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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

(**Fig. 1.**).

Objectives

The primary objective was to evaluate whether the proportion 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

Trial Design

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

Participants

Participants were recruited by a trained nurse at the IWK Health Centre – a tertiary and primary care center for women and children with approximately 5000 newborns delivered per year. Overnight polysomnograms (PSGs) were conducted at the Queen Elizabeth II (QEII) Health Sciences Centre Sleep Disorders Clinic. The IWK and QEII are teaching hospitals associated with Dalhousie University in Halifax, Canada. Halifax has a population of approximately 400,000. Participants expressing interest in the study (paper flyer, online advertisement) were screened.

Participants were eligible if they had a low-risk singleton pregnancy and were 18 years of age or older, more than 20 weeks gestation at screening, and residing in the Halifax Regional Municipality. Exclusion criteria included BMI ≥35 at the first antenatal appointment for the current pregnancy, pregnancy complicated by obstetric conditions (e.g., hypertension, diabetes, intra-uterine growth restriction), sleep complicated by any medical conditions (e.g., known obstructive sleep apnea, insomnia, musculoskeletal deformity affecting sleep position), multiple pregnancy, known fetal-abnormality, and non-English speaking and reading.

All participants in the trial gave written informed consent. This trial was approved by the IWK Health Centre Research Ethics Board in June 2015 (Project No. 1018753). There was no independent data monitoring committee.

Interventions

Each participant underwent two overnight PSG studies (not required to be consecutive dates) between 28-37 weeks gestation. The only difference between the two nights was the intervention (PrenaBelt or sham) and that participants completed a demographic questionnaire on the 1st PSG night only. The PrenaBelt is worn at the level of the waist and has four firm plastic balls embedded into foam inserts within the pockets posteriorly (**Fig.1.**). When supine, the balls apply pressure points across the user's lower back, prompting her to reposition herself in a lateral position to maintain comfort. The sham was identical in appearance, materials, and construction to the PrenaBelt, but had soft foam balls instead of firm plastic balls and did not have foam inserts; as such, the sham did not provide pressure points. Participants crossed over to the alternative intervention on the 2nd PSG night.

PSG set-up was by trained research assistants (RAs), in accordance with the American Academy of Sleep Medicine 2014 guidelines,(32) and in a private clinical room with continuous monitoring by an RA in a separate room through audio/visual and Embla Sandman Elite sleep diagnostic software (Natus Medical Incorporated, Pleasanton, USA).

Immediately before the participant settled to sleep, the unblinded research personnel (co-PI [AK] or study coordinator [JW]) entered the room to assist her in donning the assigned intervention (PrenaBelt/sham) without disclosing the identity of the intervention to the participant or the RA in order to maintain blinding. Upon waking for the day, the participants immediately removed the intervention and placed it in an opaque closed box for collection by the unblinded personnel in order to keep it concealed from the RA. The RA subsequently entered the room and unhooked the PSG equipment. The participant completed a feedback questionnaire and placed it in a sealed envelope for the unblinded personnel. The questionnaire elicited participants' perceptions of body position at sleep onset and waking, changes in position and reason for changes, and estimates of proportion/time spent in each position during sleep. Participants also ranked their satisfaction, comfort level, and intention to continue using the PrenaBelt (if it were available) on a 10-point Likert scale (with 10 out of 10 reflecting the highest satisfaction, comfort, and intention to use, and 1 out of 10 the lowest). Participants were permitted bathroom breaks and to remove the intervention and/or PSG equipment at any point if they became uncomfortable.

Scoring of PSG's was performed by blinded Registered PSG Technicians, and interpretation was by a blinded sleep medicine physician (DM).

Outcomes

The primary outcome, proportion of time spent supine during sleep, was documented continuously by an RA via video feed.

Respiration was measured using respiratory inductance plethysmography (Philips Respironics Pro-Tech zRIP Durabelt, Murrysville, USA). Airflow, including snoring, was measured by differential pressure transducers (BRAEBON Medical Corporation PT1, Kanata, Canada) and via audio by an RA. Maternal peripheral oxygen saturation (SpO_2) was measured via fingertip pulse oximetry. Electrodes (Natus Medical Incorporated, Pleasanton, USA) for electrocardiography (ECG), electroencephalography (EEG), electrooculography (EOG), and electromyography (EMG) were applied for determination of maternal heart rate, sleep architecture, and leg movements.

No changes were made to the trial outcomes after trial commencement.

Sample Size

This is the first trial investigating PT in pregnant women to reduce supine sleep time. A sample size of twenty-five (n=25) participants was selected. 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 (difference in mean proportion of time spent sleeping supine by half a standard deviation), which is a medium effect size per the literature regarding Cohen.(33) All statistical analyses were conducted using the R Statistical Software package (version 3.2.4 (2016-03-10)).(34) There was no planned interim analysis or stopping guidelines.

Randomization

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

Blinding

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

Statistical Methods

In the primary analysis, we specified a linear mixed-effects model with the proportion of time spent supine during sleep as the response variable and the interventions (PrenaBelt, sham) as the fixed effects. To account for the cross-over design, participants and PSG night (1st or 2nd) were treated as random effects.

Secondary outcomes were compared between interventions by paired t-tests (normal) and Wilcoxon signed rank tests (non-normal). Cohen's Kappa (κ) was used to assess agreement between categorical variables. Spearman's Rho (ρ) and Bland-Altman plots were used for continuous variables.

For continuous variables, normality was assessed using Q-Q plots and Anderson-Darling test. All testing was performed at a 0.05 significance level. Treatment effects (differences in means and odds ratios) and associated confidence intervals were presented at a 95% confidence level with p-values.

RESULTS

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

Sample Characteristics

Baseline demographic, obstetric, and sleep habit characteristics of the 23 randomized participants are shown in **Table 1**. The two randomized groups were well balanced with respect to the sample characteristics – there were no statistically significant differences in baseline characteristics between groups ($\alpha=0.05$). The mean age was 30.4 years. The majority (83%) were Caucasian. The mean pre-pregnancy BMI was 26.6 kg/m^2 and rose to a mean of 30.7 kg/m^2 at the time of the 1st PSG, which took place at a mean gestational age of 30.8 weeks. More than half (57%) of participants were nulliparous.

The mean self-reported overnight sleep duration at the time of the 1st PSG was 7.5 hours. In the week previous to the 1st PSG (when pregnant), left was the most common position at sleep onset (74%) and waking (52%), although a large proportion of women also reported the supine position at sleep onset and waking (22% and 35%, respectively). When not pregnant, prone was the most common position at sleep onset

(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 apnea (OSA) has sustained efficacy in the long term but decreasing compliance from 93% at 1 month,(35) 74% at three months,(36) and 60% at six months.(37)

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 devices like the PrenaBelt.(36,38) In comparison to a study of pressure-point PT in non-pregnant individuals with positional OSA by Heinzer et al.,(36) the PrenaBelt resulted in a lesser reduction in mean proportion of sleep time supine; however, in contrast, we did not have a non-intervention night as Heinzer et al. did. The sham, by intrinsic characteristics, may have caused a reduction in supine sleep in comparison to a non-intervention night. O'Brien and Warland (6) reported a non-interventional, one-night, in-home study of 51 healthy women in their 2nd and 3rd trimester using ambulatory PSG; in a subgroup of participants in their 3rd trimester (n=33), the median proportion of overall sleep time spent supine was 26.5%. McIntyre et al.,(7) in a similar non-interventional, one-night, in-home, ambulatory PSG study in 30 healthy women in the 3rd trimester, reported the median proportion of overall sleep time spent supine to be 19%. Participants were not asked to adopt or try to maintain any sleep position in either study. Both of these studies reported a greater median proportion of overall sleep time spent supine than that in the current study (16.4%), which indicates that the sham device may have affected position. This, along with differences inherent to pregnancy (e.g., body habitus, increased sleep disruption) may account for the lesser reduction in mean proportion of sleep time supine achieved by the PrenaBelt in comparison Heinzer et al. (36)

Zaremba et al. undertook a randomized, cross-over, PSG study in 30 post-partum women sleeping in non-elevated and 45° elevated body position and reported moderate to severe OSA in 20% of the participants.(39) The minimum SpO2 was higher (p 0.03) and AHI was reduced (p 0.03) in the 45° elevated body position in comparison to non-elevated without affecting sleep quantity or quality. This is congruent with our analysis of secondary outcomes, which demonstrated no difference in sleep architecture nor in duration despite a significant difference in body position (less supine time).

Seventy-three percent of participants in the study by McIntyre et al.(7) recalled their sleep onset position accurately (κ 0.52), which is a lower accuracy than our results (85% accurate, κ 0.62) possibly because each of our participants underwent two PSG nights and, after being asked to recall various details about their sleep after their 1st PSG night, may have anticipated these questions again after their 2nd PSG night. Forty percent of McIntyre et al.'s participants recalled their waking position accurately (κ 0.24), which is a lower accuracy than our results (70% accurate, κ 0.42). Being an ambulatory PSG, McIntyre et al.'s study did not include electroencephalography (EEG) – they estimated sleep and wake times by pre-defined video criteria (i.e., lack of movement) and not by brain activity and noted that this may have introduced discrepancy between their participants' self-reports and the video assessment criteria, thus reducing their calculated accuracy. We reported a weak relationship (κ 0.24) between sleep onset and waking position via PSG-determination, whereas previous studies have reported discrepant results – McIntyre et al. reported no relationship (κ -0.13) via video-determination, and the Auckland Stillbirth Study reported a strong relationship (Pearson r 0.72) via self-reports;(2), however, our study has shown self-reports of sleep onset and waking position to have only moderate and weak agreement with the gold standard (PSG), respectively, which points to reliance on non-PSG methods (e.g., self-reports) as a potential source of this discrepancy.

Warland and Dorrian reported a three-night observational study of 30 healthy women in late pregnancy and found moderate basic correlation between self-reported and video-determined time on the left (r=0.418);(40) however, they did not report correlations for right or supine sleep. We report a good correlation between self-reported and PSG-determined time on the left (Spearman's ρ 0.76, p<0.01). Notably, we found poor correlation between self-reports and PSG-determined supine time and that pregnant women tend to underestimate this value, which could have significant clinical implications if supine sleep needs to be avoided and self-reports are relied upon by maternity care providers for risk stratification. There are only two other studies investigating reliability of adults' self-reports of sleep position;(41,42) both consist of non-pregnant adults, have conflicting results with each other, and are not reported in adequate detail for comparison to our results.

In the non-pregnant population, approximately 20% of a typical night's sleep is spent in the REM state and 80% is spent in the NREM state. The sleep architecture in the current study is consistent with previously reported patterns during pregnancy, that is, reduced slow-wave sleep (SWS), REM sleep, and sleep efficiency.(43–47)

Meaning of the Study

The previous studies by Owusu et al.(1) and O'Brien and Warland (6) recommended the development and testing of a PT device for pregnant women. In our study, a PT intervention was implemented in a population of healthy, third-trimester, pregnant women during sleep in a clinical sleep laboratory environment over two nights. This study extends the work of Stacey et al.,(2) Gordon et al.,(3) McCowan et al.,(4) and Warland and Mitchell (48) by finding that supine sleep position in late pregnancy can be reduced with PT.

Left side sleeping is common among pregnant women. This may be a more comfortable position but also may be related to the "sleep-on-side" messages prevalent on the internet and among maternity care providers. Women in our study preferentially settled to sleep on their left for 73% of the nights and right for 20% of the nights. This is corroborated by McCowan et al.(4) who reported a significant increase in left-sided going-to-sleep position (43% to 58%) and small decrease in supine going-to-sleep position (5% to 3.8%) in New Zealand over an approximate 5 year period following publicity of The Auckland Stillbirth Study by Stacey et al.(2) If the supine sleeper is to be identified by history-taking and stratified for targeted education or intervention, obstetricians, midwives, and nurses should be aware that despite sleep-on-side knowledge and high rates of lateral going-to-sleep position, most pregnant women continue to spend a significant amount of time supine during sleep in late pregnancy. Also, pregnant women's estimates of time in each sleep position, while relatively accurate for lateral sleeping positions, underestimate the time they spend supine. This suggests that any public health education campaign may need to recommend interventions to prevent unintentional supine positioning during sleep.

Strengths

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

Weaknesses

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

Future Research

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

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

statistical analysis. JW maintained the study master record, facilitated PSG studies as an unblinded personnel, monitored data collection, and cleaned and analyzed the data. AI negotiated the research contract and managed the trial funds. DM, HS, LMO, AB, JW, MB, KC, and AI made intellectual contributions to the paper.

Competing Interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: Dr. Borazjani reports grants from Grand Challenges Canada (Grant 0629-01-10) during the conduct of the study; Mr. Wells reports personal fees from Grand Challenges Canada (Grant 0629-01-10) during the conduct of the study; Ms. Chu reports personal fees from Global Innovations for Reproductive Health & Life (Cleveland, USA) during the conduct of the study; Mr. Kember, Dr. Scott, and Dr. Morrison report grants from Grand Challenges Canada (Grant 0629-01-10) and from the IWK Health Centre (Dr. H. B. Atlee Endowment Award) during the conduct of the study; Dr. Morrison reports grants from Bresotec and grants from CIHR/Industry Grant (Phillips) outside the submitted work. Mr. Butler, Dr. Isaac, and Dr. O'Brien have declared no support from any organization for the submitted work, no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

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Data Sharing: Statistical code and complete dataset are available from the Dryad repository, DOI: [Will insert DOI for dataset here. Per Dryad, BMJ Open has "integrated article submission with data submission", meaning we will submit our manuscript first, 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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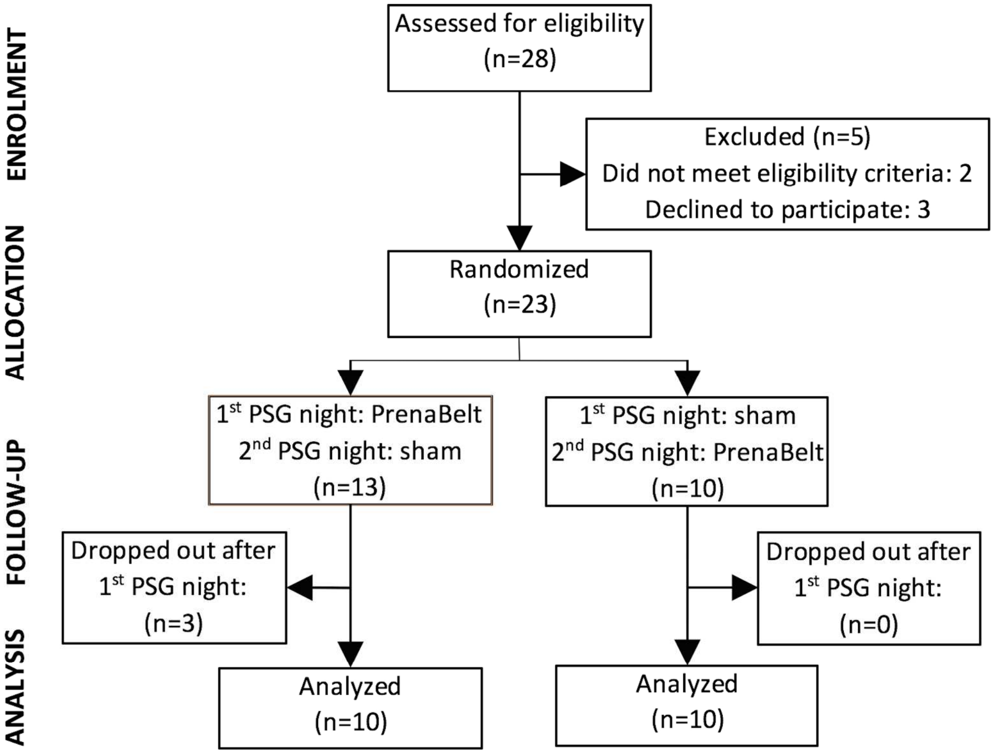

Fig. 2. Enrollment, allocation, and analysis of trial participants.

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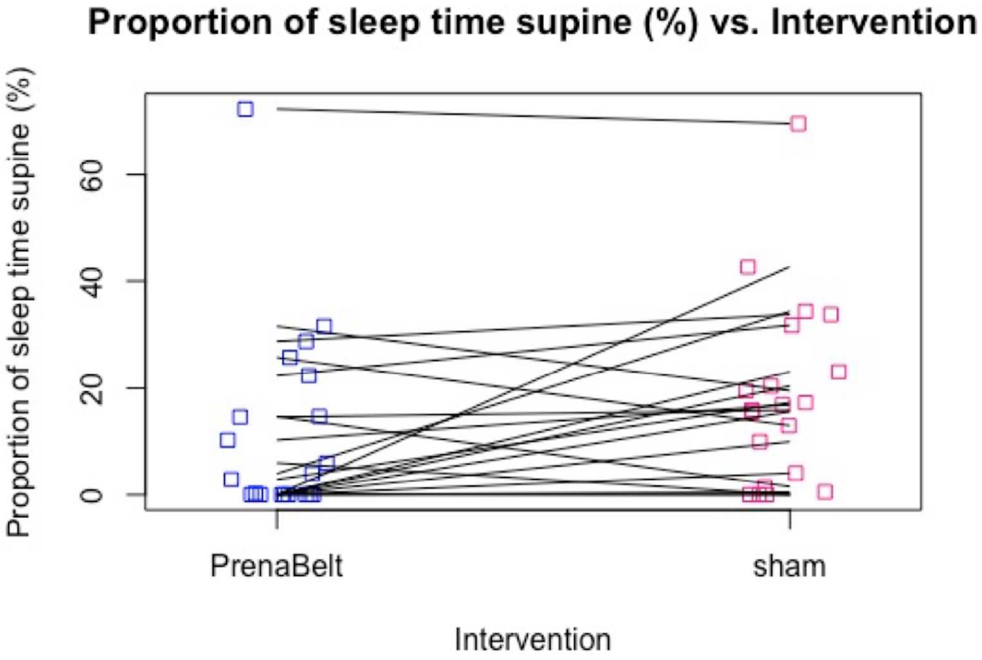

Fig. 3. Scatter plot of proportion of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

216x162mm (300 x 300 DPI)

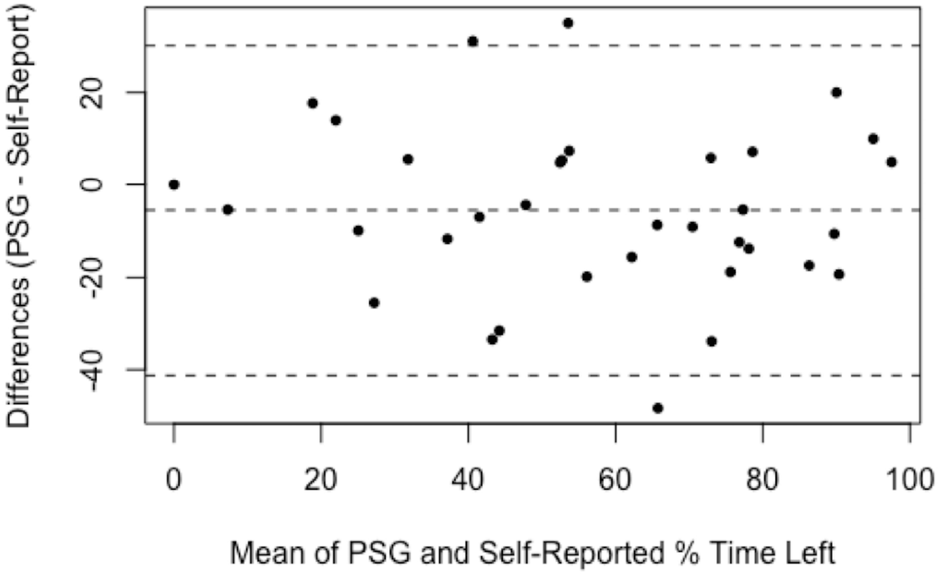

Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

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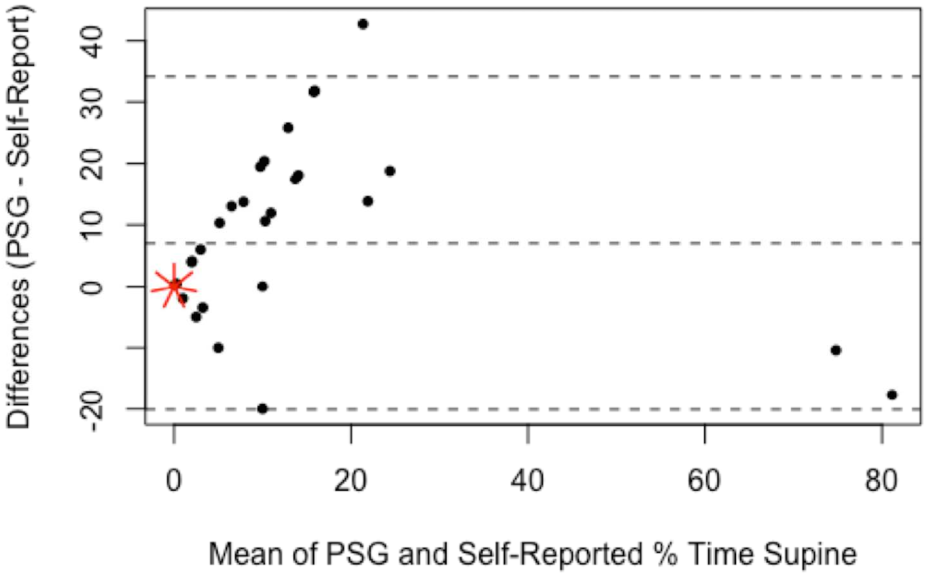

Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point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

216x162mm (300 x 300 DPI)

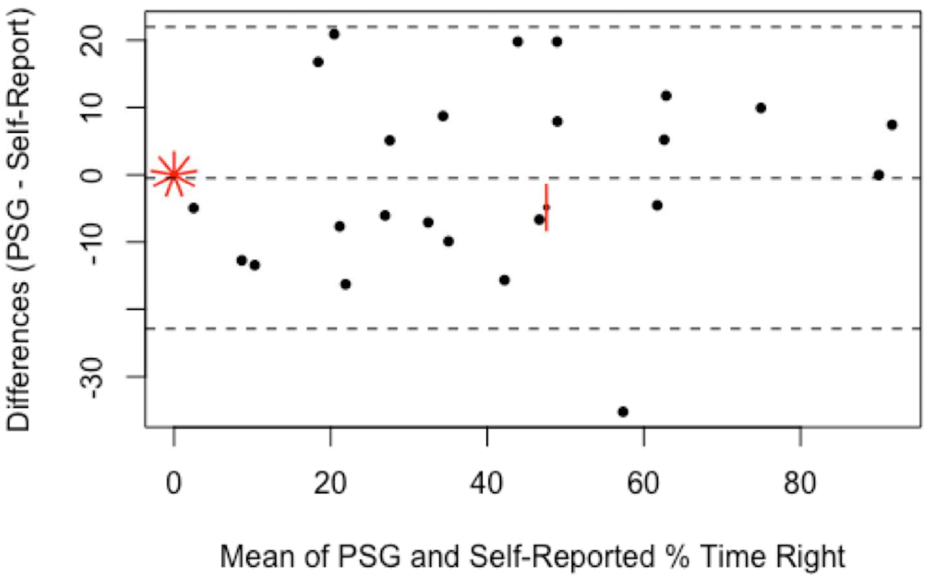

Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional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

216x162mm (300 x 300 DPI)

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

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6-7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	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 10-11
	13b	For each group, losses and exclusions after randomisation, together with reasons	10-11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	11
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11
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)	13-16
	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)	16
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16-20, 21-22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	20-22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16-21
Other information			
Registration	23	Registration number and name of trial registry	2, 23
Protocol	24	Where the full trial protocol can be accessed, if available	23
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24

*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 Pilot Trial

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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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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

Participants were recruited by a trained nurse at the IWK Health Centre – a tertiary and primary care center for women and children with approximately 5000 newborns delivered per year. Overnight polysomnograms (PSGs) were conducted at the Queen Elizabeth II (QEII) Health Sciences Centre Sleep Disorders Clinic. The IWK and QEII are teaching hospitals associated with Dalhousie University in Halifax, Canada. Halifax has a population of approximately 400,000. Participants expressing interest in the study (paper flyer, online advertisement) were screened.

Participants were eligible if they had a low-risk singleton pregnancy and were 18 years of age or older, more than 20 weeks gestation at screening, and residing in the Halifax Regional Municipality. Exclusion criteria included BMI ≥35 at the first antenatal appointment for the current pregnancy, pregnancy complicated by obstetric conditions (e.g., hypertension, diabetes, intra-uterine growth restriction), sleep complicated by any medical conditions (e.g., known obstructive sleep apnea, insomnia, musculoskeletal deformity affecting sleep position), multiple pregnancy, known fetal-abnormality, and non-English speaking and reading.

All participants in the trial gave written informed consent. This trial was approved by the IWK Health Centre Research Ethics Board in June 2015 (Project No. 1018753). There was no independent data monitoring committee.

Interventions

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

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

Immediately before the participant settled to sleep, the unblinded research personnel (co-PI [AK] or study coordinator [JW]) entered the room to assist her in donning the assigned intervention (PrenaBelt/sham) without disclosing the identity of the intervention to the participant or the RA in order to maintain blinding. Upon waking for the day, the participants immediately removed the intervention and placed it in an opaque closed box for collection by the unblinded personnel in order to keep it concealed from the RA. The RA subsequently entered the room and unhooked the PSG equipment. The participant completed a feedback questionnaire and placed it in a sealed envelope for the unblinded personnel. The questionnaire elicited participants' perceptions of body position at sleep onset and waking, changes in position and reason for changes, and estimates of percentage/time spent in each position during sleep. Participants also ranked their satisfaction, comfort level, and intention to continue using the PrenaBelt (if it were available) on a 10-point Likert scale (with 10 out of 10 reflecting the highest satisfaction, comfort, and intention to use, and 1 out of 10 the lowest). Participants were permitted bathroom breaks and to remove the intervention and/or PSG equipment at any point if they became uncomfortable.

Scoring of PSG's was performed by blinded Registered PSG Technicians, and interpretation was by a blinded sleep medicine physician (DM).

Outcomes

The primary outcome, percentage of time spent supine during sleep, was documented continuously by an RA via video feed.

Respiration was measured using respiratory inductance plethysmography (Philips Respironics Pro-Tech zRIP Durabelt, Murrysville, USA). Airflow, including snoring, was measured by differential pressure transducers (BRAEBON Medical Corporation PT1, Kanata, Canada) and via audio by an RA. Maternal peripheral oxygen saturation (SpO_2) was measured via fingertip pulse oximetry. Electrodes (Natus Medical Incorporated, Pleasanton, USA) for electrocardiography (ECG), electroencephalography (EEG), electrooculography (EOG), and electromyography (EMG) were applied for determination of maternal heart rate, sleep architecture, and leg movements.

No changes were made to the trial outcomes after trial commencement.

Sample Size

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

Randomization

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

Blinding

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

Statistical Methods

In the primary analysis, we specified a linear mixed-effects model with the percentage of time spent supine during sleep as the response variable and the interventions (PrenaBelt, sham) as the fixed effects. To account for the cross-over design, participants and PSG night (1st or 2nd) were treated as random effects.

Secondary outcomes were compared between interventions by paired t-tests (normal) and Wilcoxon signed rank tests (non-normal). Cohen's Kappa (κ) was used to assess agreement between categorical variables. Spearman's Rho (ρ) and Bland-Altman plots were used for continuous variables.

For continuous variables, normality was assessed using Q-Q plots and Anderson-Darling test. All testing was performed at a 0.05 significance level. Treatment effects (differences in means and odds ratio) and associated confidence intervals were presented at a 95% confidence level with p-values.

RESULTS

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

Sample Characteristics

Baseline demographic, obstetric, and sleep habit characteristics (see **Supplementary File 1**) of the 20 participants who completed the study are shown in **Table 1** per randomized group (n=10 each). The two randomized groups were well balanced with respect to the sample characteristics – there were no statistically significant differences in baseline characteristics between groups (α=0.05). The mean (SD) age was 30.9 (5.0) years. The majority (80%) were Caucasian. The mean (SD) pre-pregnancy BMI was 26.6 kg/m^2 (3.3) and rose to a mean of 30.4 kg/m^2 (3.6) at the time of the 1st PSG, which took place at a median (IQR) gestational age of 30.0 weeks (28-33.1). Half (50%) of the participants were nulliparous.

The median (IQR) self-reported overnight sleep duration at the time of the 1st PSG was 8 (7-8) hours. In the week previous to the 1st PSG (when pregnant), left was the most common position at sleep onset (85%) and waking (60%), although a large proportion of women also reported the supine position at sleep onset and waking (25% and 40%, respectively). When not pregnant, prone was the most common position at sleep onset (65%), and supine was the most common at waking (55%). Most participants used a pillow under their head (90%) and between their knees (70%).

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/m^2), 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.**). 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 † 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 6.8% absolute reduction (38% relative reduction, 24.4 minutes) in the mean 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 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,(39) 74% at three months,(40) and 60% at six months.(41)

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 devices like the PrenaBelt.(40,42) In comparison to a study of pressure-point PT in non-pregnant individuals with positional OSA by Heinzer et al.,(40) the PrenaBelt resulted in a lesser reduction in mean percentage of sleep time supine; however, in contrast, we did not have a non-intervention night as Heinzer et al. did. The sham, by intrinsic characteristics, may have caused a reduction in supine sleep in comparison to a non-intervention night. O'Brien and Warland (6) reported a non-interventional, one-night, in-home study of 51 healthy women in their 2nd and 3rd trimester using ambulatory PSG; in a subgroup of participants in their 3rd trimester (n=33), the median percentage of overall sleep time spent supine was 26.5%. McIntyre et al.,(7) in a similar non-interventional, one-night, in-home, ambulatory PSG study in 30 healthy women in the 3rd trimester, reported the median percentage of overall sleep time spent supine to be 19%. Participants were not asked to adopt or try to maintain any sleep position in either study. Both of these studies reported a greater median percentage of overall sleep time spent supine than that in the current study (16.4%), which indicates that the sham device may have affected position. This, along with differences inherent to pregnancy (e.g., body habitus, increased sleep disruption) may account for the lesser reduction in mean percentage of sleep time supine achieved by the PrenaBelt in comparison Heinzer et al.(40)

Zaremba et al. undertook a randomized, cross-over, PSG study in 30 post-partum women sleeping in non-elevated and 45° elevated body position and reported moderate to severe OSA in 20% of the participants.(43) The minimum SpO2 was higher (p 0.03) and AHI was reduced (p 0.03) in the 45° elevated body position in comparison to non-elevated without affecting sleep quantity or quality. In our analysis, we were unable to demonstrate any differences in sleep architecture or duration despite a significant difference in body position (less supine time).

Seventy-three percent of participants in the study by McIntyre et al.(7) recalled their sleep onset position accurately (κ 0.52), which is a lower accuracy than our results (85% accurate, κ 0.62) possibly because each of our participants underwent two PSG nights and, after being asked to recall various details about their sleep after their 1st

PSG night, may have anticipated these questions again after their 2nd PSG night. Forty percent of McIntyre et al.’s participants recalled their waking position accurately (κ 0.24), which is a lower accuracy than our results (70% accurate, κ 0.42). Being an ambulatory PSG, McIntyre et al.’s study did not include electroencephalography (EEG) – they estimated sleep and wake times by pre-defined video criteria (i.e., lack of movement) and not by brain activity and noted that this may have introduced discrepancy between their participants’ self-reports and the video assessment criteria, thus reducing their calculated accuracy. We reported a weak relationship (κ 0.24) between sleep onset and waking position via PSG-determination, whereas previous studies have reported discrepant results – McIntyre et al. reported no relationship (κ -0.13) via video-determination, and the Auckland Stillbirth Study reported a strong relationship (Pearson r 0.72) via self-reports;(2), however, our study has shown self-reports of sleep onset and waking position to have only moderate and weak agreement with the gold standard (PSG), respectively, which points to reliance on non-PSG methods (e.g., self-reports) as a potential source of this discrepancy.

Warland and Dorrian reported a three-night observational study of 30 healthy women in late pregnancy and found moderate basic correlation between self-reported and video-determined time on the left (r=0.418);(8) however, they did not report correlations for right or supine sleep. We report a good correlation between self-reported and PSG-determined time on the left (Spearman’s ρ 0.76, p<0.01). Notably, we found poor correlation between self-reports and PSG-determined supine time and that pregnant women tend to underestimate this value. There are only two other studies investigating reliability of adults' self-reports of sleep position;(44,45) both consist of non-pregnant adults, have conflicting results with each other, and are not reported in adequate detail for comparison to our results.

In the non-pregnant population, approximately 20% of a typical night's sleep is spent in the REM state and 80% is spent in the NREM state. The sleep architecture in the current study is consistent with previously reported patterns during pregnancy, that is, reduced slow-wave sleep (SWS), REM sleep, and sleep efficiency.(46–50)

Meaning of the Study

The previous studies by Owusu et al.(1) and O'Brien and Warland (6) recommended the development and testing of a PT device for pregnant women. In our study, a PT intervention was implemented in a population of healthy, third-trimester, pregnant women during sleep in a clinical sleep laboratory environment over two nights. This study extends the work of Stacey et al.,(2) Gordon et al.,(3) McCowan et al.,(4) and Warland and Mitchell (51) by finding that supine sleep position in late pregnancy can be reduced with PT.

Left side sleeping is common among pregnant women. This may be a more comfortable position but also may be related to the "sleep-on-side" messages prevalent on the internet and among maternity care providers. Women in our study preferentially settled to sleep on their left for 73% of the nights and right for 20% of the nights. This is corroborated by McCowan et al.(4) who reported a significant increase in left-sided going-to-sleep position (43% to 58%) and small decrease in supine going-to-sleep position (5% to 3.8%) in New Zealand over an approximate 5 year period following publicity of The Auckland Stillbirth Study by Stacey et al.(2) If the supine sleeper is to be identified by history-taking and stratified for targeted education or intervention, obstetricians, midwives, and nurses should be aware that despite sleep-on-side knowledge and high rates of lateral going-to-sleep position, most pregnant women continue to spend a significant amount of time supine during sleep in late pregnancy per our study and previous studies.(6–8) Also, per our study, pregnant women's estimates of time in each sleep position, while relatively accurate for lateral sleeping positions, underestimate the time they spend supine. Together, this suggests that healthcare providers may need to recommend interventions to prevent unintentional supine positioning during sleep.

Strengths

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

Weaknesses

Weaknesses of this study included that we had no baseline sleep data (run-in measurement) to which we could compare the PrenaBelt and sham nights; therefore, conclusions cannot be made regarding the effect, if any, of the PrenaBelt on sleep architecture and respiration in relation to no intervention. Participants' unfamiliarity with the sleep environment also may have affected sleep quantity and quality; however, we were unaware of any impact reported by participants. Period effects and carryover may have occurred due to advancing gestation and familiarization with the sleep environment/equipment; however, given the median washout period (1 day) was negligible in the context of a 12-week third trimester, period effects from the washout were, at most, minimal. Our LME model incorporated the PSG night (1^{st} or 2^{nd}) as a random effect to control for within-subject variation in our measured outcomes due to increased familiarity with the process. On the 2^{nd} PSG night, participants were exposed to the alternate intervention and could have unblinded themselves if they remembered what the intervention felt like on the 1^{st} PSG night; however, we are unaware of what effect this may have had. The current study was conducted in a cohort of healthy, non-obese, and majority Caucasian pregnant women. Due to the small sample size, this study may be underpowered and potentially overstate the true reduction in percentage of supine sleep; however, the sleep time in our study was relatively short (median 5.87

hours). Our participants reported a median of 8 hours overnight sleep duration at home; therefore, even if the reduction in supine sleep is lower than we observed, over a longer sleep duration, the PrenaBelt is still likely to result in a significant amount of supine sleep avoided. The power analysis was performed using the one-sided t-test, which could be a source of systemic confounding. Because of the fragility of our primary outcome (p 0.04), a confounding could shift our conclusions into statistical non-significance. This stresses the importance of future research to ascertain if our observed effects persist.

Future Research

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

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 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 statistical analysis. JW maintained the study master record, facilitated PSG studies as an unblinded personnel, monitored data collection, and cleaned and analyzed the data. AI negotiated the research contract and managed the trial funds. DM, HS, LMO, AB, JW, MB, KC, and AI made intellectual contributions to the paper.

Competing Interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: Dr. Borazjani reports grants from Grand Challenges Canada (Grant 0629-01-10) during the conduct of the study; Mr. Wells reports personal fees from Grand Challenges Canada (Grant 0629-01-10) during the conduct of the study; Ms. Chu reports personal fees from Global Innovations for Reproductive Health & Life (Cleveland, USA) during the conduct of the study; Mr. Kember, Dr. Scott, and Dr. Morrison report grants from Grand Challenges Canada (Grant 0629-01-10) and from the IWK Health Centre (Dr. H. B. Atlee Endowment Award) during the conduct of the study; Dr. Morrison reports grants from Bresotec and grants from CIHR/Industry Grant (Phillips) outside the submitted work. Mr. Butler, Dr. Isaac, and Dr. O'Brien have declared no support from any organization for the submitted work, no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

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Data Sharing: Data analysis scripts and output are attached as supplementary files.

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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

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

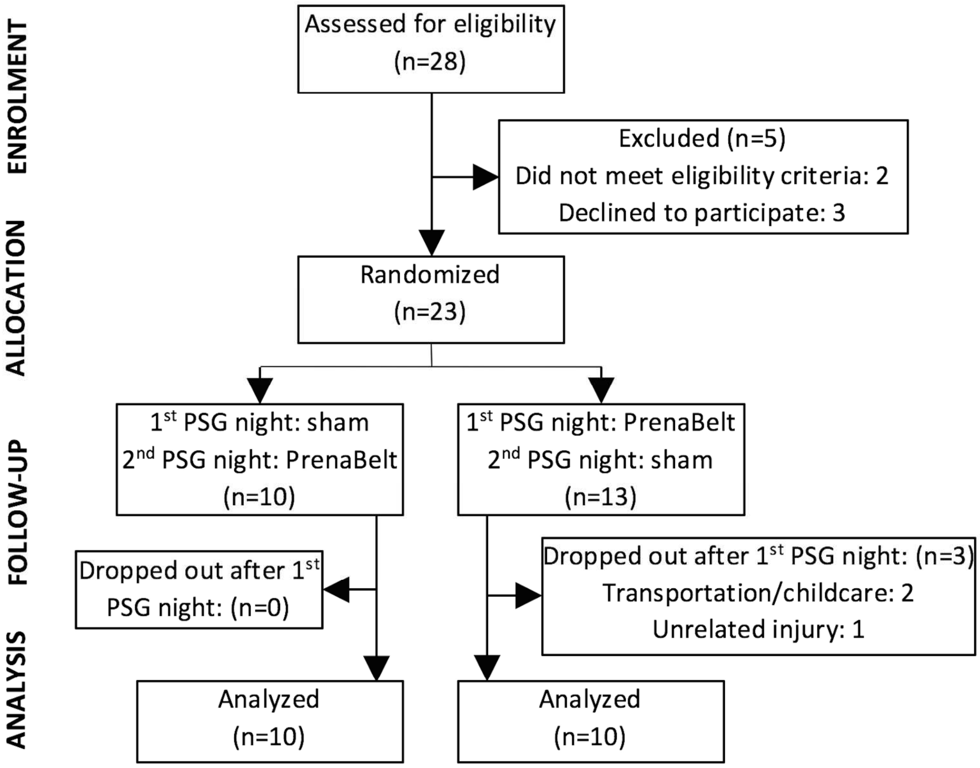
Table 2. Primary outcome: percentage of sleep time supine

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)



Enrollment, allocation, and analysis of trial participants.

293x227mm (300 x 300 DPI)

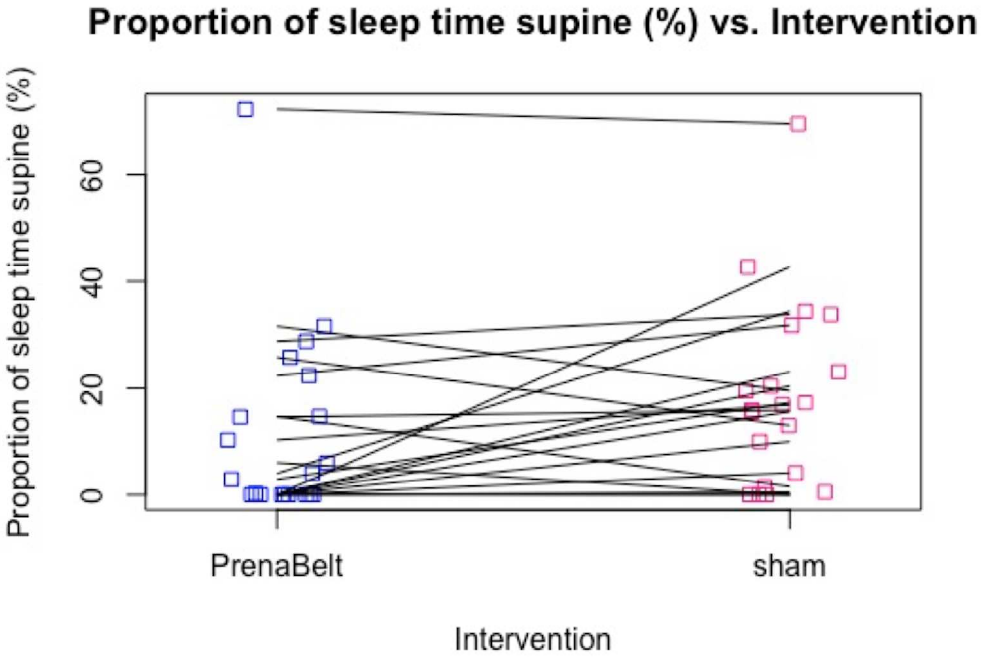


Fig. 3. Scatter plot of percentage of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

216x162mm (300 x 300 DPI)

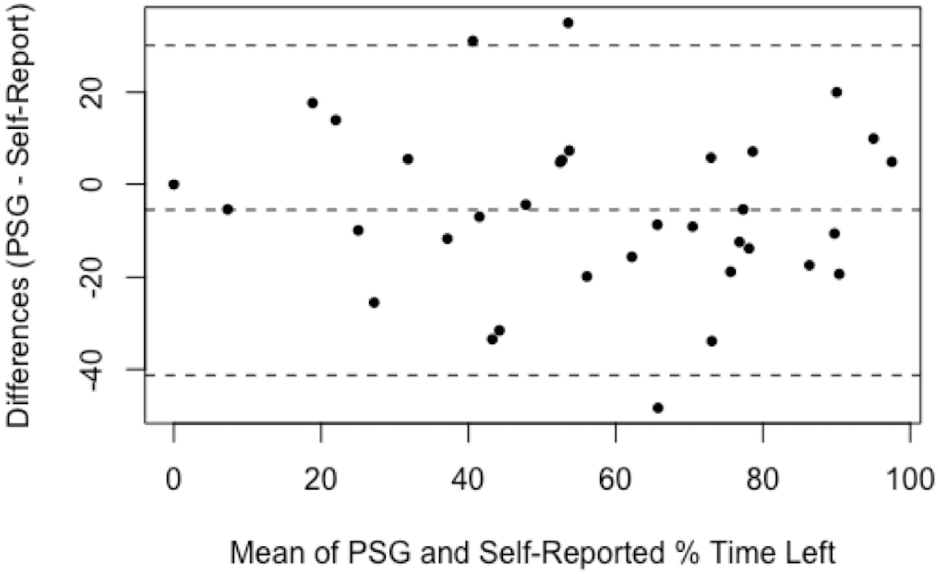


Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

216x162mm (300 x 300 DPI)

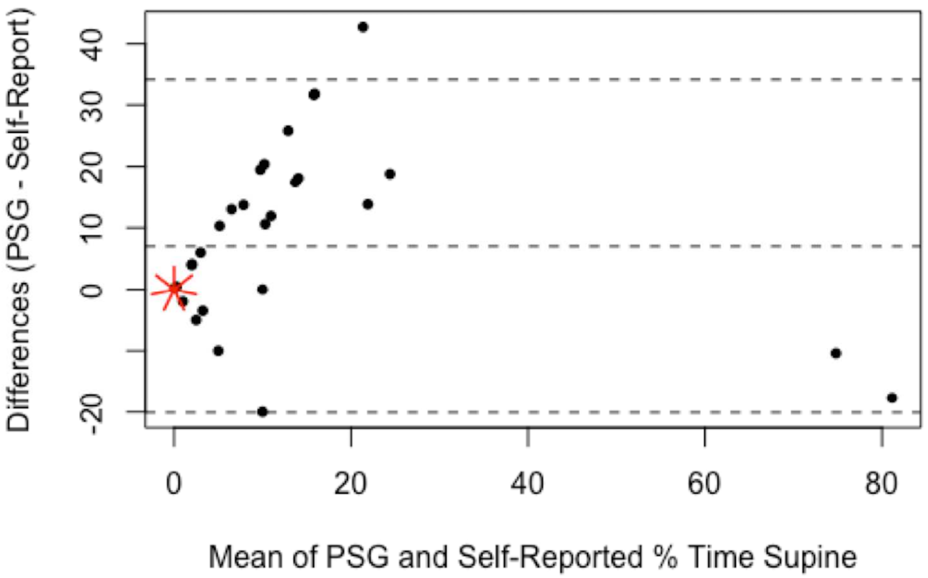


Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point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

216x162mm (300 x 300 DPI)

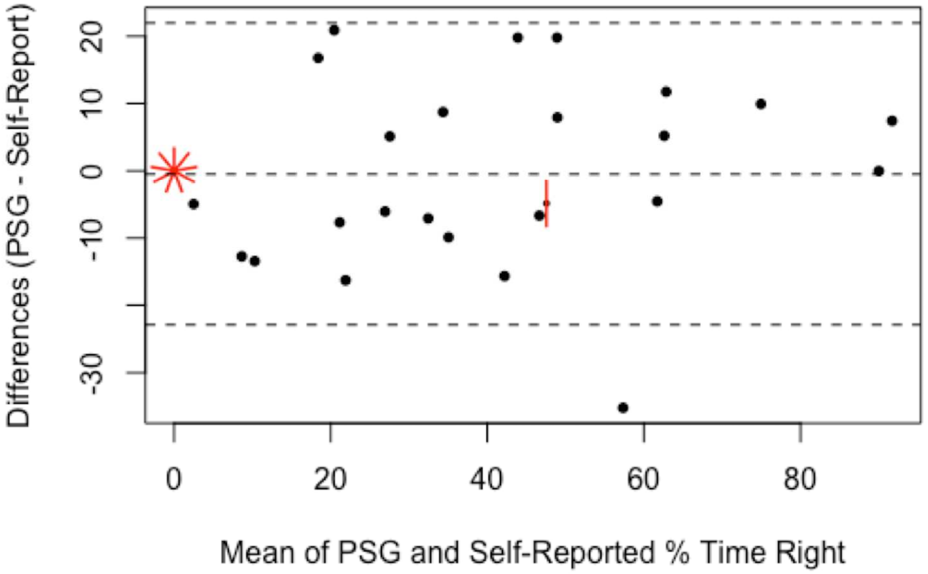


Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional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

216x162mm (300 x 300 DPI)

Supplementary file 1: Code and output – demographic analysis

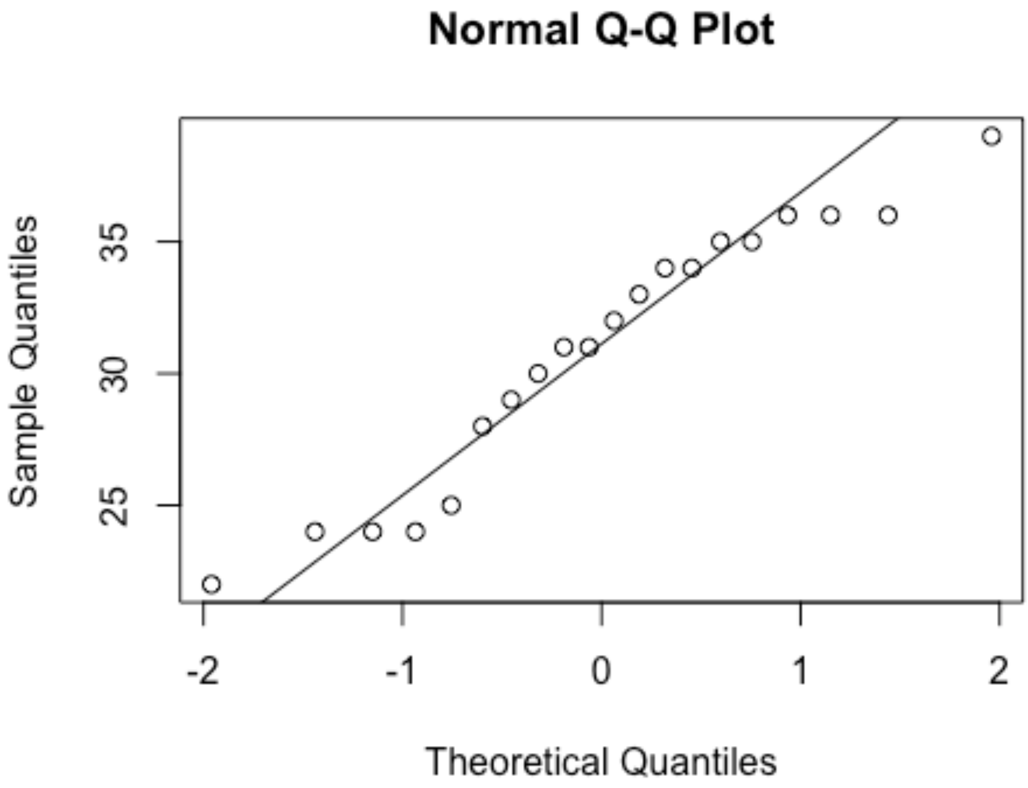
Demographic_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 15:54:34 2018

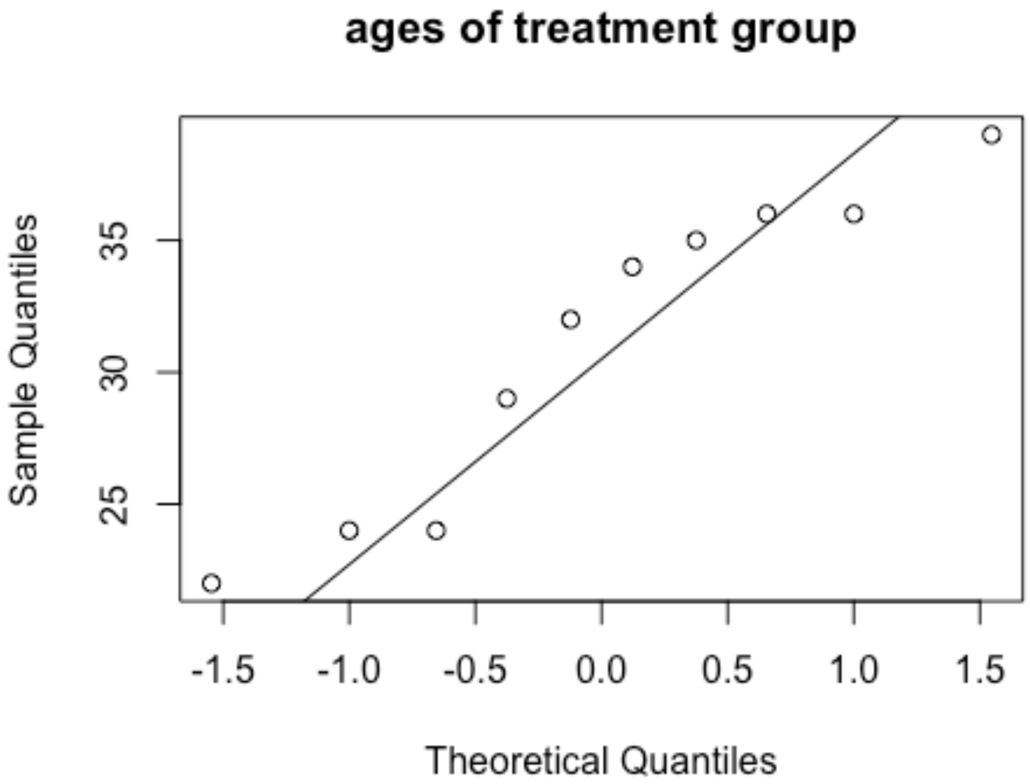
```
#Description of code:
#This code summarizes the demographic, obstetric, and sleep behaviour of the
participants
#and compares these data between all participants whose first sleep test was
PrenaBelt
#versus all participants whose first sleep test was sham-PrenaBelt.

#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)
```

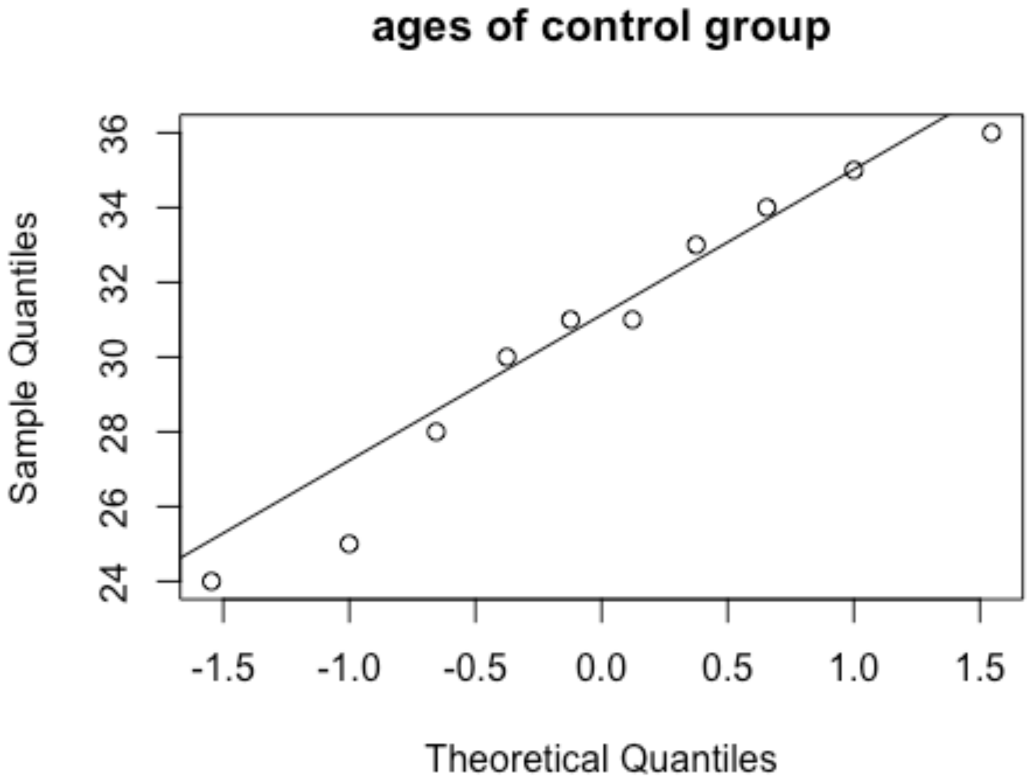


```
ad.test(DCFdata$age)

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

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   26.00   26.50   27.00   26.67   27.00   27.00

#Treatment ages
treatment.ages=na.omit(subset(DCFdata, intervention == "Treatment")$age)
length(treatment.ages)

## [1] 10

summary(treatment.ages)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   22.00   25.25   33.00   31.10   35.75   39.00

sd(treatment.ages)

## [1] 5.989806

#check for normality
qqnorm(treatment.ages, main = "ages of treatment group")
qqline(treatment.ages)
```

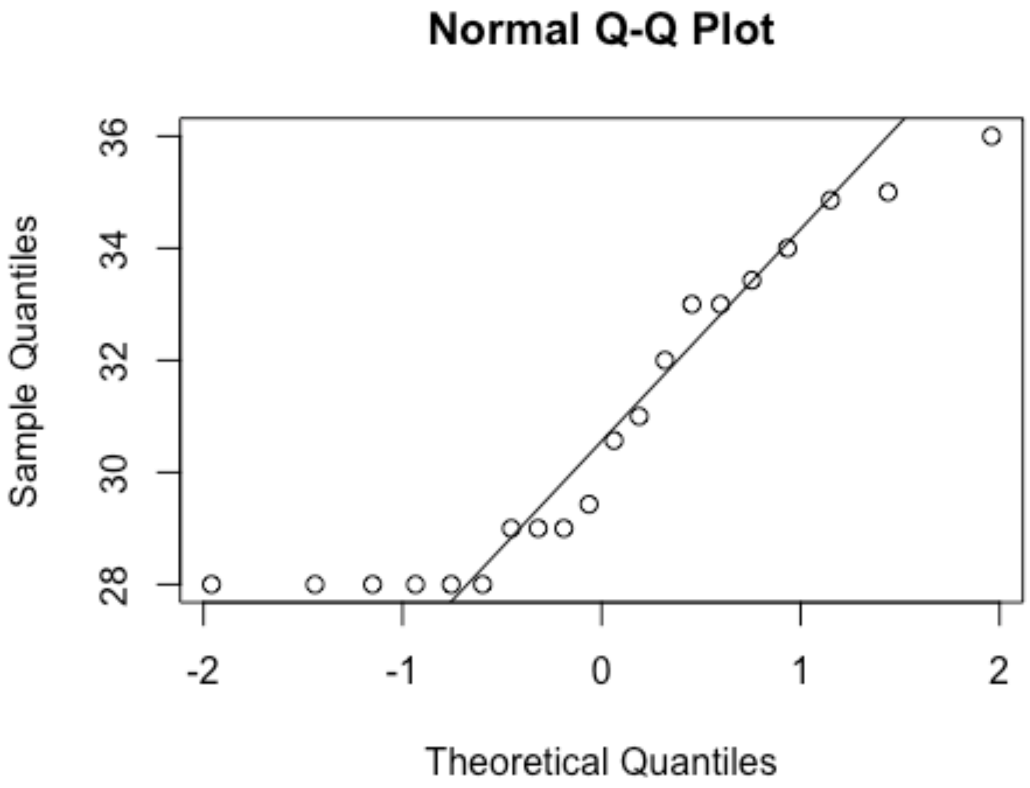


```
ad.test(treatment.ages)

##
##  Anderson-Darling normality test
##
## data:  treatment.ages
## A = 0.4521, p-value = 0.2133

#normal

#Control ages
control.ages=na.omit(subset(DCFdata, intervention == "Control")$age)
length(control.ages)

## [1] 10

summary(control.ages)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   24.00   28.50   31.00   30.70   33.75   36.00

sd(control.ages)

## [1] 4.056545

#check for normality
qqnorm(control.ages, main = "ages of control group")
qqline(control.ages)
```



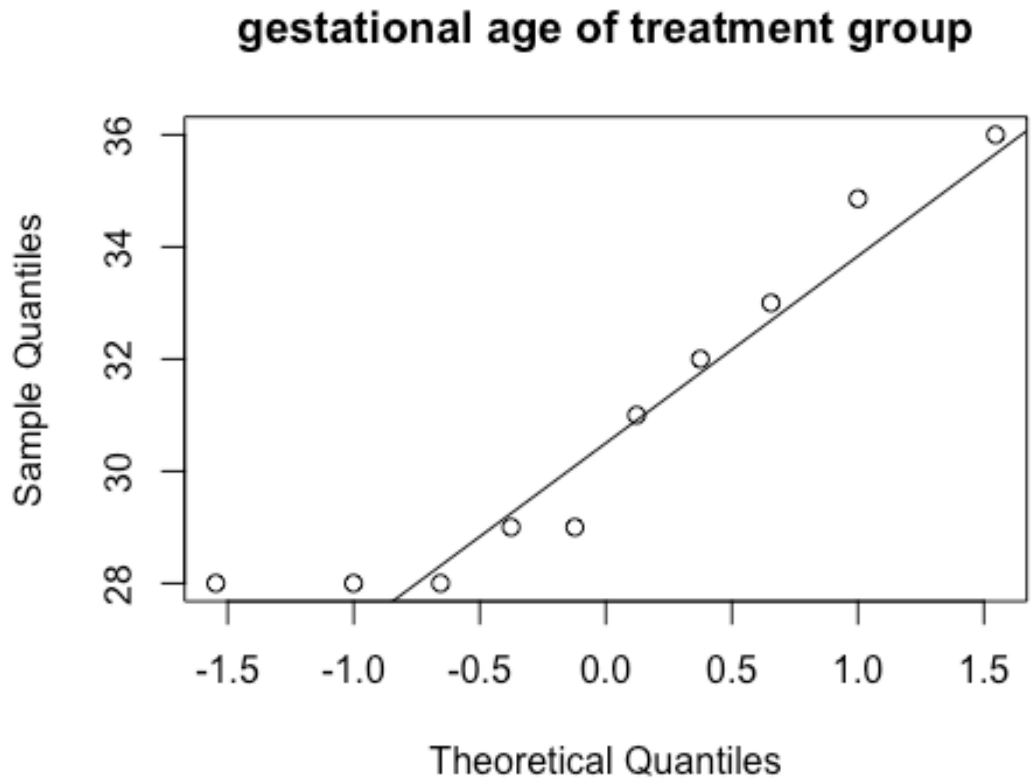
```
ad.test(control.ages)

##
##  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)
```

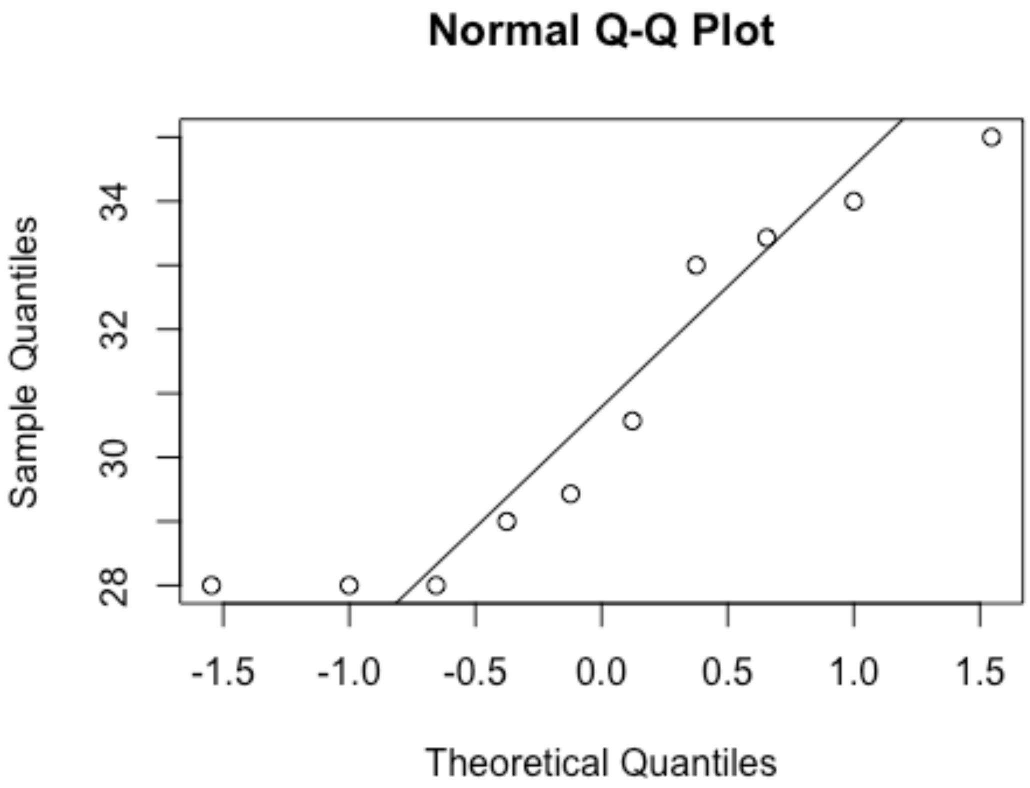


```
ad.test(DCFdata$gar)

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

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   29.00   29.50   30.00   30.62   31.43   32.86

#Treatment gestational age @ First Sleep Test
treatment.gar=na.omit(subset(DCFdata, intervention == "Treatment")$gar)
length(treatment.gar)

## [1] 10

summary(treatment.gar)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   28.00   28.25   30.00   30.89   32.75   36.00

sd(treatment.gar)

## [1] 2.977128

#check for normality
qqnorm(treatment.gar, main = "gestational age of treatment group")
qqline(treatment.gar)
```



```
ad.test(treatment.gar)

##
##  Anderson-Darling normality test
##
## data:  treatment.gar
## A = 0.4918, p-value = 0.1663

#normal

#Control gestational age @ First Sleep Test
control.gar=na.omit(subset(DCFdata, intervention == "Control")$gar)
length(control.gar)

## [1] 10

summary(control.gar)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   28.00   28.25   30.00   30.84   33.32   35.00

sd(control.gar)

## [1] 2.754959

#check for normality
qqnorm(control.gar)
qqline(control.gar)
```



```
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 T
est
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:
```

```
## mean of x mean of y
##    30.886    30.843

####################GRAVIDITY#######################
summary(DCFdata$gravidity)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     1.0     1.0     1.5     1.5     2.0     2.0

sd(na.omit(DCFdata$gravidity))

## [1] 0.5129892

length(DCFdata$gravidity)

## [1] 20

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

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

#Treatment gravidity
treatment.gravidity=na.omit(subset(DCFdata, intervention == "Treatment")$grav
idity)
length(treatment.gravidity)

## [1] 10

summary(treatment.gravidity)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     1.0     1.0     2.0     1.6     2.0     2.0

sd(treatment.gravidity)

## [1] 0.5163978

#Control gravidity
control.gravidity=na.omit(subset(DCFdata, intervention == "Control")$gravidit
y)
length(control.gravidity)

## [1] 10

summary(control.gravidity)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     1.0     1.0     1.0     1.4     2.0     2.0

sd(control.gravidity)

## [1] 0.5163978
```

```
#Tabulate the data
xtabs(~gravidity + intervention, data = DCFdata)

##          intervention
## gravidity Control Treatment
##         1       6         4
##         2       4         6

#Perform Fisher's Exact Test
fisher.test(xtabs(~gravidity + intervention, data = DCFdata))

## 
##  Fisher's Exact Test for Count Data
## 
## data:  xtabs(~gravidity + intervention, data = DCFdata)
## p-value = 0.6563
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2773893 19.1425577
## sample estimates:
## odds ratio 
##   2.158166

####################ETHNICITY######################
summary(DCFdata$ethnicity)

##      caucasian       Filipino         Indian Middle Eastern 
##             16              1              1              2

length(DCFdata$ethnicity)

## [1] 20

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

##      caucasian       Filipino         Indian Middle Eastern 
##              3              0              0              0

#Tabulate the data
xtabs(~ethnicity + intervention, data = DCFdata)

##                  intervention
## ethnicity        Control Treatment
##   caucasian           10         6
##   Filipino             0         1
##   Indian               0         1
##   Middle Eastern       0         2

#Perform Fisher's Exact Test
fisher.test(xtabs(~ethnicity + intervention, data = DCFdata))
```

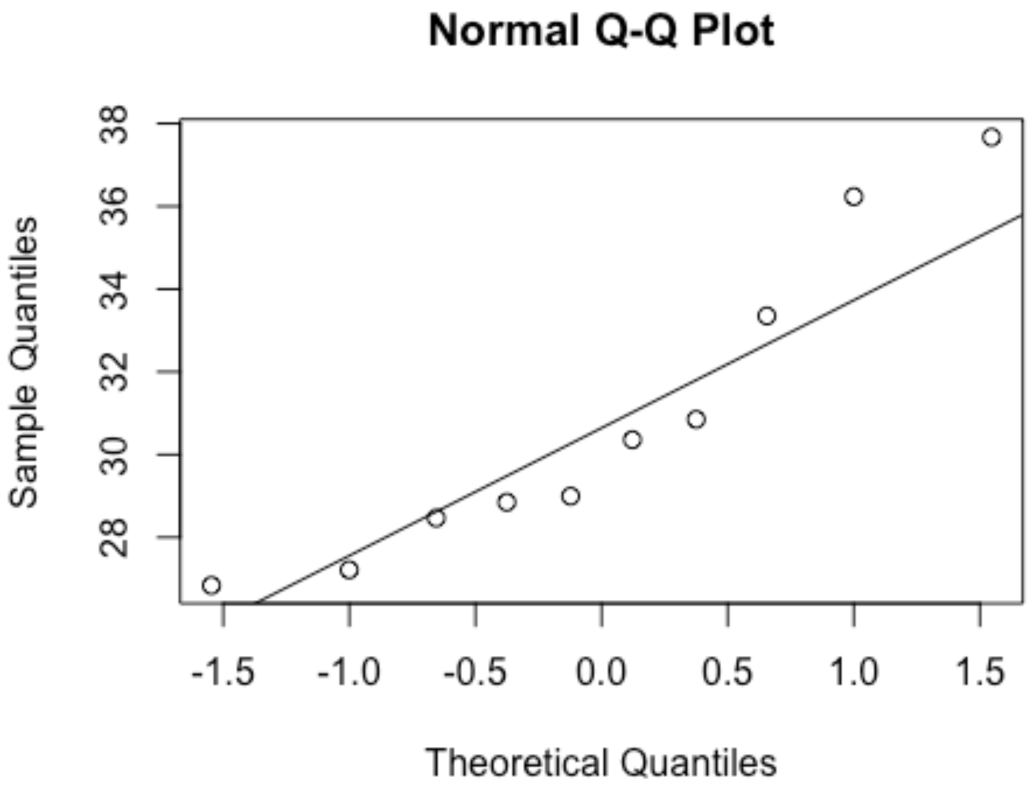
```
##
##  Fisher's Exact Test for Count Data
##
## data:  xtabs(~ethnicity + intervention, data = DCFdata)
## p-value = 0.08669
## alternative hypothesis: two.sided
```

```
temp_table <- xtabs(~ethnicity + intervention, data = DCFdata)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}
```

```
## [1] "caucasian"
##           Control Treatment
## caucasian      10         6
## Other           0         4
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.08669
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.7703894       Inf
## sample estimates:
## odds ratio
##        Inf
##
## [1] "Filipino"
##          Control Treatment
## Filipino       0         1
## Other         10         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
```

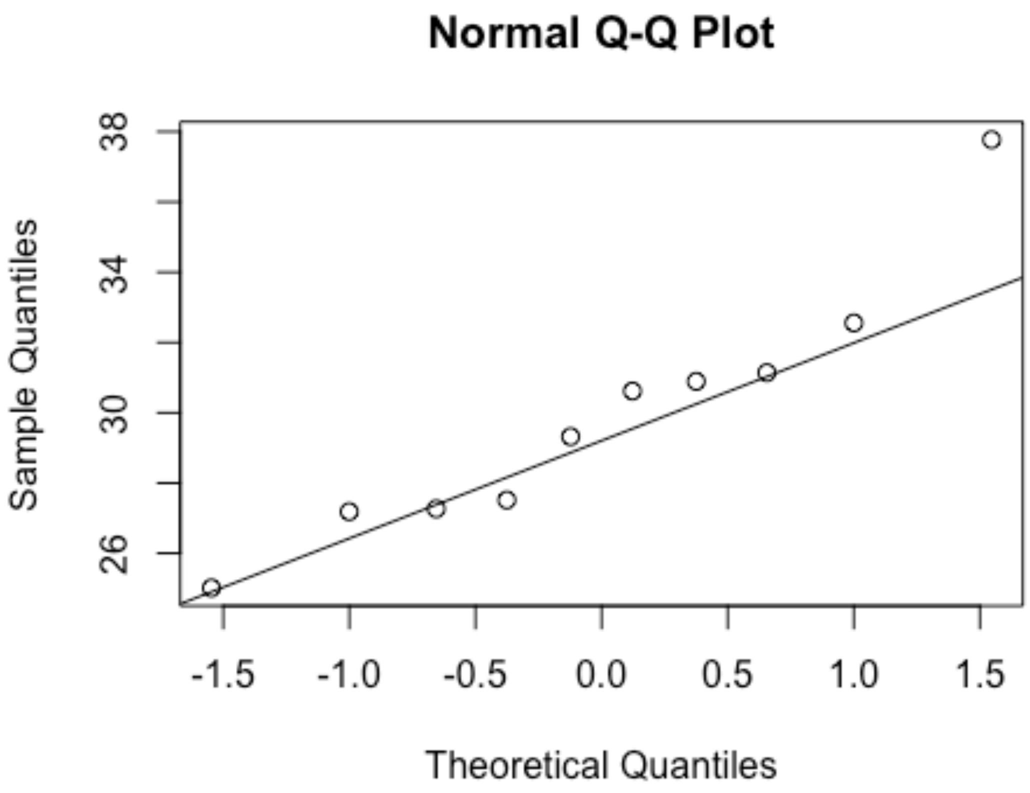
```
## 95 percent confidence interval:
##   0.00000 39.00055
## sample estimates:
## odds ratio
##          0
##
## [1] "Indian"
##        Control Treatment
## Indian       0         1
## Other       10         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.00000 39.00055
## sample estimates:
## odds ratio
##          0
##
## [1] "Middle Eastern"
##                Control Treatment
## Middle Eastern       0         2
## Other               10         8
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.4737
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.000000 5.231968
## sample estimates:
## odds ratio
##          0

####################HEIGHT.CURRENT#######################
summary(DCFdata$height.current.inches)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   59.00   63.75   65.00   64.73   66.62   70.00

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

## [1] 2.955734

length(DCFdata$height.current.inches)

## [1] 20
```

```
###################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)
```



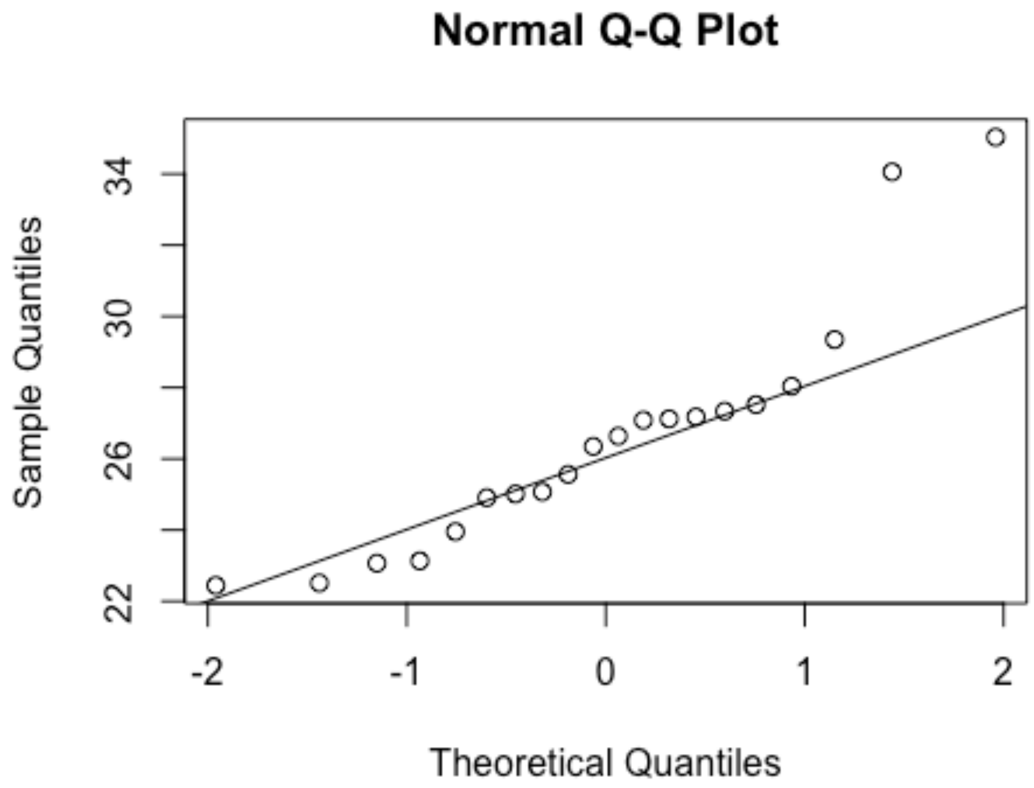
```
ad.test(treatment.current.BMI)

##
##  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)
```



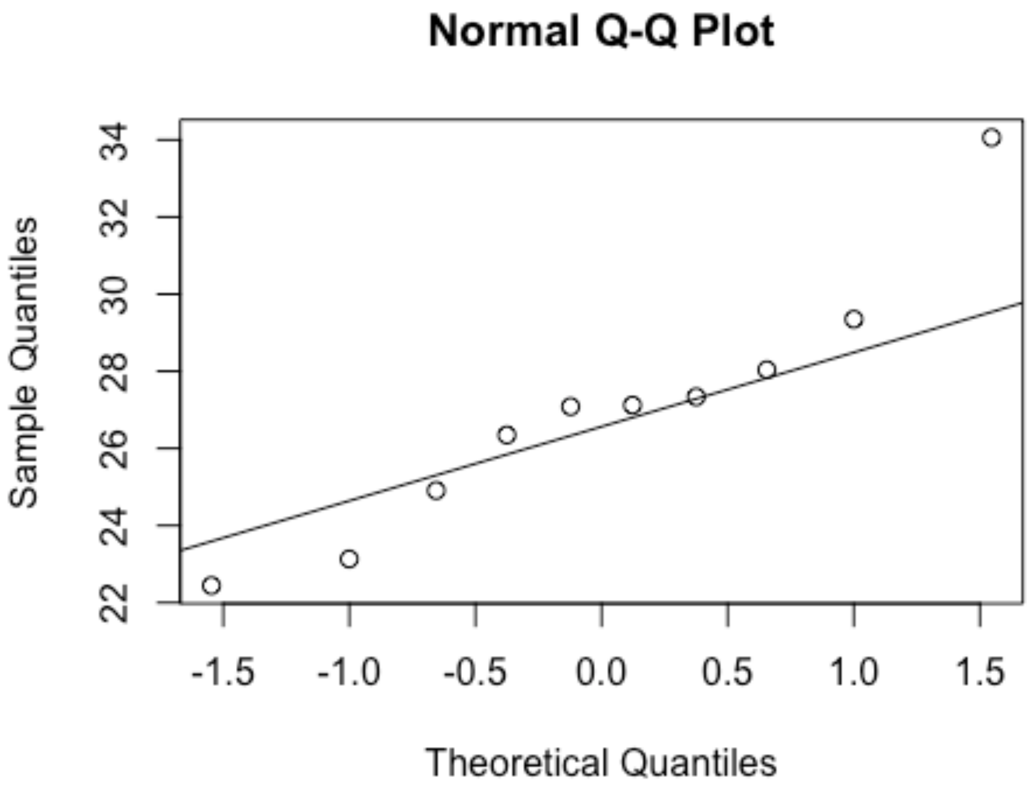
```
ad.test(control.current.BMI)

##
##  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
```

```
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -2.480620  4.391192
## sample estimates:
## mean of x mean of y
##  30.88316  29.92787

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

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

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

## [1] 20.45863

length(DCFdata$weight.before.lbs)

## [1] 20

####################BMI.BEFORE#######################
summary(DCFdata$BMI.before)

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

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

## [1] 3.347304

length(DCFdata$BMI.before)

## [1] 20

qqnorm(DCFdata$BMI.before)
qqline(DCFdata$BMI.before)
```



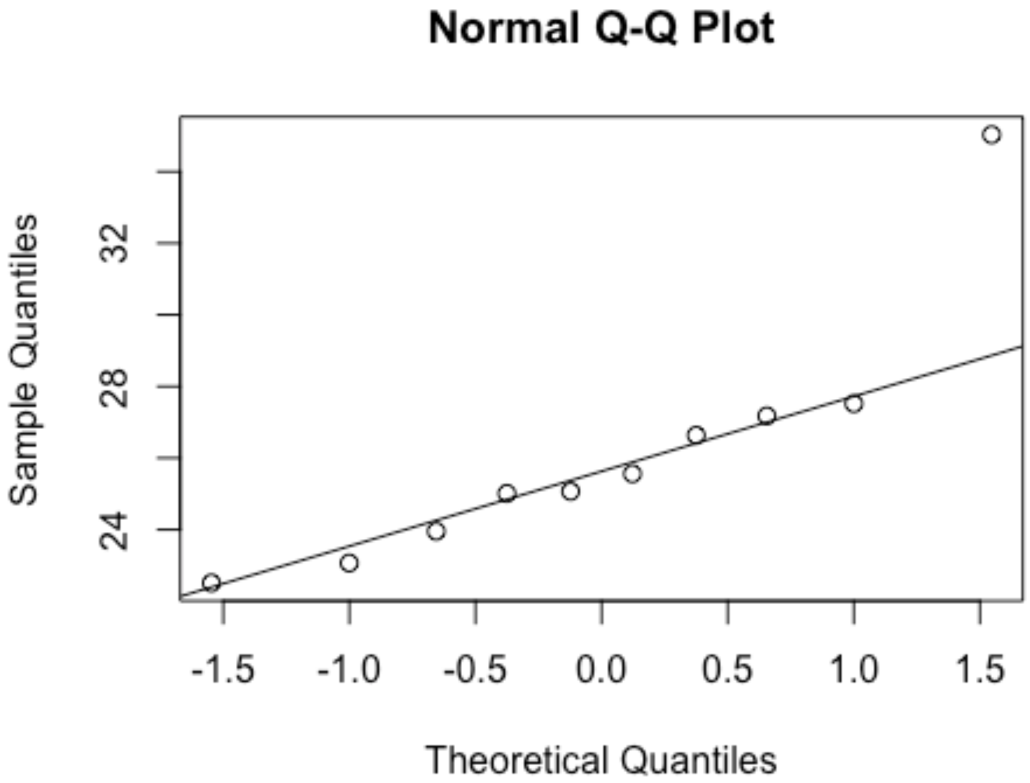
```
ad.test(DCFdata$BMI.before)

##
##  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")$BM
I.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
```

```
sd(treatment.before.BMI)

## [1] 3.283838

#normality check
qqnorm(treatment.before.BMI)
qqline(treatment.before.BMI)
```



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

##
##  Anderson-Darling normality test
##
## data:  treatment.before.BMI
## A = 0.35509, p-value = 0.3831

#normal

#Control BMI before pregnancy
control.before.BMI=na.omit((subset(DCFdata, intervention == "Control")$BMI.be
fore))
length(control.before.BMI)

## [1] 10
```

```
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)
```



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

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

#non-normal
```

```
#Perform non-parametric method (Wilcoxon rank sum test)
wilcox.test(treatment.before.BMI, control.before.BMI, conf.int = TRUE)

##
##  Wilcoxon rank sum test
##
## data:  treatment.before.BMI and control.before.BMI
## W = 60, p-value = 0.4813
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.728710  3.835403
## sample estimates:
## difference in location
##               1.115286

####################BED TIME#######################
summary(DCFdata$bedtime.hrs)

##  0:00  1:00 21:00 22:00 23:00
##     4     1     1     6     8

#Tabulate the data
xtabs(~bedtime.hrs + intervention, data = DCFdata)

##             intervention
## bedtime.hrs Control Treatment
##       0:00        2         2
##       1:00        0         1
##       21:00       1         0
##       22:00       3         3
##       23:00       4         4

#Perform Fisher's Exact Test
fisher.test(xtabs(~bedtime.hrs + intervention, data = DCFdata))

##
##  Fisher's Exact Test for Count Data
##
## data:  xtabs(~bedtime.hrs + intervention, data = DCFdata)
## p-value = 1
## alternative hypothesis: two.sided

temp_table <- xtabs(~bedtime.hrs + intervention, data = DCFdata)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}
```

```
## [1] "0:00"
##       Control Treatment
## 0:00        2         2
## Other       8         8
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.0585532 17.0784861
## sample estimates:
## odds ratio
##          1
##
## [1] "1:00"
##       Control Treatment
## 1:00        0         1
## Other      10         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.00000 39.00055
## sample estimates:
## odds ratio
##          0
##
## [1] "21:00"
##       Control Treatment
## 21:00       1         0
## Other       9        10
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
```

```
##  0.02564066        Inf
## sample estimates:
## odds ratio
##        Inf
##
## [1] "22:00"
##       Control Treatment
## 22:00       3         3
## Other       7         7
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.09678719 10.33194569
## sample estimates:
## odds ratio
##          1
##
## [1] "23:00"
##       Control Treatment
## 23:00       4         4
## Other       6         6
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.118794 8.417935
## sample estimates:
## odds ratio
##          1
```

```
####################WAKE TIME#######################
summary(DCFdata$waketime.hrs)
```

```
## 5:00 6:00 7:00 8:00 9:00
##    0    5    8    4    3
```

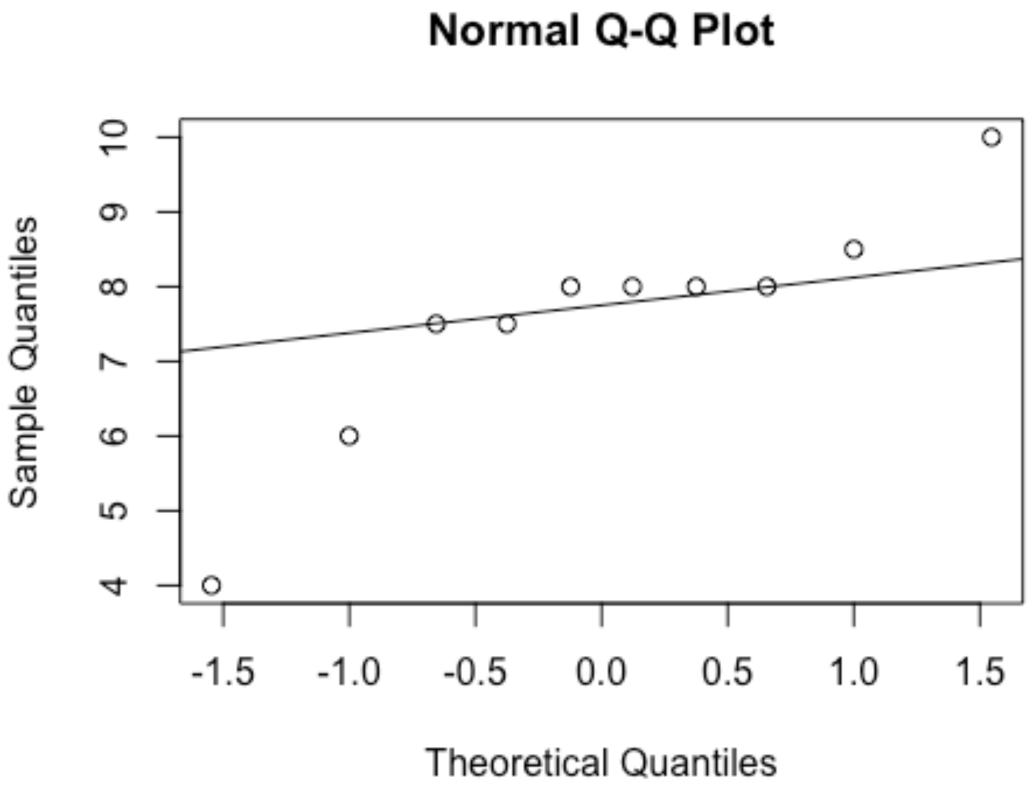
```
#Tabulate the data
xtabs(~waketime.hrs + intervention, data = DCFdata)
```

```
##             intervention
## waketime.hrs Control Treatment
##         5:00       0         0
##         6:00       4         1
##         7:00       2         6
```

```
##        8:00       3         1
##        9:00       1         2

#Perform Fisher's Exact Test
fisher.test(xtabs(~waketime.hrs + intervention, data = DCFdata))

##
##  Fisher's Exact Test for Count Data
##
## data:  xtabs(~waketime.hrs + intervention, data = DCFdata)
## p-value = 0.2044
## alternative hypothesis: two.sided

temp_table <- xtabs(~waketime.hrs + intervention, data = DCFdata)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "5:00"
##       Control Treatment
## 5:00        0         0
## Other      10        10
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0 Inf
## sample estimates:
## odds ratio
##          0
##
## [1] "6:00"
##       Control Treatment
## 6:00        4         1
## Other       6         9
##
```

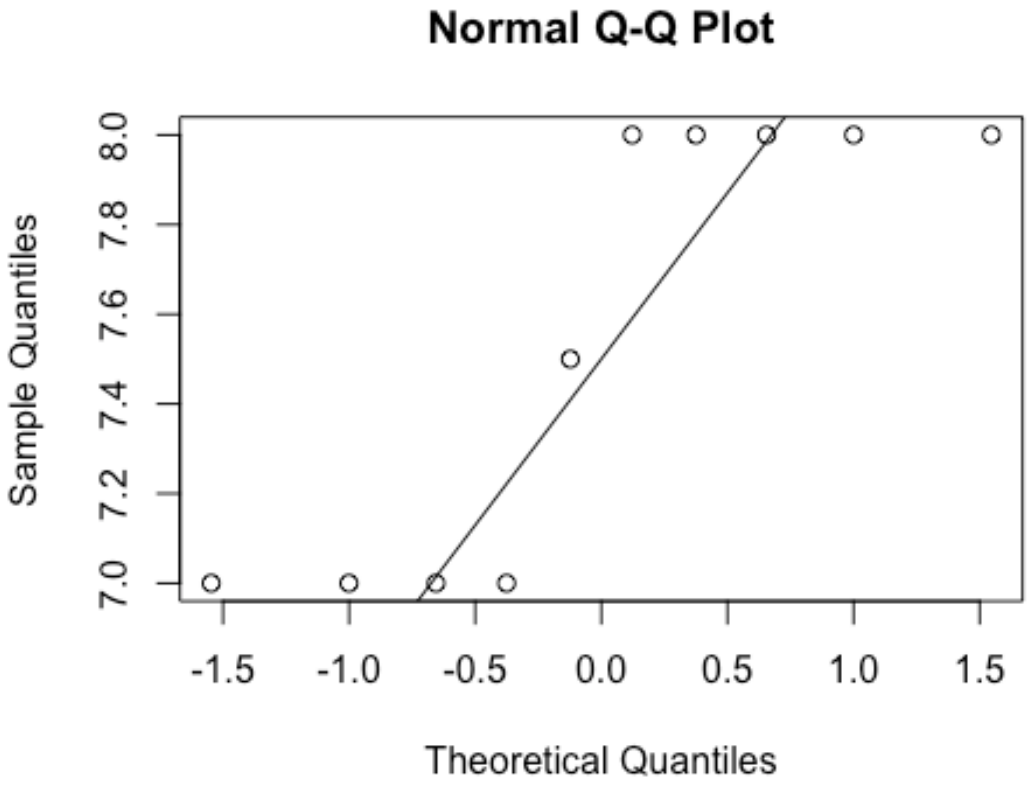
```
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.3034
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0.4075889 326.8267297
## sample estimates:
## odds ratio
##   5.485861
##
## [1] "7:00"
##       Control Treatment
## 7:00        2         6
## Other       8         4
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.1698
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.01252647 1.65925396
## sample estimates:
## odds ratio
##  0.1841181
##
## [1] "8:00"
##       Control Treatment
## 8:00        3         1
## Other       7         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.582
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0.2301177 224.1916418
## sample estimates:
## odds ratio
##   3.610815
##
## [1] "9:00"
##       Control Treatment
## 9:00        1         2
## Other       9         8
##
##  Fisher's Exact Test for Count Data
##
```

```
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.0067986 10.5137419
## sample estimates:
## odds ratio
##  0.4624944

####################SLEEP DURATION REPORTED######################
summary(DCFdata$sleep.reported.hrs)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    4.00    7.00    8.00    7.55    8.00   10.00

sd(DCFdata$sleep.reported.hrs, na.rm = TRUE)

## [1] 1.145931

length(DCFdata$sleep.reported.hrs)

## [1] 20

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   5.500   6.250   7.000   6.833   7.500   8.000

#Treatment sleep duration reported
treatment.sleep.reported.hrs=na.omit((subset(DCFdata,
                                             intervention == "Treatment")$sle
ep.reported.hrs))
length(treatment.sleep.reported.hrs)

## [1] 10

summary(treatment.sleep.reported.hrs)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    4.00    7.50    8.00    7.55    8.00   10.00

sd(treatment.sleep.reported.hrs)

## [1] 1.589025

#normality check
qqnorm(treatment.sleep.reported.hrs)
qqline(treatment.sleep.reported.hrs)
```



```
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
```

```
## Warning in wilcox.test.default(treatment.sleep.reported.hrs,
## control.sleep.reported.hrs, : cannot compute exact confidence intervals
## with ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  treatment.sleep.reported.hrs and control.sleep.reported.hrs
## W = 59, p-value = 0.498
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.5000247  0.9999945
## sample estimates:
## difference in location
##           3.045828e-05

#########FALL ASLEEP POSITION IN PAST WEEK###########
summary(DCFdata$fell.asleep.in.past.week)

##                 left          left, right  left, right, prone
##                    7                    4                   1
## left, right, supine         left, supine               right
##                    3                    2                   3
##       right, supine
##                    0

length(DCFdata$fell.asleep.in.past.week)

## [1] 20

#Tabulate the data
xtabs(~fell.asleep.in.past.week + intervention, data = DCFdata)

##                           intervention
## fell.asleep.in.past.week Control Treatment
##      left                      7         0
##      left, right               1         3
##      left, right, prone        0         1
##      left, right, supine       2         1
##      left, supine              0         2
##      right                     0         3
##      right, supine             0         0

#Perform Fisher's Exact Test
#fisher.test(xtabs(~fell.asleep.in.past.week + intervention, data = DCFdata))
#build 2-row table for fisher test: control vs treatment
fell.asleep.in.past.week_table <- matrix(c(10,7,3,8,2,3,0,1),
                                         nrow = 2)
colnames(fell.asleep.in.past.week_table) <- c("left","right","supine","prone"
)
rownames(fell.asleep.in.past.week_table) <- c("Control",
```

```
                                                "Treatment")
t(fell.asleep.in.past.week_table)

##          Control Treatment
## left          10         7
## right          3         8
## supine         2         3
## prone          0         1

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$fell.asleep.in.past.week)

##                 left          left, right  left, right, prone
##                    0                    1                   0
## left, right, supine        left, supine               right
##                    1                    0                   0
##        right, supine
##                    1

#Perform Fisher's Exact Test
fisher.test(fell.asleep.in.past.week_table)

##
##  Fisher's Exact Test for Count Data
##
## data:  fell.asleep.in.past.week_table
## p-value = 0.3141
## alternative hypothesis: two.sided

temp_table <- t(fell.asleep.in.past.week_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "left"
##         Control Treatment
## left         10         7
## Other         5        12
##
```

```
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.1663
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.680546 18.170891
## sample estimates:
## odds ratio
##   3.299199
##
## [1] "right"
##       Control Treatment
## right       3         8
## Other      12        11
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.2714
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.04812652 1.98278653
## sample estimates:
## odds ratio
##  0.3547015
##
## [1] "supine"
##        Control Treatment
## supine       2         3
## Other       13        16
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.06037268 8.38423263
## sample estimates:
## odds ratio
##  0.8252566
##
## [1] "prone"
##       Control Treatment
## prone       0         1
## Other      15        18
##
##  Fisher's Exact Test for Count Data
##
```

```
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.00000 49.36267
## sample estimates:
## odds ratio
##          0
```

```
######FALL ASLEEP POSITION WHEN NOT PREGNANT#########
summary(DCFdata$fell.asleep.when.not.pregnant)
```

```
##                       left                left, prone
##                          1                          1
##                left, right        left, right, supine
##                          1                          1
## left, right, supine, prone                      prone
##                          1                          8
##                      right               right, prone
##                          2                          1
##                     supine              supine, prone
##                          2                          2
```

```
length(DCFdata$fell.asleep.when.not.pregnant)
```

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

```
#Tabulate the data
xtabs(~fell.asleep.when.not.pregnant + intervention, data = DCFdata)
```

```
##                               intervention
## fell.asleep.when.not.pregnant Control Treatment
##    left                             1         0
##    left, prone                      1         0
##    left, right                      0         1
##    left, right, supine              0         1
##    left, right, supine, prone       1         0
##    prone                            2         6
##    right                            2         0
##    right, prone                     1         0
##    supine                           1         1
##    supine, prone                    1         1
```

```
#Perform Fisher's Exact Test
#fisher.test(xtabs(~fell.asleep.when.not.pregnant + intervention, data = DCFd
ata))
#build 2-row table for fisher test: control vs treatment
fell.asleep.when.not.pregnant_table <- matrix(c(3,2,4,2,3,3,6,7),
                                         nrow = 2)
colnames(fell.asleep.when.not.pregnant_table) <- c("left","right","supine","p
rone")
```

```
rownames(fell.asleep.when.not.pregnant_table) <- c("Control",
                                                  "Treatment")
t(fell.asleep.when.not.pregnant_table)

##        Control Treatment
## left         3         2
## right        4         2
## supine       3         3
## prone        6         7

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$fell.asleep.when.not.pregnant)

##                        left                 left, prone
##                           0                           0
##                 left, right         left, right, supine
##                           0                           1
## left, right, supine, prone                       prone
##                           0                           0
##                       right                right, prone
##                           0                           0
##                      supine               supine, prone
##                           2                           0

#Perform Fisher's Exact Test
fisher.test(fell.asleep.when.not.pregnant_table)

##
##  Fisher's Exact Test for Count Data
##
## data:  fell.asleep.when.not.pregnant_table
## p-value = 0.9528
## alternative hypothesis: two.sided

temp_table <- t(fell.asleep.when.not.pregnant_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}
```

```
## [1] "left"
##       Control Treatment
## left        3         2
## Other      13        12
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.1319695 19.0880365
## sample estimates:
## odds ratio
##    1.36981
##
## [1] "right"
##       Control Treatment
## right       4         2
## Other      12        12
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.6567
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2279875 25.5286215
## sample estimates:
## odds ratio
##    1.95517
##
## [1] "supine"
##        Control Treatment
## supine       3         3
## Other       13        11
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.09371084 7.70893039
## sample estimates:
## odds ratio
##  0.8508967
##
## [1] "prone"
##       Control Treatment
```

```
## prone       6         7
## Other      10         7
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7131
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1101751 3.2231312
## sample estimates:
## odds ratio
##  0.6104211

#########WAKE UP POSITION IN PAST WEEK###########
summary(DCFdata$woke.up.in.past.week)

##                left         left, right left, right, supine
##                   3                   5                   2
##        left, supine               right       right, supine
##                   2                   4                   0
##              supine
##                   4

length(DCFdata$woke.up.in.past.week)

## [1] 20

#Tabulate the data
xtabs(~woke.up.in.past.week + intervention, data = DCFdata)

##                       intervention
## woke.up.in.past.week  Control Treatment
##   left                      1         2
##   left, right               1         4
##   left, right, supine       1         1
##   left, supine              1         1
##   right                     4         0
##   right, supine             0         0
##   supine                    2         2

#Perform Fisher's Exact Test
#fisher.test(xtabs(~woke.up.in.past.week + intervention, data = DCFdata))
#build 2-row table for fisher test: control vs treatment
woke.up.in.past.week_table <- matrix(c(4,8,6,5,4,4),
                                              nrow = 2)
colnames(woke.up.in.past.week_table) <- c("left","right","supine")
rownames(woke.up.in.past.week_table) <- c("Control",
                                                   "Treatment")
t(woke.up.in.past.week_table)
```

```
##        Control Treatment
## left         4         8
## right        6         5
## supine       4         4

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$woke.up.in.past.week)

##                left         left, right left, right, supine
##                   0                   2                   0
##        left, supine               right       right, supine
##                   0                   0                   1
##              supine
##                   0

#Perform Fisher's Exact Test
fisher.test(woke.up.in.past.week_table)

##
##  Fisher's Exact Test for Count Data
##
## data:  woke.up.in.past.week_table
## p-value = 0.6555
## alternative hypothesis: two.sided

temp_table <- t(woke.up.in.past.week_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "left"
##       Control Treatment
## left        4         8
## Other      10         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.4607
```

```
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.07417123 2.49180269
## sample estimates:
## odds ratio
##  0.4618727
##
## [1] "right"
##       Control Treatment
## right       6         5
## Other       8        12
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.4775
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.3207388 10.2754454
## sample estimates:
## odds ratio
##   1.765584
##
## [1] "supine"
##        Control Treatment
## supine       4         4
## Other       10        13
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1885274 8.8685637
## sample estimates:
## odds ratio
##   1.288954

#########WAKE UP POSITION WHEN NOT PREGNANT###########
summary(DCFdata$woke.up.when.not.pregnant)

##                       left                left, right
##                          3                          1
##         left, right, prone        left, right, supine
##                          1                          1
## left, right, supine, prone        left, supine, prone
##                          2                          1
##                      prone                      right
##                          2                          2
```

```
##              right, supine                     supine
##                          0                          4
##              supine, prone
##                          3

length(DCFdata$woke.up.when.not.pregnant)

## [1] 20

#Tabulate the data
xtabs(~woke.up.when.not.pregnant + intervention, data = DCFdata)

##                              intervention
## woke.up.when.not.pregnant    Control Treatment
##   left                             2         1
##   left, right                      0         1
##   left, right, prone               0         1
##   left, right, supine              0         1
##   left, right, supine, prone       1         1
##   left, supine, prone              1         0
##   prone                            0         2
##   right                            1         1
##   right, supine                    0         0
##   supine                           3         1
##   supine, prone                    2         1

#Perform Fisher's Exact Test
#fisher.test(xtabs(~woke.up.when.not.pregnant + intervention, data = DCFdata)
)
#build 2-row table for fisher test: control vs treatment
woke.up.when.not.pregnant_table <- matrix(c(4,5,2,5,7,4,4,5),
                                     nrow = 2)
colnames(woke.up.when.not.pregnant_table) <- c("left","right","supine","prone
")
rownames(woke.up.when.not.pregnant_table) <- c("Control",
                                          "Treatment")
t(woke.up.when.not.pregnant_table)

##        Control Treatment
## left         4         5
## right        2         5
## supine       7         4
## prone        4         5

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$woke.up.when.not.pregnant)

##                       left                left, right
##                          0                          0
##         left, right, prone        left, right, supine
##                          0                          1
## left, right, supine, prone        left, supine, prone
```

```
##                           0                           0
##                       prone                       right
##                           1                           0
##               right, supine                      supine
##                           1                           0
##               supine, prone
##                           0
```

```
#Perform Fisher's Exact Test
fisher.test(woke.up.when.not.pregnant_table)
```

```
## 
##  Fisher's Exact Test for Count Data
## 
## data:  woke.up.when.not.pregnant_table
## p-value = 0.56
## alternative hypothesis: two.sided
```

```
temp_table <- t(woke.up.when.not.pregnant_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}
```

```
## [1] "left"
##       Control Treatment
## left        4         5
## Other      13        14
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.13878 5.04642
## sample estimates:
## odds ratio 
##  0.8651067 
## 
```

```
## [1] "right"
##       Control Treatment
## right       2         5
## Other      15        14
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.408
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.03161314 2.82646603
## sample estimates:
## odds ratio 
##  0.3834022 
## 
## [1] "supine"
##        Control Treatment
## supine       7         4
## Other       10        15
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.2814
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.4917611 15.3003743
## sample estimates:
## odds ratio 
##   2.553445 
## 
## [1] "prone"
##       Control Treatment
## prone       4         5
## Other      13        14
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.13878 5.04642
## sample estimates:
## odds ratio 
##  0.8651067

#########PART OF BED PARTICIPANT SLEEPS ON###########
summary(DCFdata$side.of.bed)
```

```
##              center                left left, right, center 
##                   2                   8                   1 
##               right       right, center 
##                   9                   0

length(DCFdata$side.of.bed)

## [1] 20

#Tabulate the data
xtabs(~side.of.bed + intervention, data = DCFdata)

##                      intervention
## side.of.bed           Control Treatment
##   center                    0         2
##   left                      5         3
##   left, right, center       0         1
##   right                     5         4
##   right, center             0         0

#Perform Fisher's Exact Test
#fisher.test(xtabs(~side.of.bed + intervention, data = DCFdata))
#build 2-row table for fisher test: control vs treatment
side.of.bed_table <- matrix(c(5,4,5,5,0,3),
                                          nrow = 2)
colnames(side.of.bed_table) <- c("left","right","center")
rownames(side.of.bed_table) <- c("Control",
                                               "Treatment")
t(side.of.bed_table)

##        Control Treatment
## left         5         4
## right        5         5
## center       0         3

#Perform Fisher's Exact Test
fisher.test(side.of.bed_table)

## 
##  Fisher's Exact Test for Count Data
## 
## data:  side.of.bed_table
## p-value = 0.357
## alternative hypothesis: two.sided

temp_table <- t(side.of.bed_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "left"
##       Control Treatment
## left        5         4
## Other       5         8
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.6656
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2637526 15.6036729
## sample estimates:
## odds ratio
##   1.936521
##
## [1] "right"
##       Control Treatment
## right       5         5
## Other       5         7
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.1920501 10.2898393
## sample estimates:
## odds ratio
##   1.378598
##
## [1] "center"
##        Control Treatment
## center       0         3
## Other       10         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
```

```
## p-value = 0.2208
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.000000 2.779036
## sample estimates:
## odds ratio
##          0

###################BED PARTNER###################
summary(DCFdata$sleeps.with.without.partner)

##    with without
##      17       3

length(DCFdata$sleeps.with.without.partner)

## [1] 20

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$sleeps.with.without.partner)

##    with without
##       3       0

#Tabulate the data
xtabs(~sleeps.with.without.partner + intervention, data = DCFdata)

##                            intervention
## sleeps.with.without.partner Control Treatment
##                       with         10         7
##                       without       0         3

#Perform Fisher's Exact Test
fisher.test(xtabs(~sleeps.with.without.partner + intervention, data = DCFdata
))

##
##  Fisher's Exact Test for Count Data
##
## data:  xtabs(~sleeps.with.without.partner + intervention, data = DCFdata)
## p-value = 0.2105
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.443414      Inf
## sample estimates:
## odds ratio
##        Inf

###################PILLOW USE###################
summary(DCFdata$pillow)
```

```
##                                         pregnancy pillow
##                                                        2
##                                               under head
##                                                        1
##                             under head and between knees
##                                                        4
##                          under head and pregnancy pillow
##                                                        1
##                                 under head between knees
##                                                        1
##                 under head between knees and behind back
##                                                        2
##            under head between knees and pregnancy pillow
##                                                        1
##                 under head between knees and under tummy
##                                                        1
## under head between knees behind back and pregnany pillow
##                                                        1
##                     under head between knees under tummy
##                                                        1
##     under head between knees under tummy and behind back
##                                                        3
##                   under head under tummy and behind back
##                                                        2
```

```
length(DCFdata$pillow)
```

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

```
#Tabulate the data
xtabs(~pillow + intervention, data = DCFdata)
```

```
##                                                            intervention
## pillow                                                      Control
##   pregnancy pillow                                                1
##   under head                                                      1
##   under head and between knees                                    3
##   under head and pregnancy pillow                                 0
##   under head between knees                                        0
##   under head between knees and behind back                        1
##   under head between knees and pregnancy pillow                   0
##   under head between knees and under tummy                        0
##   under head between knees behind back and pregnany pillow       0
##   under head between knees under tummy                            0
##   under head between knees under tummy and behind back            2
##   under head under tummy and behind back                          2
##                                                            intervention
## pillow                                                      Treatment
##   pregnancy pillow                                                  1
##   under head                                                        0
##   under head and between knees                                      1
```

```
##   under head and pregnancy pillow                                  1
##   under head between knees                                         1
##   under head between knees and behind back                         1
##   under head between knees and pregnancy pillow                    1
##   under head between knees and under tummy                         1
##   under head between knees behind back and pregnany pillow         1
##   under head between knees under tummy                             1
##   under head between knees under tummy and behind back             1
##   under head under tummy and behind back                           0

#Perform Fisher's Exact Test
fisher.test(xtabs(~pillow + intervention, data = DCFdata))

## 
##  Fisher's Exact Test for Count Data
## 
## data:  xtabs(~pillow + intervention, data = DCFdata)
## p-value = 0.7563
## alternative hypothesis: two.sided

#build 2-row table for fisher test: control vs treatment
pillow_table <- matrix(c(1,4,9,9,6,8,5,3,4,3),
                            nrow = 2)
colnames(pillow_table) <- c("pregnancy pillow","under head","btw knees","behi
nd back","under tummy")
rownames(pillow_table) <- c("Control",
                                 "Treatment")
t(pillow_table)

##                  Control Treatment
## pregnancy pillow       1         4
## under head             9         9
## btw knees              6         8
## behind back            5         3
## under tummy            4         3

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

##                                          pregnancy pillow 
##                                                         0 
##                                                under head 
##                                                         0 
##                             under head and between knees 
##                                                         1 
##                          under head and pregnancy pillow 
##                                                         0 
##                                 under head between knees 
##                                                         0 
##                 under head between knees and behind back 
##                                                         1
```

```
##            under head between knees and pregnancy pillow
##                                                        0
##                 under head between knees and under tummy
##                                                        1
## under head between knees behind back and pregnany pillow
##                                                        0
##                     under head between knees under tummy
##                                                        0
##     under head between knees under tummy and behind back
##                                                        0
##                   under head under tummy and behind back
##                                                        0

#Perform Fisher's Exact Test
fisher.test(pillow_table)

##
##  Fisher's Exact Test for Count Data
##
## data:  pillow_table
## p-value = 0.6624
## alternative hypothesis: two.sided

temp_table <- t(pillow_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "pregnancy pillow"
##                  Control Treatment
## pregnancy pillow       1         4
## Other                 24        23
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.3517
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
```

```
##  0.004679473 2.727254390
## sample estimates:
## odds ratio
##  0.2455393
##
## [1] "under head"
##            Control Treatment
## under head       9         9
## Other           16        18
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.3077428 4.1067353
## sample estimates:
## odds ratio
##    1.12245
##
## [1] "btw knees"
##           Control Treatment
## btw knees       6         8
## Other          19        19
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7587
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1779795 3.0415532
## sample estimates:
## odds ratio
##  0.7541601
##
## [1] "behind back"
##             Control Treatment
## behind back       5         3
## Other            20        24
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.4583
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.3355811 14.3021716
## sample estimates:
```

```
## odds ratio
##   1.973559
##
## [1] "under tummy"
##             Control Treatment
## under tummy       4         3
## Other            21        24
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.6983
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2268471 11.5245873
## sample estimates:
## odds ratio
##   1.511484

###################SNORING#######################
summary(DCFdata$snores.3.times.or.more.per.week.does.not.snore)

## does not snore          snores
##             13              7

length(DCFdata$snores.3.times.or.more.per.week.does.not.snore)

## [1] 20

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$snores.3.times.or.more.per.week.does.not.snore)

## does not snore          snores
##              2              1

#Tabulate the data
xtabs(~snores.3.times.or.more.per.week.does.not.snore + intervention, data =
DCFdata)

##                                                intervention
## snores.3.times.or.more.per.week.does.not.snore Control Treatment
##                                 does not snore       7         6
##                                 snores               3         4

#Perform Fisher's Exact Test
fisher.test(xtabs(~snores.3.times.or.more.per.week.does.not.snore + intervent
ion, data = DCFdata))

##
##  Fisher's Exact Test for Count Data
##
## data:
```

```
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.1731447 15.0151265
## sample estimates:
## odds ratio
##   1.521346
```

```
summary(DCFdata$how.long.snores)
```

```
##
##
14
##
2-3 months
##
1
##
7.5 months
##
1
## I think so, my husband informs me that I do + it gets worse the further al
ong in pregnancy (louder/same frequency)
##
1
##
lifetime
##
1
##
several years
##
1
##
Since before I was pregnant
##
1
##
Since being pregnant
##
0
```

```
length(DCFdata$how.long.snores)
```

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

```
###################PREGNANCY HISTORY######################
summary(DCFdata$pregnancy.related.medical.conditions)
```

```
## none
##   20
```

```
length(DCFdata$pregnancy.related.medical.conditions)

## [1] 20

temp <- matrix(c(10,0,10,0), nrow = 2)
temp

##      [,1] [,2]
## [1,]   10   10
## [2,]    0    0

fisher.test(temp)

##
##  Fisher's Exact Test for Count Data
##
## data:  temp
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0 Inf
## sample estimates:
## odds ratio
##          0

#The End
```

Supplementary file 2: Code and output – PSG analysis

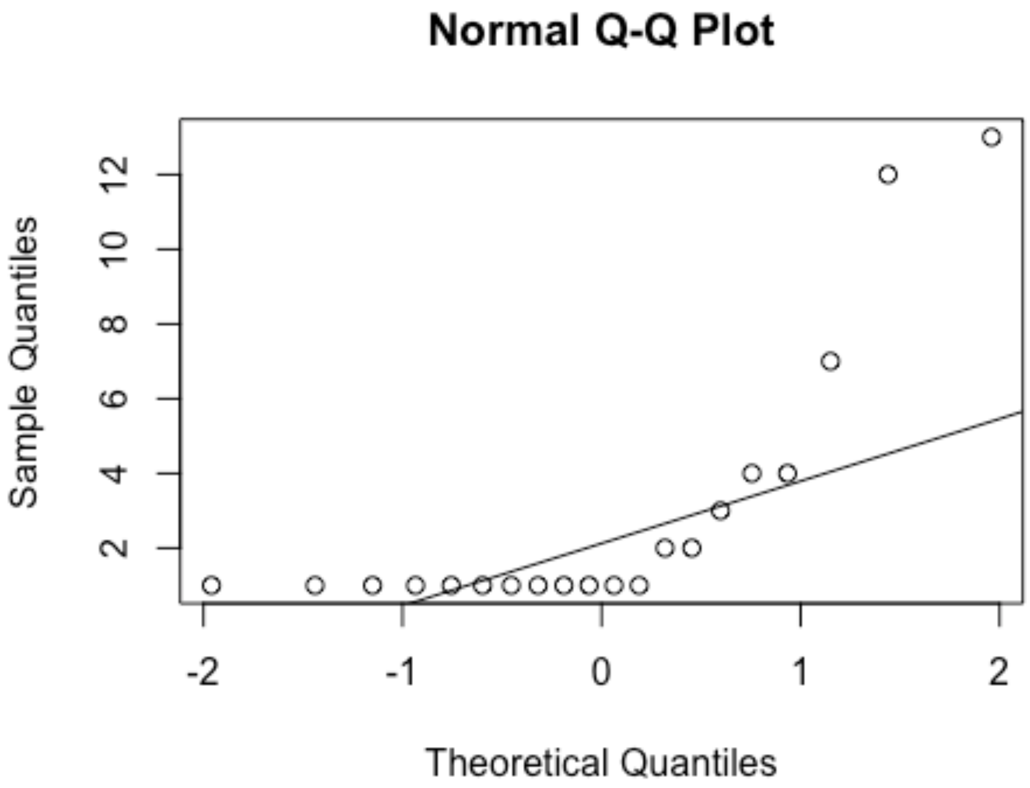
PSG_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 16:08:13 2018

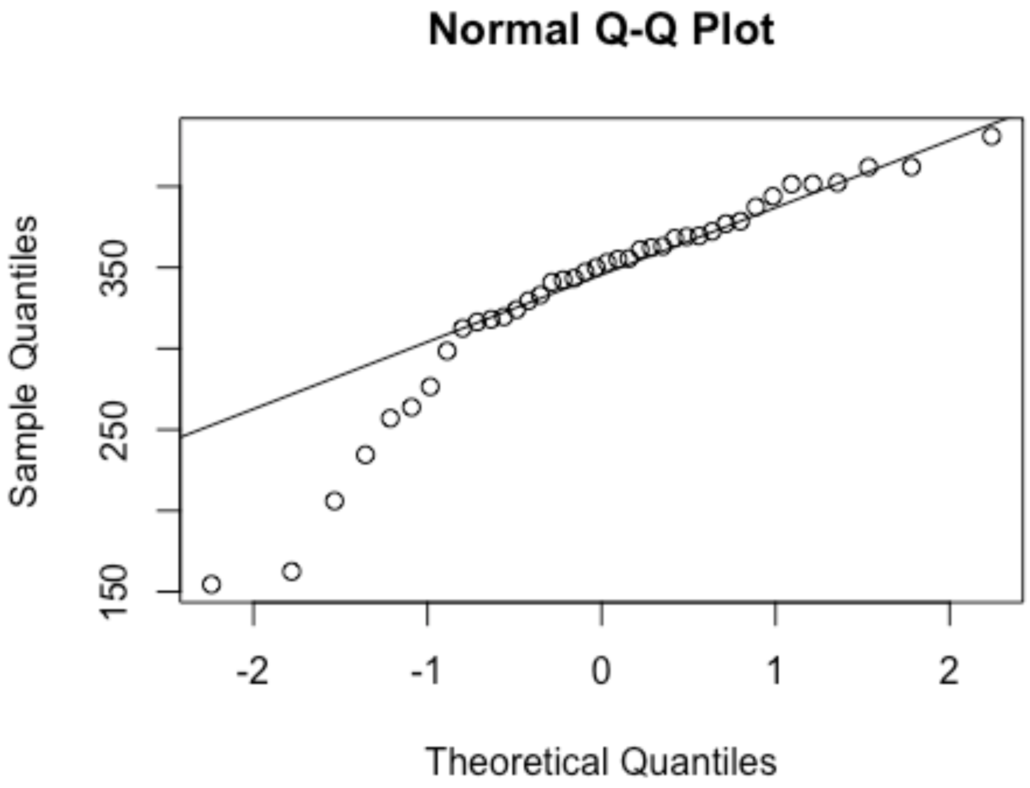
```
#Description of code: this code process the polysomnography (PSG) sleep repor
ts in full.
#Within-participant comparisons and between-participant comparisons are compu
ted. Linear
#mixed effects model is constructed for the percentage of time spent sleeping
supine and
#the number of minutes spent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

#Summary: results reveal a statistically significant reduction in the percent
age 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 so
ftware
#will perform this calculation for you. If the p value from the ANOVA is sign
ificant
#(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)

##  N  Y
## 40  6

#6 nights = 3 participants
#Remove the drop outs ("Y")
SSdata <- SSdatafull[!(SSdatafull$drop.out=="Y"),]
nrow(SSdata)

## [1] 40

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

################### Time between studies (days) ##########################
#Summary
summary(SSdata$time.between.studies..days.)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##    1.00    1.00    1.00    2.95    3.25   13.00      20

sd(SSdata$time.between.studies..days., na.rm = TRUE)

## [1] 3.619756

length(SSdata$time.between.studies..days.)

## [1] 40

#Check for normality
qqnorm(SSdata$time.between.studies..days.)
qqline(SSdata$time.between.studies..days.)
```



```
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
```

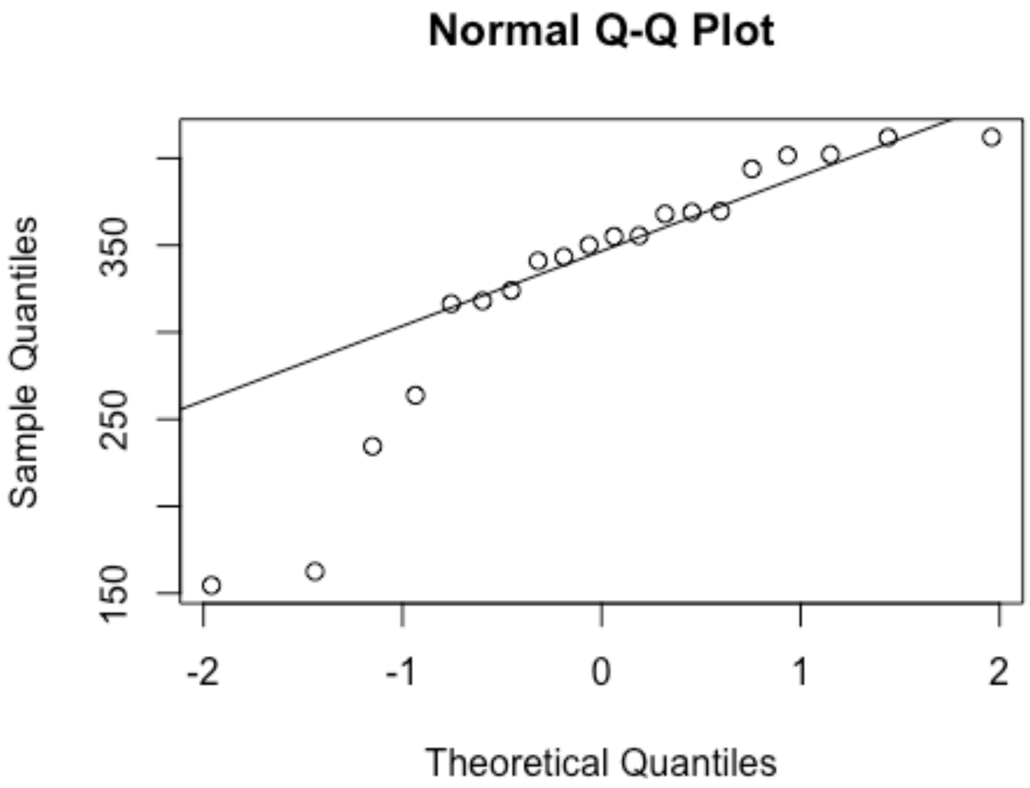
```
qqnorm(SSdata$total.sleep.time)
qqline(SSdata$total.sleep.time)
```



```
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
```

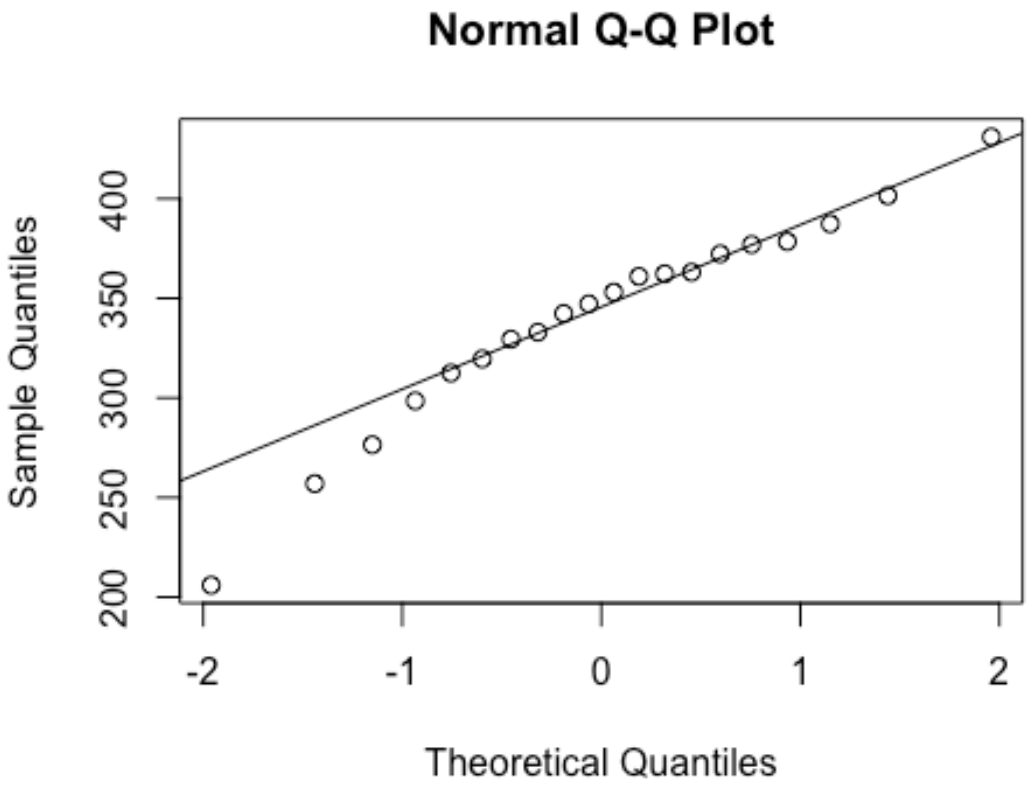
```
## intervention:night  1      3     2.8  0.0006 0.9800
## Residuals          36 155266  4312.9

#No association between intervention or night on sleeptime, even when account
ing for
#both factors at the same time. It does not matter whether they received the
PrenaBelt
#on night one or night two.

#within-participants (paired) comparison
#need to remove drop outs in order to have balanced pairs
#Exclude drop outs
#How many drop outs?
summary(SSdata$drop.out)

##  N  Y
## 40  0

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

## [1] 40

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

##
##  Wilcoxon signed rank test
##
## data:  subset(SSdataCompletes, intervention == "sham")$total.sleep.time an
d subset(SSdataCompletes, intervention == "PrenaBelt")$total.sleep.time
## V = 112, p-value = 0.8124
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -21.80  33.75
## sample estimates:
## (pseudo)median
##           3.55

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   154.5   317.6   352.6   332.4   375.6   412.1

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

## [1] 75.04747
```

```
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)
```



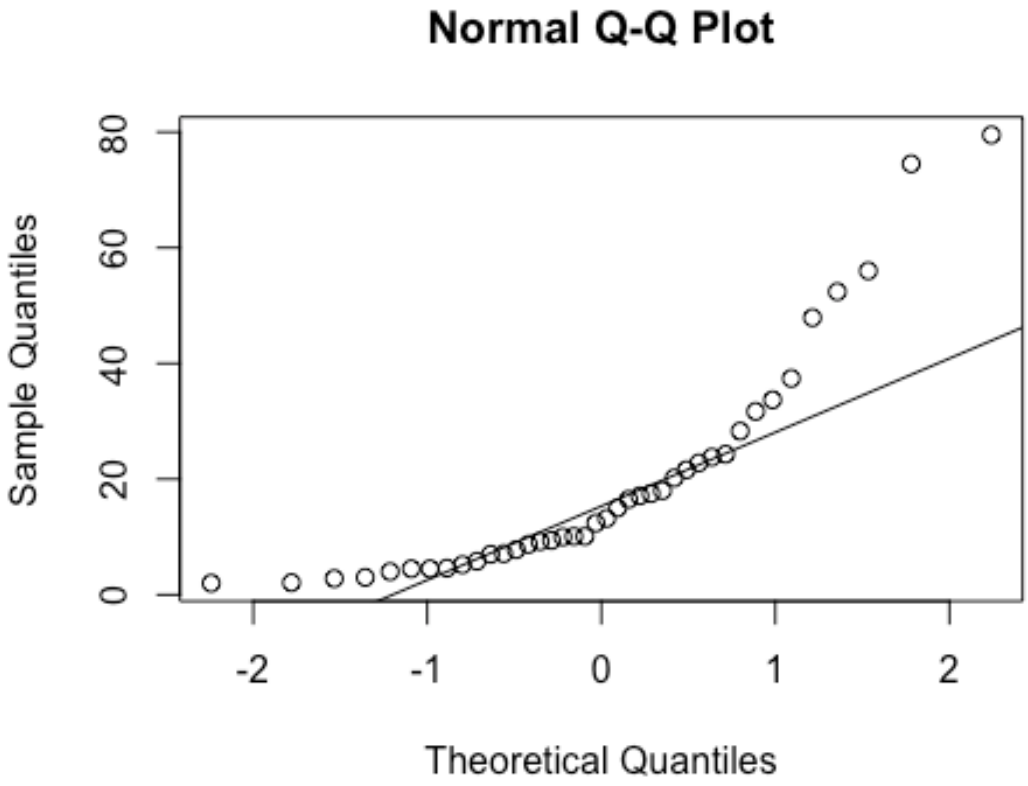
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)

##
##  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)
```



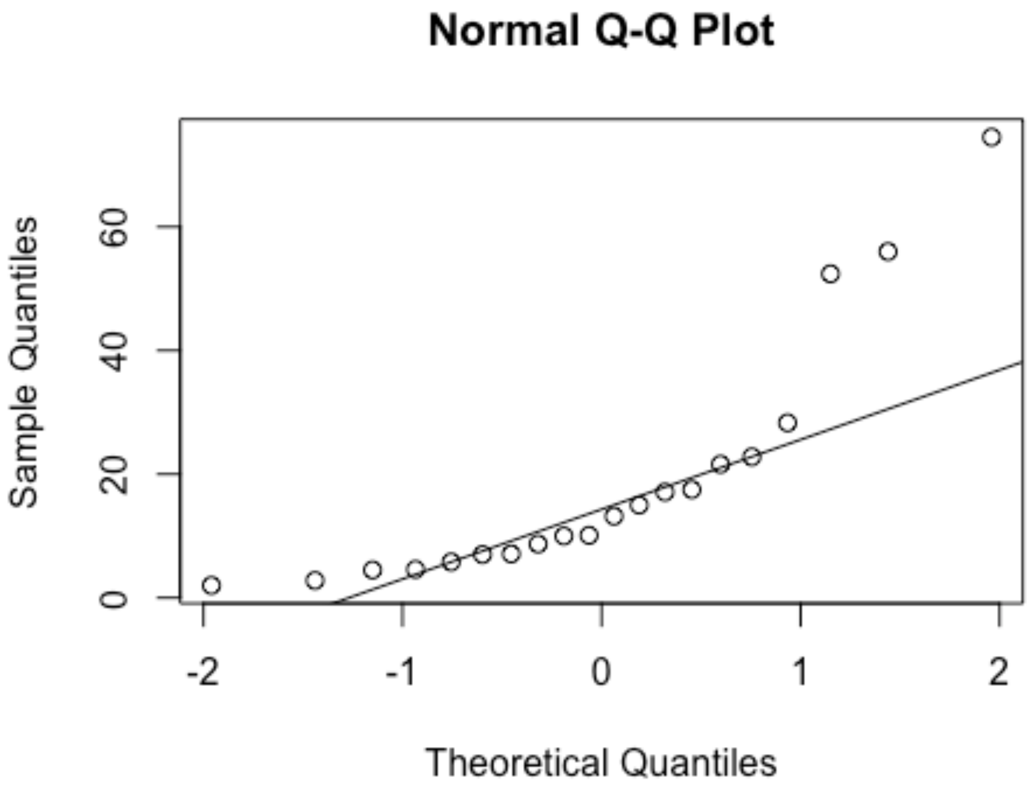
```
ad.test(subset(SSdata, intervention == "sham")$total.sleep.time)

##
##  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
```

```
##
## data:  subset(SSdata, intervention == "sham")$total.sleep.time and subset(
SSdata, intervention == "PrenaBelt")$total.sleep.time
## W = 196, p-value = 0.9254
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -35.1  32.3
## sample estimates:
## difference in location
##                   -2.2

####################Sleep Latency######################
#Summary
summary(SSdata$sleep.latency)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    2.00    6.70   12.80   19.54   23.92   79.50

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

## [1] 19.13941

length(SSdata$sleep.latency)

## [1] 40

qqnorm(SSdata$sleep.latency)
qqline(SSdata$sleep.latency)
```

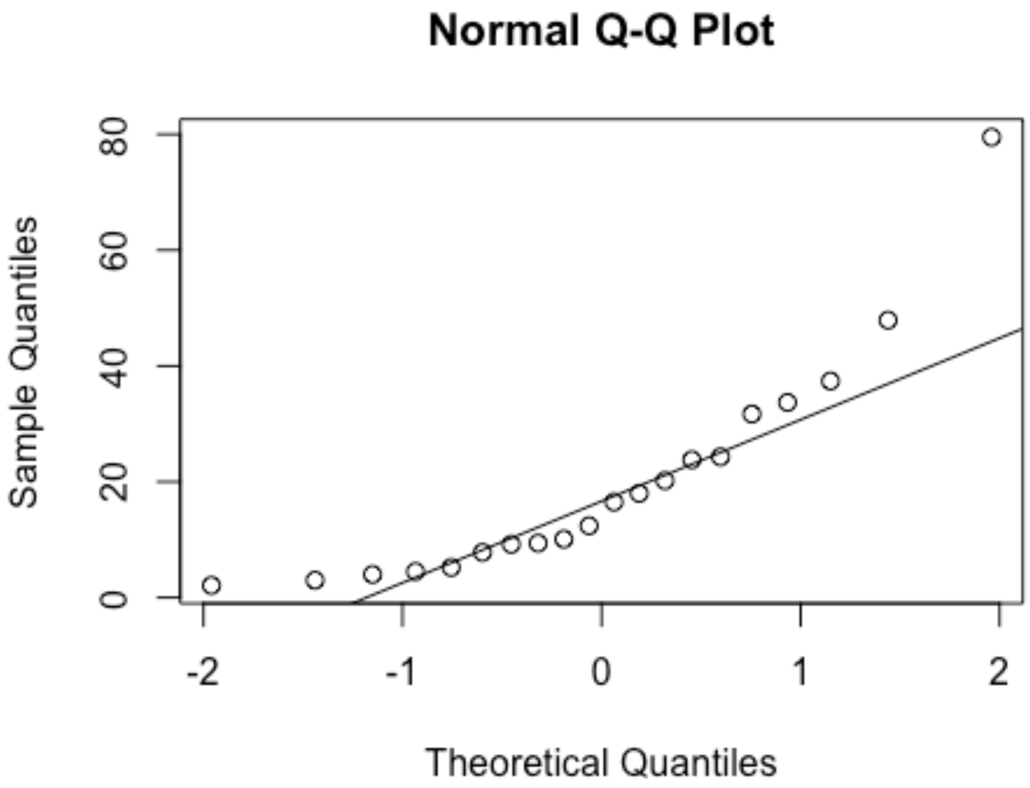


```
ad.test(SSdata$sleep.latency)

##
##  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
```

```
#within-participants (paired) comparison
wilcox.test(subset(SSdataCompletes, intervention == "sham")$sleep.latency,
       subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.latency,
       paired = TRUE, conf.int = TRUE)

##
##  Wilcoxon signed rank test
##
## data:  subset(SSdataCompletes, intervention == "sham")$sleep.latency and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$sleep.latency
## V = 92, p-value = 0.6477
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -9.40  7.15
## sample estimates:
## (pseudo)median
##             -2

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    2.00    6.70   11.65   19.05   21.90   74.50

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

## [1] 19.76593

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

## [1] 20

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

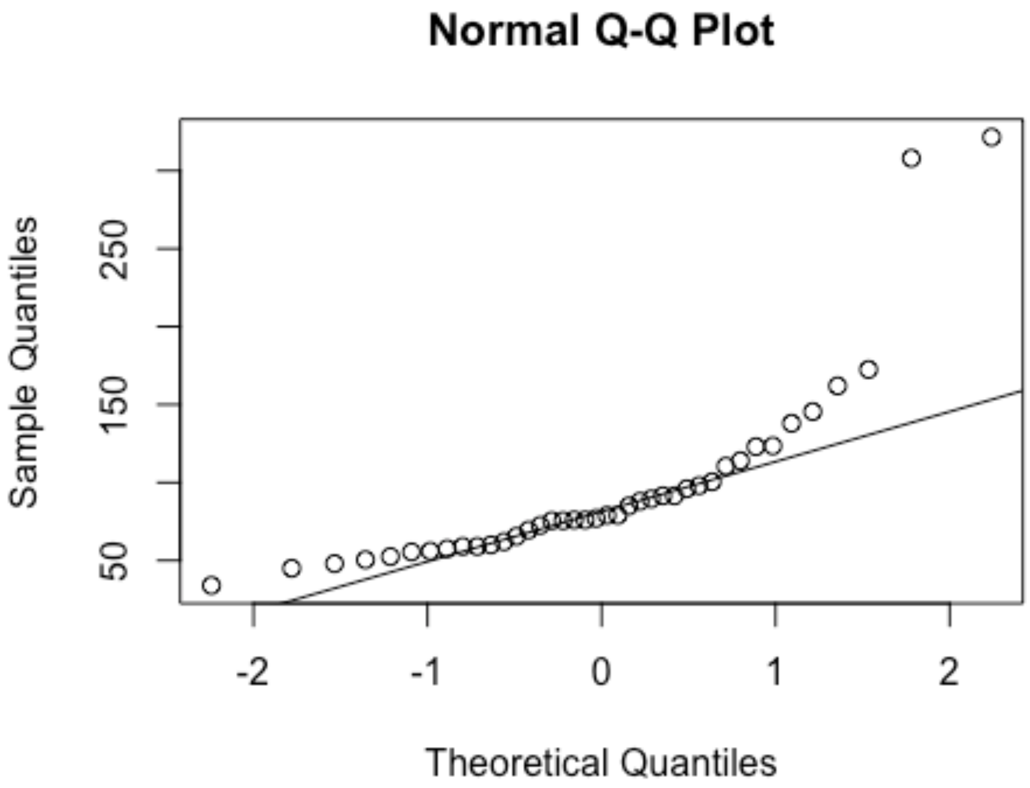


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)

##
##  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)
```



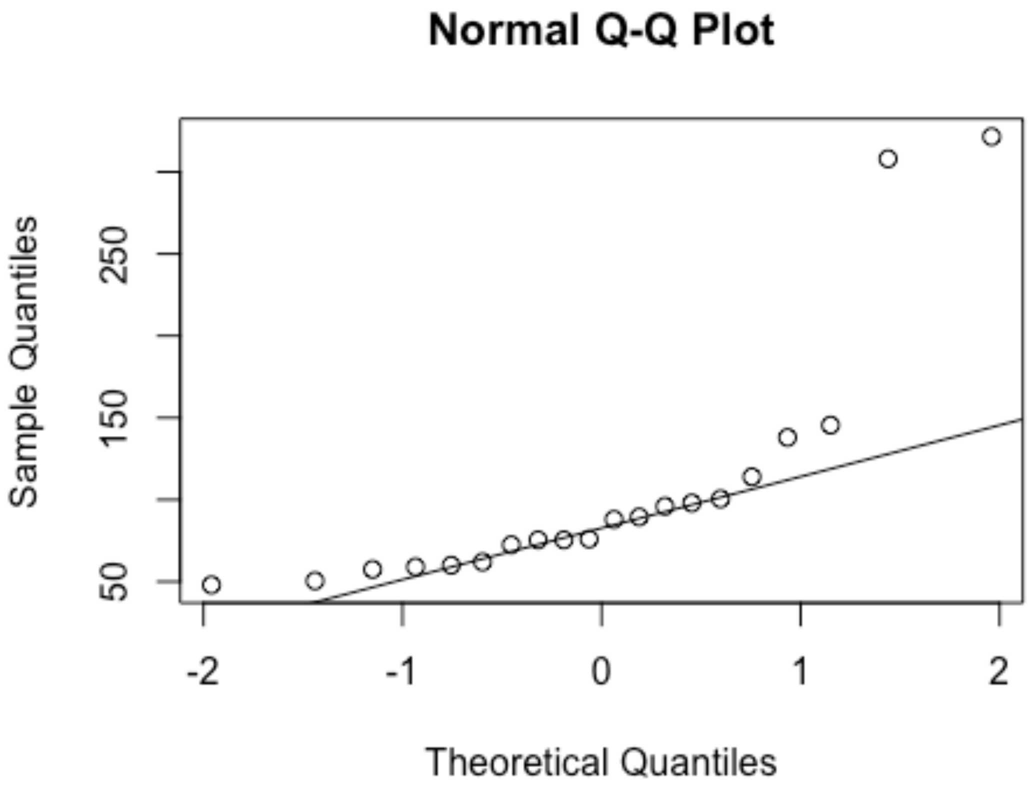
```
ad.test(subset(SSdata, intervention == "sham")$sleep.latency)

##
##  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")$sleep.latency and subset(SSd
ata, intervention == "PrenaBelt")$sleep.latency
```

```
## W = 214, p-value = 0.715
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -5.700008 10.099985
## sample estimates:
## difference in location
##                1.01358

####################REM Latency######################
#Summary
summary(SSdata$rem.latency)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   34.00   59.75   78.00   96.08  103.00  321.50

sd(SSdata$rem.latency, na.rm = TRUE)

## [1] 59.89655

length(SSdata$rem.latency)

## [1] 40

qqnorm(SSdata$rem.latency)
qqline(SSdata$rem.latency)
```



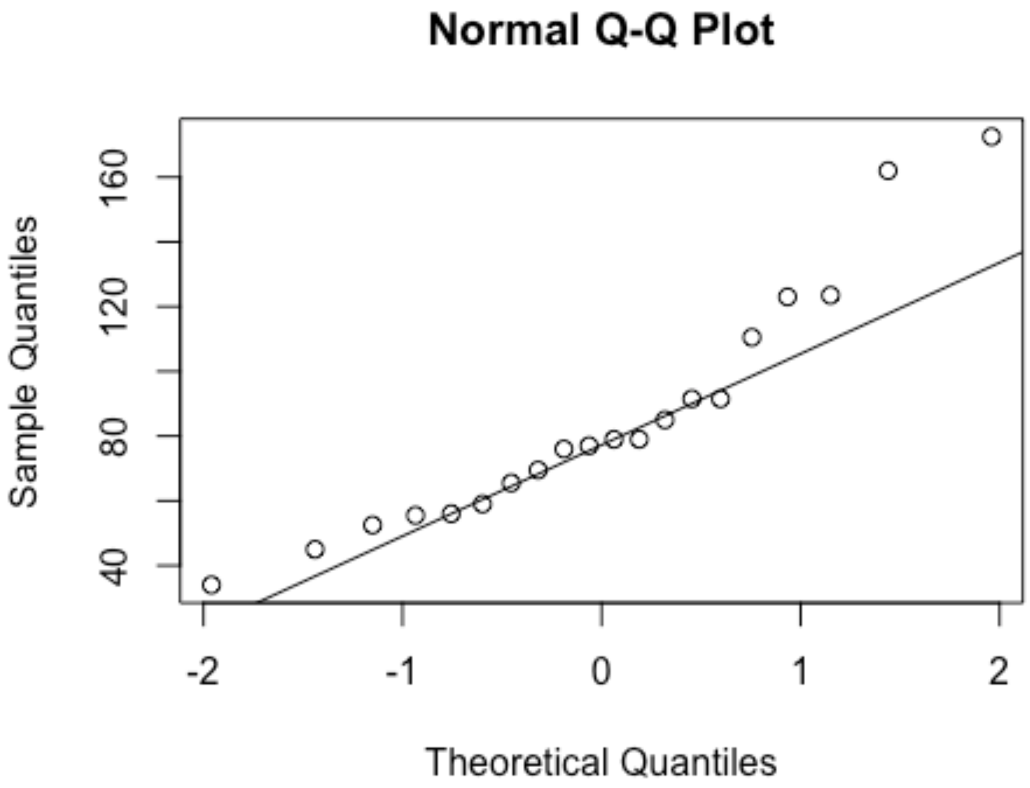
```
ad.test(SSdata$rem.latency)

##
##  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

#within-participants (paired) comparison
wilcox.test(subset(SSdataCompletes, intervention == "sham")$rem.latency,
       subset(SSdataCompletes, intervention == "PrenaBelt")$rem.latency,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$rem.latency and sub
set(SSdataCompletes, intervention == "PrenaBelt")$rem.latency
## V = 80.5, p-value = 0.37
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -35.50005  17.50006
## sample estimates:
## (pseudo)median
##      -5.190503

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$rem.latency)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##    48.0    61.5    82.0   106.8   103.9   321.5

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

## [1] 75.95402

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

## [1] 20

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



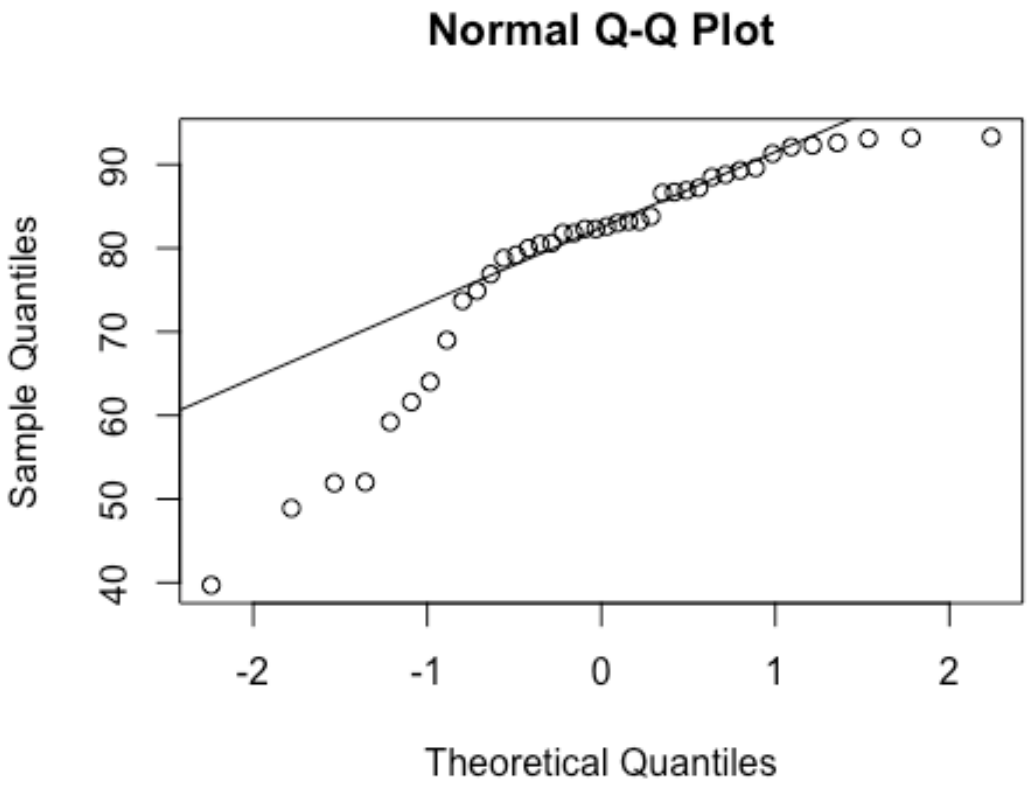
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$rem.latency)

## 
##  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)
```



```
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)
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")$rem.latency and subset(SSdat
a, intervention == "PrenaBelt")$rem.latency
## W = 178, p-value = 0.5608
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -27.50004  15.50003
## sample estimates:
## difference in location
##              -6.499973

####################Sleep Efficiency#######################
#Summary
summary(SSdata$sleep.efficiency)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   39.70   76.40   82.45   79.16   88.58   93.30

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

## [1] 13.44863

length(SSdata$sleep.efficiency)

## [1] 40

qqnorm(SSdata$sleep.efficiency)
qqline(SSdata$sleep.efficiency)
```



```
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
```

```
#within-participants (paired) comparison
wilcox.test(subset(SSdataCompletes, intervention == "sham")$sleep.efficiency,
       subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.efficiency,
       paired = TRUE, conf.int = TRUE)
```

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

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

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$sleep.efficiency an
d subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.efficiency
## V = 125.5, p-value = 0.4552
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.000041  5.899953
## sample estimates:
## (pseudo)median
##       1.444485
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   39.70   76.10   81.45   78.14   89.00   93.20
```

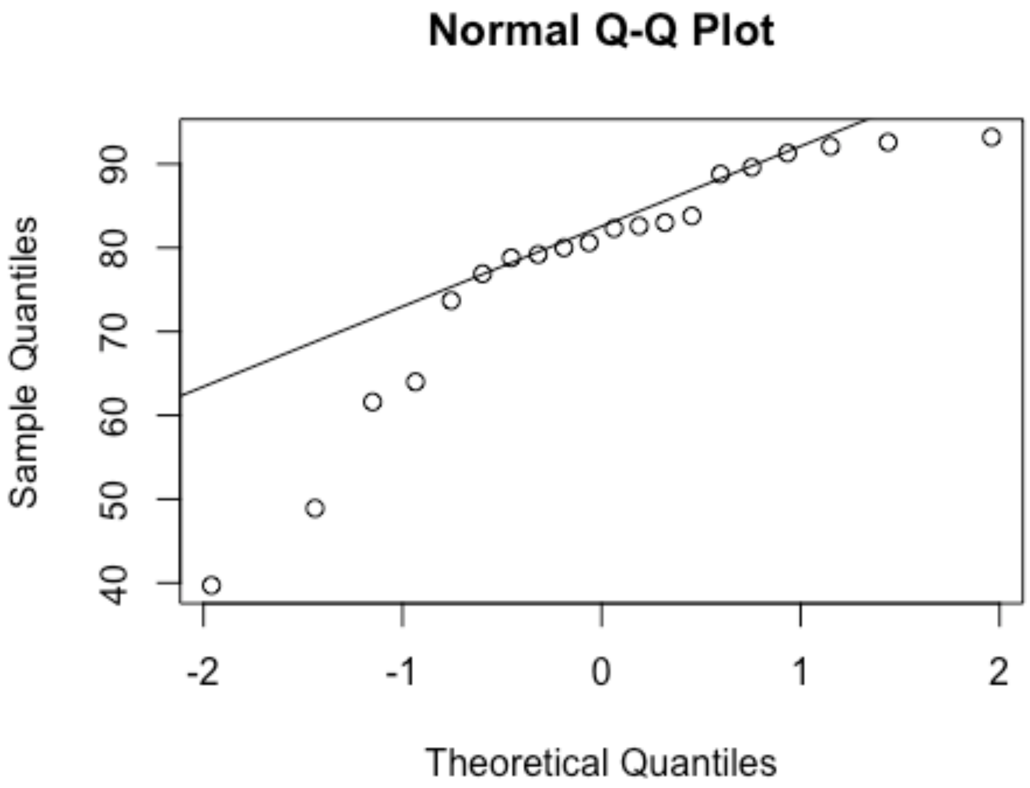
```
sd(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
```

```
## [1] 14.47362
```

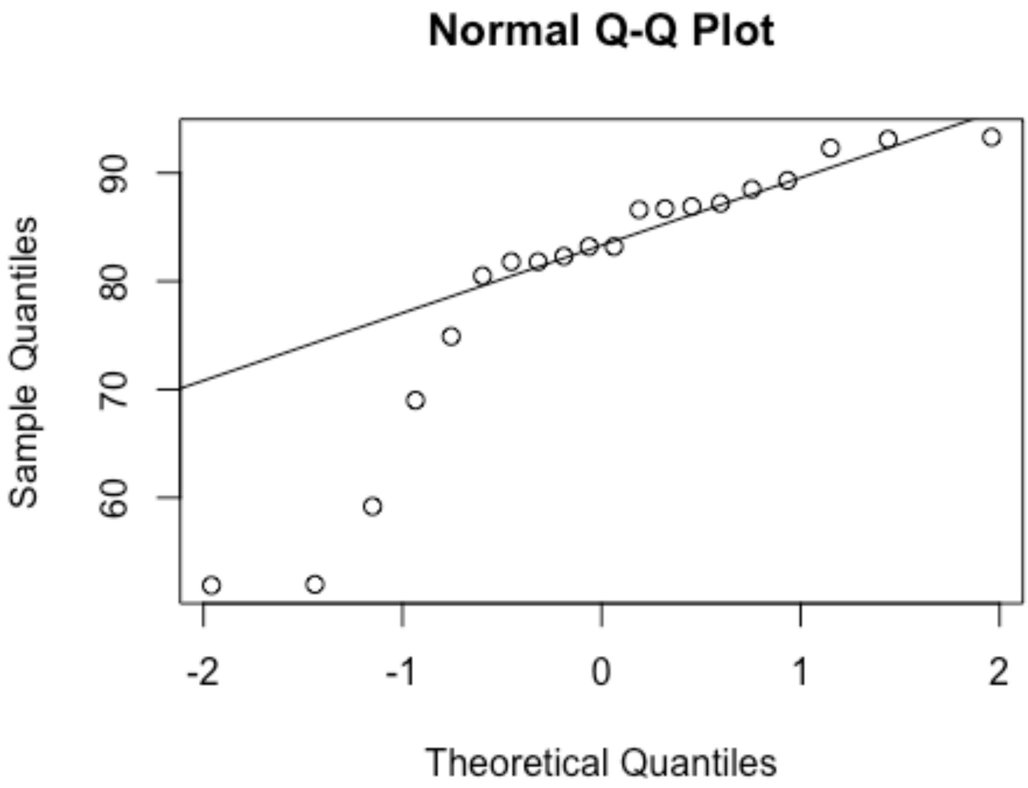
```
length(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)
```

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

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

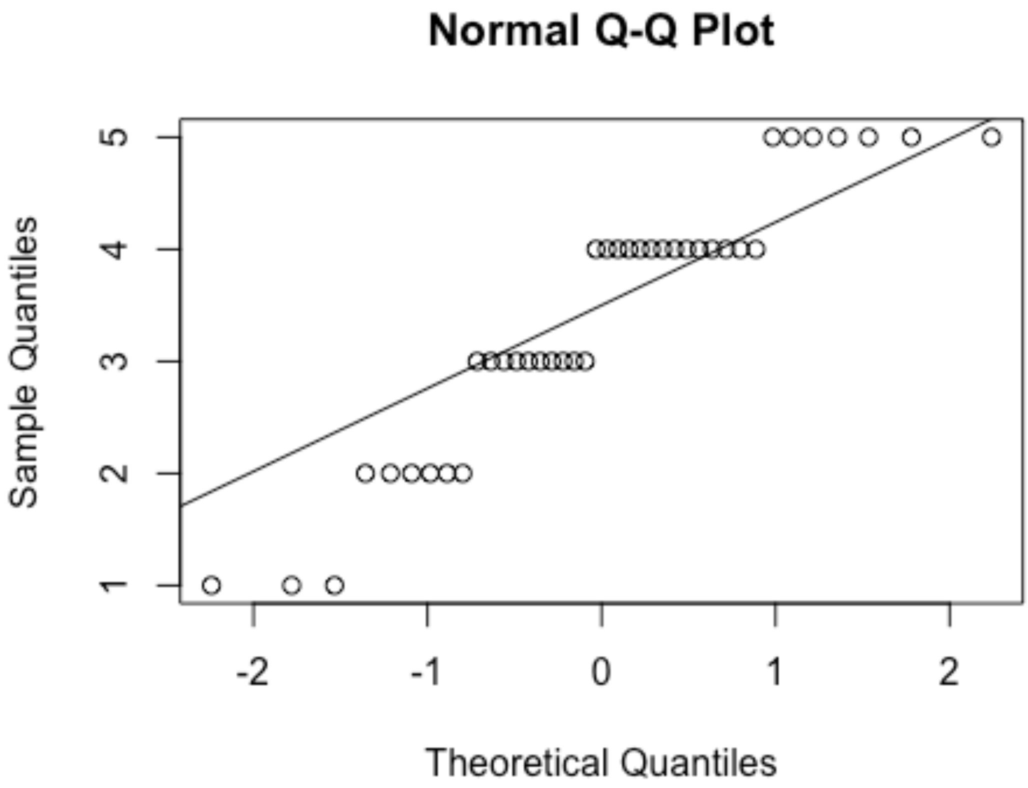


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)

##
##  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)
wilcox.test(subset(SSdata, intervention == "sham")$sleep.efficiency,
            subset(SSdata, intervention == "PrenaBelt")$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
##
```

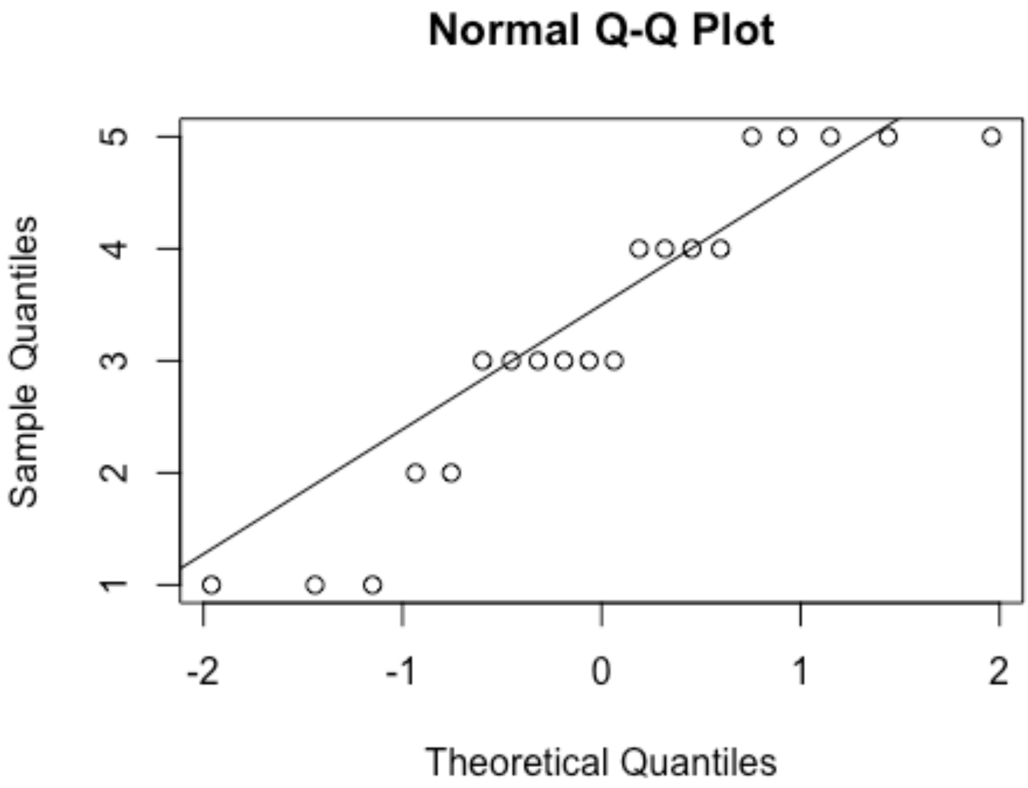
```
## data:  subset(SSdata, intervention == "sham")$sleep.efficiency and subset(
SSdata, intervention == "PrenaBelt")$sleep.efficiency
## W = 222.5, p-value = 0.5517
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.800018  7.900004
## sample estimates:
## difference in location
##               1.799971

####################Number of REM Periods######################
#Summary
summary(SSdata$num.rem.periods)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     1.0     3.0     4.0     3.4     4.0     5.0

sd(SSdata$num.rem.periods, na.rm = TRUE)

## [1] 1.172331

length(SSdata$num.rem.periods)

## [1] 40

qqnorm(SSdata$num.rem.periods)
qqline(SSdata$num.rem.periods)
```



```
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
```

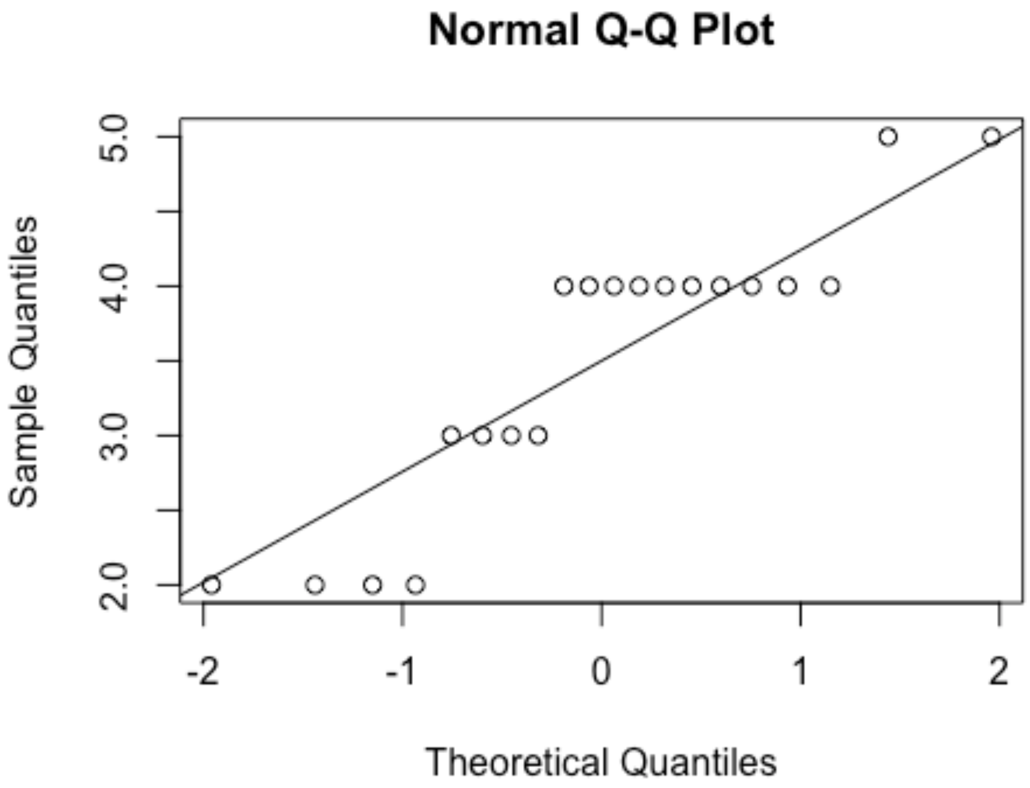
```
#within-participants (paired) comparison
t.test(subset(SSdataCompletes, intervention == "sham")$num.rem.periods,
       subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$num.rem.periods and
subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods
## t = 0.80943, df = 19, p-value = 0.4283
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.3171618  0.7171618
## sample estimates:
## mean of the differences
##                     0.2

wilcox.test(subset(SSdataCompletes, intervention == "sham")$num.rem.periods,
       subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$num.rem.periods and
subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods
## V = 73.5, p-value = 0.432
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.4999577  1.0000552
## sample estimates:
## (pseudo)median
##   4.422455e-05

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
```

```
##    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)
```

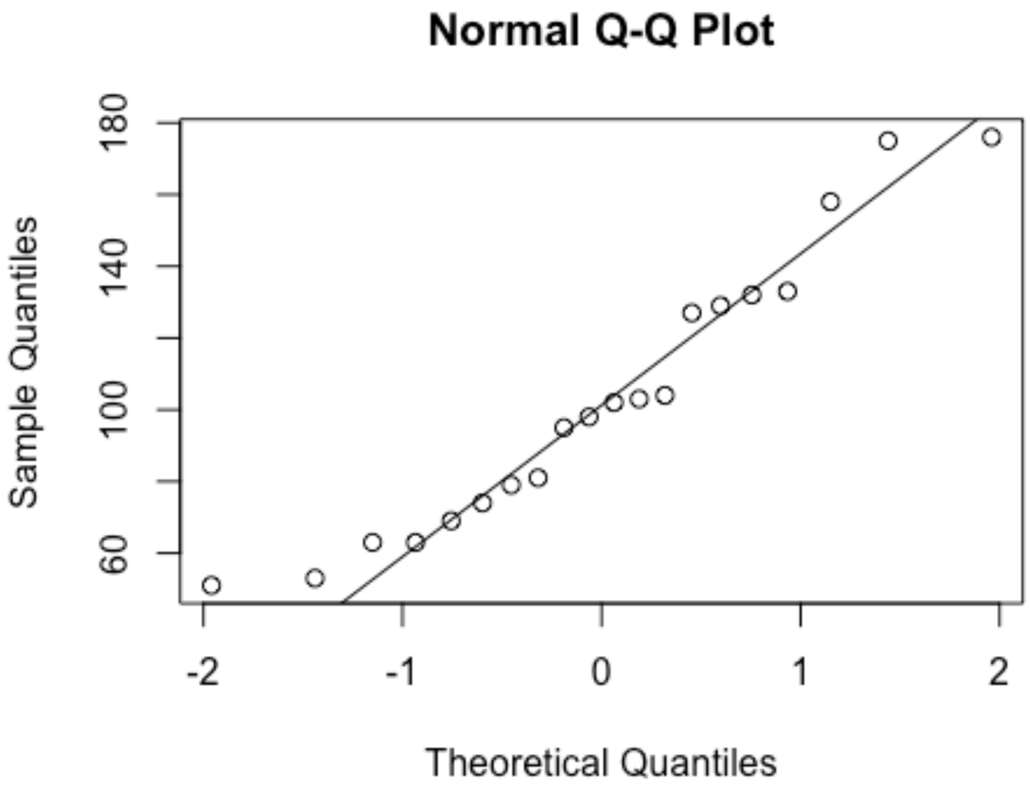
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     2.0     3.0     4.0     3.5     4.0     5.0

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)
```



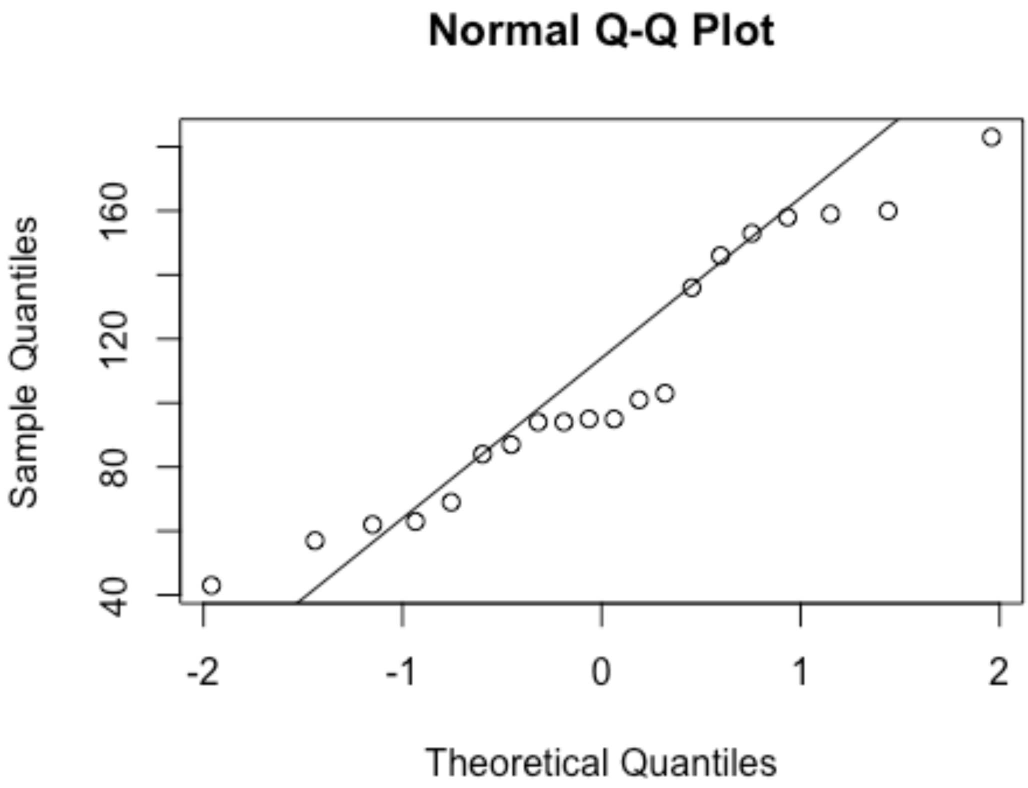
```
ad.test(subset(SSdata, intervention == "sham")$num.rem.periods)

##
##  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)
```

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

## 
##  Welch Two Sample t-test
## 
## data:  subset(SSdata, intervention == "sham")$num.rem.periods and subset(S
Sdata, intervention == "PrenaBelt")$num.rem.periods
## t = 0.53452, df = 33.621, p-value = 0.5965
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.5607122  0.9607122
## sample estimates:
## mean of x mean of y 
##       3.5       3.3

wilcox.test(subset(SSdata, intervention == "sham")$num.rem.periods,
            subset(SSdata, intervention == "PrenaBelt")$num.rem.periods,
            conf.int = TRUE)

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

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

## 
##  Wilcoxon rank sum test with continuity correction
## 
## data:  subset(SSdata, intervention == "sham")$num.rem.periods and subset(S
Sdata, intervention == "PrenaBelt")$num.rem.periods
## W = 213, p-value = 0.7263
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.9999963  1.0000309
## sample estimates:
## difference in location 
##           1.121393e-06

####################Number of Stage Shifts######################
#Summary
summary(SSdata$num.stage.shifts)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   43.00   72.75   96.50  105.20  133.80  183.00

sd(SSdata$num.stage.shifts, na.rm = TRUE)

## [1] 39.29043

length(SSdata$num.stage.shifts)
```

```
## [1] 40

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

## Analysis of Variance Table
##
## Response: num.stage.shifts
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1    148  148.22  0.0912 0.7644
## night               1     60   60.03  0.0369 0.8487
## intervention:night  1   1501 1500.63  0.9235 0.3430
## Residuals          36  58497 1624.91

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$num.stage.shifts,
       subset(SSdataCompletes, intervention == "PrenaBelt")$num.stage.shifts,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$num.stage.shifts an
d subset(SSdataCompletes, intervention == "PrenaBelt")$num.stage.shifts
## t = 0.77738, df = 19, p-value = 0.4465
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -6.515809 14.215809
## sample estimates:
## mean of the differences
##                    3.85

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   51.00   72.75  100.00  103.20  129.80  176.00

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

## [1] 38.44459

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

## [1] 20

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



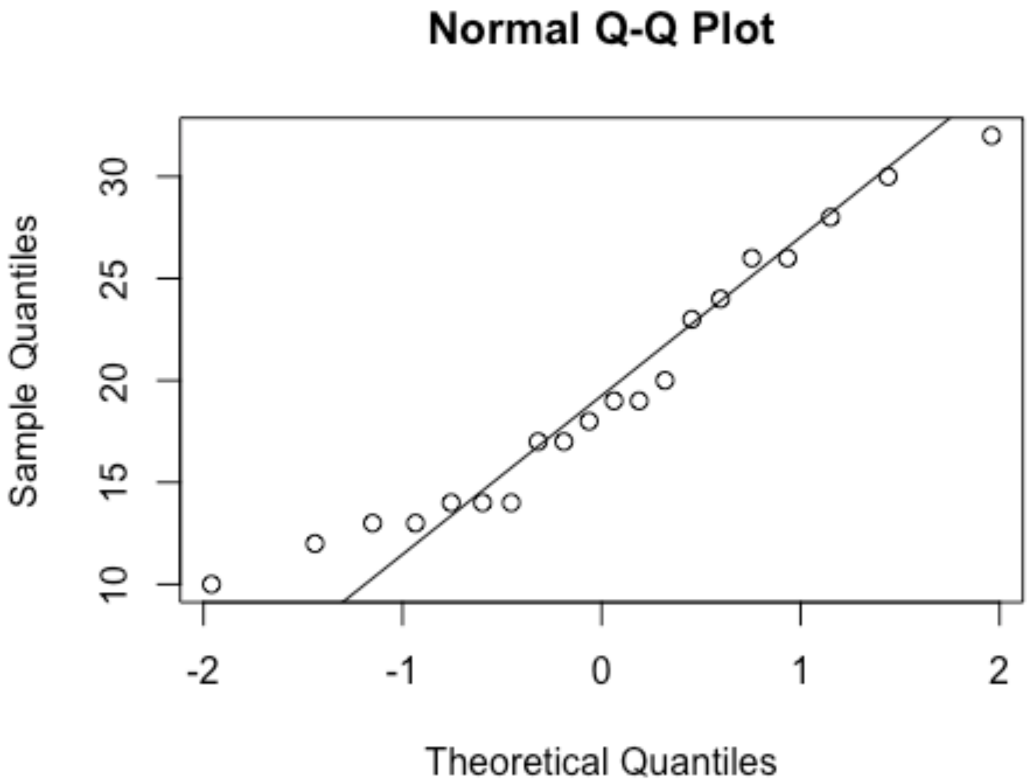
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)

##
##  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

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:
```

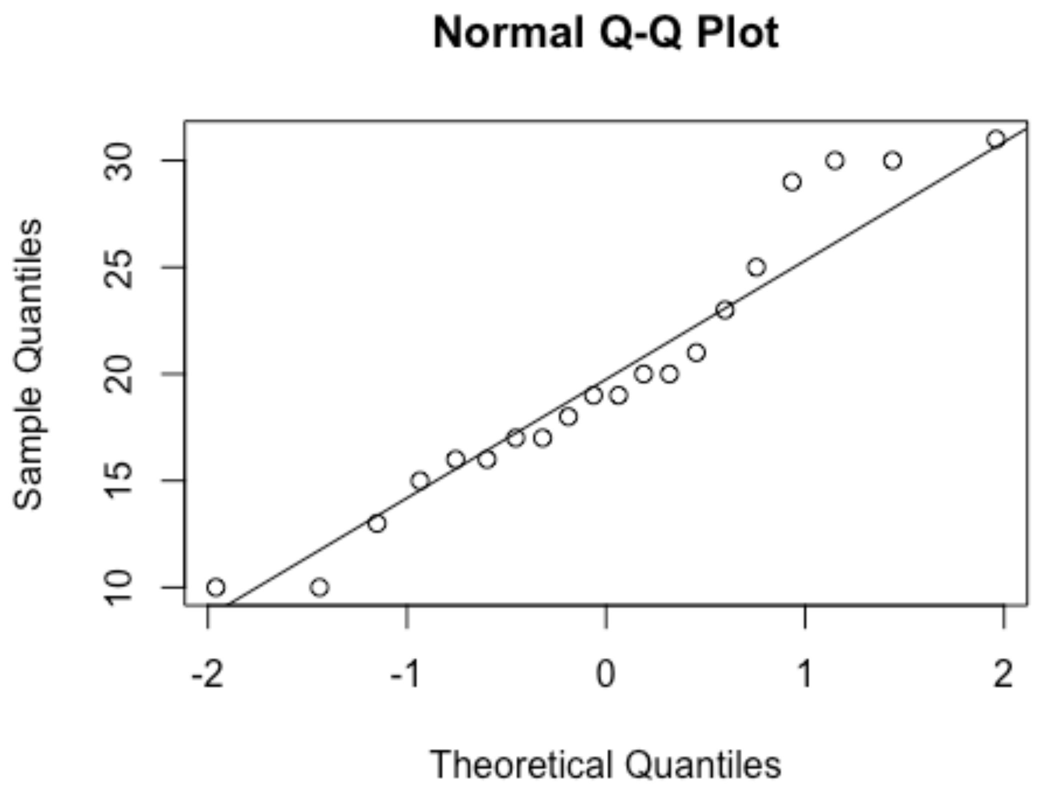
```
## mean of x mean of y
##    107.10    103.25

####################Awakenings######################
#Summary
summary(SSdata$awakenings)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   10.00   14.75   19.00   19.70   24.25   32.00

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

## [1] 6.329418

length(SSdata$awakenings)

## [1] 40

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

## Analysis of Variance Table
##
## Response: awakenings
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1    2.5    2.50  0.0589 0.8096
## night               1   19.6   19.60  0.4617 0.5012
## intervention:night  1   12.1   12.10  0.2850 0.5967
## Residuals          36 1528.2   42.45

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$awakenings,
       subset(SSdataCompletes, intervention == "PrenaBelt")$awakenings,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$awakenings and subs
et(SSdataCompletes, intervention == "PrenaBelt")$awakenings
## t = 0.38863, df = 19, p-value = 0.7019
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -2.192823  3.192823
## sample estimates:
## mean of the differences
##                      0.5
```

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   10.00   14.00   18.50   19.45   24.50   32.00

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

## [1] 6.460202

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

## [1] 20

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



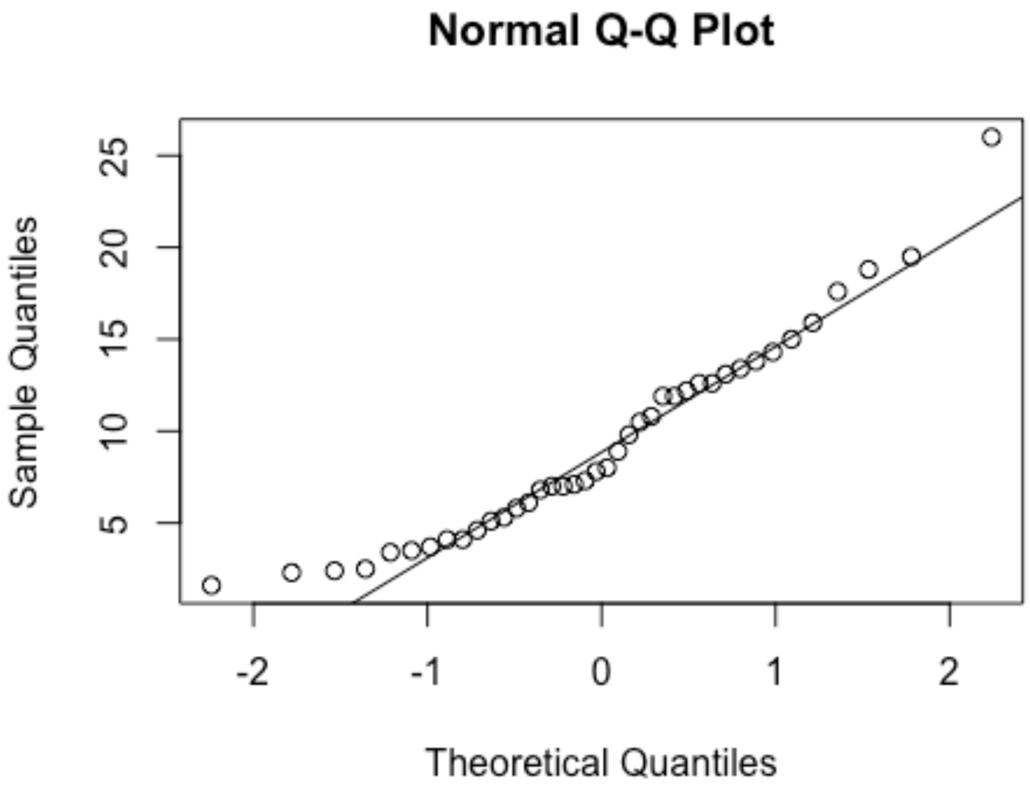
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$awakenings)

## 
##  Anderson-Darling normality test
## 
## data:  subset(SSdata, intervention == "PrenaBelt")$awakenings
## A = 0.44596, p-value = 0.2537
```

```
#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)
```



