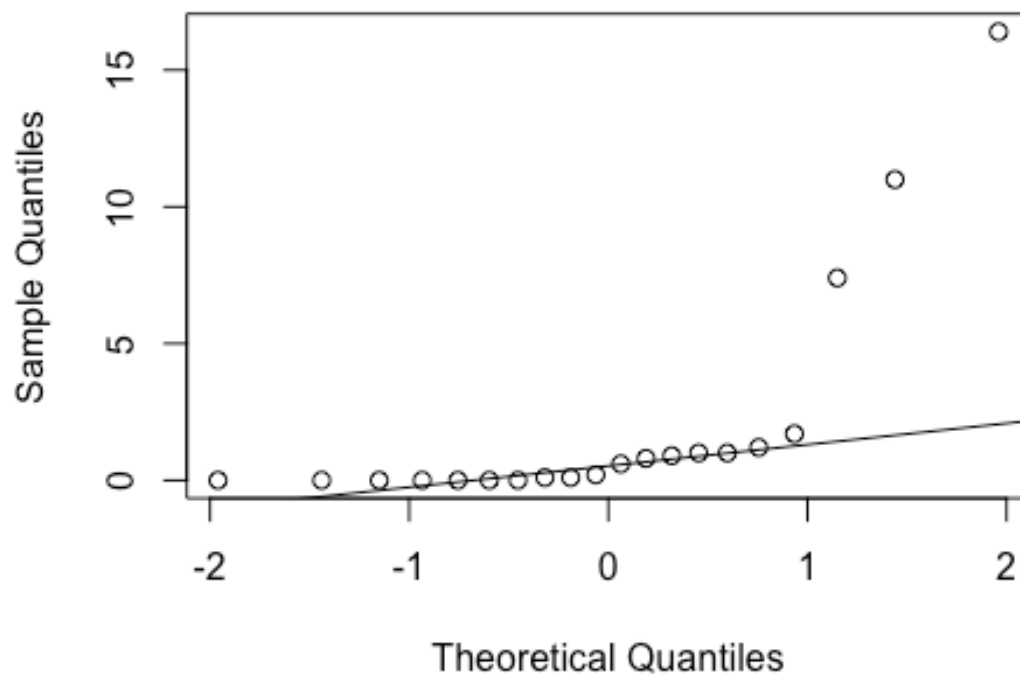
```

```

1
2
3 ## [1] 4.371149
4
5 length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
6 .index)
7
8 ## [1] 20
9
10 qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
11 .index)
12 qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
13 .index)
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43

```

Normal Q-Q Plot



```

44 ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tota
45 l.index)
46
47 ##
48 ## Anderson-Darling normality test
49 ##
50 ## data: subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.to
51 tal.index
52 ## A = 3.9897, p-value = 2.416e-10
53
54 #non-normal
55
56
57
58
59
60

```

```

summary(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.000  0.000  0.350  1.635  1.025  11.700

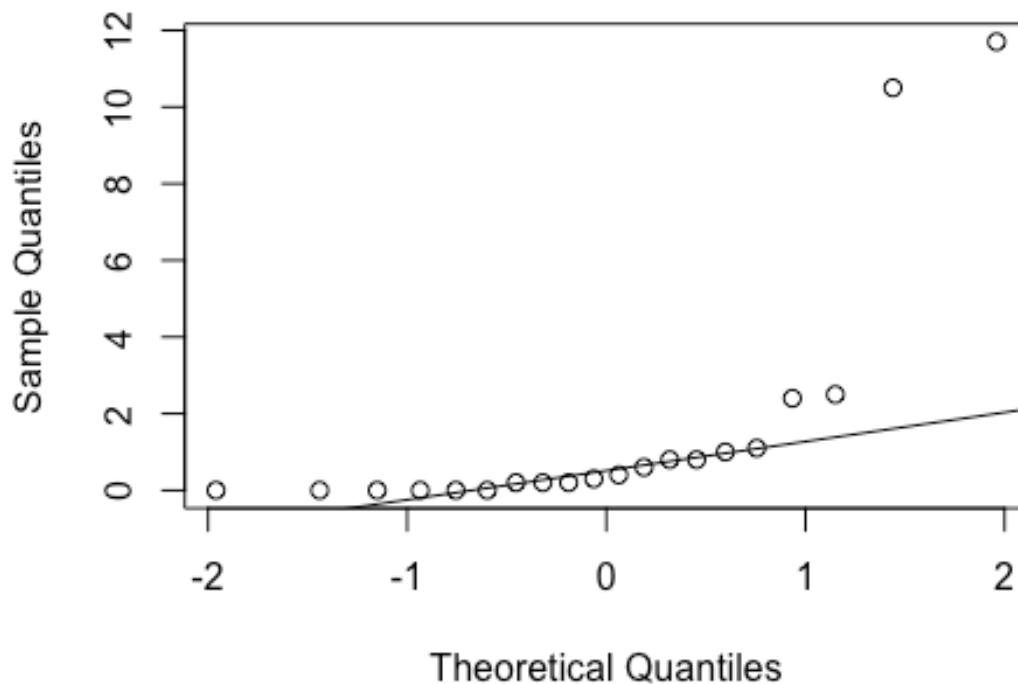
sd(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
## [1] 3.323802

length(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)

```

Normal Q-Q Plot



```

ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
##
## Anderson-Darling normality test

```

```

1
2
3  ##
4  ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.total.i
5  ndex
6  ## A = 4.0437, p-value = 1.767e-10
7
8  #non-normal
9
10 #FYI - unpaired test
11 wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.total
12 .index,
13             subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.
14 total.index,
15             conf.int = TRUE)
16
17 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
18 ## $respiratory.arousals.total.index, : cannot compute exact p-value with tie
19 s
20
21 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
22 ## $respiratory.arousals.total.index, : cannot compute exact confidence
23 ## intervals with ties
24
25
26 ##
27 ## Wilcoxon rank sum test with continuity correction
28 ##
29 ## data: subset(SSdata, intervention == "sham")$respiratory.arousals.total.i
30 ndex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tot
31 al.index
32 ## W = 203, p-value = 0.9451
33 ## alternative hypothesis: true location shift is not equal to 0
34 ## 95 percent confidence interval:
35 ## -0.5999724 0.3999323
36 ## sample estimates:
37 ## difference in location
38 ## 9.000537e-06
39
40 ##### Arousing events NOT meeting respiratory criteria Index in NREM ##
41 #####
42 #FYI: this data was generated in our PSG reports per default configuration bu
43 t is not a
44 #pre-specified secondary outcome per the research protocol or trial registry.
45 FYI only.
46 #Summary
47 summary(SSdata$arousals.with.respiratory.nrem.index)
48
49 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
50 ##      0.000  0.000  0.000  0.045  0.000  0.400
51
52 sd(SSdata$arousals.with.respiratory.nrem.index, na.rm = TRUE)
53
54 ## [1] 0.09594336
55
56
57
58
59
60

```

```

1 length(SSdata$arousals.with.respiratory.nrem.index)
2
3
4
5 ## [1] 40
6
7 #ANOVA
8 night_tx_difference <- anova(lm(arousals.with.respiratory.nrem.index ~ interv
9 ention * night,
10                               data = SSdata))
11
12 night_tx_difference
13
14 ## Analysis of Variance Table
15 ##
16 ## Response: arousalswith.respiratory.nrem.index
17 ##              Df Sum Sq  Mean Sq F value Pr(>F)
18 ## intervention    1  0.001  0.0010000  0.1034 0.7496
19 ## night           1  0.001  0.0010000  0.1034 0.7496
20 ## intervention:night 1  0.009  0.0090000  0.9310 0.3410
21 ## Residuals      36  0.348  0.0096667
22
23 #within-participants (paired) comparison
24 #Paired Wilcoxon
25 wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
26 piratory.nrem.index,
27              subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
28 piratory.nrem.index,
29              paired = TRUE)
30
31 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
32 ## "sham")$arousals.with.respiratory.nrem.index, : cannot compute exact p-
33 ## value with ties
34
35 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
36 ## "sham")$arousals.with.respiratory.nrem.index, : cannot compute exact p-
37 ## value with zeroes
38
39 ##
40 ## Wilcoxon signed rank test with continuity correction
41 ##
42 ## data: subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
43 ratory.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$ar
44 ousals.with.respiratory.nrem.index
45 ## V = 2, p-value = 0.7728
46 ## alternative hypothesis: true location shift is not equal to 0
47
48 #between participants (grouped) comparison
49 summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
50 .nrem.index)
51
52 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
53 ##      0.00   0.00   0.00   0.05   0.00   0.40
54
55
56
57
58
59
60

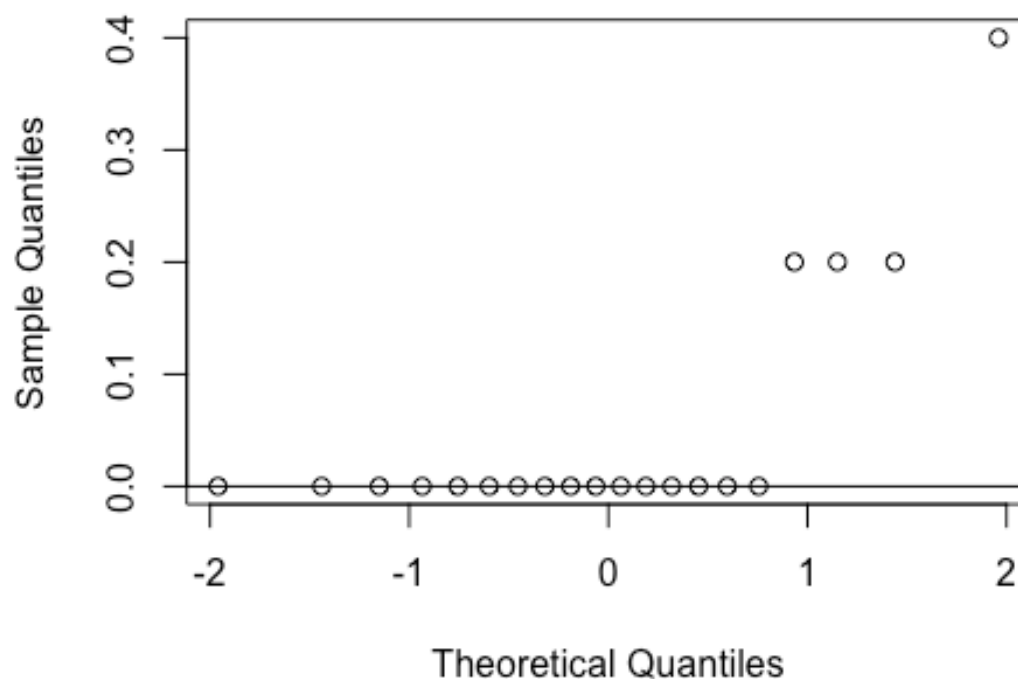
```

```

1 sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.nrem
2 .index)
3
4 ## [1] 0.1100239
5
6 length(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
7 nrem.index)
8
9 ## [1] 20
10
11 qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
12 nrem.index)
13
14 qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
15 nrem.index)
16
17
18
19
20
21
22

```

Normal Q-Q Plot



```

23 ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
24 .nrem.index)
25
26 ##
27 ## Anderson-Darling normality test
28 ##
29 ## data: subset(SSdata, intervention == "PrenaBelt")$arousals.with.respirato
30 ry.nrem.index
31 ## A = 4.6088, p-value = 6.743e-12
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

```

```
#non-normal
```

```
summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.index)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00   0.00   0.00   0.04   0.00   0.20
```

```
sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.index)
```

```
## [1] 0.08207827
```

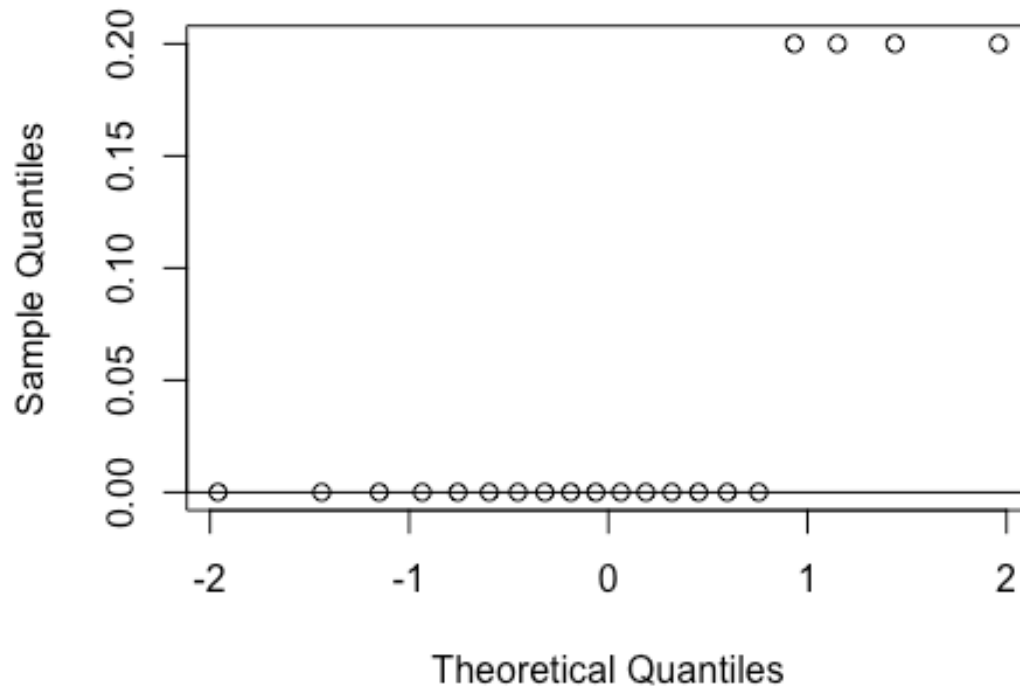
```
length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.index)
```

```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.index)
```

```
qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.index)
```

Normal Q-Q Plot



```

1
2
3 ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem
4 .index)
5
6 ##
7 ## Anderson-Darling normality test
8 ##
9 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.index
10 em.index
11 ## A = 5.1941, p-value = 2.32e-13
12
13 #non-normal
14
15 #FYI - unpaired test
16 wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
17 nrem.index,
18 subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.nrem.index,
19 conf.int = TRUE)
20
21 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
22 ## $arousals.with.respiratory.nrem.index, : cannot compute exact p-value with
23 ## ties
24
25 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
26 ## $arousals.with.respiratory.nrem.index, : cannot compute exact confidence
27 ## intervals with ties
28
29 ##
30 ## Wilcoxon rank sum test with continuity correction
31 ##
32 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.nrem.index
33 em.index
34 ## W = 198, p-value = 0.9534
35 ## alternative hypothesis: true location shift is not equal to 0
36 ## 95 percent confidence interval:
37 ## -1.407869e-05 9.852765e-06
38 ## sample estimates:
39 ## difference in location
40 ## -3.692335e-06
41
42 ##### Arousing events NOT meeting respiratory criteria Index in REM #####
43 ##
44 #FYI: this data was generated in our PSG reports per default configuration but is not a
45 #pre-specified secondary outcome per the research protocol or trial registry.
46 FYI only.
47 #Summary
48 summary(SSdata$arousals.with.respiratory.rem.index)
49
50
51
52
53
54
55
56
57
58
59
60

```



```

1
2
3   ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4   ##    0.000  0.000  0.000  0.015  0.000  0.600
5
6   sd(SSdata$arousals.with.respiratory.rem.index, na.rm = TRUE)
7
8   ## [1] 0.09486833
9
10  length(SSdata$arousals.with.respiratory.rem.index)
11
12  ## [1] 40
13
14  #ANOVA
15  night_tx_difference <- anova(lm(arousals.with.respiratory.rem.index ~ interve
16  ntion * night,
17                                data = SSdata))
18  night_tx_difference
19
20  ## Analysis of Variance Table
21  ##
22  ## Response: arousalswith.respiratory.rem.index
23  ##
24  ##           Df Sum Sq Mean Sq F value Pr(>F)
25  ## intervention      1  0.009   0.009      1  0.324
26  ## night              1  0.009   0.009      1  0.324
27  ## intervention:night  1  0.009   0.009      1  0.324
28  ## Residuals        36  0.324   0.009
29
30  #within-participants (paired) comparison
31  #Paired Wilcoxon
32  wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
33  piratory.rem.index,
34              subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
35  piratory.rem.index,
36              paired = TRUE)
37
38  ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
39  ## "sham")$arousals.with.respiratory.rem.index, : cannot compute exact p-valu
40  e
41  ## with zeroes
42
43  ##
44  ## Wilcoxon signed rank test with continuity correction
45  ##
46  ## data: subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
47  ratory.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$aro
48  usals.with.respiratory.rem.index
49  ## V = 1, p-value = 1
50  ## alternative hypothesis: true location shift is not equal to 0
51
52  #between participants (grouped) comparison
53  summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
54  .rem.index)
55
56
57
58
59
60

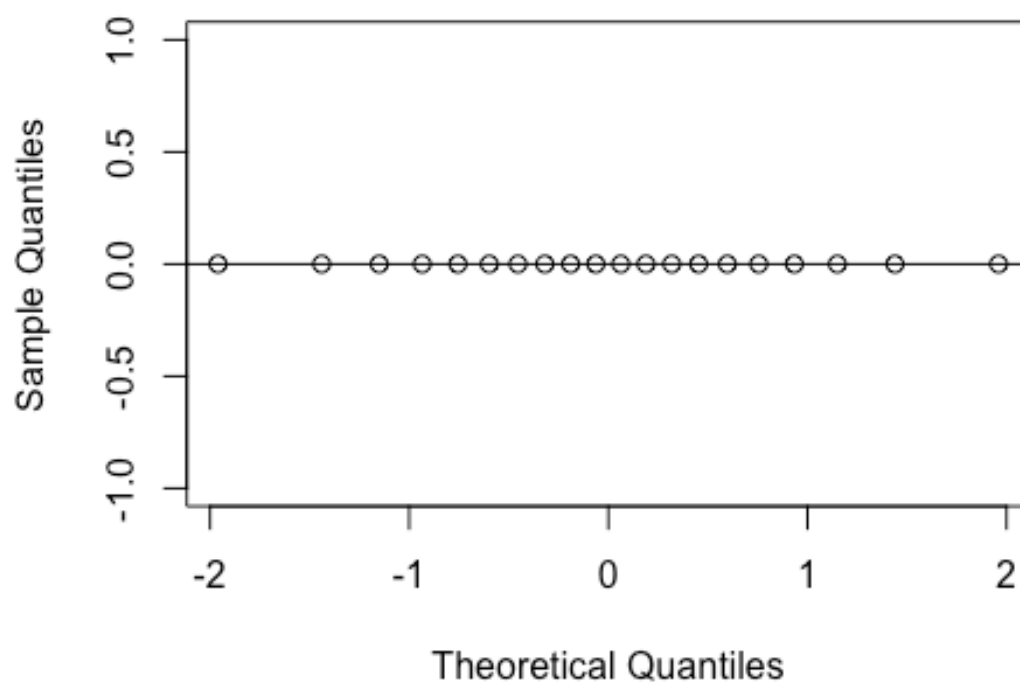
```

```

1
2
3
4  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
5  ##      0      0      0      0      0      0
6
7  sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.rem.
8  index)
9
10 ## [1] 0
11
12 length(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
13 rem.index)
14
15 ## [1] 20
16
17 qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
18 rem.index)
19
20 qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
21 rem.index)

```

Normal Q-Q Plot



```

50 #ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respirator
51 y.rem.index)
52 #distribution is entirely zeroes
53
54 summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.
55 index)
56
57
58
59
60

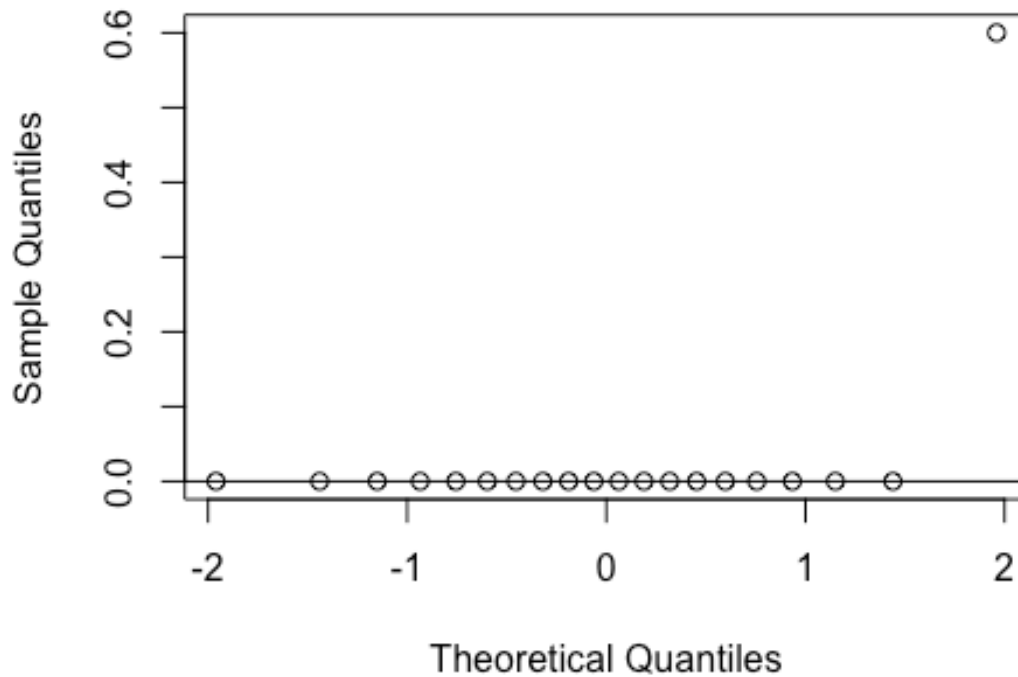
```

```

1
2
3  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
4  ##      0.00   0.00   0.00   0.03   0.00   0.60
5
6  sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.index
7  )
8
9  ## [1] 0.1341641
10
11 length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
12 ndex)
13
14 ## [1] 20
15
16 qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
17 ndex)
18 qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
19 ndex)
20
21
22
23

```

Normal Q-Q Plot



```

50 ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.
51 index)
52
53 ##
54 ## Anderson-Darling normality test
55 ##
56 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.re
57
58
59
60

```

```

1
2
3 m.index
4 ## A = 7.1762, p-value < 2.2e-16
5
6 #non-normal
7
8 #FYI - unpaired test
9 wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
10 rem.index,
11             subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
12 tory.rem.index,
13             conf.int = TRUE)
14
15 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
16 ## $arousals.with.respiratory.rem.index, : cannot compute exact p-value with
17 ## ties
18
19 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
20 ## $arousals.with.respiratory.rem.index, : cannot compute exact confidence
21 ## intervals with ties
22
23 ##
24 ## Wilcoxon rank sum test with continuity correction
25 ##
26 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.re
27 m.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
28 tory.rem.index
29 ## W = 210, p-value = 0.3421
30 ## alternative hypothesis: true location shift is not equal to 0
31 ## 95 percent confidence interval:
32 ##  0  0
33 ## sample estimates:
34 ## difference in location
35 ##
36 ##
37 ##
38 ##### Arousing events NOT meeting respiratory criteria Index (TST = NREM +
39 REM) #####
40 #FYI: this data was generated in our PSG reports per default configuration bu
41 t is not a
42 #pre-specified secondary outcome per the research protocol or trial registry.
43 FYI only.
44 #Summary
45 summary(SSdata$arousals.with.respiratory.total.index)
46
47 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
48 ##  0.0000  0.0000  0.0000  0.0425  0.0000  0.4000
49
50 sd(SSdata$arousals.with.respiratory.total.index, na.rm = TRUE)
51
52 ## [1] 0.09577618
53
54 length(SSdata$arousals.with.respiratory.total.index)
55
56
57
58
59
60

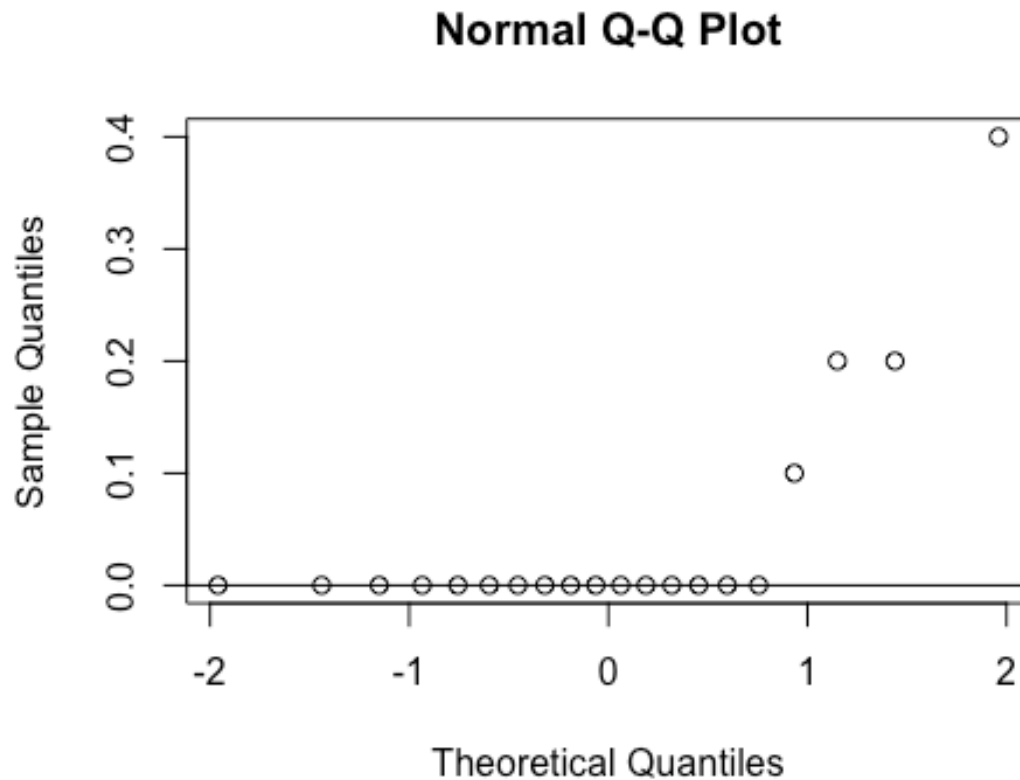
```

```

1
2
3  ## [1] 40
4
5  #ANOVA
6  night_tx_difference <- anova(lm(arousals.with.respiratory.total.index ~ inter
7  vention * night,
8                                data = SSdata))
9
10 night_tx_difference
11
12 ## Analysis of Variance Table
13 ##
14 ## Response: arousals.with.respiratory.total.index
15 ##
16 ##           Df Sum Sq Mean Sq F value Pr(>F)
17 ## intervention      1 0.00025 0.00025  0.0256 0.8737
18 ## night              1 0.00025 0.00025  0.0256 0.8737
19 ## intervention:night  1 0.00625 0.00625  0.6410 0.4286
20 ## Residuals         36 0.35100 0.00975
21
22 #within-participants (paired) comparison
23 #Paired Wilcoxon
24 wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
25 piratory.total.index,
26             subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
27 piratory.total.index,
28             paired = TRUE, conf.int = TRUE)
29
30 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
31 ## "sham")$arousals.with.respiratory.total.index, : requested conf.level not
32 ## achievable
33
34 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
35 ## "sham")$arousals.with.respiratory.total.index, : cannot compute exact p-
36 ## value with ties
37
38 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
39 ## "sham")$arousals.with.respiratory.total.index, : cannot compute exact
40 ## confidence interval with ties
41
42 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
43 ## "sham")$arousals.with.respiratory.total.index, : cannot compute exact p-
44 ## value with zeroes
45
46 ## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
47 ## "sham")$arousals.with.respiratory.total.index, : cannot compute exact
48 ## confidence interval with zeroes
49
50 ##
51 ## Wilcoxon signed rank test with continuity correction
52 ##
53 ## data: subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
54 ratory.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$a
55 rousals.with.respiratory.total.index
56 ## V = 5.5, p-value = 0.6831
57
58
59
60

```

```
1
2
3 ## alternative hypothesis: true location shift is not equal to 0
4 ## 90 percent confidence interval:
5 ## -0.2 0.2
6 ## sample estimates:
7 ## (pseudo)median
8 ## -5.079939e-05
9
10 #between participants (grouped) comparison
11 summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
12 .total.index)
13
14 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
15 ##  0.000  0.000  0.000  0.045  0.000  0.400
16
17 sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.tota
18 l.index)
19
20 ## [1] 0.1050063
21
22 length(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
23 total.index)
24
25 ## [1] 20
26
27 qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
28 total.index)
29 qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
30 total.index)
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
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55
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```



```

ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
.total.index)

##
## Anderson-Darling normality test
##
## data: subset(SSdata, intervention == "PrenaBelt")$arousals.with.respirato
ry.total.index
## A = 4.5718, p-value = 8.347e-12

#non-normal

summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.tota
l.index)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00  0.00   0.00   0.04  0.00   0.30

sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total.ind
ex)

## [1] 0.088258

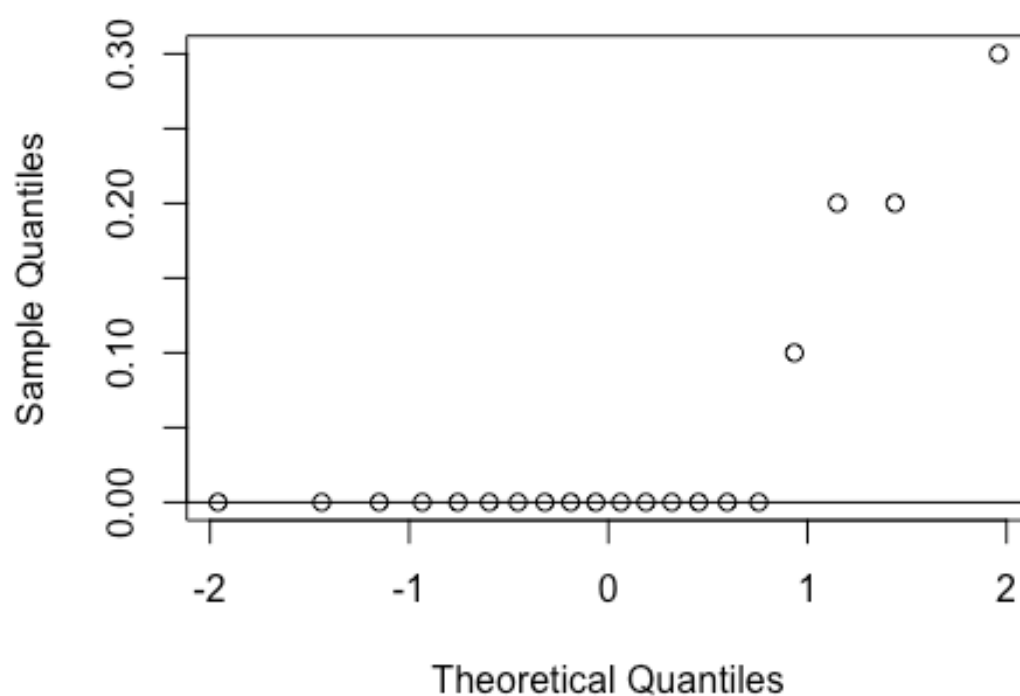
```

```

1 length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
2 .index)
3
4 ## [1] 20
5
6 qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
7 .index)
8
9 qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
10 .index)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41

```

Normal Q-Q Plot



```

42 ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.tota
43 l.index)
44
45 ##
46 ## Anderson-Darling normality test
47 ##
48 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.to
49 tal.index
50 ## A = 4.6836, p-value = 4.379e-12
51
52 #non-normal
53
54 #FYI - unpaired test
55 wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
56
57
58
59
60

```



```
1
2
3 total.index,
4     subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
5 tory.total.index,
6     conf.int = TRUE)
7
8 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
9 ## $arousals.with.respiratory.total.index, : cannot compute exact p-value wit
10 h
11 ## ties
12
13 ## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
14 ## $arousals.with.respiratory.total.index, : cannot compute exact confidence
15 ## intervals with ties
16
17 ##
18 ## Wilcoxon rank sum test with continuity correction
19 ##
20 ## data: subset(SSdata, intervention == "sham")$arousals.with.respiratory.to
21 tal.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respi
22 ratory.total.index
23 ## W = 199.5, p-value = 1
24 ## alternative hypothesis: true location shift is not equal to 0
25 ## 95 percent confidence interval:
26 ## -5.011195e-06 5.395622e-05
27 ## sample estimates:
28 ## difference in location
29 ## -6.56778e-05
30
31
32 #end
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

1
2
3 **Supplementary file 3: Code and output – feedback analysis**
4
5
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For peer review only

Feedback_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 16:14:40 2018

```

#Description of code: this code processes the PUFQs Looking at summary of the
#se data,
#within-participant comparison of PUFQ data ("before/after"), and between-par
#ticipants
#comparison of PUFQ data (bulk test for differences btw all treatment nights
#vs all
#sham nights)

#Summary/Status:
#08APR: No difference on within-participant or between-participant compariso
#n (treatment
#vs. sham) for all variables.