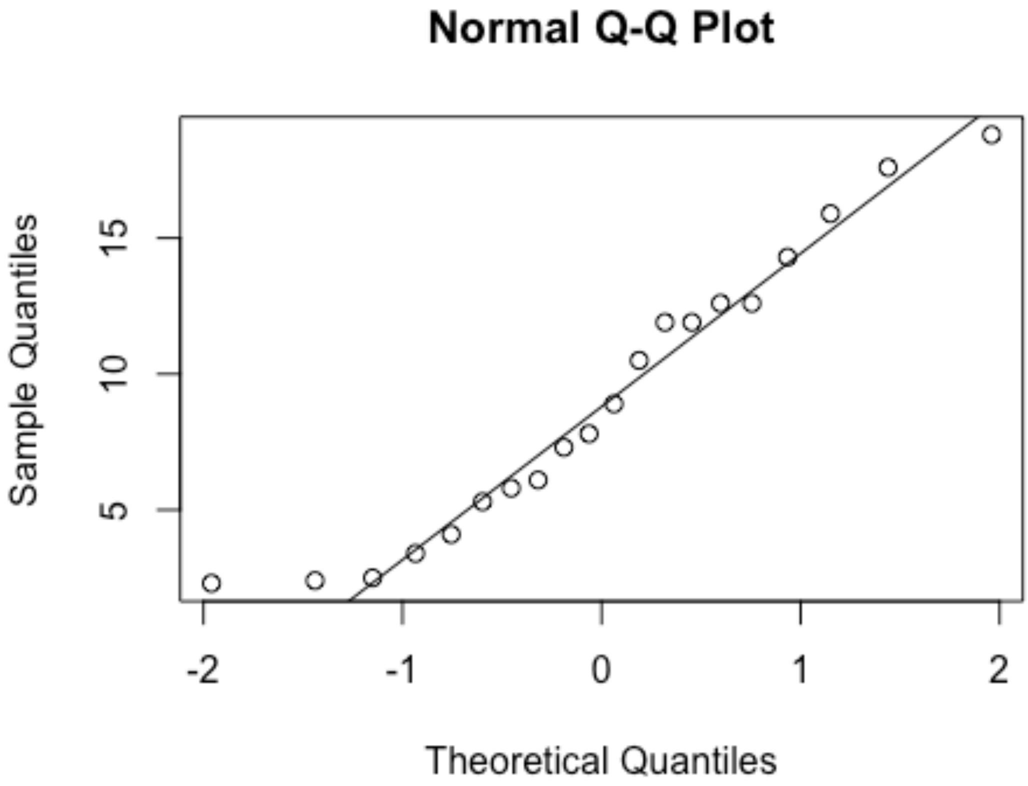
```
ad.test(subset(SSdata, intervention == "sham")$awakenings)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$awakenings
## A = 0.47198, p-value = 0.2179
```

```
#normal

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

##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$awakenings and subset(SSdata
, intervention == "PrenaBelt")$awakenings
## t = 0.24678, df = 37.989, p-value = 0.8064
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -3.601622  4.601622
## sample estimates:
## mean of x mean of y
##     19.95     19.45

#################### % Stage 1 Sleep #######################
#Summary
summary(SSdata$Pstage.1)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.600   4.975   7.900   9.353  12.720  26.000

sd(SSdata$Pstage.1, na.rm = TRUE)

## [1] 5.561267

length(SSdata$Pstage.1)

## [1] 40

qqnorm(SSdata$Pstage.1)
qqline(SSdata$Pstage.1)
```

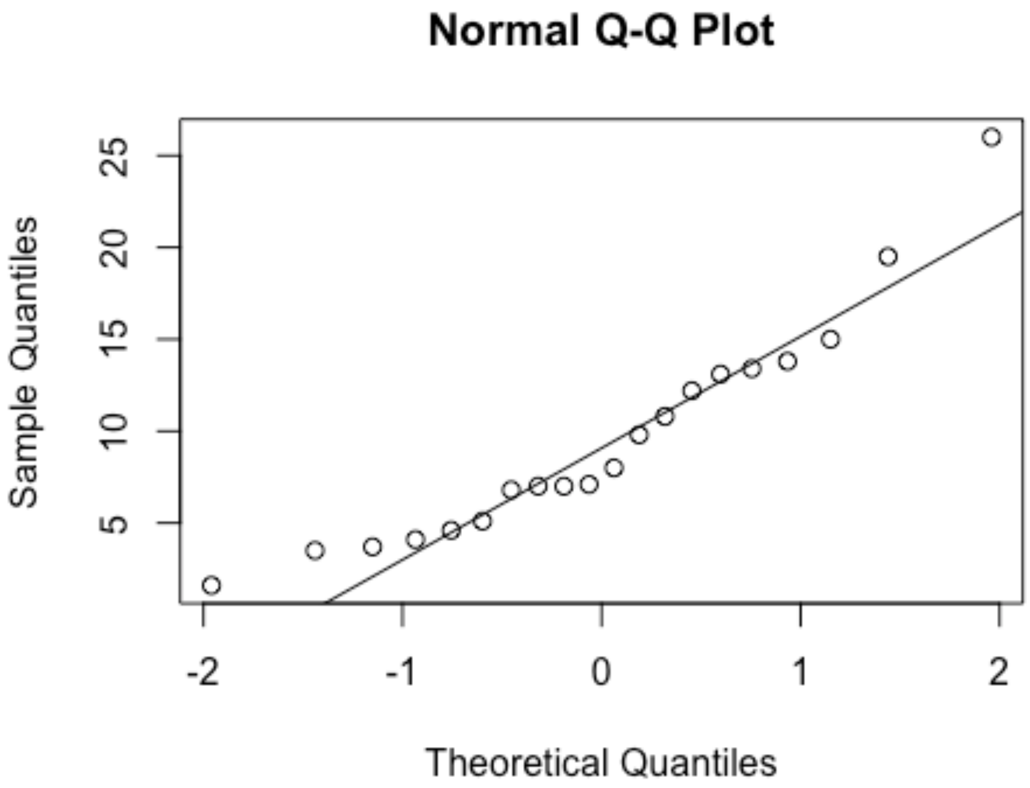


```
ad.test(SSdata$Pstage.1)

##
##  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
```

```
#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.1,
       subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.1,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$Pstage.1 and subset
(SSdataCompletes, intervention == "PrenaBelt")$Pstage.1
## t = 0.59457, df = 19, p-value = 0.5591
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -1.272708  2.282708
## sample estimates:
## mean of the differences
##                   0.505

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    2.30    5.00    8.35    9.10   12.60   18.80

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

## [1] 5.197368

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

## [1] 20

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

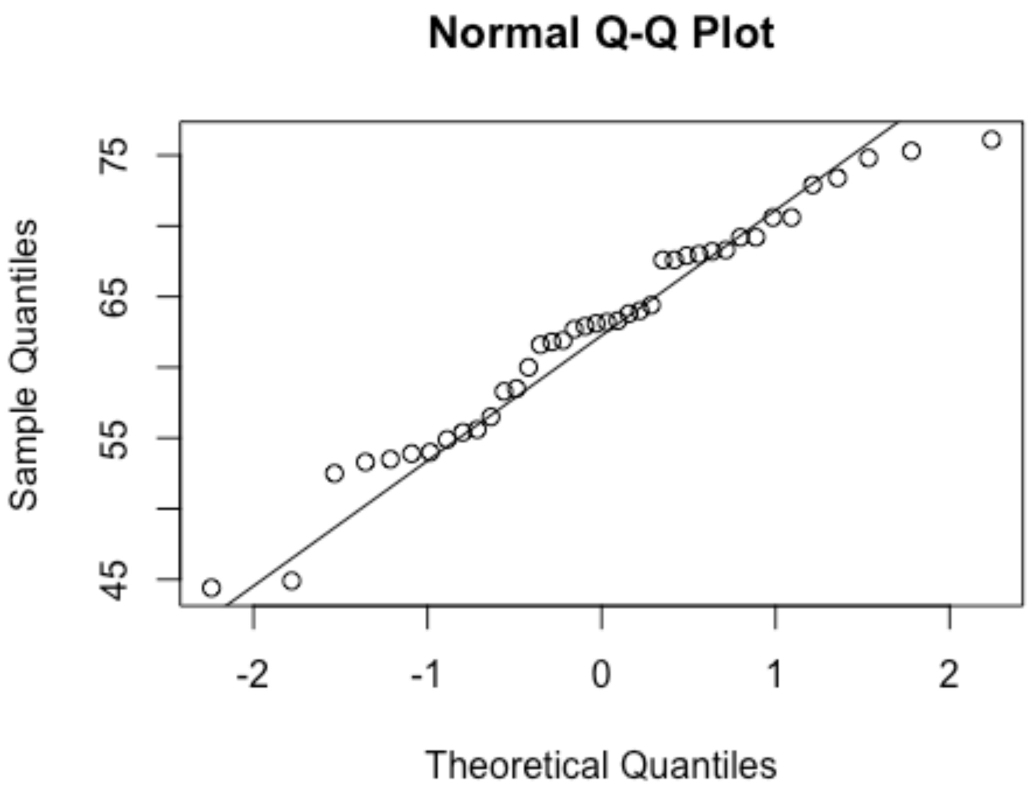


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)

##
##  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:
```

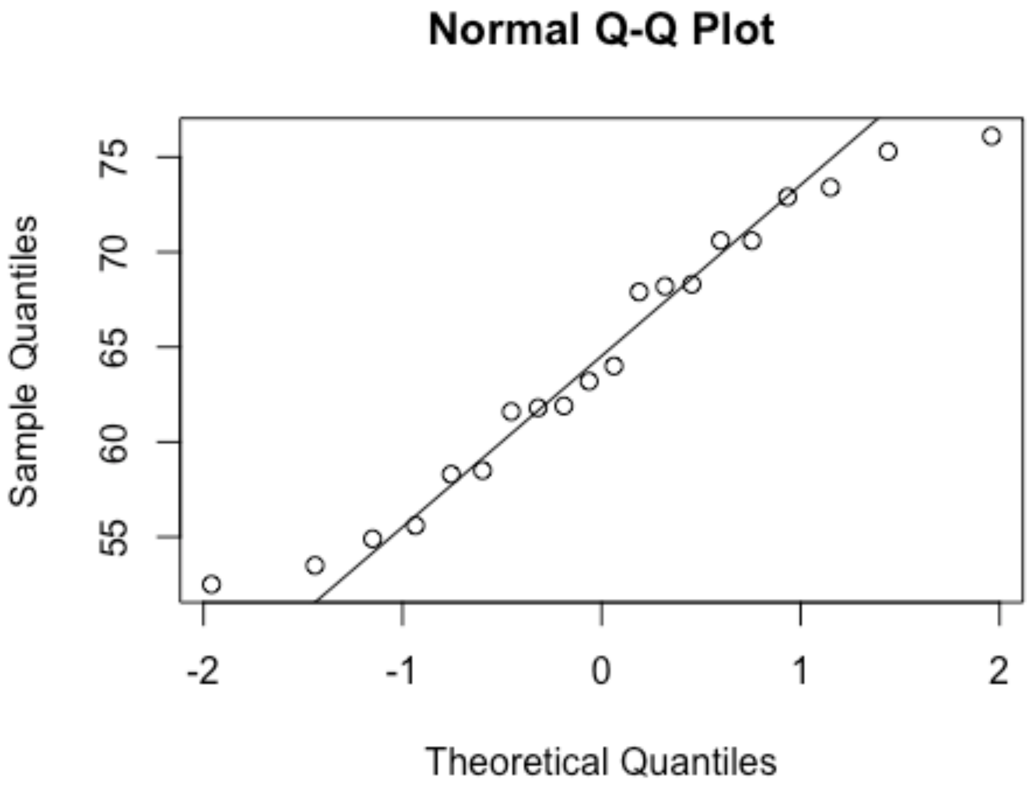
```
## mean of x mean of y
##     9.605     9.100

#################### % Stage 2 Sleep #######################
#Summary
summary(SSdata$Pstage.2)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   44.40   56.28   63.15   62.70   68.23   76.10

sd(SSdata$Pstage.2, na.rm = TRUE)

## [1] 7.870376

length(SSdata$Pstage.2)

## [1] 40

qqnorm(SSdata$Pstage.2)
qqline(SSdata$Pstage.2)
```



```
ad.test(SSdata$Pstage.2)

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

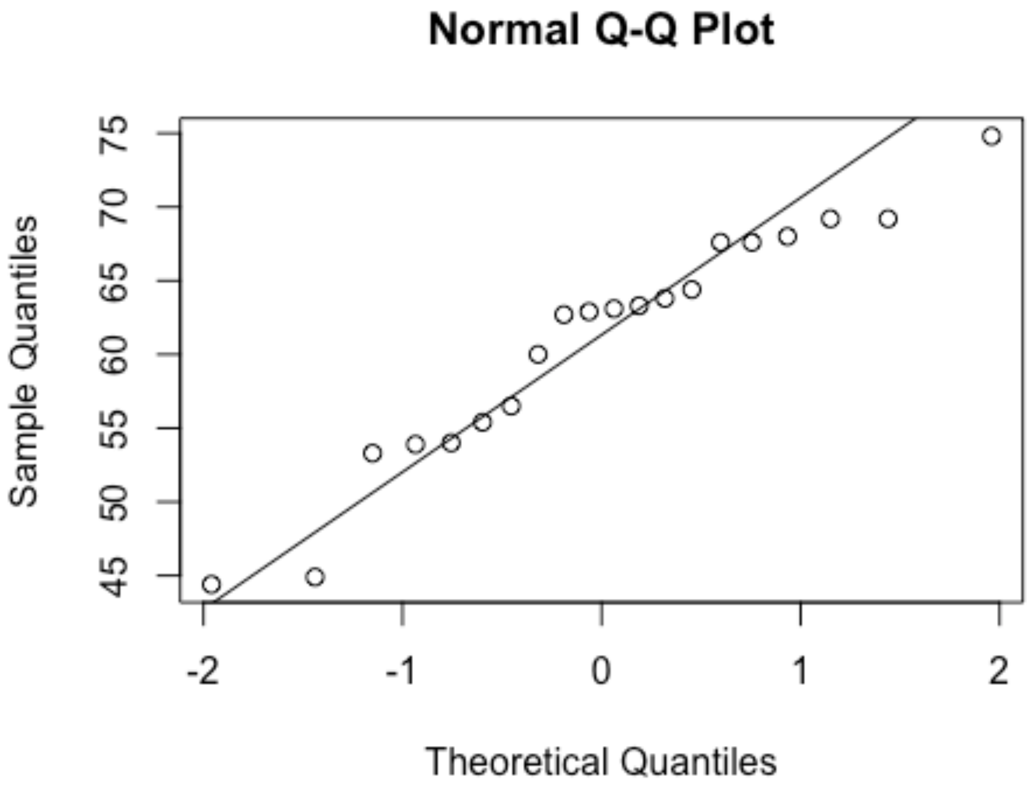
```
##
## data:  SSdata$Pstage.2
## A = 0.37344, p-value = 0.4014

#normal

#ANOVA
night_tx_difference <- anova(lm(Pstage.2 ~ intervention*night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: Pstage.2
##                      Df  Sum Sq Mean Sq F value Pr(>F)
## intervention          1  122.85 122.850  2.0304 0.1628
## night                 1   58.32  58.322  0.9639 0.3328
## intervention:night    1   56.41  56.406  0.9323 0.3407
## Residuals            36 2178.19  60.505

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.2,
       subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.2,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$Pstage.2 and subset
(SSdataCompletes, intervention == "PrenaBelt")$Pstage.2
## t = -1.9128, df = 19, p-value = 0.07097
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -7.3402984  0.3302984
## sample estimates:
## mean of the differences
##                  -3.505

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   52.50   58.45   63.60   64.46   70.60   76.10

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

## [1] 7.434803

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

## [1] 20
```

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



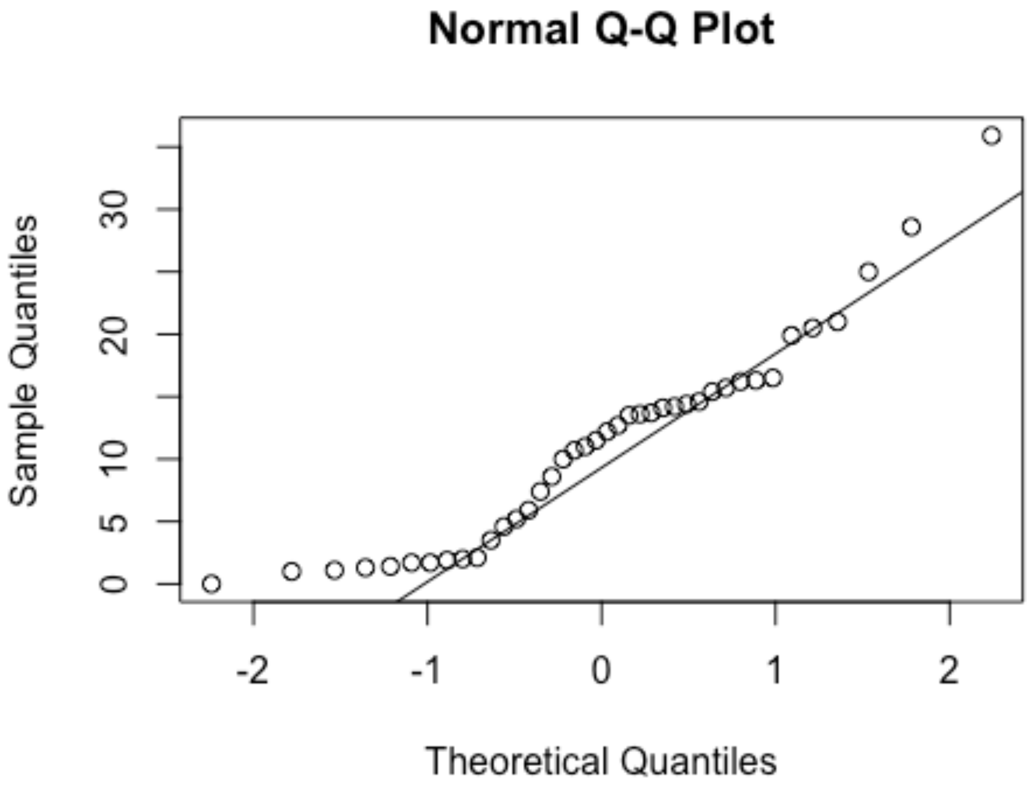
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)

##
##  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:
```

```
##  -8.478912  1.468912
## sample estimates:
## mean of x mean of y
##    60.950    64.455

#################### % Stage 3 Sleep ######################
#Summary
summary(SSdata$Pstage.3)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    3.15   11.85   11.16   15.48   35.90

sd(SSdata$Pstage.3, na.rm = TRUE)

## [1] 8.302226

length(SSdata$Pstage.3)

## [1] 40

qqnorm(SSdata$Pstage.3)
qqline(SSdata$Pstage.3)
```



```
ad.test(SSdata$Pstage.3)
```

```
##
##  Anderson-Darling normality test
##
## data:  SSdata$Pstage.3
## A = 0.79648, p-value = 0.03569
```

```
#non-normal

#ANOVA
night_tx_difference <- anova(lm(Pstage.3 ~ intervention * night,
                                data = SSdata))
night_tx_difference
```

```
## Analysis of Variance Table
##
## Response: Pstage.3
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1    3.97   3.969  0.0535 0.8184
## night               1    3.60   3.600  0.0485 0.8269
## intervention:night  1   10.40  10.404  0.1403 0.7102
## Residuals          36 2670.18  74.172
```

```
#within-participants (paired) comparison
#Paired t-test (individual distributions are normal)
t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.3,
       subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.3,
       paired = TRUE)
```

```
##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$Pstage.3 and subset
(SSdataCompletes, intervention == "PrenaBelt")$Pstage.3
## t = 0.65795, df = 19, p-value = 0.5185
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -1.374115  2.634115
## sample estimates:
## mean of the differences
##                    0.63
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
```

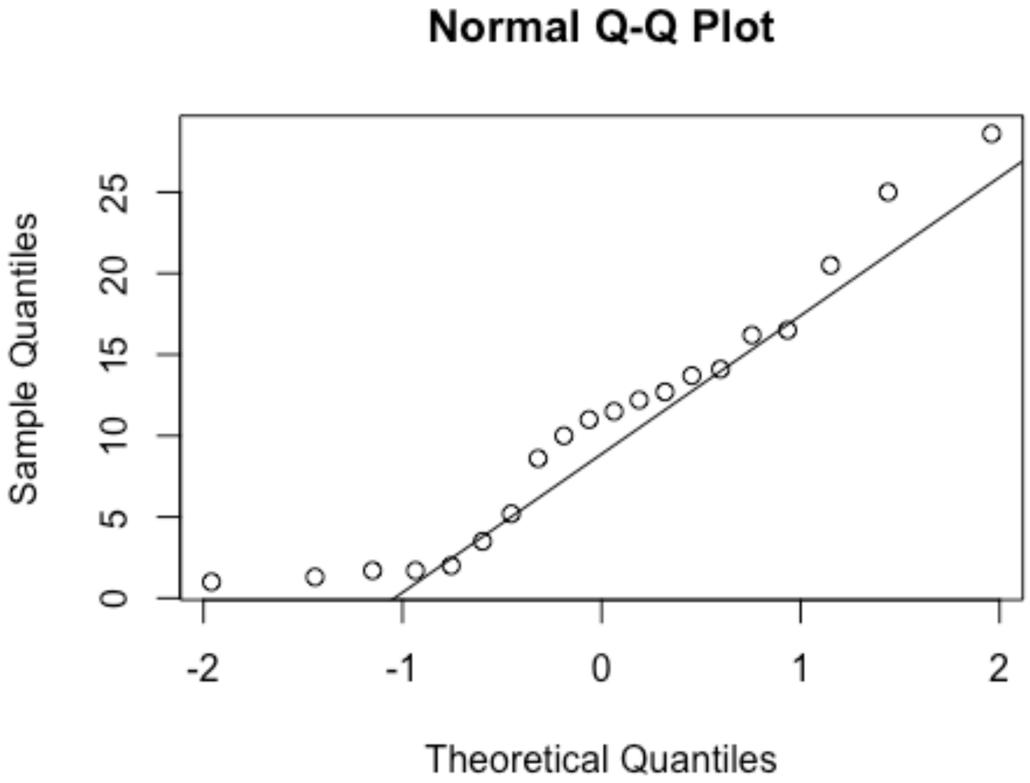
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.000   3.125  11.250  10.850  14.620  28.600
```

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

```
## [1] 8.010027
```

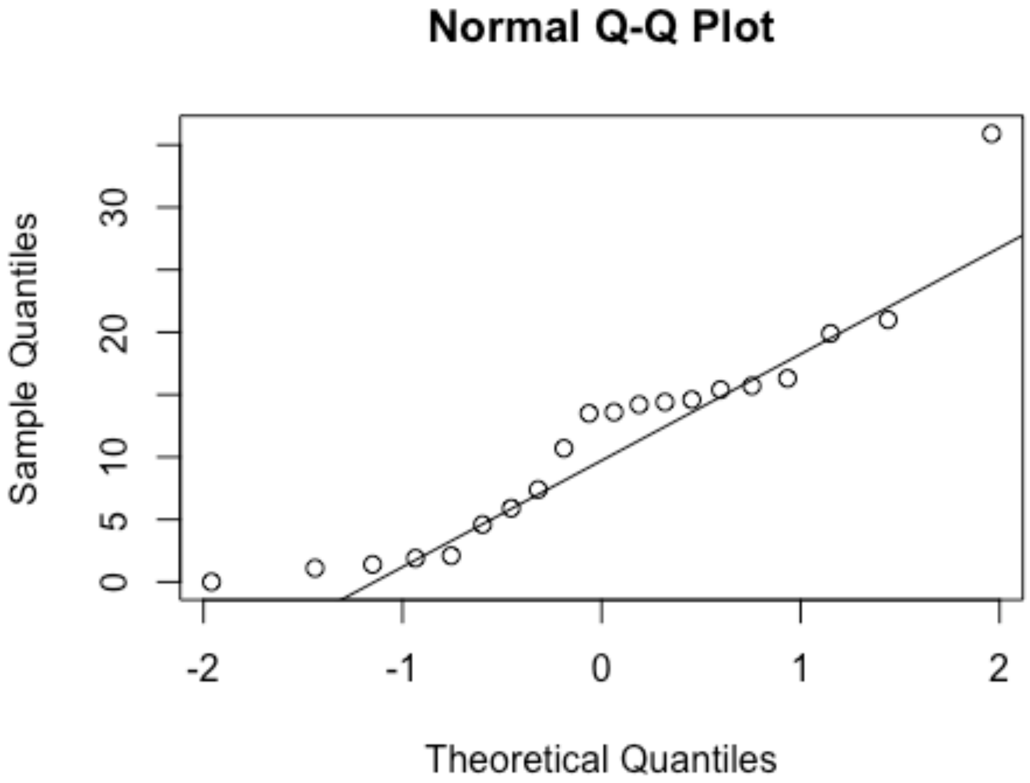
```
length(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)
```

```
## [1] 20

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



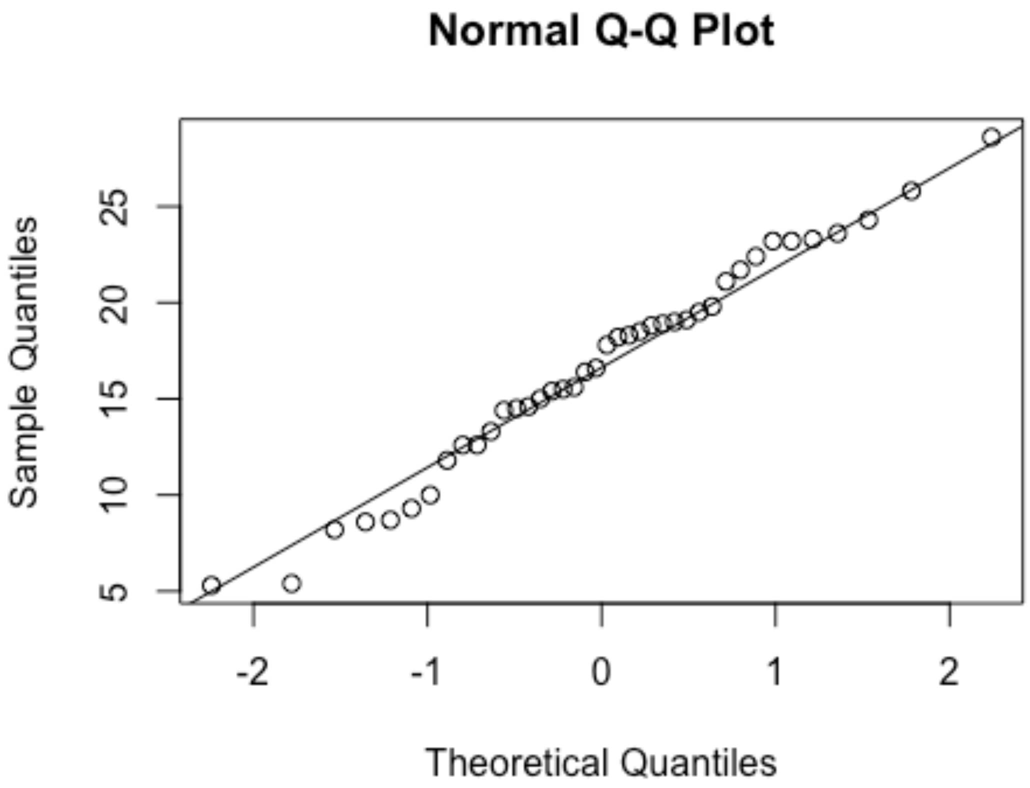
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)

##
##  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)
```



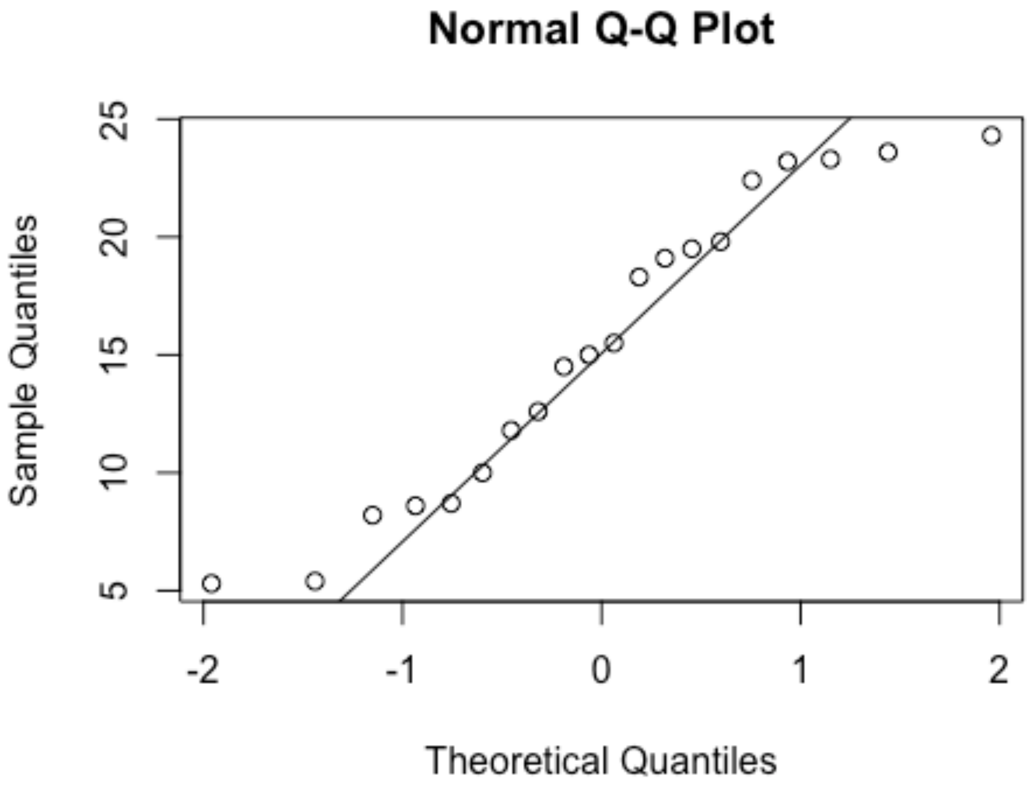
```
ad.test(subset(SSdata, intervention == "sham")$Pstage.3)

##
##  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
```

```
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -4.75182  6.01182
## sample estimates:
## mean of x mean of y
##     11.48     10.85

#################### % Stage REM ######################
#Summary
summary(SSdata$Prem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    5.30   13.13   17.20   16.72   20.12   28.60

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

## [1] 5.62027

length(SSdata$Prem)

## [1] 40

qqnorm(SSdata$Prem)
qqline(SSdata$Prem)
```



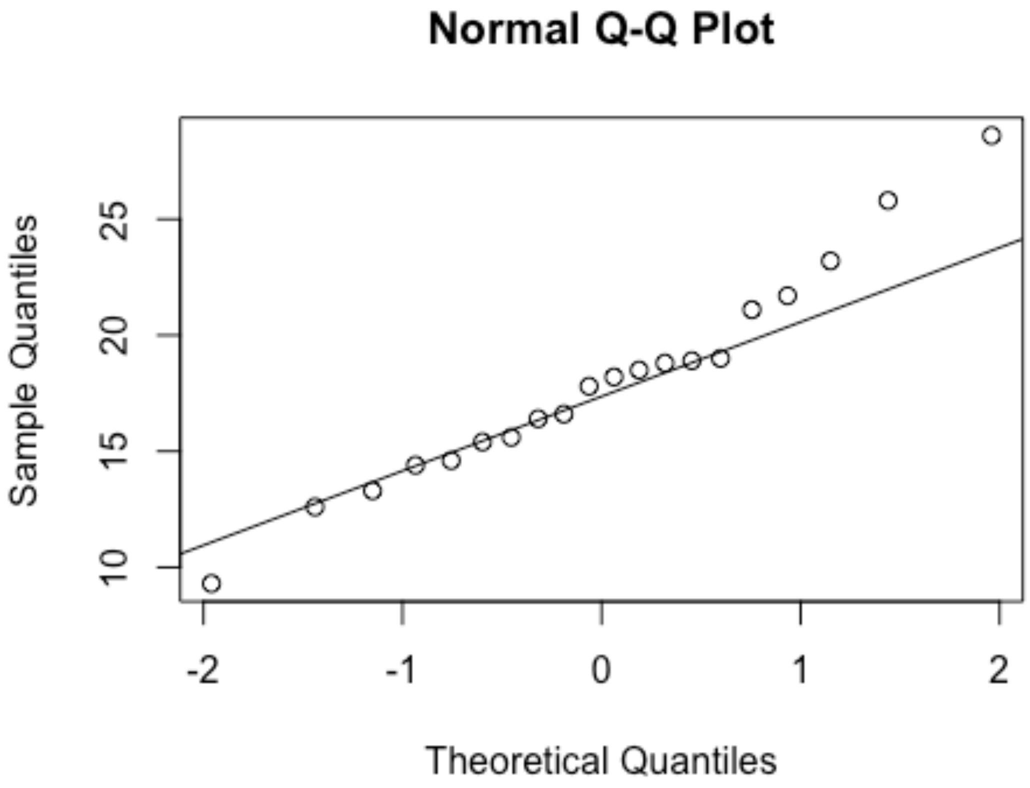
```
ad.test(SSdata$Prem)

## 
##  Anderson-Darling normality test
## 
## data:  SSdata$Prem
## A = 0.23648, p-value = 0.7728

#normal

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

## Analysis of Variance Table
## 
## Response: Prem
##                    Df  Sum Sq Mean Sq F value  Pr(>F)  
## intervention        1   64.26  64.262  2.2623 0.14128  
## night               1   89.10  89.102  3.1367 0.08501 .
## intervention:night  1   55.93  55.932  1.9690 0.16912  
## Residuals          36 1022.61  28.406                  
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$Prem,
       subset(SSdataCompletes, intervention == "PrenaBelt")$Prem,
       paired = TRUE)

## 
##  Paired t-test
## 
## data:  subset(SSdataCompletes, intervention == "sham")$Prem and subset(SSd
ataCompletes, intervention == "PrenaBelt")$Prem
## t = 2.0564, df = 19, p-value = 0.05374
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.04510822  5.11510822
## sample estimates:
## mean of the differences 
##                   2.535

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   5.300   9.675  15.250  15.460  20.450  24.300

sd(subset(SSdata, intervention == "PrenaBelt")$Prem)
```

```
## [1] 6.377714

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

## [1] 20

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



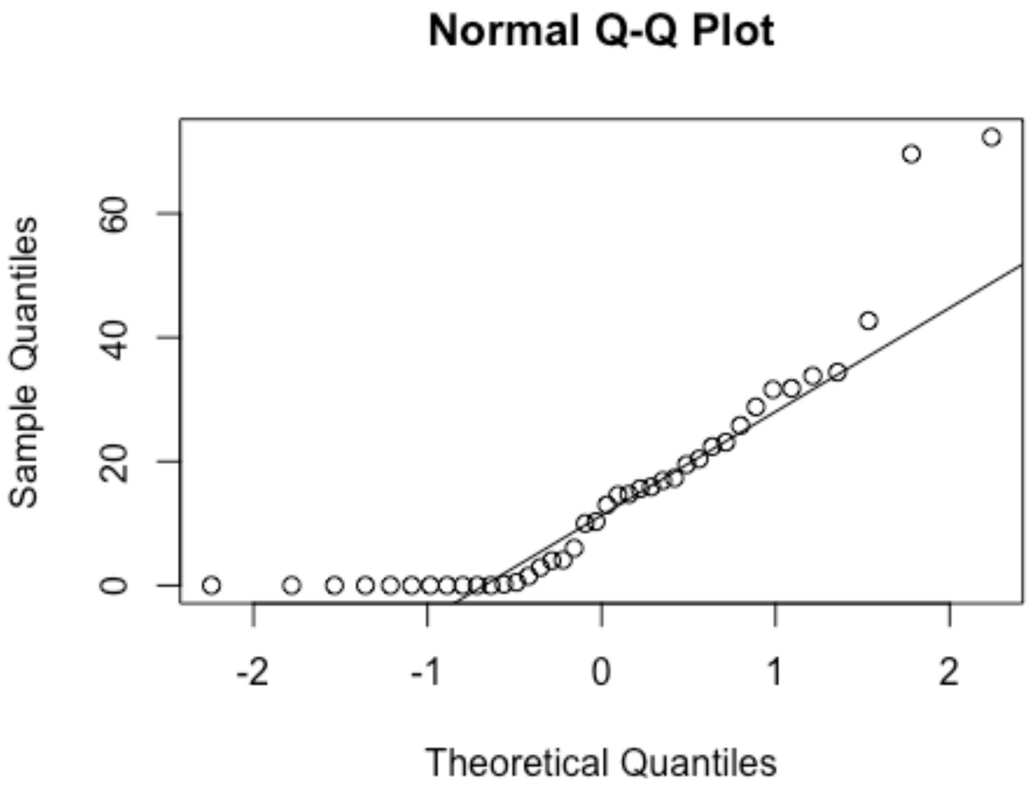
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Prem)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$Prem
## A = 0.44545, p-value = 0.2545

#normal

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    9.30   15.20   18.00   17.99   19.52   28.60

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

```
## [1] 4.558497

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

## [1] 20

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



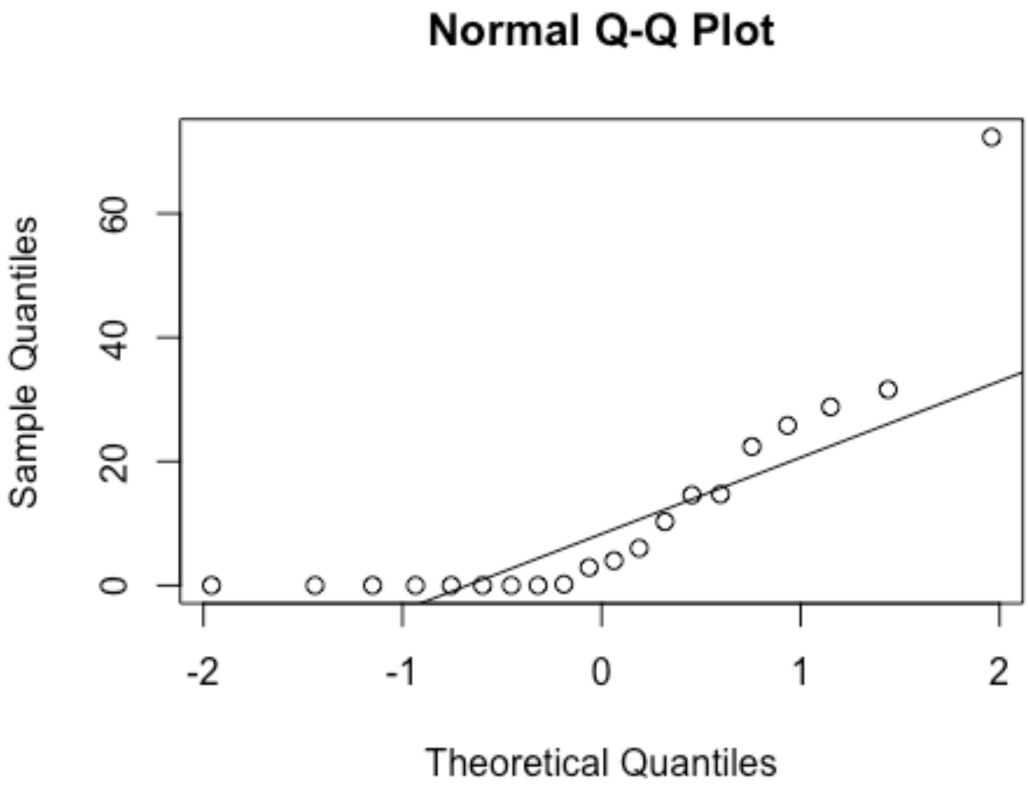
```
ad.test(subset(SSdata, intervention == "sham")$Prem)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$Prem
## A = 0.27628, p-value = 0.6181

#normal

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

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

```
##
## data:  subset(SSdata, intervention == "sham")$Prem and subset(SSdata, inte
rvention == "PrenaBelt")$Prem
## t = 1.4462, df = 34.395, p-value = 0.1572
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -1.025871  6.095871
## sample estimates:
## mean of x mean of y
##    17.990    15.455

#################### %TST Supine #######################
#Summary
summary(SSdata$PtstSupine)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   11.65   15.09   22.57   72.30

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

## [1] 17.83904

length(SSdata$PtstSupine)

## [1] 40

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

## Analysis of Variance Table
##
## Response: PtstSupine
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1   465.8  465.81  1.4119 0.2425
## night               1    64.8   64.77  0.1963 0.6604
## intervention:night  1     3.4    3.42  0.0104 0.9194
## Residuals          36 11877.0  329.92

qqnorm(SSdata$PtstSupine)
qqline(SSdata$PtstSupine)
```

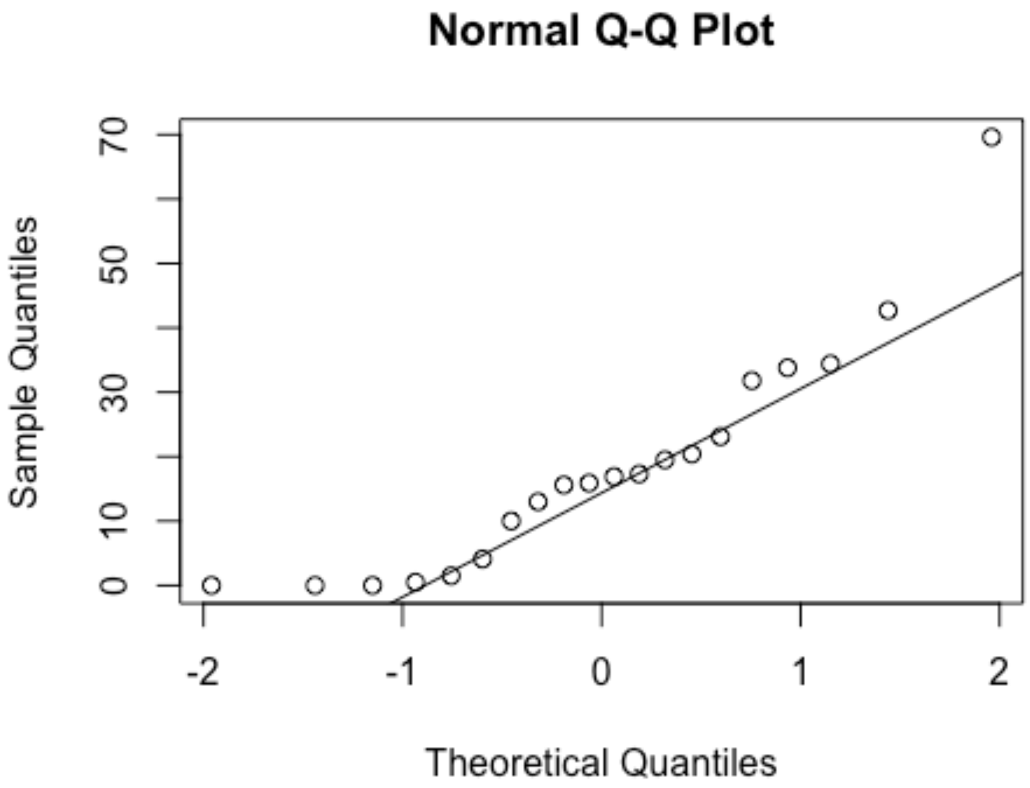


```
ad.test(SSdata$PtstSupine)

##
##  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
```

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$PtstSupine and subs
et(SSdataCompletes, intervention == "PrenaBelt")$PtstSupine
## V = 142, p-value = 0.03065
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  0.7000854       Inf
## sample estimates:
## (pseudo)median
##       5.804603

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    3.45   11.68   16.62   72.30

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

## [1] 17.9033

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

## [1] 20

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

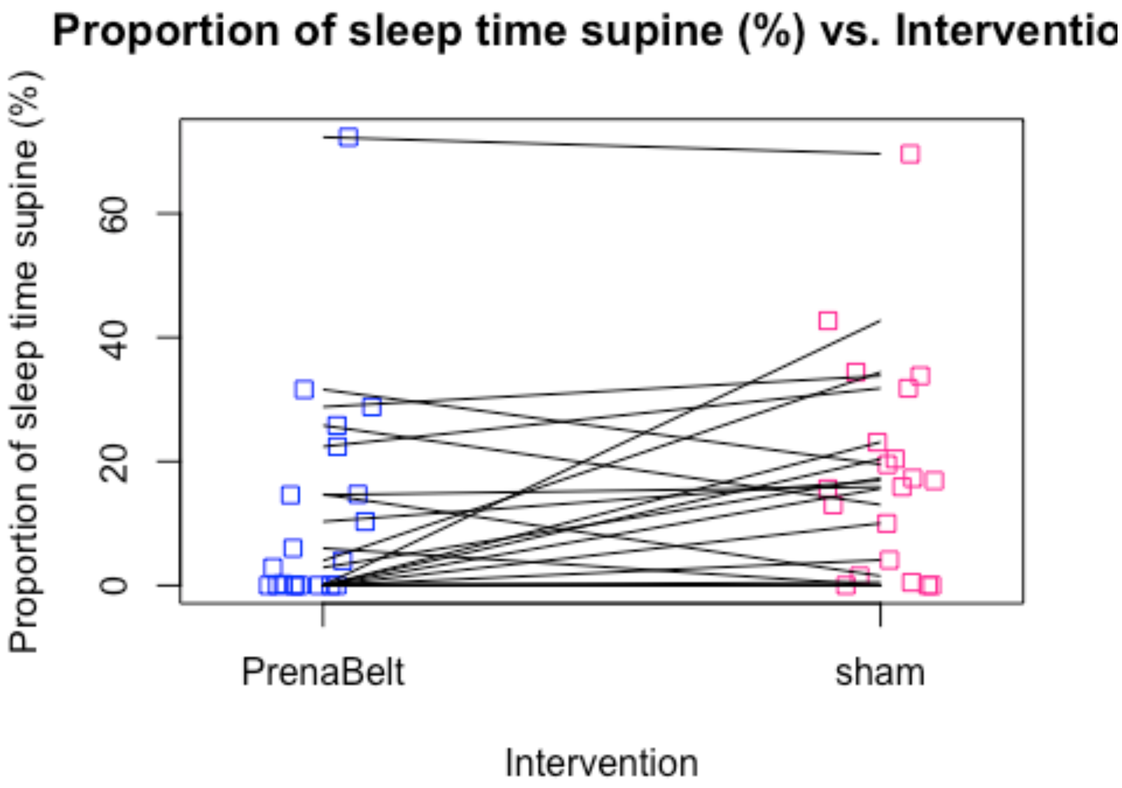


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)

##
##  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)
```

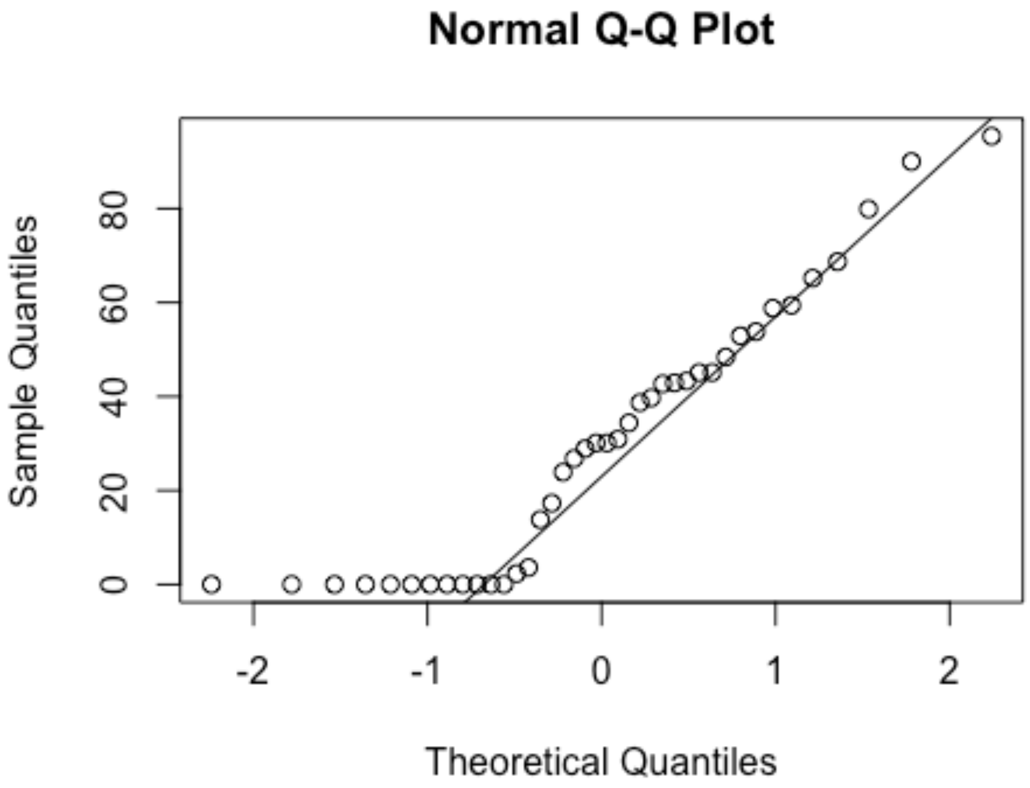


```
ad.test(subset(SSdata, intervention == "sham")$PtstSupine)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$PtstSupine and subset(SSdata
, intervention == "PrenaBelt")$PtstSupine
## W = 267, p-value = 0.03456
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  2.150084e-05          Inf
## sample estimates:
## difference in location
##               6.666346

# Use droplevels to remove the empty levels from the list of levels
SSdata$intervention <- droplevels(SSdata$intervention)
summary(SSdata$intervention)

## PrenaBelt      sham
##        20        20

stripchart(SSdata$PtstSupine~SSdata$intervention,
           vertical = TRUE, method="jitter", col=c("blue","deeppink"),
           ylab='Proportion of sleep time supine (%)', xlab='Intervention',
           main='Proportion of sleep time supine (%) vs. Intervention',)

for(participant.s.code in split(SSdata, SSdata$participant.s.code))
  lines(PtstSupine ~ intervention, participant.s.code)
```

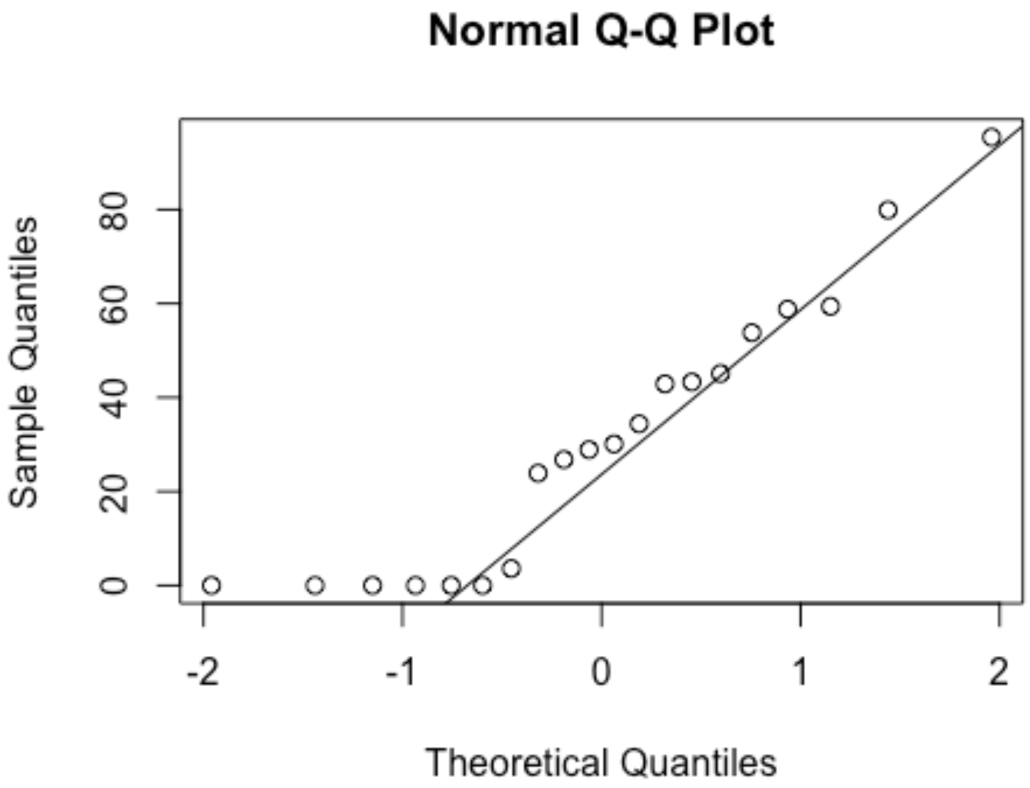


```
#################### %TST Right #######################
#Summary
summary(SSdata$PtstRight)

##    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)
```

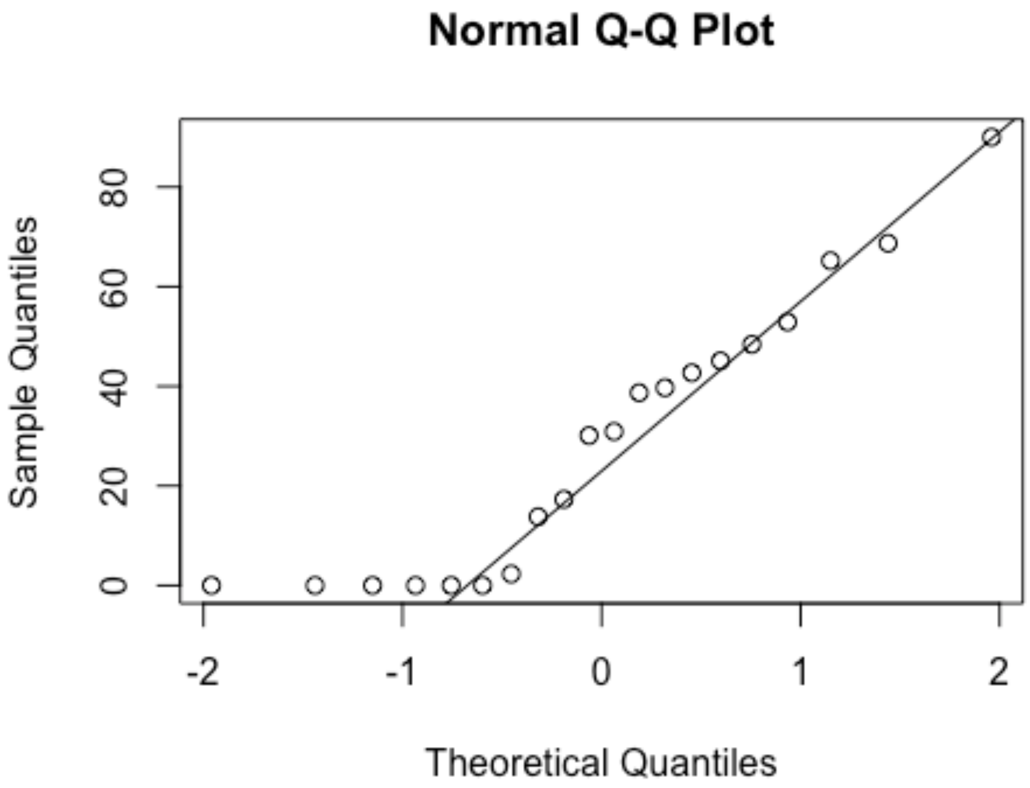


```
ad.test(SSdata$PtstRight)

##
##  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

#within-participants (paired) comparison
#Paired t-test (individual distributions are normally distributed)
t.test(subset(SSdataCompletes, intervention == "sham")$PtstRight,
       subset(SSdataCompletes, intervention == "PrenaBelt")$PtstRight,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$PtstRight and subse
t(SSdataCompletes, intervention == "PrenaBelt")$PtstRight
## t = -0.52565, df = 19, p-value = 0.6052
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -10.088139   6.038139
## sample estimates:
## mean of the differences
##                  -2.025

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   29.50   31.32   47.28   95.40

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

## [1] 28.77236

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

## [1] 20

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

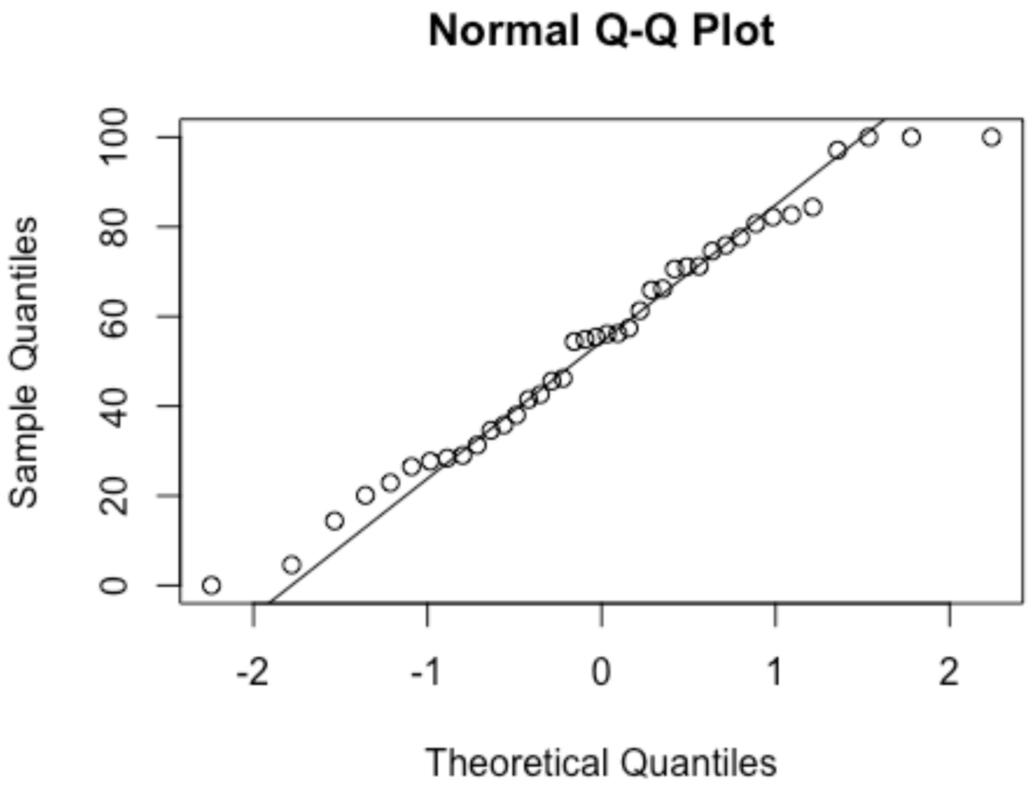


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstRight)

##
##  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)
```



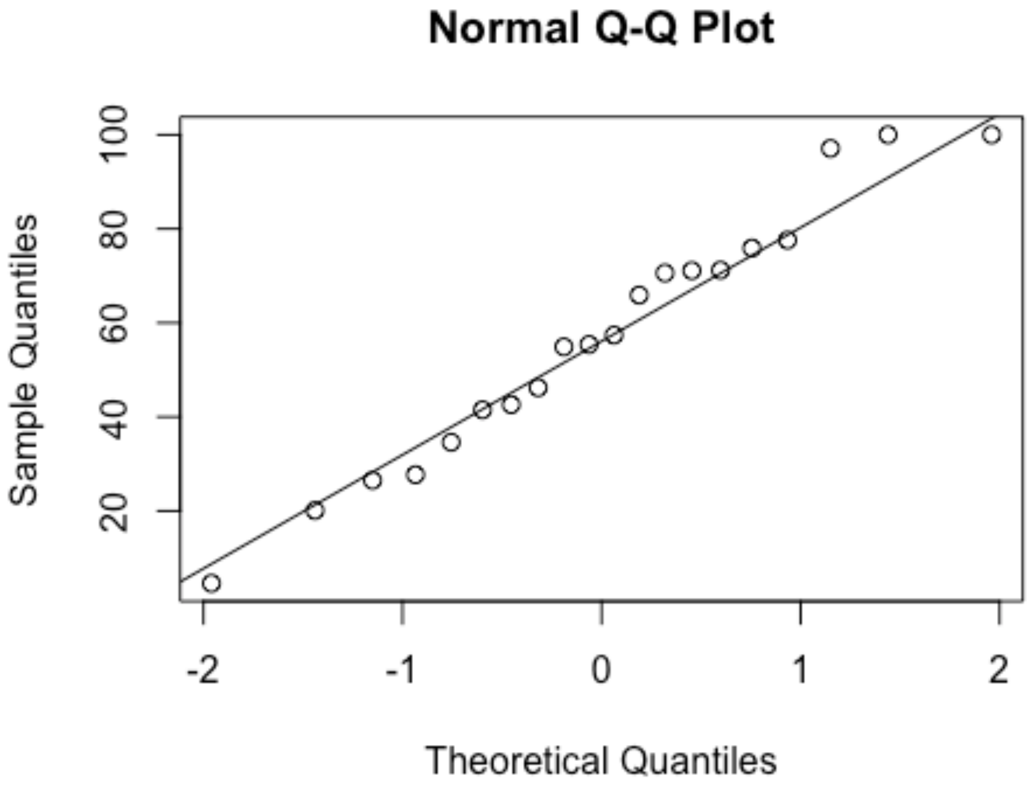
```
ad.test(subset(SSdata, intervention == "sham")$PtstRight)

##
##  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:
```

```
## mean of x mean of y
##    29.290    31.315

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

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$PtstRight and subset(SSdata,
intervention == "PrenaBelt")$PtstRight
## W = 195, p-value = 0.9018
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -23.89994  14.80004
## sample estimates:
## difference in location
##          -3.997034e-06

#################### %TST Left #######################
#Summary
summary(SSdata$PtstLeft)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00   33.78   55.75   54.63   74.92  100.00

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

## [1] 26.70052

length(SSdata$PtstLeft)

## [1] 40

qqnorm(SSdata$PtstLeft)
qqline(SSdata$PtstLeft)
```

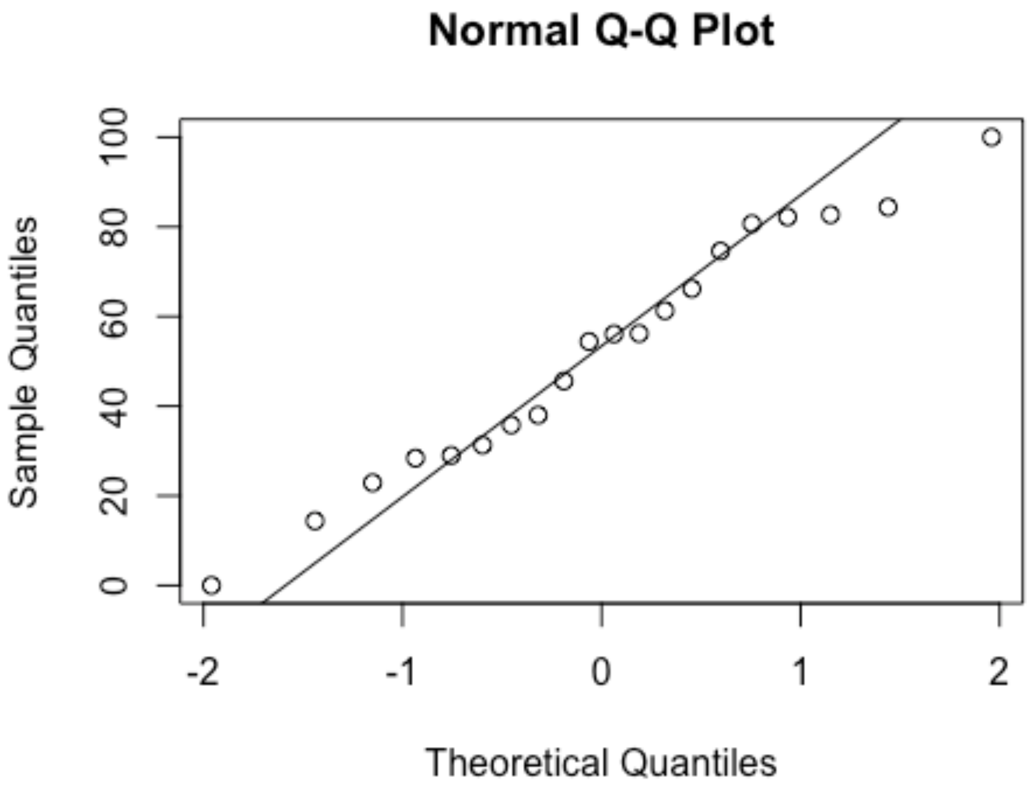


```
ad.test(SSdata$PtstLeft)

##
##  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
```

```
#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$PtstLeft,
       subset(SSdataCompletes, intervention == "PrenaBelt")$PtstLeft,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$PtstLeft and subset
(SSdataCompletes, intervention == "PrenaBelt")$PtstLeft
## t = -1.0137, df = 19, p-value = 0.3234
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -14.817699   5.147699
## sample estimates:
## mean of the differences
##                  -4.835

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    4.60   39.78   56.40   57.04   72.38  100.00

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

## [1] 26.8734

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

## [1] 20

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

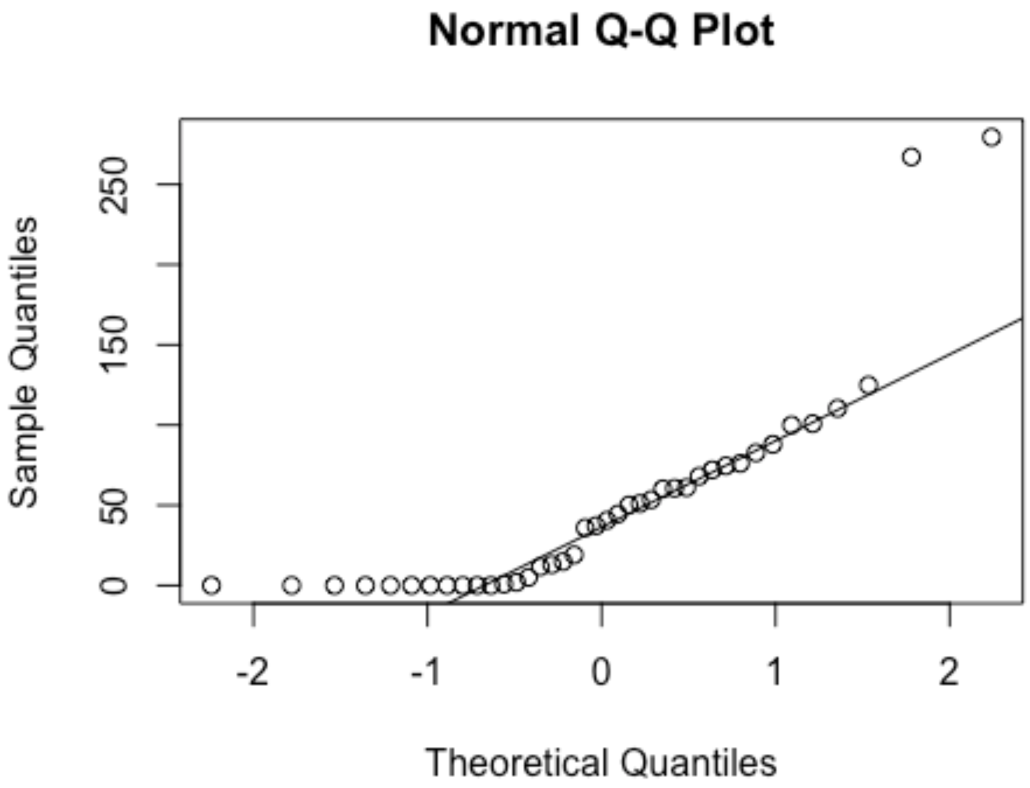


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)

##
##  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:
```

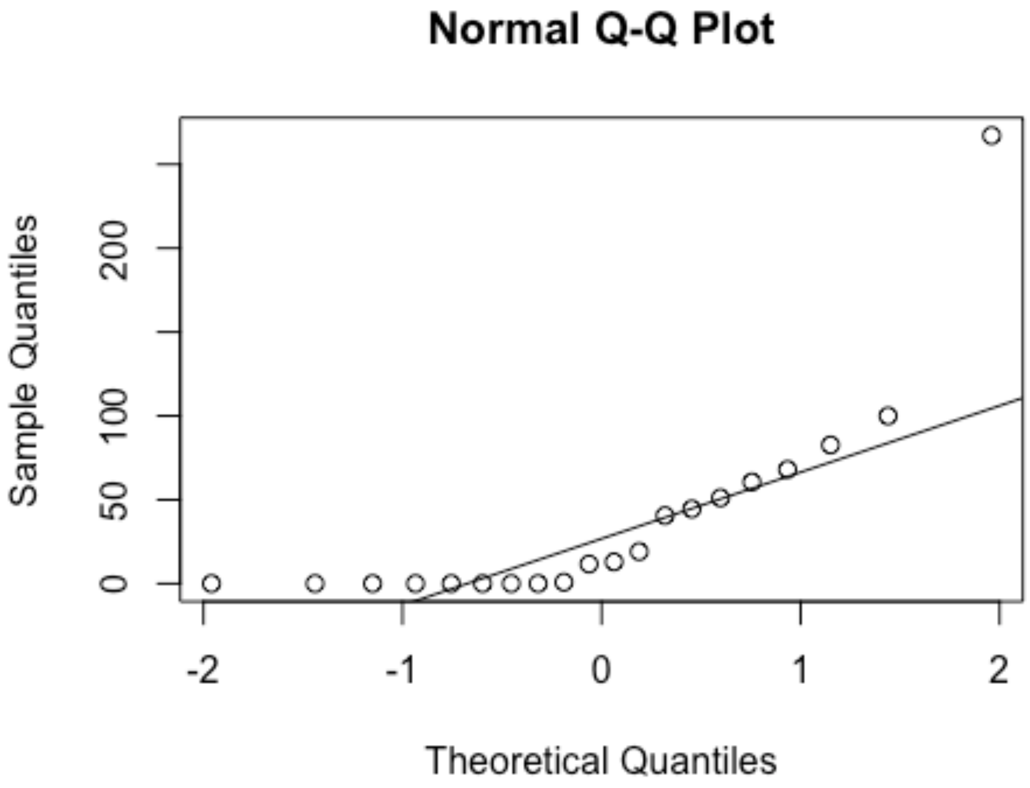
```
## mean of x mean of y 
##    52.210    57.045

#no time was spent prone
summary(SSdata$PtstProne)

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

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

## [1] 0

length(SSdata$PtstProne)

## [1] 40

#################### Minutes Sleeping Supine #######################
#Summary
summary(SSdata$minutesTSTSupine)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##    0.00    0.00   38.90   50.13   72.67  279.40

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

## [1] 63.82465

length(SSdata$minutesTSTSupine)

## [1] 40

qqnorm(SSdata$minutesTSTSupine)
qqline(SSdata$minutesTSTSupine)
```



```
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
```

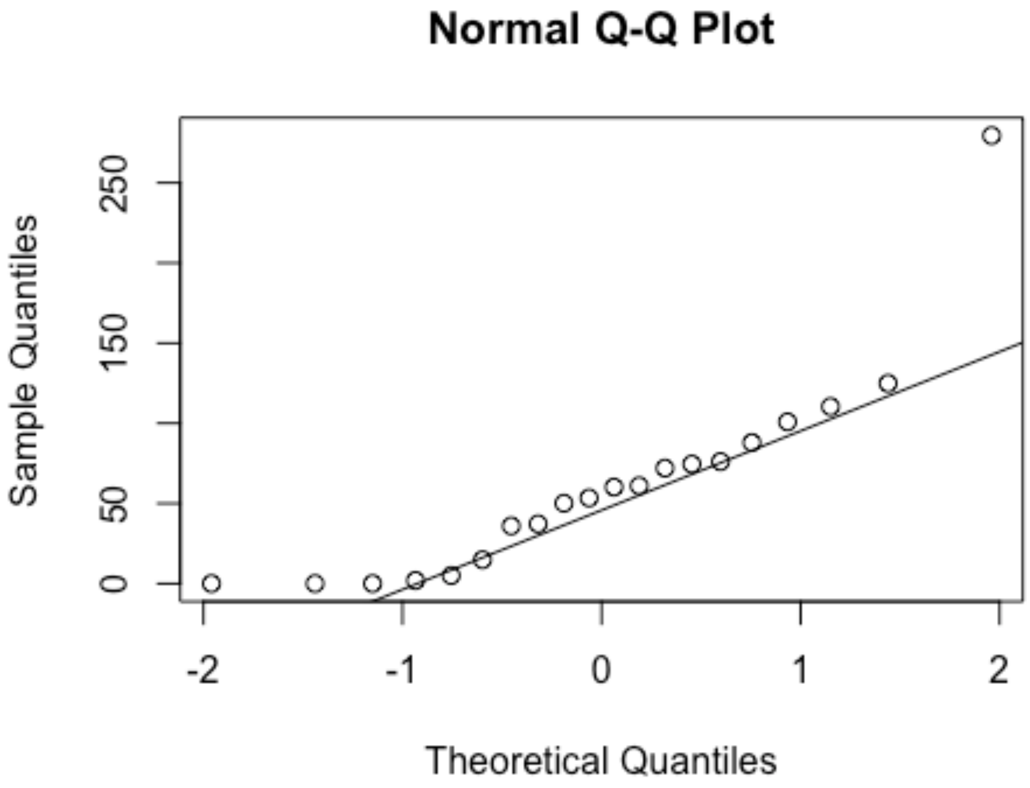
```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine,
            subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSu
pine,
            paired = TRUE, conf.int = TRUE, alternative = "greater")

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine an
d subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine
## V = 150, p-value = 0.01415
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  7.025017      Inf
## sample estimates:
## (pseudo)median
##       26.37306

#Paired t-test to double check and confirm non-parametric results
t.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine,
      subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine,
     paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine an
d subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine
## t = 2.3911, df = 19, p-value = 0.02731
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##   3.03469 45.65601
## sample estimates:
## mean of the differences
##                24.34535

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   12.30   37.95   53.48  267.10

sd(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
```

```
## [1] 62.65788

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

## [1] 20

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



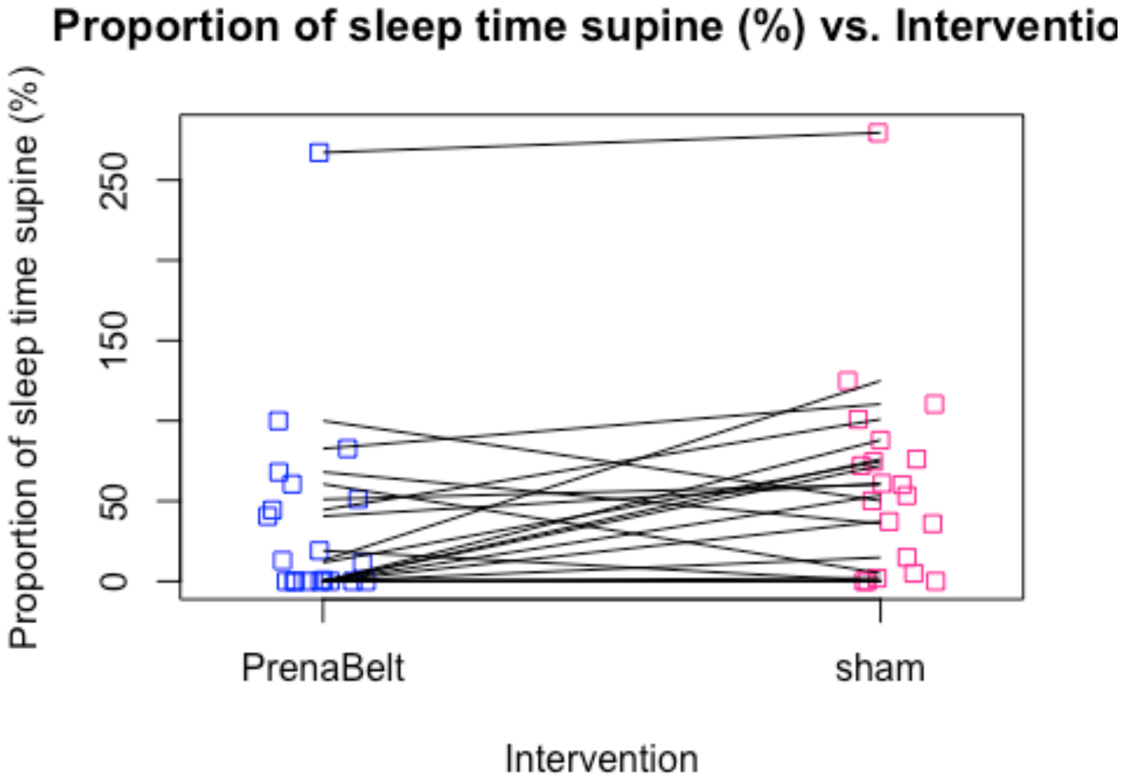
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine
## A = 2.2269, p-value = 7.014e-06

#non-normal

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00   12.39   56.80   62.30   79.08  279.40

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

```
## [1] 64.21539

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

## [1] 20

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

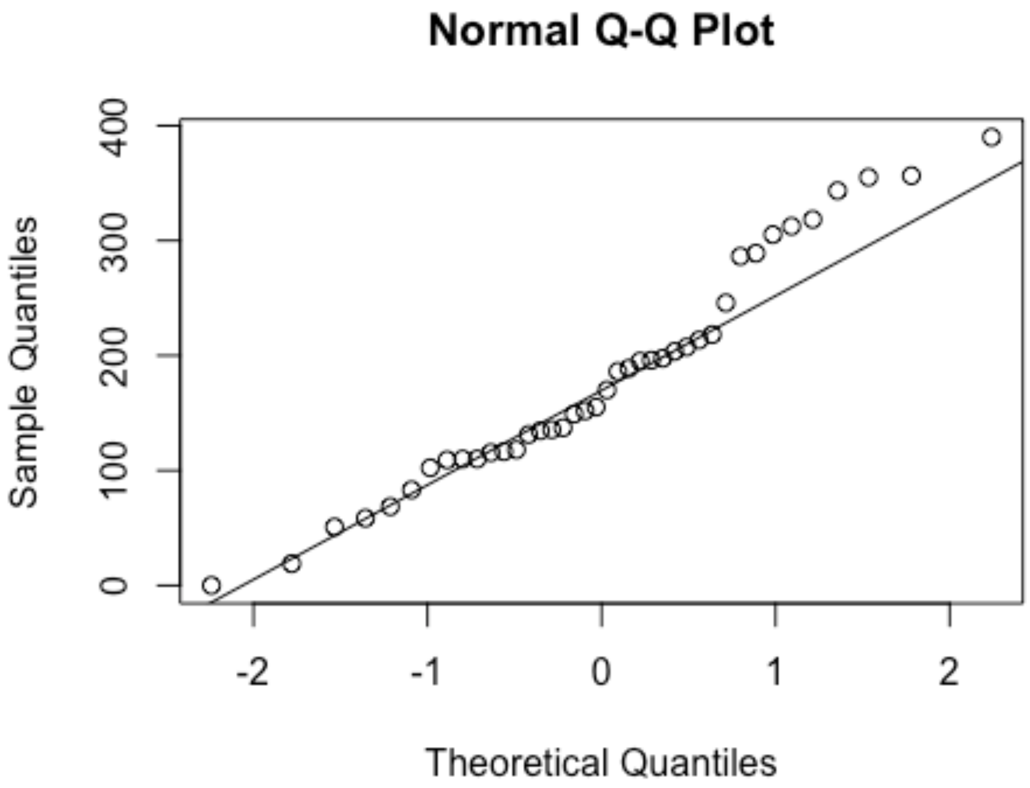


```
ad.test(subset(SSdata, intervention == "sham")$minutesTSTSupine)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$minutesTSTSupine
## A = 0.96839, p-value = 0.01163

#non-normal

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

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$minutesTSTSupine and subset(
SSdata, intervention == "PrenaBelt")$minutesTSTSupine
## W = 271, p-value = 0.02699
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  6.926608e-05          Inf
## sample estimates:
## difference in location
##               24.28712

# Use droplevels to remove the empty levels from the list of levels
SSdata$intervention <- droplevels(SSdata$intervention)
summary(SSdata$intervention)

## PrenaBelt      sham
##        20        20

stripchart(SSdata$minutesTSTSupine~SSdata$intervention,
           vertical = TRUE, method="jitter", col=c("blue","deeppink"),
           ylab='Proportion of sleep time supine (%)', xlab='Intervention',
           main='Proportion of sleep time supine (%) vs. Intervention',)

for(participant.s.code in split(SSdata, SSdata$participant.s.code))
  lines(minutesTSTSupine ~ intervention, participant.s.code)
```

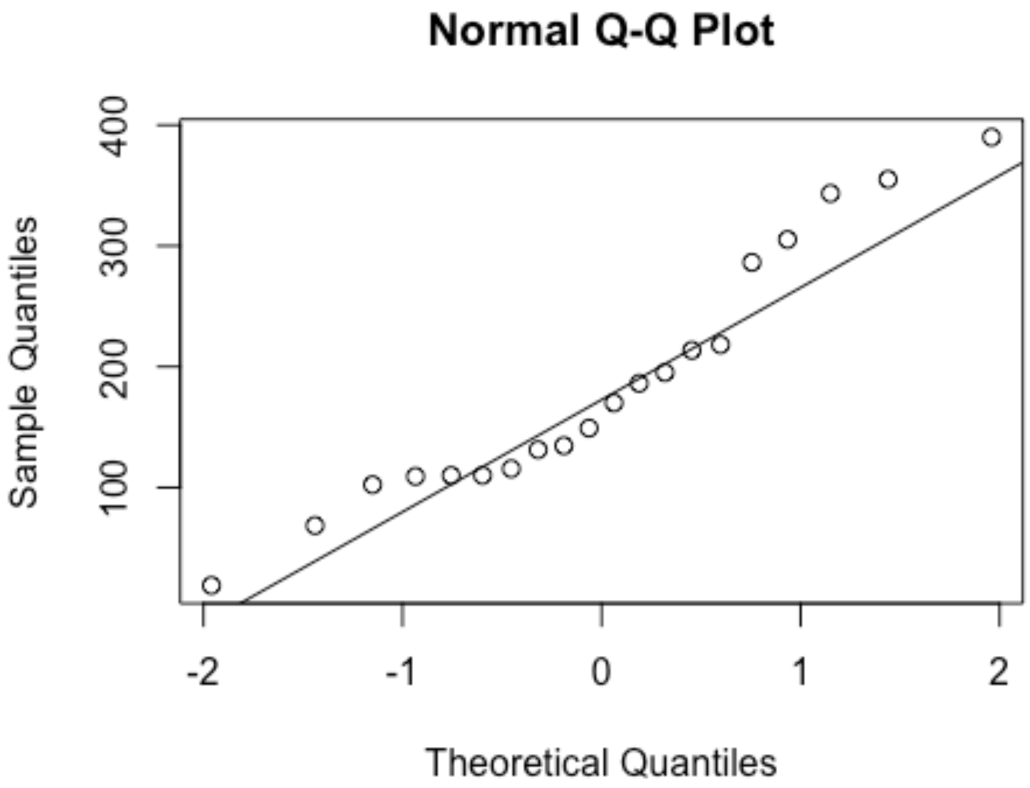


```
#################### Minutes Sleeping Left #######################
#Summary
summary(SSdata$minutesTSTLeft)

##    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)
```

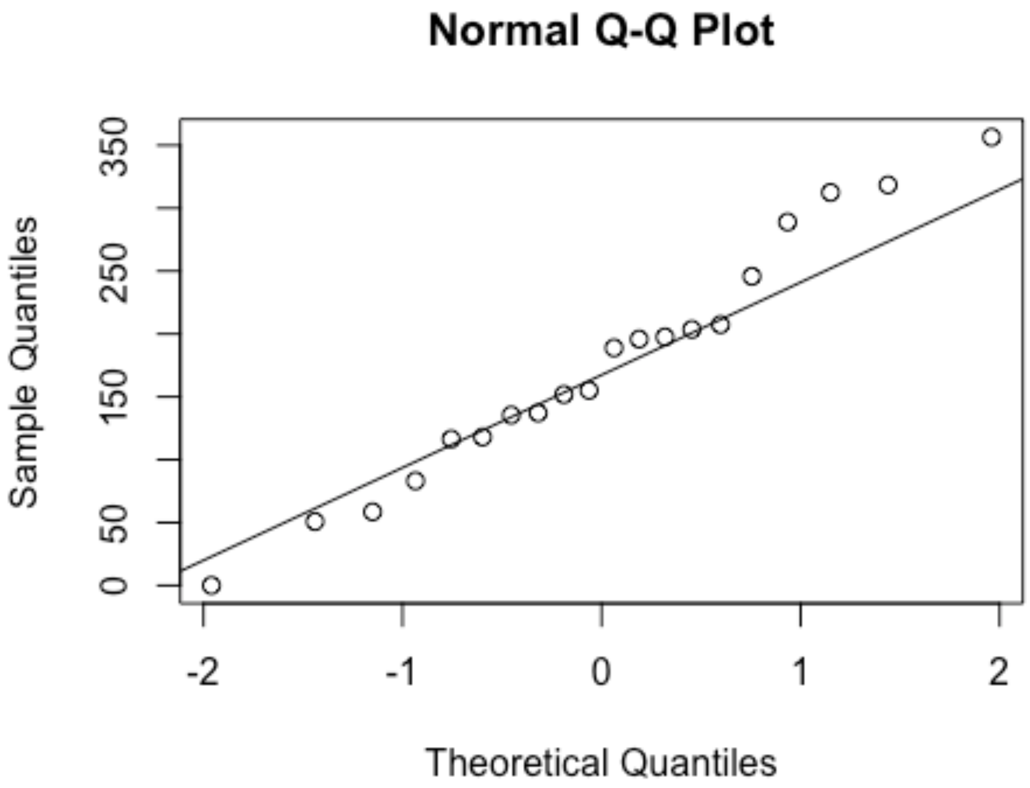


```
ad.test(SSdata$minutesTSTLeft)

##
##  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
```

```
#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTLeft,
      subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTLeft,
      paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$minutesTSTLeft and
subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTLeft
## t = -0.59061, df = 19, p-value = 0.5617
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -43.33418  24.26038
## sample estimates:
## mean of the differences
##                 -9.5369

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   18.95  110.00  159.60  185.60  235.30  390.00

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

## [1] 102.4677

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

## [1] 20

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

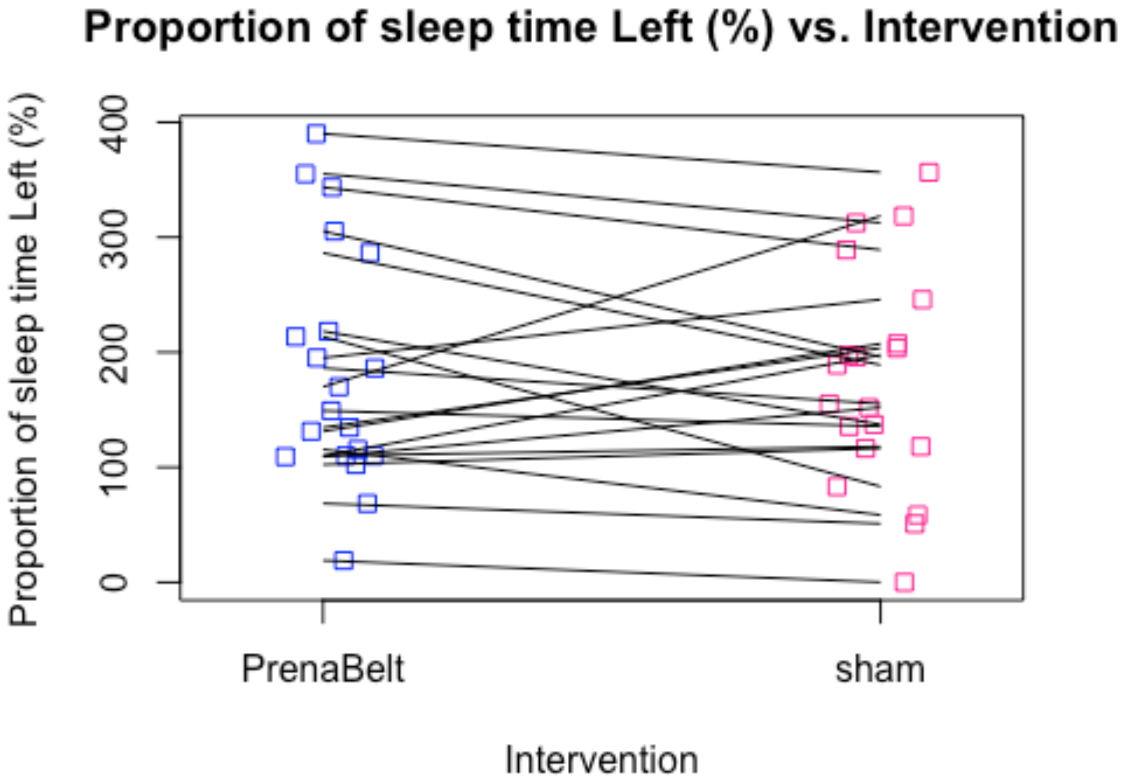


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)

##
##  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)
```



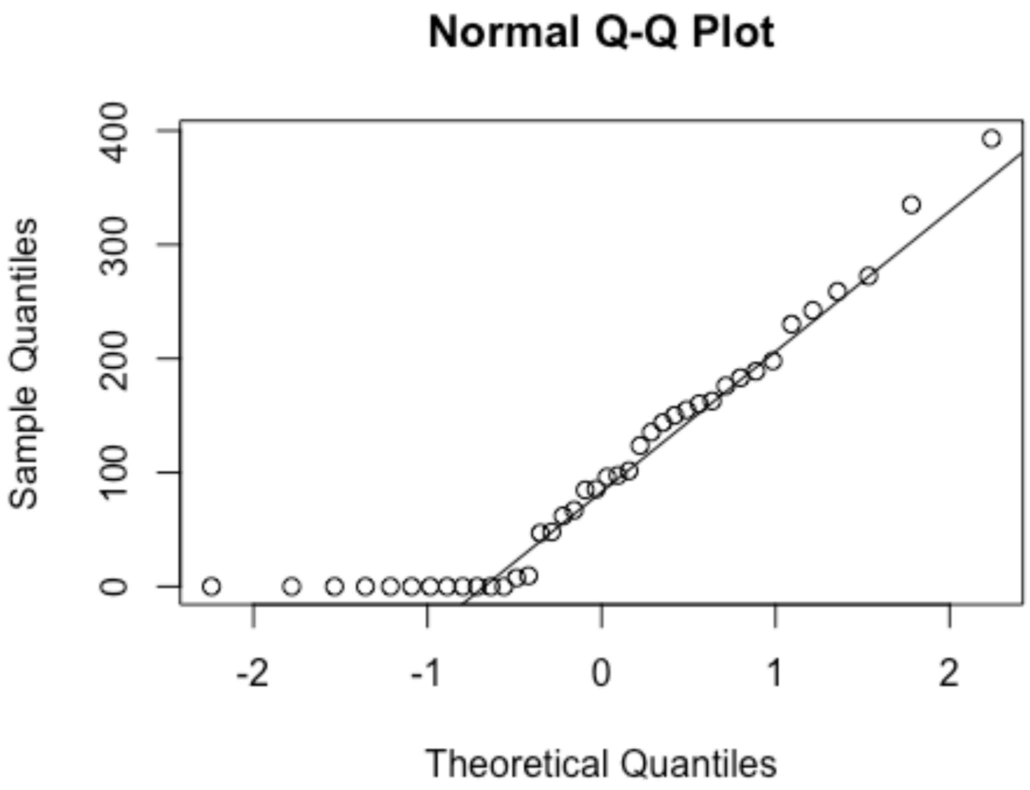
```
ad.test(subset(SSdata, intervention == "sham")$minutesTSTLeft)

##
##  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:
```

```
## mean of x mean of y
##  176.1083  185.6452

# Use droplevels to remove the empty levels from the list of levels
SSdata$intervention <- droplevels(SSdata$intervention)
summary(SSdata$intervention)

## PrenaBelt      sham
##        20        20

stripchart(SSdata$minutesTSTLeft~SSdata$intervention,
           vertical = TRUE, method="jitter", col=c("blue","deeppink"),
           ylab='Proportion of sleep time Left (%)', xlab='Intervention',
           main='Proportion of sleep time Left (%) vs. Intervention',)

for(participant.s.code in split(SSdata, SSdata$participant.s.code))
  lines(minutesTSTLeft ~ intervention, participant.s.code)
```



```
#################### Minutes Sleeping Right ############################
#Summary
summary(SSdata$minutesTSTRight)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   90.78  105.40  166.10  393.00
```

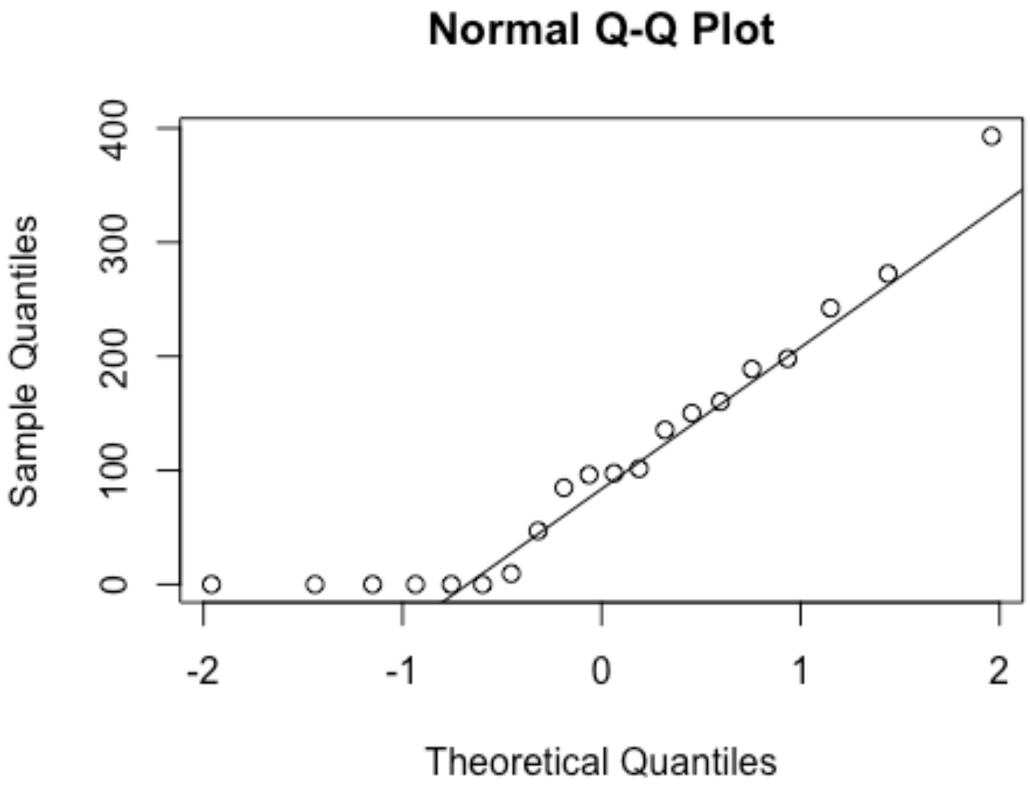
```
sd(SSdata$minutesTSTRight, na.rm = TRUE)

## [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,
```

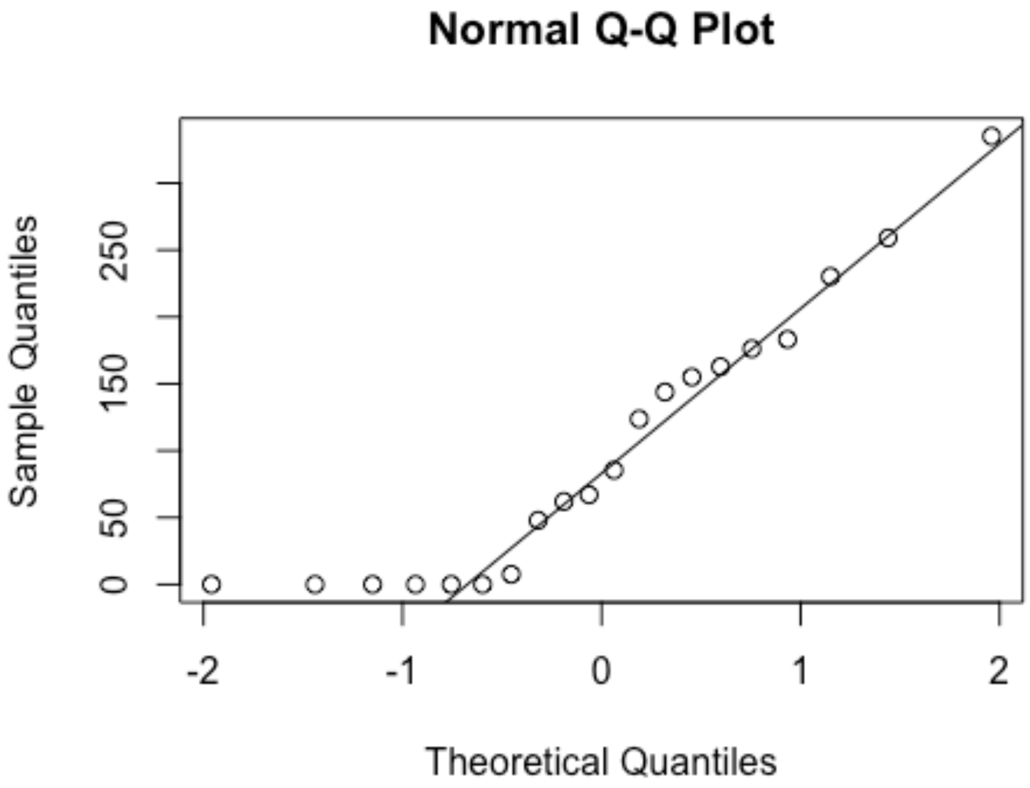
```
                                    data = SSdata))
night_tx_difference

## 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)
```



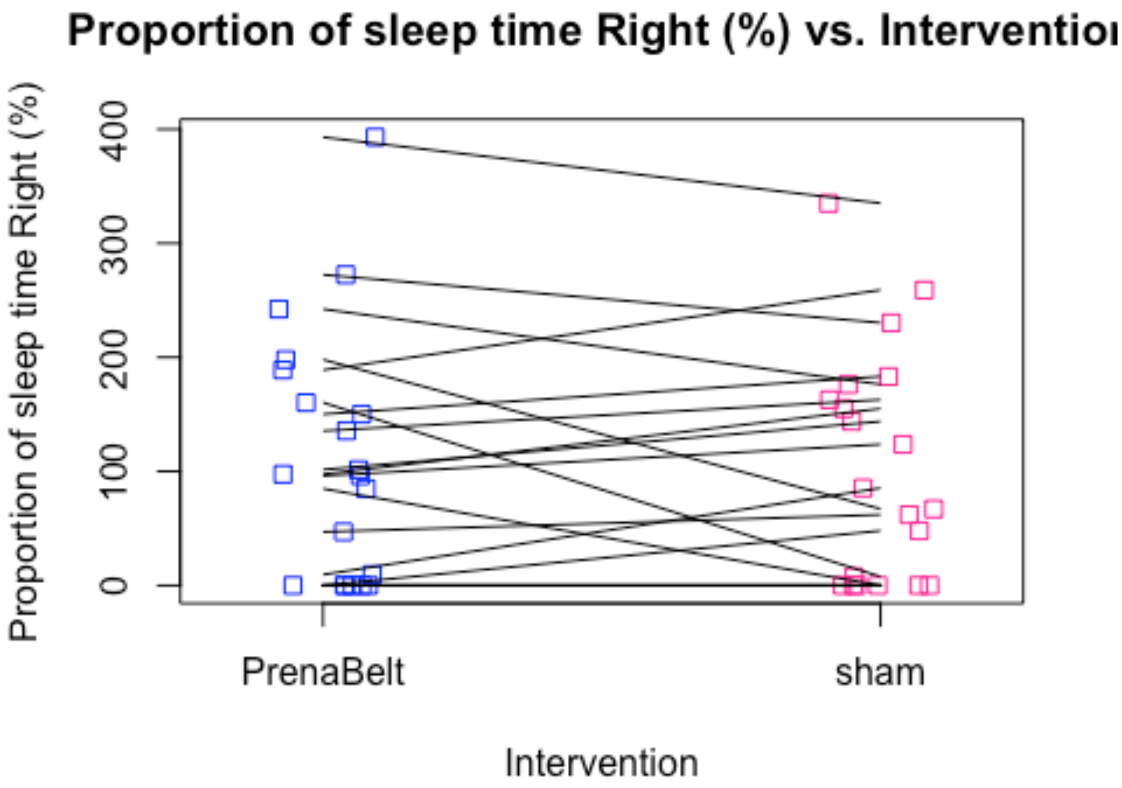
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

##
##  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
```

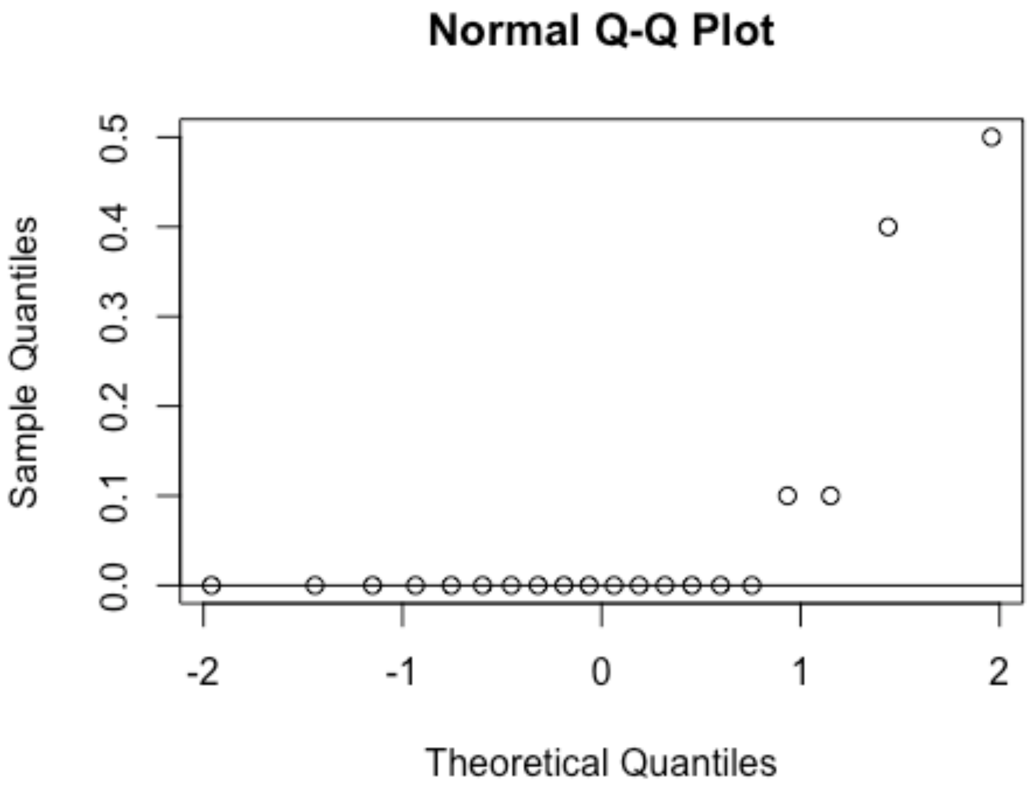
```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$minutesTSTRight and subset(S
Sdata, intervention == "PrenaBelt")$minutesTSTRight
## W = 195, p-value = 0.5599
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  -54.15088       Inf
## sample estimates:
## difference in location
##          -3.909212e-05

# Use droplevels to remove the empty levels from the list of levels
SSdata$intervention <- droplevels(SSdata$intervention)
summary(SSdata$intervention)

## PrenaBelt      sham
##        20        20

stripchart(SSdata$minutesTSTRight~SSdata$intervention,
           vertical = TRUE, method="jitter", col=c("blue","deeppink"),
           ylab='Proportion of sleep time Right (%)', xlab='Intervention',
           main='Proportion of sleep time Right (%) vs. Intervention',)

for(participant.s.code in split(SSdata, SSdata$participant.s.code))
  lines(minutesTSTRight ~ intervention, participant.s.code)
```



```
#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)
```

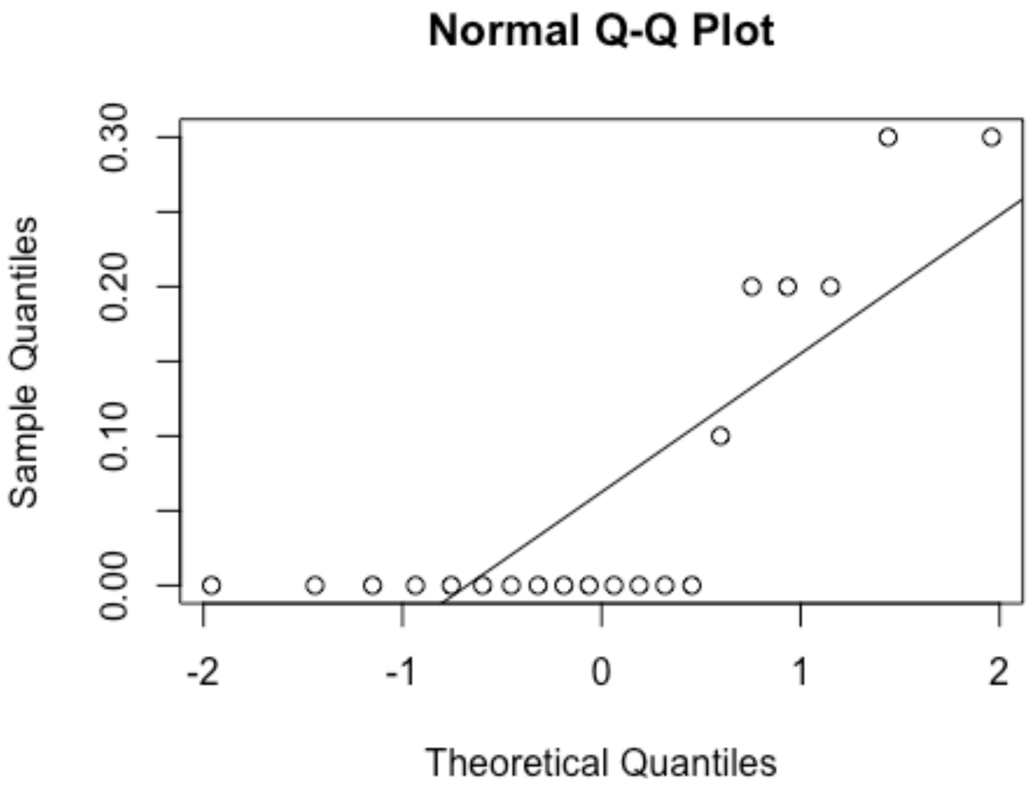
```
## intervention        1  0.001 0.001000  0.0679 0.79587  
## night               1  0.001 0.001000  0.0679 0.79587  
## intervention:night  1  0.064 0.064000  4.3472 0.04422 *
## Residuals          36  0.530 0.014722                  
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$central.apneas.in
dex,
       subset(SSdataCompletes, intervention == "PrenaBelt")$central.apneas.in
dex,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

## 
##  Wilcoxon signed rank test with continuity correction
## 
## data:  subset(SSdataCompletes, intervention == "sham")$central.apneas.inde
x and subset(SSdataCompletes, intervention == "PrenaBelt")$central.apneas.ind
ex
## V = 26.5, p-value = 0.6746
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.1500585  0.2000332
## sample estimates:
## (pseudo)median 
##     0.04999741

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   0.000   0.000   0.000   0.055   0.000   0.500

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
```

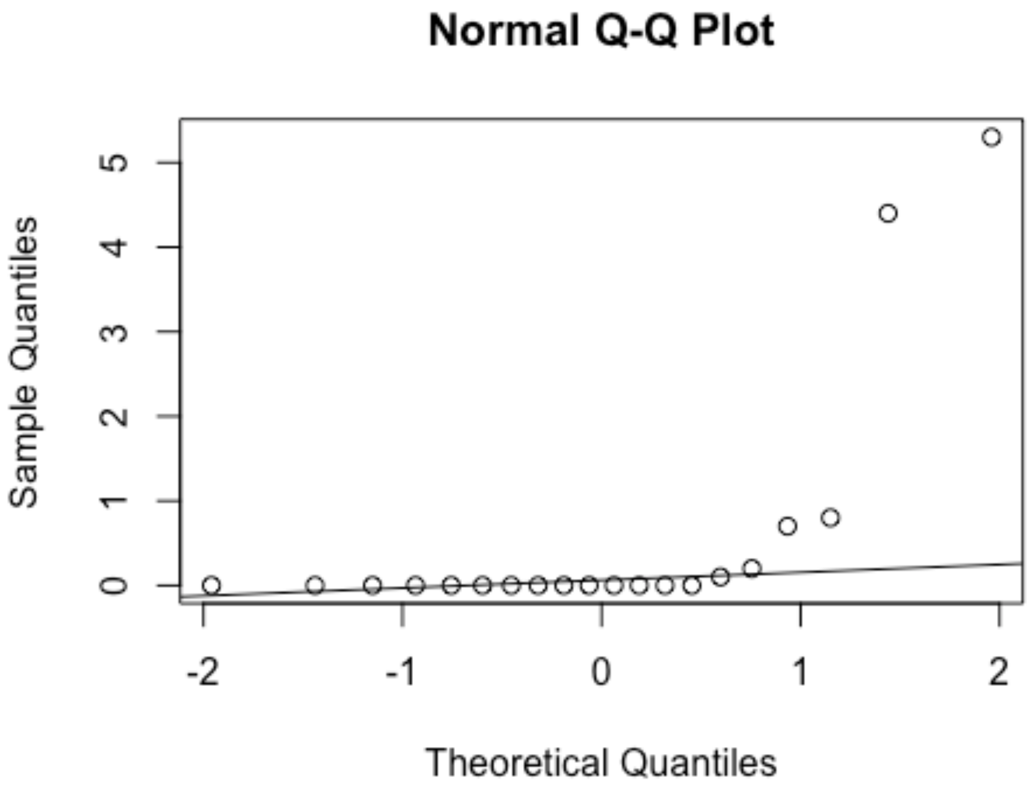
```
length(subset(SSdata, intervention == "sham")$central.apneas.index)

## [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

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
```

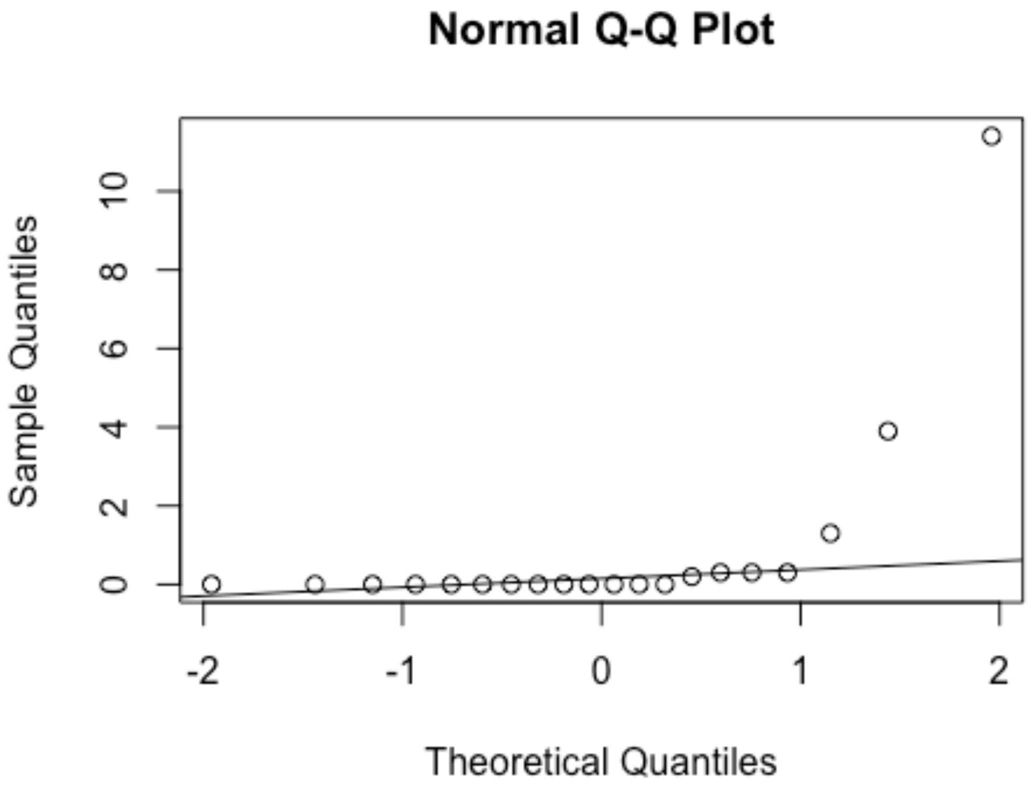
```
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $central.apneas.index, : cannot compute exact confidence intervals with
## ties

##
##  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 #######################
#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)
## intervention  1   0.961  0.9610  0.2065 0.6521
## night         1   1.369  1.3690  0.2942 0.5908
## Residuals    37 172.154  4.6528

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$obstructive.apnea
s.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.apnea
```

```
s.index,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$obstructive.apneas.
index and subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.ap
neas.index
## V = 18, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.7499621  3.5499235
## sample estimates:
## (pseudo)median
##     0.03901549

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.575   0.125   5.300

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

## [1] 1.487094

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

## [1] 20

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



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

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.inde
x
## 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
```

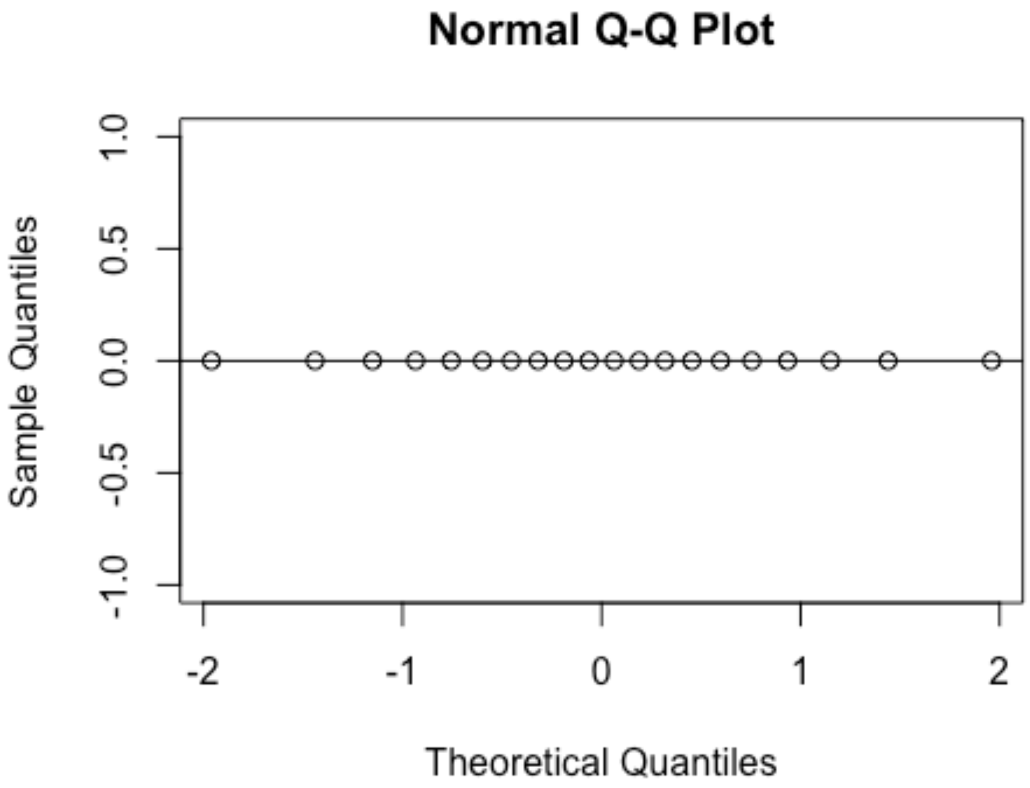
```
qqnorm(subset(SSdata, intervention == "sham")$obstructive.apneas.index)
qqline(subset(SSdata, intervention == "sham")$obstructive.apneas.index)
```



```
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
```

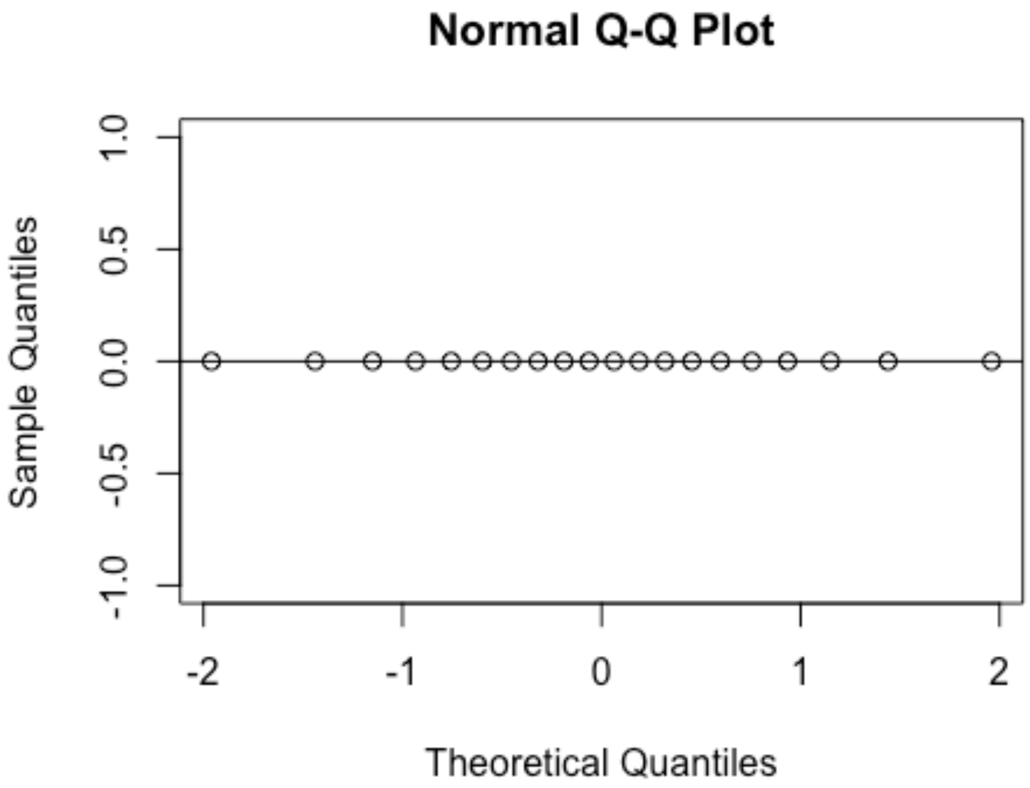
```
h
## ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$obstructive.apneas.index and
subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index
## W = 210.5, p-value = 0.7451
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.671494e-05  4.691508e-05
## sample estimates:
## difference in location
##           2.019957e-05

#################### Mixed Apnea Index #######################
#Summary
summary(SSdata$mixed.apneas.index)

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

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

## [1] 0

length(SSdata$mixed.apneas.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: mixed.apneas.index
##               Df Sum Sq Mean Sq F value Pr(>F)
## intervention  1      0       0
## night         1      0       0
## Residuals    37      0       0

#within-participants (paired) comparison
#distribution is made entirely of zeroes
#difference testing not applicable

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)
```

```
##    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)
```



```
#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
```

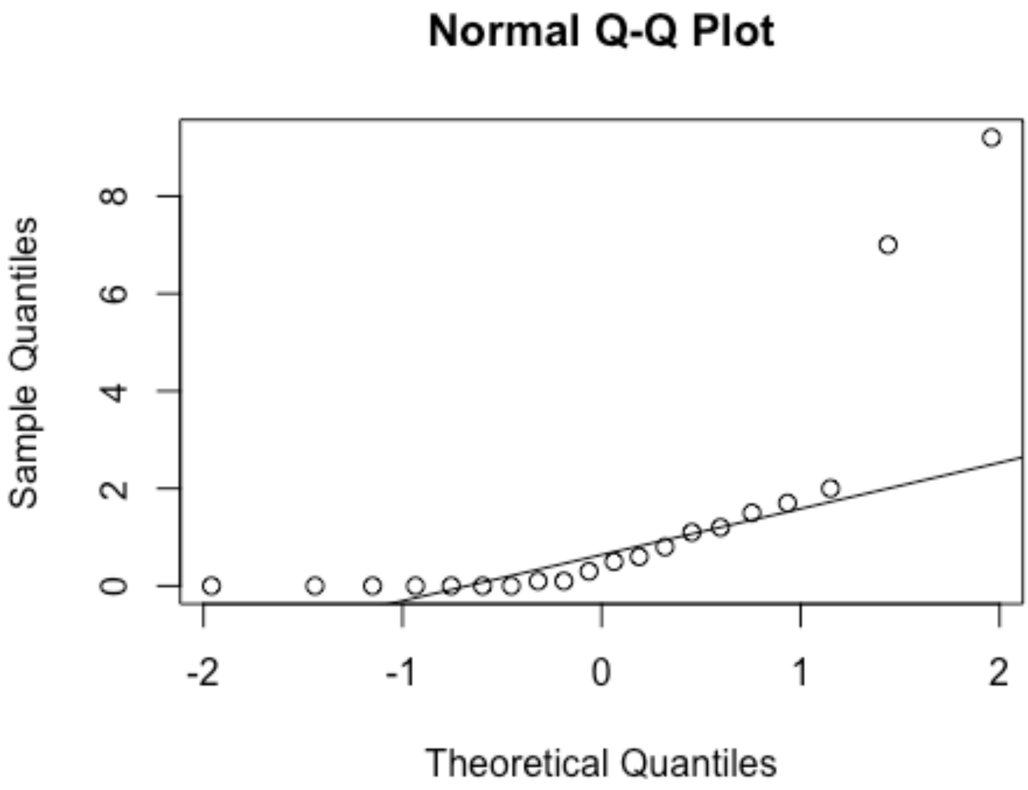
```
length(subset(SSdata, intervention == "sham")$mixed.apneas.index)

## [1] 20

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



```
#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
```

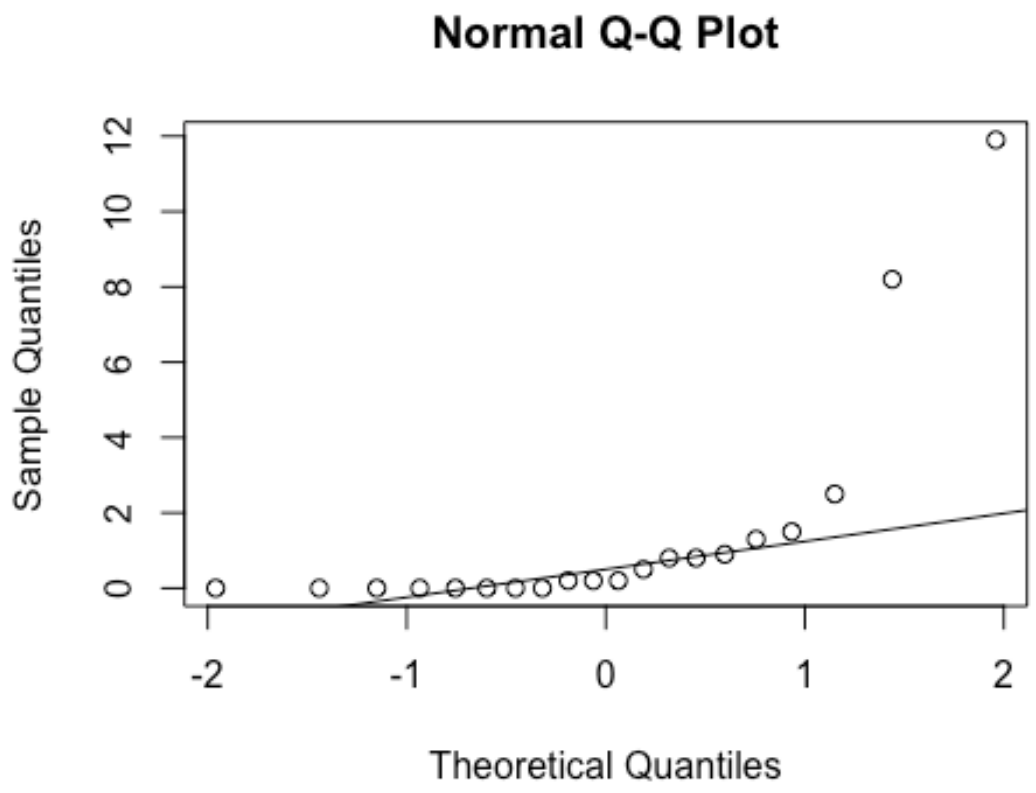
```
#ANOVA
night_tx_difference <- anova(lm(obstructive.hypopneas.index ~ intervention +
night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: obstructive.hypopneas.index
##              Df  Sum Sq Mean Sq F value Pr(>F)
## intervention  1   0.210  0.2103  0.0267 0.8711
## night         1   0.702  0.7023  0.0891 0.7669
## Residuals    37 291.477  7.8778

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$obstructive.hypop
neas.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.hypop
neas.index,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$obstructive.hypopne
as.index and subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive
.hypopneas.index
## V = 87, p-value = 0.6357
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.2999835  0.5499741
## sample estimates:
## (pseudo)median
##     0.09999107
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.ind
ex)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.400   1.305   1.275   9.200

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

## [1] 2.435802

length(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
x)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
x)
qqline(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
x)
```



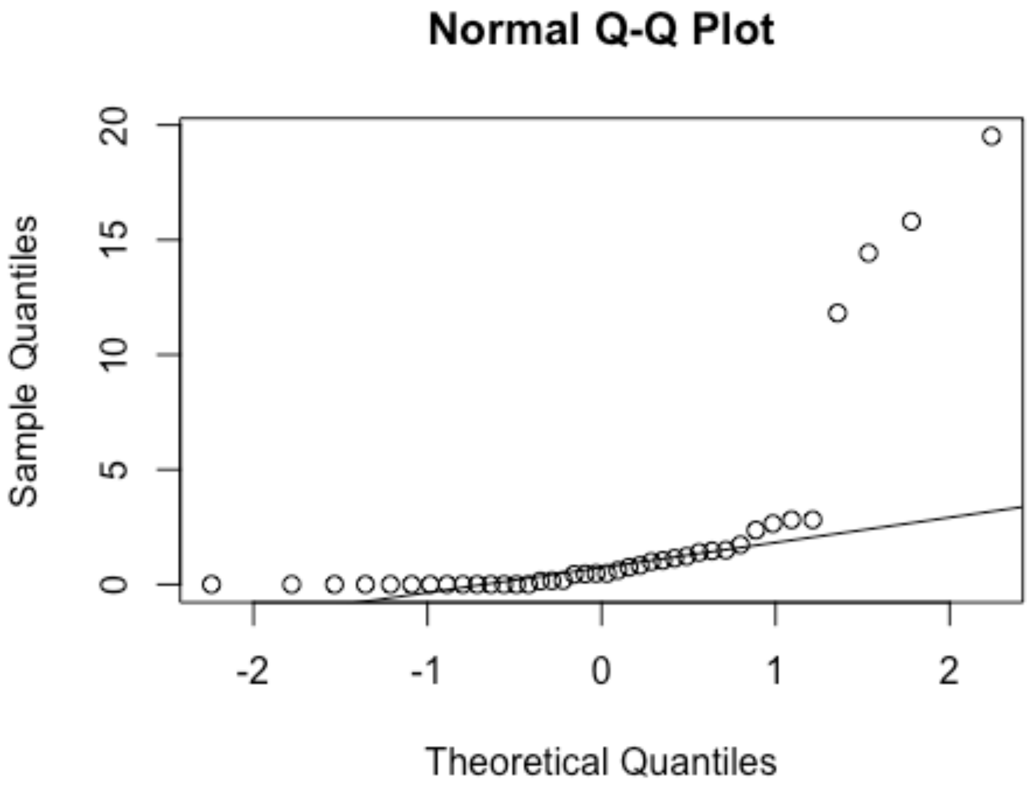
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.ind
ex)
```

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.i
ndex
## 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)
```



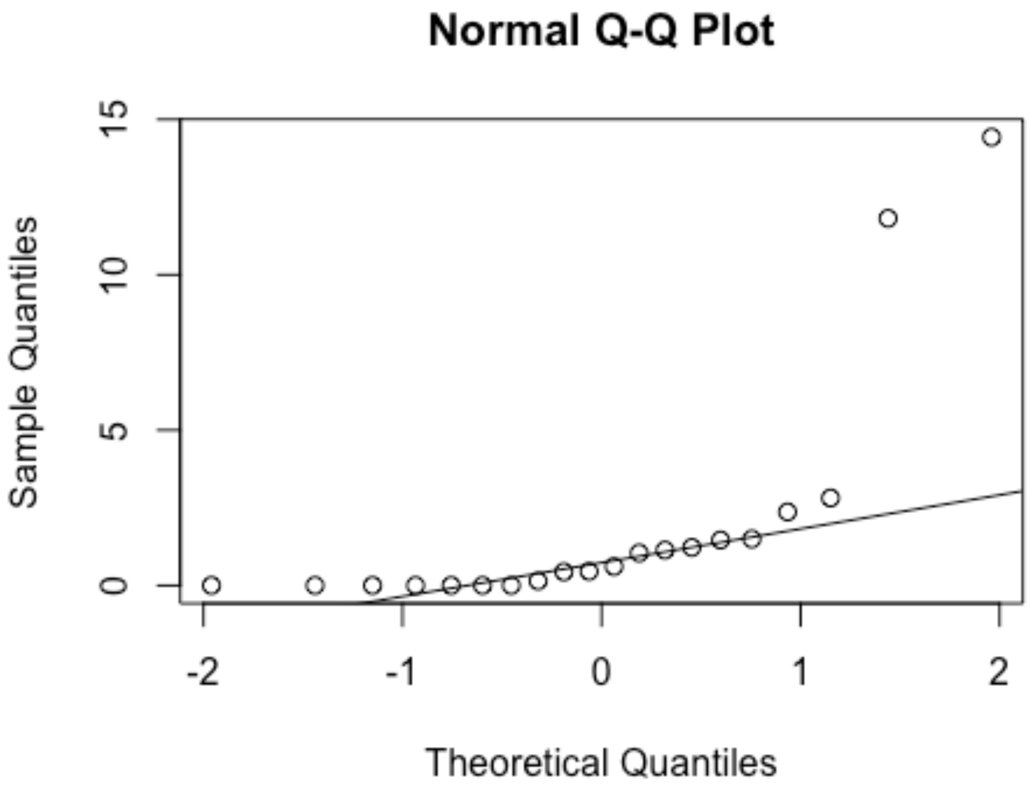
```
ad.test(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$obstructive.hypopneas.index
## A = 3.9511, p-value = 3.022e-10

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$obstructive.hypopneas.inde
x,
            subset(SSdata, intervention == "PrenaBelt")$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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$obstructive.hypopneas.index
and subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index
## W = 191, p-value = 0.8132
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.5000080  0.2999871
## sample estimates:
## difference in location
##          -1.817308e-06

##################### Apnea-Hypopnea Index #######################
#Summary
summary(SSdata$AHI.calculated)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.4765  2.1800  1.4700 19.5100

sd(SSdata$AHI.calculated, na.rm = TRUE)

## [1] 4.622751

length(SSdata$AHI.calculated)

## [1] 40
```

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

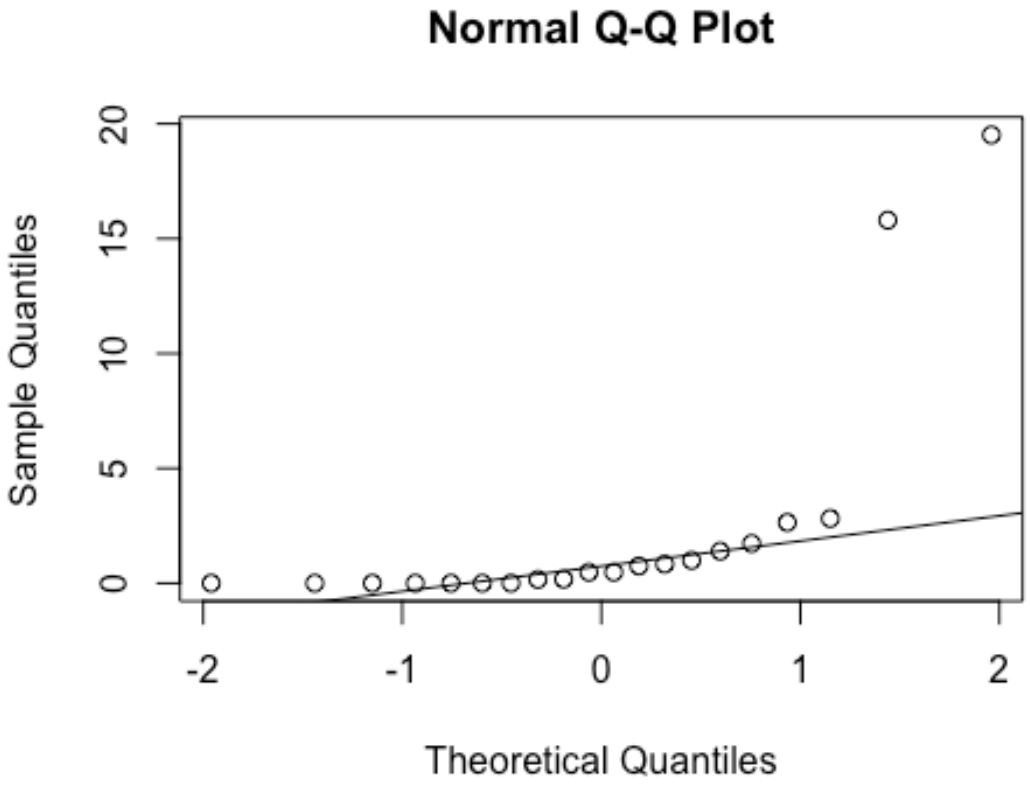


```
ad.test(SSdata$AHI.calculated)

##
##  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
```

```
## intervention:night  1 106.12 106.123  5.2990 0.02723 *
## Residuals          36 720.97  20.027
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$AHI.calculated,
       subset(SSdataCompletes, intervention == "PrenaBelt")$AHI.calculated,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$AHI.calculated and
subset(SSdataCompletes, intervention == "PrenaBelt")$AHI.calculated
## V = 91, p-value = 0.5075
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.4367014  0.7981902
## sample estimates:
## (pseudo)median
##      0.1385676

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.5321  1.9720  1.4700 14.4300

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

## [1] 3.924224

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

## [1] 20

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



```
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
```

```
data, intervention == "PrenaBelt")$AHI.calculated
## W = 198.5, p-value = 0.9779
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.6092948  0.4774410
## sample estimates:
## difference in location
##          -1.726505e-05

#################### Central hypopneas Index #######################
#Summary
summary(SSdata$central.hypopneas.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.015   0.000   0.600

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

## [1] 0.09486833

length(SSdata$central.hypopneas.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(central.hypopneas.index ~ intervention + nigh
t,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: central.hypopneas.index
##              Df Sum Sq Mean Sq F value Pr(>F)
## intervention  1  0.009   0.009       1 0.3238
## night         1  0.009   0.009       1 0.3238
## Residuals    37  0.333   0.009

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$central.hypopneas
.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$central.hypopneas
.index,
       paired = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$central.hypopneas.index, : cannot compute exact p-value with zeroe
s

##
##  Wilcoxon signed rank test with continuity correction
```

```
##
## data:  subset(SSdataCompletes, intervention == "sham")$central.hypopneas.i
ndex and subset(SSdataCompletes, intervention == "PrenaBelt")$central.hypopne
as.index
## V = 0, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.03    0.00    0.60
```

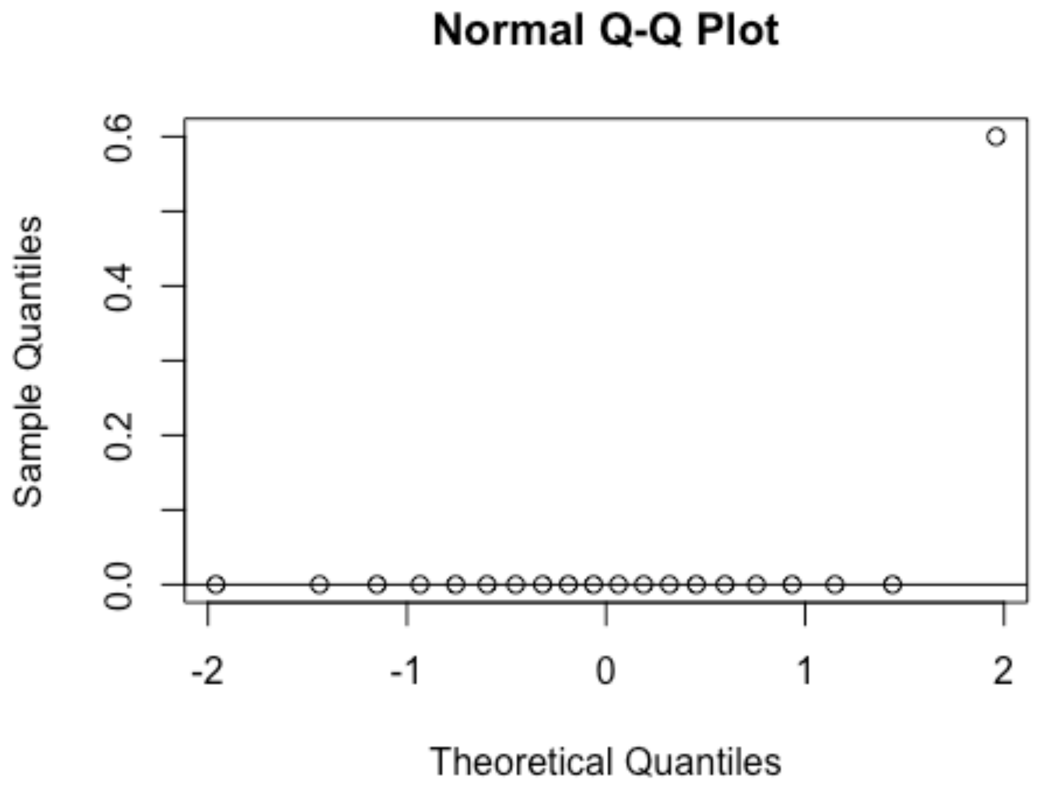
```
sd(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
```

```
## [1] 0.1341641
```

```
length(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
```

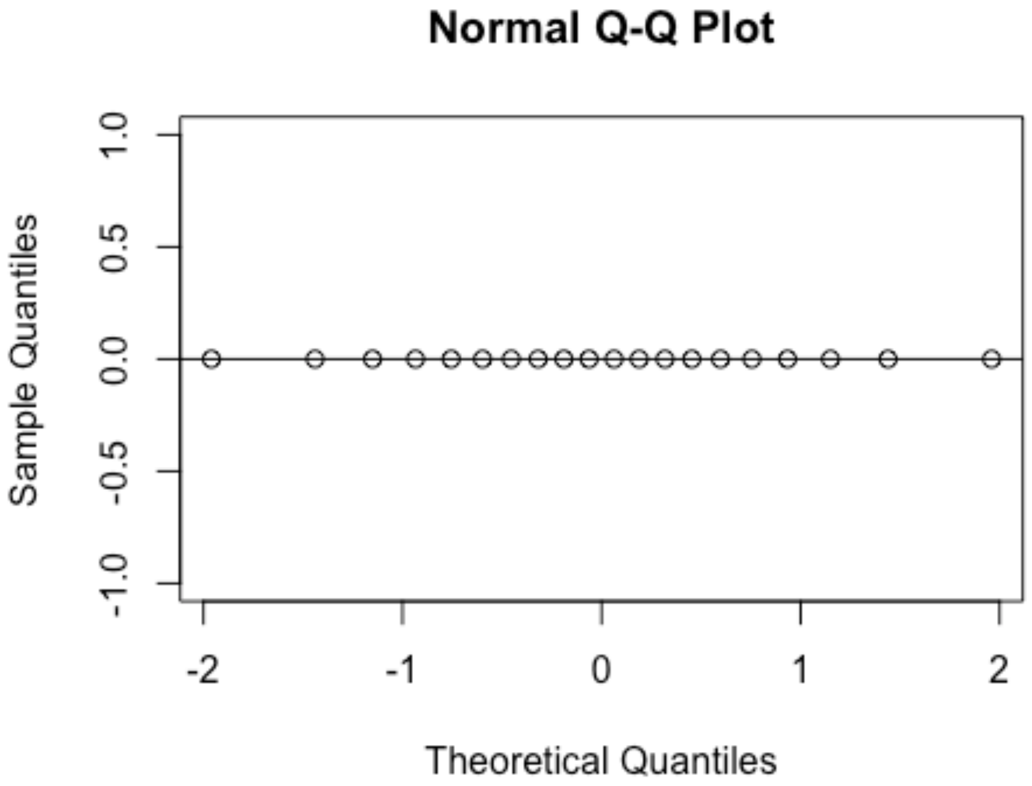
```
## [1] 20
```

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

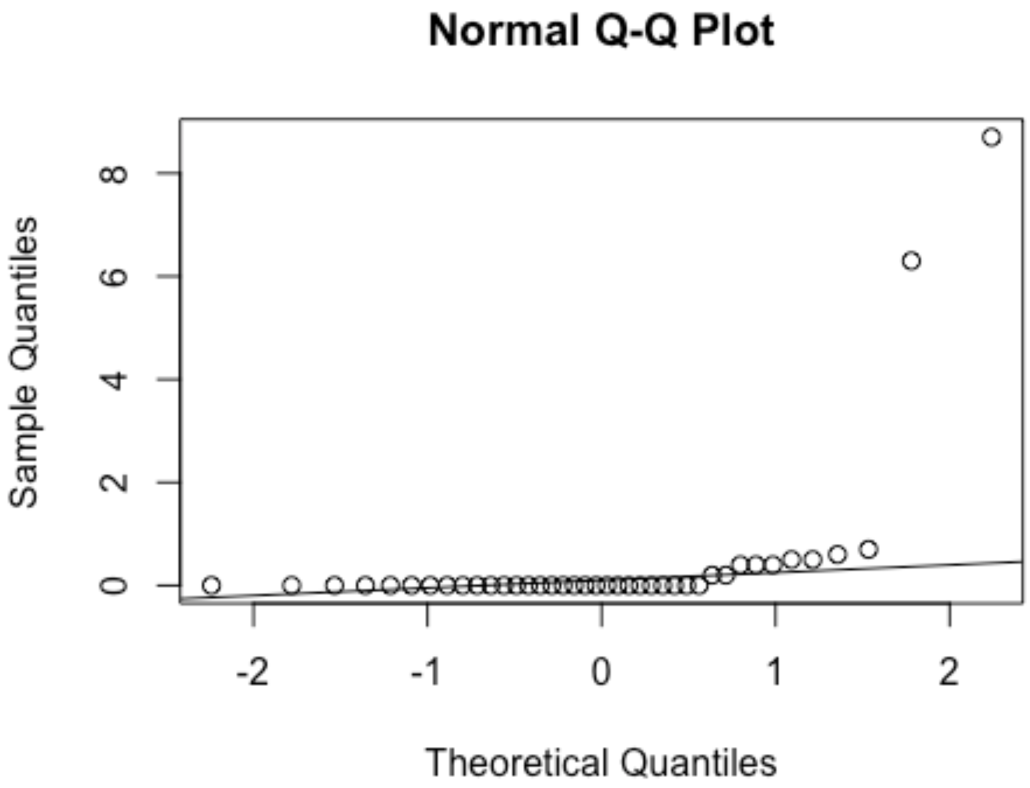


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)
```

```
##
##  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)
```

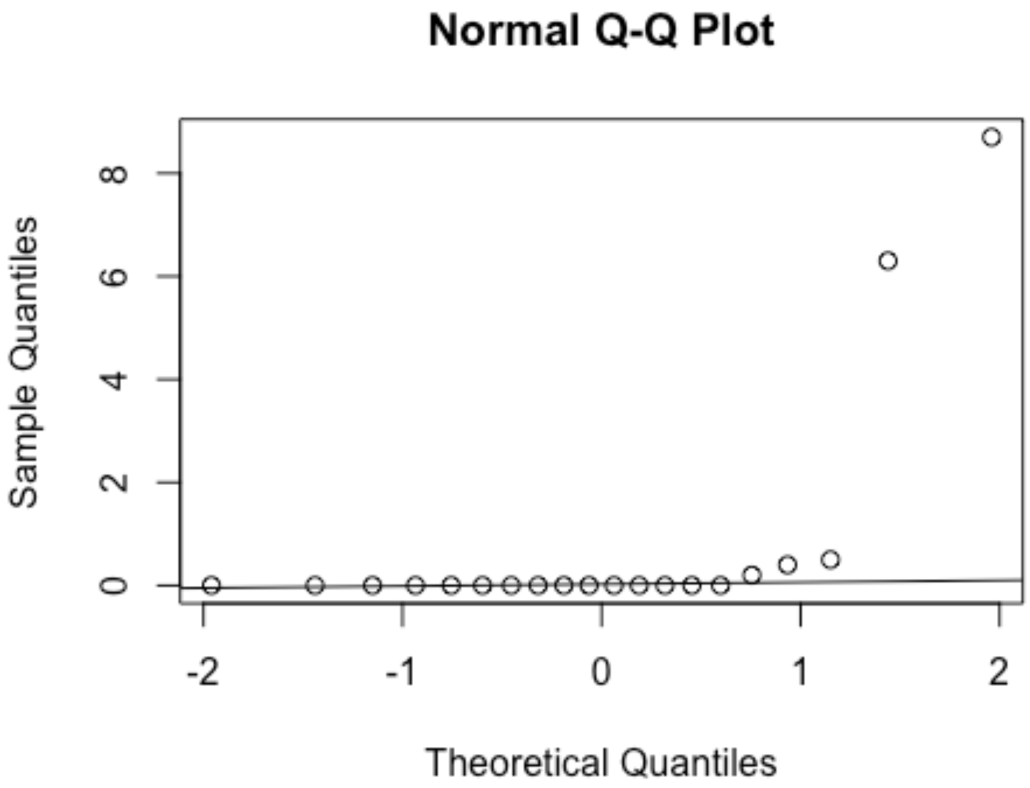


```
#ad.test(subset(SSdata, intervention == "sham")$central.hypopneas.index)
#distribution is made entirely of zeroes

wilcox.test(subset(SSdata, intervention == "sham")$central.hypopneas.index,
            subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.ind
ex,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$central.hypopneas.index and
subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index
## W = 190, p-value = 0.3421
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  0 0
## sample estimates:
## difference in location
##                      0

#################### RERAs Index ######################
#Summary
summary(SSdata$reras.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.0000  0.4725  0.2000  8.7000

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

## [1] 1.66687

length(SSdata$reras.index)

## [1] 40

qqnorm(SSdata$reras.index)
qqline(SSdata$reras.index)
```

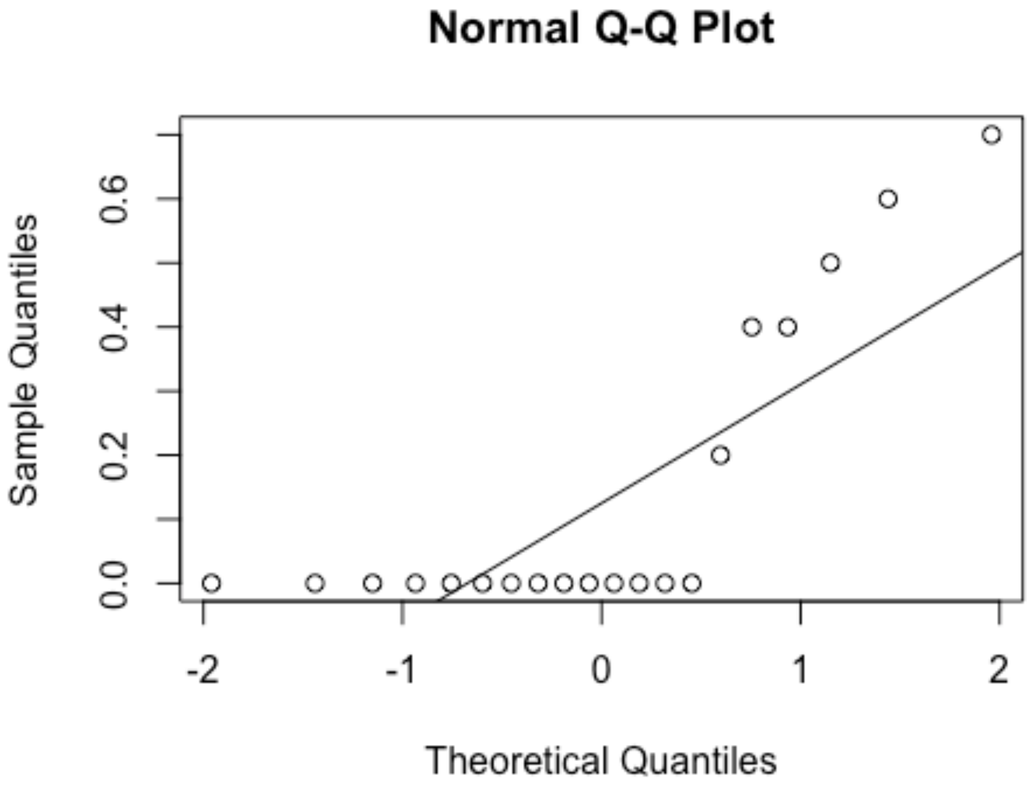


```
ad.test(SSdata$reras.index)

##
##  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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$reras.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$reras.index,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

## 
##  Wilcoxon signed rank test with continuity correction
## 
## data:  subset(SSdataCompletes, intervention == "sham")$reras.index and sub
set(SSdataCompletes, intervention == "PrenaBelt")$reras.index
## V = 15.5, p-value = 0.7789
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.5999963  0.3500676
## sample estimates:
## (pseudo)median 
##     -0.1499727

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   0.000   0.000   0.000   0.805   0.050   8.700

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

## [1] 2.32684

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

## [1] 20

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

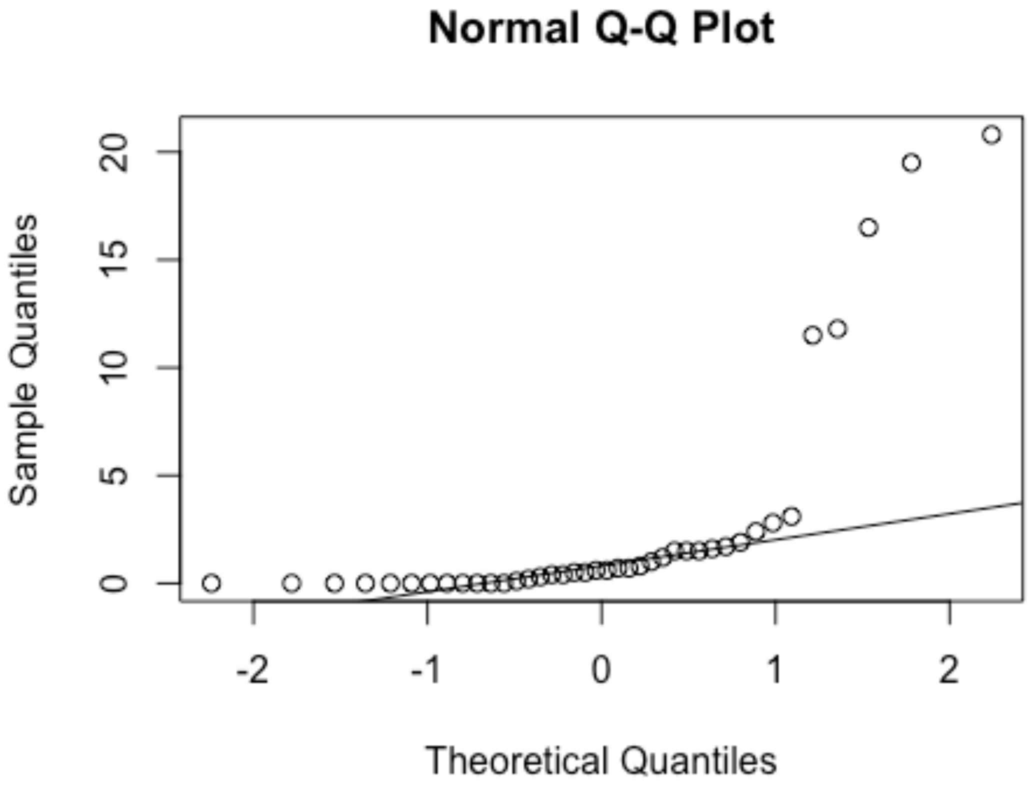


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$reras.index)

##
##  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)
```



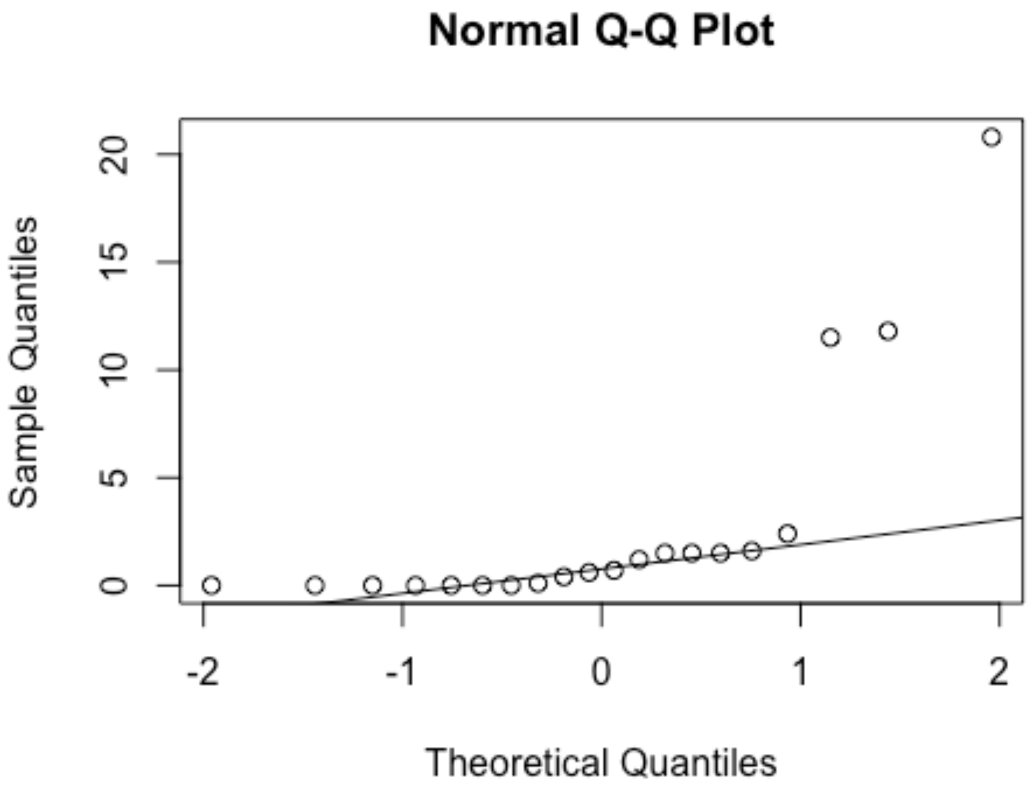
```
ad.test(subset(SSdata, intervention == "sham")$reras.index)

##
##  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
```

```
a, intervention == "PrenaBelt")$reras.index
## W = 207, p-value = 0.8231
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.950633e-05  5.862469e-06
## sample estimates:
## difference in location
##           4.901185e-05

#################### Respiratory Disturbance Index #######################
#Summary
summary(SSdata$rdi.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.600   2.652   1.625  20.800

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

## [1] 5.358817

length(SSdata$rdi.index)

## [1] 40

qqnorm(SSdata$rdi.index)
qqline(SSdata$rdi.index)
```

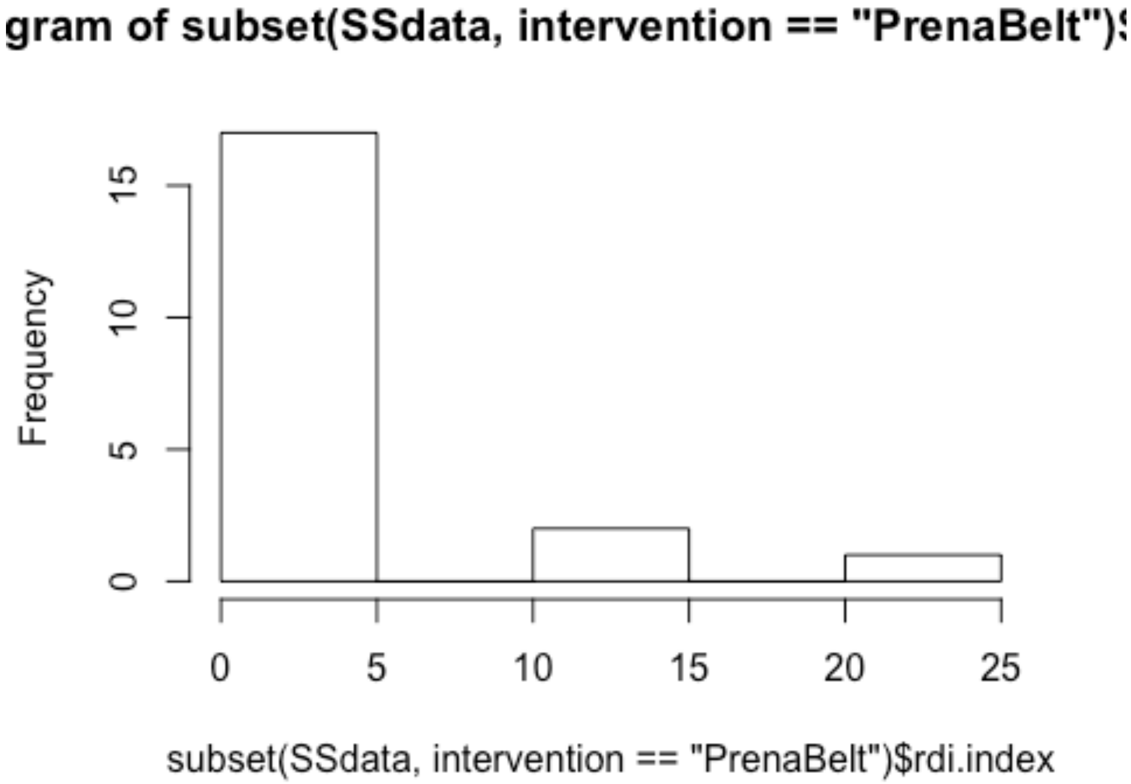


```
ad.test(SSdata$rdi.index)

##
##  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
```

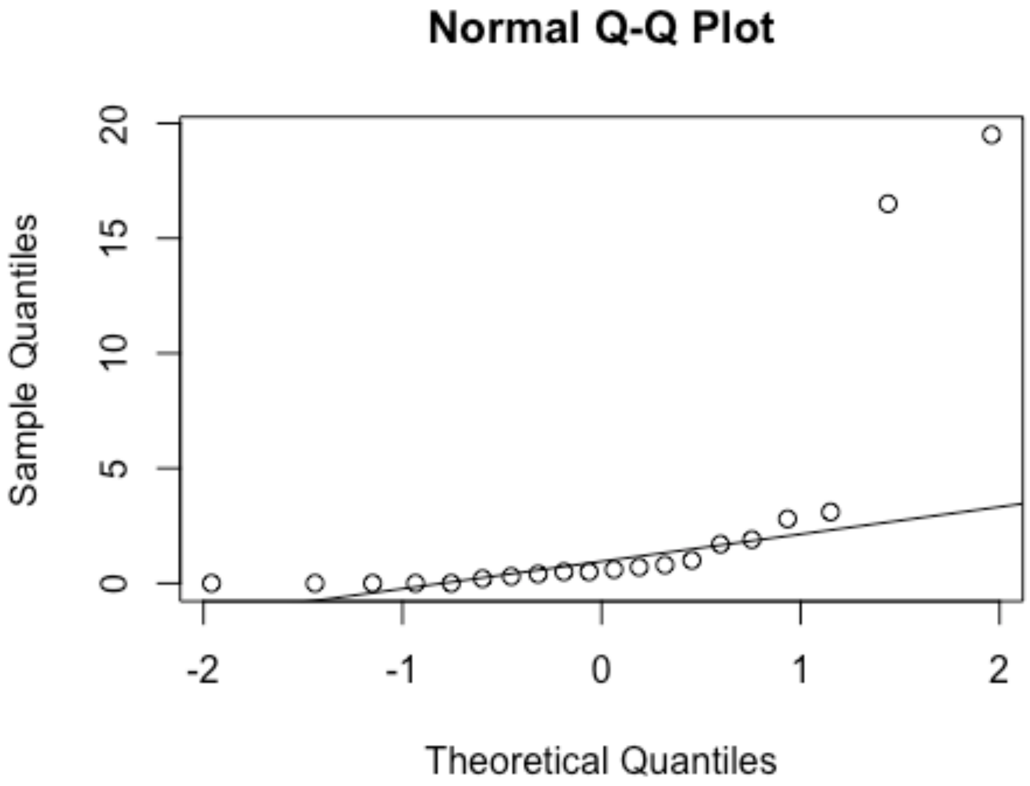
```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#non-normal - do Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$rdi.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$rdi.index,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$rdi.index and subse
t(SSdataCompletes, intervention == "PrenaBelt")$rdi.index
## V = 67, p-value = 0.6699
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.1999821  0.6499711
## sample estimates:
## (pseudo)median
##      -0.199951

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.650   2.780   1.525  20.800

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

## [1] 5.463236

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

## [1] 20

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



```
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)
```

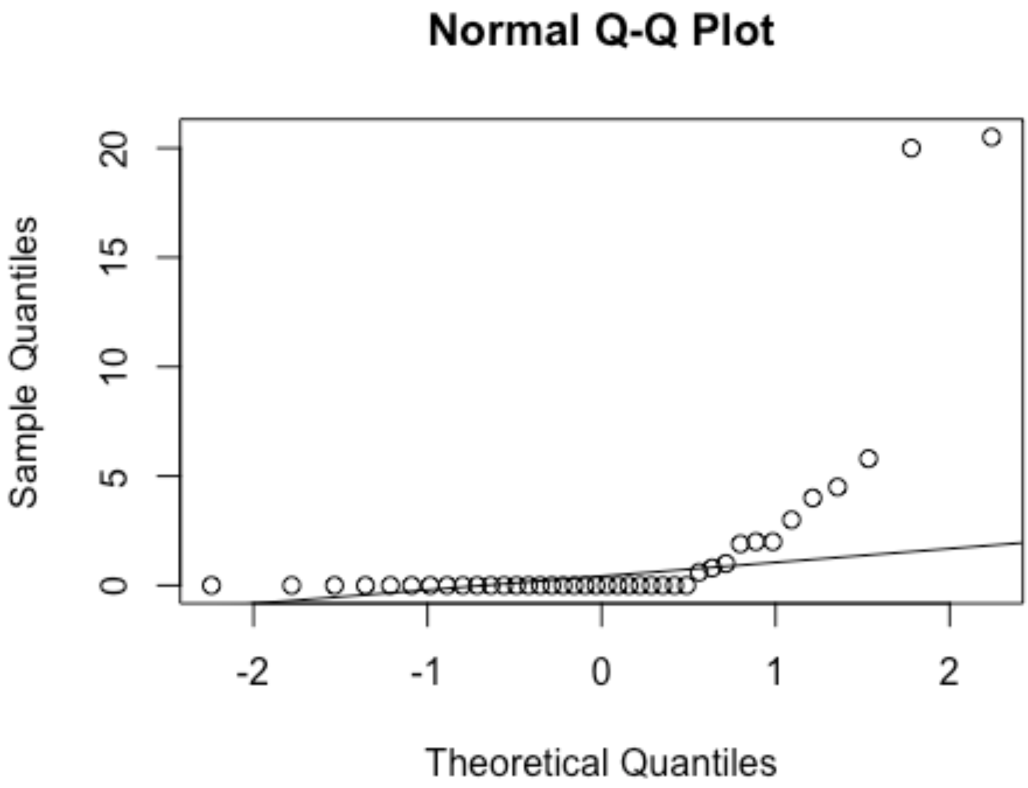


```
#non-normal

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)
```



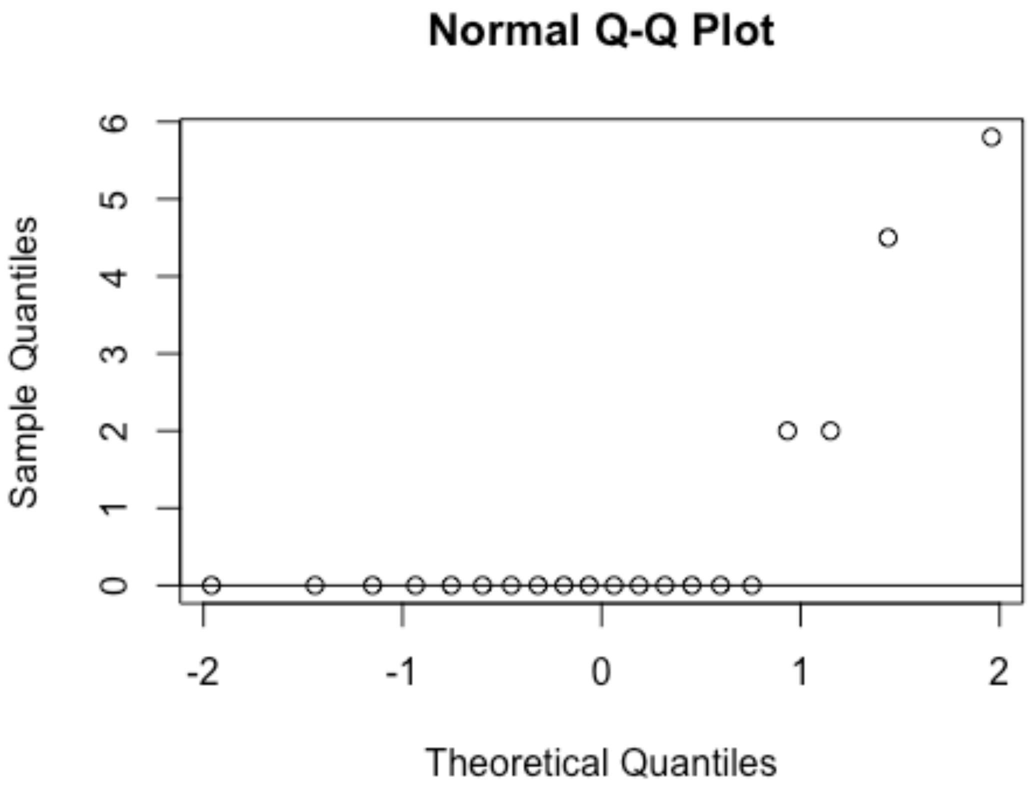
```
ad.test(subset(SSdata, intervention == "sham")$rdi.index)

##
##  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,
```

```
intervention == "PrenaBelt")$rdi.index
## W = 206, p-value = 0.8801
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.7000762  0.5000008
## sample estimates:
## difference in location
##           8.805182e-05

#################### Supine Event Index #######################
#Summary
summary(SSdata$index.of.supine.events)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   0.000   0.000   0.000   1.652   0.850  20.500

sd(SSdata$index.of.supine.events, na.rm = TRUE)

## [1] 4.539061

length(SSdata$index.of.supine.events)

## [1] 40

qqnorm(SSdata$index.of.supine.events)
qqline(SSdata$index.of.supine.events)
```

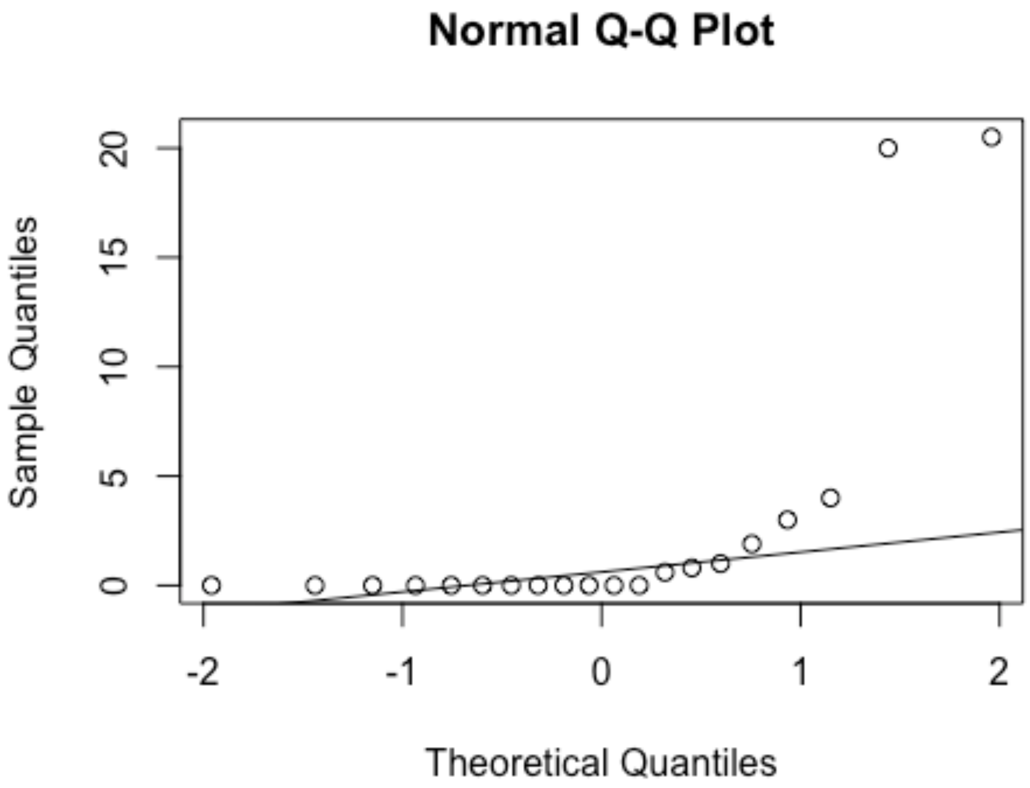


```
ad.test(SSdata$index.of.supine.events)

##
##  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
```

```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$index.of.supine.e
vents,
       subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.supine.e
vents,
       paired = TRUE)

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$index.of.supine.eve
nts and subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.supine.
events
## V = 35, p-value = 0.4755
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.715   0.000   5.800

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

## [1] 1.649011

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

## [1] 20

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

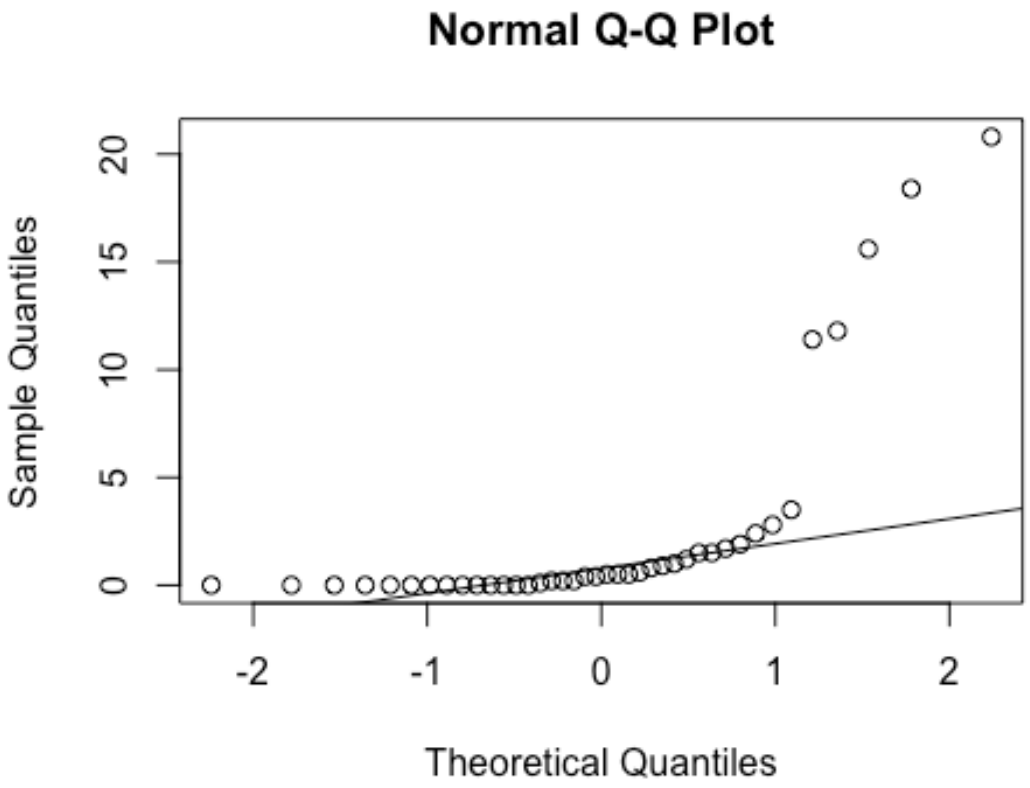


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)

##
##  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)
```



```
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.event
s,
            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
```

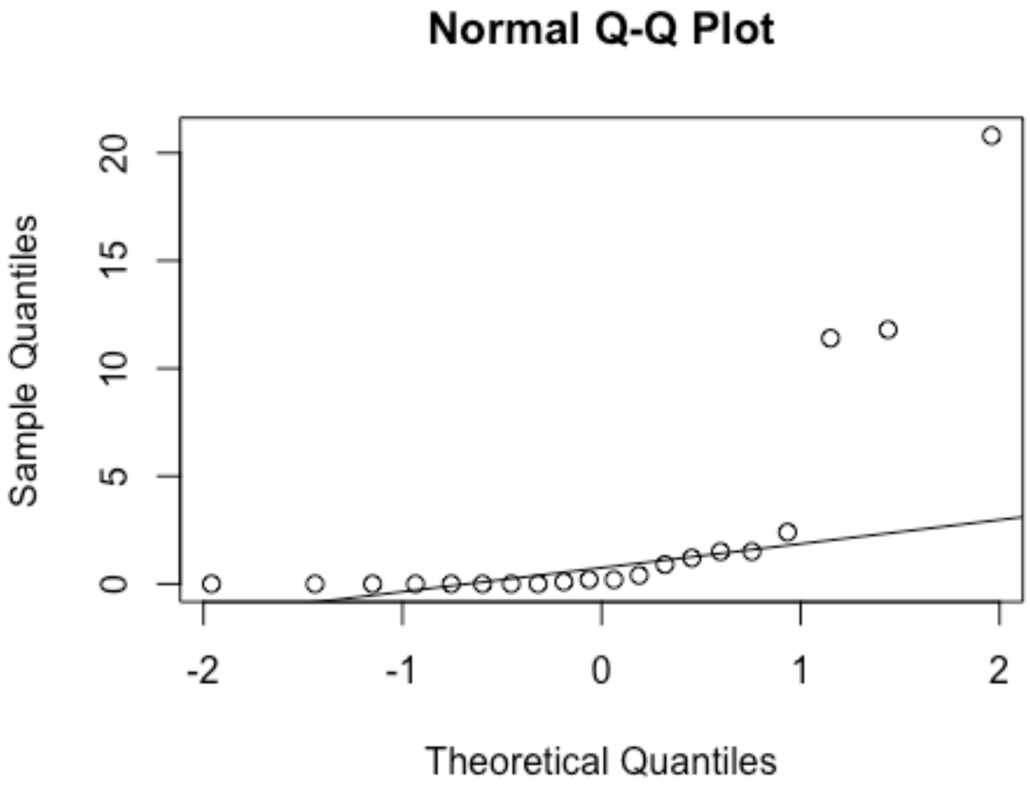
```
##
## data:  subset(SSdata, intervention == "sham")$index.of.supine.events and s
ubset(SSdata, intervention == "PrenaBelt")$index.of.supine.events
## W = 236, p-value = 0.2362
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.0000813554  0.6000459383
## sample estimates:
## difference in location
##           7.189321e-06

#################### Non-Supine Event Index #######################
#Summary
summary(SSdata$index.of.non.supine.events)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.45    2.52    1.55   20.80

sd(SSdata$index.of.non.supine.events, na.rm = TRUE)

## [1] 5.242929

length(SSdata$index.of.non.supine.events)

## [1] 40

qqnorm(SSdata$index.of.non.supine.events)
qqline(SSdata$index.of.non.supine.events)
```



```
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
```

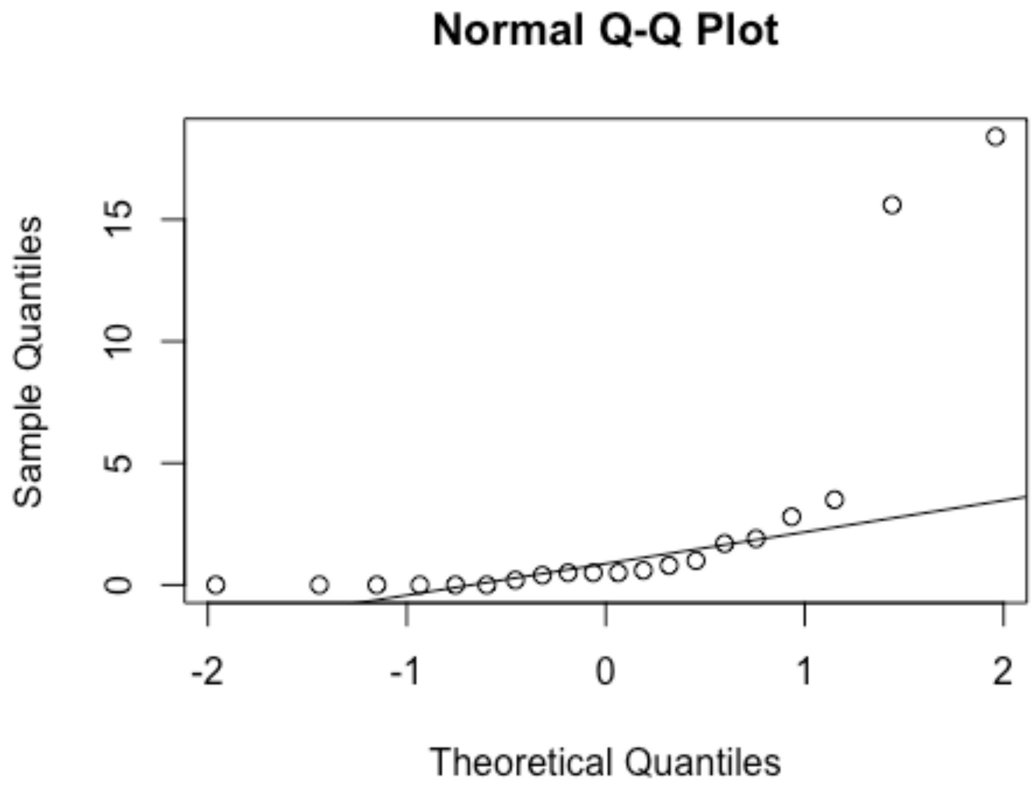
```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#non-normal - use Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$index.of.non.supi
ne.events,
       subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.non.supi
ne.events,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$index.of.non.supine
.events and subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.non
.supine.events
## V = 70.5, p-value = 0.9176
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.0000733  0.8499829
## sample estimates:
## (pseudo)median
##     0.04999832

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.event
s)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.20    2.62    1.50   20.80

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

## [1] 5.512245
```

```
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
)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.event
s)

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

#non-normal

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

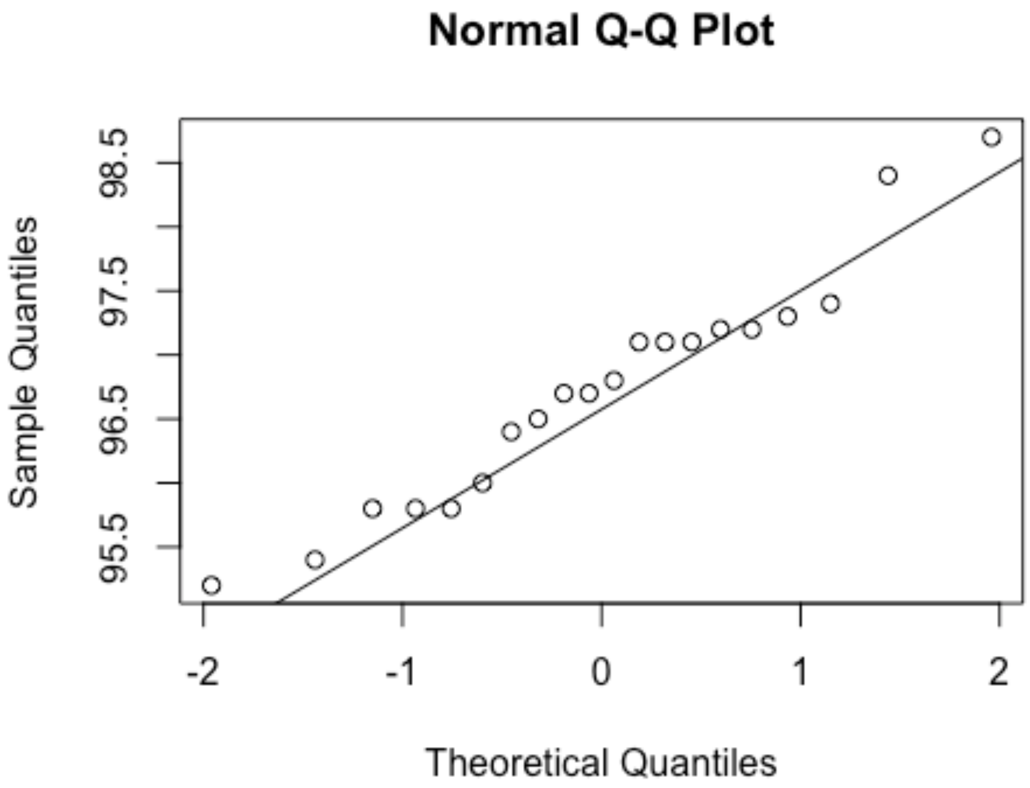
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.50    2.42    1.75   18.40

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)
```



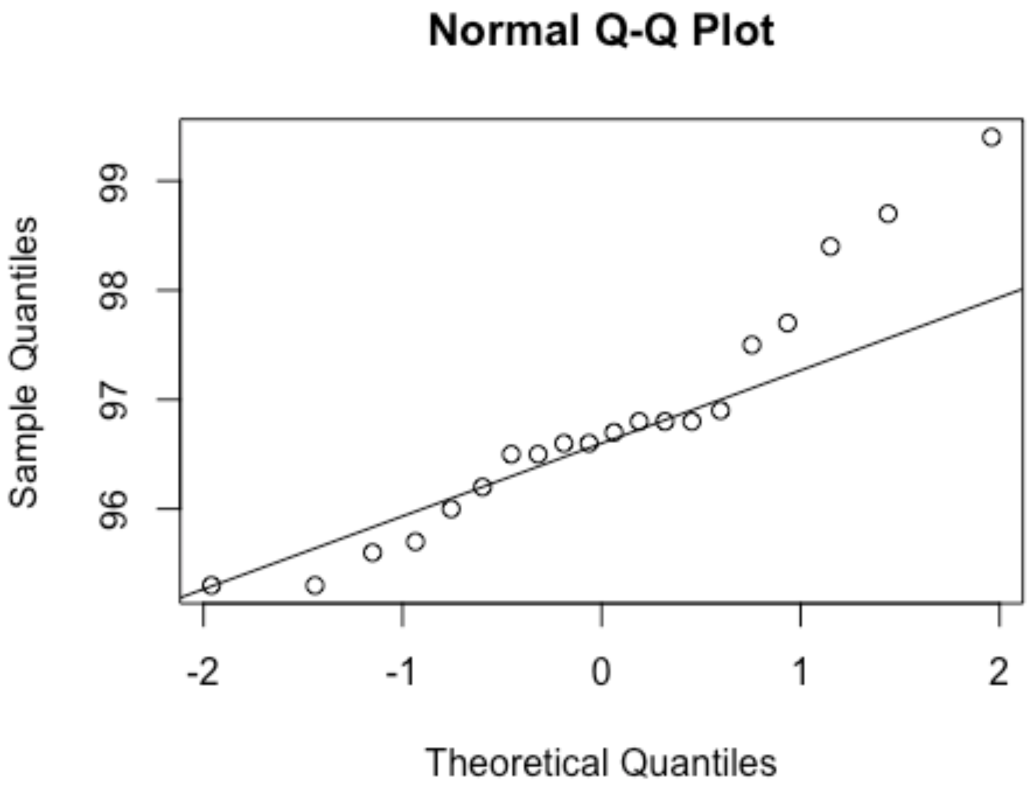
```
ad.test(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

##
##  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
```

```
,
            subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.e
vents,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$index.of.non.supine.events a
nd subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
## W = 222.5, p-value = 0.5428
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.3999612  0.5999875
## sample estimates:
## difference in location
##           5.005918e-06

#################### Mean SaO2 AWAKE ######################
#Summary
summary(SSdata$mean.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   95.20   96.00   96.70   96.76   97.20   99.40

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

## [1] 0.99242

length(SSdata$mean.sao2.awake)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(mean.sao2.awake ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: mean.sao2.awake
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.049  0.0490  0.0464 0.8306
## night               1  0.256  0.2560  0.2425 0.6254
```

```
## intervention:night  1  0.100  0.1000  0.0947 0.7600
## Residuals          36 38.006  1.0557

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.awake,
       subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.awake,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.awake and
subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.awake
## t = 0.53846, df = 19, p-value = 0.5965
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.2020931  0.3420931
## sample estimates:
## mean of the differences
##                    0.07

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   95.20   95.95   96.75   96.73   97.20   98.70

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

## [1] 0.909077

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

## [1] 20

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

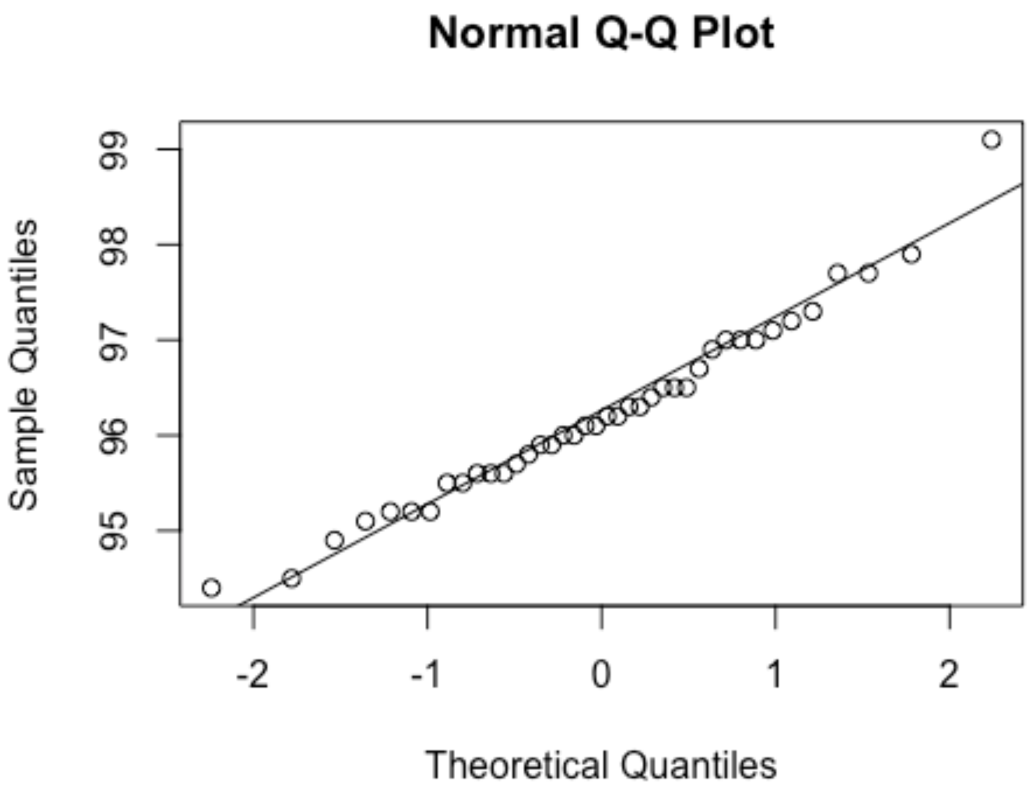


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)

##
##  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:
```

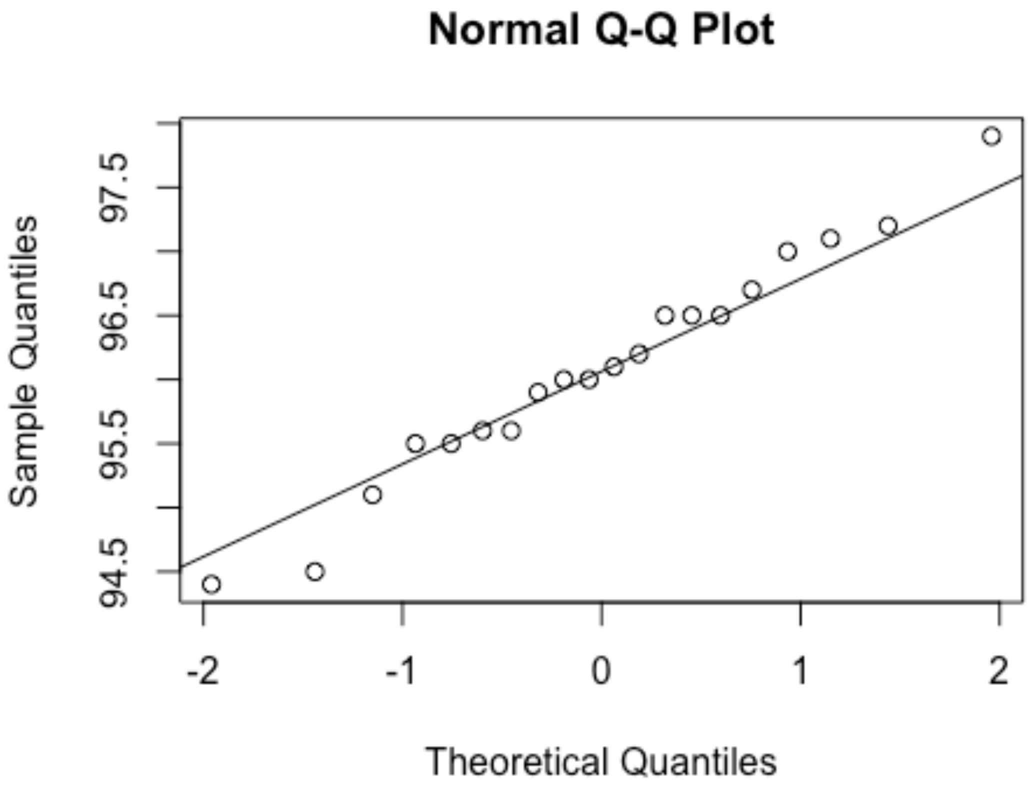
```
## mean of x mean of y
##     96.80     96.73

#################### 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)
```



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

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

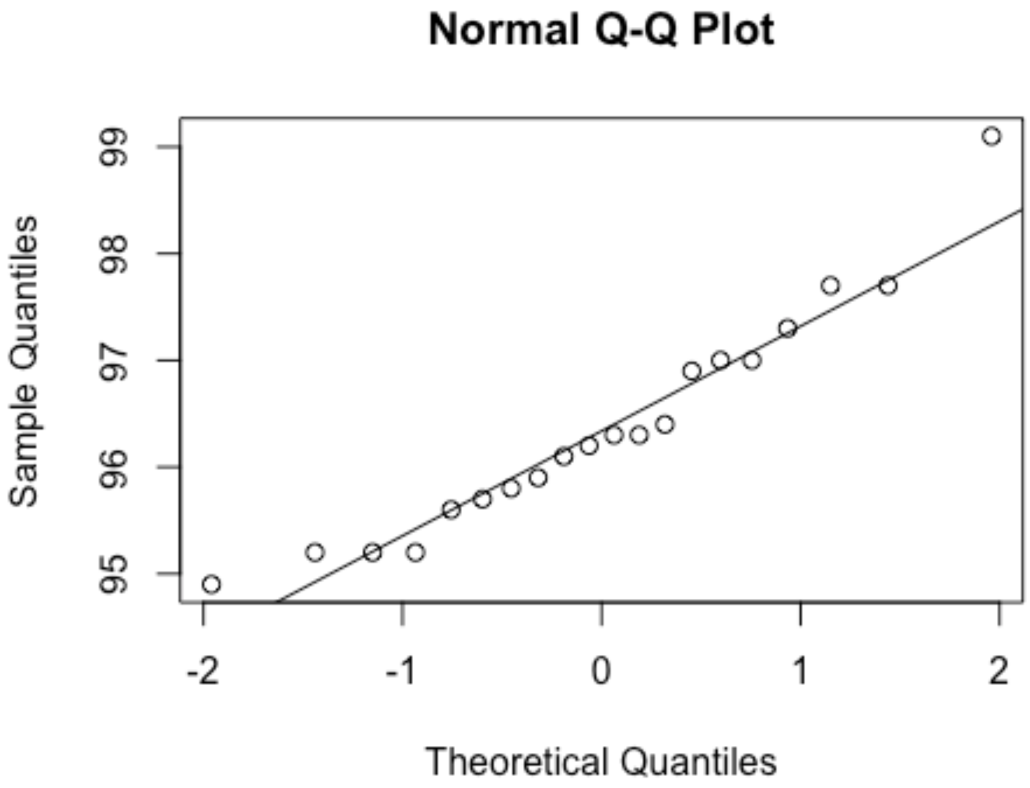
```
##
## data:  SSdata$mean.sao2.nrem
## A = 0.24673, p-value = 0.7391

#normal

#ANOVA
night_tx_difference <- anova(lm(mean.sao2.nrem ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: mean.sao2.nrem
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.812 0.81225  0.8438 0.3644
## night               1  0.992 0.99225  1.0308 0.3167
## intervention:night  1  0.090 0.09025  0.0938 0.7612
## Residuals          36 34.653 0.96258

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.nrem,
       subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.nrem,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.nrem and
subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.nrem
## t = 1.4182, df = 19, p-value = 0.1723
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.1356036  0.7056036
## sample estimates:
## mean of the differences
##                   0.285

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   94.40   95.57   96.05   96.09   96.55   97.90

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

## [1] 0.8837123

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

## [1] 20
```

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



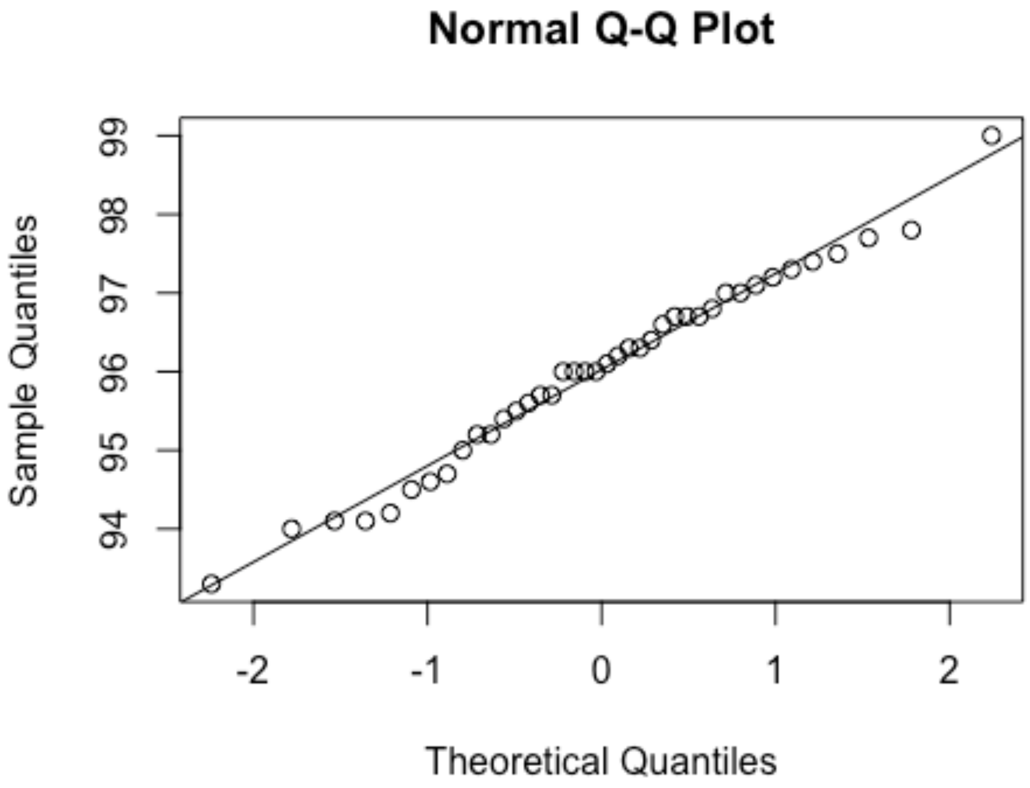
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)

##
##  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:
```

```
##  -0.3363889  0.9063889
## sample estimates:
## mean of x mean of y
##    96.375    96.090

#################### Mean SaO2 REM #######################
#Summary
summary(SSdata$mean.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   93.30   95.20   96.05   96.02   96.85   99.00

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

## [1] 1.234244

length(SSdata$mean.sao2.rem)

## [1] 40

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



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

```
##
##  Anderson-Darling normality test
##
## data:  SSdata$mean.sao2.rem
## A = 0.23901, p-value = 0.7646
```

```r
#normal

#ANOVA
night_tx_difference <- anova(lm(mean.sao2.rem ~ intervention * night,
                                data = SSdata))
night_tx_difference
```

```
## Analysis of Variance Table
##
## Response: mean.sao2.rem
##                      Df Sum Sq Mean Sq F value Pr(>F)
## intervention          1  2.116  2.1160  1.4834 0.2312
## night                 1  3.025  3.0250  2.1206 0.1540
## intervention:night    1  2.916  2.9160  2.0442 0.1614
## Residuals            36 51.354  1.4265
```

```r
#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.rem,
       subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.rem,
       paired = TRUE)
```

```
##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.rem and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.rem
## t = 1.5919, df = 19, p-value = 0.1279
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.1447888  1.0647888
## sample estimates:
## mean of the differences
##                    0.46
```

```r
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
```

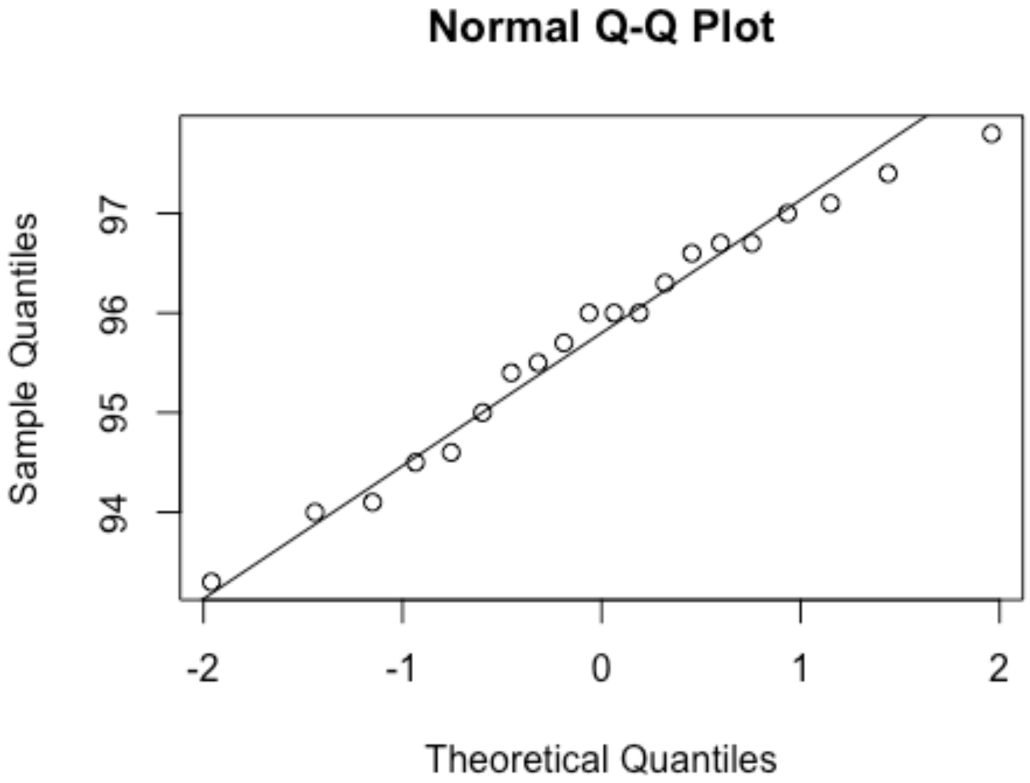
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   93.30   94.90   96.00   95.78   96.70   97.80
```

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

```
## [1] 1.229581
```

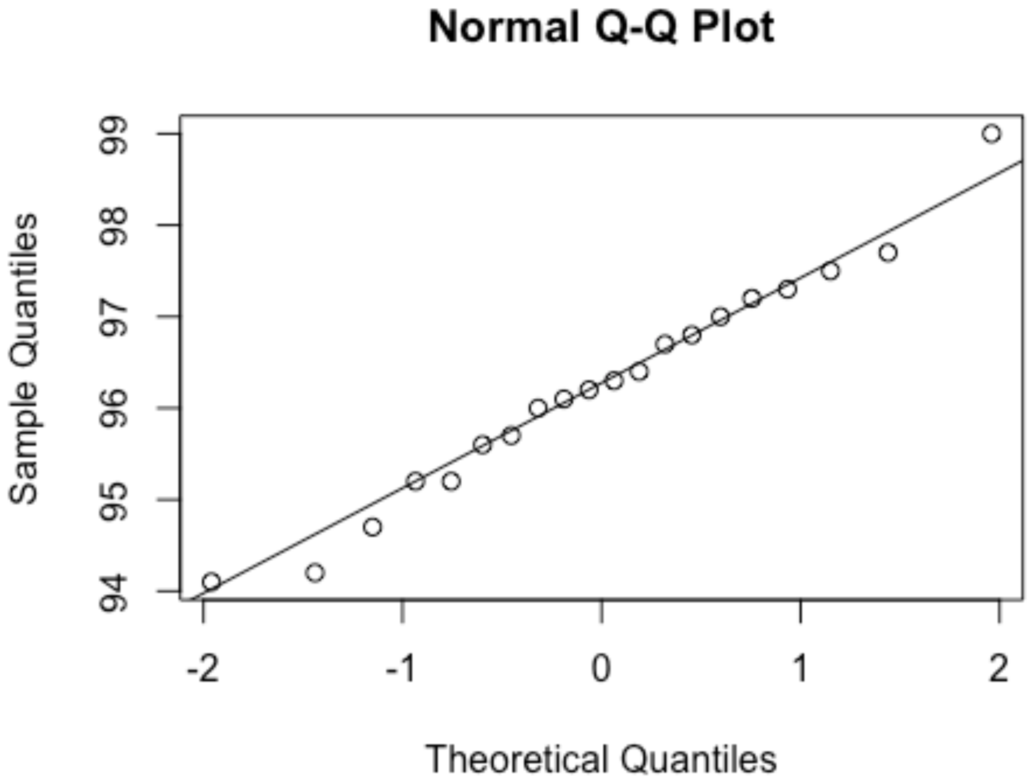
```r
length(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)
```

```
## [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)
```

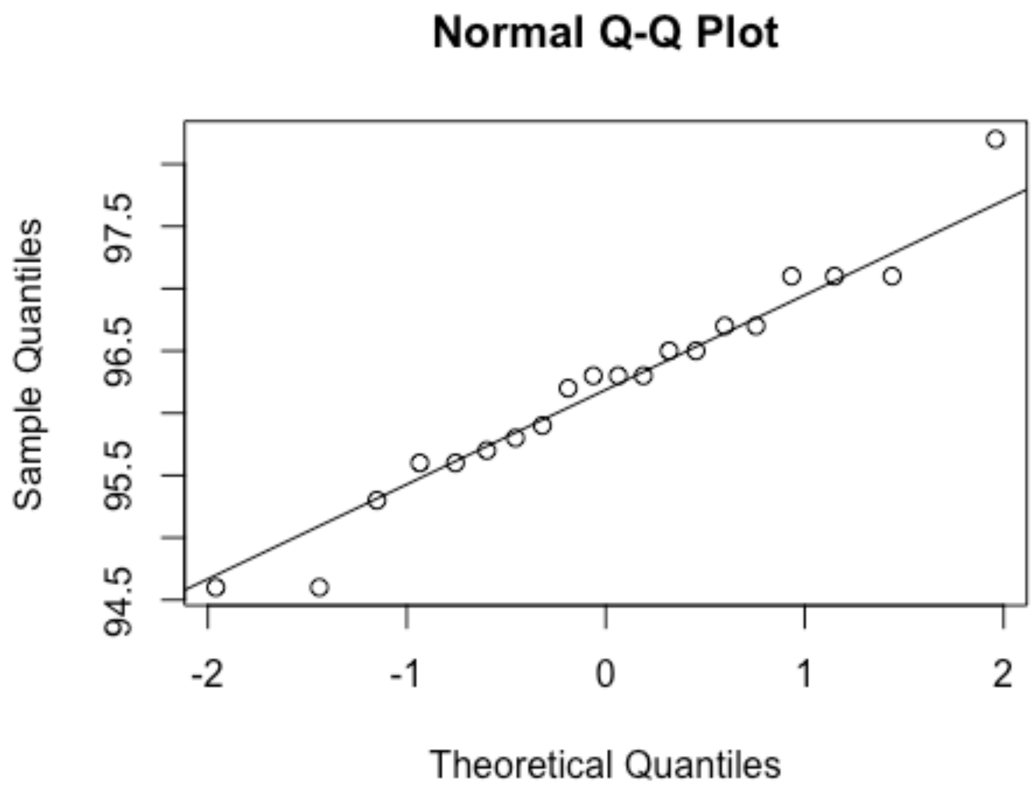
```
## [1] 20

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")$mean.sao2.rem and subset(SSd
ata, intervention == "PrenaBelt")$mean.sao2.rem
## t = 1.1847, df = 38, p-value = 0.2435
```

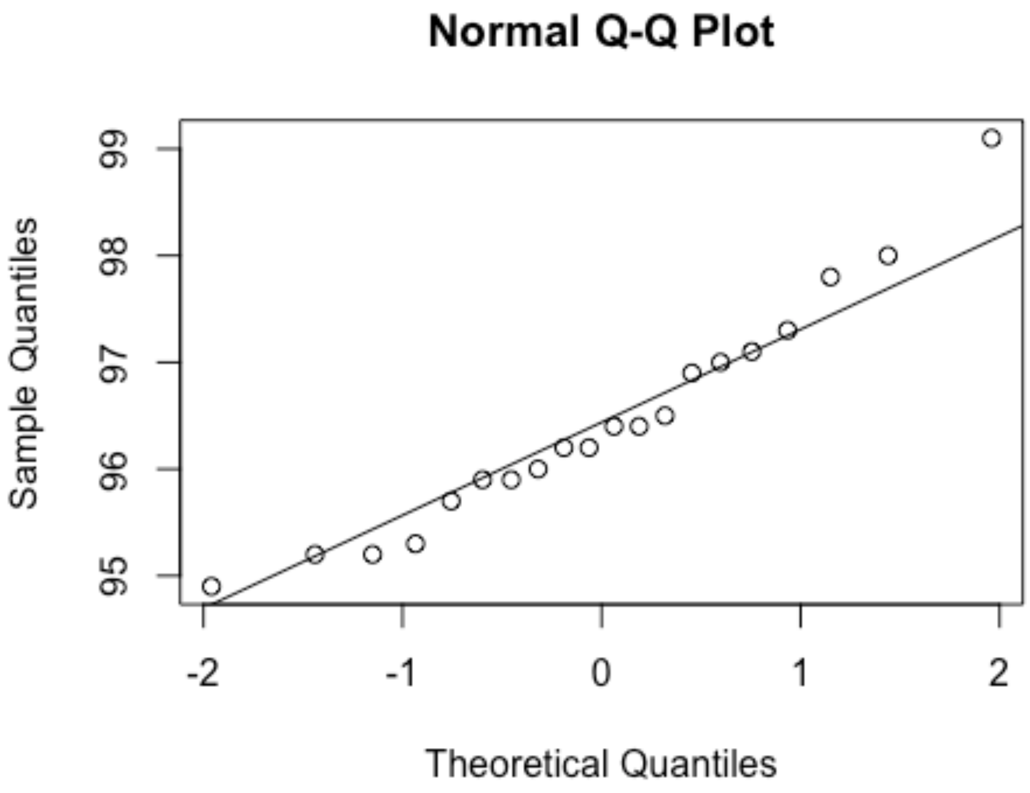
```
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.3260709  1.2460709
## sample estimates:
## mean of x mean of y
##    96.245    95.785

#################### Mean SaO2 TST #######################
#Summary
summary(SSdata$mean.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   94.60   95.70   96.30   96.33   96.93   99.10

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

## [1] 0.9626319

length(SSdata$mean.sao2.tst)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(mean.sao2.tst ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: mean.sao2.tst
##                     Df Sum Sq Mean Sq F value Pr(>F)
## intervention         1  0.600 0.60025  0.6241 0.4347
## night                1  0.870 0.87025  0.9048 0.3479
## intervention:night   1  0.042 0.04225  0.0439 0.8352
## Residuals           36 34.627 0.96186

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.tst,
       subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.tst,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.tst and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.tst
## t = 1.3161, df = 19, p-value = 0.2038
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.1446432  0.6346432
## sample estimates:
```

```
## mean of the differences
##                   0.245

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   94.60   95.68   96.30   96.20   96.70   98.20

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

## [1] 0.8672249

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

## [1] 20

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



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

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

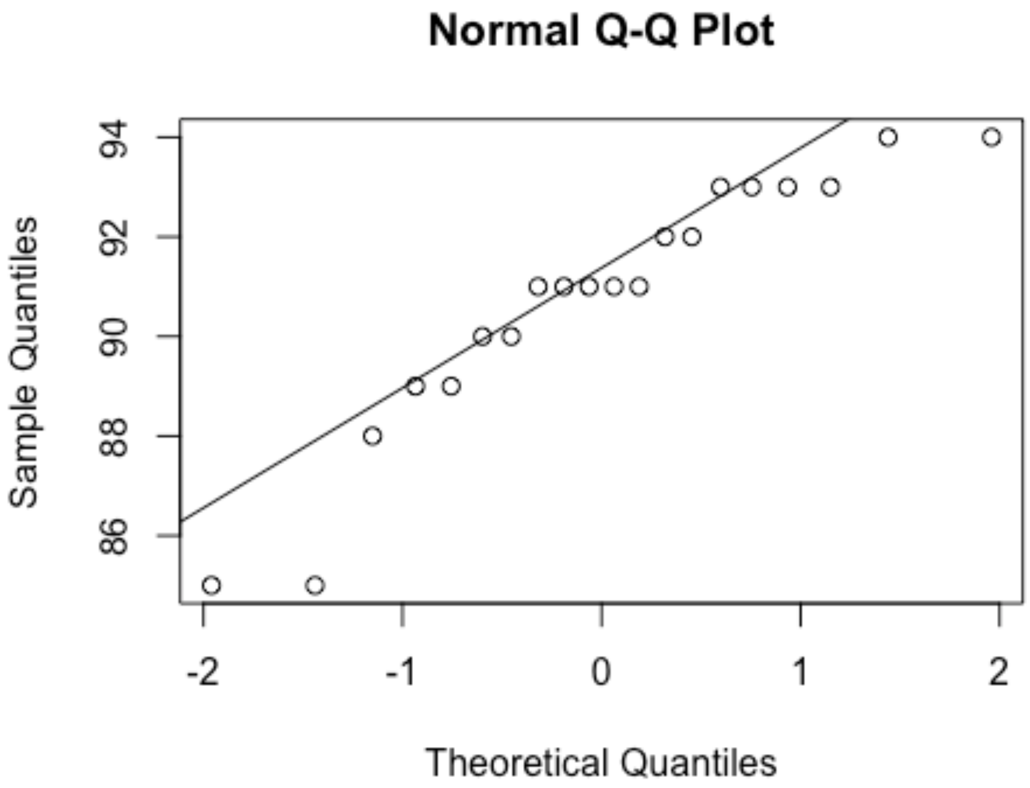
```
## data:  subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst
## A = 0.2726, p-value = 0.6304

#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)
```



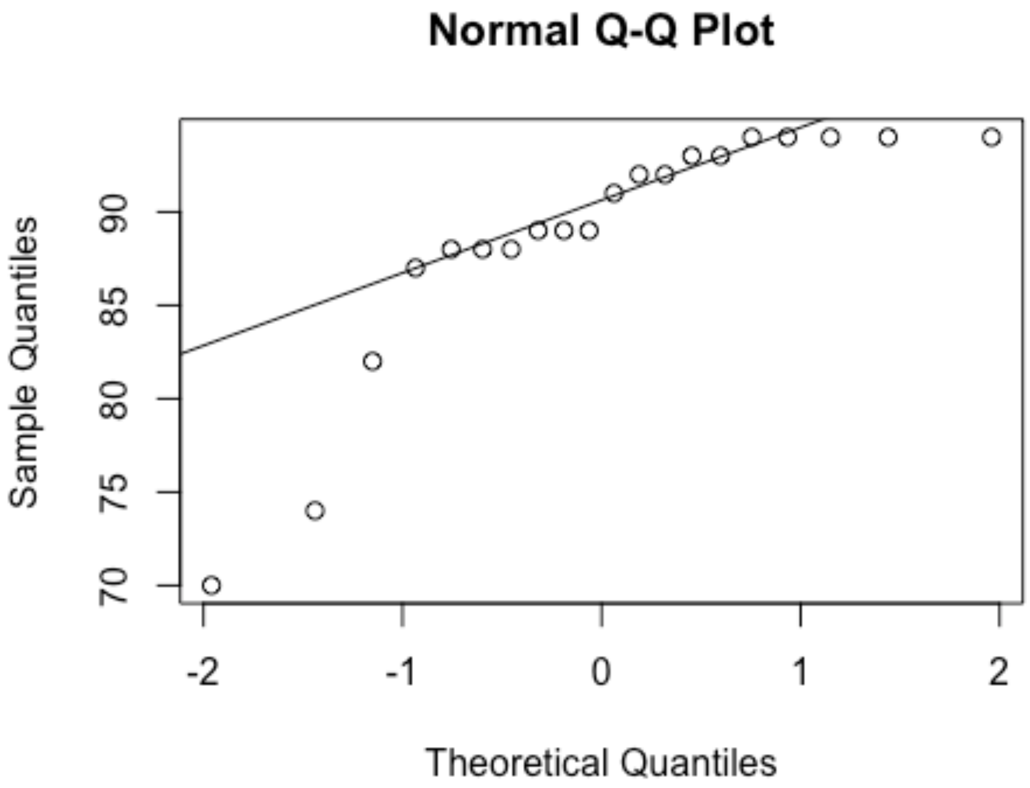
```
ad.test(subset(SSdata, intervention == "sham")$mean.sao2.tst)

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

```
##
## data:  subset(SSdata, intervention == "sham")$mean.sao2.tst
## A = 0.30299, p-value = 0.5413

#normal

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

##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$mean.sao2.tst and subset(SSd
ata, intervention == "PrenaBelt")$mean.sao2.tst
## t = 0.80113, df = 36.596, p-value = 0.4282
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.3748781  0.8648781
## sample estimates:
## mean of x mean of y
##    96.450    96.205

#################### Min SaO2 AWAKE #######################
#Summary
summary(SSdata$min.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   70.00   88.75   91.00   89.75   93.00   94.00

sd(SSdata$min.sao2.awake, na.rm = TRUE)

## [1] 5.026851

length(SSdata$min.sao2.awake)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(min.sao2.awake ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: min.sao2.awake
##                     Df Sum Sq Mean Sq F value  Pr(>F)
## intervention         1   40.0   40.00  1.8391 0.18350
## night                1   25.6   25.60  1.1770 0.28518
## intervention:night   1  136.9  136.90  6.2943 0.01676 *
## Residuals           36  783.0   21.75
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.awake,
       subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.awake,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.awake, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.awake, : cannot compute exact confidence interval with
## ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.awake, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.awake, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.awake and
subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.awake
## V = 53, p-value = 0.1609
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.9999632  0.5000467
## sample estimates:
## (pseudo)median
##       -1.49991

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   85.00   89.75   91.00   90.75   93.00   94.00

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

## [1] 2.572629

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

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
```

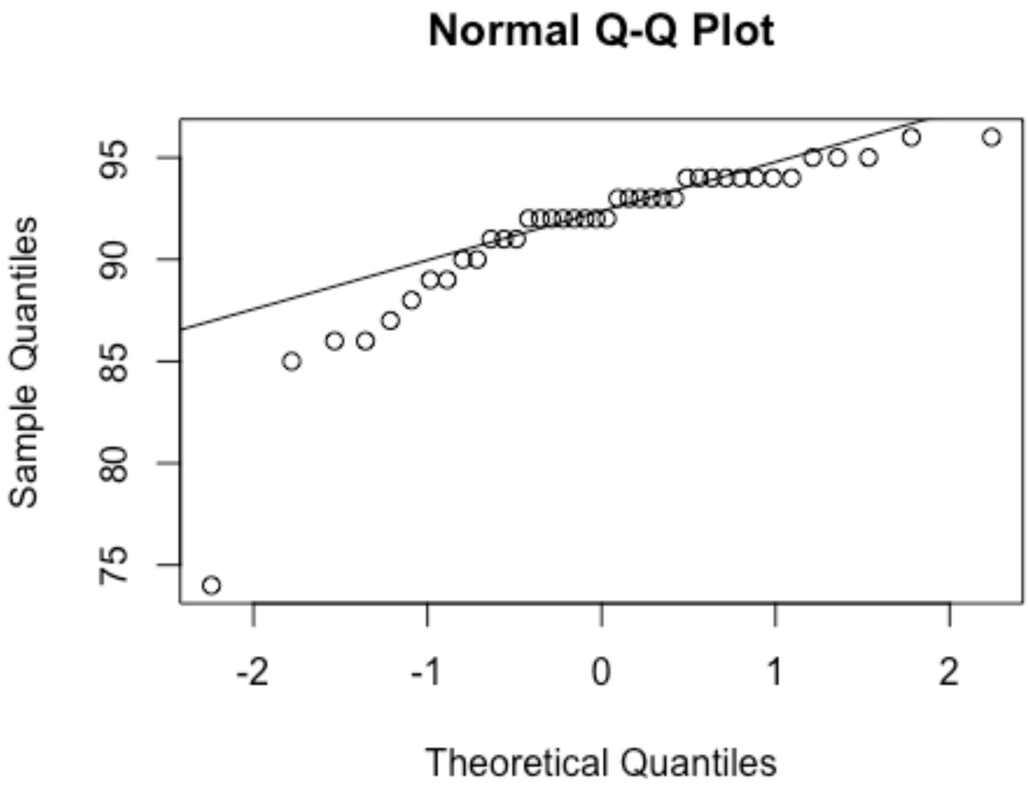


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)

##
##  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)
```



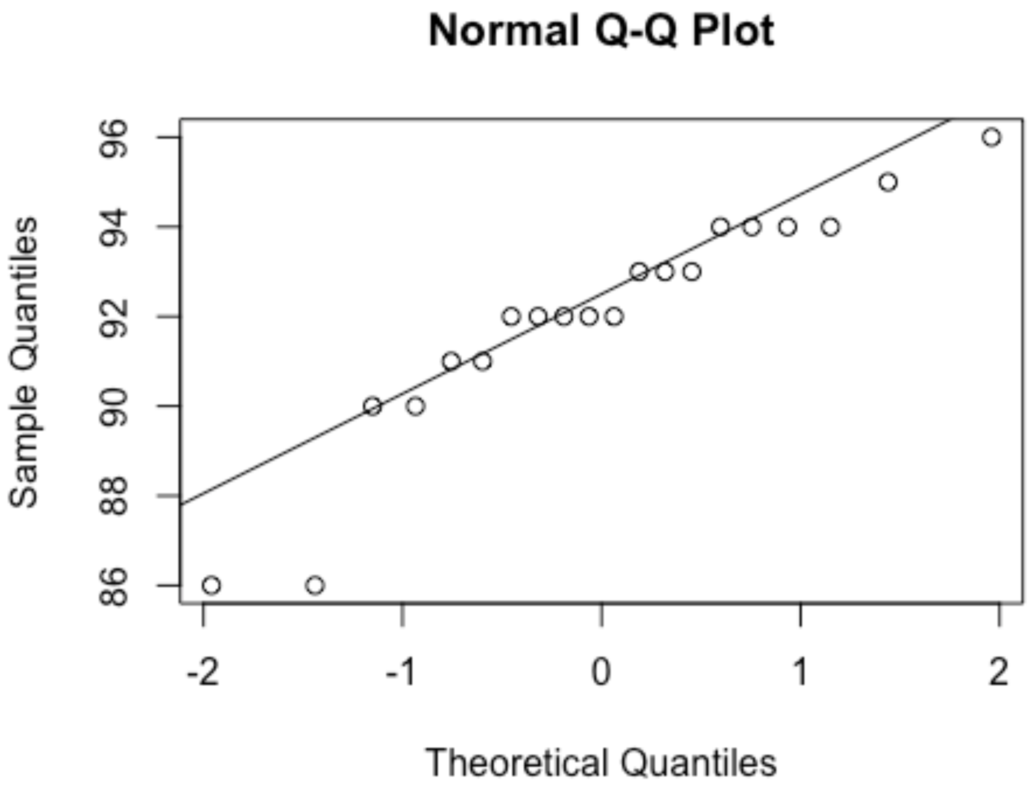
```
ad.test(subset(SSdata, intervention == "sham")$min.sao2.awake)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$min.sao2.awake
## A = 1.7154, p-value = 0.0001417

#non-normal

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
```

```
data, intervention == "PrenaBelt")$min.sao2.awake
## W = 184, p-value = 0.6726
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.999945  1.000048
## sample estimates:
## difference in location
##          -7.483333e-05

#################### Min SaO2 NREM #######################
#Summary
summary(SSdata$min.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   74.00   90.75   92.00   91.50   94.00   96.00

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

## [1] 3.928854

length(SSdata$min.sao2.nrem)

## [1] 40

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

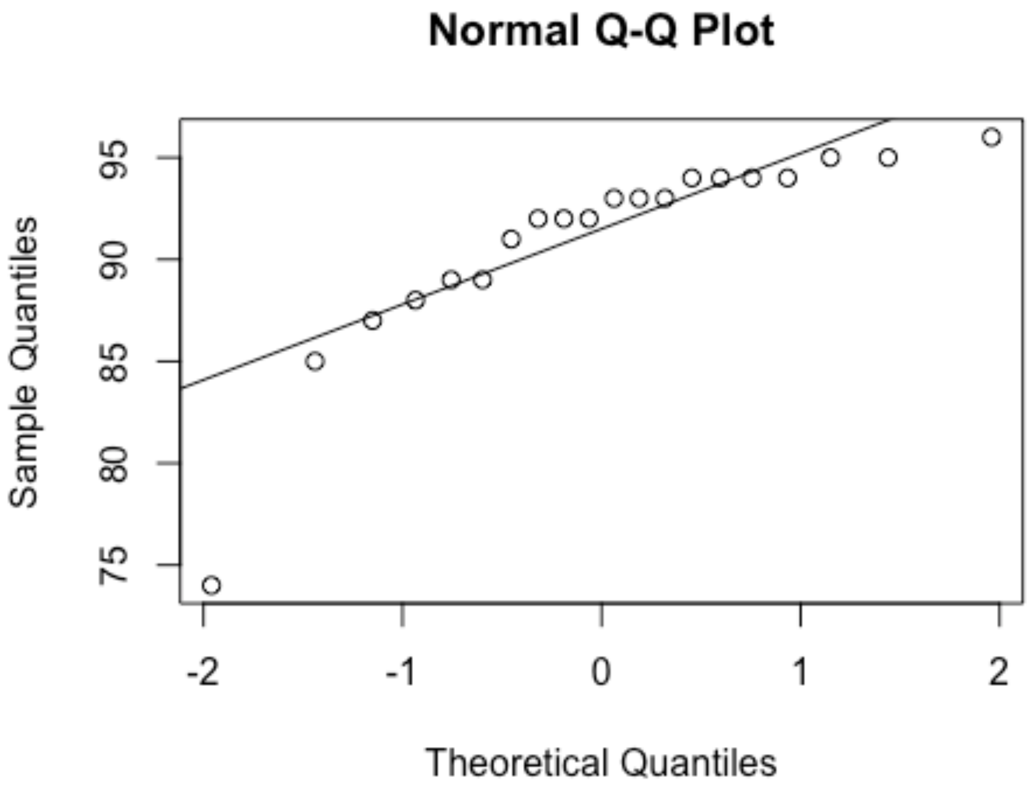


```
ad.test(SSdata$min.sao2.nrem)

##
##  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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.nrem,
       subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.nrem,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.nrem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.nrem, : cannot compute exact confidence interval with tie
s

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.nrem, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.nrem, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.nrem and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.nrem
## V = 46, p-value = 0.26
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.4999583  0.5000763
## sample estimates:
## (pseudo)median
##      -0.500039

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      86      91      92      92      94      96

sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

## [1] 2.575185

length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

## [1] 20

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

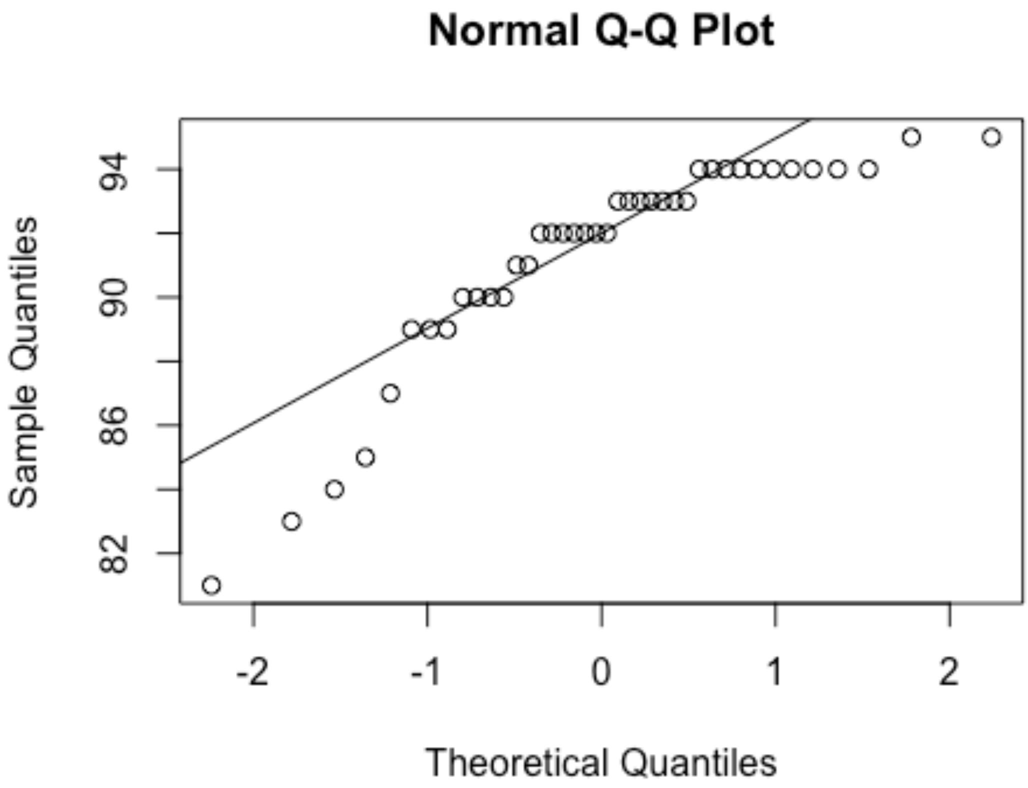


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

##
##  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)
```



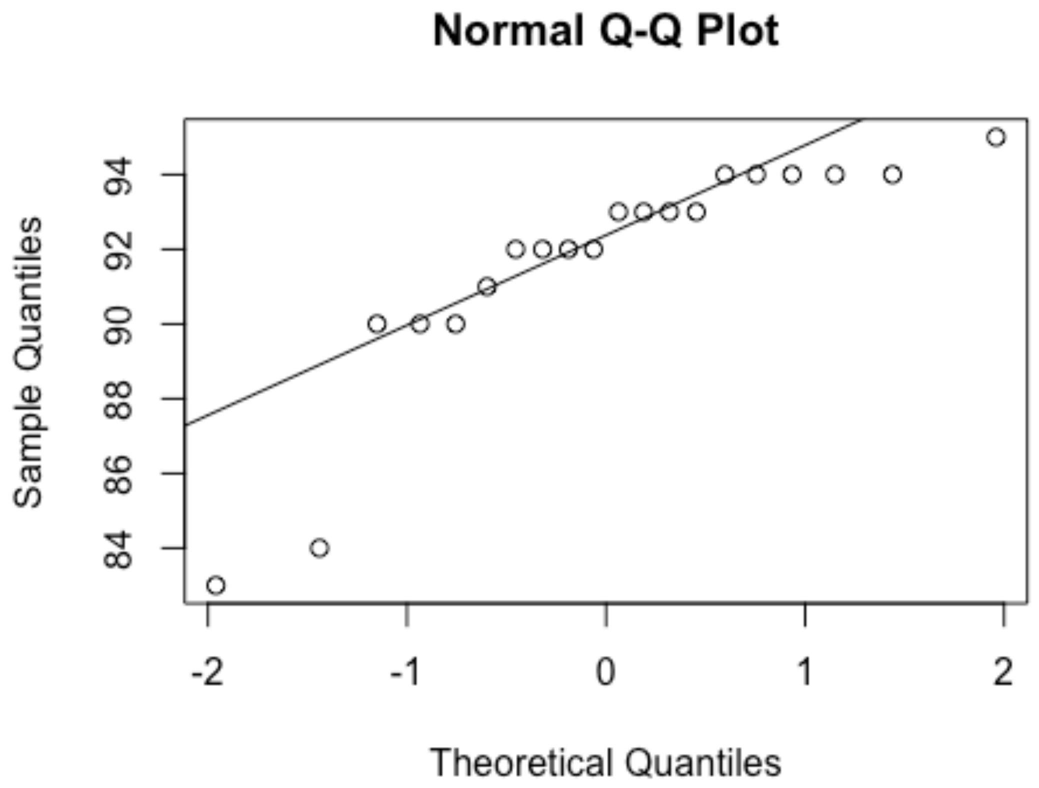
```
ad.test(subset(SSdata, intervention == "sham")$min.sao2.nrem)

##
##  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
```

```
ata, intervention == "PrenaBelt")$min.sao2.nrem
## W = 196.5, p-value = 0.9347
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.000016  1.999967
## sample estimates:
## difference in location
##          -3.487271e-05

#################### Min SaO2 REM #######################
#Summary
summary(SSdata$min.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   81.00   90.00   92.00   91.35   94.00   95.00

sd(SSdata$min.sao2.rem, na.rm = TRUE)

## [1] 3.332436

length(SSdata$min.sao2.rem)

## [1] 40

qqnorm(SSdata$min.sao2.rem)
qqline(SSdata$min.sao2.rem)
```

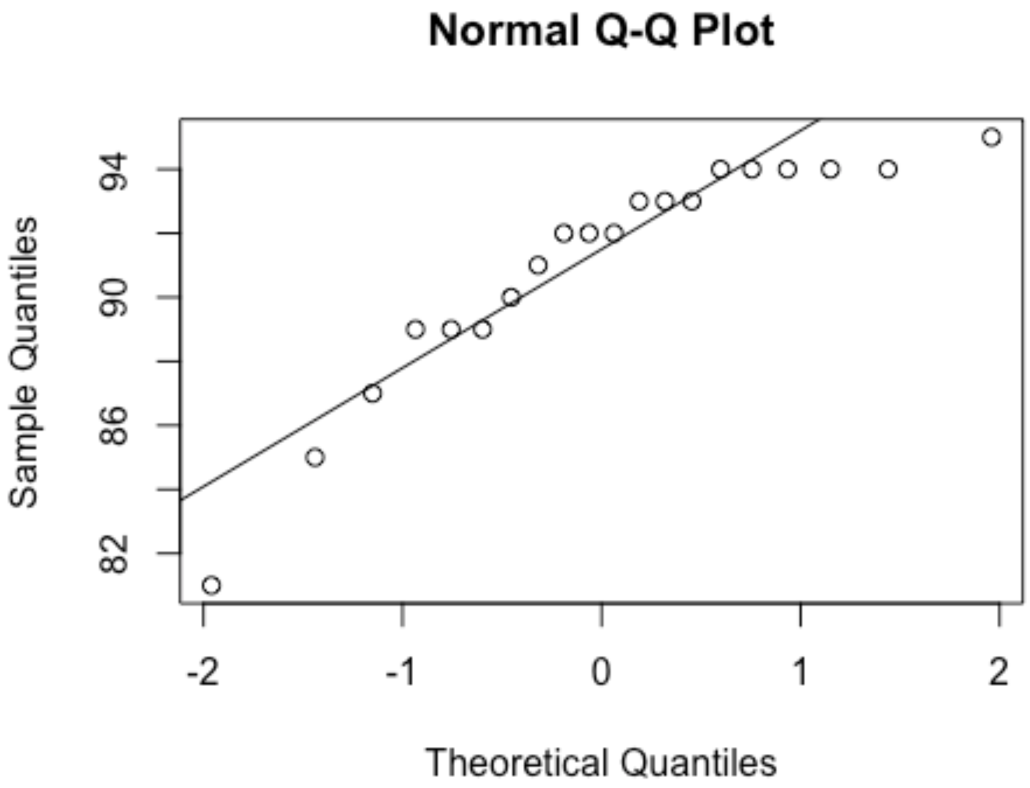


```
ad.test(SSdata$min.sao2.rem)

##
##  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
```

```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.rem,
            subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.rem
,
            paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.rem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.rem, : cannot compute exact confidence interval with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.rem, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.rem, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.rem and su
bset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.rem
## V = 45, p-value = 0.4029
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.4999536  0.9999402
## sample estimates:
## (pseudo)median
##     -0.4999916

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   83.00   90.75   92.50   91.65   94.00   95.00

sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

## [1] 3.150188

length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

## [1] 20

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



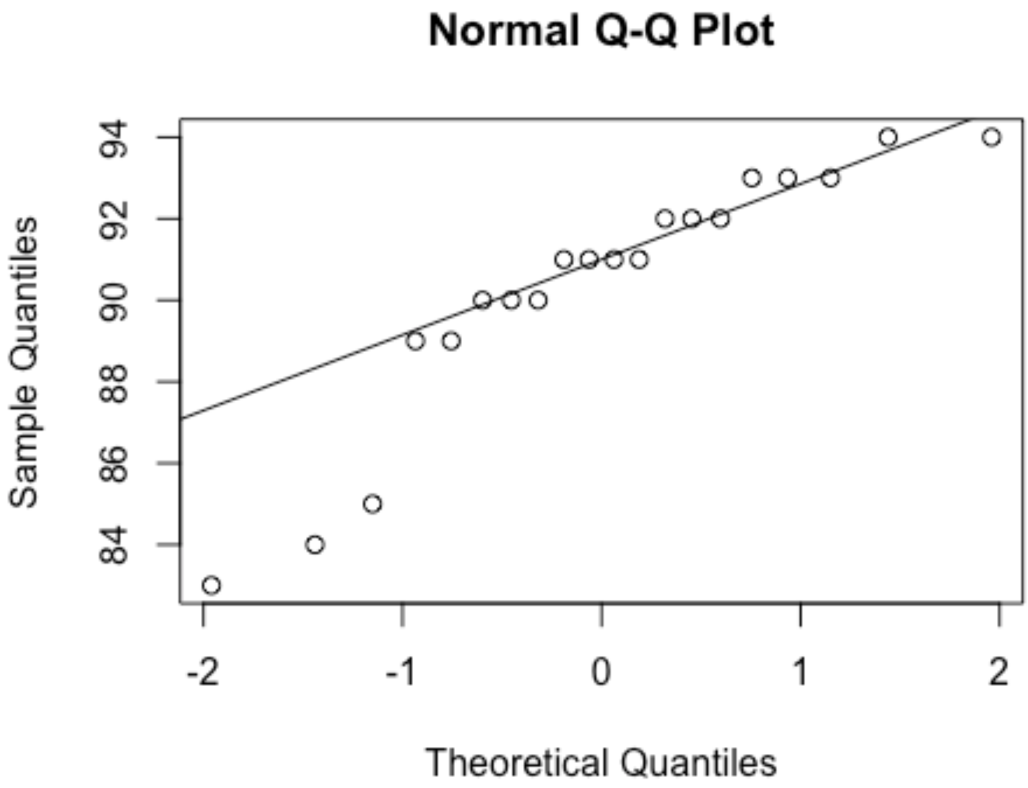
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

##
##  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)
```



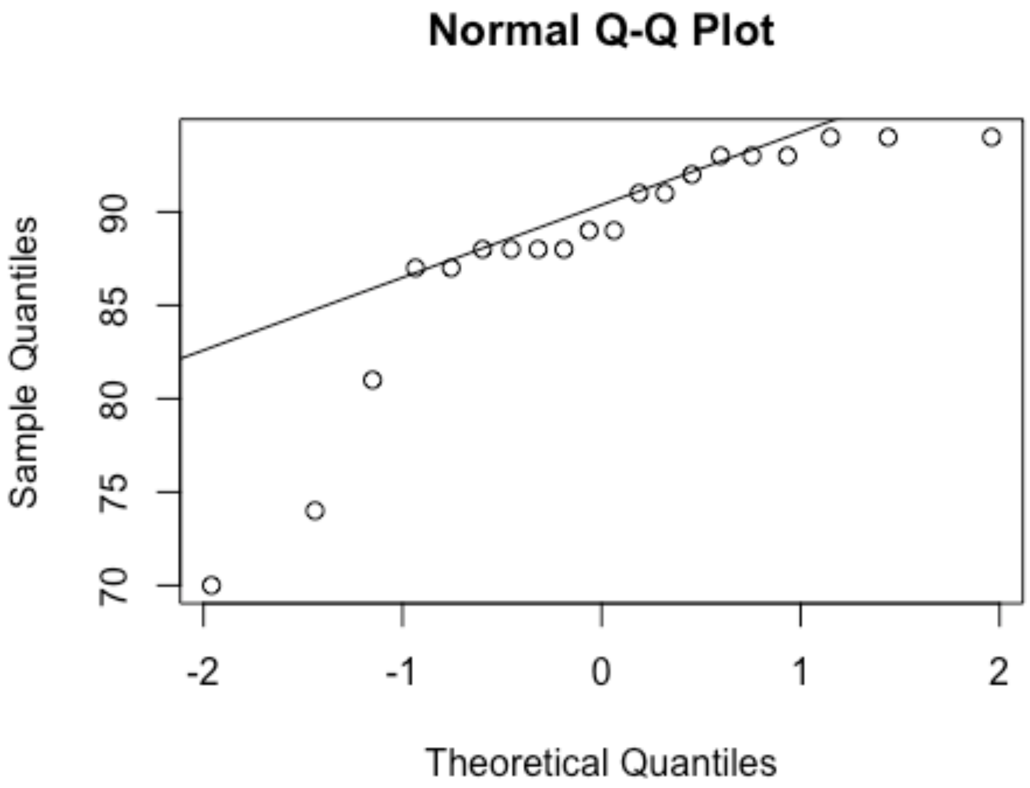
```
ad.test(subset(SSdata, intervention == "sham")$min.sao2.rem)

##
##  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
```

```
ta, intervention == "PrenaBelt")$min.sao2.rem
## W = 181, p-value = 0.6118
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.000020  1.000041
## sample estimates:
## difference in location
##          -6.982535e-05

#################### Min SaO2 TST #######################
#Summary
summary(SSdata$min.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   70.00   88.00   91.00   89.28   93.00   94.00 

sd(SSdata$min.sao2.tst, na.rm = TRUE)

## [1] 5.11402

length(SSdata$min.sao2.tst)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(min.sao2.tst ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
## 
## Response: min.sao2.tst
##                    Df Sum Sq Mean Sq F value  Pr(>F)  
## intervention        1  46.22  46.225  2.0356 0.16227  
## night               1  15.63  15.625  0.6881 0.41229  
## intervention:night  1 140.62 140.625  6.1927 0.01759 *
## Residuals          36 817.50  22.708                  
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.tst,
       subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.tst,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.tst, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.tst, : cannot compute exact confidence interval with ties
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.tst, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.tst, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.tst and su
bset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.tst
## V = 45, p-value = 0.07952
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.999980e+00  6.891261e-05
## sample estimates:
## (pseudo)median
##      -1.500056

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   83.00   89.75   91.00   90.35   92.25   94.00

sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

## [1] 3.116594

length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
```



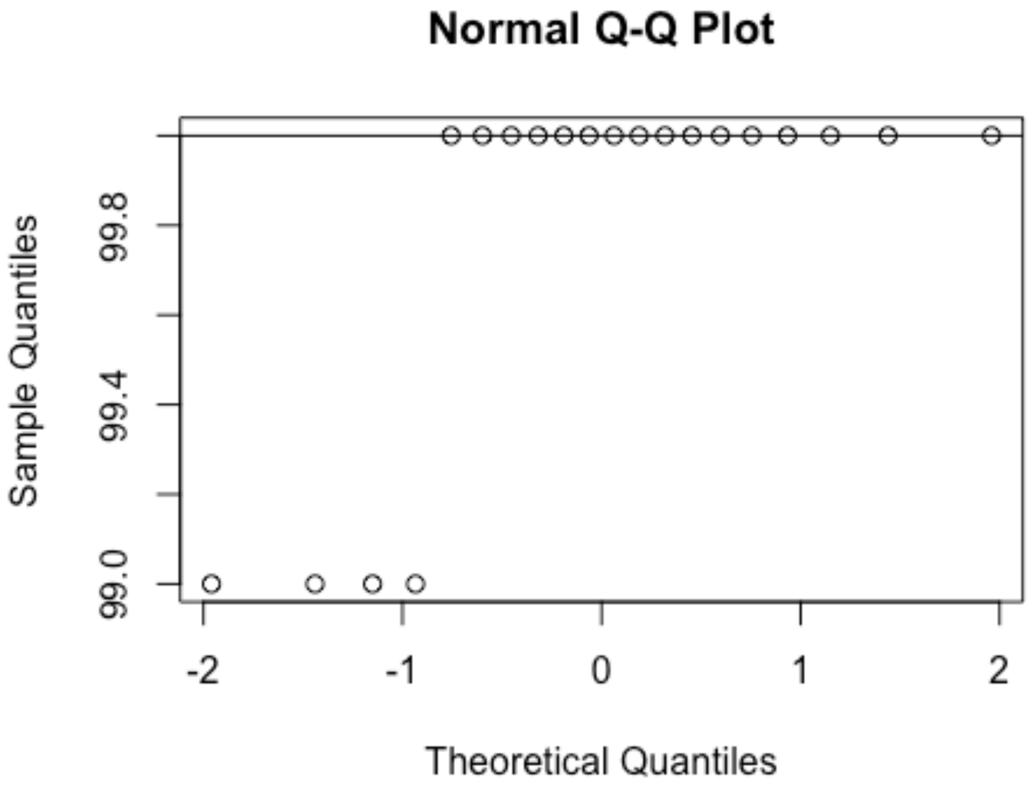
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

##
##  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
```

```
ta, intervention == "PrenaBelt")$min.sao2.tst
## W = 166, p-value = 0.362
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.000006  1.000035
## sample estimates:
## difference in location
##              -1.000019

#################### Max SaO2 AWAKE #######################
#Summary
summary(SSdata$max.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   98.00   99.00  100.00   99.68  100.00  100.00

sd(SSdata$max.sao2.awake, na.rm = TRUE)

## [1] 0.5256254

length(SSdata$max.sao2.awake)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(max.sao2.awake ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
## 
## Response: max.sao2.awake
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.625   0.625  2.2727 0.1404
## night               1  0.025   0.025  0.0909 0.7648
## intervention:night  1  0.225   0.225  0.8182 0.3717
## Residuals          36  9.900   0.275

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.awake,
       subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.awake,
       paired = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.awake, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.awake, : cannot compute exact p-value with zeroes

## 
##  Wilcoxon signed rank test with continuity correction
```

```
##
## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.awake and
subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.awake
## V = 4, p-value = 0.0726
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    99.0   100.0   100.0    99.8   100.0   100.0

sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)

## [1] 0.4103913

length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
```



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

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake
## A = 5.1941, p-value = 2.32e-13
```

```
#non-normal

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

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   98.00   99.00  100.00   99.55  100.00  100.00
```

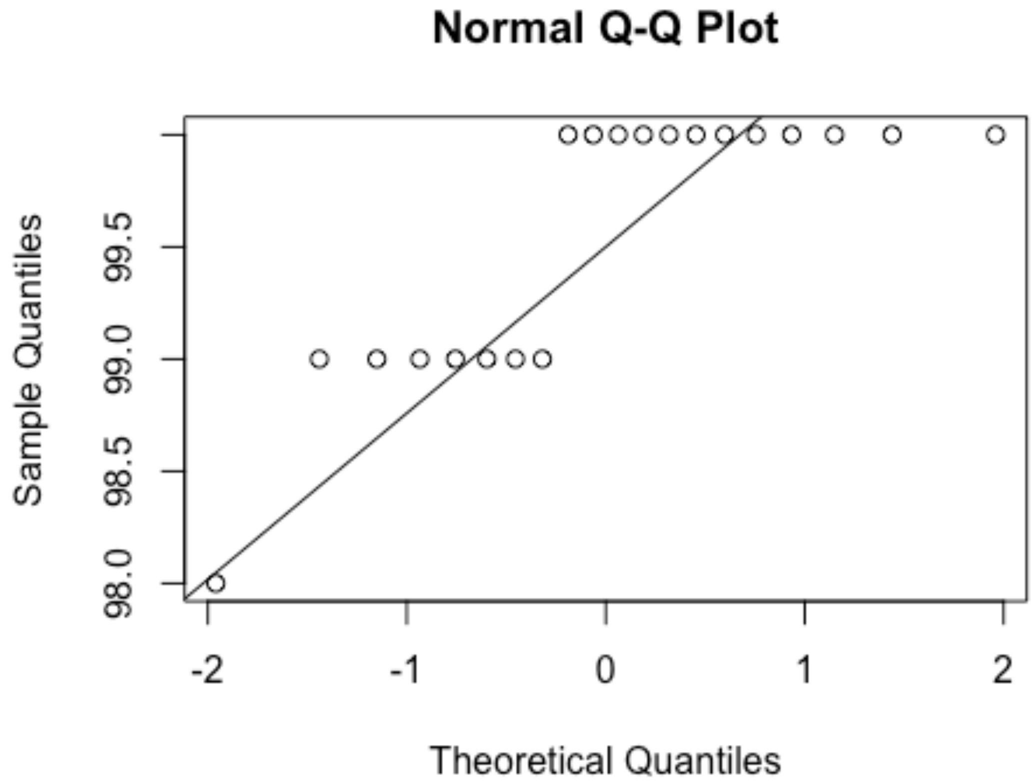
```
sd(subset(SSdata, intervention == "sham")$max.sao2.awake)
```

```
## [1] 0.6048053
```

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

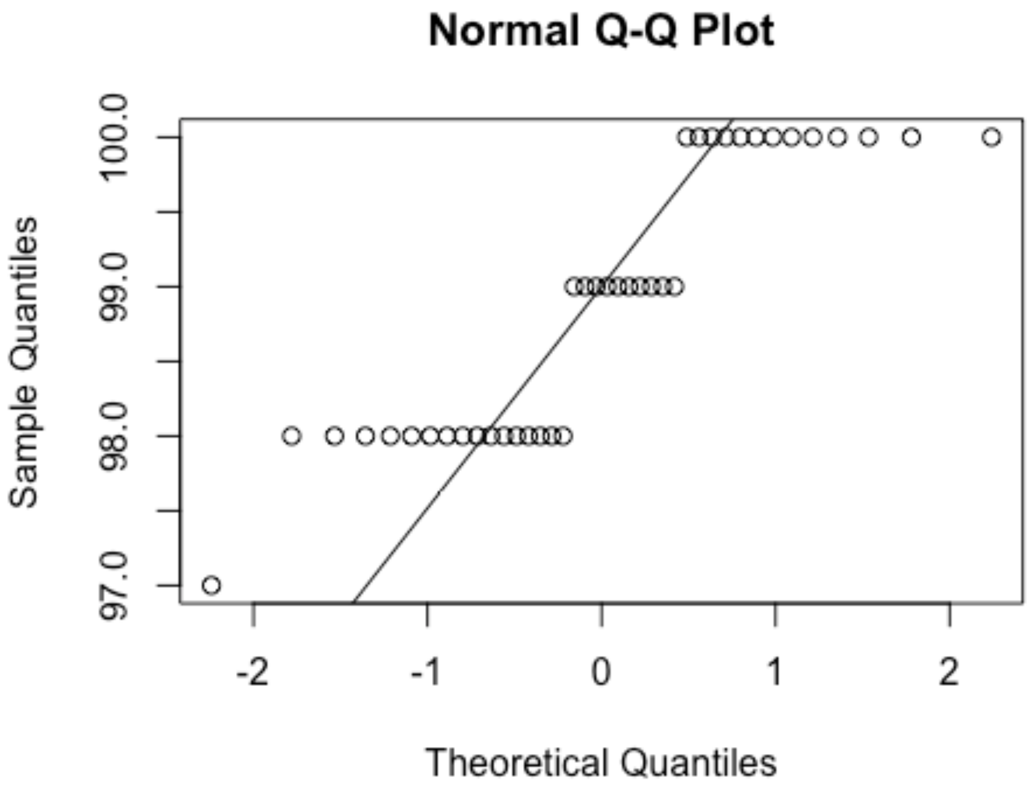
```
## [1] 20
```

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



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

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$max.sao2.awake
## A = 2.8091, p-value = 2.322e-07

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.awake,
            subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.awake, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.awake, : cannot compute exact confidence intervals with ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$max.sao2.awake and subset(SS
data, intervention == "PrenaBelt")$max.sao2.awake
## W = 158, p-value = 0.1594
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -9.999288e-01  1.199059e-06
## sample estimates:
## difference in location
##          -1.027475e-05

#################### Max SaO2 NREM #######################
#Summary
summary(SSdata$max.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   97.00   98.00   99.00   98.88  100.00  100.00

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

## [1] 0.9111137

length(SSdata$max.sao2.nrem)

## [1] 40

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



```
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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.nrem,
                  subset(SSdataCompletes, intervention == "PrenaBelt")$max.sa
o2.nrem,
                 paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : requested conf.level not achievable

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : cannot compute exact confidence interval with tie
s

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.nrem and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.nrem
## V = 20, p-value = 0.4575
## alternative hypothesis: true location shift is not equal to 0
## 90 percent confidence interval:
##  -1.499922  1.000000
## sample estimates:
## (pseudo)median
##     -0.4999789
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   98.00   98.00   99.00   98.95  100.00  100.00
```

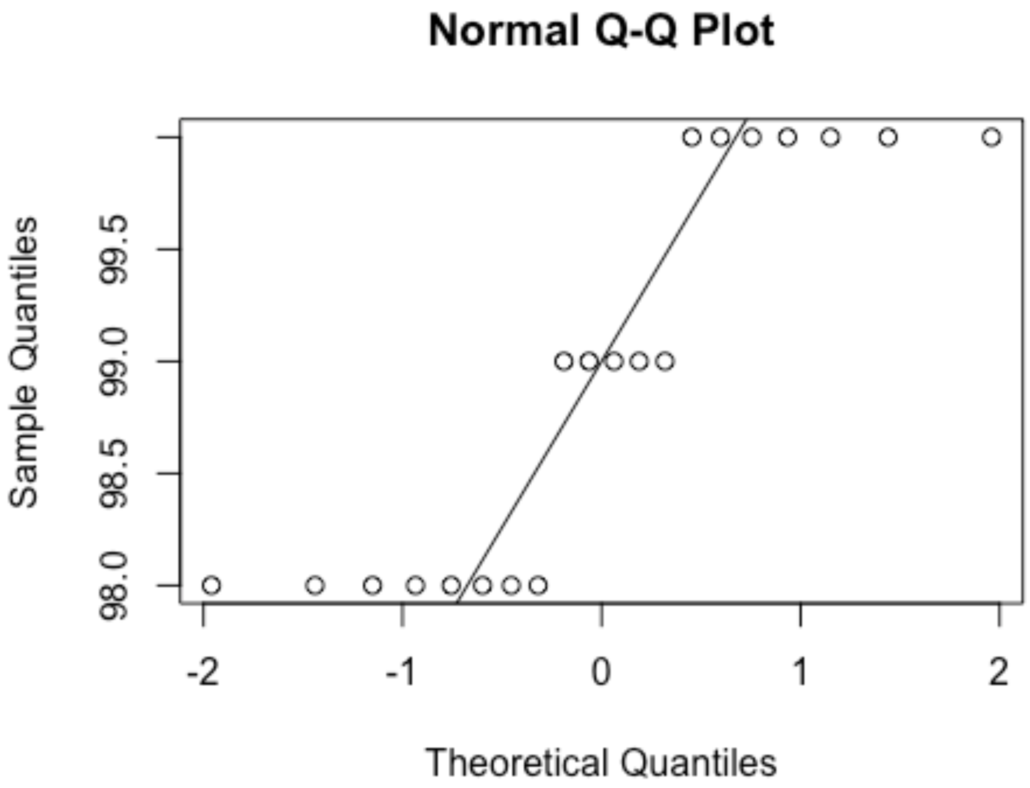
```
sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
```

```
## [1] 0.8870412
```

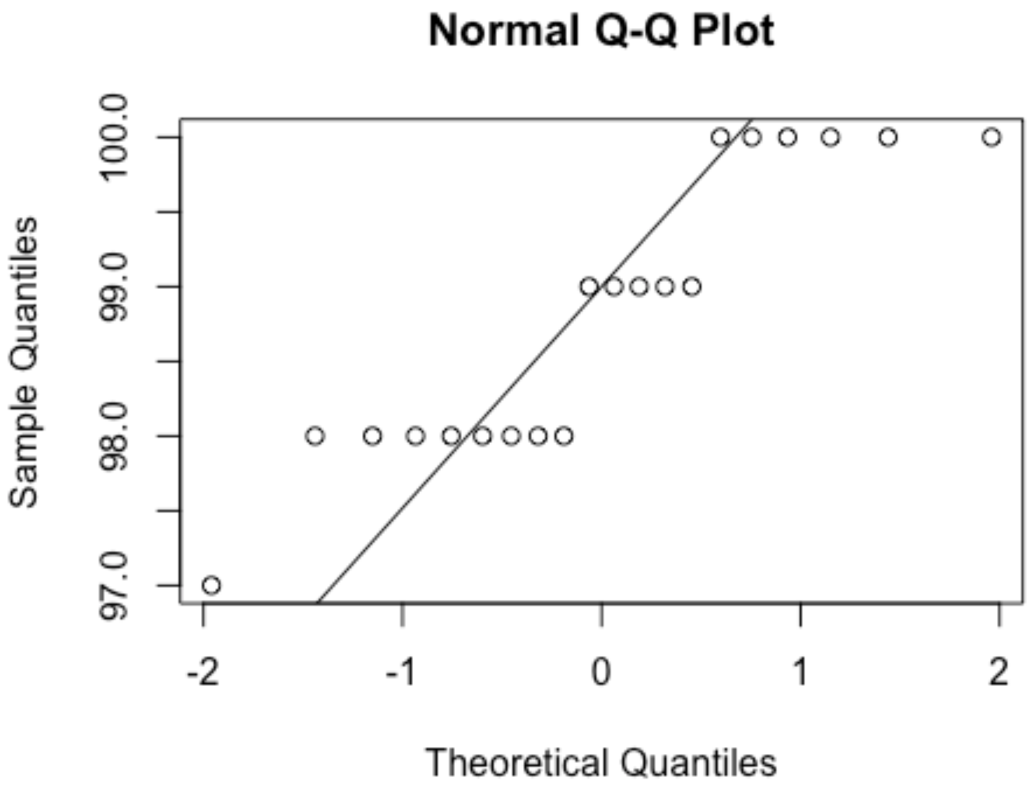
```
length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)
```

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

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

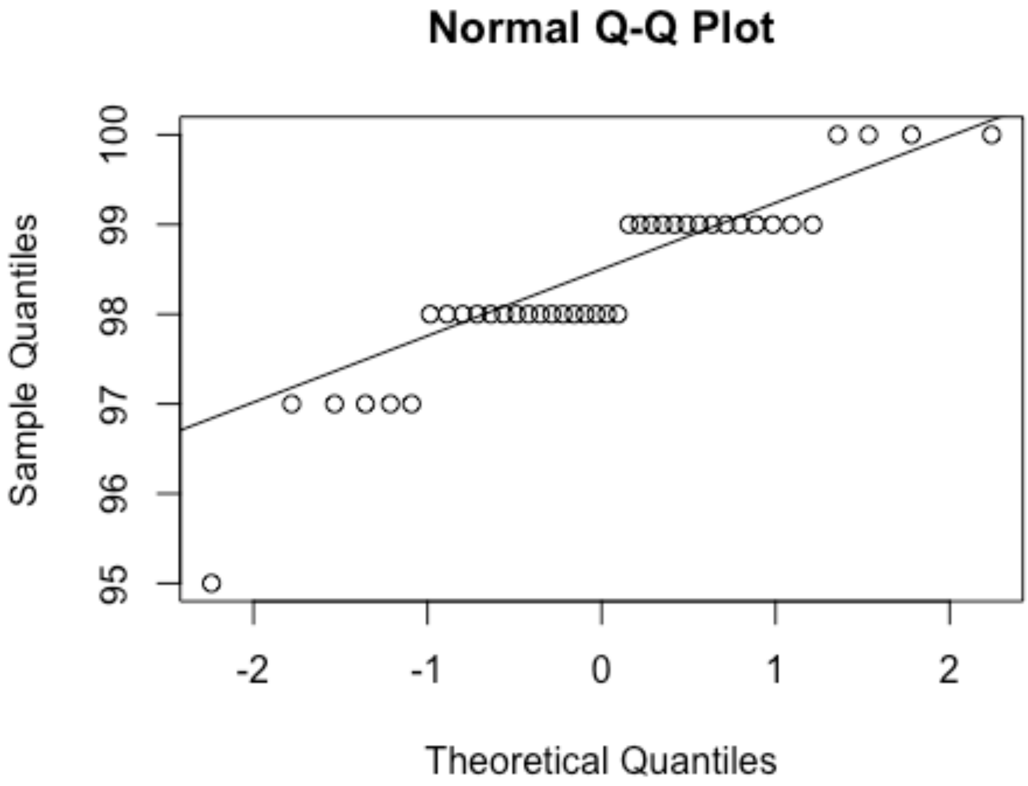


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)

##
##  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)
```



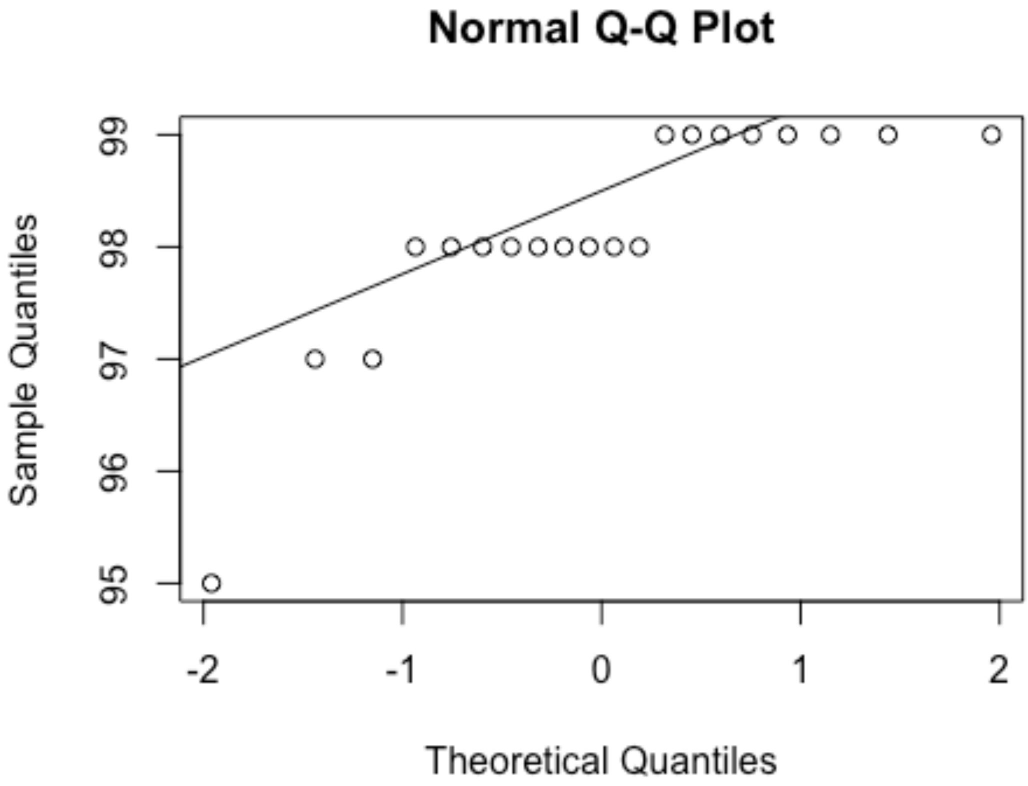
```
ad.test(subset(SSdata, intervention == "sham")$max.sao2.nrem)

##
##  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
```

```
ata, intervention == "PrenaBelt")$max.sao2.nrem
## W = 183.5, p-value = 0.6458
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -9.999960e-01  6.876513e-05
## sample estimates:
## difference in location
##          -7.969806e-05

#################### Max SaO2 REM #######################
#Summary
summary(SSdata$max.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   95.00   98.00   98.00   98.35   99.00  100.00

sd(SSdata$max.sao2.rem, na.rm = TRUE)

## [1] 1.001281

length(SSdata$max.sao2.rem)

## [1] 40

qqnorm(SSdata$max.sao2.rem)
qqline(SSdata$max.sao2.rem)
```

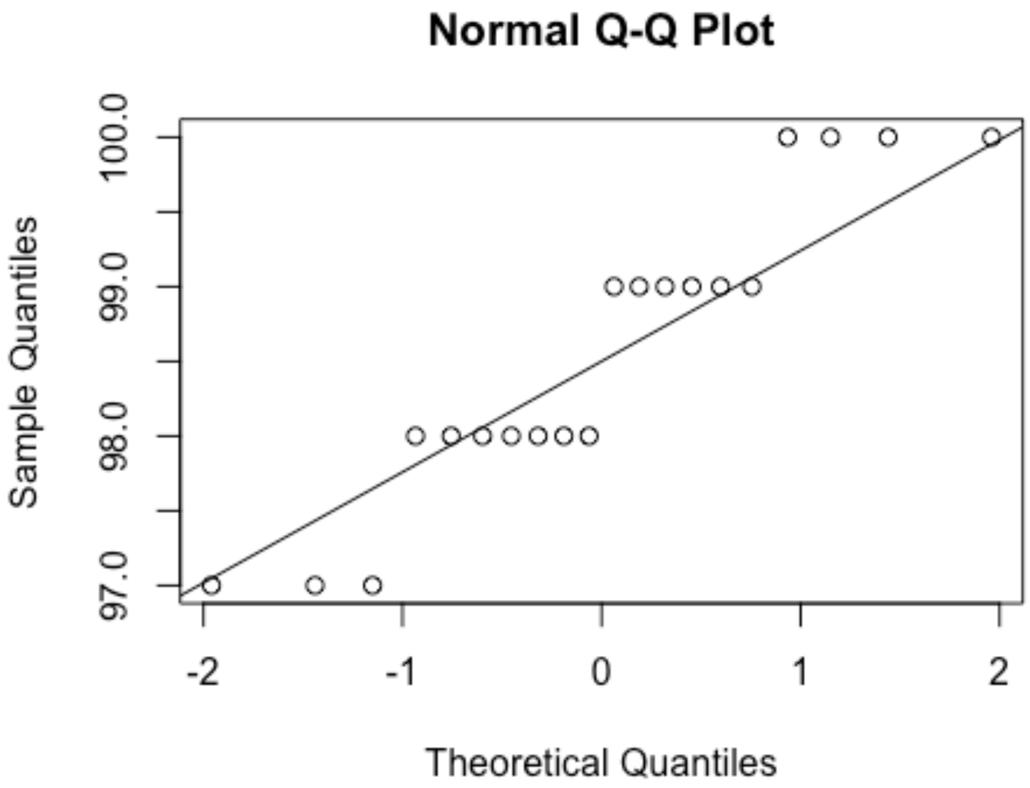


```
ad.test(SSdata$max.sao2.rem)

##
##  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
```

```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.rem,
            subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.rem
,
            paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.rem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.rem, : cannot compute exact confidence interval with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.rem, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.rem, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.rem and su
bset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.rem
## V = 78, p-value = 0.2819
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -5.341455e-06  1.000049e+00
## sample estimates:
## (pseudo)median
##   4.140595e-05

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   95.00   98.00   98.00   98.15   99.00   99.00

sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

## [1] 0.9880869

length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

## [1] 20

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



```
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
```

```
ta, intervention == "PrenaBelt")$max.sao2.rem
## W = 234.5, p-value = 0.3298
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -5.707564e-05  9.999595e-01
## sample estimates:
## difference in location
##           5.182881e-05

#################### Max SaO2 TST #######################
#Summary
summary(SSdata$max.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   98.00   99.00  100.00   99.68  100.00  100.00

sd(SSdata$max.sao2.tst, na.rm = TRUE)

## [1] 0.5256254

length(SSdata$max.sao2.tst)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(max.sao2.tst ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: max.sao2.tst
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.625   0.625  2.2727 0.1404
## night               1  0.025   0.025  0.0909 0.7648
## intervention:night  1  0.225   0.225  0.8182 0.3717
## Residuals          36  9.900   0.275

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.tst,
            subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.tst
,
            paired = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.tst, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.tst, : cannot compute exact p-value with zeroes
```

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.tst and su
bset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.tst
## V = 4, p-value = 0.0726
## alternative hypothesis: true location shift is not equal to 0
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    99.0   100.0   100.0    99.8   100.0   100.0
```

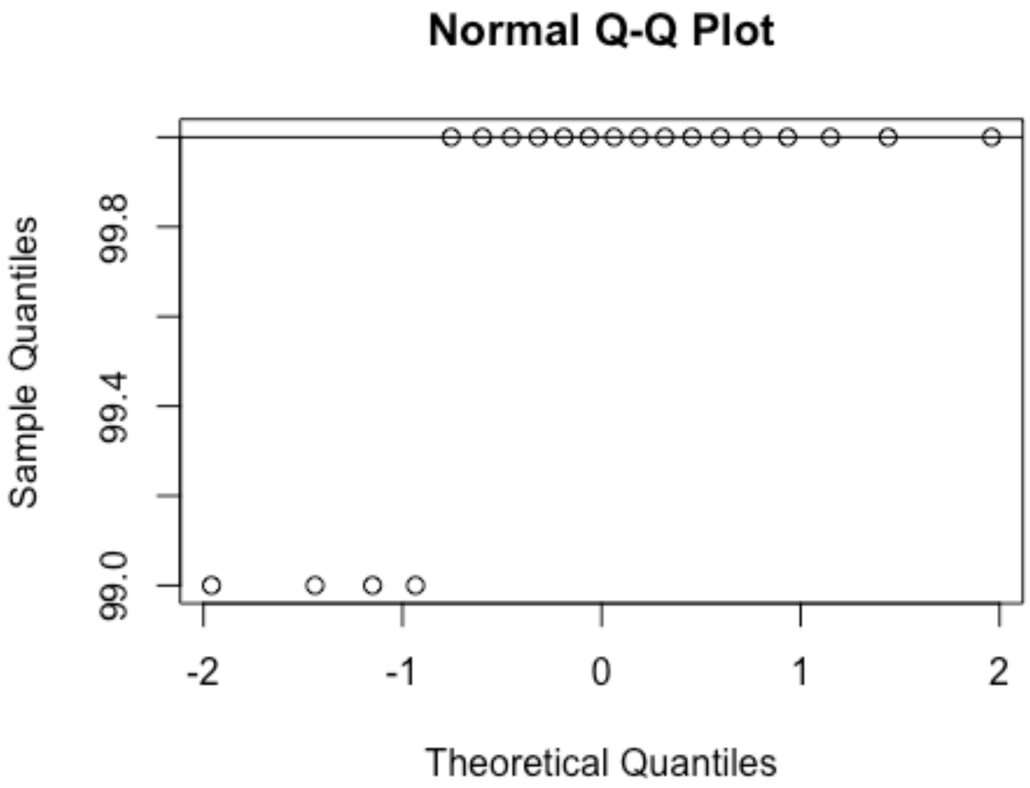
```
sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
```

```
## [1] 0.4103913
```

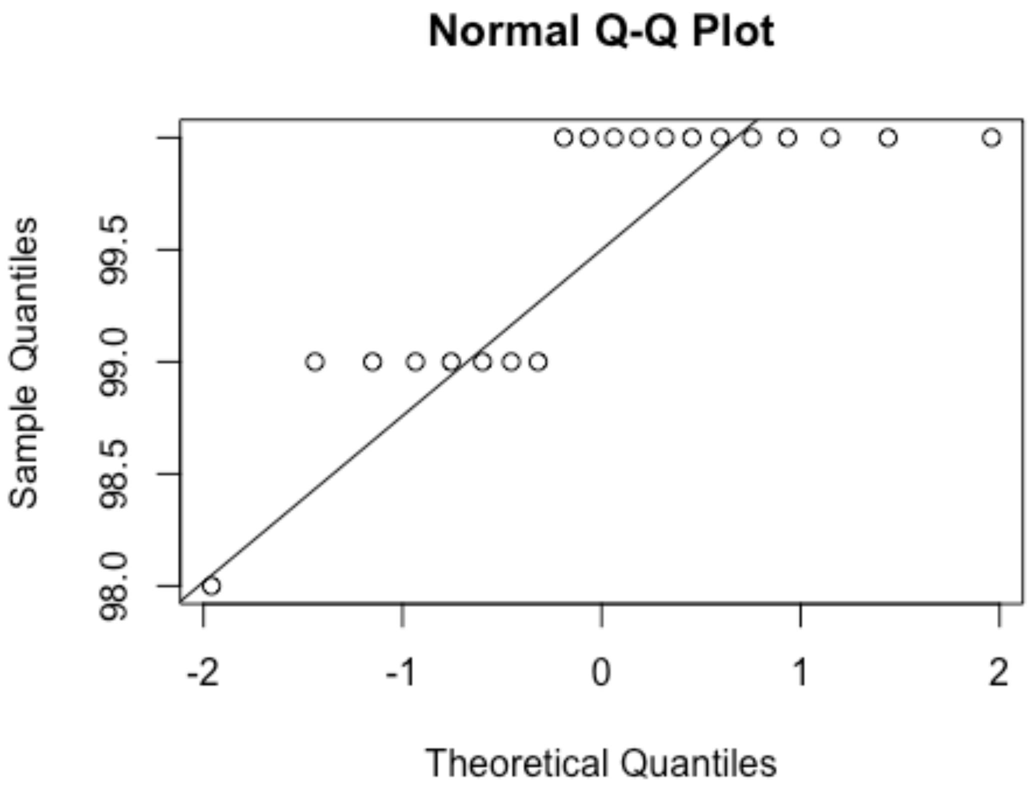
```
length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
```

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

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
```



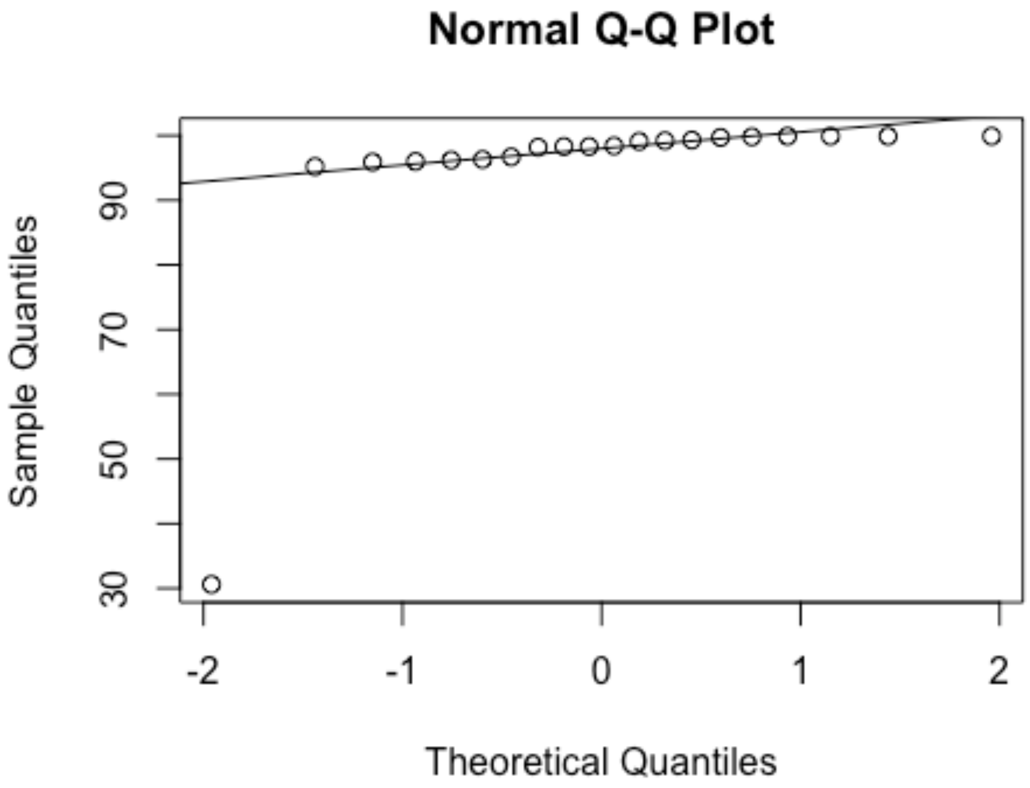
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)

##
##  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

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
##
## data:  subset(SSdata, intervention == "sham")$max.sao2.tst and subset(SSda
ta, intervention == "PrenaBelt")$max.sao2.tst
## W = 158, p-value = 0.1594
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -9.999288e-01  1.199059e-06
## sample estimates:
## difference in location
##          -1.027475e-05

#################### %TST with SaO2 90-100% #######################
#Summary
summary(SSdata$sao2.Ptst.100to90)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   30.60   96.48   98.40   96.47   99.60  100.00

sd(SSdata$sao2.Ptst.100to90, na.rm = TRUE)

## [1] 10.81533

length(SSdata$sao2.Ptst.100to90)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(sao2.Ptst.100to90 ~ intervention * night,
                                data = SSdata))
night_tx_difference
```

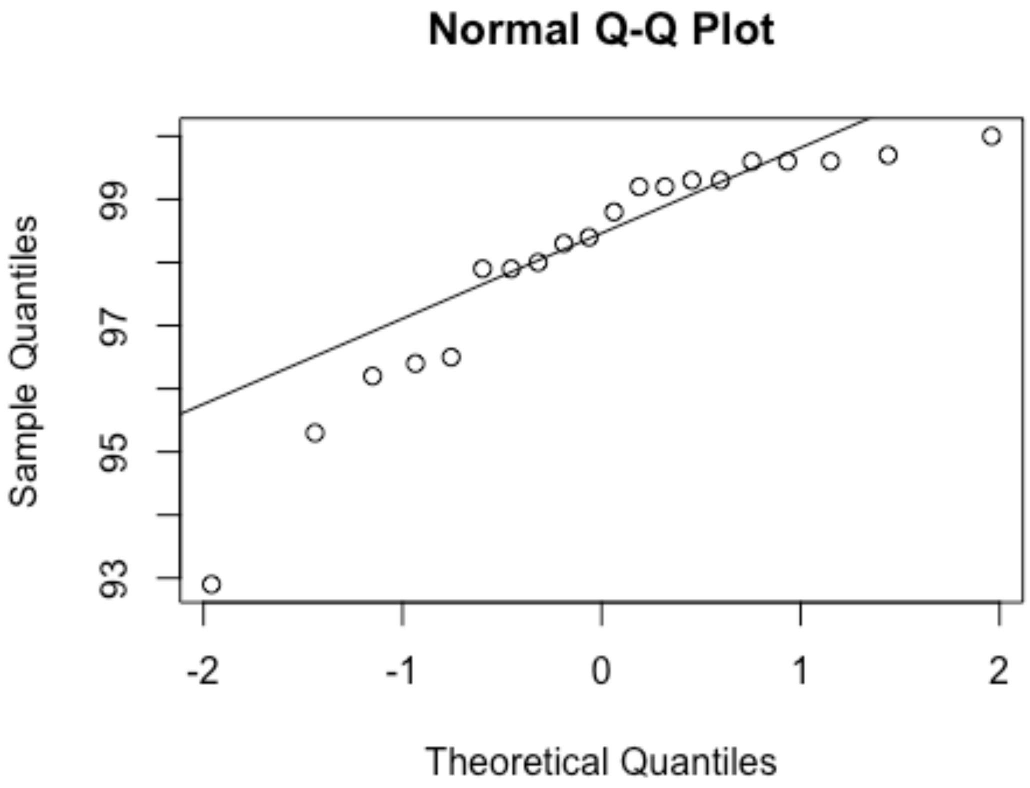
```
## Analysis of Variance Table
##
## Response: sao2.Ptst.100to90
##                      Df Sum Sq Mean Sq F value Pr(>F)
## intervention          1  106.6  106.60  0.9253 0.3425
## night                 1  130.0  129.96  1.1280 0.2953
## intervention:night    1  177.7  177.66  1.5420 0.2223
## Residuals            36 4147.7  115.21

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.100to90
,
       subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.100to90
,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.100to90, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.100to90, : cannot compute exact confidence interval with
## ties

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.100to90 a
nd subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.100to90
## V = 108, p-value = 0.9256
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.7499482  1.2500240
## sample estimates:
## (pseudo)median
##     0.02366365

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   30.60   96.28   98.35   94.84   99.72   99.90

sd(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

## [1] 15.20458

length(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

## [1] 20
```

```
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
```

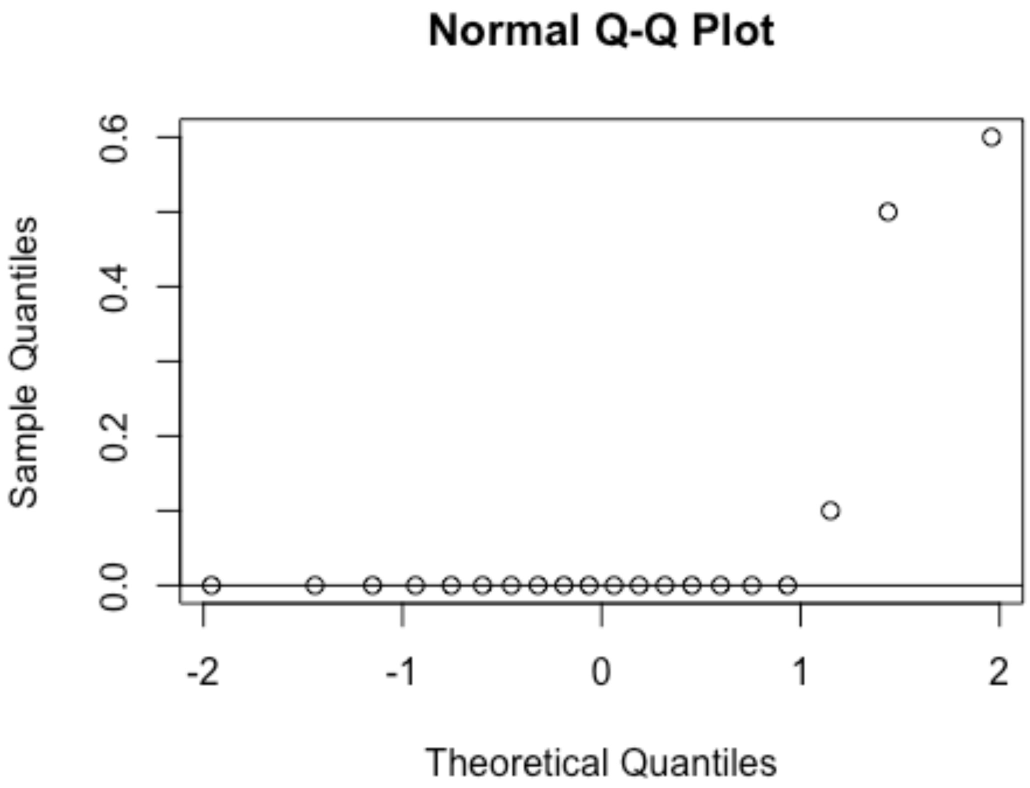
```
qqnorm(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)
qqline(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)
```



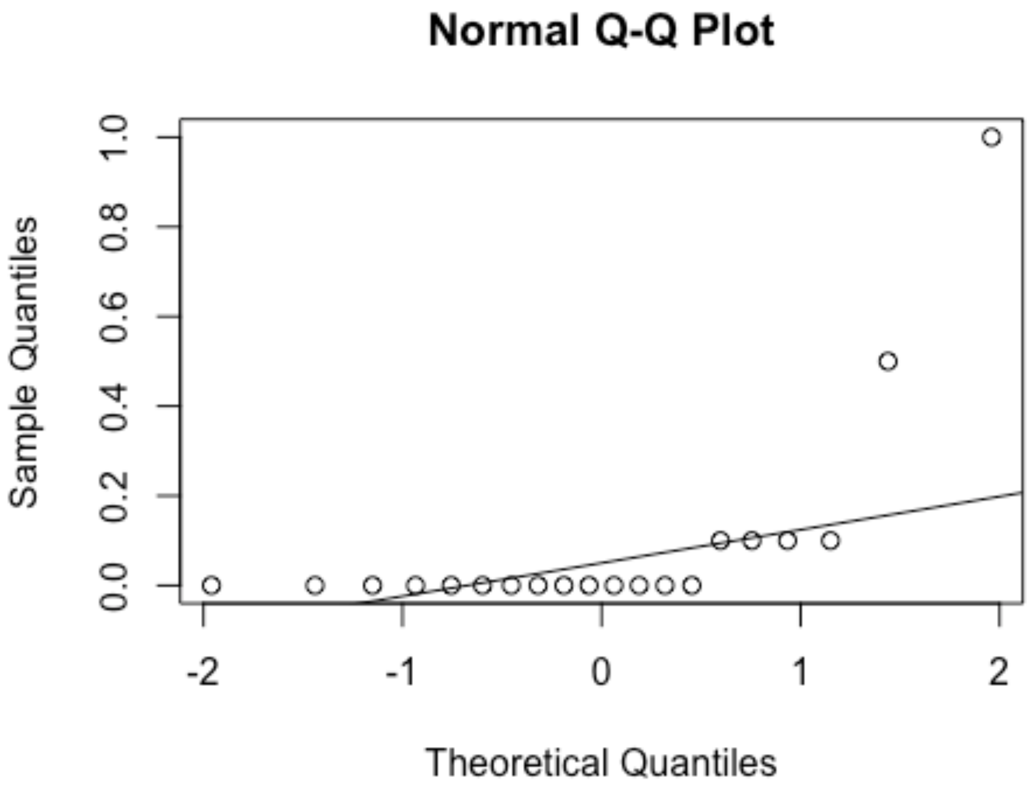
```
ad.test(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

##
##  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
```

```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$sao2.Ptst.100to90 and subset
(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90
## W = 199.5, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.7000278  1.2000028
## sample estimates:
## difference in location
##          -3.177747e-05

#################### %TST with SaO2 85-89.9% #######################
#Summary
summary(SSdata$sao2.Ptst.89.9to85)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.0000  0.0775  0.0000  1.0000

sd(SSdata$sao2.Ptst.89.9to85, na.rm = TRUE)

## [1] 0.2069157

length(SSdata$sao2.Ptst.89.9to85)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(sao2.Ptst.89.9to85 ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: sao2.Ptst.89.9to85
##                    Df  Sum Sq  Mean Sq F value  Pr(>F)
## intervention        1 0.01225 0.012250  0.2994 0.58764
## night               1 0.00225 0.002250  0.0550 0.81593
## intervention:night  1 0.18225 0.182250  4.4542 0.04183 *
## Residuals          36 1.47300 0.040917
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.89.9to8
5,
       subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.89.9to8
5,
       paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.89.9to85, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.89.9to85, : cannot compute exact confidence interval wit
h
## ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.89.9to85, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.89.9to85, : cannot compute exact confidence interval wit
h
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.89.9to85
and subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
## V = 18, p-value = 0.1198
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.0999194  0.3999194
## sample estimates:
## (pseudo)median
##      0.1000482

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.06    0.00    0.60

sd(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

## [1] 0.1698296

length(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
qqline(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
```



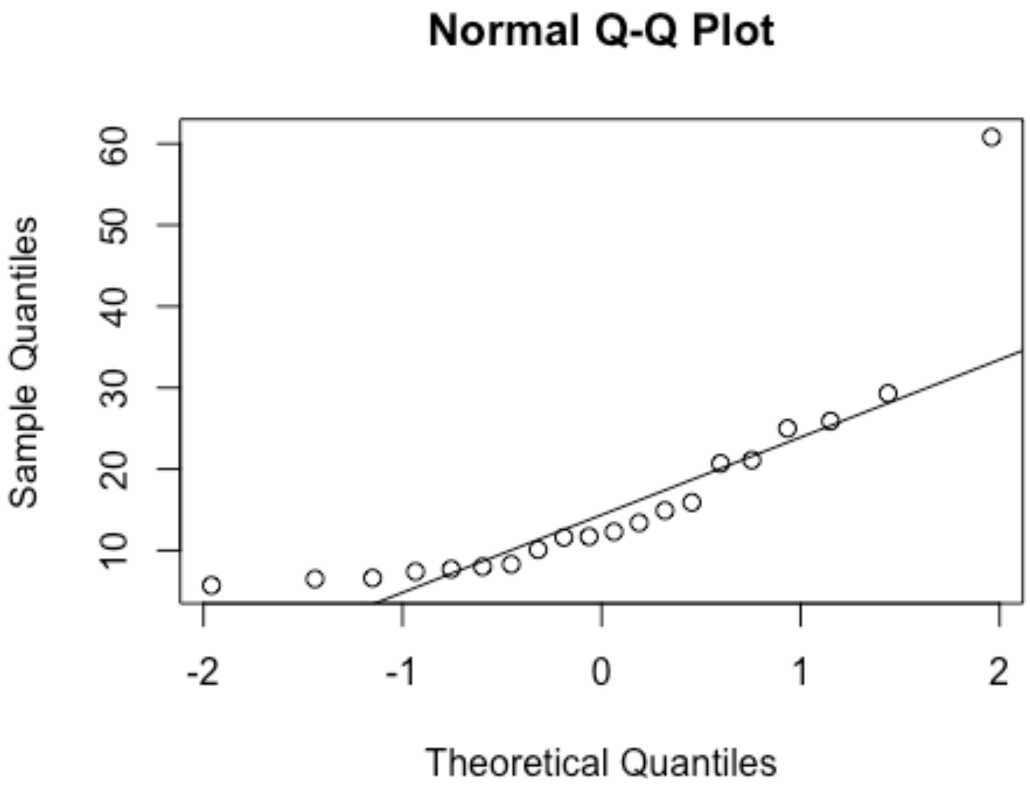
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

##
##  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)
```



```
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
```

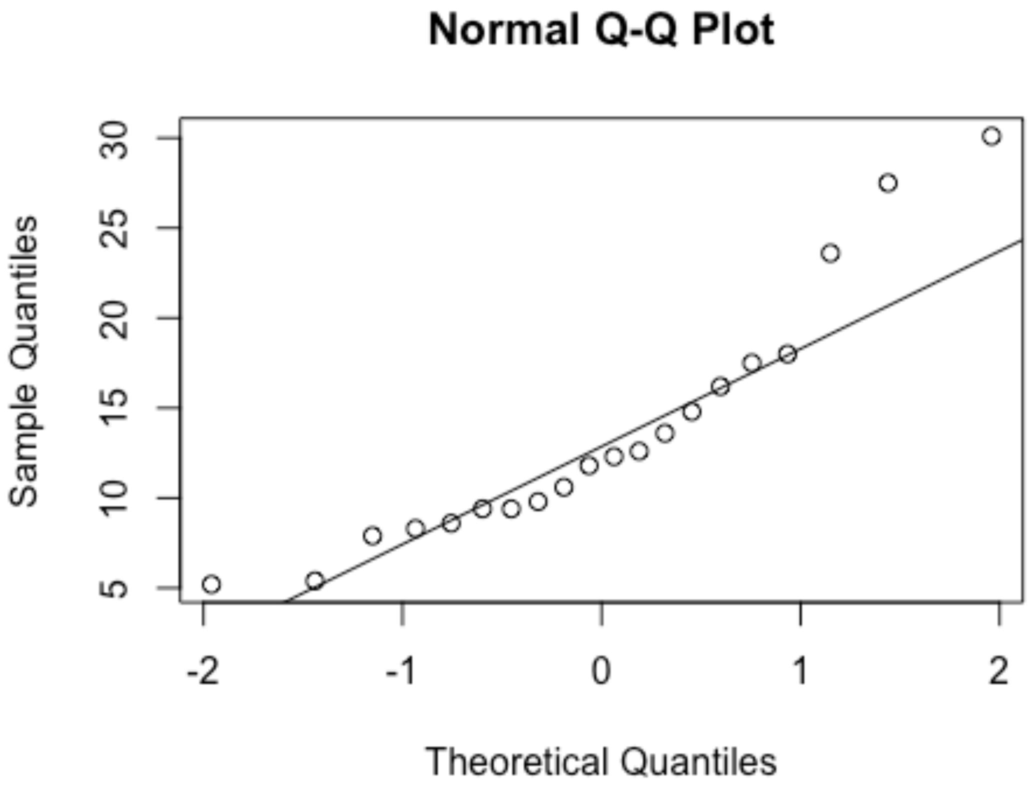
```
t(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
## W = 227.5, p-value = 0.317
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.534144e-05  1.959457e-05
## sample estimates:
## difference in location
##           3.556854e-06

#################### Total Arousal Index in NREM #######################
#Summary
summary(SSdata$total.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    5.20    8.30   12.05   14.89   17.62   60.80

sd(SSdata$total.arousals.nrem.index, na.rm = TRUE)

## [1] 10.14672

length(SSdata$total.arousals.nrem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(total.arousals.nrem.index ~ intervention * ni
ght,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: total.arousals.nrem.index
##                     Df Sum Sq Mean Sq F value Pr(>F)
## intervention         1   63.3  63.252  0.6102 0.4398
## night                1  190.5 190.532  1.8381 0.1836
## intervention:night   1   29.8  29.756  0.2871 0.5954
## Residuals           36 3731.7 103.660

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.nr
em.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals.nr
em.index,
       paired = TRUE, conf.int = TRUE)

##
##  Wilcoxon signed rank test
##
## data:  subset(SSdataCompletes, intervention == "sham")$total.arousals.nrem
.index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousal
```

```
s.nrem.index
## V = 100, p-value = 0.8695
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.70  1.65
## sample estimates:
## (pseudo)median
##           -0.2

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   5.700   7.925  12.000  16.140  20.800  60.800

sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)

## [1] 12.68192

length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.ind
ex
## 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
```

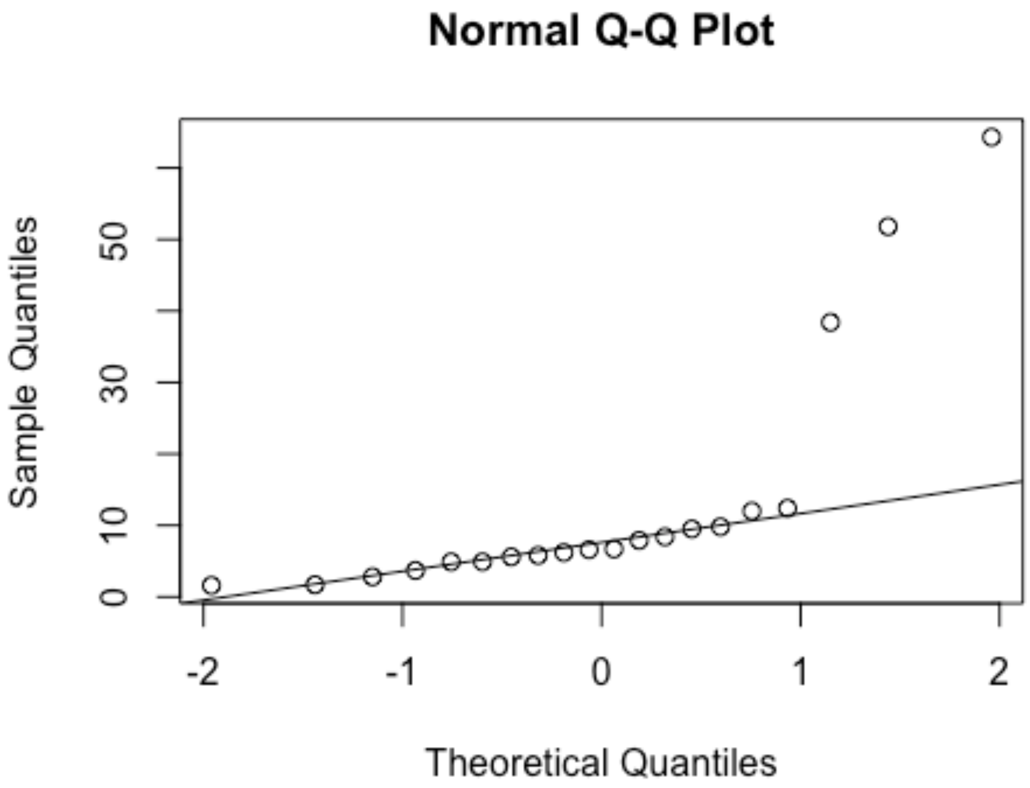
```
qqnorm(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
qqline(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
```



```
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
```

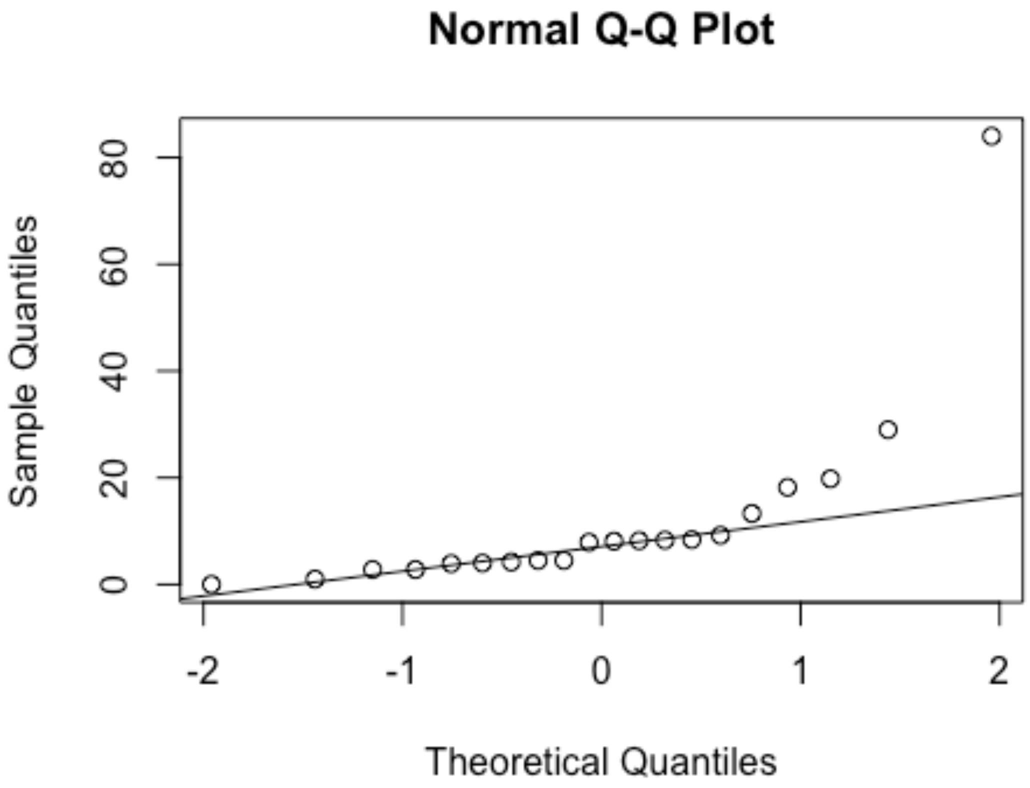
```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$total.arousals.nrem.index an
d subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
## W = 198, p-value = 0.9676
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.900032  3.200041
## sample estimates:
## difference in location
##            -0.09996643

#################### Total Arousal Index in REM #######################
#Summary
summary(SSdata$total.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    4.15    7.30   12.68   10.35   84.00

sd(SSdata$total.arousals.rem.index, na.rm = TRUE)

## [1] 17.59224

length(SSdata$total.arousals.rem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(total.arousals.rem.index ~ intervention * nig
ht,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: total.arousals.rem.index
##                      Df  Sum Sq Mean Sq F value  Pr(>F)
## intervention          1    13.1   13.11  0.0447 0.83377
## night                 1    10.3   10.30  0.0351 0.85241
## intervention:night    1  1484.7 1484.74  5.0607 0.03068 *
## Residuals            36 10561.8  293.38
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired t-test
wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.re
m.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals.re
m.index,
       paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$total.arousals.rem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention
## == "sham")$total.arousals.rem.index, : cannot compute exact confidence
## interval with ties

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$total.arousals.rem.
index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals
.rem.index
## V = 91, p-value = 0.6142
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.350040  2.100039
## sample estimates:
## (pseudo)median
##     -0.4334441

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.60    4.90    6.65   13.25   10.35   64.30

sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

## [1] 17.26717

length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
```



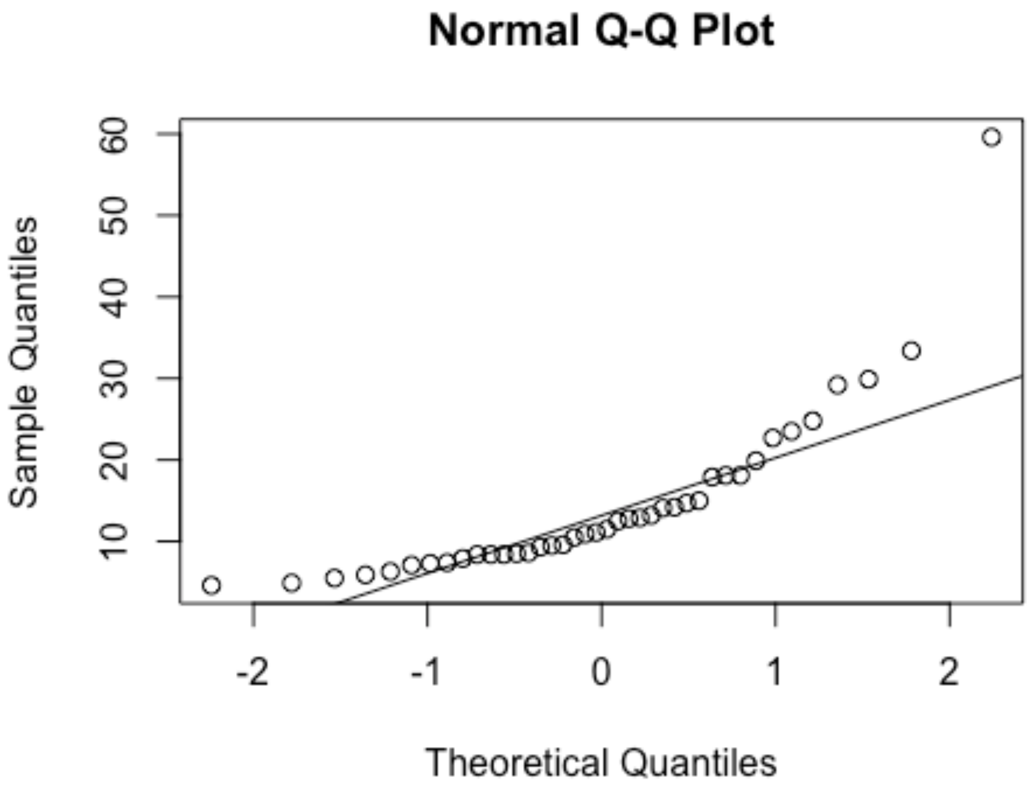
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.inde
x
## 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)
```



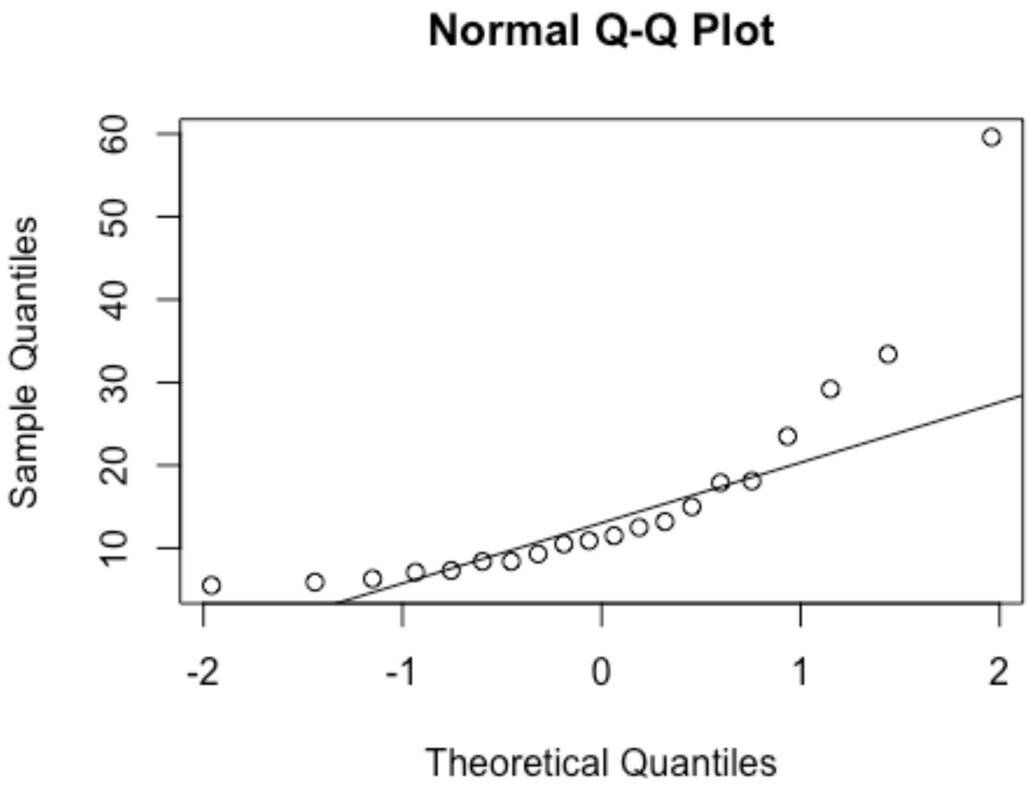
```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

##
##  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
```

```
h
## ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$total.arousals.rem.index and
subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index
## W = 186, p-value = 0.7149
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.899974  2.800023
## sample estimates:
## difference in location
##             -0.6999841

#################### Total Arousal Index (TST = NREM + REM) #################
######
#Summary
summary(SSdata$total.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    4.60    8.40   11.30   14.45   17.95   59.60

sd(SSdata$total.arousals.total.index, na.rm = TRUE)

## [1] 10.25068

length(SSdata$total.arousals.total.index)

## [1] 40

qqnorm(SSdata$total.arousals.total.index)
qqline(SSdata$total.arousals.total.index)
```



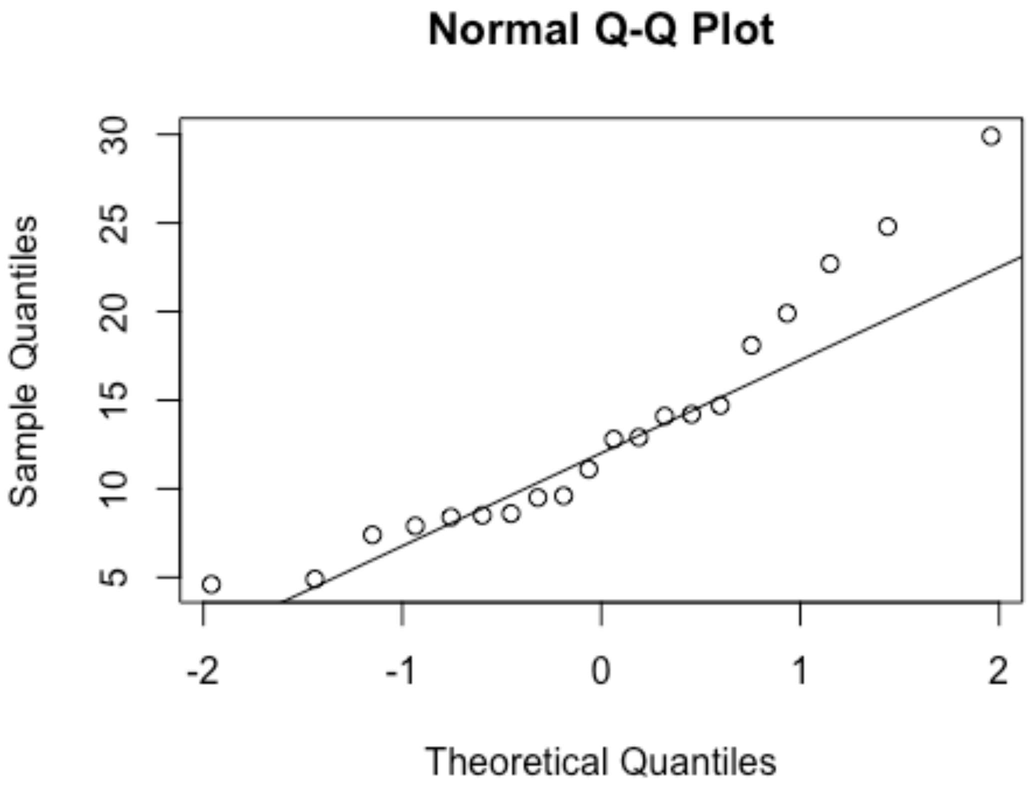
```
ad.test(SSdata$total.arousals.total.index)

##
##  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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.to
tal.index,
                  subset(SSdataCompletes, intervention == "PrenaBelt")$total.
arousals.total.index,
                 paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$total.arousals.tota
l.index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousa
ls.total.index
## V = 90, p-value = 0.5883
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.499935  1.499994
## sample estimates:
## (pseudo)median
##     -0.5984439

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.inde
x)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   5.500   8.125  11.200  15.680  17.950  59.600

sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index)

## [1] 12.89508

length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
)
qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.inde
x)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.in
dex
## 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)
```

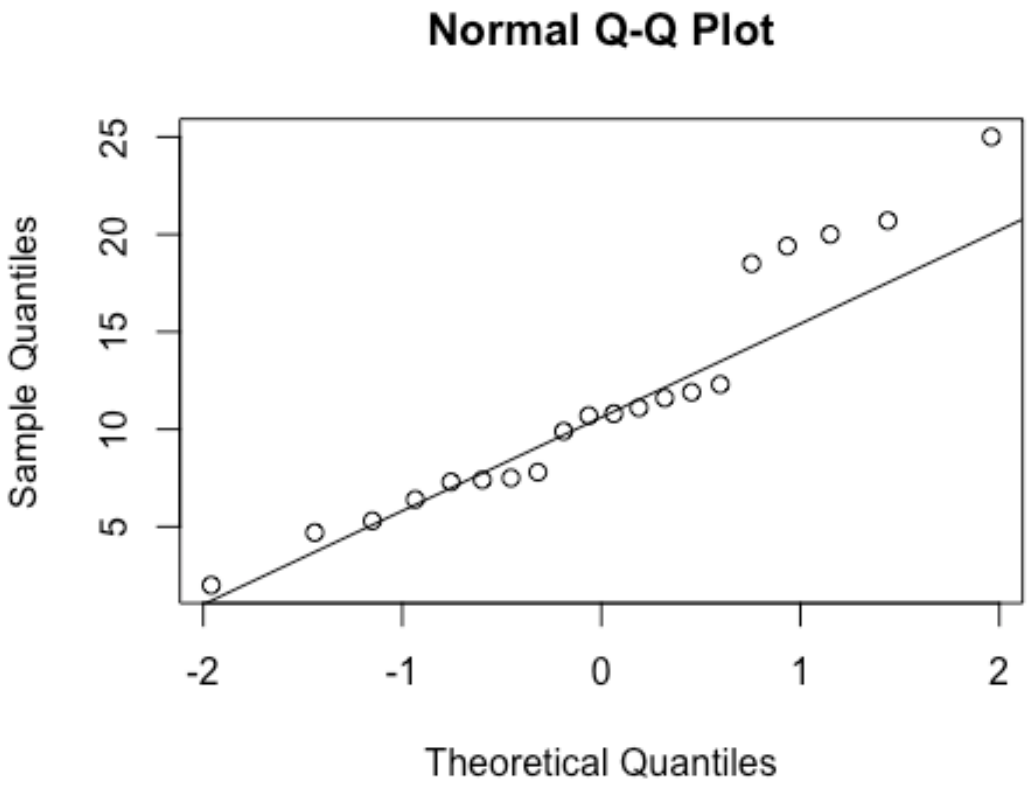


```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.total.index)

##
##  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")$total.arousals.total.index a
nd subset(SSdata, intervention == "PrenaBelt")$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
```

```
## 95 percent confidence interval:
##  -9.11411  4.22411
## sample estimates:
## mean of x mean of y
##    13.230    15.675

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

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$total.arousals.total.index a
nd subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
## W = 201.5, p-value = 0.9784
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.099936  3.599950
## sample estimates:
## difference in location
##             0.04235554

#################### Spontaneous Arousal Index in NREM #####################
#
#Summary
summary(SSdata$spontaneous.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.800   7.475  10.550  11.490  13.180  26.500

sd(SSdata$spontaneous.arousals.nrem.index, na.rm = TRUE)

## [1] 6.188624

length(SSdata$spontaneous.arousals.nrem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(spontaneous.arousals.nrem.index ~ interventio
n * night,
```

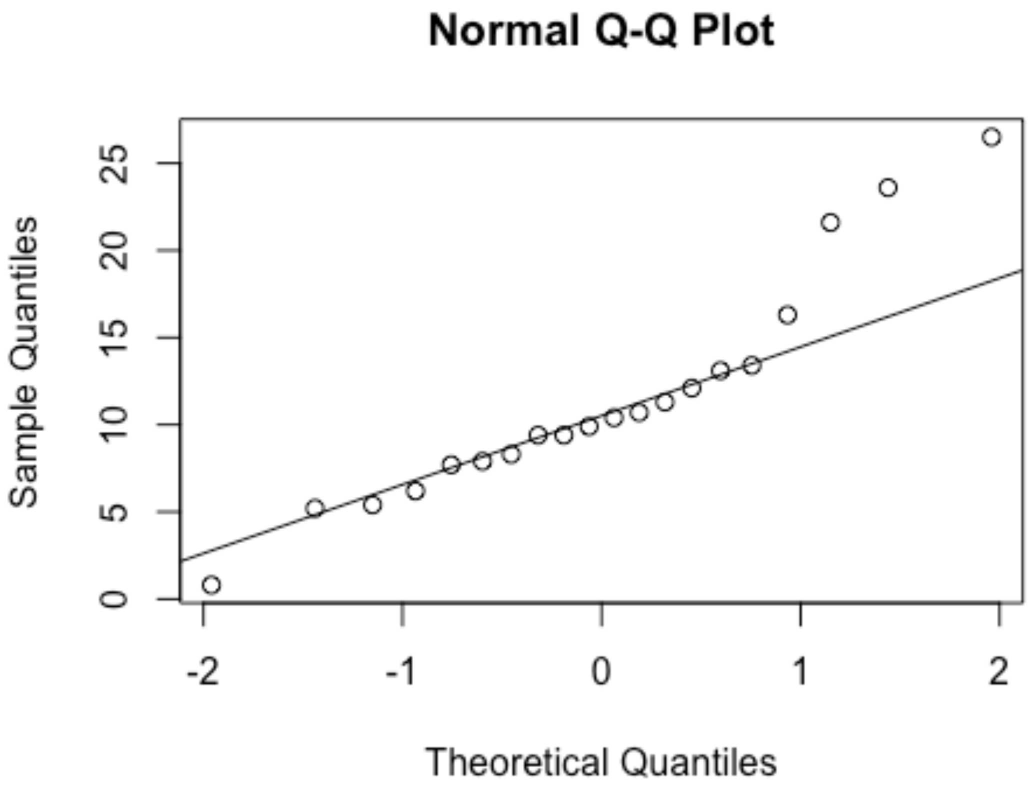
```
                                data = SSdata))
night_tx_difference

## 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")$spontaneous.arous
als.nrem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
als.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")$spontaneous.arousal
s.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$spontan
eous.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.inde
x)
```

```
## [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.nr
em.index
## A = 0.69502, p-value = 0.05869

#normal
```

```
summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.inde
x)

##    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
)
```

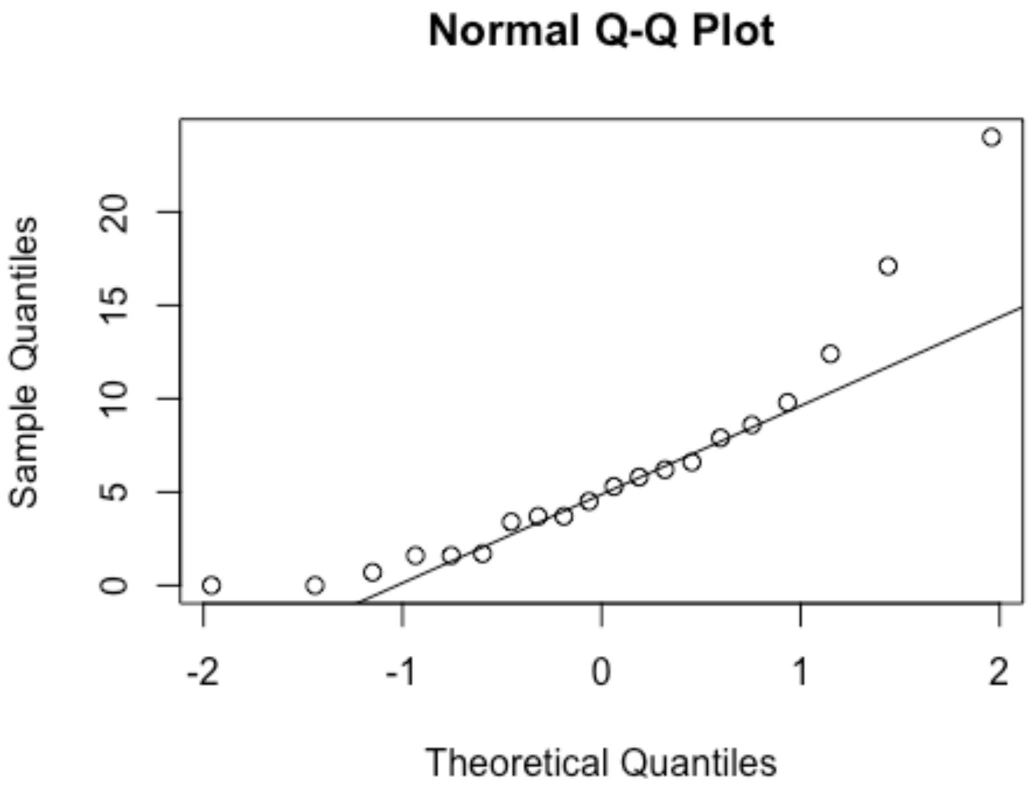


```
ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.inde
x)

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

```
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
dex
## A = 0.77235, p-value = 0.03712

#non-normal

t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index
,
       subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
index)

##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
dex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
.index
## t = -0.027742, df = 37.952, p-value = 0.978
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -4.068685  3.958685
## sample estimates:
## mean of x mean of y
##    11.460    11.515

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

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
dex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
.index
## W = 203, p-value = 0.9461
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.399998  3.200034
## sample estimates:
```

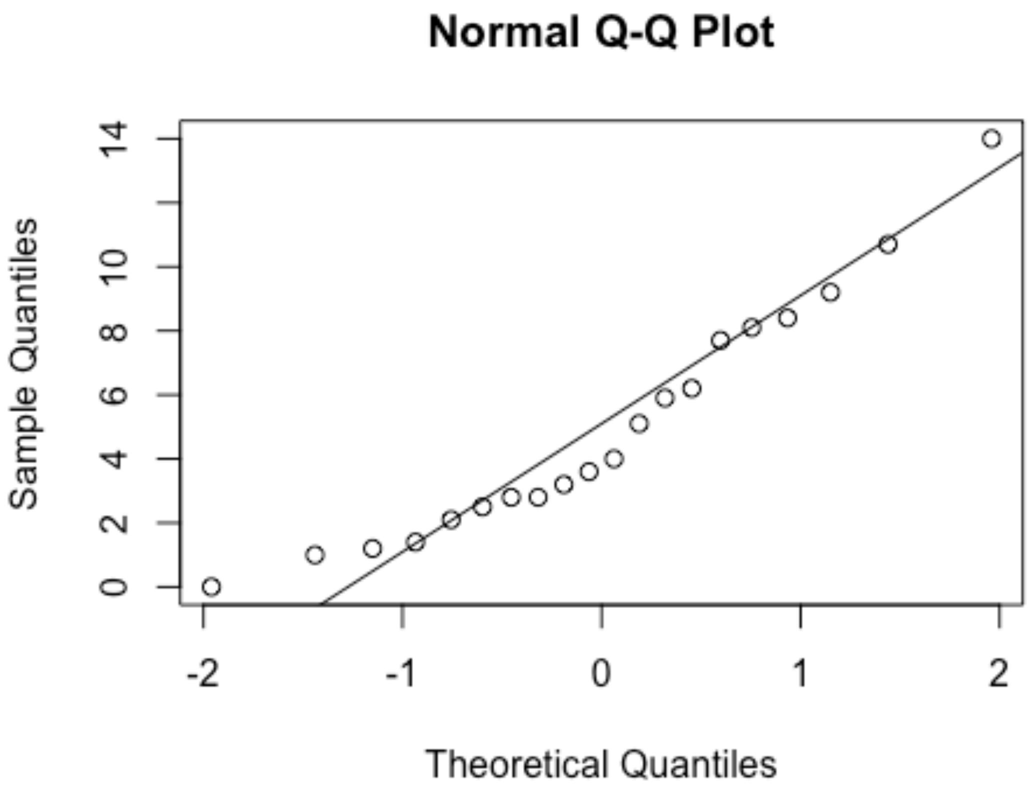
```
## difference in location
##                    0.15

#################### Spontaneous Arousal Index in REM #######################
#Summary
summary(SSdata$spontaneous.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   2.000   4.250   5.612   7.950  24.000

sd(SSdata$spontaneous.arousals.rem.index, na.rm = TRUE)

## [1] 4.976312

length(SSdata$spontaneous.arousals.rem.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: spontaneous.arousals.rem.index
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  15.25  15.252  0.6246 0.4345
## night               1  37.44  37.442  1.5334 0.2236
## intervention:night  1  34.04  34.040  1.3941 0.2455
## Residuals          36 879.05  24.418

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
als.rem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
als.rem.index,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$spontaneous.arousals.rem.index, : cannot compute exact p-value wit
h
## ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$spontaneous.arousals.rem.index, : cannot compute exact confidence
## interval with ties

##
##  Wilcoxon signed rank test with continuity correction
```

```
##
## data:  subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
s.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$spontane
ous.arousals.rem.index
## V = 93, p-value = 0.6676
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.950065  1.549957
## sample estimates:
## (pseudo)median
##     -0.3500398

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.
index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   1.675   4.900   6.230   8.075  24.000

sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index
)

## [1] 6.025132

length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex)
qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex)
```



```
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)
```

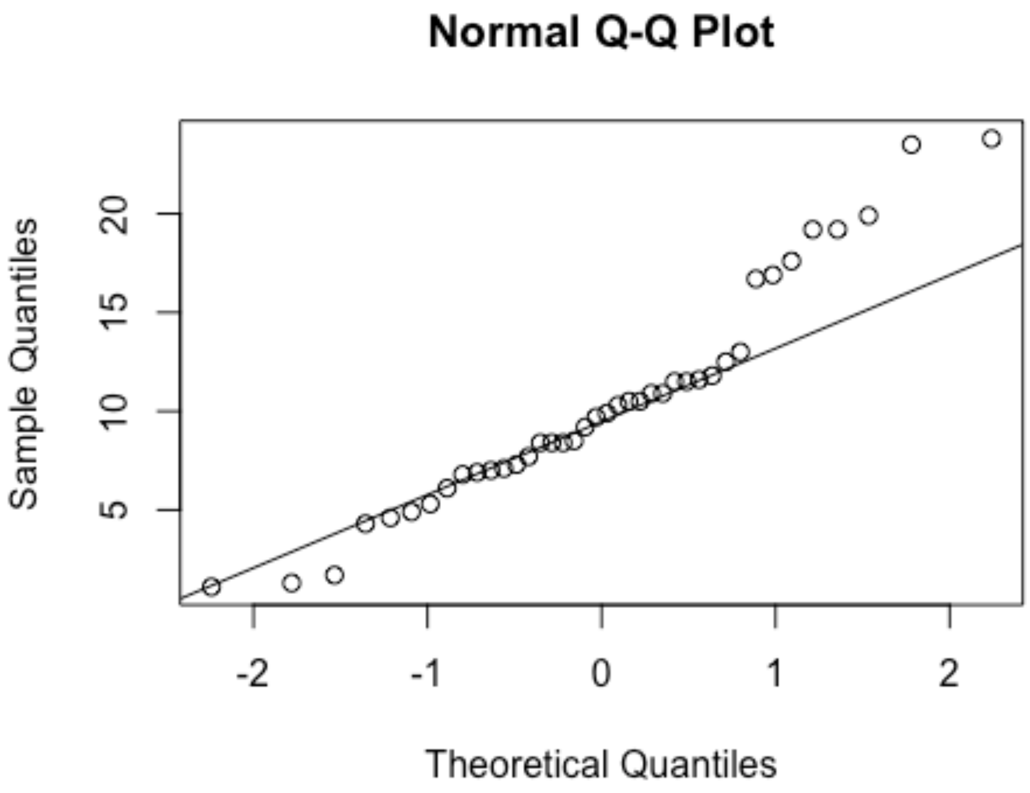
```
## [1] 20

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.ind
ex
## 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.i
ndex)

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

```
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.ind
ex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex
## t = -0.78086, df = 31.571, p-value = 0.4407
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -4.458294  1.988294
## sample estimates:
## mean of x mean of y
##     4.995     6.230

wilcox.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.i
ndex,
            subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.
rem.index,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.ind
ex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex
## W = 185.5, p-value = 0.7048
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.199951  2.099934
## sample estimates:
## difference in location
##             -0.4476729

#################### Spontaneous Arousal Index (TST = NREM + REM) ###########
############
#Summary
summary(SSdata$spontaneous.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.100   6.975   9.800  10.410  11.980  23.800

sd(SSdata$spontaneous.arousals.total.index, na.rm = TRUE)

## [1] 5.594264

length(SSdata$spontaneous.arousals.total.index)
```

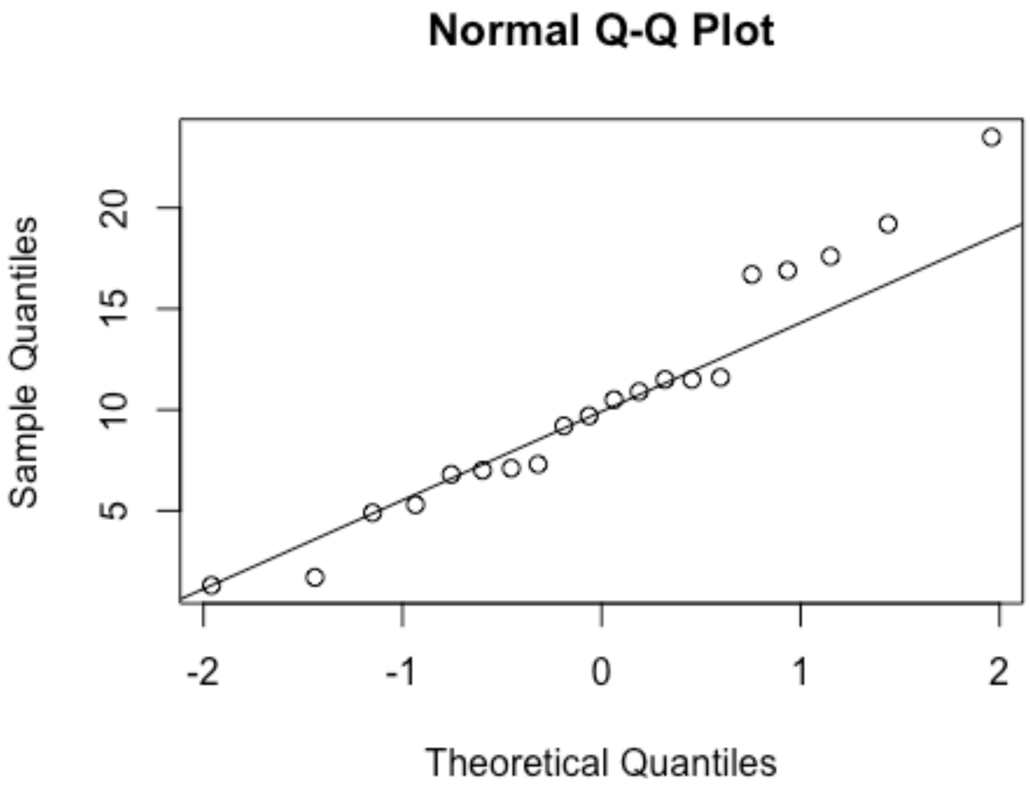
```
## [1] 40

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
```

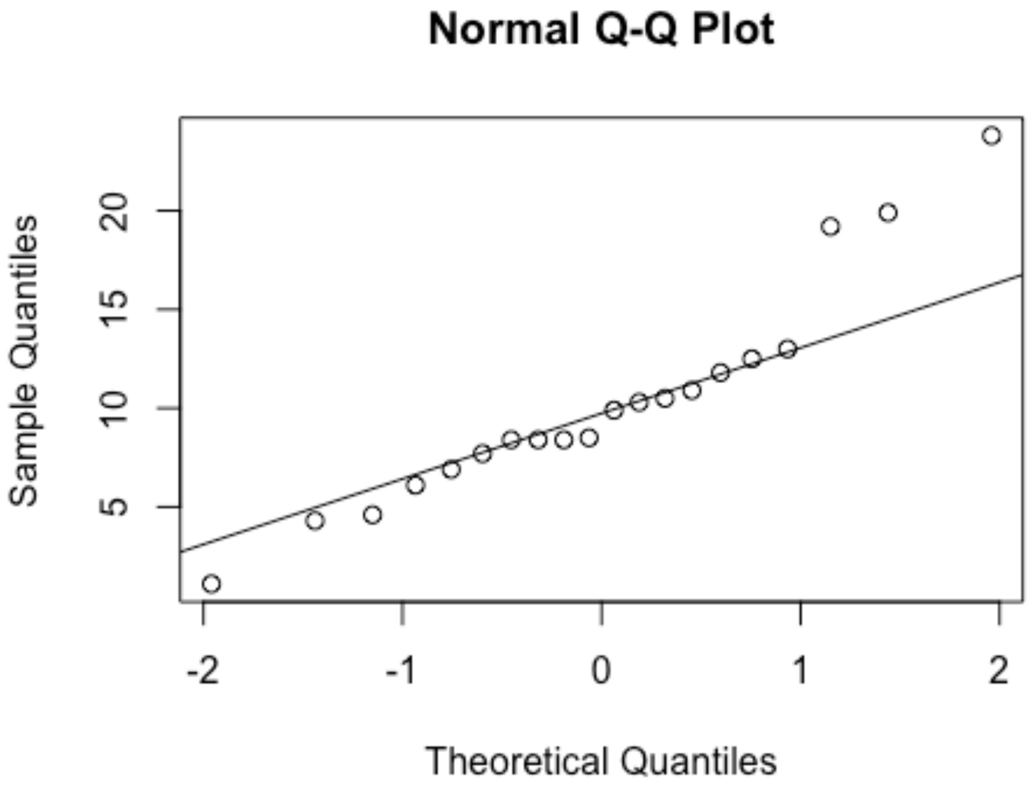
```
##                     Df  Sum Sq Mean Sq F value Pr(>F)
## intervention         1    0.40   0.400  0.0120 0.9132
## night                1   23.72  23.716  0.7138 0.4038
## intervention:night   1    0.26   0.256  0.0077 0.9305
## Residuals           36 1196.16  33.227

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arousals.t
otal.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
als.total.index,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$sponta
neous.arousals.total.index
## t = -0.17543, df = 19, p-value = 0.8626
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -2.586125  2.186125
## sample estimates:
## mean of the differences
##                    -0.2

#Double check with Wilcoxon (borderline normal)
wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
als.total.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
als.total.index,
       paired = TRUE, conf.int = TRUE)

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$spontaneous.arousals.total.index, : cannot compute exact confidenc
e
## interval with ties

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$sponta
neous.arousals.total.index
## V = 114.5, p-value = 0.7368
```

```
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.500005  1.850093
## sample estimates:
## (pseudo)median
##           0.25

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.tota
l.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.30    6.95   10.10   10.51   12.88   23.50

sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.ind
ex)

## [1] 5.841854

length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total
.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total
.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total
.index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.tota
l.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.to
tal.index
## A = 0.37989, p-value = 0.3699

#normal

summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.ind
ex)

##    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.inde
x)
```

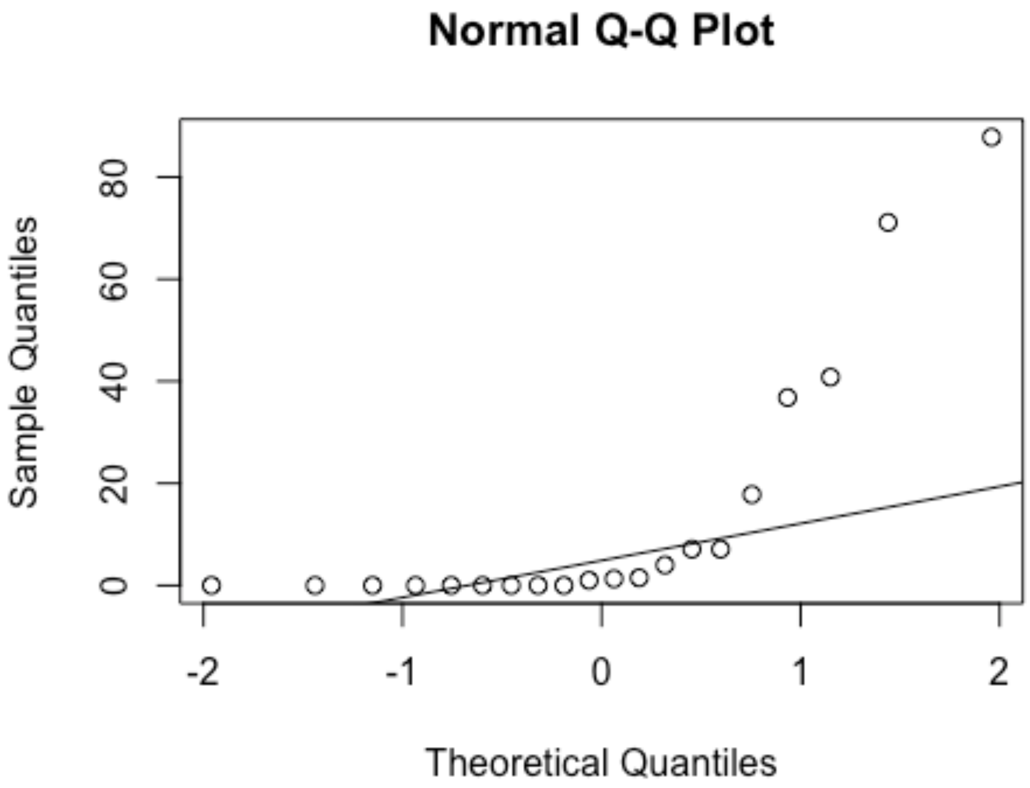
```
## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
x)
qqline(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
x)
```



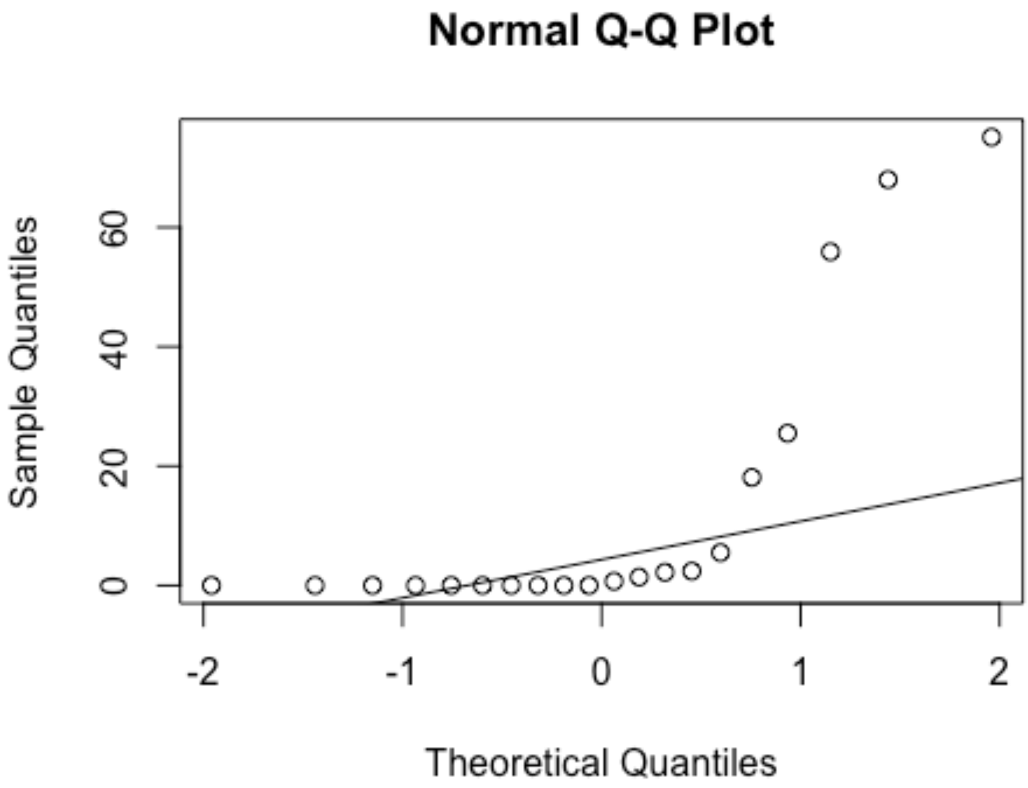
```
ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.ind
ex)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.total.i
ndex
## A = 0.71308, p-value = 0.05273

#normal

t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
x,
       subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total
.index)
```

```
##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.total.i
ndex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.tot
al.index
## t = -0.11161, df = 37.85, p-value = 0.9117
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -3.827971  3.427971
## sample estimates:
## mean of x mean of y
##     10.31     10.51

#################### PLMs Index in NREM #######################
#Summary
summary(SSdata$plms.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.850  13.280   9.775  87.800

sd(SSdata$plms.nrem.index, na.rm = TRUE)

## [1] 24.58884

length(SSdata$plms.nrem.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: plms.nrem.index
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1    11.6   11.56  0.0178 0.8945
## night               1   213.9  213.91  0.3303 0.5691
## intervention:night  1    40.6   40.60  0.0627 0.8037
## Residuals          36 23313.8  647.60

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.nrem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plms.nrem.index,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plms.nrem.index and
subset(SSdataCompletes, intervention == "PrenaBelt")$plms.nrem.index
## V = 29, p-value = 0.4561
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -18.84993  13.74994
## sample estimates:
## (pseudo)median
##     -0.8327795

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   1.150  13.820   9.775  87.800

sd(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

## [1] 25.55123

length(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
```



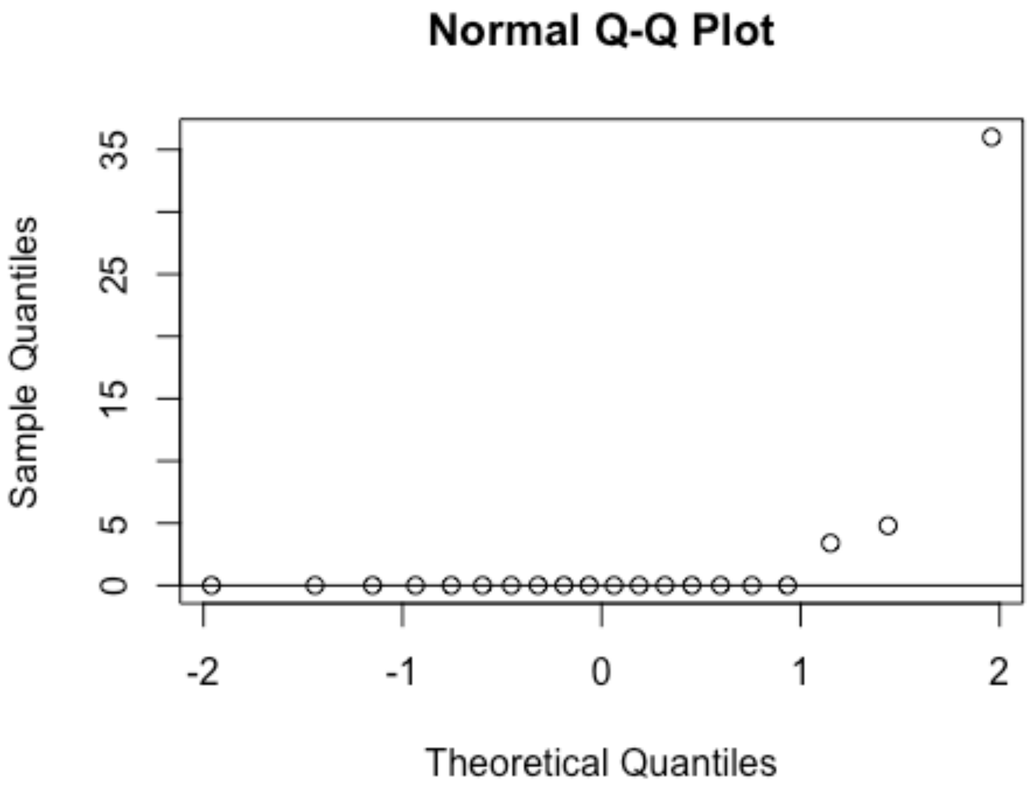
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

##
##  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)
```



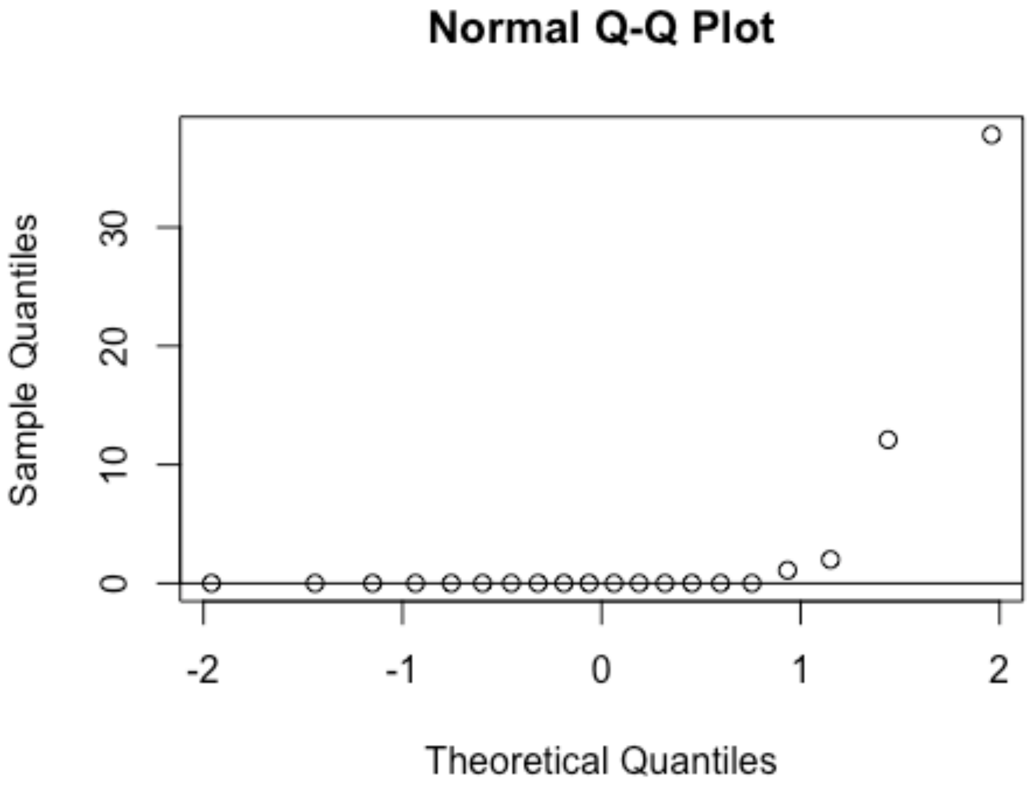
```
ad.test(subset(SSdata, intervention == "sham")$plms.nrem.index)

##
##  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
```

```
Sdata, intervention == "PrenaBelt")$plms.nrem.index
## W = 189, p-value = 0.7637
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.800001  1.100068
## sample estimates:
## difference in location
##          -3.550462e-05

#################### PLMs Index in REM #######################
#Summary
summary(SSdata$plms.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    2.43    0.00   37.80

sd(SSdata$plms.rem.index, na.rm = TRUE)

## [1] 8.281682

length(SSdata$plms.rem.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: plms.rem.index
##                      Df  Sum Sq Mean Sq F value Pr(>F)
## intervention          1    1.94   1.936  0.0268 0.8708
## night                 1    0.04   0.036  0.0005 0.9823
## intervention:night    1   73.98  73.984  1.0248 0.3181
## Residuals            36 2598.91  72.192

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.rem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plms.rem.index,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plms.rem.index, : requested conf.level not achievable

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plms.rem.index and
subset(SSdataCompletes, intervention == "PrenaBelt")$plms.rem.index
## V = 11, p-value = 0.4185
## alternative hypothesis: true location shift is not equal to 0
## 80 percent confidence interval:
##  -0.8000532  4.5500270
## sample estimates:
## (pseudo)median
##       1.799949

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    2.21    0.00   36.00

sd(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

## [1] 8.055459

length(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
```



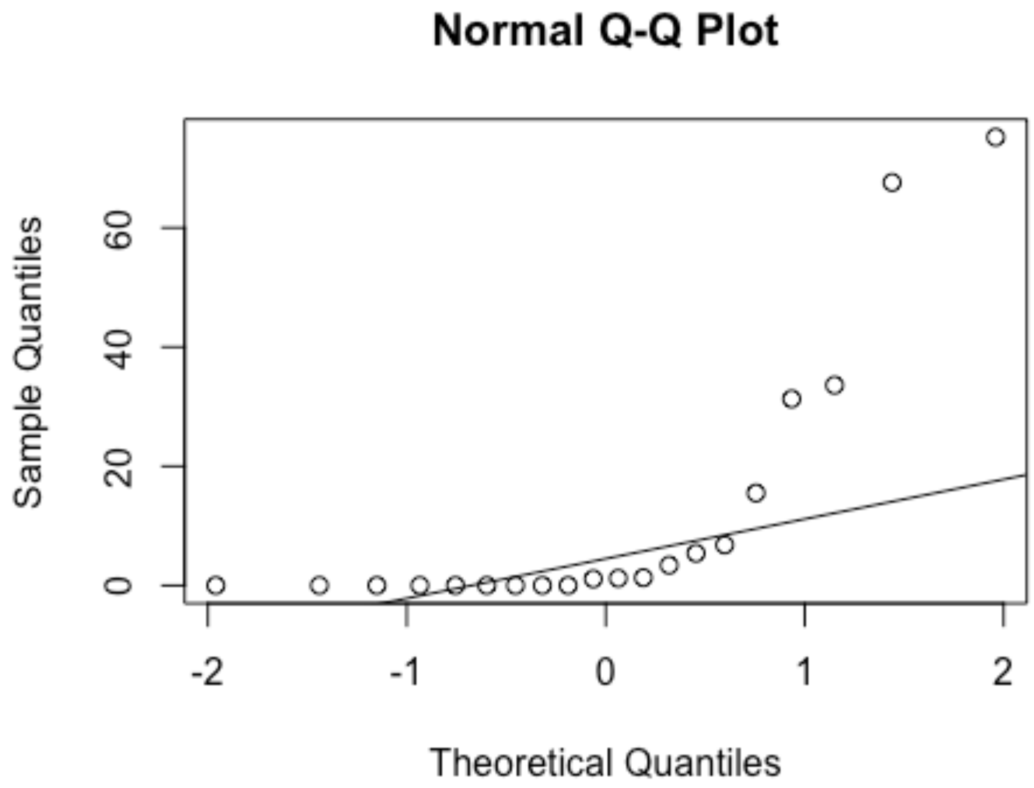
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

##
##  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)
```



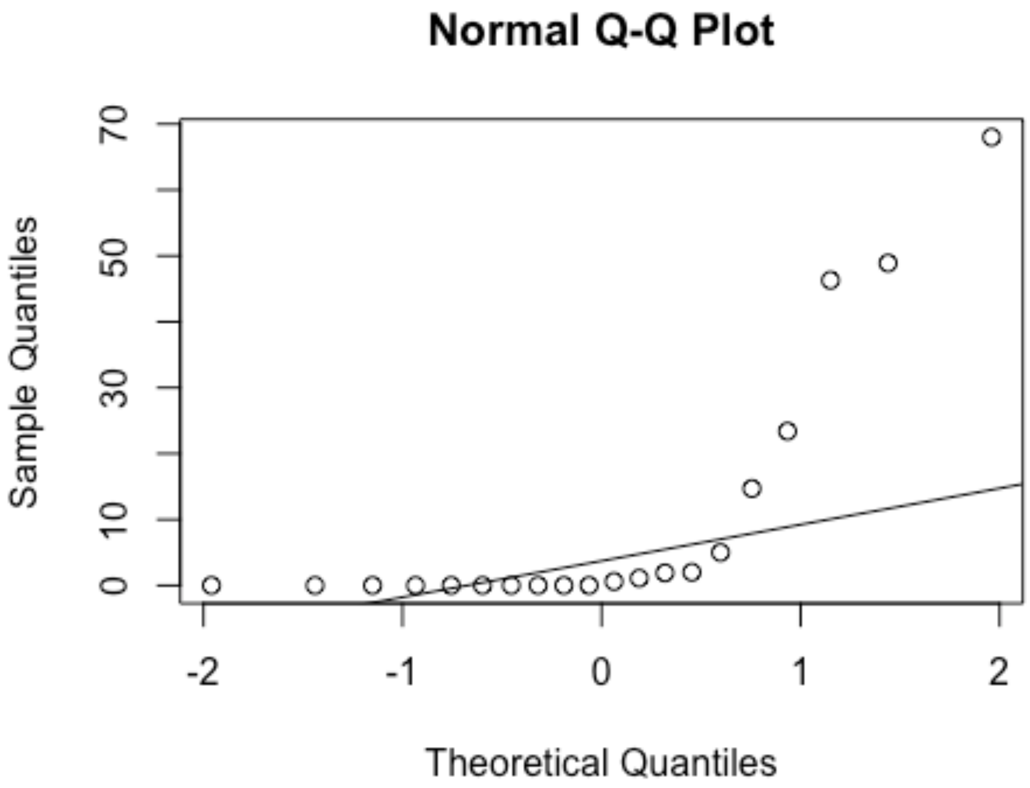
```
ad.test(subset(SSdata, intervention == "sham")$plms.rem.index)

##
##  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
```

```
data, intervention == "PrenaBelt")$plms.rem.index
## W = 209, p-value = 0.7285
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.226857e-05  1.825006e-06
## sample estimates:
## difference in location
##           4.496583e-05

#################### PLMs Total Index (TST = NREM + REM) ####################
###
#Summary
summary(SSdata$plms.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.850  11.360   8.775  75.200

sd(SSdata$plms.total.index, na.rm = TRUE)

## [1] 21.15996

length(SSdata$plms.total.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: plms.total.index
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1    23.3   23.26  0.0487 0.8265
## night               1   219.5  219.49  0.4599 0.5020
## intervention:night  1    37.1   37.06  0.0776 0.7821
## Residuals          36 17182.2  477.28

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.total.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plms.total.index,
       paired = TRUE, conf.int = TRUE)

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

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

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plms.total.index an
d subset(SSdataCompletes, intervention == "PrenaBelt")$plms.total.index
## V = 25, p-value = 0.2896
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -17.249992   8.399971
## sample estimates:
## (pseudo)median
##      -1.298512

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   1.150  12.120   8.975  75.200

sd(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

## [1] 22.62638

length(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
```



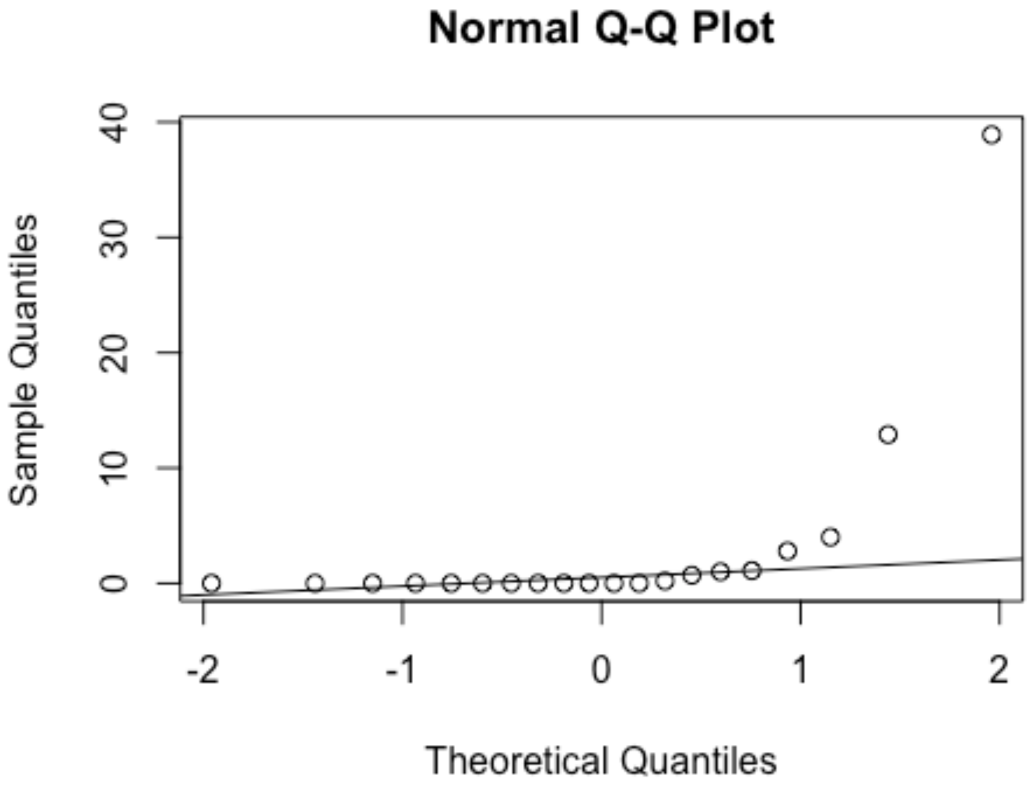
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

##
##  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)
```



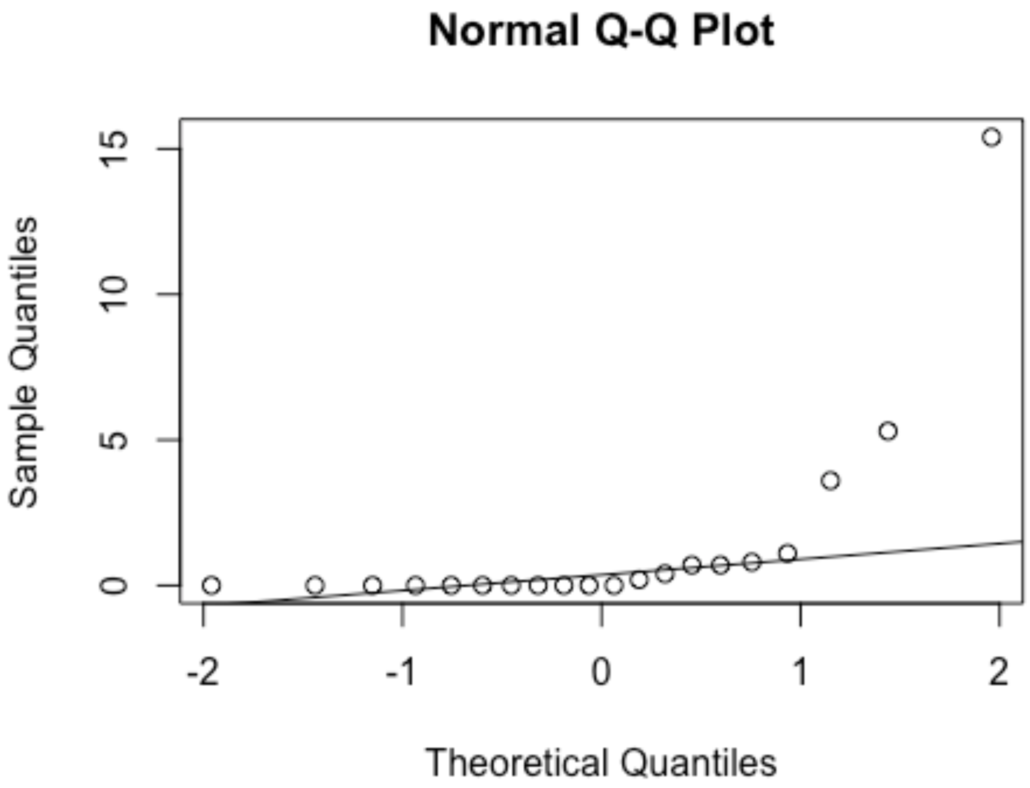
```
ad.test(subset(SSdata, intervention == "sham")$plms.total.index)