#setting the workspace directory
setwd("/Users/Allan/Desktop/HPTStats/08APR2017")

#importing the PrenaBelt User Feedback (PBUF) Data
PBUFdata=read.csv("PUFD Data Halifax - 08APR2017.csv")

#Loading the functions (ad.test, etc.) into your workspace
library(nortest)

#Exclude drop outs
#How many drop outs?
summary(PBUFdata$drop.out)

## N Y
## 40 6

#6 dropout nights = 3 participants
#Remove the drop outs ("Y")
PBUFdata <- PBUFdata[!(PBUFdata$drop.out=="Y"),]
nrow(PBUFdata)

## [1] 40

#Separate into sham and treat group for within-participant comparisons
PBUF_sham <- subset(PBUFdata, Intervention == "sham")
PBUF_treat <- subset(PBUFdata, Intervention == "treatment")

#####SR POSITION ADOPTED#####

```

```

1
2
3 #summary data
4 summary(PBUFdata$SR.position.adopted)
5
6 ##           left left and right left and supine
7 ##           0           27           5           1
8 ##      right           supine
9 ##           5           2
10
11 length(PBUFdata$SR.position.adopted)
12
13 ## [1] 40
14
15 #between participants (grouped) comparison
16 xtabs(~SR.position.adopted + Intervention, data = PBUFdata)
17
18 ##           Intervention
19 ## SR.position.adopted sham treatment
20 ##           0           0
21 ## left           13           14
22 ## left and right  2           3
23 ## left and supine 1           0
24 ## right           3           2
25 ## supine          1           1
26
27 #build 2-row table for fisher test: sham vs treatment
28 SR.position.adopted_table <- matrix(c(16,17,5,5,2,1),
29                                     nrow = 2)
30
31 colnames(SR.position.adopted_table) <- c("left", "right", "supine")
32 rownames(SR.position.adopted_table) <- c("Sham",
33                                           "Treatment")
34
35 SR.position.adopted_table
36
37 ##           left right supine
38 ## Sham           16    5    2
39 ## Treatment      17    5    1
40
41 t(SR.position.adopted_table)
42
43 ##           Sham Treatment
44 ## left           16    17
45 ## right          5     5
46 ## supine         2     1
47
48 #Perform Fisher's Exact Tests
49
50 temp_table <- t(SR.position.adopted_table)
51 j=nrow(temp_table)
52 ControlCsum=colSums(temp_table)[1]
53 TreatmentCsum=colSums(temp_table)[2]
54 for(i in 1:j) {
55   a=temp_table[i,1]
56   b=temp_table[i,2]
57
58
59
60

```

```

1
2
3   c=ControlCsum-a
4   d=TreatmentCsum-b
5   ORtable <- matrix(c(a,c,b,d),nrow = 2)
6   colnames(ORtable) <- c("Sham","Treatment")
7   rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
8   print(row.names(temp_table)[i])
9   print(ORtable)
10  print(fisher.test(ORtable))
11
12 }
13
14 ## [1] "left"
15 ##      Sham Treatment
16 ## left   16         17
17 ## Other   7          6
18 ##
19 ## Fisher's Exact Test for Count Data
20 ##
21 ## data:  ORtable
22 ## p-value = 1
23 ## alternative hypothesis: true odds ratio is not equal to 1
24 ## 95 percent confidence interval:
25 ##  0.181121 3.522335
26 ## sample estimates:
27 ## odds ratio
28 ##  0.810505
29 ##
30 ## [1] "right"
31 ##      Sham Treatment
32 ## right   5          5
33 ## Other  18         18
34 ##
35 ## Fisher's Exact Test for Count Data
36 ##
37 ## data:  ORtable
38 ## p-value = 1
39 ## alternative hypothesis: true odds ratio is not equal to 1
40 ## 95 percent confidence interval:
41 ##  0.1927805 5.1872475
42 ## sample estimates:
43 ## odds ratio
44 ##          1
45 ##
46 ## [1] "supine"
47 ##      Sham Treatment
48 ## supine   2          1
49 ## Other   21         22
50 ##
51 ## Fisher's Exact Test for Count Data
52 ##
53 ## data:  ORtable

```

```

1
2
3  ## p-value = 1
4  ## alternative hypothesis: true odds ratio is not equal to 1
5  ## 95 percent confidence interval:
6  ##    0.1003416 129.0322645
7  ## sample estimates:
8  ## odds ratio
9  ##    2.062812
10
11 #####SR POSITION FELL ASLEEP#####
12 #####
13
14 #summary data
15 summary(PBUFdata$SR.position.fell.asleep)
16
17 ##                left          left and right
18 ##                0             27             5
19 ## left, right and back      right          supine
20 ##                1             5             2
21
22 length(PBUFdata$SR.position.fell.asleep)
23
24 ## [1] 40
25
26 #between participants (grouped) comparison
27 xtabs(~SR.position.fell.asleep + Intervention, data = PBUFdata)
28
29 ##                Intervention
30 ## SR.position.fell.asleep sham treatment
31 ##                0             0
32 ## left            13            14
33 ## left and right  2             3
34 ## left, right and back  1             0
35 ## right           3             2
36 ## supine          1             1
37
38 #build 2-row table for fisher test: sham vs treatment
39 SR.position.fell.asleep_table <- matrix(c(16,17,6,5,2,1),
40                                         nrow = 2)
41 colnames(SR.position.fell.asleep_table) <- c("left", "right", "supine")
42 rownames(SR.position.fell.asleep_table) <- c("Sham",
43                                             "Treatment")
44 t(SR.position.fell.asleep_table)
45
46 ##          Sham Treatment
47 ## left     16          17
48 ## right    6           5
49 ## supine   2           1
50
51 #Perform Fisher's Exact Tests
52
53 temp_table <- t(SR.position.fell.asleep_table)
54 j=nrow(temp_table)
55 ControlCsum=colSums(temp_table)[1]

```

```

1
2
3 TreatmentCsum=colSums(temp_table)[2]
4 for(i in 1:j) {
5   a=temp_table[i,1]
6   b=temp_table[i,2]
7   c=ControlCsum-a
8   d=TreatmentCsum-b
9
10  ORtable <- matrix(c(a,c,b,d),nrow = 2)
11  colnames(ORtable) <- c("Sham","Treatment")
12  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
13  print(row.names(temp_table)[i])
14  print(ORtable)
15  print(fisher.test(ORtable))
16 }
17
18 ## [1] "left"
19 ##      Sham Treatment
20 ## left   16      17
21 ## Other   8      6
22 ##
23 ## Fisher's Exact Test for Count Data
24 ##
25 ## data:  ORtable
26 ## p-value = 0.7516
27 ## alternative hypothesis: true odds ratio is not equal to 1
28 ## 95 percent confidence interval:
29 ##  0.1630989 2.9521011
30 ## sample estimates:
31 ## odds ratio
32 ##  0.7111464
33 ##
34 ## [1] "right"
35 ##      Sham Treatment
36 ## right   6      5
37 ## Other  18     18
38 ##
39 ## Fisher's Exact Test for Count Data
40 ##
41 ## data:  ORtable
42 ## p-value = 1
43 ## alternative hypothesis: true odds ratio is not equal to 1
44 ## 95 percent confidence interval:
45 ##  0.2513307 5.9379379
46 ## sample estimates:
47 ## odds ratio
48 ##  1.195355
49 ##
50 ## [1] "supine"
51 ##      Sham Treatment
52 ## supine   2      1
53 ## Other   22     22

```

```

1
2
3
4  ## Fisher's Exact Test for Count Data
5  ##
6  ## data: ORtable
7  ## p-value = 1
8  ## alternative hypothesis: true odds ratio is not equal to 1
9  ## 95 percent confidence interval:
10 ## 0.09605226 123.17436447
11 ## sample estimates:
12 ## odds ratio
13 ## 1.971677
14
15
16 #####SR SNORING#####
17 #summary data
18 summary(PBUFdata$SR.snored.last.night)
19
20 ##           don't know           no           yes
21 ##           3             26             8             3
22
23 length(PBUFdata$SR.snored.last.night)
24
25 ## [1] 40
26
27 #between participants (grouped) comparison
28 xtabs(~SR.snored.last.night + Intervention, data = PBUFdata)[-1,]
29
30 ##           Intervention
31 ## SR.snored.last.night sham treatment
32 ##           don't know    13         13
33 ##           no             4         4
34 ##           yes           1         2
35
36 #Perform Fisher's Exact Tests
37 temp_table <- xtabs(~SR.snored.last.night + Intervention, data = PBUFdata)[-1
38 ,]
39 j=nrow(temp_table)
40 ControlCsum=colSums(temp_table)[1]
41 TreatmentCsum=colSums(temp_table)[2]
42 for(i in 1:j) {
43   a=temp_table[i,1]
44   b=temp_table[i,2]
45   c=ControlCsum-a
46   d=TreatmentCsum-b
47   ORtable <- matrix(c(a,c,b,d),nrow = 2)
48   colnames(ORtable) <- c("Sham","Treatment")
49   rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
50   print(row.names(temp_table)[i])
51   print(ORtable)
52   print(fisher.test(ORtable))
53 }
54
55
56
57
58
59
60

```



```
1
2
3   ## [1] "don't know"
4   ##           Sham Treatment
5   ## don't know  13          13
6   ## Other      5           6
7   ##
8   ## Fisher's Exact Test for Count Data
9   ##
10  ## data: ORtable
11  ## p-value = 1
12  ## alternative hypothesis: true odds ratio is not equal to 1
13  ## 95 percent confidence interval:
14  ##  0.2341604 6.3402606
15  ## sample estimates:
16  ## odds ratio
17  ##    1.1941
18  ##
19  ## [1] "no"
20  ##           Sham Treatment
21  ## no         4           4
22  ## Other     14          15
23  ##
24  ## Fisher's Exact Test for Count Data
25  ##
26  ## data: ORtable
27  ## p-value = 1
28  ## alternative hypothesis: true odds ratio is not equal to 1
29  ## 95 percent confidence interval:
30  ##  0.1643428 6.9643241
31  ## sample estimates:
32  ## odds ratio
33  ##    1.06941
34  ##
35  ## [1] "yes"
36  ##           Sham Treatment
37  ## yes        1           2
38  ## Other     17          17
39  ##
40  ## Fisher's Exact Test for Count Data
41  ##
42  ## data: ORtable
43  ## p-value = 1
44  ## alternative hypothesis: true odds ratio is not equal to 1
45  ## 95 percent confidence interval:
46  ##  0.008017856 10.654170427
47  ## sample estimates:
48  ## odds ratio
49  ##    0.509154
```

```

#####SR LEGS TWITCH/JERK#####
#summary data
summary(PBUFdata$SR.legs.twitch.jerk)

##           don't know           no           yes
##           3             19           14           4

length(PBUFdata$SR.legs.twitch.jerk)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.legs.twitch.jerk + Intervention, data = PBUFdata)[-1,]

##           Intervention
## SR.legs.twitch.jerk sham treatment
##           don't know           9           10
##           no                 8           6
##           yes                 2           2

#Perform Fisher's Exact Tests
temp_table <- xtabs(~SR.legs.twitch.jerk + Intervention, data = PBUFdata)[-1,
]
j=nrow(temp_table)
ControlCsum=colSums(temp_table)[1]
TreatmentCsum=colSums(temp_table)[2]
for(i in 1:j) {
  a=temp_table[i,1]
  b=temp_table[i,2]
  c=ControlCsum-a
  d=TreatmentCsum-b
  ORtable <- matrix(c(a,c,b,d),nrow = 2)
  colnames(ORtable) <- c("Sham", "Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "don't know"
##           Sham Treatment
## don't know           9           10
## Other                 10           8
##
## Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7459
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1631369 3.1478545

```

```

1
2
3   ## sample estimates:
4   ## odds ratio
5   ## 0.7264619
6   ##
7   ## [1] "no"
8   ##      Sham Treatment
9   ## no      8          6
10  ## Other  11         12
11  ##
12  ## Fisher's Exact Test for Count Data
13  ##
14  ## data: ORtable
15  ## p-value = 0.7374
16  ## alternative hypothesis: true odds ratio is not equal to 1
17  ## 95 percent confidence interval:
18  ## 0.3156971 6.8777204
19  ## sample estimates:
20  ## odds ratio
21  ## 1.439815
22  ##
23  ## [1] "yes"
24  ##      Sham Treatment
25  ## yes      2          2
26  ## Other  17         16
27  ##
28  ## Fisher's Exact Test for Count Data
29  ##
30  ## data: ORtable
31  ## p-value = 1
32  ## alternative hypothesis: true odds ratio is not equal to 1
33  ## 95 percent confidence interval:
34  ## 0.06145761 14.45806216
35  ## sample estimates:
36  ## odds ratio
37  ## 0.9426919
38
39  #####SR WAKE POSITION#####
40  #summary data
41  summary(PBUFdata$SR.position.woke.up)
42
43  ##      left right
44  ##      0      28      12
45
46  length(PBUFdata$SR.position.woke.up)
47
48  ## [1] 40
49
50  #between participants (grouped) comparison
51  xtabs(~SR.position.woke.up + Intervention, data = PBUFdata)[-1,]
52
53
54
55
56
57
58
59
60

```

```

1
2
3      ##              Intervention
4      ## SR.position.woke.up sham treatment
5      ##           left      13      15
6      ##           right     7       5
7
8      fisher.test(xtabs(~SR.position.woke.up + Intervention, data = PBUFdata)[-1,])
9
10     ##
11     ## Fisher's Exact Test for Count Data
12     ##
13     ## data:
14     ## p-value = 0.7311
15     ## alternative hypothesis: true odds ratio is not equal to 1
16     ## 95 percent confidence interval:
17     ##  0.1235598 2.9574108
18     ## sample estimates:
19     ## odds ratio
20     ##  0.6265621
21
22
23     #####SR - did you change positions?#####
24     #####
25     #summary data
26     summary(PBUFdata$SR.position.changed)
27
28     ##              don\xcdt know          no          yes
29     ##              1              1          3          35
30
31     length(PBUFdata$SR.position.changed)
32
33     ## [1] 40
34
35     #between participants (grouped) comparison
36     xtabs(~SR.position.changed + Intervention, data = PBUFdata)[-1,]
37
38     ##              Intervention
39     ## SR.position.changed sham treatment
40     ## don\xcdt know      1      0
41     ## no                 1      2
42     ## yes                 18     17
43
44     #Perform Fisher's Exact Tests
45     temp_table <- xtabs(~SR.position.changed + Intervention, data = PBUFdata)[-1,
46 ]
47     j=nrow(temp_table)
48     ControlCsum=colSums(temp_table)[1]
49     TreatmentCsum=colSums(temp_table)[2]
50     for(i in 1:j) {
51       a=temp_table[i,1]
52       b=temp_table[i,2]
53       c=ControlCsum-a
54       d=TreatmentCsum-b
55       ORtable <- matrix(c(a,c,b,d),nrow = 2)
56
57
58
59
60

```

```

1
2
3   colnames(ORtable) <- c("Sham", "Treatment")
4   rownames(ORtable) <- c(row.names(temp_table)[i], "Other")
5   print(row.names(temp_table)[i])
6   print(ORtable)
7   print(fisher.test(ORtable))
8
9 }
10
11 ## [1] "don\xcdt know"
12 ##           Sham Treatment
13 ## don\xcdt know   1         0
14 ## Other           19        19
15 ##
16 ## Fisher's Exact Test for Count Data
17 ##
18 ## data:  ORtable
19 ## p-value = 1
20 ## alternative hypothesis: true odds ratio is not equal to 1
21 ## 95 percent confidence interval:
22 ##  0.02435859      Inf
23 ## sample estimates:
24 ## odds ratio
25 ##           Inf
26 ##
27 ## [1] "no"
28 ##           Sham Treatment
29 ## no           1           2
30 ## Other       19          17
31 ##
32 ## Fisher's Exact Test for Count Data
33 ##
34 ## data:  ORtable
35 ## p-value = 0.605
36 ## alternative hypothesis: true odds ratio is not equal to 1
37 ## 95 percent confidence interval:
38 ##  0.007216433  9.507277143
39 ## sample estimates:
40 ## odds ratio
41 ##  0.456456
42 ##
43 ## [1] "yes"
44 ##           Sham Treatment
45 ## yes          18          17
46 ## Other         2           2
47 ##
48 ## Fisher's Exact Test for Count Data
49 ##
50 ## data:  ORtable
51 ## p-value = 1
52 ## alternative hypothesis: true odds ratio is not equal to 1
53 ## 95 percent confidence interval:

```

```

1
2
3 ## 0.0693477 16.1216542
4 ## sample estimates:
5 ## odds ratio
6 ## 1.057301
7
8 #Take out the pts that we don't have complete data on (these participants' st
9 udies were
10 #before the PUFQ was revised to ask about the participant's estimate of how m
11 uch time
12 #she spent in each position)
13 PBUF_shamSRpos <- PBUF_sham[-c(1,2,3),]
14 PBUF_treatSRpos <- PBUF_treat[-c(1,2,3),]
15
16 #####SR PROPORTION OF TIME ON LEFT#####
17 #####
18 #summary data
19 summary(PBUFdata$SR.Ptime.left)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
22 ##      0.00  41.50   66.00   59.91  84.00  100.00     5
23
24 sd(PBUFdata$SR.Ptime.left, na.rm = TRUE)
25
26 ## [1] 28.14915
27
28 length(na.omit(PBUFdata$SR.Ptime.left))
29
30 ## [1] 35
31
32 #within-participants (paired) comparison
33 #Paired t-test
34 t.test(PBUF_shamSRpos$SR.Ptime.left, PBUF_treatSRpos$SR.Ptime.left, paired =
35 TRUE)
36
37 ##
38 ## Paired t-test
39 ##
40 ## data: PBUF_shamSRpos$SR.Ptime.left and PBUF_treatSRpos$SR.Ptime.left
41 ## t = 0.38979, df = 16, p-value = 0.7018
42 ## alternative hypothesis: true difference in means is not equal to 0
43 ## 95 percent confidence interval:
44 ## -6.266297  9.089826
45 ## sample estimates:
46 ## mean of the differences
47 ## 1.411765
48
49 #between participants (grouped) comparison
50 summary(PBUF_treatSRpos$SR.Ptime.left)
51
52 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
53 ##      10.00  36.00   60.00   58.76  85.00   95.00
54
55
56
57
58
59
60

```

```

sd(PBUF_treatSRpos$SR.Ptime.left)

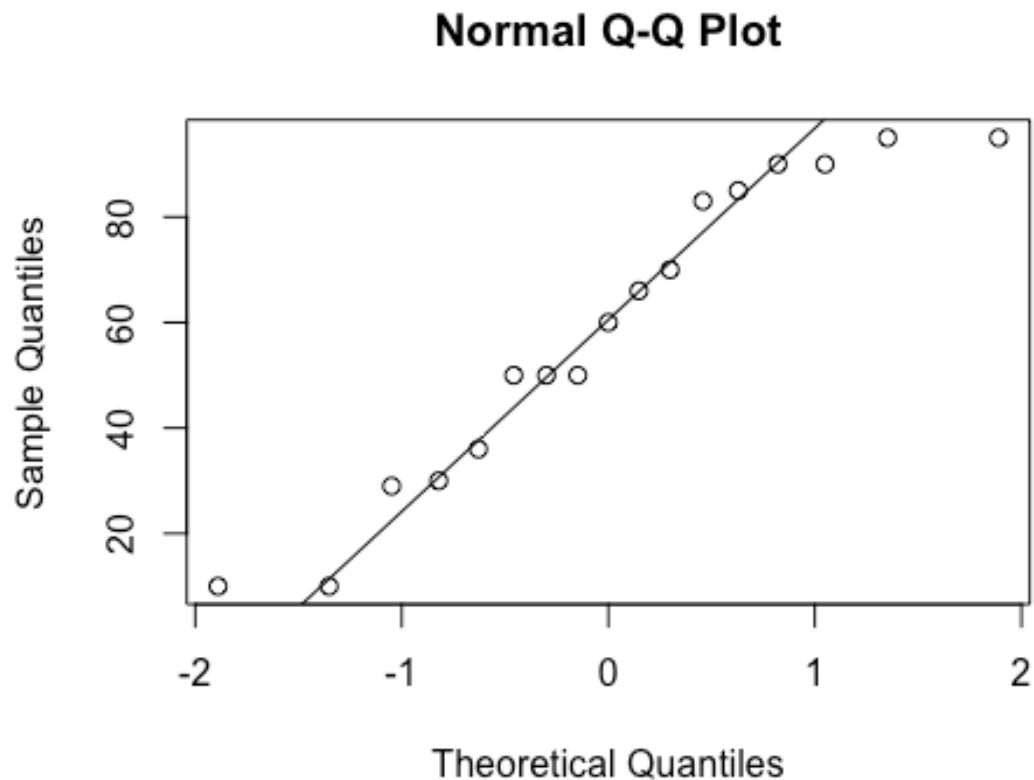
## [1] 28.77831

length(PBUF_treatSRpos$SR.Ptime.left)

## [1] 17

qqnorm(PBUF_treatSRpos$SR.Ptime.left)
qqline(PBUF_treatSRpos$SR.Ptime.left)

```



```

ad.test(PBUF_treatSRpos$SR.Ptime.left)

##
## Anderson-Darling normality test
##
## data: PBUF_treatSRpos$SR.Ptime.left
## A = 0.40809, p-value = 0.3093

#normal

summary(PBUF_shamSRpos$SR.Ptime.left)

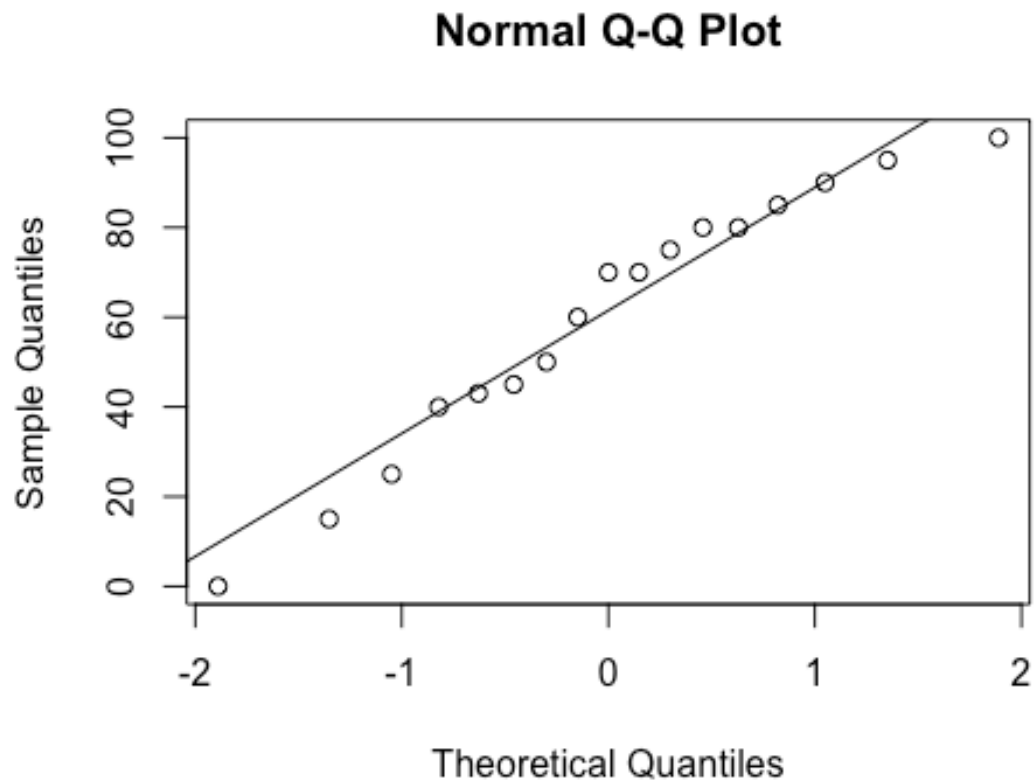
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.00  43.00   70.00   60.18  80.00  100.00

```

```
sd(PBUF_shamSRpos$SR.Ptime.left)
## [1] 28.9811

length(PBUF_shamSRpos$SR.Ptime.left)
## [1] 17

qqnorm(PBUF_shamSRpos$SR.Ptime.left)
qqline(PBUF_shamSRpos$SR.Ptime.left)
```



```
ad.test(PBUF_shamSRpos$SR.Ptime.left)
##
## Anderson-Darling normality test
##
## data: PBUF_shamSRpos$SR.Ptime.left
## A = 0.31945, p-value = 0.506

#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_shamSRpos$SR.Ptime.left, PBUF_treatSRpos$SR.Ptime.left)
```