##
##  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(
```

```
SSdata, intervention == "PrenaBelt")$plms.total.index
## W = 186.5, p-value = 0.7098
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.8000395  0.7000302
## sample estimates:
## difference in location
##           -4.60136e-05

#################### PLM Arousals Index in NREM #######################
#Summary
summary(SSdata$plm.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   2.245   0.850  38.900

sd(SSdata$plm.arousals.nrem.index, na.rm = TRUE)

## [1] 6.766886

length(SSdata$plm.arousals.nrem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(plm.arousals.nrem.index ~ intervention * nigh
t,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: plm.arousals.nrem.index
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1   27.89  27.889  0.5852 0.4493
## night               1   40.80  40.804  0.8563 0.3610
## intervention:night  1    1.60   1.600  0.0336 0.8556
## Residuals          36 1715.55  47.654

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.nrem
.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nrem
.index,
       paired = TRUE, conf.int = TRUE)

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.nrem.index, : cannot compute exact confidence interva
```

```
l
## with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.nrem.index, : cannot compute exact p-value with zeroe
s

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.nrem.index, : cannot compute exact confidence interva
l
## with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plm.arousals.nrem.i
ndex and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nr
em.index
## V = 24.5, p-value = 0.4767
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -15.000023   1.300048
## sample estimates:
## (pseudo)median
##     -0.2999436

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   3.080   1.025  38.900

sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

## [1] 8.933886

length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
```



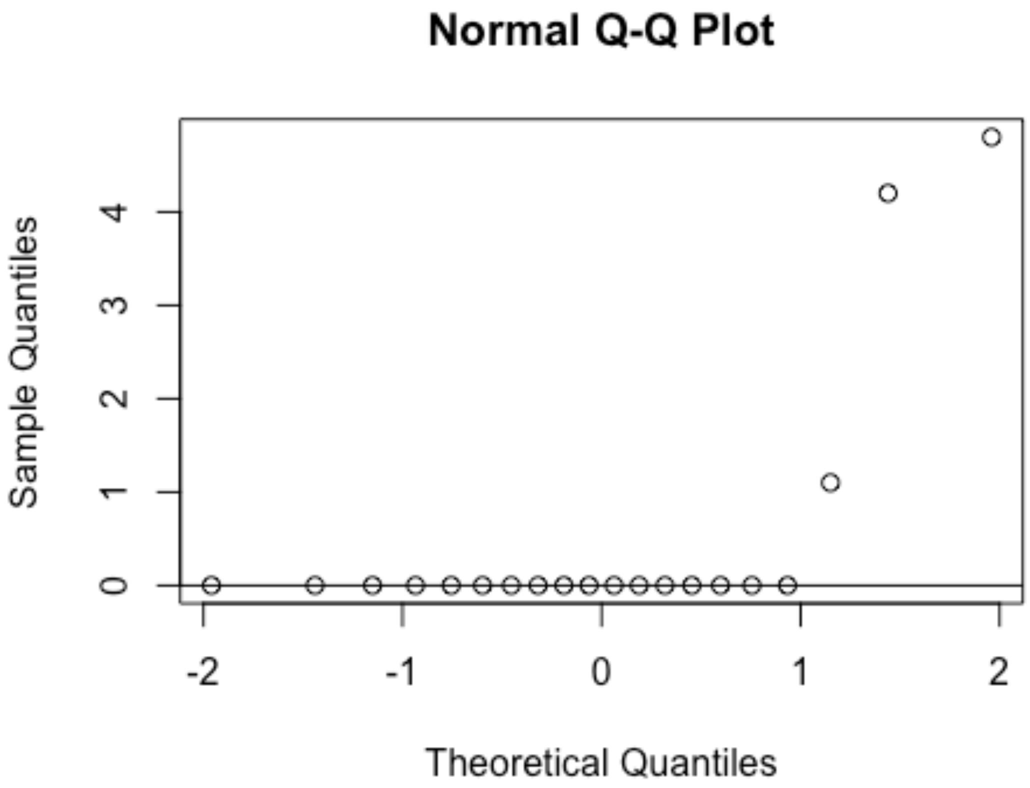
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

##
##  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)
```



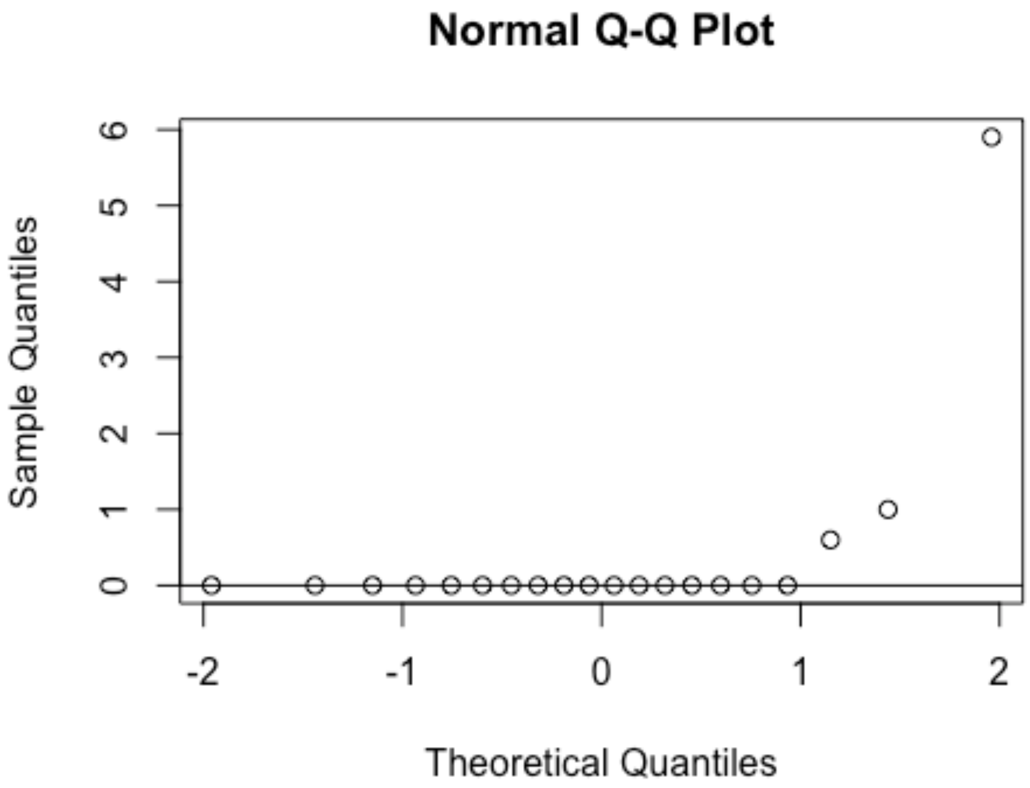
```
ad.test(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$plm.arousals.nrem.index
## A = 4.353, p-value = 2.952e-11

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.ind
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

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

```
##
## data:  subset(SSdata, intervention == "sham")$plm.arousals.nrem.index and
subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index
## W = 202, p-value = 0.964
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.1999861  0.1999049
## sample estimates:
## difference in location
##           4.324873e-05

#################### PLM Arousals Index in REM #######################
#Summary
summary(SSdata$plm.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.44    0.00    5.90

sd(SSdata$plm.arousals.rem.index, na.rm = TRUE)

## [1] 1.342749

length(SSdata$plm.arousals.rem.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: plm.arousals.rem.index
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.169  0.1690  0.0894 0.7666
## night               1  1.600  1.6000  0.8468 0.3636
## intervention:night  1  0.529  0.5290  0.2800 0.6000
## Residuals          36 68.018  1.8894

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.rem.
index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.rem.
index,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.rem.index, : requested conf.level not achievable
```

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plm.arousals.rem.in
dex and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.rem
.index
## V = 7, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
## 80 percent confidence interval:
##  -2.100052  1.150009
## sample estimates:
## (pseudo)median
##    -0.05003072

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.505   0.000   4.800

sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

## [1] 1.391506

length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
```

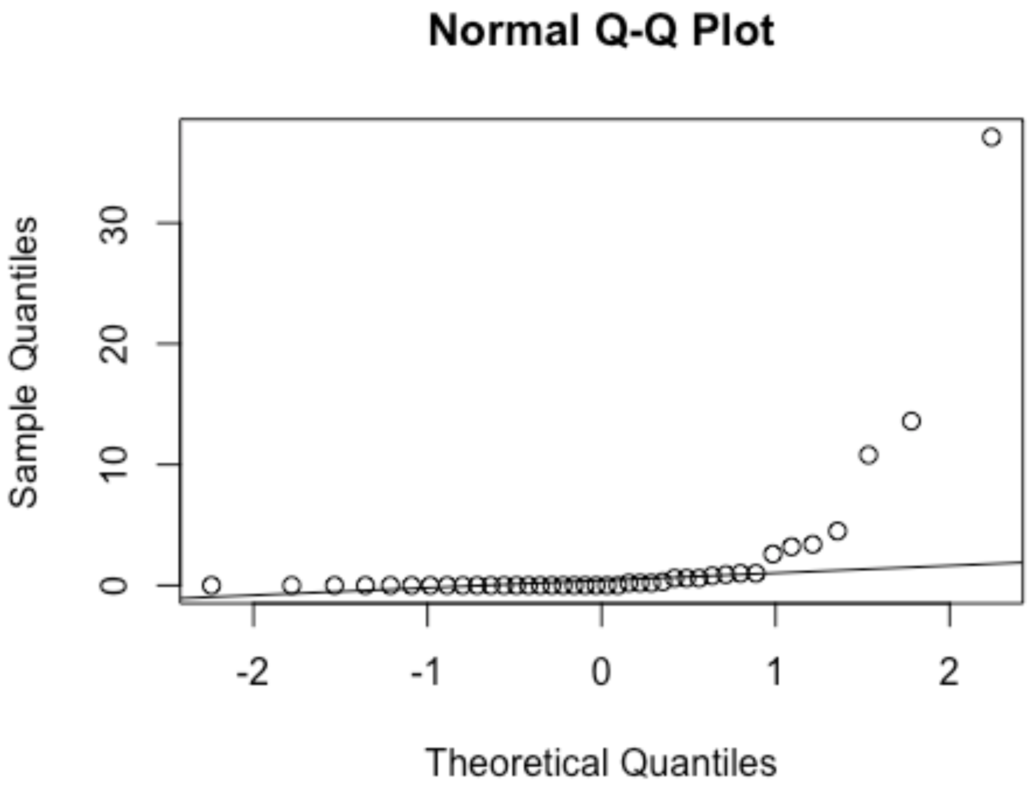


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

##
##  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)
```



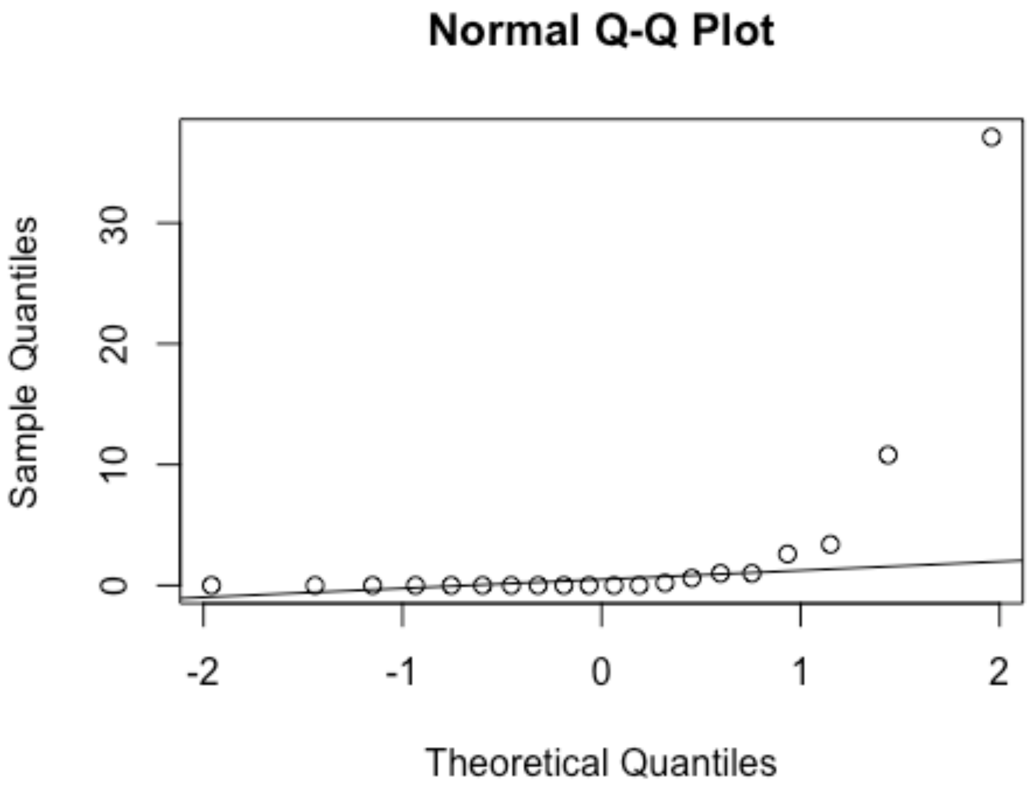
```
ad.test(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

##
##  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.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

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

```
##
## data:  subset(SSdata, intervention == "sham")$plm.arousals.rem.index and s
ubset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index
## W = 198.5, p-value = 0.9653
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.538669e-05  6.131588e-05
## sample estimates:
## difference in location
##          -3.635924e-05

#################### PLM Arousals Total Index (TST = NREM + REM) ############
###########
#Summary
summary(SSdata$plm.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   2.040   0.825  37.100

sd(SSdata$plm.arousals.total.index, na.rm = TRUE)

## [1] 6.334877

length(SSdata$plm.arousals.total.index)

## [1] 40

qqnorm(SSdata$plm.arousals.total.index)
qqline(SSdata$plm.arousals.total.index)
```



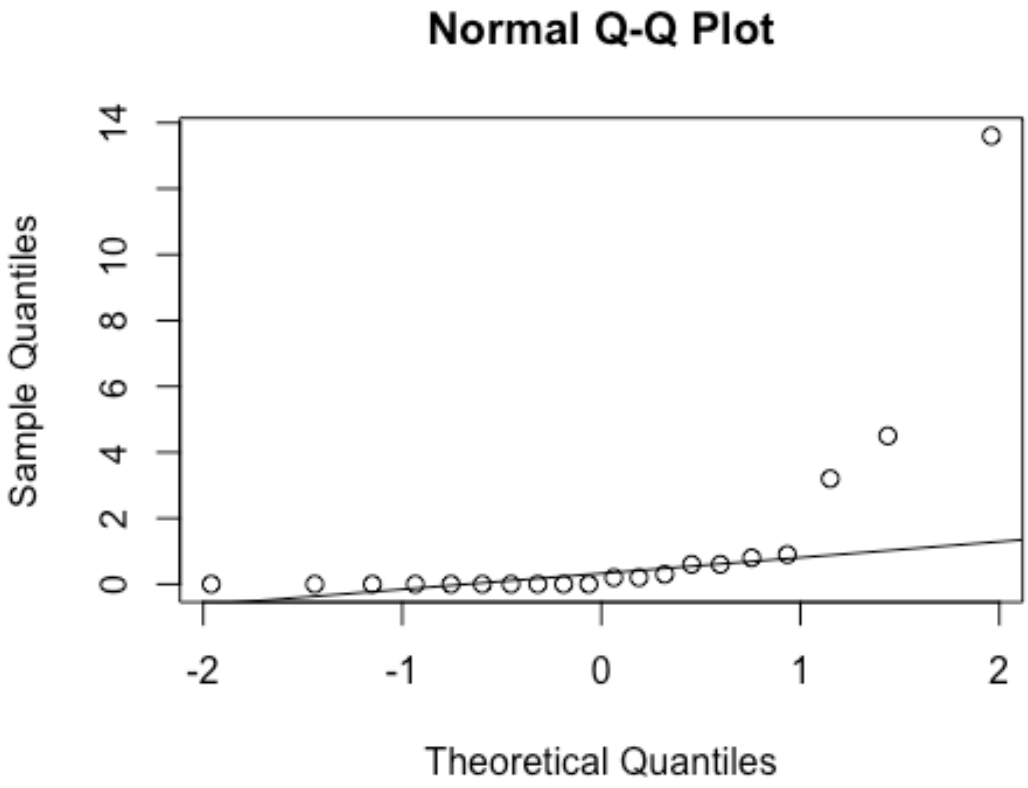
```
ad.test(SSdata$plm.arousals.total.index)

##
##  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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.tota
l.index,
            subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals
.total.index,
            paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plm.arousals.total.
index and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.t
otal.index
## V = 23, p-value = 0.6835
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -15.999946   1.499952
## sample estimates:
## (pseudo)median
##     -0.2999886

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   2.835   1.000  37.100

sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

## [1] 8.438712

length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.inde
x
## 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)
```

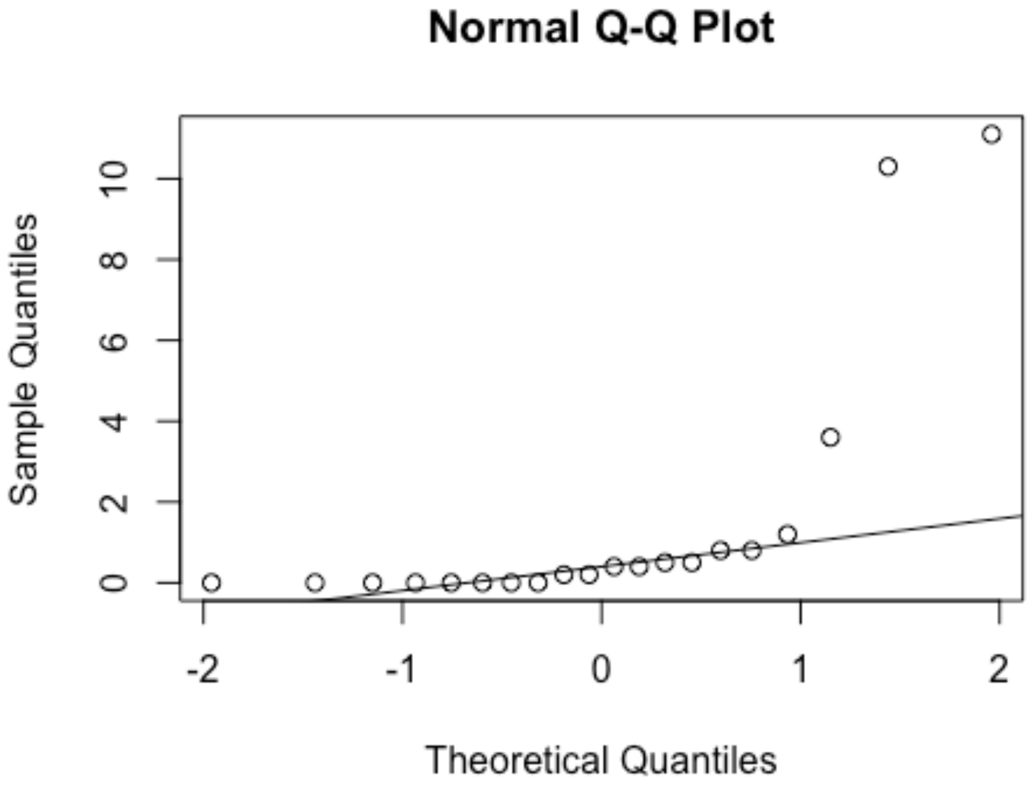


```
ad.test(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

##
##  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
```

```
h
## ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$plm.arousals.total.index and
subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index
## W = 207, p-value = 0.8472
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.1999686  0.2000065
## sample estimates:
## difference in location
##           4.063208e-05

#################### Respiratory Arousals Index in NREM #####################
##
#Summary
summary(SSdata$respiratory.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.20    1.11    0.80   11.10

sd(SSdata$respiratory.arousals.nrem.index, na.rm = TRUE)

## [1] 2.639716

length(SSdata$respiratory.arousals.nrem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(respiratory.arousals.nrem.index ~ interventio
n * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: respiratory.arousals.nrem.index
##                    Df  Sum Sq Mean Sq F value  Pr(>F)
## intervention        1   6.084  6.0840  0.9328 0.34058
## night               1   4.624  4.6240  0.7089 0.40535
## intervention:night  1  26.244 26.2440  4.0237 0.05242 .
## Residuals          36 234.804  6.5223
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arous
```

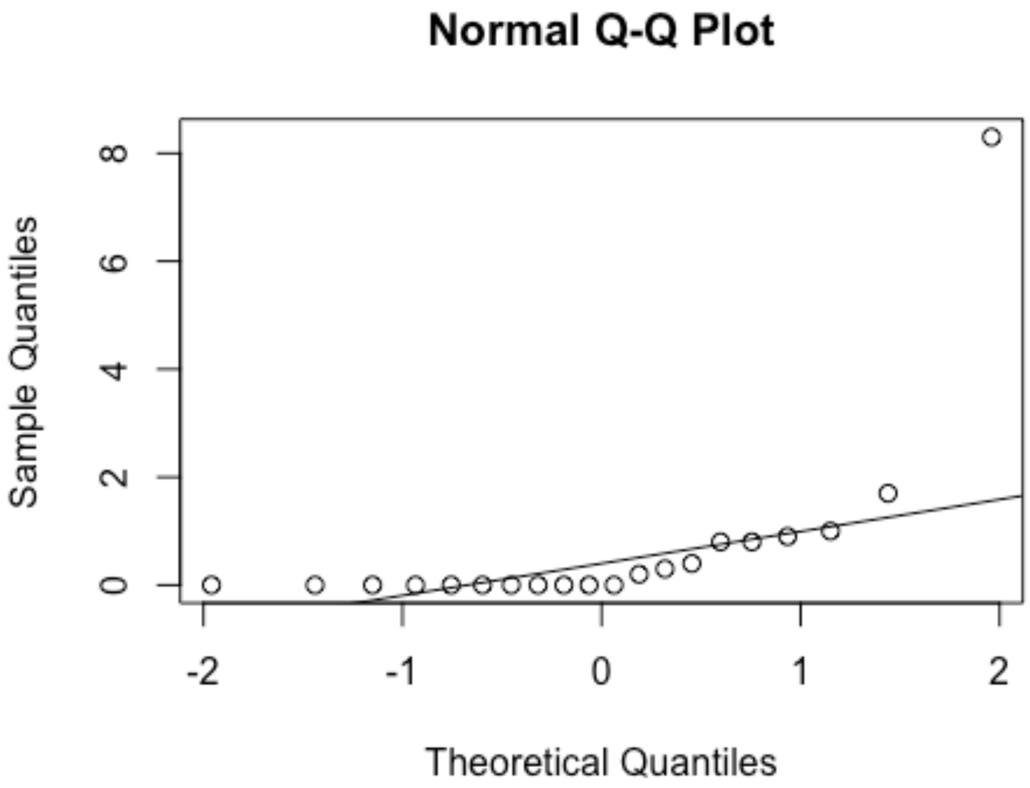
```
als.nrem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arous
als.nrem.index,
       paired = TRUE, conf.int = TRUE)

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.nrem.index, : cannot compute exact confidence
## interval with ties

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
s.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respira
tory.arousals.nrem.index
## V = 30, p-value = 0.09338
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.15001291  0.05002172
## sample estimates:
## (pseudo)median
##     -0.3500664

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     0.0     0.0     0.3     1.5     0.8    11.1

sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.inde
x)

## [1] 3.251558

length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
index)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
index)
qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nr
em.index
## A = 4.3757, p-value = 2.59e-11

#non-normal

summary(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.inde
x)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.72    0.80    8.30

sd(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index)
```

```
## [1] 1.846647

length(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
)
qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
)
```



```
ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.inde
x)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.in
dex
## A = 4.3196, p-value = 3.581e-11

#non-normal
```

```
wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.
index,
            subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.
nrem.index,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.in
dex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
.index
## W = 171, p-value = 0.4142
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.000240e-01  3.702807e-05
## sample estimates:
## difference in location
##           -5.97387e-05

#################### Respiratory Arousals Index in REM ######################
#
#Summary
summary(SSdata$respiratory.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.950   6.612   4.225  70.000

sd(SSdata$respiratory.arousals.rem.index, na.rm = TRUE)

## [1] 14.61077

length(SSdata$respiratory.arousals.rem.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: respiratory.arousals.rem.index
```

```
##                     Df Sum Sq Mean Sq F value  Pr(>F)
## intervention         1    0.4    0.42  0.0021 0.96365
## night                1   18.6   18.63  0.0934 0.76166
## intervention:night   1 1124.7 1124.66  5.6376 0.02303 *
## Residuals           36 7181.8  199.49
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arous
als.rem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arous
als.rem.index,
       paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.rem.index, : cannot compute exact p-value wit
h
## ties
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.rem.index, : cannot compute exact confidence
## interval with ties
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.rem.index, : cannot compute exact p-value wit
h
## zeroes
```

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

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
s.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respirat
ory.arousals.rem.index
## V = 67, p-value = 0.7119
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.249966  3.599990
## sample estimates:
## (pseudo)median
##      0.3582702
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.
index)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.55    6.51    4.35   47.10
```

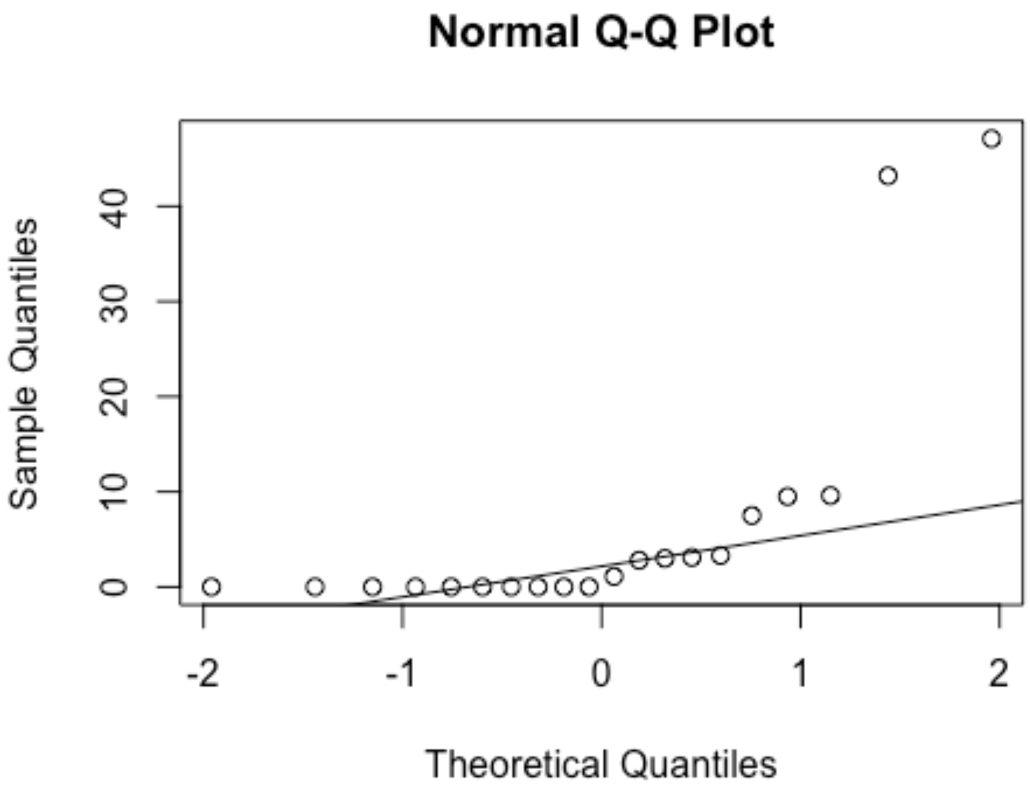
```
sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.index
)
```

```
## [1] 13.60003
```

```
length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
ndex)
```

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

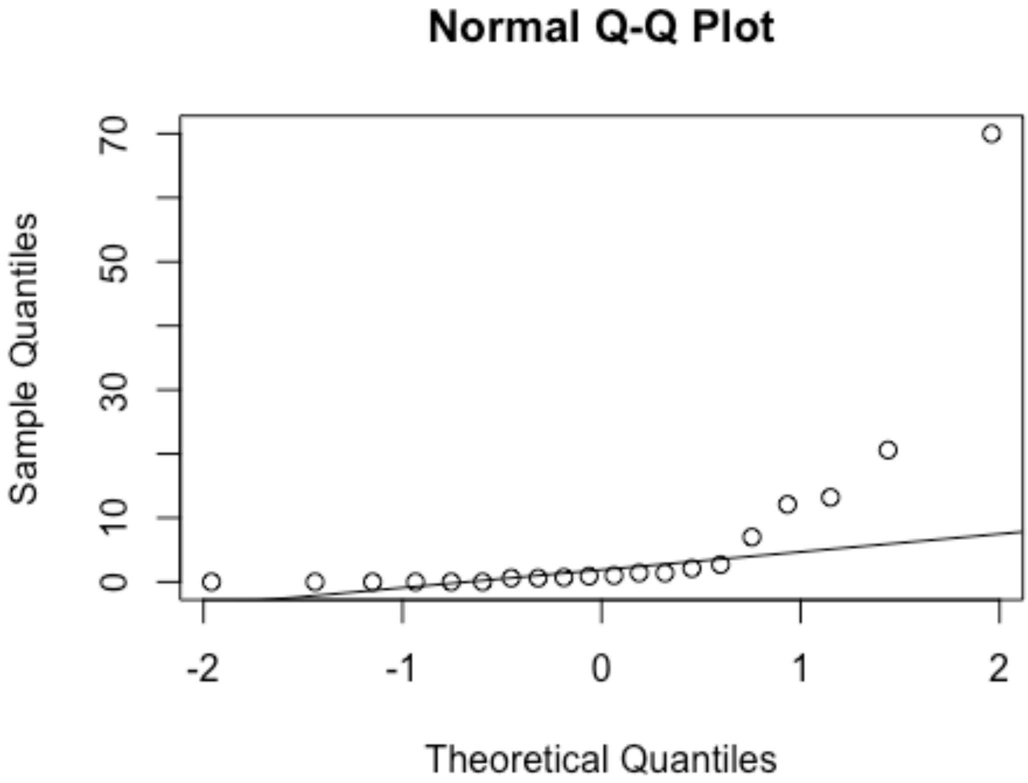
```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
ndex)
qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
ndex)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.
index)
```

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.re
```

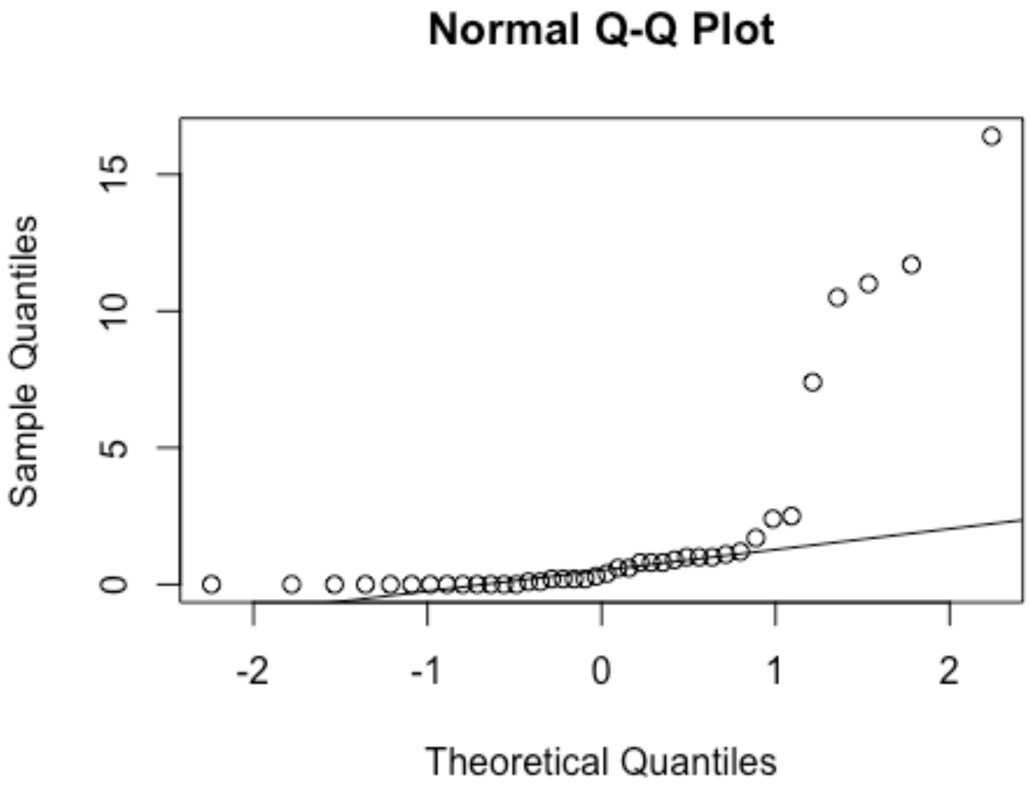
```
m.index
## A = 4.0123, p-value = 2.119e-10

#non-normal

summary(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.950   6.715   3.775  70.000

sd(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)

## [1] 15.9123

length(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
)
```

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.rem.ind
ex
## A = 4.0308, p-value = 1.904e-10

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.i
ndex,
            subset(SSdata, intervention == "PrenaBelt")$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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.rem.ind
ex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
ndex
## W = 213, p-value = 0.7267
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.900003  1.399993
## sample estimates:
## difference in location
##            5.850022e-05

#################### Respiratory Arousals Total Index (TST = NREM + REM) ####
###########
#Summary
summary(SSdata$respiratory.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.350   1.878   1.025  16.400

sd(SSdata$respiratory.arousals.total.index, na.rm = TRUE)

## [1] 3.840706

length(SSdata$respiratory.arousals.total.index)

## [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
```

```
## 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
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

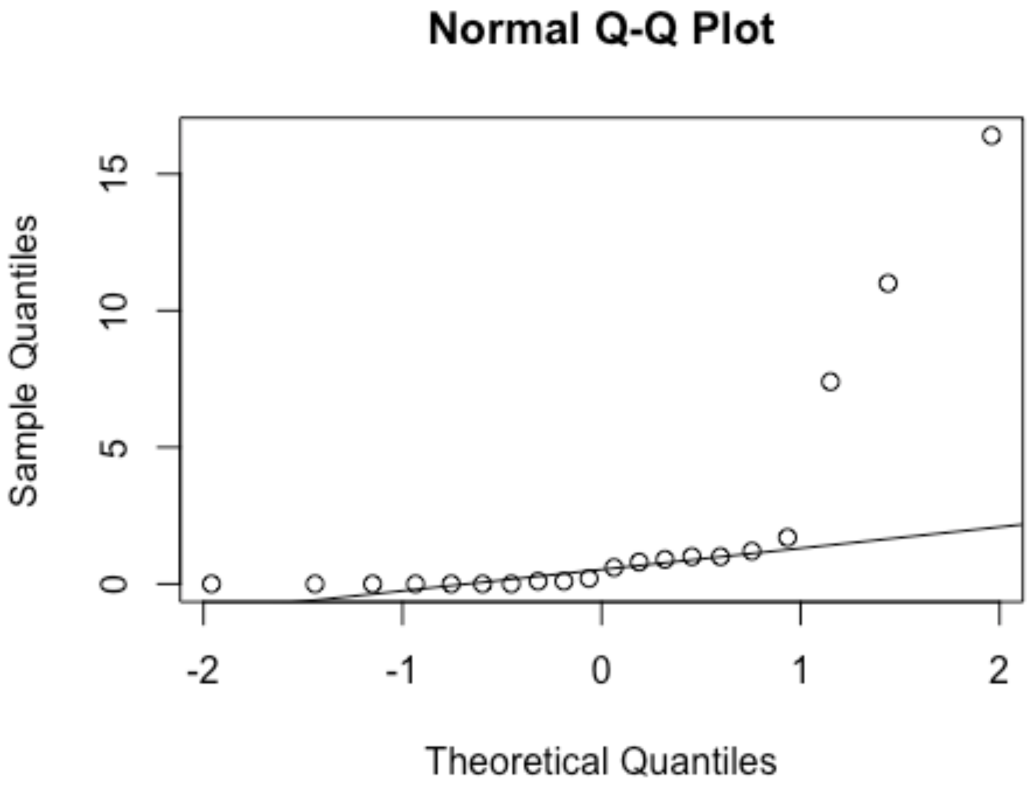
```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arous
als.total.index,
            subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.
arousals.total.index,
            paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.total.index, : cannot compute exact p-value
## with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.total.index, : cannot compute exact confidenc
e
## interval with ties

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.total.index, : cannot compute exact confidenc
e
## interval with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respir
atory.arousals.total.index
## V = 62, p-value = 0.776
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.0999697  0.5000137
## sample estimates:
## (pseudo)median
##     -0.1000365
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tota
l.index)
```

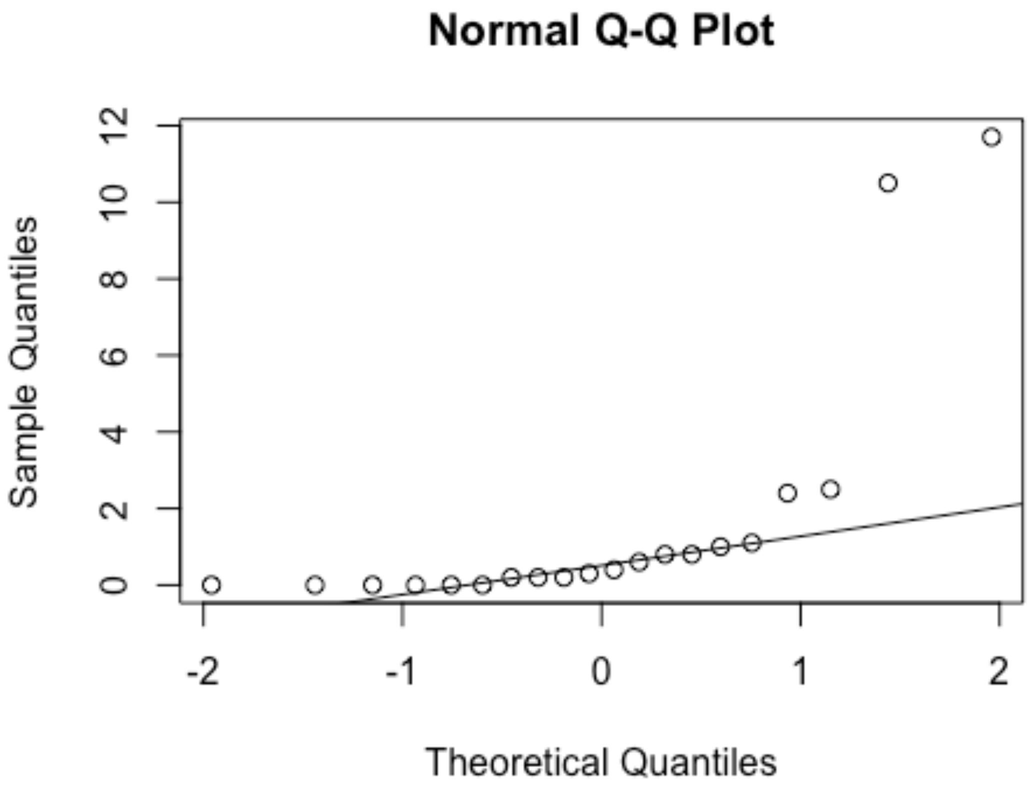
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.40    2.12    1.05   16.40
```

```
sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.ind
ex)

## [1] 4.371149

length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
.index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tota
l.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.to
tal.index
## A = 3.9897, p-value = 2.416e-10
```

```
#non-normal

summary(subset(SSdata, intervention == "sham")$respiratory.arousals.total.ind
ex)

##    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.inde
x)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.total.inde
x)
qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.total.inde
x)
```

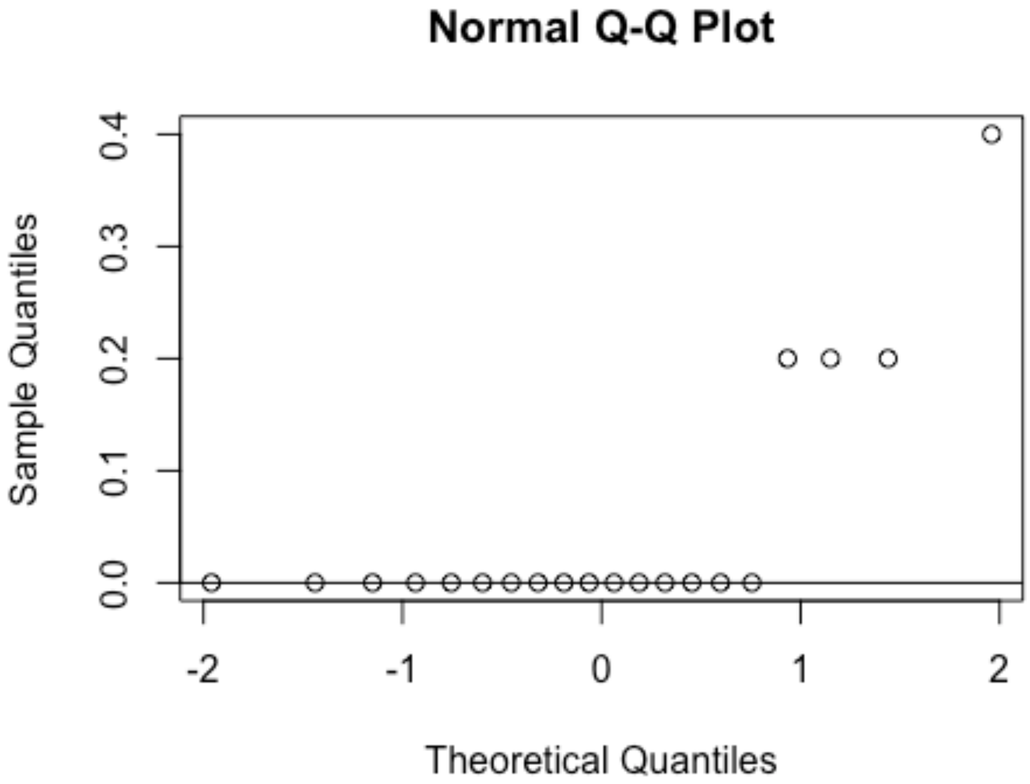


```
ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.total.ind
ex)
```

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.total.i
ndex
## A = 4.0437, p-value = 1.767e-10

#non-normal

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

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $respiratory.arousals.total.index, : cannot compute exact p-value with tie
s

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.total.i
ndex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tot
al.index
## W = 203, p-value = 0.9451
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.5999724  0.3999323
## sample estimates:
## difference in location
##           9.000537e-06

########### Arousing events NOT meeting respiratory criteria Index in NREM ##
#########
#Summary
summary(SSdata$arousals.with.respiratory.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.045   0.000   0.400

sd(SSdata$arousals.with.respiratory.nrem.index, na.rm = TRUE)

## [1] 0.09594336

length(SSdata$arousals.with.respiratory.nrem.index)

## [1] 40
```

```
#ANOVA
night_tx_difference <- anova(lm(arousals.with.respiratory.nrem.index ~ interv
ention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: arousals.with.respiratory.nrem.index
##                     Df Sum Sq   Mean Sq F value Pr(>F)
## intervention         1  0.001 0.0010000  0.1034 0.7496
## night                1  0.001 0.0010000  0.1034 0.7496
## intervention:night   1  0.009 0.0090000  0.9310 0.3410
## Residuals           36  0.348 0.0096667

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
piratory.nrem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
piratory.nrem.index,
       paired = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
ratory.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$ar
ousals.with.respiratory.nrem.index
## V = 2, p-value = 0.7728
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.05    0.00    0.40

sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.nrem
.index)

## [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)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.04    0.00    0.20
```

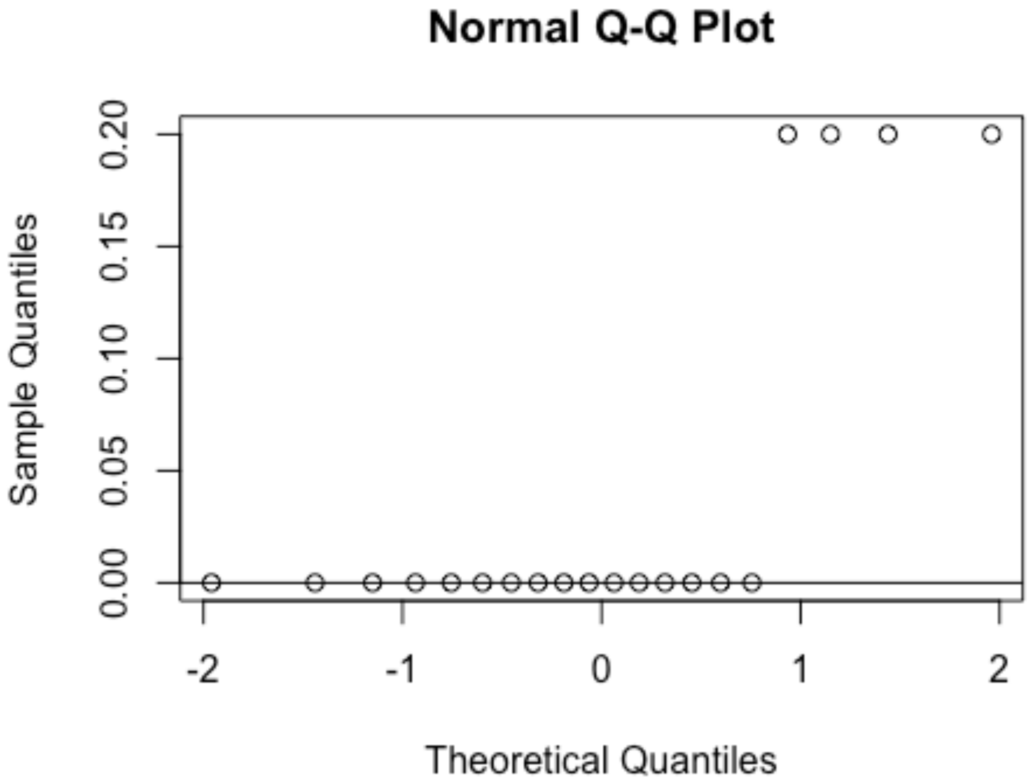
```
sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem.inde
x)
```

```
## [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)
```



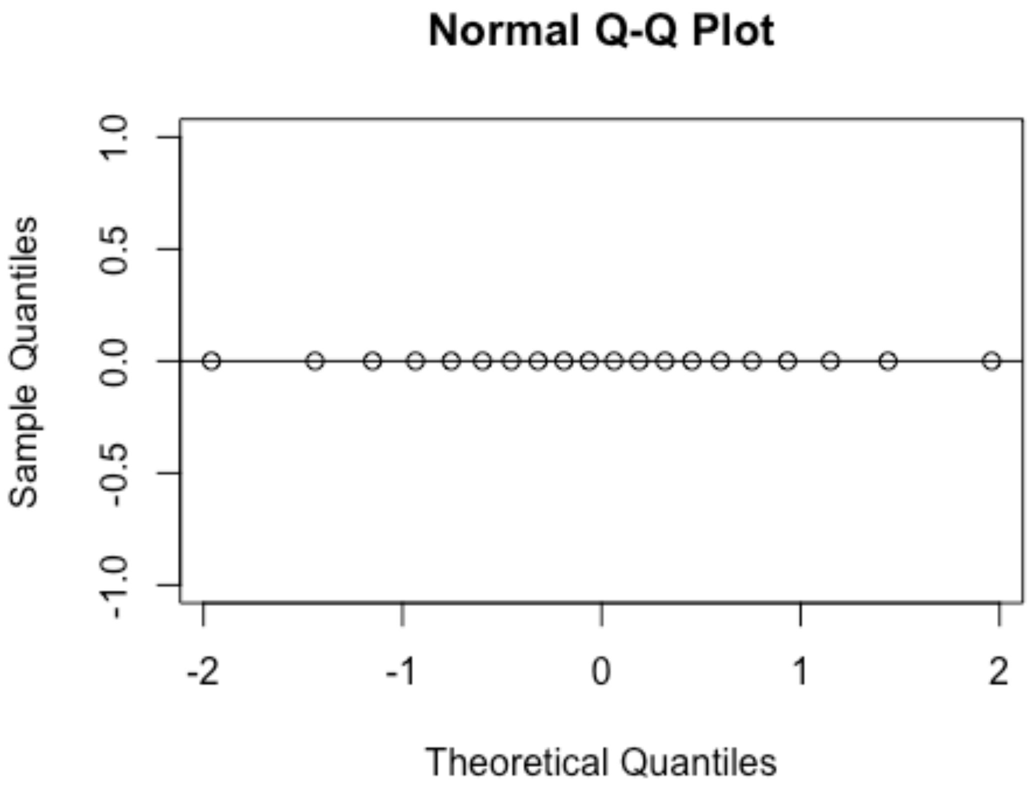
```
ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem
.index)
```

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.nr
```

```
em.index
## A = 5.1941, p-value = 2.32e-13

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
tory.nrem.index,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.nr
em.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respir
atory.nrem.index
## W = 198, p-value = 0.9534
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.407869e-05  9.852765e-06
## sample estimates:
## difference in location
##          -3.692335e-06

####### Arousing events NOT meeting respiratory criteria Index in REM #######
##
#Summary
summary(SSdata$arousals.with.respiratory.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.015   0.000   0.600

sd(SSdata$arousals.with.respiratory.rem.index, na.rm = TRUE)

## [1] 0.09486833

length(SSdata$arousals.with.respiratory.rem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(arousals.with.respiratory.rem.index ~ interve
ntion * night,
```

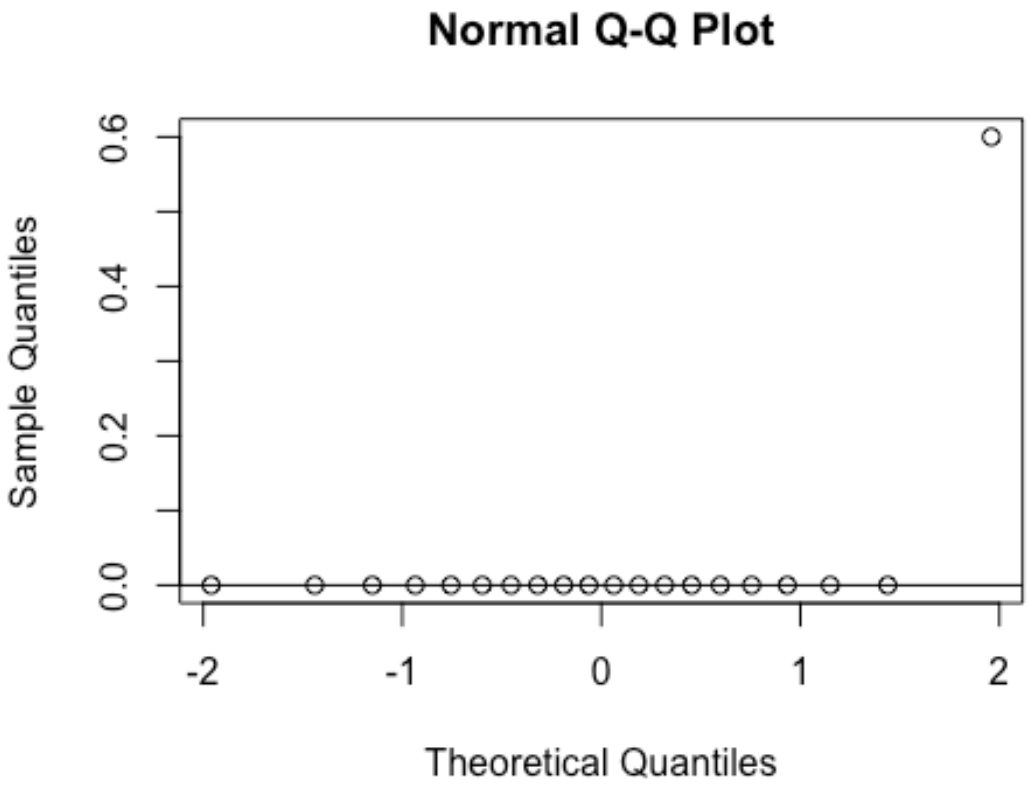
```
                                data = SSdata))
night_tx_difference

## 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")$arousals.with.res
piratory.rem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
piratory.rem.index,
       paired = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$arousals.with.respiratory.rem.index, : cannot compute exact p-valu
e
## with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
ratory.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$aro
usals.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
```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
rem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
rem.index)
```



```
#ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respirator
y.rem.index)
#distribution is entirely zeroes

summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.
index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.03    0.00    0.60

sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.index
)

## [1] 0.1341641

length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
ndex)

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
ndex)
qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
ndex)
```



```
ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.
index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.re
m.index
## A = 7.1762, p-value < 2.2e-16

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
rem.index,
            subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
tory.rem.index,
            conf.int = TRUE)
```

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

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

## 
##  Wilcoxon rank sum test with continuity correction
## 
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.re
m.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
tory.rem.index
## W = 210, p-value = 0.3421
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  0 0
## sample estimates:
## difference in location 
##                      0

####### Arousing events NOT meeting respiratory criteria Index (TST = NREM + 
REM) ######
#Summary
summary(SSdata$arousals.with.respiratory.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##  0.0000  0.0000  0.0000  0.0425  0.0000  0.4000

sd(SSdata$arousals.with.respiratory.total.index, na.rm = TRUE)

## [1] 0.09577618

length(SSdata$arousals.with.respiratory.total.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(arousals.with.respiratory.total.index ~ inter
vention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
## 
## Response: arousals.with.respiratory.total.index
##                     Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1 0.00025 0.00025  0.0256 0.8737
## night               1 0.00025 0.00025  0.0256 0.8737
## intervention:night  1 0.00625 0.00625  0.6410 0.4286
## Residuals          36 0.35100 0.00975
```

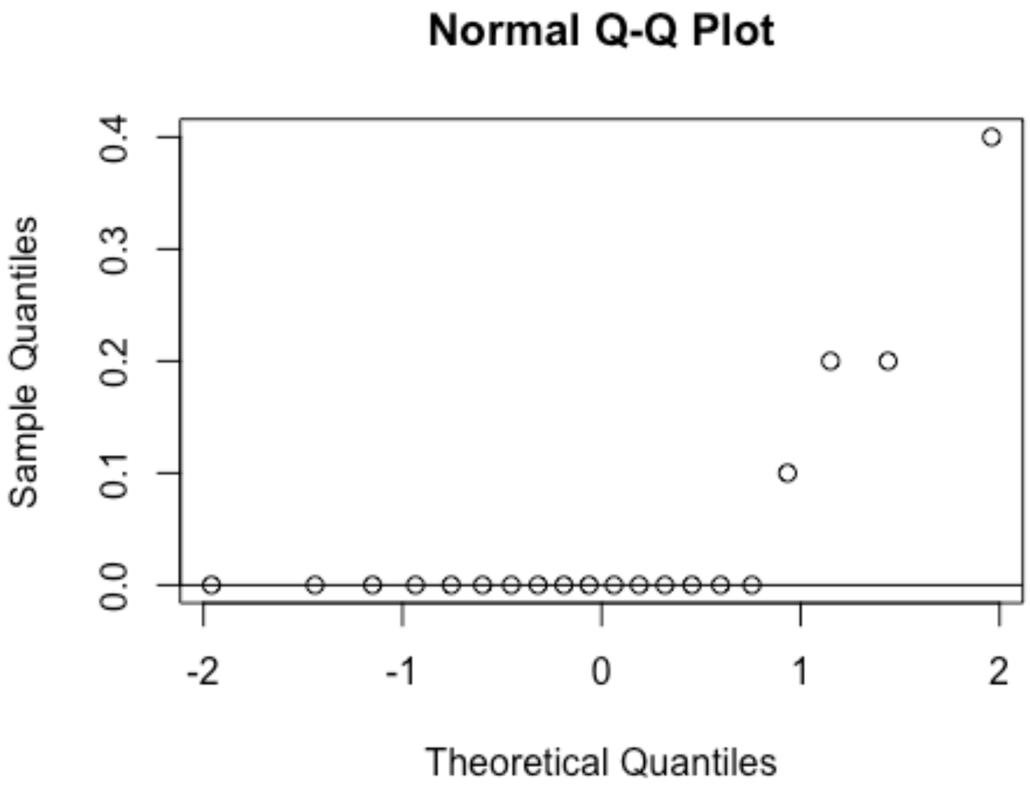
```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
piratory.total.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
piratory.total.index,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$arousals.with.respiratory.total.index, : requested conf.level not
## achievable

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$arousals.with.respiratory.total.index, : cannot compute exact
## confidence interval with ties

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
ratory.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$a
rousals.with.respiratory.total.index
## V = 5.5, p-value = 0.6831
## alternative hypothesis: true location shift is not equal to 0
## 90 percent confidence interval:
##  -0.2  0.2
## sample estimates:
## (pseudo)median
##  -5.079939e-05

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.045   0.000   0.400

sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.tota
l.index)
```

```
## [1] 0.1050063
```

```
length(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
total.index)
```

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

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
total.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
total.index)
```



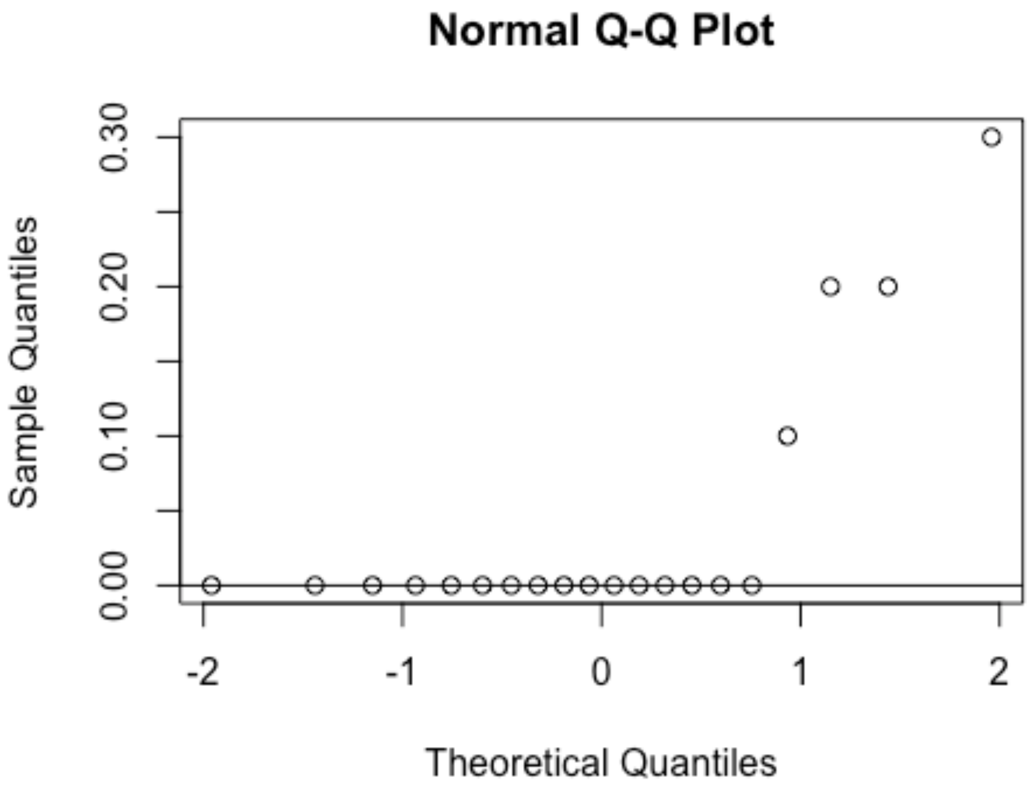
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
.total.index)
```

```
##
##  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

length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
.index)
qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
.index)
ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.tota
l.index)

## 
##  Anderson-Darling normality test
## 
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.to
tal.index
## A = 4.6836, p-value = 4.379e-12

#non-normal

wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
total.index,
            subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
tory.total.index,
            conf.int = TRUE)

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

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

## 
##  Wilcoxon rank sum test with continuity correction
## 
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.to
tal.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respi
```

```
ratory.total.index
## W = 199.5, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -5.011195e-06  5.395622e-05
## sample estimates:
## difference in location
##           -6.56778e-05

###################### Linear Mixed Effects Model #################
library(epiDisplay)

## Loading required package: foreign

## Loading required package: survival

## Loading required package: MASS

## Loading required package: nnet

#linear mixed effects model
library(lme4)

## Loading required package: Matrix
```



```
#PERCENTAGE sleep time supine:
#response variable: PtstSupine
#fixed effects: intervention (PrenaBelt, sham)
#random effects: participant, night

#Specify that the sham intervention is the reference
SSdata$intervention <- relevel(SSdata$intervention,
                       ref = "sham")

#Specify model
intervention.lme <- lmer(PtstSupine ~ intervention + (1 | participant.s.code)
+
                           (1 | night),
                     data = SSdata)

#Print out results
intervention.lme
```

```
## Linear mixed model fit by REML ['lmerMod']
## Formula:
## PtstSupine ~ intervention + (1 | participant.s.code) + (1 | night)
##    Data: SSdata
## REML criterion at convergence: 321.3263
## Random effects:
##  Groups             Name        Std.Dev.
##  participant.s.code (Intercept) 14.44
##  night              (Intercept)  0.00
##  Residual                       10.29
## Number of obs: 40, groups:  participant.s.code, 20; night, 2
## Fixed Effects:
##           (Intercept)  interventionPrenaBelt
##                18.505                 -6.825
```

```
summary(intervention.lme)
```

```
## Linear mixed model fit by REML ['lmerMod']
## Formula:
## PtstSupine ~ intervention + (1 | participant.s.code) + (1 | night)
##    Data: SSdata
##
## REML criterion at convergence: 321.3
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -1.62094 -0.60673 -0.00144  0.39109  1.86710
##
## Random effects:
##  Groups             Name        Variance Std.Dev.
##  participant.s.code (Intercept) 208.6    14.44
##  night              (Intercept)   0.0     0.00
```

```
##  Residual                         105.8    10.29
## Number of obs: 40, groups:  participant.s.code, 20; night, 2
##
## Fixed effects:
##                          Estimate Std. Error t value
## (Intercept)                18.505      3.965   4.668
## interventionPrenaBelt      -6.825      3.252  -2.098
##
## Correlation of Fixed Effects:
##             (Intr)
## intrvntnPrB -0.410

#compute 95% CI (two-sided)
confint(intervention.lme)

## Computing profile confidence intervals ...

##                             2.5 %     97.5 %
## .sig01                   9.058653 21.1339282
## .sig02                   0.000000  9.4829922
## .sigma                   7.569426 14.1618877
## (Intercept)             10.639735 26.3703919
## interventionPrenaBelt -13.348929 -0.3010706

#compute p-value using formula p = 2*pt(t-value, dof=length(SSdata)-1)
p=2*pt(-2.098, 39)
p

## [1] 0.04243394

#p<0.05, statistically significant: 6.8% absolute reduction in PtstSupine wit
h PrenaBelt
#(18.5% down to 11.5%), which is a 38% relative reduction.

#MINUTES sleep time supine:
#response variable: MinutesTSTSupine
#fixed effects: intervention (treatment, sham)
#random effects: participant, night

#Specify that the sham intervention is the reference
SSdata$intervention <- relevel(SSdata$intervention,ref = "sham")

#Specify model
intervention.lme <- lmer(minutesTSTSupine ~ intervention + (1 | participant.s
.code) +
                           (1 | night),
                         data = SSdata)

#Print out results
intervention.lme
```

```
## Linear mixed model fit by REML ['lmerMod']
## Formula: minutesTSTSupine ~ intervention + (1 | participant.s.code) +
##     (1 | night)
##    Data: SSdata
## REML criterion at convergence: 414.0174
## Random effects:
##  Groups             Name        Std.Dev.
##  participant.s.code (Intercept) 54.66
##  night              (Intercept)  0.00
##  Residual                       32.20
## Number of obs: 40, groups:  participant.s.code, 20; night, 2
## Fixed Effects:
##          (Intercept)  interventionPrenaBelt
##                62.30                 -24.35
```

```
summary(intervention.lme)
```

```
## Linear mixed model fit by REML ['lmerMod']
## Formula: minutesTSTSupine ~ intervention + (1 | participant.s.code) +
##     (1 | night)
##    Data: SSdata
##
## REML criterion at convergence: 414
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -1.32084 -0.61087  0.05957  0.57539  1.44671
##
## Random effects:
##  Groups             Name        Variance Std.Dev.
##  participant.s.code (Intercept) 2988     54.66
##  night              (Intercept)    0      0.00
##  Residual                       1037     32.20
## Number of obs: 40, groups:  participant.s.code, 20; night, 2
##
## Fixed effects:
##                       Estimate Std. Error t value
## (Intercept)              62.30      14.19   4.392
## interventionPrenaBelt   -24.35      10.18  -2.391
##
## Correlation of Fixed Effects:
##             (Intr)
## intrvntnPrB -0.359
```

```
#compute 95% CI (two-sided)
confint(intervention.lme)
```

```
## Computing profile confidence intervals ...
```

```
##                           2.5 %    97.5 %
## .sig01                 36.66838 78.512673
```

```
## .sig02                     0.00000 30.670482
## .sigma                    23.69611 44.333544
## (Intercept)               34.21546 90.383559
## interventionPrenaBelt -44.76840 -3.922302

#compute p-value using formula p = 2*pt(t-value, dof=length(SSdata)-1)
p=2*pt(-2.697, 39)
p

## [1] 0.01027937

#p<0.05, statistically significant: 24.4 minute reduction in number of minute
s spent
#supine with the PrenaBelt.

########END######
```

Supplementary file 3: Code and output – feedback analysis

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 comparison
s (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############################
```

```
#summary data
summary(PBUFdata$SR.position.adopted)

##                            left  left and right left and supine
##               0              27               5               1
##           right          supine
##               5               2

length(PBUFdata$SR.position.adopted)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.position.adopted + Intervention, data = PBUFdata)

##                     Intervention
## SR.position.adopted sham treatment
##                        0         0
##     left              13        14
##     left and right     2         3
##     left and supine    1         0
##     right              3         2
##     supine             1         1

#build 2-row table for fisher test: sham vs treatment
SR.position.adopted_table <- matrix(c(16,17,5,5,2,1),
                                         nrow = 2)
colnames(SR.position.adopted_table) <- c("left","right","supine")
rownames(SR.position.adopted_table) <- c("Sham",
                                              "Treatment")
SR.position.adopted_table

##            left right supine
## Sham         16     5      2
## Treatment    17     5      1

t(SR.position.adopted_table)

##         Sham Treatment
## left     16        17
## right     5         5
## supine    2         1

#Perform Fisher's Exact Tests

temp_table <- t(SR.position.adopted_table)
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] "left"
##       Sham Treatment
## left    16        17
## Other    7         6
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.181121 3.522335
## sample estimates:
## odds ratio
##   0.810505
##
## [1] "right"
##       Sham Treatment
## right    5         5
## Other   18        18
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1927805 5.1872475
## sample estimates:
## odds ratio
##          1
##
## [1] "supine"
##        Sham Treatment
## supine    2         1
## Other    21        22
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
```

```
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0.1003416 129.0322645
## sample estimates:
## odds ratio
##   2.062812

#############################SR POSITION FELL ASLEEP#########################
####
#summary data
summary(PBUFdata$SR.position.fell.asleep)

##                                       left       left and right
##                    0                    27                    5
## left, right and back                right               supine
##                    1                    5                    2

length(PBUFdata$SR.position.fell.asleep)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.position.fell.asleep + Intervention, data = PBUFdata)

##                         Intervention
## SR.position.fell.asleep sham treatment
##                            0         0
##    left                   13        14
##    left and right          2         3
##    left, right and back    1         0
##    right                   3         2
##    supine                  1         1

#build 2-row table for fisher test: sham vs treatment
SR.position.fell.asleep_table <- matrix(c(16,17,6,5,2,1),
                                    nrow = 2)
colnames(SR.position.fell.asleep_table) <- c("left","right","supine")
rownames(SR.position.fell.asleep_table) <- c("Sham",
                                         "Treatment")
t(SR.position.fell.asleep_table)

##         Sham Treatment
## left     16        17
## right     6         5
## supine    2         1

#Perform Fisher's Exact Tests

temp_table <- t(SR.position.fell.asleep_table)
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] "left"
##       Sham Treatment
## left    16        17
## Other    8         6
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.7516
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1630989 2.9521011
## sample estimates:
## odds ratio 
##  0.7111464 
## 
## [1] "right"
##       Sham Treatment
## right    6         5
## Other   18        18
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.2513307 5.9379379
## sample estimates:
## odds ratio 
##   1.195355 
## 
## [1] "supine"
##        Sham Treatment
## supine    2         1
## Other    22        22
```

```
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0.09605226 123.17436447
## sample estimates:
## odds ratio
##   1.971677
```

```
#############################SR SNORING#############################
#summary data
summary(PBUFdata$SR.snored.last.night)
```

```
##            don't know         no        yes
##          3         26          8          3
```

```
length(PBUFdata$SR.snored.last.night)
```

```
## [1] 40
```

```
#between participants (grouped) comparison
xtabs(~SR.snored.last.night + Intervention, data = PBUFdata)[-1,]
```

```
##                      Intervention
## SR.snored.last.night sham treatment
##           don't know   13        13
##           no            4         4
##           yes           1         2
```

```
#Perform Fisher's Exact Tests
temp_table <- xtabs(~SR.snored.last.night + 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   13        13
## Other         5         6
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.2341604 6.3402606
## sample estimates:
## odds ratio 
##     1.1941 
## 
## [1] "no"
##        Sham Treatment
## no       4         4
## Other   14        15
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1643428 6.9643241
## sample estimates:
## odds ratio 
##    1.06941 
## 
## [1] "yes"
##        Sham Treatment
## yes      1         2
## Other   17        17
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.008017856 10.654170427
## sample estimates:
## odds ratio 
##   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
```

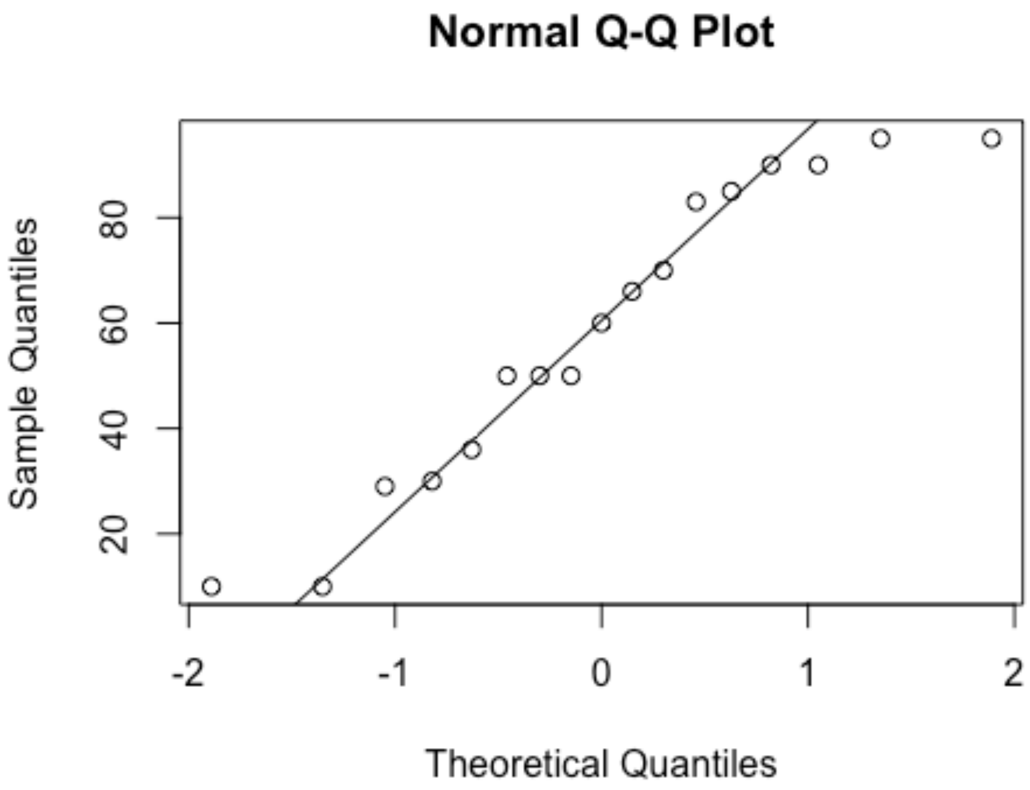
```
## sample estimates:
## odds ratio
##  0.7264619
##
## [1] "no"
##       Sham Treatment
## no       8         6
## Other   11        12
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7374
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.3156971 6.8777204
## sample estimates:
## odds ratio
##   1.439815
##
## [1] "yes"
##       Sham Treatment
## yes      2         2
## Other   17        16
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.06145761 14.45806216
## sample estimates:
## odds ratio
##  0.9426919

#############################SR WAKE POSITION#############################
#summary data
summary(PBUFdata$SR.position.woke.up)

##        left right
##     0    28    12

length(PBUFdata$SR.position.woke.up)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.position.woke.up + Intervention, data = PBUFdata)[-1,]
```

```
##                     Intervention
## SR.position.woke.up sham treatment
##               left    13        15
##               right    7         5

fisher.test(xtabs(~SR.position.woke.up + Intervention, data = PBUFdata)[-1,])

##
##  Fisher's Exact Test for Count Data
##
## data:
## p-value = 0.7311
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1235598 2.9574108
## sample estimates:
## odds ratio
##  0.6265621

##############################SR - did you change positions?##################
###########
#summary data
summary(PBUFdata$SR.position.changed)

##               don\xcdt know            no           yes
##             1             1             3            35

length(PBUFdata$SR.position.changed)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.position.changed + Intervention, data = PBUFdata)[-1,]

##                     Intervention
## SR.position.changed sham treatment
##       don\xcdt know    1         0
##       no               1         2
##       yes             18        17

#Perform Fisher's Exact Tests
temp_table <- xtabs(~SR.position.changed + 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\xcdt know"
##                 Sham Treatment
## don\xcdt know    1         0
## Other           19        19
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.02435859        Inf
## sample estimates:
## odds ratio 
##        Inf 
## 
## [1] "no"
##       Sham Treatment
## no       1         2
## Other   19        17
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.605
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.007216433 9.507277143
## sample estimates:
## odds ratio 
##   0.456456 
## 
## [1] "yes"
##       Sham Treatment
## yes     18        17
## Other    2         2
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
```

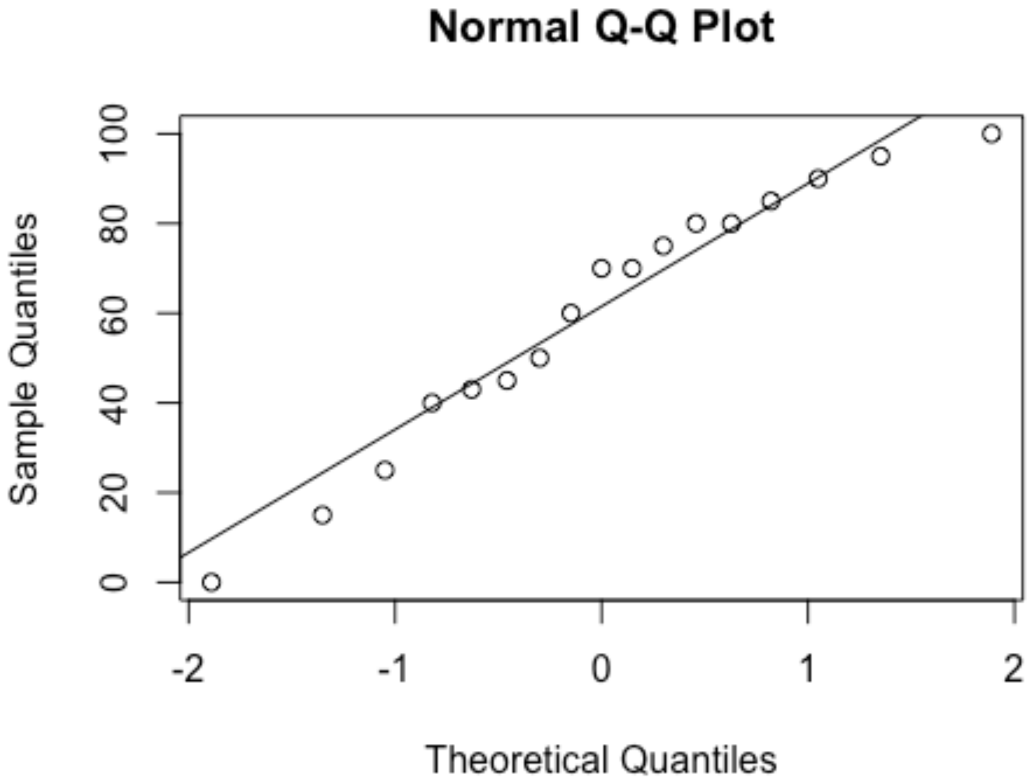
```
##   0.0693477 16.1216542
## sample estimates:
## odds ratio
##   1.057301

#Take out the pts that we don't have complete data on (these participants' st
udies were
#before the PUFQ was revised to ask about the participant's estimate of how m
uch time
#she spent in each position)
PBUF_shamSRpos <- PBUF_sham[-c(1,2,3),]
PBUF_treatSRpos <- PBUF_treat[-c(1,2,3),]

#############################SR PROPORTION OF TIME ON LEFT###################
##########
#summary data
summary(PBUFdata$SR.Ptime.left)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##    0.00   41.50   66.00   59.91   84.00  100.00       5

sd(PBUFdata$SR.Ptime.left, na.rm = TRUE)

## [1] 28.14915

length(na.omit(PBUFdata$SR.Ptime.left))

## [1] 35

#within-participants (paired) comparison
#Paired t-test
t.test(PBUF_shamSRpos$SR.Ptime.left, PBUF_treatSRpos$SR.Ptime.left, paired =
TRUE)

##
##  Paired t-test
##
## data:  PBUF_shamSRpos$SR.Ptime.left and PBUF_treatSRpos$SR.Ptime.left
## t = 0.38979, df = 16, p-value = 0.7018
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -6.266297  9.089826
## sample estimates:
## mean of the differences
##                1.411765

#between participants (grouped) comparison
summary(PBUF_treatSRpos$SR.Ptime.left)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   10.00   36.00   60.00   58.76   85.00   95.00
```

```
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
```

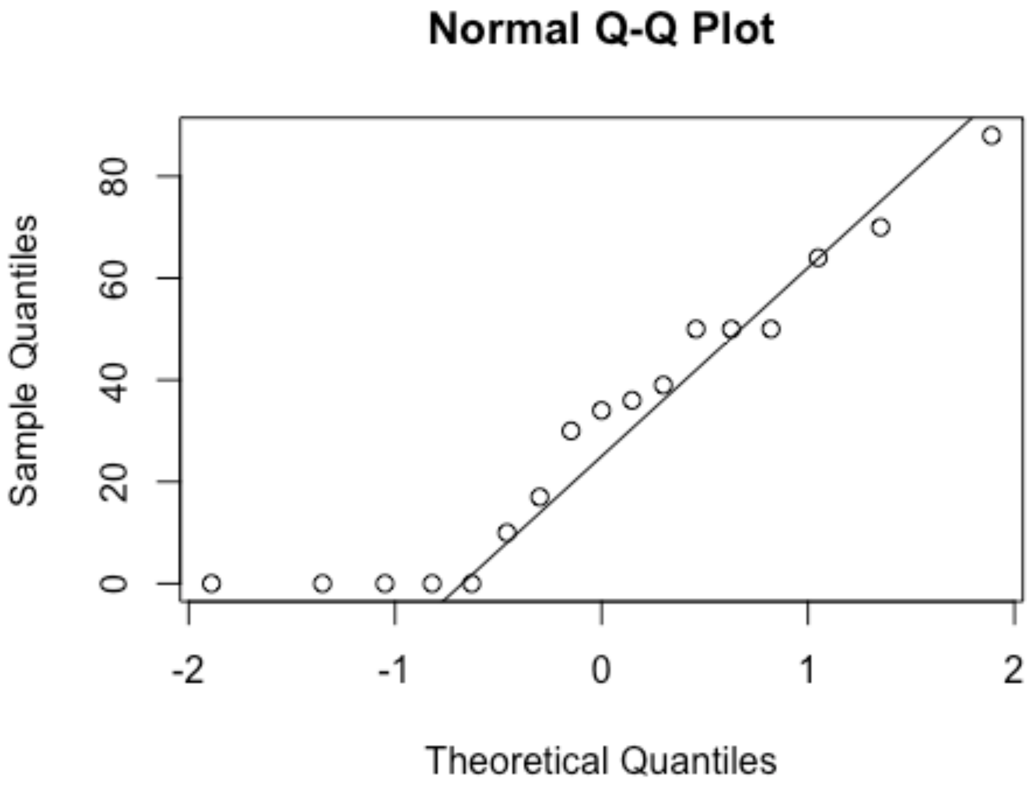
```
sd(PBUF_shamSRpos$SR.Ptime.left)

## [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)
```

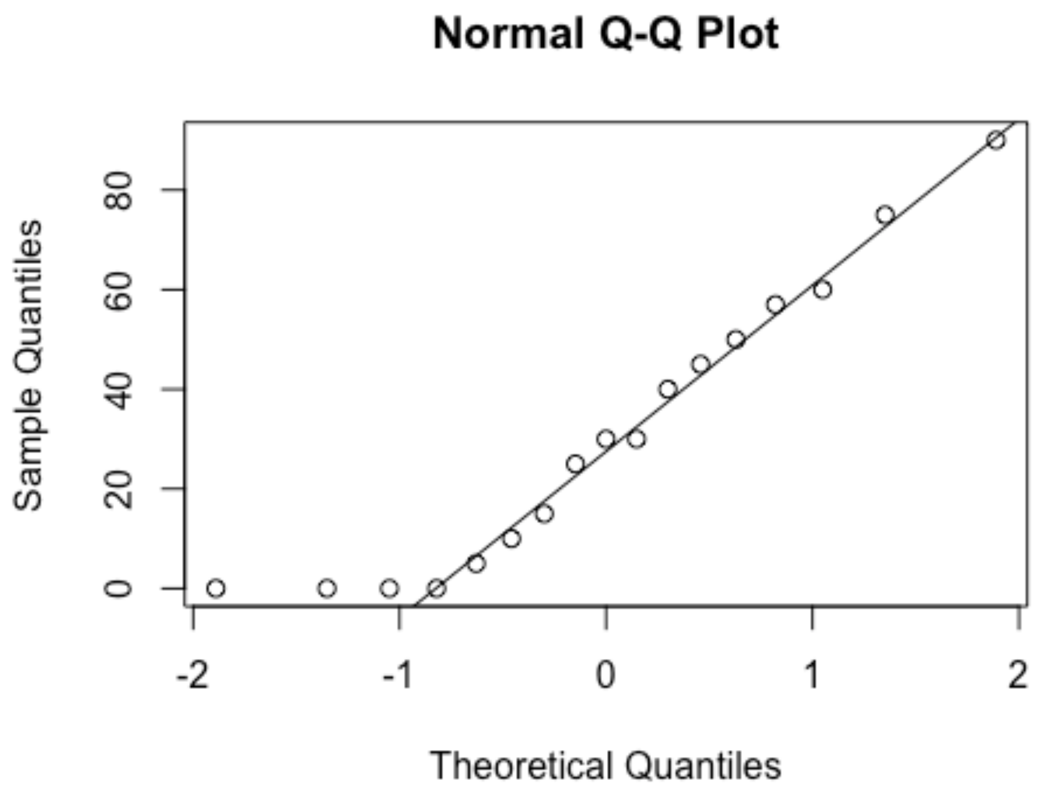
```
##
##  Welch Two Sample t-test
##
## data:  PBUF_shamSRpos$SR.Ptime.left and PBUF_treatSRpos$SR.Ptime.left
## t = 0.14252, df = 31.998, p-value = 0.8876
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -18.76556  21.58909
## sample estimates:
## mean of x mean of y
##  60.17647  58.76471

#############################SR PROPORTION OF TIME ON RIGHT##################
###########
#summary data
summary(PBUFdata$SR.Ptime.right)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##    0.00    2.50   30.00   31.29   50.00   90.00       5

sd(PBUFdata$SR.Ptime.right, na.rm = TRUE)

## [1] 27.30177

length(na.omit(PBUFdata$SR.Ptime.right))

## [1] 35

#within-participants (paired) comparison
#Paired t-test
t.test(PBUF_shamSRpos$SR.Ptime.right, PBUF_treatSRpos$SR.Ptime.right, paired
= TRUE)

##
##  Paired t-test
##
## data:  PBUF_shamSRpos$SR.Ptime.right and PBUF_treatSRpos$SR.Ptime.right
## t = -0.10277, df = 16, p-value = 0.9194
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -7.633106  6.927224
## sample estimates:
## mean of the differences
##              -0.3529412

#between participants (grouped) comparison
summary(PBUF_treatSRpos$SR.Ptime.right)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   34.00   31.65   50.00   88.00

sd(PBUF_treatSRpos$SR.Ptime.right)
```

```
## [1] 27.92387

length(PBUF_treatSRpos$SR.Ptime.right)

## [1] 17

qqnorm(PBUF_treatSRpos$SR.Ptime.right)
qqline(PBUF_treatSRpos$SR.Ptime.right)
```



```
ad.test(PBUF_treatSRpos$SR.Ptime.right)

##
##  Anderson-Darling normality test
##
## data:  PBUF_treatSRpos$SR.Ptime.right
## A = 0.51449, p-value = 0.1649

#normal

summary(PBUF_shamSRpos$SR.Ptime.right)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    5.00   30.00   31.29   50.00   90.00

sd(PBUF_shamSRpos$SR.Ptime.right)
```

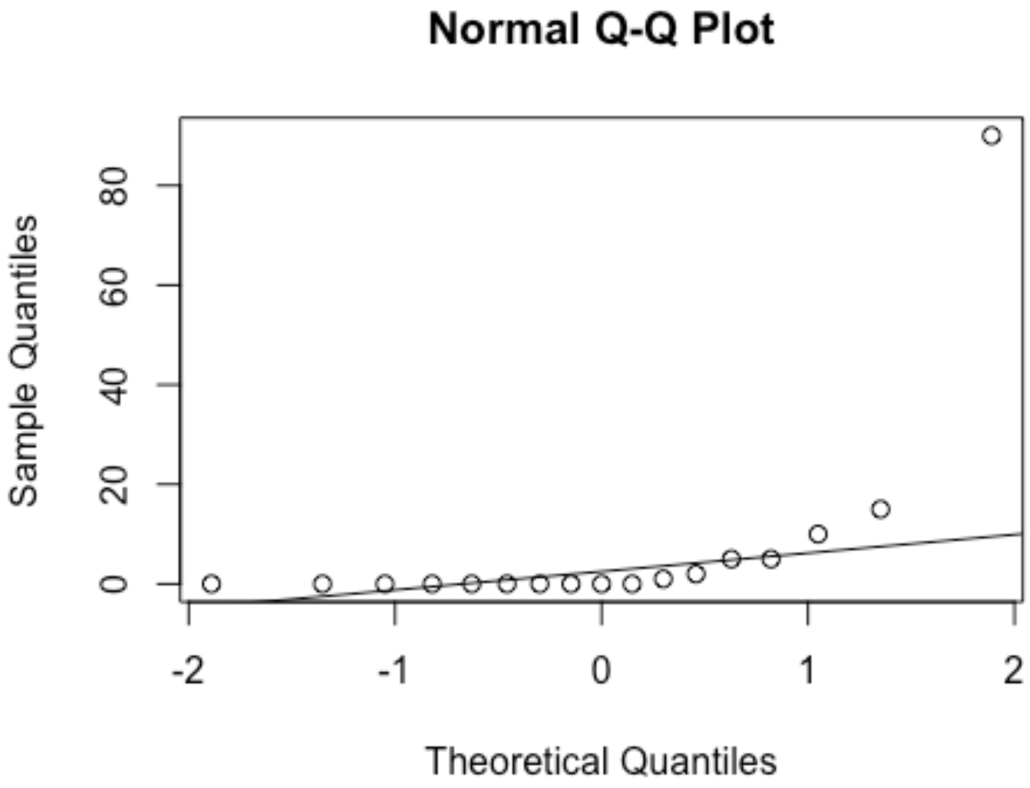
```
## [1] 28.31246

length(PBUF_shamSRpos$SR.Ptime.right)

## [1] 17

qqnorm(PBUF_shamSRpos$SR.Ptime.right)
qqline(PBUF_shamSRpos$SR.Ptime.right)
```



```
ad.test(PBUF_shamSRpos$SR.Ptime.right)

##
##  Anderson-Darling normality test
##
## data:  PBUF_shamSRpos$SR.Ptime.right
## A = 0.43793, p-value = 0.2602

#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_shamSRpos$SR.Ptime.right, PBUF_treatSRpos$SR.Ptime.right)

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

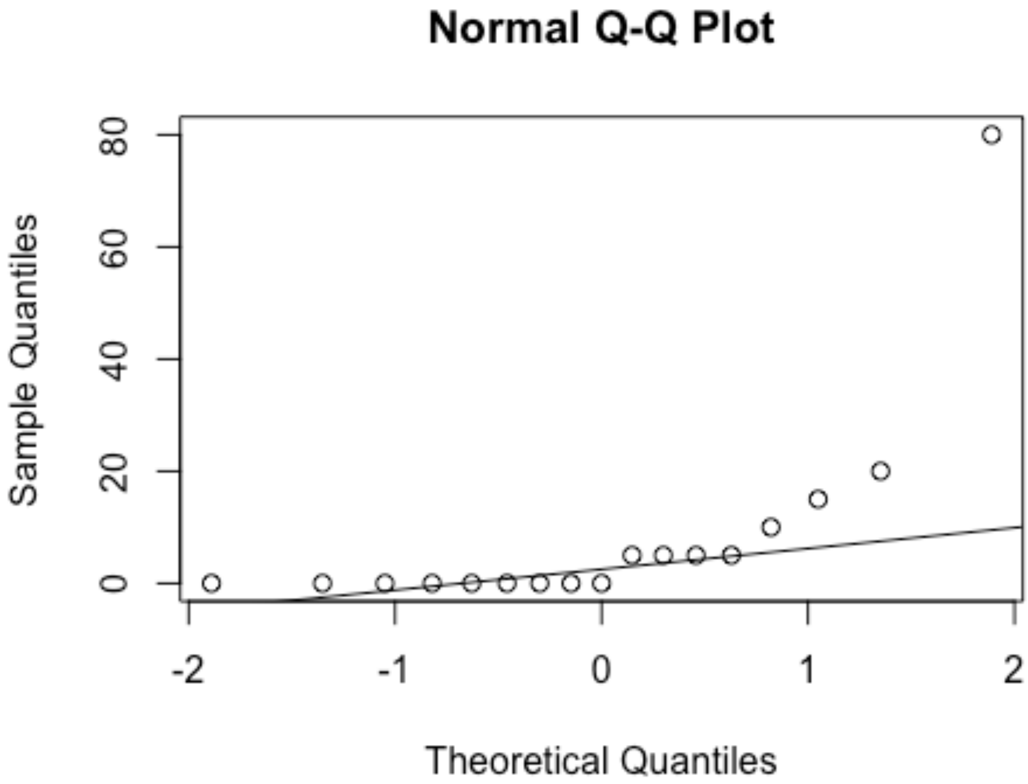
```
##
## data:  PBUF_shamSRpos$SR.Ptime.right and PBUF_treatSRpos$SR.Ptime.right
## t = -0.036594, df = 31.994, p-value = 0.971
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -19.99866  19.29278
## sample estimates:
## mean of x mean of y
##  31.29412  31.64706

#############################SR PROPORTION OF TIME ON BACK##################
##########
#summary data
summary(PBUFdata$SR.Ptime.back)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##     0.0     0.0     0.0     7.8     5.0    90.0       5

sd(PBUFdata$SR.Ptime.back, na.rm = TRUE)

## [1] 19.98205

length(na.omit(PBUFdata$SR.Ptime.back))

## [1] 35

#within-participants (paired) comparison - non-normal, use parametric test (W
ilcoxon)
wilcox.test(PBUF_shamSRpos$SR.Ptime.back, PBUF_treatSRpos$SR.Ptime.back,
            paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence interval
## with ties

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence interval
## with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  PBUF_shamSRpos$SR.Ptime.back and PBUF_treatSRpos$SR.Ptime.back
## V = 18.5, p-value = 0.4951
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
```

```
## -7.499958  8.999966
## sample estimates:
## (pseudo)median
##       4.090518

#between participants (grouped) comparison
summary(PBUF_treatSRpos$SR.Ptime.back)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   7.529   5.000  90.000

sd(PBUF_treatSRpos$SR.Ptime.back)

## [1] 21.67406

length(PBUF_treatSRpos$SR.Ptime.back)

## [1] 17

qqnorm(PBUF_treatSRpos$SR.Ptime.back)
qqline(PBUF_treatSRpos$SR.Ptime.back)
```



```
ad.test(PBUF_treatSRpos$SR.Ptime.back)
```

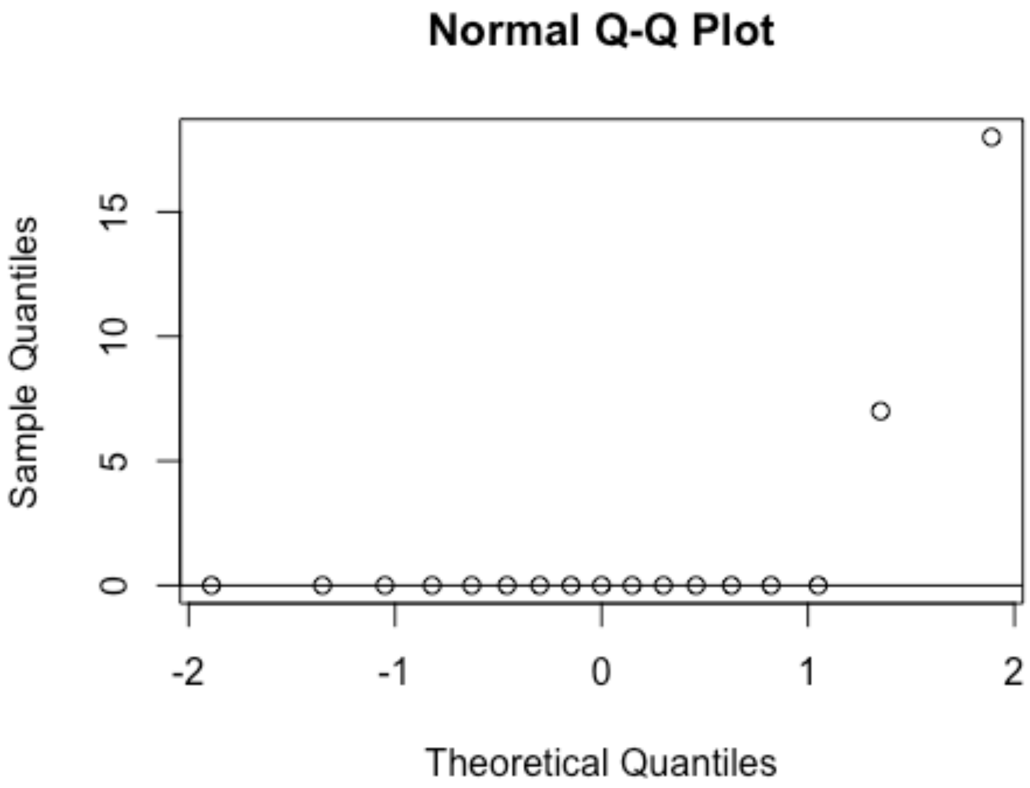
```
##
##  Anderson-Darling normality test
##
## data:  PBUF_treatSRpos$SR.Ptime.back
## A = 4.2859, p-value = 3.533e-11

#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)
```



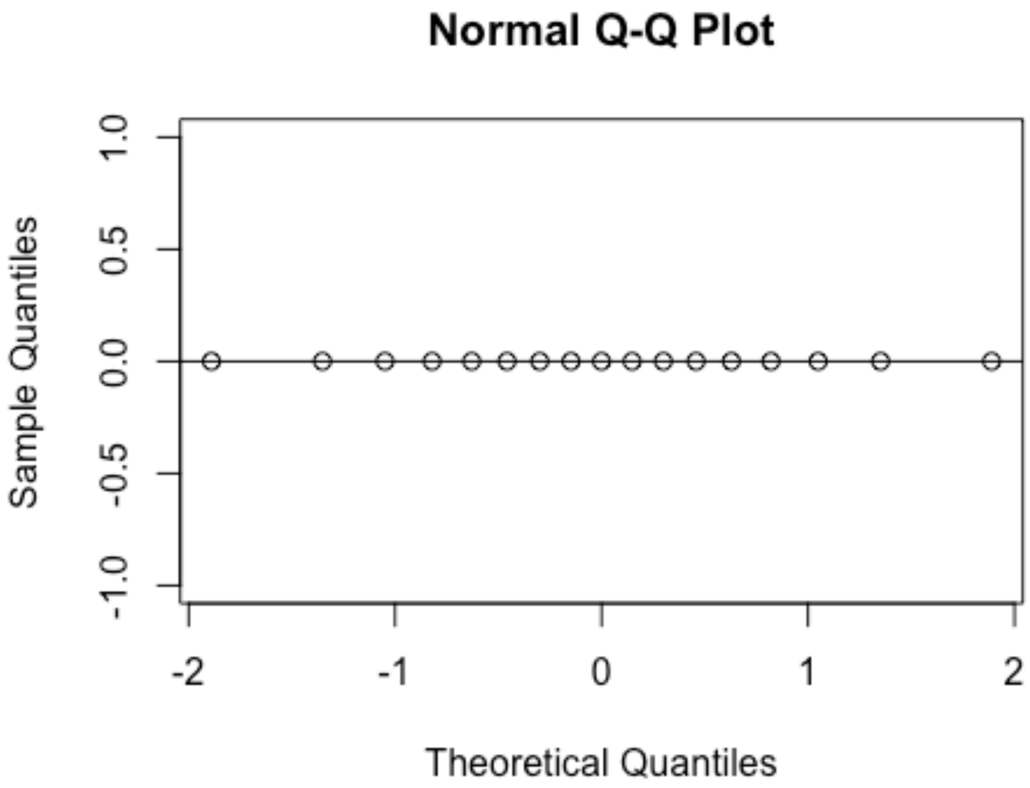
```
ad.test(PBUF_shamSRpos$SR.Ptime.back)
```

```
##
##  Anderson-Darling normality test
##
## data:  PBUF_shamSRpos$SR.Ptime.back
## A = 3.3048, p-value = 1.097e-08

#non-normal

#Perform non-parametric test (Wilcoxon)
wilcox.test(PBUF_shamSRpos$SR.Ptime.back, PBUF_treatSRpos$SR.Ptime.back, conf
.int = TRUE)

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence intervals
## with ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  PBUF_shamSRpos$SR.Ptime.back and PBUF_treatSRpos$SR.Ptime.back
## W = 159, p-value = 0.5944
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.745025e-05  4.999982e+00
## sample estimates:
## difference in location
##             3.7504e-05

#############################SR PROPORTION OF TIME ON STOMACH###############
#############
#summary data
summary(PBUFdata$SR.Ptime.stomach)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##  0.0000  0.0000  0.0000  0.7143  0.0000 18.0000       5

sd(PBUFdata$SR.Ptime.stomach, na.rm = TRUE)

## [1] 3.231931

length(na.omit(PBUFdata$SR.Ptime.stomach))

## [1] 35

#within-participants (paired) comparison - non-normal, use parametric test (W
ilcoxon)
wilcox.test(PBUF_shamSRpos$SR.Ptime.stomach, PBUF_treatSRpos$SR.Ptime.stomach
,
            paired = TRUE)
```

```
## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.stomach,
## PBUF_treatSRpos$SR.Ptime.stomach, : cannot compute exact p-value with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  PBUF_shamSRpos$SR.Ptime.stomach and PBUF_treatSRpos$SR.Ptime.stomac
h
## V = 0, p-value = 0.3711
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(PBUF_treatSRpos$SR.Ptime.stomach)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   1.471   0.000  18.000

sd(PBUF_treatSRpos$SR.Ptime.stomach)

## [1] 4.58418

length(PBUF_treatSRpos$SR.Ptime.stomach)

## [1] 17

qqnorm(PBUF_treatSRpos$SR.Ptime.stomach)
qqline(PBUF_treatSRpos$SR.Ptime.stomach)
```



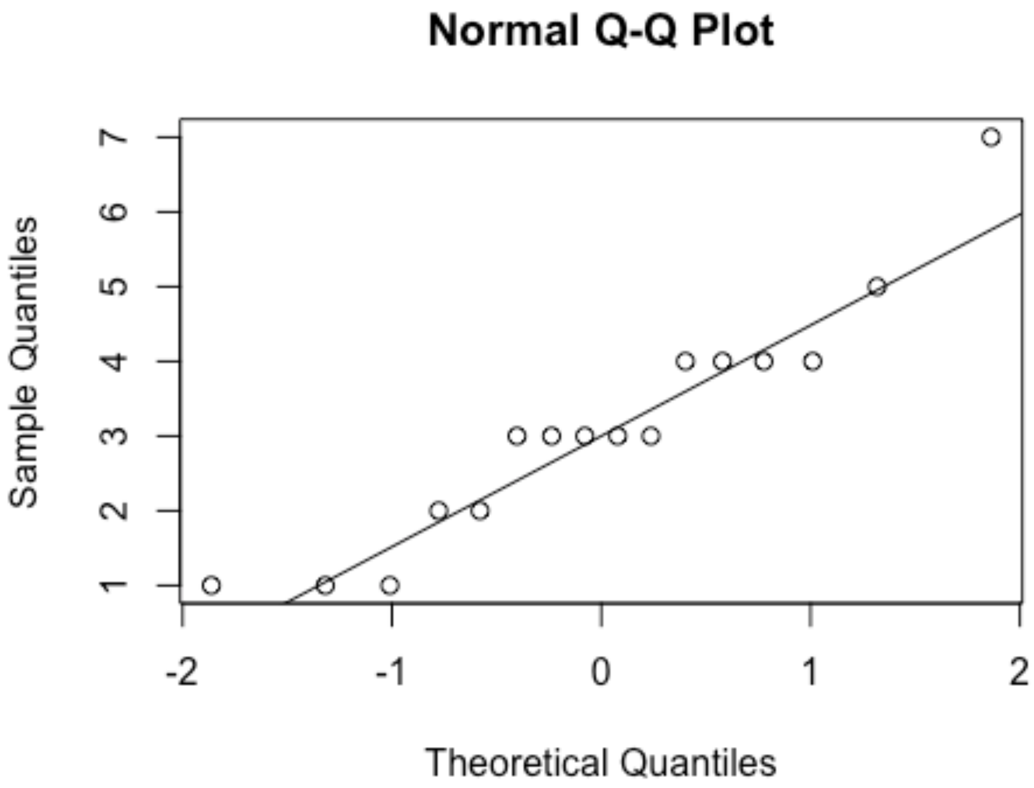
```
ad.test(PBUF_treatSRpos$SR.Ptime.stomach)

##
##  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)
```



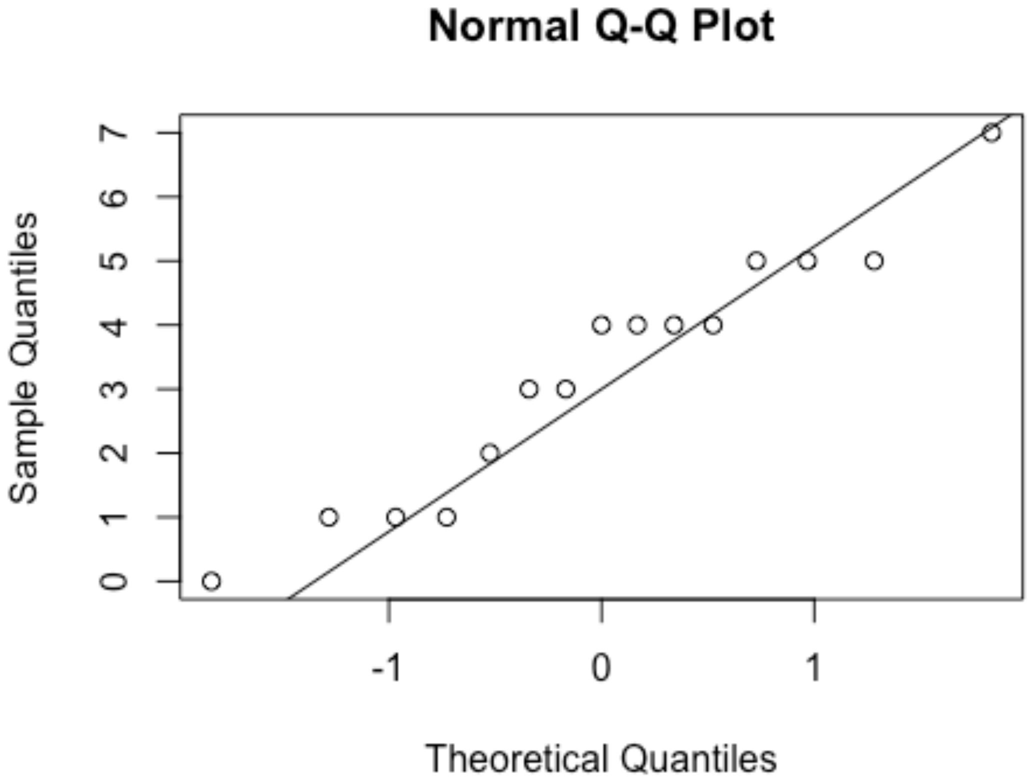
```
#ad.test(PBUF_shamSRpos$SR.Ptime.stomach)
#distribution is entirely zeroes

#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.stomac
h
## 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:
```

```
## difference in location
##                      0

#############################REMEMBER CHANGING POSITIONS#####################
########
#summary data
summary(PBUFdata$remember.changing.positions)

##      no yes
##   0   7  33

length(PBUFdata$remember.changing.positions)

## [1] 40

#between participants (grouped) comparison
xtabs(~remember.changing.positions + Intervention, data = PBUFdata)[-1,]

##                            Intervention
## remember.changing.positions sham treatment
##                         no     4         3
##                         yes   16        17

fisher.test(xtabs(~remember.changing.positions + Intervention, data = PBUFdat
a)[-1,])

##
##  Fisher's Exact Test for Count Data
##
## data:
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2020801 11.1277720
## sample estimates:
## odds ratio
##   1.404393

#Remove rows with missing data or with participants who did not change positi
on or did
#not remember changing positions
PBUF_shamSRchangepos <- PBUF_sham[-c(1,5,6,7,14,19),]
PBUF_treatSRchangepos <- PBUF_treat[-c(1,5,6,7,14,19),]

#############################SR NUMBER OF TIMES CHANGED POSITION############
##############
#summary data
summary(PBUFdata$SR.how.many.times.changed.positions)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##   0.000   2.000   3.000   3.194   4.000   7.000       9
```

```
sd(PBUFdata$SR.how.many.times.changed.positions, na.rm = TRUE)

## [1] 1.740103

length(na.omit(PBUFdata$SR.how.many.times.changed.positions))

## [1] 31

#within-participants (paired) comparison
#Paired t-test
t.test(PBUF_shamSRchangepos$SR.how.many.times.changed.positions,
       PBUF_treatSRchangepos$SR.how.many.times.changed.positions,
       paired = TRUE)

##
##  Paired t-test
##
## data:  PBUF_shamSRchangepos$SR.how.many.times.changed.positions and PBUF_t
reatSRchangepos$SR.how.many.times.changed.positions
## t = 0.31382, df = 13, p-value = 0.7586
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.8405766  1.1262909
## sample estimates:
## mean of the differences
##               0.1428571

#between participants (grouped) comparison
summary(PBUF_treat$SR.how.many.times.changed.positions)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##   1.000   2.000   3.000   3.125   4.000   7.000       4

sd(PBUF_treat$SR.how.many.times.changed.positions, na.rm = TRUE)

## [1] 1.586401

length(na.omit(PBUF_treat$SR.how.many.times.changed.positions))

## [1] 16

qqnorm(PBUF_treat$SR.how.many.times.changed.positions)
qqline(PBUF_treat$SR.how.many.times.changed.positions)
```

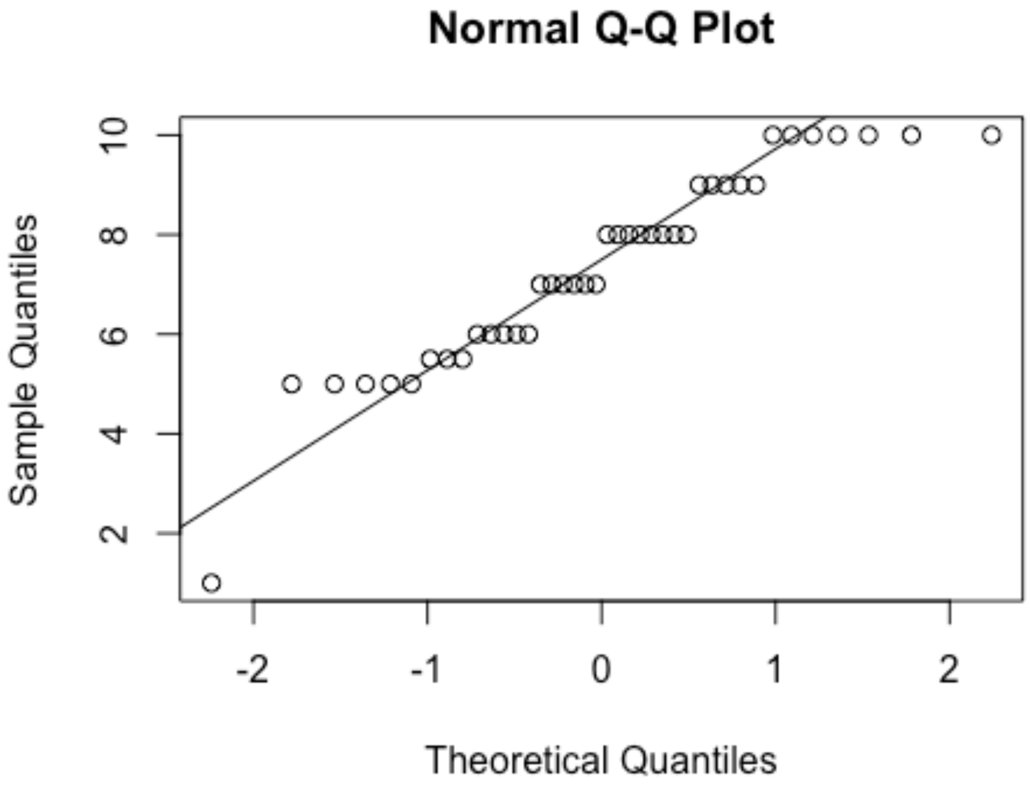


```
ad.test(PBUF_treat$SR.how.many.times.changed.positions)

##
##  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)
```



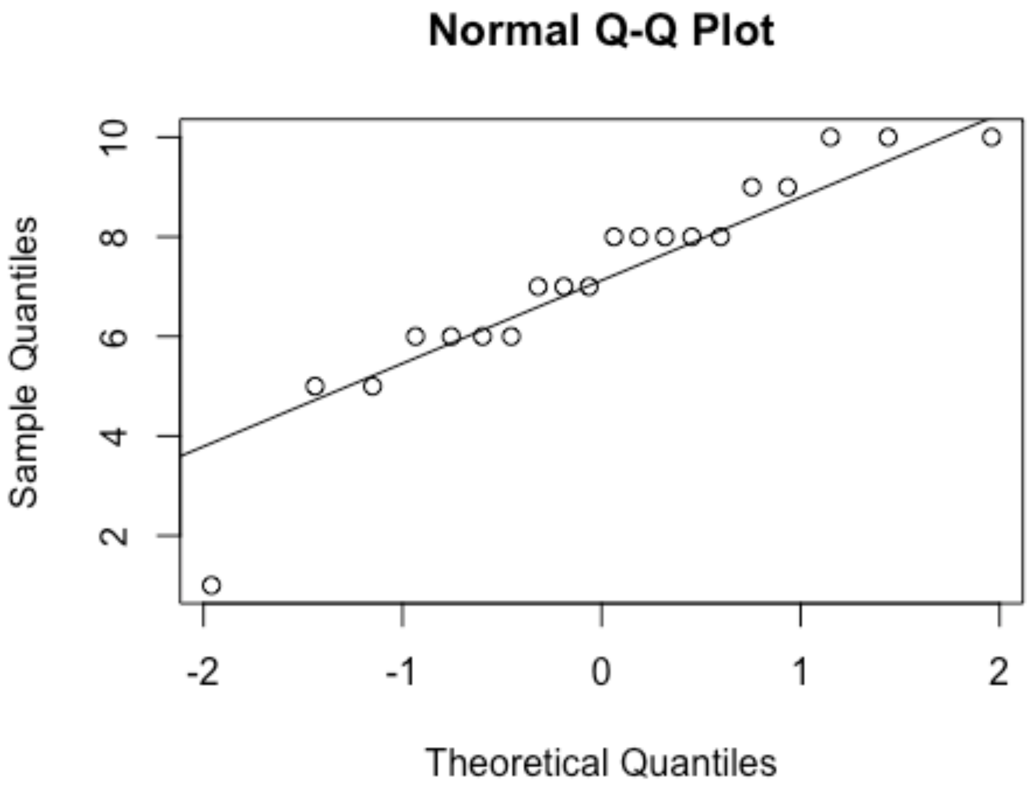
```
ad.test(PBUF_sham$SR.how.many.times.changed.positions)

##
##  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:
```

```
## mean of x mean of y
##  3.266667  3.125000

#############################SATISFACTION LEVEL#############################
#summary data
summary(PBUFdata$satisfaction.level)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.000   6.000   7.500   7.338   9.000  10.000

sd(PBUFdata$satisfaction.level)

## [1] 1.988388

length(PBUFdata$satisfaction.level)

## [1] 40

qqnorm(PBUFdata$satisfaction.level)
qqline(PBUFdata$satisfaction.level)
```

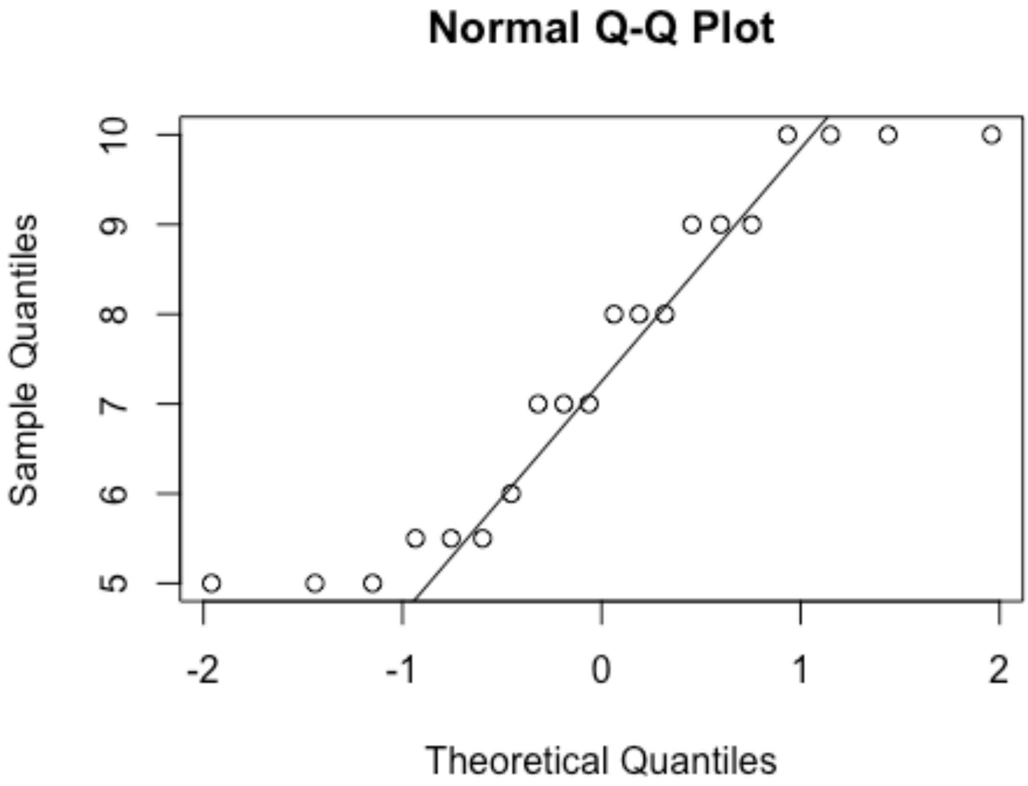


```
ad.test(PBUFdata$satisfaction.level)

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

```
##
## data:  PBUFdata$satisfaction.level
## A = 0.79381, p-value = 0.03625

#within-participants (paired) comparison
#t-test (individual distributions are normal)
t.test(PBUF_sham$satisfaction.level,PBUF_treat$satisfaction.level, paired = T
RUE)

##
##  Paired t-test
##
## data:  PBUF_sham$satisfaction.level and PBUF_treat$satisfaction.level
## t = 0.74891, df = 19, p-value = 0.4631
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.4935575  1.0435575
## sample estimates:
## mean of the differences
##                   0.275

#between participants (grouped) comparison
summary(PBUF_treat$satisfaction.level)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.00    6.00    7.50    7.20    8.25   10.00

sd(PBUF_treat$satisfaction.level, na.rm = TRUE)

## [1] 2.142306

length(na.omit(PBUF_treat$satisfaction.level))

## [1] 20

qqnorm(PBUF_treat$satisfaction.level)
qqline(PBUF_treat$satisfaction.level)
```

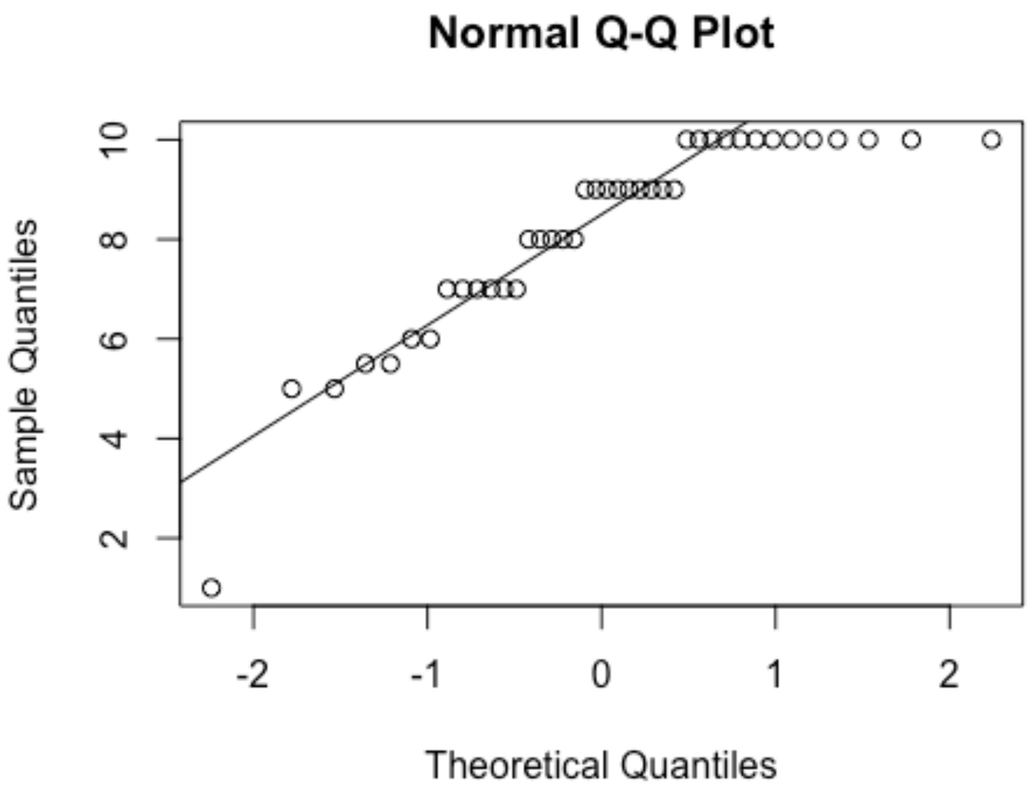


```
ad.test(PBUF_treat$satisfaction.level)

##
##  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)
```



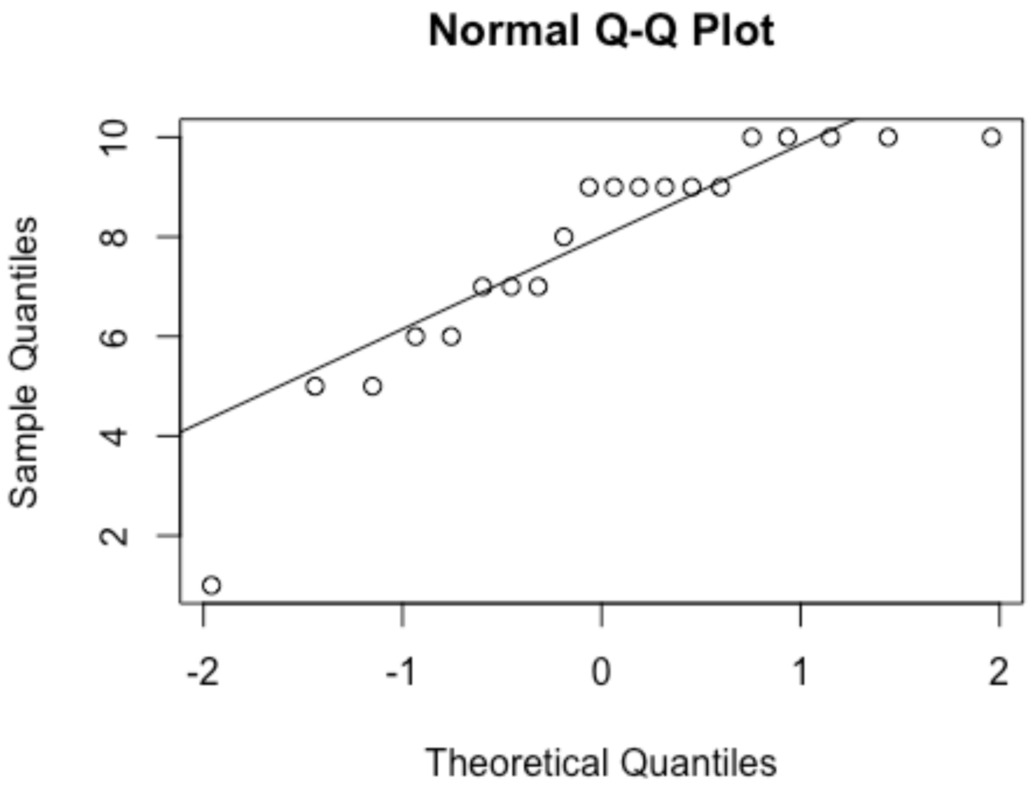
```
ad.test(PBUF_sham$satisfaction.level)

##
##  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:
```

```
## mean of x mean of y
##     7.475     7.200

##############################COMFORT LEVEL##############################
#summary data
summary(PBUFdata$comfort.level)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.000   7.000   9.000   8.175  10.000  10.000

sd(PBUFdata$comfort.level)

## [1] 1.982455

length(PBUFdata$comfort.level)

## [1] 40

qqnorm(PBUFdata$comfort.level)
qqline(PBUFdata$comfort.level)
```

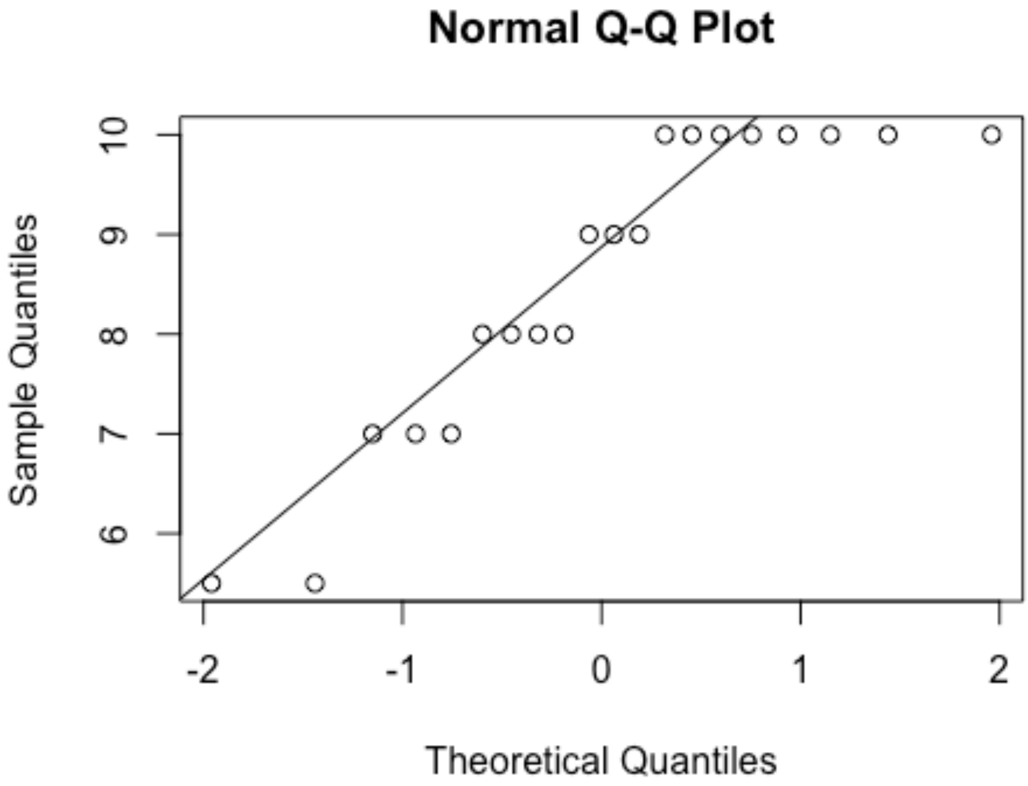


```
ad.test(PBUFdata$comfort.level)

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

```
##
## data:  PBUFdata$comfort.level
## A = 1.8563, p-value = 7.865e-05

#within-participants (paired) comparison
#non-normal - perform Wilcoxon
wilcox.test(PBUF_sham$comfort.level,PBUF_treat$comfort.level,
            paired = TRUE, 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 interval with ties

## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
## $comfort.level, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
## $comfort.level, : cannot compute exact confidence interval with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  PBUF_sham$comfort.level and PBUF_treat$comfort.level
## V = 54.5, p-value = 0.0574
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.0000318032  2.7499508366
## sample estimates:
## (pseudo)median
##       1.000052

#between participants (grouped) comparison
summary(PBUF_treat$comfort.level)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.00    6.75    9.00    7.80    9.25   10.00

sd(PBUF_treat$comfort.level, na.rm = TRUE)

## [1] 2.330575

length(na.omit(PBUF_treat$comfort.level))

## [1] 20

qqnorm(PBUF_treat$comfort.level)
qqline(PBUF_treat$comfort.level)
```

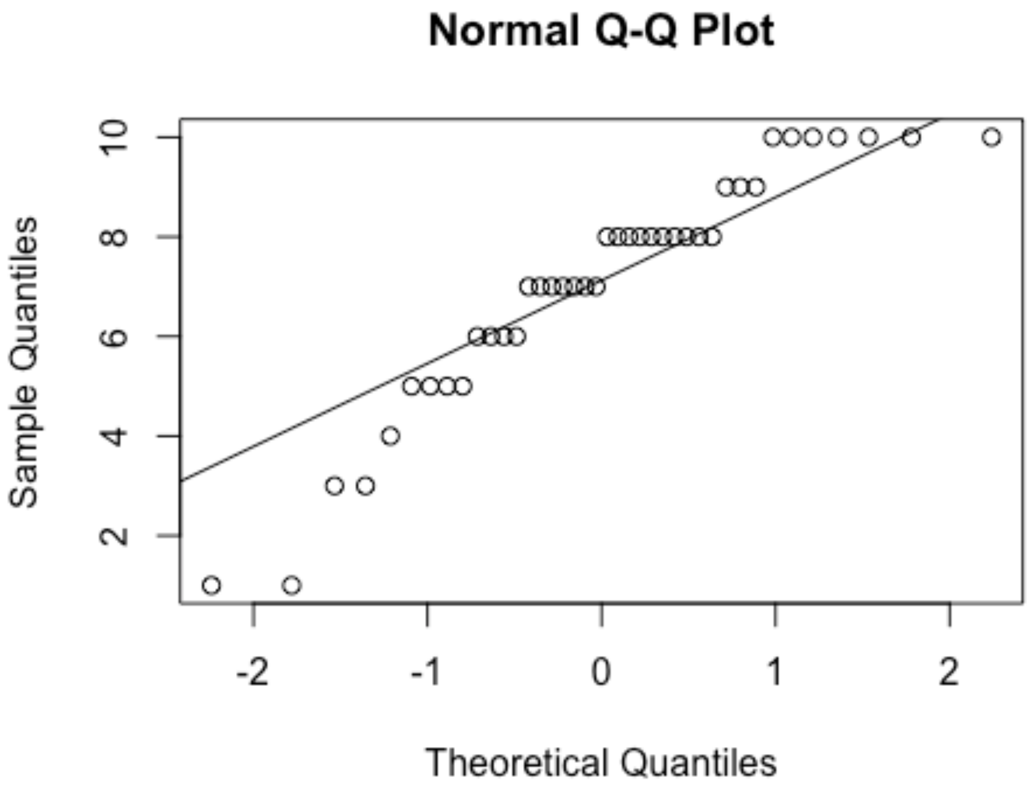


```
ad.test(PBUF_treat$comfort.level)

##
##  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)
```



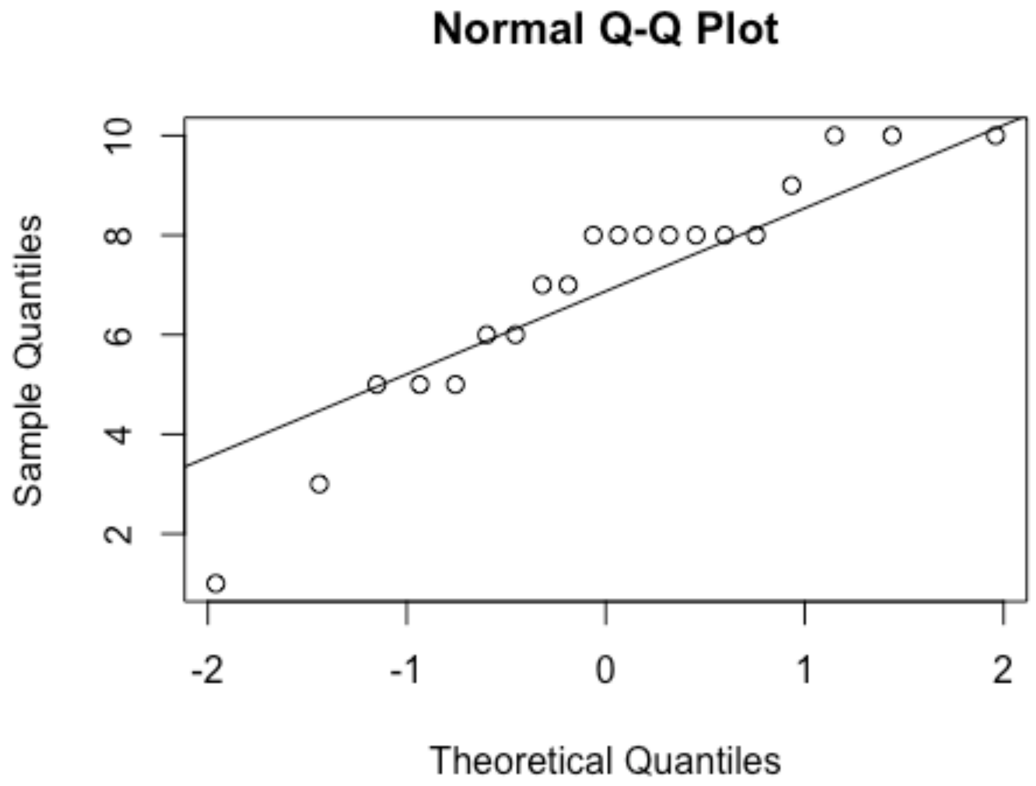
```
ad.test(PBUF_sham$comfort.level)

##
##  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 = TRU
E)

## 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
```

```
## W = 235.5, p-value = 0.3312
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.4999358  1.0000188
## sample estimates:
## difference in location
##              0.3425784

#################INTENTION TO USE IN FUTURE PREGNANCY LEVEL##################
####
#summary data
summary(PBUFdata$intention.to.use)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.00    6.00    7.50    7.05    8.25   10.00

sd(PBUFdata$intention.to.use)

## [1] 2.363722

length(PBUFdata$intention.to.use)

## [1] 40

qqnorm(PBUFdata$intention.to.use)
qqline(PBUFdata$intention.to.use)
```



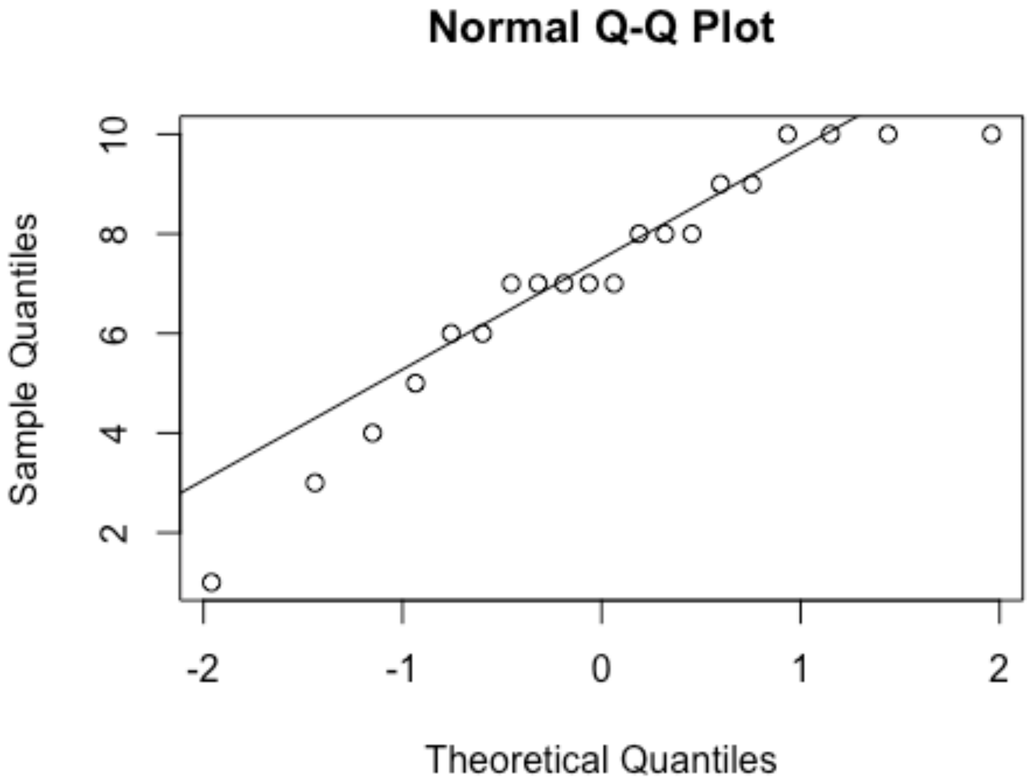
```
ad.test(PBUFdata$intention.to.use)

##
##  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)
```



```
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)
```



```
ad.test(PBUF_sham$intention.to.use)

##
##  Anderson-Darling normality test
##
## data:  PBUF_sham$intention.to.use
## A = 0.54305, p-value = 0.1424
```

```
#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_sham$intention.to.use,
       PBUF_treat$intention.to.use)

##
##  Welch Two Sample t-test
##
## data:  PBUF_sham$intention.to.use and PBUF_treat$intention.to.use
## t = 0.13209, df = 37.923, p-value = 0.8956
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -1.432714  1.632714
## sample estimates:
## mean of x mean of y
##       7.1       7.0

#################WOULD MAKE CHANGES#####################
#summary data
summary(PBUFdata$would.make.changes)

##      no yes
##   2  31   7

length(PBUFdata$would.make.changes)

## [1] 40

#7 nights, but only 6 participants of 20 (30%)

#between participants (grouped) comparison
xtabs(~would.make.changes + Intervention, data = PBUFdata)[-1,]

##                   Intervention
## would.make.changes sham treatment
##                no    16        15
##                yes    3         4

fisher.test(xtabs(~would.make.changes + Intervention, data = PBUFdata)[-1,])

##
##  Fisher's Exact Test for Count Data
##
## data:
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2007118 11.2700012
## sample estimates:
## odds ratio
##   1.409106
```

```
#END
```

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

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 c
ode compares
#the participants' perception of their sleep behaviours (as recorded on the P
renaBelt
#User Feedback Questionnaires) to the polysomnography-determined sleep behavi
ours.

#Summary: Participants recalled their sleep onset position accurately for 34
of 40 nights
#(85%, κ 0.62, moderate agreement). Participants recalled their waking positi
on accurately
#for 28 of 40 nights (70%, κ 0.42, weak agreement). There was a weak relation
ship 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 h
ad 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/
```

```
#Bland-Altman's plots - recall of continuous variables
#https://cran.r-project.org/web/packages/BlandAltmanLeh/vignettes/Intro.html

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

#importing the SR accuracy data
SRdatafull=read.csv("Self Reported vs Recorded Sleep Postions.csv")

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

##  N  Y
## 40  6

#6 nights = 3 participants
#Remove the drop outs ("Y")
SRdata <- SRdatafull[!(SRdatafull$drop.out=="Y"),]
nrow(SRdata)

## [1] 40

#Loading the functions into the workspace
library(nortest)
library(irr)

## Loading required package: lpSolve

library(ggplot2)

## Warning: package 'ggplot2' was built under R version 3.2.5

library(BlandAltmanLeh)

####################Fall asleep position#######################
#droplevels to remove empty levels from the list of levels
SRdata$PSG.fall.asleep.position <- droplevels(SRdata$PSG.fall.asleep.position
)
SRdata$SR.fall.asleep.position <- droplevels(SRdata$SR.fall.asleep.position)
#Summary
#Polysomnography (PSG)
summary(SRdata$PSG.fall.asleep.position)

##   left  right supine
##     29      8      3

length(SRdata$PSG.fall.asleep.position)

## [1] 40
```

```
#Self-Report (SR)
summary(SRdata$SR.fall.asleep.position)

##   left  right supine
##     31      7      2

length(SRdata$SR.fall.asleep.position)

## [1] 40

#Cohen's Kappa
item1<-as.matrix(cbind(SRdata$PSG.fall.asleep.position, SRdata$SR.fall.asleep
.position))
kappa2(item1[,c(1,2)])

##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 40
##    Raters = 2
##     Kappa = 0.624
##
##         z = 4.87
##   p-value = 1.13e-06

####################Wake up position######################
#droplevels to remove empty levels from the list of levels
SRdata$PSG.wake.position <- droplevels(SRdata$PSG.wake.position)
SRdata$SR.wake.position <- droplevels(SRdata$SR.wake.position)
#Summary
#PSG
summary(SRdata$PSG.wake.position)

##   left  right supine
##     22     13      5

length(SRdata$PSG.wake.position)

## [1] 40

#SR
summary(SRdata$SR.wake.position)

##  left right
##    28    12

length(SRdata$SR.wake.position)

## [1] 40

#Cohen's Kappa
item1<-as.matrix(cbind(SRdata$PSG.wake.position, SRdata$SR.wake.position))
kappa2(item1[,c(1,2)])
```

```
##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 40
##    Raters = 2
##     Kappa = 0.42
##
##         z = 3.31
##   p-value = 0.000946
```

```
####################Look at relationship btw fall asleep and wake position###
########
#Cohen's Kappa
#PSG
item1<-as.matrix(cbind(SRdata$PSG.fall.asleep.position, SRdata$PSG.wake.posit
ion))
kappa2(item1[,c(1,2)])
```

```
##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 40
##    Raters = 2
##     Kappa = 0.241
##
##         z = 2.05
##   p-value = 0.0399
```

```
####################Number of position changes#######################
#Before running the number of position changes analyses below, we need to rem
ove the rows
#corresponding to the 10 nights when participants did not give a self-report
of the number
#of position changes because if these rows remain, they will make the summary
statistics
#(summary,#SD, length) inaccurate for the PSG data (n=40 instead of n=30)....
note that
#the Cohens, ICC, and bland-altman will automatically drop these from their r
espective
#analyses if the data point is continuous or ordinal (not if text! e.g., snor
ing
#analysis).

#Remove CDD night 1, LOH night 1, TBW night 1, WVE night1, YOG night 1 and 2,
PBY night 1
#and 2, and KEQ night 1 and 2.
SRdata1 = SRdata[-c(3,7,19,23,25,26,27,28,37,38),]
nrow(SRdata1)
```

```
## [1] 30
```

```
#Summary
#PSG
summary(SRdata1$PSG.number.position.changes)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   1.000   3.250   6.000   6.833  10.000  15.000

length(SRdata1$PSG.number.position.changes)

## [1] 30

#SR
summary(SRdata1$SR.number.position.changes)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##     1.0     2.0     3.0     3.3     4.0     7.0

length(SRdata1$SR.number.position.changes)

## [1] 30

#Cohen's Kappa
item1<-as.matrix(cbind(SRdata$PSG.number.position.changes,
                       SRdata$SR.number.position.changes))
kappa2(item1[,c(1,2)], weight="equal")

##  Cohen's Kappa for 2 Raters (Weights: equal)
## 
##  Subjects = 30 
##    Raters = 2 
##     Kappa = 0.169 
## 
##         z = 1.61 
##   p-value = 0.107

####################Snoring######################
#droplevels to remove empty levels from the list of levels
SRdata$PSG.snore <- droplevels(SRdata$PSG.snore)
SRdata$SRSnore <- droplevels(SRdata$SRSnore)
#Summary
#PSG
summary(SRdata$PSG.snore)

##  N  Y 
## 14 26

length(SRdata$PSG.snore)

## [1] 40

summary(subset(SRdata, intervention == "treatment")$PSG.snore)
```

```
##  N  Y 
##  5 15
```

```
summary(subset(SRdata, intervention == "sham")$PSG.snore)
```

```
##  N  Y 
##  9 11
```

```
xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.levels = TRUE)
```

```
##          intervention
## PSG.snore sham treatment
##         N    9         5
##         Y   11        15
```

```
fisher.test(xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.level
s = TRUE))
```

```
## 
##  Fisher's Exact Test for Count Data
## 
## data:  xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.levels
= TRUE)
## p-value = 0.3203
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.5373446 11.9301555
## sample estimates:
## odds ratio 
##   2.398796
```

```
#SR
summary(SRdata$SRSnore)
```

```
##            don't know          N          Y 
##          3         26          8          3
```

```
length(SRdata$SRSnore)
```

```
## [1] 40
```

```
#Take a quick look at the data
data.frame(SRdata$PSG.snore, SRdata$SRSnore)
```

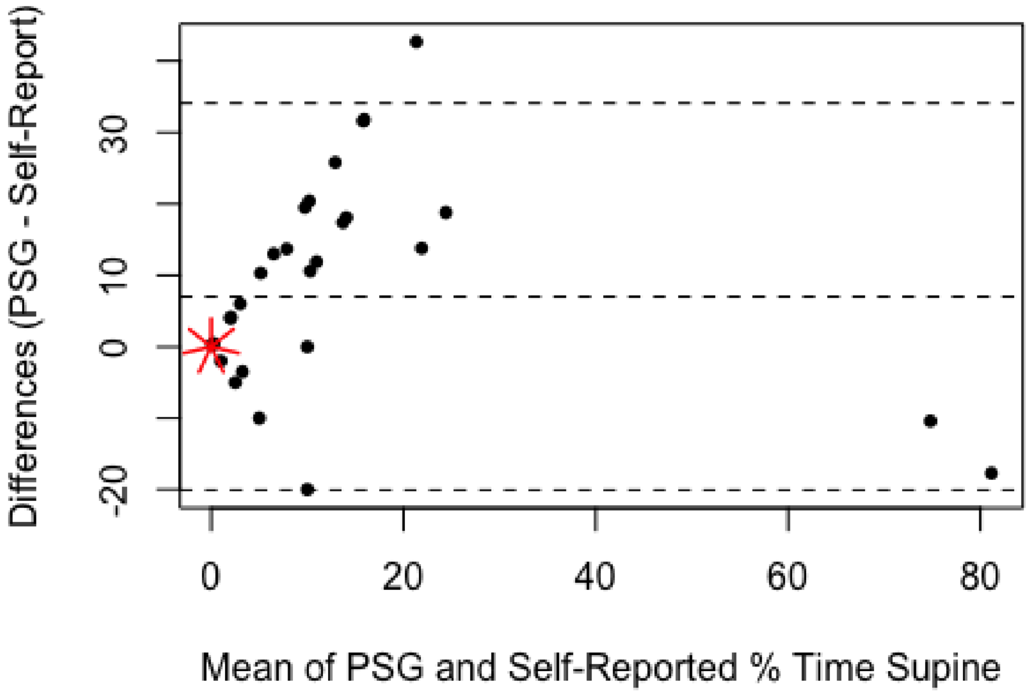
```
##    SRdata.PSG.snore SRdata.SRSnore
## 1                 Y     don't know
## 2                 Y     don't know
## 3                 N     don't know
## 4                 Y              N
## 5                 N              N
## 6                 Y     don't know
## 7                 Y
```

```
## 8                 Y
## 9                 N     don't know
## 10                Y     don't know
## 11                Y              Y
## 12                Y              Y
## 13                Y     don't know
## 14                Y              N
## 15                Y     don't know
## 16                Y     don't know
## 17                N     don't know
## 18                N              N
## 19                Y     don't know
## 20                Y              Y
## 21                N     don't know
## 22                N     don't know
## 23                Y     don't know
## 24                Y     don't know
## 25                N              N
## 26                N              N
## 27                Y     don't know
## 28                Y     don't know
## 29                Y     don't know
## 30                Y     don't know
## 31                N     don't know
## 32                N              N
## 33                Y     don't know
## 34                N     don't know
## 35                N              N
## 36                N
## 37                Y     don't know
## 38                Y     don't know
## 39                Y     don't know
## 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
```

```
#Take a quick look at the data
data.frame(SRdataSnore$PSG.snore, SRdataSnore$SRSnore)

##    SRdataSnore.PSG.snore SRdataSnore.SRSnore
## 1                      Y                   N
## 2                      N                   N
## 3                      Y                   Y
## 4                      Y                   Y
## 5                      Y                   N
## 6                      N                   N
## 7                      Y                   Y
## 8                      N                   N
## 9                      N                   N
## 10                     N                   N
## 11                     N                   N

#Cohen's Kappa
item1 <- data.frame(SRdataSnore$PSG.snore, SRdataSnore$SRSnore)
kappa2(item1[,c(1,2)])

##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 11
##    Raters = 2
##     Kappa = 0.621
##
##         z = 2.22
##   p-value = 0.0261

####################Body Position - Supine######################
#Before running the position analyses below, we need to remove the rows corre
sponding to
#the 5 nights when participants did not give a self-report of proportion of t
ime in each
#position (these five nights occured before the REB approved the change to ou
r PrenaBelt
#User Feedback Questionnaire) because if these rows remain, they will make th
e summary
#statistics (summary, #SD, length) inaccurate for the PSG data (n=40 instead
of n=35)....
#note that the Cohens, #ICC, and bland-altman will automatically drop these f
rom their
#respective analyses if #the data point is continuous or ordinal (not if text
! e.g.,
#snoring analysis).

#Remove LIQ nights 1 and 2, LOH nights 1 and 2, and LQI night 1:
SRdata1 = SRdata[-c(5,6,7,8,9),]
nrow(SRdata1)

## [1] 35
```

```
#Summary
#PSG
summary(SRdata1$PtstSupine)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##    0.00    0.00   10.00   14.82   22.75   72.30

sd(SRdata1$PtstSupine)

## [1] 18.69348

length(SRdata1$PtstSupine)

## [1] 35

#SR
summary(SRdata1$SRSupine)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##     0.0     0.0     0.0     7.8     5.0    90.0

sd(SRdata1$SRSupine)

## [1] 19.98205

length(SRdata1$SRSupine)

## [1] 35

#Test of association btw paired samples
cor.test(SRdata$PtstSupine, SRdata$SRSupine, method = "spearman")

## Warning in cor.test.default(SRdata$PtstSupine, SRdata$SRSupine, method =
## "spearman"): Cannot compute exact p-value with ties

## 
##  Spearman's rank correlation rho
## 
## data:  SRdata$PtstSupine and SRdata$SRSupine
## S = 5190.2, p-value = 0.1125
## alternative hypothesis: true rho is not equal to 0
## sample estimates:
##       rho 
## 0.2730782

#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00

bland.altman.plot(SRdata$PtstSupine, SRdata$SRSupine,
                  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 Supine",
                  ylab="Differences (PSG - Self-Report)")
```

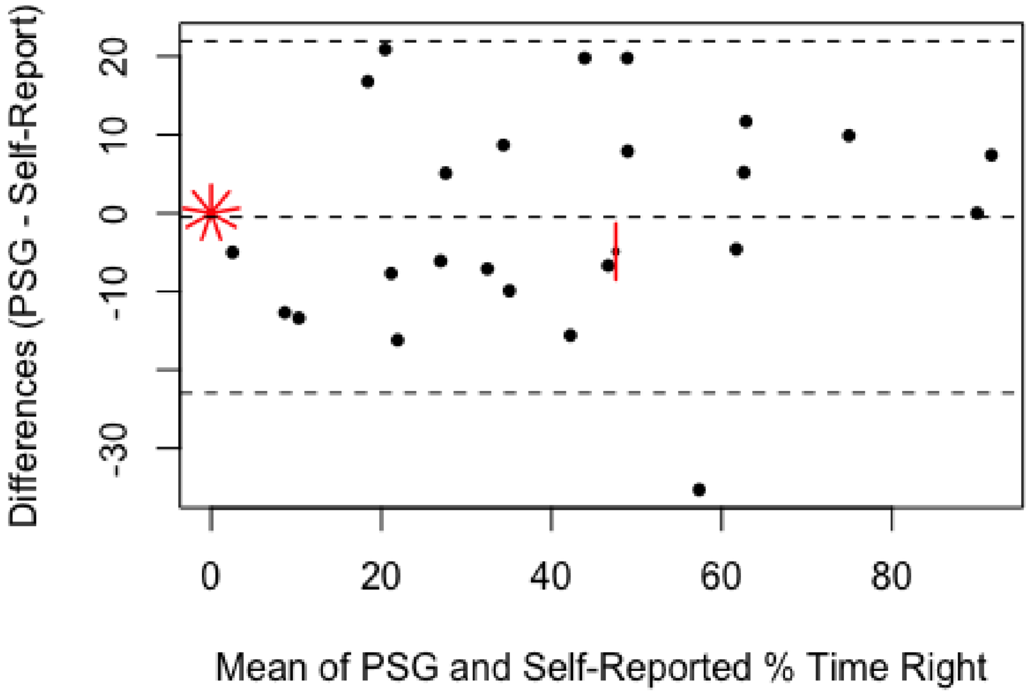


```
## $means
##  [1]  0.00  0.10 15.90 13.70  2.00  0.00 10.20  3.00  0.00 12.90  6.50
## [12] 10.95  5.15  9.75 15.80 24.40 21.90  3.25  7.85 10.30  2.50 10.00
## [23]  5.00  0.00  2.05  0.00  0.25  0.00 14.05 81.15 74.80  0.00 21.35
## [34]  1.00 10.00
##
## $diffs
##  [1]   0.0   0.2  31.8  17.4   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
```

```
## 12   20.4      0
## 13    6.0      0
## 14    0.0      0
## 15   25.8      0
## 16   13.0      0
## 17   16.9      5
## 18   10.3      0
## 19   19.5      0
## 20   31.6      0
## 21   33.8     15
## 22   28.8     15
## 23    1.5      5
## 24   14.7      1
## 25   15.6      5
## 26    0.0      5
## 27    0.0     20
## 28    0.0     10
## 29    0.0      0
## 30    4.1      0
## 31    0.0      0
## 32    0.5      0
## 33    0.0      0
## 34   23.1      5
## 35   72.3     90
## 36   69.6     80
## 37    0.0      0
## 38   42.7      0
## 39    0.0      2
## 40   10.0     10
##
## $based.on
## [1] 35
##
## $lower.limit
## [1] -20.0717
##
## $mean.diffs
## [1] 7.017143
##
## $upper.limit
## [1] 34.10599
##
## $lines
## lower.limit  mean.diffs upper.limit
##  -20.071701    7.017143   34.105987
##
## $CI.lines
## lower.limit.ci.lower lower.limit.ci.upper   mean.diff.ci.lower
##           -20.071701           -20.071701             7.017143
##   mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
```

```
##              7.017143             34.105987            34.105987
##
## $two
## [1] 1.96
##
## $critical.diff
## [1] 27.08884

####################Body Position - Right######################
#Summary
#PSG
summary(SRdata1$PtstRight)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     0.0     0.0    30.1    30.8    49.0    95.4

sd(SRdata1$PtstRight)

## [1] 28.50465

length(SRdata1$PtstRight)

## [1] 35

#SR
summary(SRdata1$SRRight)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    2.50   30.00   31.29   50.00   90.00

sd(SRdata1$SRRight)

## [1] 27.30177

length(SRdata1$SRRight)

## [1] 35

#Test of association btw paired samples
cor.test(SRdata$PtstRight, SRdata$SRRight, method = "spearman")

## Warning in cor.test.default(SRdata$PtstRight, SRdata$SRRight, method =
## "spearman"): Cannot compute exact p-value with ties

##
##  Spearman's rank correlation rho
##
## data:  SRdata$PtstRight and SRdata$SRRight
## S = 505.71, p-value = 8.061e-16
## alternative hypothesis: true rho is not equal to 0
## sample estimates:
##       rho
## 0.9291716
```

```
#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)")
```

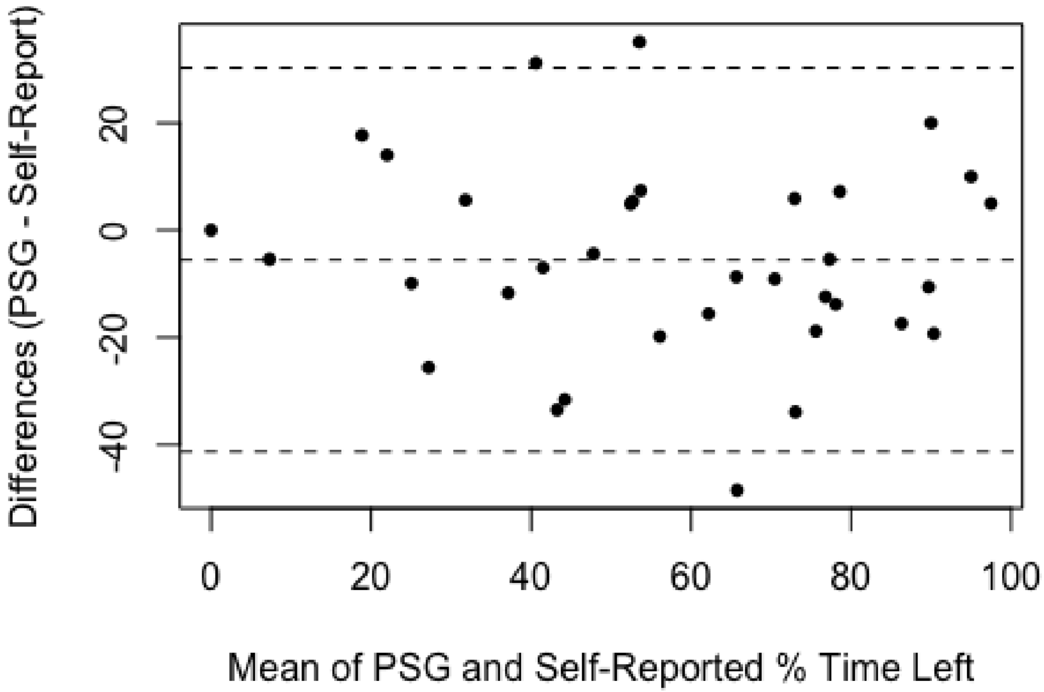


```
## $means
##  [1] 34.35 26.95 21.90  0.00 27.55 74.95 62.60 61.70 62.85 10.30 20.45
## [12] 47.55 42.20  0.00 18.40  0.00  0.00 48.95 48.90  0.00  0.00  0.00
## [23]  0.00 46.65 57.35 43.90 21.15 47.55  8.65  0.00  2.50 32.45 35.05
## [34] 91.70 90.00
## 
## $diffs
##  [1]   8.7  -6.1 -16.2   0.0   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
```

```
##    group1 group2
## 1    38.7     30
## 2    23.9     30
## 3    13.8     30
## 4     0.0      0
## 10   30.1     25
## 11   79.9     70
## 12   65.2     60
## 13   59.4     64
## 14   68.7     57
## 15    3.6     17
## 16   30.9     10
## 17   45.1     50
## 18   34.4     50
## 19    0.0      0
## 20   26.8     10
## 21    0.0      0
## 22    0.0      0
## 23   52.9     45
## 24   58.8     39
## 25    0.0      0
## 26    0.0      0
## 27    0.0      0
## 28    0.0      0
## 29   43.3     50
## 30   39.7     75
## 31   53.8     34
## 32   17.3     25
## 33   45.1     50
## 34    2.3     15
## 35    0.0      0
## 36    0.0      5
## 37   28.9     36
## 38   30.1     40
## 39   95.4     88
## 40   90.0     90
##
## $based.on
## [1] 35
##
## $lower.limit
## [1] -22.91233
##
## $mean.diffs
## [1] -0.4828571
##
## $upper.limit
## [1] 21.94661
##
## $lines
```

```
## lower.limit  mean.diffs upper.limit
## -22.9123292  -0.4828571  21.9466149
##
## $CI.lines
## lower.limit.ci.lower lower.limit.ci.upper   mean.diff.ci.lower
##          -22.9123292          -22.9123292           -0.4828571
##   mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
##           -0.4828571           21.9466149           21.9466149
##
## $two
## [1] 1.96
##
## $critical.diff
## [1] 22.42947

####################Body Position - Left#######################
#Summary
#PSG
summary(SRdata1$PtstLeft)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00   32.95   56.10   54.40   72.90  100.00

sd(SRdata1$PtstLeft)

## [1] 26.40423

length(SRdata1$PtstLeft)

## [1] 35

#SR
summary(SRdata1$SRLeft)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00   41.50   66.00   59.91   84.00  100.00

sd(SRdata1$SRLeft)

## [1] 28.14915

length(SRdata1$SRLeft)

## [1] 35

#Test of association btw paired samples
cor.test(SRdata$PtstLeft, SRdata$SRLeft, method = "spearman")

## Warning in cor.test.default(SRdata$PtstLeft, SRdata$SRLeft, method =
## "spearman"): Cannot compute exact p-value with ties

##
##  Spearman's rank correlation rho
```

```
##
## data:  SRdata$PtstLeft and SRdata$SRLeft
## S = 1691.2, p-value = 9.796e-08
## alternative hypothesis: true rho is not equal to 0
## sample estimates:
##       rho
## 0.7631423

#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00

bland.altman.plot(SRdata$PtstLeft, SRdata$SRLeft,
                  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 Left",
                  ylab="Differences (PSG - Self-Report)")
```



```
## $means
##  [1] 65.65 72.95 62.20 86.30 70.45 25.05 27.20 31.80 37.15 76.80 73.05
## [12] 41.50 52.70 90.35 65.75 75.60 78.10 47.80 43.25 89.70 97.50 90.00
## [23] 95.00 53.70 40.60 56.10 78.60 52.45 77.30 18.85 22.00 53.55 44.20
## [34]  7.30  0.00
```

```
##
## $diffs
##  [1]  -8.7   5.9 -15.6 -17.4  -9.1  -9.9 -25.6   5.6 -11.7 -12.4 -33.9
## [12]  -7.0   5.4 -19.3 -48.5 -18.8 -13.8  -4.4 -33.5 -10.6   5.0  20.0
## [23]  10.0   7.4  31.2 -19.8   7.2   4.9  -5.4  17.7  14.0  35.1 -31.6
## [34]  -5.4   0.0
##
## $groups
##    group1 group2
## 1    61.3     70
## 2    75.9     70
## 3    54.4     70
## 4    77.6     95
## 10   65.9     75
## 11   20.1     30
## 12   14.4     40
## 13   34.6     29
## 14   31.3     43
## 15   70.6     83
## 16   56.1     90
## 17   38.0     45
## 18   55.4     50
## 19   80.7    100
## 20   41.5     90
## 21   66.2     85
## 22   71.2     85
## 23   45.6     50
## 24   26.5     60
## 25   84.4     95
## 26  100.0     95
## 27  100.0     80
## 28  100.0     90
## 29   57.4     50
## 30   56.2     25
## 31   46.2     66
## 32   82.2     75
## 33   54.9     50
## 34   74.6     80
## 35   27.7     10
## 36   29.0     15
## 37   71.1     36
## 38   28.4     60
## 39    4.6     10
## 40    0.0      0
##
## $based.on
## [1] 35
##
## $lower.limit
## [1] -41.27743
```

```
##
## $mean.diffs
## [1] -5.514286
##
## $upper.limit
## [1] 30.24886
##
## $lines
## lower.limit  mean.diffs upper.limit
##  -41.277427   -5.514286   30.248856
##
## $CI.lines
## lower.limit.ci.lower lower.limit.ci.upper   mean.diff.ci.lower
##           -41.277427           -41.277427            -5.514286
##   mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
##            -5.514286            30.248856            30.248856
##
## $two
## [1] 1.96
##
## $critical.diff
## [1] 35.76314
```

```
####################Body Position - Prone######################
#Summary
#PSG
summary(SRdata$PtstProne)
```

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

```
length(SRdata$PtstProne)
```

```
## [1] 40
```

```
#SR
summary(SRdata$SRProne)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##  0.0000  0.0000  0.0000  0.7143  0.0000 18.0000       5
```

```
length(SRdata$SRProne)
```

```
## [1] 40
```

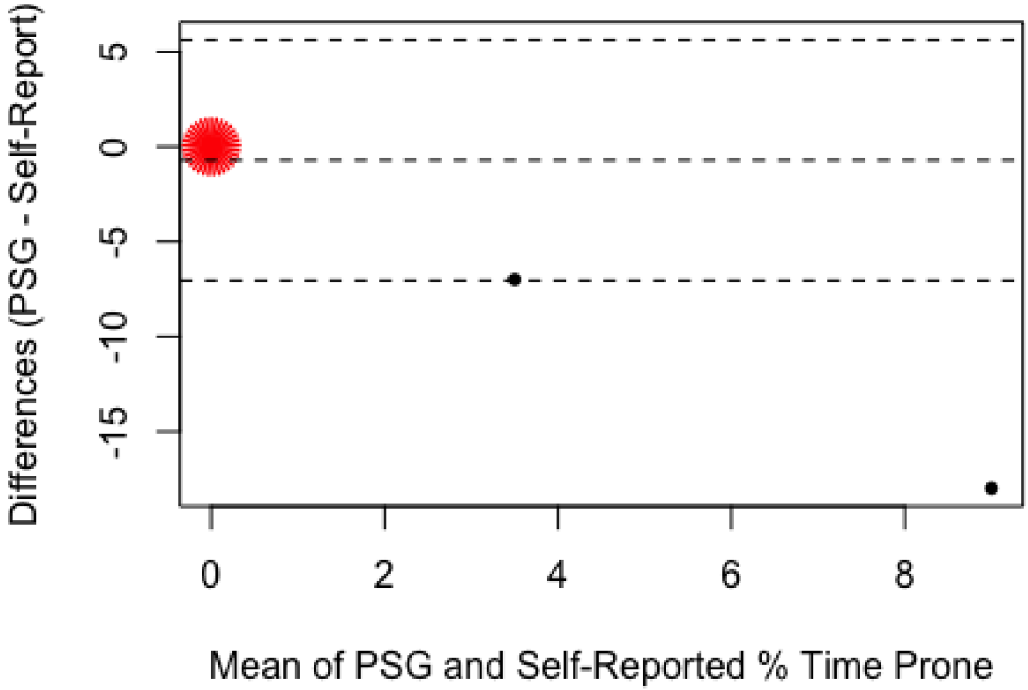
```
#Test of association btw paired samples
cor.test(SRdata$PtstProne, SRdata$SRProne, method = "spearman")
```

```
## Warning in cor(rank(x), rank(y)): the standard deviation is zero
```

```
##
##  Spearman's rank correlation rho
```

```
##
## data:  SRdata$PtstProne and SRdata$SRProne
## S = NA, p-value = NA
## alternative hypothesis: true rho is not equal to 0
## sample estimates:
## rho
##  NA
```

```
#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00

bland.altman.plot(SRdata$PtstProne, SRdata$SRProne,
                  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 Prone",
                  ylab="Differences (PSG - Self-Report)")
```



```
## $means
##  [1] 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 0.0
## [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 9.0 0.0 0.0
## [35] 0.0
##
```

```
## $diffs
##  [1]   0   0   0   0   0   0   0  -7   0   0   0   0   0   0   0   0   0
## [18]   0   0   0   0   0   0   0   0   0   0   0   0   0   0 -18   0   0
## [35]   0
##
## $groups
##    group1 group2
## 1       0      0
## 2       0      0
## 3       0      0
## 4       0      0
## 10      0      0
## 11      0      0
## 12      0      0
## 13      0      7
## 14      0      0
## 15      0      0
## 16      0      0
## 17      0      0
## 18      0      0
## 19      0      0
## 20      0      0
## 21      0      0
## 22      0      0
## 23      0      0
## 24      0      0
## 25      0      0
## 26      0      0
## 27      0      0
## 28      0      0
## 29      0      0
## 30      0      0
## 31      0      0
## 32      0      0
## 33      0      0
## 34      0      0
## 35      0      0
## 36      0      0
## 37      0     18
## 38      0      0
## 39      0      0
## 40      0      0
##
## $based.on
## [1] 35
##
## $lower.limit
## [1] -7.048871
##
## $mean.diffs
```

```
## [1] -0.7142857
##
## $upper.limit
## [1] 5.620299
##
## $lines
## lower.limit  mean.diffs upper.limit
##  -7.0488705  -0.7142857   5.6202991
##
## $CI.lines
## lower.limit.ci.lower lower.limit.ci.upper   mean.diff.ci.lower
##           -7.0488705           -7.0488705           -0.7142857
##   mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
##           -0.7142857            5.6202991            5.6202991
##
## $two
## [1] 1.96
##
## $critical.diff
## [1] 6.334585

####################PLMs/Restless Legs#######################
#droplevels to remove empty levels from the list of levels
SRdata$PSG.legs.restless <- droplevels(SRdata$PSG.legs.restless)
SRdata$SR.legs.restless <- droplevels(SRdata$SR.legs.restless)
#Summary
#PSG
summary(SRdata$PSG.legs.restless)

##  N  Y
## 26 14

length(SRdata$PSG.legs.restless)

## [1] 40

#SR
summary(SRdata$SR.legs.restless)

##            don't know          N          Y
##          3         19         14          4

length(SRdata$SR.legs.restless)

## [1] 40

#Take a quick look at the data
data.frame(SRdata$PSG.legs.restless, SRdata$SR.legs.restless)

##    SRdata.PSG.legs.restless SRdata.SR.legs.restless
## 1                         N              don't know
## 2                         N              don't know
```

```
## 3                          N                        N
## 4                          N                        N
## 5                          Y                        N
## 6                          Y                        Y
## 7                          N
## 8                          N
## 9                          N                        N
## 10                         N               don't know
## 11                         N                        N
## 12                         N                        N
## 13                         Y               don't know
## 14                         Y                        Y
## 15                         N               don't know
## 16                         N               don't know
## 17                         N               don't know
## 18                         N               don't know
## 19                         N                        N
## 20                         Y                        N
## 21                         Y               don't know
## 22                         Y               don't know
## 23                         N               don't know
## 24                         N               don't know
## 25                         Y                        Y
## 26                         Y                        N
## 27                         Y                        N
## 28                         Y                        N
## 29                         Y               don't know
## 30                         Y               don't know
## 31                         N               don't know
## 32                         N               don't know
## 33                         N
## 34                         N               don't know
## 35                         N               don't know
## 36                         N                        N
## 37                         Y                        Y
## 38                         N               don't know
## 39                         N                        N
## 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
```

```
SRdataLegs <- SRdataLegs[!(SRdataLegs$SR.legs.restless=="don't know"),]
nrow(SRdataLegs)

## [1] 18

#Take a quick look at the data
data.frame(SRdataLegs$PSG.legs.restless, SRdataLegs$SR.legs.restless)

##    SRdataLegs.PSG.legs.restless SRdataLegs.SR.legs.restless
## 1                              N                           N
## 2                              N                           N
## 3                              Y                           N
## 4                              Y                           Y
## 5                              N                           N
## 6                              N                           N
## 7                              N                           N
## 8                              Y                           Y
## 9                              N                           N
## 10                             Y                           N
## 11                             Y                           Y
## 12                             Y                           N
## 13                             Y                           N
## 14                             Y                           N
## 15                             N                           N
## 16                             Y                           Y
## 17                             N                           N
## 18                             N                           N

#Cohen's Kappa
item1 <- data.frame(SRdataLegs$PSG.legs.restless, SRdataLegs$SR.legs.restless
)
kappa2(item1[,c(1,2)])

##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 18
##    Raters = 2
##     Kappa = 0.444
##
##         z = 2.27
##   p-value = 0.0233

#End
```

Supplementary file 5: Research protocol

March 15th, 2016

To: The IWK Health Centre – Research Ethics Board
Research Services, Richard Goldbloom Gallery, Main Floor
5850/5980 University Avenue, Halifax, NS, B3K 6R8

From: Allan Kember
Research Administrator, Global Innovations for Reproductive Health and Life
Project Lead, Grand Challenges Canada Grant #S7 0629-01-10
17 Oceanview Dr.
Halifax, NS, B3P 2H4

Subject: Research Protocol

Project Title: A Maternal Device for the Prevention of Stillbirth and Low Birthweight

Foreword

This project, entitled A Maternal Device for the Prevention of Stillbirth and Low Birthweight, was originally submitted on March 10th, 2014 to Grand Challenges Canada in response to their Request for Proposals: Stars in Global Health – Round 7 Phase I. Grand Challenges Canada's peer review of this proposal was led by the Canadian Institutes of Health Research. This proposal was recommended to proceed to the next stage of the *Stars in Global Health* grant process, which involved due diligence and grant agreement negotiations between the primary organization for this project, Innovative Canadians for Change Foundation (ICChange – Edmonton, AB), and Grand Challenges Canada, which were completed on December 19th, 2014. Funding for this project was approved on December 19th, 2014.

Note that this proposal includes two feasibility studies – one in Halifax, Canada, and one in Accra, Ghana. Both studies include human participants; therefore, both studies will require ethics approval. For the study in Halifax, ethics approval was received on June 16th, 2015 (Project #1018753) from The IWK Health Centre Review Ethics Board (REB). For the study in Accra, ethics approval was received from The IWK-REB on June 16th, 2015 (Project #1019318) and from the Noguchi Memorial Institute for Medical Research Institutional Review Board (local ethics board) on March 4th, 2015 (CPN 069/14-15).

The purpose of this document is to set forth the research protocol for the study related to The IWK Health Centre in Halifax, Canada as per the guidelines given in the document Protocol Components provided under the New Submissions – Guidelines and Templates section of the IWK Health Centre Research website:

http://www.iwk.nshealth.ca/research/application-materials-forms

This research protocol is submitted for review by The IWK Health Centre's Review Ethics Board as part of the requirements in the document Researcher's Checklist for Submissions: Delegated Review.

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

Allan Kember

1 Scientific

1.1 Introduction

According to the WHO, stillbirth (SB) is defined as fetal death at gestation ≥28 weeks or weight ≥1000g [1]. In Canada, the definition of SB is wider, including fetal death at gestation ≥20 weeks or weight ≥500g [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].

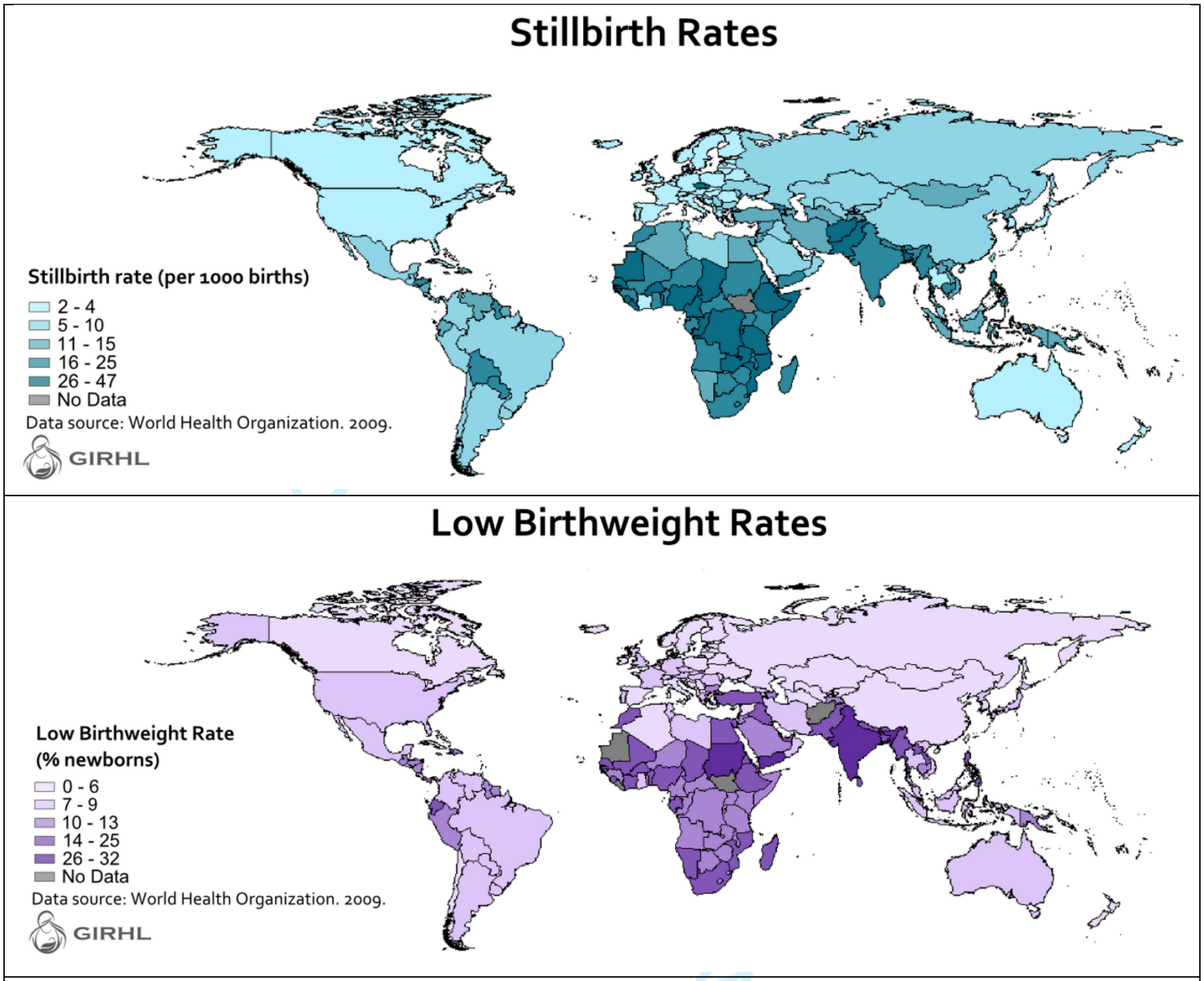
Maternal sleep position during pregnancy has recently emerged as a risk factor for LBW and SB [14] [15] [16]. A device to modify maternal sleep position and mitigate this risk factor has been developed (see section 1.1.3). The purpose of this *Stars in Global Health* project is to test the effectiveness 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.


Stillbirth Rates

Data source: World Health Organization. 2009.

Low Birthweight Rates

Data source: World Health Organization. 2009.

Figure 1. Maps of global stillbirth and low birthweight rates. Data source: World Health Organization, 2009.

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

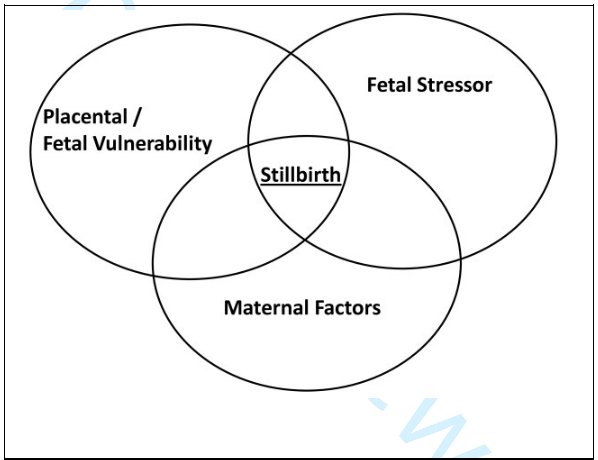


Figure 2. Triple risk model for unexplained late stillbirth **[25]**.

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].

Maternal sleep position has recently been implicated as a potential modifiable risk factor for LBW and SB [14] [15] [16]. Hence, a simple, low-cost, and easily-implemented device has been developed for use by pregnant women to mitigate this risk factor. We anticipate that using this device will remove the need for the woman to make a conscious effort to avoid the supine sleeping position. The device name is 'PrenaBelt'. The PrenaBelt is currently at the prototype stage of development, and as such, this proposal is a proof-of-concept/feasibility project.

The PrenaBelt is a belt-like, positional therapy device designed specifically for pregnant women. While the PrenaBelt does not prevent the user from lying on her back or right side during sleep, it is expected to significantly decrease the amount of time she spends in these two positions via the mechanism of positional therapy. Positional therapy is a simple, non-invasive, inexpensive, long-established, safe, and effective intervention for preventing people with positional-dependent snoring or mild to moderate obstructive sleep apnea from sleeping on their back [27] [28] – a position that exacerbates their condition [29] [30] [31] [32].

The PrenaBelt is worn at the level of the waist. By virtue of its design and position on the user's body, the PrenaBelt affects subtle pressure points around the midriff (back and right side) of the user when she lies on her back or right side, respectively. These subtle pressure points activate her body's natural mechanism to spontaneously reposition itself to relieve discomfort [33] [34] [35], thereby reducing the amount of time she remains on her back or right side. Alternatively, the PrenaBelt can be worn at the level of the thorax with the back of the device centered at the mid-back, in which case the front of the device would sit just below the breasts at the level of the fundus (upper abdomen).

The PrenaBelt is also designed for adjustability and comfort. As such, its configuration can be easily adapted by the user to only help her avoid sleeping on her back if she requires the option of sleeping on her right side as well as her left for comfort reasons.

Members of our team at Global Innovations for Reproductive Health and Life (GIRHL, Cleveland) have developed a Body Position Sensor (BPS) to be integrated into the PrenaBelt. The BPS is a small, electronic data acquisition device developed for research purposes only and in accordance with the original proposal to our funder, Grand Challenges Canada. The BPS fits into a pocket on the PrenaBelt and uses a three axes accelerometer to detect orientation of the PrenaBelt, and thus the user, in three-dimensional space. The accelerometer data is collected and stored on the BPS hard drive and can be accessed via connecting it to a computer.

The PrenaBelt only comes into contact with intact skin and, as such, is a non-invasive medical device. As per Rule 7, subrule (1) in the Government of Canada's Medical Devices Regulation – Classification Rules For Medical Devices, the PrenaBelt is classified as a Class I medical device [36]. The BPS is a research-use only device and, as such, does not fall under medical device regulation.

Per the Government of Canada's Medical Devices Regulation – Part 3: Medical Devices For Investigational Testing Involving Human Subjects, Section 80, Subsection (3), "A manufacturer or importer of a Class I medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer possesses records that contain all the 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 acceptable[1] 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

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[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 outcomes[2].
- **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

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[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 <u>Unexpected Events Contact Form</u> and give it to the research assistant. This will only takes a few minutes to complete.
  - Participants will be asked to complete the <u>Data Collection Form</u>. 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

For each participant, identical measurements (below, collectively referred to as "sleep variables" in Section 1.4.1.6) will be recorded on both nights using the same methods, equipment, and software. The sleep tests will be set up and monitored by a research assistant trained in polysomnography and under the supervision of a sleep technologist except on Friday and Saturday evenings. On Friday and Saturday evenings, either two research assistants will be present or one research assistant and one authorized study personnel will be present and a sleep technician will be on call. The sleep tests will be scored by a sleep technologist holding board certification in sleep technology (RPSGT). Scoring will be according to the current American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated Events. The sleep tests and scores will be interpreted and reported by a sleep specialist physician. Note that the measurements, methods, equipment, and software employed will be non-invasive:

a. Maternal position: direct observation by the sleep technologist through real-time or recorded audio/video and by an electronic Body Position Sensor incorporated into the PrenaBelt
b. Chest and abdominal respiratory movement: respiratory inductance plethysmography (RIP) via Pro-Tech zRIP DuraBelt with Sandman PSG software
c. Nasal and oral airflow and presence of snoring: Braebon nasal pressure transducer. If the participant is a total mouth breather, Braebon thermistor will be available as a back-up.
d. Arterial blood oxygenation: pulse oximetry (SpO_2) via Embla Sandman
e. Heartbeat rate and regularity: via electrocardiography (EKG)
f. Sleep staging: via electroencephalography (EEG), electromyography (EMG), and electrooculography (EOG). Note that if a participant is uncomfortable or cannot tolerate some of the EEG, EMG, or EOG electrodes/leads, e.g., EMG electrodes/leads on arms and legs, these electrodes/leads may be removed.

In the morning following each sleep test, before each participant is discharged home, she will be asked to complete the approved PrenaBelt User Feedback Questionnaire and seal it in a provided envelope for the researchers. Participants will be asked:

a. What position she adopted upon settling down last night
b. What position she fell asleep in last night
c. What position she woke up in this morning
d. If she changed position during night
e. If she remembers changing positions
f. Her level of satisfaction with the PrenaBelt as it relates to the quantity and quality of her sleep last night
g. Her level of comfort while wearing and sleeping with the PrenaBelt
h. Her intention to use the PrenaBelt for the remainder of her pregnancy if it was available to her
i. Any suggestions of changes/ modifications/ improvements she may have for the 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 (SpO_2)
- 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 SpO_2 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, Respirologist, 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-five[3] (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.

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[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, Respirologist, 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 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 discuss her results with her at her next antenatal care appointment. We have found in previous studies that most women appreciate this.

If severe OSA is identified for a given participant, she and her maternity care physician will be notified immediately, given the sleep test results, and advised to discuss this issue together at earliest opportunity to ensure proper management and care. Proper management of her OSA may result in instant and long-term benefits for her and her baby.

In addition, the opportunity to assist in the advancement of sleep-in-pregnancy knowledge and the possibility of benefiting other pregnant women globally in the future may be a source of immediate satisfaction to participants.

2.1.2 Others

Note: the following section refers to the WHO definition of stillbirth and not the definition used by Statistics Canada (see Section 1.1).

In Canada, three babies are stillborn every day (≥1000g birthweight or ≥28 weeks completed gestation) [1]. This is a largely unrecognized national tragedy yet pales in comparison to Ghana, where 47 babies are stillborn every day [1] (Note: in Ghana, the birth rate is 2 times greater than that in Canada, but the stillbirth rate is more than 15 times greater). In addition, every day, 61 Canadian babies are born with low birthweight (≤2500g) [48], and 232 Ghanaian babies are born with low birthweight [49] – many of whom will die in infancy or suffer lifelong consequences. These statistics and disparities are unconscionable, yet even they pale when compared to regions of further impoverishment where the state of affairs has been aptly described by one author as 'obstetric carnage' [50].

Maternal supine sleep has recently emerged as a potential risk factor for SB and LBW [14] [15] [16]. If supine sleep has a causative role in LBW and subsequently SB, the population attributable risk (PAR%) suggests that up to 17% of LBW, and consequently 26% of SB, might be averted by changing maternal sleep position [16] – this translates to the aversion of 3.7 million LBW and 676,000 SB annually [1] [5]. Since LBW is a major contributor to stillbirth [4], morbidity [5] [11] [12], and neonatal mortality (60-80%) [6] [7] [8] [9], further benefit may be realized.

This study will test a novel approach to reducing the global incidence of SB and LBW by determining whether this potential risk factor can be mitigated via treatment with a simple, positional therapy device. Demonstrating that maternal sleep position is, in fact, amenable to positional therapy will be a valuable contribution to existing knowledge and may be a key component to reducing the rates of SB and LBW in Canada and worldwide.

Currently, research is underway to determine whether a causal relationship between maternal sleep position and SB and LBW exists and collect a robust evidence base from which to advise whether a public health intervention should be considered (dissemination of research findings expected by August 2016) [24]. If a public health intervention is advised, our study will be at the forefront of scientific investigation into one possible intervention, i.e., positional therapy.

Following successful completion of this proof-of-concept (Phase I) study, there is potential for transition-to-scale (Phase II) funding from Grand Challenges Canada (contingent on 50% matching through partnerships) of up to $1,000,000 CAD for up to 2-3 years. In addition to this funding, other grant options in the area of maternal, newborn, and child health (MNCH) are available, e.g., Bill and Melinda Gates Foundation, Saving Lives at Birth. Such grants would enable exploration of the effectiveness of this intervention in populations that have very high perinatal mortality rates.

Finally, this project may bring beneficial opportunities to members of the research team. For example, it may cultivate future research collaboration with other teams worldwide through publication in journals and presentations/networking at global health conventions. Another example is that the inventors of the PrenaBelt (Mr. Borazjani, Mr. Kember) plan to establish or partner with a social enterprise organization to ensure sustainability and maximum benefit to mothers and their babies globally.

2.2 Potential Harms to Participants and Others

This study is minimal risk. Participants in this study are at no greater risk of harms when completing the activities of this study than those risks they encounter in their everyday life.

The PrenaBelt device is a non-invasive medical device of Class I designation (see section 1.1.3). Pregnant women typically sleep with many pillows supporting their body, including a pillow behind their back to avoid the supine position. The PrenaBelt is a positional therapy device that may assist pregnant women to avoid supine sleep. Positional therapy devices have been shown to be safe and approved for use by humans by the US Food and Drug Administration [37]. In addition, maternal body pillows, regular pillows, and pelvic belts (lumbar support) have been used by pregnant women during sleep without reports of serious adverse effects for the mother or neonate [51].

In Halifax, wearing the PrenaBelt and sleep monitoring equipment may be uncomfortable for a participant and disturb her sleep. Each participant will be told that she can remove these devices at any time overnight if she becomes too uncomfortable.

In order to ensure the monitor electrodes remain adhered to participant's skin, the research assistant will need to prepare the area of skin, which involves cleaning and slight abrasion with an abrasive skin preparation gel. In the morning, after the monitors are removed, participants may experience slight discomfort and redness on the regions of their skin that were in contact with the electrodes. Rarely, a person will have a minor skin reaction on the area of his/her skin that was in contact with the electrodes. This reaction is not dangerous and usually goes away on its own within 24 hours to a few days.

Since personal information will be collected from participants, there always exists the potential harm should breach of confidentiality inadvertently occur.

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.

Upon enrolment in the study, each participant will be assigned a random, six-digit, alphanumeric code. All data collected from participants during the studies will be collected only in association with this code, thus automatically de-identifying the data and minimizing the risk of identification. The key to the code, which links the codes to patient names and contact information, will be kept in a secure location away from the de-identified study data, thus minimizing the risk of re-identification. The de-identified data in forms (paper) and files (electronic) will be secured in a locked filing cabinet and in password-protected files on a password-protected computer, respectively, in a locked office with limited access.

For all study activities, all data collected from participants will be protected from unauthorized access to safeguard participant privacy and confidentiality in accordance with TCPS2, PHIPA, and PIPEDA and personal information policies at the IWK Health Centre.

There is a reasonable foreseeable risk that the Unexpected Events Contact Form for a given participant (contains participant's first name, name of contact, phone numbers of contact, and relationship of contact) could be matched with her Data Collection Form, PrenaBelt User Feedback Questionnaires, or sleep recording files (which contain her alphanumeric code) and be used to re-identify her de-identified information. To mitigate this risk of re-identification, the research assistant will be the only person who will have access to the Unexpected Events Contact Form and will be instructed to keep it in a separate secure location and shred it in a cross-cut shredder after the second sleep test is complete. In addition, the research assistant will not have access to the Data Collection Form or PrenaBelt User Feedback Questionnaires, which will be delivered and retrieved from each participant in a sealed envelope.

Study data will only be exchanged in de-identified form and between authorized research team members per the approved EAS Form. Data will be protected in electronic transfers through password protection and encryption if deemed necessary.

After study closure, study data will be stored securely (locked cabinets, password-protected files, password-protected computers, locked offices) in de-identified form for five years, after which it will be destroyed in a secure manner (e.g., incineration and cross-cut shredding).

2.5 Process for Seeking Consent

1. **Ethical Approval and Training:** The study requires approval from the Review Ethics Board at the IWK Health Centre (Halifax, Canada). All study personnel will be trained to the approved Research Protocol by Mr. Allan Kember (Sub-investigator, Project Lead).

2. **Recruitment:**

   - The IWK OB/GYN will review charts of her/his patients scheduled for their routine antenatal visit at the clinic to identify potential participants. These patients will then be screened by the OB/GYN within their circle of care using the Screening Inclusion Form to determine if they meet the inclusion/exclusion criteria for this study.
   - Patients who meet the inclusion/exclusion criteria will be invited to participate in the study by their OB/GYN at the end of their antenatal care visit via the approved Flyer. The Flyer will

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

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

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6-7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	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 10-11
	13b	For each group, losses and exclusions after randomisation, together with reasons	10-11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	11
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12-13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11
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
	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)	17
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-20, 22-23
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Other information			
Registration	23	Registration number and name of trial registry	2, 24
Protocol	24	Where the full trial protocol can be accessed, if available	24
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	26

*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.

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

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Title: Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with 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 smaller scale (*pilot*) to evaluate it for use in a full-scale randomized controlled trial.(33)

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

Randomized 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

Participants were recruited by a trained nurse at the IWK Health Centre – a tertiary and primary care center for women and children with approximately 5000 newborns delivered per year. Overnight polysomnograms (PSGs) were conducted at the Queen Elizabeth II (QEII) Health Sciences Centre Sleep Disorders Clinic. The IWK and QEII are teaching hospitals associated with Dalhousie University in Halifax, Canada. Halifax has a population of approximately 400,000. Participants expressing interest in the study (paper flyer, online advertisement) were screened.

Participants were eligible if they had a low-risk singleton pregnancy and were 18 years of age or older, more than 20 weeks gestation at screening, and residing in the Halifax Regional Municipality. Exclusion criteria included BMI ≥35 at the first antenatal appointment for the current pregnancy, pregnancy complicated by obstetric conditions (e.g., hypertension, diabetes, intra-uterine growth restriction), sleep complicated by any medical conditions (e.g., known obstructive sleep apnea, insomnia, musculoskeletal deformity affecting sleep position), multiple pregnancy, known fetal-abnormality, and non-English speaking and reading.

All participants in the trial gave written informed consent. This trial was approved by the IWK Health Centre Research Ethics Board in June 2015 (Project No. 1018753). There was no independent data monitoring committee.

Interventions

There was no run-in measurement of baseline sleep habits. Each participant underwent two overnight PSG studies between 28-37 weeks gestation. The study nights were not required to be consecutive dates, and we did not specify a defined washout period. The only difference between the two nights was the intervention (PrenaBelt or sham) and that participants completed a demographic questionnaire on the 1st PSG night only. The PrenaBelt is worn at the level of the waist and has four firm plastic balls embedded into foam inserts within the pockets posteriorly (**Fig.1.**). The mechanism of action of the PrenaBelt is theoretical and based on the tennis-ball technique of PT:(34–36) when supine, the balls apply pressure points across the user's lower back, prompting her to reposition herself in a lateral position to maintain comfort. The sham was identical in appearance, materials, and construction to the PrenaBelt, but had soft foam balls instead of firm plastic balls and did not have foam inserts; as such, the sham did not provide pressure points. Participants crossed over to the alternative intervention on the 2nd PSG night.

PSG set-up, including Pro-Tech zRIP Durabelts (Philips Respironics, Murrysville, USA) for respiration, PT1 pressure transducers (BRAEBON Medical Corporation, Kanata, Canada) for airflow and snoring, electrodes (Natus Medical Incorporated, Pleasanton, USA) for ECG/EEG/EOG/EMG, and finger-tip pulse oximetry, was by trained research assistants (RAs), in accordance with the American Academy of Sleep Medicine 2014 guidelines,(37) and in a private clinical room with continuous monitoring by an RA in a separate room through audio/visual and Embla Sandman Elite sleep diagnostic software (Natus Medical Incorporated, Pleasanton, USA).

Immediately before the participant settled to sleep, the unblinded research personnel (co-PI [AK] or study coordinator [JW]) entered the room to assist her in donning the assigned intervention (PrenaBelt/sham) without disclosing the identity of the intervention to the participant or the RA in order to maintain blinding. Upon waking for the day, the participants immediately removed the intervention and placed it in an opaque closed box for collection by the unblinded personnel in order to keep it concealed from the RA. The RA subsequently entered the room and unhooked the PSG equipment. The participant completed a feedback questionnaire and placed it in a sealed envelope for the unblinded personnel. Participants were permitted bathroom breaks and to remove the intervention and/or PSG equipment at any point if they became uncomfortable.

Scoring of PSG's was performed by blinded Registered PSG Technicians, and interpretation was by a blinded sleep medicine physician (DM).

Outcomes

The pre-specified primary outcomes per protocol were the percent of time spent in the supine and right-lateral positions (we originally intended to minimize both) and the feedback questionnaire; however, for reporting clarity and participant comfort, the PrenaBelt was configured to provide pressure points only when the user was supine, the primary outcome was further specified to be the percentage of time spent supine during sleep only, and the other pre-specified primary outcomes were instead reported as secondary outcomes. The primary outcome was documented continuously by an RA via video feed.

Secondary outcomes were total sleep time, sleep time in each position (left-lateral, right-lateral, supine, prone), percentage of sleep left and right, sleep latency, sleep efficiency, sleep indices (total arousal, spontaneous arousal, periodic limb movement, respiratory arousal, apnea-hypopnea, respiratory effort-related arousal), percentage of sleep stage (1, 2, 3, and rapid eye movement (REM)), peripheral oxygen saturation (SpO2) during sleep, snoring, and feedback questionnaire. The questionnaire elicited participants' perceptions of body position at sleep onset and waking, number of changes in position, and estimates of percentage/time spent in each position during sleep. Participants also ranked their satisfaction, comfort level, and intention to continue using the PrenaBelt (if it were available) on a 10-point Likert scale (with 10 out of 10 reflecting the highest satisfaction, comfort, and intention to use, and 1 out of 10 the lowest).

Per our research protocol and trial registry, supine and non-supine apnea-hypopnea index (AHI), min/mean/max SpO2 while awake, and min/mean/max maternal heart rate during wake, REM, and non-REM states, were also specified as secondary outcomes; however, we were unable to report the supine and non-supine AHI and heart rate data due a software configuration issue nor the awake SpO2 values due to data artifact.

Sample Size

This is the first trial investigating PT in pregnant women to reduce supine sleep time. For a one-sided paired t-test with power (β) of 0.80, significance level (α) of 0.05, and detectable effect (d) of -0.5 (difference in mean percentage of time spent sleeping supine by half a standard deviation), which is a medium effect size per the literature regarding Cohen,(38) a sample size of twenty-five (n=25) participants was required. All statistical analyses were conducted using the R Statistical Software package (version 3.2.4 (2016-03-10)).(39) There was no planned interim analysis or stopping guidelines.

Randomization

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

Blinding

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

Statistical Methods

Primary and secondary outcomes were compared between interventions by paired t-tests (normal) and Wilcoxon signed rank tests (non-normal). Cohen's Kappa (κ) was used to assess agreement between categorical variables. Spearman's Rho (ρ) and Bland-Altman plots were used for continuous variables.

For continuous variables, normality was assessed using Q-Q plots and Anderson-Darling test. All testing was performed at a 0.05 significance level. Treatment effects (differences in means and odds ratio) and associated confidence intervals were presented at a 95% confidence level with p-values.

RESULTS

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

Sample Characteristics

Baseline demographic, obstetric, and sleep habit characteristics (see **Supplementary File 1**) of the 20 participants who completed the study are shown in **Table 1** per randomized group (n=10 each). The two randomized groups were well balanced with respect to the sample characteristics – there were no statistically significant differences in baseline characteristics between groups (α=0.05). The mean (SD) age was 30.9 (5.0) years. The majority (80%) were Caucasian. The mean (SD) pre-pregnancy BMI was 26.6 kg/m^2 (3.3) and rose to a mean of 30.4 kg/m^2 (3.6) at the time of the 1st PSG, which took place at a median (IQR) gestational age of 30.0 weeks (28-33.1). Half (50%) of the participants were nulliparous.

The median (IQR) self-reported overnight sleep duration at the time of the 1st PSG was 8 (7-8) hours. In the week previous to the 1st PSG (when pregnant), left was the most common position at sleep onset (85%) and waking (60%), although a large proportion of women also reported the supine position at sleep onset and waking (25% and 40%, respectively). When not pregnant, prone was the most common position at sleep onset (65%), and supine was the most common at waking (55%). Most participants used a pillow under their head (90%) and between their knees (70%).

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/m^2), 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 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)	-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 devices like the PrenaBelt.(41,43) In comparison to a study of pressure-point PT in non-pregnant individuals with positional OSA by Heinzer et al.,(41) the PrenaBelt resulted in a lesser reduction in mean percentage of sleep time supine; however, in contrast, we did not have a non-intervention night as Heinzer et al. did. The sham, by intrinsic characteristics, may have caused a reduction in supine sleep in comparison to a non-intervention night. O'Brien and Warland (6) reported a non-interventional, one-night, in-home study of 51 healthy women in their 2nd and 3rd trimester using ambulatory PSG; in a subgroup of participants in their 3rd trimester (n=33), the median percentage of overall sleep time spent supine was 26.5%. McIntyre et al.,(7) in a similar non-interventional, one-night, in-home, ambulatory PSG study in 30 healthy women in the 3rd trimester, reported the median percentage of overall sleep time spent supine to be 19%. Participants were not asked to adopt or try to maintain any sleep position in either study. Both of these studies reported a greater median percentage of overall sleep time spent supine than that in the current study (16.4%), which indicates that the sham device may have affected position. This, along with differences inherent to pregnancy (e.g., body habitus, increased sleep disruption) may account for the lesser reduction in mean percentage of sleep time supine achieved by the PrenaBelt in comparison Heinzer et al. (41)

Zaremba et al. undertook a randomized, cross-over, PSG study in 30 post-partum women sleeping in non-elevated and 45° elevated body position and reported moderate to severe OSA in 20% of the participants.(44) The minimum SpO_2 was higher (p 0.03) and AHI was reduced (p 0.03) in the 45° elevated body position in comparison to non-elevated without affecting sleep quantity or quality. In our analysis, we were unable to demonstrate any differences in sleep architecture or duration despite a significant difference in body position (less supine time).

Seventy-three percent of participants in the study by McIntyre et al.(7) recalled their sleep onset position accurately (κ 0.52), which is a lower accuracy than our results (85% accurate, κ 0.62) possibly because each of our participants underwent two PSG nights and, after being asked to recall various details about their sleep after their 1st PSG night, may have anticipated these questions again after their 2nd PSG night. Forty percent of McIntyre et al.'s participants recalled their waking position accurately (κ 0.24), which is a lower accuracy than our results (70% accurate, κ 0.42). Being an ambulatory PSG, McIntyre et al.'s study did not include electroencephalography (EEG) – they estimated sleep and wake times by pre-defined video criteria (i.e., lack of movement) and not by brain activity and noted that this may have introduced discrepancy between their participants' self-reports and the video assessment criteria, thus reducing their calculated accuracy. We reported a weak relationship (κ 0.24) between sleep onset and waking position via PSG-determination, whereas previous studies have reported discrepant results – McIntyre et al. reported no relationship (κ -0.13) via video-determination, and the Auckland Stillbirth Study reported a strong relationship (Pearson r 0.72) via self-reports;(2), however, our study has shown self-reports of sleep onset and waking position to have only moderate and weak agreement with the gold standard (PSG), respectively, which points to reliance on non-PSG methods (e.g., self-reports) as a potential source of this discrepancy.

Warland and Dorrian reported a three-night observational study of 30 healthy women in late pregnancy and found moderate basic correlation between self-reported and video-determined time on the left (r=0.418);(8) however, they did not report correlations for right or supine sleep. We report a good correlation between self-reported and PSG-determined time on the left (Spearman's ρ 0.76, p<0.01). Notably, we found poor correlation between self-reports and PSG-determined supine time and that pregnant women tend to underestimate this value. There are only two other studies investigating reliability of adults' self-reports of sleep position;(45,46) both consist of non-pregnant adults, have conflicting results with each other, and are not reported in adequate detail for comparison to our results.

In the non-pregnant population, approximately 20% of a typical night's sleep is spent in the REM state and 80% is spent in the NREM state. The sleep architecture in the current study is consistent with previously reported patterns during pregnancy, that is, reduced slow-wave sleep (SWS), REM sleep, and sleep efficiency.(47–51)

Meaning of the Study

The previous studies by Owusu et al.(1) and O'Brien and Warland (6) recommended the development and testing of a PT device for pregnant women. In our study, a PT intervention was implemented in a population of healthy, third-trimester, pregnant women during sleep in a clinical sleep laboratory environment over two nights. This study extends the work of Stacey et al.,(2) Gordon et al.,(3) McCowan et al.,(4) and

Warland and Mitchell (52) by finding that supine sleep position in late pregnancy can be reduced with PT.

Left side sleeping is common among pregnant women. This may be a more comfortable position but also may be related to the “sleep-on-side” messages prevalent on the internet and among maternity care providers. Women in our study preferentially settled to sleep on their left for 73% of the nights and right for 20% of the nights. This is corroborated by McCowan et al.(4) who reported a significant increase in left-sided going-to-sleep position (43% to 58%) and small decrease in supine going-to-sleep position (5% to 3.8%) in New Zealand over an approximate 5 year period following publicity of The Auckland Stillbirth Study by Stacey et al.(2) If the supine sleeper is to be identified by history-taking and stratified for targeted education or intervention, obstetricians, midwives, and nurses should be aware that despite sleep-on-side knowledge and high rates of lateral going-to-sleep position, most pregnant women continue to spend a significant amount of time supine during sleep in late pregnancy per our study and previous studies.(6–8) Also, per our study, pregnant women’s estimates of time in each sleep position, while relatively accurate for lateral sleeping positions, underestimate the time they spend supine. Together, this suggests that healthcare providers may need to recommend interventions to prevent unintentional supine positioning during sleep.

Strengths

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

Weaknesses

Weaknesses of this study included that we had no baseline sleep data (run-in measurement) to which we could compare the PrenaBelt and sham nights; therefore, conclusions cannot be made regarding the effect, if any, of the PrenaBelt on sleep architecture and respiration in relation to no intervention. Participants' unfamiliarity with the sleep environment also may have affected sleep quantity and quality; however, we were unaware of any impact reported by participants. Period effects and carryover may have occurred due to advancing gestation and familiarization with the sleep environment/equipment; however, given the median washout period (1 day) was negligible in the context of a 12-week third trimester, period effects from the washout were, at most, minimal. On the 2nd PSG night, participants were exposed to the alternate intervention and could have unblinded themselves if they remembered what the intervention felt like on the 1st PSG night; however, we are unaware of what effect this may have had. The current study was conducted in a cohort of healthy, non-obese, and majority Caucasian pregnant women. Due to the small sample size, this study may be underpowered and potentially overstate the true reduction in percentage of supine sleep; however, the sleep time in our study was relatively short (median 5.87 hours). Our participants reported a median of 8 hours overnight sleep duration at home; therefore, even if the reduction in supine sleep is lower than we observed, over a longer sleep duration, the PrenaBelt is still likely to result in a significant amount of supine sleep avoided. The power analysis was performed using the one-sided t-test, which could be a source of systemic confounding. Because of the fragility of our primary outcome (p 0.03), a confounding could shift our conclusions into statistical non-significance. This stresses the importance of future research to ascertain if our observed effects persist.

Future Research

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

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, JC, 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 statistical analysis. JW maintained the study master record, facilitated PSG studies as an unblinded personnel, monitored data collection, and cleaned and analyzed the data. AI negotiated the research contract and managed the trial funds. DM, HS, LMO, AB, JC, JW, MB, KC, and AI made intellectual contributions to the paper.

Competing Interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: Mr. Kember and Dr. Borazjani, are officers at GIRHL, which has a patent application for the PrenaBelt (#WO2016176632A1) on which Mr. Kember, Dr. Borazjani, and Ms. Chu are listed as Inventors. Dr. Morrison reports grants from Bresotec and grants from CIHR/Industry Grant (Phillips) outside the submitted work. Dr. Scott, Dr. Coleman, Mr. Wells, Mr. Butler, Dr. Isaac, and Dr. O'Brien have declared no support from any organization for the submitted work, no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

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Data Sharing: Data analysis scripts and output are attached as supplementary files.

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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

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

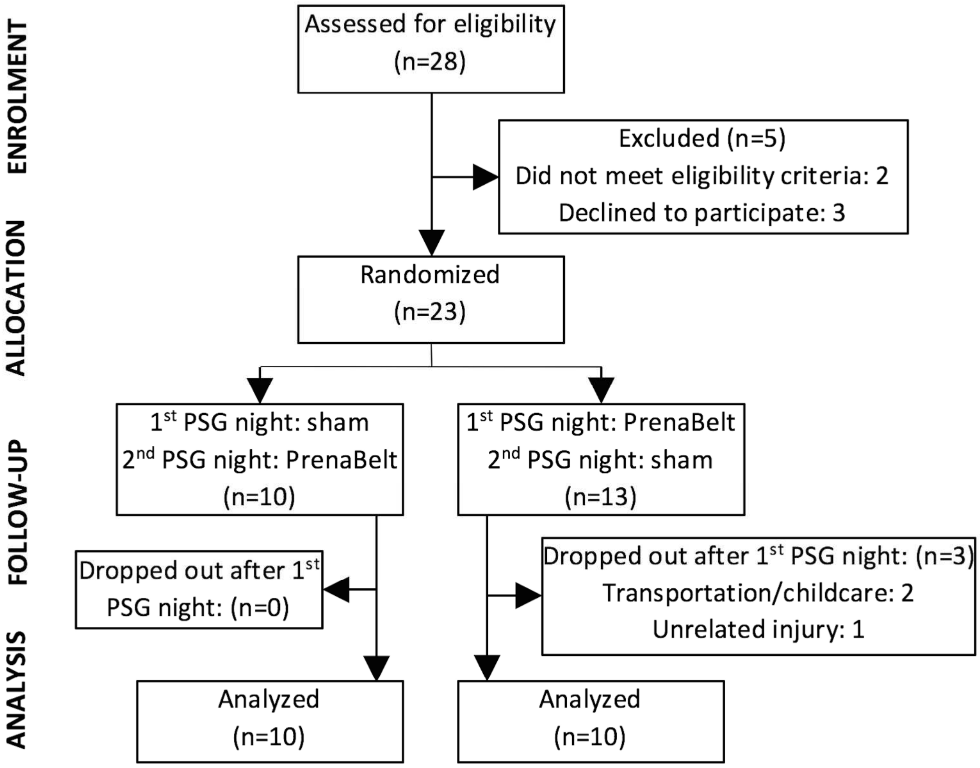
Table 2. Primary outcome: percentage of sleep time supine

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)



Enrollment, allocation, and analysis of trial participants.

293x227mm (300 x 300 DPI)

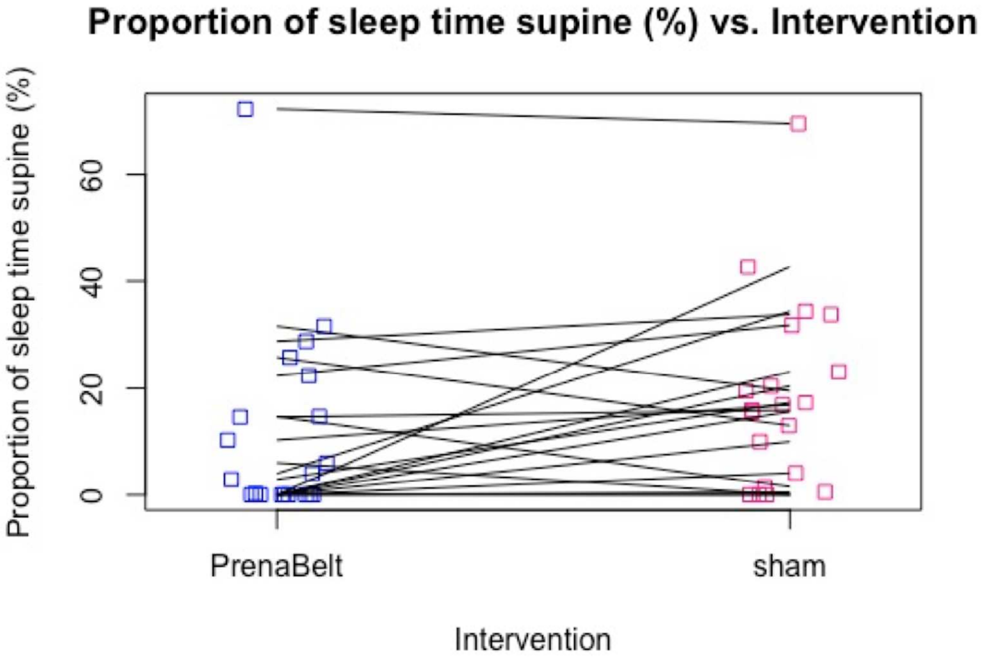


Fig. 3. Scatter plot of percentage of sleep time supine (%) versus intervention (PrenaBelt, sham) for each participant. Each line represents one participant.

216x162mm (300 x 300 DPI)

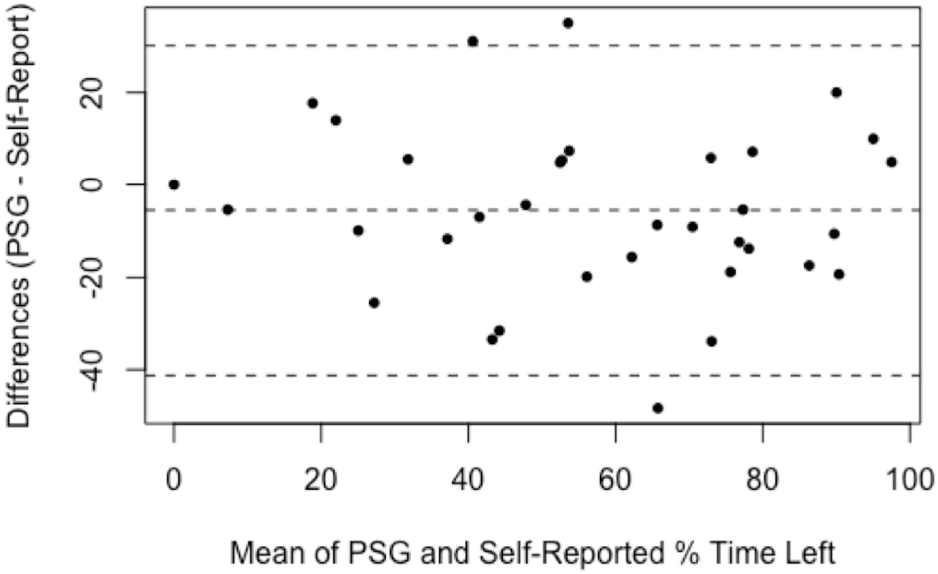


Fig. 4. Bland-Altman plot for percentage of time spent sleeping on the left side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval).

216x162mm (300 x 300 DPI)

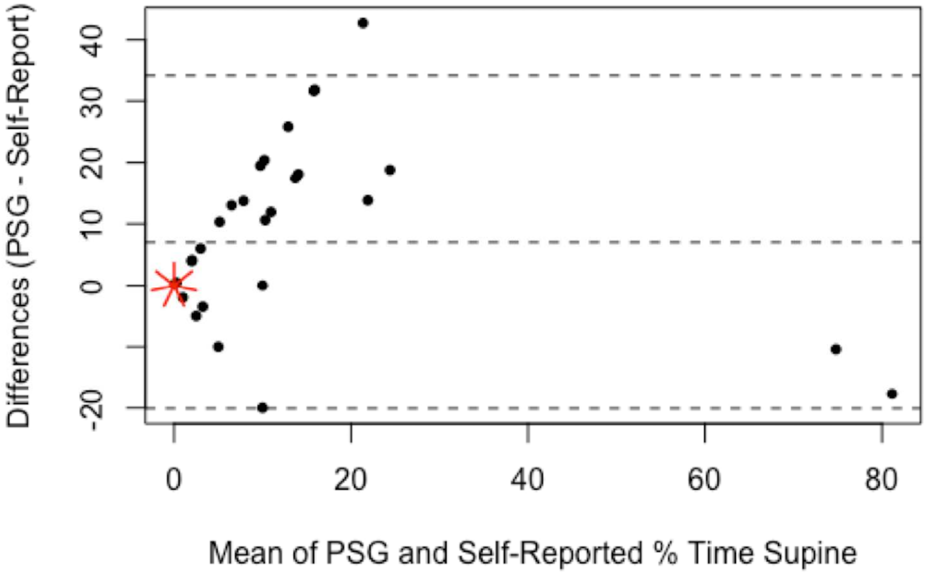


Fig. 5. Bland-Altman plot for percentage of time spent sleeping supine; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional data point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

216x162mm (300 x 300 DPI)

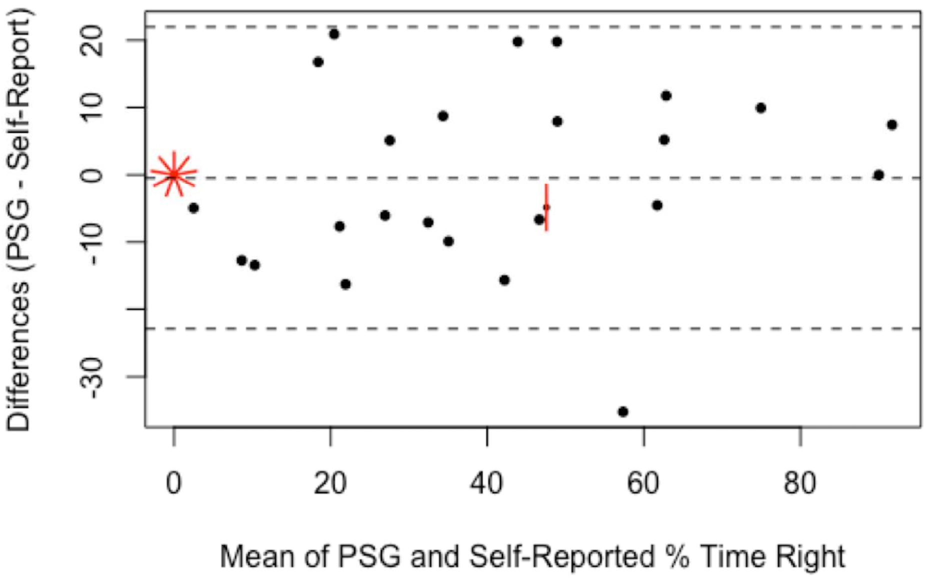


Fig. 6. Bland-Altman plot for percentage of time spent sleeping on the right side; difference between self-reported estimate and PSG-determined values. Broken lines indicate mean difference and upper and lower limits of agreement (95% confidence interval). Each short red line indicates an additional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

216x162mm (300 x 300 DPI)

Supplementary file 1: Code and output – demographic analysis

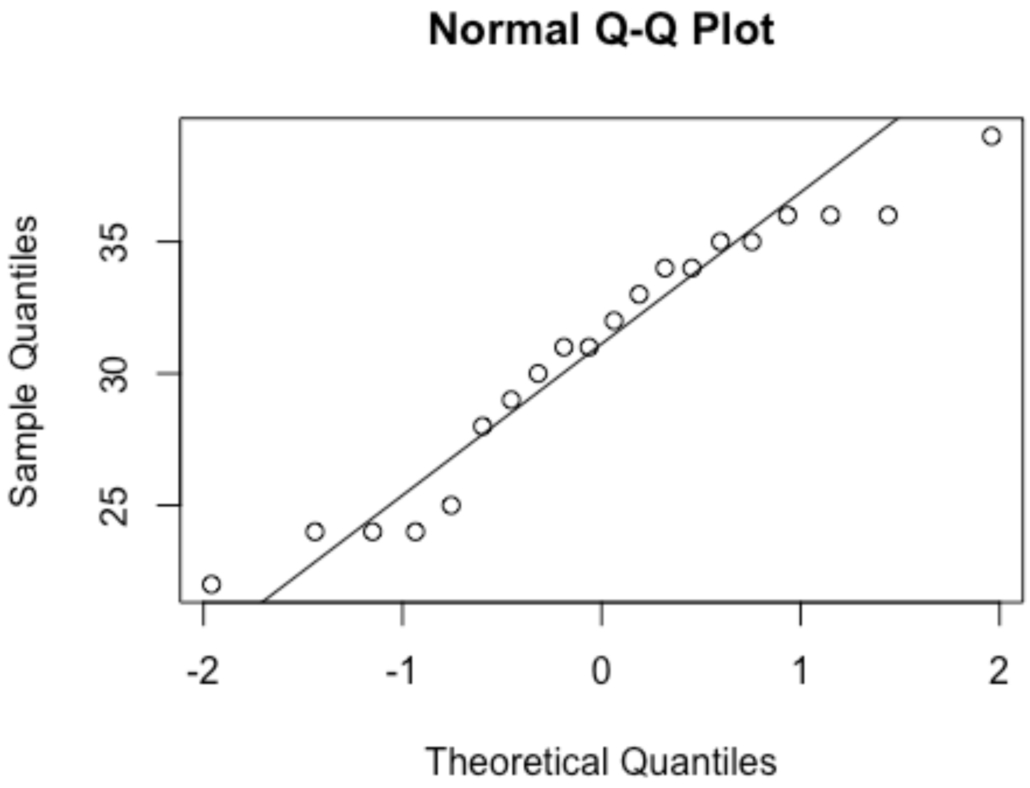
Demographic_Analysis_-_BMJSubmission.R

Allan Kember

Tue Feb 20 15:54:34 2018

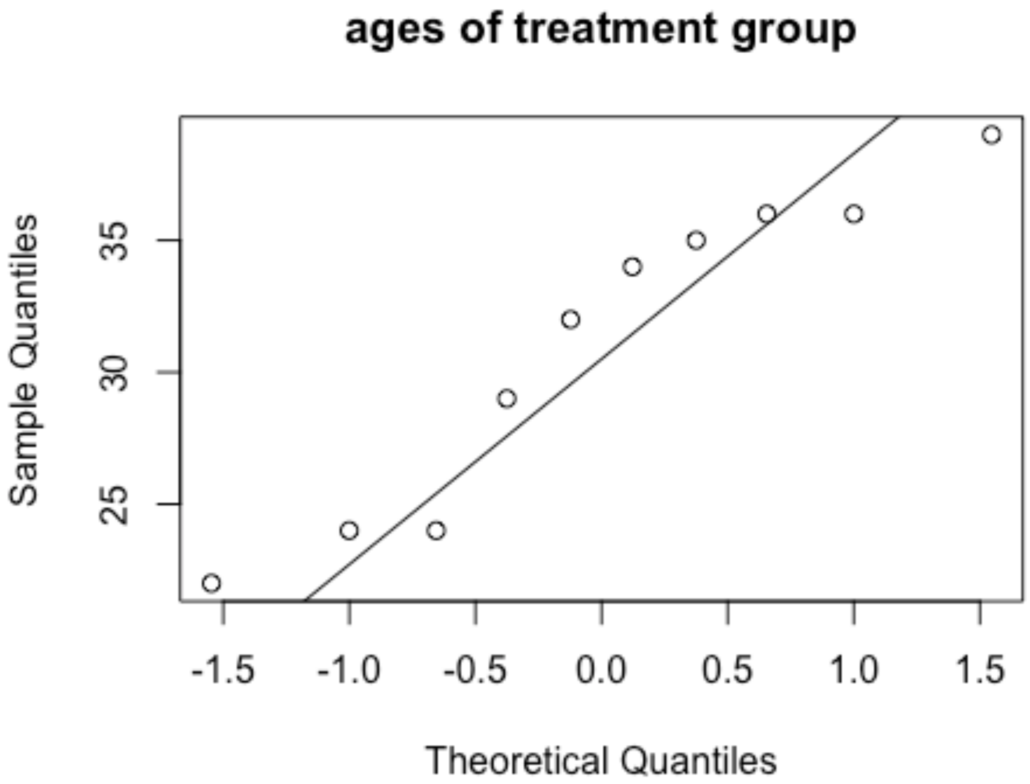
```
#Description of code:
#This code summarizes the demographic, obstetric, and sleep behaviour of the
participants
#and compares these data between all participants whose first sleep test was
PrenaBelt
#versus all participants whose first sleep test was sham-PrenaBelt.

#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)
```

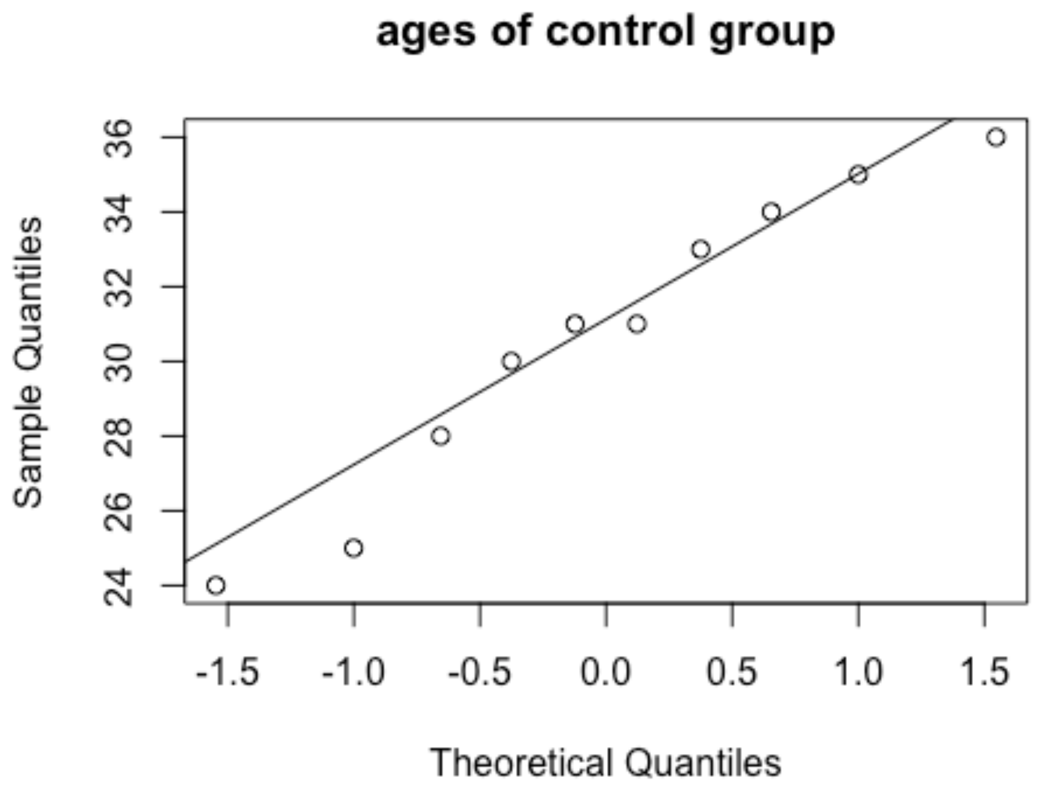


```
ad.test(DCFdata$age)

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

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   26.00   26.50   27.00   26.67   27.00   27.00

#Treatment ages
treatment.ages=na.omit(subset(DCFdata, intervention == "Treatment")$age)
length(treatment.ages)

## [1] 10

summary(treatment.ages)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   22.00   25.25   33.00   31.10   35.75   39.00

sd(treatment.ages)

## [1] 5.989806

#check for normality
qqnorm(treatment.ages, main = "ages of treatment group")
qqline(treatment.ages)
```

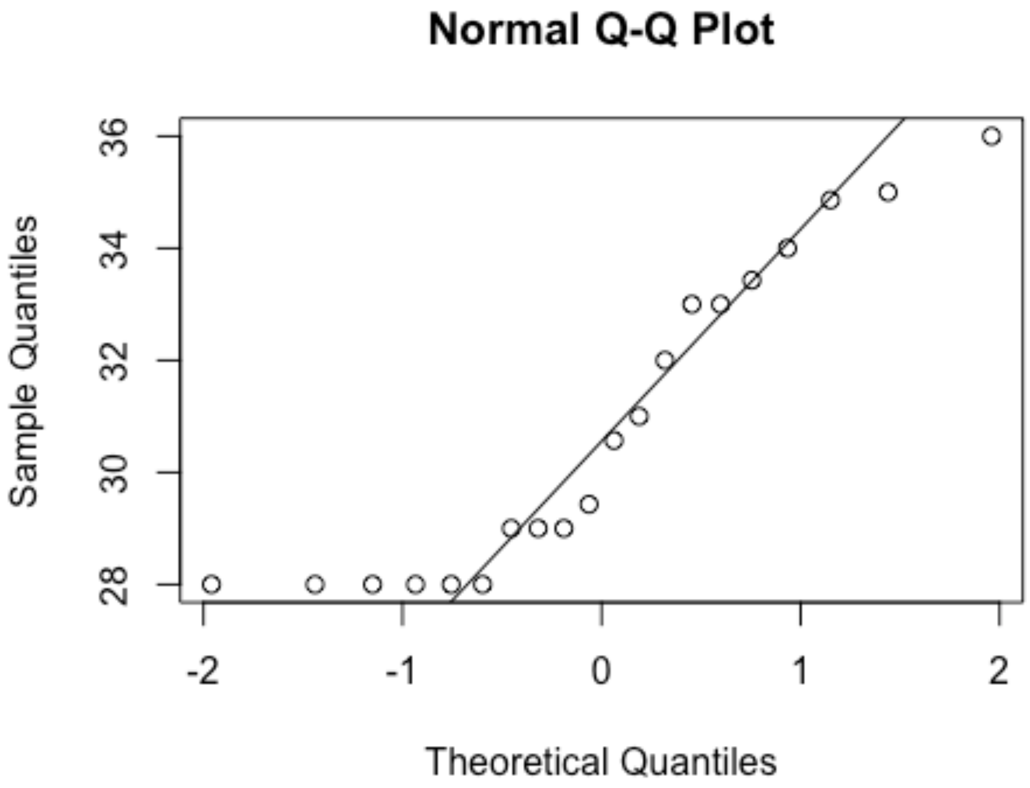


```
ad.test(treatment.ages)

##
##  Anderson-Darling normality test
##
## data:  treatment.ages
## A = 0.4521, p-value = 0.2133

#normal

#Control ages
control.ages=na.omit(subset(DCFdata, intervention == "Control")$age)
length(control.ages)

## [1] 10

summary(control.ages)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   24.00   28.50   31.00   30.70   33.75   36.00

sd(control.ages)

## [1] 4.056545

#check for normality
qqnorm(control.ages, main = "ages of control group")
qqline(control.ages)
```



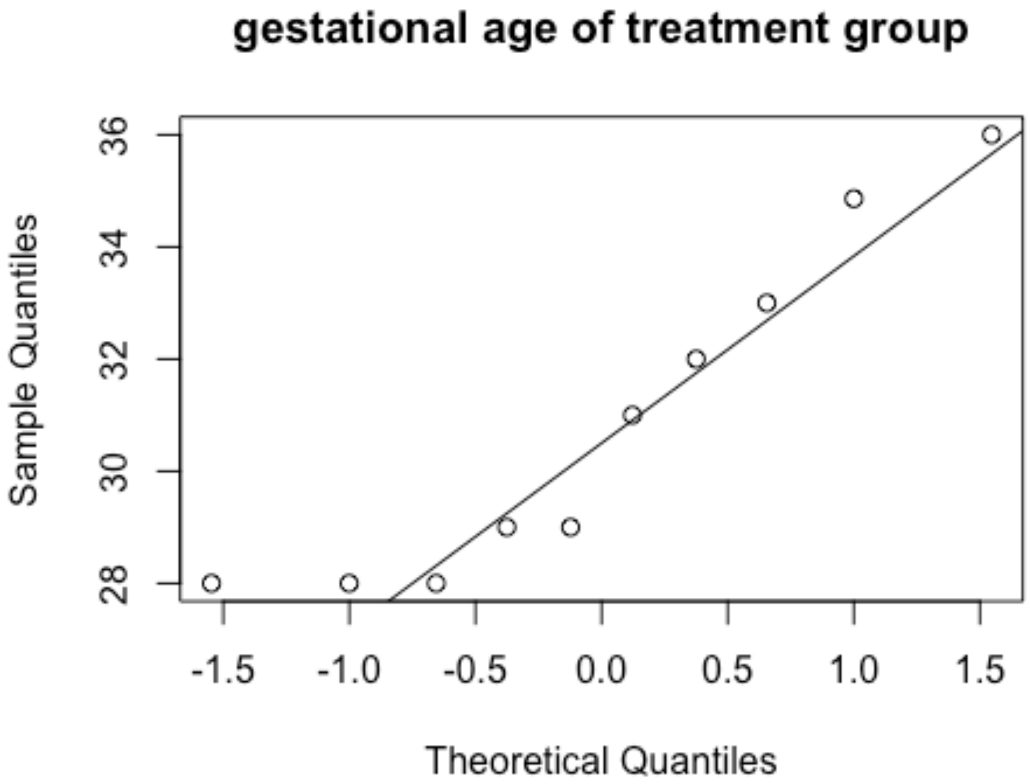
```
ad.test(control.ages)

##
##  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)
```

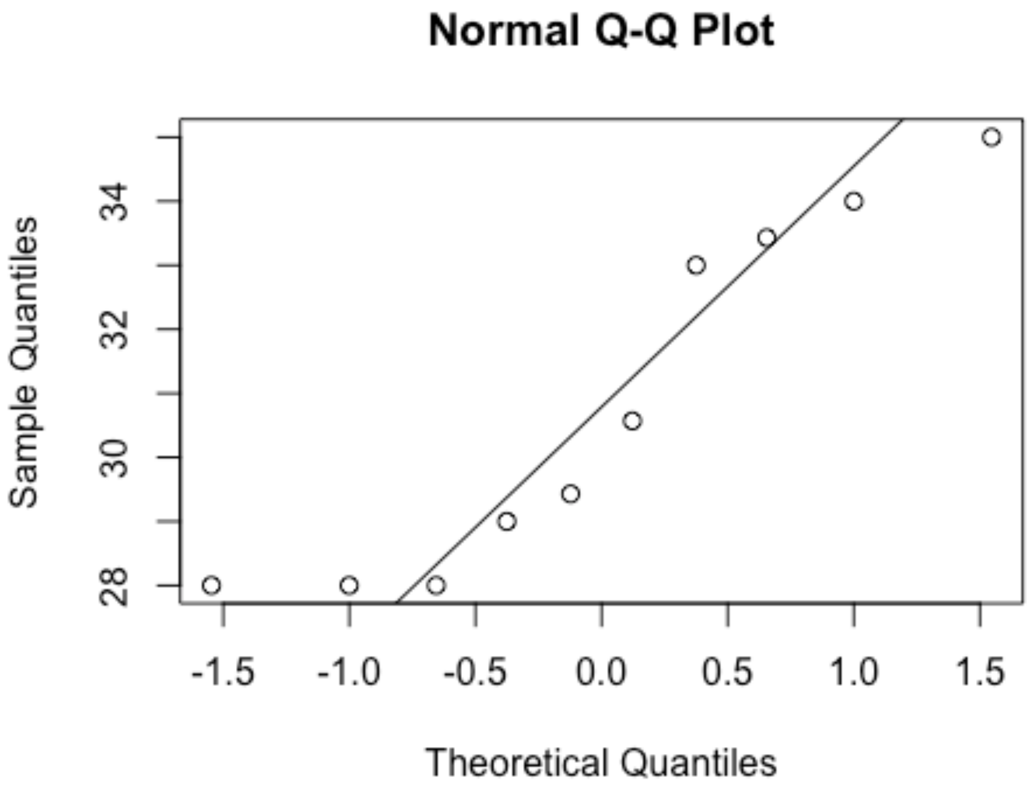


```
ad.test(DCFdata$gar)

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

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   29.00   29.50   30.00   30.62   31.43   32.86

#Treatment gestational age @ First Sleep Test
treatment.gar=na.omit(subset(DCFdata, intervention == "Treatment")$gar)
length(treatment.gar)

## [1] 10

summary(treatment.gar)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   28.00   28.25   30.00   30.89   32.75   36.00

sd(treatment.gar)

## [1] 2.977128

#check for normality
qqnorm(treatment.gar, main = "gestational age of treatment group")
qqline(treatment.gar)
```



```
ad.test(treatment.gar)

##
##  Anderson-Darling normality test
##
## data:  treatment.gar
## A = 0.4918, p-value = 0.1663

#normal

#Control gestational age @ First Sleep Test
control.gar=na.omit(subset(DCFdata, intervention == "Control")$gar)
length(control.gar)

## [1] 10

summary(control.gar)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   28.00   28.25   30.00   30.84   33.32   35.00

sd(control.gar)

## [1] 2.754959

#check for normality
qqnorm(control.gar)
qqline(control.gar)
```



```
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 T
est
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:
```

```
## mean of x mean of y 
##    30.886    30.843 

####################GRAVIDITY#######################
summary(DCFdata$gravidity)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##     1.0     1.0     1.5     1.5     2.0     2.0 

sd(na.omit(DCFdata$gravidity))

## [1] 0.5129892

length(DCFdata$gravidity)

## [1] 20

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

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

#Treatment gravidity
treatment.gravidity=na.omit(subset(DCFdata, intervention == "Treatment")$grav
idity)
length(treatment.gravidity)

## [1] 10

summary(treatment.gravidity)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##     1.0     1.0     2.0     1.6     2.0     2.0 

sd(treatment.gravidity)

## [1] 0.5163978

#Control gravidity
control.gravidity=na.omit(subset(DCFdata, intervention == "Control")$gravidit
y)
length(control.gravidity)

## [1] 10

summary(control.gravidity)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##     1.0     1.0     1.0     1.4     2.0     2.0 

sd(control.gravidity)

## [1] 0.5163978
```

```
#Tabulate the data
xtabs(~gravidity + intervention, data = DCFdata)

##          intervention
## gravidity Control Treatment
##         1       6         4
##         2       4         6

#Perform Fisher's Exact Test
fisher.test(xtabs(~gravidity + intervention, data = DCFdata))

## 
##  Fisher's Exact Test for Count Data
## 
## data:  xtabs(~gravidity + intervention, data = DCFdata)
## p-value = 0.6563
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2773893 19.1425577
## sample estimates:
## odds ratio 
##   2.158166

####################ETHNICITY#######################
summary(DCFdata$ethnicity)

##       caucasian        Filipino          Indian Middle Eastern 
##              16               1               1              2

length(DCFdata$ethnicity)

## [1] 20

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

##       caucasian        Filipino          Indian Middle Eastern 
##               3               0               0              0

#Tabulate the data
xtabs(~ethnicity + intervention, data = DCFdata)

##                  intervention
## ethnicity        Control Treatment
##   caucasian           10         6
##   Filipino             0         1
##   Indian               0         1
##   Middle Eastern       0         2

#Perform Fisher's Exact Test
fisher.test(xtabs(~ethnicity + intervention, data = DCFdata))
```

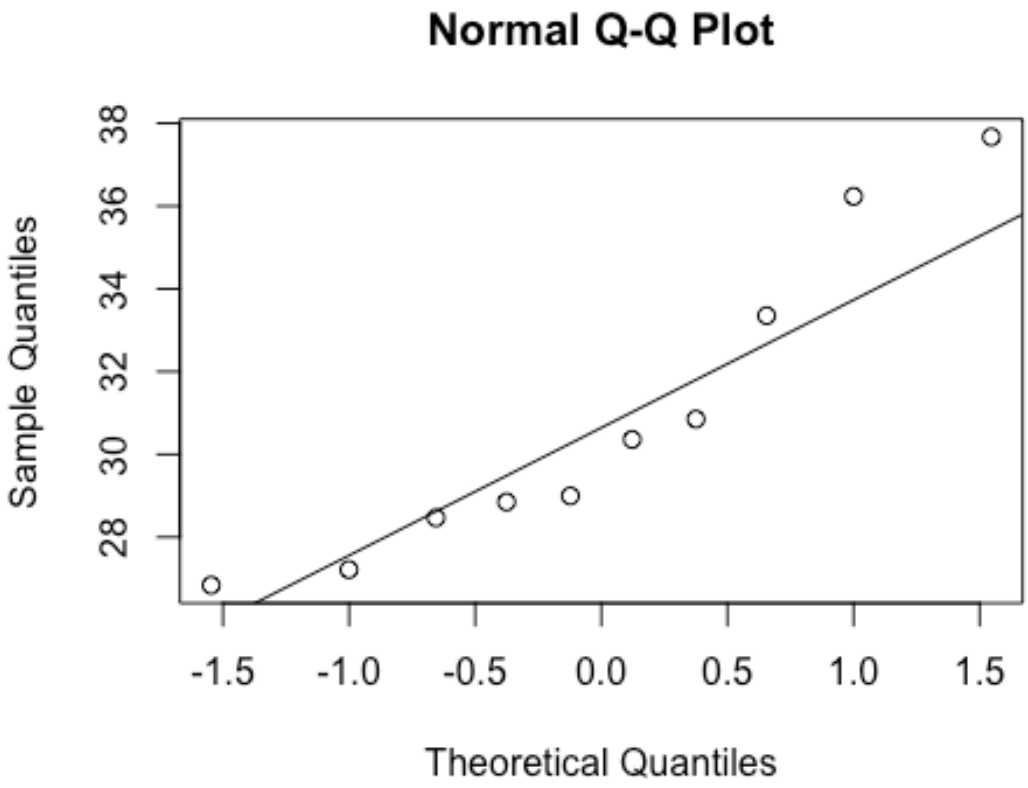
```
##
##  Fisher's Exact Test for Count Data
##
## data:  xtabs(~ethnicity + intervention, data = DCFdata)
## p-value = 0.08669
## alternative hypothesis: two.sided
```

```
temp_table <- xtabs(~ethnicity + intervention, data = DCFdata)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}
```

```
## [1] "caucasian"
##           Control Treatment
## caucasian      10         6
## Other           0         4
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.08669
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.7703894       Inf
## sample estimates:
## odds ratio
##        Inf
##
## [1] "Filipino"
##          Control Treatment
## Filipino       0         1
## Other         10         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
```

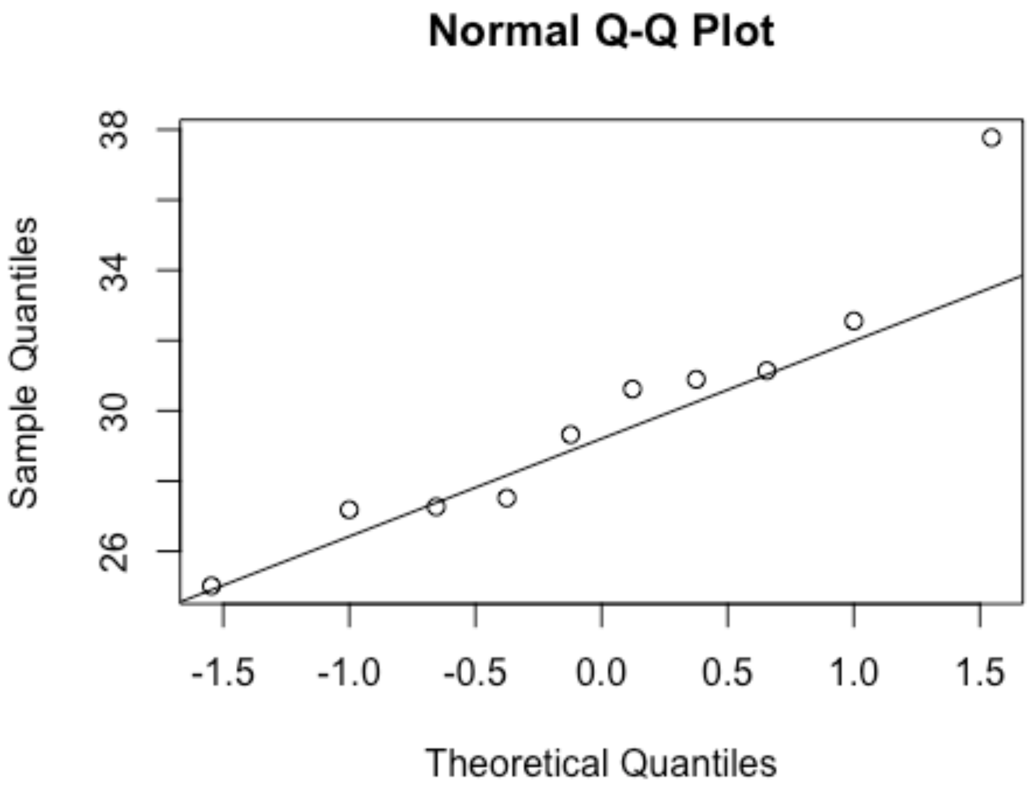
```
## 95 percent confidence interval:
##   0.00000 39.00055
## sample estimates:
## odds ratio 
##          0 
## 
## [1] "Indian"
##         Control Treatment
## Indian        0         1
## Other        10         9
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.00000 39.00055
## sample estimates:
## odds ratio 
##          0 
## 
## [1] "Middle Eastern"
##                 Control Treatment
## Middle Eastern       0         2
## Other               10         8
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.4737
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.000000 5.231968
## sample estimates:
## odds ratio 
##          0 

###################HEIGHT.CURRENT######################
summary(DCFdata$height.current.inches)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   59.00   63.75   65.00   64.73   66.62   70.00 

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

## [1] 2.955734

length(DCFdata$height.current.inches)

## [1] 20
```

```
###################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)
```



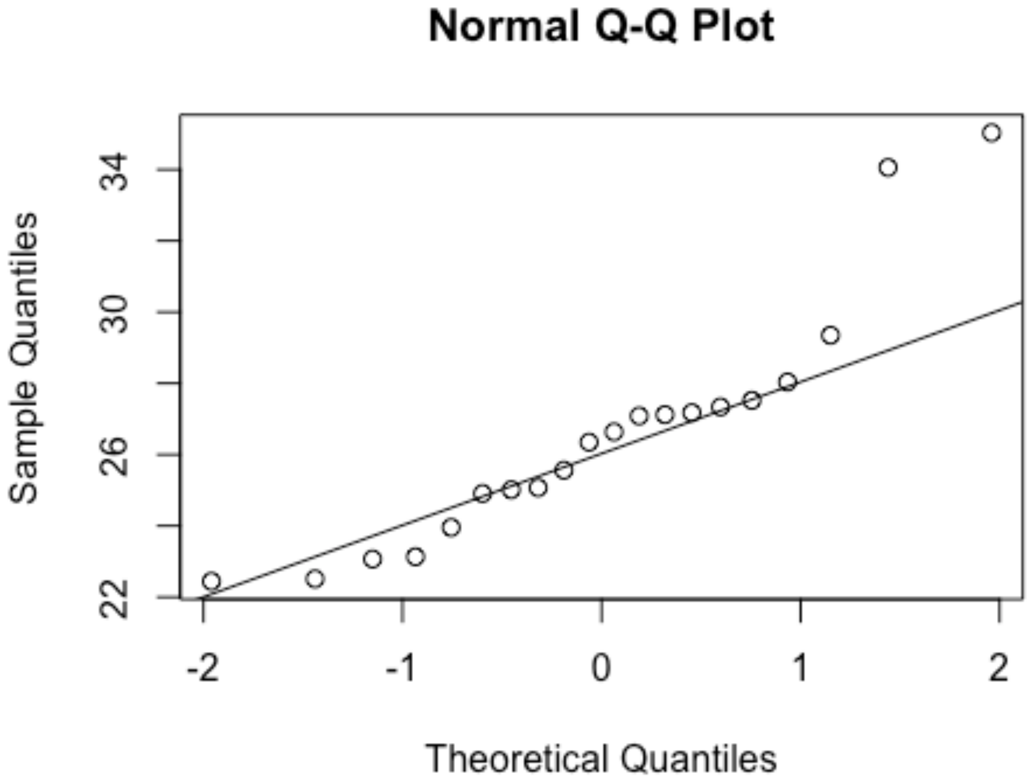
```
ad.test(treatment.current.BMI)

##
##  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)
```



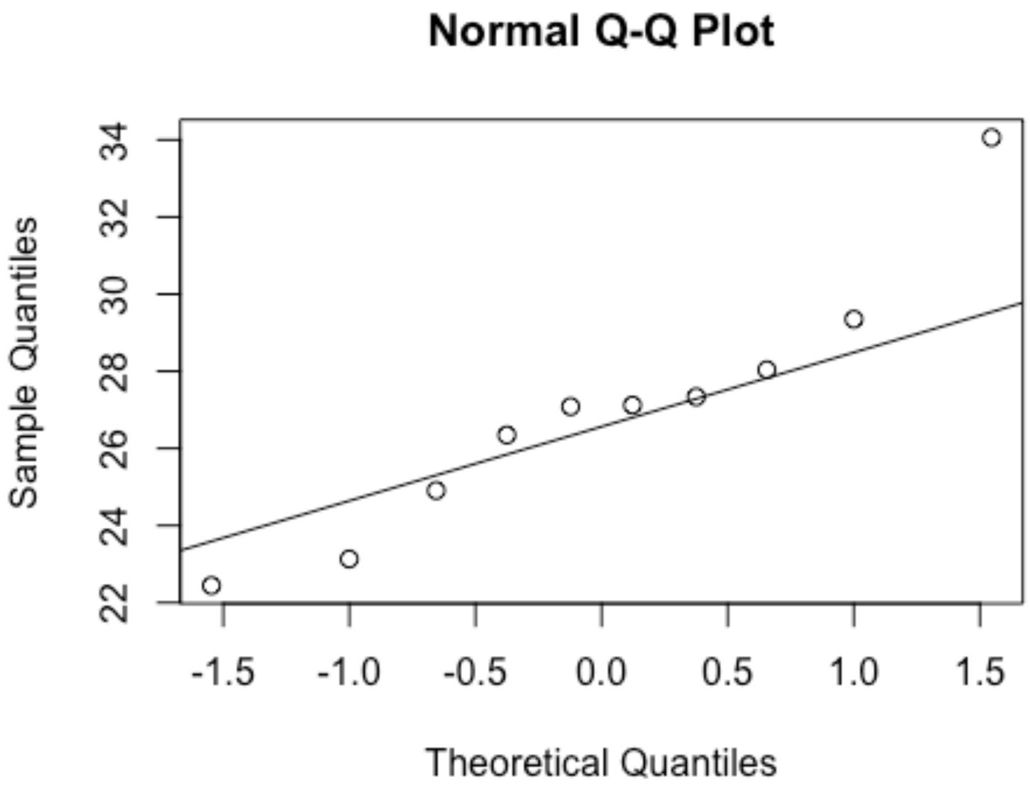
```
ad.test(control.current.BMI)

##
##  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
```

```
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -2.480620  4.391192
## sample estimates:
## mean of x mean of y
##  30.88316  29.92787

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

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

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

## [1] 20.45863

length(DCFdata$weight.before.lbs)

## [1] 20

####################BMI.BEFORE#######################
summary(DCFdata$BMI.before)

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

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

## [1] 3.347304

length(DCFdata$BMI.before)

## [1] 20

qqnorm(DCFdata$BMI.before)
qqline(DCFdata$BMI.before)
```



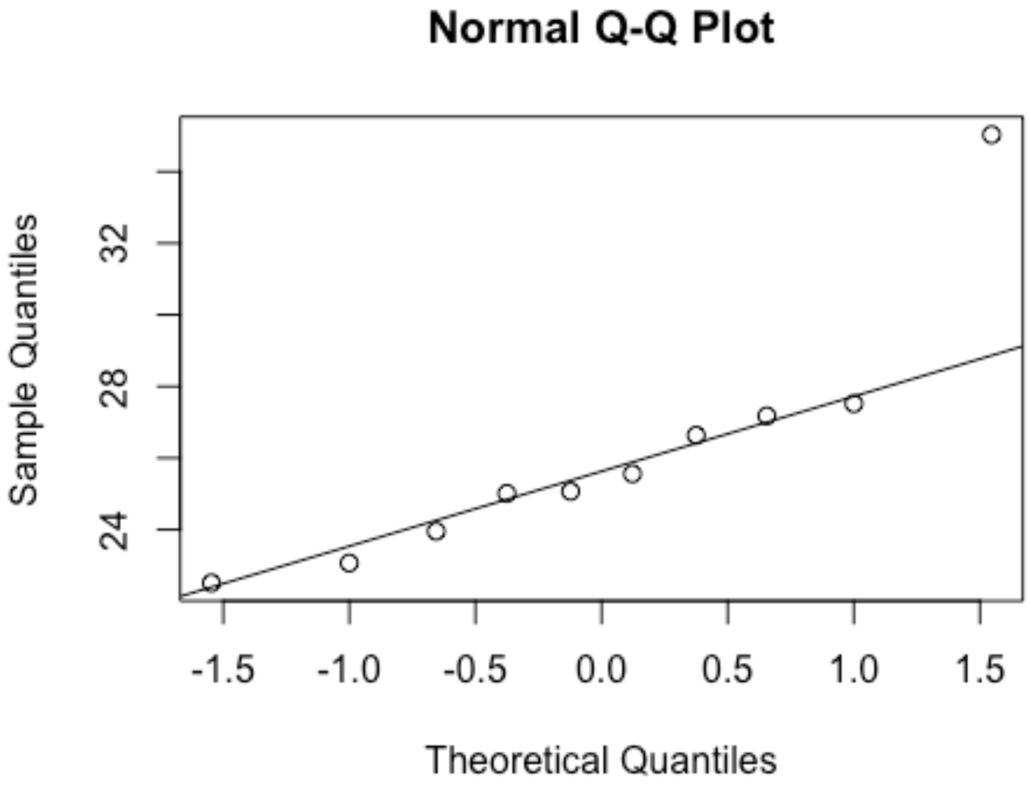
```
ad.test(DCFdata$BMI.before)

##
##  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")$BM
I.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
```

```
sd(treatment.before.BMI)

## [1] 3.283838

#normality check
qqnorm(treatment.before.BMI)
qqline(treatment.before.BMI)
```



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

##
##  Anderson-Darling normality test
##
## data:  treatment.before.BMI
## A = 0.35509, p-value = 0.3831

#normal

#Control BMI before pregnancy
control.before.BMI=na.omit((subset(DCFdata, intervention == "Control")$BMI.be
fore))
length(control.before.BMI)

## [1] 10
```

```
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)
```



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

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

#non-normal
```

```
#Perform non-parametric method (Wilcoxon rank sum test)
wilcox.test(treatment.before.BMI, control.before.BMI, conf.int = TRUE)

##
##  Wilcoxon rank sum test
##
## data:  treatment.before.BMI and control.before.BMI
## W = 60, p-value = 0.4813
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.728710  3.835403
## sample estimates:
## difference in location
##               1.115286

####################BED TIME#######################
summary(DCFdata$bedtime.hrs)

##  0:00  1:00 21:00 22:00 23:00
##     4     1     1     6     8

#Tabulate the data
xtabs(~bedtime.hrs + intervention, data = DCFdata)

##             intervention
## bedtime.hrs Control Treatment
##       0:00        2         2
##       1:00        0         1
##       21:00       1         0
##       22:00       3         3
##       23:00       4         4

#Perform Fisher's Exact Test
fisher.test(xtabs(~bedtime.hrs + intervention, data = DCFdata))

##
##  Fisher's Exact Test for Count Data
##
## data:  xtabs(~bedtime.hrs + intervention, data = DCFdata)
## p-value = 1
## alternative hypothesis: two.sided

temp_table <- xtabs(~bedtime.hrs + intervention, data = DCFdata)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "0:00"
##       Control Treatment
## 0:00        2         2
## Other       8         8
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.0585532 17.0784861
## sample estimates:
## odds ratio
##          1
##
## [1] "1:00"
##       Control Treatment
## 1:00        0         1
## Other      10         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.00000 39.00055
## sample estimates:
## odds ratio
##          0
##
## [1] "21:00"
##       Control Treatment
## 21:00       1         0
## Other       9        10
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
```

```
##  0.02564066        Inf
## sample estimates:
## odds ratio
##        Inf
##
## [1] "22:00"
##       Control Treatment
## 22:00       3         3
## Other       7         7
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.09678719 10.33194569
## sample estimates:
## odds ratio
##          1
##
## [1] "23:00"
##       Control Treatment
## 23:00       4         4
## Other       6         6
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.118794 8.417935
## sample estimates:
## odds ratio
##          1
```

```
####################WAKE TIME#######################
summary(DCFdata$waketime.hrs)
```

```
## 5:00 6:00 7:00 8:00 9:00
##    0    5    8    4    3
```

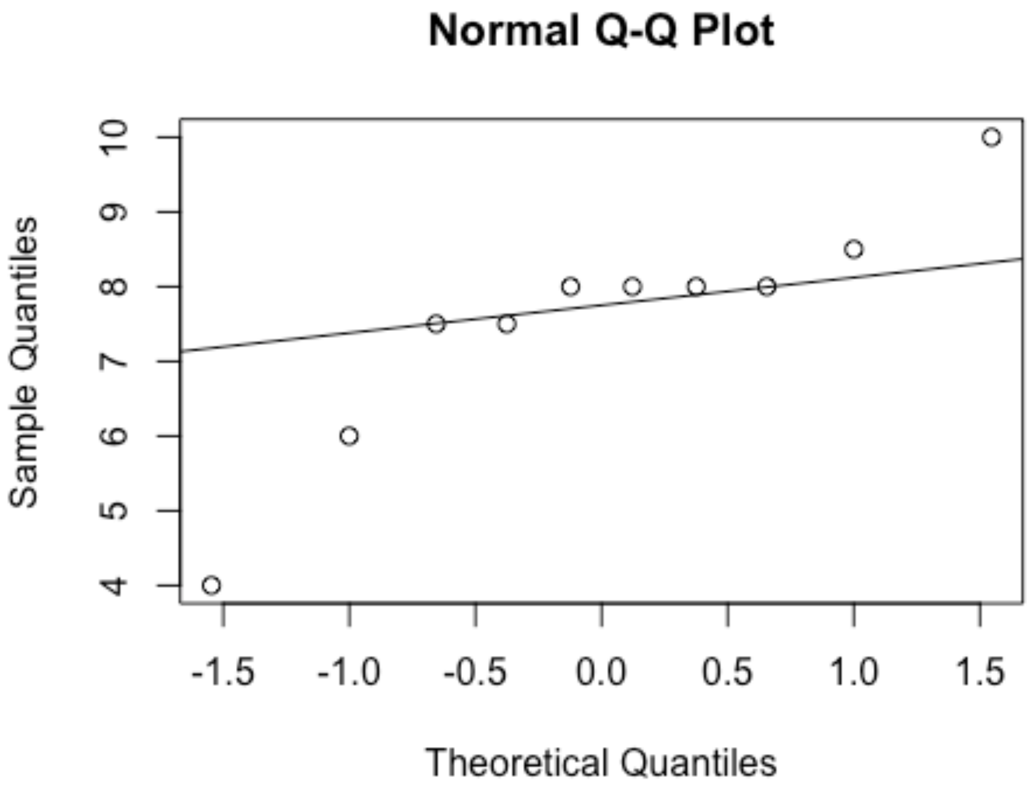
```
#Tabulate the data
xtabs(~waketime.hrs + intervention, data = DCFdata)
```

```
##             intervention
## waketime.hrs Control Treatment
##         5:00       0         0
##         6:00       4         1
##         7:00       2         6
```

```
##         8:00       3         1
##         9:00       1         2

#Perform Fisher's Exact Test
fisher.test(xtabs(~waketime.hrs + intervention, data = DCFdata))

##
##  Fisher's Exact Test for Count Data
##
## data:  xtabs(~waketime.hrs + intervention, data = DCFdata)
## p-value = 0.2044
## alternative hypothesis: two.sided

temp_table <- xtabs(~waketime.hrs + intervention, data = DCFdata)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "5:00"
##       Control Treatment
## 5:00        0         0
## Other      10        10
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0 Inf
## sample estimates:
## odds ratio
##          0
##
## [1] "6:00"
##       Control Treatment
## 6:00        4         1
## Other       6         9
##
```

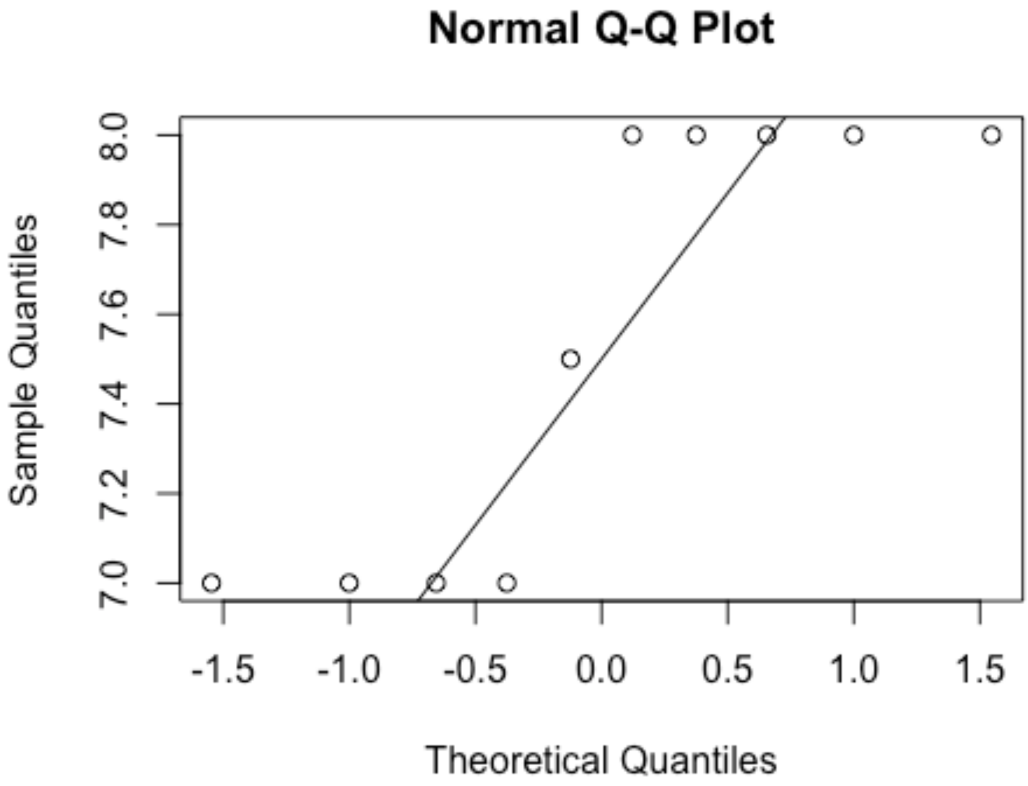
```
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.3034
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0.4075889 326.8267297
## sample estimates:
## odds ratio 
##   5.485861 
## 
## [1] "7:00"
##       Control Treatment
## 7:00        2         6
## Other       8         4
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.1698
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.01252647 1.65925396
## sample estimates:
## odds ratio 
##  0.1841181 
## 
## [1] "8:00"
##       Control Treatment
## 8:00        3         1
## Other       7         9
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.582
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0.2301177 224.1916418
## sample estimates:
## odds ratio 
##   3.610815 
## 
## [1] "9:00"
##       Control Treatment
## 9:00        1         2
## Other       9         8
## 
##  Fisher's Exact Test for Count Data
## 
```

```
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.0067986 10.5137419
## sample estimates:
## odds ratio
##  0.4624944

####################SLEEP DURATION REPORTED#######################
summary(DCFdata$sleep.reported.hrs)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    4.00    7.00    8.00    7.55    8.00   10.00

sd(DCFdata$sleep.reported.hrs, na.rm = TRUE)

## [1] 1.145931

length(DCFdata$sleep.reported.hrs)

## [1] 20

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   5.500   6.250   7.000   6.833   7.500   8.000

#Treatment sleep duration reported
treatment.sleep.reported.hrs=na.omit((subset(DCFdata,
                                             intervention == "Treatment")$sle
ep.reported.hrs))
length(treatment.sleep.reported.hrs)

## [1] 10

summary(treatment.sleep.reported.hrs)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    4.00    7.50    8.00    7.55    8.00   10.00

sd(treatment.sleep.reported.hrs)

## [1] 1.589025

#normality check
qqnorm(treatment.sleep.reported.hrs)
qqline(treatment.sleep.reported.hrs)
```



```
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
```

```
## Warning in wilcox.test.default(treatment.sleep.reported.hrs,
## control.sleep.reported.hrs, : cannot compute exact confidence intervals
## with ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  treatment.sleep.reported.hrs and control.sleep.reported.hrs
## W = 59, p-value = 0.498
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.5000247  0.9999945
## sample estimates:
## difference in location
##           3.045828e-05

#########FALL ASLEEP POSITION IN PAST WEEK###########
summary(DCFdata$fell.asleep.in.past.week)

##                 left          left, right  left, right, prone
##                    7                    4                   1
## left, right, supine         left, supine               right
##                    3                    2                   3
##        right, supine
##                    0

length(DCFdata$fell.asleep.in.past.week)

## [1] 20

#Tabulate the data
xtabs(~fell.asleep.in.past.week + intervention, data = DCFdata)

##                         intervention
## fell.asleep.in.past.week Control Treatment
##      left                      7         0
##      left, right               1         3
##      left, right, prone        0         1
##      left, right, supine       2         1
##      left, supine              0         2
##      right                     0         3
##      right, supine             0         0

#Perform Fisher's Exact Test
#fisher.test(xtabs(~fell.asleep.in.past.week + intervention, data = DCFdata))
#build 2-row table for fisher test: control vs treatment
fell.asleep.in.past.week_table <- matrix(c(10,7,3,8,2,3,0,1),
                                         nrow = 2)
colnames(fell.asleep.in.past.week_table) <- c("left","right","supine","prone"
)
rownames(fell.asleep.in.past.week_table) <- c("Control",
```

```
                                              "Treatment")
t(fell.asleep.in.past.week_table)

##        Control Treatment
## left        10         7
## right        3         8
## supine       2         3
## prone        0         1

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$fell.asleep.in.past.week)

##                 left          left, right  left, right, prone
##                    0                    1                    0
## left, right, supine         left, supine                right
##                    1                    0                    0
##       right, supine
##                    1

#Perform Fisher's Exact Test
fisher.test(fell.asleep.in.past.week_table)

##
##  Fisher's Exact Test for Count Data
##
## data:  fell.asleep.in.past.week_table
## p-value = 0.3141
## alternative hypothesis: two.sided

temp_table <- t(fell.asleep.in.past.week_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "left"
##       Control Treatment
## left       10         7
## Other       5        12
##
```

```
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.1663
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.680546 18.170891
## sample estimates:
## odds ratio 
##   3.299199 
## 
## [1] "right"
##       Control Treatment
## right       3         8
## Other      12        11
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.2714
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.04812652 1.98278653
## sample estimates:
## odds ratio 
##  0.3547015 
## 
## [1] "supine"
##        Control Treatment
## supine       2         3
## Other       13        16
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.06037268 8.38423263
## sample estimates:
## odds ratio 
##  0.8252566 
## 
## [1] "prone"
##       Control Treatment
## prone       0         1
## Other      15        18
## 
##  Fisher's Exact Test for Count Data
## 
```

```
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.00000 49.36267
## sample estimates:
## odds ratio
##          0

######FALL ASLEEP POSITION WHEN NOT PREGNANT#########
summary(DCFdata$fell.asleep.when.not.pregnant)

##                        left                 left, prone
##                           1                           1
##                 left, right        left, right, supine
##                           1                           1
## left, right, supine, prone                       prone
##                           1                           8
##                       right                right, prone
##                           2                           1
##                      supine              supine, prone
##                           2                           2

length(DCFdata$fell.asleep.when.not.pregnant)

## [1] 20

#Tabulate the data
xtabs(~fell.asleep.when.not.pregnant + intervention, data = DCFdata)

##                                intervention
## fell.asleep.when.not.pregnant Control Treatment
##    left                             1         0
##    left, prone                      1         0
##    left, right                      0         1
##    left, right, supine              0         1
##    left, right, supine, prone       1         0
##    prone                            2         6
##    right                            2         0
##    right, prone                     1         0
##    supine                           1         1
##    supine, prone                    1         1

#Perform Fisher's Exact Test
#fisher.test(xtabs(~fell.asleep.when.not.pregnant + intervention, data = DCFd
ata))
#build 2-row table for fisher test: control vs treatment
fell.asleep.when.not.pregnant_table <- matrix(c(3,2,4,2,3,3,6,7),
                                              nrow = 2)
colnames(fell.asleep.when.not.pregnant_table) <- c("left","right","supine","p
rone")
```

```
rownames(fell.asleep.when.not.pregnant_table) <- c("Control",
                                                    "Treatment")
t(fell.asleep.when.not.pregnant_table)

##        Control Treatment
## left         3         2
## right        4         2
## supine       3         3
## prone        6         7

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$fell.asleep.when.not.pregnant)

##                       left                left, prone
##                          0                          0
##                left, right        left, right, supine
##                          0                          1
## left, right, supine, prone                      prone
##                          0                          0
##                      right               right, prone
##                          0                          0
##                     supine              supine, prone
##                          2                          0

#Perform Fisher's Exact Test
fisher.test(fell.asleep.when.not.pregnant_table)

##
##  Fisher's Exact Test for Count Data
##
## data:  fell.asleep.when.not.pregnant_table
## p-value = 0.9528
## alternative hypothesis: two.sided

temp_table <- t(fell.asleep.when.not.pregnant_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}
```

```
## [1] "left"
##       Control Treatment
## left        3         2
## Other      13        12
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.1319695 19.0880365
## sample estimates:
## odds ratio
##    1.36981
## 
## [1] "right"
##       Control Treatment
## right       4         2
## Other      12        12
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.6567
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2279875 25.5286215
## sample estimates:
## odds ratio
##    1.95517
## 
## [1] "supine"
##        Control Treatment
## supine       3         3
## Other       13        11
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.09371084 7.70893039
## sample estimates:
## odds ratio
##  0.8508967
## 
## [1] "prone"
##       Control Treatment
```

```
## prone       6         7
## Other      10         7
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7131
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1101751 3.2231312
## sample estimates:
## odds ratio
##  0.6104211

#########WAKE UP POSITION IN PAST WEEK###########
summary(DCFdata$woke.up.in.past.week)

##                 left          left, right left, right, supine
##                    3                    5                   2
##         left, supine                right       right, supine
##                    2                    4                   0
##               supine
##                    4

length(DCFdata$woke.up.in.past.week)

## [1] 20

#Tabulate the data
xtabs(~woke.up.in.past.week + intervention, data = DCFdata)

##                       intervention
## woke.up.in.past.week  Control Treatment
##   left                      1         2
##   left, right               1         4
##   left, right, supine       1         1
##   left, supine              1         1
##   right                     4         0
##   right, supine             0         0
##   supine                    2         2

#Perform Fisher's Exact Test
#fisher.test(xtabs(~woke.up.in.past.week + intervention, data = DCFdata))
#build 2-row table for fisher test: control vs treatment
woke.up.in.past.week_table <- matrix(c(4,8,6,5,4,4),
                                              nrow = 2)
colnames(woke.up.in.past.week_table) <- c("left","right","supine")
rownames(woke.up.in.past.week_table) <- c("Control",
                                                   "Treatment")
t(woke.up.in.past.week_table)
```

```
##        Control Treatment
## left         4         8
## right        6         5
## supine       4         4

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$woke.up.in.past.week)

##                 left         left, right left, right, supine
##                    0                   2                   0
##         left, supine               right       right, supine
##                    0                   0                   1
##               supine
##                    0

#Perform Fisher's Exact Test
fisher.test(woke.up.in.past.week_table)

## 
##  Fisher's Exact Test for Count Data
## 
## data:  woke.up.in.past.week_table
## p-value = 0.6555
## alternative hypothesis: two.sided

temp_table <- t(woke.up.in.past.week_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "left"
##       Control Treatment
## left        4         8
## Other      10         9
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.4607
```

```
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.07417123 2.49180269
## sample estimates:
## odds ratio
##  0.4618727
##
## [1] "right"
##       Control Treatment
## right       6         5
## Other       8        12
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.4775
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.3207388 10.2754454
## sample estimates:
## odds ratio
##   1.765584
##
## [1] "supine"
##        Control Treatment
## supine       4         4
## Other       10        13
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1885274 8.8685637
## sample estimates:
## odds ratio
##   1.288954

#########WAKE UP POSITION WHEN NOT PREGNANT###########
summary(DCFdata$woke.up.when.not.pregnant)

##                        left                 left, right
##                           3                           1
##         left, right, prone        left, right, supine
##                           1                           1
## left, right, supine, prone        left, supine, prone
##                           2                           1
##                       prone                       right
##                           2                           2
```

```
##              right, supine                     supine
##                          0                          4
##              supine, prone
##                          3
```

```
length(DCFdata$woke.up.when.not.pregnant)
```

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

```
#Tabulate the data
xtabs(~woke.up.when.not.pregnant + intervention, data = DCFdata)
```

```
##                              intervention
## woke.up.when.not.pregnant    Control Treatment
##   left                             2         1
##   left, right                      0         1
##   left, right, prone               0         1
##   left, right, supine              0         1
##   left, right, supine, prone       1         1
##   left, supine, prone              1         0
##   prone                            0         2
##   right                            1         1
##   right, supine                    0         0
##   supine                           3         1
##   supine, prone                    2         1
```

```
#Perform Fisher's Exact Test
#fisher.test(xtabs(~woke.up.when.not.pregnant + intervention, data = DCFdata)
)
#build 2-row table for fisher test: control vs treatment
woke.up.when.not.pregnant_table <- matrix(c(4,5,2,5,7,4,4,5),
                                     nrow = 2)
colnames(woke.up.when.not.pregnant_table) <- c("left","right","supine","prone
")
rownames(woke.up.when.not.pregnant_table) <- c("Control",
                                          "Treatment")
t(woke.up.when.not.pregnant_table)
```

```
##        Control Treatment
## left         4         5
## right        2         5
## supine       7         4
## prone        4         5
```

```
#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$woke.up.when.not.pregnant)
```

```
##                       left                left, right
##                          0                          0
##         left, right, prone        left, right, supine
##                          0                          1
## left, right, supine, prone        left, supine, prone
```

```
##                          0                          0
##                      prone                      right
##                          1                          0
##              right, supine                     supine
##                          1                          0
##              supine, prone
##                          0
```

```
#Perform Fisher's Exact Test
fisher.test(woke.up.when.not.pregnant_table)
```

```
## 
##  Fisher's Exact Test for Count Data
## 
## data:  woke.up.when.not.pregnant_table
## p-value = 0.56
## alternative hypothesis: two.sided
```

```
temp_table <- t(woke.up.when.not.pregnant_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}
```

```
## [1] "left"
##       Control Treatment
## left        4         5
## Other      13        14
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.13878 5.04642
## sample estimates:
## odds ratio 
##  0.8651067 
## 
```

```
## [1] "right"
##       Control Treatment
## right       2         5
## Other      15        14
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.408
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.03161314 2.82646603
## sample estimates:
## odds ratio 
##  0.3834022 
## 
## [1] "supine"
##        Control Treatment
## supine       7         4
## Other       10        15
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.2814
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.4917611 15.3003743
## sample estimates:
## odds ratio 
##   2.553445 
## 
## [1] "prone"
##       Control Treatment
## prone       4         5
## Other      13        14
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.13878 5.04642
## sample estimates:
## odds ratio 
##  0.8651067

#########PART OF BED PARTICIPANT SLEEPS ON###########
summary(DCFdata$side.of.bed)
```

```
##               center                left left, right, center
##                    2                   8                   1
##                right        right, center
##                    9                   0

length(DCFdata$side.of.bed)

## [1] 20

#Tabulate the data
xtabs(~side.of.bed + intervention, data = DCFdata)

##                      intervention
## side.of.bed           Control Treatment
##   center                    0         2
##   left                      5         3
##   left, right, center       0         1
##   right                     5         4
##   right, center             0         0

#Perform Fisher's Exact Test
#fisher.test(xtabs(~side.of.bed + intervention, data = DCFdata))
#build 2-row table for fisher test: control vs treatment
side.of.bed_table <- matrix(c(5,4,5,5,0,3),
                                          nrow = 2)
colnames(side.of.bed_table) <- c("left","right","center")
rownames(side.of.bed_table) <- c("Control",
                                               "Treatment")
t(side.of.bed_table)

##        Control Treatment
## left         5         4
## right        5         5
## center       0         3

#Perform Fisher's Exact Test
fisher.test(side.of.bed_table)

## 
##  Fisher's Exact Test for Count Data
## 
## data:  side.of.bed_table
## p-value = 0.357
## alternative hypothesis: two.sided

temp_table <- t(side.of.bed_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "left"
##       Control Treatment
## left        5         4
## Other       5         8
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.6656
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2637526 15.6036729
## sample estimates:
## odds ratio
##   1.936521
##
## [1] "right"
##       Control Treatment
## right       5         5
## Other       5         7
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.1920501 10.2898393
## sample estimates:
## odds ratio
##   1.378598
##
## [1] "center"
##        Control Treatment
## center       0         3
## Other       10         9
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
```

```
## p-value = 0.2208
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.000000 2.779036
## sample estimates:
## odds ratio
##          0

###################BED PARTNER###################
summary(DCFdata$sleeps.with.without.partner)

##    with without
##      17       3

length(DCFdata$sleeps.with.without.partner)

## [1] 20

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$sleeps.with.without.partner)

##    with without
##       3       0

#Tabulate the data
xtabs(~sleeps.with.without.partner + intervention, data = DCFdata)

##                            intervention
## sleeps.with.without.partner Control Treatment
##                      with         10         7
##                      without       0         3

#Perform Fisher's Exact Test
fisher.test(xtabs(~sleeps.with.without.partner + intervention, data = DCFdata
))

## 
##  Fisher's Exact Test for Count Data
## 
## data:  xtabs(~sleeps.with.without.partner + intervention, data = DCFdata)
## p-value = 0.2105
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.443414      Inf
## sample estimates:
## odds ratio
##        Inf

###################PILLOW USE###################
summary(DCFdata$pillow)
```

```
##                                          pregnancy pillow
##                                                         2
##                                                under head
##                                                         1
##                              under head and between knees
##                                                         4
##                           under head and pregnancy pillow
##                                                         1
##                                  under head between knees
##                                                         1
##                  under head between knees and behind back
##                                                         2
##             under head between knees and pregnancy pillow
##                                                         1
##                  under head between knees and under tummy
##                                                         1
## under head between knees behind back and pregnany pillow
##                                                         1
##                      under head between knees under tummy
##                                                         1
##      under head between knees under tummy and behind back
##                                                         3
##                    under head under tummy and behind back
##                                                         2
```

```
length(DCFdata$pillow)
```

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

```
#Tabulate the data
xtabs(~pillow + intervention, data = DCFdata)
```

```
##                                                            intervention
## pillow                                                      Control
##   pregnancy pillow                                                1
##   under head                                                      1
##   under head and between knees                                    3
##   under head and pregnancy pillow                                 0
##   under head between knees                                        0
##   under head between knees and behind back                        1
##   under head between knees and pregnancy pillow                   0
##   under head between knees and under tummy                        0
##   under head between knees behind back and pregnany pillow       0
##   under head between knees under tummy                            0
##   under head between knees under tummy and behind back            2
##   under head under tummy and behind back                          2
##                                                            intervention
## pillow                                                      Treatment
##   pregnancy pillow                                                  1
##   under head                                                        0
##   under head and between knees                                      1
```

```
##   under head and pregnancy pillow                              1
##   under head between knees                                     1
##   under head between knees and behind back                     1
##   under head between knees and pregnancy pillow                1
##   under head between knees and under tummy                     1
##   under head between knees behind back and pregnany pillow     1
##   under head between knees under tummy                         1
##   under head between knees under tummy and behind back         1
##   under head under tummy and behind back                       0

#Perform Fisher's Exact Test
fisher.test(xtabs(~pillow + intervention, data = DCFdata))

##
##  Fisher's Exact Test for Count Data
##
## data:  xtabs(~pillow + intervention, data = DCFdata)
## p-value = 0.7563
## alternative hypothesis: two.sided

#build 2-row table for fisher test: control vs treatment
pillow_table <- matrix(c(1,4,9,9,6,8,5,3,4,3),
                            nrow = 2)
colnames(pillow_table) <- c("pregnancy pillow","under head","btw knees","behi
nd back","under tummy")
rownames(pillow_table) <- c("Control",
                                 "Treatment")
t(pillow_table)

##                   Control Treatment
## pregnancy pillow       1         4
## under head             9         9
## btw knees              6         8
## behind back            5         3
## under tummy            4         3

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

##                                             pregnancy pillow
##                                                            0
##                                                   under head
##                                                            0
##                                 under head and between knees
##                                                            1
##                              under head and pregnancy pillow
##                                                            0
##                                     under head between knees
##                                                            0
##                     under head between knees and behind back
##                                                            1
```

```
##            under head between knees and pregnancy pillow 
##                                                        0 
##                 under head between knees and under tummy 
##                                                        1 
## under head between knees behind back and pregnany pillow 
##                                                        0 
##                     under head between knees under tummy 
##                                                        0 
##     under head between knees under tummy and behind back 
##                                                        0 
##                   under head under tummy and behind back 
##                                                        0

#Perform Fisher's Exact Test
fisher.test(pillow_table)

## 
##  Fisher's Exact Test for Count Data
## 
## data:  pillow_table
## p-value = 0.6624
## alternative hypothesis: two.sided

temp_table <- t(pillow_table)
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("Control","Treatment")
  rownames(ORtable) <- c(row.names(temp_table)[i],"Other")
  print(row.names(temp_table)[i])
  print(ORtable)
  print(fisher.test(ORtable))
}

## [1] "pregnancy pillow"
##                  Control Treatment
## pregnancy pillow       1         4
## Other                 24        23
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.3517
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
```

```
##  0.004679473 2.727254390
## sample estimates:
## odds ratio
##  0.2455393
##
## [1] "under head"
##            Control Treatment
## under head       9         9
## Other           16        18
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.3077428 4.1067353
## sample estimates:
## odds ratio
##    1.12245
##
## [1] "btw knees"
##           Control Treatment
## btw knees       6         8
## Other          19        19
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7587
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1779795 3.0415532
## sample estimates:
## odds ratio
##  0.7541601
##
## [1] "behind back"
##             Control Treatment
## behind back       5         3
## Other            20        24
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.4583
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.3355811 14.3021716
## sample estimates:
```

```
## odds ratio
##   1.973559
##
## [1] "under tummy"
##             Control Treatment
## under tummy       4         3
## Other            21        24
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.6983
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2268471 11.5245873
## sample estimates:
## odds ratio
##   1.511484

###################SNORING#######################
summary(DCFdata$snores.3.times.or.more.per.week.does.not.snore)

## does not snore         snores
##             13              7

length(DCFdata$snores.3.times.or.more.per.week.does.not.snore)

## [1] 20

#Compare above with those who did not complete the study (n=3):
summary(DropOutdata$snores.3.times.or.more.per.week.does.not.snore)

## does not snore         snores
##              2              1

#Tabulate the data
xtabs(~snores.3.times.or.more.per.week.does.not.snore + intervention, data =
DCFdata)

##                                                intervention
## snores.3.times.or.more.per.week.does.not.snore Control Treatment
##                                 does not snore       7         6
##                                 snores               3         4

#Perform Fisher's Exact Test
fisher.test(xtabs(~snores.3.times.or.more.per.week.does.not.snore + intervent
ion, data = DCFdata))

##
##  Fisher's Exact Test for Count Data
##
## data:
```

```
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.1731447 15.0151265
## sample estimates:
## odds ratio
##   1.521346
```

```
summary(DCFdata$how.long.snores)
```

```
##
##
14
##
2-3 months
##
1
##
7.5 months
##
1
## I think so, my husband informs me that I do + it gets worse the further al
ong in pregnancy (louder/same frequency)
##
1
##
lifetime
##
1
##
several years
##
1
##
Since before I was pregnant
##
1
##
Since being pregnant
##
0
```

```
length(DCFdata$how.long.snores)
```

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

```
###################PREGNANCY HISTORY#######################
summary(DCFdata$pregnancy.related.medical.conditions)
```

```
## none
##   20
```

```
length(DCFdata$pregnancy.related.medical.conditions)

## [1] 20

temp <- matrix(c(10,0,10,0), nrow = 2)
temp

##      [,1] [,2]
## [1,]   10   10
## [2,]    0    0

fisher.test(temp)

##
##  Fisher's Exact Test for Count Data
##
## data:  temp
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0 Inf
## sample estimates:
## odds ratio
##          0

#The End
```

Supplementary file 2: Code and output – PSG analysis

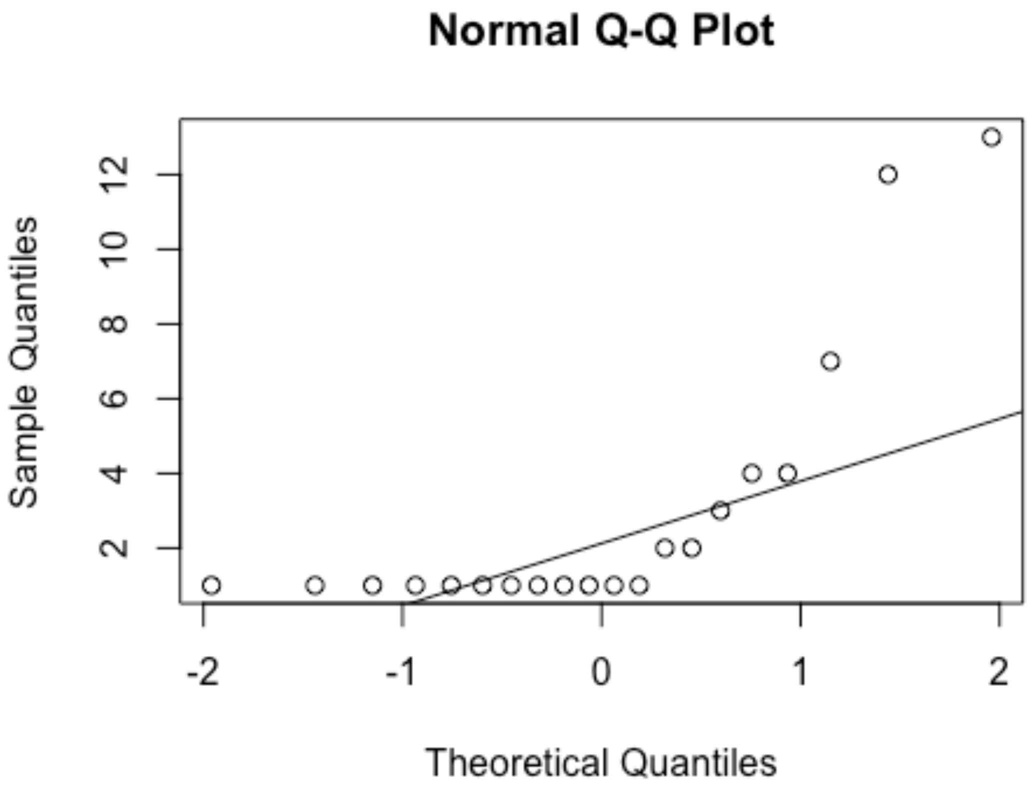
PSG_Analysis_-_BMJSubmission2.R

Allan Kember

Mon May 21 22:49:35 2018

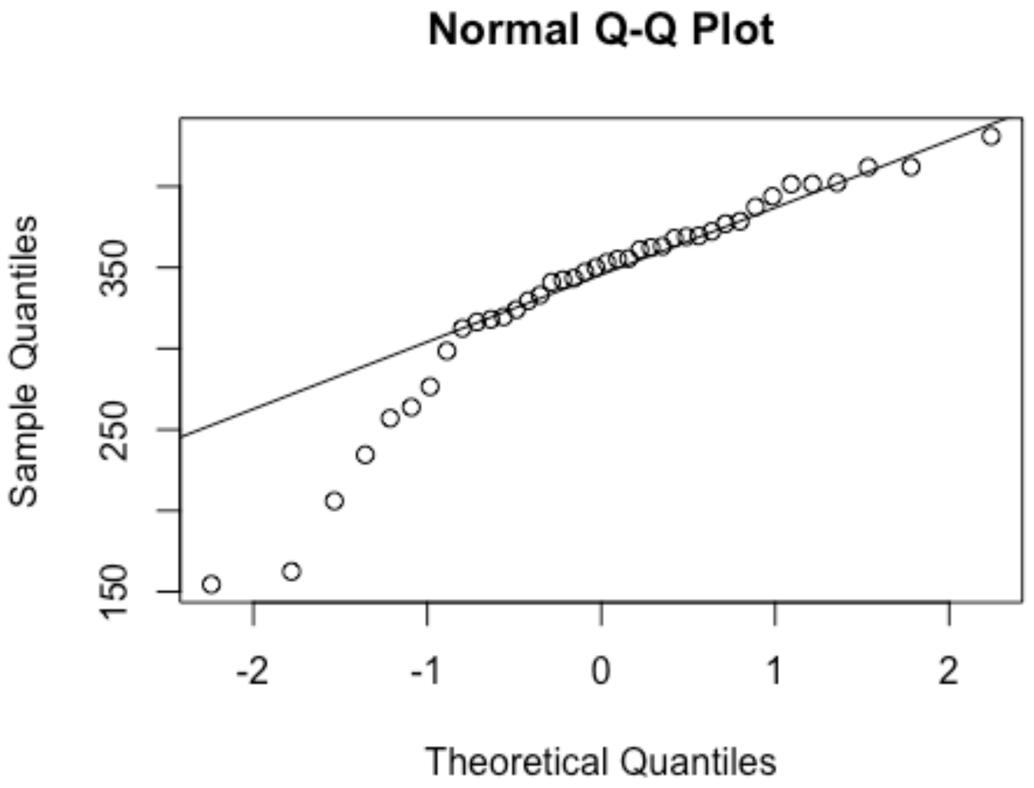
```
#Description of code: this code process the polysomnography (PSG) sleep repor
ts in full.
#Within-participant (paired) comparisons are computed.
#Between-participant comparisons are computed FYI only.

#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 wit
h 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 so
ftware
#will perform this calculation for you. If the p value from the ANOVA is sign
ificant
#(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)
```

```
##   N  Y
## 40  6

#6 nights = 3 participants
#Remove the drop outs ("Y")
SSdata <- SSdatafull[!(SSdatafull$drop.out=="Y"),]
nrow(SSdata)

## [1] 40

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

################### Time between studies (days) ##########################
#FYI: this data was not a pre-specified secondary outcome per the research pr
otocol or
#trial registry. FYI only for purposes of peer reviewer's questions/comments.
#Summary
summary(SSdata$time.between.studies..days.)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##    1.00    1.00    1.00    2.95    3.25   13.00      20

sd(SSdata$time.between.studies..days., na.rm = TRUE)

## [1] 3.619756

length(SSdata$time.between.studies..days.)

## [1] 40

#Check for normality
qqnorm(SSdata$time.between.studies..days.)
qqline(SSdata$time.between.studies..days.)
```



```
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
```

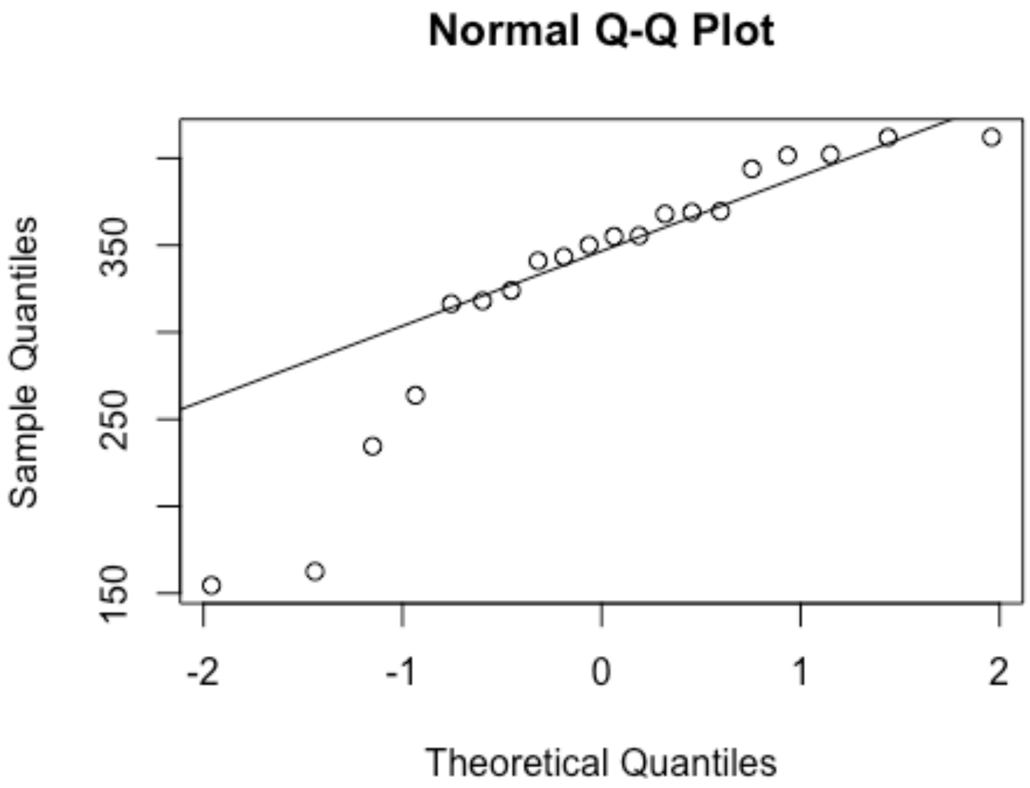
```
qqnorm(SSdata$total.sleep.time)
qqline(SSdata$total.sleep.time)
```



```
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
```

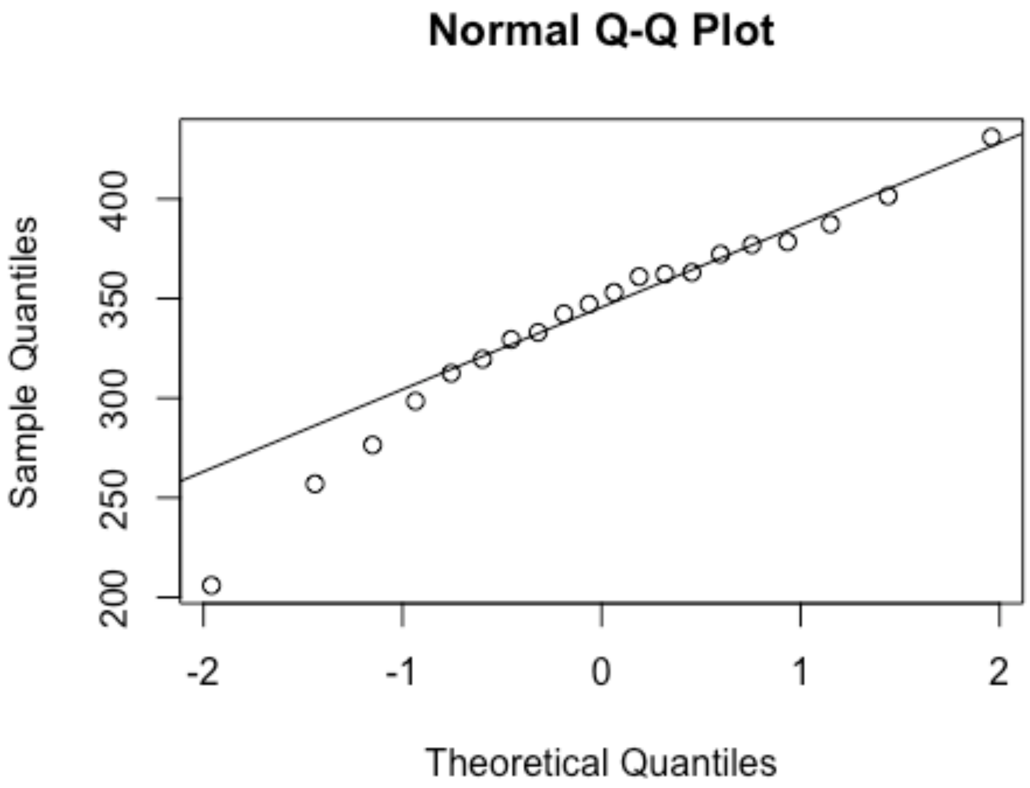
```
## intervention:night  1      3     2.8  0.0006 0.9800
## Residuals          36 155266  4312.9

#No association between intervention or night on sleeptime, even when account
ing for
#both factors at the same time. It does not matter whether they received the
PrenaBelt
#on night one or night two.

#within-participants (paired) comparison
#need to remove drop outs in order to have balanced pairs
#Exclude drop outs
#How many drop outs?
summary(SSdata$drop.out)

##  N  Y
## 40  0

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

## [1] 40

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

##
##  Wilcoxon signed rank test
##
## data:  subset(SSdataCompletes, intervention == "sham")$total.sleep.time an
d subset(SSdataCompletes, intervention == "PrenaBelt")$total.sleep.time
## V = 112, p-value = 0.8124
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -21.80  33.75
## sample estimates:
## (pseudo)median
##           3.55

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   154.5   317.6   352.6   332.4   375.6   412.1

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

## [1] 75.04747
```

```
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)
```



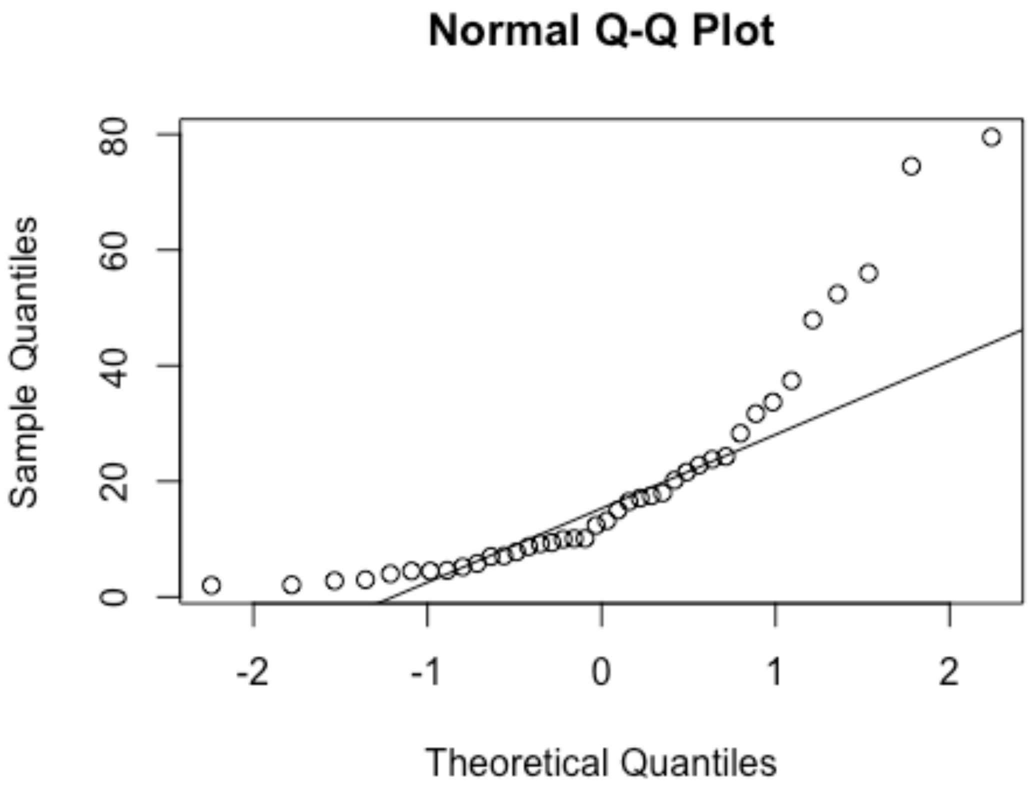
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$total.sleep.time)

##
##  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)
```



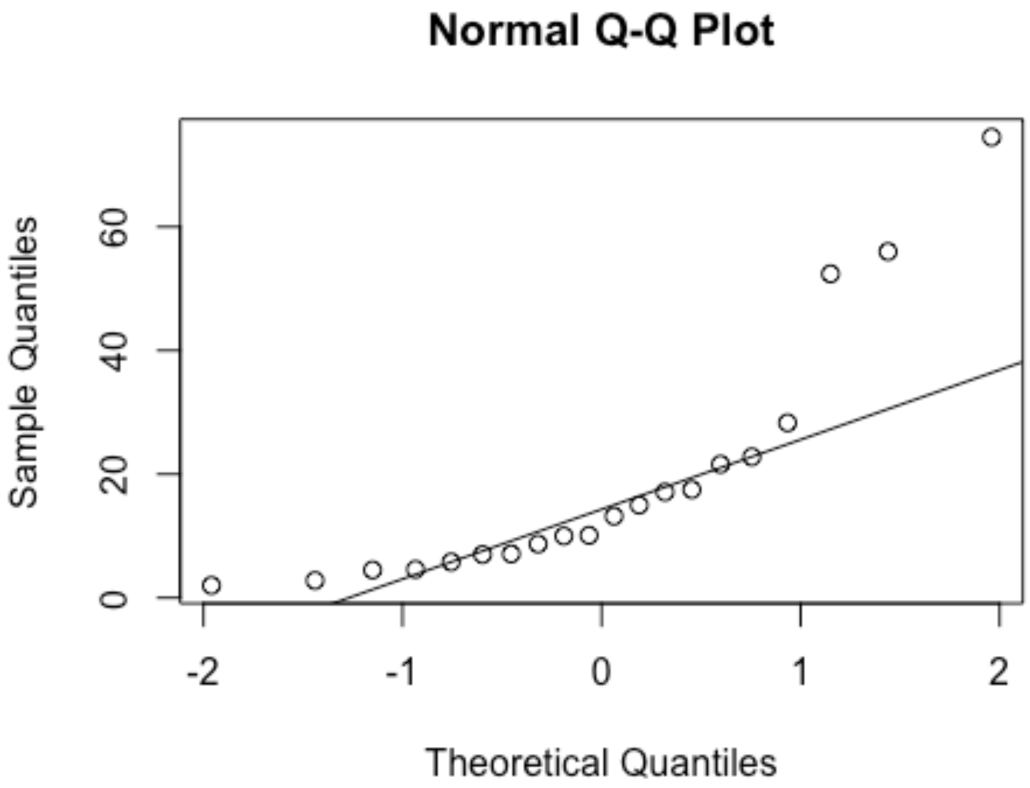
```
ad.test(subset(SSdata, intervention == "sham")$total.sleep.time)

##
##  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)
```

```
##
##  Wilcoxon rank sum test
##
## data:  subset(SSdata, intervention == "sham")$total.sleep.time and subset(
SSdata, intervention == "PrenaBelt")$total.sleep.time
## W = 196, p-value = 0.9254
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -35.1  32.3
## sample estimates:
## difference in location
##                   -2.2

###################Sleep Latency#######################
#Summary
summary(SSdata$sleep.latency)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    2.00    6.70   12.80   19.54   23.92   79.50

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

## [1] 19.13941

length(SSdata$sleep.latency)

## [1] 40

qqnorm(SSdata$sleep.latency)
qqline(SSdata$sleep.latency)
```

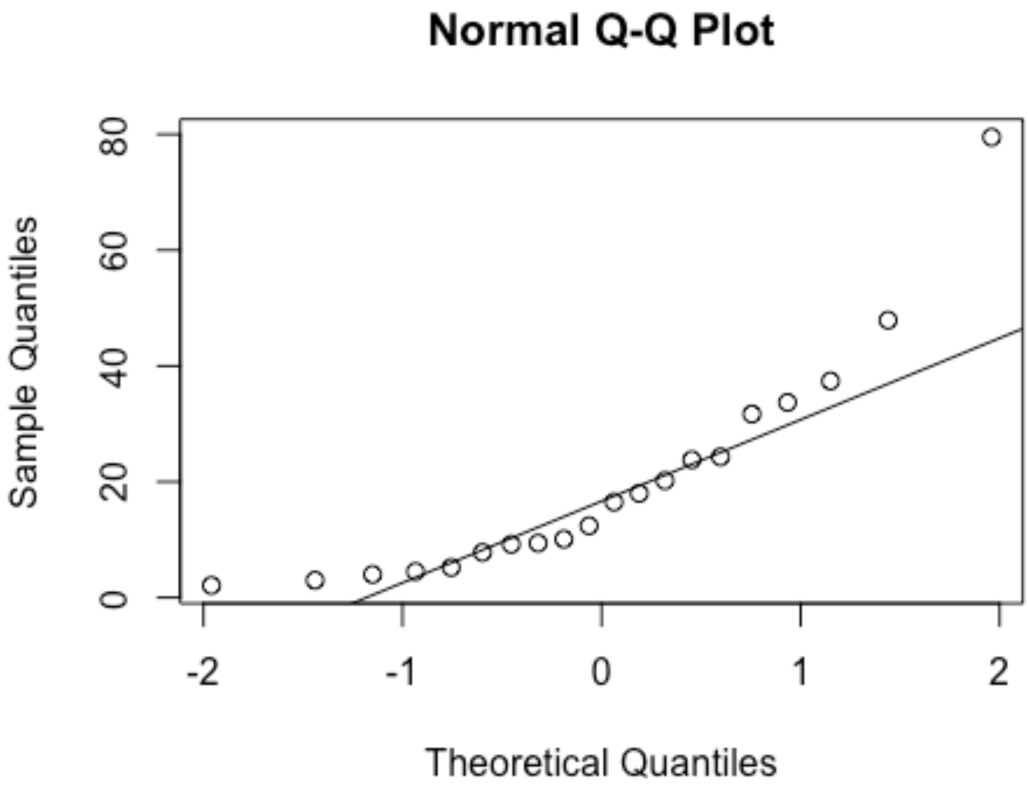


```
ad.test(SSdata$sleep.latency)

##
##  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
```

```
#within-participants (paired) comparison
wilcox.test(subset(SSdataCompletes, intervention == "sham")$sleep.latency,
       subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.latency,
       paired = TRUE, conf.int = TRUE)

##
##  Wilcoxon signed rank test
##
## data:  subset(SSdataCompletes, intervention == "sham")$sleep.latency and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$sleep.latency
## V = 92, p-value = 0.6477
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -9.40  7.15
## sample estimates:
## (pseudo)median
##             -2

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    2.00    6.70   11.65   19.05   21.90   74.50

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

## [1] 19.76593

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

## [1] 20

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

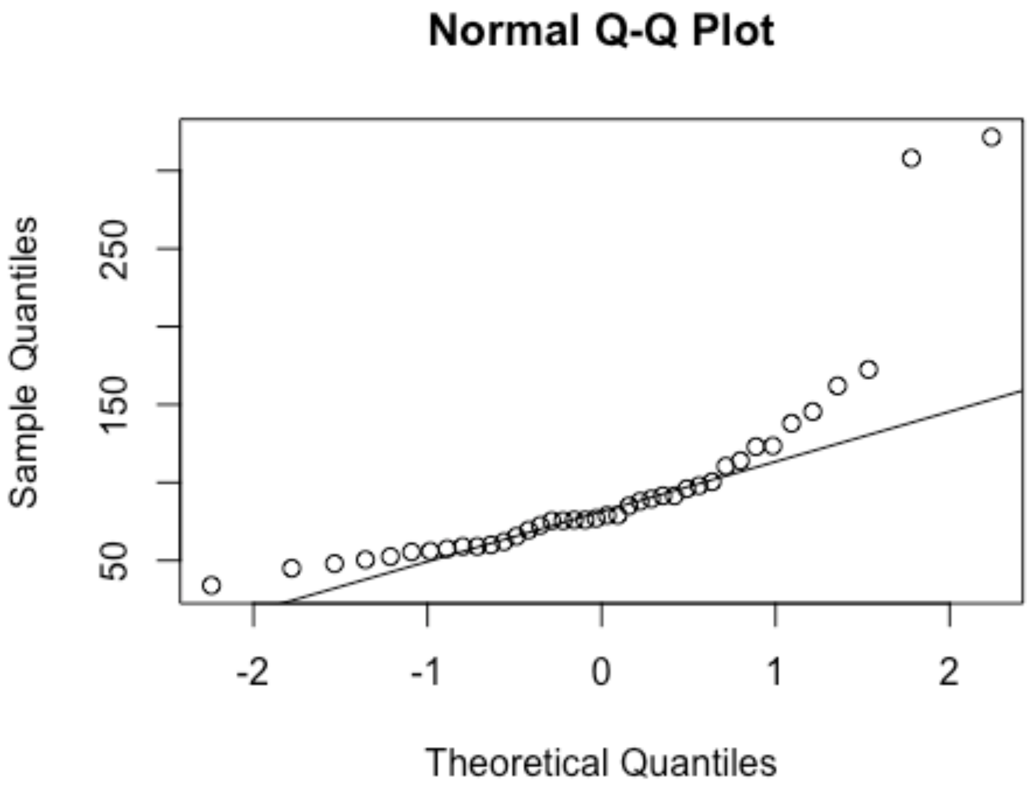


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sleep.latency)

##
##  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)
```



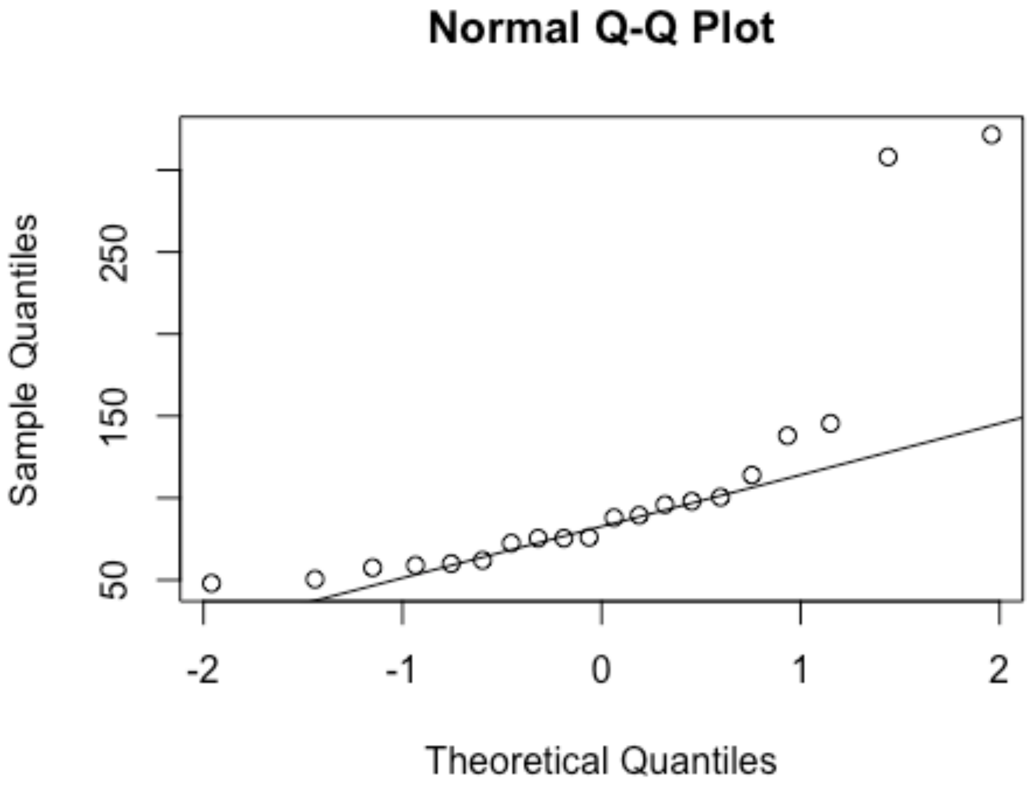
```
ad.test(subset(SSdata, intervention == "sham")$sleep.latency)

##
##  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
```

```
ata, intervention == "PrenaBelt")$sleep.latency
## W = 214, p-value = 0.715
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -5.700008 10.099985
## sample estimates:
## difference in location
##                1.01358

####################REM Latency######################
#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$rem.latency)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   34.00   59.75   78.00   96.08  103.00  321.50

sd(SSdata$rem.latency, na.rm = TRUE)

## [1] 59.89655

length(SSdata$rem.latency)

## [1] 40

qqnorm(SSdata$rem.latency)
qqline(SSdata$rem.latency)
```

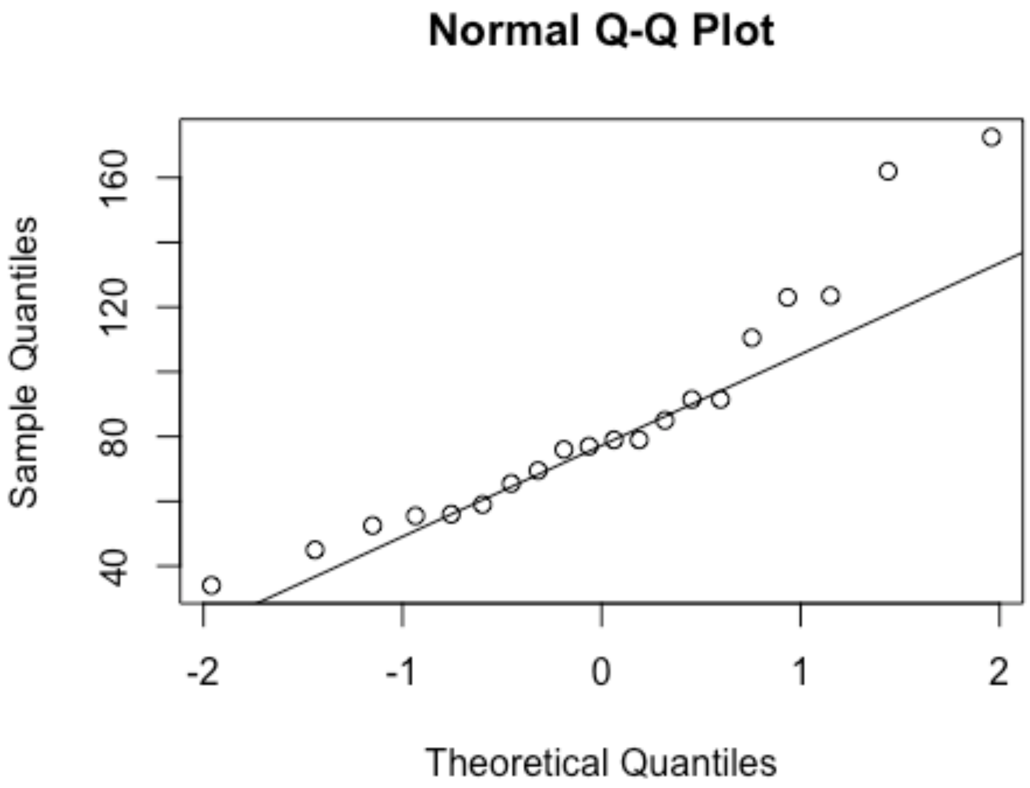


```
ad.test(SSdata$rem.latency)

##
##  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
```

```
#within-participants (paired) comparison
wilcox.test(subset(SSdataCompletes, intervention == "sham")$rem.latency,
       subset(SSdataCompletes, intervention == "PrenaBelt")$rem.latency,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$rem.latency and sub
set(SSdataCompletes, intervention == "PrenaBelt")$rem.latency
## V = 80.5, p-value = 0.37
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -35.50005  17.50006
## sample estimates:
## (pseudo)median
##      -5.190503

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    48.0    61.5    82.0   106.8   103.9   321.5

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

## [1] 75.95402

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

## [1] 20

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

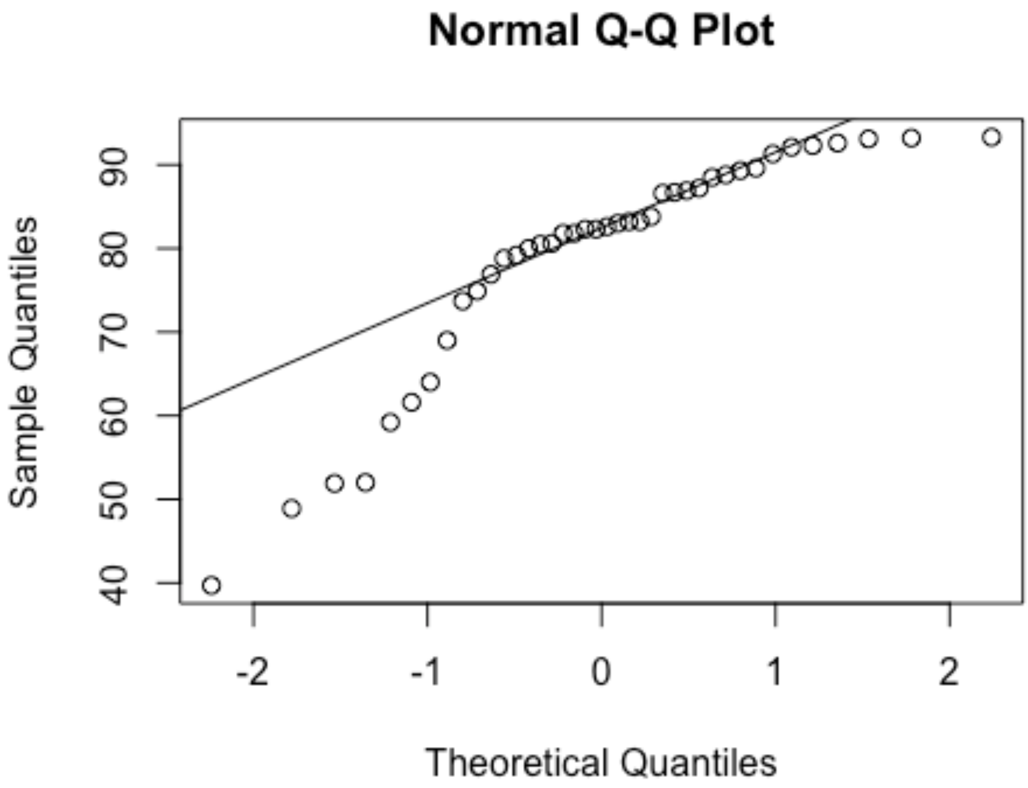


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$rem.latency)

##
##  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)
```



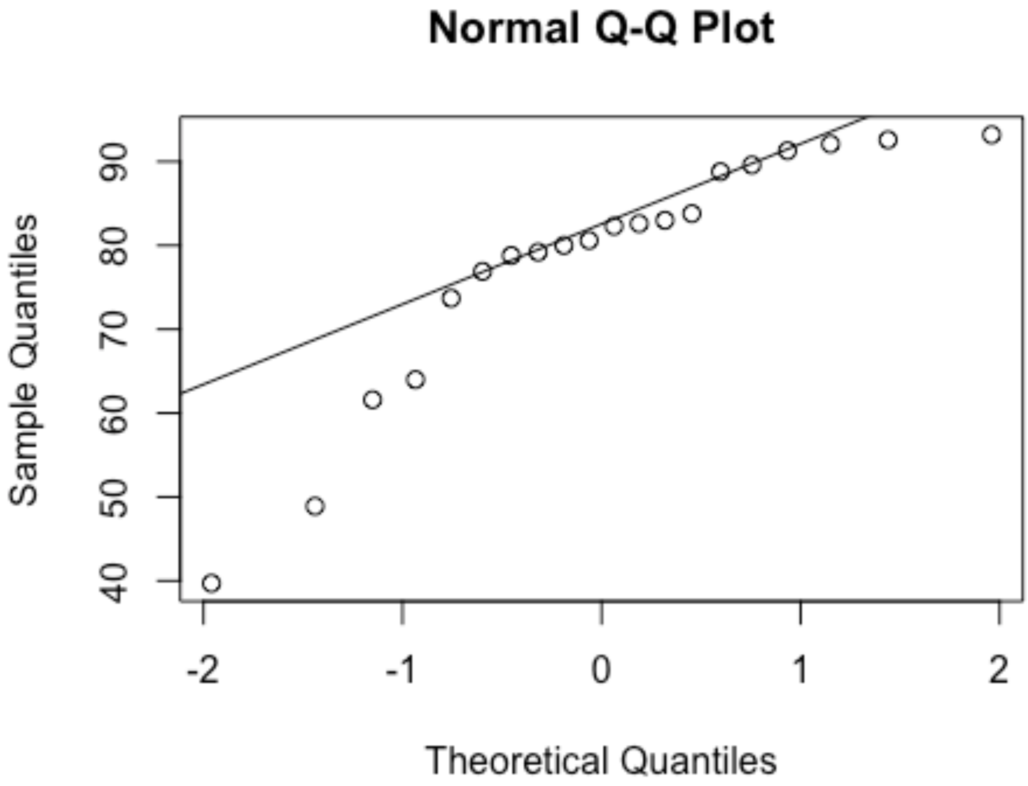
```
ad.test(subset(SSdata, intervention == "sham")$rem.latency)

##
##  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
```

```
a, intervention == "PrenaBelt")$rem.latency
## W = 178, p-value = 0.5608
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -27.50004  15.50003
## sample estimates:
## difference in location
##              -6.499973

####################Sleep Efficiency#######################
#Summary
summary(SSdata$sleep.efficiency)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   39.70   76.40   82.45   79.16   88.58   93.30

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

## [1] 13.44863

length(SSdata$sleep.efficiency)

## [1] 40

qqnorm(SSdata$sleep.efficiency)
qqline(SSdata$sleep.efficiency)
```

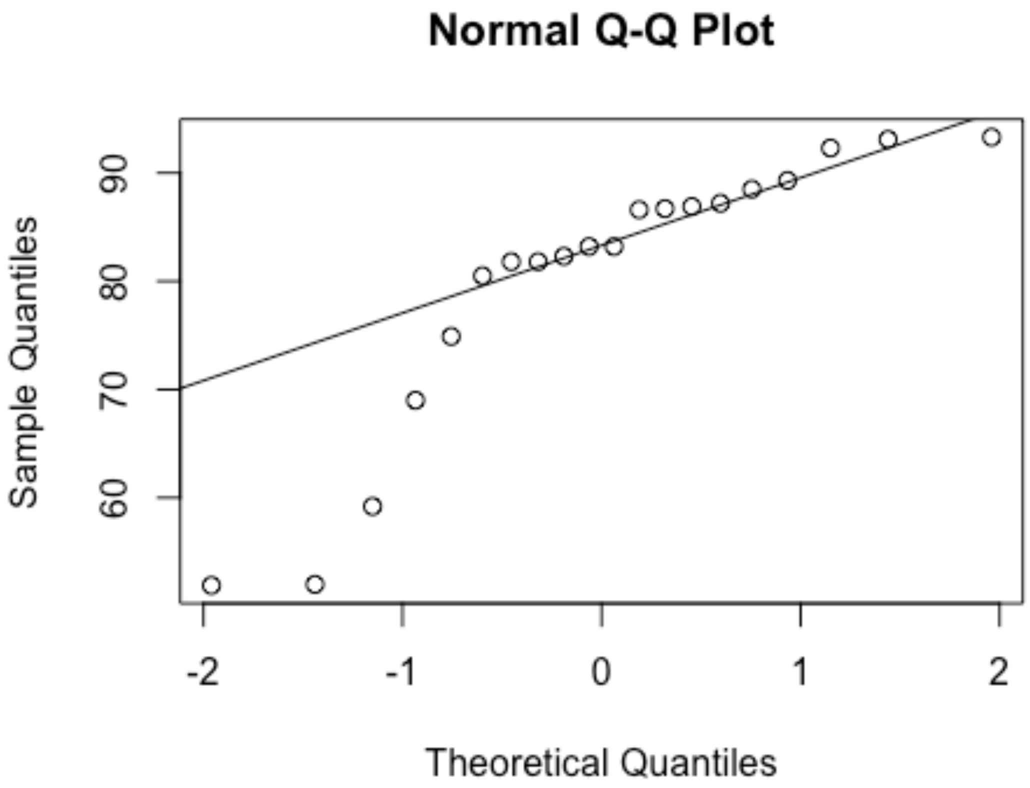


```
ad.test(SSdata$sleep.efficiency)

##
##  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
```

```
#within-participants (paired) comparison
wilcox.test(subset(SSdataCompletes, intervention == "sham")$sleep.efficiency,
       subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.efficiency,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$sleep.efficiency an
d subset(SSdataCompletes, intervention == "PrenaBelt")$sleep.efficiency
## V = 125.5, p-value = 0.4552
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.000041  5.899953
## sample estimates:
## (pseudo)median
##       1.444485

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   39.70   76.10   81.45   78.14   89.00   93.20

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

## [1] 14.47362

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

## [1] 20

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

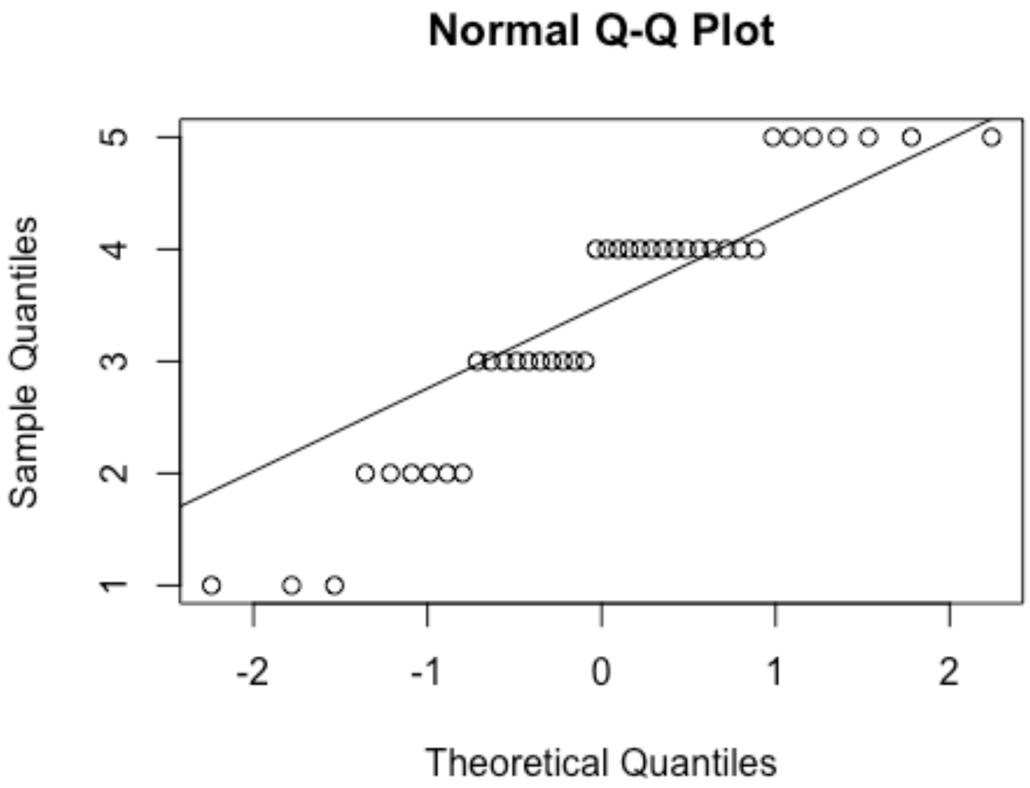


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sleep.efficiency)

##
##  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")$sleep.efficiency,
            subset(SSdata, intervention == "PrenaBelt")$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
```

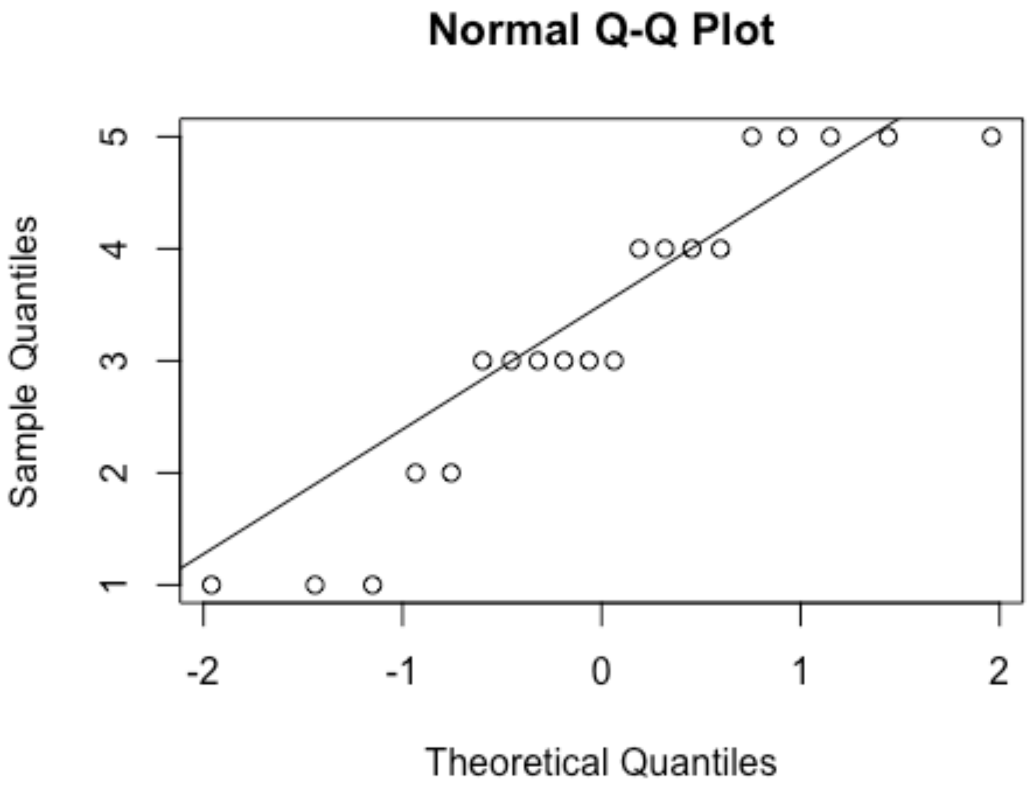
```
##
## data:  subset(SSdata, intervention == "sham")$sleep.efficiency and subset(
SSdata, intervention == "PrenaBelt")$sleep.efficiency
## W = 222.5, p-value = 0.5517
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.800018  7.900004
## sample estimates:
## difference in location
##               1.799971

####################Number of REM Periods#######################
#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$num.rem.periods)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     1.0     3.0     4.0     3.4     4.0     5.0

sd(SSdata$num.rem.periods, na.rm = TRUE)

## [1] 1.172331

length(SSdata$num.rem.periods)

## [1] 40

qqnorm(SSdata$num.rem.periods)
qqline(SSdata$num.rem.periods)
```



```
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
```

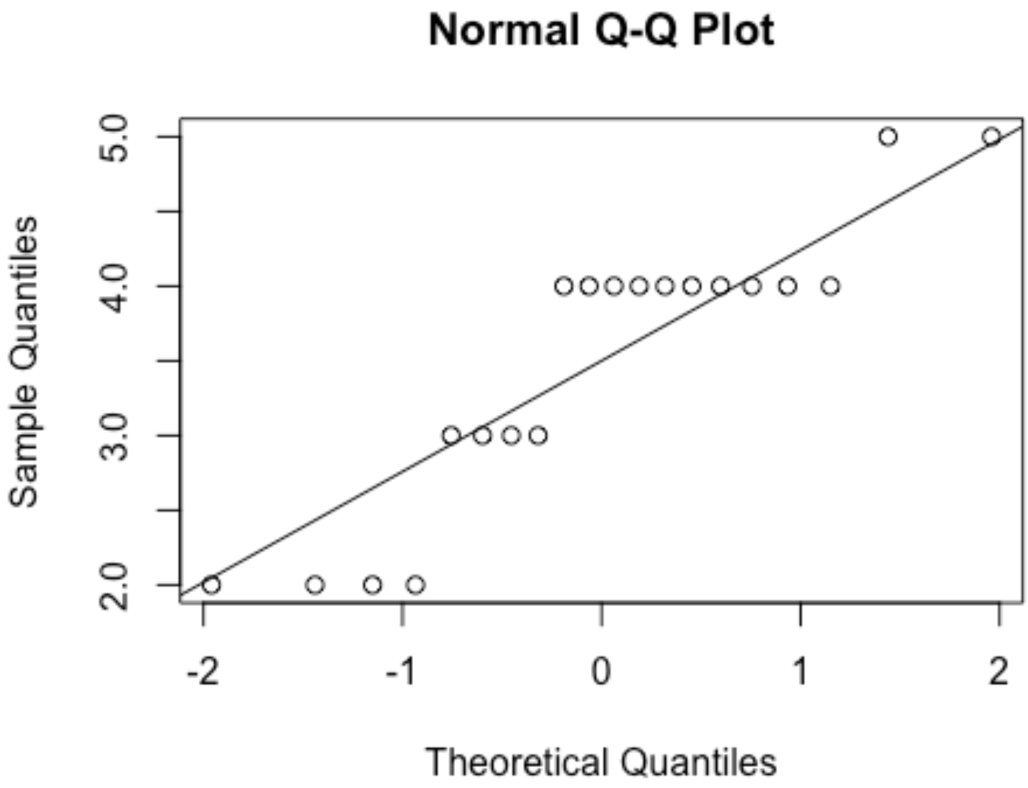
```
#within-participants (paired) comparison
t.test(subset(SSdataCompletes, intervention == "sham")$num.rem.periods,
       subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$num.rem.periods and
subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods
## t = 0.80943, df = 19, p-value = 0.4283
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.3171618  0.7171618
## sample estimates:
## mean of the differences
##                     0.2

wilcox.test(subset(SSdataCompletes, intervention == "sham")$num.rem.periods,
       subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$num.rem.periods and
subset(SSdataCompletes, intervention == "PrenaBelt")$num.rem.periods
## V = 73.5, p-value = 0.432
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.4999577  1.0000552
## sample estimates:
## (pseudo)median
##   4.422455e-05

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$num.rem.periods)
```

```
##    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)
```

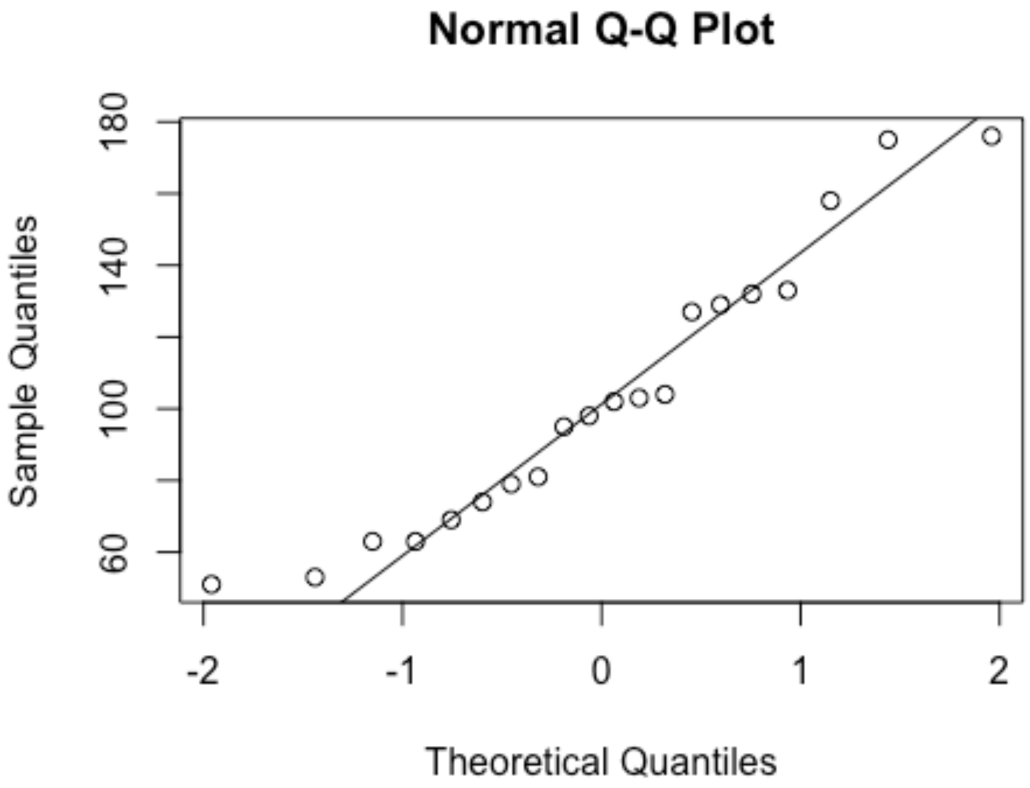


```
ad.test(subset(SSdata, intervention == "sham")$num.rem.periods)

## 
##  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)

#FYI - unpaired test
```

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

##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$num.rem.periods and subset(S
Sdata, intervention == "PrenaBelt")$num.rem.periods
## t = 0.53452, df = 33.621, p-value = 0.5965
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.5607122  0.9607122
## sample estimates:
## mean of x mean of y
##       3.5       3.3

wilcox.test(subset(SSdata, intervention == "sham")$num.rem.periods,
            subset(SSdata, intervention == "PrenaBelt")$num.rem.periods,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$num.rem.periods and subset(S
Sdata, intervention == "PrenaBelt")$num.rem.periods
## W = 213, p-value = 0.7263
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.9999963  1.0000309
## sample estimates:
## difference in location
##           1.121393e-06

####################Number of Stage Shifts######################
#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$num.stage.shifts)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   43.00   72.75   96.50  105.20  133.80  183.00

sd(SSdata$num.stage.shifts, na.rm = TRUE)
```

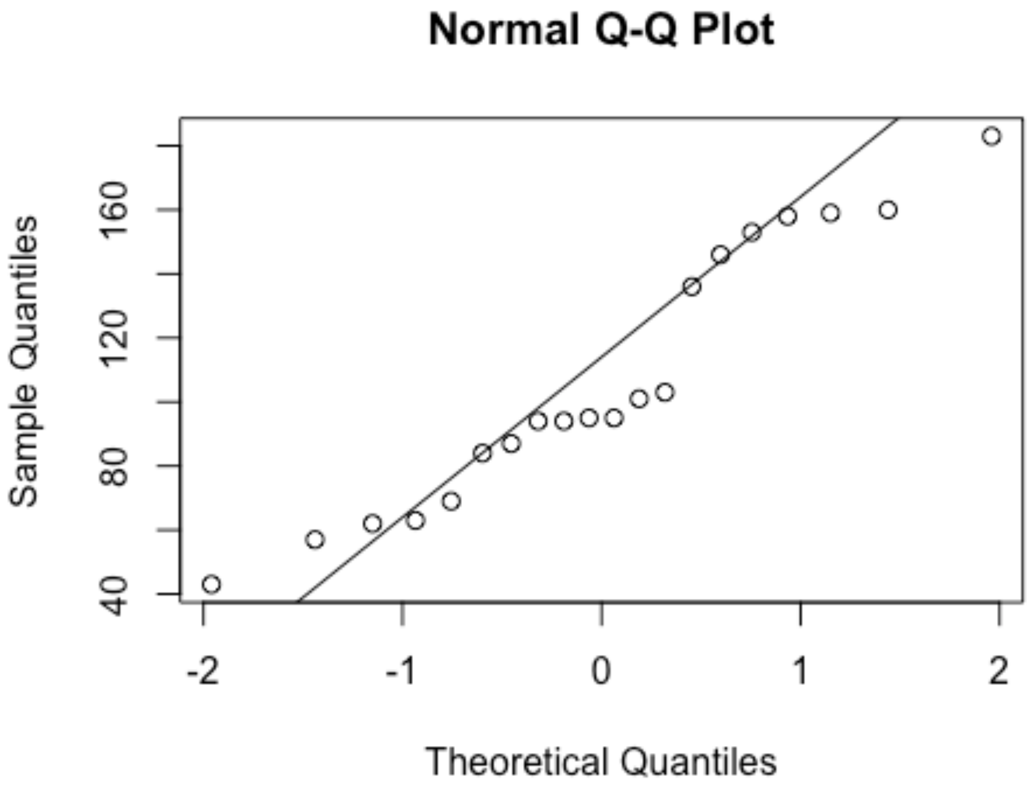
```
## [1] 39.29043

length(SSdata$num.stage.shifts)

## [1] 40

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

## Analysis of Variance Table
##
## Response: num.stage.shifts
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1    148  148.22  0.0912 0.7644
## night               1     60   60.03  0.0369 0.8487
## intervention:night  1   1501 1500.63  0.9235 0.3430
## Residuals          36  58497 1624.91

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$num.stage.shifts,
       subset(SSdataCompletes, intervention == "PrenaBelt")$num.stage.shifts,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$num.stage.shifts an
d subset(SSdataCompletes, intervention == "PrenaBelt")$num.stage.shifts
## t = 0.77738, df = 19, p-value = 0.4465
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -6.515809 14.215809
## sample estimates:
## mean of the differences
##                    3.85

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$num.stage.shifts)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   51.00   72.75  100.00  103.20  129.80  176.00

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

## [1] 38.44459

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

## [1] 20
```

```
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
```

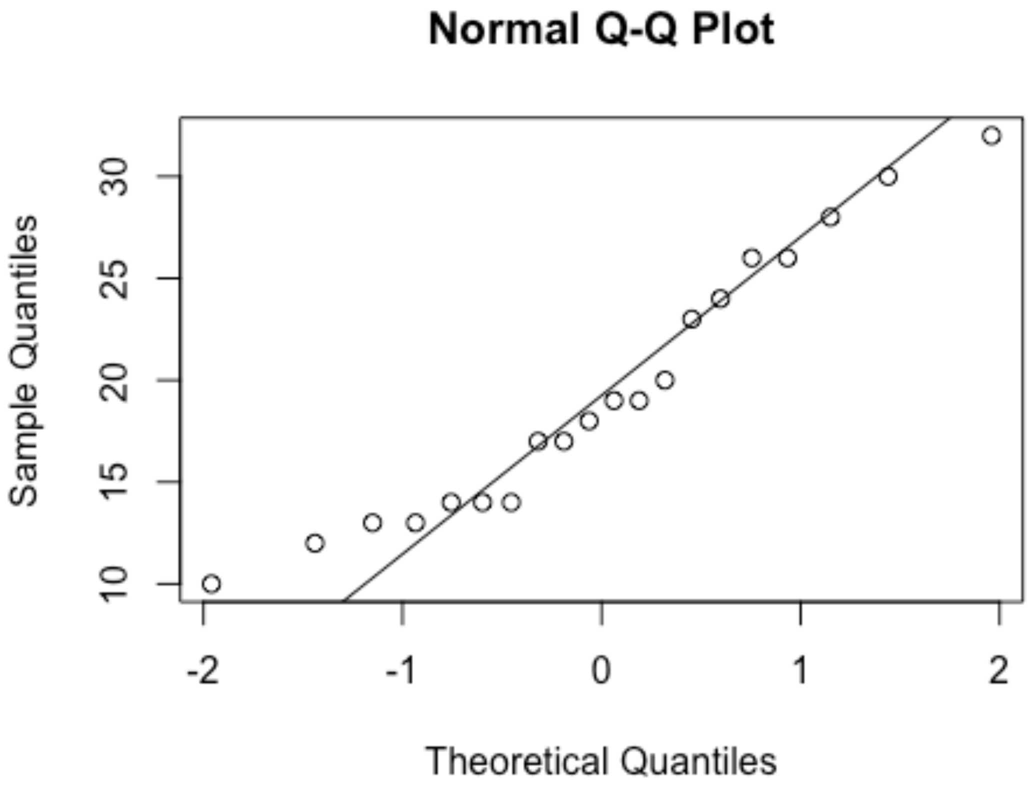
```
qqnorm(subset(SSdata, intervention == "sham")$num.stage.shifts)
qqline(subset(SSdata, intervention == "sham")$num.stage.shifts)
```



```
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
```

```
## 95 percent confidence interval:
##  -21.60347  29.30347
## sample estimates:
## mean of x mean of y
##    107.10    103.25

####################Awakenings######################
#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$awakenings)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   10.00   14.75   19.00   19.70   24.25   32.00

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

## [1] 6.329418

length(SSdata$awakenings)

## [1] 40

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

## Analysis of Variance Table
##
## Response: awakenings
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1    2.5    2.50  0.0589 0.8096
## night               1   19.6   19.60  0.4617 0.5012
## intervention:night  1   12.1   12.10  0.2850 0.5967
## Residuals          36 1528.2   42.45

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$awakenings,
       subset(SSdataCompletes, intervention == "PrenaBelt")$awakenings,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$awakenings and subs
et(SSdataCompletes, intervention == "PrenaBelt")$awakenings
## t = 0.38863, df = 19, p-value = 0.7019
## alternative hypothesis: true difference in means is not equal to 0
```

```
## 95 percent confidence interval:
##  -2.192823  3.192823
## sample estimates:
## mean of the differences
##                      0.5

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   10.00   14.00   18.50   19.45   24.50   32.00

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

## [1] 6.460202

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

## [1] 20

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



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

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$awakenings
## A = 0.44596, p-value = 0.2537
```

```
#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
```

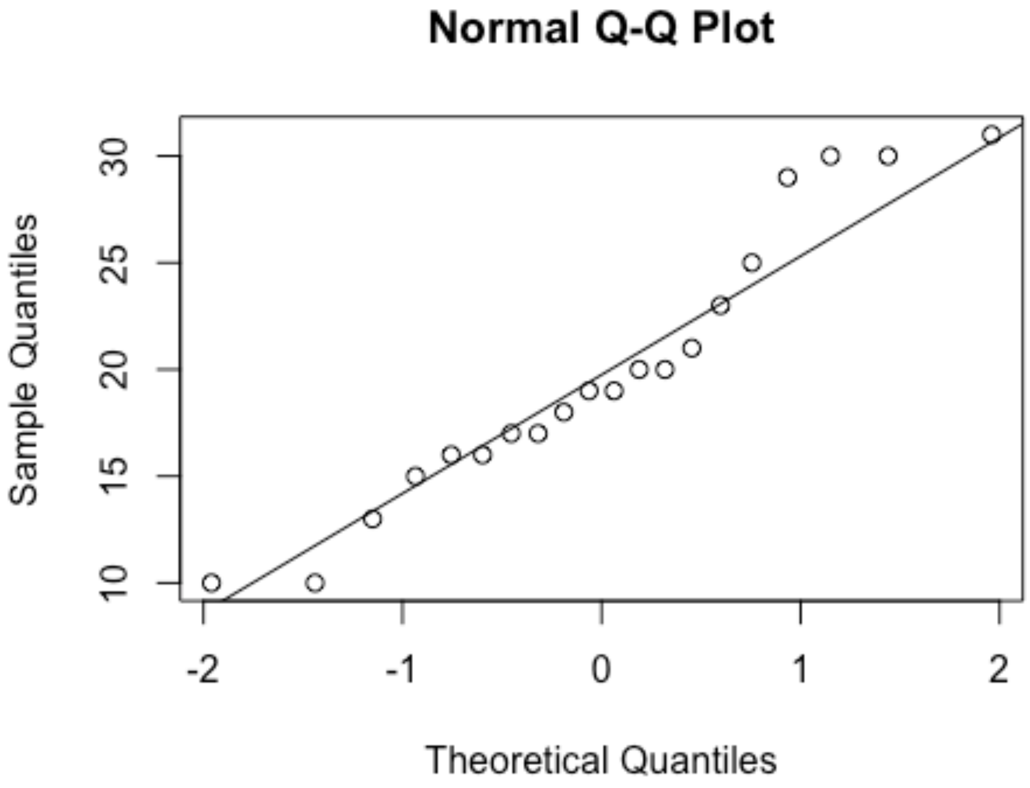
```
sd(subset(SSdata, intervention == "sham")$awakenings)
```

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

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

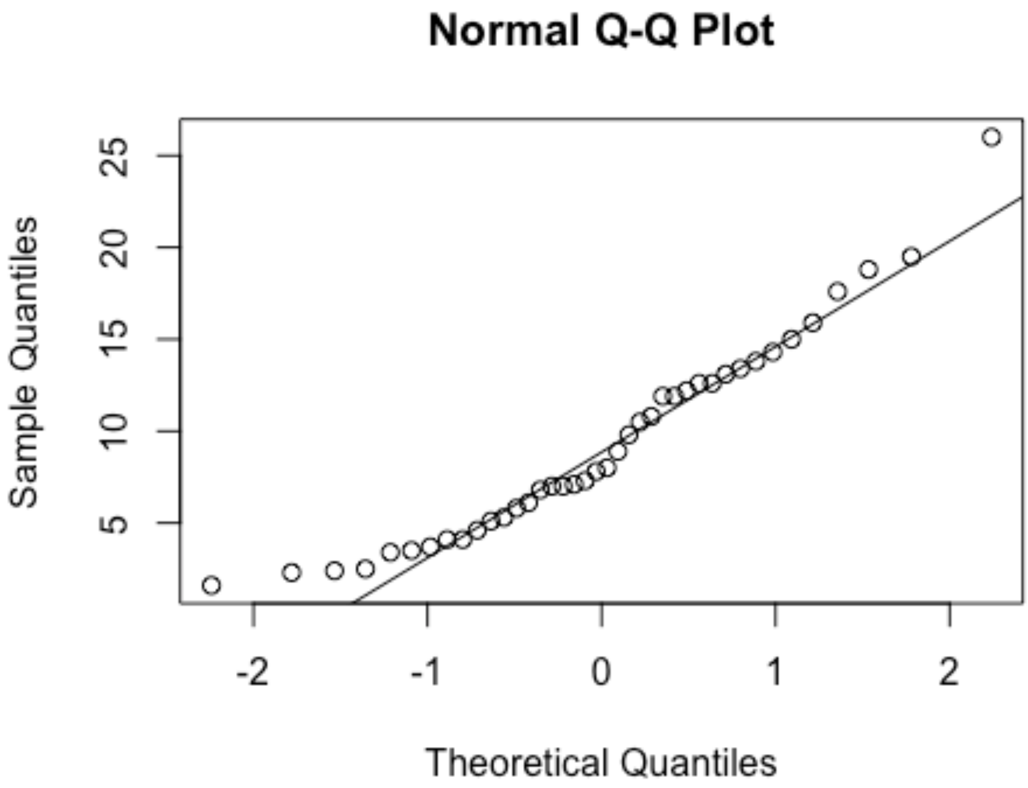
```
## [1] 20
```

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



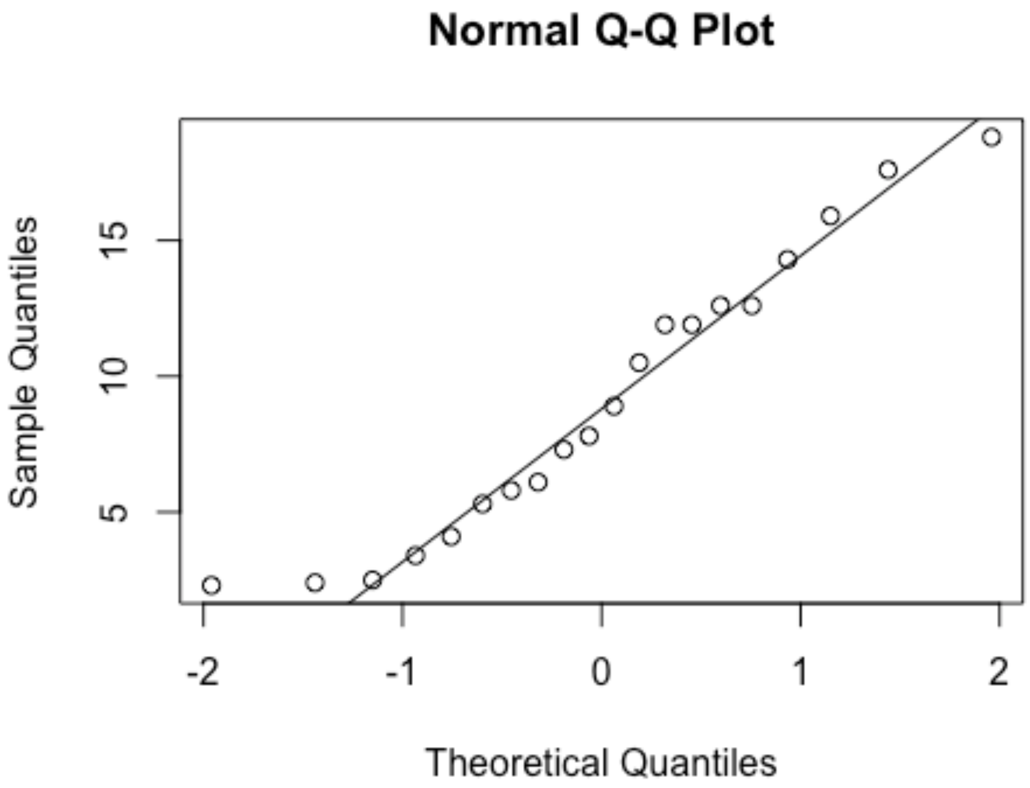
```
ad.test(subset(SSdata, intervention == "sham")$awakenings)
```

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$awakenings
## A = 0.47198, p-value = 0.2179

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$awakenings,
       subset(SSdata, intervention == "PrenaBelt")$awakenings)

##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$awakenings and subset(SSdata
, intervention == "PrenaBelt")$awakenings
## t = 0.24678, df = 37.989, p-value = 0.8064
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -3.601622  4.601622
## sample estimates:
## mean of x mean of y
##     19.95     19.45

#################### % Stage 1 Sleep ######################
#Summary
summary(SSdata$Pstage.1)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.600   4.975   7.900   9.353  12.720  26.000

sd(SSdata$Pstage.1, na.rm = TRUE)

## [1] 5.561267

length(SSdata$Pstage.1)

## [1] 40

qqnorm(SSdata$Pstage.1)
qqline(SSdata$Pstage.1)
```

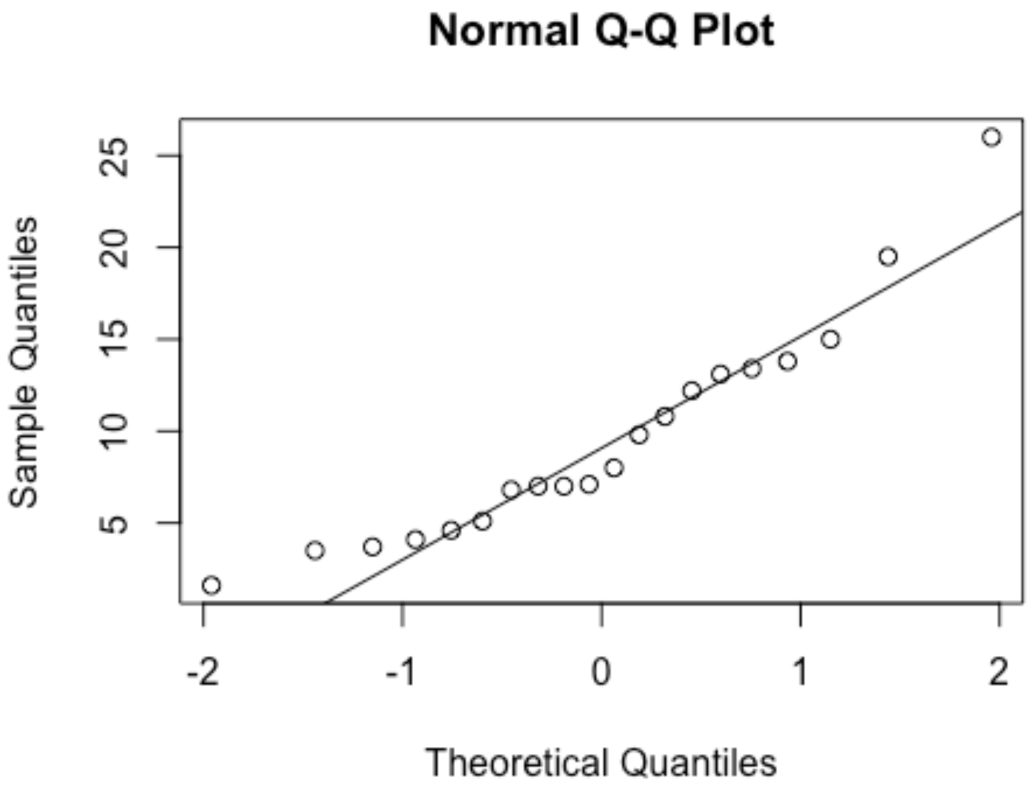


```
ad.test(SSdata$Pstage.1)

##
##  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
```

```
#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.1,
       subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.1,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$Pstage.1 and subset
(SSdataCompletes, intervention == "PrenaBelt")$Pstage.1
## t = 0.59457, df = 19, p-value = 0.5591
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -1.272708  2.282708
## sample estimates:
## mean of the differences
##                   0.505

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    2.30    5.00    8.35    9.10   12.60   18.80