```

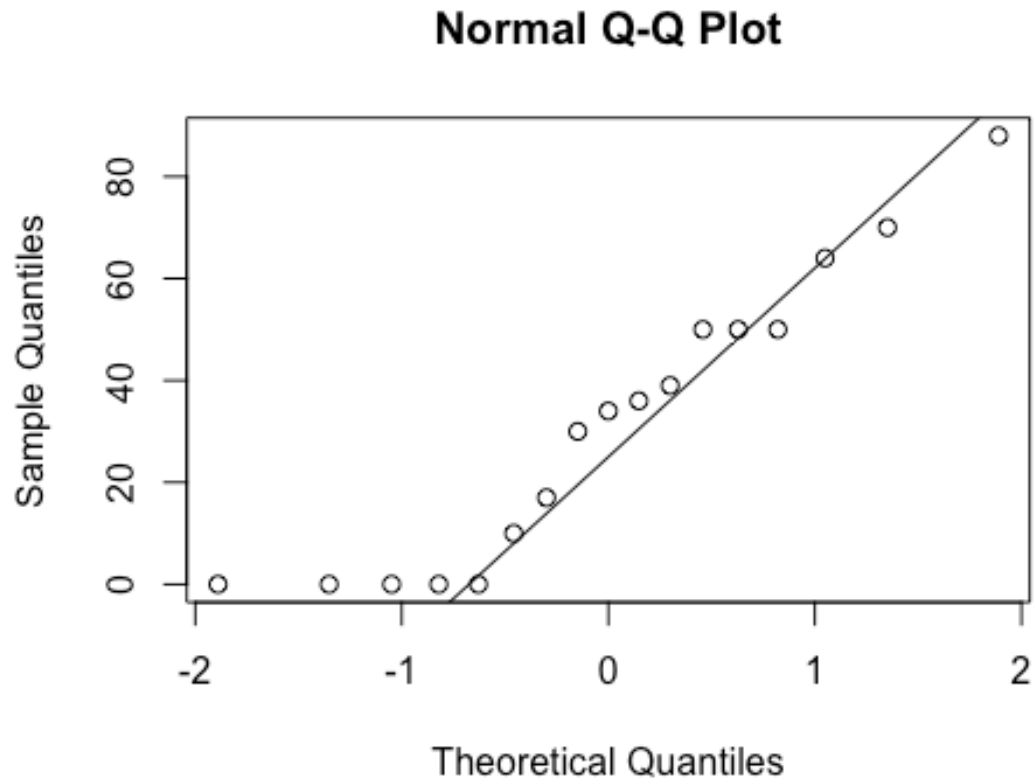
1
2
3
4  ##
5  ## Welch Two Sample t-test
6  ##
7  ## data: PBUF_shamSRpos$SR.Ptime.left and PBUF_treatSRpos$SR.Ptime.left
8  ## t = 0.14252, df = 31.998, p-value = 0.8876
9  ## alternative hypothesis: true difference in means is not equal to 0
10 ## 95 percent confidence interval:
11 ## -18.76556 21.58909
12 ## sample estimates:
13 ## mean of x mean of y
14 ## 60.17647 58.76471
15
16 #####SR PROPORTION OF TIME ON RIGHT#####
17 #####
18 #summary data
19 summary(PBUFdata$SR.Ptime.right)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.     NA's
22 ##      0.00   2.50   30.00   31.29   50.00   90.00      5
23
24 sd(PBUFdata$SR.Ptime.right, na.rm = TRUE)
25
26 ## [1] 27.30177
27
28 length(na.omit(PBUFdata$SR.Ptime.right))
29
30 ## [1] 35
31
32 #within-participants (paired) comparison
33 #Paired t-test
34 t.test(PBUF_shamSRpos$SR.Ptime.right, PBUF_treatSRpos$SR.Ptime.right, paired
35 = TRUE)
36
37 ##
38 ## Paired t-test
39 ##
40 ## data: PBUF_shamSRpos$SR.Ptime.right and PBUF_treatSRpos$SR.Ptime.right
41 ## t = -0.10277, df = 16, p-value = 0.9194
42 ## alternative hypothesis: true difference in means is not equal to 0
43 ## 95 percent confidence interval:
44 ## -7.633106 6.927224
45 ## sample estimates:
46 ## mean of the differences
47 ##                -0.3529412
48
49 #between participants (grouped) comparison
50 summary(PBUF_treatSRpos$SR.Ptime.right)
51
52 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
53 ##      0.00   0.00   34.00   31.65   50.00   88.00
54
55 sd(PBUF_treatSRpos$SR.Ptime.right)
56
57
58
59
60

```

```

1
2
3 ## [1] 27.92387
4
5 length(PBUF_treatSRpos$SR.Ptime.right)
6
7 ## [1] 17
8
9 qqnorm(PBUF_treatSRpos$SR.Ptime.right)
10 qqline(PBUF_treatSRpos$SR.Ptime.right)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

```



```

41 ad.test(PBUF_treatSRpos$SR.Ptime.right)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: PBUF_treatSRpos$SR.Ptime.right
47 ## A = 0.51449, p-value = 0.1649
48
49 #normal
50
51 summary(PBUF_shamSRpos$SR.Ptime.right)
52
53 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
54 ##      0.00   5.00   30.00   31.29   50.00   90.00
55
56 sd(PBUF_shamSRpos$SR.Ptime.right)
57
58
59
60

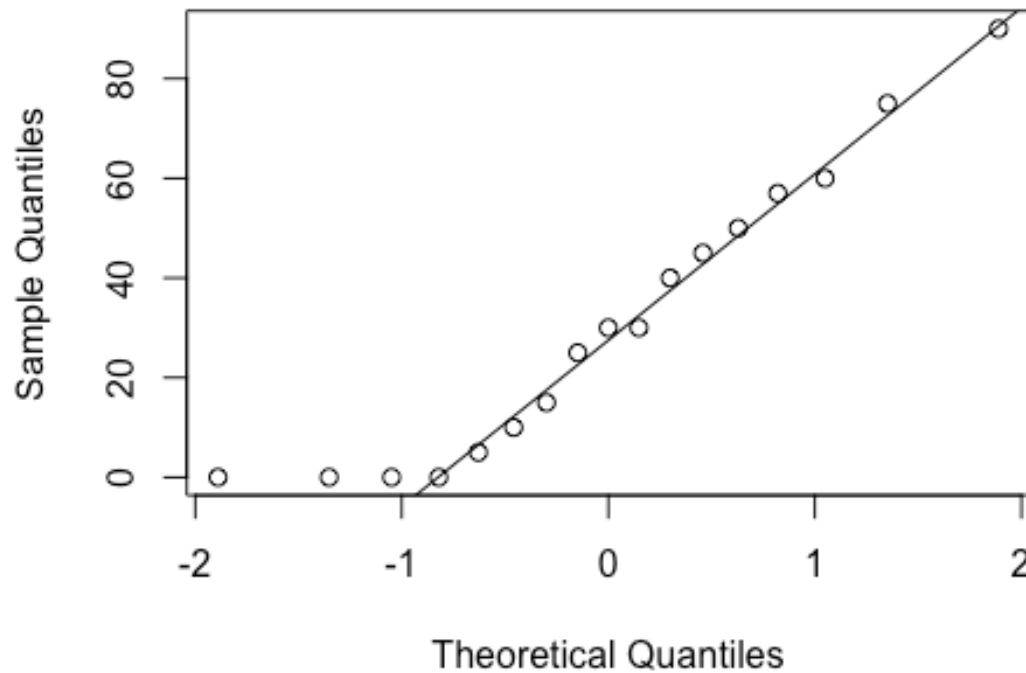
```

```

1
2
3 ## [1] 28.31246
4
5 length(PBUF_shamSRpos$SR.Ptime.right)
6
7 ## [1] 17
8
9 qqnorm(PBUF_shamSRpos$SR.Ptime.right)
10 qqline(PBUF_shamSRpos$SR.Ptime.right)
11
12
13
14
15
16

```

Normal Q-Q Plot



```

36
37
38
39
40
41 ad.test(PBUF_shamSRpos$SR.Ptime.right)
42
43 ##
44 ## Anderson-Darling normality test
45 ##
46 ## data: PBUF_shamSRpos$SR.Ptime.right
47 ## A = 0.43793, p-value = 0.2602
48
49 #normal
50
51 #Perform 2-sample t-test (Welch's t-test)
52 t.test(PBUF_shamSRpos$SR.Ptime.right, PBUF_treatSRpos$SR.Ptime.right)
53
54 ##
55 ## Welch Two Sample t-test
56
57
58
59
60

```

```

1
2
3
4  ##
5  ## data: PBUF_shamSRpos$SR.Ptime.right and PBUF_treatSRpos$SR.Ptime.right
6  ## t = -0.036594, df = 31.994, p-value = 0.971
7  ## alternative hypothesis: true difference in means is not equal to 0
8  ## 95 percent confidence interval:
9  ## -19.99866 19.29278
10 ## sample estimates:
11 ## mean of x mean of y
12 ## 31.29412 31.64706
13
14 #####SR PROPORTION OF TIME ON BACK#####
15 #####
16 #summary data
17 summary(PBUFdata$SR.Ptime.back)
18
19 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
20 ##      0.0     0.0     0.0     7.8     5.0    90.0     5
21
22 sd(PBUFdata$SR.Ptime.back, na.rm = TRUE)
23
24 ## [1] 19.98205
25
26 length(na.omit(PBUFdata$SR.Ptime.back))
27
28 ## [1] 35
29
30 #within-participants (paired) comparison - non-normal, use parametric test (Wilcoxon)
31 wilcox.test(PBUF_shamSRpos$SR.Ptime.back, PBUF_treatSRpos$SR.Ptime.back,
32              paired = TRUE, conf.int = TRUE)
33
34 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
35 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with ties
36
37 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
38 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence interval
39 ## with ties
40
41 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
42 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with zeroes
43
44 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
45 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence interval
46 ## with zeroes
47
48 ##
49 ## Wilcoxon signed rank test with continuity correction
50 ##
51 ## data: PBUF_shamSRpos$SR.Ptime.back and PBUF_treatSRpos$SR.Ptime.back
52 ## V = 18.5, p-value = 0.4951
53 ## alternative hypothesis: true location shift is not equal to 0
54 ## 95 percent confidence interval:
55
56
57
58
59
60

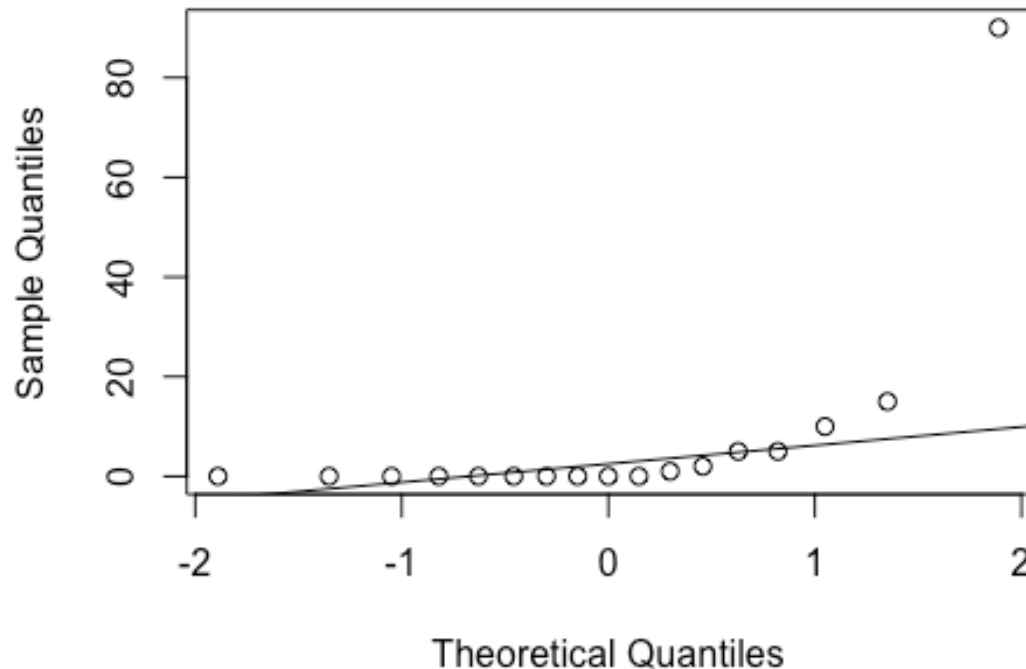
```

```

1
2
3 ## -7.499958 8.999966
4 ## sample estimates:
5 ## (pseudo)median
6 ## 4.090518
7
8 #between participants (grouped) comparison
9 summary(PBUF_treatSRpos$SR.Ptime.back)
10
11 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
12 ## 0.000 0.000 0.000 7.529 5.000 90.000
13
14 sd(PBUF_treatSRpos$SR.Ptime.back)
15
16 ## [1] 21.67406
17
18 length(PBUF_treatSRpos$SR.Ptime.back)
19
20 ## [1] 17
21
22 qqnorm(PBUF_treatSRpos$SR.Ptime.back)
23 qqline(PBUF_treatSRpos$SR.Ptime.back)

```

Normal Q-Q Plot



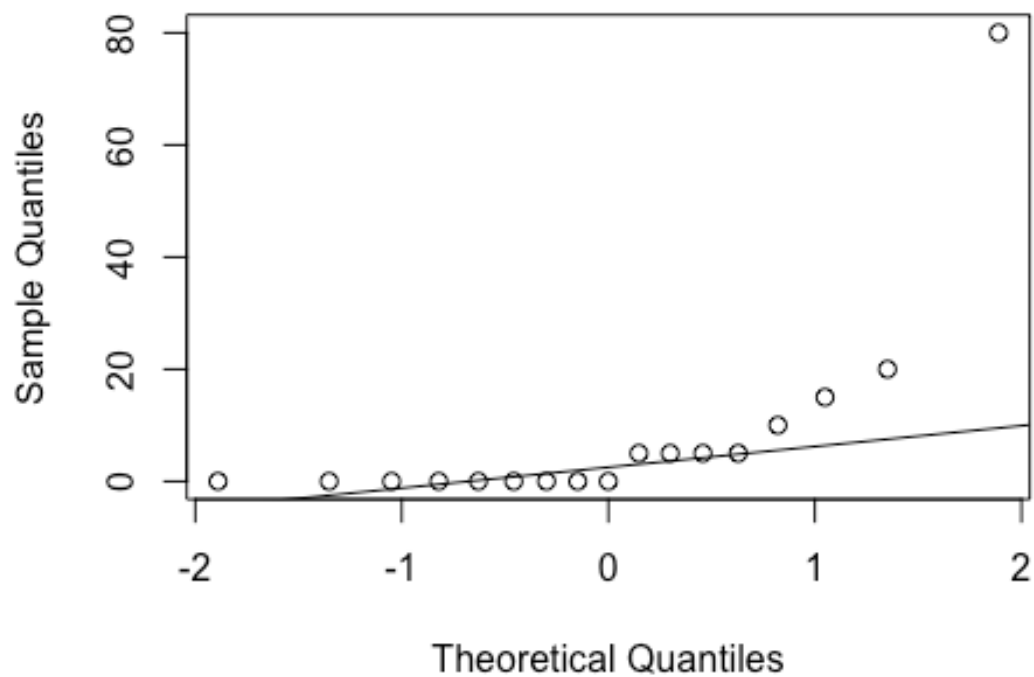
```

54 ad.test(PBUF_treatSRpos$SR.Ptime.back)
55
56
57
58
59
60

```

```
##
## Anderson-Darling normality test
##
## data: PBUF_treatSRpos$SR.Ptime.back
## A = 4.2859, p-value = 3.533e-11
#non-normal
summary(PBUF_shamSRpos$SR.Ptime.back)
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0.000  0.000  0.000   8.529  5.000  80.000
sd(PBUF_shamSRpos$SR.Ptime.back)
## [1] 19.34592
length(PBUF_shamSRpos$SR.Ptime.back)
## [1] 17
qqnorm(PBUF_shamSRpos$SR.Ptime.back)
qqline(PBUF_shamSRpos$SR.Ptime.back)
```

Normal Q-Q Plot



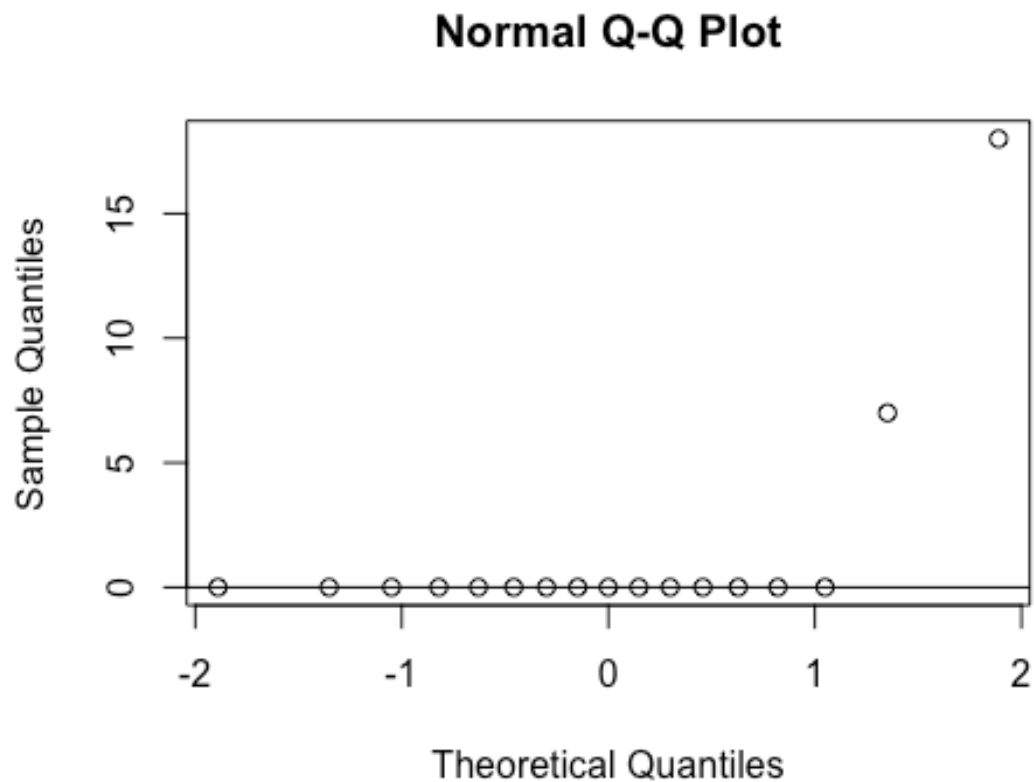
```
ad.test(PBUF_shamSRpos$SR.Ptime.back)
```

```

1
2
3  ##
4  ## Anderson-Darling normality test
5  ##
6  ## data: PBUF_shamSRpos$SR.Ptime.back
7  ## A = 3.3048, p-value = 1.097e-08
8
9  #non-normal
10
11
12 #Perform non-parametric test (Wilcoxon)
13 wilcox.test(PBUF_shamSRpos$SR.Ptime.back, PBUF_treatSRpos$SR.Ptime.back, conf
14 .int = TRUE)
15
16 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
17 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with ties
18
19 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
20 ## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence intervals
21 ## with ties
22
23 ##
24 ## Wilcoxon rank sum test with continuity correction
25 ##
26 ## data: PBUF_shamSRpos$SR.Ptime.back and PBUF_treatSRpos$SR.Ptime.back
27 ## W = 159, p-value = 0.5944
28 ## alternative hypothesis: true location shift is not equal to 0
29 ## 95 percent confidence interval:
30 ## -3.745025e-05  4.999982e+00
31 ## sample estimates:
32 ## difference in location
33 ##          3.7504e-05
34
35 #####SR PROPORTION OF TIME ON STOMACH#####
36 #####
37 #summary data
38 summary(PBUFdata$SR.Ptime.stomach)
39
40 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.   NA's
41 ##  0.0000  0.0000  0.0000  0.7143  0.0000  18.0000     5
42
43 sd(PBUFdata$SR.Ptime.stomach, na.rm = TRUE)
44
45 ## [1] 3.231931
46
47 length(na.omit(PBUFdata$SR.Ptime.stomach))
48
49 ## [1] 35
50
51 #within-participants (paired) comparison - non-normal, use parametric test (W
52 ilcoxon)
53 wilcox.test(PBUF_shamSRpos$SR.Ptime.stomach, PBUF_treatSRpos$SR.Ptime.stomach
54 ,
55           paired = TRUE)
56
57
58
59
60

```

```
1
2
3 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.stomach,
4 ## PBUF_treatSRpos$SR.Ptime.stomach, : cannot compute exact p-value with
5 ## zeroes
6
7 ##
8 ## Wilcoxon signed rank test with continuity correction
9 ##
10 ## data: PBUF_shamSRpos$SR.Ptime.stomach and PBUF_treatSRpos$SR.Ptime.stomac
11 h
12 ## V = 0, p-value = 0.3711
13 ## alternative hypothesis: true location shift is not equal to 0
14
15 #between participants (grouped) comparison
16 summary(PBUF_treatSRpos$SR.Ptime.stomach)
17
18 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
19 ##      0.000  0.000  0.000   1.471  0.000  18.000
20
21 sd(PBUF_treatSRpos$SR.Ptime.stomach)
22
23 ## [1] 4.58418
24
25 length(PBUF_treatSRpos$SR.Ptime.stomach)
26
27 ## [1] 17
28
29 qqnorm(PBUF_treatSRpos$SR.Ptime.stomach)
30 qqline(PBUF_treatSRpos$SR.Ptime.stomach)
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
```

```

ad.test(PBUF_treatSRpos$SR.Ptime.stomach)

##
## Anderson-Darling normality test
##
## data: PBUF_treatSRpos$SR.Ptime.stomach
## A = 4.9879, p-value = 5.961e-13
##
#non-normal

summary(PBUF_shamSRpos$SR.Ptime.stomach)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      0         0         0         0         0         0

sd(PBUF_shamSRpos$SR.Ptime.stomach)

## [1] 0

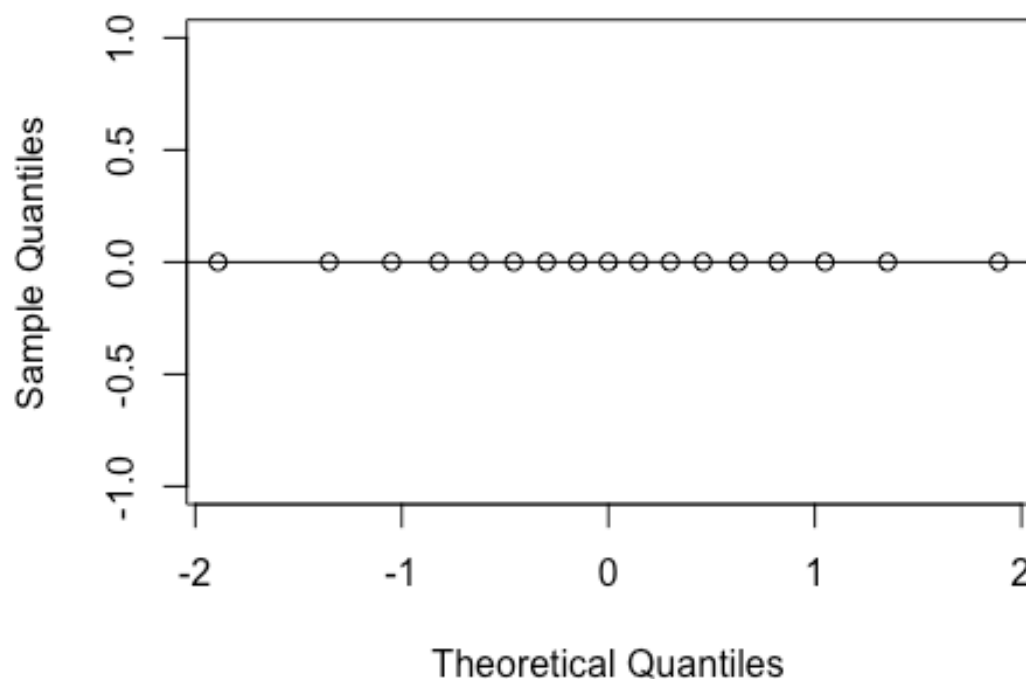
length(PBUF_shamSRpos$SR.Ptime.stomach)

## [1] 17

qqnorm(PBUF_shamSRpos$SR.Ptime.stomach)
qqline(PBUF_shamSRpos$SR.Ptime.stomach)

```

Normal Q-Q Plot



```

32 #ad.test(PBUF_shamSRpos$SR.Ptime.stomach)
33 #distribution is entirely zeroes
34
35 #Perform non-parametric test (Wilcoxon)
36 wilcox.test(PBUF_shamSRpos$SR.Ptime.stomach, PBUF_treatSRpos$SR.Ptime.stomach
37 , conf.int = TRUE)
38
39 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.stomach,
40 ## PBUF_treatSRpos$SR.Ptime.stomach, : cannot compute exact p-value with ties
41
42 ## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.stomach,
43 ## PBUF_treatSRpos$SR.Ptime.stomach, : cannot compute exact confidence
44 ## intervals with ties
45
46 ##
47 ## Wilcoxon rank sum test with continuity correction
48 ##
49 ## data: PBUF_shamSRpos$SR.Ptime.stomach and PBUF_treatSRpos$SR.Ptime.stomach
50 h
51 ## W = 127.5, p-value = 0.1635
52 ## alternative hypothesis: true location shift is not equal to 0
53 ## 95 percent confidence interval:
54 ## -7.272004e-05 0.000000e+00
55 ## sample estimates:
56

```

```

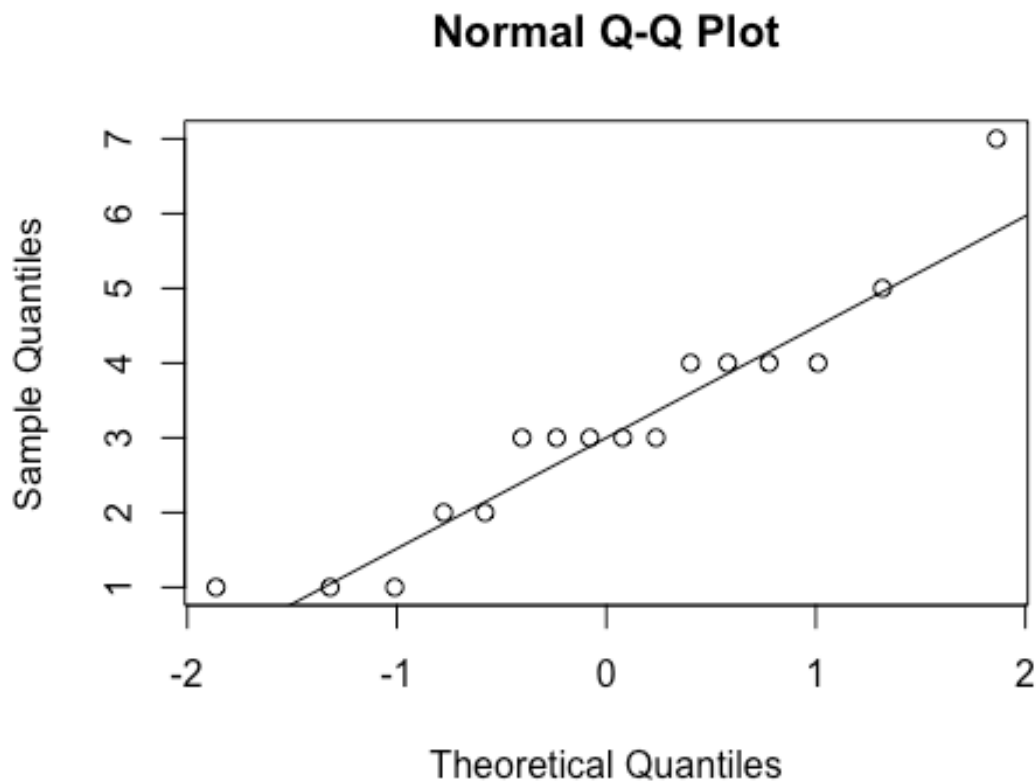
1
2
3  ## difference in location
4  ##           0
5
6  #####REMEMBER CHANGING POSITIONS#####
7  #####
8  #summary data
9  summary(PBUFdata$remember.changing.positions)
10
11  ##      no yes
12  ##    0  7 33
13
14  length(PBUFdata$remember.changing.positions)
15
16  ## [1] 40
17
18  #between participants (grouped) comparison
19  xtabs(~remember.changing.positions + Intervention, data = PBUFdata)[-1,]
20
21  ##                Intervention
22  ## remember.changing.positions sham treatment
23  ##                no      4      3
24  ##                yes     16     17
25
26  fisher.test(xtabs(~remember.changing.positions + Intervention, data = PBUFdata)[-1,])
27
28
29  ##
30  ## Fisher's Exact Test for Count Data
31  ##
32  ## data:
33  ## p-value = 1
34  ## alternative hypothesis: true odds ratio is not equal to 1
35  ## 95 percent confidence interval:
36  ##  0.2020801 11.1277720
37  ## sample estimates:
38  ## odds ratio
39  ##  1.404393
40
41  #Remove rows with missing data or with participants who did not change position or did
42  #not remember changing positions
43  PBUF_shamSRchangeupos <- PBUF_sham[-c(1,5,6,7,14,19),]
44  PBUF_treatSRchangeupos <- PBUF_treat[-c(1,5,6,7,14,19),]
45
46  #####SR NUMBER OF TIMES CHANGED POSITION#####
47  #####
48  #summary data
49  summary(PBUFdata$SR.how.many.times.changed.positions)
50
51  ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
52  ##    0.000  2.000  3.000  3.194  4.000  7.000     9
53
54
55
56
57
58
59
60

```