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

## [1] 5.197368

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

## [1] 20

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

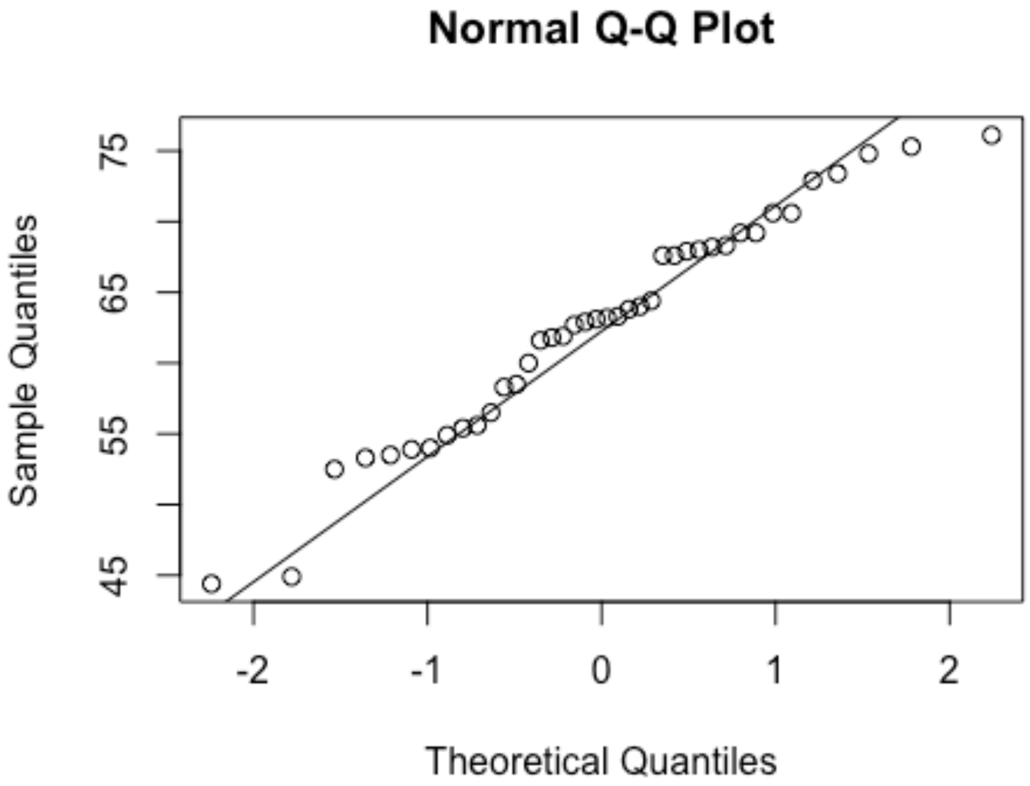


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.1)

##
##  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

#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:
```

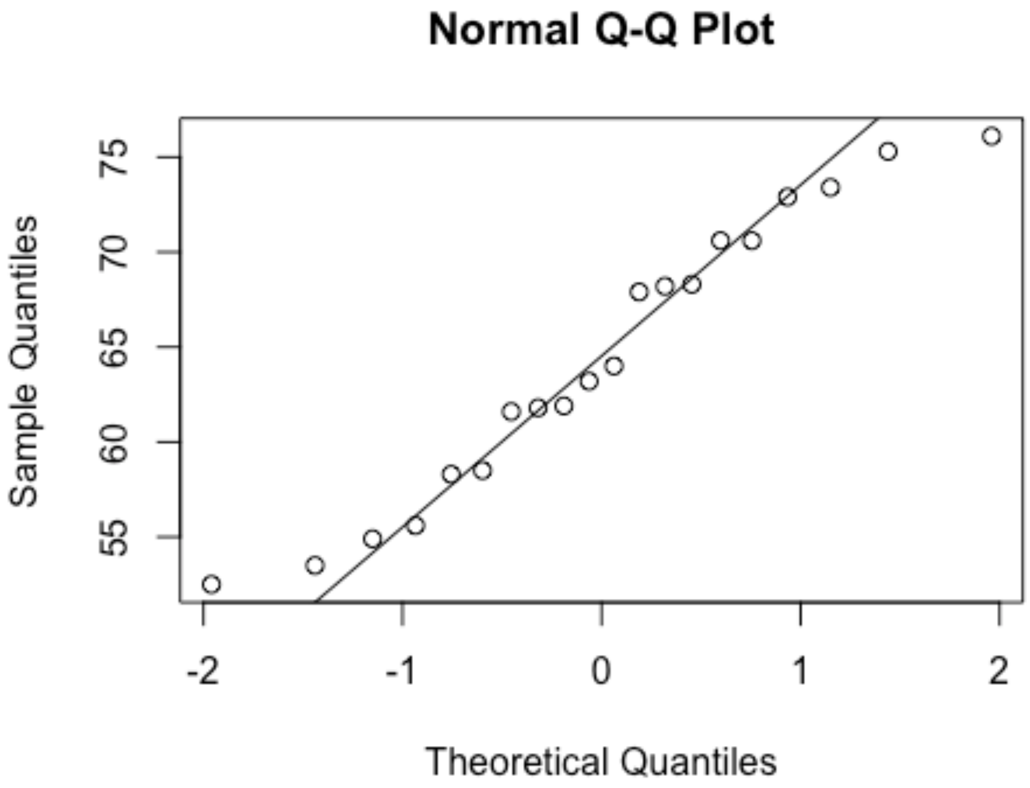
```
## mean of x mean of y
##     9.605     9.100

#################### % Stage 2 Sleep #######################
#Summary
summary(SSdata$Pstage.2)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   44.40   56.28   63.15   62.70   68.23   76.10

sd(SSdata$Pstage.2, na.rm = TRUE)

## [1] 7.870376

length(SSdata$Pstage.2)

## [1] 40

qqnorm(SSdata$Pstage.2)
qqline(SSdata$Pstage.2)
```



```
ad.test(SSdata$Pstage.2)

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

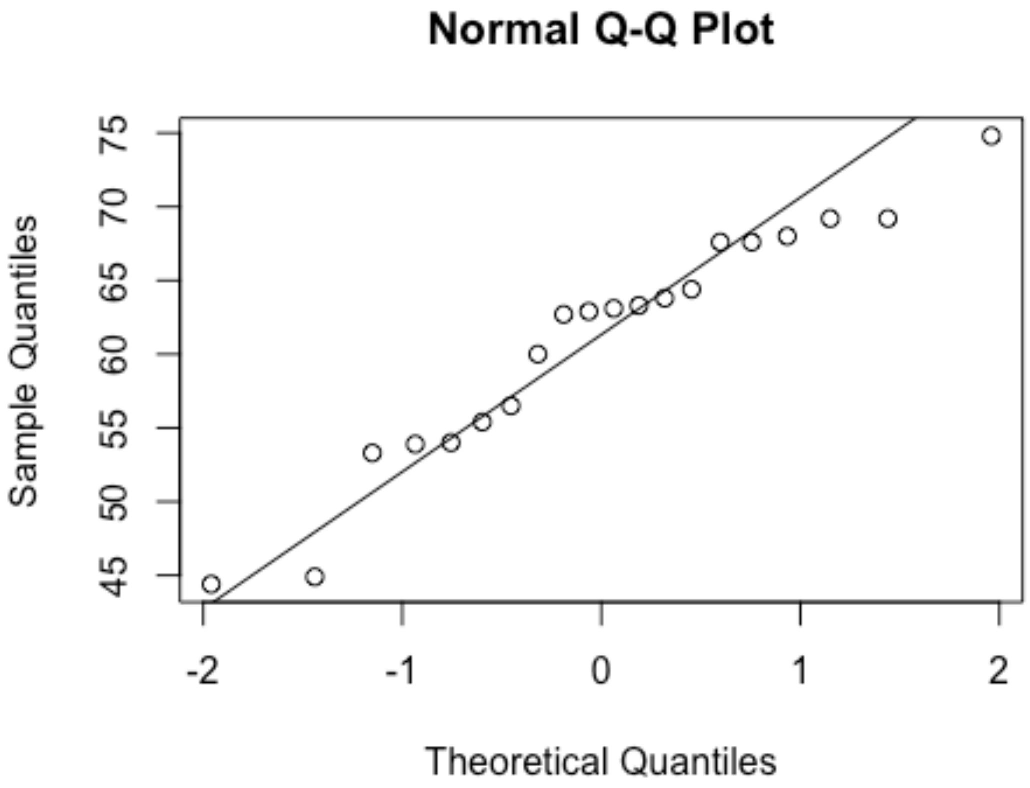
```
##
## data:  SSdata$Pstage.2
## A = 0.37344, p-value = 0.4014

#normal

#ANOVA
night_tx_difference <- anova(lm(Pstage.2 ~ intervention*night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: Pstage.2
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1  122.85 122.850  2.0304 0.1628
## night               1   58.32  58.322  0.9639 0.3328
## intervention:night  1   56.41  56.406  0.9323 0.3407
## Residuals          36 2178.19  60.505

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.2,
       subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.2,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$Pstage.2 and subset
(SSdataCompletes, intervention == "PrenaBelt")$Pstage.2
## t = -1.9128, df = 19, p-value = 0.07097
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -7.3402984  0.3302984
## sample estimates:
## mean of the differences
##                  -3.505

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   52.50   58.45   63.60   64.46   70.60   76.10

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

## [1] 7.434803

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

## [1] 20
```

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



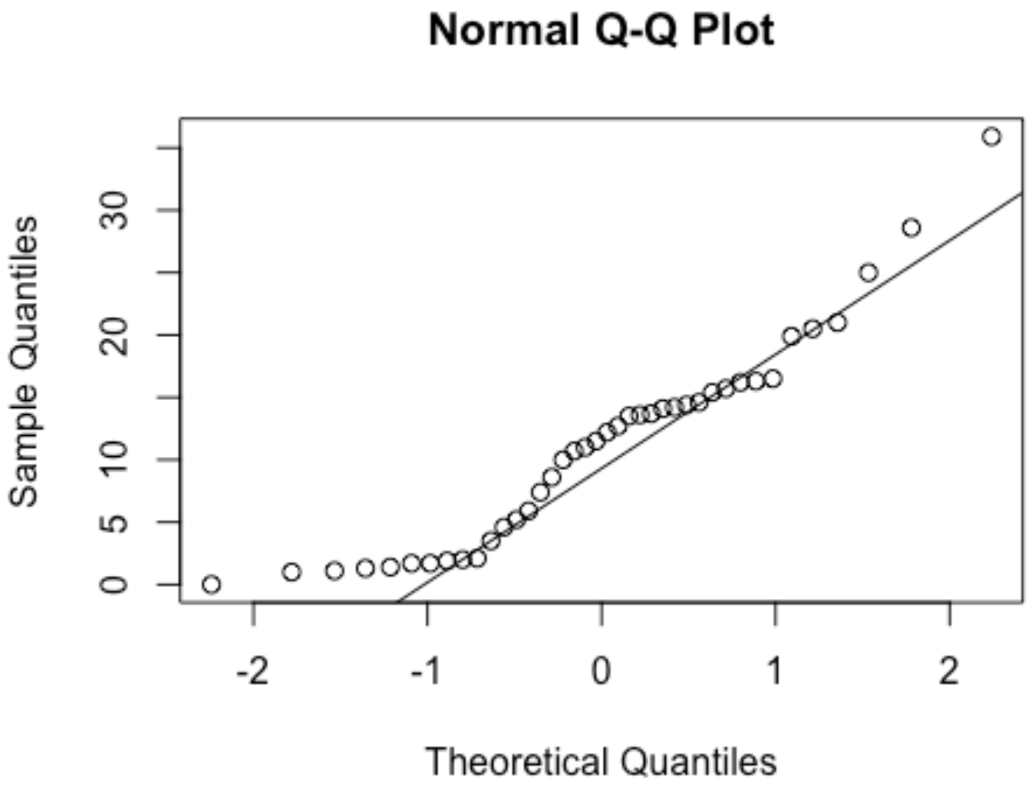
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.2)

##
##  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
```

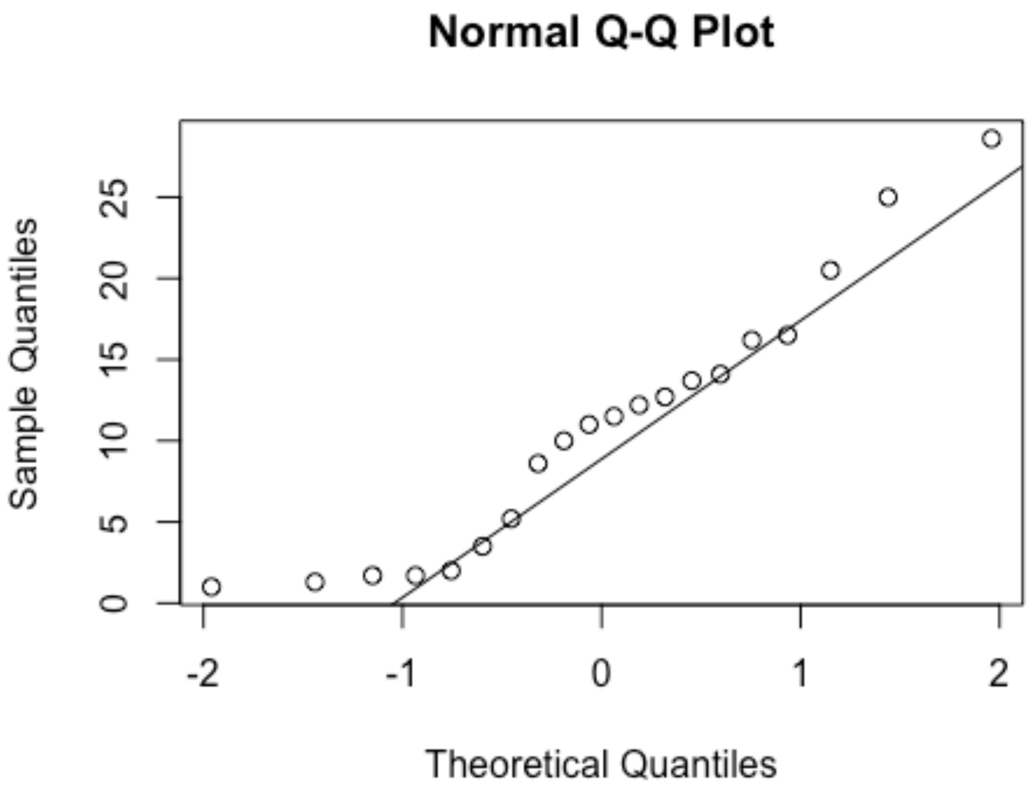
```
## 95 percent confidence interval:
##  -8.478912  1.468912
## sample estimates:
## mean of x mean of y
##    60.950    64.455

#################### % Stage 3 Sleep #######################
#Summary
summary(SSdata$Pstage.3)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    3.15   11.85   11.16   15.48   35.90

sd(SSdata$Pstage.3, na.rm = TRUE)

## [1] 8.302226

length(SSdata$Pstage.3)

## [1] 40

qqnorm(SSdata$Pstage.3)
qqline(SSdata$Pstage.3)
```



```
ad.test(SSdata$Pstage.3)
```

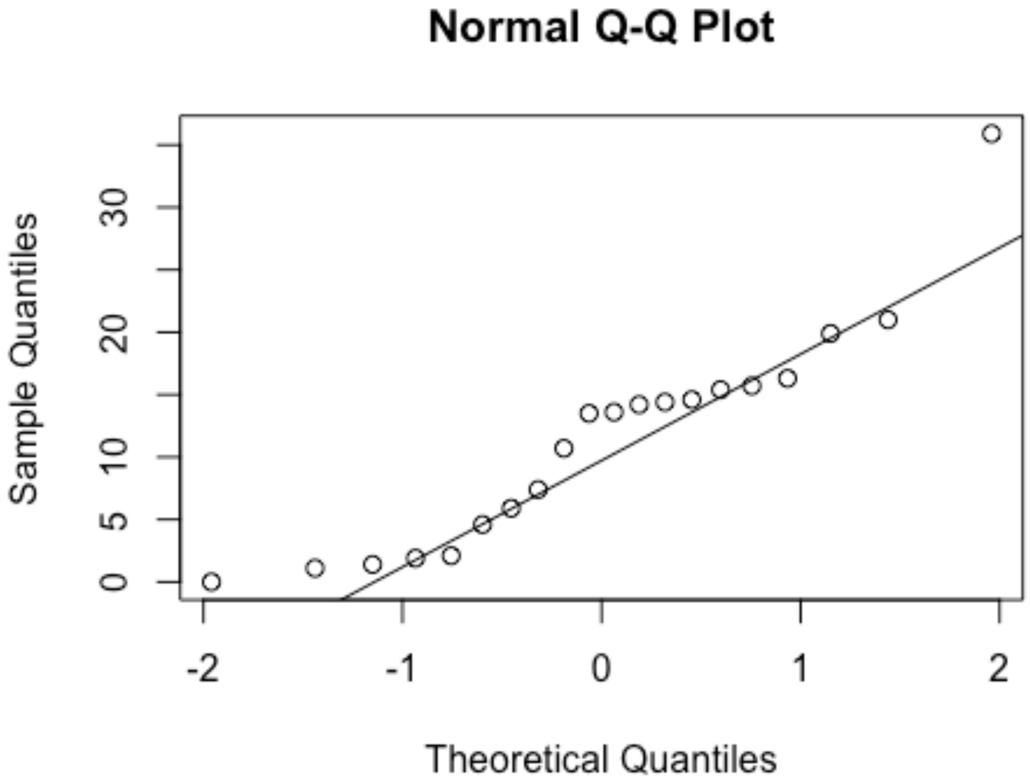
```
##
##  Anderson-Darling normality test
##
## data:  SSdata$Pstage.3
## A = 0.79648, p-value = 0.03569

#non-normal

#ANOVA
night_tx_difference <- anova(lm(Pstage.3 ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: Pstage.3
##                      Df  Sum Sq Mean Sq F value Pr(>F)
## intervention          1    3.97   3.969  0.0535 0.8184
## night                 1    3.60   3.600  0.0485 0.8269
## intervention:night    1   10.40  10.404  0.1403 0.7102
## Residuals            36 2670.18  74.172

#within-participants (paired) comparison
#Paired t-test (individual distributions are normal)
t.test(subset(SSdataCompletes, intervention == "sham")$Pstage.3,
       subset(SSdataCompletes, intervention == "PrenaBelt")$Pstage.3,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$Pstage.3 and subset
(SSdataCompletes, intervention == "PrenaBelt")$Pstage.3
## t = 0.65795, df = 19, p-value = 0.5185
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -1.374115  2.634115
## sample estimates:
## mean of the differences
##                    0.63

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.000   3.125  11.250  10.850  14.620  28.600

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

## [1] 8.010027

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

```
## [1] 20

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



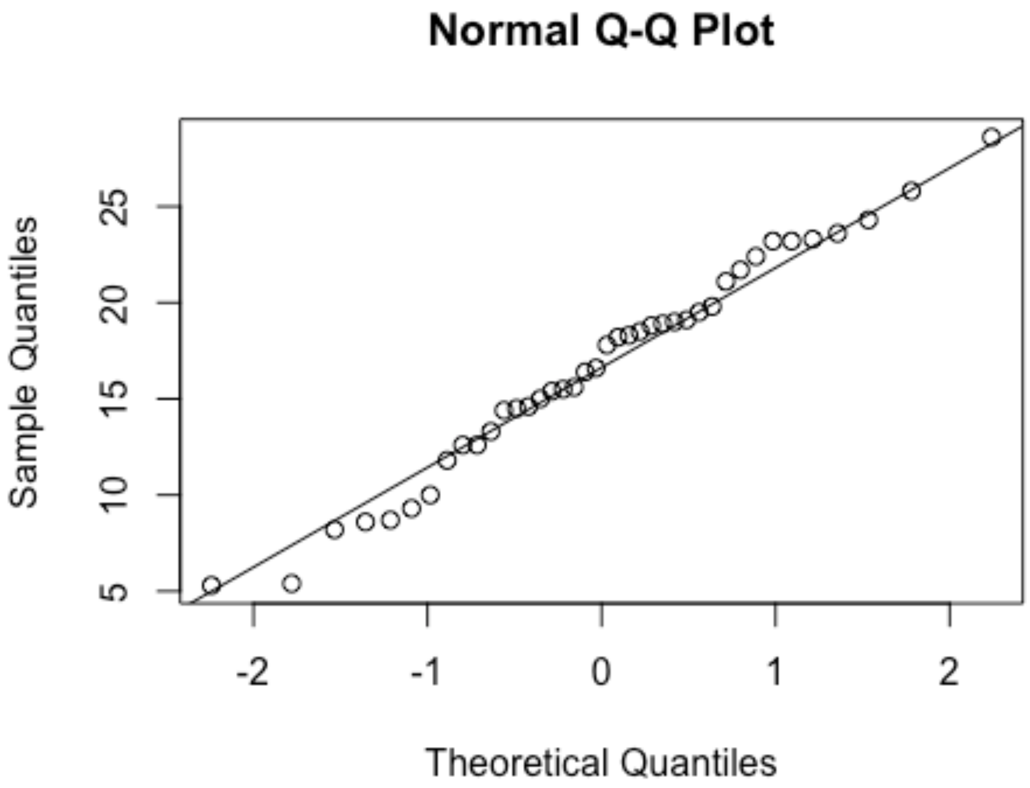
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$Pstage.3)

##
##  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)
```



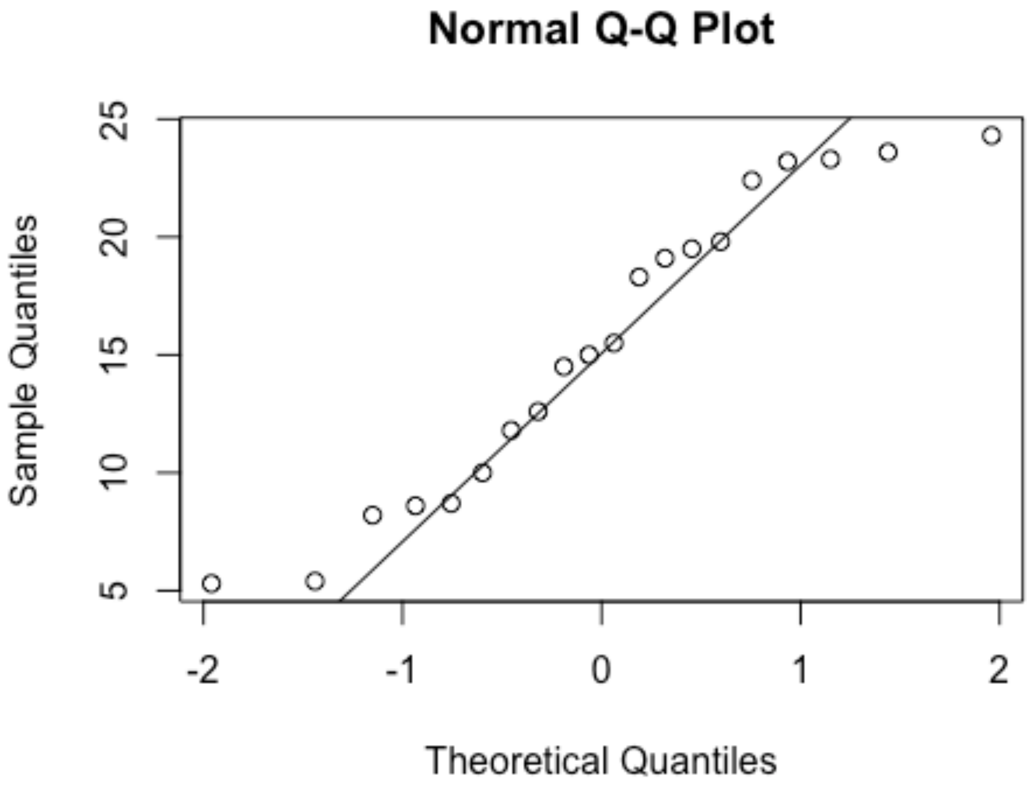
```
ad.test(subset(SSdata, intervention == "sham")$Pstage.3)

##
##  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
```

```
## t = 0.23704, df = 37.683, p-value = 0.8139
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -4.75182  6.01182
## sample estimates:
## mean of x mean of y
##     11.48     10.85

#################### % Stage REM ######################
#Summary
summary(SSdata$Prem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    5.30   13.13   17.20   16.72   20.12   28.60

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

## [1] 5.62027

length(SSdata$Prem)

## [1] 40

qqnorm(SSdata$Prem)
qqline(SSdata$Prem)
```



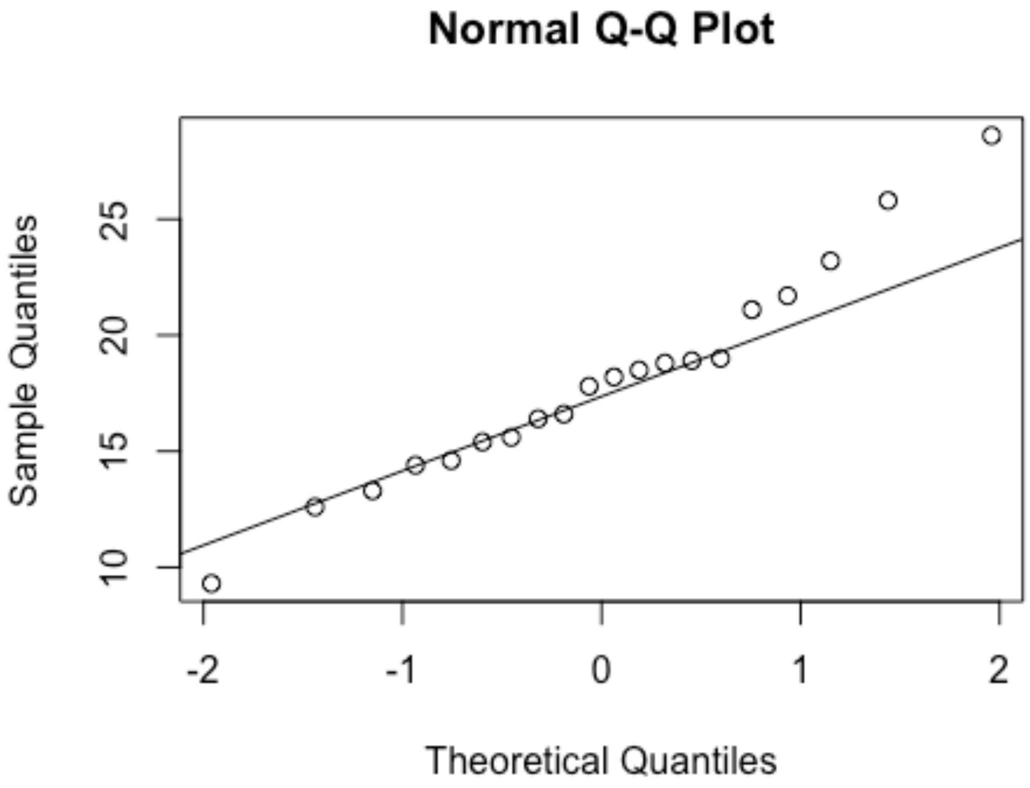
```
ad.test(SSdata$Prem)

##
##  Anderson-Darling normality test
##
## data:  SSdata$Prem
## A = 0.23648, p-value = 0.7728

#normal

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

## Analysis of Variance Table
##
## Response: Prem
##                    Df  Sum Sq Mean Sq F value  Pr(>F)
## intervention        1   64.26  64.262  2.2623 0.14128
## night               1   89.10  89.102  3.1367 0.08501 .
## intervention:night  1   55.93  55.932  1.9690 0.16912
## Residuals          36 1022.61  28.406
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$Prem,
       subset(SSdataCompletes, intervention == "PrenaBelt")$Prem,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$Prem and subset(SSd
ataCompletes, intervention == "PrenaBelt")$Prem
## t = 2.0564, df = 19, p-value = 0.05374
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.04510822  5.11510822
## sample estimates:
## mean of the differences
##                   2.535

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   5.300   9.675  15.250  15.460  20.450  24.300

sd(subset(SSdata, intervention == "PrenaBelt")$Prem)
```

```
## [1] 6.377714

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

## [1] 20

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



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

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$Prem
## A = 0.44545, p-value = 0.2545

#normal

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    9.30   15.20   18.00   17.99   19.52   28.60

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

```
## [1] 4.558497

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

## [1] 20

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



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

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$Prem
## A = 0.27628, p-value = 0.6181

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$Prem,
       subset(SSdata, intervention == "PrenaBelt")$Prem)
```

```
##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$Prem and subset(SSdata, inte
rvention == "PrenaBelt")$Prem
## t = 1.4462, df = 34.395, p-value = 0.1572
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -1.025871  6.095871
## sample estimates:
## mean of x mean of y
##    17.990    15.455
```

```
#################### %TST Supine #######################
#Summary
summary(SSdata$PtstSupine)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   11.65   15.09   22.57   72.30
```

```
sd(SSdata$PtstSupine, na.rm = TRUE)
```

```
## [1] 17.83904
```

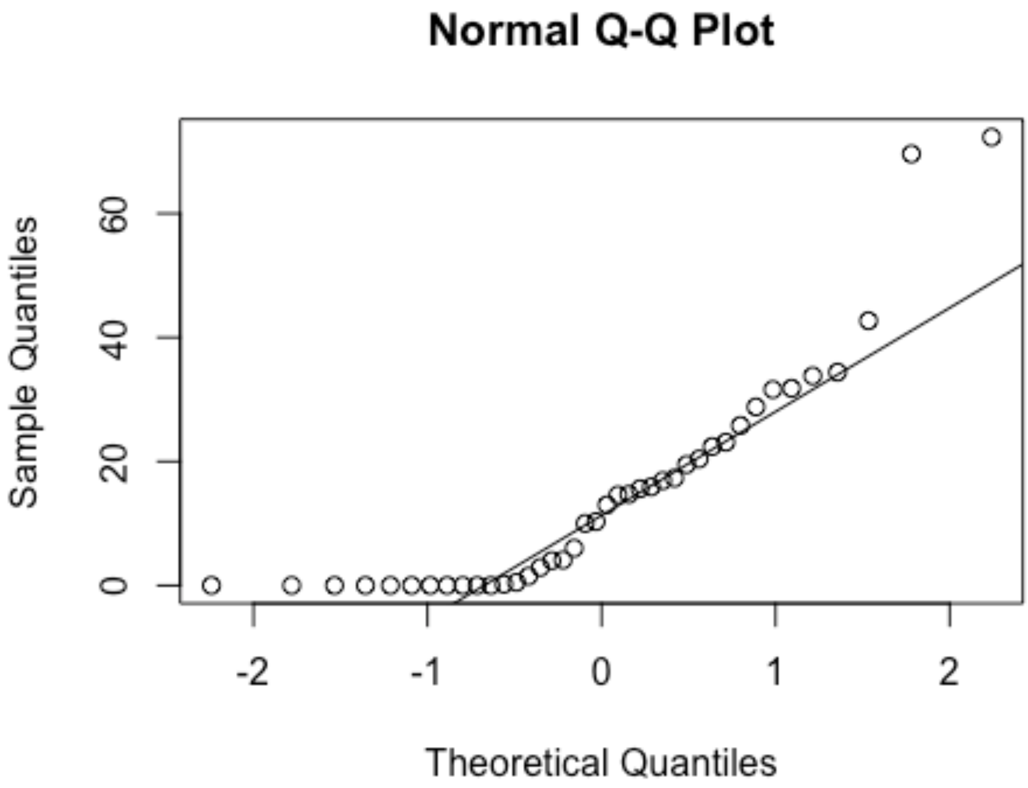
```
length(SSdata$PtstSupine)
```

```
## [1] 40
```

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

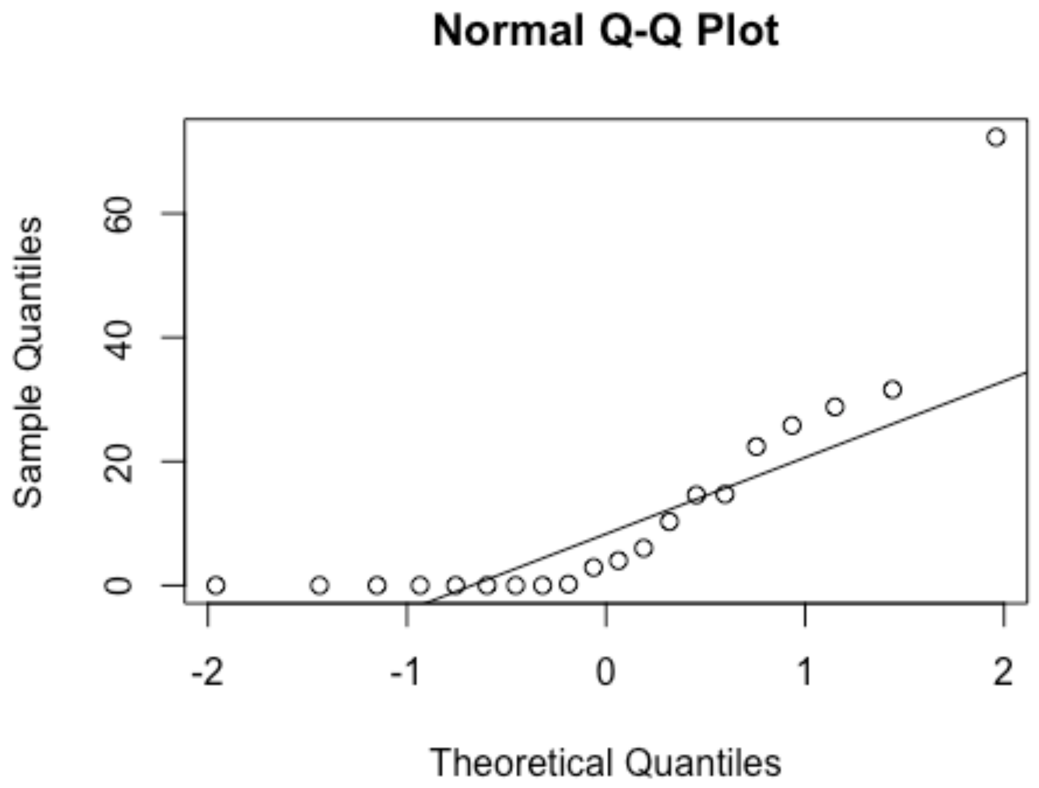
```
## Analysis of Variance Table
##
## Response: PtstSupine
##                     Df  Sum Sq Mean Sq F value Pr(>F)
## intervention         1   465.8  465.81  1.4119 0.2425
## night                1    64.8   64.77  0.1963 0.6604
## intervention:night   1     3.4    3.42  0.0104 0.9194
## Residuals           36 11877.0  329.92
```

```
qqnorm(SSdata$PtstSupine)
qqline(SSdata$PtstSupine)
```

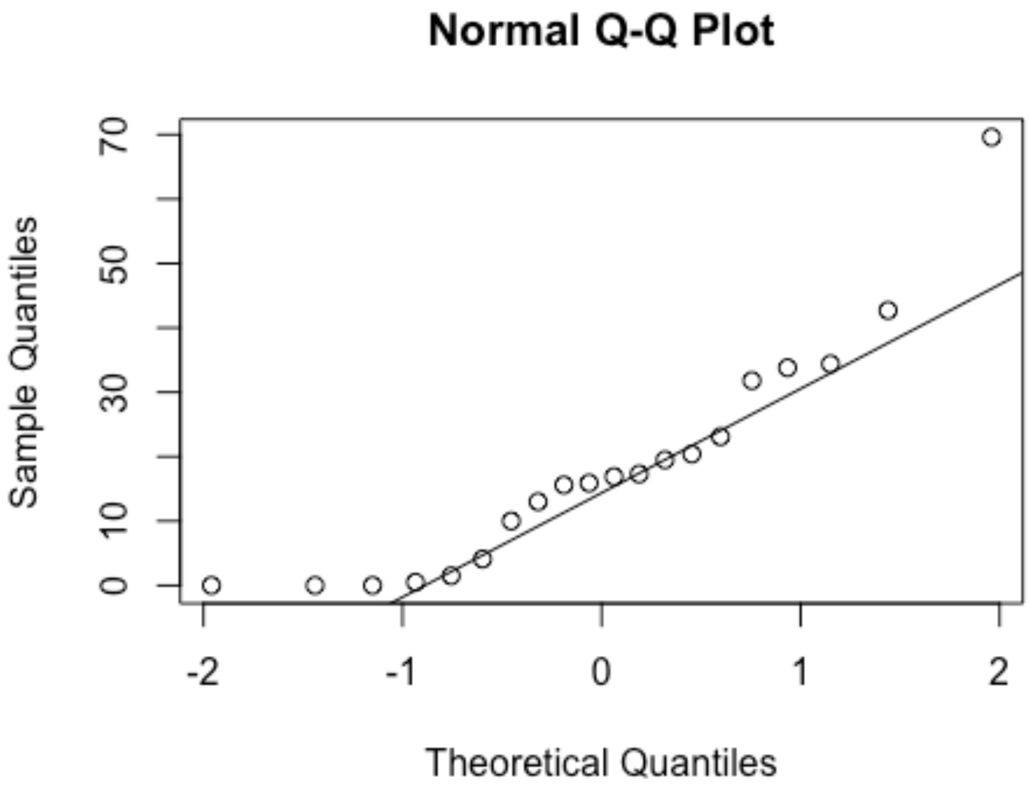


```
ad.test(SSdata$PtstSupine)

##
##  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
```

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$PtstSupine and subs
et(SSdataCompletes, intervention == "PrenaBelt")$PtstSupine
## V = 142, p-value = 0.03065
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  0.7000854       Inf
## sample estimates:
## (pseudo)median
##       5.804603

#difference in medians = 16.4 - 3.5 = 12.9 (corresponds to Wilcoxon rank sum
test)
#median of differences = pseudomedian = 5.8 (corresponds to Wilcoxon signed r
ank test)

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    3.45   11.68   16.62   72.30

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

## [1] 17.9033

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

## [1] 20

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

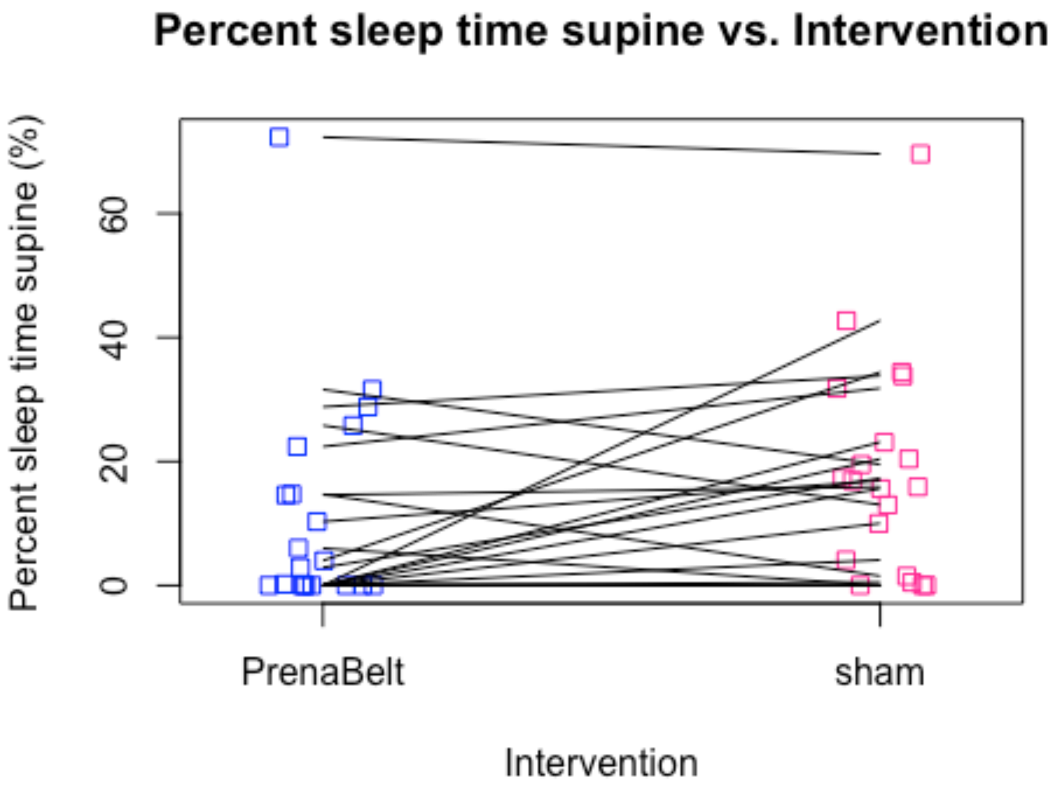


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstSupine)

##
##  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)
```



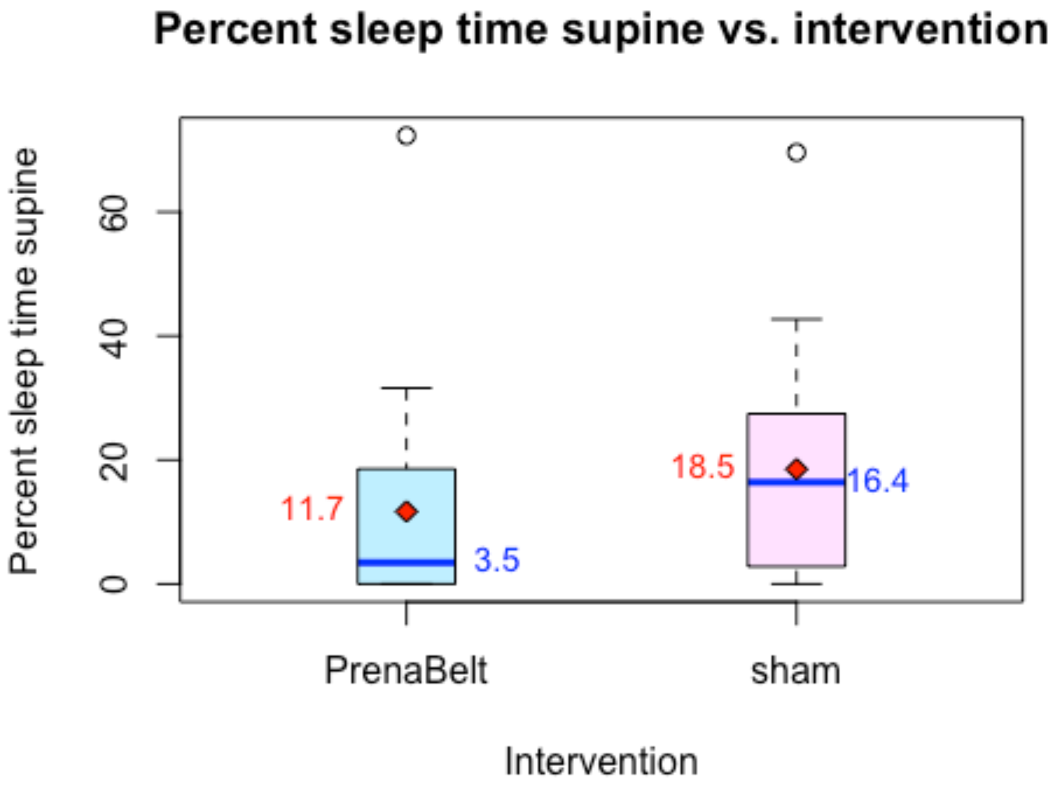
```
ad.test(subset(SSdata, intervention == "sham")$PtstSupine)

##
##  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
```

```
##
## data:  subset(SSdata, intervention == "sham")$PtstSupine and subset(SSdata
, intervention == "PrenaBelt")$PtstSupine
## W = 267, p-value = 0.03456
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  2.150084e-05          Inf
## sample estimates:
## difference in location
##               6.666346

# Use droplevels to remove the empty levels from the list of levels
SSdata$intervention <- droplevels(SSdata$intervention)
summary(SSdata$intervention)

## PrenaBelt      sham
##        20        20

stripchart(SSdata$PtstSupine~SSdata$intervention,
           vertical = TRUE, method="jitter", col=c("blue","deeppink"),
           ylab='Percent sleep time supine (%)', xlab='Intervention',
           main='Percent sleep time supine vs. Intervention',)

for(participant.s.code in split(SSdata, SSdata$participant.s.code))
  lines(PtstSupine ~ intervention, participant.s.code)
```

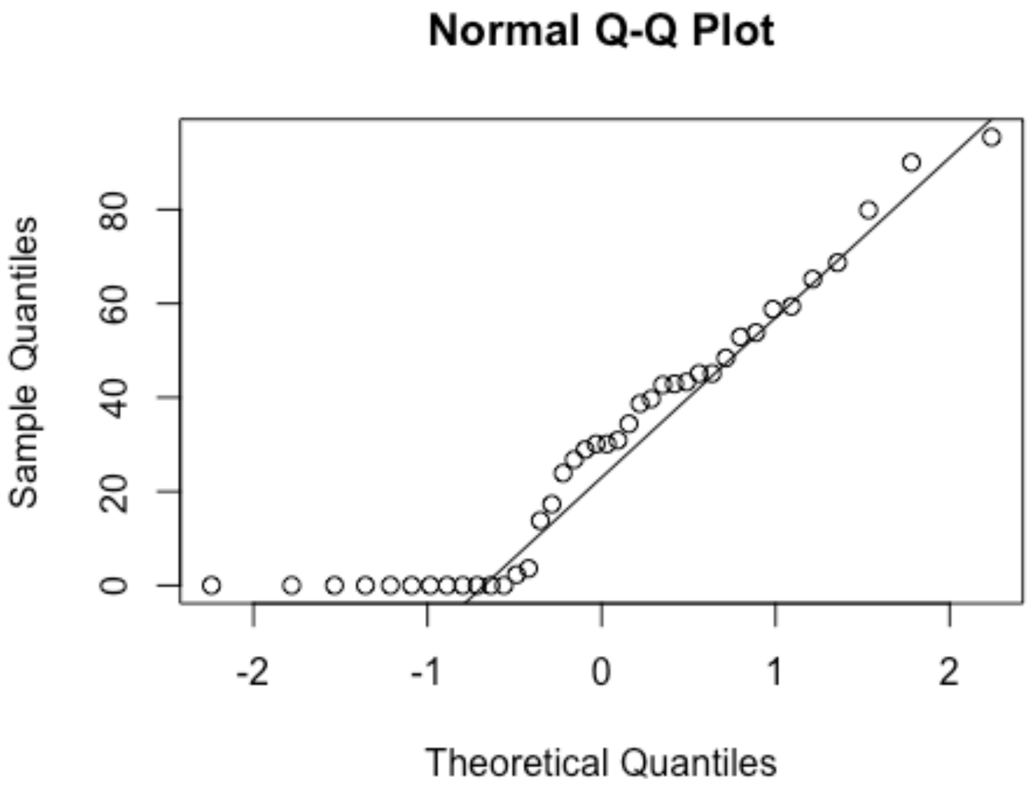


```
boxplot(SSdata$PtstSupine~SSdata$intervention,
        col=c("lightblue1","thistle1"),
        ylab='Percent sleep time supine', xlab='Intervention',
        main='Percent sleep time supine vs. intervention',
        medcol="blue", boxwex = 0.25)

#Get the group means & medians
means <- by(SSdata$PtstSupine, SSdata$intervention, mean)
medians <- by(SSdata$PtstSupine, SSdata$intervention, median)

#Plot symbols for each mean, centered on x = 1 and x = 2, which are the defau
lt
#center values.
points(1:2, means, pch = 23, cex = 1.0, bg = "red")
#Now label the means, formatting the values to one decimal place. Place the v
alues
#to the left of each group plot.
text(1:2 - 0.1, means,
     labels = formatC(means, format = "f", digits = 1),
     pos = 2, cex = 0.9, col = "red")

## Warning in formatC(means, format = "f", digits = 1): class of 'x' was
## 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
```

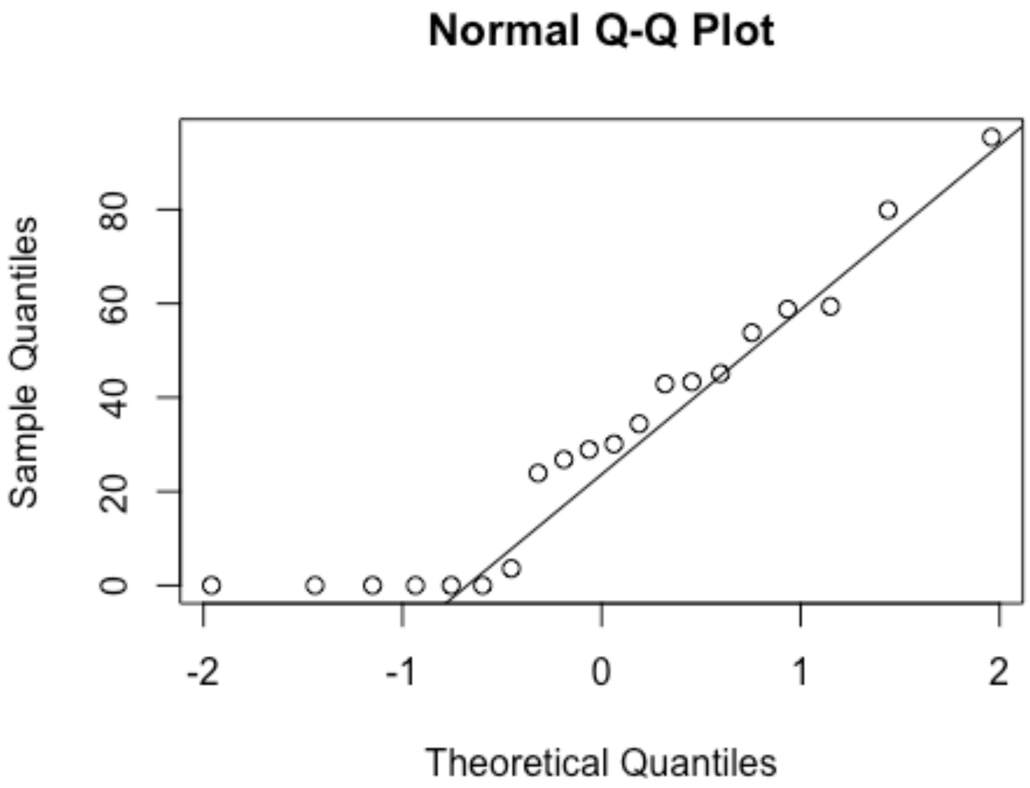


```
#################### %TST Right #######################
#Summary
summary(SSdata$PtstRight)

##    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)
```

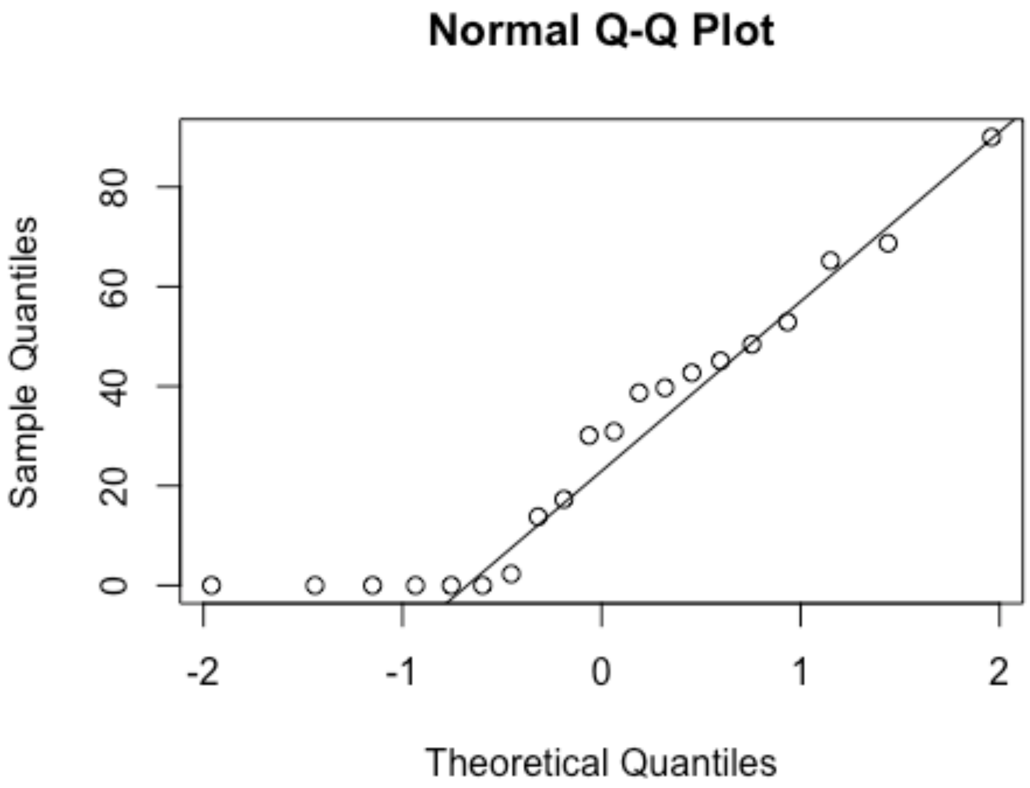


```
ad.test(SSdata$PtstRight)

##
##  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
```

```
#within-participants (paired) comparison
#Paired t-test (individual distributions are normally distributed)
t.test(subset(SSdataCompletes, intervention == "sham")$PtstRight,
       subset(SSdataCompletes, intervention == "PrenaBelt")$PtstRight,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$PtstRight and subse
t(SSdataCompletes, intervention == "PrenaBelt")$PtstRight
## t = -0.52565, df = 19, p-value = 0.6052
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -10.088139   6.038139
## sample estimates:
## mean of the differences
##                  -2.025

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   29.50   31.32   47.28   95.40

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

## [1] 28.77236

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

## [1] 20

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

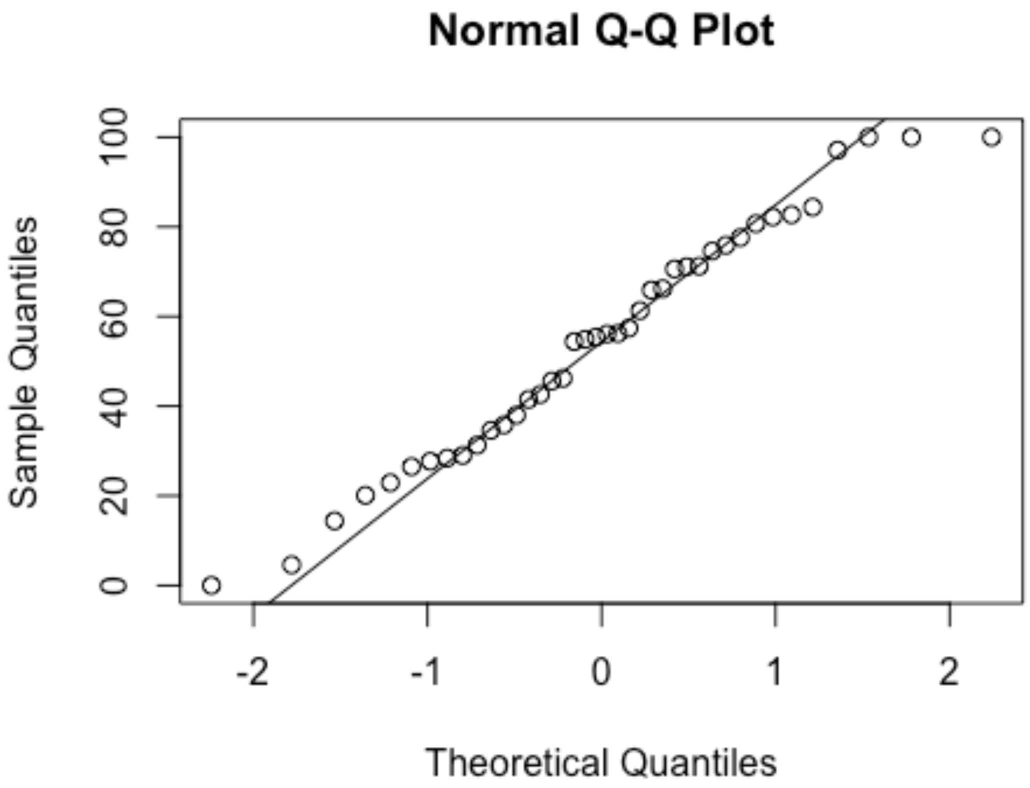


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstRight)

##
##  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)
```



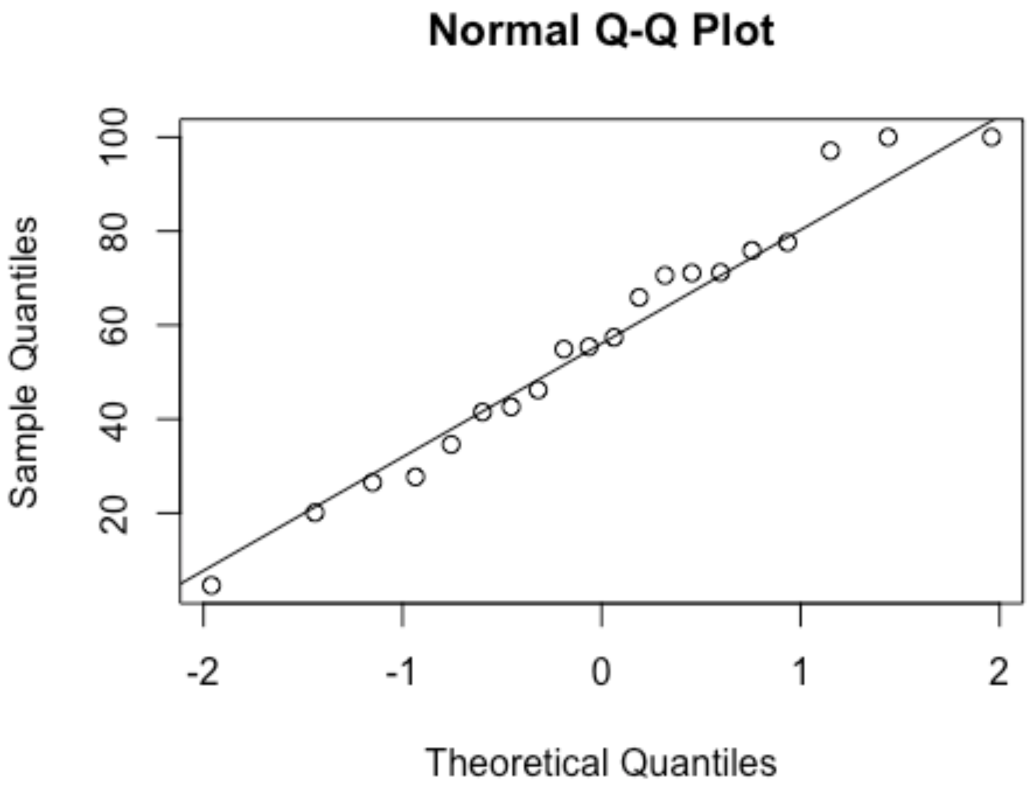
```
ad.test(subset(SSdata, intervention == "sham")$PtstRight)

##
##  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:
```

```
## mean of x mean of y 
##    29.290    31.315

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

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

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

## 
##  Wilcoxon rank sum test with continuity correction
## 
## data:  subset(SSdata, intervention == "sham")$PtstRight and subset(SSdata, 
intervention == "PrenaBelt")$PtstRight
## W = 195, p-value = 0.9018
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -23.89994  14.80004
## sample estimates:
## difference in location 
##           -3.997034e-06

#################### %TST Left #######################
#Summary
summary(SSdata$PtstLeft)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##    0.00   33.78   55.75   54.63   74.92  100.00

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

## [1] 26.70052

length(SSdata$PtstLeft)

## [1] 40

qqnorm(SSdata$PtstLeft)
qqline(SSdata$PtstLeft)
```

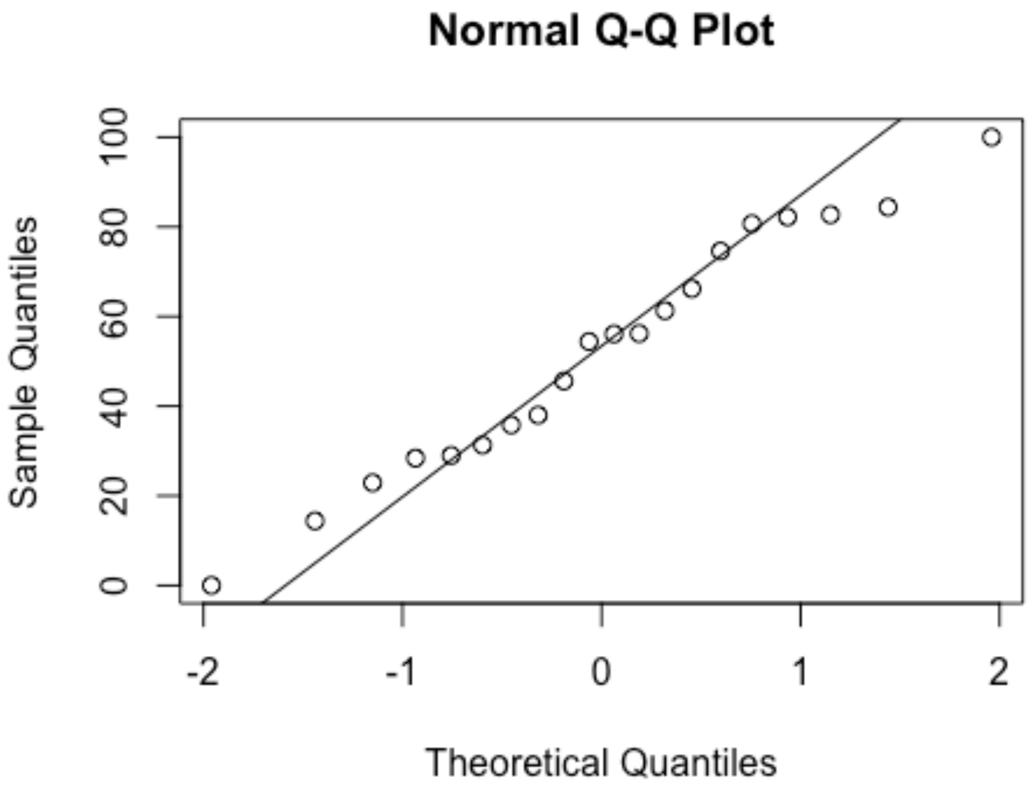


```
ad.test(SSdata$PtstLeft)

##
##  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
```

```
#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$PtstLeft,
       subset(SSdataCompletes, intervention == "PrenaBelt")$PtstLeft,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$PtstLeft and subset
(SSdataCompletes, intervention == "PrenaBelt")$PtstLeft
## t = -1.0137, df = 19, p-value = 0.3234
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -14.817699   5.147699
## sample estimates:
## mean of the differences
##                  -4.835

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    4.60   39.78   56.40   57.04   72.38  100.00

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

## [1] 26.8734

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

## [1] 20

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

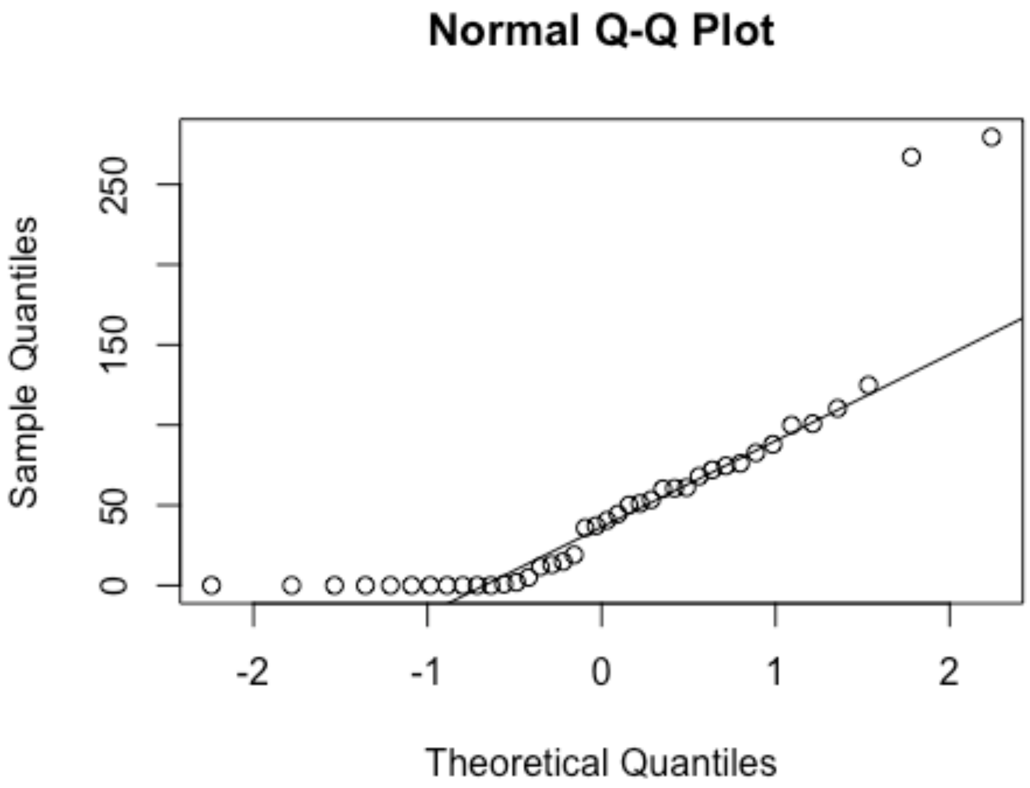


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$PtstLeft)

##
##  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:
```

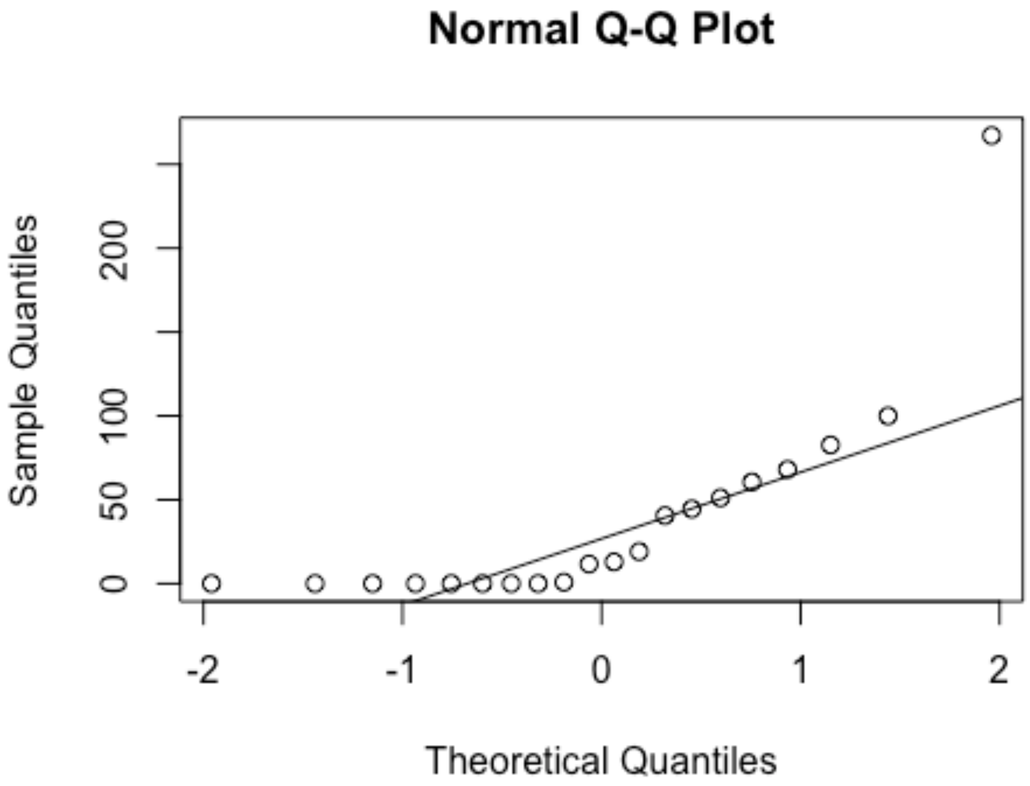
```
## mean of x mean of y
##    52.210    57.045

#no time was spent prone
summary(SSdata$PtstProne)

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

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

## [1] 0

length(SSdata$PtstProne)

## [1] 40

#################### Minutes Sleeping Supine #######################
#Summary
summary(SSdata$minutesTSTSupine)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   38.90   50.13   72.67  279.40

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

## [1] 63.82465

length(SSdata$minutesTSTSupine)

## [1] 40

qqnorm(SSdata$minutesTSTSupine)
qqline(SSdata$minutesTSTSupine)
```



```
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
```

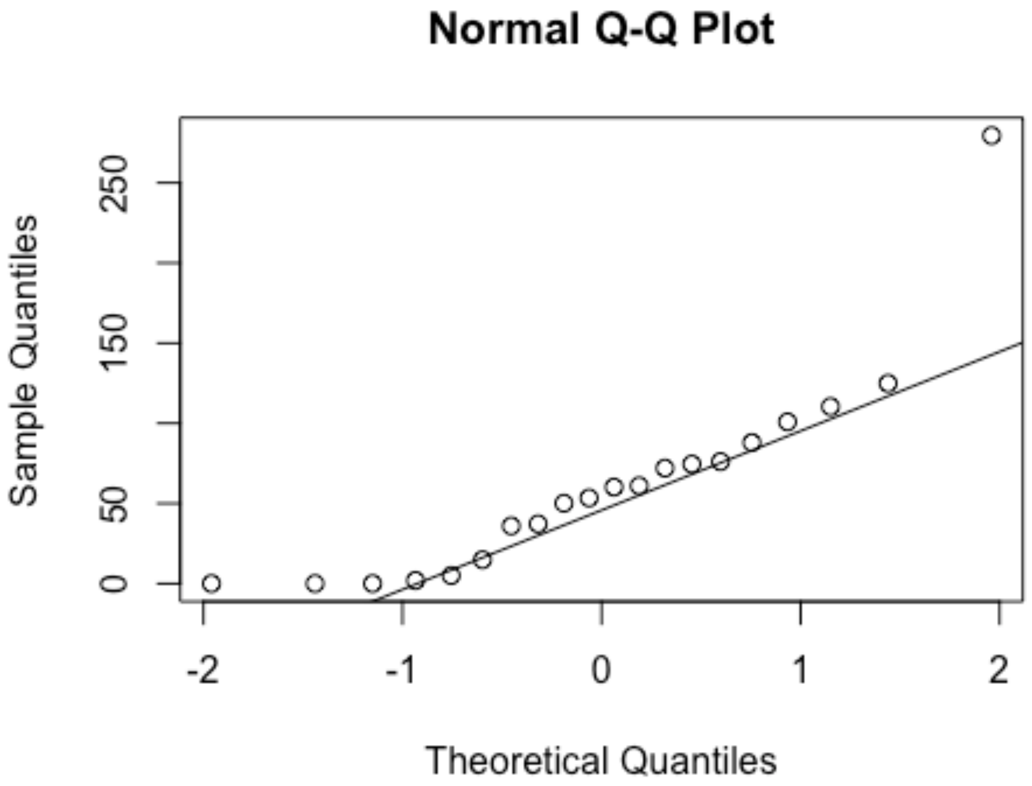
```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine,
            subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSu
pine,
            paired = TRUE, conf.int = TRUE, alternative = "two.sided")

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine an
d subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine
## V = 150, p-value = 0.02829
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##   2.557336 49.892997
## sample estimates:
## (pseudo)median
##       26.37306

#Paired t-test to double check and confirm non-parametric results
t.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine,
      subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine,
     paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$minutesTSTSupine an
d subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTSupine
## t = 2.3911, df = 19, p-value = 0.02731
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##   3.03469 45.65601
## sample estimates:
## mean of the differences
##                24.34535

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   12.30   37.95   53.48  267.10

sd(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)
```

```
## [1] 62.65788

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

## [1] 20

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



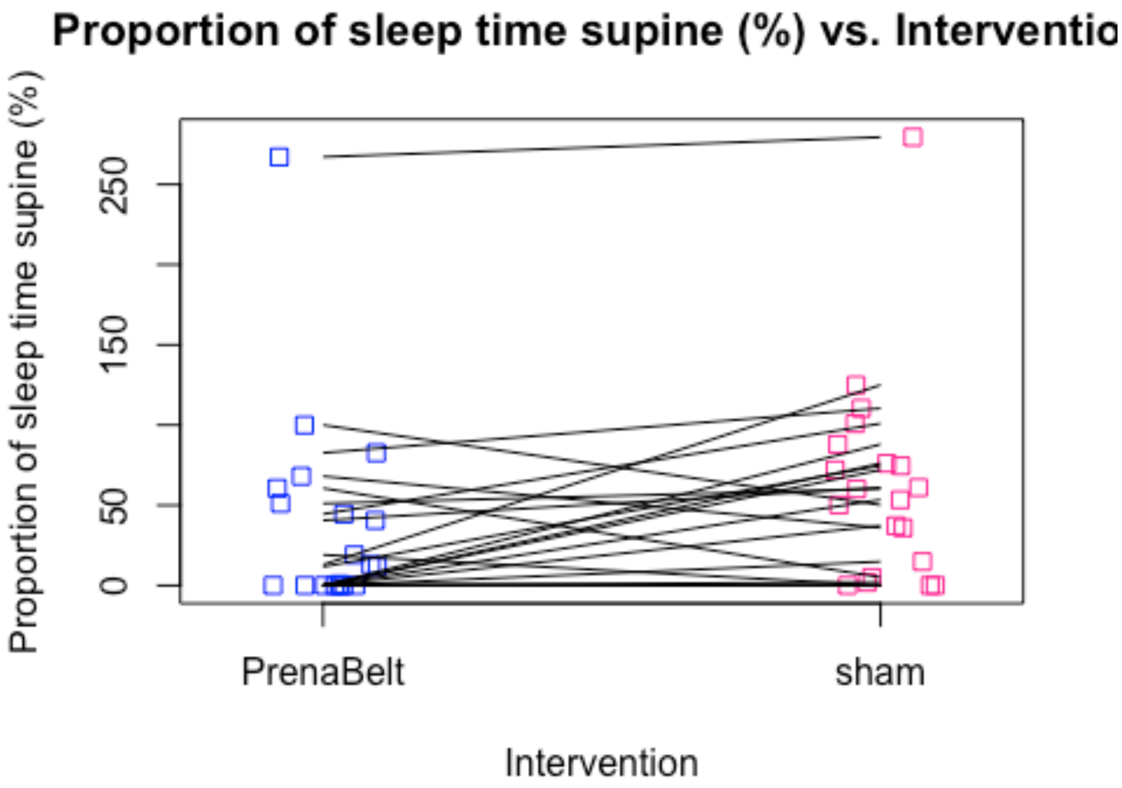
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine
## A = 2.2269, p-value = 7.014e-06

#non-normal

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00   12.39   56.80   62.30   79.08  279.40

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

```
## [1] 64.21539

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

## [1] 20

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

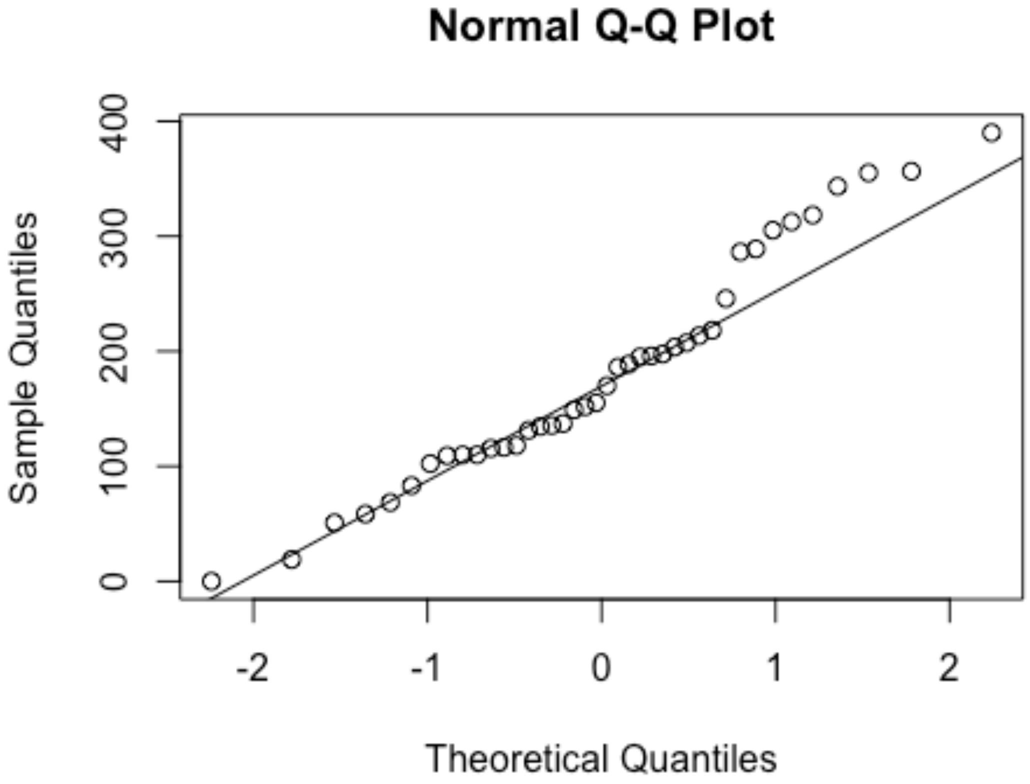


```
ad.test(subset(SSdata, intervention == "sham")$minutesTSTSupine)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$minutesTSTSupine
## A = 0.96839, p-value = 0.01163

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$minutesTSTSupine,
            subset(SSdata, intervention == "PrenaBelt")$minutesTSTSupine,
            conf.int = TRUE, alternative = "greater")
```

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$minutesTSTSupine and subset(
SSdata, intervention == "PrenaBelt")$minutesTSTSupine
## W = 271, p-value = 0.02699
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  6.926608e-05          Inf
## sample estimates:
## difference in location
##               24.28712

# Use droplevels to remove the empty levels from the list of levels
SSdata$intervention <- droplevels(SSdata$intervention)
summary(SSdata$intervention)

## PrenaBelt      sham
##        20        20

stripchart(SSdata$minutesTSTSupine~SSdata$intervention,
           vertical = TRUE, method="jitter", col=c("blue","deeppink"),
           ylab='Proportion of sleep time supine (%)', xlab='Intervention',
           main='Proportion of sleep time supine (%) vs. Intervention',)

for(participant.s.code in split(SSdata, SSdata$participant.s.code))
  lines(minutesTSTSupine ~ intervention, participant.s.code)
```

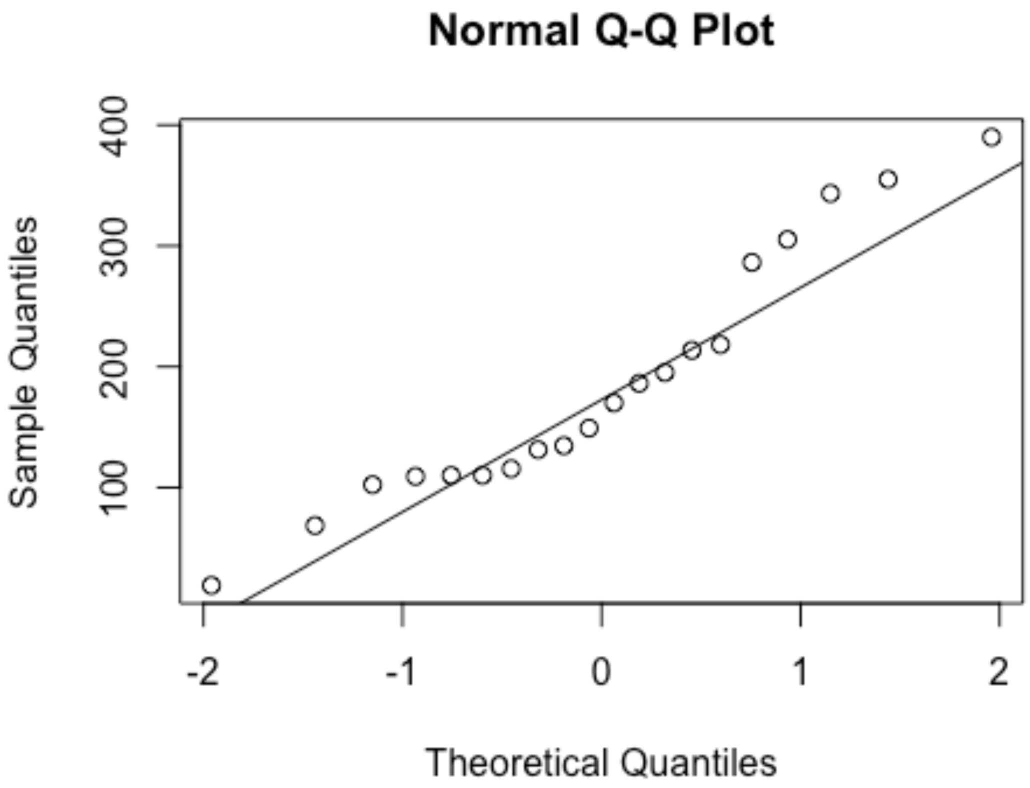


```
#################### Minutes Sleeping Left #######################
#Summary
summary(SSdata$minutesTSTLeft)

##    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)
```

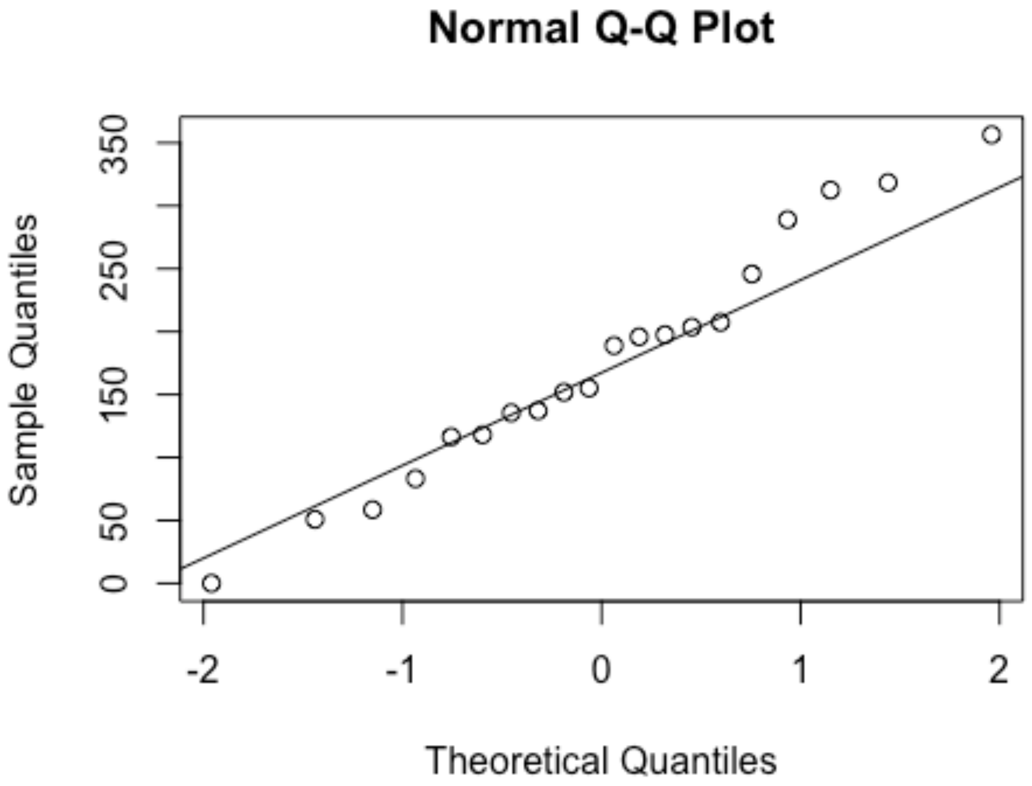


```
ad.test(SSdata$minutesTSTLeft)

##
##  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
```

```
#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$minutesTSTLeft,
      subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTLeft,
      paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$minutesTSTLeft and
subset(SSdataCompletes, intervention == "PrenaBelt")$minutesTSTLeft
## t = -0.59061, df = 19, p-value = 0.5617
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -43.33418  24.26038
## sample estimates:
## mean of the differences
##                -9.5369

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   18.95  110.00  159.60  185.60  235.30  390.00

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

## [1] 102.4677

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

## [1] 20

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

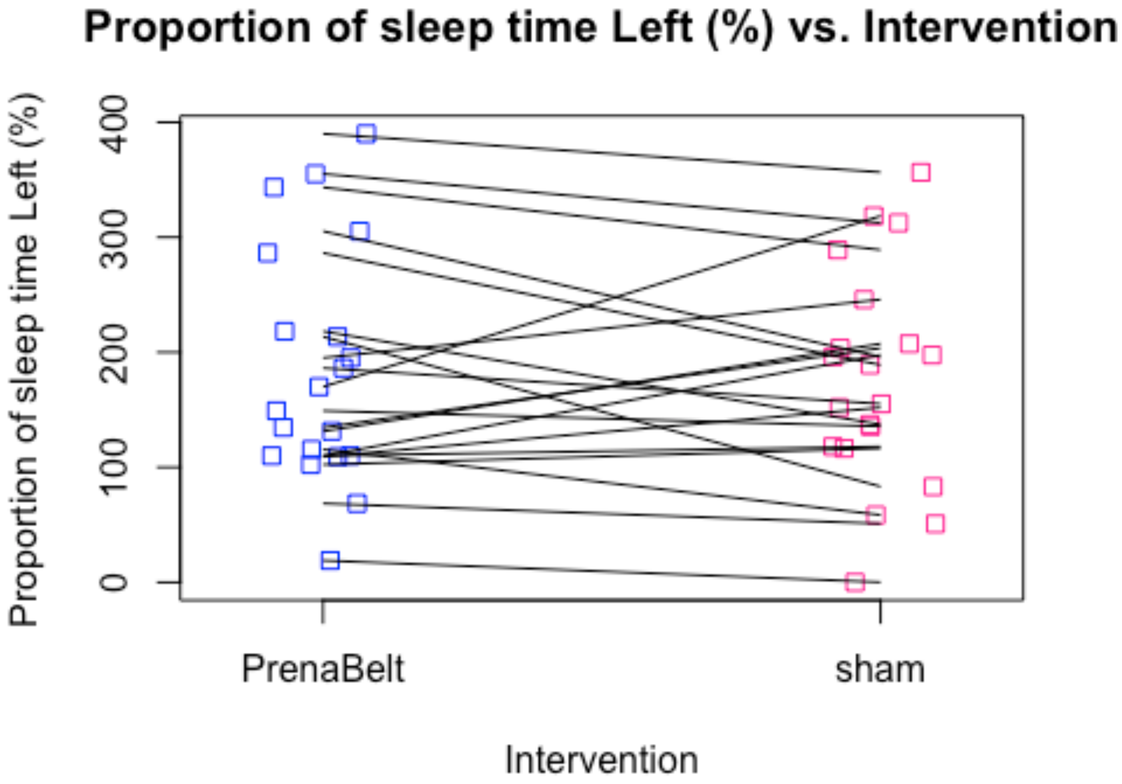


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTLeft)

##
##  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)
```



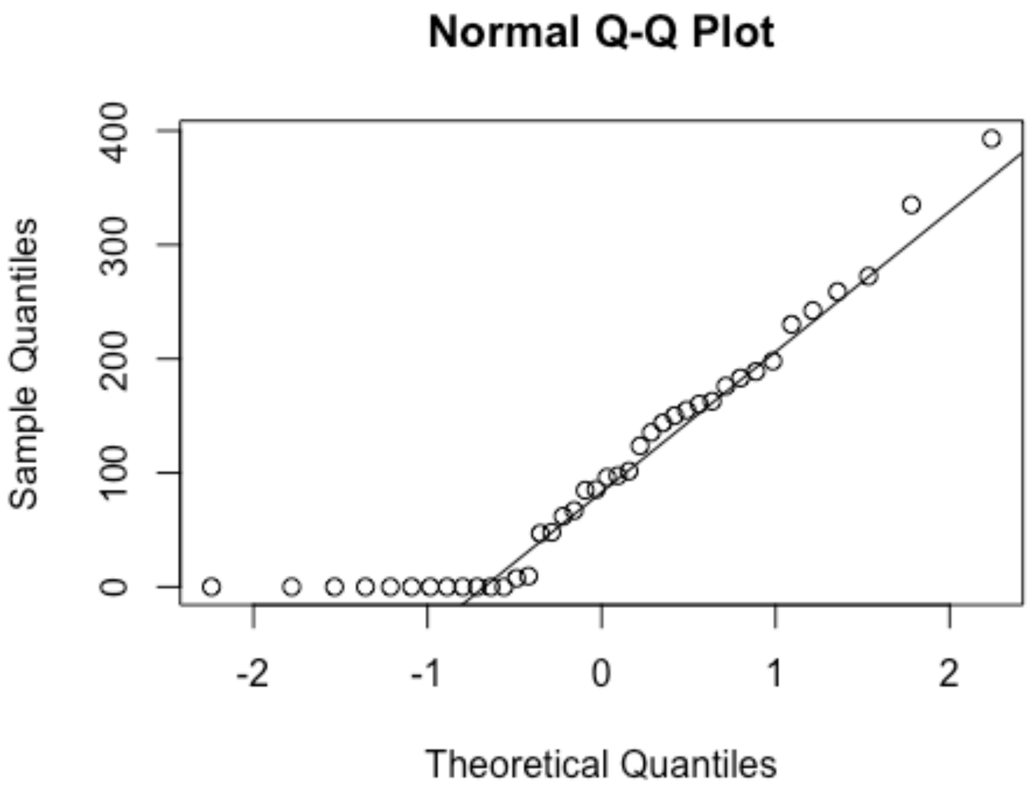
```
ad.test(subset(SSdata, intervention == "sham")$minutesTSTLeft)

##
##  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:
```

```
## mean of x mean of y
##  176.1083  185.6452

# Use droplevels to remove the empty levels from the list of levels
SSdata$intervention <- droplevels(SSdata$intervention)
summary(SSdata$intervention)

## PrenaBelt      sham
##        20        20

stripchart(SSdata$minutesTSTLeft~SSdata$intervention,
           vertical = TRUE, method="jitter", col=c("blue","deeppink"),
           ylab='Proportion of sleep time Left (%)', xlab='Intervention',
           main='Proportion of sleep time Left (%) vs. Intervention',)

for(participant.s.code in split(SSdata, SSdata$participant.s.code))
  lines(minutesTSTLeft ~ intervention, participant.s.code)
```



```
#################### Minutes Sleeping Right ############################
#Summary
summary(SSdata$minutesTSTRight)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   90.78  105.40  166.10  393.00
```

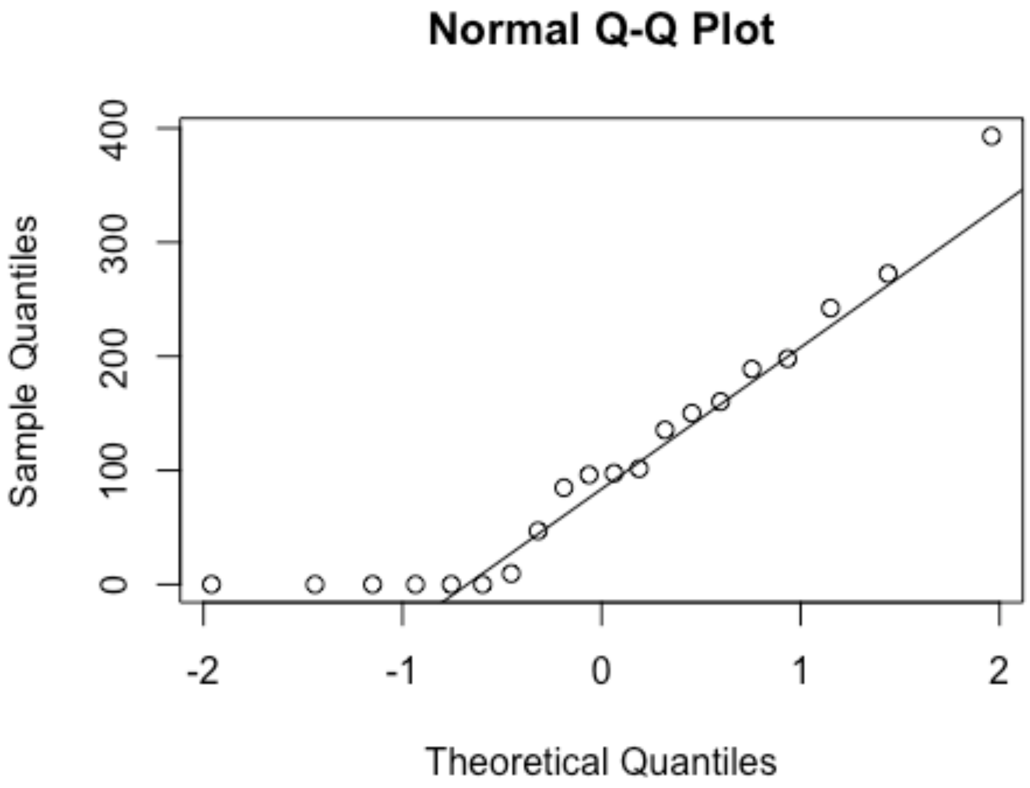
```
sd(SSdata$minutesTSTRight, na.rm = TRUE)

## [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,
```

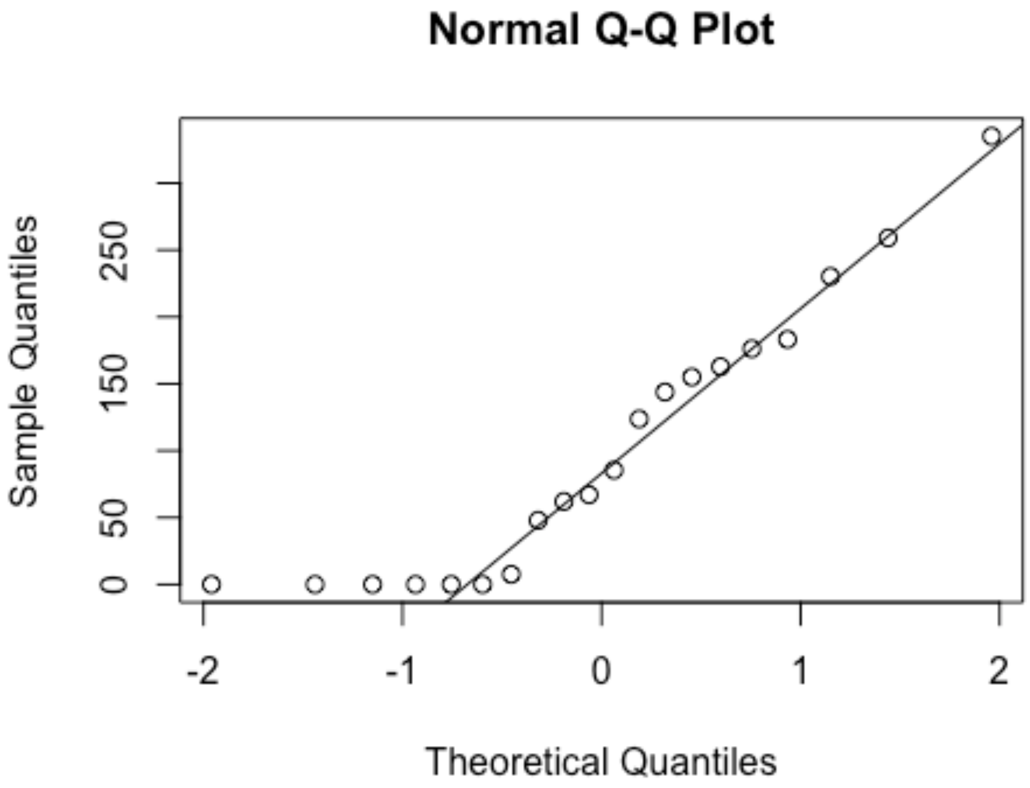
```
                                 data = SSdata))
night_tx_difference

## 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)
```



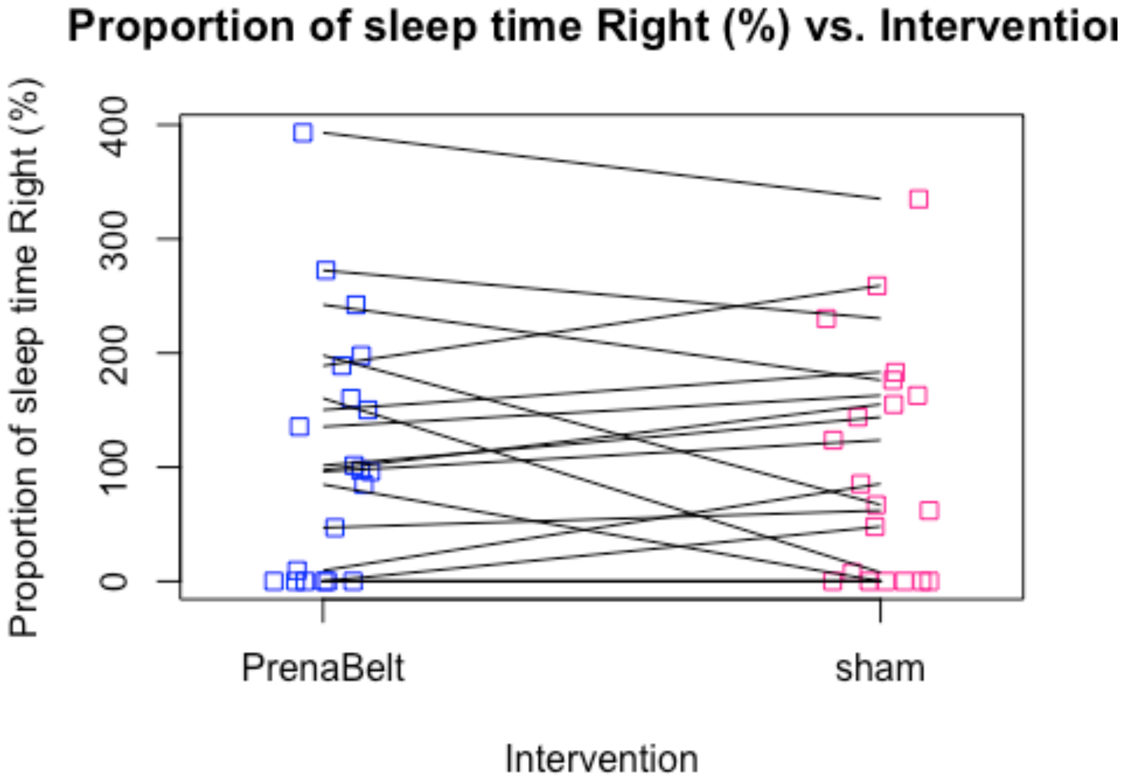
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$minutesTSTRight)

##
##  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

#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
```

```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$minutesTSTRight and subset(S
Sdata, intervention == "PrenaBelt")$minutesTSTRight
## W = 195, p-value = 0.5599
## alternative hypothesis: true location shift is greater than 0
## 95 percent confidence interval:
##  -54.15088       Inf
## sample estimates:
## difference in location
##          -3.909212e-05

# Use droplevels to remove the empty levels from the list of levels
SSdata$intervention <- droplevels(SSdata$intervention)
summary(SSdata$intervention)

## PrenaBelt      sham
##        20        20

stripchart(SSdata$minutesTSTRight~SSdata$intervention,
           vertical = TRUE, method="jitter", col=c("blue","deeppink"),
           ylab='Proportion of sleep time Right (%)', xlab='Intervention',
           main='Proportion of sleep time Right (%) vs. Intervention',)

for(participant.s.code in split(SSdata, SSdata$participant.s.code))
  lines(minutesTSTRight ~ intervention, participant.s.code)
```



```
#Considering index (events per hour) data now:
#################### Central 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$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)
## intervention          1  0.001 0.001000  0.0679 0.79587
## night                 1  0.001 0.001000  0.0679 0.79587
## intervention:night    1  0.064 0.064000  4.3472 0.04422 *
## Residuals            36  0.530 0.014722
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$central.apneas.in
dex,
       subset(SSdataCompletes, intervention == "PrenaBelt")$central.apneas.in
dex,
       paired = TRUE, conf.int = TRUE)
```

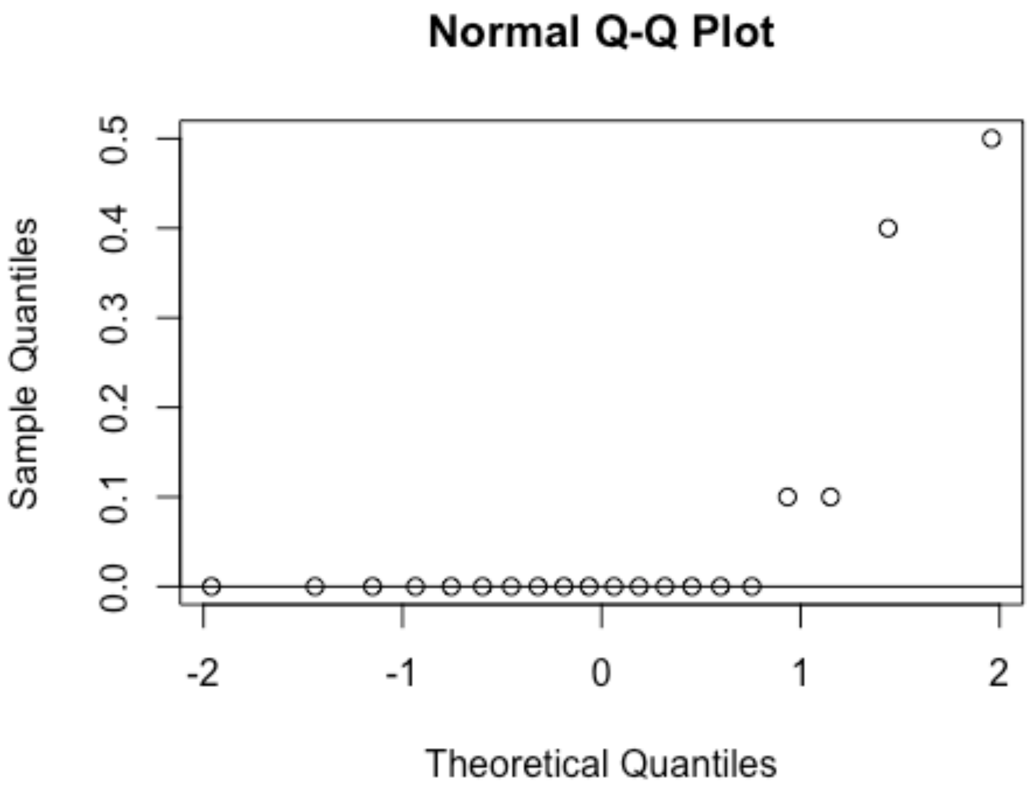
```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$central.apneas.index, : cannot compute exact p-value with ties

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

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

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

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$central.apneas.inde
x and subset(SSdataCompletes, intervention == "PrenaBelt")$central.apneas.ind
ex
## V = 26.5, p-value = 0.6746
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.1500585  0.2000332
## sample estimates:
## (pseudo)median
##     0.04999741
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$central.apneas.index)
```

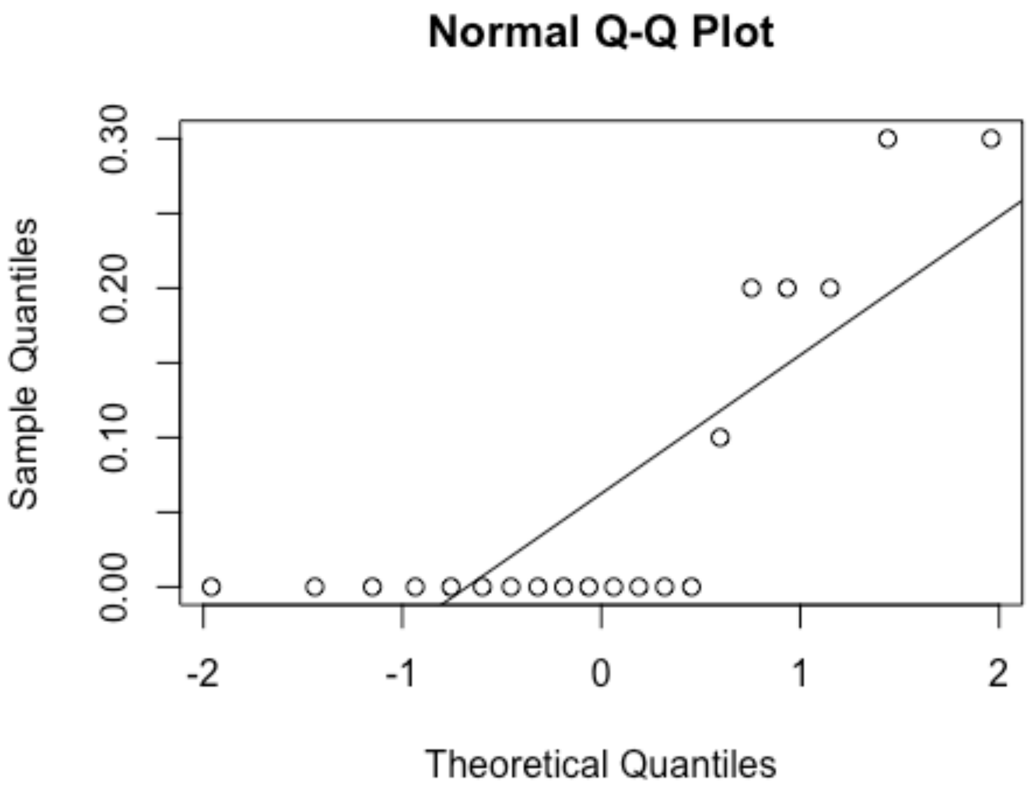
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.055   0.000   0.500
```

```
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
```

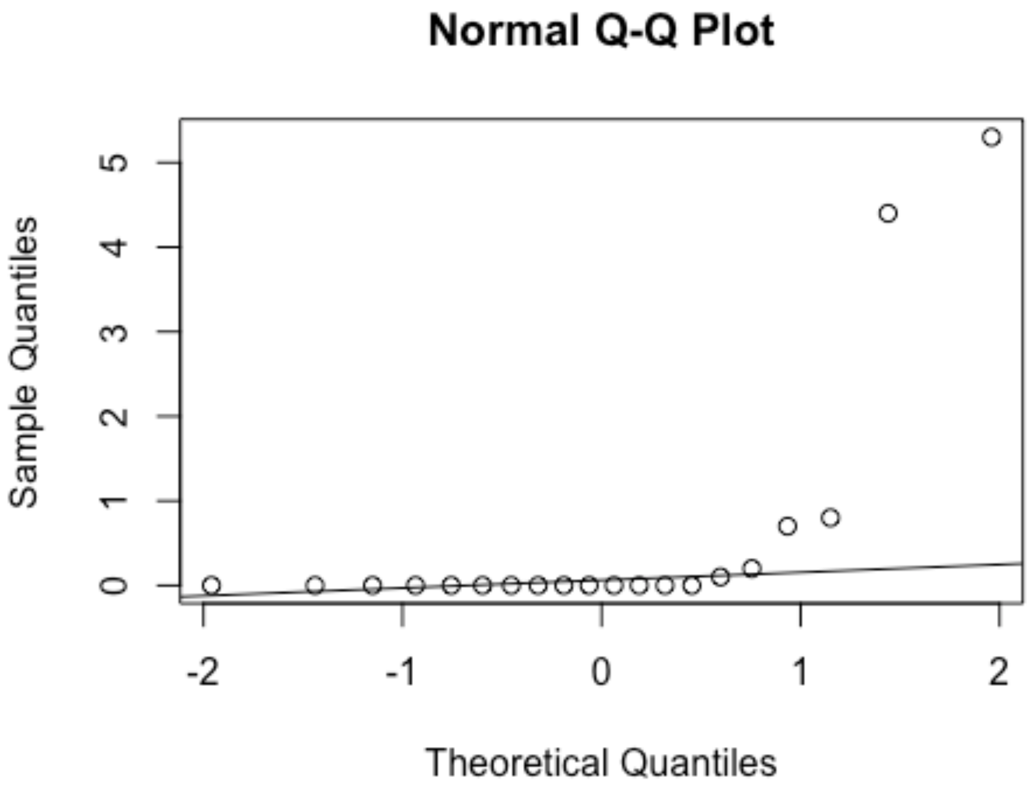
```
sd(subset(SSdata, intervention == "sham")$central.apneas.index)

## [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,
```

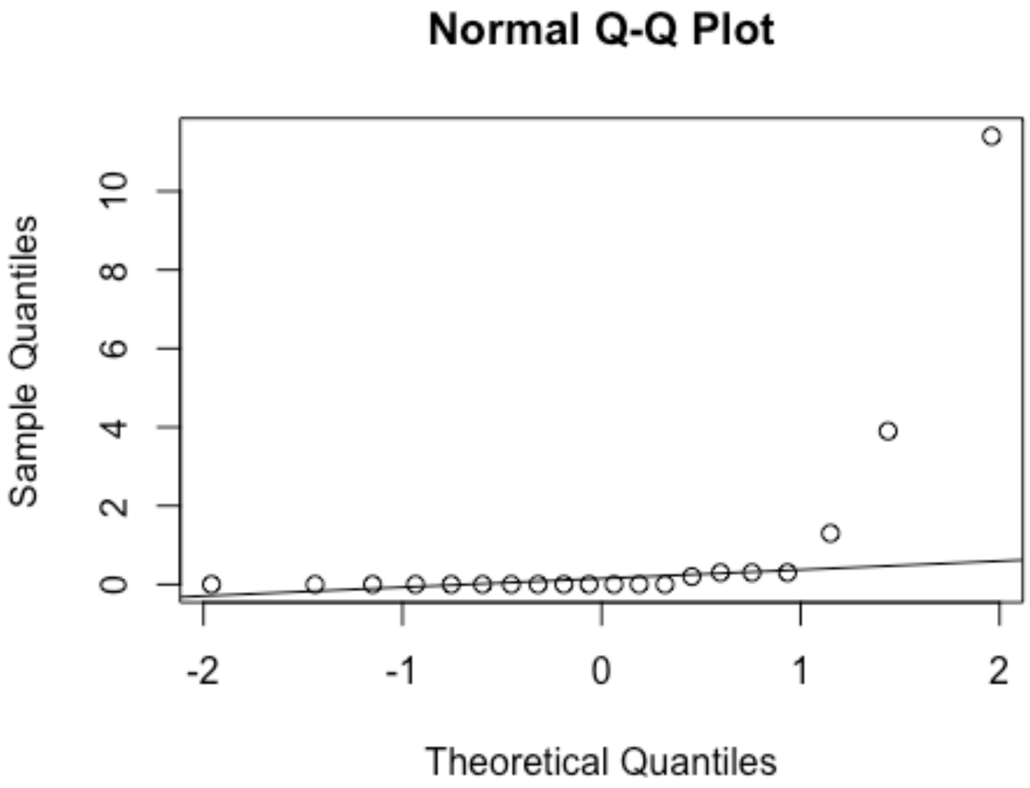
```
            subset(SSdata, intervention == "PrenaBelt")$central.apneas.index,
            conf.int = TRUE)

## 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)
```

```
## intervention  1   0.961  0.9610  0.2065 0.6521
## night         1   1.369  1.3690  0.2942 0.5908
## Residuals    37 172.154  4.6528

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$obstructive.apnea
s.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.apnea
s.index,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$obstructive.apneas.
index and subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.ap
neas.index
## V = 18, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.7499621  3.5499235
## sample estimates:
## (pseudo)median
##     0.03901549

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.575   0.125   5.300

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

## [1] 1.487094

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

## [1] 20

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



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

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.inde
x
## 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
```

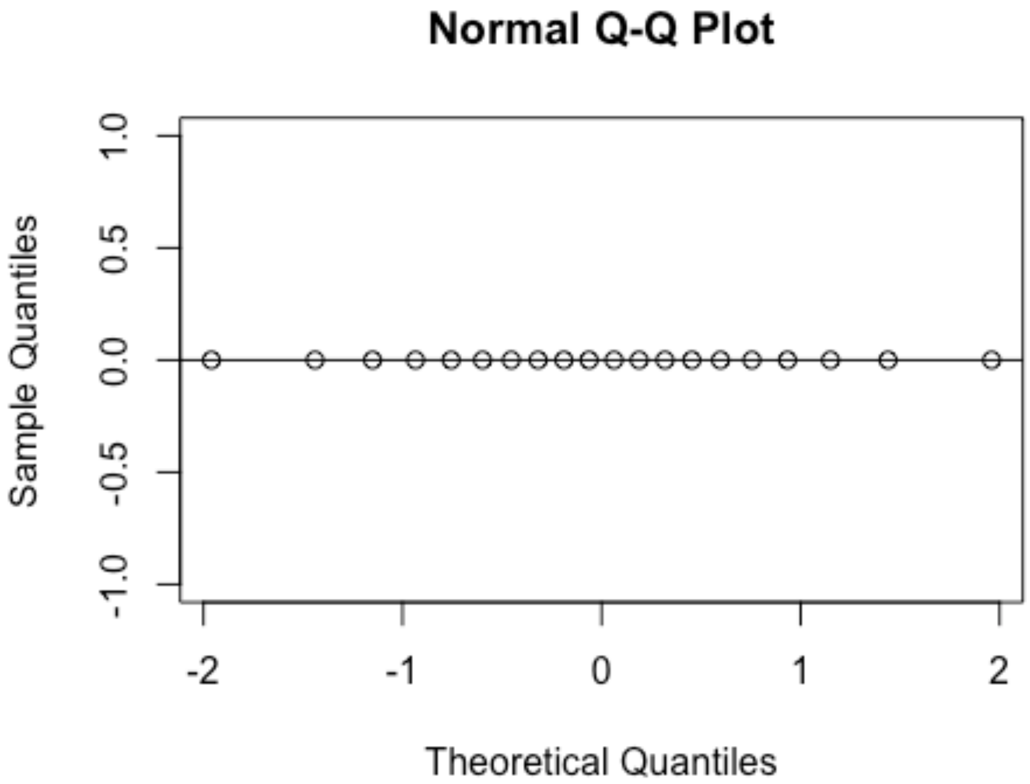
```
qqnorm(subset(SSdata, intervention == "sham")$obstructive.apneas.index)
qqline(subset(SSdata, intervention == "sham")$obstructive.apneas.index)
```



```
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
```

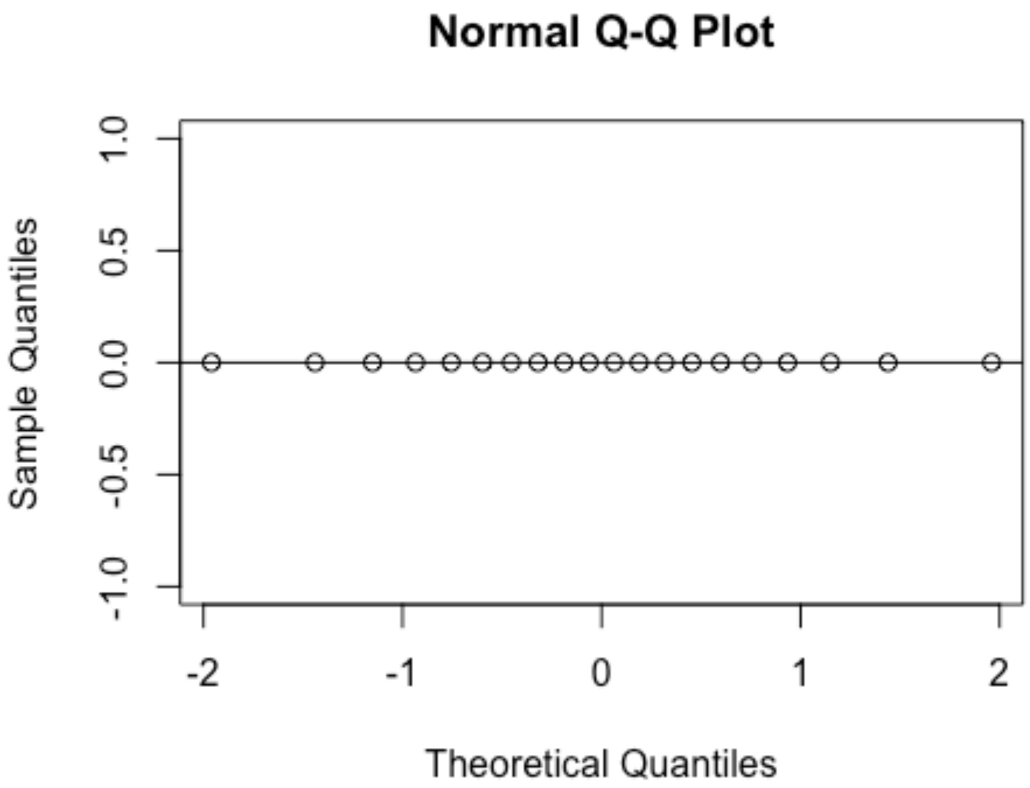
```
h
## ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$obstructive.apneas.index and
subset(SSdata, intervention == "PrenaBelt")$obstructive.apneas.index
## W = 210.5, p-value = 0.7451
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.671494e-05  4.691508e-05
## sample estimates:
## difference in location
##           2.019957e-05

#################### Mixed 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$mixed.apneas.index)

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

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

## [1] 0

length(SSdata$mixed.apneas.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: mixed.apneas.index
##              Df Sum Sq Mean Sq F value Pr(>F)
## intervention  1      0       0
## night         1      0       0
## Residuals    37      0       0

#within-participants (paired) comparison
#distribution is made entirely of zeroes
#difference testing not applicable
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mixed.apneas.index)

##    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)
```



```
#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
```

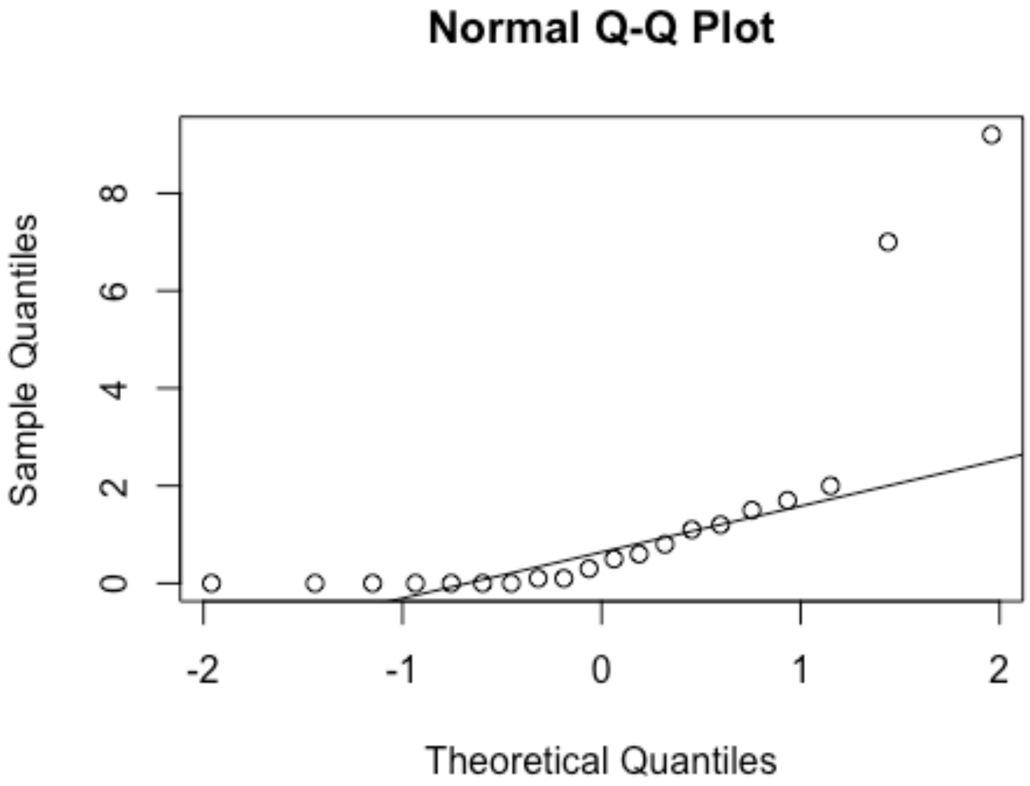
```
sd(subset(SSdata, intervention == "sham")$mixed.apneas.index)

## [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)
```



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

#################### Obstructive hypopneas 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.hypopneas.index)
```

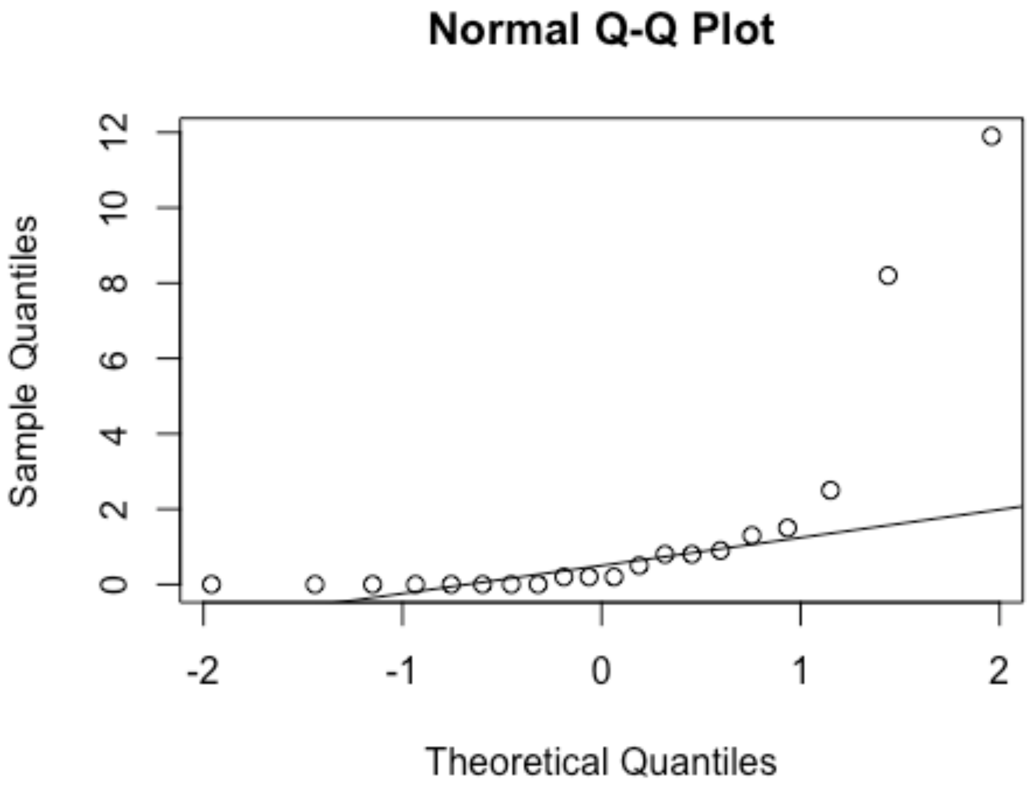
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.250   1.378   1.225  11.900

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

## [1] 2.738097

length(SSdata$obstructive.hypopneas.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(obstructive.hypopneas.index ~ intervention +
night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: obstructive.hypopneas.index
##              Df  Sum Sq Mean Sq F value Pr(>F)
## intervention  1   0.210  0.2103  0.0267 0.8711
## night         1   0.702  0.7023  0.0891 0.7669
## Residuals    37 291.477  7.8778

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$obstructive.hypop
neas.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive.hypop
neas.index,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
```

```
## data:  subset(SSdataCompletes, intervention == "sham")$obstructive.hypopne
as.index and subset(SSdataCompletes, intervention == "PrenaBelt")$obstructive
.hypopneas.index
## V = 87, p-value = 0.6357
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.2999835  0.5499741
## sample estimates:
## (pseudo)median
##     0.09999107

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.ind
ex)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.400   1.305   1.275   9.200

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

## [1] 2.435802

length(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
x)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
x)
qqline(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.inde
x)
```



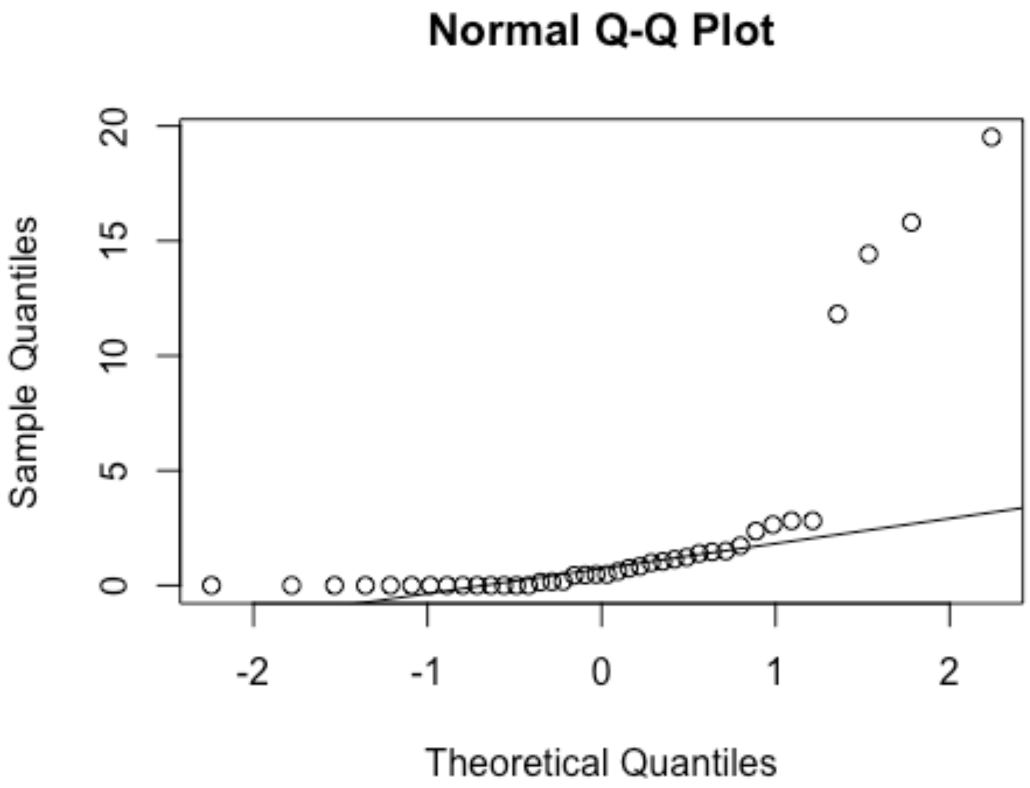
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.ind
ex)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.i
ndex
## 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)
```



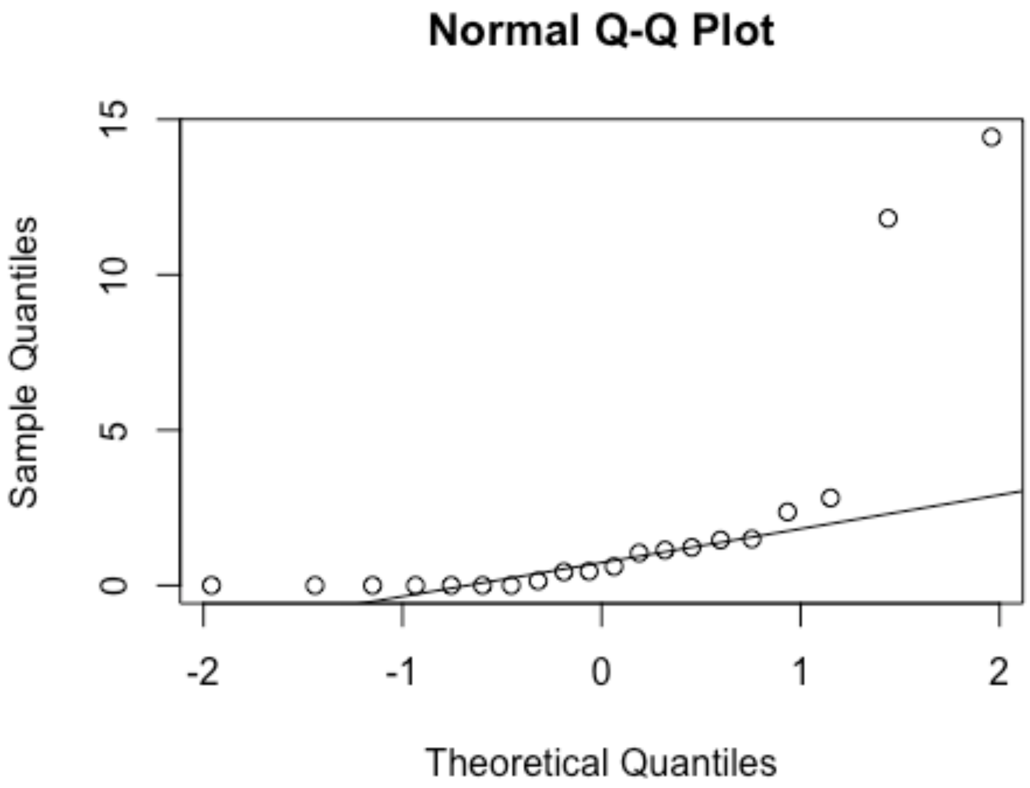
```
ad.test(subset(SSdata, intervention == "sham")$obstructive.hypopneas.index)

##
##  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")$obstructive.hypopneas.inde
x,
            subset(SSdata, intervention == "PrenaBelt")$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
```

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$obstructive.hypopneas.index
and subset(SSdata, intervention == "PrenaBelt")$obstructive.hypopneas.index
## W = 191, p-value = 0.8132
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.5000080  0.2999871
## sample estimates:
## difference in location
##          -1.817308e-06

##################### Apnea-Hypopnea Index #######################
#Summary
summary(SSdata$AHI.calculated)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.4765  2.1800  1.4700 19.5100

sd(SSdata$AHI.calculated, na.rm = TRUE)

## [1] 4.622751

length(SSdata$AHI.calculated)

## [1] 40

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

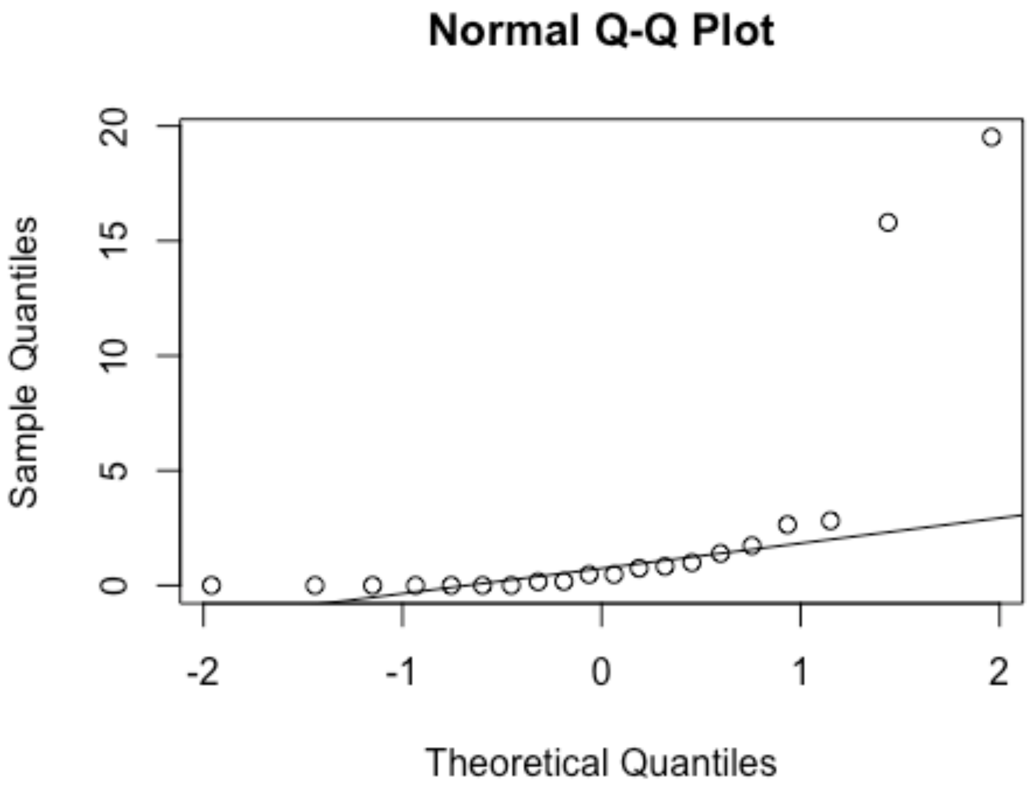


```
ad.test(SSdata$AHI.calculated)

##
##  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
## intervention:night  1 106.12 106.123  5.2990 0.02723 *
## Residuals          36 720.97  20.027
```

```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$AHI.calculated,
       subset(SSdataCompletes, intervention == "PrenaBelt")$AHI.calculated,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$AHI.calculated and
subset(SSdataCompletes, intervention == "PrenaBelt")$AHI.calculated
## V = 91, p-value = 0.5075
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.4367014  0.7981902
## sample estimates:
## (pseudo)median
##      0.1385676

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.5321  1.9720  1.4700 14.4300

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

## [1] 3.924224

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

## [1] 20

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



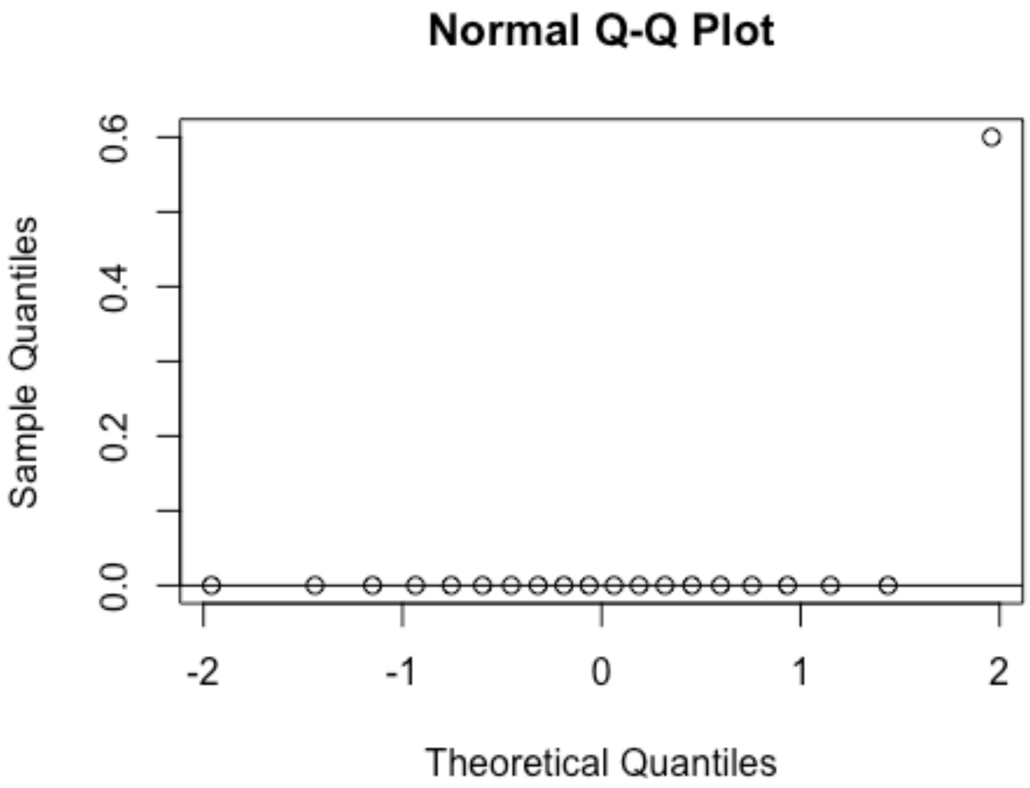
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$AHI.calculated)

##
##  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)
```



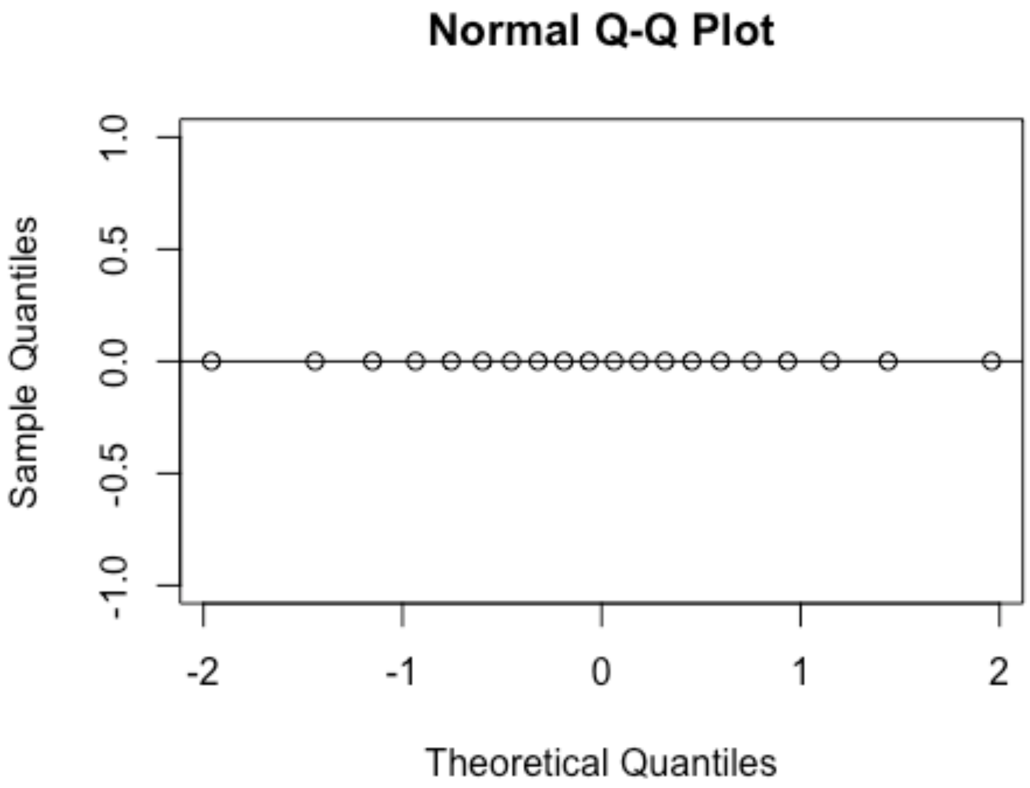
```
ad.test(subset(SSdata, intervention == "sham")$AHI.calculated)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$AHI.calculated and subset(SS
data, intervention == "PrenaBelt")$AHI.calculated
## W = 198.5, p-value = 0.9779
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.6092948  0.4774410
## sample estimates:
## difference in location
##          -1.726505e-05

#################### Central hypopneas 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$central.hypopneas.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.015   0.000   0.600

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

## [1] 0.09486833

length(SSdata$central.hypopneas.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(central.hypopneas.index ~ intervention + nigh
t,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: central.hypopneas.index
##              Df Sum Sq Mean Sq F value Pr(>F)
## intervention  1  0.009   0.009       1 0.3238
## night         1  0.009   0.009       1 0.3238
## Residuals    37  0.333   0.009

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$central.hypopneas
.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$central.hypopneas
.index,
       paired = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$central.hypopneas.index, : cannot compute exact p-value with zeroe
s

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$central.hypopneas.i
ndex and subset(SSdataCompletes, intervention == "PrenaBelt")$central.hypopne
as.index
## V = 0, p-value = 1
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.03    0.00    0.60

sd(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)

## [1] 0.1341641

length(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)

## [1] 20

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

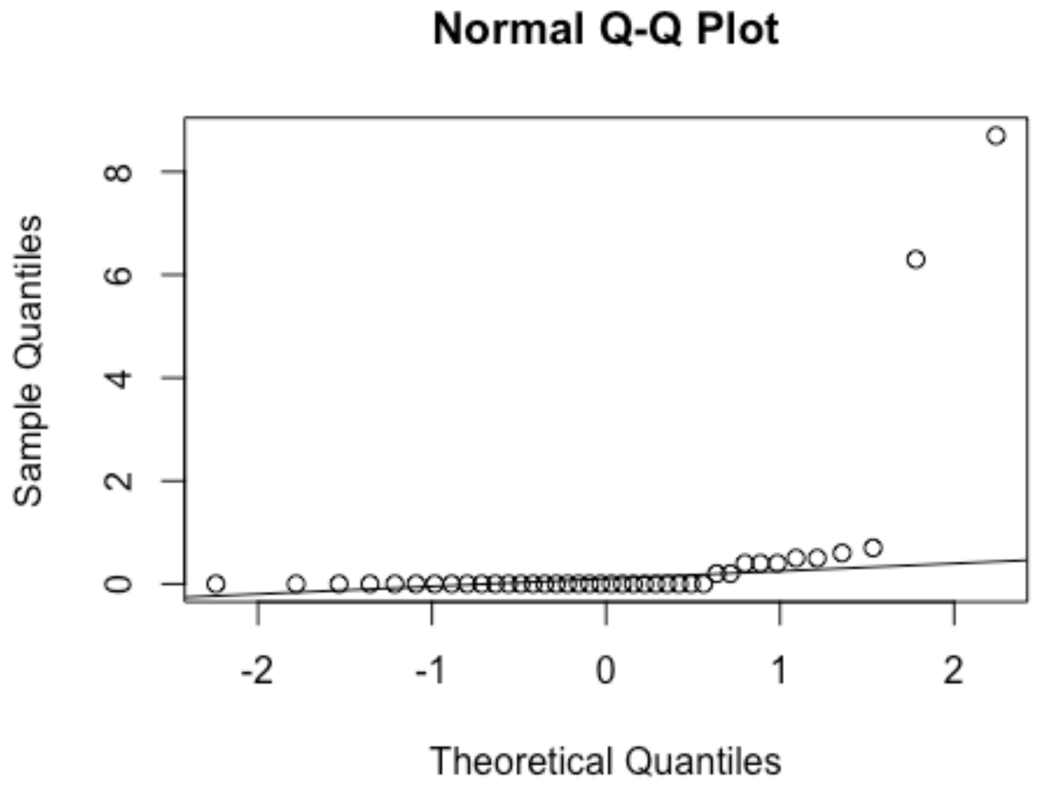


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index)

##
##  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)
```



```
#ad.test(subset(SSdata, intervention == "sham")$central.hypopneas.index)
#distribution is made entirely of zeroes

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$central.hypopneas.index,
            subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.ind
ex,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$central.hypopneas.index and
subset(SSdata, intervention == "PrenaBelt")$central.hypopneas.index
## W = 190, p-value = 0.3421
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
```

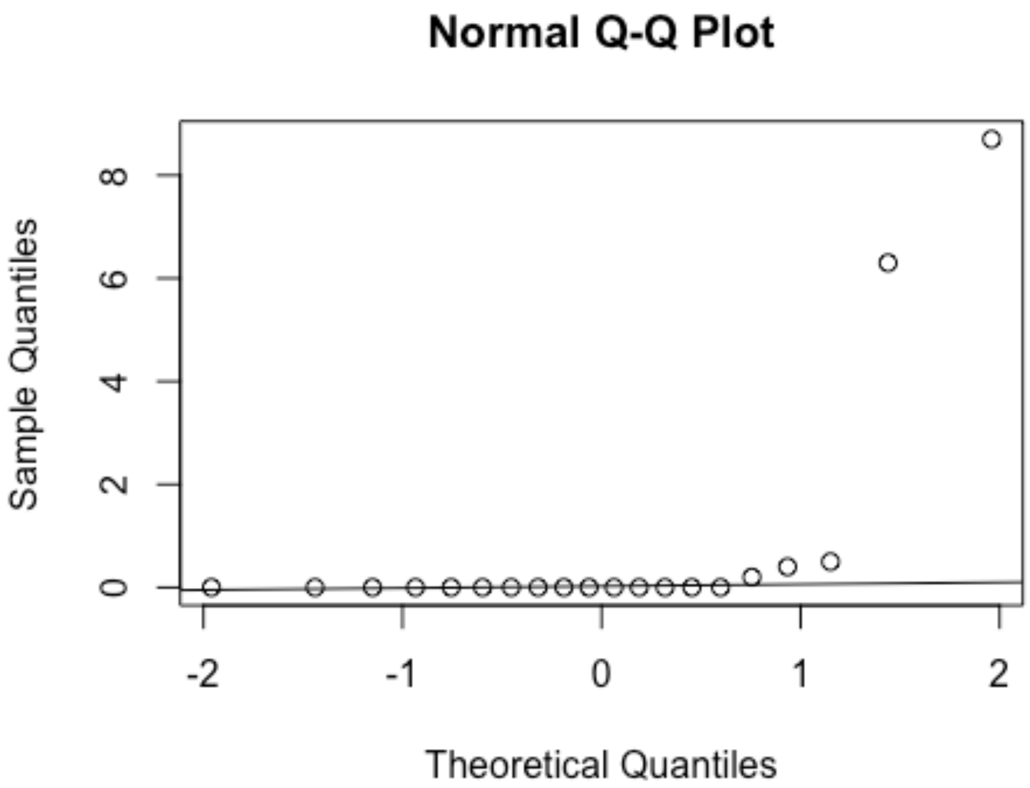
```
##  0 0
## sample estimates:
## difference in location
##                      0

#################### RERAs Index #######################
#Summary
summary(SSdata$reras.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.0000  0.4725  0.2000  8.7000

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

## [1] 1.66687

length(SSdata$reras.index)

## [1] 40

qqnorm(SSdata$reras.index)
qqline(SSdata$reras.index)
```



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

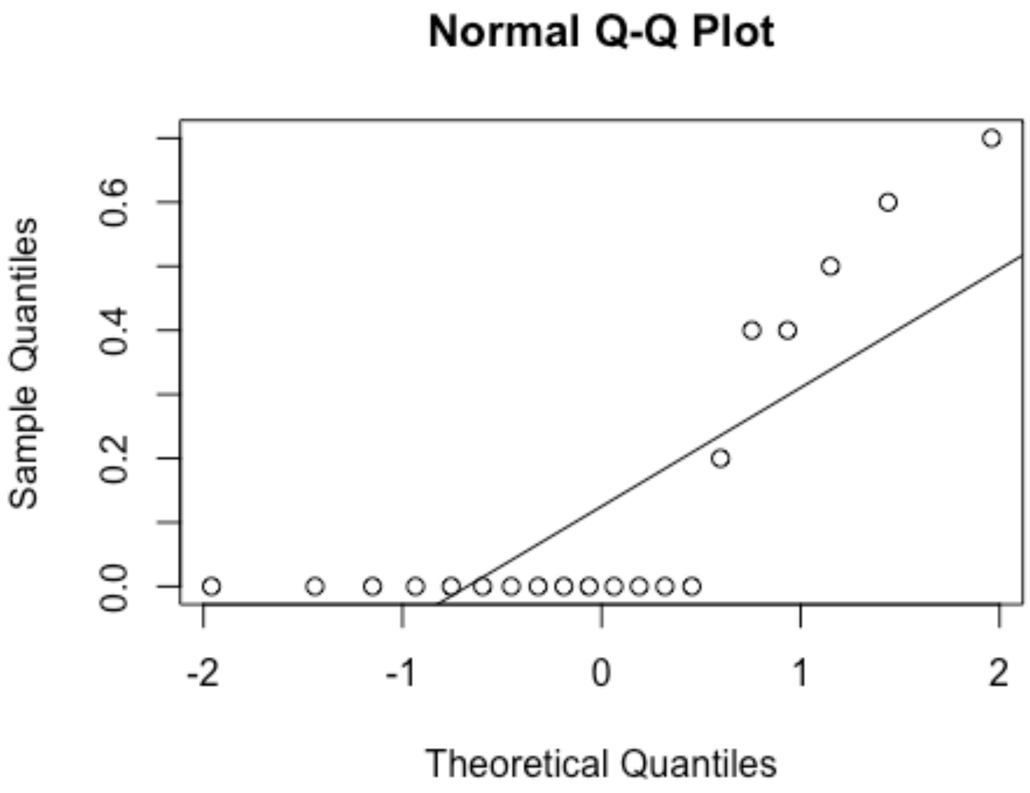
```
##
##  Anderson-Darling normality test
##
## data:  SSdata$reras.index
## A = 11.649, p-value < 2.2e-16

#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

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$reras.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$reras.index,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$reras.index and sub
set(SSdataCompletes, intervention == "PrenaBelt")$reras.index
## V = 15.5, p-value = 0.7789
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.5999963  0.3500676
## sample estimates:
```

```
## (pseudo)median
##     -0.1499727

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.805   0.050   8.700

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

## [1] 2.32684

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

## [1] 20

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



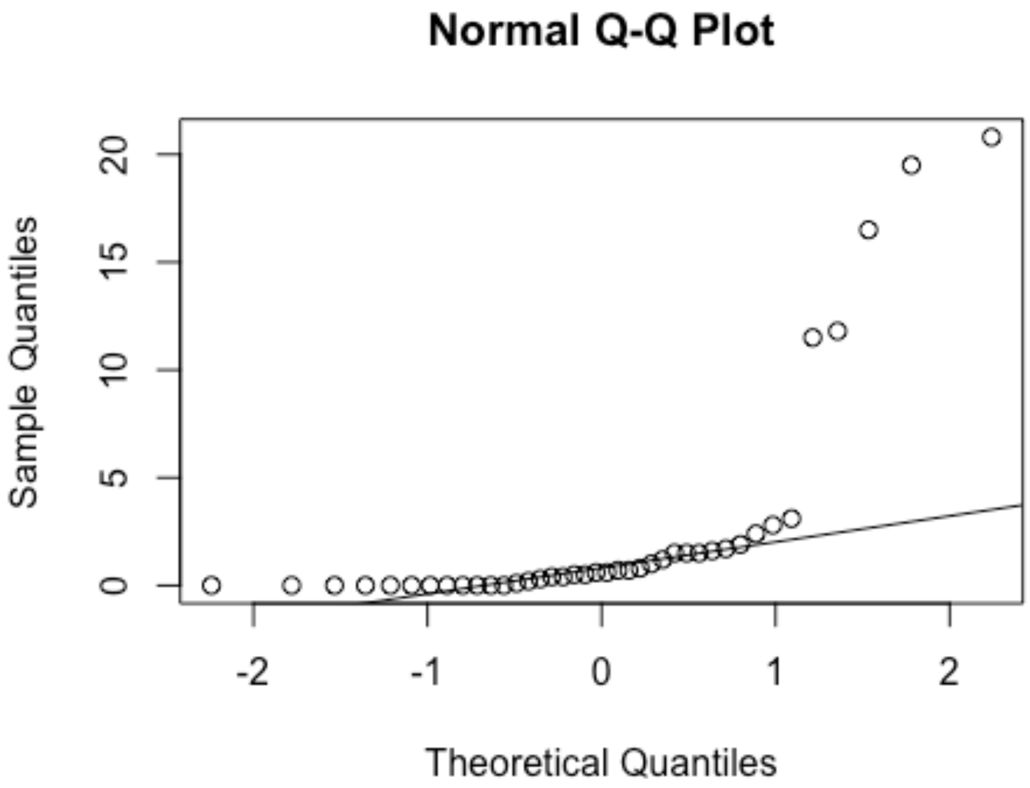
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$reras.index)

##
##  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)
```



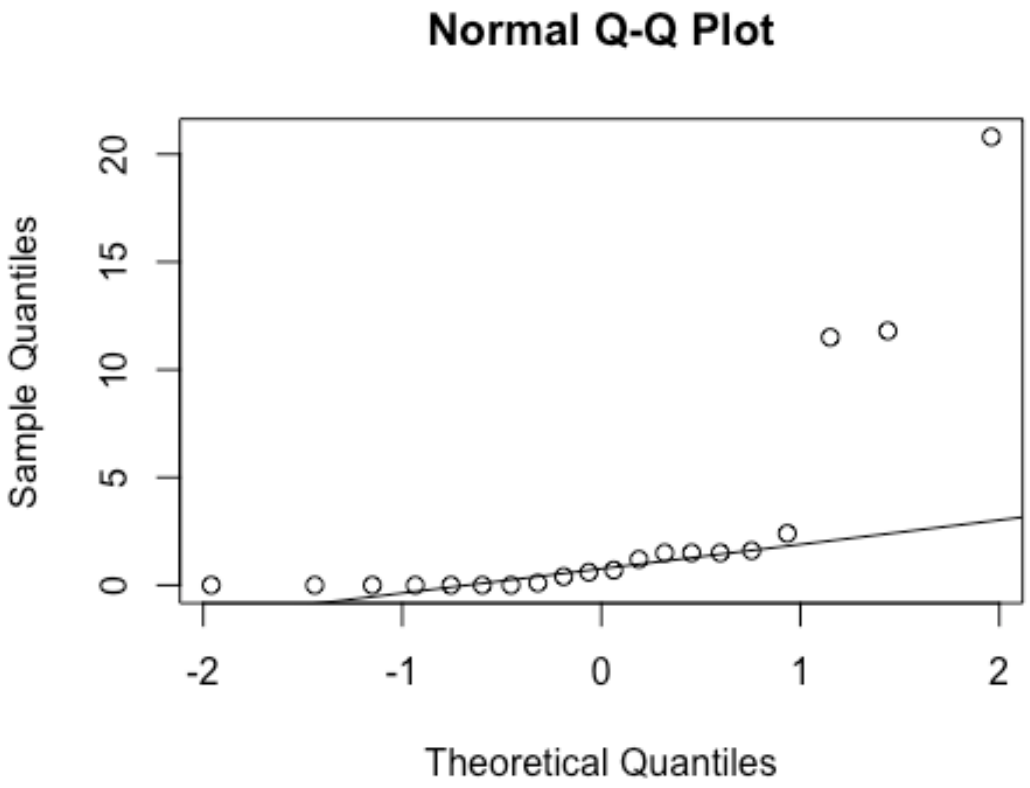
```
ad.test(subset(SSdata, intervention == "sham")$reras.index)

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

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

#non-normal

#FYI - unpaired test
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")$reras.index and subset(SSdat
a, intervention == "PrenaBelt")$reras.index
## W = 207, p-value = 0.8231
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.950633e-05  5.862469e-06
## sample estimates:
## difference in location
##           4.901185e-05

#################### Respiratory Disturbance Index #######################
#Summary
summary(SSdata$rdi.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.600   2.652   1.625  20.800

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

## [1] 5.358817

length(SSdata$rdi.index)

## [1] 40

qqnorm(SSdata$rdi.index)
qqline(SSdata$rdi.index)
```

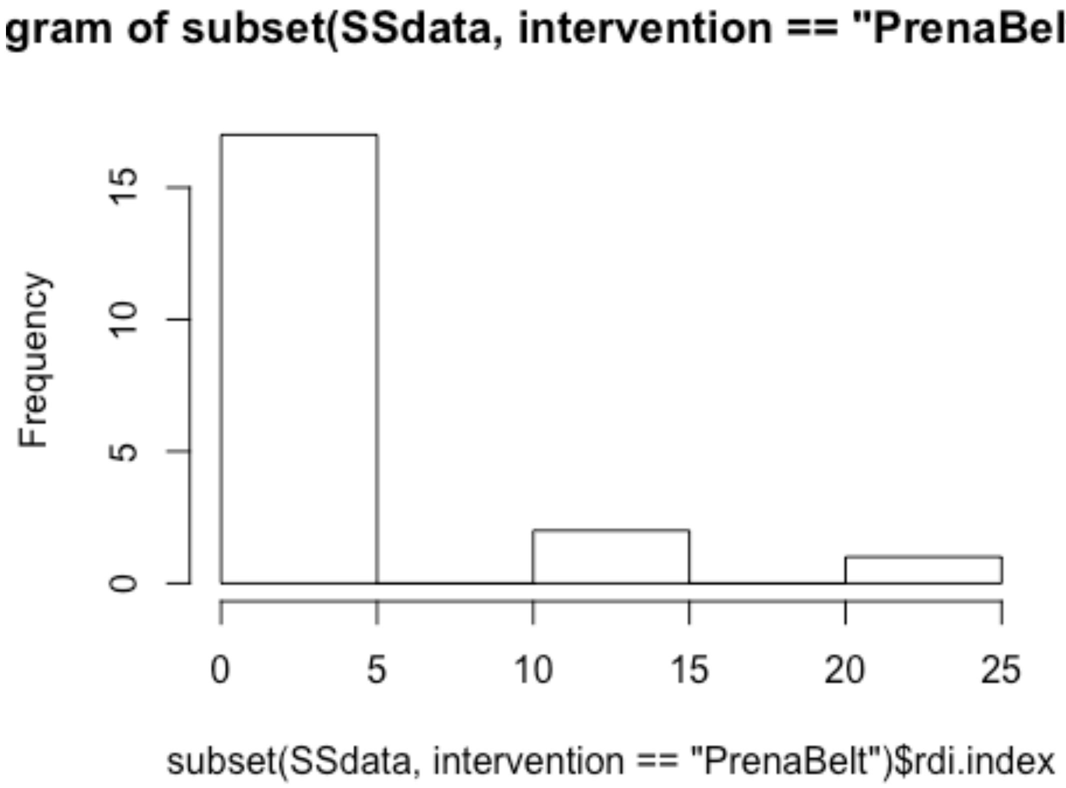


```
ad.test(SSdata$rdi.index)

##
##  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
```

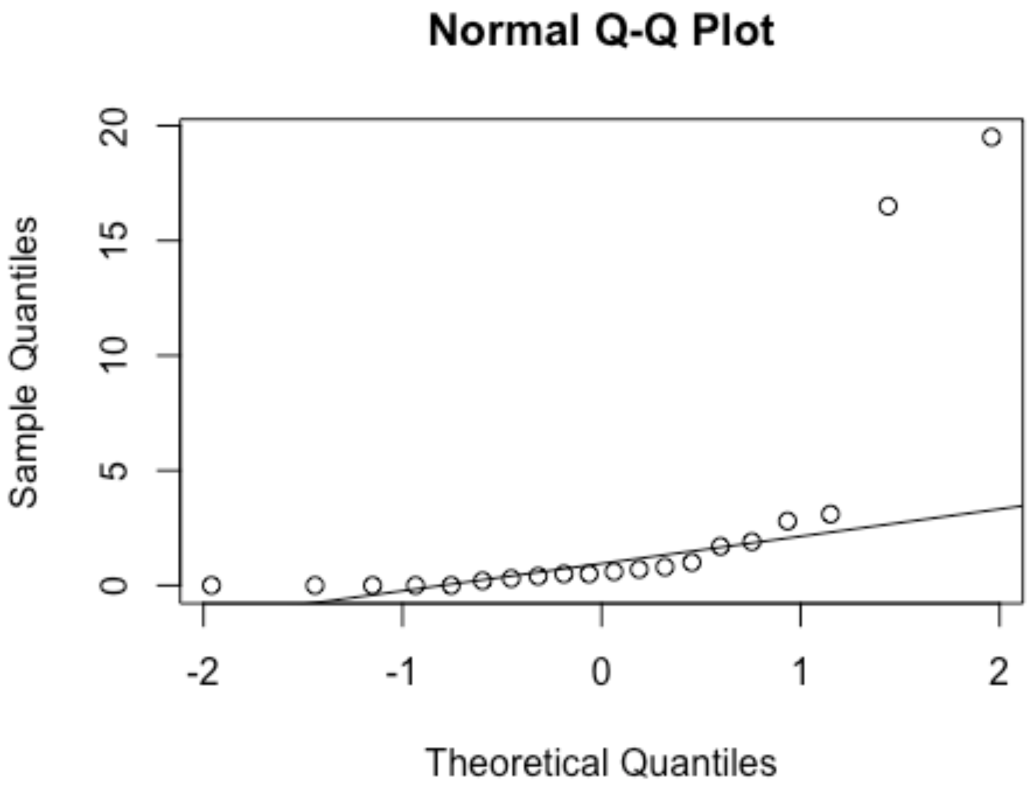
```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#non-normal - do Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$rdi.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$rdi.index,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

## 
##  Wilcoxon signed rank test with continuity correction
## 
## data:  subset(SSdataCompletes, intervention == "sham")$rdi.index and subse
t(SSdataCompletes, intervention == "PrenaBelt")$rdi.index
## V = 67, p-value = 0.6699
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.1999821  0.6499711
## sample estimates:
## (pseudo)median 
##      -0.199951

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

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   0.000   0.000   0.650   2.780   1.525  20.800

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

## [1] 5.463236

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

## [1] 20

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



```
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)
```

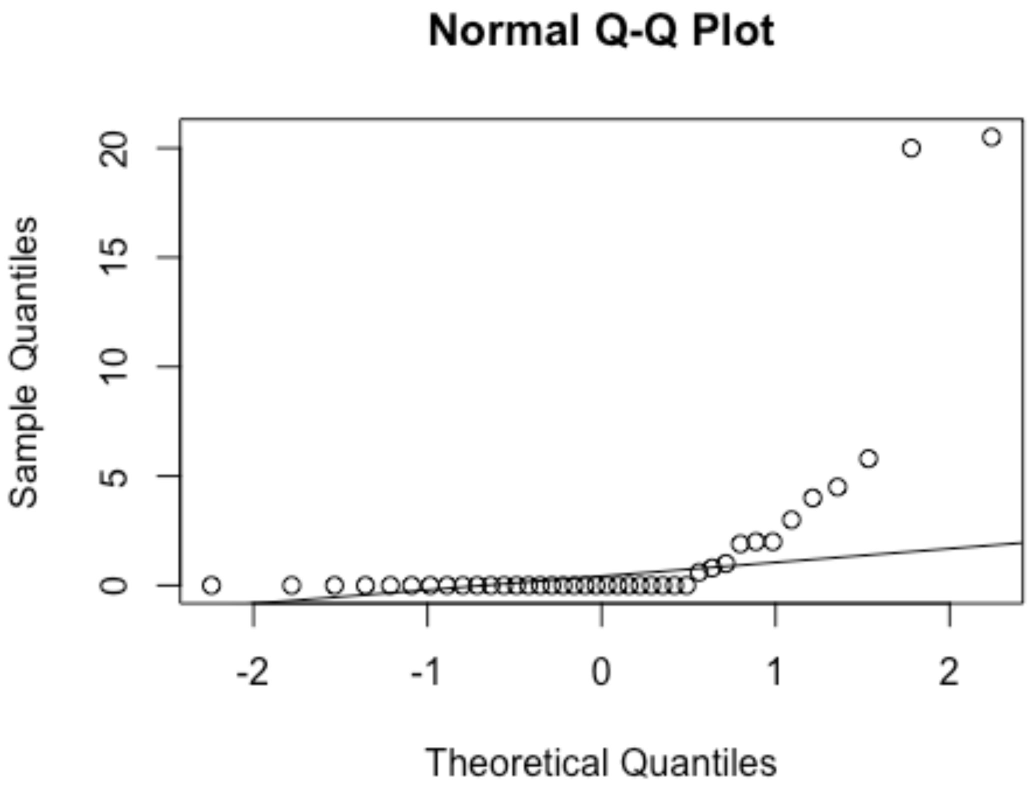


```
#non-normal

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)
```



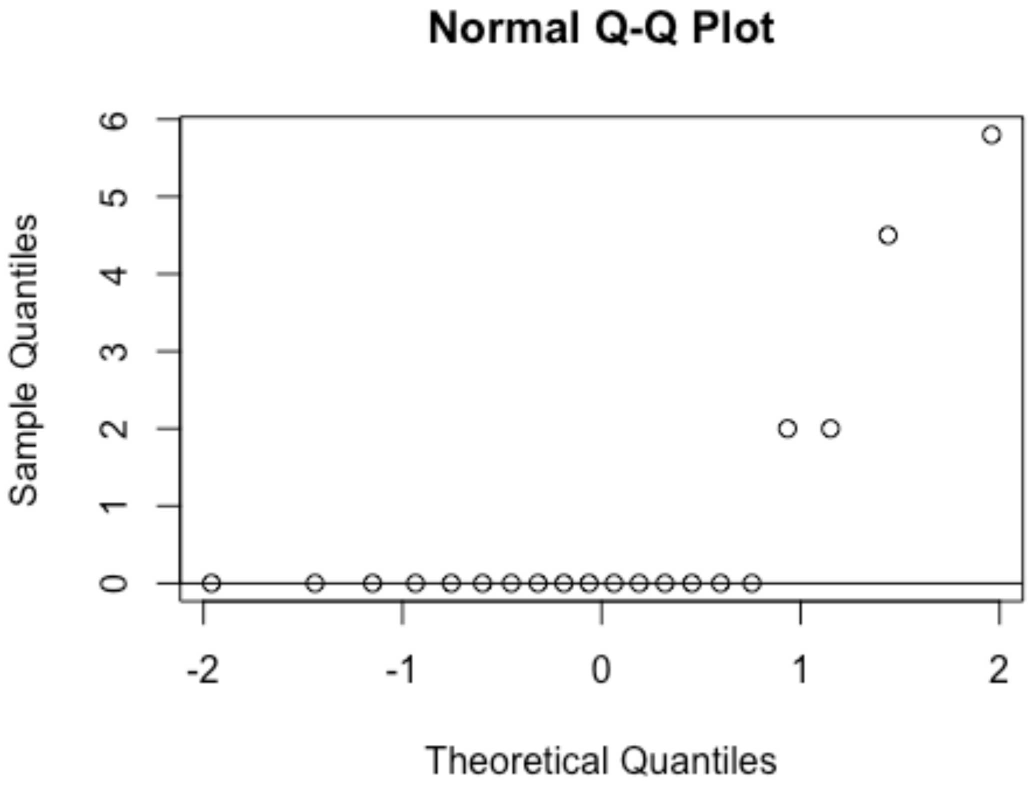
```
ad.test(subset(SSdata, intervention == "sham")$rdi.index)

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

#non-normal

#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
##
```

```
## data:  subset(SSdata, intervention == "sham")$rdi.index and subset(SSdata,
intervention == "PrenaBelt")$rdi.index
## W = 206, p-value = 0.8801
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.7000762  0.5000008
## sample estimates:
## difference in location
##           8.805182e-05

#################### Supine Event Index #######################
#Summary
summary(SSdata$index.of.supine.events)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   1.652   0.850  20.500

sd(SSdata$index.of.supine.events, na.rm = TRUE)

## [1] 4.539061

length(SSdata$index.of.supine.events)

## [1] 40

qqnorm(SSdata$index.of.supine.events)
qqline(SSdata$index.of.supine.events)
```

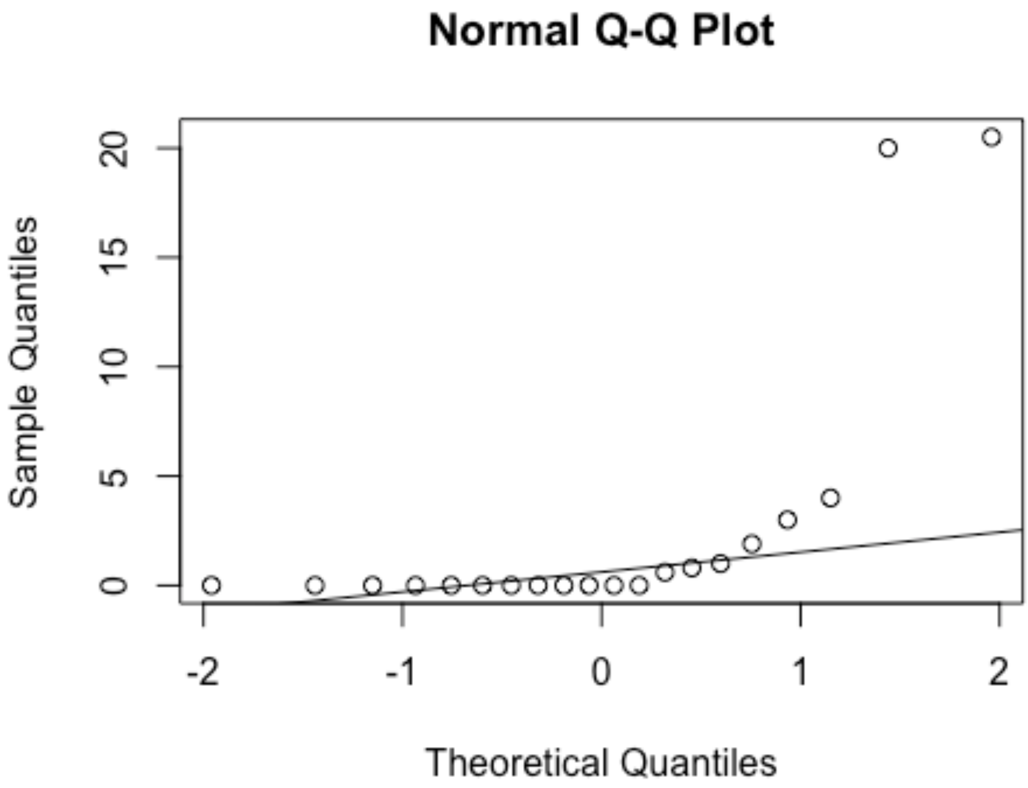


```
ad.test(SSdata$index.of.supine.events)

##
##  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
```

```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$index.of.supine.e
vents,
       subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.supine.e
vents,
       paired = TRUE)

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$index.of.supine.eve
nts and subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.supine.
events
## V = 35, p-value = 0.4755
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.715   0.000   5.800

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

## [1] 1.649011

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

## [1] 20

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

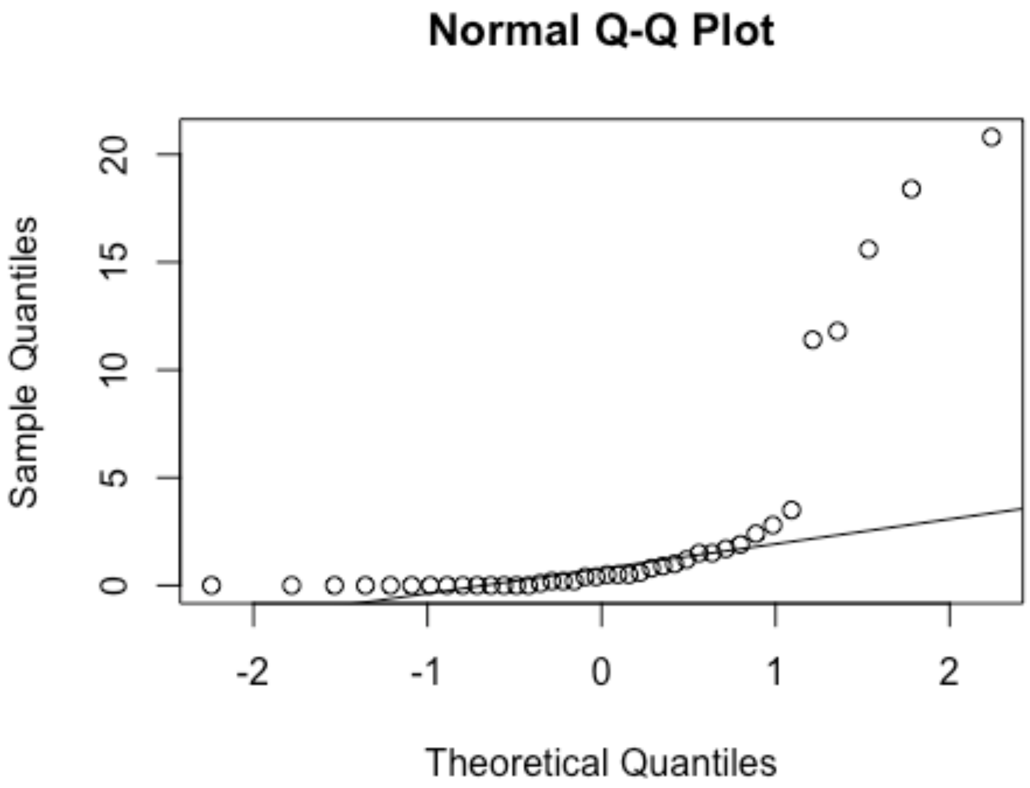


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$index.of.supine.events)

##
##  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)
```



```
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

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$index.of.supine.events,
            subset(SSdata, intervention == "PrenaBelt")$index.of.supine.event
s,
            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
```

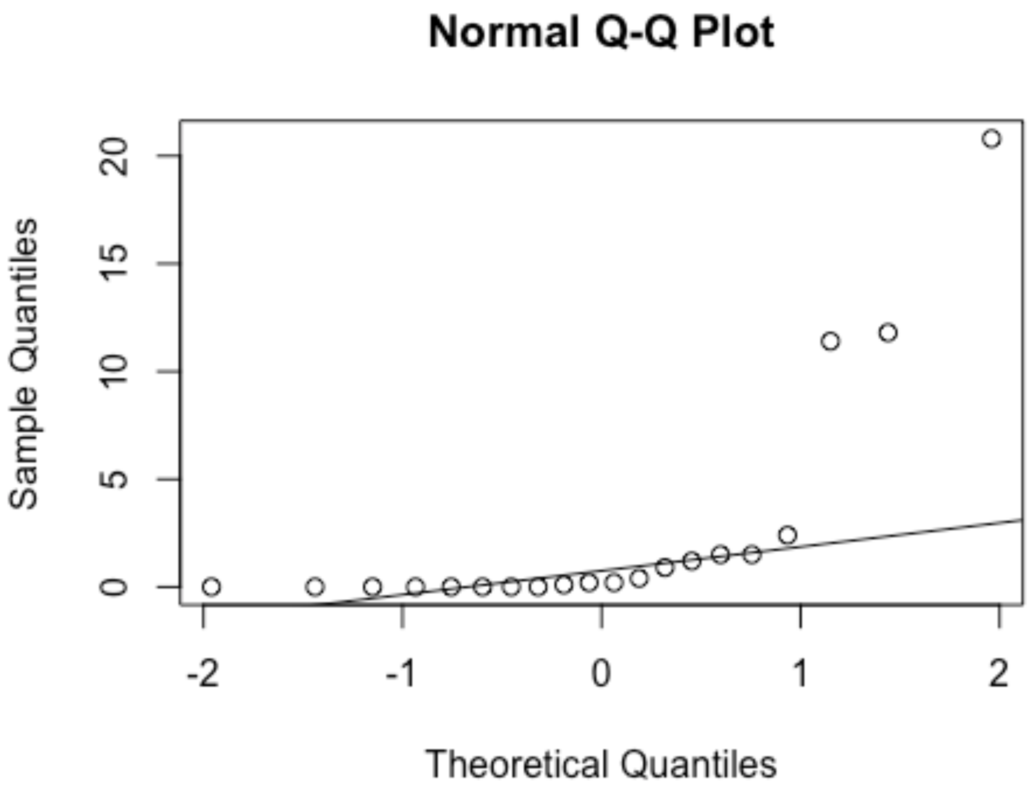
```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$index.of.supine.events and s
ubset(SSdata, intervention == "PrenaBelt")$index.of.supine.events
## W = 236, p-value = 0.2362
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.0000813554  0.6000459383
## sample estimates:
## difference in location
##           7.189321e-06

#################### Non-Supine Event Index #######################
#Summary
summary(SSdata$index.of.non.supine.events)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.45    2.52    1.55   20.80

sd(SSdata$index.of.non.supine.events, na.rm = TRUE)

## [1] 5.242929

length(SSdata$index.of.non.supine.events)

## [1] 40

qqnorm(SSdata$index.of.non.supine.events)
qqline(SSdata$index.of.non.supine.events)
```



```
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
```

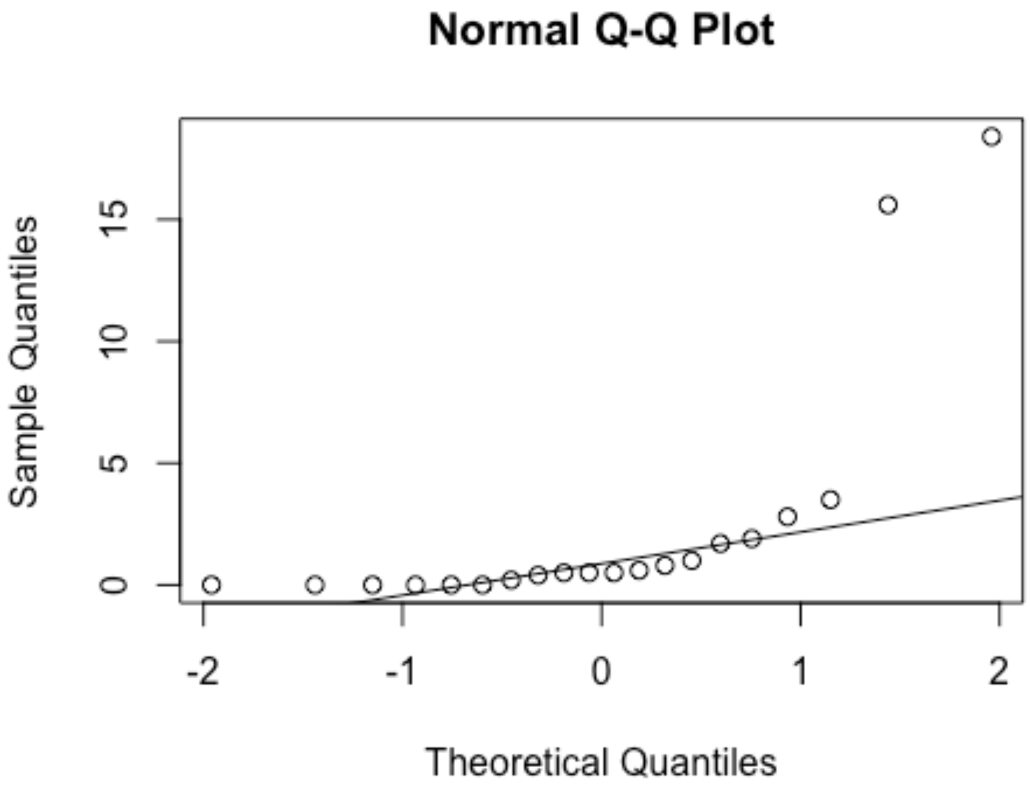
```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#non-normal - use Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$index.of.non.supi
ne.events,
       subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.non.supi
ne.events,
       paired = TRUE, conf.int = TRUE)

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

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

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$index.of.non.supine
.events and subset(SSdataCompletes, intervention == "PrenaBelt")$index.of.non
.supine.events
## V = 70.5, p-value = 0.9176
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.0000733  0.8499829
## sample estimates:
## (pseudo)median
##     0.04999832

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.event
s)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.20    2.62    1.50   20.80

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

## [1] 5.512245
```

```
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
)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.event
s)

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

#non-normal

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

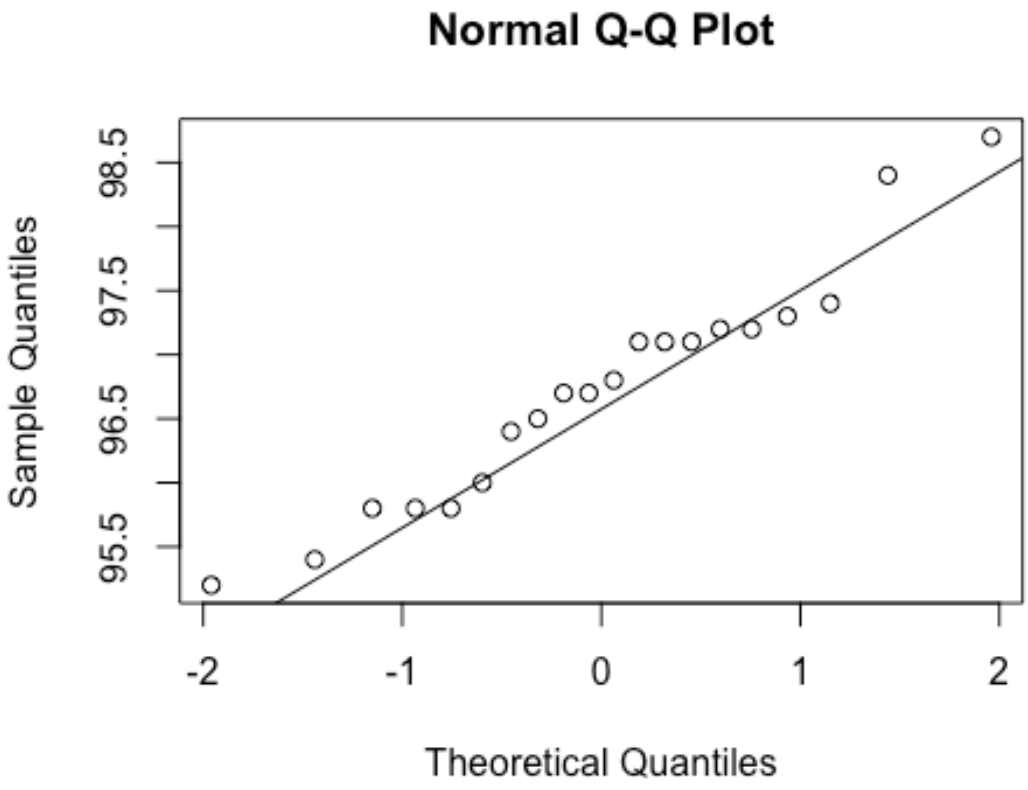
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.50    2.42    1.75   18.40

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)
```



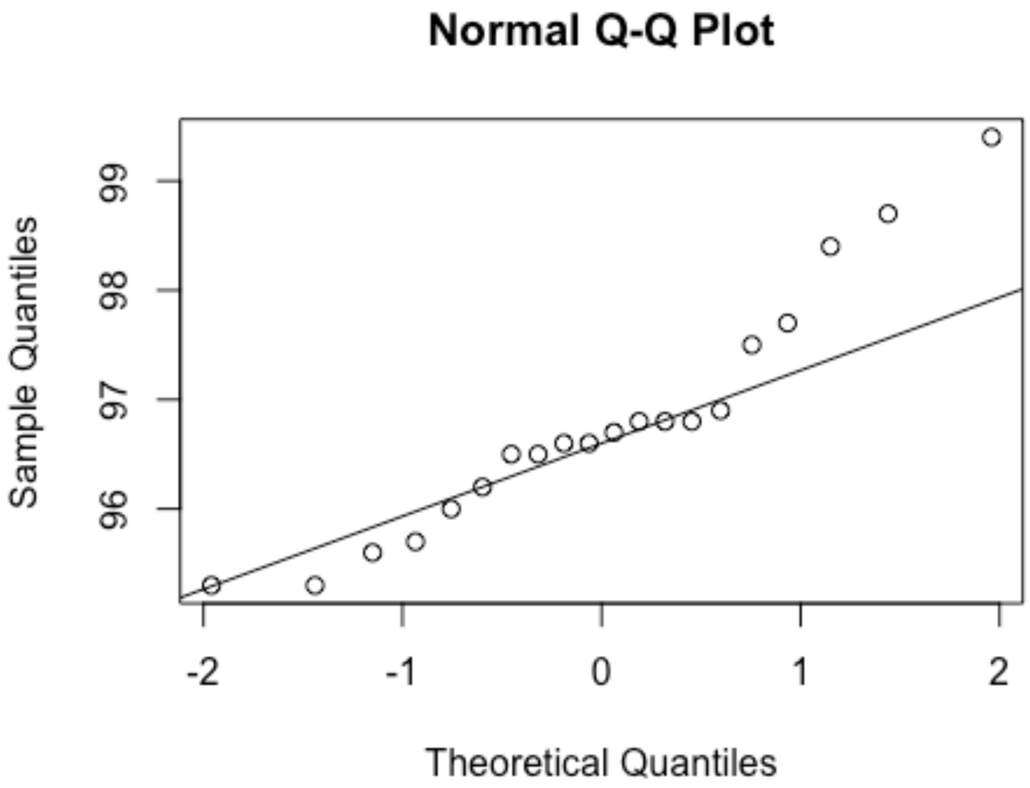
```
ad.test(subset(SSdata, intervention == "sham")$index.of.non.supine.events)

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

#non-normal


#FYI - unpaired test
```

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

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$index.of.non.supine.events a
nd subset(SSdata, intervention == "PrenaBelt")$index.of.non.supine.events
## W = 222.5, p-value = 0.5428
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.3999612  0.5999875
## sample estimates:
## difference in location
##           5.005918e-06

#################### Mean SpO2 AWAKE #######################
#Summary
summary(SSdata$mean.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   95.20   96.00   96.70   96.76   97.20   99.40

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

## [1] 0.99242

length(SSdata$mean.sao2.awake)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(mean.sao2.awake ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: mean.sao2.awake
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.049  0.0490  0.0464 0.8306
## night               1  0.256  0.2560  0.2425 0.6254
```

```
## intervention:night  1  0.100  0.1000  0.0947 0.7600
## Residuals          36 38.006  1.0557

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.awake,
       subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.awake,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.awake and
subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.awake
## t = 0.53846, df = 19, p-value = 0.5965
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.2020931  0.3420931
## sample estimates:
## mean of the differences
##                    0.07

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   95.20   95.95   96.75   96.73   97.20   98.70

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

## [1] 0.909077

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

## [1] 20

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

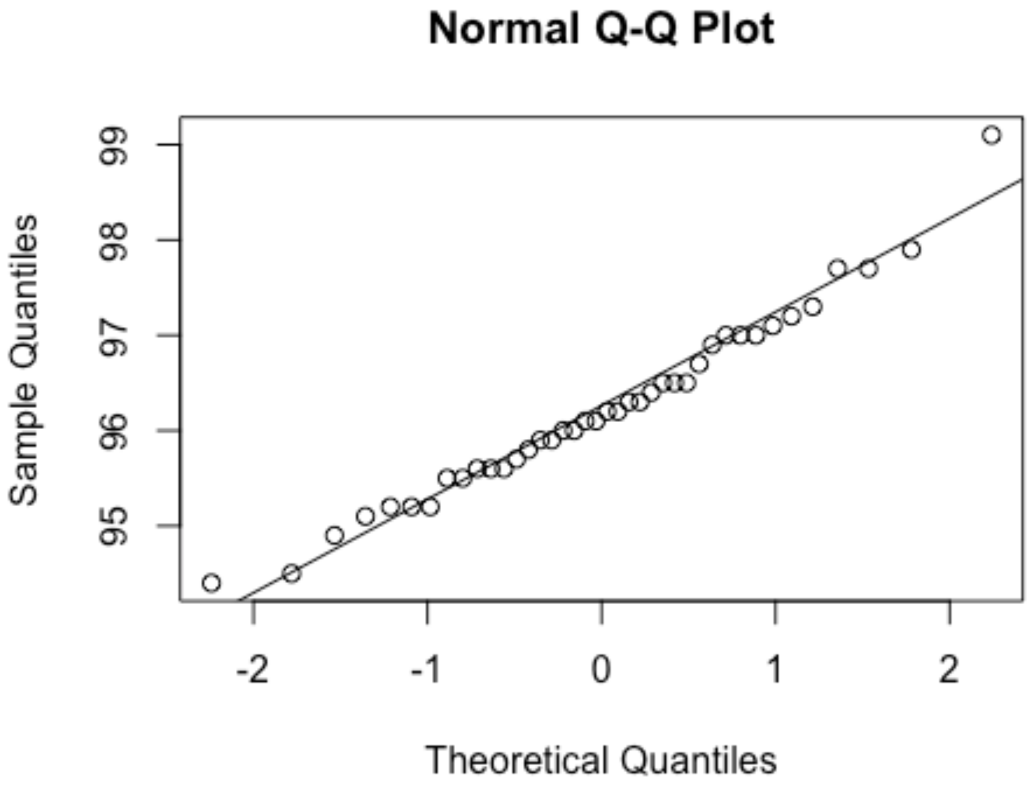


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.awake)

##
##  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

#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:
```

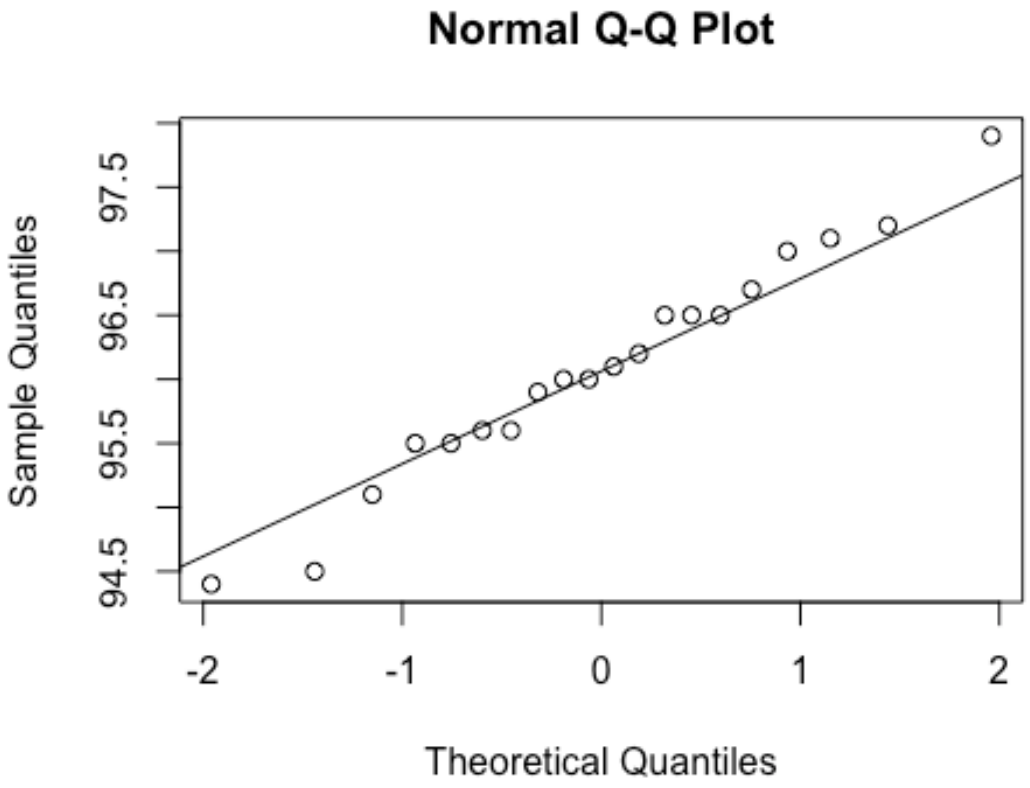
```
## mean of x mean of y
##     96.80     96.73

#################### Mean SpO2 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)
```



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

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

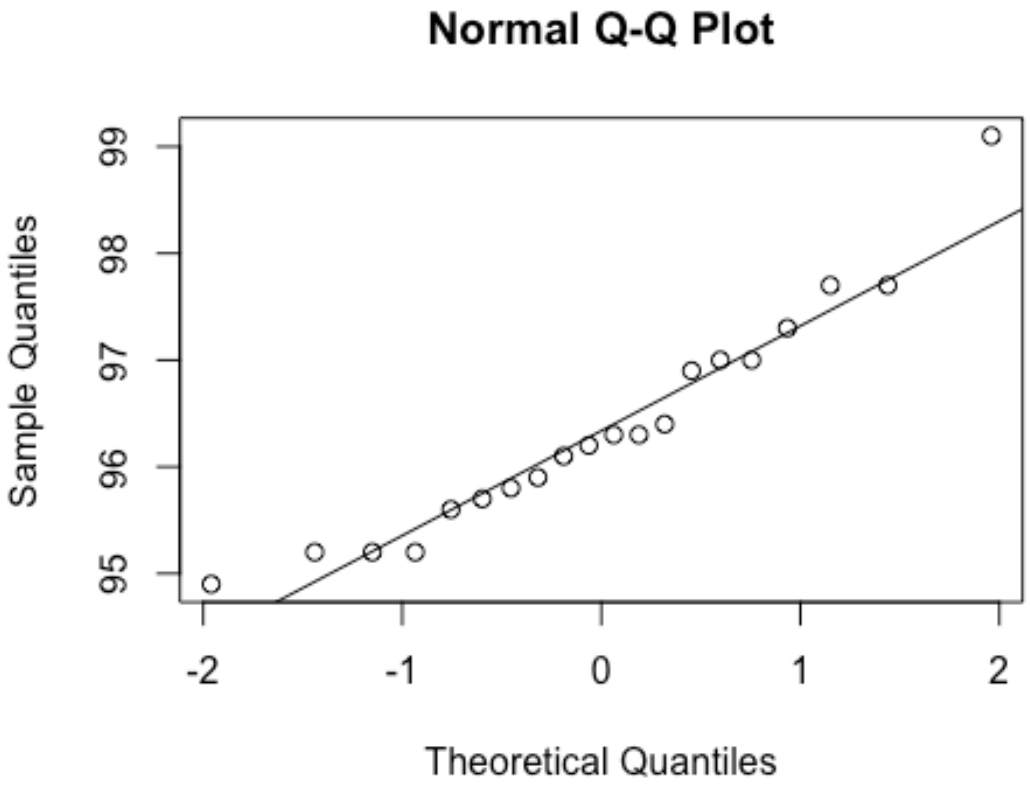
```
##
## data:  SSdata$mean.sao2.nrem
## A = 0.24673, p-value = 0.7391

#normal

#ANOVA
night_tx_difference <- anova(lm(mean.sao2.nrem ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: mean.sao2.nrem
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.812 0.81225  0.8438 0.3644
## night               1  0.992 0.99225  1.0308 0.3167
## intervention:night  1  0.090 0.09025  0.0938 0.7612
## Residuals          36 34.653 0.96258

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.nrem,
       subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.nrem,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.nrem and
subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.nrem
## t = 1.4182, df = 19, p-value = 0.1723
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.1356036  0.7056036
## sample estimates:
## mean of the differences
##                   0.285

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   94.40   95.57   96.05   96.09   96.55   97.90

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

## [1] 0.8837123

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

## [1] 20
```

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



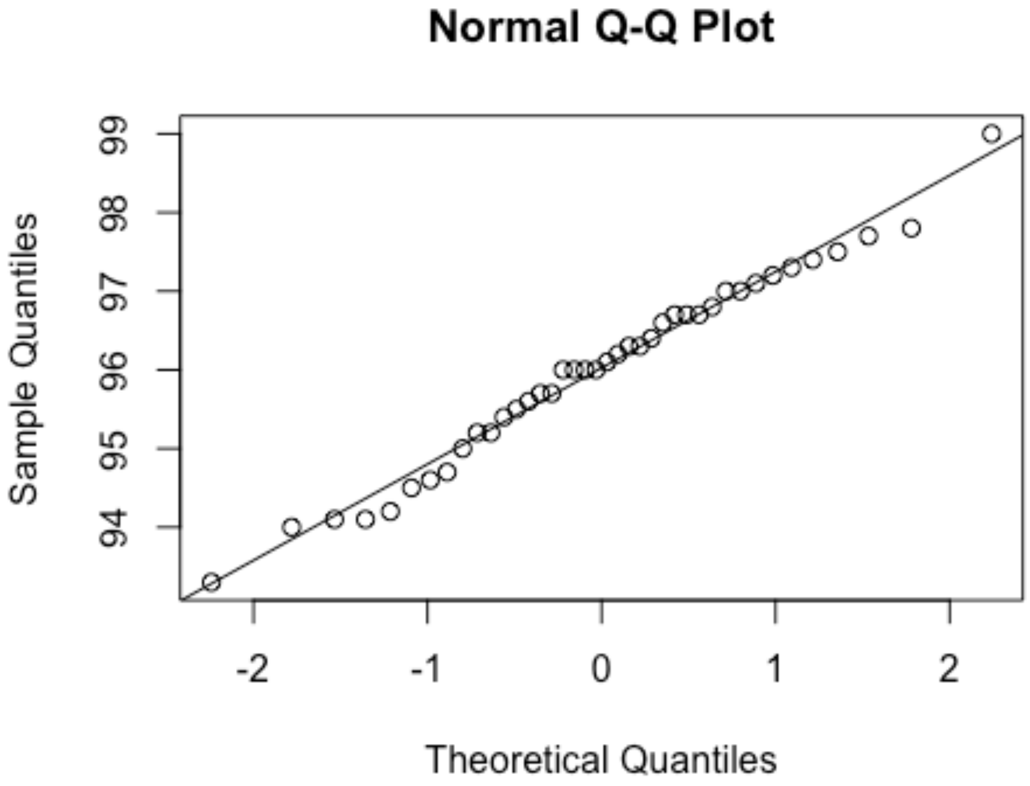
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.nrem)

##
##  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
```

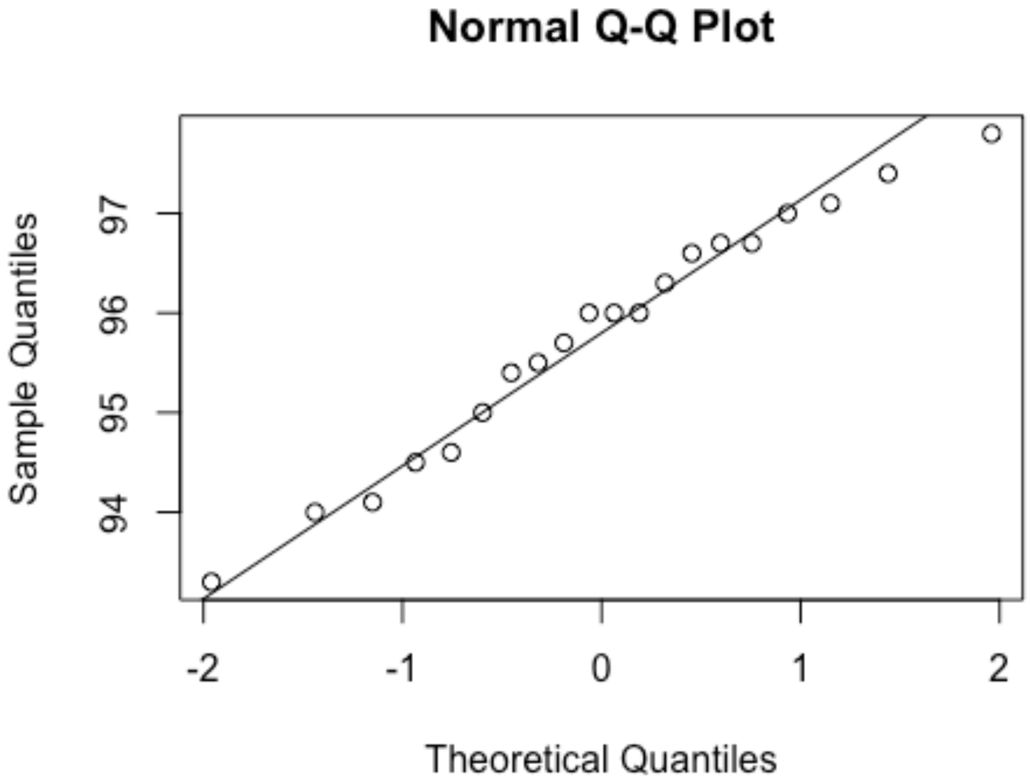
```
## 95 percent confidence interval:
##  -0.3363889  0.9063889
## sample estimates:
## mean of x mean of y
##    96.375    96.090

#################### Mean SpO2 REM #######################
#Summary
summary(SSdata$mean.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   93.30   95.20   96.05   96.02   96.85   99.00

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

## [1] 1.234244

length(SSdata$mean.sao2.rem)

## [1] 40

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



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

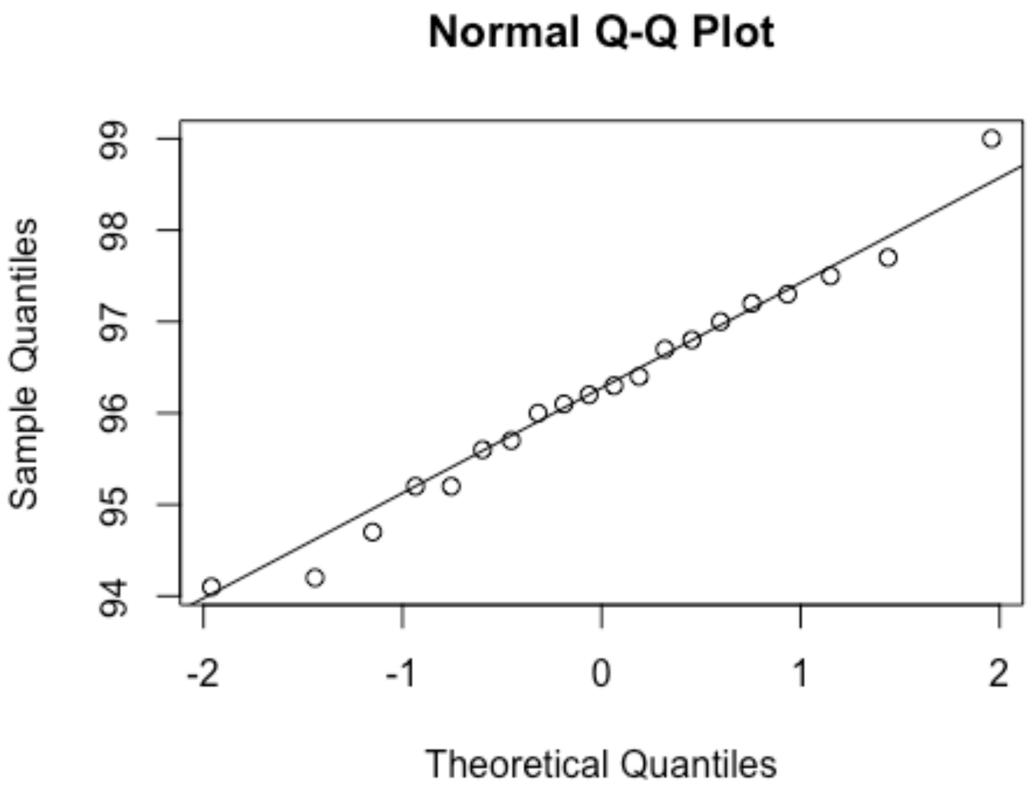
```
##
##  Anderson-Darling normality test
##
## data:  SSdata$mean.sao2.rem
## A = 0.23901, p-value = 0.7646

#normal

#ANOVA
night_tx_difference <- anova(lm(mean.sao2.rem ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: mean.sao2.rem
##                     Df Sum Sq Mean Sq F value Pr(>F)
## intervention         1  2.116  2.1160  1.4834 0.2312
## night                1  3.025  3.0250  2.1206 0.1540
## intervention:night   1  2.916  2.9160  2.0442 0.1614
## Residuals           36 51.354  1.4265

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.rem,
       subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.rem,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.rem and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.rem
## t = 1.5919, df = 19, p-value = 0.1279
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.1447888  1.0647888
## sample estimates:
## mean of the differences
##                    0.46

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   93.30   94.90   96.00   95.78   96.70   97.80

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

## [1] 1.229581

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

```
## [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)
```

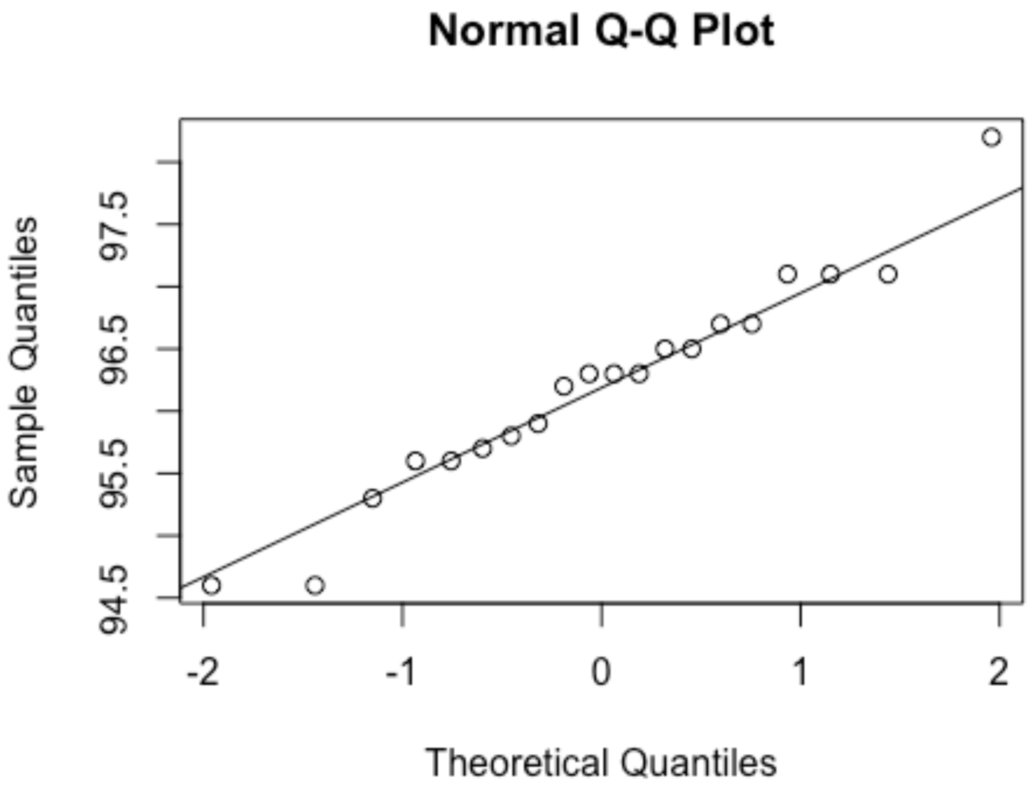
```
## [1] 20

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



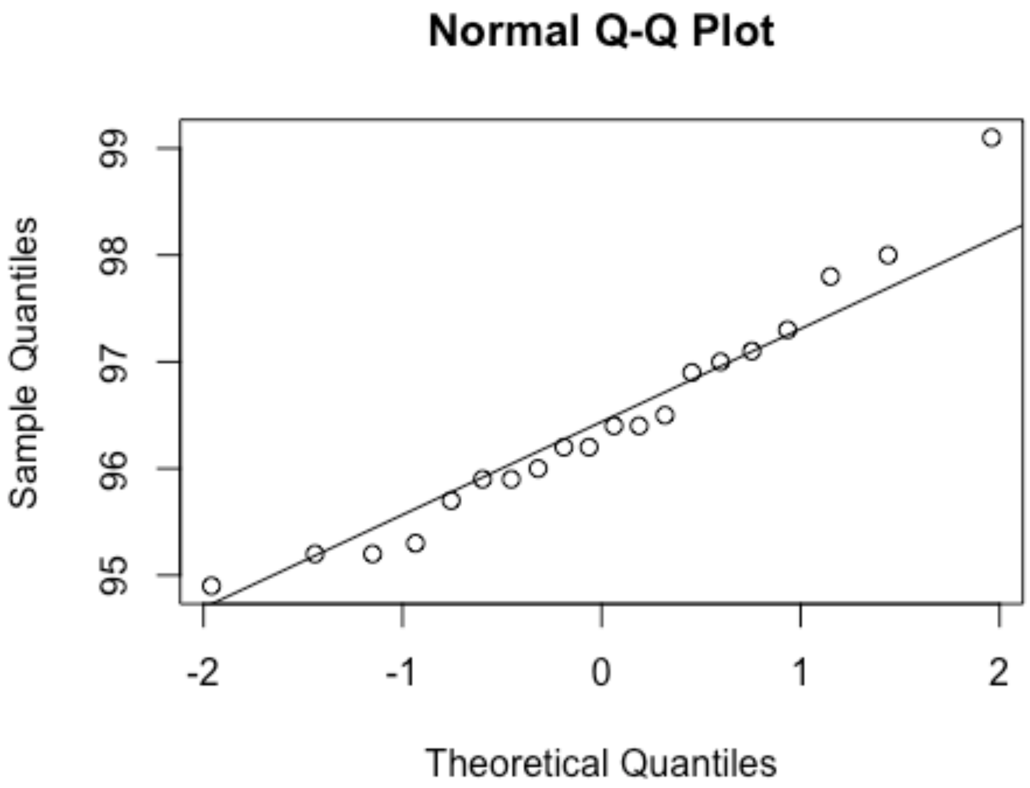
```
ad.test(subset(SSdata, intervention == "sham")$mean.sao2.rem)

##
##  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")$mean.sao2.rem and subset(SSd
ata, intervention == "PrenaBelt")$mean.sao2.rem
```

```
## t = 1.1847, df = 38, p-value = 0.2435
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.3260709  1.2460709
## sample estimates:
## mean of x mean of y
##    96.245    95.785

#################### Mean SpO2 TST ######################
#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$mean.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   94.60   95.70   96.30   96.33   96.93   99.10

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

## [1] 0.9626319

length(SSdata$mean.sao2.tst)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(mean.sao2.tst ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: mean.sao2.tst
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.600 0.60025  0.6241 0.4347
## night               1  0.870 0.87025  0.9048 0.3479
## intervention:night  1  0.042 0.04225  0.0439 0.8352
## Residuals          36 34.627 0.96186

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$mean.sao2.tst,
       subset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.tst,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$mean.sao2.tst and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$mean.sao2.tst
```

```
## t = 1.3161, df = 19, p-value = 0.2038
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.1446432  0.6346432
## sample estimates:
## mean of the differences
##                   0.245

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   94.60   95.68   96.30   96.20   96.70   98.20

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

## [1] 0.8672249

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

## [1] 20

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



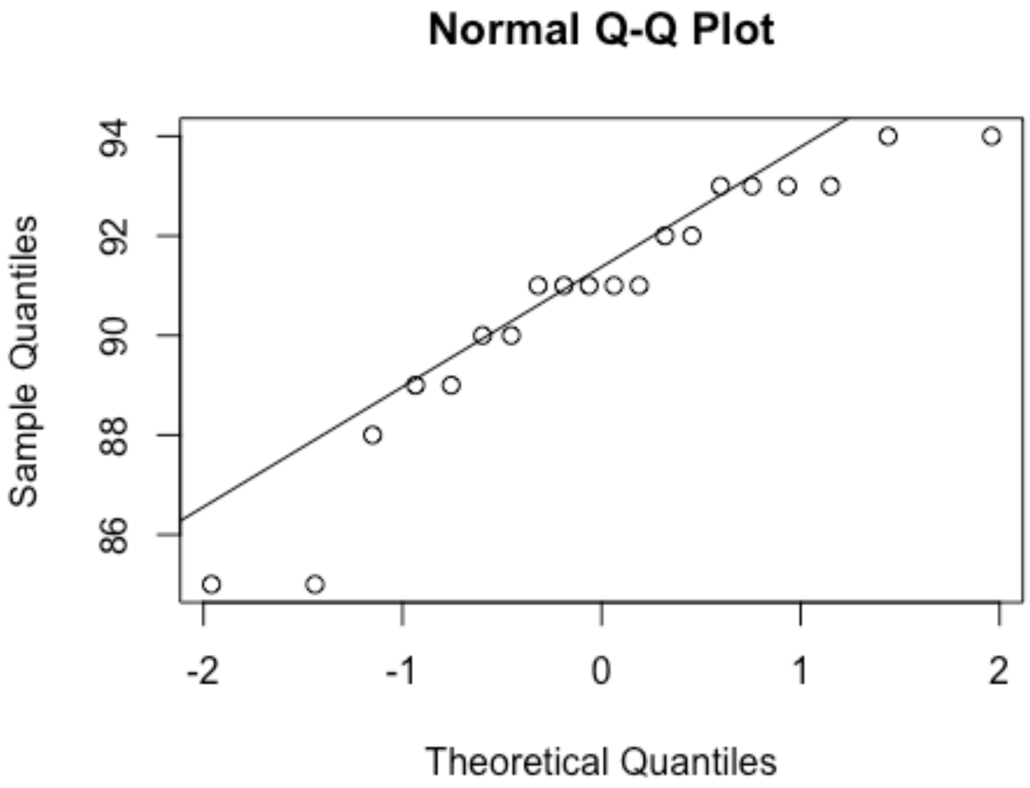
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)

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



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

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$mean.sao2.tst
## A = 0.30299, p-value = 0.5413

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$mean.sao2.tst,
       subset(SSdata, intervention == "PrenaBelt")$mean.sao2.tst)

##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$mean.sao2.tst and subset(SSd
ata, intervention == "PrenaBelt")$mean.sao2.tst
## t = 0.80113, df = 36.596, p-value = 0.4282
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.3748781  0.8648781
## sample estimates:
## mean of x mean of y
##    96.450    96.205

#################### Min SpO2 AWAKE #######################
#Summary
summary(SSdata$min.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   70.00   88.75   91.00   89.75   93.00   94.00

sd(SSdata$min.sao2.awake, na.rm = TRUE)

## [1] 5.026851

length(SSdata$min.sao2.awake)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(min.sao2.awake ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: min.sao2.awake
##                    Df Sum Sq Mean Sq F value  Pr(>F)
## intervention        1   40.0   40.00  1.8391 0.18350
```

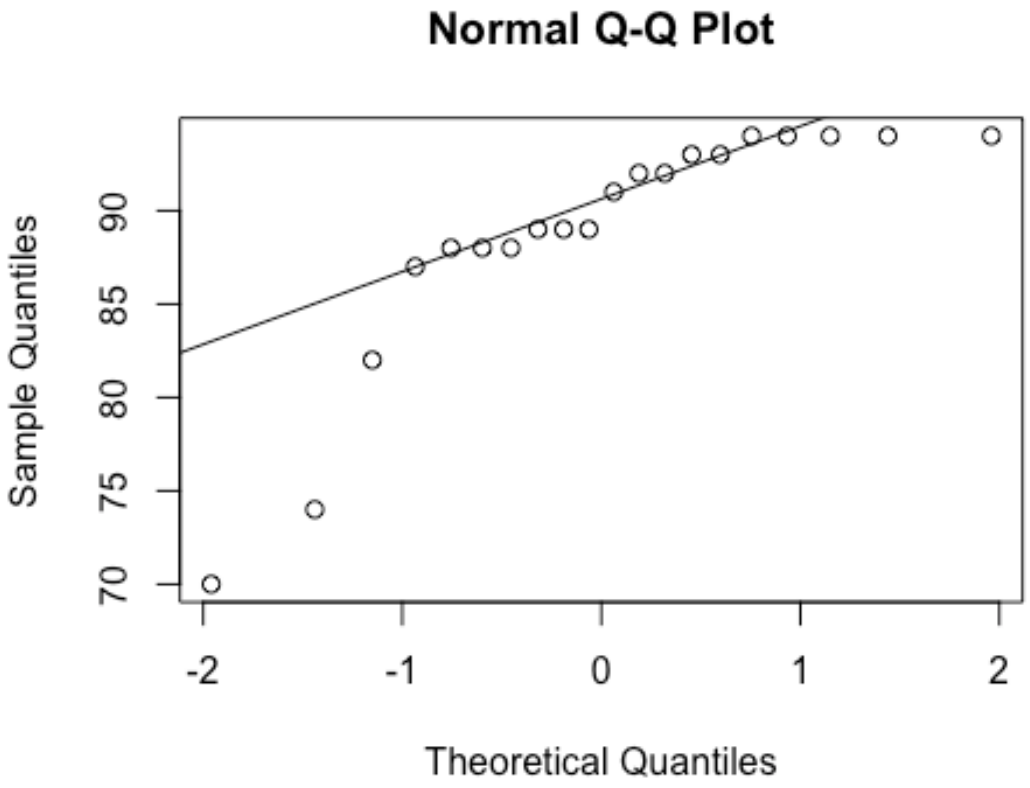
```
## night                1   25.6   25.60  1.1770 0.28518  
## intervention:night  1  136.9  136.90  6.2943 0.01676 *
## Residuals          36  783.0   21.75                  
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.awake,
       subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.awake,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.awake, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.awake, : cannot compute exact confidence interval with
## ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.awake, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.awake, : cannot compute exact confidence interval with
## zeroes

## 
##  Wilcoxon signed rank test with continuity correction
## 
## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.awake and 
subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.awake
## V = 53, p-value = 0.1609
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.9999632  0.5000467
## sample estimates:
## (pseudo)median 
##       -1.49991

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   85.00   89.75   91.00   90.75   93.00   94.00

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

## [1] 2.572629

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

## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)
```



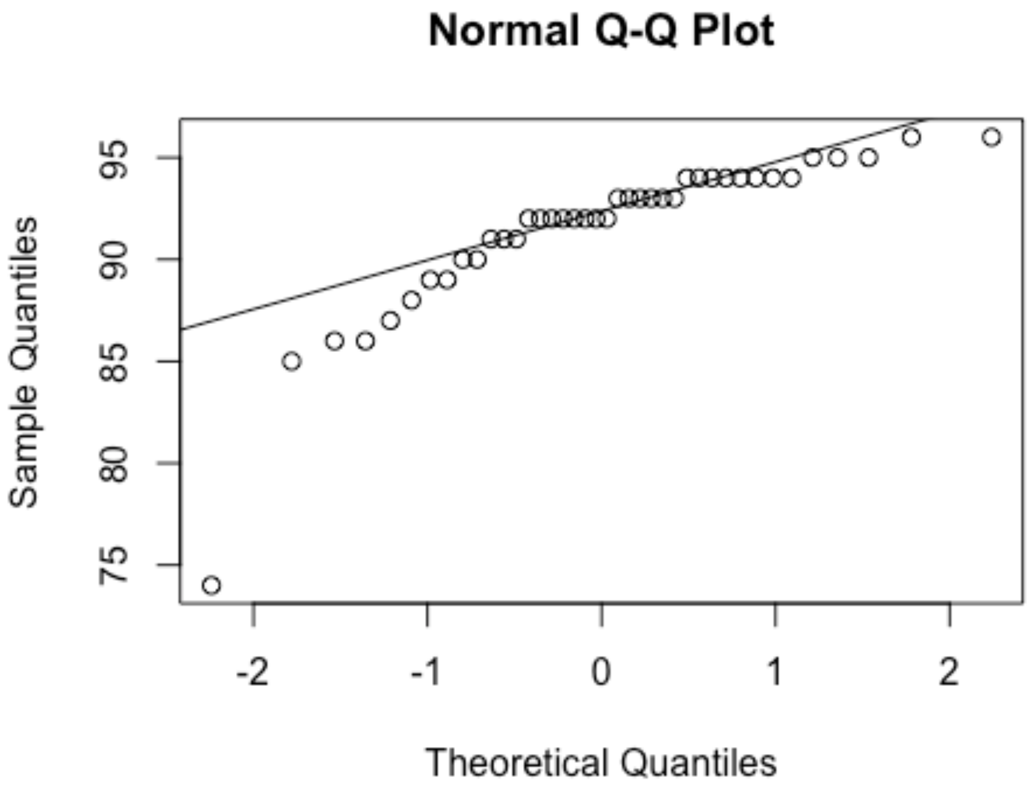
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.awake)

##
##  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)
```



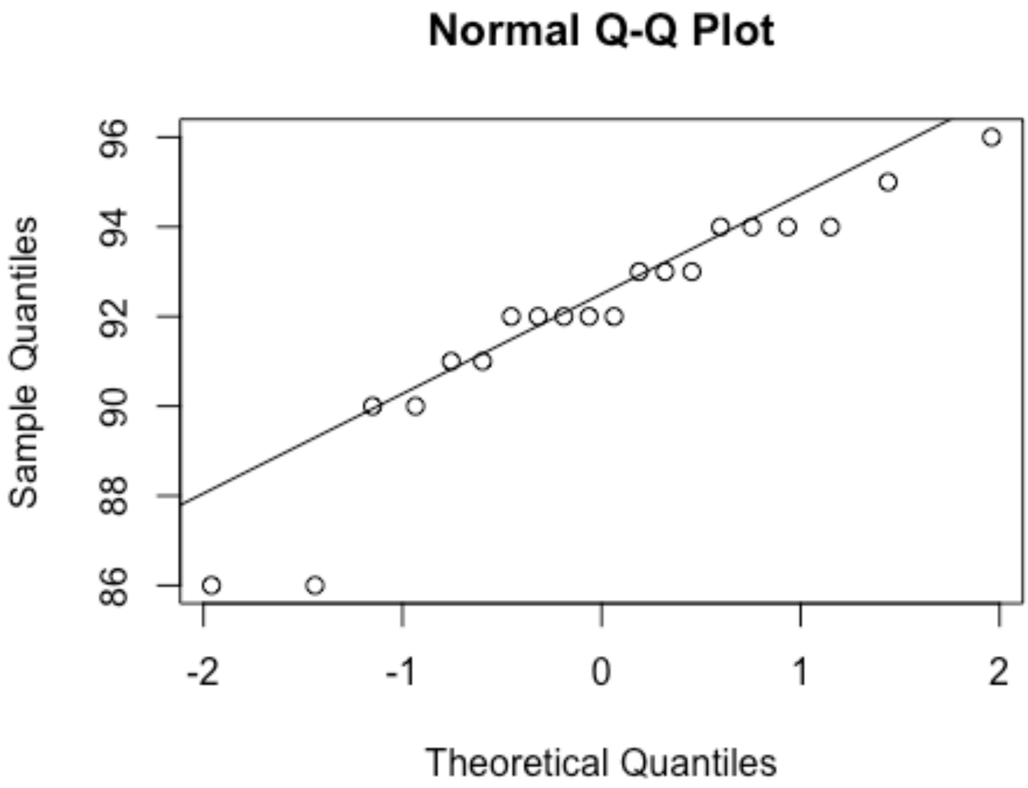
```
ad.test(subset(SSdata, intervention == "sham")$min.sao2.awake)

##
##  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
```

```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$min.sao2.awake and subset(SS
data, intervention == "PrenaBelt")$min.sao2.awake
## W = 184, p-value = 0.6726
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.999945  1.000048
## sample estimates:
## difference in location
##          -7.483333e-05

#################### Min SpO2 NREM #######################
#Summary
summary(SSdata$min.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   74.00   90.75   92.00   91.50   94.00   96.00

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

## [1] 3.928854

length(SSdata$min.sao2.nrem)

## [1] 40

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

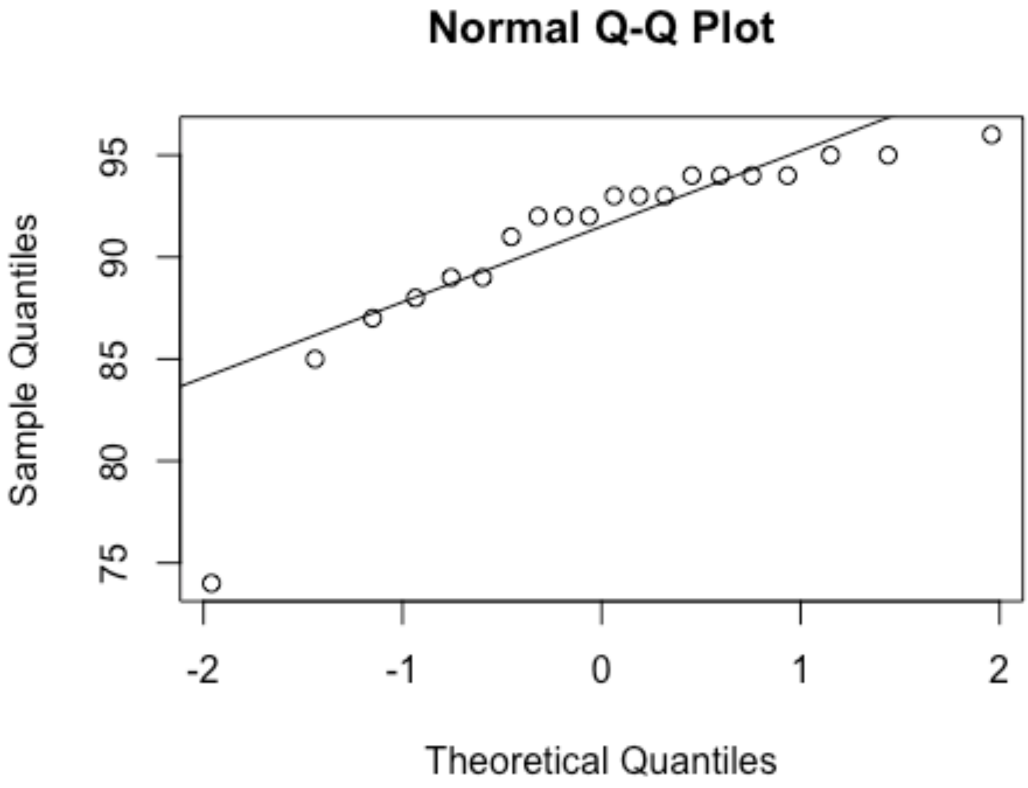


```
ad.test(SSdata$min.sao2.nrem)

##
##  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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.nrem,
       subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.nrem,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.nrem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.nrem, : cannot compute exact confidence interval with tie
s

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.nrem, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.nrem, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.nrem and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.nrem
## V = 46, p-value = 0.26
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.4999583  0.5000763
## sample estimates:
## (pseudo)median
##      -0.500039

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##      86      91      92      92      94      96

sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

## [1] 2.575185

length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

## [1] 20

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

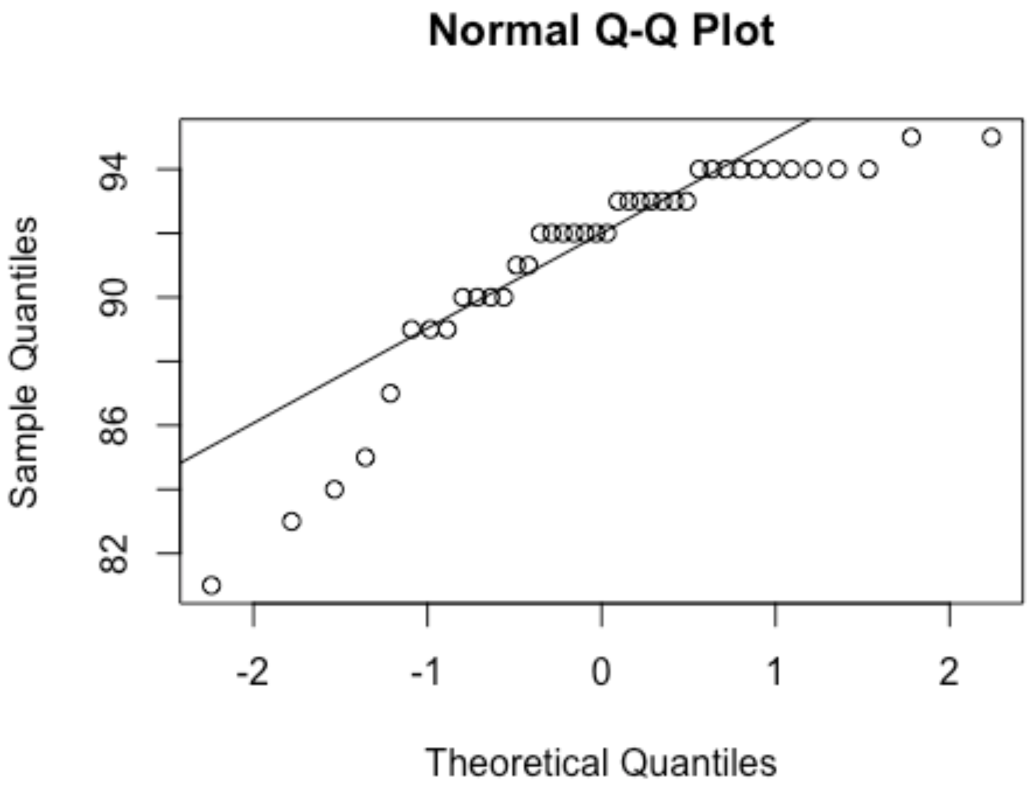


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.nrem)

##
##  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)
```



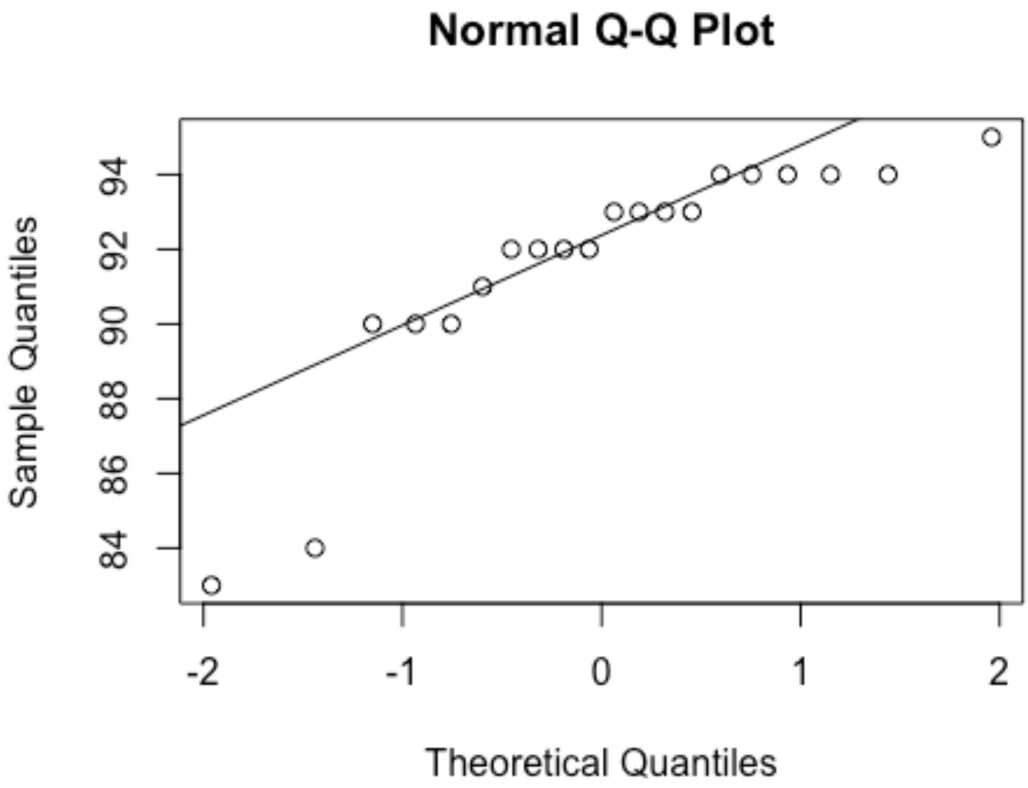
```
ad.test(subset(SSdata, intervention == "sham")$min.sao2.nrem)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$min.sao2.nrem and subset(SSd
ata, intervention == "PrenaBelt")$min.sao2.nrem
## W = 196.5, p-value = 0.9347
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.000016  1.999967
## sample estimates:
## difference in location
##          -3.487271e-05

#################### Min SpO2 REM #######################
#Summary
summary(SSdata$min.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   81.00   90.00   92.00   91.35   94.00   95.00

sd(SSdata$min.sao2.rem, na.rm = TRUE)

## [1] 3.332436

length(SSdata$min.sao2.rem)

## [1] 40

qqnorm(SSdata$min.sao2.rem)
qqline(SSdata$min.sao2.rem)
```

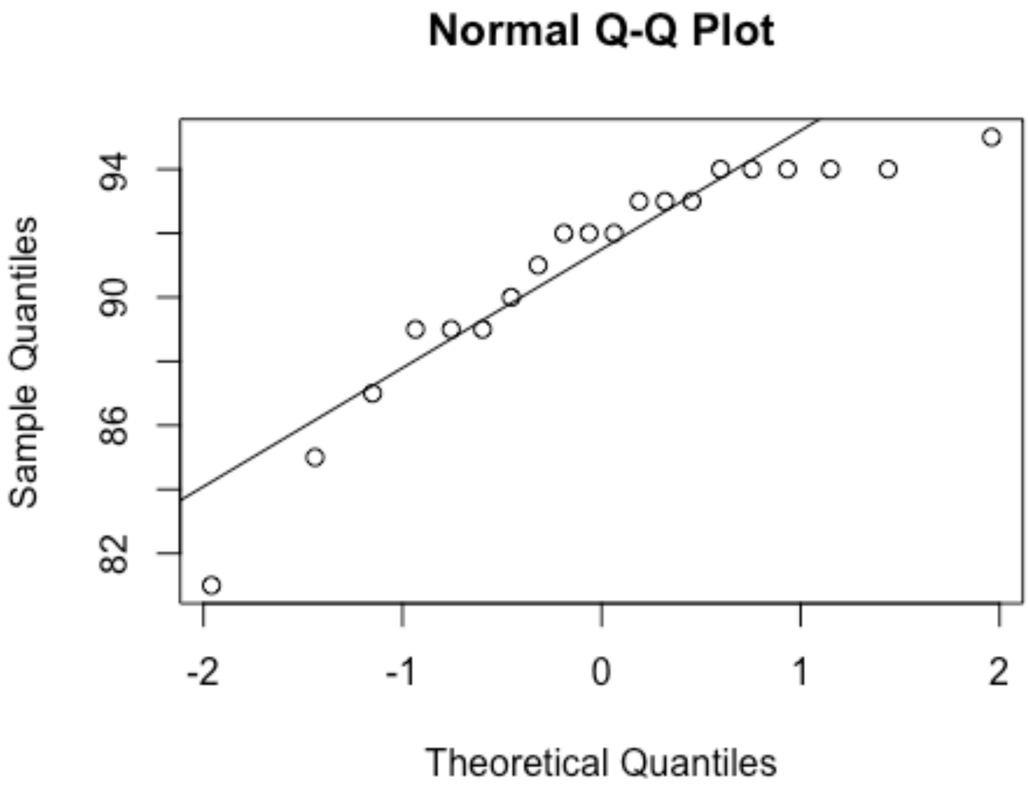


```
ad.test(SSdata$min.sao2.rem)

##
##  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
```

```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.rem,
            subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.rem
,
            paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.rem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.rem, : cannot compute exact confidence interval with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.rem, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.rem, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.rem and su
bset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.rem
## V = 45, p-value = 0.4029
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.4999536  0.9999402
## sample estimates:
## (pseudo)median
##     -0.4999916

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   83.00   90.75   92.50   91.65   94.00   95.00

sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

## [1] 3.150188

length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

## [1] 20

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



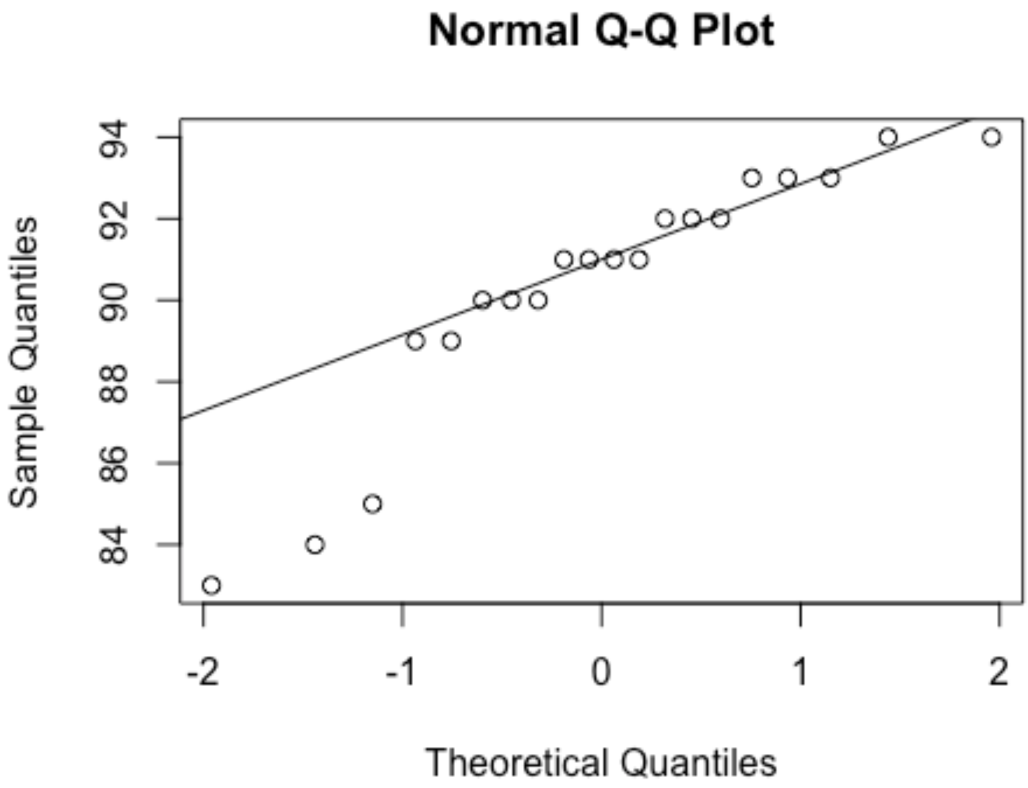
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$min.sao2.rem)

##
##  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)
```



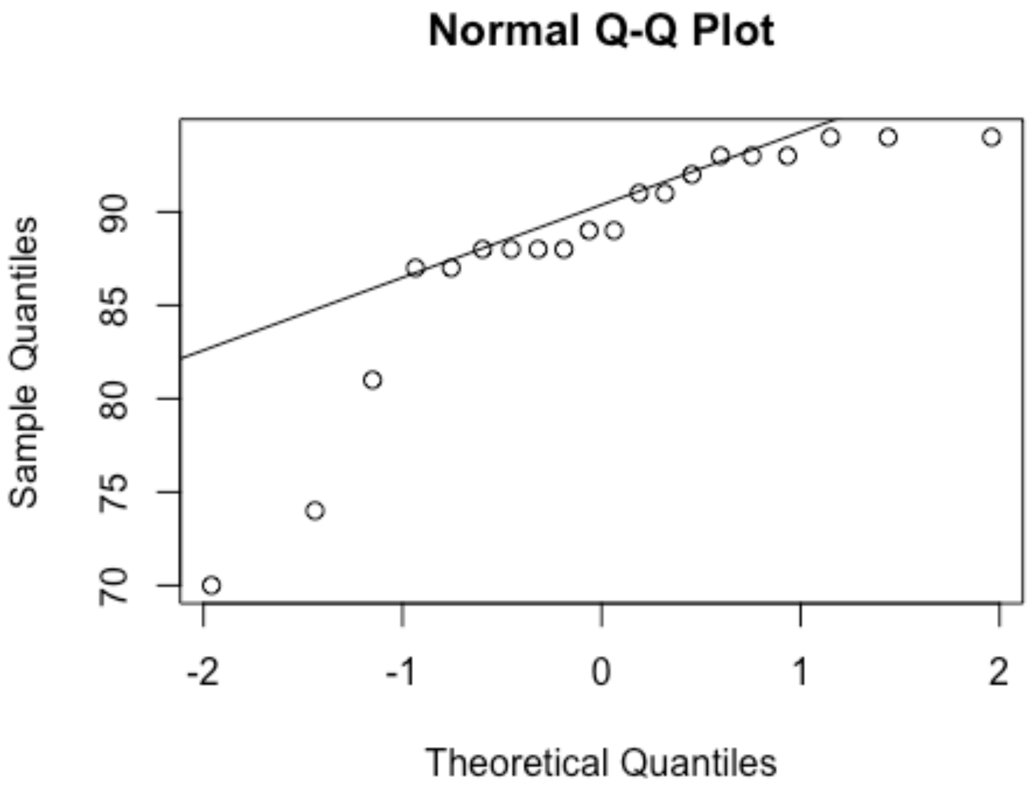
```
ad.test(subset(SSdata, intervention == "sham")$min.sao2.rem)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$min.sao2.rem and subset(SSda
ta, intervention == "PrenaBelt")$min.sao2.rem
## W = 181, p-value = 0.6118
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.000020  1.000041
## sample estimates:
## difference in location
##          -6.982535e-05

#################### Min SpO2 TST #######################
#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$min.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   70.00   88.00   91.00   89.28   93.00   94.00

sd(SSdata$min.sao2.tst, na.rm = TRUE)

## [1] 5.11402

length(SSdata$min.sao2.tst)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(min.sao2.tst ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: min.sao2.tst
##                    Df Sum Sq Mean Sq F value  Pr(>F)
## intervention        1  46.22  46.225  2.0356 0.16227
## night               1  15.63  15.625  0.6881 0.41229
## intervention:night  1 140.62 140.625  6.1927 0.01759 *
## Residuals          36 817.50  22.708
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$min.sao2.tst,
       subset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.tst,
       paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.tst, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.tst, : cannot compute exact confidence interval with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.tst, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$min.sao2.tst, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$min.sao2.tst and su
bset(SSdataCompletes, intervention == "PrenaBelt")$min.sao2.tst
## V = 45, p-value = 0.07952
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.999980e+00  6.891261e-05
## sample estimates:
## (pseudo)median
##      -1.500056

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   83.00   89.75   91.00   90.35   92.25   94.00

sd(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

## [1] 3.116594

length(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
qqline(subset(SSdata, intervention == "PrenaBelt")$min.sao2.tst)
```



```
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
##
```

```
## data:  subset(SSdata, intervention == "sham")$min.sao2.tst and subset(SSda
ta, intervention == "PrenaBelt")$min.sao2.tst
## W = 166, p-value = 0.362
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.000006  1.000035
## sample estimates:
## difference in location
##              -1.000019

#################### Max SpO2 AWAKE #######################
#Summary
summary(SSdata$max.sao2.awake)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   98.00   99.00  100.00   99.68  100.00  100.00

sd(SSdata$max.sao2.awake, na.rm = TRUE)

## [1] 0.5256254

length(SSdata$max.sao2.awake)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(max.sao2.awake ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: max.sao2.awake
##                     Df Sum Sq Mean Sq F value Pr(>F)
## intervention         1  0.625   0.625  2.2727 0.1404
## night                1  0.025   0.025  0.0909 0.7648
## intervention:night   1  0.225   0.225  0.8182 0.3717
## Residuals           36  9.900   0.275

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.awake,
       subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.awake,
       paired = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.awake, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.awake, : cannot compute exact p-value with zeroes
```

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.awake and
subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.awake
## V = 4, p-value = 0.0726
## alternative hypothesis: true location shift is not equal to 0
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    99.0   100.0   100.0    99.8   100.0   100.0
```

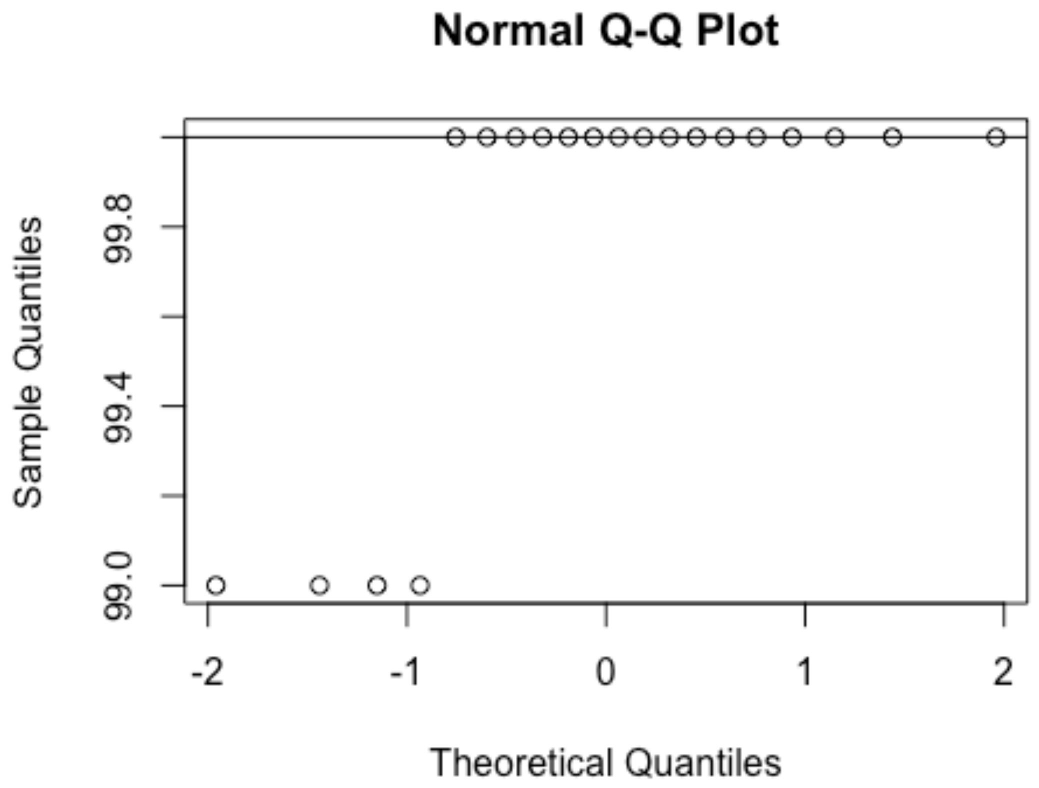
```
sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
```

```
## [1] 0.4103913
```

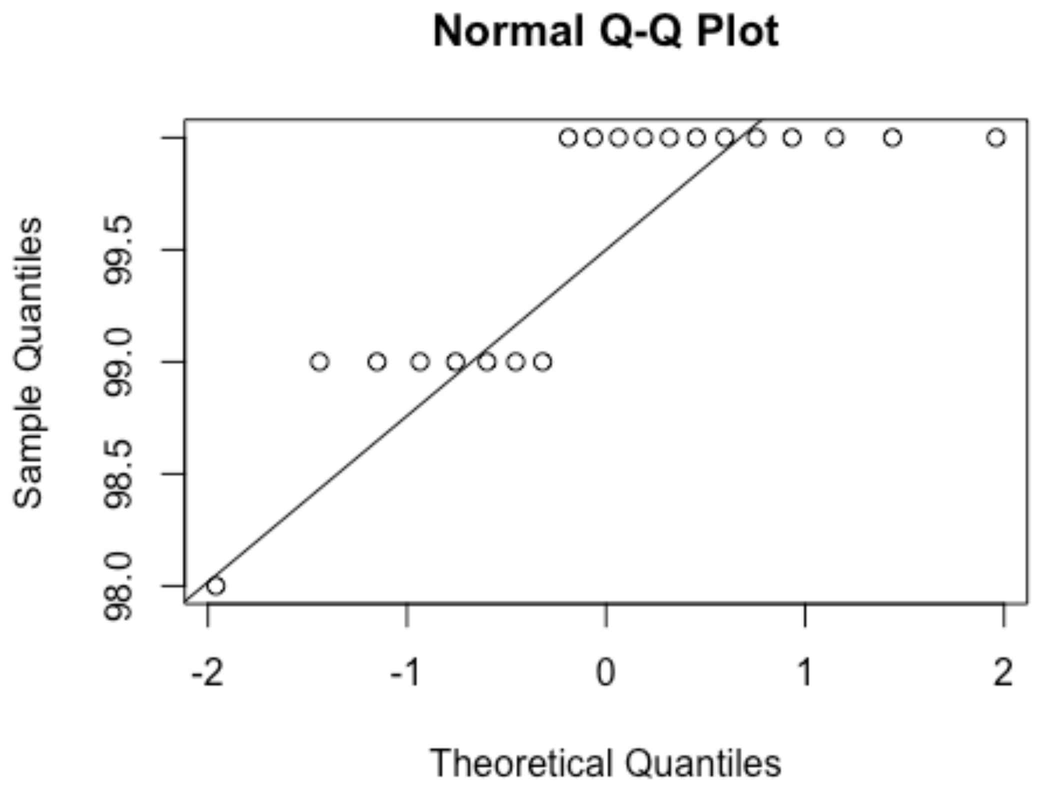
```
length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
```

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

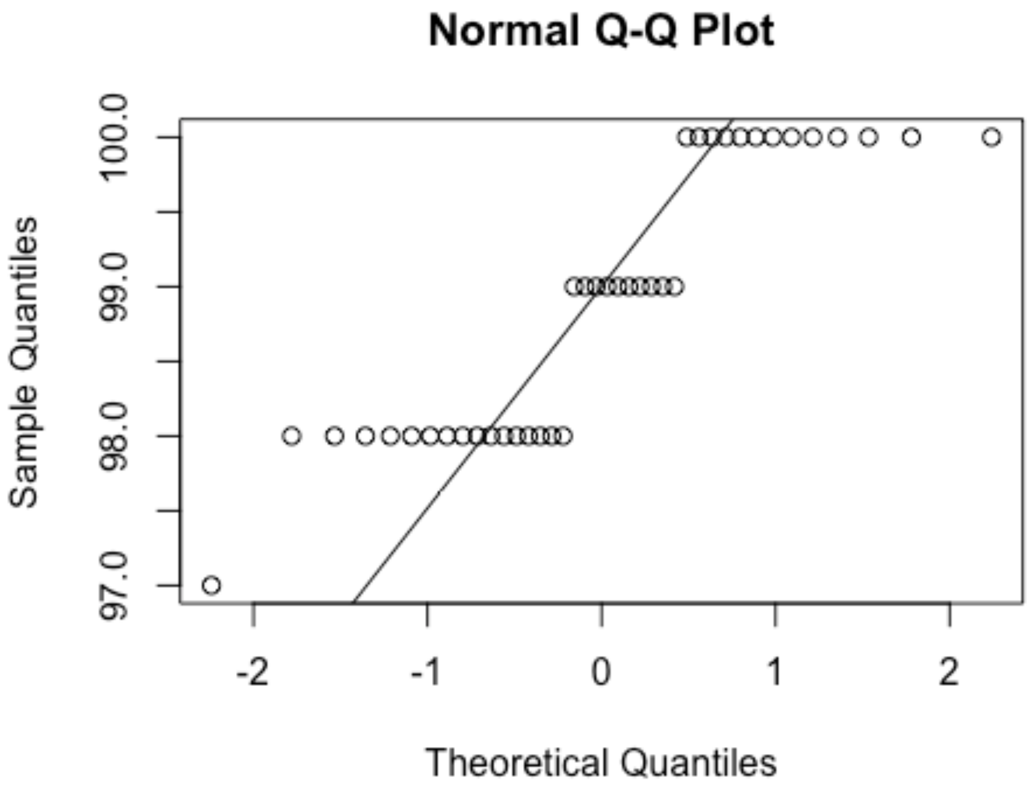
```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake)
```



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

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake
## A = 5.1941, p-value = 2.32e-13

#non-normal

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

##    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.awake)

## [1] 0.6048053

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

## [1] 20

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

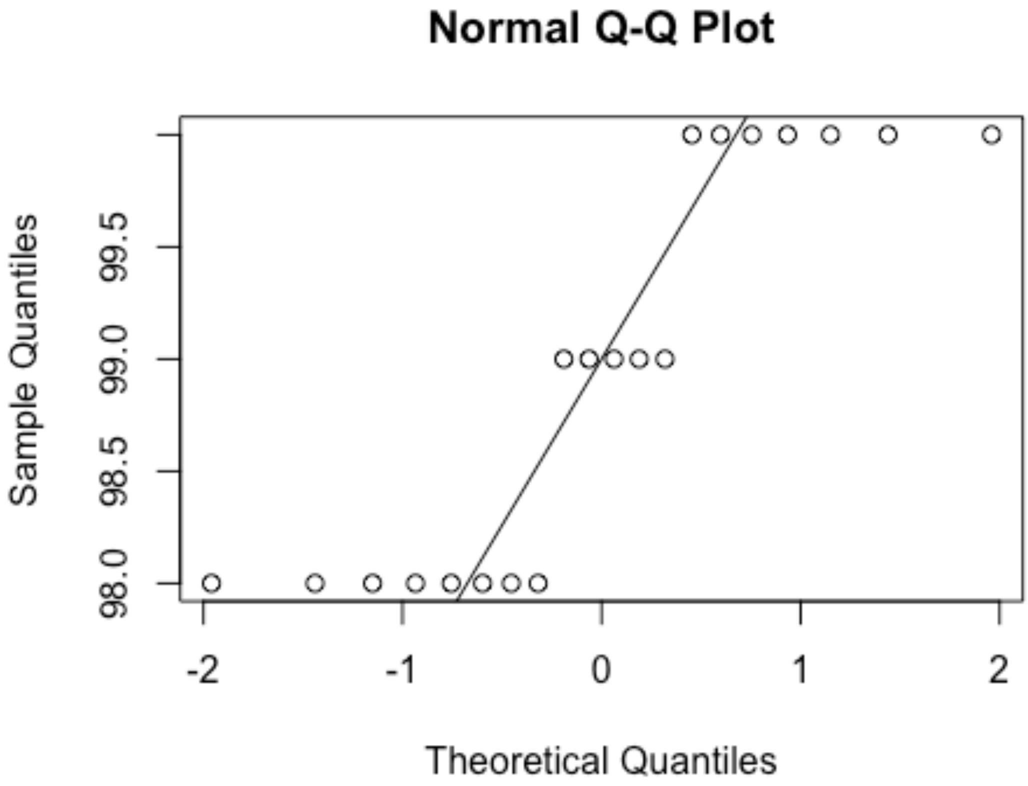


```
ad.test(subset(SSdata, intervention == "sham")$max.sao2.awake)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$max.sao2.awake
## A = 2.8091, p-value = 2.322e-07

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$max.sao2.awake,
            subset(SSdata, intervention == "PrenaBelt")$max.sao2.awake,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.awake, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $max.sao2.awake, : cannot compute exact confidence intervals with ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$max.sao2.awake and subset(SS
data, intervention == "PrenaBelt")$max.sao2.awake
## W = 158, p-value = 0.1594
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -9.999288e-01  1.199059e-06
## sample estimates:
## difference in location
##          -1.027475e-05

#################### Max SpO2 NREM #######################
#Summary
summary(SSdata$max.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   97.00   98.00   99.00   98.88  100.00  100.00

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

## [1] 0.9111137

length(SSdata$max.sao2.nrem)

## [1] 40

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

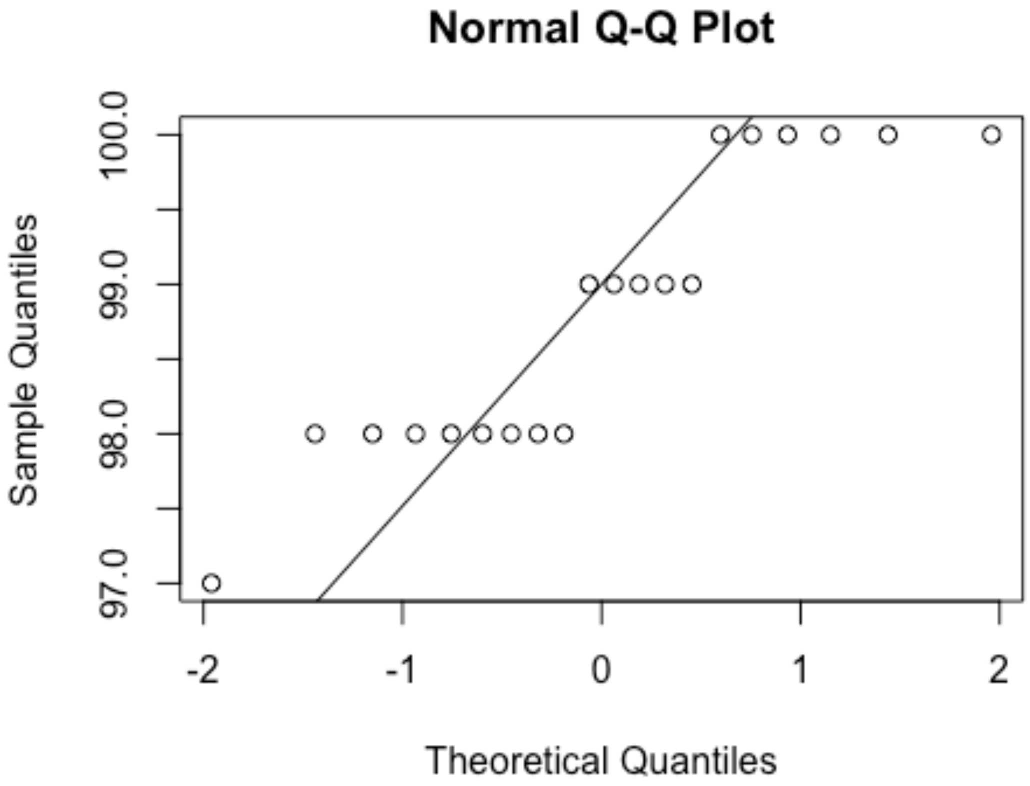


```
ad.test(SSdata$max.sao2.nrem)

##
##  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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.nrem,
                  subset(SSdataCompletes, intervention == "PrenaBelt")$max.sa
o2.nrem,
                 paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : requested conf.level not achievable

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : cannot compute exact confidence interval with tie
s

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.nrem, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.nrem and s
ubset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.nrem
## V = 20, p-value = 0.4575
## alternative hypothesis: true location shift is not equal to 0
## 90 percent confidence interval:
##  -1.499922  1.000000
## sample estimates:
## (pseudo)median
##     -0.4999789

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   98.00   98.00   99.00   98.95  100.00  100.00

sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)

## [1] 0.8870412

length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)

## [1] 20

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

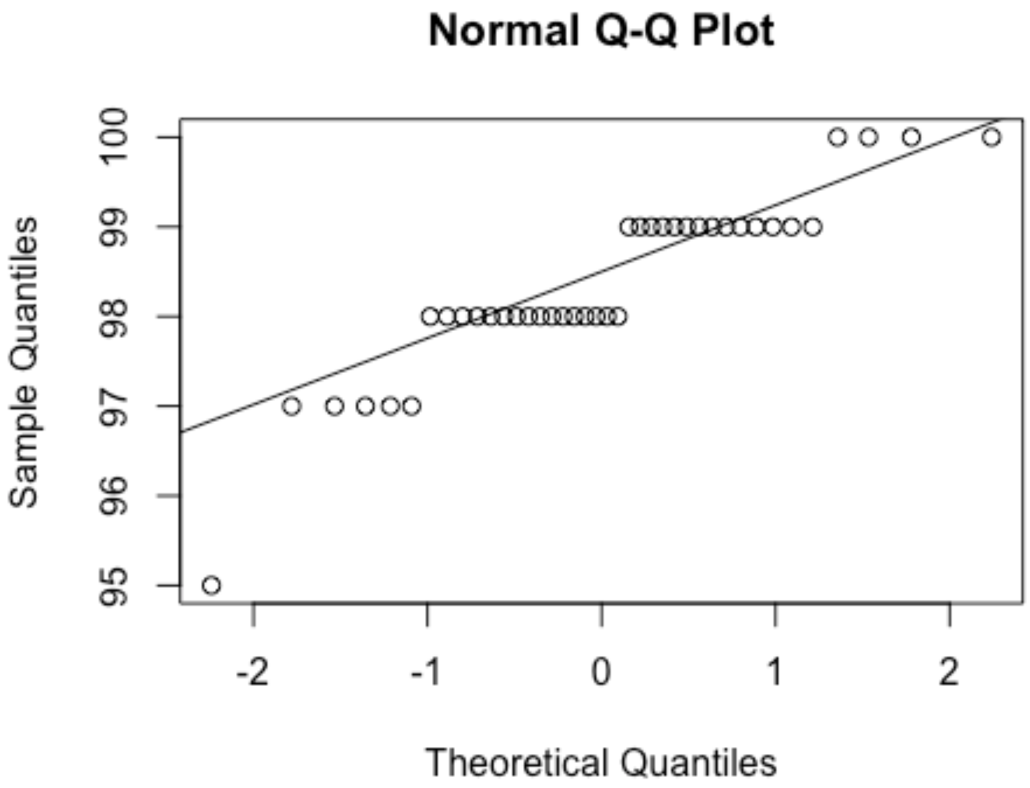


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.nrem)

##
##  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)
```



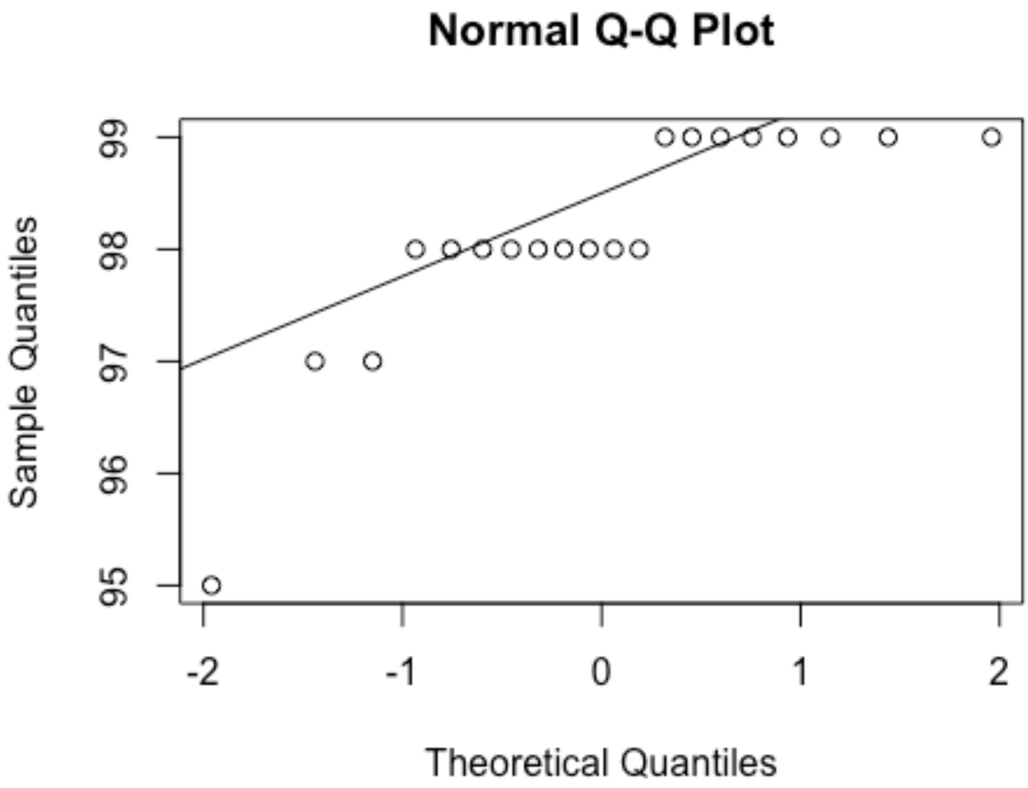
```
ad.test(subset(SSdata, intervention == "sham")$max.sao2.nrem)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$max.sao2.nrem and subset(SSd
ata, intervention == "PrenaBelt")$max.sao2.nrem
## W = 183.5, p-value = 0.6458
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -9.999960e-01  6.876513e-05
## sample estimates:
## difference in location
##          -7.969806e-05

#################### Max SpO2 REM #######################
#Summary
summary(SSdata$max.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   95.00   98.00   98.00   98.35   99.00  100.00

sd(SSdata$max.sao2.rem, na.rm = TRUE)

## [1] 1.001281

length(SSdata$max.sao2.rem)

## [1] 40

qqnorm(SSdata$max.sao2.rem)
qqline(SSdata$max.sao2.rem)
```

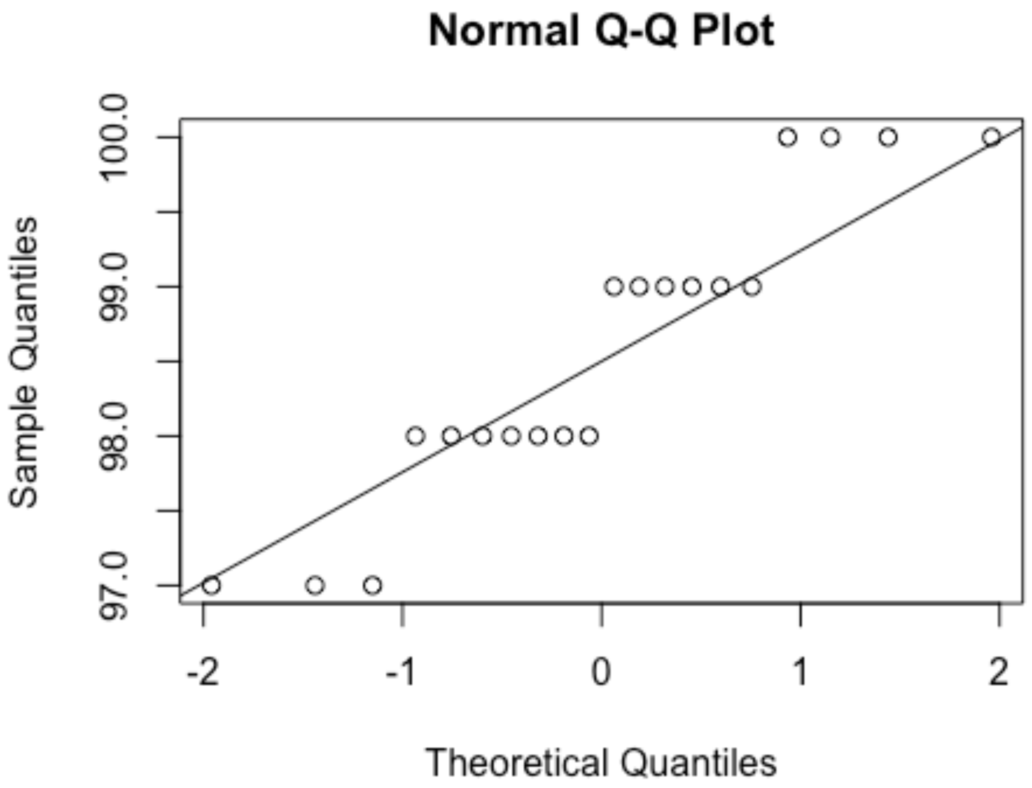


```
ad.test(SSdata$max.sao2.rem)

##
##  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
```

```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.rem,
            subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.rem
,
            paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.rem, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.rem, : cannot compute exact confidence interval with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.rem, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.rem, : cannot compute exact confidence interval with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.rem and su
bset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.rem
## V = 78, p-value = 0.2819
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -5.341455e-06  1.000049e+00
## sample estimates:
## (pseudo)median
##   4.140595e-05

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   95.00   98.00   98.00   98.15   99.00   99.00

sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

## [1] 0.9880869

length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

## [1] 20

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



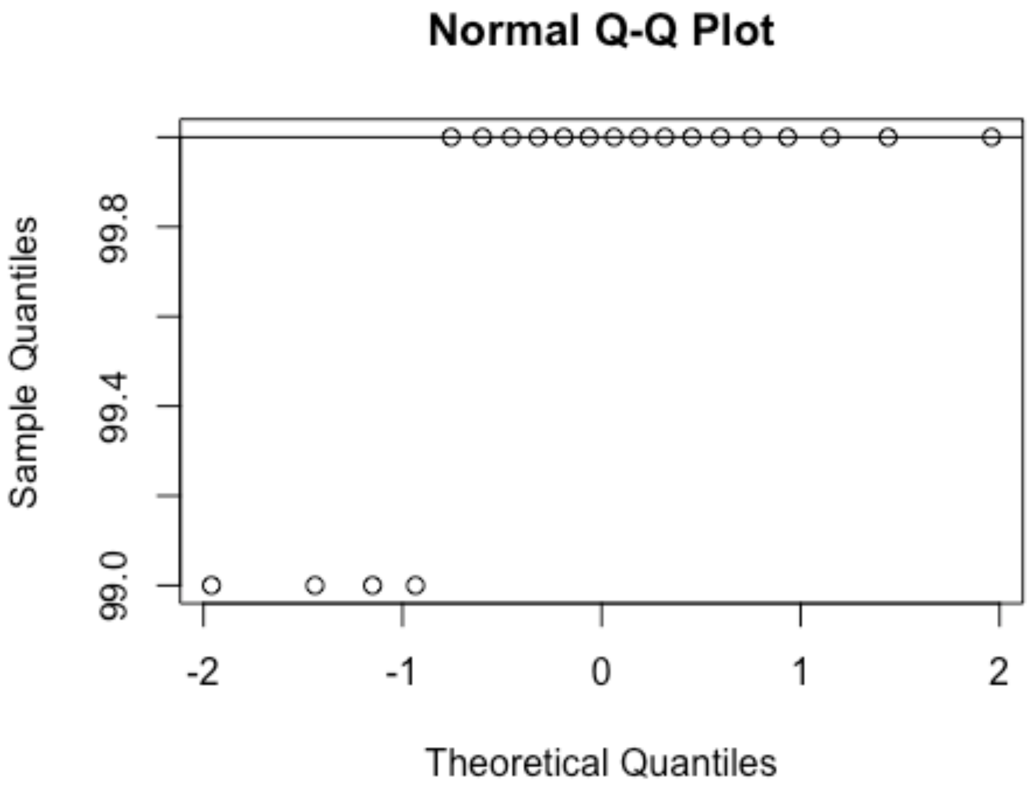
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.rem)

##
##  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)
```



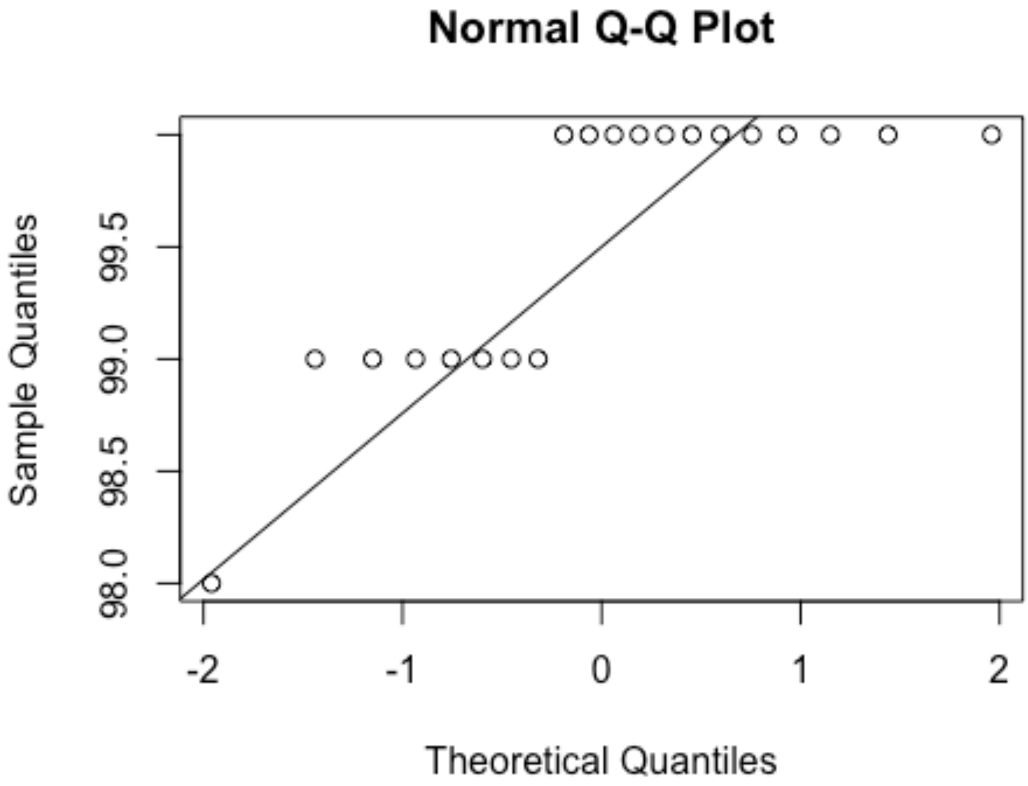
```
ad.test(subset(SSdata, intervention == "sham")$max.sao2.rem)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$max.sao2.rem and subset(SSda
ta, intervention == "PrenaBelt")$max.sao2.rem
## W = 234.5, p-value = 0.3298
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -5.707564e-05  9.999595e-01
## sample estimates:
## difference in location
##           5.182881e-05

#################### Max SpO2 TST #######################
#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$max.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   98.00   99.00  100.00   99.68  100.00  100.00

sd(SSdata$max.sao2.tst, na.rm = TRUE)

## [1] 0.5256254

length(SSdata$max.sao2.tst)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(max.sao2.tst ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: max.sao2.tst
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.625   0.625  2.2727 0.1404
## night               1  0.025   0.025  0.0909 0.7648
## intervention:night  1  0.225   0.225  0.8182 0.3717
## Residuals          36  9.900   0.275

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$max.sao2.tst,
            subset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.tst
,
            paired = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.tst, : cannot compute exact p-value with ties
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$max.sao2.tst, : cannot compute exact p-value with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$max.sao2.tst and su
bset(SSdataCompletes, intervention == "PrenaBelt")$max.sao2.tst
## V = 4, p-value = 0.0726
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    99.0   100.0   100.0    99.8   100.0   100.0

sd(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)

## [1] 0.4103913

length(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
qqline(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)
```



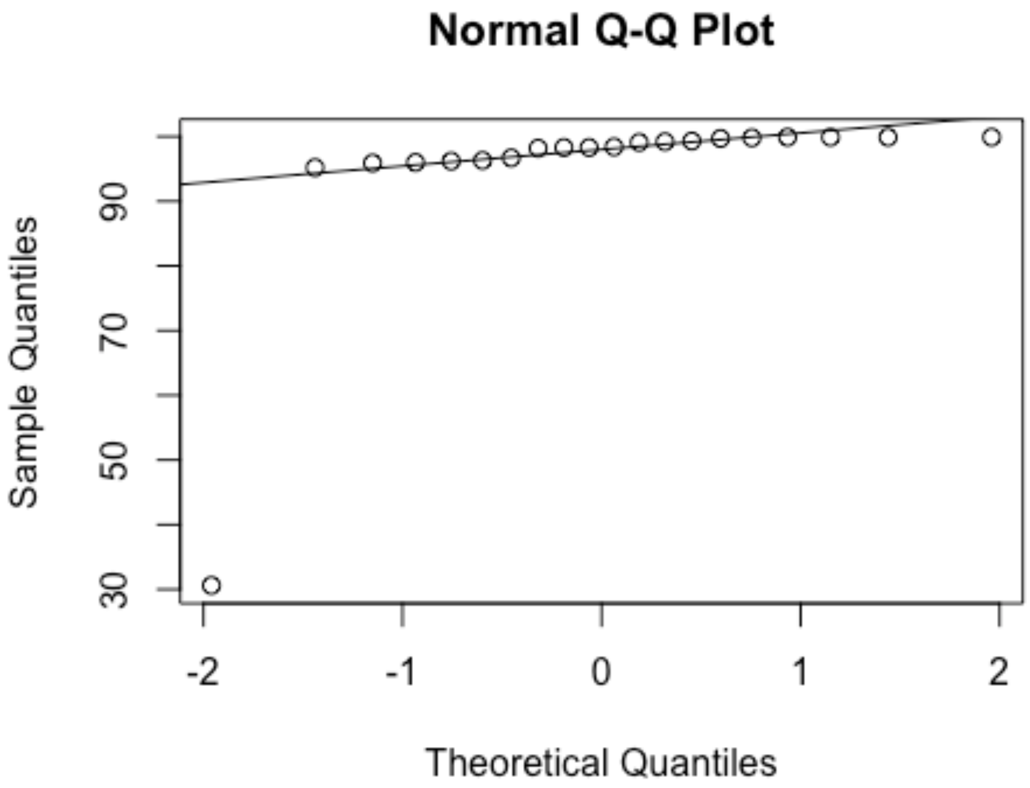
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$max.sao2.tst)

##
##  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)
```



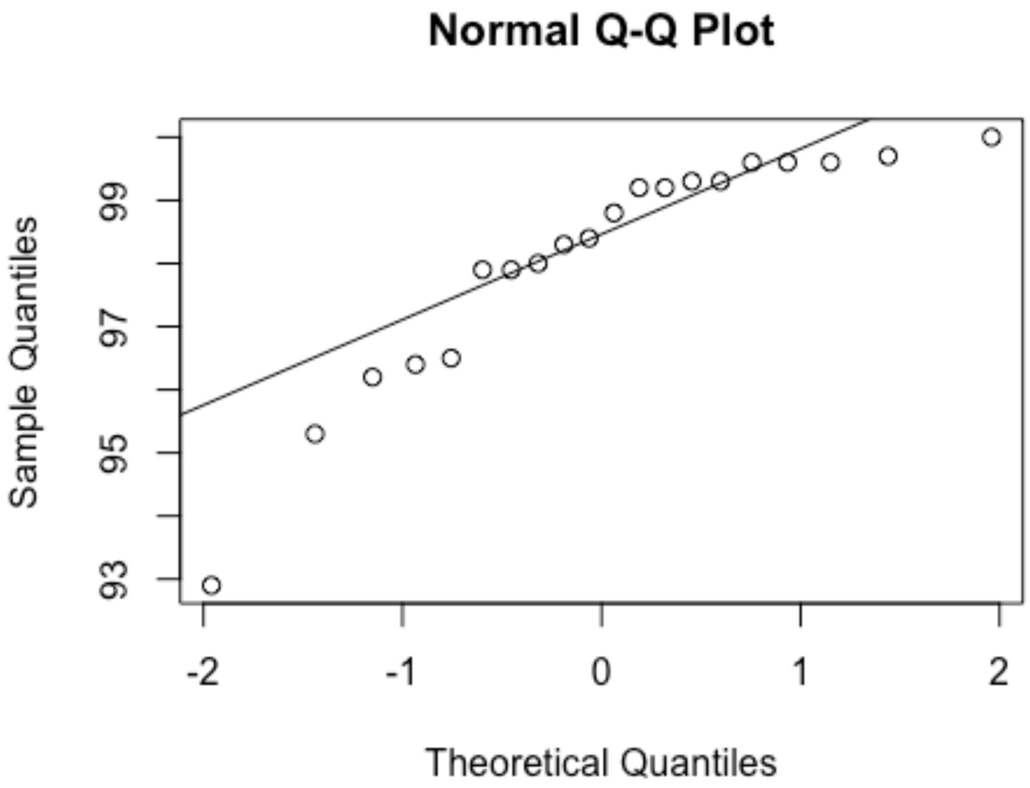
```
ad.test(subset(SSdata, intervention == "sham")$max.sao2.tst)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$max.sao2.tst and subset(SSda
ta, intervention == "PrenaBelt")$max.sao2.tst
## W = 158, p-value = 0.1594
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -9.999288e-01  1.199059e-06
## sample estimates:
## difference in location
##          -1.027475e-05

#################### %TST with SpO2 90-100% ######################
#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$sao2.Ptst.100to90)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   30.60   96.48   98.40   96.47   99.60  100.00

sd(SSdata$sao2.Ptst.100to90, na.rm = TRUE)

## [1] 10.81533

length(SSdata$sao2.Ptst.100to90)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(sao2.Ptst.100to90 ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: sao2.Ptst.100to90
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  106.6  106.60  0.9253 0.3425
## night               1  130.0  129.96  1.1280 0.2953
## intervention:night  1  177.7  177.66  1.5420 0.2223
## Residuals          36 4147.7  115.21

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.100to90
,
       subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.100to90
,
       paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.100to90, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.100to90, : cannot compute exact confidence interval with
## ties

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.100to90 a
nd subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.100to90
## V = 108, p-value = 0.9256
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.7499482  1.2500240
## sample estimates:
## (pseudo)median
##     0.02366365

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   30.60   96.28   98.35   94.84   99.72   99.90

sd(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

## [1] 15.20458

length(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
qqline(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)
```



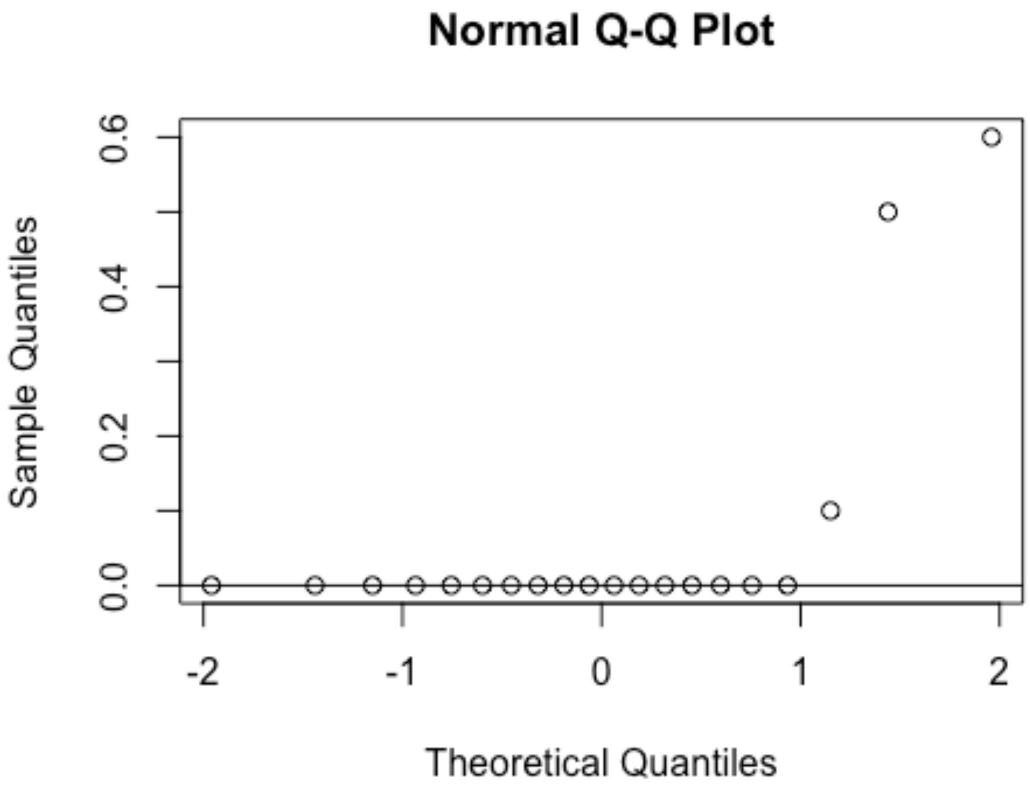
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90)

##
##  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)
```



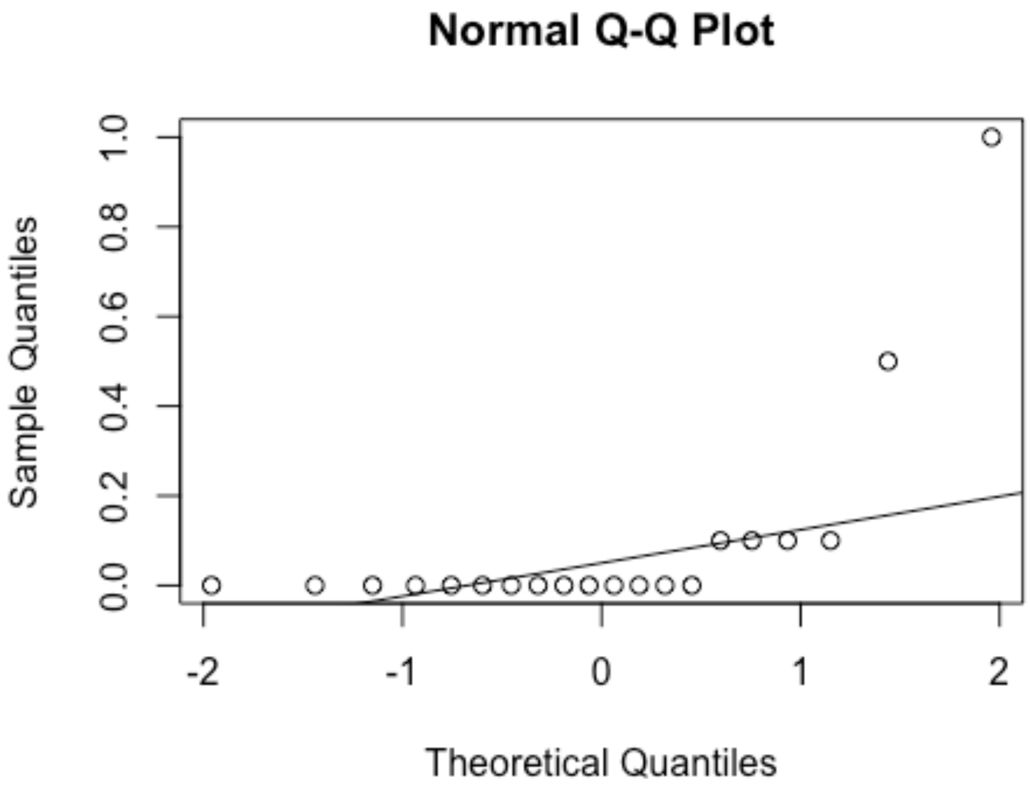
```
ad.test(subset(SSdata, intervention == "sham")$sao2.Ptst.100to90)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$sao2.Ptst.100to90
## A = 1.0547, p-value = 0.006979

#non-normal

#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
##
```

```
## data:  subset(SSdata, intervention == "sham")$sao2.Ptst.100to90 and subset
(SSdata, intervention == "PrenaBelt")$sao2.Ptst.100to90
## W = 199.5, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.7000278  1.2000028
## sample estimates:
## difference in location
##          -3.177747e-05

#################### %TST with SpO2 85-89.9% #######################
#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$sao2.Ptst.89.9to85)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.0000  0.0775  0.0000  1.0000

sd(SSdata$sao2.Ptst.89.9to85, na.rm = TRUE)

## [1] 0.2069157

length(SSdata$sao2.Ptst.89.9to85)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(sao2.Ptst.89.9to85 ~ intervention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: sao2.Ptst.89.9to85
##                    Df  Sum Sq  Mean Sq F value  Pr(>F)
## intervention        1 0.01225 0.012250  0.2994 0.58764
## night               1 0.00225 0.002250  0.0550 0.81593
## intervention:night  1 0.18225 0.182250  4.4542 0.04183 *
## Residuals          36 1.47300 0.040917
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.89.9to8
5,
       subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.89.9to8
5,
       paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.89.9to85, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.89.9to85, : cannot compute exact confidence interval wit
h
## ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.89.9to85, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$sao2.Ptst.89.9to85, : cannot compute exact confidence interval wit
h
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$sao2.Ptst.89.9to85
and subset(SSdataCompletes, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
## V = 18, p-value = 0.1198
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.0999194  0.3999194
## sample estimates:
## (pseudo)median
##      0.1000482

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.06    0.00    0.60

sd(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

## [1] 0.1698296

length(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
qqline(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)
```



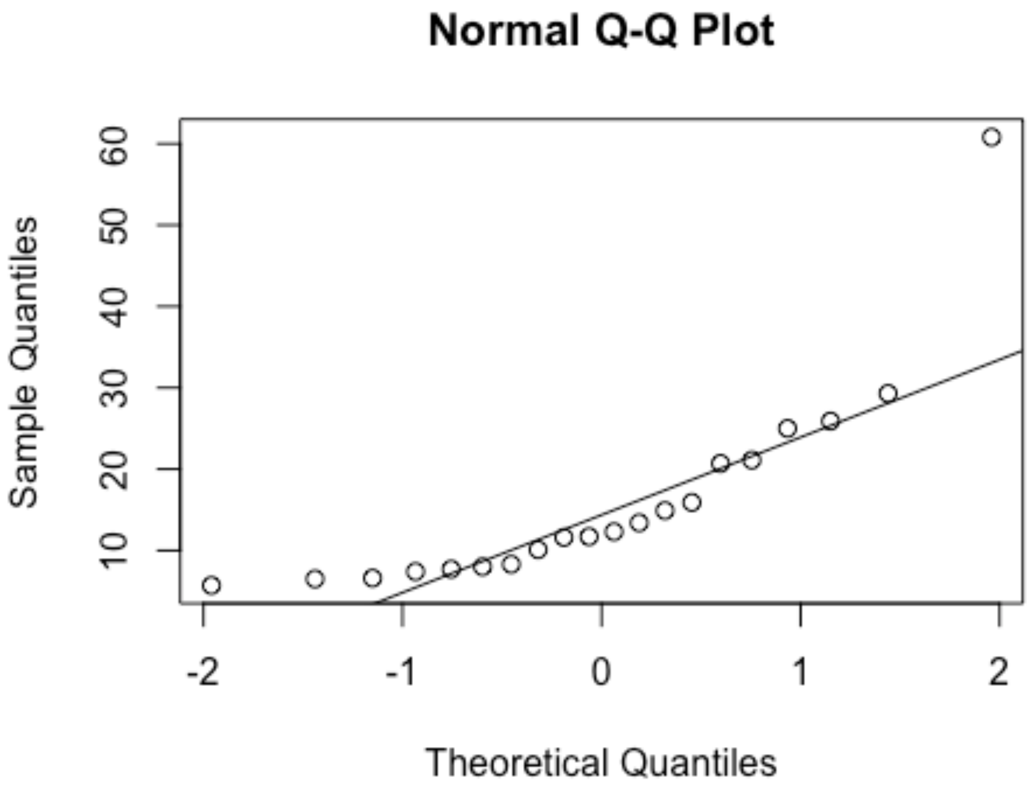
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85)

##
##  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)
```



```
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
##
```

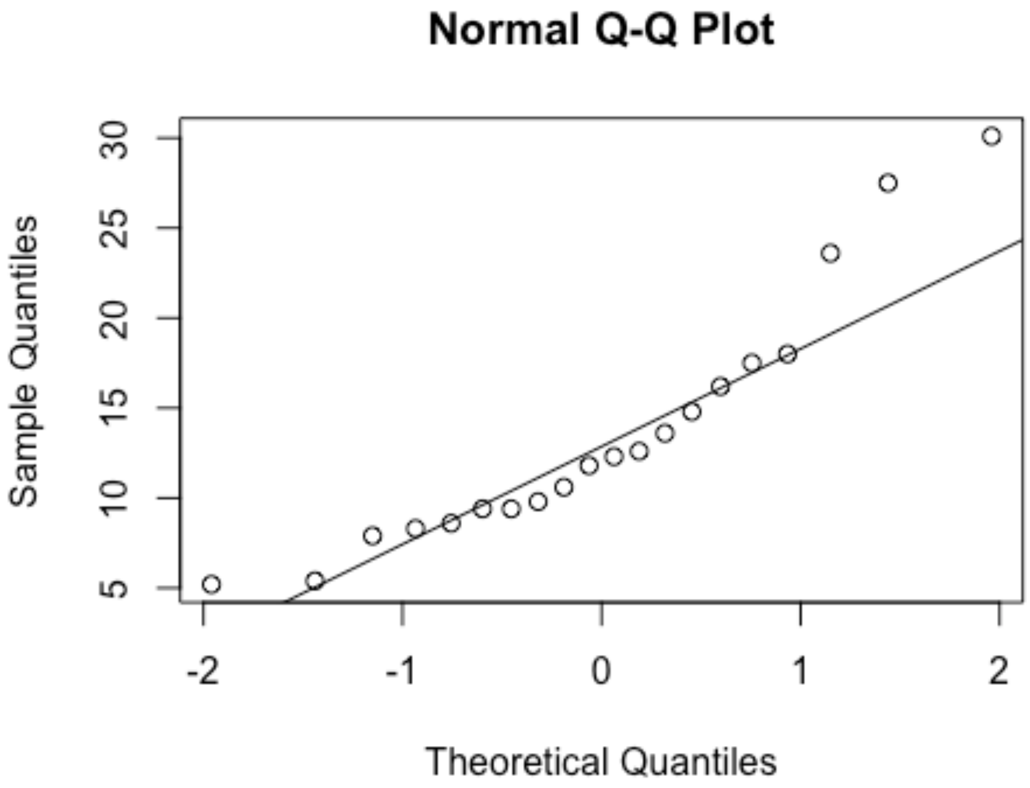
```
## data:  subset(SSdata, intervention == "sham")$sao2.Ptst.89.9to85 and subse
t(SSdata, intervention == "PrenaBelt")$sao2.Ptst.89.9to85
## W = 227.5, p-value = 0.317
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.534144e-05  1.959457e-05
## sample estimates:
## difference in location
##           3.556854e-06

#################### Total Arousal Index in NREM #######################
#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$total.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    5.20    8.30   12.05   14.89   17.62   60.80

sd(SSdata$total.arousals.nrem.index, na.rm = TRUE)

## [1] 10.14672

length(SSdata$total.arousals.nrem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(total.arousals.nrem.index ~ intervention * ni
ght,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: total.arousals.nrem.index
##                     Df Sum Sq Mean Sq F value Pr(>F)
## intervention         1   63.3  63.252  0.6102 0.4398
## night                1  190.5 190.532  1.8381 0.1836
## intervention:night   1   29.8  29.756  0.2871 0.5954
## Residuals           36 3731.7 103.660

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.nr
em.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals.nr
em.index,
       paired = TRUE, conf.int = TRUE)
```

```
##
##  Wilcoxon signed rank test
##
## data:  subset(SSdataCompletes, intervention == "sham")$total.arousals.nrem
.index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousal
s.nrem.index
## V = 100, p-value = 0.8695
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.70  1.65
## sample estimates:
## (pseudo)median
##           -0.2

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   5.700   7.925  12.000  16.140  20.800  60.800

sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)

## [1] 12.68192

length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.ind
ex
## 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
```

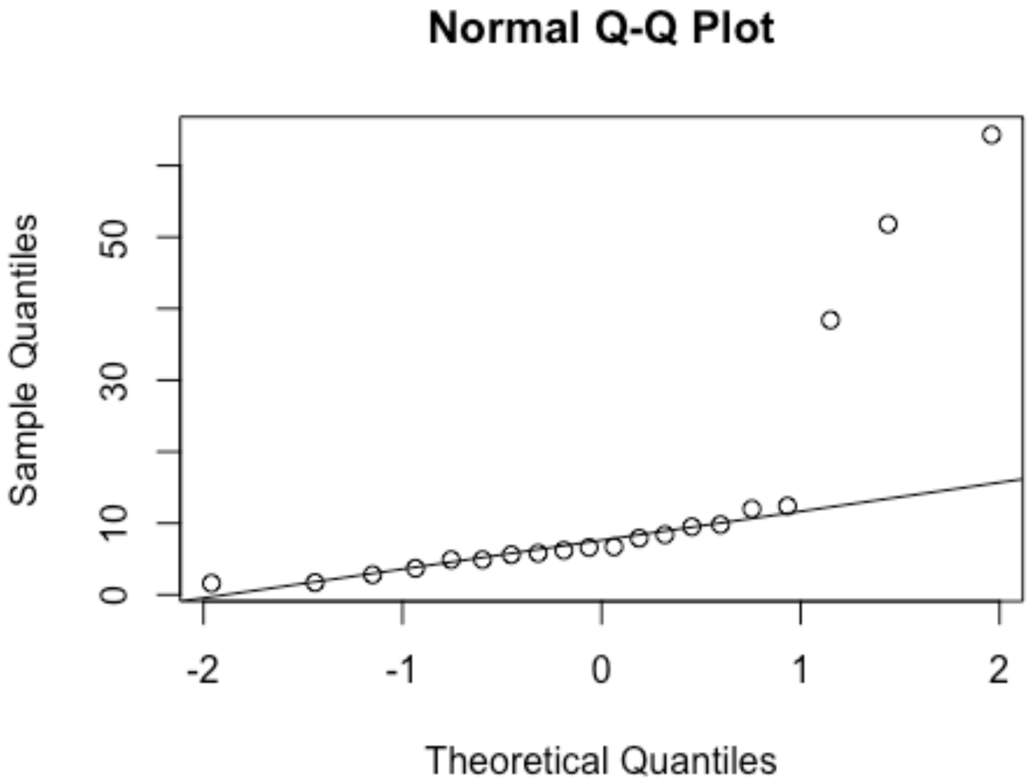
```
qqnorm(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
qqline(subset(SSdata, intervention == "sham")$total.arousals.nrem.index)
```



```
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
```

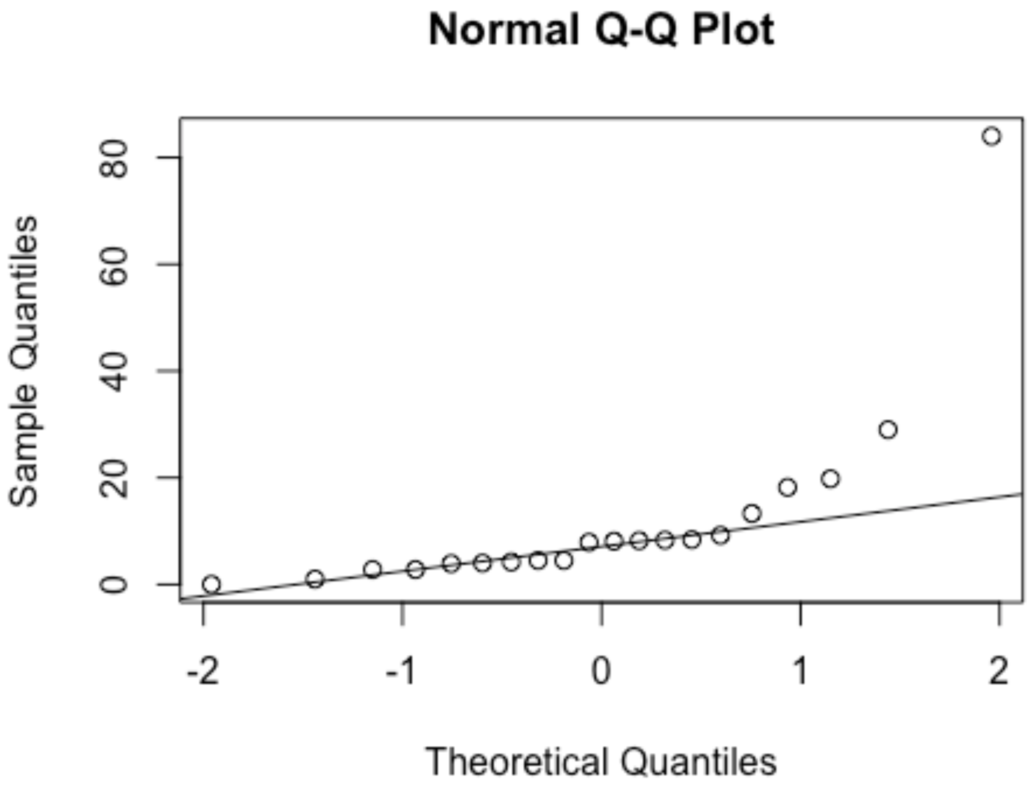
```
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $total.arousals.nrem.index, : cannot compute exact confidence intervals
## with ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$total.arousals.nrem.index an
d subset(SSdata, intervention == "PrenaBelt")$total.arousals.nrem.index
## W = 198, p-value = 0.9676
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.900032  3.200041
## sample estimates:
## difference in location
##            -0.09996643

#################### Total Arousal Index in REM #######################
#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$total.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    4.15    7.30   12.68   10.35   84.00

sd(SSdata$total.arousals.rem.index, na.rm = TRUE)

## [1] 17.59224

length(SSdata$total.arousals.rem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(total.arousals.rem.index ~ intervention * nig
ht,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: total.arousals.rem.index
##                     Df  Sum Sq Mean Sq F value  Pr(>F)
## intervention         1    13.1   13.11  0.0447 0.83377
## night                1    10.3   10.30  0.0351 0.85241
## intervention:night   1  1484.7 1484.74  5.0607 0.03068 *
## Residuals           36 10561.8  293.38
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

```
#within-participants (paired) comparison
#Paired t-test
wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.re
m.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals.re
m.index,
       paired = TRUE, conf.int = TRUE)

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention
## == "sham")$total.arousals.rem.index, : cannot compute exact confidence
## interval with ties

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$total.arousals.rem.
index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousals
.rem.index
## V = 91, p-value = 0.6142
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.350040  2.100039
## sample estimates:
## (pseudo)median
##     -0.4334441

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.60    4.90    6.65   13.25   10.35   64.30

sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

## [1] 17.26717

length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)
```



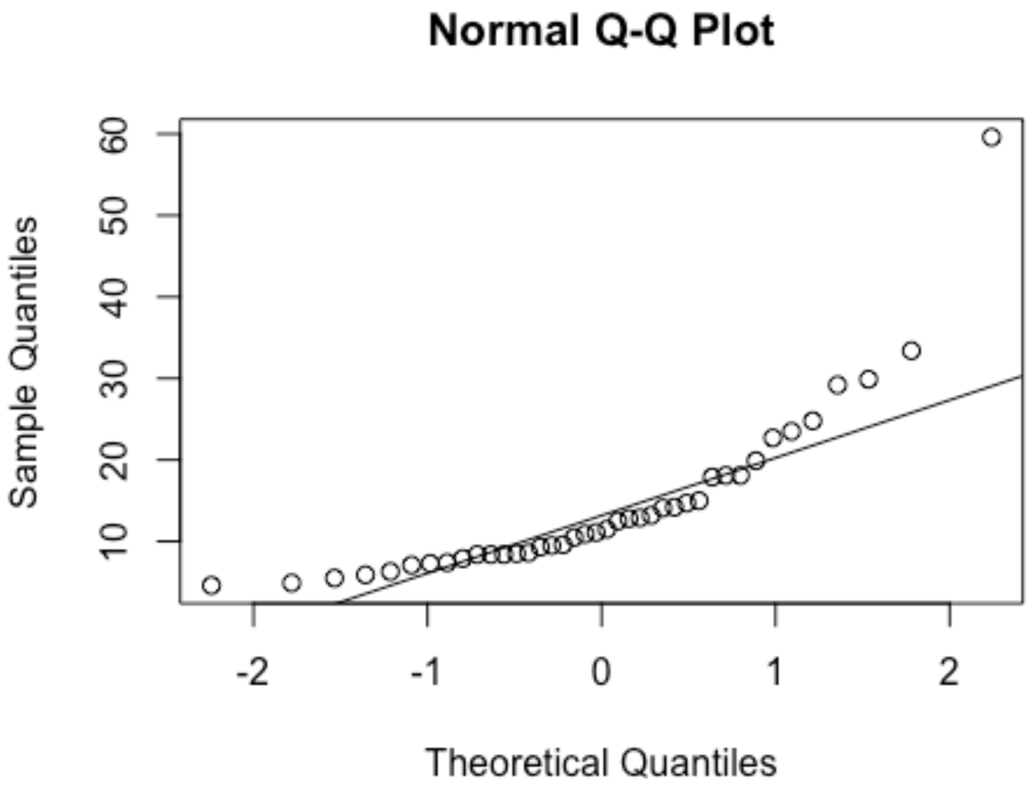
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.inde
x
## 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)
```



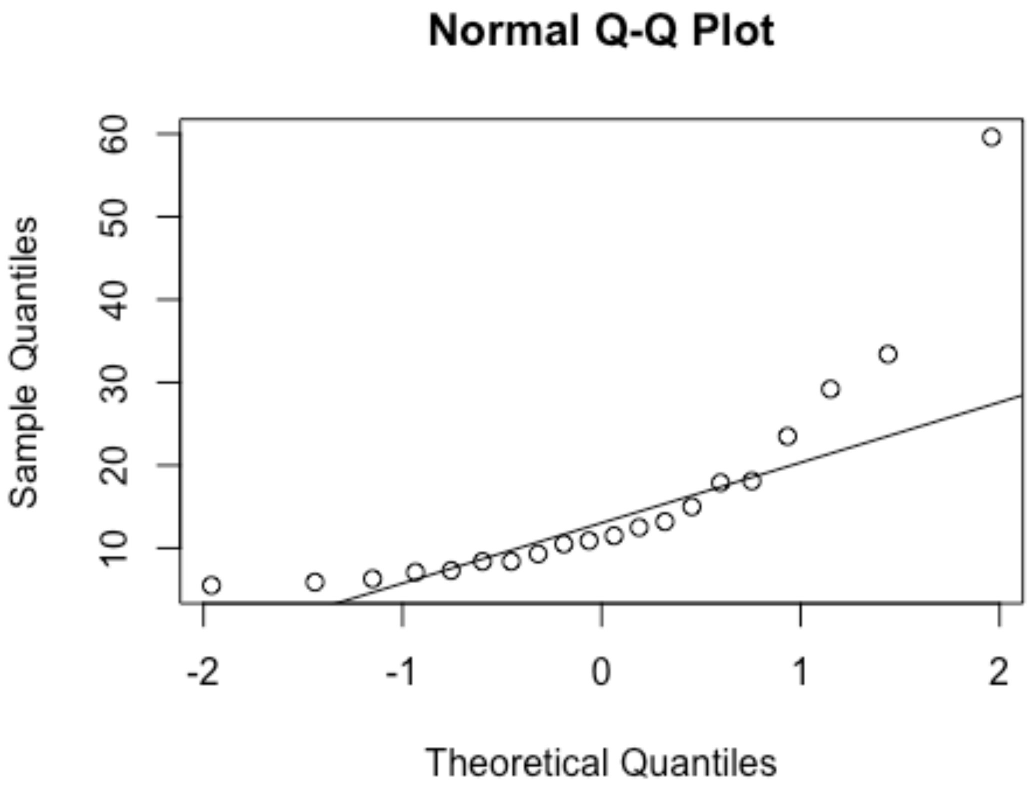
```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.rem.index)

##
##  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
```

```
h
## ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$total.arousals.rem.index and
subset(SSdata, intervention == "PrenaBelt")$total.arousals.rem.index
## W = 186, p-value = 0.7149
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.899974  2.800023
## sample estimates:
## difference in location
##             -0.6999841

#################### Total Arousal Index (TST = NREM + REM) #################
######
#Summary
summary(SSdata$total.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    4.60    8.40   11.30   14.45   17.95   59.60

sd(SSdata$total.arousals.total.index, na.rm = TRUE)

## [1] 10.25068

length(SSdata$total.arousals.total.index)

## [1] 40

qqnorm(SSdata$total.arousals.total.index)
qqline(SSdata$total.arousals.total.index)
```



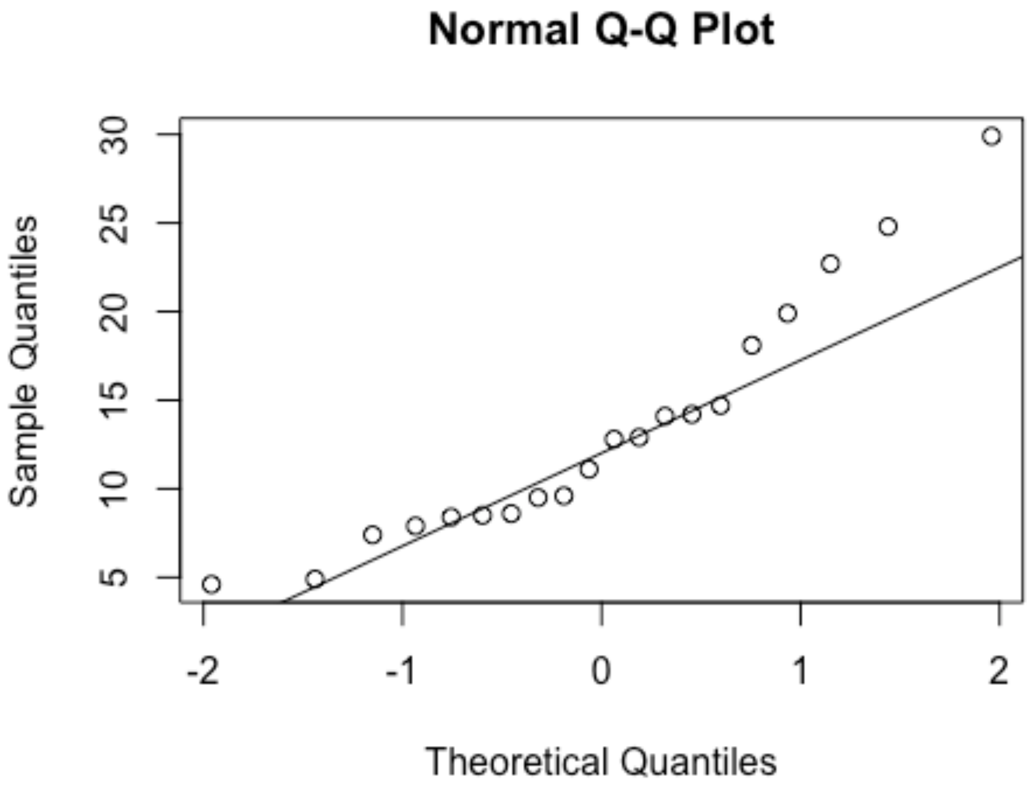
```
ad.test(SSdata$total.arousals.total.index)

##
##  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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$total.arousals.to
tal.index,
                  subset(SSdataCompletes, intervention == "PrenaBelt")$total.
arousals.total.index,
                 paired = TRUE, conf.int = TRUE)

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

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

## 
##  Wilcoxon signed rank test with continuity correction
## 
## data:  subset(SSdataCompletes, intervention == "sham")$total.arousals.tota
l.index and subset(SSdataCompletes, intervention == "PrenaBelt")$total.arousa
ls.total.index
## V = 90, p-value = 0.5883
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.499935  1.499994
## sample estimates:
## (pseudo)median 
##     -0.5984439

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.inde
x)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   5.500   8.125  11.200  15.680  17.950  59.600

sd(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index)

## [1] 12.89508

length(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
)
qqline(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.inde
x)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.in
dex
## 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)
```

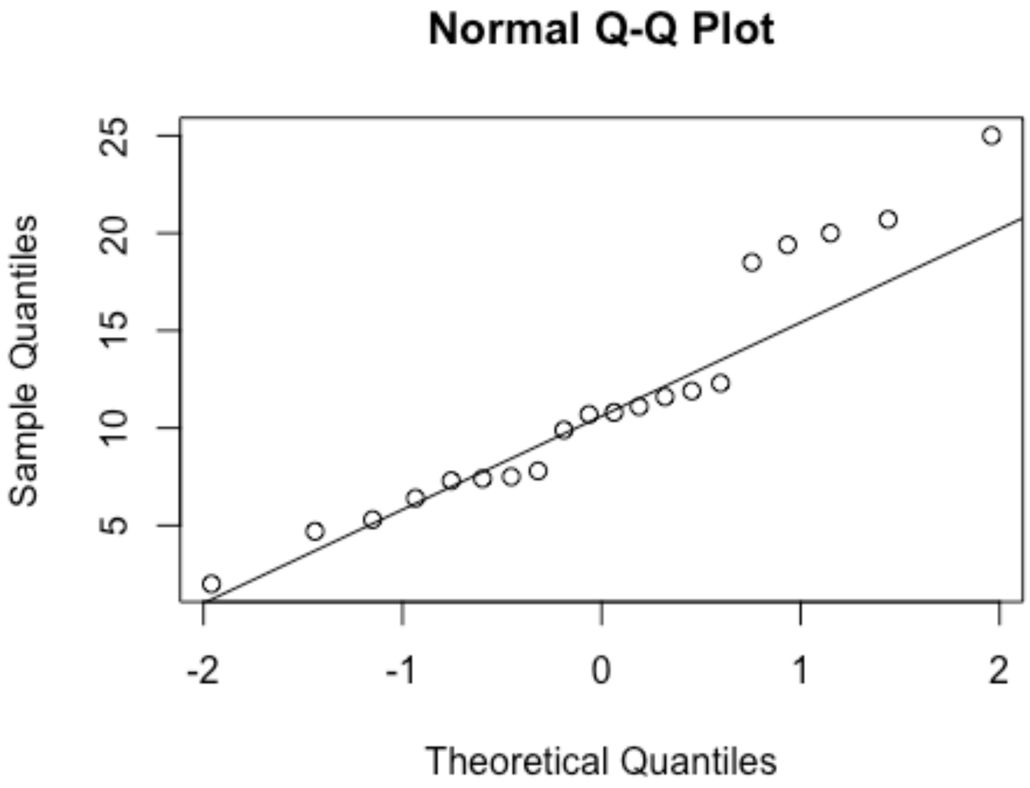


```
ad.test(subset(SSdata, intervention == "sham")$total.arousals.total.index)

##
##  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")$total.arousals.total.index a
nd subset(SSdata, intervention == "PrenaBelt")$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
## 95 percent confidence interval:
##  -9.11411  4.22411
## sample estimates:
## mean of x mean of y
##    13.230    15.675

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

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

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

## 
##  Wilcoxon rank sum test with continuity correction
## 
## data:  subset(SSdata, intervention == "sham")$total.arousals.total.index a
nd subset(SSdata, intervention == "PrenaBelt")$total.arousals.total.index
## W = 201.5, p-value = 0.9784
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.099936  3.599950
## sample estimates:
## difference in location
##             0.04235554

#################### Spontaneous Arousal Index in NREM #####################
#
#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$spontaneous.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.800   7.475  10.550  11.490  13.180  26.500

sd(SSdata$spontaneous.arousals.nrem.index, na.rm = TRUE)

## [1] 6.188624

length(SSdata$spontaneous.arousals.nrem.index)

## [1] 40
```

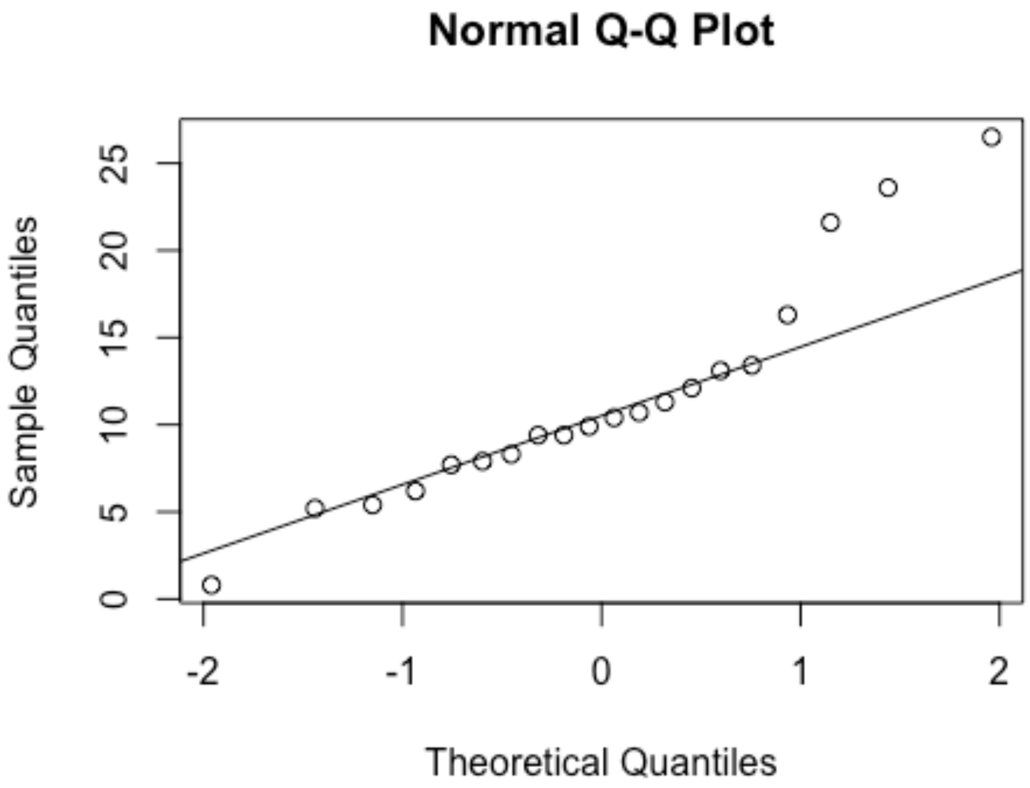
```
#ANOVA
night_tx_difference <- anova(lm(spontaneous.arousals.nrem.index ~ interventio
n * night,
                                data = SSdata))
night_tx_difference

## 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")$spontaneous.arous
als.nrem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
als.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")$spontaneous.arousal
s.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$spontan
eous.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.inde
x)

## [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.nr
em.index
## A = 0.69502, p-value = 0.05869
```

```
#normal

summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.inde
x)

##    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
)
```

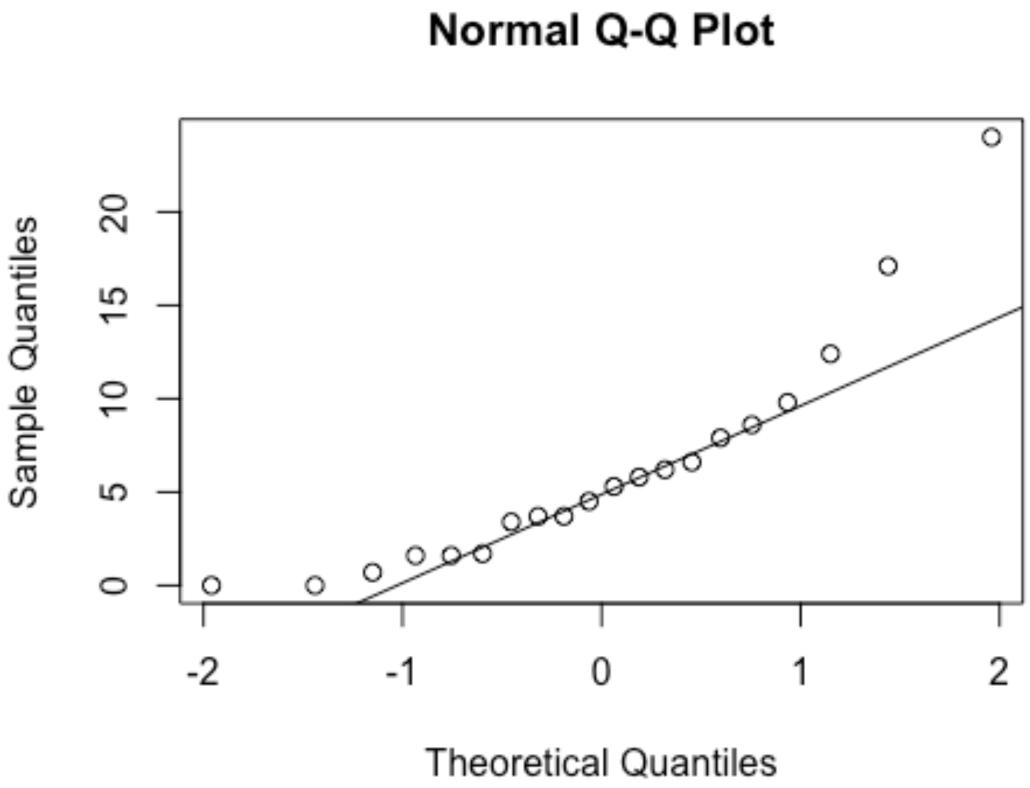


```
ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.inde
x)
```

```
##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
dex
## A = 0.77235, p-value = 0.03712

#non-normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.index
,
       subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem.
index)

##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
dex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
.index
## t = -0.027742, df = 37.952, p-value = 0.978
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -4.068685  3.958685
## sample estimates:
## mean of x mean of y
##    11.460    11.515

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

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.nrem.in
dex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.nrem
.index
## W = 203, p-value = 0.9461
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
```

```
##  -3.399998  3.200034
## sample estimates:
## difference in location
##                   0.15

################### Spontaneous Arousal Index in REM ######################
#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$spontaneous.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   2.000   4.250   5.612   7.950  24.000

sd(SSdata$spontaneous.arousals.rem.index, na.rm = TRUE)

## [1] 4.976312

length(SSdata$spontaneous.arousals.rem.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: spontaneous.arousals.rem.index
##                      Df Sum Sq Mean Sq F value Pr(>F)
## intervention          1  15.25  15.252  0.6246 0.4345
## night                 1  37.44  37.442  1.5334 0.2236
## intervention:night    1  34.04  34.040  1.3941 0.2455
## Residuals            36 879.05  24.418

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
als.rem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
als.rem.index,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$spontaneous.arousals.rem.index, : cannot compute exact p-value wit
h
## ties
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$spontaneous.arousals.rem.index, : cannot compute exact confidence
## interval with ties

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
s.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$spontane
ous.arousals.rem.index
## V = 93, p-value = 0.6676
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.950065  1.549957
## sample estimates:
## (pseudo)median
##     -0.3500398

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.
index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   1.675   4.900   6.230   8.075  24.000

sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.index
)

## [1] 6.025132

length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex)
qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex)
```



```
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
)
```

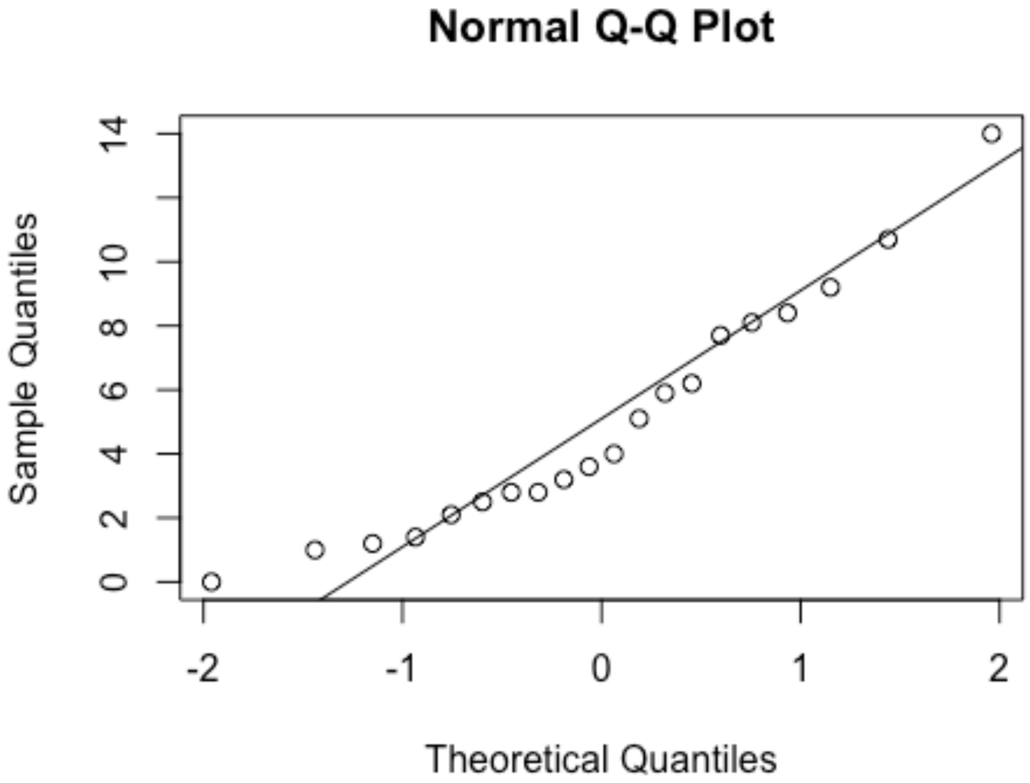
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   2.400   3.800   4.995   7.800  14.000
```

```
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.ind
ex
## A = 0.47886, p-value = 0.2093

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.index,
       subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex)

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

```
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.ind
ex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex
## t = -0.78086, df = 31.571, p-value = 0.4407
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -4.458294  1.988294
## sample estimates:
## mean of x mean of y
##     4.995     6.230
```

```
wilcox.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.i
ndex,
            subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.
rem.index,
            conf.int = TRUE)
```

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

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

```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.rem.ind
ex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.rem.i
ndex
## W = 185.5, p-value = 0.7048
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.199951  2.099934
## sample estimates:
## difference in location
##             -0.4476729
```

```
#################### Spontaneous Arousal Index (TST = NREM + REM) ###########
############
#Summary
summary(SSdata$spontaneous.arousals.total.index)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.100   6.975   9.800  10.410  11.980  23.800
```

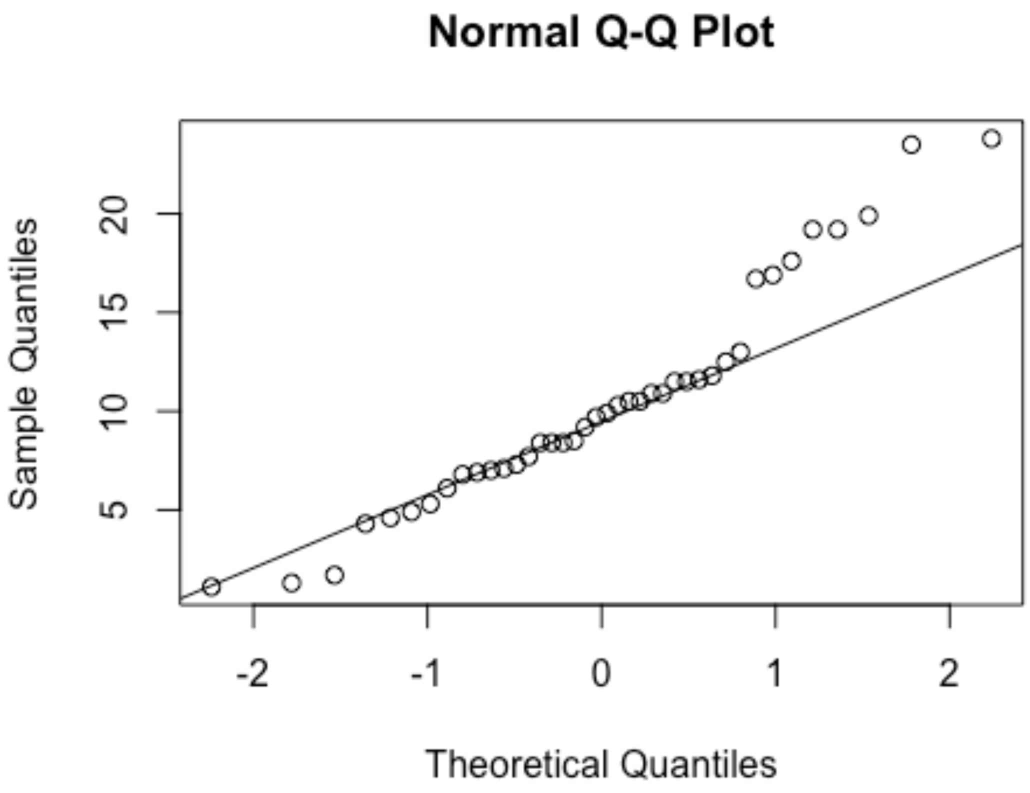
```
sd(SSdata$spontaneous.arousals.total.index, na.rm = TRUE)
```

```
## [1] 5.594264
```

```
length(SSdata$spontaneous.arousals.total.index)
```

```
## [1] 40
```

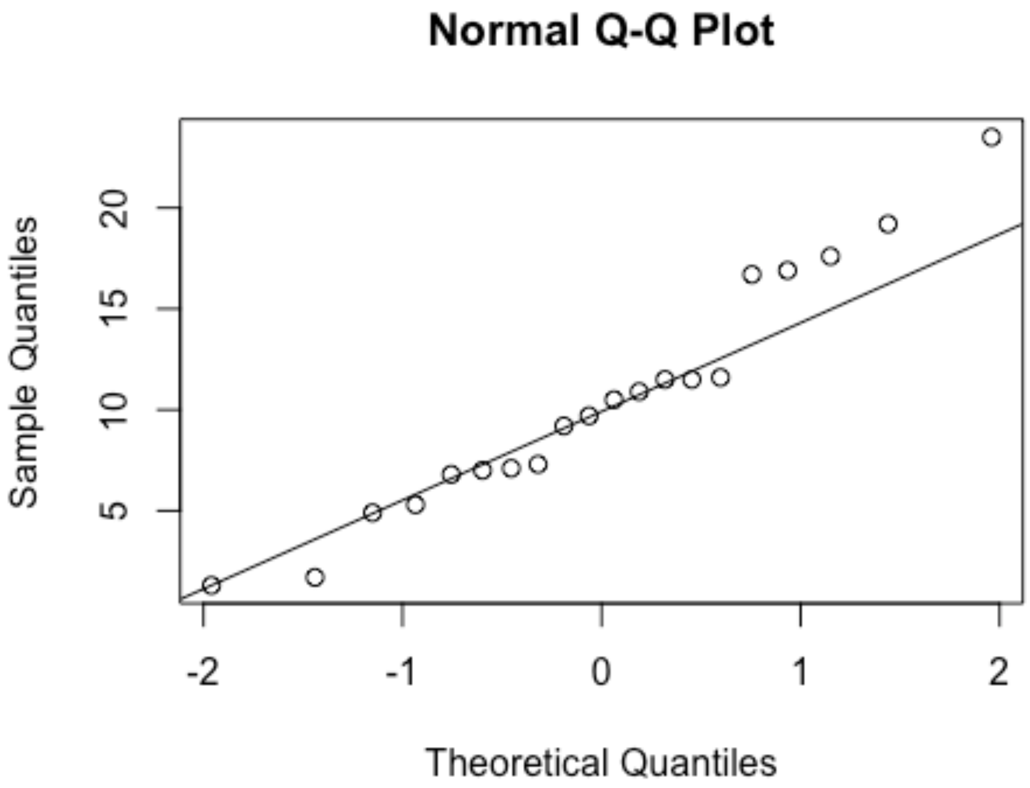
```
qqnorm(SSdata$spontaneous.arousals.total.index)
qqline(SSdata$spontaneous.arousals.total.index)
```



```
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
```

```
##                     Df  Sum Sq Mean Sq F value Pr(>F)
## intervention         1    0.40   0.400  0.0120 0.9132
## night                1   23.72  23.716  0.7138 0.4038
## intervention:night   1    0.26   0.256  0.0077 0.9305
## Residuals           36 1196.16  33.227

#within-participants (paired) comparison
#Paired t-test
t.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arousals.t
otal.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
als.total.index,
       paired = TRUE)

##
##  Paired t-test
##
## data:  subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$sponta
neous.arousals.total.index
## t = -0.17543, df = 19, p-value = 0.8626
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -2.586125  2.186125
## sample estimates:
## mean of the differences
##                    -0.2

#Double check with Wilcoxon (borderline normal)
wilcox.test(subset(SSdataCompletes, intervention == "sham")$spontaneous.arous
als.total.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$spontaneous.arous
als.total.index,
       paired = TRUE, conf.int = TRUE)

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$spontaneous.arousals.total.index, : cannot compute exact confidenc
e
## interval with ties

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$spontaneous.arousal
s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$sponta
neous.arousals.total.index
## V = 114.5, p-value = 0.7368
```

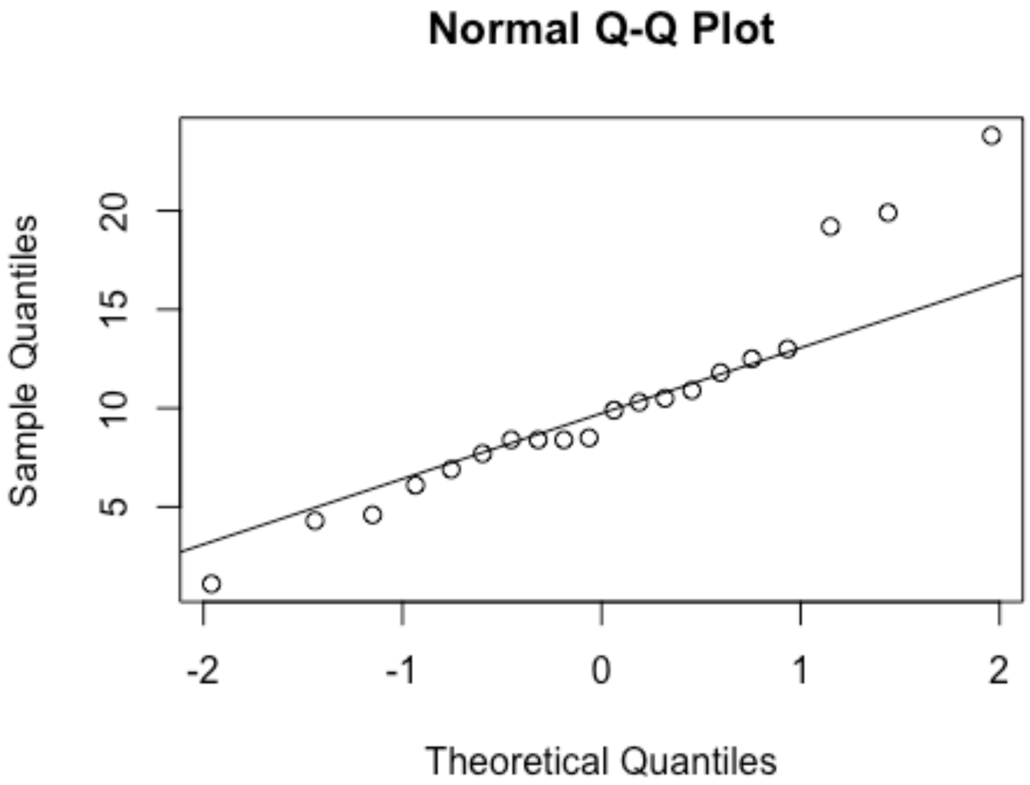
```
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.500005  1.850093
## sample estimates:
## (pseudo)median
##           0.25

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.tota
l.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.30    6.95   10.10   10.51   12.88   23.50

sd(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total.ind
ex)

## [1] 5.841854

length(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total
.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total
.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total
.index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.tota
l.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.to
tal.index
## A = 0.37989, p-value = 0.3699

#normal

summary(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.ind
ex)

##    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.inde
x)
```

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

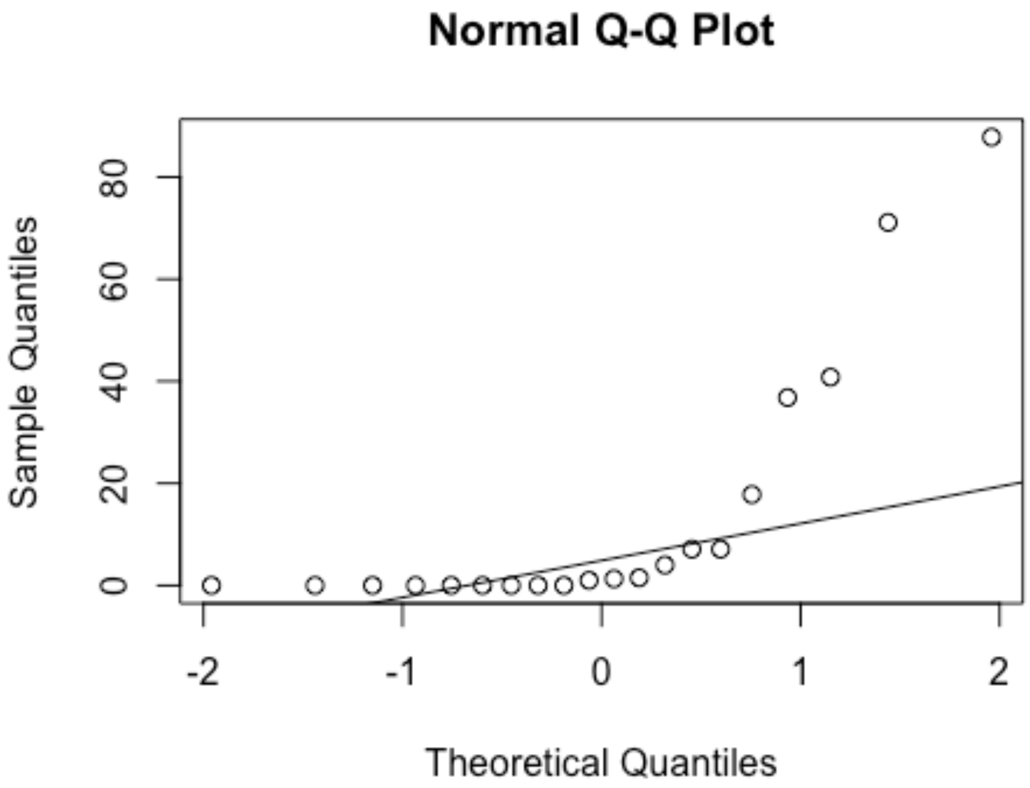
```
qqnorm(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
x)
qqline(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
x)
```



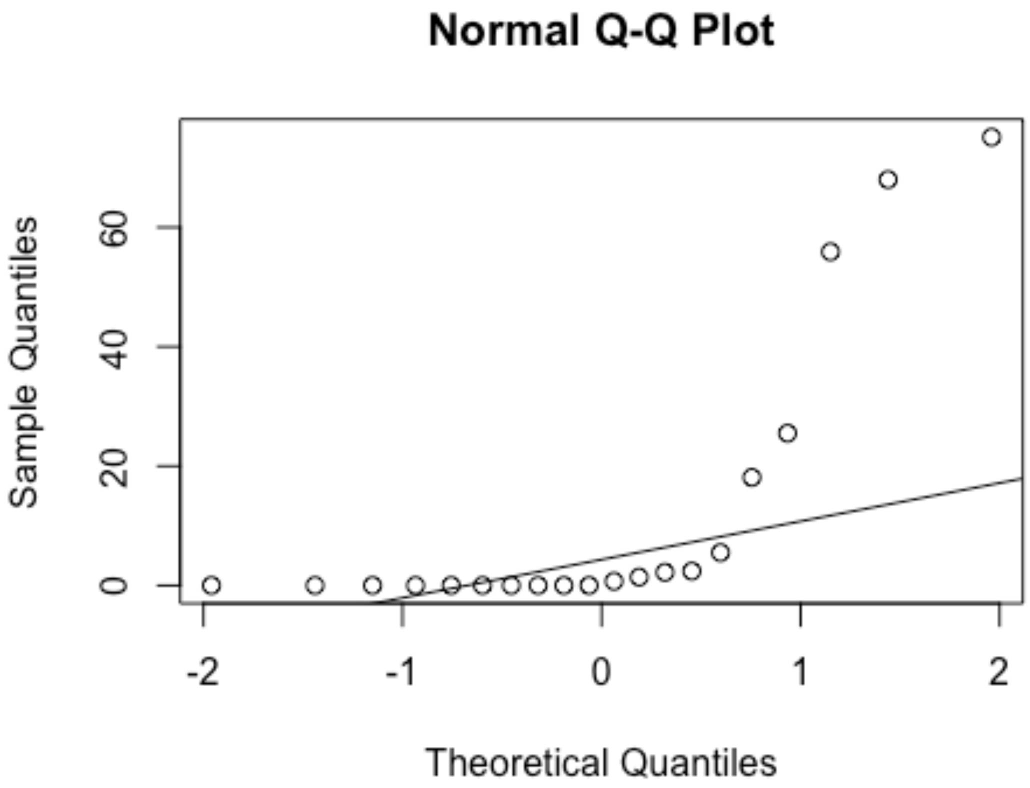
```
ad.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.ind
ex)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.total.i
ndex
## A = 0.71308, p-value = 0.05273

#normal

#FYI - unpaired test
t.test(subset(SSdata, intervention == "sham")$spontaneous.arousals.total.inde
x,
       subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.total
.index)
```

```
##
##  Welch Two Sample t-test
##
## data:  subset(SSdata, intervention == "sham")$spontaneous.arousals.total.i
ndex and subset(SSdata, intervention == "PrenaBelt")$spontaneous.arousals.tot
al.index
## t = -0.11161, df = 37.85, p-value = 0.9117
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -3.827971  3.427971
## sample estimates:
## mean of x mean of y
##     10.31     10.51

#################### PLMs Index in NREM ######################
#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$plms.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.850  13.280   9.775  87.800

sd(SSdata$plms.nrem.index, na.rm = TRUE)

## [1] 24.58884

length(SSdata$plms.nrem.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: plms.nrem.index
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1    11.6   11.56  0.0178 0.8945
## night               1   213.9  213.91  0.3303 0.5691
## intervention:night  1    40.6   40.60  0.0627 0.8037
## Residuals          36 23313.8  647.60

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.nrem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plms.nrem.index,
       paired = TRUE, conf.int = TRUE)
```

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plms.nrem.index and
subset(SSdataCompletes, intervention == "PrenaBelt")$plms.nrem.index
## V = 29, p-value = 0.4561
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -18.84993  13.74994
## sample estimates:
## (pseudo)median
##     -0.8327795

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   1.150  13.820   9.775  87.800

sd(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

## [1] 25.55123

length(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)
```



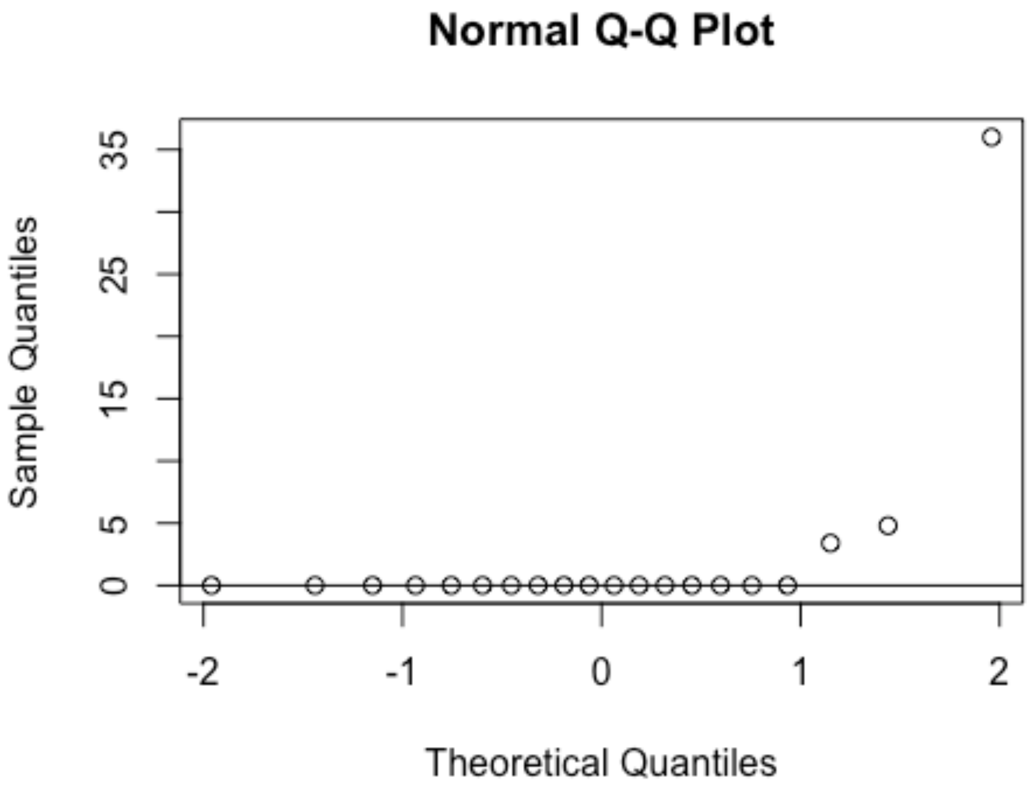
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.nrem.index)

##
##  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)
```



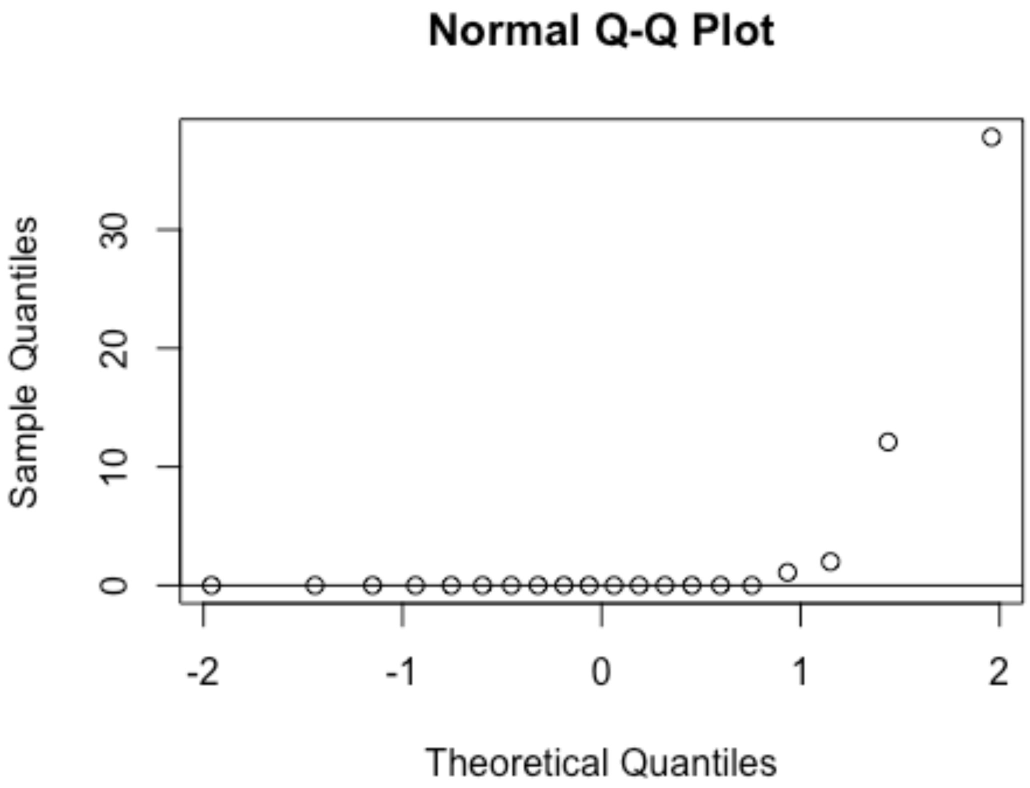
```
ad.test(subset(SSdata, intervention == "sham")$plms.nrem.index)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$plms.nrem.index and subset(S
Sdata, intervention == "PrenaBelt")$plms.nrem.index
## W = 189, p-value = 0.7637
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.800001  1.100068
## sample estimates:
## difference in location
##          -3.550462e-05

#################### PLMs Index in REM ######################
#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$plms.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##    0.00    0.00    0.00    2.43    0.00   37.80

sd(SSdata$plms.rem.index, na.rm = TRUE)

## [1] 8.281682

length(SSdata$plms.rem.index)

## [1] 40

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

## Analysis of Variance Table
## 
## Response: plms.rem.index
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1    1.94   1.936  0.0268 0.8708
## night               1    0.04   0.036  0.0005 0.9823
## intervention:night  1   73.98  73.984  1.0248 0.3181
## Residuals          36 2598.91  72.192

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.rem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plms.rem.index,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plms.rem.index, : requested conf.level not achievable
```

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plms.rem.index and
subset(SSdataCompletes, intervention == "PrenaBelt")$plms.rem.index
## V = 11, p-value = 0.4185
## alternative hypothesis: true location shift is not equal to 0
## 80 percent confidence interval:
##  -0.8000532  4.5500270
## sample estimates:
## (pseudo)median
##       1.799949

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    2.21    0.00   36.00

sd(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

## [1] 8.055459

length(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)
```



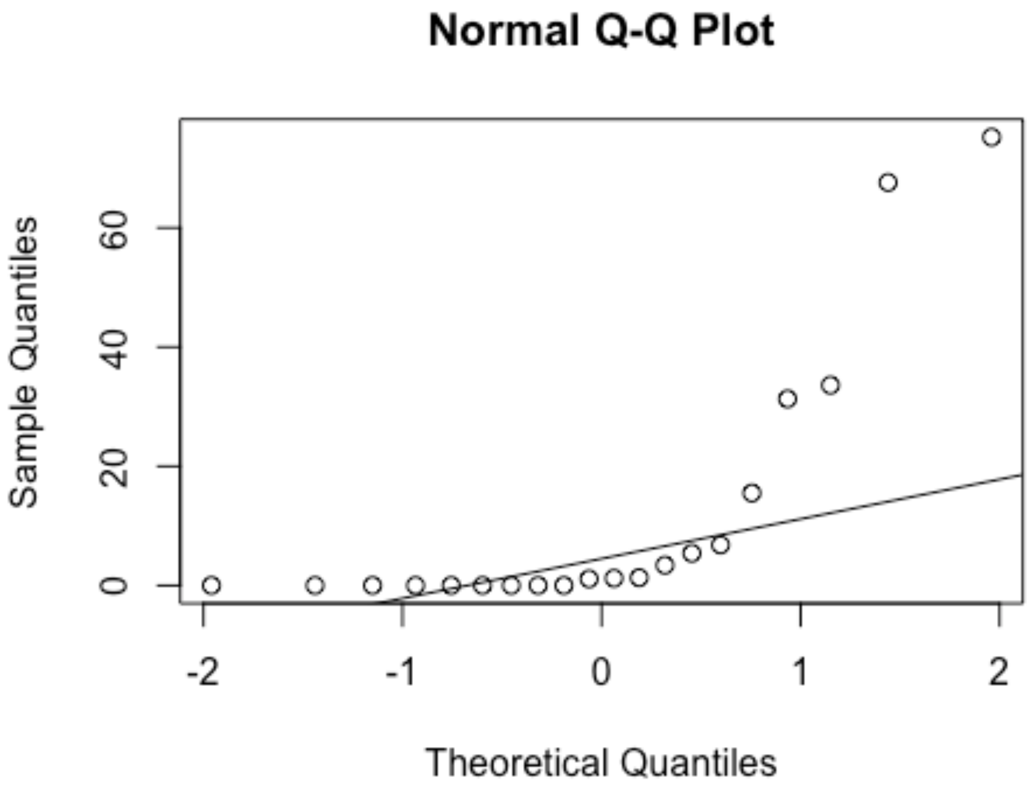
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.rem.index)

##
##  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)
```



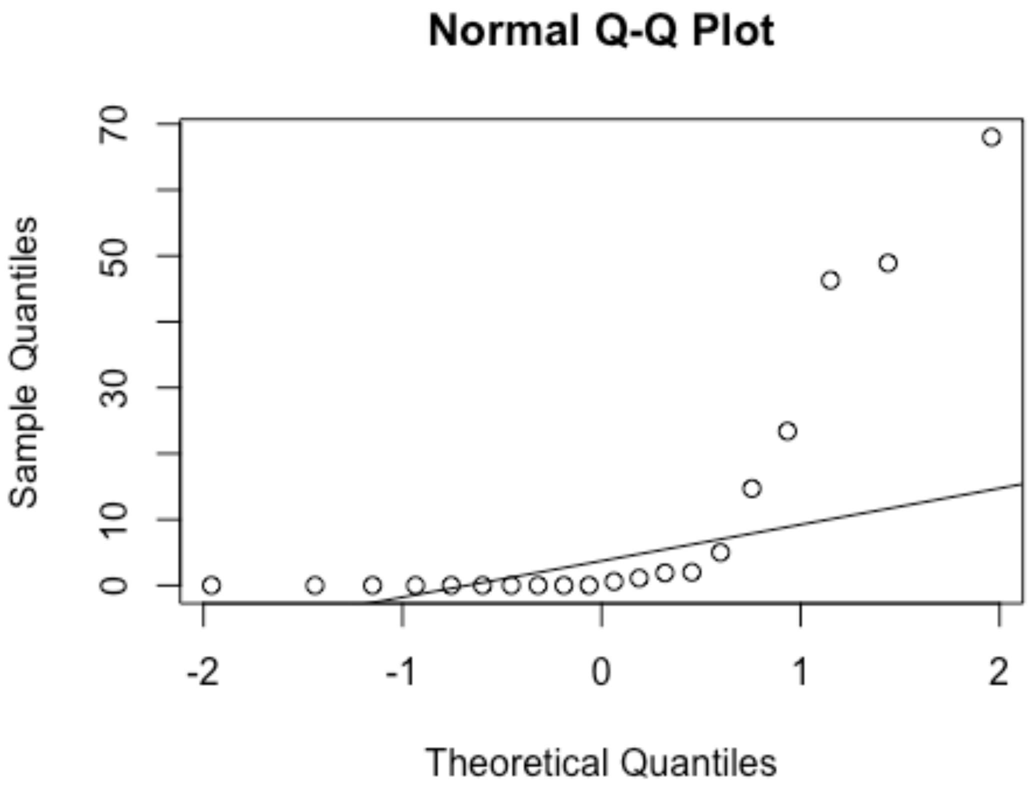
```
ad.test(subset(SSdata, intervention == "sham")$plms.rem.index)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$plms.rem.index and subset(SS
data, intervention == "PrenaBelt")$plms.rem.index
## W = 209, p-value = 0.7285
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.226857e-05  1.825006e-06
## sample estimates:
## difference in location 
##           4.496583e-05

#################### PLMs Total Index (TST = NREM + REM) ####################
###
#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$plms.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   0.000   0.000   0.850  11.360   8.775  75.200

sd(SSdata$plms.total.index, na.rm = TRUE)

## [1] 21.15996

length(SSdata$plms.total.index)

## [1] 40

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

## Analysis of Variance Table
## 
## Response: plms.total.index
##                     Df  Sum Sq Mean Sq F value Pr(>F)
## intervention         1    23.3   23.26  0.0487 0.8265
## night                1   219.5  219.49  0.4599 0.5020
## intervention:night   1    37.1   37.06  0.0776 0.7821
## Residuals           36 17182.2  477.28

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plms.total.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plms.total.index,
       paired = TRUE, conf.int = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plms.total.index an
d subset(SSdataCompletes, intervention == "PrenaBelt")$plms.total.index
## V = 25, p-value = 0.2896
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -17.249992   8.399971
## sample estimates:
## (pseudo)median
##      -1.298512

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   1.150  12.120   8.975  75.200

sd(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

## [1] 22.62638

length(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)
```



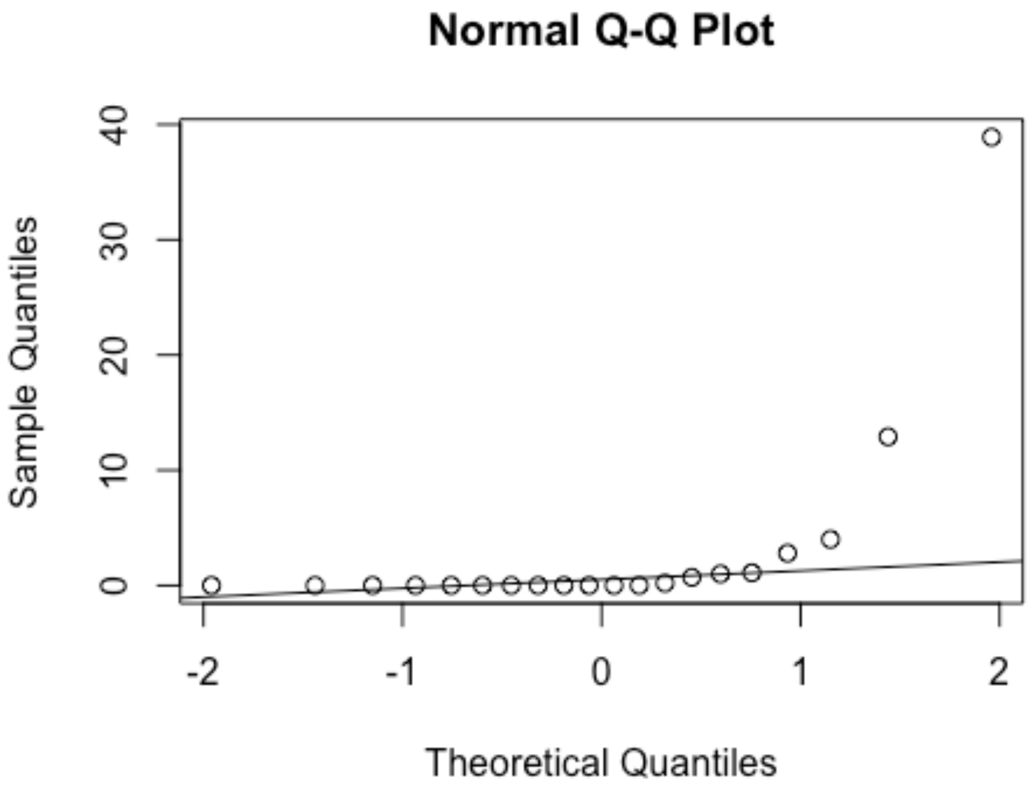
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plms.total.index)

##
##  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)
```