```

1
2
3 sd(PBUFdata$SR.how.many.times.changed.positions, na.rm = TRUE)
4
5 ## [1] 1.740103
6
7 length(na.omit(PBUFdata$SR.how.many.times.changed.positions))
8
9 ## [1] 31
10
11 #within-participants (paired) comparison
12 #Paired t-test
13 t.test(PBUF_shamSRchangeupos$SR.how.many.times.changed.positions,
14        PBUF_treatSRchangeupos$SR.how.many.times.changed.positions,
15        paired = TRUE)
16
17 ##
18 ## Paired t-test
19 ##
20 ## data: PBUF_shamSRchangeupos$SR.how.many.times.changed.positions and PBUF_t
21 reatSRchangeupos$SR.how.many.times.changed.positions
22 ## t = 0.31382, df = 13, p-value = 0.7586
23 ## alternative hypothesis: true difference in means is not equal to 0
24 ## 95 percent confidence interval:
25 ## -0.8405766 1.1262909
26 ## sample estimates:
27 ## mean of the differences
28 ## 0.1428571
29
30 #between participants (grouped) comparison
31 summary(PBUF_treat$SR.how.many.times.changed.positions)
32
33 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
34 ##      1.000  2.000  3.000  3.125  4.000  7.000     4
35
36 sd(PBUF_treat$SR.how.many.times.changed.positions, na.rm = TRUE)
37
38 ## [1] 1.586401
39
40 length(na.omit(PBUF_treat$SR.how.many.times.changed.positions))
41
42 ## [1] 16
43
44 qqnorm(PBUF_treat$SR.how.many.times.changed.positions)
45 qqline(PBUF_treat$SR.how.many.times.changed.positions)
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

```



```

ad.test(PBUF_treat$SR.how.many.times.changed.positions)

##
## Anderson-Darling normality test
##
## data: PBUF_treat$SR.how.many.times.changed.positions
## A = 0.51178, p-value = 0.1658

#normal

summary(PBUF_sham$SR.how.many.times.changed.positions)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.   NA's
##  0.000  1.500   4.000   3.267  4.500   7.000     5

sd(PBUF_sham$SR.how.many.times.changed.positions, na.rm = TRUE)

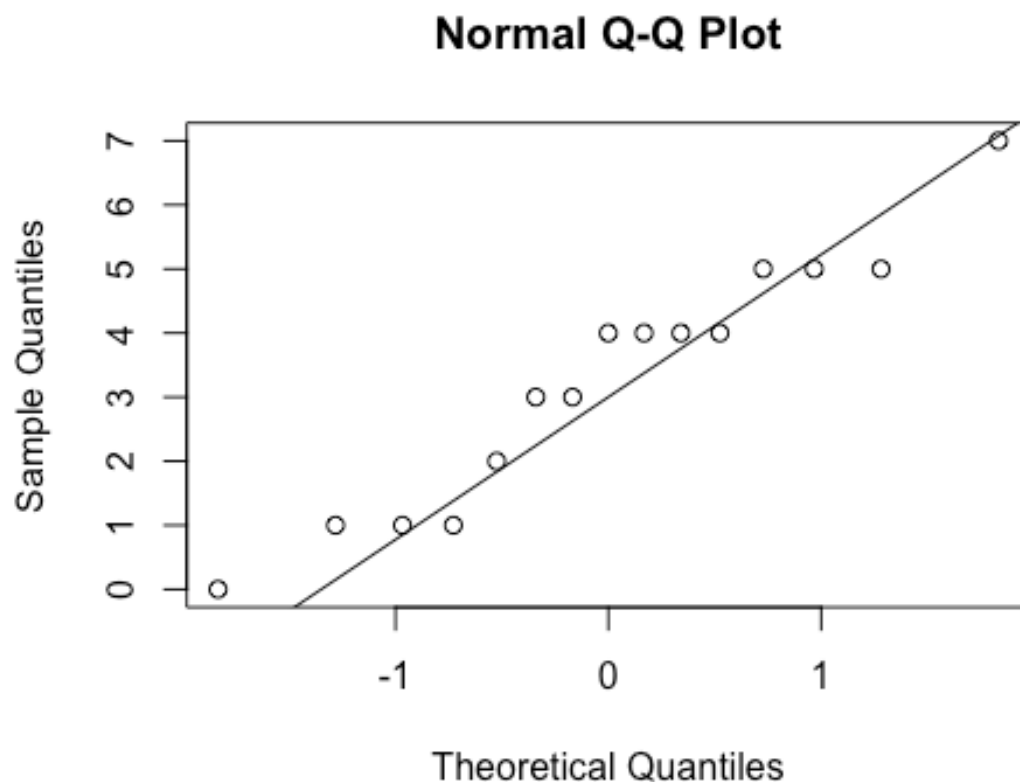
## [1] 1.944467

length(na.omit(PBUF_sham$SR.how.many.times.changed.positions))

## [1] 15

qqnorm(PBUF_sham$SR.how.many.times.changed.positions)
qqline(PBUF_sham$SR.how.many.times.changed.positions)

```



```

ad.test(PBUF_sham$SR.how.many.times.changed.positions)

##
## Anderson-Darling normality test
##
## data: PBUF_sham$SR.how.many.times.changed.positions
## A = 0.41783, p-value = 0.287

#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_sham$SR.how.many.times.changed.positions,
       PBUF_treat$SR.how.many.times.changed.positions)

##
## Welch Two Sample t-test
##
## data: PBUF_sham$SR.how.many.times.changed.positions and PBUF_treat$SR.how
## .many.times.changed.positions
## t = 0.22142, df = 27.082, p-value = 0.8264
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -1.170927 1.454261
## sample estimates:

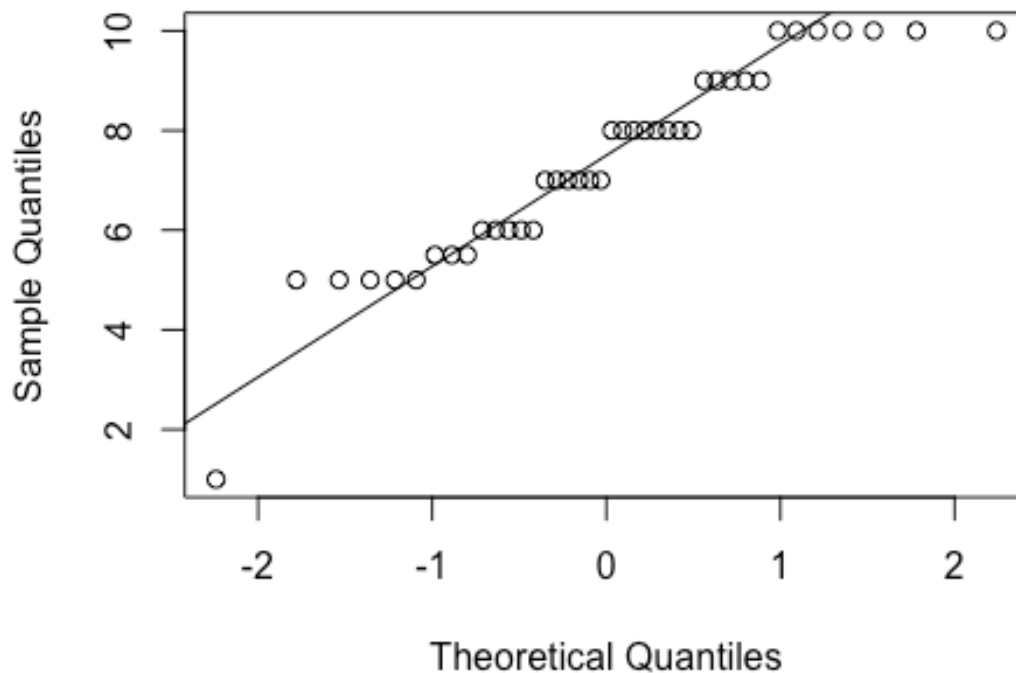
```

```

1
2
3 ## mean of x mean of y
4 ## 3.266667 3.125000
5
6 #####SATISFACTION LEVEL#####
7 #summary data
8 summary(PBUFdata$satisfaction.level)
9
10 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11 ##  1.000   6.000   7.500   7.338   9.000  10.000
12
13 sd(PBUFdata$satisfaction.level)
14
15 ## [1] 1.988388
16
17 length(PBUFdata$satisfaction.level)
18
19 ## [1] 40
20
21 qqnorm(PBUFdata$satisfaction.level)
22 qqline(PBUFdata$satisfaction.level)

```

Normal Q-Q Plot



```

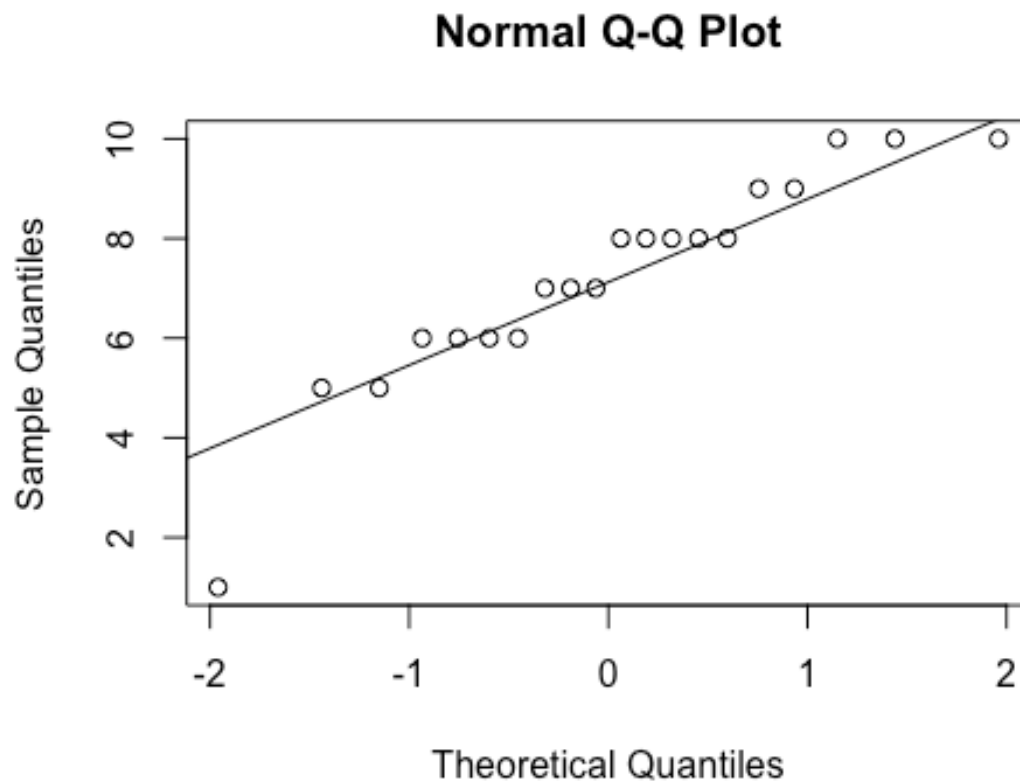
52 ad.test(PBUFdata$satisfaction.level)
53
54 ##
55 ## Anderson-Darling normality test
56
57
58
59
60

```

```

1
2
3 ##
4 ## data: PBUFdata$satisfaction.level
5 ## A = 0.79381, p-value = 0.03625
6
7 #within-participants (paired) comparison
8 #t-test (individual distributions are normal)
9 t.test(PBUF_sham$satisfaction.level,PBUF_treat$satisfaction.level, paired = T
10 RUE)
11
12 ##
13 ## Paired t-test
14 ##
15 ## data: PBUF_sham$satisfaction.level and PBUF_treat$satisfaction.level
16 ## t = 0.74891, df = 19, p-value = 0.4631
17 ## alternative hypothesis: true difference in means is not equal to 0
18 ## 95 percent confidence interval:
19 ## -0.4935575 1.0435575
20 ## sample estimates:
21 ## mean of the differences
22 ## 0.275
23
24 #between participants (grouped) comparison
25 summary(PBUF_treat$satisfaction.level)
26
27 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
28 ##      1.00   6.00   7.50   7.20   8.25   10.00
29
30 sd(PBUF_treat$satisfaction.level, na.rm = TRUE)
31
32 ## [1] 2.142306
33
34 length(na.omit(PBUF_treat$satisfaction.level))
35
36 ## [1] 20
37
38 qqnorm(PBUF_treat$satisfaction.level)
39 qqline(PBUF_treat$satisfaction.level)
40
41
42
43
44
45
46
47
48
49
50
51
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60

```

```

ad.test(PBUF_treat$satisfaction.level)

##
## Anderson-Darling normality test
##
## data: PBUF_treat$satisfaction.level
## A = 0.54062, p-value = 0.1445

#normal

summary(PBUF_sham$satisfaction.level)

##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  5.000  5.500   7.500   7.475  9.000  10.000

sd(PBUF_sham$satisfaction.level, na.rm = TRUE)

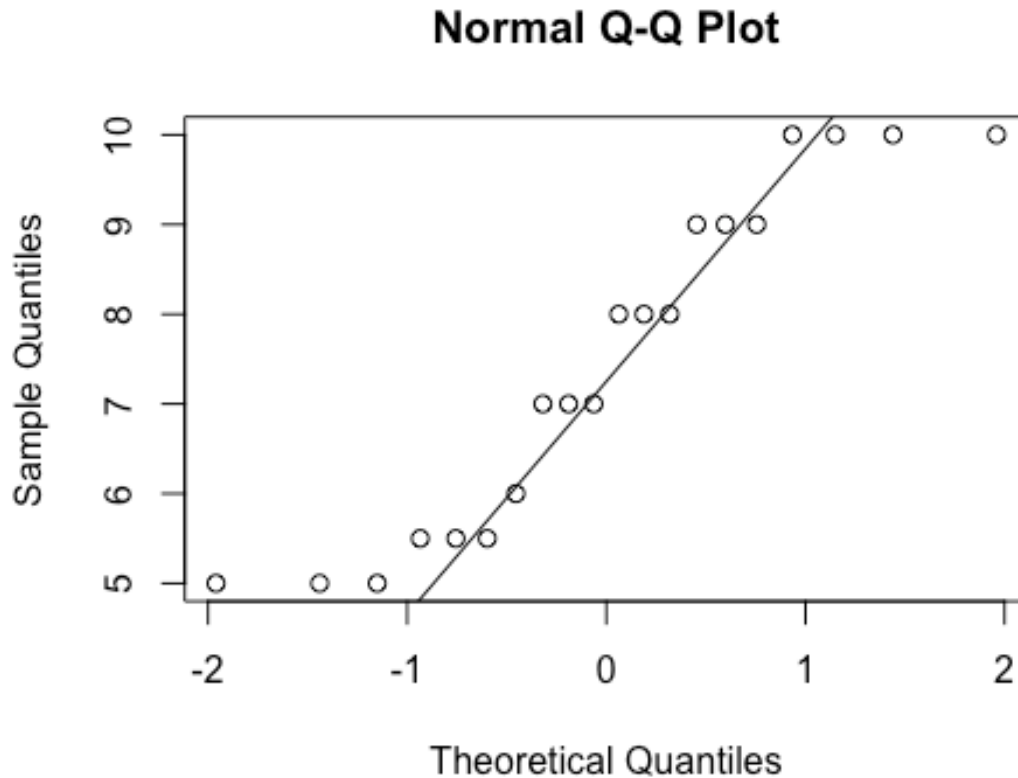
## [1] 1.867133

length(na.omit(PBUF_sham$satisfaction.level))

## [1] 20

qqnorm(PBUF_sham$satisfaction.level)
qqline(PBUF_sham$satisfaction.level)

```



```

ad.test(PBUF_sham$satisfaction.level)

##
## Anderson-Darling normality test
##
## data: PBUF_sham$satisfaction.level
## A = 0.69241, p-value = 0.0596

#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_sham$satisfaction.level,
       PBUF_treat$satisfaction.level)

##
## Welch Two Sample t-test
##
## data: PBUF_sham$satisfaction.level and PBUF_treat$satisfaction.level
## t = 0.43277, df = 37.304, p-value = 0.6677
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -1.012168 1.562168
## sample estimates:

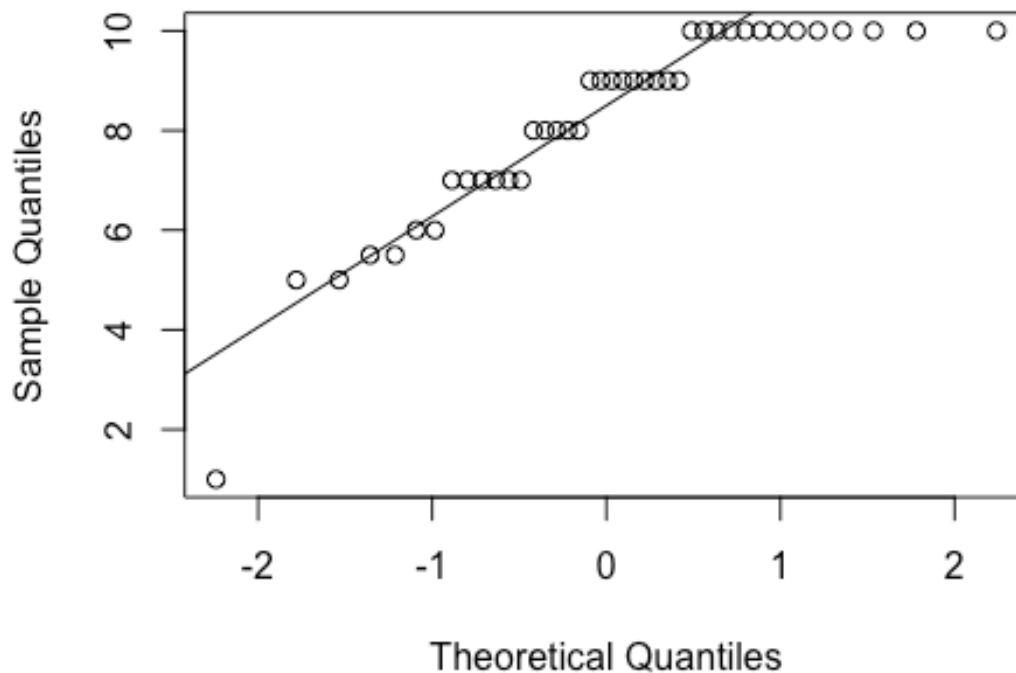
```

```

1
2
3  ## mean of x mean of y
4  ##      7.475      7.200
5
6  #####COMFORT LEVEL#####
7  #summary data
8  summary(PBUFdata$comfort.level)
9
10 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
11 ##      1.000   7.000   9.000   8.175  10.000  10.000
12
13 sd(PBUFdata$comfort.level)
14
15 ## [1] 1.982455
16
17 length(PBUFdata$comfort.level)
18
19 ## [1] 40
20
21 qqnorm(PBUFdata$comfort.level)
22 qqline(PBUFdata$comfort.level)

```

Normal Q-Q Plot



```

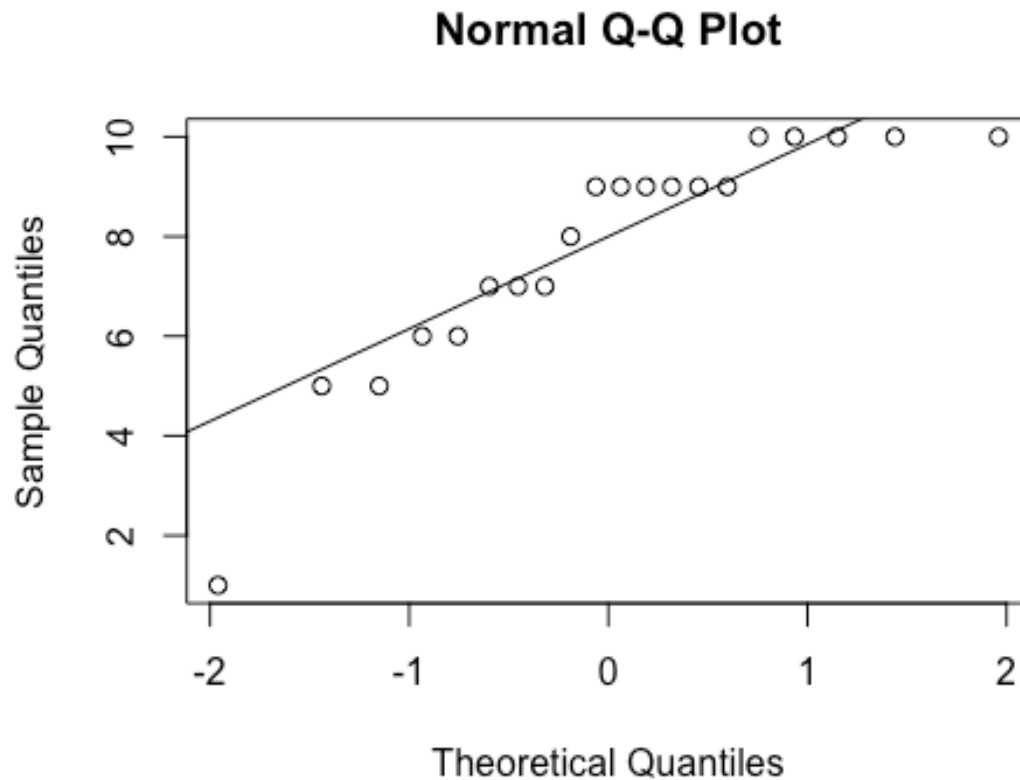
53 ad.test(PBUFdata$comfort.level)
54
55 ##
56 ## Anderson-Darling normality test

```

```

1
2
3
4  ##
5  ## data: PBUFdata$comfort.level
6  ## A = 1.8563, p-value = 7.865e-05
7
8  #within-participants (paired) comparison
9  #non-normal - perform Wilcoxon
10 wilcox.test(PBUF_sham$comfort.level,PBUF_treat$comfort.level,
11             paired = TRUE, conf.int = TRUE)
12
13 ## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
14 ## $comfort.level, : cannot compute exact p-value with ties
15
16 ## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
17 ## $comfort.level, : cannot compute exact confidence interval with ties
18
19 ## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
20 ## $comfort.level, : cannot compute exact p-value with zeroes
21
22 ## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
23 ## $comfort.level, : cannot compute exact confidence interval with zeroes
24
25 ##
26 ## Wilcoxon signed rank test with continuity correction
27 ##
28 ## data: PBUF_sham$comfort.level and PBUF_treat$comfort.level
29 ## V = 54.5, p-value = 0.0574
30 ## alternative hypothesis: true location shift is not equal to 0
31 ## 95 percent confidence interval:
32 ## -0.0000318032  2.7499508366
33 ## sample estimates:
34 ## (pseudo)median
35 ##      1.000052
36
37 #between participants (grouped) comparison
38 summary(PBUF_treat$comfort.level)
39
40 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
41 ##      1.00   6.75   9.00   7.80   9.25   10.00
42
43 sd(PBUF_treat$comfort.level, na.rm = TRUE)
44
45 ## [1] 2.330575
46
47 length(na.omit(PBUF_treat$comfort.level))
48
49 ## [1] 20
50
51 qqnorm(PBUF_treat$comfort.level)
52 qqline(PBUF_treat$comfort.level)
53
54
55
56
57
58
59
60

```



```

ad.test(PBUF_treat$comfort.level)

##
## Anderson-Darling normality test
##
## data: PBUF_treat$comfort.level
## A = 1.0308, p-value = 0.008039

#non-normal

summary(PBUF_sham$comfort.level)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      5.50   7.75   9.00   8.55  10.00  10.00

sd(PBUF_sham$comfort.level, na.rm = TRUE)

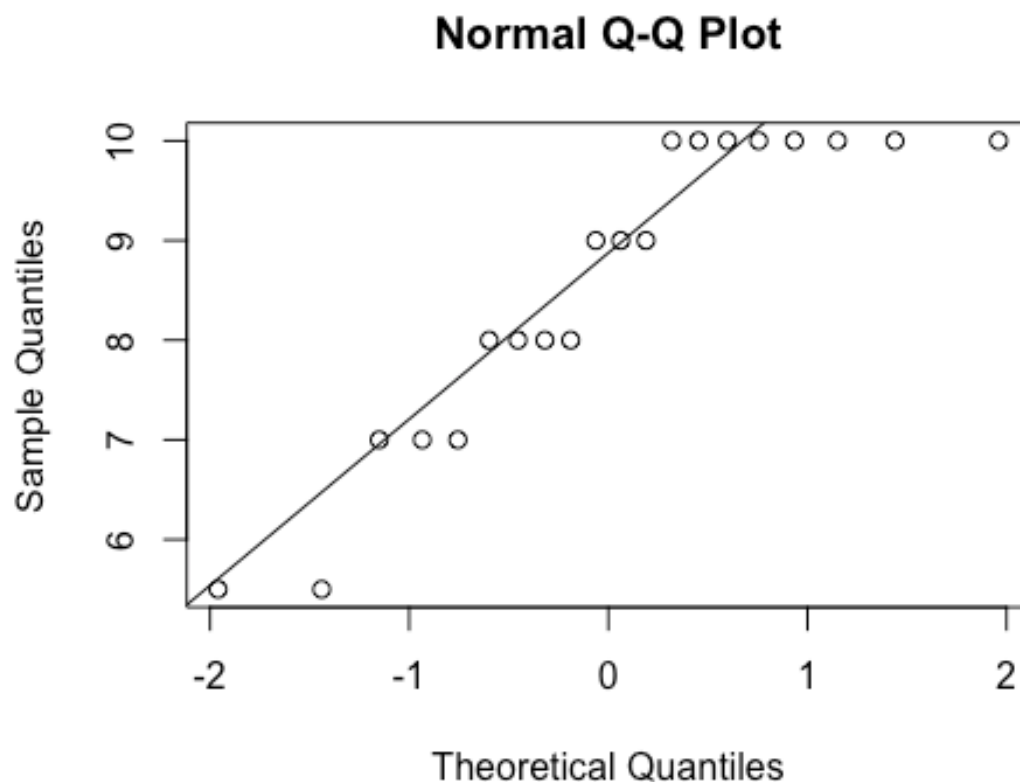
## [1] 1.529534

length(na.omit(PBUF_sham$comfort.level))

## [1] 20

qqnorm(PBUF_sham$comfort.level)
qqline(PBUF_sham$comfort.level)

```



```

ad.test(PBUF_sham$comfort.level)

##
## Anderson-Darling normality test
##
## data: PBUF_sham$comfort.level
## A = 1.1179, p-value = 0.004803

#non-normal

#Perform non-parametric test (Wilcoxon)
wilcox.test(PBUF_sham$comfort.level, PBUF_treat$comfort.level, conf.int = TRUE)

## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
## $comfort.level, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
## $comfort.level, : cannot compute exact confidence intervals with ties

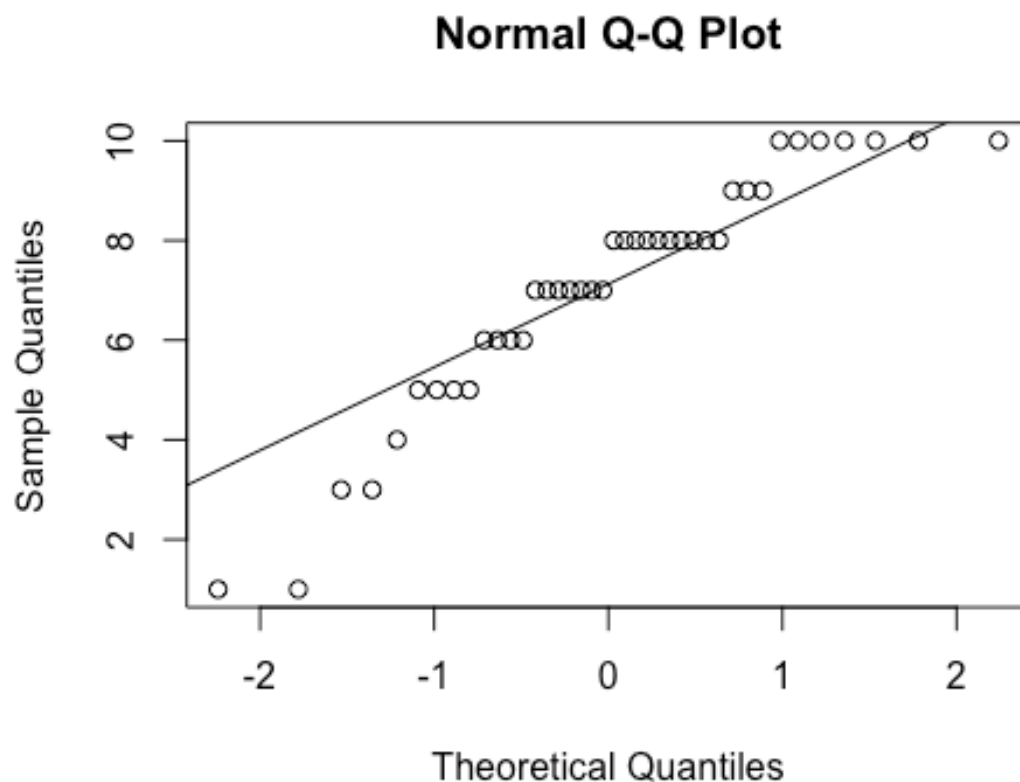
##
## Wilcoxon rank sum test with continuity correction
##
## data: PBUF_sham$comfort.level and PBUF_treat$comfort.level

```

```

1
2
3  ## W = 235.5, p-value = 0.3312
4  ## alternative hypothesis: true location shift is not equal to 0
5  ## 95 percent confidence interval:
6  ## -0.4999358  1.0000188
7  ## sample estimates:
8  ## difference in location
9  ##           0.3425784
10
11 #####INTENTION TO USE IN FUTURE PREGNANCY LEVEL#####
12 #####
13 #summary data
14 summary(PBUFdata$intention.to.use)
15
16 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
17 ##      1.00   6.00   7.50   7.05   8.25   10.00
18
19 sd(PBUFdata$intention.to.use)
20
21 ## [1] 2.363722
22
23 length(PBUFdata$intention.to.use)
24
25 ## [1] 40
26
27 qqnorm(PBUFdata$intention.to.use)
28 qqline(PBUFdata$intention.to.use)
29
30
31
32
33
34
35
36
37
38
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42
43
44
45
46
47
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49
50
51
52
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57
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```



```

ad.test(PBUFdata$intention.to.use)

##
## Anderson-Darling normality test
##
## data: PBUFdata$intention.to.use
## A = 1.0575, p-value = 0.00788

#within-participants (paired) comparison
#t-test (individual distributions are normal)
t.test(PBUF_sham$intention.to.use,PBUF_treat$intention.to.use, paired = TRUE)

##
## Paired t-test
##
## data: PBUF_sham$intention.to.use and PBUF_treat$intention.to.use
## t = 0.24031, df = 19, p-value = 0.8127
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
## -0.7709543 0.9709543
## sample estimates:
## mean of the differences
## 0.1

```



```
#between participants (grouped) comparison
summary(PBUF_treat$intention.to.use)

##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      1.00   5.75   8.00   7.00   8.00   10.00

sd(PBUF_treat$intention.to.use, na.rm = TRUE)

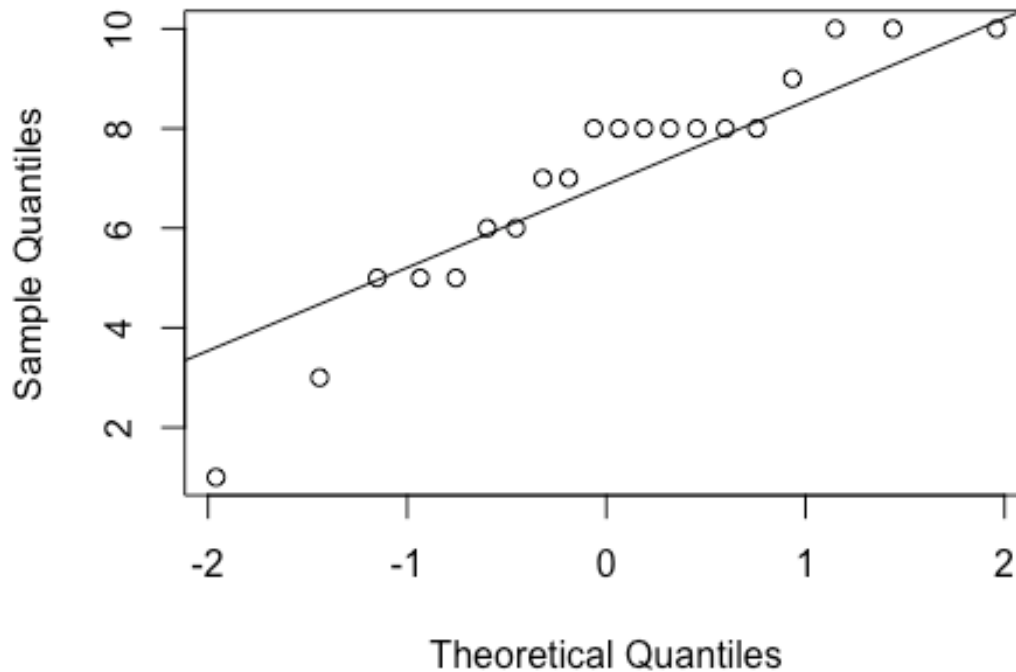
## [1] 2.339591

length(na.omit(PBUF_treat$intention.to.use))

## [1] 20

qqnorm(PBUF_treat$intention.to.use)
qqline(PBUF_treat$intention.to.use)
```

Normal Q-Q Plot



```
ad.test(PBUF_treat$intention.to.use)

##
## Anderson-Darling normality test
##
## data: PBUF_treat$intention.to.use
## A = 0.70743, p-value = 0.05453
```

```
#normal
```

```
summary(PBUF_sham$intention.to.use)
```

```
##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      1.0     6.0     7.0     7.1     9.0    10.0
```

```
sd(PBUF_sham$intention.to.use, na.rm = TRUE)
```

```
## [1] 2.44734
```

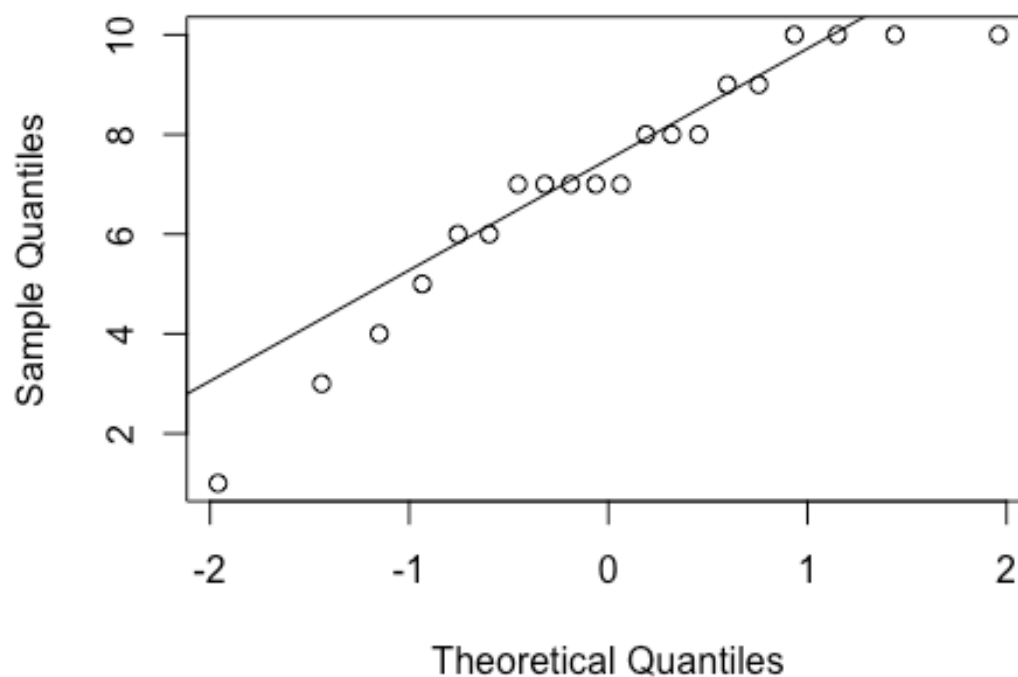
```
length(na.omit(PBUF_sham$intention.to.use))
```

```
## [1] 20
```

```
qqnorm(PBUF_sham$intention.to.use)
```

```
qqline(PBUF_sham$intention.to.use)
```

Normal Q-Q Plot



```
ad.test(PBUF_sham$intention.to.use)
```

```
##
## Anderson-Darling normality test
##
## data:  PBUF_sham$intention.to.use
## A = 0.54305, p-value = 0.1424
```

```

1
2
3 #normal
4
5 #Perform 2-sample t-test (Welch's t-test)
6 t.test(PBUF_sham$intention.to.use,
7         PBUF_treat$intention.to.use)
8
9
10 ##
11 ## Welch Two Sample t-test
12 ##
13 ## data: PBUF_sham$intention.to.use and PBUF_treat$intention.to.use
14 ## t = 0.13209, df = 37.923, p-value = 0.8956
15 ## alternative hypothesis: true difference in means is not equal to 0
16 ## 95 percent confidence interval:
17 ## -1.432714 1.632714
18 ## sample estimates:
19 ## mean of x mean of y
20 ##      7.1      7.0
21
22 #####WOULD MAKE CHANGES#####
23 #summary data
24 summary(PBUFdata$would.make.changes)
25
26 ##      no yes
27 ## 2 31 7
28
29 length(PBUFdata$would.make.changes)
30
31 ## [1] 40
32
33 #7 nights, but only 6 participants of 20 (30%)
34
35 #between participants (grouped) comparison
36 xtabs(~would.make.changes + Intervention, data = PBUFdata)[-1,]
37
38 ##
39 ## Intervention
40 ## would.make.changes sham treatment
41 ##      no 16 15
42 ##      yes 3 4
43
44 fisher.test(xtabs(~would.make.changes + Intervention, data = PBUFdata)[-1,])
45
46 ##
47 ## Fisher's Exact Test for Count Data
48 ##
49 ## data:
50 ## p-value = 1
51 ## alternative hypothesis: true odds ratio is not equal to 1
52 ## 95 percent confidence interval:
53 ## 0.2007118 11.2700012
54 ## sample estimates:
55 ## odds ratio
56 ## 1.409106
57
58
59
60

```

#END

For peer review only

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Supplementary file 4: Code and output – self-report accuracy analysis

For peer review only

Self-Report_Accuracy_Analysis_-_BMJSubmission.R

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#Description of code: Self-reported sleep behaviour accuracy analysis. This code compares the participants' perception of their sleep behaviours (as recorded on the PrenaBelt User Feedback Questionnaires) to the polysomnography-determined sleep behaviours.

#Summary: Participants recalled their sleep onset position accurately for 34 of 40 nights (85%, κ 0.62, moderate agreement). Participants recalled their waking position accurately for 28 of 40 nights (70%, κ 0.42, weak agreement). There was a weak relationship between sleep onset and waking position (κ 0.24). There was no agreement between the self-reported and PSG-reported number of position changes (κ 0.17). Percentage of time in each position, left, supine, and right, as estimated per self-report and measured per PSG had Spearman's ρ of 0.76 (good correlation, $p < 0.01$), 0.27 (poor correlation, $p = 0.11$), and 0.93 (excellent correlation, $p < 0.01$), respectively.

#Notes:

*#Spearman's rho - use for continuous variables
#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00*

#Cohen's kappa - use for categorical variables

#If the data is ordinal, then it may be appropriate to use a weighted Kappa (squared

or equal/linear). Unweighted calculation (used in the tests for non-ordinal data) treats

#all differences as the same.

#values ≤ 0 as indicating no agreement

#0.01-0.20 no agreement

#0.21-0.39 minimal

#0.40- 0.59 weak

#0.60-0.79 moderate

#0.80-0.90 strong

#0.91-1.00 near perfect

#<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3900052/>

```

1
2
3
4 #Bland-Altman's plots - recall of continuous variables
5 #https://cran.r-project.org/web/packages/BlandAltmanLeh/vignettes/Intro.html
6
7
8 #setting the workspace directory
9 setwd("/Users/Allan/Desktop/HPTStats/08APR2017")
10
11 #importing the SR accuracy data
12 SRdatafull=read.csv("Self Reported vs Recorded Sleep Postions.csv")
13
14 #Exclude drop outs
15 #How many drop outs?
16 summary(SRdatafull$drop.out)
17
18 ## N Y
19 ## 40 6
20
21 #6 nights = 3 participants
22 #Remove the drop outs ("Y")
23 SRdata <- SRdatafull[!(SRdatafull$drop.out=="Y"),]
24 nrow(SRdata)
25
26 ## [1] 40
27
28 #Loading the functions into the workspace
29 library(nortest)
30 library(irr)
31
32 ## Loading required package: lpSolve
33
34 library(ggplot2)
35
36 ## Warning: package 'ggplot2' was built under R version 3.2.5
37
38 library(BlandAltmanLeh)
39
40 #####Fall asleep position#####
41 #droplevels to remove empty levels from the list of levels
42 SRdata$PSG.fall.asleep.position <- droplevels(SRdata$PSG.fall.asleep.position
43 )
44 SRdata$SR.fall.asleep.position <- droplevels(SRdata$SR.fall.asleep.position)
45 #Summary
46 #Polysomnography (PSG)
47 summary(SRdata$PSG.fall.asleep.position)
48
49 ## left right supine
50 ## 29 8 3
51
52 length(SRdata$PSG.fall.asleep.position)
53
54 ## [1] 40
55
56
57
58
59
60

```

```

1
2
3 #Self-Report (SR)
4 summary(SRdata$SR.fall.asleep.position)
5
6 ## left right supine
7 ## 31 7 2
8
9 length(SRdata$SR.fall.asleep.position)
10
11 ## [1] 40
12
13 #Cohen's Kappa
14 item1<-as.matrix(cbind(SRdata$PSG.fall.asleep.position, SRdata$SR.fall.asleep
15 .position))
16 kappa2(item1[,c(1,2)])
17
18 ## Cohen's Kappa for 2 Raters (Weights: unweighted)
19 ##
20 ## Subjects = 40
21 ## Raters = 2
22 ## Kappa = 0.624
23 ##
24 ## z = 4.87
25 ## p-value = 1.13e-06
26
27 #####Wake up position#####
28 #droplevels to remove empty levels from the list of levels
29 SRdata$PSG.wake.position <- droplevels(SRdata$PSG.wake.position)
30 SRdata$SR.wake.position <- droplevels(SRdata$SR.wake.position)
31 #Summary
32 #PSG
33 summary(SRdata$PSG.wake.position)
34
35 ## left right supine
36 ## 22 13 5
37
38 length(SRdata$PSG.wake.position)
39
40 ## [1] 40
41
42 #SR
43 summary(SRdata$SR.wake.position)
44
45 ## left right
46 ## 28 12
47
48 length(SRdata$SR.wake.position)
49
50 ## [1] 40
51
52 #Cohen's Kappa
53 item1<-as.matrix(cbind(SRdata$PSG.wake.position, SRdata$SR.wake.position))
54 kappa2(item1[,c(1,2)])
55
56
57
58
59
60

```



```

1
2
3  ## Cohen's Kappa for 2 Raters (Weights: unweighted)
4  ##
5  ## Subjects = 40
6  ## Raters = 2
7  ## Kappa = 0.42
8  ##
9  ## z = 3.31
10 ## p-value = 0.000946
11
12 #####Look at relationship btw fall asleep and wake position###
13 #####
14 #Cohen's Kappa
15 #PSG
16 item1<-as.matrix(cbind(SRdata$PSG.fall.asleep.position, SRdata$PSG.wake.position))
17 kappa2(item1[,c(1,2)])
18
19 ## Cohen's Kappa for 2 Raters (Weights: unweighted)
20 ##
21 ## Subjects = 40
22 ## Raters = 2
23 ## Kappa = 0.241
24 ##
25 ## z = 2.05
26 ## p-value = 0.0399
27
28 #####Number of position changes#####
29 #Before running the number of position changes analyses below, we need to remove the rows
30 #corresponding to the 10 nights when participants did not give a self-report of the number
31 #of position changes because if these rows remain, they will make the summary statistics
32 inaccurate for the PSG data (n=40 instead of n=30).... note that
33 #the Cohens, ICC, and bland-altman will automatically drop these from their respective
34 analyses if the data point is continuous or ordinal (not if text! e.g., snoring analysis).
35
36 #Remove CDD night 1, LOH night 1, TBW night 1, WVE night1, YOG night 1 and 2, PBY night 1
37 #and 2, and KEQ night 1 and 2.
38 SRdata1 = SRdata[-c(3,7,19,23,25,26,27,28,37,38), ]
39 nrow(SRdata1)
40
41 ## [1] 30

```

```

1
2
3 #Summary
4 #PSG
5 summary(SRdata1$PSG.number.position.changes)
6
7 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
8 ##  1.000  3.250   6.000   6.833 10.000  15.000
9
10 length(SRdata1$PSG.number.position.changes)
11
12 ## [1] 30
13
14 #SR
15 summary(SRdata1$SR.number.position.changes)
16
17 ##   Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
18 ##   1.0    2.0    3.0    3.3    4.0    7.0
19
20 length(SRdata1$SR.number.position.changes)
21
22 ## [1] 30
23
24 #Cohen's Kappa
25 item1<-as.matrix(cbind(SRdata$PSG.number.position.changes,
26                        SRdata$SR.number.position.changes))
27 kappa2(item1[,c(1,2)], weight="equal")
28
29 ## Cohen's Kappa for 2 Raters (Weights: equal)
30 ##
31 ## Subjects = 30
32 ## Raters = 2
33 ## Kappa = 0.169
34 ##
35 ## z = 1.61
36 ## p-value = 0.107
37
38 #####Snoring#####
39 #droplevels to remove empty levels from the list of levels
40 SRdata$PSG.snore <- droplevels(SRdata$PSG.snore)
41 SRdata$SRsnore <- droplevels(SRdata$SRsnore)
42 #Summary
43 #PSG
44 summary(SRdata$PSG.snore)
45
46 ## N Y
47 ## 14 26
48
49 length(SRdata$PSG.snore)
50
51 ## [1] 40
52
53 summary(subset(SRdata, intervention == "treatment")$PSG.snore)
54
55
56
57
58
59
60

```

```

1
2
3 ## N Y
4 ## 5 15
5
6 summary(subset(SRdata, intervention == "sham")$PSG.snore)
7
8 ## N Y
9 ## 9 11
10
11 xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.levels = TRUE)
12
13 ##          intervention
14 ## PSG.snore sham treatment
15 ##          N      9      5
16 ##          Y     11     15
17
18 fisher.test(xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.level
19 s = TRUE))
20
21 ##
22 ## Fisher's Exact Test for Count Data
23 ##
24 ## data:  xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.levels
25 = TRUE)
26 ## p-value = 0.3203
27 ## alternative hypothesis: true odds ratio is not equal to 1
28 ## 95 percent confidence interval:
29 ##  0.5373446 11.9301555
30 ## sample estimates:
31 ## odds ratio
32 ##  2.398796
33
34 #SR
35 summary(SRdata$SRSnore)
36
37 ##          don't know          N          Y
38 ##          3          26          8          3
39
40 length(SRdata$SRSnore)
41
42 ## [1] 40
43
44 #Take a quick Look at the data
45 data.frame(SRdata$PSG.snore, SRdata$SRSnore)
46
47 ##      SRdata.PSG.snore SRdata.SRSnore
48 ## 1                Y     don't know
49 ## 2                Y     don't know
50 ## 3                N     don't know
51 ## 4                Y              N
52 ## 5                N              N
53 ## 6                Y     don't know
54 ## 7                Y

```

```

1
2
3   ## 8           Y
4   ## 9           N   don't know
5   ## 10          Y   don't know
6   ## 11          Y           Y
7   ## 12          Y           Y
8   ## 13          Y   don't know
9   ## 14          Y           N
10  ## 15          Y   don't know
11  ## 16          Y   don't know
12  ## 17          N   don't know
13  ## 18          N           N
14  ## 19          Y   don't know
15  ## 20          Y           Y
16  ## 21          N   don't know
17  ## 22          N   don't know
18  ## 23          Y   don't know
19  ## 24          Y   don't know
20  ## 25          N           N
21  ## 26          N           N
22  ## 27          Y   don't know
23  ## 28          Y   don't know
24  ## 29          Y   don't know
25  ## 30          Y   don't know
26  ## 31          N   don't know
27  ## 32          N           N
28  ## 33          Y   don't know
29  ## 34          N   don't know
30  ## 35          N           N
31  ## 36          N
32  ## 37          Y   don't know
33  ## 38          Y   don't know
34  ## 39          Y   don't know
35  ## 40          Y   don't know

```

#Drop the "" (blank) levels... for some reason, R includes them in the Kappa2 if the

#variable is text and blank

```
SRdataSnore <- SRdata[!(SRdata$SRsnore==""),]
```

```
nrow(SRdataSnore)
```

```
## [1] 37
```

#Drop the "don't know" levels because the PSG cannot answer "don't know", so these ratings

#should be excluded from the agreement analysis

```
SRdataSnore <- SRdataSnore[!(SRdataSnore$SRsnore=="don't know"),]
```

```
nrow(SRdataSnore)
```

```
## [1] 11
```

```

1
2
3 #Take a quick Look at the data
4 data.frame(SRdataSnore$PSG.snore, SRdataSnore$SRSnore)
5
6 ## SRdataSnore.PSG.snore SRdataSnore.SRSnore
7 ## 1 Y N
8 ## 2 N N
9 ## 3 Y Y
10 ## 4 Y Y
11 ## 5 Y N
12 ## 6 N N
13 ## 7 Y Y
14 ## 8 N N
15 ## 9 N N
16 ## 10 N N
17 ## 11 N N
18
19
20 #Cohen's Kappa
21 item1 <- data.frame(SRdataSnore$PSG.snore, SRdataSnore$SRSnore)
22 kappa2(item1[,c(1,2)])
23
24 ## Cohen's Kappa for 2 Raters (Weights: unweighted)
25 ##
26 ## Subjects = 11
27 ## Raters = 2
28 ## Kappa = 0.621
29 ##
30 ## z = 2.22
31 ## p-value = 0.0261
32
33 #####Body Position - Supine#####
34 #Before running the position analyses below, we need to remove the rows corre
35 sponding to
36 #the 5 nights when participants did not give a self-report of proportion of t
37 ime in each
38 #position (these five nights occured before the REB approved the change to ou
39 r PrenaBelt
40 #User Feedback Questionnaire) because if these rows remain, they will make th
41 e summary
42 #statistics (summary, #SD, Length) inaccurate for the PSG data (n=40 instead
43 of n=35)....
44 #note that the Cohens, #ICC, and bland-altman will automatically drop these f
45 rom their
46 #respective analyses if #the data point is continuous or ordinal (not if text
47 ! e.g.,
48 #snoring analysis).
49
50
51 #Remove LIQ nights 1 and 2, LOH nights 1 and 2, and LQI night 1:
52 SRdata1 = SRdata[-c(5,6,7,8,9),]
53 nrow(SRdata1)
54
55 ## [1] 35
56
57
58
59
60

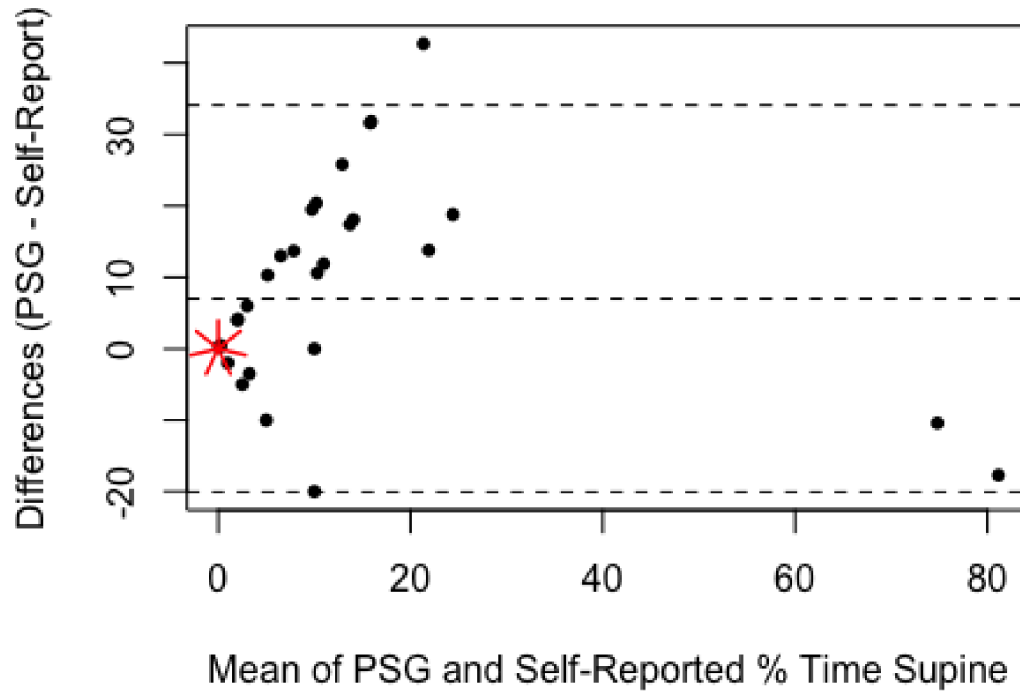
```

```

1
2
3 #Summary
4 #PSG
5 summary(SRdata1$PtstSupine)
6
7 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
8 ##      0.00   0.00   10.00   14.82  22.75   72.30
9
10 sd(SRdata1$PtstSupine)
11
12 ## [1] 18.69348
13
14 length(SRdata1$PtstSupine)
15
16 ## [1] 35
17
18 #SR
19 summary(SRdata1$SRSupine)
20
21 ##      Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
22 ##      0.0    0.0    0.0    7.8    5.0    90.0
23
24 sd(SRdata1$SRSupine)
25
26 ## [1] 19.98205
27
28 length(SRdata1$SRSupine)
29
30 ## [1] 35
31
32 #Test of association btw paired samples
33 cor.test(SRdata$PtstSupine, SRdata$SRSupine, method = "spearman")
34
35 ## Warning in cor.test.default(SRdata$PtstSupine, SRdata$SRSupine, method =
36 ## "spearman"): Cannot compute exact p-value with ties
37
38 ##
39 ## Spearman's rank correlation rho
40 ##
41 ## data:  SRdata$PtstSupine and SRdata$SRSupine
42 ## S = 5190.2, p-value = 0.1125
43 ## alternative hypothesis: true rho is not equal to 0
44 ## sample estimates:
45 ##      rho
46 ## 0.2730782
47
48 #fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00
49
50 bland.altman.plot(SRdata$PtstSupine, SRdata$SRSupine,
51                   two = 1.96, mode = 1, graph.sys = "base", conf.int = 0, sil
52 ent = FALSE,
53                   sunflower = TRUE,
54                   main="",
55
56
57
58
59
60

```

```
xlab="Mean of PSG and Self-Reported % Time Supine",
ylab="Differences (PSG - Self-Report)")
```



```
## $means
## [1] 0.00 0.10 15.90 13.70 2.00 0.00 10.20 3.00 0.00 12.90 6.50
## [12] 10.95 5.15 9.75 15.80 24.40 21.90 3.25 7.85 10.30 2.50 10.00
## [23] 5.00 0.00 2.05 0.00 0.25 0.00 14.05 81.15 74.80 0.00 21.35
## [34] 1.00 10.00
##
## $diffs
## [1] 0.0 0.2 31.8 17.4 4.0 0.0 20.4 6.0 0.0 25.8 13.0
## [12] 11.9 10.3 19.5 31.6 18.8 13.8 -3.5 13.7 10.6 -5.0 -20.0
## [23] -10.0 0.0 4.1 0.0 0.5 0.0 18.1 -17.7 -10.4 0.0 42.7
## [34] -2.0 0.0
##
## $groups
## group1 group2
## 1 0.0 0
## 2 0.2 0
## 3 31.8 0
## 4 22.4 5
## 10 4.0 0
## 11 0.0 0
```

```

1
2
3    ## 12    20.4    0
4    ## 13     6.0    0
5    ## 14     0.0    0
6    ## 15    25.8    0
7    ## 16    13.0    0
8    ## 17    16.9    5
9    ## 18    10.3    0
10   ## 19    19.5    0
11   ## 20    31.6    0
12   ## 21    33.8    15
13   ## 22    28.8    15
14   ## 23     1.5     5
15   ## 24    14.7     1
16   ## 25    15.6     5
17   ## 26     0.0     5
18   ## 27     0.0    20
19   ## 28     0.0    10
20   ## 29     0.0     0
21   ## 30     4.1     0
22   ## 31     0.0     0
23   ## 32     0.5     0
24   ## 33     0.0     0
25   ## 34    23.1     5
26   ## 35    72.3    90
27   ## 36    69.6    80
28   ## 37     0.0     0
29   ## 38    42.7     0
30   ## 39     0.0     2
31   ## 40    10.0    10
32   ##
33   ## $based.on
34   ## [1] 35
35   ##
36   ## $lower.limit
37   ## [1] -20.0717
38   ##
39   ## $mean.diffs
40   ## [1] 7.017143
41   ##
42   ## $upper.limit
43   ## [1] 34.10599
44   ##
45   ## $lines
46   ## lower.limit mean.diffs upper.limit
47   ## -20.071701    7.017143    34.105987
48   ##
49   ## $CI.lines
50   ## lower.limit.ci.lower lower.limit.ci.upper mean.diff.ci.lower
51   ## -20.071701          -20.071701          7.017143
52   ## mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper

```



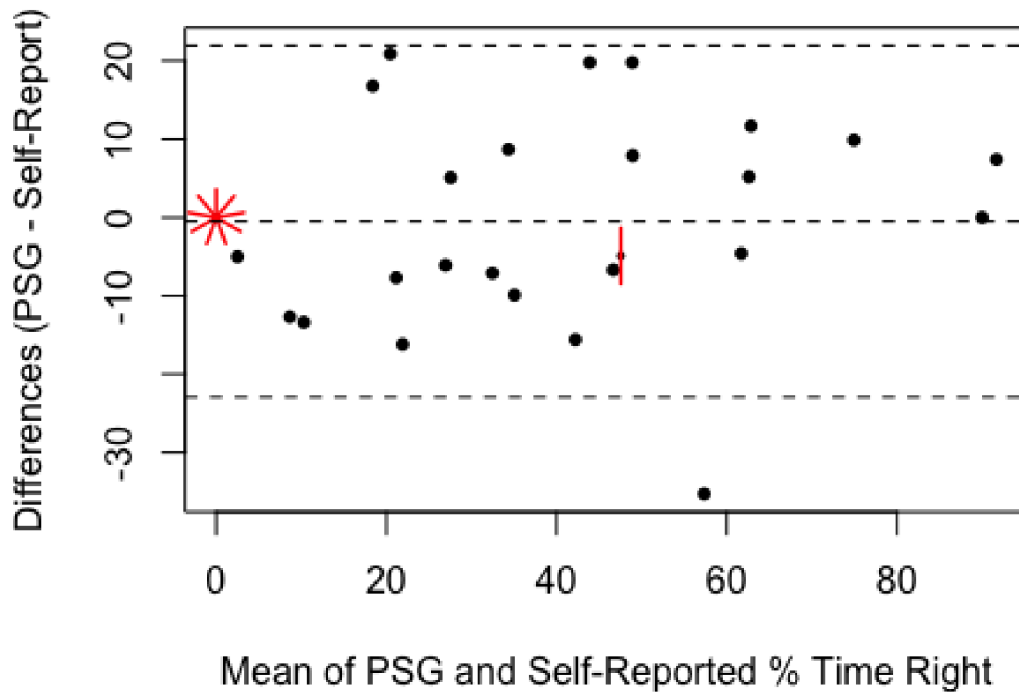
```

1
2
3      ##                7.017143                34.105987                34.105987
4      ##
5      ## $two
6      ## [1] 1.96
7      ##
8      ## $critical.diff
9      ## [1] 27.08884
10
11 #####Body Position - Right#####
12 #Summary
13 #PSG
14 summary(SRdata1$PtstRight)
15
16 ##      Min. 1st Qu.  Median      Mean 3rd Qu.      Max.
17 ##      0.0      0.0      30.1      30.8      49.0      95.4
18
19 sd(SRdata1$PtstRight)
20
21 ## [1] 28.50465
22
23 length(SRdata1$PtstRight)
24
25 ## [1] 35
26
27 #SR
28 summary(SRdata1$SRRight)
29
30 ##      Min. 1st Qu.  Median      Mean 3rd Qu.      Max.
31 ##      0.00      2.50      30.00      31.29      50.00      90.00
32
33 sd(SRdata1$SRRight)
34
35 ## [1] 27.30177
36
37 length(SRdata1$SRRight)
38
39 ## [1] 35
40
41 #Test of association btw paired samples
42 cor.test(SRdata$PtstRight, SRdata$SRRight, method = "spearman")
43
44 ## Warning in cor.test.default(SRdata$PtstRight, SRdata$SRRight, method =
45 ## "spearman"): Cannot compute exact p-value with ties
46
47 ##
48 ## Spearman's rank correlation rho
49 ##
50 ## data:  SRdata$PtstRight and SRdata$SRRight
51 ## S = 505.71, p-value = 8.061e-16
52 ## alternative hypothesis: true rho is not equal to 0
53 ## sample estimates:
54 ##      rho
55 ## 0.9291716
56
57
58
59
60

```

```
#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00

bland.altman.plot(SRdata$PtstRight, SRdata$SRRight,
                  two = 1.96, mode = 1, graph.sys = "base", conf.int = 0, sil
ent = FALSE,
                  sunflower = TRUE,
                  main="",
                  xlab="Mean of PSG and Self-Reported % Time Right",
                  ylab="Differences (PSG - Self-Report)")
```



```
## $means
## [1] 34.35 26.95 21.90 0.00 27.55 74.95 62.60 61.70 62.85 10.30 20.45
## [12] 47.55 42.20 0.00 18.40 0.00 0.00 48.95 48.90 0.00 0.00 0.00
## [23] 0.00 46.65 57.35 43.90 21.15 47.55 8.65 0.00 2.50 32.45 35.05
## [34] 91.70 90.00
##
## $diffs
## [1] 8.7 -6.1 -16.2 0.0 5.1 9.9 5.2 -4.6 11.7 -13.4 20.9
## [12] -4.9 -15.6 0.0 16.8 0.0 0.0 7.9 19.8 0.0 0.0 0.0
## [23] 0.0 -6.7 -35.3 19.8 -7.7 -4.9 -12.7 0.0 -5.0 -7.1 -9.9
## [34] 7.4 0.0
##
## $groups
```

```

1
2
3      ##      group1 group2
4      ## 1      38.7    30
5      ## 2      23.9    30
6      ## 3      13.8    30
7      ## 4       0.0     0
8      ## 10     30.1    25
9      ## 11     79.9    70
10     ## 12     65.2    60
11     ## 13     59.4    64
12     ## 14     68.7    57
13     ## 15      3.6    17
14     ## 16     30.9    10
15     ## 17     45.1    50
16     ## 18     34.4    50
17     ## 19      0.0     0
18     ## 20     26.8    10
19     ## 21      0.0     0
20     ## 22      0.0     0
21     ## 23     52.9    45
22     ## 24     58.8    39
23     ## 25      0.0     0
24     ## 26      0.0     0
25     ## 27      0.0     0
26     ## 28      0.0     0
27     ## 29     43.3    50
28     ## 30     39.7    75
29     ## 31     53.8    34
30     ## 32     17.3    25
31     ## 33     45.1    50
32     ## 34      2.3    15
33     ## 35      0.0     0
34     ## 36      0.0     5
35     ## 37     28.9    36
36     ## 38     30.1    40
37     ## 39     95.4    88
38     ## 40     90.0    90
39
40
41     ##
42     ## $based.on
43     ## [1] 35
44     ##
45     ## $lower.limit
46     ## [1] -22.91233
47     ##
48     ## $mean.diffs
49     ## [1] -0.4828571
50     ##
51     ## $upper.limit
52     ## [1] 21.94661
53     ##
54     ## $lines
55
56
57
58
59
60

```

```

1
2
3  ## lower.limit mean.diff upper.limit
4  ## -22.9123292 -0.4828571 21.9466149
5  ##
6  ## $CI.lines
7  ## lower.limit.ci.lower lower.limit.ci.upper mean.diff.ci.lower
8  ## -22.9123292 -22.9123292 -0.4828571
9  ## mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
10 ## -0.4828571 21.9466149 21.9466149
11 ##
12 ## $two
13 ## [1] 1.96
14 ##
15 ## $critical.diff
16 ## [1] 22.42947
17
18 #####Body Position - Left#####
19 #Summary
20 #PSG
21 summary(SRdata1$PtstLeft)
22
23 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
24 ## 0.00 32.95 56.10 54.40 72.90 100.00
25
26 sd(SRdata1$PtstLeft)
27
28 ## [1] 26.40423
29
30 length(SRdata1$PtstLeft)
31
32 ## [1] 35
33
34 #SR
35 summary(SRdata1$SRLeft)
36
37 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
38 ## 0.00 41.50 66.00 59.91 84.00 100.00
39
40 sd(SRdata1$SRLeft)
41
42 ## [1] 28.14915
43
44 length(SRdata1$SRLeft)
45
46 ## [1] 35
47
48 #Test of association btw paired samples
49 cor.test(SRdata$PtstLeft, SRdata$SRLeft, method = "spearman")
50
51 ## Warning in cor.test.default(SRdata$PtstLeft, SRdata$SRLeft, method =
52 ## "spearman"): Cannot compute exact p-value with ties
53
54 ##
55 ## Spearman's rank correlation rho

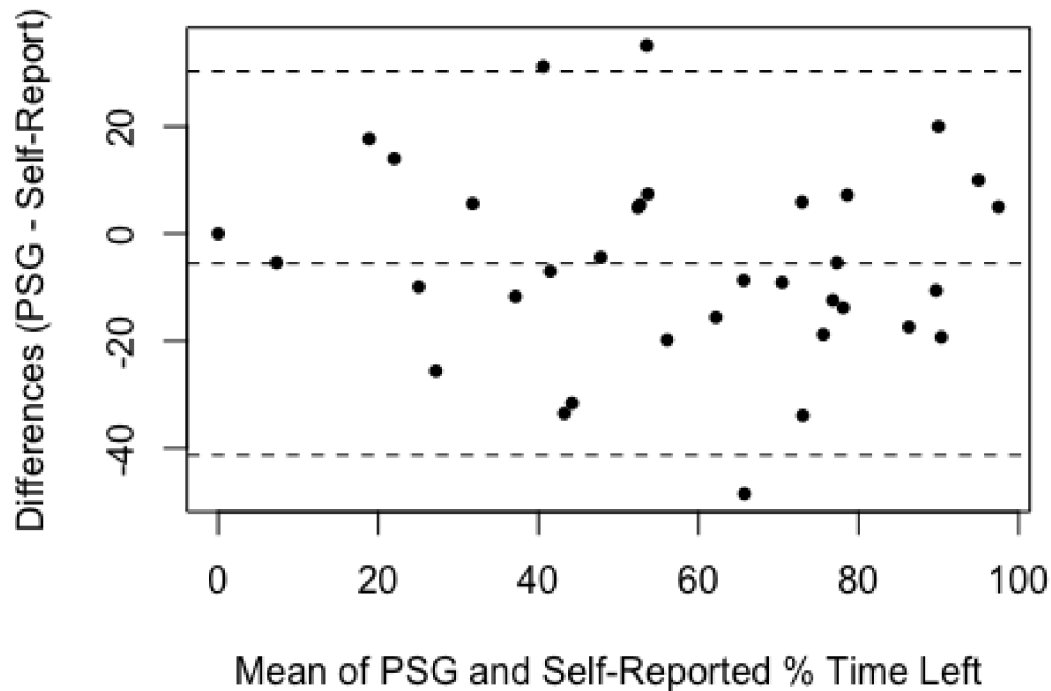
```

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```

1  ##
2  ## data: SRdata$PtstLeft and SRdata$SRLeft
3  ## S = 1691.2, p-value = 9.796e-08
4  ## alternative hypothesis: true rho is not equal to 0
5  ## sample estimates:
6  ##      rho
7  ## 0.7631423
8
9  #fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00
10
11 bland.altman.plot(SRdata$PtstLeft, SRdata$SRLeft,
12                   two = 1.96, mode = 1, graph.sys = "base", conf.int = 0, sil
13 ent = FALSE,
14                   sunflower = TRUE,
15                   main="",
16                   xlab="Mean of PSG and Self-Reported % Time Left",
17                   ylab="Differences (PSG - Self-Report)")
18
19
20
21
22
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24
25
26
27

```



```

51 ## $means
52 ## [1] 65.65 72.95 62.20 86.30 70.45 25.05 27.20 31.80 37.15 76.80 73.05
53 ## [12] 41.50 52.70 90.35 65.75 75.60 78.10 47.80 43.25 89.70 97.50 90.00
54 ## [23] 95.00 53.70 40.60 56.10 78.60 52.45 77.30 18.85 22.00 53.55 44.20
55 ## [34] 7.30 0.00
56
57
58
59
60

```

```

1
2
3 ##
4 ## $diffs
5 ## [1] -8.7 5.9 -15.6 -17.4 -9.1 -9.9 -25.6 5.6 -11.7 -12.4 -33.9
6 ## [12] -7.0 5.4 -19.3 -48.5 -18.8 -13.8 -4.4 -33.5 -10.6 5.0 20.0
7 ## [23] 10.0 7.4 31.2 -19.8 7.2 4.9 -5.4 17.7 14.0 35.1 -31.6
8 ## [34] -5.4 0.0
9 ##
10 ## $groups
11 ## group1 group2
12 ## 1 61.3 70
13 ## 2 75.9 70
14 ## 3 54.4 70
15 ## 4 77.6 95
16 ## 10 65.9 75
17 ## 11 20.1 30
18 ## 12 14.4 40
19 ## 13 34.6 29
20 ## 14 31.3 43
21 ## 15 70.6 83
22 ## 16 56.1 90
23 ## 17 38.0 45
24 ## 18 55.4 50
25 ## 19 80.7 100
26 ## 20 41.5 90
27 ## 21 66.2 85
28 ## 22 71.2 85
29 ## 23 45.6 50
30 ## 24 26.5 60
31 ## 25 84.4 95
32 ## 26 100.0 95
33 ## 27 100.0 80
34 ## 28 100.0 90
35 ## 29 57.4 50
36 ## 30 56.2 25
37 ## 31 46.2 66
38 ## 32 82.2 75
39 ## 33 54.9 50
40 ## 34 74.6 80
41 ## 35 27.7 10
42 ## 36 29.0 15
43 ## 37 71.1 36
44 ## 38 28.4 60
45 ## 39 4.6 10
46 ## 40 0.0 0
47 ##
48 ## $based.on
49 ## [1] 35
50 ##
51 ## $lower.limit
52 ## [1] -41.27743
53
54
55
56
57
58
59
60

```

```

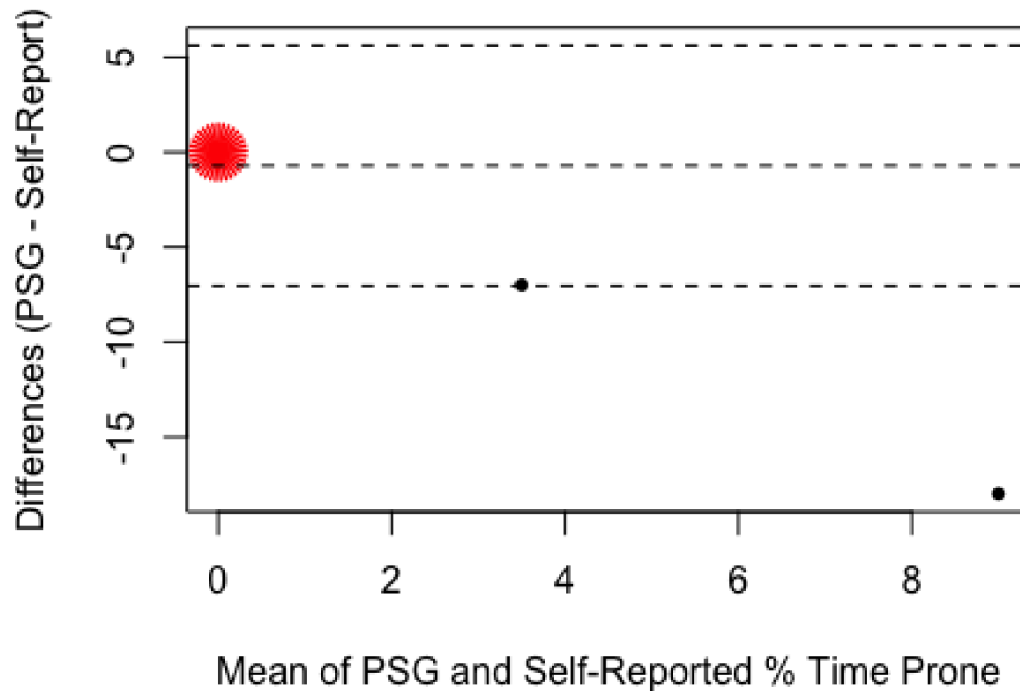
1
2
3  ##
4  ## $mean.diffs
5  ## [1] -5.514286
6  ##
7  ## $upper.limit
8  ## [1] 30.24886
9  ##
10 ##
11 ## $lines
12 ## lower.limit mean.diffs upper.limit
13 ## -41.277427 -5.514286 30.248856
14 ##
15 ## $CI.lines
16 ## lower.limit.ci.lower lower.limit.ci.upper mean.diff.ci.lower
17 ## -41.277427 -41.277427 -5.514286
18 ## mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
19 ## -5.514286 30.248856 30.248856
20 ##
21 ## $two
22 ## [1] 1.96
23 ##
24 ## $critical.diff
25 ## [1] 35.76314
26
27 #####Body Position - Prone#####
28 #Summary
29 #PSG
30 summary(SRdata$PtstProne)
31
32 ## Min. 1st Qu. Median Mean 3rd Qu. Max.
33 ## 0 0 0 0 0 0
34
35 length(SRdata$PtstProne)
36
37 ## [1] 40
38
39 #SR
40 summary(SRdata$SRProne)
41
42 ## Min. 1st Qu. Median Mean 3rd Qu. Max. NA's
43 ## 0.0000 0.0000 0.0000 0.7143 0.0000 18.0000 5
44
45 length(SRdata$SRProne)
46
47 ## [1] 40
48
49 #Test of association btw paired samples
50 cor.test(SRdata$PtstProne, SRdata$SRProne, method = "spearman")
51
52 ## Warning in cor(rank(x), rank(y)): the standard deviation is zero
53
54 ##
55 ## Spearman's rank correlation rho
56
57
58
59
60

```

```

1  ##
2  ## data: SRdata$PtstProne and SRdata$SRProne
3  ## S = NA, p-value = NA
4  ## alternative hypothesis: true rho is not equal to 0
5  ## sample estimates:
6  ## rho
7  ## NA
8
9  #fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00
10
11 bland.altman.plot(SRdata$PtstProne, SRdata$SRProne,
12                   two = 1.96, mode = 1, graph.sys = "base", conf.int = 0, sil
13 ent = FALSE,
14                   sunflower = TRUE,
15                   main="",
16                   xlab="Mean of PSG and Self-Reported % Time Prone",
17                   ylab="Differences (PSG - Self-Report)")
18
19
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```



```

51 ## $means
52 ## [1] 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 3.5 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0
53 ## [18] 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 9.0 0.0
54 ## [35] 0.0
55 ##
56
57
58
59
60

```



```

1
2
3      ## $diffs
4      ## [1]  0  0  0  0  0  0  0  0 -7  0  0  0  0  0  0  0  0
5      ## [18]  0  0  0  0  0  0  0  0  0  0  0  0  0  0  0 -18  0  0
6      ## [35]  0
7      ##
8      ## $groups
9      ##   group1 group2
10     ## 1      0      0
11     ## 2      0      0
12     ## 3      0      0
13     ## 4      0      0
14     ## 10     0      0
15     ## 11     0      0
16     ## 12     0      0
17     ## 13     0      7
18     ## 14     0      0
19     ## 15     0      0
20     ## 16     0      0
21     ## 17     0      0
22     ## 18     0      0
23     ## 19     0      0
24     ## 20     0      0
25     ## 21     0      0
26     ## 22     0      0
27     ## 23     0      0
28     ## 24     0      0
29     ## 25     0      0
30     ## 26     0      0
31     ## 27     0      0
32     ## 28     0      0
33     ## 29     0      0
34     ## 30     0      0
35     ## 31     0      0
36     ## 32     0      0
37     ## 33     0      0
38     ## 34     0      0
39     ## 35     0      0
40     ## 36     0      0
41     ## 37     0     18
42     ## 38     0      0
43     ## 39     0      0
44     ## 40     0      0
45     ##
46     ## $based.on
47     ## [1] 35
48     ##
49     ## $lower.limit
50     ## [1] -7.048871
51     ##
52     ## $mean.diffs

```

```

1
2
3 ## [1] -0.7142857
4 ##
5 ## $upper.limit
6 ## [1] 5.620299
7 ##
8 ## $lines
9 ## lower.limit mean.diffs upper.limit
10 ## -7.0488705 -0.7142857 5.6202991
11 ##
12 ## $CI.lines
13 ## lower.limit.ci.lower lower.limit.ci.upper mean.diff.ci.lower
14 ## -7.0488705 -7.0488705 -0.7142857
15 ## mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
16 ## -0.7142857 5.6202991 5.6202991
17 ##
18 ## $two
19 ## [1] 1.96
20 ##
21 ## $critical.diff
22 ## [1] 6.334585
23
24 #####PLMs/Restless Legs#####
25 #droplevels to remove empty levels from the list of levels
26 SRdata$PSG.legs.restless <- droplevels(SRdata$PSG.legs.restless)
27 SRdata$SR.legs.restless <- droplevels(SRdata$SR.legs.restless)
28 #Summary
29 #PSG
30 summary(SRdata$PSG.legs.restless)
31
32 ## N Y
33 ## 26 14
34
35 length(SRdata$PSG.legs.restless)
36
37 ## [1] 40
38
39 #SR
40 summary(SRdata$SR.legs.restless)
41
42 ## don't know N Y
43 ## 3 19 14 4
44
45 length(SRdata$SR.legs.restless)
46
47 ## [1] 40
48
49 #Take a quick look at the data
50 data.frame(SRdata$PSG.legs.restless, SRdata$SR.legs.restless)
51
52 ## SRdata.PSG.legs.restless SRdata.SR.legs.restless
53 ## 1 N don't know
54 ## 2 N don't know
55
56
57
58
59
60

```

```

1
2
3      ## 3          N          N
4      ## 4          N          N
5      ## 5          Y          N
6      ## 6          Y          Y
7      ## 7          N
8      ## 8          N
9      ## 9          N          N
10     ## 10         N          don't know
11     ## 11         N          N
12     ## 12         N          N
13     ## 13         Y          don't know
14     ## 14         Y          Y
15     ## 15         N          don't know
16     ## 16         N          don't know
17     ## 17         N          don't know
18     ## 18         N          don't know
19     ## 19         N          N
20     ## 20         Y          N
21     ## 21         Y          don't know
22     ## 22         Y          don't know
23     ## 23         N          don't know
24     ## 24         N          don't know
25     ## 25         Y          Y
26     ## 26         Y          N
27     ## 27         Y          N
28     ## 28         Y          N
29     ## 29         Y          don't know
30     ## 30         Y          don't know
31     ## 31         N          don't know
32     ## 32         N          don't know
33     ## 33         N
34     ## 34         N          don't know
35     ## 35         N          don't know
36     ## 36         N          N
37     ## 37         Y          Y
38     ## 38         N          don't know
39     ## 39         N          N
40     ## 40         N          N

```

#Drop the "" (blank) Levels... for some reason, R includes them in the Kappa2 if the

#variable is text and blank

```
SRdataLegs <- SRdata[!(SRdata$SR.legs.restless==""),]
```

```
nrow(SRdataLegs)
```

```
## [1] 37
```

#Drop the "don't know" Levels because the PSG cannot answer "don't know", so these ratings

#should be excluded from the agreement analysis

```

1
2
3 SRdataLegs <- SRdataLegs[!(SRdataLegs$SR.legs.restless=="don't know"),]
4 nrow(SRdataLegs)
5
6 ## [1] 18
7
8 #Take a quick look at the data
9 data.frame(SRdataLegs$PSG.legs.restless, SRdataLegs$SR.legs.restless)
10
11 ##      SRdataLegs.PSG.legs.restless  SRdataLegs.SR.legs.restless
12 ## 1                N                N
13 ## 2                N                N
14 ## 3                Y                N
15 ## 4                Y                Y
16 ## 5                N                N
17 ## 6                N                N
18 ## 7                N                N
19 ## 8                Y                Y
20 ## 9                N                N
21 ## 10               Y                N
22 ## 11               Y                Y
23 ## 12               Y                N
24 ## 13               Y                N
25 ## 14               Y                N
26 ## 15               N                N
27 ## 16               Y                Y
28 ## 17               N                N
29 ## 18               N                N
30
31
32 #Cohen's Kappa
33 item1 <- data.frame(SRdataLegs$PSG.legs.restless, SRdataLegs$SR.legs.restless
34 )
35 kappa2(item1[,c(1,2)])
36
37 ## Cohen's Kappa for 2 Raters (Weights: unweighted)
38 ##
39 ## Subjects = 18
40 ## Raters = 2
41 ## Kappa = 0.444
42 ##
43 ## z = 2.27
44 ## p-value = 0.0233
45
46 #End
47
48
49
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Supplementary file 5: Research protocol

For peer review only

1
2
3 March 15th, 2016
4

5 **To:** The IWK Health Centre – Research Ethics Board
6 Research Services, Richard Goldbloom Gallery, Main Floor
7 5850/5980 University Avenue, Halifax, NS, B3K 6R8
8
9

10 **From:** Allan Kember
11 Research Administrator, Global Innovations for Reproductive Health and Life
12 Project Lead, Grand Challenges Canada Grant #S7 0629-01-10
13 17 Oceanview Dr.
14 Halifax, NS, B3P 2H4
15
16

17 **Subject:** Research Protocol
18

19 **Project Title:** A Maternal Device for the Prevention of Stillbirth and Low Birthweight
20
21

22 **Foreword**

23 This project, entitled A Maternal Device for the Prevention of Stillbirth and Low Birthweight, was
24 originally submitted on March 10th, 2014 to Grand Challenges Canada in response to their Request for
25 Proposals: Stars in Global Health – Round 7 Phase I. Grand Challenges Canada's peer review of this
26 proposal was led by the Canadian Institutes of Health Research. This proposal was recommended to
27 proceed to the next stage of the *Stars in Global Health* grant process, which involved due diligence and
28 grant agreement negotiations between the primary organization for this project, Innovative Canadians
29 for Change Foundation (ICChange – Edmonton, AB), and Grand Challenges Canada, which were
30 completed on December 19th, 2014. Funding for this project was approved on December 19th, 2014.
31
32

33 Note that this proposal includes two feasibility studies – one in Halifax, Canada, and one in Accra,
34 Ghana. Both studies include human participants; therefore, both studies will require ethics approval. For
35 the study in Halifax, ethics approval was received on June 16th, 2015 (Project #1018753) from The IWK
36 Health Centre Review Ethics Board (REB). For the study in Accra, ethics approval was received from The
37 IWK-REB on June 16th, 2015 (Project #1019318) and from the Noguchi Memorial Institute for Medical
38 Research Institutional Review Board (local ethics board) on March 4th, 2015 (CPN 069/14-15).
39
40

41 The purpose of this document is to set forth the research protocol for the study related to The IWK
42 Health Centre in Halifax, Canada as per the guidelines given in the document Protocol Components
43 provided under the New Submissions – Guidelines and Templates section of the IWK Health Centre
44 Research website:
45
46

47 <http://www.iwk.nshealth.ca/research/application-materials-forms>
48
49

50 This research protocol is submitted for review by The IWK Health Centre's Review Ethics Board as part of
51 the requirements in the document Researcher's Checklist for Submissions: Delegated Review.
52
53

This document is divided into two main sections. The first section – “Scientific” – describes the scientific aspect of the study. The second section – “Ethical” – describes the ethical aspect of the study.

Sincerely,



Allan Kember

For peer review only

1 Scientific

1.1 Introduction

According to the WHO, stillbirth (SB) is defined as fetal death at gestation ≥ 28 weeks or weight ≥ 1000 g [1]. In Canada, the definition of SB is wider, including fetal death at gestation ≥ 20 weeks or weight ≥ 500 g [2]. In addition to the loss of life for the stillborn baby, SB assails parents with psychological grief of losing their baby and results in markedly increased mortality when compared with non-bereaved parents [3]. Current risk factors for SB in high-income countries are well established and documented. In a recent systematic review with meta-analysis [4], the three most important modifiable risk factors for SB were found to be obesity (population attributable risk (PAR) 8-18%), advanced maternal age (PAR 6-8%), and smoking (PAR 4-7%). Of these, smoking is the only modifiable risk factor that can be realistically addressed during the course of a pregnancy.

Low birthweight (LBW) is defined as a weight less than 2500g at birth [5]. LBW is a significant contributor to SB [4], and infants with LBW are 20 times more likely to die in the first year than heavier babies [5]. Although LBW babies constitute only about 15% of live births, they account for 60-80% of neonatal deaths [6] [7] [8] [9]. Neonatal deaths (death within the first year of life) account for 40% of all deaths under the age of five years [10]. LBW also accounts for significant morbidity such as cognitive impairment [11], and chronic diseases later in life [5] [12]. LBW arises through short gestation (preterm birth) or in-utero growth restriction, or both [13].

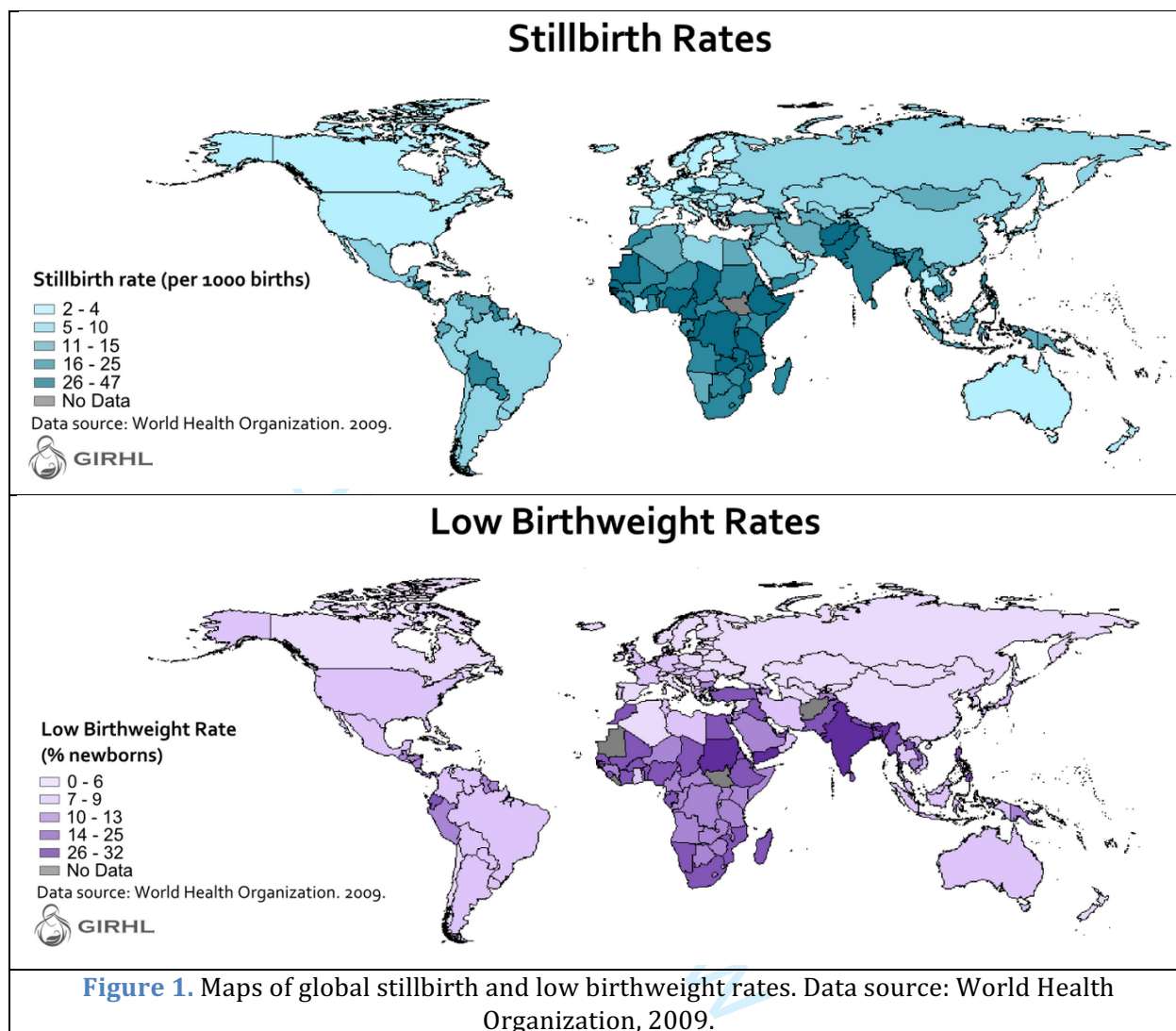
Maternal sleep position during pregnancy has recently emerged as a risk factor for LBW and SB [14] [15] [16]. A device to modify maternal sleep position and mitigate this risk factor has been developed (see section 1.1.3). The purpose of this *Stars in Global Health* project is to test the effectiveness of this device and assess the feasibility of incorporating this device into an antenatal care clinic in Ghana. Data will be used in effect size calculations for large-scale trials targeted at reducing poor pregnancy outcomes in Canada and worldwide.

1.1.1 Research Problem

In 2009, the World Health Organization reported the global prevalence of stillbirth (SB) to be 2.6 million (uncertainty range: 2.1-3.8 million), of which 98% occur in countries of low and middle income [1] – see Figure 1. Sub-Saharan Africa has the highest rate of SB worldwide and has made the least progress in SB reduction [1]. Little is known about effective interventions for SB, especially those that can be implemented in resource-limited settings.

In addition to the global burden of SB, the global incidence of LBW infants remains a significant public health challenge. Each year, there are over 20 million infants born with LBW, of which 96% occur in developing countries with the highest concentrations in Asia and Africa [5] – see Figure 1. Efforts to reduce the incidence of LBW have not been successful in these regions, and thus the incidence has remained largely unchanged [5].

Low- and middle-income countries urgently require simple, inexpensive, and effective interventions to reduce the rates of SB and LBW.



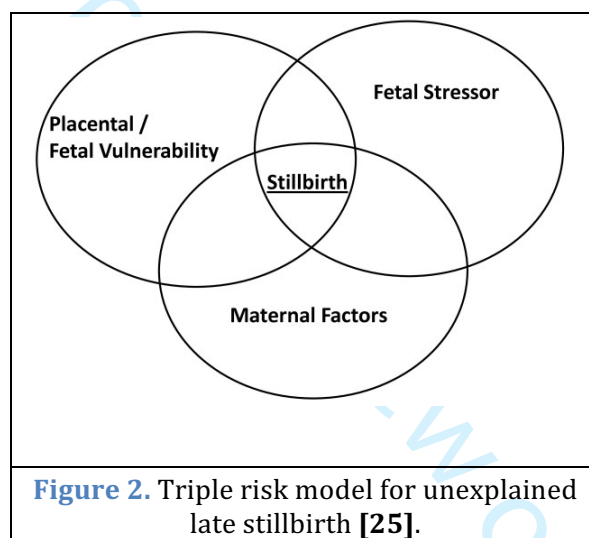
1.1.2 Background – Maternal Position

In obstetrics, it is well-known that when a pregnant woman assumes the supine position during the day, maternal cardiovascular parameters [17] [18] [19] and/or fetal oxygenation [20] are altered, often causing fetal distress, particularly during labour [21]. However, until recently, there has been little evidence on the effect of supine position during sleep in pregnancy. Recently, three studies have suggested that maternal sleep position may be a risk factor for SB [14] [15] [16] and LBW [16]. This is significant given that the majority of third trimester pregnant women spend up to 25% of their sleep time supine [22]. In the Auckland Stillbirth Study [15], the population attributable risk (PAR) for non-left sleep position was found to be 37%, which is greater than the PARs of the three most important modifiable risk factors for stillbirth (obesity, advanced maternal age, and smoking) combined [4]. In an African population [16], the newborns of women who reported supine sleep during pregnancy were at increased risk of low birth weight (OR, 5.0; 95% CI, 1.2–20.2; P=0.025) and stillbirth (OR, 8.0; 95% CI, 1.5–43.2; P=0.016) with a logistic regression that controlled for the covariates maternal age, gestational age, parity, and the presence of pre-eclampsia. Notably, low birth weight was found to mediate the relationship between supine sleep and stillbirth [16]. Currently, there is much interest [23] and follow up

research occurring worldwide, with a growing body of evidence regarding the detrimental effects of supine sleep position on pregnancy outcomes [24].

One proposed hypothesis is that the maternal supine position during sleep plays a causative role in LBW and SB via compression of the abdominal aorta and inferior vena cava ('aortocaval compression'), resulting in negative sequelae. In 2014, drawing on the triple risk model that has been useful in understanding the pathogenesis of sudden infant death syndrome, Warland and Mitchell [25] proposed a similar triple risk model (see Figure 2) to explain the inter-relationship between risk factors and stressors that may result in SB. Although any one risk factor may be insufficient to cause death, together they may produce a lethal combination (as represented by the intersection of the circles), particularly if the fetus is vulnerable [25]. Examples of factors and stressors for each circle are:

- Placental and Fetal vulnerability – e.g., intrauterine growth restriction, placental insufficiency.
- Maternal factors – e.g., obesity, advanced maternal age, smoking
- Fetal stressors – e.g., maternal aortocaval compression, umbilical cord compression



We consider that by addressing these factors and preventing their intersection, we may protect the vulnerable fetus from LBW or SB and thereby effect a significant reduction in the global rates of LBW and SB. In this *Stars in Global Health* project, we focus on how we may intervene to reduce the likelihood of a fetal stressor occurring, in particular maternal aortocaval compression caused via the maternal supine sleeping position.

1.1.3 Background – Maternal Device

Some pregnant women sleep with many pillows supporting their body, including a pillow behind their back to avoid the supine position. Asking women to sleep on their left increases the percentage of left sided sleep to approximately 60% of the night; however, this may come at a cost of a slightly reduced sleep duration, perhaps due to the women feeling they need to make a conscious effort to maintain sleep position [26].

1
2
3 Maternal sleep position has recently been implicated as a potential modifiable risk factor for LBW and
4 SB [14] [15] [16]. Hence, a simple, low-cost, and easily-implemented device has been developed for use
5 by pregnant women to mitigate this risk factor. We anticipate that using this device will remove the
6 need for the woman to make a conscious effort to avoid the supine sleeping position. The device name
7 is 'PrenaBelt'. The PrenaBelt is currently at the prototype stage of development, and as such, this
8 proposal is a proof-of-concept/feasibility project.
9

10
11 The PrenaBelt is a belt-like, positional therapy device designed specifically for pregnant women. While
12 the PrenaBelt does not prevent the user from lying on her back or right side during sleep, it is expected
13 to significantly decrease the amount of time she spends in these two positions via the mechanism of
14 positional therapy. Positional therapy is a simple, non-invasive, inexpensive, long-established, safe, and
15 effective intervention for preventing people with positional-dependent snoring or mild to moderate
16 obstructive sleep apnea from sleeping on their back [27] [28] – a position that exacerbates their
17 condition [29] [30] [31] [32].
18

19
20 The PrenaBelt is worn at the level of the waist. By virtue of its design and position on the user's body,
21 the PrenaBelt affects subtle pressure points around the midriff (back and right side) of the user when
22 she lies on her back or right side, respectively. These subtle pressure points activate her body's natural
23 mechanism to spontaneously reposition itself to relieve discomfort [33] [34] [35], thereby reducing the
24 amount of time she remains on her back or right side. Alternatively, the PrenaBelt can be worn at the
25 level of the thorax with the back of the device centered at the mid-back, in which case the front of the
26 device would sit just below the breasts at the level of the fundus (upper abdomen).
27

28
29 The PrenaBelt is also designed for adjustability and comfort. As such, its configuration can be easily
30 adapted by the user to only help her avoid sleeping on her back if she requires the option of sleeping on
31 her right side as well as her left for comfort reasons.
32

33
34 Members of our team at Global Innovations for Reproductive Health and Life (GIRHL, Cleveland) have
35 developed a Body Position Sensor (BPS) to be integrated into the PrenaBelt. The BPS is a small,
36 electronic data acquisition device developed for research purposes only and in accordance with the
37 original proposal to our funder, Grand Challenges Canada. The BPS fits into a pocket on the PrenaBelt
38 and uses a three axes accelerometer to detect orientation of the PrenaBelt, and thus the user, in three-
39 dimensional space. The accelerometer data is collected and stored on the BPS hard drive and can be
40 accessed via connecting it to a computer.
41

42
43 The PrenaBelt only comes into contact with intact skin and, as such, is a non-invasive medical device. As
44 per Rule 7, subrule (1) in the Government of Canada's Medical Devices Regulation – Classification Rules
45 For Medical Devices, the PrenaBelt is classified as a Class I medical device [36]. The BPS is a research-use
46 only device and, as such, does not fall under medical device regulation.
47

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49 Per the Government of Canada's Medical Devices Regulation – Part 3: Medical Devices For
50 Investigational Testing Involving Human Subjects, Section 80, Subsection (3), "A manufacturer or
51 importer of a Class I medical device may sell the device to a qualified investigator for the purpose of
52 conducting investigational testing if the manufacturer or importer possesses records that contain all the
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information and documents required by Section 81” [36]. Note that the information and documents required by Section 81 can be found in the [Product Information](#) document.

To date, no studies have investigated positional therapy in the pregnant population, and no positional therapy devices have been designed specifically for pregnant women (see Attachment 1). This is likely because the association between maternal sleeping position and adverse pregnancy outcomes has only recently been discovered and published in the literature [14] [15] [16]. The only FDA-approved product for treatment of positional dependent snoring and mild obstructive sleep apnea is the Zzoma Positional Sleeper by Sleep Specialists, LLC (Abington, PA) [37]. However, the Zzoma device was designed specifically for patients with positional-dependent snoring and mild obstructive sleep apnea and not for pregnant women, who are notably different in many aspects including anatomy (e.g., the gravid uterus) and nocturnal behaviour (e.g., rising up more often during the night).

1.1.4 Hypotheses

The following are hypotheses for the study proposed for Halifax:

1. When compared to one night of sleep with no positional therapy (PT) treatment, treatment with a PT intervention (PrenaBelt) during one night of sleep in the third trimester of pregnancy will significantly reduce the percentage of time spent in the supine and right-lateral positions and, thereby, have a favourable effect on maternal respiratory and cardiovascular parameters.
2. Maternal satisfaction, comfort, and desire to continue use of the PrenaBelt during third trimester sleep will be acceptable¹ after one night of use.

1.2 Relevant Literature

Below, is a list of additional relevant literature that has not been discussed in this research protocol.

1.2.1 Maternal Sleep Practices as Risk Factors for Adverse Pregnancy Outcomes

Romero R and Badr MS. *A role for sleep disorders in pregnancy complications: challenges and opportunities.* American Journal of Obstetrics & Gynecology, 2014; DOI: <http://dx.doi.org/10.1016/j.ajog.2013.11.020>

O’Brien LM, Bullough AS, Owusu JT, Tremblay KA, Brincat CA, Chames MC, Kalbfleisch JD, and Chervin RD. *Snoring during Pregnancy and Delivery Outcomes: A Cohort Study.* Sleep, 2013; 36(11):1625-1632.

1.2.2 Sleep Position and Polysomnography During Pregnancy

O’Brien LM, Bullough AS, Shelgikar AV, Chames MC, Armitage R, and Chervin RD. *Validation of Watch-PAT-200 Against Polysomnography During Pregnancy.* Journal of Clinical Sleep Medicine, 2012; 8(3):287-294

¹ “Acceptable” for each of these measures (satisfaction, comfort, intention to use) is defined independently for each measure as being rated 5 out of 10 or higher on a scale from 1 to 10 on the [PrenaBelt User Feedback Questionnaire](#). Each measure has a note indicating the user’s subjective evaluation correlated with various numbers on the scale.

1.2.3 Stillbirth and Low Birthweight

Bukowski R, et al. *Fetal Growth and Risk of Stillbirth: A Population-Based Case-Control Study.* PLOS Medicine, 2014; 11(4):e1001633

1.2.4 Positional Therapy (as a Treatment Option for Sleep Disordered Breathing)

Jokic R, Klimaszewski A, Crossley M, Sridhar G, and Fitzpatrick MF. *Positional treatment vs continuous positive airway pressure in patients with positional obstructive sleep apnea syndrome.* Chest, 1999; 115(3):771-781

Skinner MA, Kingshott RN, Filsell S, and Taylor DR. *Efficacy of the 'tennis ball technique' versus nCPAP in the management of position-dependent obstructive sleep apnoea syndrome.* Respirology, 2008; 13(5):708-715

Permut I, et al. *Comparison of positional therapy to CPAP in patients with positional obstructive sleep apnea.* Journal of Clinical Sleep Medicine, 2010; 6(3):238-243

1.3 Feasibility Study Objectives

The following are objectives for the study proposed for Halifax:

1. Compare maternal sleep position in third trimester pregnant women between a night with and a night without a positional therapy (PT) intervention (PrenaBelt).
2. Obtain PrenaBelt user experience feedback to evaluate PrenaBelt feasibility and acceptability and optimize PrenaBelt design for future research.

1.4 Research Design and Methodology

In Halifax, the utility of the PrenaBelt in modifying maternal sleeping position and the effect of the PrenaBelt on maternal respiratory and cardiovascular parameters during sleep and sleep staging in the third trimester of pregnancy will be evaluated via a two-night, randomized, cross-over, sham-controlled, triple-blind, sleep study in third trimester pregnant women.

- **Two Nights:** one night with positional therapy (PT) and one night with sham-PT to determine treatment effect on outcomes².
- **Randomized:** participants will be randomized to treatment order: sham-PT on first night, then true PT on second night, or vice versa. This will avoid the potential impact of changes to sleep across the two nights resulting from familiarization with the equipment, which could bias the results.
- **Cross-over:** on the second night, each participant will be crossed over from PT to sham-PT (or vice versa, depending on randomization order) to allow each participant to act as her own control for comparison of treatment effect on outcomes.
- **Sham-controlled:** a sham-PT device that has the same feel, fit, and form of the true PT device but without the ability of function (pressure points) will be used as a control. The purpose of a

² These nights need not be consecutive as this may be onerous on some participants who may have children at home; therefore, we will accommodate the schedule and wishes of the participants in the sleep test booking.

sham-PT device is to identify any specific benefit of one element of a PT device (e.g., fit or form) above and beyond all benefits that might be attributed to everything else about a that device (e.g., function). Note that there is no established effective therapy for the population for the indication under study.

- **Triple-blind:** participants, research assistants monitoring and sleep technologists scoring the sleep tests, and the specialized sleep physician reviewing and reporting the sleep test results will be blinded to the intervention – PrenaBelt or sham-PrenaBelt – received each night.
- **Laboratory:** conducting this study in a controlled lab setting will allow for continual, real time monitoring of various cardiovascular, respiratory, uterine, and sleep parameters of each participant by the research assistant. This contributes to a more controlled and safer study overall.
- **Sleep Test:** body position, various cardiovascular and respiratory parameters, uterine contractions, and sleep staging will be continuously recorded while the participants are sleeping. Sleep lab procedures will be followed by the personnel conducting, scoring, reviewing, and reporting the sleep tests from participant preparation through discharge.

1.4.1.1 Methods

After the recruitment, consent, and enrolment processes (see Section 2.5), each participant will be contacted by a researcher and booked for two overnight sleep tests at the Capital Health Sleep Disorders Clinic (4th floor, Abbie J Lane Building, QEII Hospital, 5909 Veterans Memorial Lane, Halifax, NS). These sleep tests will be booked to take place late in her pregnancy (28-37 weeks) but not beyond 37 weeks unless she is comfortable doing so. These two tests need not be consecutive nights as this may be onerous on the participants, who may have children at home; we will accommodate the schedules and wishes of the participants. The sleep clinic has two beds that can be dedicated to research; therefore, two participants should be booked into the clinic per night for budgetary reasons: two participants can be monitored by one research assistant in a twelve hour shift (see section 1.7).

Each participant will be told that she will be randomized by the researchers to which intervention – PrenaBelt device or sham-PrenaBelt – she will receive on the first night and not informed of the treatment order. On the second night, each participant will be switched over to the alternate intervention. Since the PrenaBelt and sham-PrenaBelt will be virtually identical (except for functional PT capability), each participant will be essentially blinded to the intervention received on each night. The PrenaBelt and sham-PrenaBelt will be randomly labeled as either “Device A” or “Device B” by one of the researchers not directly involved in sleep test monitoring, scoring, interpretation, or reporting. The research assistant monitoring and sleep technologist scoring the sleep tests and the sleep specialist physician interpreting and reporting the results will be blind to the intervention used on each night because they will not be told the true identification of “Device A” and “Device B”. As such, this triple-blind, cross-over, sham-controlled design enables each participant to serve as her own control and measurements/results can be compared between her sleep tests.

In preparing for the sleep tests, each participant will be directed to follow the instructions within the Information and Consent Form, which are standard instructions that the sleep clinic has published on its website:

- Participants will be asked to not drink alcohol on the days of their sleep tests.
- Participants will be asked to not drink or eat caffeine after 5:00pm on the days of their sleep tests.
- Participants will be informed that there will be healthy snacks and beverages available at the sleep clinic at no cost to them.
- If a participant becomes sick with a cold, flu, chest infection or any other physical/medical disorder that could interfere with her sleep, she will be asked to contact a member of the study team as soon as possible as her sleep tests may need to be rebooked.
- Participants will be asked to try to maintain their regular daytime schedule and, if at all possible, avoid napping on the days of their sleep tests.
- Participants will be asked to bring all of their regular medication to the sleep clinic. Unless otherwise instructed beforehand, participants should continue to take their medication as usual.
- Participants will be required to wear sleep attire and will be asked to try to avoid silky material. Pajamas, or walking shorts and a t-shirt are ideal. Participants can bring their own pillow and/or favorite blanket if they wish.
- To ensure the paste and tape for the various monitors adhere to the participant's skin, participants will be discouraged from using body and facial moisturizers. Participants will be asked to remove artificial fingernails and nail polish from at least one finger before the test as they prevent the function of the pulse oximeter.
- Presently, the sleep clinic does not have shower facilities but is able to provide participants with face cloths and towels. If participants wish to have access to shampoo, soap and combs/brushes, they will be asked to bring their own.
- Participants will be encouraged to bring reading material, puzzles, a movie (on DVD) or some other interest to help them relax before Lights Out. The sleep clinic has portable DVD players that participants can borrow.
- Onsite underground parking is available and presently costs \$4.00 for an overnight stay (in after 4:30pm, out before 8:00am). Participants will be reimbursed for this if they choose overnight parking.

The following are the specific details about how the sleep test will proceed:

- Sleep tests will be done in a private clinical/research room with continuous monitoring by a research assistant (in a separate room) through audio-visual and Sandman sleep software.
- Participants (1-4 per night) will be asked to arrive at the sleep clinic waiting room between 7:00pm and 8:00pm on the evenings of their sleep tests. The research assistant and/or study personnel will meet the participants in the waiting room, provide them with two forms to complete (below, first sleep test night only), and bring them to their respective rooms.
 - Participants will be asked to complete the Unexpected Events Contact Form and give it to the research assistant. This will only takes a few minutes to complete.
 - Participants will be asked to complete the Data Collection Form. This form will take about 5-10 minutes to complete. This form will be placed in a sealed envelope for the researchers.

- The forms can be completed before or after hook up.
- The research assistant will hook up one participant at a time. Several monitors (explained below) will be attached to each participant. Hook up will be according to the American Academy of Sleep Medicine 2014 guidelines. Monitors and software will be used to measure, record, and process the following information during the sleep tests:
 - Body position will be measured by direct observation by the research assistant through audio/video recording and by an electronic Body Position Sensor incorporated into the PrenaBelt.
 - Apnea-hypopnea index, which is a standardized measurement of how many times the breathing pauses or slows during sleep, will be calculated by measuring:
 - Chest and abdominal movement (respiratory effort) by having the participant wear two soft, stretchy belts with sensors (respiratory inductance plethysmography). One belt will be positioned around the rib cage just below the breasts, and one belt will be positioned near the umbilicus.
 - The airflow through the participant's mouth and nose by a soft, rubber tube placed just under the nares at its opening, which measures inspiration and expiration. This tube will also detect if snoring is present and how much.
 - The arterial oxygen saturation will be measured by a pulse oximeter placed on one of the participant's fingers.
 - Heart rate and regularity will be measured by electrocardiography (EKG), which involves attaching two electrodes to the skin on the chest and using wires and tape to connect the electrodes to the central box for signal processing.
 - Sleep staging (wake, stage 1, 2, 3, and REM) will be measured by a combination of EEG, EOG, and EMG, which involves attaching electrodes, tape, and wires (similar to above) to the skin on the head, face, chin, neck, arms, and legs.
- The research assistant and/or study personnel will use a demonstration PrenaBelt to show the participant how to don and doff the PrenaBelt. The participants will be informed that they can remove the PrenaBelt and/or sleep test equipment at any point of the sleep test if they become too uncomfortable.
- Bathroom visits during sleep tests are always possible. The research assistant and/or study personnel will discuss the bathroom visit process with participants before their sleep test. Bathroom breaks during sleep tests are part of routine practice at the sleep clinic. The research assistant will assist the participants when bathroom breaks are required and ensure privacy.
- The research assistant will not be apprised of whether the participant has been assigned the PrenaBelt or sham-PrenaBelt. The study personnel will place the appropriate device in a box in the participant's room. The participant will open the box and put on the PrenaBelt before lights out.
- The PrenaBelt will be preconfigured for the participant by the study personnel based on whether the participant indicated to the IWK Research Assistant that she would like the option of sleeping on her right side. If the right side sleeping position is requested, the balls will be removed from the pockets on the right side of the PrenaBelt. When the balls are removed from

the right side pockets, the configuration of the PrenaBelt as such will then only help the user avoid sleeping on her back.

- Lights Out is usually between 10:30pm to 11:00pm. Just before lights out, the research assistant will run calibration testing, which requires participation from the participants (e.g., “close your eyes, open your eyes, roll your eyes, look left, look right, clench your teeth, breath through your mouth, breath through your nose, hold your breath and move your belly in and out,...”). The research assistant will monitor the incoming sleep data in real time throughout the night for quality assurance.
- If a channel faults, the research assistant may fix it if the participant is still awake or wakes up for a bathroom break. If the research assistant cannot solve the fault, he/she may consult with the sleep technician (if present) or call the on-call sleep technician (Friday and Saturday evenings). Throughout the night, the research assistant may also add notes to the data that may assist with subsequent scoring of the data.
- If the device (PrenaBelt or Sham-PrenaBelt) cannot be tolerated by the participant and is removed during the sleep test (note that the Information and Consent Form clearly informs the participants that they are free to remove the device at any time at no penalty if it becomes too uncomfortable), this will be noted by the research assistant via the Sandman software. The sleep test data recording will continue until morning. Study personnel will follow up with the participant to determine whether or not she wishes to withdraw from participating in the study.
- The sleep tests will be finished between 6:00am and 6:30am. When the participant awakes, the research assistant will enter the room and unhook the participant from the sleep test equipment. It is expected that participants will be out of the sleep clinic bedrooms by 7:00am whenever possible.
- After participants are unhooked and before they leave the sleep clinic, they will be asked to complete the PrenaBelt User Feedback Questionnaire, which will take 5-10 minutes and will be sealed in an envelope for the researchers.

1.4.1.2 Measures

The information collected from her on the Data Collection Form is collectively referred to as “demographic and sleep habits information” in Section 1.4.1.6:

- Gestational age at time of sleep test
- Parity
- Maternal age
- Ethnicity/race
- BMI (weight, height) at time of sleep test and BMI at conception or early pregnancy
- Typical bed and rise times, usual sleep duration, habitual snoring (3 or more nights per week; if present, for how long this has been the case), typical position she goes to sleep in and wakes up in currently and when she is not pregnant, what part of the bed she sleeps on, if she has a bed partner, and if she uses pillows when she sleeps (if so, how)
- Presence of new pregnancy-related conditions since signing the consent form for this study

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3 For each participant, identical measurements (below, collectively referred to as “sleep variables” in
4 Section 1.4.1.6) will be recorded on both nights using the same methods, equipment, and software. The
5 sleep tests will be set up and monitored by a research assistant trained in polysomnography and under
6 the supervision of a sleep technologist except on Friday and Saturday evenings. On Friday and Saturday
7 evenings, either two research assistants will be present or one research assistant and one authorized
8 study personnel will be present and a sleep technician will be on call. The sleep tests will be scored by a
9 sleep technologist holding board certification in sleep technology (RPSGT). Scoring will be according to
10 the current American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated
11 Events. The sleep tests and scores will be interpreted and reported by a sleep specialist physician. Note
12 that the measurements, methods, equipment, and software employed will be non-invasive:
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- 16 a. Maternal position: direct observation by the sleep technologist through real-time or
17 recorded audio/video and by an electronic Body Position Sensor incorporated into the
18 PrenaBelt
- 19 b. Chest and abdominal respiratory movement: respiratory inductance plethysmography
20 (RIP) via Pro-Tech zRIP DuraBelt with Sandman PSG software
- 21 c. Nasal and oral airflow and presence of snoring: Braebon nasal pressure transducer. If
22 the participant is a total mouth breather, Braebon thermistor will be available as a back-
23 up.
- 24 d. Arterial blood oxygenation: pulse oximetry (SpO₂) via Embla Sandman
- 25 e. Heartbeat rate and regularity: via electrocardiography (EKG)
- 26 f. Sleep staging: via electroencephalography (EEG), electromyography (EMG), and
27 electrooculography (EOG). Note that if a participant is uncomfortable or cannot tolerate
28 some of the EEG, EMG, or EOG electrodes/leads, e.g., EMG electrodes/leads on arms
29 and legs, these electrodes/leads may be removed.

30
31 In the morning following each sleep test, before each participant is discharged home, she will be asked
32 to complete the approved PrenaBelt User Feedback Questionnaire and seal it in a provided envelope for
33 the researchers. Participants will be asked:
34
35

- 36 a. What position she adopted upon settling down last night
- 37 b. What position she fell asleep in last night
- 38 c. What position she woke up in this morning
- 39 d. If she changed position during night
- 40 e. If she remembers changing positions
- 41 f. Her level of satisfaction with the PrenaBelt as it relates to the quantity and quality of her
42 sleep last night
- 43 g. Her level of comfort while wearing and sleeping with the PrenaBelt
- 44 h. Her intention to use the PrenaBelt for the remainder of her pregnancy if it was available
45 to her
- 46 i. Any suggestions of changes/ modifications/ improvements she may have for the
47 PrenaBelt

1.4.1.3 Outcomes

Primary Outcomes: For both sleep tests, the following are the primary outcomes for each participant:

- % of time spent in the supine and right-lateral positions with each intervention
- PrenaBelt User Feedback Questionnaires

The following data will be collected from each participant across each intervention and serve as pilot data to inform effect size calculations for future research.

- Apnea Hypopnea Index (AHI)
- Arterial blood oxygenation (SpO₂)
- Maternal heart rate (ECG)
- Sleep parameters (total sleep time, presence of snoring, RDI, sleep onset latency, sleep efficiency, sleep quality, number of arousals, number of position changes, mean AHI while supine, mean SpO₂ while supine)

When the two sleep tests are complete (interpreted and reported by the sleep specialist physician), the results will be provided to the participant's maternity care physician who will discuss her results with her at her next antenatal care visit. If warranted by the results of the sleep tests for a given participant (e.g., severe obstructive sleep apnea is discovered), contact will be made with the participant and her maternity care physician by a researcher to allow for proper management and care at the earliest opportunity. If her maternity care physician has any concerns about the sleep test results and plan for further investigation/management, he/she may consult with Dr. Debra Morrison (Site-Investigator, Respiriologist, Sleep Specialist Physician) who will be available to address these concerns.

1.4.1.4 Inclusion/Exclusion Criteria

Inclusion criteria: ≥18 years old, low-risk singleton pregnancy, in the last trimester of pregnancy (≥28 weeks of gestation), and residing in the Halifax Regional Municipality.

Exclusion criteria: BMI ≥ 35 at booking (first antenatal appointment for current pregnancy), pregnancy complicated by obstetric complications (hypertension [pre-eclampsia, gestational hypertension, chronic hypertension], diabetes [gestational or not], or intra-uterine growth restriction [<10th %ile for growth]), sleep complicated by medical conditions (known obstructive sleep apnea, known to get <4 hours of sleep per night due to insomnia, or musculoskeletal disorder that prevents sleeping on a certain side [e.g., arthritic shoulder]), multiple pregnancy, known fetal abnormality, non-English speaking and reading.

1.4.1.5 Sample size

To date, there has never been a positional therapy study performed on pregnant women [38]; therefore, there is little-to-no relevant data on which to base a proper sample size analysis. As a feasibility study, this study will be used to generate preliminary data to be used in effect size calculations for future clinical trials targeted at reducing poor pregnancy outcomes in Canada and globally.

A sample size of twenty-five³ (n=25) pregnant volunteers is selected for this feasibility study.

Rationale:

- For a one-sided paired t-test with power (β) of 0.80, significance level (α) of 0.05, n=25 pairs enable a detectable effect (d) of -0.5, which is a medium effect size per the literature regarding Cohen.
- Based on expert opinion (Dr. Louise O'Brien, Scientific Mentor on *Stars In Global Health* project, University of Michigan), n=25 was originally budgeted and proposed to Grand Challenges Canada, which was subsequently approved by Grand Challenges Canada and the Canadian Institute for Health Research.

1.4.1.6 Justification of Statistical Methods

Cross-over study design: each participant is her own control for comparison.

Descriptive statistics (mean, median, standard deviation, maximum, minimum) for demographic and sleep habits information and sleep variables (Section **Error! Reference source not found.**) will be reported.

For continuous variables, the assumption of normality will be assessed using Q-Q plots and the Anderson-Darling test. If normal, paired t-test will be used for evaluating differences. If non-normal, Wilcoxon signed rank test will be used for evaluating differences. For dichotomous data, we will evaluate for differences using McNemar's test for repeated measurements.

1.5 Timeline

November 2014 to May 2015: Halifax study preparation, PrenaBelt development and production of test samples, obtain ethical and research protocol approval from the IWK Health Centre REB.

November 2015 to July 2016: Training, recruitment, consent, enrolment, and data collection in Halifax.

July 2016 to August 2016: Data analysis, report writing, dissemination of findings from Halifax.

November 2014 to May 2015: Ghana study preparation, obtain ethical and research protocol approval from Noguchi Memorial Institute for Medical Research IRB, IWK Health Centre REB, and the Ghana FDA.

April 2015 to July 2015: Production of PrenaBelt test samples for Ghana study.

July 2015 to January 2016: Training, recruitment, consent, enrolment, and data collection in Ghana.

January 2016 to May 2016: Data analysis, report writing, dissemination of findings from Ghana.

1.6 Definition of Adverse Events

Labour is a natural process, so it will be classified as an unexpected event (not an adverse event) in this study should it begin to occur during a sleep test.

³ Note: the EAS Form submitted to the IWK states that a maximum number of thirty (n=30) participants will be recruited. The discrepancy of five (n=5) participants is a buffer to account for an approximate drop-out rate of 20%.

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3 Participants may experience minor irritation of skin in areas in contact with the stickers that hold the
4 sleep electrodes on their body.
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6 The sleep tests for a given participant may reveal that an adverse event has been occurring in her
7 pregnancy without prior knowledge. The sleep test may reveal the presence of maternal obstructive
8 sleep apnea (OSA). We do anticipate that OSA will be discovered in some participants – especially since
9 OSA is common yet often undiagnosed in pregnant women [39] [40] [41] [38] [42] [43] [44]. This adverse
10 event is not related to this study, rather it is related to other obstetric and medical factors and only
11 discovered by this study. It should also be noted that any events (e.g., OSA) that we do observe would
12 be already occurring without anyone's knowledge. If severe OSA is discovered during any of the sleep
13 tests, we will notify the participant and her maternity care physician, give them the test results, and ask
14 them to speak with one another at earliest opportunity to ensure proper management and care. Her
15 maternity care physician will also be informed that if he/she has any concerns about the sleep test
16 results and plan for further investigation/management, he/she may consult with Dr. Debra Morrison
17 (Site-Investigator, Respiriologist, Sleep Specialist Physician) who will be available to address these
18 concerns.
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24 Should a medical emergency occur, the sleep technologists at the Capital Health Sleep Disorders Clinic
25 have been trained according to internal policies and procedures for handling emergencies and
26 unexpected events during sleep tests. The sleep technologists will call EMS and provide basic life
27 support (if needed) until EMS arrives. The sleep technologists are trained in CPR.
28
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30 Although the risk is low, a participant may go into labour during the sleep study; therefore, our exclusion
31 criteria excludes women at risk of pre-term labour, and we will not book any participants for a sleep test
32 beyond 37 weeks gestation unless the participant is comfortable in doing so. The research assistant will
33 follow a basic plan of action should the participant go into labour during a sleep test:
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- 36 1. If a participant begins labour during a sleep test, stop the test immediately.
- 37 2. Urgent: if onset of labour is sudden and participant is in distress, call EHS to transport the
38 participant to the IWK. Otherwise proceed to 3.
- 39 3. Non-urgent: if onset of labour is slow and participant is stable, use the information from the
40 Unexpected Events Contact Form and assist the participant in reaching her contact to
41 transport her to the IWK.
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44 Pregnancy is associated with many risks for the mother and fetus, yet sleep tests are non-invasive and
45 safe for pregnant women and their developing baby to undergo. Although the risks that this study poses
46 to the pregnancy are minimal, all adverse events will be reported to the CDHA Patient Safety Reporting
47 System as per hospital standard operating procedures.
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50 1.7 Budget

51 For the budget related to research activities in the study in Halifax, see lines 77, 113, and 225 in the
52 Project Budget (submitted as a component of the Researcher's Checklist for Submissions: Delegated
53 Review).
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1.8 Resources

Letters of support will be obtained from the applicable institutions (denoted by †) listed in Table 1 and submitted as a component of the Researcher's Checklist for Submissions: Delegated Review.

Table 1. Resources for Halifax Study

Study Component	Institution (Department)	Key Personnel (Position)	Lab/Facility	Equipment
Grant fund administration, Project Monitoring, and Advisory Board	Innovative Canadians for Change Foundation	Dr. Andre Isaac (Project Manager)	n/a	n/a
Ethics Process	IWK Health Centre (Review Ethics Board)	Bev White (REB Manager/ Information Officer)	n/a	n/a
Participant recruitment, consent, enrolment	IWK Health Centre† (Women's and Newborn Health)	Dr. Heather Scott (Obstetrical Co-Director) Ms. Darlene Baxendale (RN, Research Assistant)	Perinatal Centre	n/a
Sleep tests	Capital Health† (Sleep Disorders Clinic)	Dr. Debra Morrison (Clinical Director, Staff Respirologist) TBD (Certified Sleep Technologist) TBD (Polysomnography Research Assistant)	Two sleep rooms in the sleep laboratory	A/V equipment, Braebon nasal pressure transducer, Braebon thermistor, Pro-Tech zRIP DuraBelt, Embla Sandman, Sandman PSG software, EKG, EEG, EMG, EOG, consumables
PrenaBelt engineering, liaison with Kaishin Design	Global Innovations for Reproductive Health and Life	Ali Borazjani (President, Co-Founder, Biomedical Engineer)	n/a	n/a
PrenaBelt samples: design, production	Kaishin Design	Kaishin Chu (Apparel Design and Development Strategist/Consultant)	n/a	n/a
Scientific Innovation	University of Michigan	Dr. Louise O'Brien	n/a	n/a
Business Innovation	Harvard Business School	Dr. John McArthur	n/a	n/a

n/a – 'not applicable'

2 Ethical

2.1 Potential Benefits to Participants and Others

2.1.1 Participants in Halifax

Undergoing a sleep test may benefit a participant and her developing baby. Due to physiological and anatomical changes in pregnancy, pregnant women have been found to be more susceptible to sleep-disordered breathing – e.g., snoring, obstructive sleep apnea (OSA) – than non-pregnant women [38]. Possible association between OSA and complications in pregnancy (gestational diabetes, gestational hypertension, pre-eclampsia, intra-uterine growth restriction) have been shown [45] [39] [40] [46] [47], and OSA is common yet often undiagnosed in pregnant women [39] [40] [41] [38] [42] [43] [44]. After the sleep tests are scored for a given participant, a researcher will follow up with her maternity care physician if she requests this in the Information and Consent Form. Her maternity care physician will

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3 discuss her results with her at her next antenatal care appointment. We have found in previous studies
4 that most women appreciate this.
5

6
7 If severe OSA is identified for a given participant, she and her maternity care physician will be notified
8 immediately, given the sleep test results, and advised to discuss this issue together at earliest
9 opportunity to ensure proper management and care. Proper management of her OSA may result in
10 instant and long-term benefits for her and her baby.
11

12
13 In addition, the opportunity to assist in the advancement of sleep-in-pregnancy knowledge and the
14 possibility of benefiting other pregnant women globally in the future may be a source of immediate
15 satisfaction to participants.
16

17 **2.1.2 Others**

18 Note: the following section refers to the WHO definition of stillbirth and not the definition used by
19 Statistics Canada (see Section 1.1).
20

21
22 In Canada, three babies are stillborn every day ($\geq 1000\text{g}$ birthweight or ≥ 28 weeks completed gestation)
23 [1]. This is a largely unrecognized national tragedy yet pales in comparison to Ghana, where 47 babies
24 are stillborn every day [1] (Note: in Ghana, the birth rate is 2 times greater than that in Canada, but the
25 stillbirth rate is more than 15 times greater). In addition, every day, 61 Canadian babies are born with
26 low birthweight ($\leq 2500\text{g}$) [48], and 232 Ghanaian babies are born with low birthweight [49] – many of
27 whom will die in infancy or suffer lifelong consequences. These statistics and disparities are
28 unconscionable, yet even they pale when compared to regions of further impoverishment where the
29 state of affairs has been aptly described by one author as ‘obstetric carnage’ [50].
30
31

32
33 Maternal supine sleep has recently emerged as a potential risk factor for SB and LBW [14] [15] [16]. If
34 supine sleep has a causative role in LBW and subsequently SB, the population attributable risk (PAR%)
35 suggests that up to 17% of LBW, and consequently 26% of SB, might be averted by changing maternal
36 sleep position [16] – this translates to the aversion of 3.7 million LBW and 676,000 SB annually [1] [5].
37 Since LBW is a major contributor to stillbirth [4], morbidity [5] [11] [12], and neonatal mortality (60-80%)
38 [6] [7] [8] [9], further benefit may be realized.
39
40

41
42 This study will test a novel approach to reducing the global incidence of SB and LBW by determining
43 whether this potential risk factor can be mitigated via treatment with a simple, positional therapy
44 device. Demonstrating that maternal sleep position is, in fact, amenable to positional therapy will be a
45 valuable contribution to existing knowledge and may be a key component to reducing the rates of SB
46 and LBW in Canada and worldwide.
47

48
49 Currently, research is underway to determine whether a causal relationship between maternal sleep
50 position and SB and LBW exists and collect a robust evidence base from which to advise whether a
51 public health intervention should be considered (dissemination of research findings expected by August
52 2016) [24]. If a public health intervention is advised, our study will be at the forefront of scientific
53 investigation into one possible intervention, i.e., positional therapy.
54
55

1
2
3 Following successful completion of this proof-of-concept (Phase I) study, there is potential for transition-
4 to-scale (Phase II) funding from Grand Challenges Canada (contingent on 50% matching through
5 partnerships) of up to \$1,000,000 CAD for up to 2-3 years. In addition to this funding, other grant
6 options in the area of maternal, newborn, and child health (MNCH) are available, e.g., Bill and Melinda
7 Gates Foundation, Saving Lives at Birth. Such grants would enable exploration of the effectiveness of
8 this intervention in populations that have very high perinatal mortality rates.
9

10
11 Finally, this project may bring beneficial opportunities to members of the research team. For example, it
12 may cultivate future research collaboration with other teams worldwide through publication in journals
13 and presentations/networking at global health conventions. Another example is that the inventors of
14 the PrenaBelt (Mr. Borazjani, Mr. Kember) plan to establish or partner with a social enterprise
15 organization to ensure sustainability and maximum benefit to mothers and their babies globally.
16
17

18 **2.2 Potential Harms to Participants and Others**

19 This study is minimal risk. Participants in this study are at no greater risk of harms when completing the
20 activities of this study than those risks they encounter in their everyday life.
21
22

23
24 The PrenaBelt device is a non-invasive medical device of Class I designation (see section 1.1.3). Pregnant
25 women typically sleep with many pillows supporting their body, including a pillow behind their back to
26 avoid the supine position. The PrenaBelt is a positional therapy device that may assist pregnant women
27 to avoid supine sleep. Positional therapy devices have been shown to be safe and approved for use by
28 humans by the US Food and Drug Administration [37]. In addition, maternal body pillows, regular
29 pillows, and pelvic belts (lumbar support) have been used by pregnant women during sleep without
30 reports of serious adverse effects for the mother or neonate [51].
31
32

33
34 In Halifax, wearing the PrenaBelt and sleep monitoring equipment may be uncomfortable for a
35 participant and disturb her sleep. Each participant will be told that she can remove these devices at any
36 time overnight if she becomes too uncomfortable.
37

38
39 In order to ensure the monitor electrodes remain adhered to participant's skin, the research assistant
40 will need to prepare the area of skin, which involves cleaning and slight abrasion with an abrasive skin
41 preparation gel. In the morning, after the monitors are removed, participants may experience slight
42 discomfort and redness on the regions of their skin that were in contact with the electrodes. Rarely, a
43 person will have a minor skin reaction on the area of his/her skin that was in contact with the
44 electrodes. This reaction is not dangerous and usually goes away on its own within 24 hours to a few
45 days.
46
47

48 Since personal information will be collected from participants, there always exists the potential harm
49 should breach of confidentiality inadvertently occur.
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2.3 Alternative Treatments or Procedures

2.3.1 Positional Therapy

There are several techniques used for positional therapy such as positional alarms, verbal instructions, special pillows, tennis balls, vests, and “shark fins”. The latter three techniques prevent the wearer from lying supine in a passive manner by applying pressure points to the wearer’s back when lying supine, which is similar to the mechanism of the PrenaBelt.

To date, no studies have investigated positional therapy in the pregnant population, and no positional therapy devices have been designed specifically for pregnant women (see Attachment 1). This is likely because the association between maternal sleeping position and pregnancy outcome has only recently been published in the literature [14] [15] [16] [25].

There are several positional therapy products for persons with positional-dependent obstructive sleep apnea (POSA) (see Attachment 1). However, these devices are designed specifically for persons with POSA, not pregnant women, who may also have POSA but are notably different in aspects such as anatomy (e.g., the gravid uterus) and nocturnal behaviour (e.g., rising up more often during the night). Of these products, only the Zzoma Thoracic Anti-Supine Band is FDA-approved for the treatment of OSA. In addition, these devices are characteristically limited in that they are designed to only prevent supine sleep. Some of these devices involve expensive electronic components and, therefore, are not feasible for widespread deployment in low-resource areas.

2.3.2 Sleep Study

Sleep studies can be performed at home or in a sleep lab setting. Sleep studies for diagnosis of sleep disordered breathing in adults can vary in complexity. A Level I sleep study includes full polysomnography, is conducted in a sleep lab setting, and is considered the gold standard in sleep testing. A Level III sleep study is less complex and is generally performed in the home setting. In Halifax, we are proposing a Level I study.

2.4 Minimization of Potential Harms

While the risks of this study to the participants and their developing babies are minimal, all adverse events will be reported to the CDHA Patient safety Reporting System as per hospital standard operating procedures

Wearing the PrenaBelt and sleep monitoring equipment may be uncomfortable for a participant and disturb her sleep. Each participant will be instructed how to, and told that she can, remove these devices and discontinue use at any time if she becomes too uncomfortable. If bothersome skin irritation occurs for a given participant as a result of contact with the electrodes, we will limit the contact of sleep electrodes to one overnight study.

Personal health information (PHI) used to identify potential participants will not be accessed by anyone other than the researchers within their circle of care.

1
2
3 Upon enrolment in the study, each participant will be assigned a random, six-digit, alphanumeric code.
4 All data collected from participants during the studies will be collected only in association with this code,
5 thus automatically de-identifying the data and minimizing the risk of identification. The key to the code,
6 which links the codes to patient names and contact information, will be kept in a secure location away
7 from the de-identified study data, thus minimizing the risk of re-identification. The de-identified data in
8 forms (paper) and files (electronic) will be secured in a locked filing cabinet and in password-protected
9 files on a password-protected computer, respectively, in a locked office with limited access.
10
11

12
13 For all study activities, all data collected from participants will be protected from unauthorized access to
14 safeguard participant privacy and confidentiality in accordance with TCPS2, PHIPA, and PIPEDA and
15 personal information policies at the IWK Health Centre.
16

17
18 There is a reasonable foreseeable risk that the Unexpected Events Contact Form for a given participant
19 (contains participant's first name, name of contact, phone numbers of contact, and relationship of
20 contact) could be matched with her Data Collection Form, PrenaBelt User Feedback Questionnaires, or
21 sleep recording files (which contain her alphanumeric code) and be used to re-identify her de-identified
22 information. To mitigate this risk of re-identification, the research assistant will be the only person who
23 will have access to the Unexpected Events Contact Form and will be instructed to keep it in a separate
24 secure location and shred it in a cross-cut shredder after the second sleep test is complete. In addition,
25 the research assistant will not have access to the Data Collection Form or PrenaBelt User Feedback
26 Questionnaires, which will be delivered and retrieved from each participant in a sealed envelope.
27
28

29
30 Study data will only be exchanged in de-identified form and between authorized research team
31 members per the approved EAS Form. Data will be protected in electronic transfers through password
32 protection and encryption if deemed necessary.
33

34
35 After study closure, study data will be stored securely (locked cabinets, password-protected files,
36 password-protected computers, locked offices) in de-identified form for five years, after which it will be
37 destroyed in a secure manner (e.g., incineration and cross-cut shredding).
38

39 2.5 Process for Seeking Consent

- 40
41 1. **Ethical Approval and Training:** The study requires approval from the Review Ethics Board at the
42 IWK Health Centre (Halifax, Canada). All study personnel will be trained to the approved
43 Research Protocol by Mr. Allan Kember (Sub-investigator, Project Lead).
44
- 45
46 2. **Recruitment:**
 - 47
48 • The IWK OB/GYN will review charts of her/his patients scheduled for their routine antenatal
49 visit at the clinic to identify potential participants. These patients will then be screened by
50 the OB/GYN within their circle of care using the Screening Inclusion Form to determine if they
51 meet the inclusion/exclusion criteria for this study.
52
 - 53
54 • Patients who meet the inclusion/exclusion criteria will be invited to participate in the study
55 by their OB/GYN at the end of their antenatal care visit via the approved Flyer. The Flyer will
56

also be posted in the clinic rooms and waiting areas. A patient who expresses interest in participating in the study will be asked if she is agreeable to speak to the IWK Research Assistant about the study.

- If she is agreeable, the IWK Research Assistant will then come to the clinic, confirm the inclusion/exclusion criteria by reviewing the patient's chart, and conduct the formal consent process using the approved Information and Consent Form.
- If she does not wish to speak with the IWK Research Assistant immediately but is still interested in participating in the study, she will be given the Information and Consent Form to take home and read and asked whether she would agree to be contacted by the IWK Research Assistant in one week's time.
 - If she agrees, her name and contact information will be given to the IWK Research Assistant who will contact her in one week's time to see if she is still interested in participating in the study.
 - If she does not agree, she will be informed that she is free to contact the IWK Research Assistant whenever she wishes to do so.
- Snowball sampling may be used as well, i.e., potential participants who are interested may tell their friends about the study (share the Flyer and Information and Consent Form with them) and direct them to contact the IWK Research Assistant.

3. **Consent and Enrolment:**

- Potential participants, having
 - met the study inclusion/exclusion criteria,
 - been invited to participate in the study,
 - shown express interest in participating in the study, and
 - given verbal consent to speak with the IWK Research Assistant,will meet with the IWK Research Assistant to complete the consent process.
- In the meeting, the IWK Research Assistant will go through the approved Information and Consent Form with the potential participant, ensuring full and accurate disclosure of the,
 - nature of the study (what is involved, who will be conducting it, how the results will be used, how confidentiality and privacy will be protected),
 - the risks and benefits involved in participating in the study, and
 - the free choice to decline participation in or withdraw from the study at any time without consequence (no adverse or negative effect on her or her family's care in any way)to each potential participant.
- The capacity of each potential participant to provide consent will be assessed by the IWK Research Assistant by asking the potential participant questions to verify she understands the information relevant to giving or refusing consent and appreciates the outcomes of both choices:

- What is this study about?
- Why is this study important?
- What will you need to do in this study?
- What are the risks to you from being involved in this study?
- What are the benefits to you from being involved in this study?
- What happens if you choose to not participate today?
- What happens if you choose to participate today and then change your mind at another time either before the study starts or during the study?
- The IWK Research Assistant will give each potential participant an opportunity to ask any questions she may have.
- Voluntary, written, informed consent (form) will be obtained by the IWK Research Assistant from a potential participant who has demonstrated capacity and maintains an interest in enrolling in the study. Authorization or refusal of consent by a potential participant will be accepted by the IWK Research Assistant.

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Attachment 1: Treatment and Device Search

PrenaBelt Patent Search

Positional Therapy for Positional-dependent Obstructive Sleep Apnea (POSA) – Product Search

Pregnancy Sleep Product Search

For peer review only

Table 1. PrenaBelt Patent Search

Publication Number	Application Number	Publication Date	Title	Potential Similarity to PrenaBelt [†]
US4471767 A	US 06/558,335	09/18/84	Therapeutic device for positional treatment for gastroesophageal reflux	1
US20110132378 A1	US 12/794,498	06/09/11	Systems and methods for controlling position	2
US 20110179573 A1	US 12/975,144	07/28/11	Suspended back pillow for sustaining a side sleeping position	1
US 20130043999 A1	US 13/695,209	02/21/13	Method and device for sleep posture correction	3
US 20120197340 A1	US 13/251,856	08/02/12	Screening devices and methods for obstructive sleep apnea therapy	1
US 20130108995 A1	US 13/286,037	05/02/13	System and method for monitoring and influencing body position	1
US 20100319131 A1	US 12/581,732	12/23/10	Suspended Back Pillow for Sustaining a Side Sleeping Position	1
US4506396 A	US 06/480,943	03/26/85	Comfort pillow for pregnant females	1
US 5359739 A	US 08/113,076	11/01/94	Patient repositioning and position maintenance device	1
US6886201 B1	US 10/698,244	05/03/05	Maternity pillow	1
USD547586 S1	US 29/192,913	07/31/07	Maternity pillow	1
WO 2008120897 A1	PCT/KR2008/001712	10/09/08	A maternity belt with vibration speaker	1
US20130067642 A1	US 13/239,179	03/21/13	Maternity belt structure	2
US20130072087 A1	US 13/239,164	03/21/13	Adjustable protective maternity belt	2
US 8396229 B2	US 11/834,085	03/12/13	Musical maternity belt	1
USD560328 S1	US 29/261,923	01/29/08	Maternity belt	1
US3315670	---	04/25/67	Maternity belt	1
US2765470	---	10/09/56	Maternity belt	2
US 20070037483 A1	US 11/271,892	02/15/07	Maternity belt	1
US2486211	---	10/25/49	Maternity belt	2
US6537132 B1	US 09/696,873	03/25/03	Maternity brace	1
US 20090142988 A1	US 11/998,477	06/04/09	Lower uterine segment maternity support belt	2
USD658350 S1	US 29/370,112	05/01/12	Asymmetric maternity support belt	1
US 3623488	---	11/30/71	Belly-band	2

Notes: [†]Subjective scoring: 1=minimal to no similarity → 5=highly similar

Table 2. Positional Therapy for Positional-dependent Obstructive Sleep Apnea (POSA) – Product Search

Company	Device(s)	Description	Cons
NightBalance B.V. (Delft, The Netherlands)	NightBalance Sleep Position Trainer	For light and moderate POSAS. Electronic sensor worn on an ergonomic strap around the chest. Vibrates when in supine position. Comfortable and user friendly. Trains user not to sleep supine. Can monitor sleep data on computer.	Expensive. Requires batteries. High-tech. Only prevents supine sleep. Available by prescription only (requires sleep examination).
Advanced Brain Monitoring(CA, USA)	Sleeptech Night Shift Sleep Positioner	For POSAS and snoring. Electronic sensor worn around the neck. Vibrates when wearer is supine and increases in intensity until wearer shifts. Can monitor sleep data on computer.	Price (\$270). Rechargeable battery lasts three nights. High-tech. Only prevents supine sleep.
N/A	Tennis ball technique	For POSAS. Simple. No electric components. A belt or shirt with pockets large enough to put a tennis ball inside. Also in the form of a pouch with straps.	Back discomfort. Low compliance long term. Only prevents supine sleep. Tennis balls can move around or fall out while sleeping.
Zzoma (PA, USA)	Zzoma Thoracic Anti-Supine Band	For POSAS. No electric components. A belt with a large piece of foam mounted on the area that covers the wearer's back. Prevents the wearer from rolling onto back while sleeping. Side elastics for comfortable breathing.	Bulky. Worn around the upper torso. If wearer wants to switch from left to right side, they must do so via the stomach. Only prevents supine sleep. Available by prescription only.

Table 3. Pregnancy Sleep Product Search

Company	Device(s)	Description	Cons
Utterly Yours (VA, USA)	Pregnancy Pillow	For maternal sleep. Simple, full-length, wedge, or U-shaped pillows to support and align the back and hips, and support the belly, knees, and/or body to help reduce pain and provide a good night sleep. Claim to benefit a pregnant mother's comfort, rest, and health.	Expensive. Bulky. Emphasizes comfort, not optimal position. Encourages lateral sleep, but does not prevent supine sleep or lateral-right sleep.
Boppy (CO, USA)	Cuddle Pillow, Custom Fit Total Body Pillow, Pregnancy Wedge		
Leachco (OK, USA)	Snoogle Total Body Pillow		
Today's Mom (CO, USA)	Coolmax, Cozy Cuddler, Cozy comfort		
Oggi (USA)	Elevation		
Yaz Design (USA)	Pillowband		
Peachy Products (South Africa)	Stress Nest		
Motherhood Maternity (USA, Canada)	Tummy Sleeve, Ultimate Maternity Belt, Maternity Support Belt	Wide pieces of stretchy fabric in a tube configuration designed to discreetly offer back support and lower belly support during pregnancy. Some have additional suspender-like straps to provide further fixation and support.	Does not affect sleeping position.
Mama Band (USA)	Belly Band		
Ingrid & Isabel (CA, USA)	Bellaband, BeBand		
Cabea, LLC (CT, USA)	BabyBellyBand		



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	10
Sample size	7a	How sample size was determined	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	11
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	11
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	11
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	11-12
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	11, 7, 11
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9, 11-12

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig. 2, pages 12-13
	13b	For each group, losses and exclusions after randomisation, together with reasons	12-13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	13
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14-15
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15-18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19-22, 24-25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	22-25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-26
Other information			
Registration	23	Registration number and name of trial registry	3, 26
Protocol	24	Where the full trial protocol can be accessed, if available	26
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	28

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.