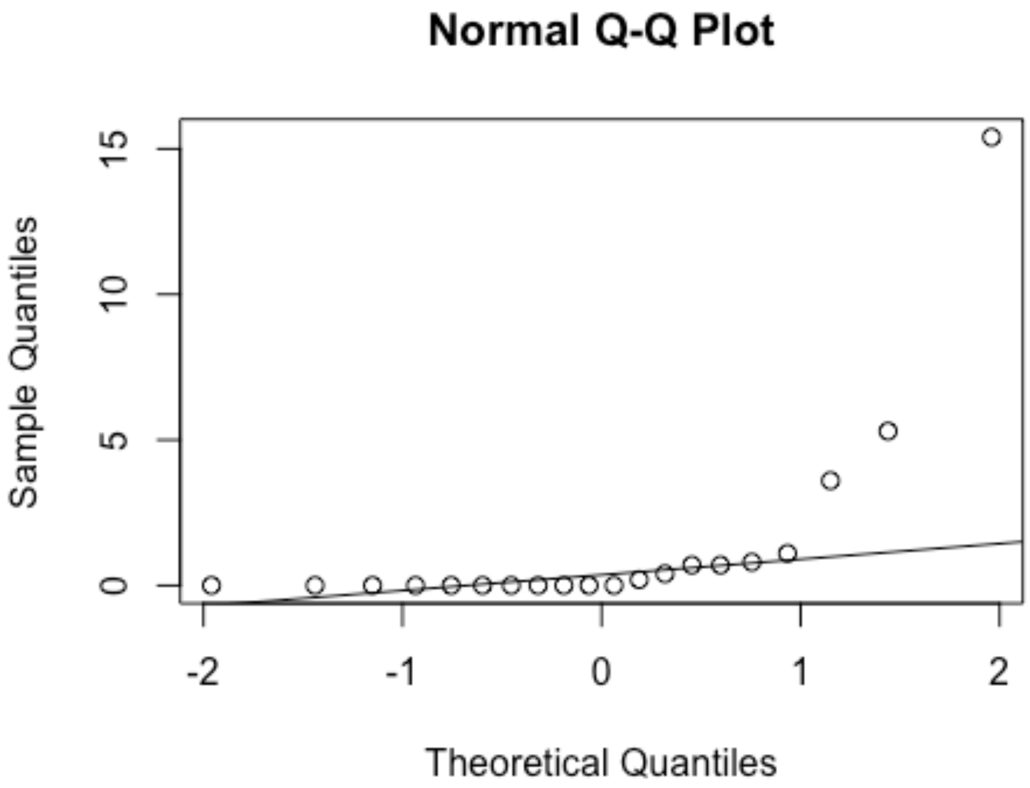
```
ad.test(subset(SSdata, intervention == "sham")$plms.total.index)

##
##  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
##
```

```
## data:  subset(SSdata, intervention == "sham")$plms.total.index and subset(
SSdata, intervention == "PrenaBelt")$plms.total.index
## W = 186.5, p-value = 0.7098
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.8000395  0.7000302
## sample estimates:
## difference in location
##           -4.60136e-05

#################### PLM Arousals Index in NREM ######################
#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$plm.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   0.000   0.000   0.000   2.245   0.850  38.900

sd(SSdata$plm.arousals.nrem.index, na.rm = TRUE)

## [1] 6.766886

length(SSdata$plm.arousals.nrem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(plm.arousals.nrem.index ~ intervention * nigh
t,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
## 
## Response: plm.arousals.nrem.index
##                    Df  Sum Sq Mean Sq F value Pr(>F)
## intervention        1   27.89  27.889  0.5852 0.4493
## night               1   40.80  40.804  0.8563 0.3610
## intervention:night  1    1.60   1.600  0.0336 0.8556
## Residuals          36 1715.55  47.654

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.nrem
.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nrem
.index,
       paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.nrem.index, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.nrem.index, : cannot compute exact confidence interva
l
## with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.nrem.index, : cannot compute exact p-value with zeroe
s

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.nrem.index, : cannot compute exact confidence interva
l
## with zeroes

## 
##  Wilcoxon signed rank test with continuity correction
## 
## data:  subset(SSdataCompletes, intervention == "sham")$plm.arousals.nrem.i
ndex and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.nr
em.index
## V = 24.5, p-value = 0.4767
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -15.000023   1.300048
## sample estimates:
## (pseudo)median 
##     -0.2999436

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   0.000   0.000   0.000   3.080   1.025  38.900

sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

## [1] 8.933886

length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)
```



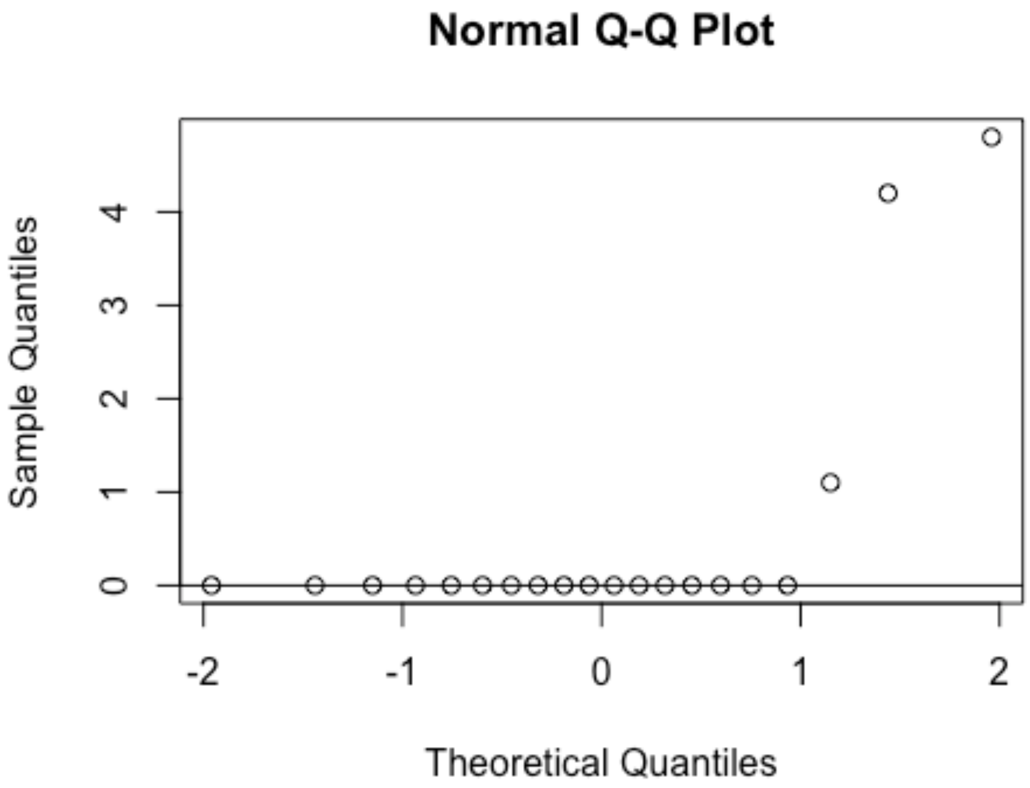
```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index)

##
##  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)
```



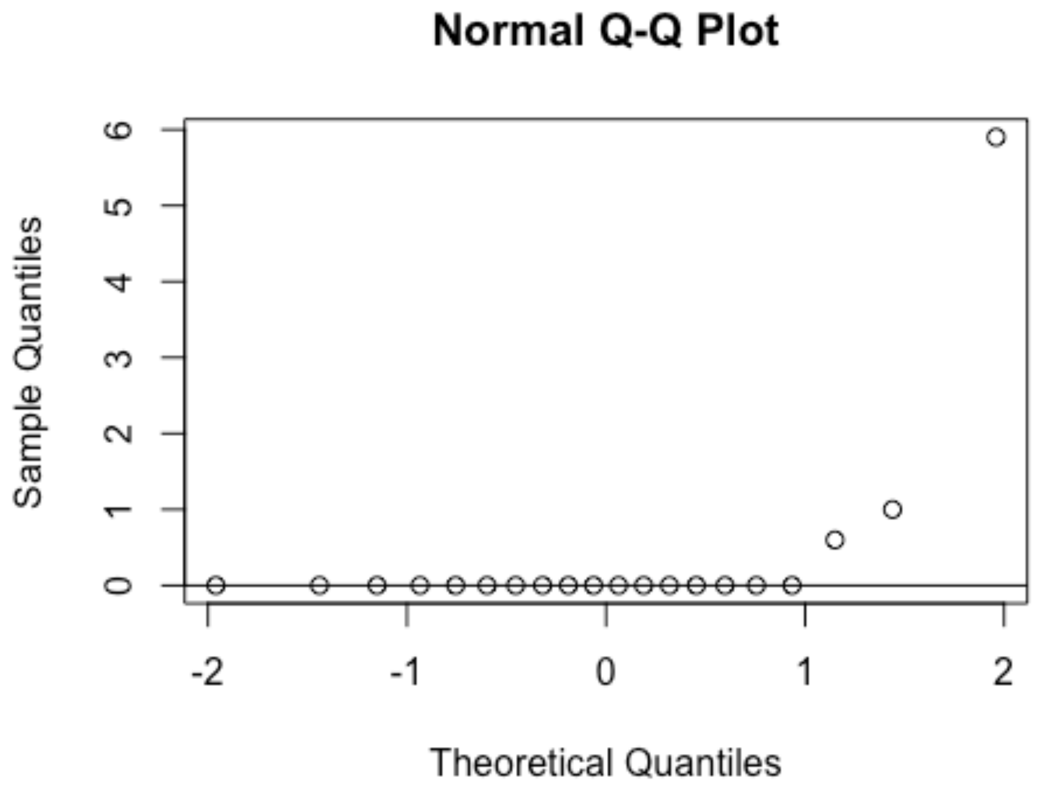
```
ad.test(subset(SSdata, intervention == "sham")$plm.arousals.nrem.index)

##
##  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")$plm.arousals.nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.ind
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
```

```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$plm.arousals.nrem.index and
subset(SSdata, intervention == "PrenaBelt")$plm.arousals.nrem.index
## W = 202, p-value = 0.964
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.1999861  0.1999049
## sample estimates:
## difference in location
##           4.324873e-05

#################### PLM Arousals Index in REM #######################
#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$plm.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.44    0.00    5.90

sd(SSdata$plm.arousals.rem.index, na.rm = TRUE)

## [1] 1.342749

length(SSdata$plm.arousals.rem.index)

## [1] 40

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

## Analysis of Variance Table
##
## Response: plm.arousals.rem.index
##                    Df Sum Sq Mean Sq F value Pr(>F)
## intervention        1  0.169  0.1690  0.0894 0.7666
## night               1  1.600  1.6000  0.8468 0.3636
## intervention:night  1  0.529  0.5290  0.2800 0.6000
## Residuals          36 68.018  1.8894

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.rem.
index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.rem.
```

```
index,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$plm.arousals.rem.index, : requested conf.level not achievable

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$plm.arousals.rem.in
dex and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.rem
.index
## V = 7, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
## 80 percent confidence interval:
##  -2.100052  1.150009
## sample estimates:
## (pseudo)median
##    -0.05003072

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.505   0.000   4.800

sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

## [1] 1.391506

length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)
```

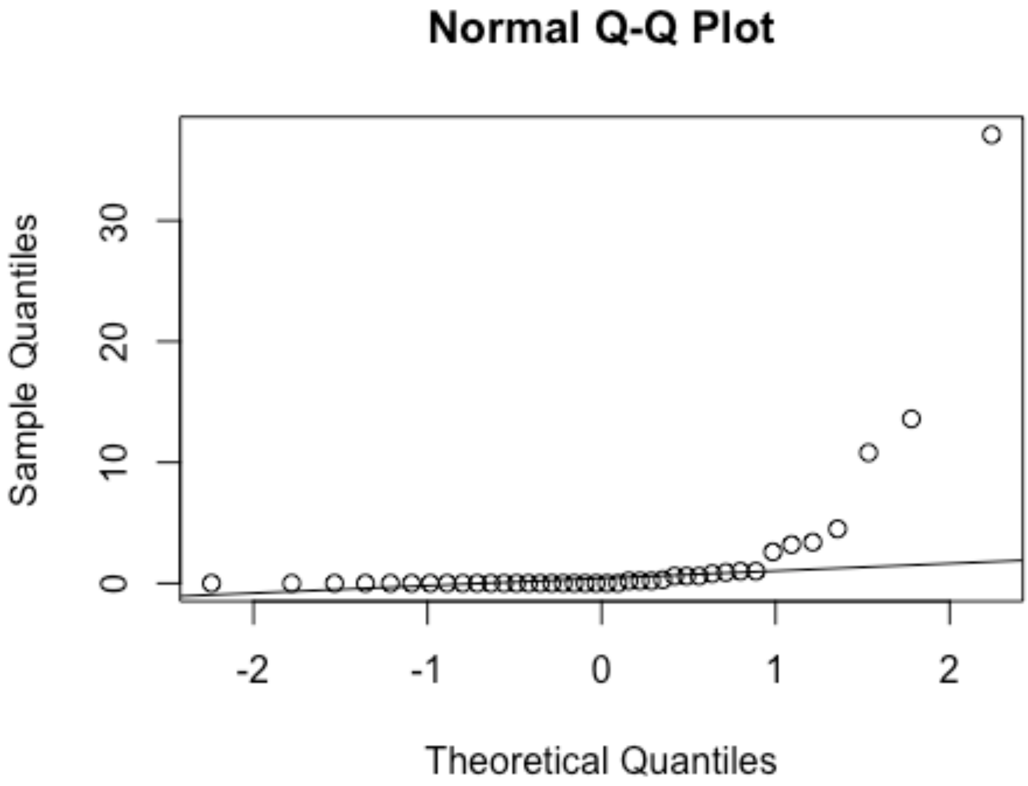


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index)

##
##  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)
```



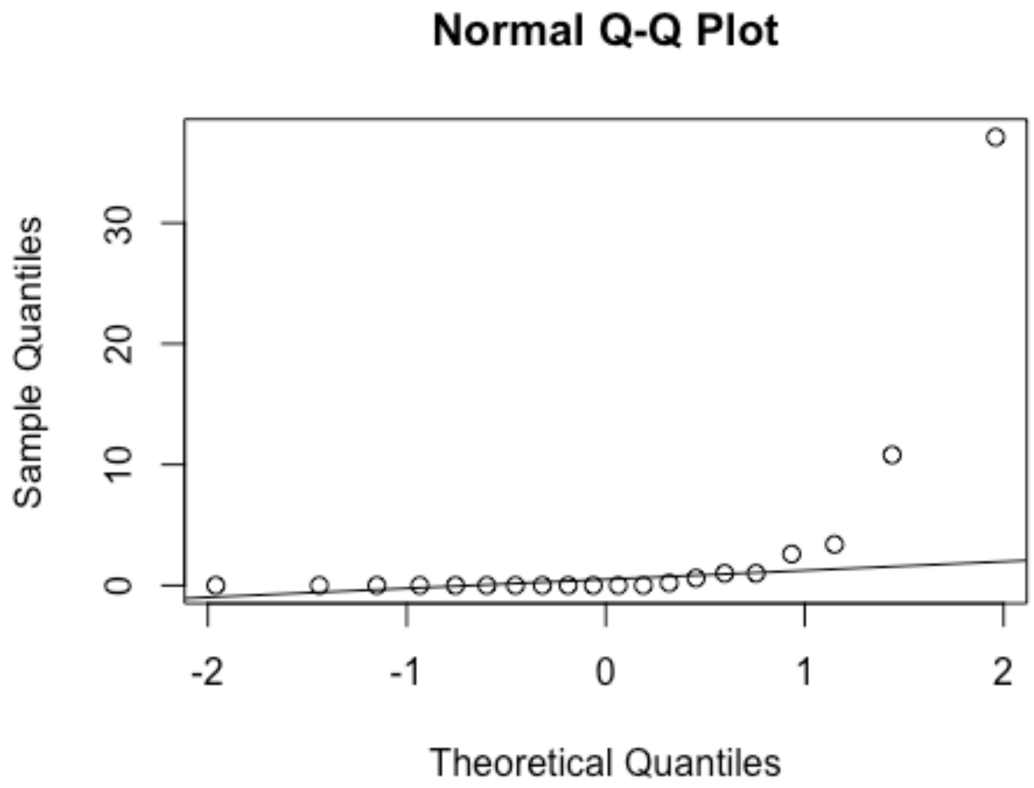
```
ad.test(subset(SSdata, intervention == "sham")$plm.arousals.rem.index)

##
##  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")$plm.arousals.rem.index,
            subset(SSdata, intervention == "PrenaBelt")$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
```

```
##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$plm.arousals.rem.index and s
ubset(SSdata, intervention == "PrenaBelt")$plm.arousals.rem.index
## W = 198.5, p-value = 0.9653
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.538669e-05  6.131588e-05
## sample estimates:
## difference in location
##          -3.635924e-05

#################### PLM Arousals Total Index (TST = NREM + REM) ############
###########
#Summary
summary(SSdata$plm.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   2.040   0.825  37.100

sd(SSdata$plm.arousals.total.index, na.rm = TRUE)

## [1] 6.334877

length(SSdata$plm.arousals.total.index)

## [1] 40

qqnorm(SSdata$plm.arousals.total.index)
qqline(SSdata$plm.arousals.total.index)
```



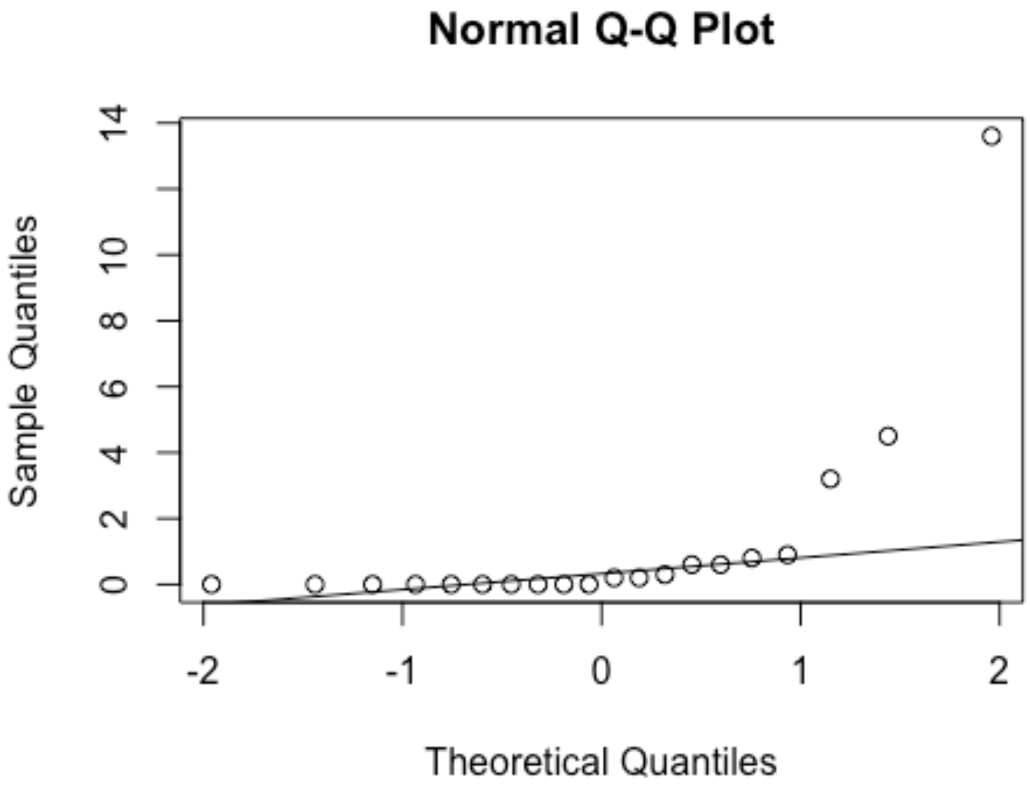
```
ad.test(SSdata$plm.arousals.total.index)

##
##  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
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$plm.arousals.tota
l.index,
            subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals
.total.index,
            paired = TRUE, conf.int = TRUE)

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

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

## 
##  Wilcoxon signed rank test with continuity correction
## 
## data:  subset(SSdataCompletes, intervention == "sham")$plm.arousals.total.
index and subset(SSdataCompletes, intervention == "PrenaBelt")$plm.arousals.t
otal.index
## V = 23, p-value = 0.6835
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -15.999946   1.499952
## sample estimates:
## (pseudo)median 
##     -0.2999886

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   0.000   0.000   0.000   2.835   1.000  37.100

sd(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

## [1] 8.438712

length(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.inde
x
## 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)
```



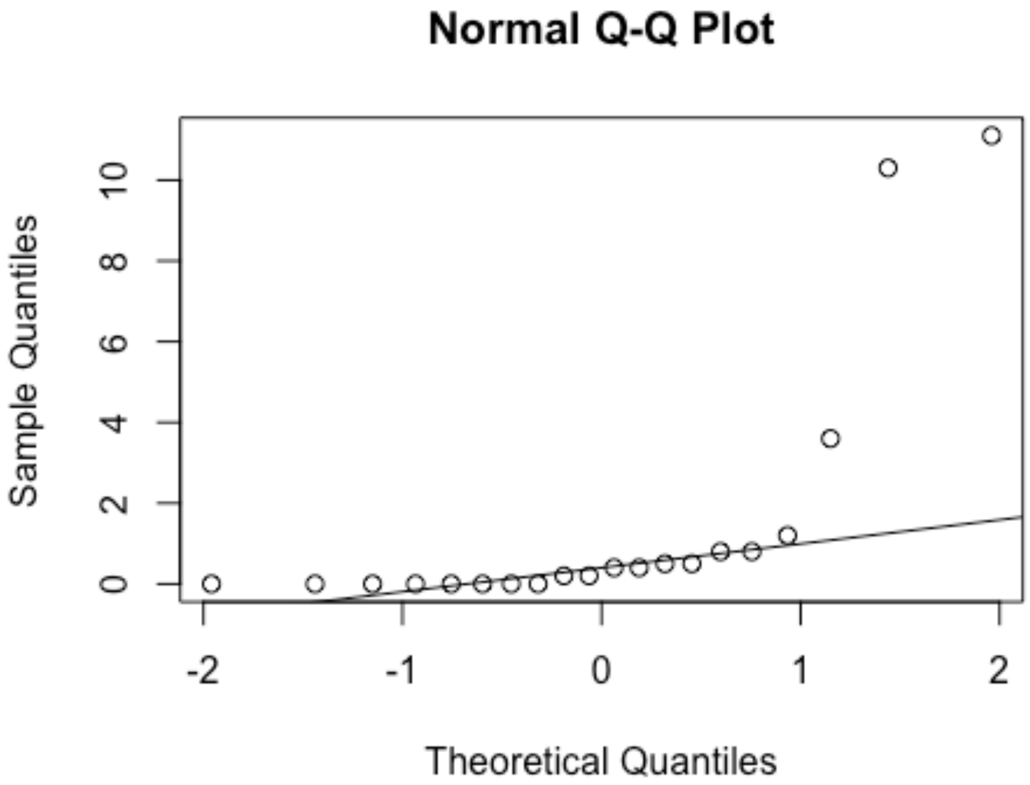
```
ad.test(subset(SSdata, intervention == "sham")$plm.arousals.total.index)

##
##  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")$plm.arousals.total.index,
            subset(SSdata, intervention == "PrenaBelt")$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
```

```
h
## ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$plm.arousals.total.index and
subset(SSdata, intervention == "PrenaBelt")$plm.arousals.total.index
## W = 207, p-value = 0.8472
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.1999686  0.2000065
## sample estimates:
## difference in location
##           4.063208e-05

#################### Respiratory Arousals Index in NREM #####################
##
#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$respiratory.arousals.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.20    1.11    0.80   11.10

sd(SSdata$respiratory.arousals.nrem.index, na.rm = TRUE)

## [1] 2.639716

length(SSdata$respiratory.arousals.nrem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(respiratory.arousals.nrem.index ~ interventio
n * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: respiratory.arousals.nrem.index
##                    Df  Sum Sq Mean Sq F value  Pr(>F)
## intervention        1   6.084  6.0840  0.9328 0.34058
## night               1   4.624  4.6240  0.7089 0.40535
## intervention:night  1  26.244 26.2440  4.0237 0.05242 .
## Residuals          36 234.804  6.5223
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arous
als.nrem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arous
als.nrem.index,
       paired = TRUE, conf.int = TRUE)

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.nrem.index, : cannot compute exact confidence
## interval with ties

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
s.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respira
tory.arousals.nrem.index
## V = 30, p-value = 0.09338
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.15001291  0.05002172
## sample estimates:
## (pseudo)median
##     -0.3500664

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     0.0     0.0     0.3     1.5     0.8    11.1

sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.inde
x)

## [1] 3.251558

length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
index)
```

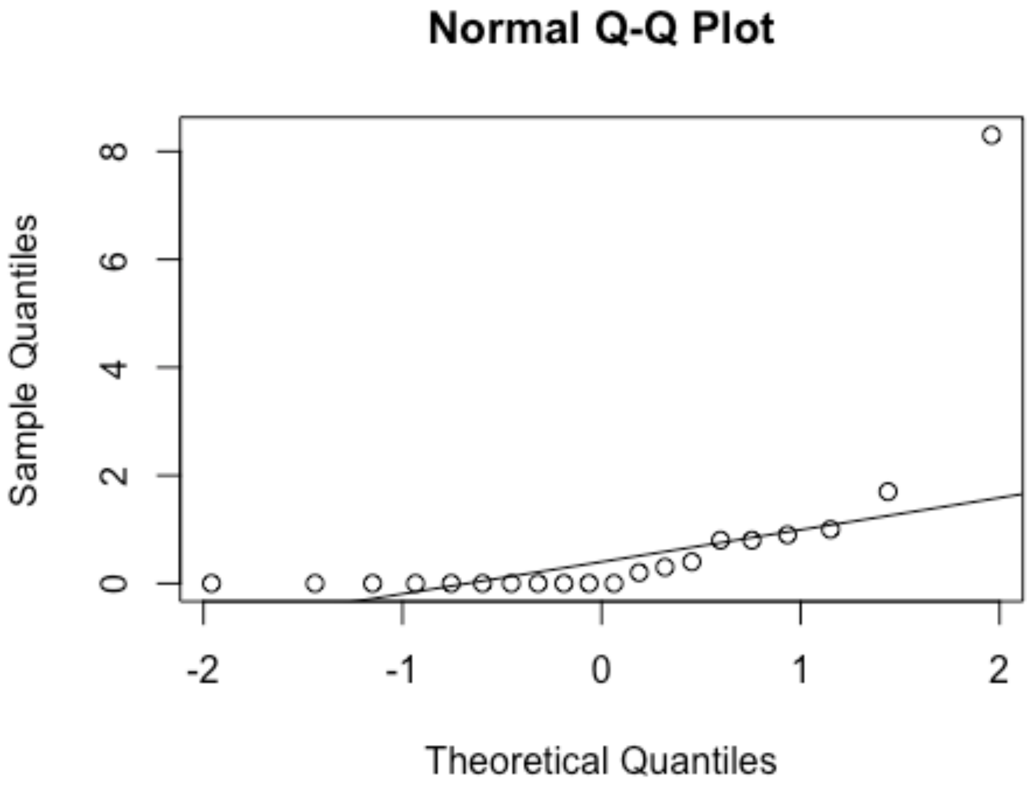
```
## [1] 20
```

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
index)
qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem.
index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nr
em.index
## A = 4.3757, p-value = 2.59e-11

#non-normal

summary(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.inde
x)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.72    0.80    8.30
```

```
sd(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index)

## [1] 1.846647

length(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
)
qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.index
)
```



```
ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.inde
x)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.in
dex
## A = 4.3196, p-value = 3.581e-11
```

```
#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.
index,
            subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.
nrem.index,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.nrem.in
dex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.nrem
.index
## W = 171, p-value = 0.4142
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -4.000240e-01  3.702807e-05
## sample estimates:
## difference in location
##           -5.97387e-05

#################### Respiratory Arousals Index in REM #####################
#
#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$respiratory.arousals.rem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.950   6.612   4.225  70.000

sd(SSdata$respiratory.arousals.rem.index, na.rm = TRUE)

## [1] 14.61077

length(SSdata$respiratory.arousals.rem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(respiratory.arousals.rem.index ~ intervention
```

```
* night,
                                data = SSdata))
night_tx_difference
```

```
## Analysis of Variance Table
##
## Response: respiratory.arousals.rem.index
##                      Df Sum Sq Mean Sq F value  Pr(>F)
## intervention          1    0.4    0.42  0.0021 0.96365
## night                 1   18.6   18.63  0.0934 0.76166
## intervention:night    1 1124.7 1124.66  5.6376 0.02303 *
## Residuals            36 7181.8  199.49
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

```
#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arous
als.rem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.arous
als.rem.index,
       paired = TRUE, conf.int = TRUE)
```

```
## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.rem.index, : cannot compute exact p-value wit
h
## ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.rem.index, : cannot compute exact confidence
## interval with ties

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.rem.index, : cannot compute exact p-value wit
h
## zeroes

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

```
##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
s.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respirat
ory.arousals.rem.index
## V = 67, p-value = 0.7119
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.249966  3.599990
```

```
## sample estimates:
## (pseudo)median
##      0.3582702
```

```
#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.
index)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.55    6.51    4.35   47.10
```

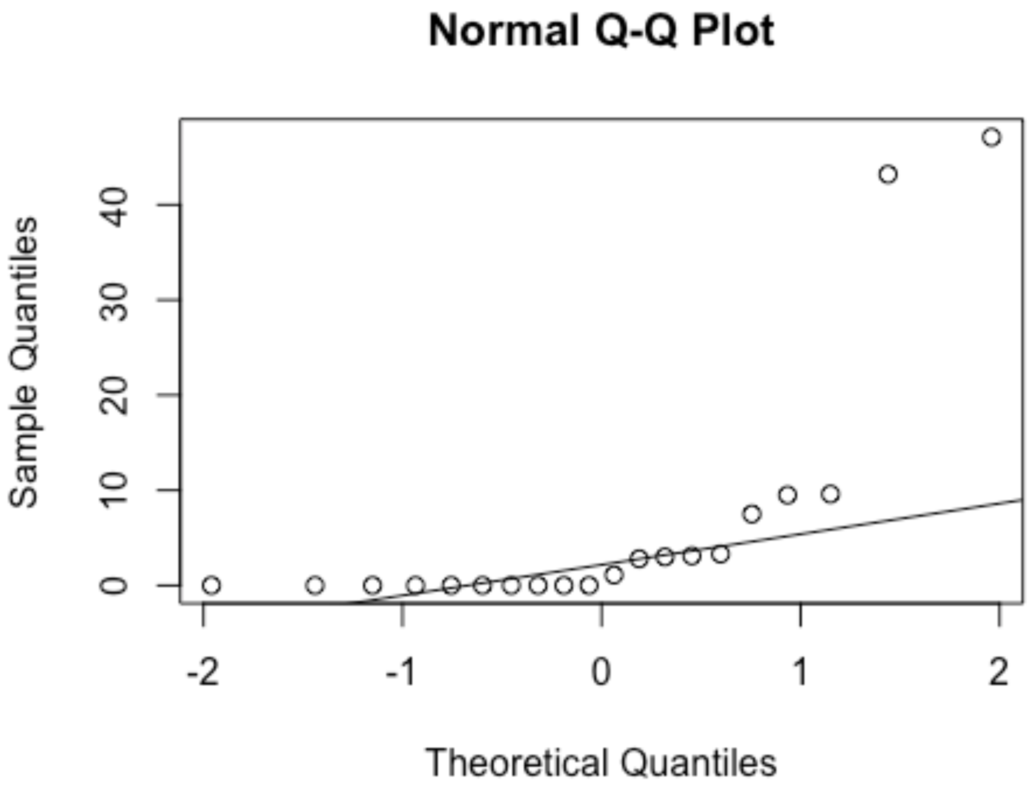
```
sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.index
)
```

```
## [1] 13.60003
```

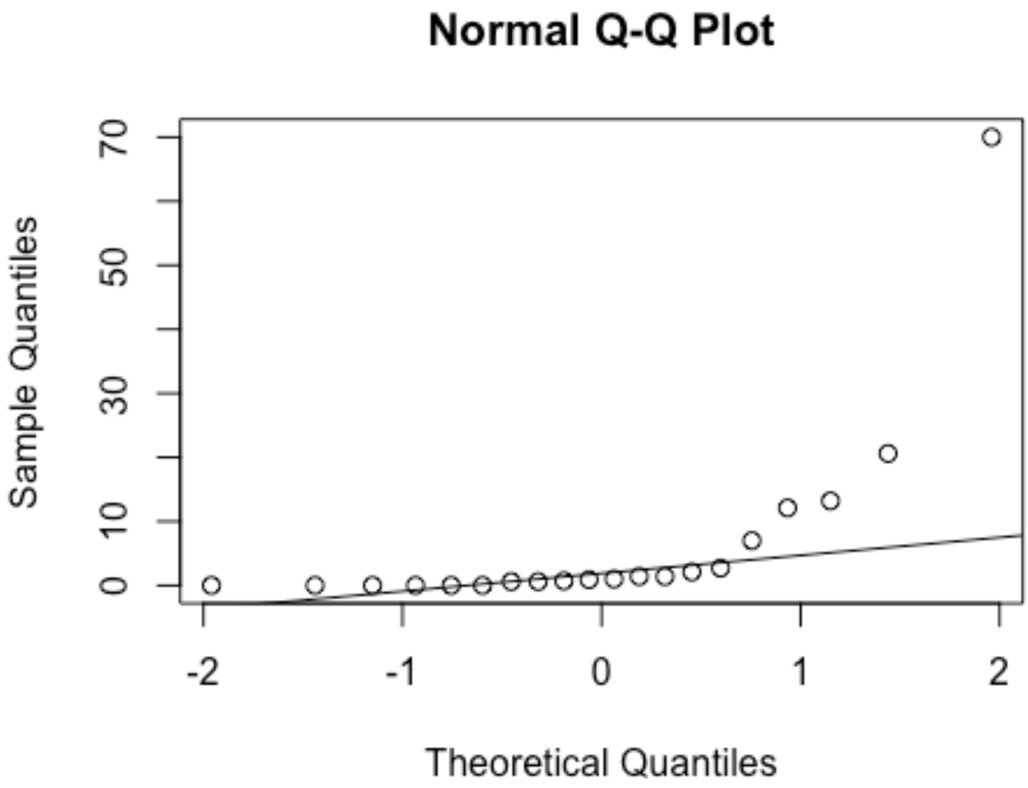
```
length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
ndex)
```

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

```
qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
ndex)
qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
ndex)
```

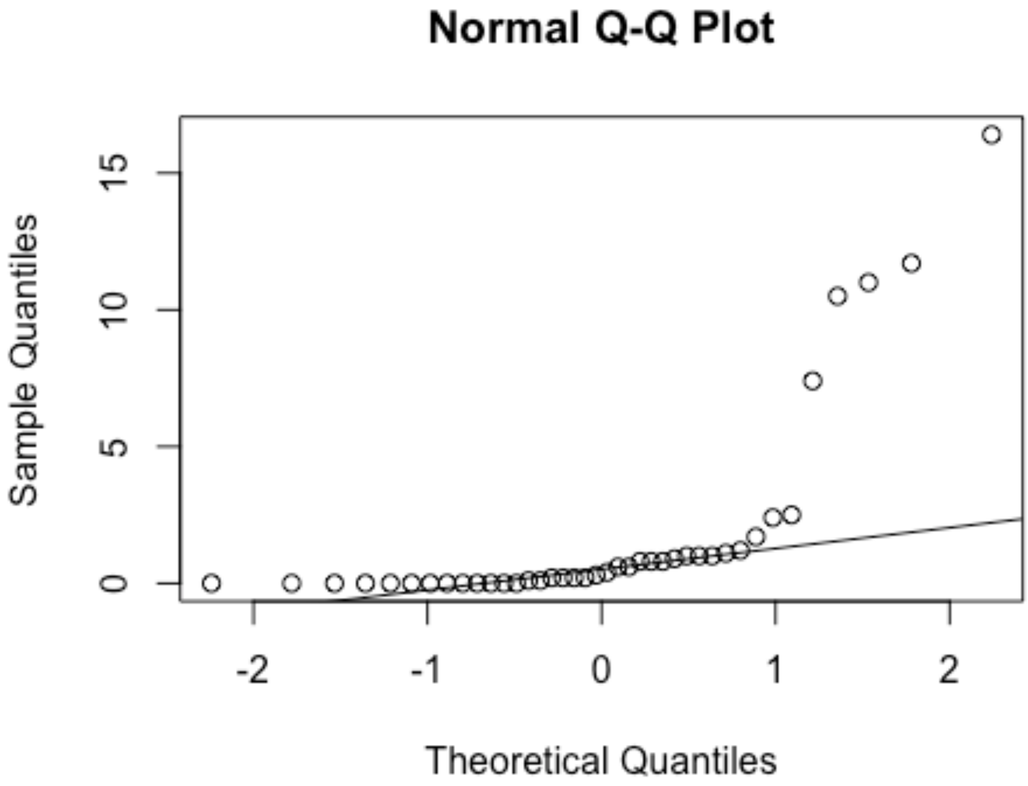


```
ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.
index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.re
m.index
## A = 4.0123, p-value = 2.119e-10

#non-normal

summary(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.950   6.715   3.775  70.000

sd(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)

## [1] 15.9123

length(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.index
)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.rem.ind
ex
## A = 4.0308, p-value = 1.904e-10

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.rem.i
ndex,
            subset(SSdata, intervention == "PrenaBelt")$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
```

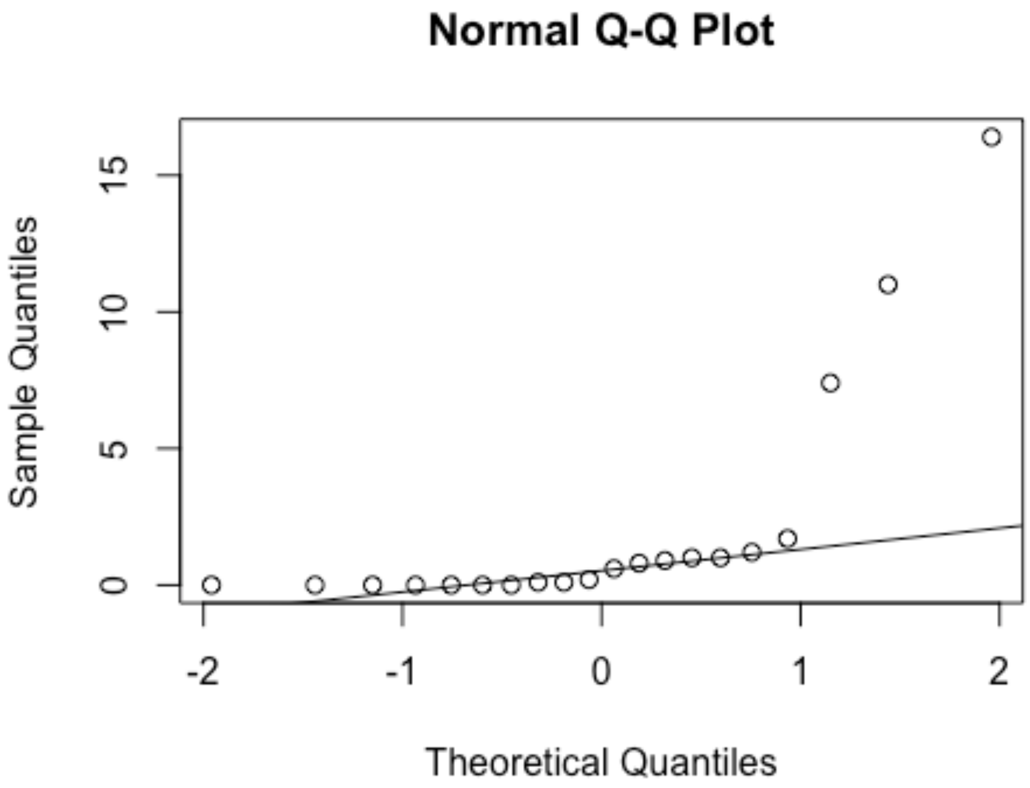
```
## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $respiratory.arousals.rem.index, : cannot compute exact confidence
## intervals with ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.rem.ind
ex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.rem.i
ndex
## W = 213, p-value = 0.7267
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.900003  1.399993
## sample estimates:
## difference in location
##            5.850022e-05

#################### Respiratory Arousals Total Index (TST = NREM + REM) ####
###########
#Summary
summary(SSdata$respiratory.arousals.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.350   1.878   1.025  16.400

sd(SSdata$respiratory.arousals.total.index, na.rm = TRUE)

## [1] 3.840706

length(SSdata$respiratory.arousals.total.index)

## [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
## 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
```

```
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$respiratory.arous
als.total.index,
            subset(SSdataCompletes, intervention == "PrenaBelt")$respiratory.
arousals.total.index,
            paired = TRUE, conf.int = TRUE)

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.total.index, : cannot compute exact confidenc
e
## interval with ties

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$respiratory.arousals.total.index, : cannot compute exact confidenc
e
## interval with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$respiratory.arousal
s.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$respir
atory.arousals.total.index
## V = 62, p-value = 0.776
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -2.0999697  0.5000137
## sample estimates:
## (pseudo)median
##     -0.1000365

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tota
l.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.40    2.12    1.05   16.40

sd(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total.ind
ex)
```

```
## [1] 4.371149

length(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.total
.index)
```



```
ad.test(subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tota
l.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.to
tal.index
## A = 3.9897, p-value = 2.416e-10

#non-normal
```

```
summary(subset(SSdata, intervention == "sham")$respiratory.arousals.total.ind
ex)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.350   1.635   1.025  11.700
```

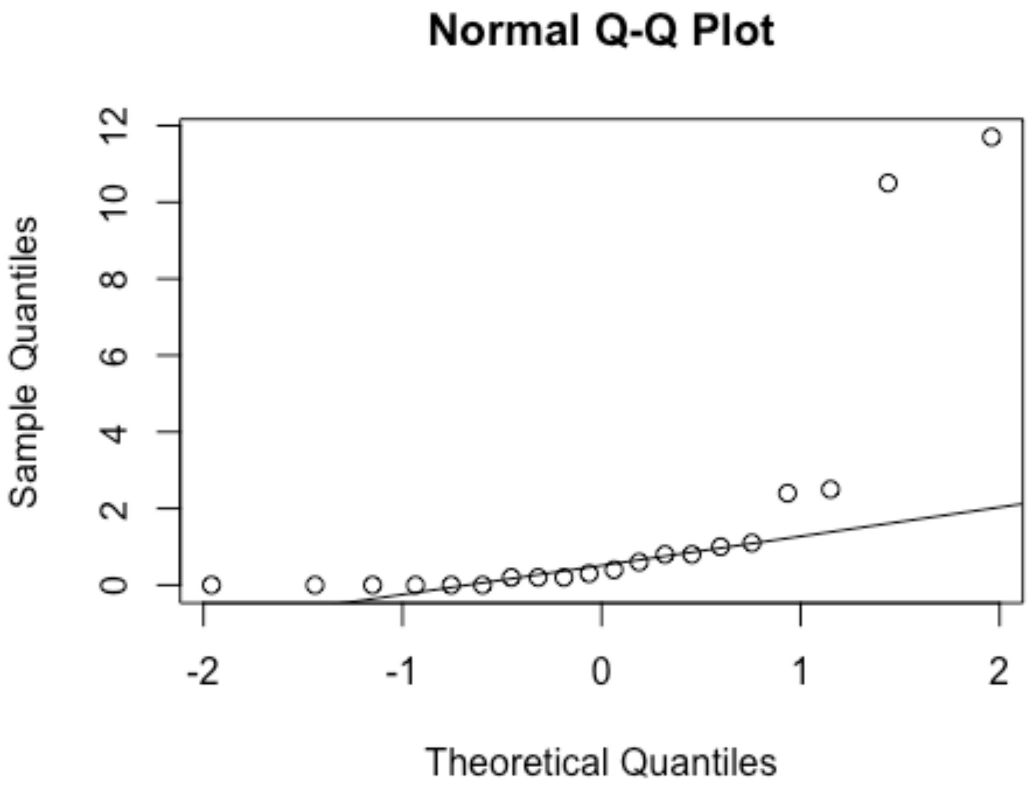
```
sd(subset(SSdata, intervention == "sham")$respiratory.arousals.total.index)
```

```
## [1] 3.323802
```

```
length(subset(SSdata, intervention == "sham")$respiratory.arousals.total.inde
x)
```

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

```
qqnorm(subset(SSdata, intervention == "sham")$respiratory.arousals.total.inde
x)
qqline(subset(SSdata, intervention == "sham")$respiratory.arousals.total.inde
x)
```



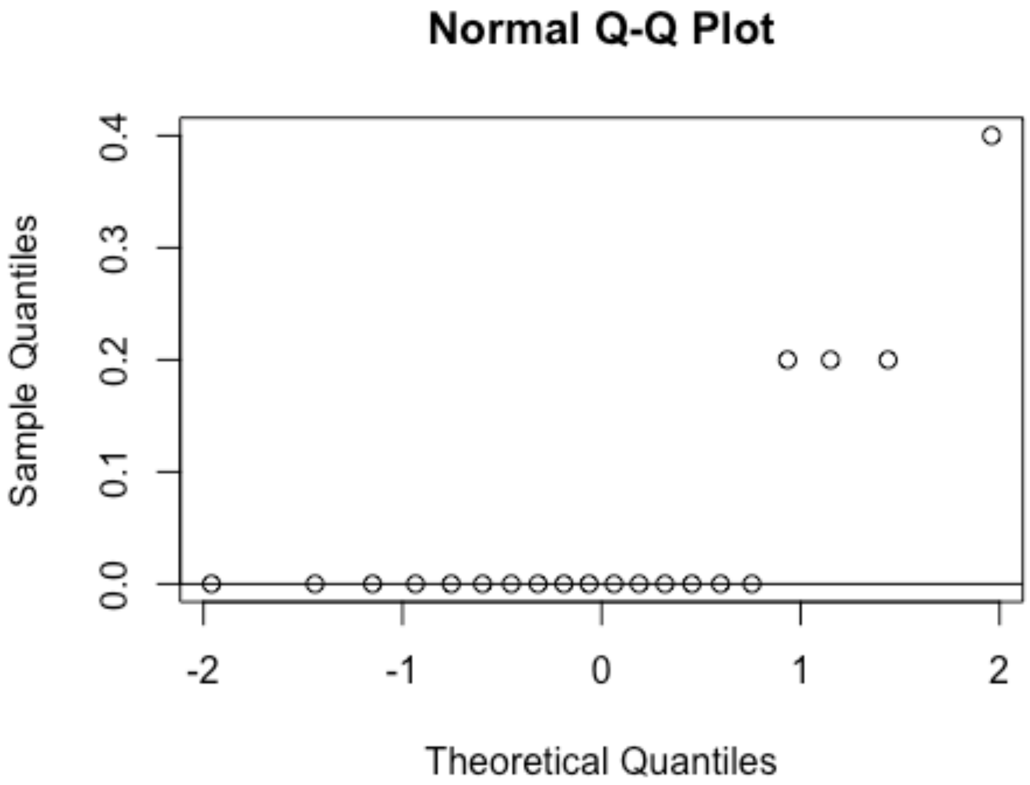
```
ad.test(subset(SSdata, intervention == "sham")$respiratory.arousals.total.ind
ex)
```

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

```
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.total.i
ndex
## A = 4.0437, p-value = 1.767e-10

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$respiratory.arousals.total
.index,
            subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.
total.index,
            conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdata, intervention == "sham")
## $respiratory.arousals.total.index, : cannot compute exact p-value with tie
s

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$respiratory.arousals.total.i
ndex and subset(SSdata, intervention == "PrenaBelt")$respiratory.arousals.tot
al.index
## W = 203, p-value = 0.9451
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.5999724  0.3999323
## sample estimates:
## difference in location
##           9.000537e-06

########### Arousing events NOT meeting respiratory criteria Index in NREM ##
#########
#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$arousals.with.respiratory.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.045   0.000   0.400

sd(SSdata$arousals.with.respiratory.nrem.index, na.rm = TRUE)

## [1] 0.09594336
```

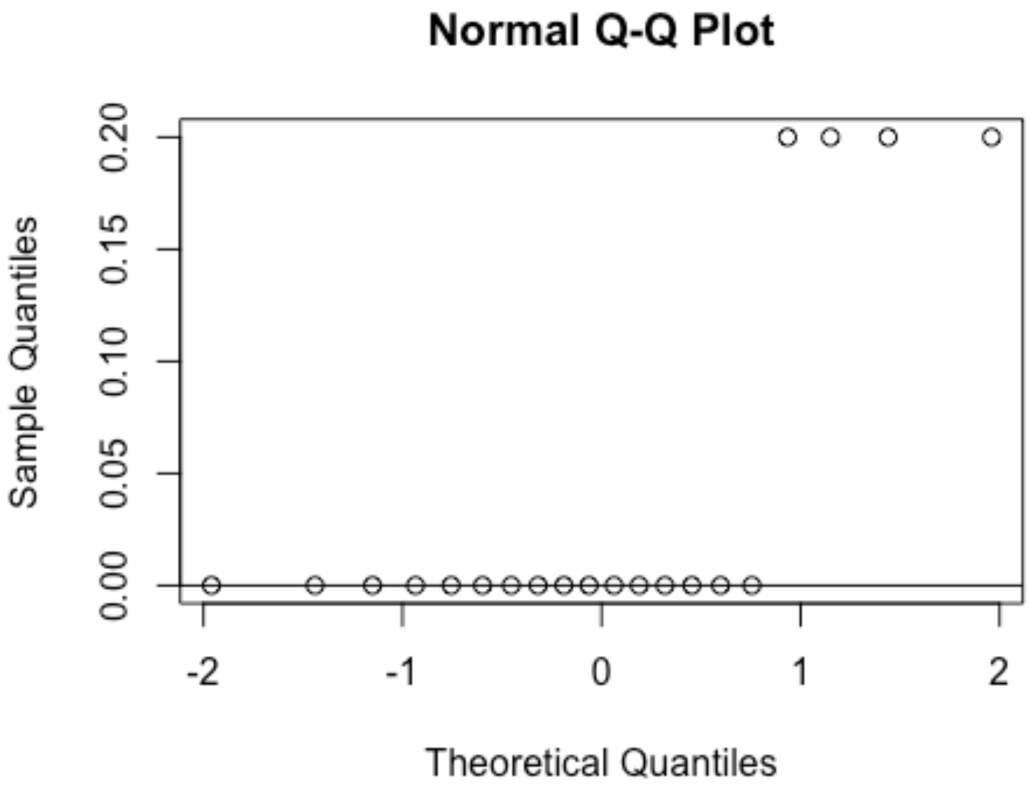
```
length(SSdata$arousals.with.respiratory.nrem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(arousals.with.respiratory.nrem.index ~ interv
ention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: arousals.with.respiratory.nrem.index
##                      Df Sum Sq   Mean Sq F value Pr(>F)
## intervention          1  0.001 0.0010000  0.1034 0.7496
## night                 1  0.001 0.0010000  0.1034 0.7496
## intervention:night    1  0.009 0.0090000  0.9310 0.3410
## Residuals            36  0.348 0.0096667

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
piratory.nrem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
piratory.nrem.index,
       paired = TRUE)

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
ratory.nrem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$ar
ousals.with.respiratory.nrem.index
## V = 2, p-value = 0.7728
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
.nrem.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00    0.00    0.05    0.00    0.40
```

```
sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.nrem
.index)

## [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
```

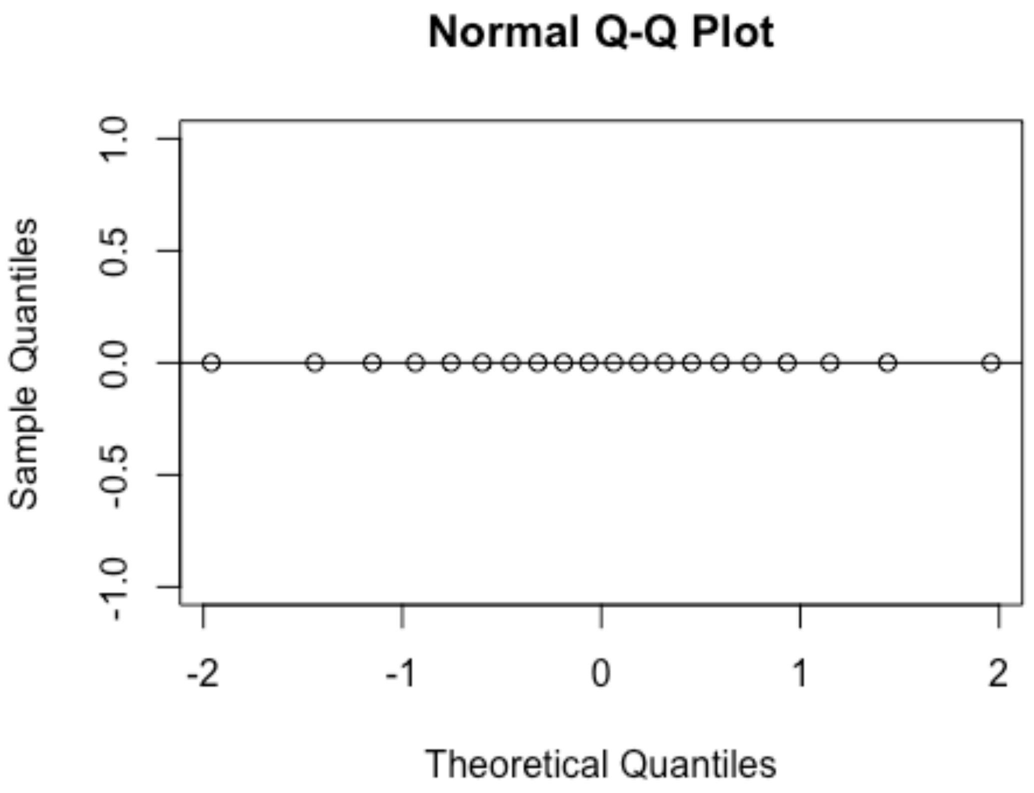
```
#non-normal

summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem
.index)

##    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.inde
x)

## [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)
```



```
ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.nrem
.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.nr
em.index
## A = 5.1941, p-value = 2.32e-13

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
nrem.index,
            subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
tory.nrem.index,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.nr
em.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respir
atory.nrem.index
## W = 198, p-value = 0.9534
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -1.407869e-05  9.852765e-06
## sample estimates:
## difference in location
##          -3.692335e-06

####### Arousing events NOT meeting respiratory criteria Index in REM #######
##
#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$arousals.with.respiratory.rem.index)
```

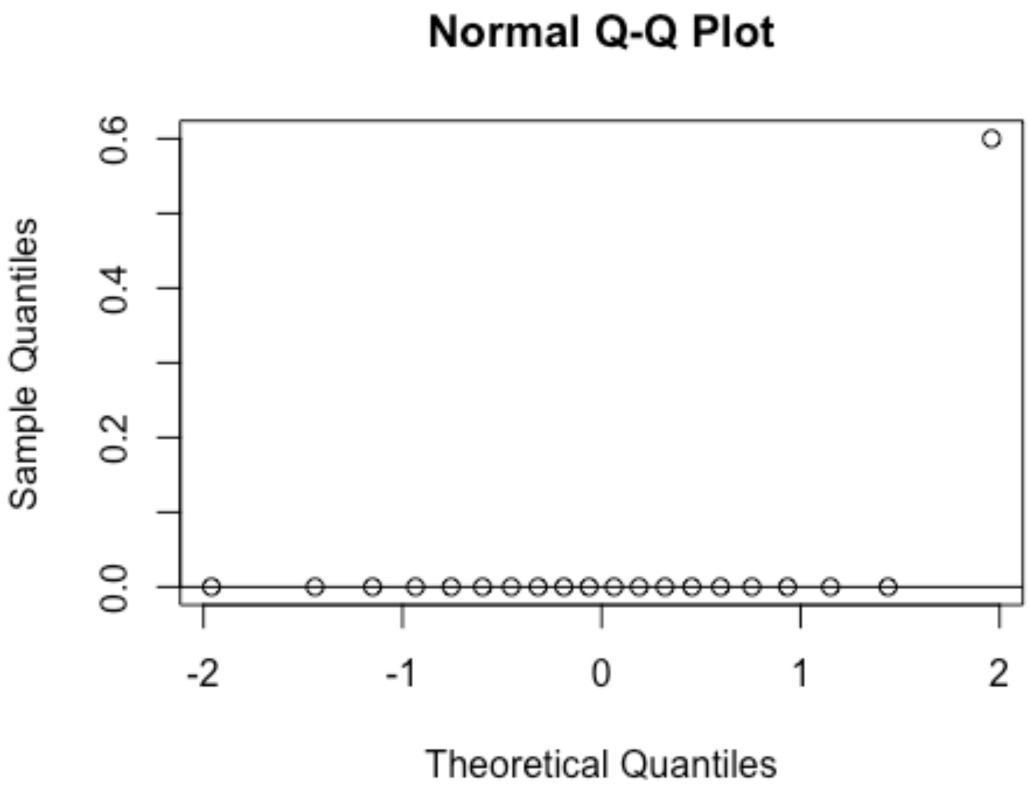
```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.015   0.000   0.600

sd(SSdata$arousals.with.respiratory.rem.index, na.rm = TRUE)

## [1] 0.09486833

length(SSdata$arousals.with.respiratory.rem.index)

## [1] 40

#ANOVA
night_tx_difference <- anova(lm(arousals.with.respiratory.rem.index ~ interve
ntion * night,
                                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")$arousals.with.res
piratory.rem.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
piratory.rem.index,
       paired = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$arousals.with.respiratory.rem.index, : cannot compute exact p-valu
e
## with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
ratory.rem.index and subset(SSdataCompletes, intervention == "PrenaBelt")$aro
usals.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

qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
rem.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
rem.index)
```



```
#ad.test(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respirator
y.rem.index)
#distribution is entirely zeroes

summary(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.
index)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##    0.00    0.00    0.00    0.03    0.00    0.60

sd(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.index
)

## [1] 0.1341641

length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
ndex)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
ndex)
qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.i
ndex)
```

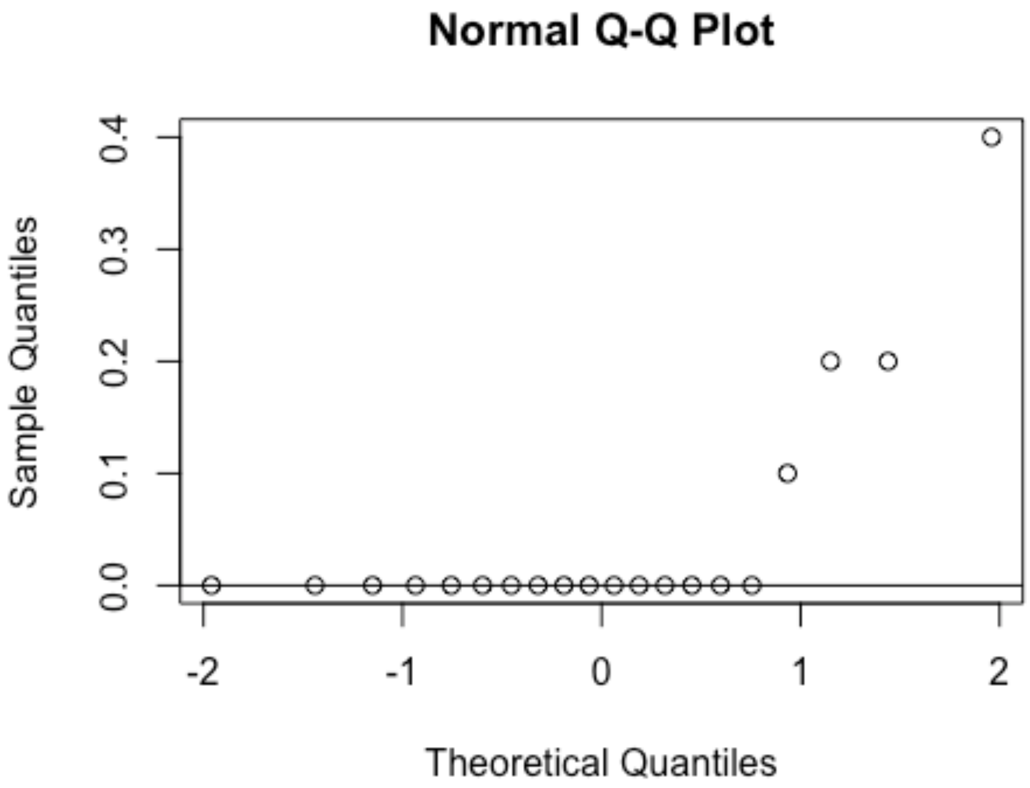


```
ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.rem.
index)

## 
##  Anderson-Darling normality test
## 
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.re
```

```
m.index
## A = 7.1762, p-value < 2.2e-16

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
rem.index,
            subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
tory.rem.index,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.re
m.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
tory.rem.index
## W = 210, p-value = 0.3421
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  0 0
## sample estimates:
## difference in location
##                      0

####### Arousing events NOT meeting respiratory criteria Index (TST = NREM +
REM) ######
#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$arousals.with.respiratory.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##  0.0000  0.0000  0.0000  0.0425  0.0000  0.4000

sd(SSdata$arousals.with.respiratory.total.index, na.rm = TRUE)

## [1] 0.09577618

length(SSdata$arousals.with.respiratory.total.index)
```

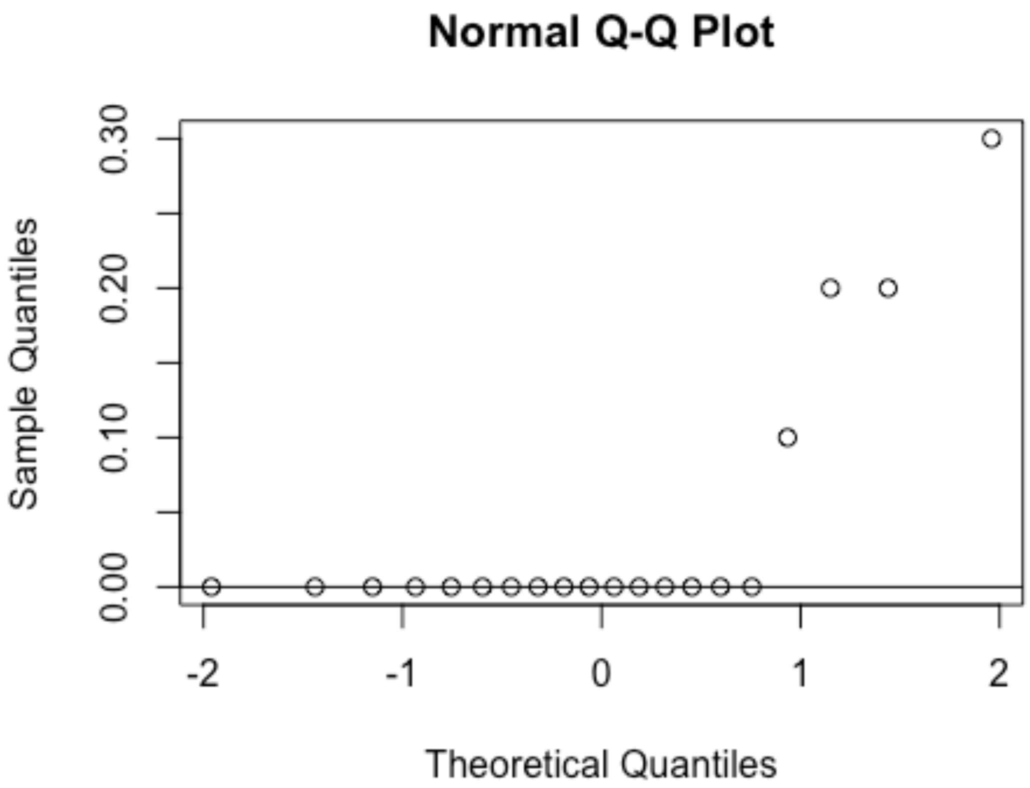
```
## [1] 40

#ANOVA
night_tx_difference <- anova(lm(arousals.with.respiratory.total.index ~ inter
vention * night,
                                data = SSdata))
night_tx_difference

## Analysis of Variance Table
##
## Response: arousals.with.respiratory.total.index
##                     Df  Sum Sq Mean Sq F value Pr(>F)
## intervention         1 0.00025 0.00025  0.0256 0.8737
## night                1 0.00025 0.00025  0.0256 0.8737
## intervention:night   1 0.00625 0.00625  0.6410 0.4286
## Residuals           36 0.35100 0.00975

#within-participants (paired) comparison
#Paired Wilcoxon
wilcox.test(subset(SSdataCompletes, intervention == "sham")$arousals.with.res
piratory.total.index,
       subset(SSdataCompletes, intervention == "PrenaBelt")$arousals.with.res
piratory.total.index,
       paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$arousals.with.respiratory.total.index, : requested conf.level not
## achievable

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

## Warning in wilcox.test.default(subset(SSdataCompletes, intervention ==
## "sham")$arousals.with.respiratory.total.index, : cannot compute exact
## confidence interval with ties

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

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

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  subset(SSdataCompletes, intervention == "sham")$arousals.with.respi
ratory.total.index and subset(SSdataCompletes, intervention == "PrenaBelt")$a
rousals.with.respiratory.total.index
## V = 5.5, p-value = 0.6831
```

```
## alternative hypothesis: true location shift is not equal to 0
## 90 percent confidence interval:
##  -0.2  0.2
## sample estimates:
## (pseudo)median
##  -5.079939e-05

#between participants (grouped) comparison
summary(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory
.total.index)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   0.045   0.000   0.400

sd(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.tota
l.index)

## [1] 0.1050063

length(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
total.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
total.index)
qqline(subset(SSdata, intervention == "PrenaBelt")$arousals.with.respiratory.
total.index)
```



```
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
```

```
length(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
.index)

## [1] 20

qqnorm(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
.index)
qqline(subset(SSdata, intervention == "sham")$arousals.with.respiratory.total
.index)
```



```
ad.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.tota
l.index)

##
##  Anderson-Darling normality test
##
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.to
tal.index
## A = 4.6836, p-value = 4.379e-12

#non-normal

#FYI - unpaired test
wilcox.test(subset(SSdata, intervention == "sham")$arousals.with.respiratory.
```

```
total.index,
            subset(SSdata, intervention == "PrenaBelt")$arousals.with.respira
tory.total.index,
            conf.int = TRUE)

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

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

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  subset(SSdata, intervention == "sham")$arousals.with.respiratory.to
tal.index and subset(SSdata, intervention == "PrenaBelt")$arousals.with.respi
ratory.total.index
## W = 199.5, p-value = 1
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -5.011195e-06  5.395622e-05
## sample estimates:
## difference in location
##           -6.56778e-05

#end
```

Supplementary file 3: Code and output – feedback analysis

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 comparison
s (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#############################
```

```
#summary data
summary(PBUFdata$SR.position.adopted)

##                             left  left and right left and supine
##                0              27               5               1
##            right          supine
##                5               2

length(PBUFdata$SR.position.adopted)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.position.adopted + Intervention, data = PBUFdata)

##                      Intervention
## SR.position.adopted sham treatment
##                        0         0
##      left             13        14
##      left and right    2         3
##      left and supine   1         0
##      right             3         2
##      supine            1         1

#build 2-row table for fisher test: sham vs treatment
SR.position.adopted_table <- matrix(c(16,17,5,5,2,1),
                                    nrow = 2)
colnames(SR.position.adopted_table) <- c("left","right","supine")
rownames(SR.position.adopted_table) <- c("Sham",
                                         "Treatment")
SR.position.adopted_table

##            left right supine
## Sham         16     5      2
## Treatment    17     5      1

t(SR.position.adopted_table)

##         Sham Treatment
## left      16        17
## right      5         5
## supine     2         1

#Perform Fisher's Exact Tests

temp_table <- t(SR.position.adopted_table)
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] "left"
##       Sham Treatment
## left    16        17
## Other    7         6
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.181121 3.522335
## sample estimates:
## odds ratio
##   0.810505
##
## [1] "right"
##       Sham Treatment
## right    5         5
## Other   18        18
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1927805 5.1872475
## sample estimates:
## odds ratio
##          1
##
## [1] "supine"
##        Sham Treatment
## supine    2         1
## Other    21        22
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
```

```
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0.1003416 129.0322645
## sample estimates:
## odds ratio
##   2.062812

#############################SR POSITION FELL ASLEEP#########################
####
#summary data
summary(PBUFdata$SR.position.fell.asleep)

##                                       left       left and right
##                    0                    27                    5
## left, right and back                right               supine
##                    1                    5                    2

length(PBUFdata$SR.position.fell.asleep)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.position.fell.asleep + Intervention, data = PBUFdata)

##                         Intervention
## SR.position.fell.asleep sham treatment
##                            0         0
##    left                   13        14
##    left and right          2         3
##    left, right and back    1         0
##    right                   3         2
##    supine                  1         1

#build 2-row table for fisher test: sham vs treatment
SR.position.fell.asleep_table <- matrix(c(16,17,6,5,2,1),
                                    nrow = 2)
colnames(SR.position.fell.asleep_table) <- c("left","right","supine")
rownames(SR.position.fell.asleep_table) <- c("Sham",
                                         "Treatment")
t(SR.position.fell.asleep_table)

##        Sham Treatment
## left     16        17
## right     6         5
## supine    2         1

#Perform Fisher's Exact Tests

temp_table <- t(SR.position.fell.asleep_table)
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] "left"
##       Sham Treatment
## left    16        17
## Other    8         6
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7516
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1630989 2.9521011
## sample estimates:
## odds ratio
##  0.7111464
##
## [1] "right"
##       Sham Treatment
## right    6         5
## Other   18        18
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.2513307 5.9379379
## sample estimates:
## odds ratio
##   1.195355
##
## [1] "supine"
##        Sham Treatment
## supine    2         1
## Other    22        22
```

```
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##    0.09605226 123.17436447
## sample estimates:
## odds ratio
##   1.971677

#############################SR SNORING#############################
#summary data
summary(PBUFdata$SR.snored.last.night)

##            don't know         no        yes
##          3         26          8          3

length(PBUFdata$SR.snored.last.night)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.snored.last.night + Intervention, data = PBUFdata)[-1,]

##                      Intervention
## SR.snored.last.night sham treatment
##           don't know   13        13
##           no            4         4
##           yes           1         2

#Perform Fisher's Exact Tests
temp_table <- xtabs(~SR.snored.last.night + 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   13        13
## Other         5         6
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.2341604 6.3402606
## sample estimates:
## odds ratio
##     1.1941
##
## [1] "no"
##       Sham Treatment
## no       4         4
## Other   14        15
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1643428 6.9643241
## sample estimates:
## odds ratio
##    1.06941
##
## [1] "yes"
##       Sham Treatment
## yes      1         2
## Other   17        17
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.008017856 10.654170427
## sample estimates:
## odds ratio
##   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
```

```
## sample estimates:
## odds ratio
##  0.7264619
##
## [1] "no"
##       Sham Treatment
## no       8         6
## Other   11        12
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 0.7374
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.3156971 6.8777204
## sample estimates:
## odds ratio
##   1.439815
##
## [1] "yes"
##       Sham Treatment
## yes      2         2
## Other   17        16
##
##  Fisher's Exact Test for Count Data
##
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.06145761 14.45806216
## sample estimates:
## odds ratio
##  0.9426919
```

```
#############################SR WAKE POSITION#############################
#summary data
summary(PBUFdata$SR.position.woke.up)
```

```
##        left right
##     0    28    12
```

```
length(PBUFdata$SR.position.woke.up)
```

```
## [1] 40
```

```
#between participants (grouped) comparison
xtabs(~SR.position.woke.up + Intervention, data = PBUFdata)[-1,]
```

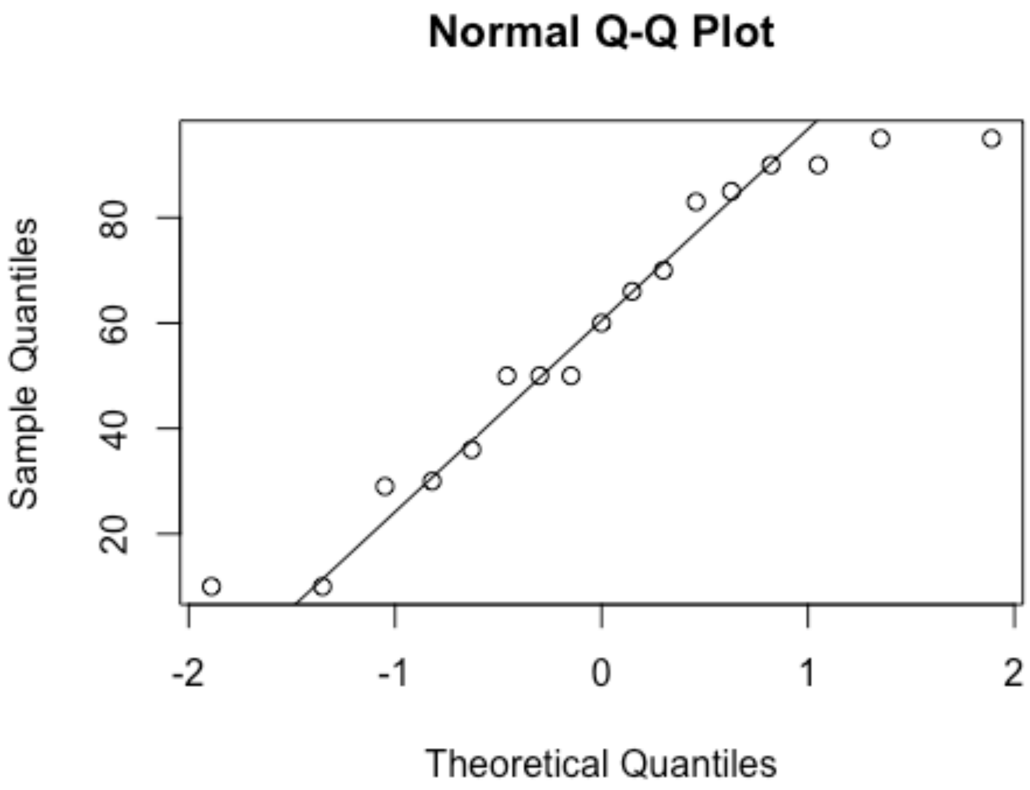
```
##                     Intervention
## SR.position.woke.up sham treatment
##               left    13        15
##               right    7         5

fisher.test(xtabs(~SR.position.woke.up + Intervention, data = PBUFdata)[-1,])

## 
##  Fisher's Exact Test for Count Data
## 
## data:  
## p-value = 0.7311
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.1235598 2.9574108
## sample estimates:
## odds ratio 
##  0.6265621

#############################SR - did you change positions?##################
###########
#summary data
summary(PBUFdata$SR.position.changed)

##               don\xcdt know            no           yes 
##             1             1             3            35

length(PBUFdata$SR.position.changed)

## [1] 40

#between participants (grouped) comparison
xtabs(~SR.position.changed + Intervention, data = PBUFdata)[-1,]

##                     Intervention
## SR.position.changed sham treatment
##       don\xcdt know    1         0
##       no               1         2
##       yes             18        17

#Perform Fisher's Exact Tests
temp_table <- xtabs(~SR.position.changed + 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\xcdt know"
##                 Sham Treatment
## don\xcdt know    1         0
## Other           19        19
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.02435859        Inf
## sample estimates:
## odds ratio 
##        Inf 
## 
## [1] "no"
##       Sham Treatment
## no       1         2
## Other   19        17
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 0.605
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##  0.007216433 9.507277143
## sample estimates:
## odds ratio 
##   0.456456 
## 
## [1] "yes"
##       Sham Treatment
## yes     18        17
## Other    2         2
## 
##  Fisher's Exact Test for Count Data
## 
## data:  ORtable
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
```

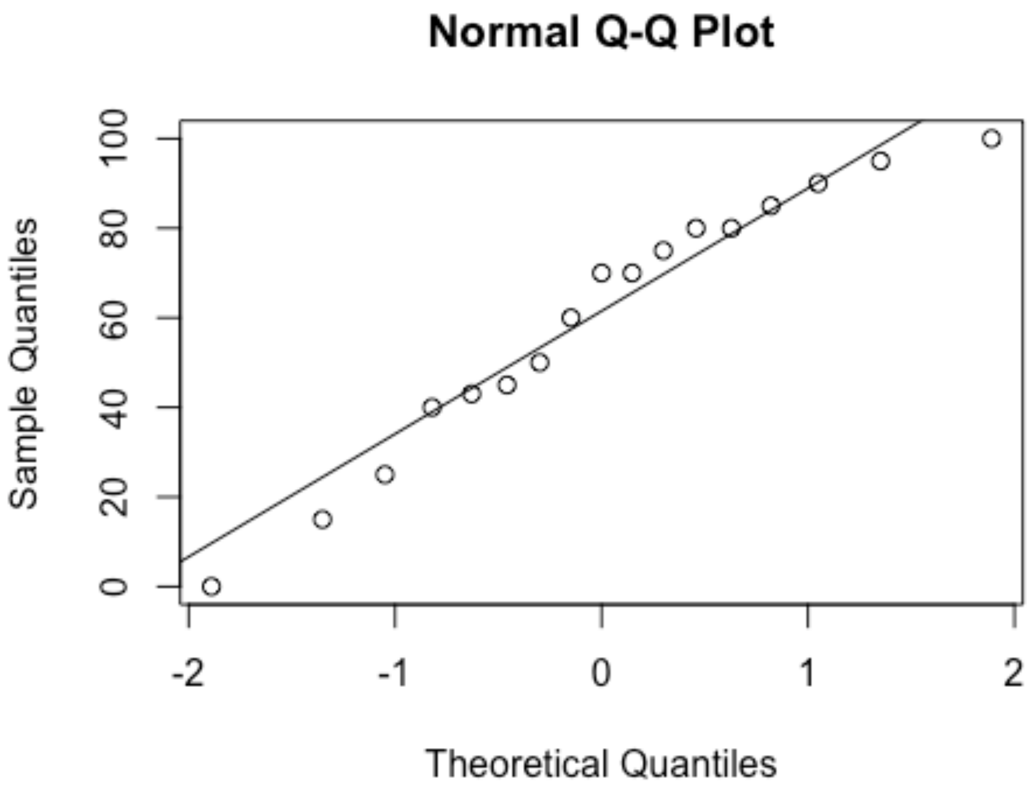
```
##   0.0693477 16.1216542
## sample estimates:
## odds ratio
##   1.057301

#Take out the pts that we don't have complete data on (these participants' st
udies were
#before the PUFQ was revised to ask about the participant's estimate of how m
uch time
#she spent in each position)
PBUF_shamSRpos <- PBUF_sham[-c(1,2,3),]
PBUF_treatSRpos <- PBUF_treat[-c(1,2,3),]

#############################SR PROPORTION OF TIME ON LEFT##################
##########
#summary data
summary(PBUFdata$SR.Ptime.left)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##    0.00   41.50   66.00   59.91   84.00  100.00       5

sd(PBUFdata$SR.Ptime.left, na.rm = TRUE)

## [1] 28.14915

length(na.omit(PBUFdata$SR.Ptime.left))

## [1] 35

#within-participants (paired) comparison
#Paired t-test
t.test(PBUF_shamSRpos$SR.Ptime.left, PBUF_treatSRpos$SR.Ptime.left, paired =
TRUE)

##
##  Paired t-test
##
## data:  PBUF_shamSRpos$SR.Ptime.left and PBUF_treatSRpos$SR.Ptime.left
## t = 0.38979, df = 16, p-value = 0.7018
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -6.266297  9.089826
## sample estimates:
## mean of the differences
##                1.411765

#between participants (grouped) comparison
summary(PBUF_treatSRpos$SR.Ptime.left)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   10.00   36.00   60.00   58.76   85.00   95.00
```

```
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
```

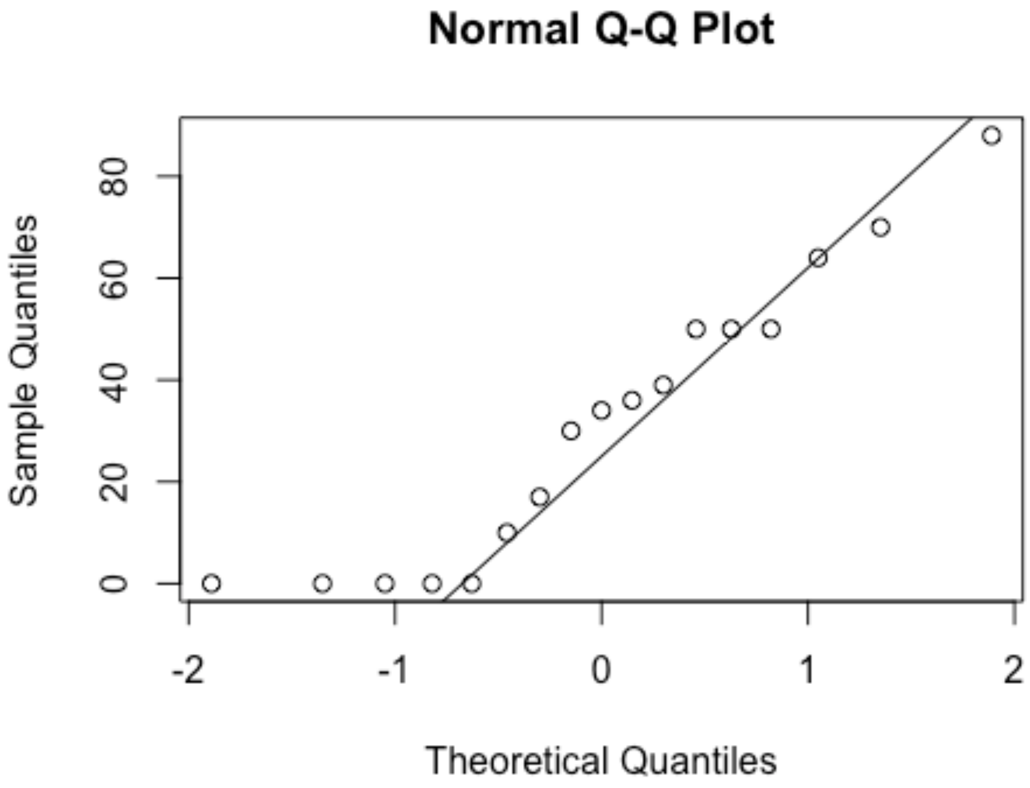
```
sd(PBUF_shamSRpos$SR.Ptime.left)

## [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)
```

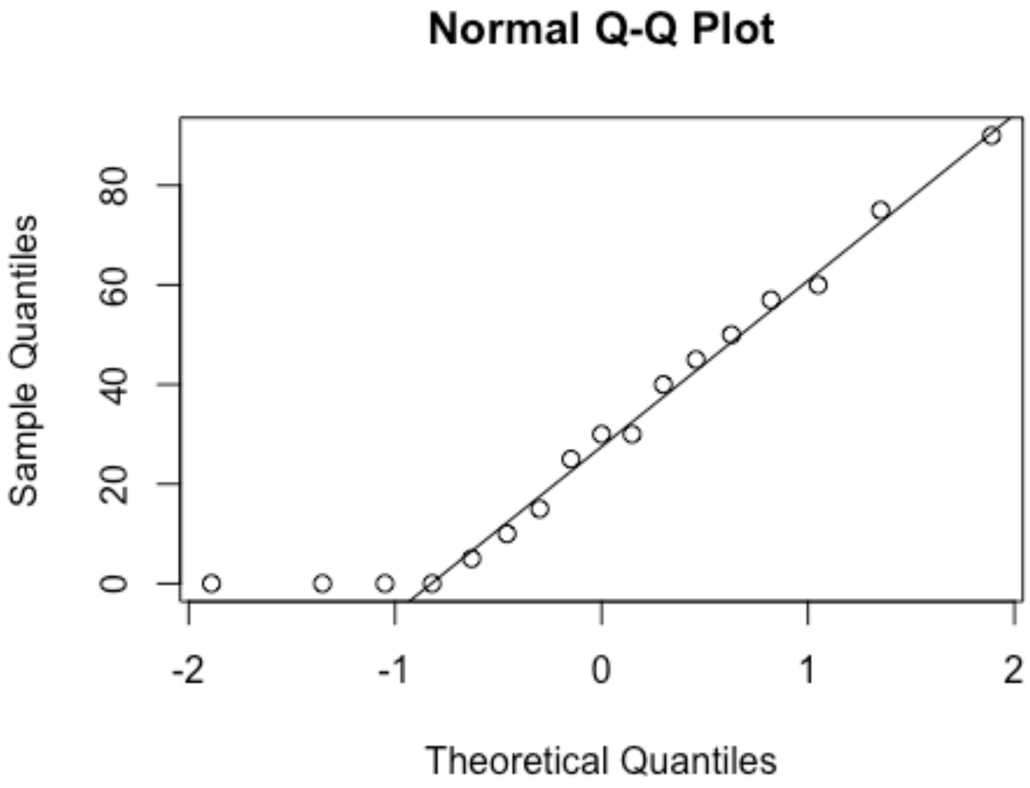
```
##
##  Welch Two Sample t-test
##
## data:  PBUF_shamSRpos$SR.Ptime.left and PBUF_treatSRpos$SR.Ptime.left
## t = 0.14252, df = 31.998, p-value = 0.8876
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -18.76556  21.58909
## sample estimates:
## mean of x mean of y
##  60.17647  58.76471

#############################SR PROPORTION OF TIME ON RIGHT#################
###########
#summary data
summary(PBUFdata$SR.Ptime.right)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##    0.00    2.50   30.00   31.29   50.00   90.00       5

sd(PBUFdata$SR.Ptime.right, na.rm = TRUE)

## [1] 27.30177

length(na.omit(PBUFdata$SR.Ptime.right))

## [1] 35

#within-participants (paired) comparison
#Paired t-test
t.test(PBUF_shamSRpos$SR.Ptime.right, PBUF_treatSRpos$SR.Ptime.right, paired
= TRUE)

##
##  Paired t-test
##
## data:  PBUF_shamSRpos$SR.Ptime.right and PBUF_treatSRpos$SR.Ptime.right
## t = -0.10277, df = 16, p-value = 0.9194
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -7.633106  6.927224
## sample estimates:
## mean of the differences
##              -0.3529412

#between participants (grouped) comparison
summary(PBUF_treatSRpos$SR.Ptime.right)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   34.00   31.65   50.00   88.00

sd(PBUF_treatSRpos$SR.Ptime.right)
```

```
## [1] 27.92387

length(PBUF_treatSRpos$SR.Ptime.right)

## [1] 17

qqnorm(PBUF_treatSRpos$SR.Ptime.right)
qqline(PBUF_treatSRpos$SR.Ptime.right)
```



```
ad.test(PBUF_treatSRpos$SR.Ptime.right)

##
##  Anderson-Darling normality test
##
## data:  PBUF_treatSRpos$SR.Ptime.right
## A = 0.51449, p-value = 0.1649

#normal

summary(PBUF_shamSRpos$SR.Ptime.right)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    5.00   30.00   31.29   50.00   90.00

sd(PBUF_shamSRpos$SR.Ptime.right)
```

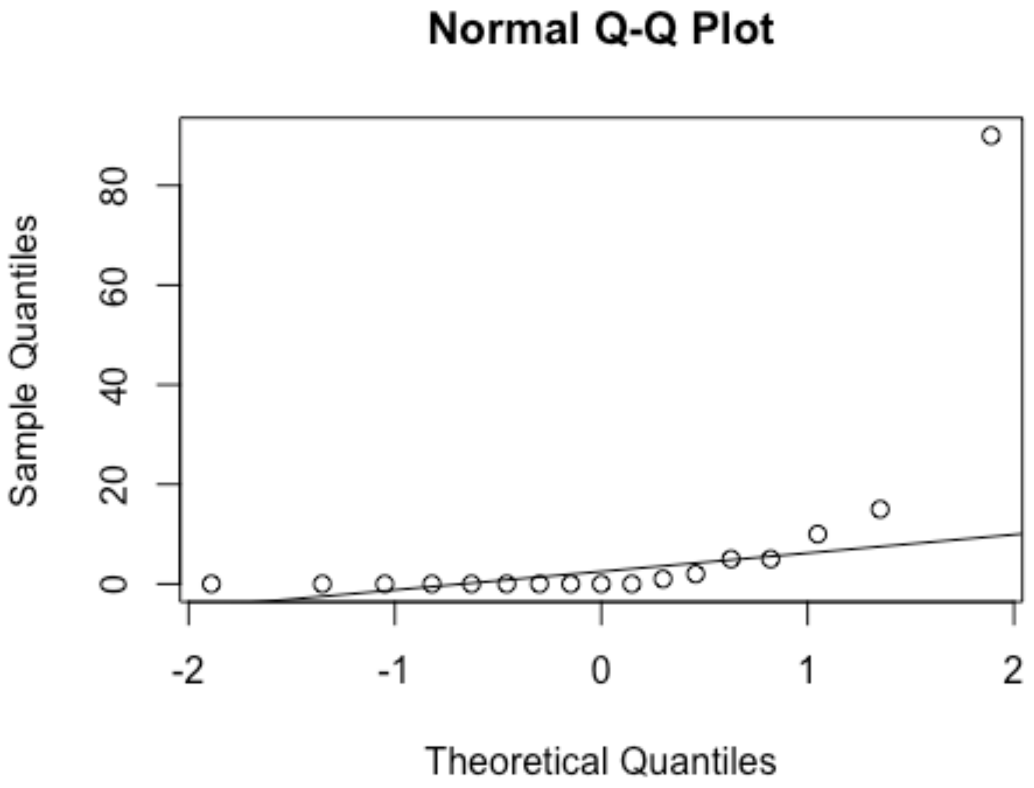
```
## [1] 28.31246

length(PBUF_shamSRpos$SR.Ptime.right)

## [1] 17

qqnorm(PBUF_shamSRpos$SR.Ptime.right)
qqline(PBUF_shamSRpos$SR.Ptime.right)
```



```
ad.test(PBUF_shamSRpos$SR.Ptime.right)

##
##  Anderson-Darling normality test
##
## data:  PBUF_shamSRpos$SR.Ptime.right
## A = 0.43793, p-value = 0.2602

#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_shamSRpos$SR.Ptime.right, PBUF_treatSRpos$SR.Ptime.right)

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

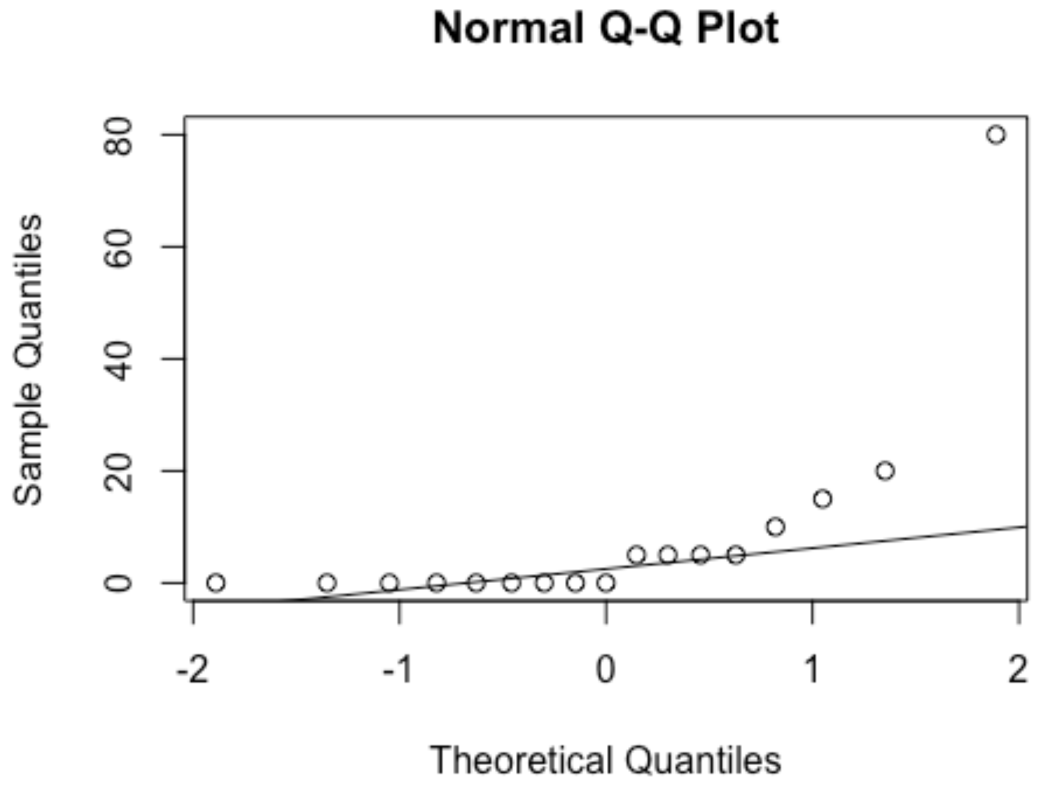
```
##
## data:  PBUF_shamSRpos$SR.Ptime.right and PBUF_treatSRpos$SR.Ptime.right
## t = -0.036594, df = 31.994, p-value = 0.971
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -19.99866  19.29278
## sample estimates:
## mean of x mean of y
##  31.29412  31.64706

#############################SR PROPORTION OF TIME ON BACK##################
##########
#summary data
summary(PBUFdata$SR.Ptime.back)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##     0.0     0.0     0.0     7.8     5.0    90.0       5

sd(PBUFdata$SR.Ptime.back, na.rm = TRUE)

## [1] 19.98205

length(na.omit(PBUFdata$SR.Ptime.back))

## [1] 35

#within-participants (paired) comparison - non-normal, use parametric test (W
ilcoxon)
wilcox.test(PBUF_shamSRpos$SR.Ptime.back, PBUF_treatSRpos$SR.Ptime.back,
            paired = TRUE, conf.int = TRUE)

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence interval
## with ties

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence interval
## with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  PBUF_shamSRpos$SR.Ptime.back and PBUF_treatSRpos$SR.Ptime.back
## V = 18.5, p-value = 0.4951
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
```

```
##  -7.499958  8.999966
## sample estimates:
## (pseudo)median
##       4.090518

#between participants (grouped) comparison
summary(PBUF_treatSRpos$SR.Ptime.back)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   7.529   5.000  90.000

sd(PBUF_treatSRpos$SR.Ptime.back)

## [1] 21.67406

length(PBUF_treatSRpos$SR.Ptime.back)

## [1] 17

qqnorm(PBUF_treatSRpos$SR.Ptime.back)
qqline(PBUF_treatSRpos$SR.Ptime.back)
```



```
ad.test(PBUF_treatSRpos$SR.Ptime.back)
```

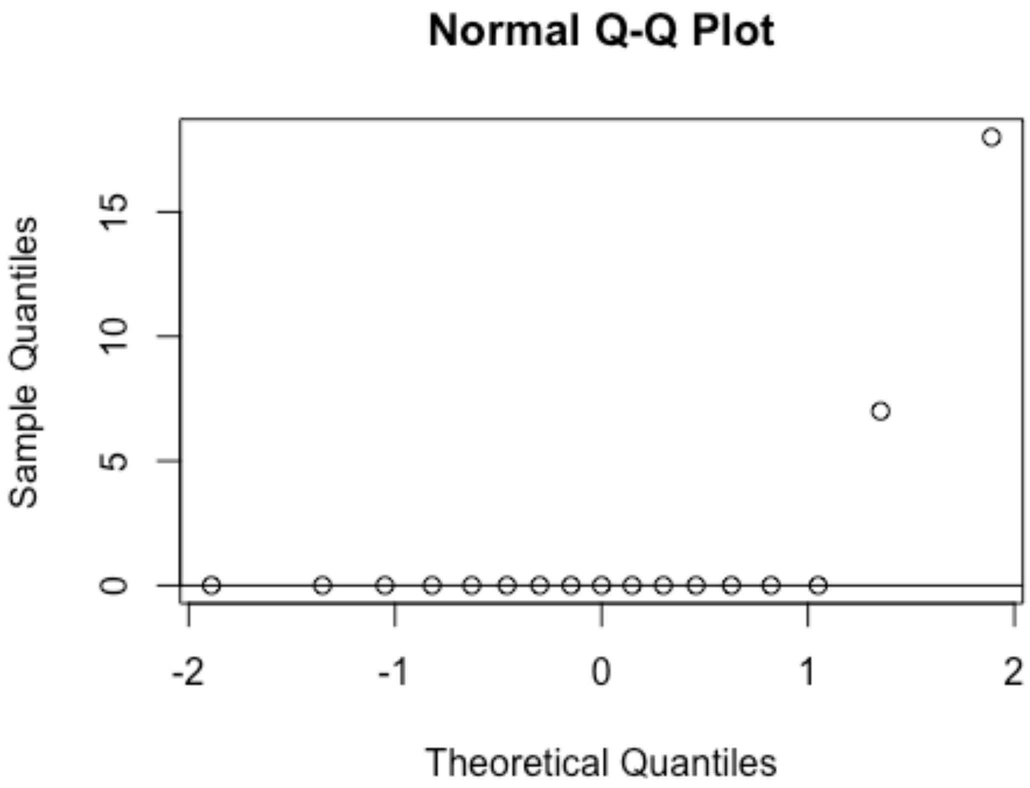
```
##
##  Anderson-Darling normality test
##
## data:  PBUF_treatSRpos$SR.Ptime.back
## A = 4.2859, p-value = 3.533e-11

#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)
```



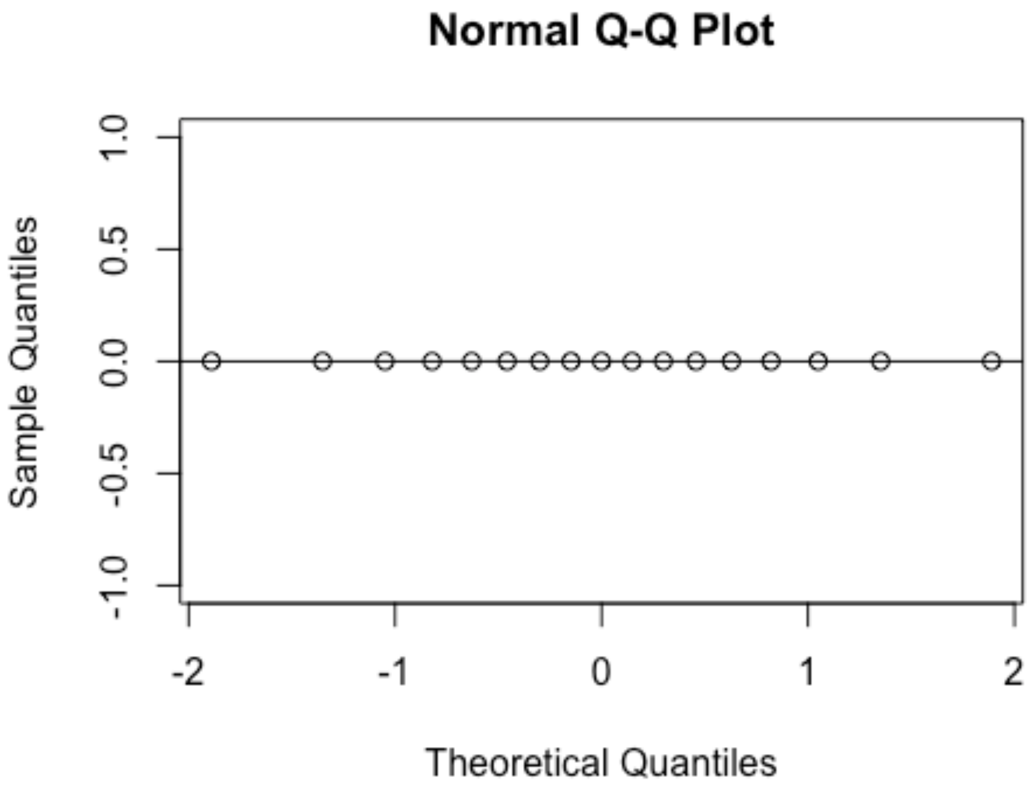
```
ad.test(PBUF_shamSRpos$SR.Ptime.back)
```

```
##
##  Anderson-Darling normality test
##
## data:  PBUF_shamSRpos$SR.Ptime.back
## A = 3.3048, p-value = 1.097e-08

#non-normal

#Perform non-parametric test (Wilcoxon)
wilcox.test(PBUF_shamSRpos$SR.Ptime.back, PBUF_treatSRpos$SR.Ptime.back, conf
.int = TRUE)

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact p-value with ties

## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.back,
## PBUF_treatSRpos$SR.Ptime.back, : cannot compute exact confidence intervals
## with ties

##
##  Wilcoxon rank sum test with continuity correction
##
## data:  PBUF_shamSRpos$SR.Ptime.back and PBUF_treatSRpos$SR.Ptime.back
## W = 159, p-value = 0.5944
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -3.745025e-05  4.999982e+00
## sample estimates:
## difference in location
##             3.7504e-05

#############################SR PROPORTION OF TIME ON STOMACH###############
#############
#summary data
summary(PBUFdata$SR.Ptime.stomach)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##  0.0000  0.0000  0.0000  0.7143  0.0000 18.0000       5

sd(PBUFdata$SR.Ptime.stomach, na.rm = TRUE)

## [1] 3.231931

length(na.omit(PBUFdata$SR.Ptime.stomach))

## [1] 35

#within-participants (paired) comparison - non-normal, use parametric test (W
ilcoxon)
wilcox.test(PBUF_shamSRpos$SR.Ptime.stomach, PBUF_treatSRpos$SR.Ptime.stomach
,
            paired = TRUE)
```

```
## Warning in wilcox.test.default(PBUF_shamSRpos$SR.Ptime.stomach,
## PBUF_treatSRpos$SR.Ptime.stomach, : cannot compute exact p-value with
## zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  PBUF_shamSRpos$SR.Ptime.stomach and PBUF_treatSRpos$SR.Ptime.stomac
h
## V = 0, p-value = 0.3711
## alternative hypothesis: true location shift is not equal to 0

#between participants (grouped) comparison
summary(PBUF_treatSRpos$SR.Ptime.stomach)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   0.000   0.000   0.000   1.471   0.000  18.000

sd(PBUF_treatSRpos$SR.Ptime.stomach)

## [1] 4.58418

length(PBUF_treatSRpos$SR.Ptime.stomach)

## [1] 17

qqnorm(PBUF_treatSRpos$SR.Ptime.stomach)
qqline(PBUF_treatSRpos$SR.Ptime.stomach)
```



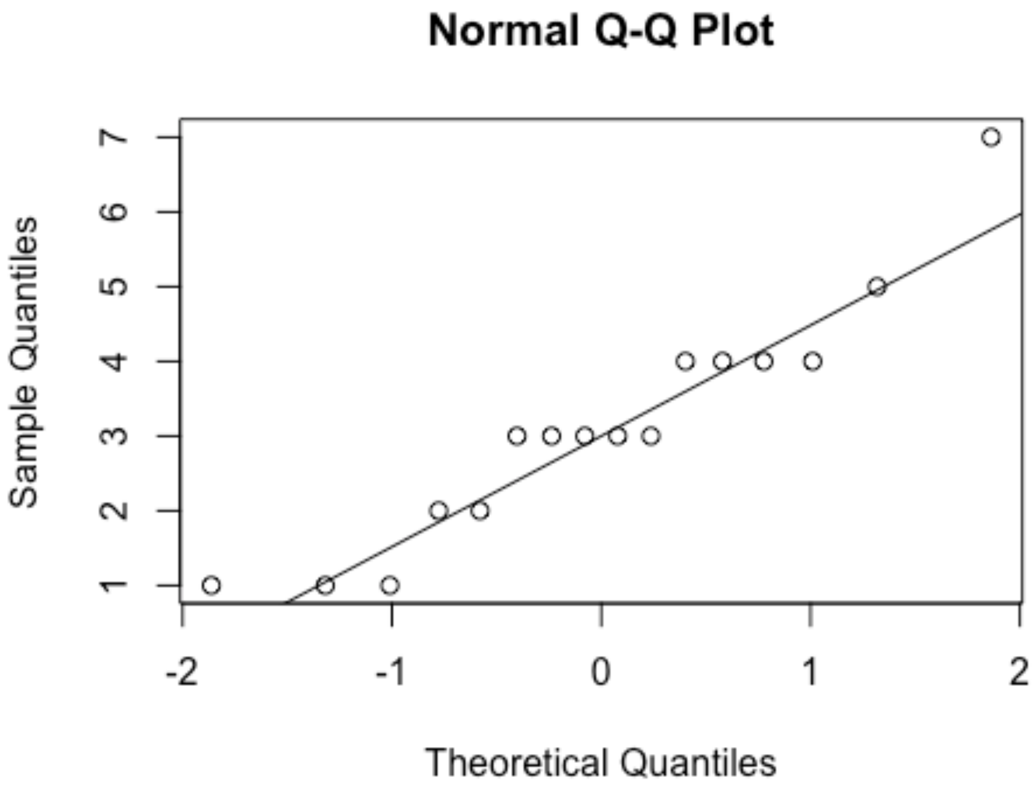
```
ad.test(PBUF_treatSRpos$SR.Ptime.stomach)

##
##  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)
```



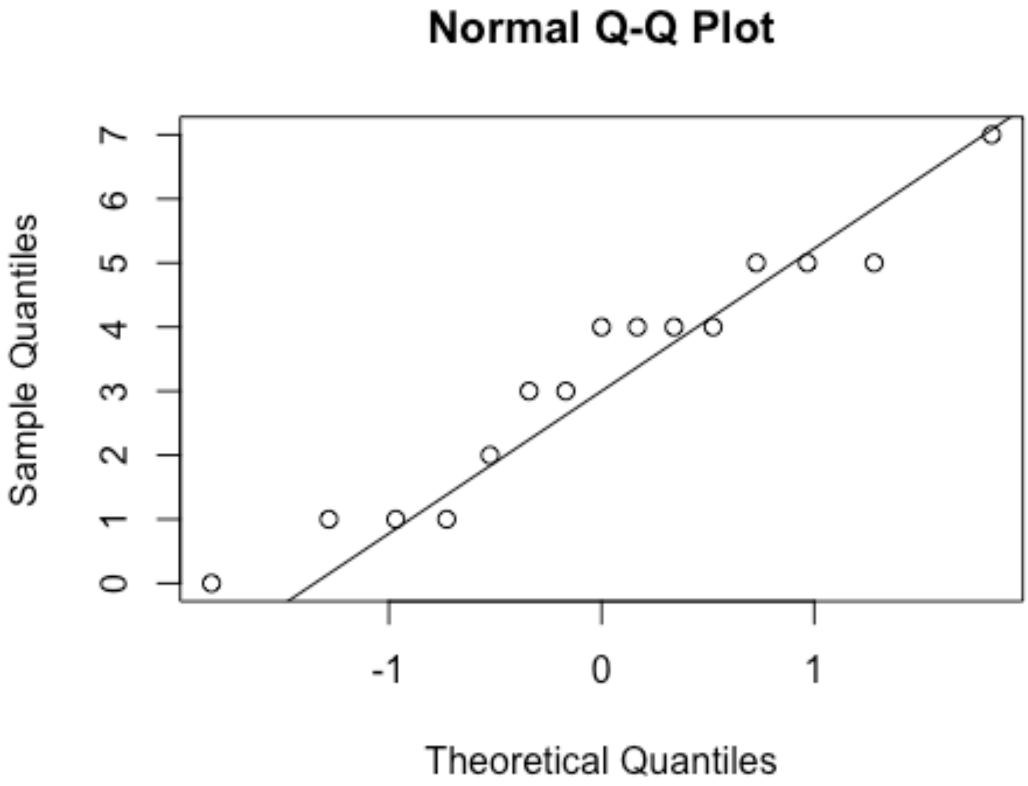
```
#ad.test(PBUF_shamSRpos$SR.Ptime.stomach)
#distribution is entirely zeroes

#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.stomac
h
## 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:
```

```
## difference in location
##                      0

#############################REMEMBER CHANGING POSITIONS#####################
########
#summary data
summary(PBUFdata$remember.changing.positions)

##      no yes
##   0   7  33

length(PBUFdata$remember.changing.positions)

## [1] 40

#between participants (grouped) comparison
xtabs(~remember.changing.positions + Intervention, data = PBUFdata)[-1,]

##                            Intervention
## remember.changing.positions sham treatment
##                         no     4         3
##                         yes   16        17

fisher.test(xtabs(~remember.changing.positions + Intervention, data = PBUFdat
a)[-1,])

##
##  Fisher's Exact Test for Count Data
##
## data:
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2020801 11.1277720
## sample estimates:
## odds ratio
##   1.404393

#Remove rows with missing data or with participants who did not change positi
on or did
#not remember changing positions
PBUF_shamSRchangepos <- PBUF_sham[-c(1,5,6,7,14,19),]
PBUF_treatSRchangepos <- PBUF_treat[-c(1,5,6,7,14,19),]

#############################SR NUMBER OF TIMES CHANGED POSITION#############
##############
#summary data
summary(PBUFdata$SR.how.many.times.changed.positions)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##   0.000   2.000   3.000   3.194   4.000   7.000       9
```

```
sd(PBUFdata$SR.how.many.times.changed.positions, na.rm = TRUE)

## [1] 1.740103

length(na.omit(PBUFdata$SR.how.many.times.changed.positions))

## [1] 31

#within-participants (paired) comparison
#Paired t-test
t.test(PBUF_shamSRchangepos$SR.how.many.times.changed.positions,
       PBUF_treatSRchangepos$SR.how.many.times.changed.positions,
       paired = TRUE)

##
##  Paired t-test
##
## data:  PBUF_shamSRchangepos$SR.how.many.times.changed.positions and PBUF_t
reatSRchangepos$SR.how.many.times.changed.positions
## t = 0.31382, df = 13, p-value = 0.7586
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.8405766  1.1262909
## sample estimates:
## mean of the differences
##               0.1428571

#between participants (grouped) comparison
summary(PBUF_treat$SR.how.many.times.changed.positions)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##   1.000   2.000   3.000   3.125   4.000   7.000       4

sd(PBUF_treat$SR.how.many.times.changed.positions, na.rm = TRUE)

## [1] 1.586401

length(na.omit(PBUF_treat$SR.how.many.times.changed.positions))

## [1] 16

qqnorm(PBUF_treat$SR.how.many.times.changed.positions)
qqline(PBUF_treat$SR.how.many.times.changed.positions)
```

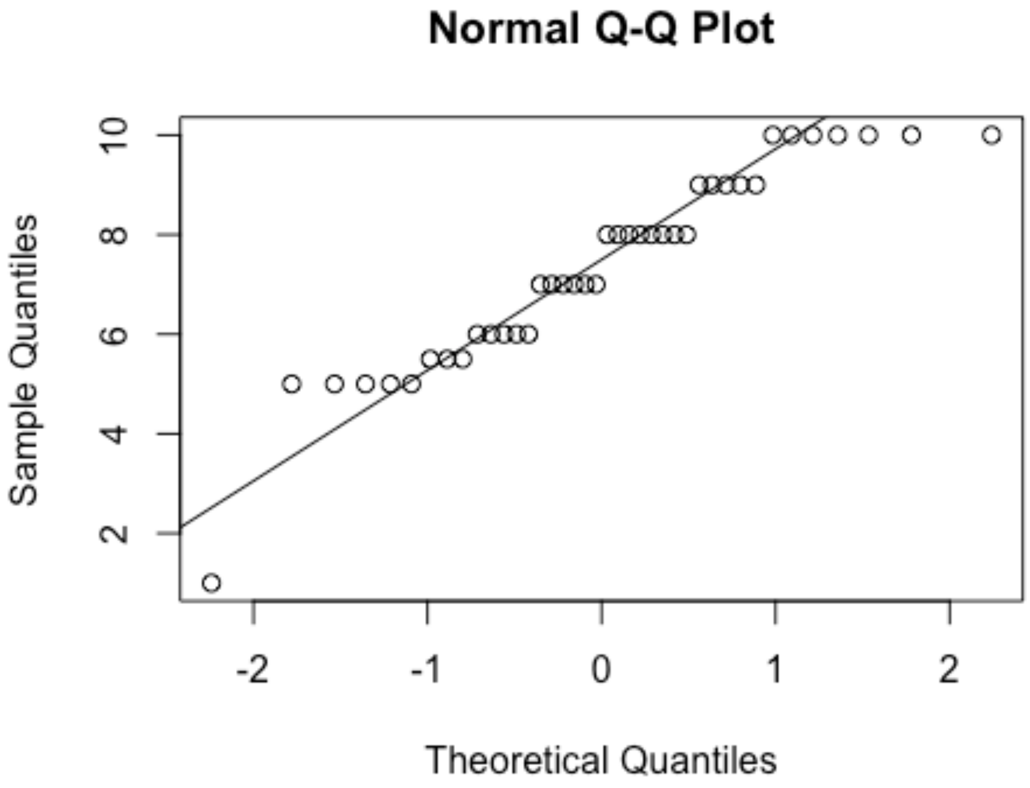


```
ad.test(PBUF_treat$SR.how.many.times.changed.positions)

##
##  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)
```



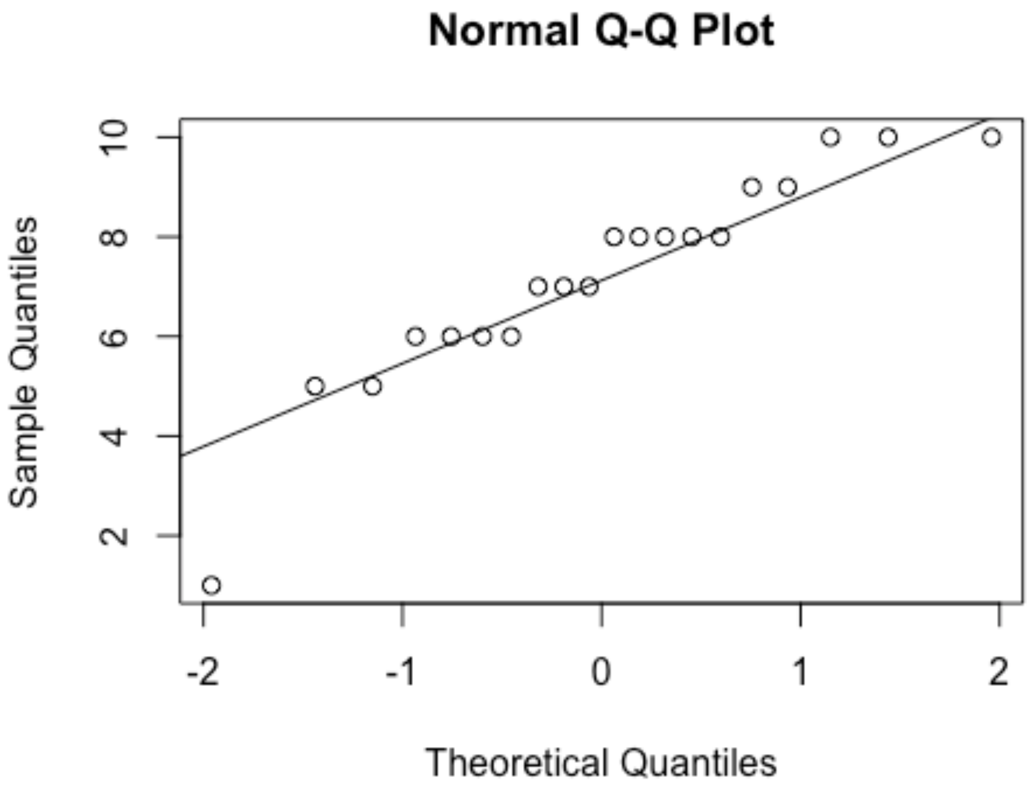
```
ad.test(PBUF_sham$SR.how.many.times.changed.positions)

##
##  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:
```

```
## mean of x mean of y
##  3.266667  3.125000

##############################SATISFACTION LEVEL##############################
#summary data
summary(PBUFdata$satisfaction.level)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.000   6.000   7.500   7.338   9.000  10.000

sd(PBUFdata$satisfaction.level)

## [1] 1.988388

length(PBUFdata$satisfaction.level)

## [1] 40

qqnorm(PBUFdata$satisfaction.level)
qqline(PBUFdata$satisfaction.level)
```

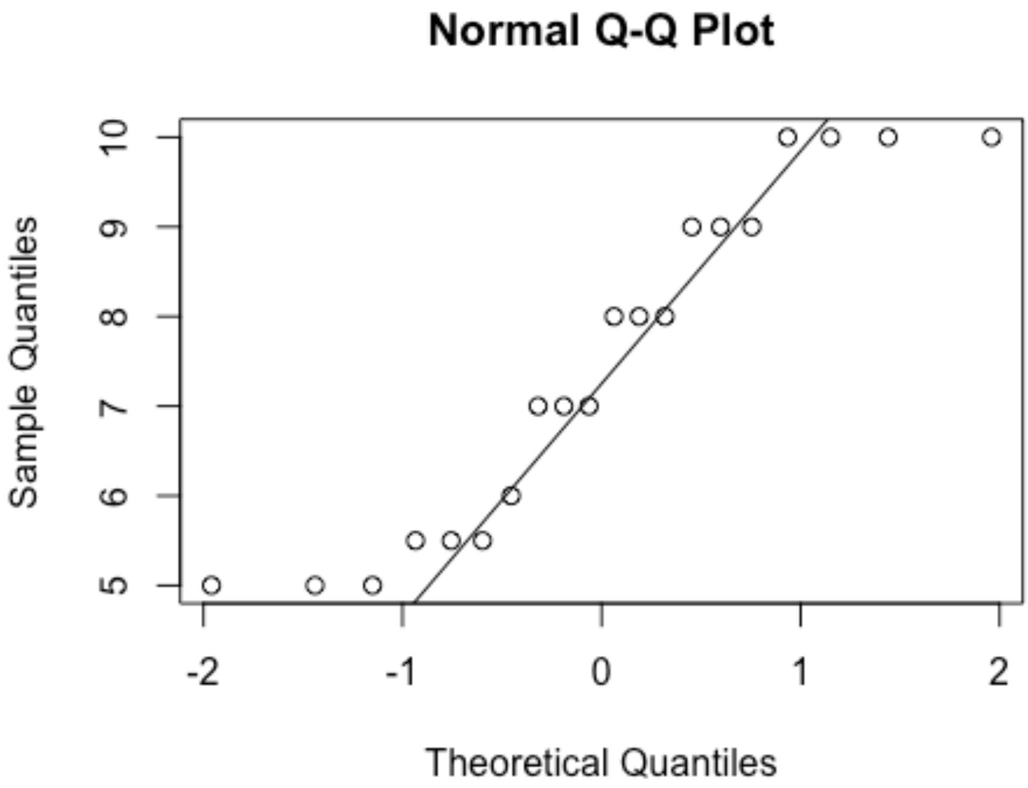


```
ad.test(PBUFdata$satisfaction.level)

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

```
##
## data:  PBUFdata$satisfaction.level
## A = 0.79381, p-value = 0.03625

#within-participants (paired) comparison
#t-test (individual distributions are normal)
t.test(PBUF_sham$satisfaction.level,PBUF_treat$satisfaction.level, paired = T
RUE)

##
##  Paired t-test
##
## data:  PBUF_sham$satisfaction.level and PBUF_treat$satisfaction.level
## t = 0.74891, df = 19, p-value = 0.4631
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -0.4935575  1.0435575
## sample estimates:
## mean of the differences
##                   0.275

#between participants (grouped) comparison
summary(PBUF_treat$satisfaction.level)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.00    6.00    7.50    7.20    8.25   10.00

sd(PBUF_treat$satisfaction.level, na.rm = TRUE)

## [1] 2.142306

length(na.omit(PBUF_treat$satisfaction.level))

## [1] 20

qqnorm(PBUF_treat$satisfaction.level)
qqline(PBUF_treat$satisfaction.level)
```

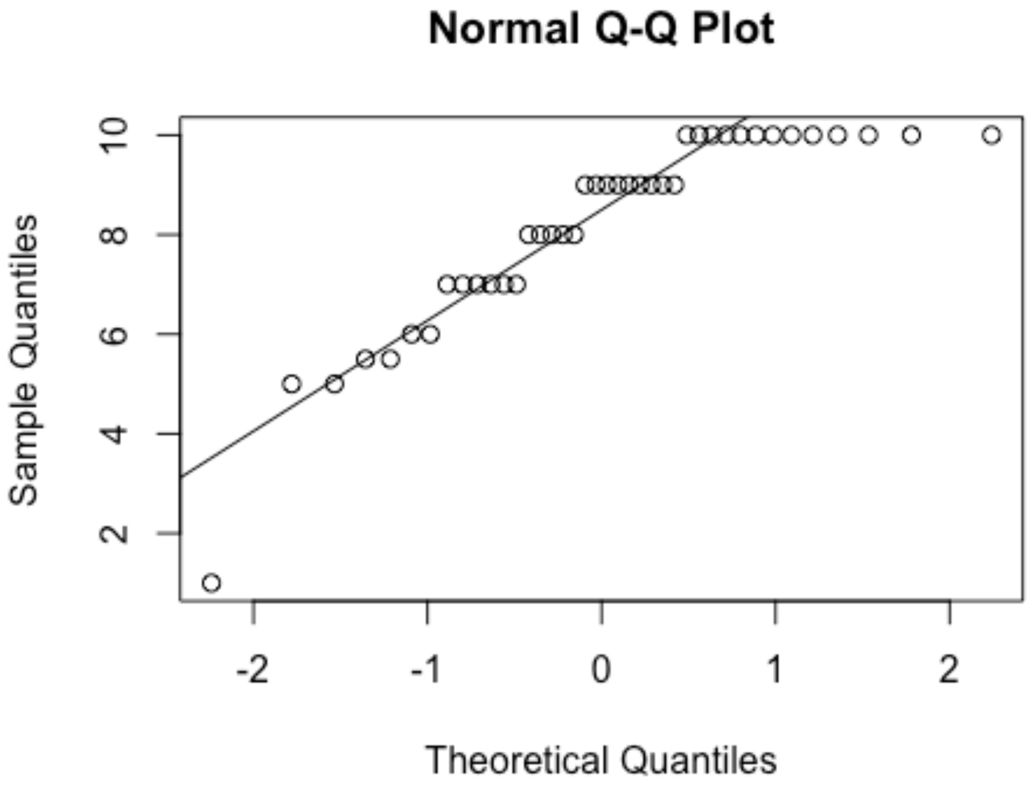


```
ad.test(PBUF_treat$satisfaction.level)

##
##  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)
```



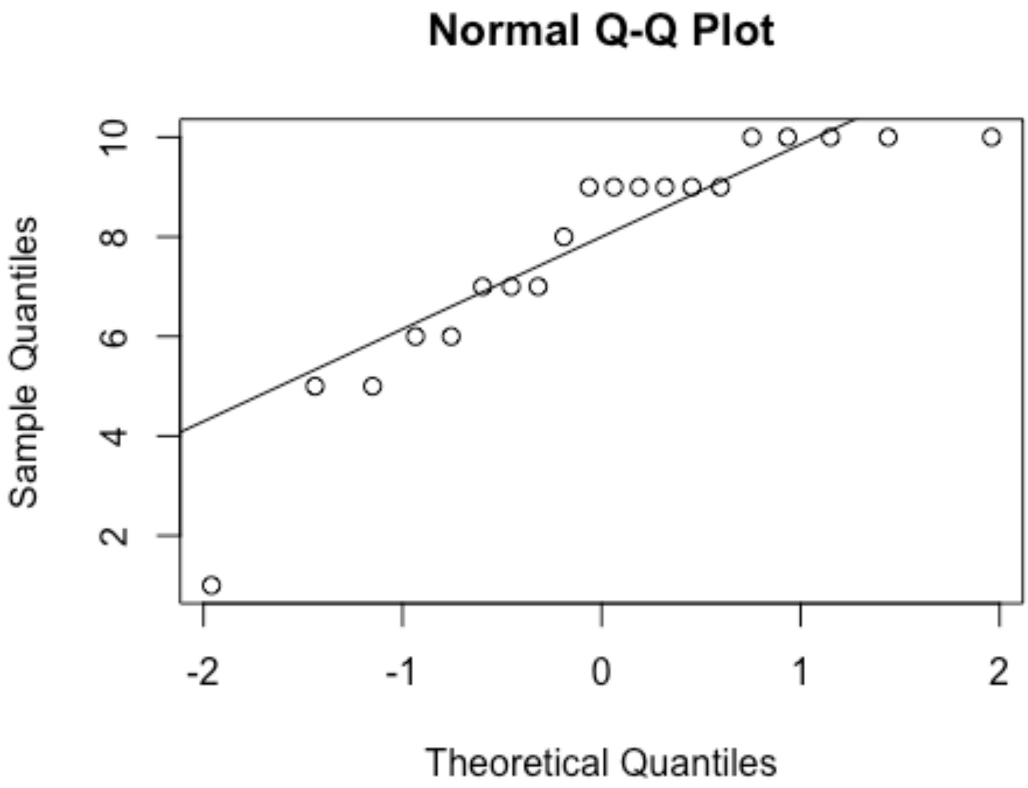
```
ad.test(PBUF_sham$satisfaction.level)

##
##  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:
```

```
## mean of x mean of y
##     7.475     7.200

##############################COMFORT LEVEL##############################
#summary data
summary(PBUFdata$comfort.level)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##   1.000   7.000   9.000   8.175  10.000  10.000

sd(PBUFdata$comfort.level)

## [1] 1.982455

length(PBUFdata$comfort.level)

## [1] 40

qqnorm(PBUFdata$comfort.level)
qqline(PBUFdata$comfort.level)
```

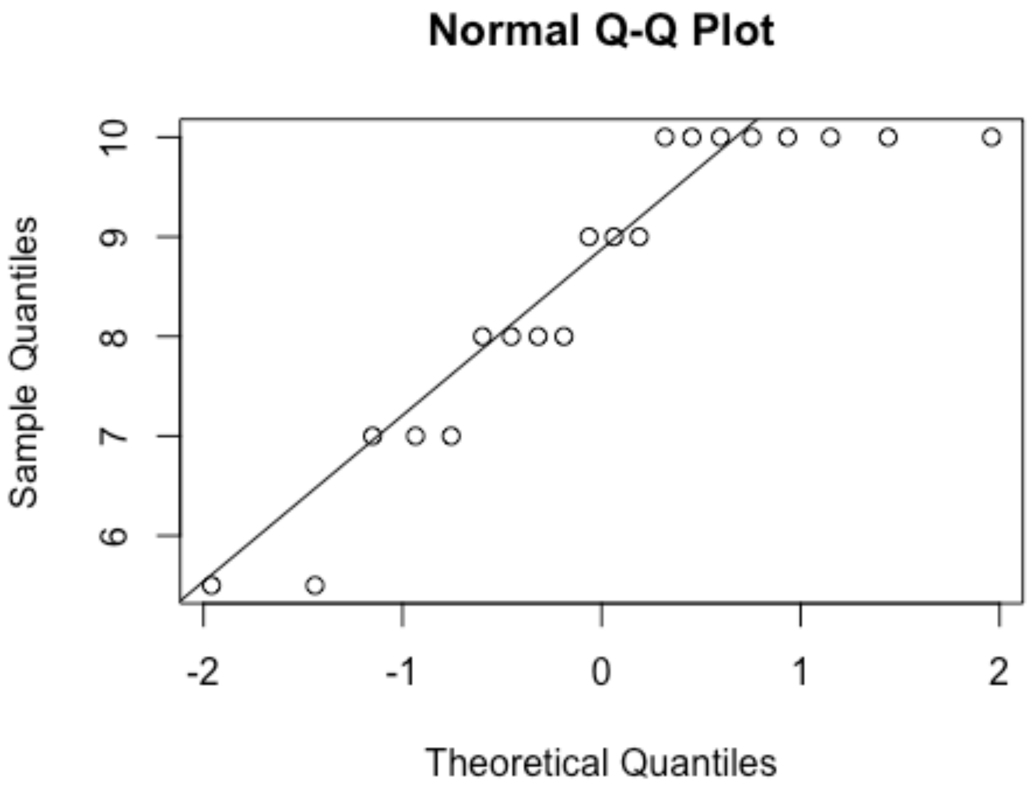


```
ad.test(PBUFdata$comfort.level)

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

```
##
## data:  PBUFdata$comfort.level
## A = 1.8563, p-value = 7.865e-05

#within-participants (paired) comparison
#non-normal - perform Wilcoxon
wilcox.test(PBUF_sham$comfort.level,PBUF_treat$comfort.level,
            paired = TRUE, 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 interval with ties

## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
## $comfort.level, : cannot compute exact p-value with zeroes

## Warning in wilcox.test.default(PBUF_sham$comfort.level, PBUF_treat
## $comfort.level, : cannot compute exact confidence interval with zeroes

##
##  Wilcoxon signed rank test with continuity correction
##
## data:  PBUF_sham$comfort.level and PBUF_treat$comfort.level
## V = 54.5, p-value = 0.0574
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.0000318032  2.7499508366
## sample estimates:
## (pseudo)median
##       1.000052

#between participants (grouped) comparison
summary(PBUF_treat$comfort.level)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.00    6.75    9.00    7.80    9.25   10.00

sd(PBUF_treat$comfort.level, na.rm = TRUE)

## [1] 2.330575

length(na.omit(PBUF_treat$comfort.level))

## [1] 20

qqnorm(PBUF_treat$comfort.level)
qqline(PBUF_treat$comfort.level)
```

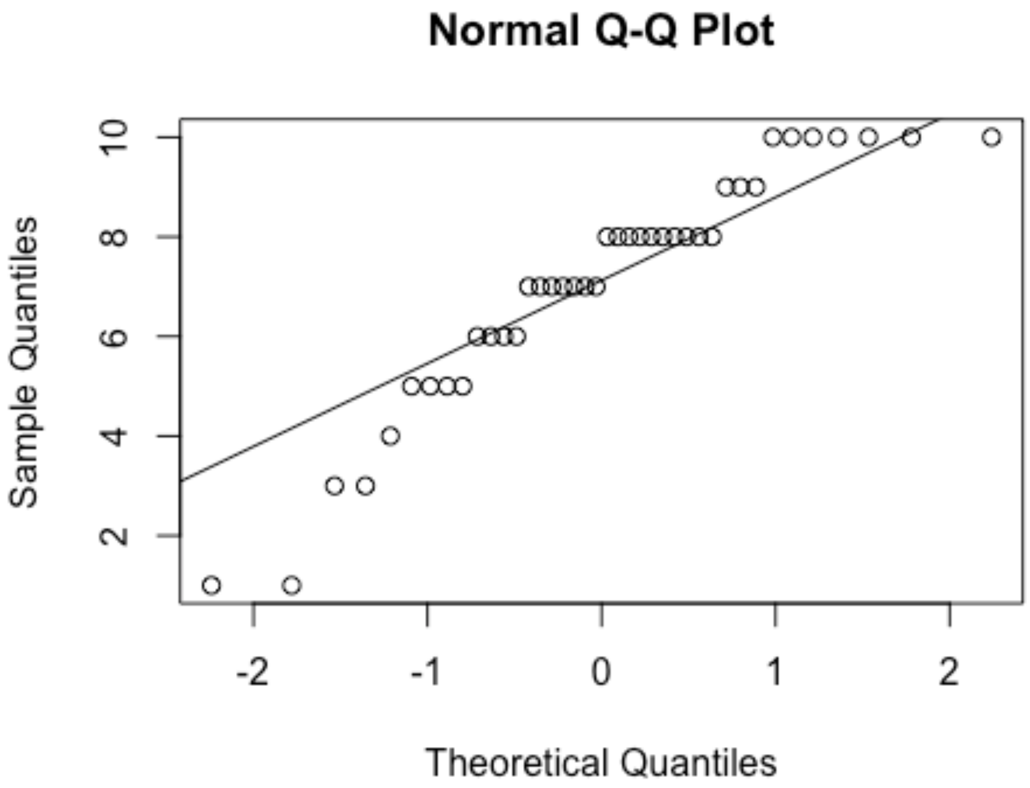


```
ad.test(PBUF_treat$comfort.level)

##
##  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)
```



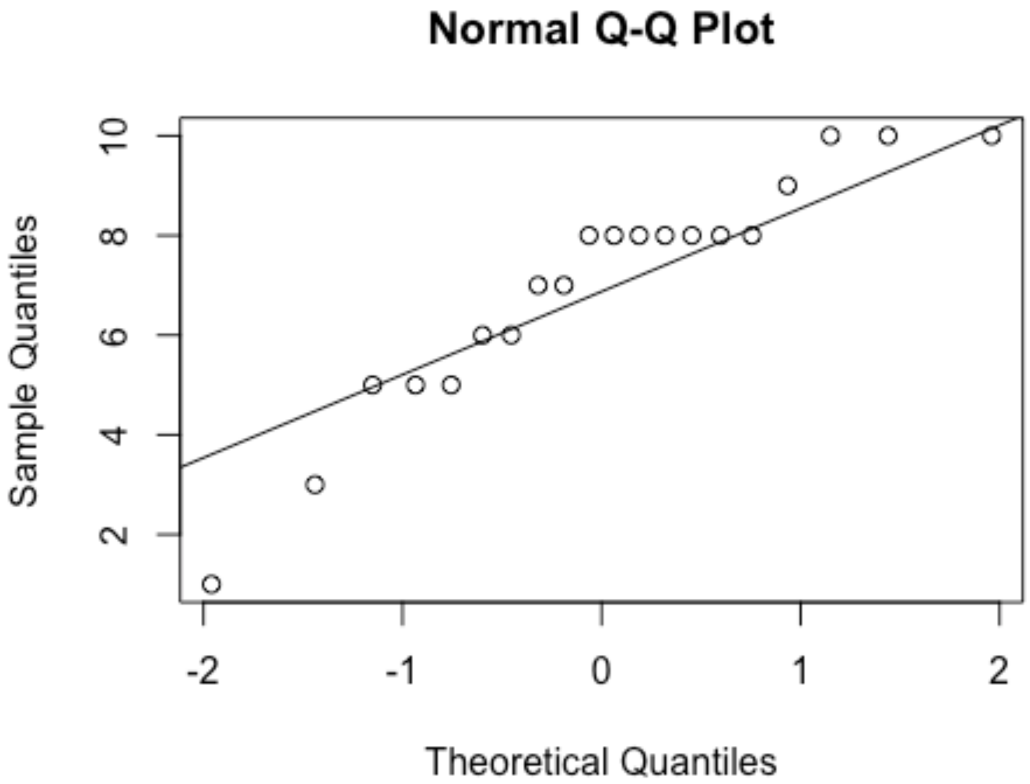
```
ad.test(PBUF_sham$comfort.level)

##
##  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 = TRU
E)

## 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
```

```
## W = 235.5, p-value = 0.3312
## alternative hypothesis: true location shift is not equal to 0
## 95 percent confidence interval:
##  -0.4999358  1.0000188
## sample estimates:
## difference in location
##              0.3425784

#################INTENTION TO USE IN FUTURE PREGNANCY LEVEL##################
####
#summary data
summary(PBUFdata$intention.to.use)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    1.00    6.00    7.50    7.05    8.25   10.00

sd(PBUFdata$intention.to.use)

## [1] 2.363722

length(PBUFdata$intention.to.use)

## [1] 40

qqnorm(PBUFdata$intention.to.use)
qqline(PBUFdata$intention.to.use)
```



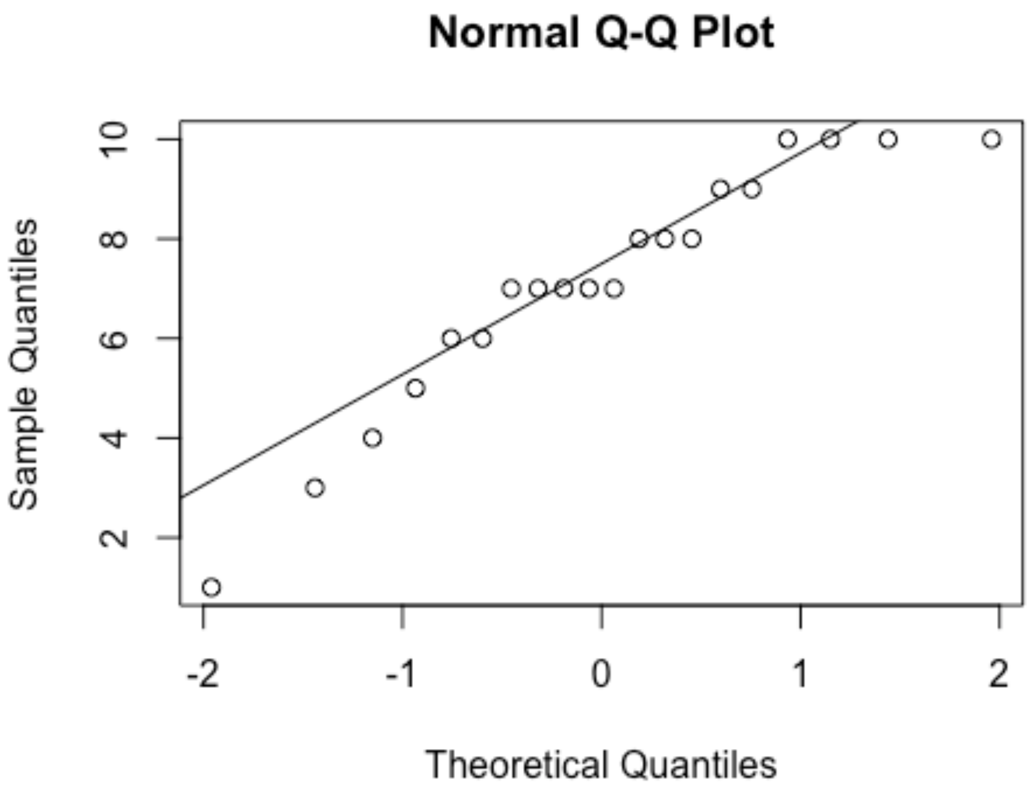
```
ad.test(PBUFdata$intention.to.use)

##
##  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)
```



```
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)
```



```
ad.test(PBUF_sham$intention.to.use)

##
##  Anderson-Darling normality test
##
## data:  PBUF_sham$intention.to.use
## A = 0.54305, p-value = 0.1424
```

```
#normal

#Perform 2-sample t-test (Welch's t-test)
t.test(PBUF_sham$intention.to.use,
       PBUF_treat$intention.to.use)

##
##  Welch Two Sample t-test
##
## data:  PBUF_sham$intention.to.use and PBUF_treat$intention.to.use
## t = 0.13209, df = 37.923, p-value = 0.8956
## alternative hypothesis: true difference in means is not equal to 0
## 95 percent confidence interval:
##  -1.432714  1.632714
## sample estimates:
## mean of x mean of y
##       7.1       7.0

#################WOULD MAKE CHANGES#####################
#summary data
summary(PBUFdata$would.make.changes)

##      no yes
##   2  31   7

length(PBUFdata$would.make.changes)

## [1] 40

#7 nights, but only 6 participants of 20 (30%)

#between participants (grouped) comparison
xtabs(~would.make.changes + Intervention, data = PBUFdata)[-1,]

##                    Intervention
## would.make.changes sham treatment
##                 no   16        15
##                yes    3         4

fisher.test(xtabs(~would.make.changes + Intervention, data = PBUFdata)[-1,])

##
##  Fisher's Exact Test for Count Data
##
## data:
## p-value = 1
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.2007118 11.2700012
## sample estimates:
## odds ratio
##   1.409106
```

```
#END
```

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

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 c
ode compares
#the participants' perception of their sleep behaviours (as recorded on the P
renaBelt
#User Feedback Questionnaires) to the polysomnography-determined sleep behavi
ours.

#Summary: Participants recalled their sleep onset position accurately for 34
of 40 nights
#(85%, κ 0.62, moderate agreement). Participants recalled their waking positi
on accurately
#for 28 of 40 nights (70%, κ 0.42, weak agreement). There was a weak relation
ship 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 h
ad 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/
```

```
#Bland-Altman's plots - recall of continuous variables
#https://cran.r-project.org/web/packages/BlandAltmanLeh/vignettes/Intro.html

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

#importing the SR accuracy data
SRdatafull=read.csv("Self Reported vs Recorded Sleep Postions.csv")

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

##  N  Y
## 40  6

#6 nights = 3 participants
#Remove the drop outs ("Y")
SRdata <- SRdatafull[!(SRdatafull$drop.out=="Y"),]
nrow(SRdata)

## [1] 40

#Loading the functions into the workspace
library(nortest)
library(irr)

## Loading required package: lpSolve

library(ggplot2)

## Warning: package 'ggplot2' was built under R version 3.2.5

library(BlandAltmanLeh)

####################Fall asleep position######################
#droplevels to remove empty levels from the list of levels
SRdata$PSG.fall.asleep.position <- droplevels(SRdata$PSG.fall.asleep.position
)
SRdata$SR.fall.asleep.position <- droplevels(SRdata$SR.fall.asleep.position)
#Summary
#Polysomnography (PSG)
summary(SRdata$PSG.fall.asleep.position)

##   left  right supine
##     29      8      3

length(SRdata$PSG.fall.asleep.position)

## [1] 40
```

```
#Self-Report (SR)
summary(SRdata$SR.fall.asleep.position)

##   left  right supine
##     31      7      2

length(SRdata$SR.fall.asleep.position)

## [1] 40

#Cohen's Kappa
item1<-as.matrix(cbind(SRdata$PSG.fall.asleep.position, SRdata$SR.fall.asleep
.position))
kappa2(item1[,c(1,2)])

##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 40
##    Raters = 2
##     Kappa = 0.624
##
##         z = 4.87
##   p-value = 1.13e-06

####################Wake up position######################
#droplevels to remove empty levels from the list of levels
SRdata$PSG.wake.position <- droplevels(SRdata$PSG.wake.position)
SRdata$SR.wake.position <- droplevels(SRdata$SR.wake.position)
#Summary
#PSG
summary(SRdata$PSG.wake.position)

##   left  right supine
##     22     13      5

length(SRdata$PSG.wake.position)

## [1] 40

#SR
summary(SRdata$SR.wake.position)

##  left right
##    28    12

length(SRdata$SR.wake.position)

## [1] 40

#Cohen's Kappa
item1<-as.matrix(cbind(SRdata$PSG.wake.position, SRdata$SR.wake.position))
kappa2(item1[,c(1,2)])
```

```
##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 40
##    Raters = 2
##     Kappa = 0.42
##
##         z = 3.31
##   p-value = 0.000946

####################Look at relationship btw fall asleep and wake position###
########
#Cohen's Kappa
#PSG
item1<-as.matrix(cbind(SRdata$PSG.fall.asleep.position, SRdata$PSG.wake.posit
ion))
kappa2(item1[,c(1,2)])

##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 40
##    Raters = 2
##     Kappa = 0.241
##
##         z = 2.05
##   p-value = 0.0399

####################Number of position changes######################
#Before running the number of position changes analyses below, we need to rem
ove the rows
#corresponding to the 10 nights when participants did not give a self-report
of the number
#of position changes because if these rows remain, they will make the summary
statistics
#(summary,#SD, length) inaccurate for the PSG data (n=40 instead of n=30)....
note that
#the Cohens, ICC, and bland-altman will automatically drop these from their r
espective
#analyses if the data point is continuous or ordinal (not if text! e.g., snor
ing
#analysis).

#Remove CDD night 1, LOH night 1, TBW night 1, WVE night1, YOG night 1 and 2,
PBY night 1
#and 2, and KEQ night 1 and 2.
SRdata1 = SRdata[-c(3,7,19,23,25,26,27,28,37,38),]
nrow(SRdata1)

## [1] 30
```

```
#Summary
#PSG
summary(SRdata1$PSG.number.position.changes)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##   1.000   3.250   6.000   6.833  10.000  15.000

length(SRdata1$PSG.number.position.changes)

## [1] 30

#SR
summary(SRdata1$SR.number.position.changes)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##     1.0     2.0     3.0     3.3     4.0     7.0

length(SRdata1$SR.number.position.changes)

## [1] 30

#Cohen's Kappa
item1<-as.matrix(cbind(SRdata$PSG.number.position.changes,
                       SRdata$SR.number.position.changes))
kappa2(item1[,c(1,2)], weight="equal")

##  Cohen's Kappa for 2 Raters (Weights: equal)
## 
##  Subjects = 30 
##    Raters = 2 
##     Kappa = 0.169 
## 
##         z = 1.61 
##   p-value = 0.107

####################Snoring######################
#droplevels to remove empty levels from the list of levels
SRdata$PSG.snore <- droplevels(SRdata$PSG.snore)
SRdata$SRSnore <- droplevels(SRdata$SRSnore)
#Summary
#PSG
summary(SRdata$PSG.snore)

##  N  Y 
## 14 26

length(SRdata$PSG.snore)

## [1] 40

summary(subset(SRdata, intervention == "treatment")$PSG.snore)
```

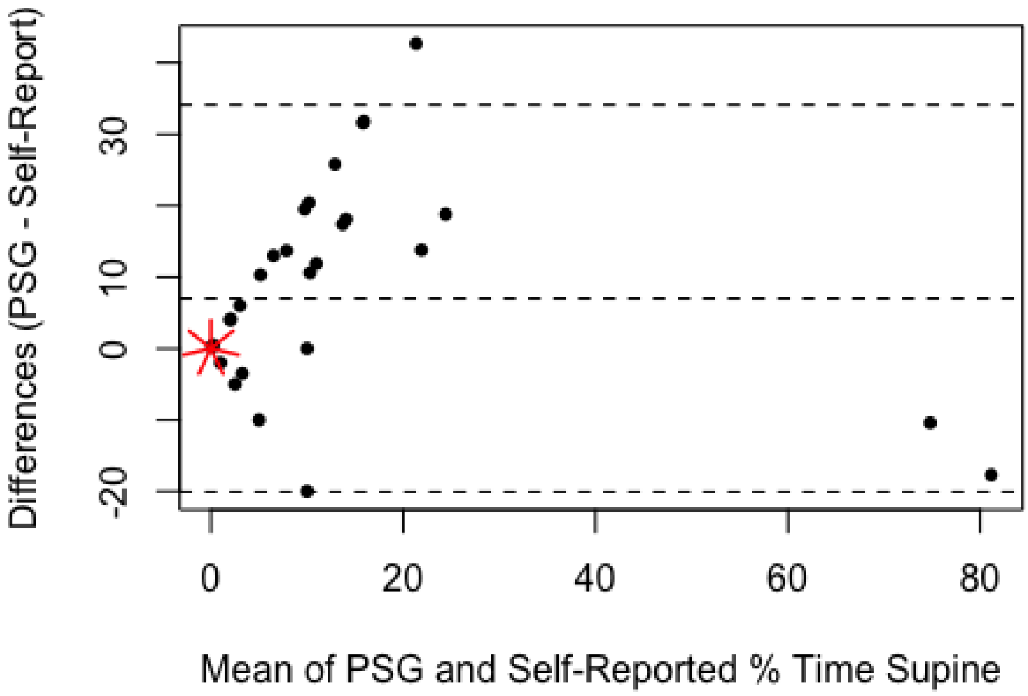
```
##  N  Y
##  5 15

summary(subset(SRdata, intervention == "sham")$PSG.snore)

##  N  Y
##  9 11

xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.levels = TRUE)

##          intervention
## PSG.snore sham treatment
##         N    9         5
##         Y   11        15

fisher.test(xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.level
s = TRUE))

## 
##  Fisher's Exact Test for Count Data
## 
## data:  xtabs(~PSG.snore + intervention, data = SRdata, drop.unused.levels
= TRUE)
## p-value = 0.3203
## alternative hypothesis: true odds ratio is not equal to 1
## 95 percent confidence interval:
##   0.5373446 11.9301555
## sample estimates:
## odds ratio 
##   2.398796

#SR
summary(SRdata$SRSnore)

##            don't know          N          Y 
##          3         26          8          3

length(SRdata$SRSnore)

## [1] 40

#Take a quick look at the data
data.frame(SRdata$PSG.snore, SRdata$SRSnore)

##    SRdata.PSG.snore SRdata.SRSnore
## 1                 Y     don't know
## 2                 Y     don't know
## 3                 N     don't know
## 4                 Y              N
## 5                 N              N
## 6                 Y     don't know
## 7                 Y
```

```
## 8                 Y
## 9                 N     don't know
## 10                Y     don't know
## 11                Y              Y
## 12                Y              Y
## 13                Y     don't know
## 14                Y              N
## 15                Y     don't know
## 16                Y     don't know
## 17                N     don't know
## 18                N              N
## 19                Y     don't know
## 20                Y              Y
## 21                N     don't know
## 22                N     don't know
## 23                Y     don't know
## 24                Y     don't know
## 25                N              N
## 26                N              N
## 27                Y     don't know
## 28                Y     don't know
## 29                Y     don't know
## 30                Y     don't know
## 31                N     don't know
## 32                N              N
## 33                Y     don't know
## 34                N     don't know
## 35                N              N
## 36                N
## 37                Y     don't know
## 38                Y     don't know
## 39                Y     don't know
## 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
```

```
#Take a quick look at the data
data.frame(SRdataSnore$PSG.snore, SRdataSnore$SRSnore)

##    SRdataSnore.PSG.snore SRdataSnore.SRSnore
## 1                      Y                   N
## 2                      N                   N
## 3                      Y                   Y
## 4                      Y                   Y
## 5                      Y                   N
## 6                      N                   N
## 7                      Y                   Y
## 8                      N                   N
## 9                      N                   N
## 10                     N                   N
## 11                     N                   N

#Cohen's Kappa
item1 <- data.frame(SRdataSnore$PSG.snore, SRdataSnore$SRSnore)
kappa2(item1[,c(1,2)])

##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 11
##    Raters = 2
##     Kappa = 0.621
##
##         z = 2.22
##   p-value = 0.0261

####################Body Position - Supine######################
#Before running the position analyses below, we need to remove the rows corre
sponding to
#the 5 nights when participants did not give a self-report of proportion of t
ime in each
#position (these five nights occured before the REB approved the change to ou
r PrenaBelt
#User Feedback Questionnaire) because if these rows remain, they will make th
e summary
#statistics (summary, #SD, length) inaccurate for the PSG data (n=40 instead
of n=35)....
#note that the Cohens, #ICC, and bland-altman will automatically drop these f
rom their
#respective analyses if #the data point is continuous or ordinal (not if text
! e.g.,
#snoring analysis).

#Remove LIQ nights 1 and 2, LOH nights 1 and 2, and LQI night 1:
SRdata1 = SRdata[-c(5,6,7,8,9),]
nrow(SRdata1)

## [1] 35
```

```
#Summary
#PSG
summary(SRdata1$PtstSupine)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00    0.00   10.00   14.82   22.75   72.30

sd(SRdata1$PtstSupine)

## [1] 18.69348

length(SRdata1$PtstSupine)

## [1] 35

#SR
summary(SRdata1$SRSupine)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##     0.0     0.0     0.0     7.8     5.0    90.0

sd(SRdata1$SRSupine)

## [1] 19.98205

length(SRdata1$SRSupine)

## [1] 35

#Test of association btw paired samples
cor.test(SRdata$PtstSupine, SRdata$SRSupine, method = "spearman")

## Warning in cor.test.default(SRdata$PtstSupine, SRdata$SRSupine, method =
## "spearman"): Cannot compute exact p-value with ties

##
##  Spearman's rank correlation rho
##
## data:  SRdata$PtstSupine and SRdata$SRSupine
## S = 5190.2, p-value = 0.1125
## alternative hypothesis: true rho is not equal to 0
## sample estimates:
##       rho
## 0.2730782

#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00

bland.altman.plot(SRdata$PtstSupine, SRdata$SRSupine,
                  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 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
```

```
## 12   20.4      0
## 13    6.0      0
## 14    0.0      0
## 15   25.8      0
## 16   13.0      0
## 17   16.9      5
## 18   10.3      0
## 19   19.5      0
## 20   31.6      0
## 21   33.8     15
## 22   28.8     15
## 23    1.5      5
## 24   14.7      1
## 25   15.6      5
## 26    0.0      5
## 27    0.0     20
## 28    0.0     10
## 29    0.0      0
## 30    4.1      0
## 31    0.0      0
## 32    0.5      0
## 33    0.0      0
## 34   23.1      5
## 35   72.3     90
## 36   69.6     80
## 37    0.0      0
## 38   42.7      0
## 39    0.0      2
## 40   10.0     10
##
## $based.on
## [1] 35
##
## $lower.limit
## [1] -20.0717
##
## $mean.diffs
## [1] 7.017143
##
## $upper.limit
## [1] 34.10599
##
## $lines
## lower.limit  mean.diffs upper.limit
##  -20.071701    7.017143   34.105987
##
## $CI.lines
## lower.limit.ci.lower lower.limit.ci.upper   mean.diff.ci.lower
##           -20.071701           -20.071701             7.017143
##   mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
```

```
##              7.017143             34.105987            34.105987
##
## $two
## [1] 1.96
##
## $critical.diff
## [1] 27.08884
```

```
####################Body Position - Right######################
#Summary
#PSG
summary(SRdata1$PtstRight)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##     0.0     0.0    30.1    30.8    49.0    95.4
```

```
sd(SRdata1$PtstRight)
```

```
## [1] 28.50465
```

```
length(SRdata1$PtstRight)
```

```
## [1] 35
```

```
#SR
summary(SRdata1$SRRight)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max. 
##    0.00    2.50   30.00   31.29   50.00   90.00
```

```
sd(SRdata1$SRRight)
```

```
## [1] 27.30177
```

```
length(SRdata1$SRRight)
```

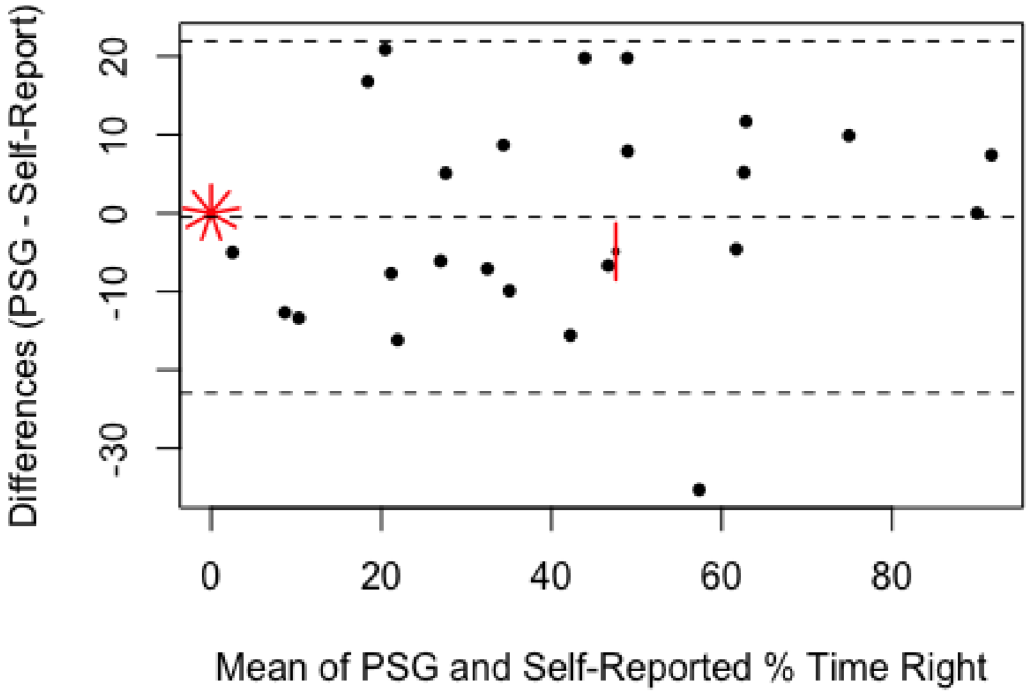
```
## [1] 35
```

```
#Test of association btw paired samples
cor.test(SRdata$PtstRight, SRdata$SRRight, method = "spearman")
```

```
## Warning in cor.test.default(SRdata$PtstRight, SRdata$SRRight, method =
## "spearman"): Cannot compute exact p-value with ties
```

```
##
##  Spearman's rank correlation rho
##
## data:  SRdata$PtstRight and SRdata$SRRight
## S = 505.71, p-value = 8.061e-16
## alternative hypothesis: true rho is not equal to 0
## sample estimates:
##       rho 
## 0.9291716
```

```
#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)")
```



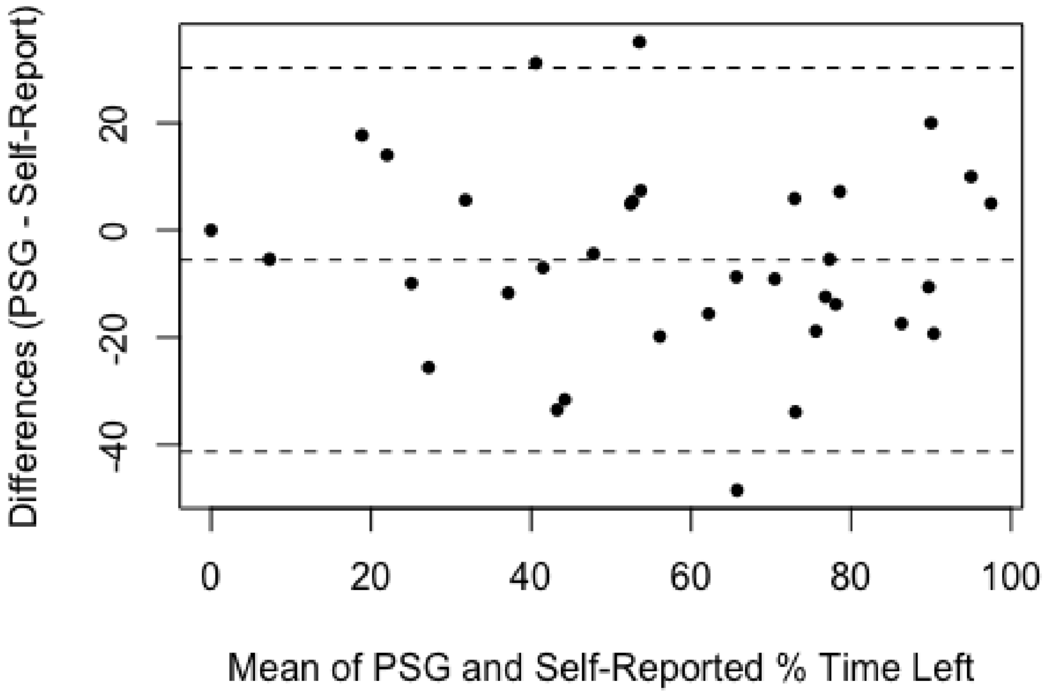
```
## $means
##  [1] 34.35 26.95 21.90  0.00 27.55 74.95 62.60 61.70 62.85 10.30 20.45
## [12] 47.55 42.20  0.00 18.40  0.00  0.00 48.95 48.90  0.00  0.00  0.00
## [23]  0.00 46.65 57.35 43.90 21.15 47.55  8.65  0.00  2.50 32.45 35.05
## [34] 91.70 90.00
##
## $diffs
##  [1]   8.7  -6.1 -16.2   0.0   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
```

```
##    group1 group2
## 1    38.7     30
## 2    23.9     30
## 3    13.8     30
## 4     0.0      0
## 10   30.1     25
## 11   79.9     70
## 12   65.2     60
## 13   59.4     64
## 14   68.7     57
## 15    3.6     17
## 16   30.9     10
## 17   45.1     50
## 18   34.4     50
## 19    0.0      0
## 20   26.8     10
## 21    0.0      0
## 22    0.0      0
## 23   52.9     45
## 24   58.8     39
## 25    0.0      0
## 26    0.0      0
## 27    0.0      0
## 28    0.0      0
## 29   43.3     50
## 30   39.7     75
## 31   53.8     34
## 32   17.3     25
## 33   45.1     50
## 34    2.3     15
## 35    0.0      0
## 36    0.0      5
## 37   28.9     36
## 38   30.1     40
## 39   95.4     88
## 40   90.0     90
##
## $based.on
## [1] 35
##
## $lower.limit
## [1] -22.91233
##
## $mean.diffs
## [1] -0.4828571
##
## $upper.limit
## [1] 21.94661
##
## $lines
```

```
## lower.limit  mean.diffs upper.limit
## -22.9123292  -0.4828571  21.9466149
##
## $CI.lines
## lower.limit.ci.lower lower.limit.ci.upper   mean.diff.ci.lower
##          -22.9123292          -22.9123292           -0.4828571
##   mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
##           -0.4828571           21.9466149           21.9466149
##
## $two
## [1] 1.96
##
## $critical.diff
## [1] 22.42947

####################Body Position - Left######################
#Summary
#PSG
summary(SRdata1$PtstLeft)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00   32.95   56.10   54.40   72.90  100.00

sd(SRdata1$PtstLeft)

## [1] 26.40423

length(SRdata1$PtstLeft)

## [1] 35

#SR
summary(SRdata1$SRLeft)

##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.
##    0.00   41.50   66.00   59.91   84.00  100.00

sd(SRdata1$SRLeft)

## [1] 28.14915

length(SRdata1$SRLeft)

## [1] 35

#Test of association btw paired samples
cor.test(SRdata$PtstLeft, SRdata$SRLeft, method = "spearman")

## Warning in cor.test.default(SRdata$PtstLeft, SRdata$SRLeft, method =
## "spearman"): Cannot compute exact p-value with ties

##
##  Spearman's rank correlation rho
```

```
##
## data:  SRdata$PtstLeft and SRdata$SRLeft
## S = 1691.2, p-value = 9.796e-08
## alternative hypothesis: true rho is not equal to 0
## sample estimates:
##       rho
## 0.7631423
```

```
#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00

bland.altman.plot(SRdata$PtstLeft, SRdata$SRLeft,
                  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 Left",
                  ylab="Differences (PSG - Self-Report)")
```



```
## $means
##  [1] 65.65 72.95 62.20 86.30 70.45 25.05 27.20 31.80 37.15 76.80 73.05
## [12] 41.50 52.70 90.35 65.75 75.60 78.10 47.80 43.25 89.70 97.50 90.00
## [23] 95.00 53.70 40.60 56.10 78.60 52.45 77.30 18.85 22.00 53.55 44.20
## [34]  7.30  0.00
```

```
##
## $diffs
##  [1]  -8.7   5.9 -15.6 -17.4  -9.1  -9.9 -25.6   5.6 -11.7 -12.4 -33.9
## [12]  -7.0   5.4 -19.3 -48.5 -18.8 -13.8  -4.4 -33.5 -10.6   5.0  20.0
## [23]  10.0   7.4  31.2 -19.8   7.2   4.9  -5.4  17.7  14.0  35.1 -31.6
## [34]  -5.4   0.0
##
## $groups
##    group1 group2
## 1    61.3     70
## 2    75.9     70
## 3    54.4     70
## 4    77.6     95
## 10   65.9     75
## 11   20.1     30
## 12   14.4     40
## 13   34.6     29
## 14   31.3     43
## 15   70.6     83
## 16   56.1     90
## 17   38.0     45
## 18   55.4     50
## 19   80.7    100
## 20   41.5     90
## 21   66.2     85
## 22   71.2     85
## 23   45.6     50
## 24   26.5     60
## 25   84.4     95
## 26  100.0     95
## 27  100.0     80
## 28  100.0     90
## 29   57.4     50
## 30   56.2     25
## 31   46.2     66
## 32   82.2     75
## 33   54.9     50
## 34   74.6     80
## 35   27.7     10
## 36   29.0     15
## 37   71.1     36
## 38   28.4     60
## 39    4.6     10
## 40    0.0      0
##
## $based.on
## [1] 35
##
## $lower.limit
## [1] -41.27743
```

```
##
## $mean.diffs
## [1] -5.514286
##
## $upper.limit
## [1] 30.24886
##
## $lines
## lower.limit  mean.diffs upper.limit
##  -41.277427   -5.514286   30.248856
##
## $CI.lines
## lower.limit.ci.lower lower.limit.ci.upper   mean.diff.ci.lower
##           -41.277427           -41.277427            -5.514286
##   mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
##            -5.514286            30.248856            30.248856
##
## $two
## [1] 1.96
##
## $critical.diff
## [1] 35.76314
```

```
####################Body Position - Prone######################
#Summary
#PSG
summary(SRdata$PtstProne)
```

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

```
length(SRdata$PtstProne)
```

```
## [1] 40
```

```
#SR
summary(SRdata$SRProne)
```

```
##    Min. 1st Qu.  Median    Mean 3rd Qu.    Max.    NA's
##  0.0000  0.0000  0.0000  0.7143  0.0000 18.0000       5
```

```
length(SRdata$SRProne)
```

```
## [1] 40
```

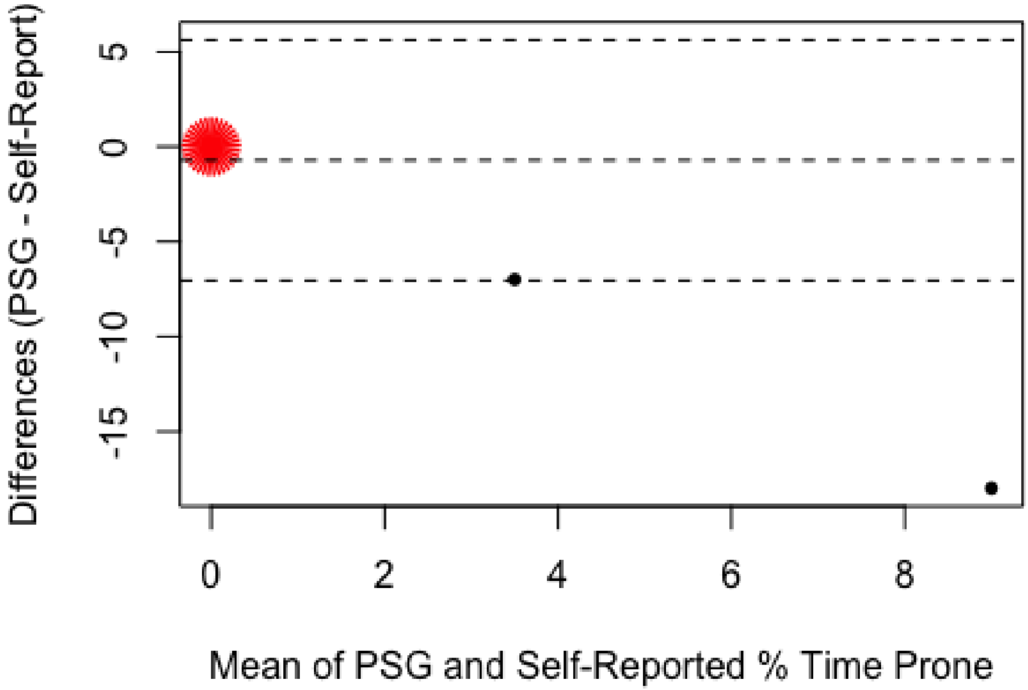
```
#Test of association btw paired samples
cor.test(SRdata$PtstProne, SRdata$SRProne, method = "spearman")
```

```
## Warning in cor(rank(x), rank(y)): the standard deviation is zero
```

```
##
##  Spearman's rank correlation rho
```

```
##
## data:  SRdata$PtstProne and SRdata$SRProne
## S = NA, p-value = NA
## alternative hypothesis: true rho is not equal to 0
## sample estimates:
## rho
##  NA
```

```
#fair = 0.40 to 0.60; good = 0.60 to 0.80; excellent = 0.80 to 1.00

bland.altman.plot(SRdata$PtstProne, SRdata$SRProne,
                  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 Prone",
                  ylab="Differences (PSG - Self-Report)")
```



```
## $means
##  [1] 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 0.0
## [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 9.0 0.0 0.0
## [35] 0.0
##
```

```
## $diffs
##  [1]   0   0   0   0   0   0   0  -7   0   0   0   0   0   0   0   0   0
## [18]   0   0   0   0   0   0   0   0   0   0   0   0   0   0 -18   0   0
## [35]   0
## 
## $groups
##    group1 group2
## 1       0      0
## 2       0      0
## 3       0      0
## 4       0      0
## 10      0      0
## 11      0      0
## 12      0      0
## 13      0      7
## 14      0      0
## 15      0      0
## 16      0      0
## 17      0      0
## 18      0      0
## 19      0      0
## 20      0      0
## 21      0      0
## 22      0      0
## 23      0      0
## 24      0      0
## 25      0      0
## 26      0      0
## 27      0      0
## 28      0      0
## 29      0      0
## 30      0      0
## 31      0      0
## 32      0      0
## 33      0      0
## 34      0      0
## 35      0      0
## 36      0      0
## 37      0     18
## 38      0      0
## 39      0      0
## 40      0      0
## 
## $based.on
## [1] 35
## 
## $lower.limit
## [1] -7.048871
## 
## $mean.diffs
```

```
## [1] -0.7142857
##
## $upper.limit
## [1] 5.620299
##
## $lines
## lower.limit  mean.diffs upper.limit
##  -7.0488705  -0.7142857   5.6202991
##
## $CI.lines
## lower.limit.ci.lower lower.limit.ci.upper   mean.diff.ci.lower
##           -7.0488705           -7.0488705           -0.7142857
##   mean.diff.ci.upper upper.limit.ci.lower upper.limit.ci.upper
##           -0.7142857            5.6202991            5.6202991
##
## $two
## [1] 1.96
##
## $critical.diff
## [1] 6.334585
```

```
####################PLMs/Restless Legs#######################
#droplevels to remove empty levels from the list of levels
SRdata$PSG.legs.restless <- droplevels(SRdata$PSG.legs.restless)
SRdata$SR.legs.restless <- droplevels(SRdata$SR.legs.restless)
#Summary
#PSG
summary(SRdata$PSG.legs.restless)
```

```
##  N  Y
## 26 14
```

```
length(SRdata$PSG.legs.restless)
```

```
## [1] 40
```

```
#SR
summary(SRdata$SR.legs.restless)
```

```
##            don't know          N          Y
##          3         19         14          4
```

```
length(SRdata$SR.legs.restless)
```

```
## [1] 40
```

```
#Take a quick look at the data
data.frame(SRdata$PSG.legs.restless, SRdata$SR.legs.restless)
```

```
##    SRdata.PSG.legs.restless SRdata.SR.legs.restless
## 1                         N              don't know
## 2                         N              don't know
```

```
## 3                            N                         N
## 4                            N                         N
## 5                            Y                         N
## 6                            Y                         Y
## 7                            N                          
## 8                            N                          
## 9                            N                         N
## 10                           N                don't know
## 11                           N                         N
## 12                           N                         N
## 13                           Y                don't know
## 14                           Y                         Y
## 15                           N                don't know
## 16                           N                don't know
## 17                           N                don't know
## 18                           N                don't know
## 19                           N                         N
## 20                           Y                         N
## 21                           Y                don't know
## 22                           Y                don't know
## 23                           N                don't know
## 24                           N                don't know
## 25                           Y                         Y
## 26                           Y                         N
## 27                           Y                         N
## 28                           Y                         N
## 29                           Y                don't know
## 30                           Y                don't know
## 31                           N                don't know
## 32                           N                don't know
## 33                           N                          
## 34                           N                don't know
## 35                           N                don't know
## 36                           N                         N
## 37                           Y                         Y
## 38                           N                don't know
## 39                           N                         N
## 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
```

```
SRdataLegs <- SRdataLegs[!(SRdataLegs$SR.legs.restless=="don't know"),]
nrow(SRdataLegs)

## [1] 18

#Take a quick look at the data
data.frame(SRdataLegs$PSG.legs.restless, SRdataLegs$SR.legs.restless)

##    SRdataLegs.PSG.legs.restless SRdataLegs.SR.legs.restless
## 1                             N                           N
## 2                             N                           N
## 3                             Y                           N
## 4                             Y                           Y
## 5                             N                           N
## 6                             N                           N
## 7                             N                           N
## 8                             Y                           Y
## 9                             N                           N
## 10                            Y                           N
## 11                            Y                           Y
## 12                            Y                           N
## 13                            Y                           N
## 14                            Y                           N
## 15                            N                           N
## 16                            Y                           Y
## 17                            N                           N
## 18                            N                           N

#Cohen's Kappa
item1 <- data.frame(SRdataLegs$PSG.legs.restless, SRdataLegs$SR.legs.restless
)
kappa2(item1[,c(1,2)])

##  Cohen's Kappa for 2 Raters (Weights: unweighted)
##
##  Subjects = 18
##    Raters = 2
##     Kappa = 0.444
##
##         z = 2.27
##   p-value = 0.0233

#End
```

Supplementary file 5: Research protocol

March 15th, 2016

To: The IWK Health Centre – Research Ethics Board
Research Services, Richard Goldbloom Gallery, Main Floor
5850/5980 University Avenue, Halifax, NS, B3K 6R8

From: Allan Kember
Research Administrator, Global Innovations for Reproductive Health and Life
Project Lead, Grand Challenges Canada Grant #S7 0629-01-10
17 Oceanview Dr.
Halifax, NS, B3P 2H4

Subject: Research Protocol

Project Title: A Maternal Device for the Prevention of Stillbirth and Low Birthweight

Foreword

This project, entitled A Maternal Device for the Prevention of Stillbirth and Low Birthweight, was originally submitted on March 10th, 2014 to Grand Challenges Canada in response to their Request for Proposals: Stars in Global Health – Round 7 Phase I. Grand Challenges Canada's peer review of this proposal was led by the Canadian Institutes of Health Research. This proposal was recommended to proceed to the next stage of the *Stars in Global Health* grant process, which involved due diligence and grant agreement negotiations between the primary organization for this project, Innovative Canadians for Change Foundation (ICChange – Edmonton, AB), and Grand Challenges Canada, which were completed on December 19th, 2014. Funding for this project was approved on December 19th, 2014.

Note that this proposal includes two feasibility studies – one in Halifax, Canada, and one in Accra, Ghana. Both studies include human participants; therefore, both studies will require ethics approval. For the study in Halifax, ethics approval was received on June 16th, 2015 (Project #1018753) from The IWK Health Centre Review Ethics Board (REB). For the study in Accra, ethics approval was received from The IWK-REB on June 16th, 2015 (Project #1019318) and from the Noguchi Memorial Institute for Medical Research Institutional Review Board (local ethics board) on March 4th, 2015 (CPN 069/14-15).

The purpose of this document is to set forth the research protocol for the study related to The IWK Health Centre in Halifax, Canada as per the guidelines given in the document Protocol Components provided under the New Submissions – Guidelines and Templates section of the IWK Health Centre Research website:

http://www.iwk.nshealth.ca/research/application-materials-forms

This research protocol is submitted for review by The IWK Health Centre's Review Ethics Board as part of the requirements in the document Researcher's Checklist for Submissions: Delegated Review.

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

Allan Kember

1 Scientific

1.1 Introduction

According to the WHO, stillbirth (SB) is defined as fetal death at gestation ≥28 weeks or weight ≥1000g [1]. In Canada, the definition of SB is wider, including fetal death at gestation ≥20 weeks or weight ≥500g [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].

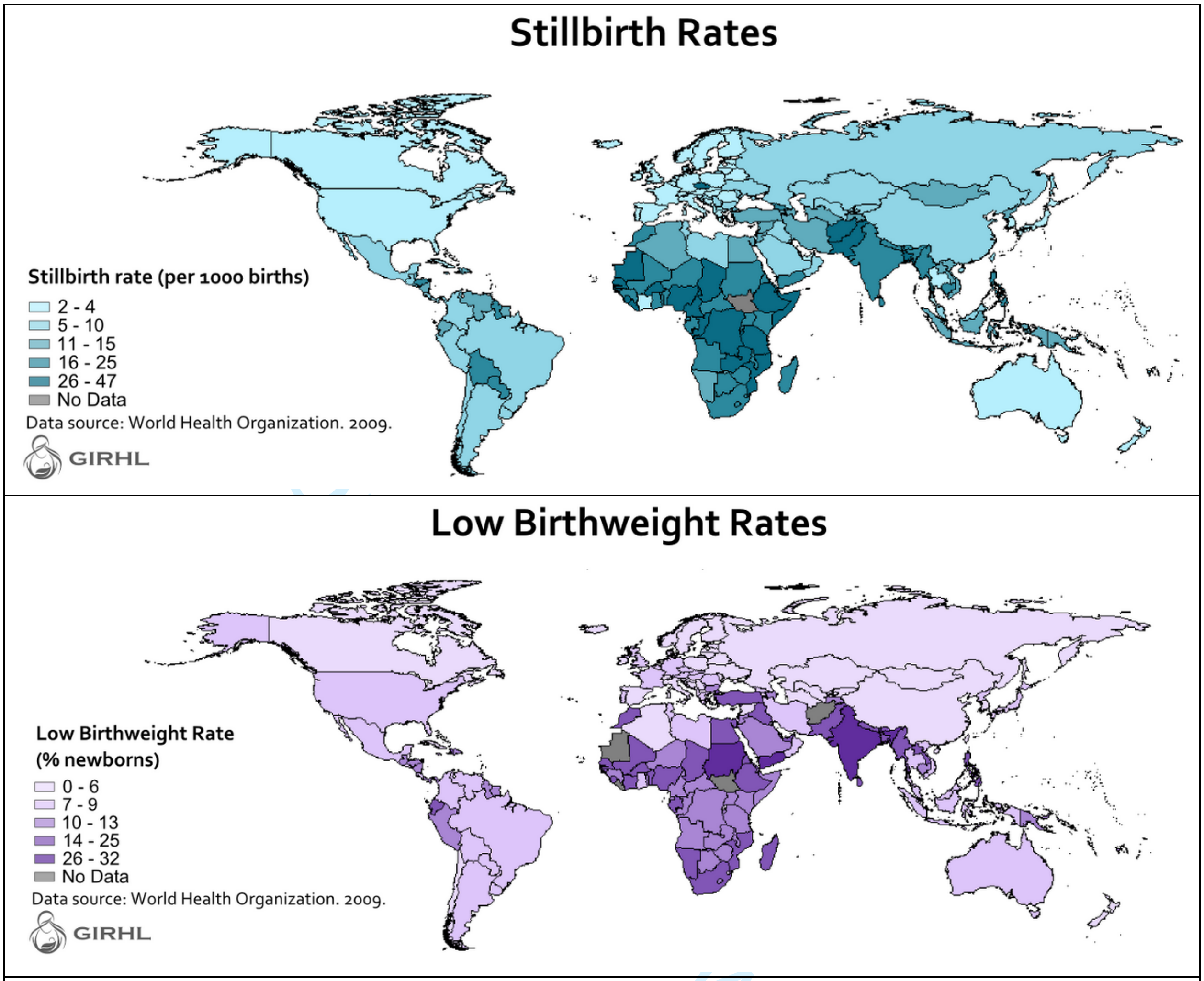
Maternal sleep position during pregnancy has recently emerged as a risk factor for LBW and SB [14] [15] [16]. A device to modify maternal sleep position and mitigate this risk factor has been developed (see section 1.1.3). The purpose of this *Stars in Global Health* project is to test the effectiveness 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.



Data source: World Health Organization. 2009.

Data source: World Health Organization. 2009.

Figure 1. Maps of global stillbirth and low birthweight rates. Data source: World Health Organization, 2009.

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

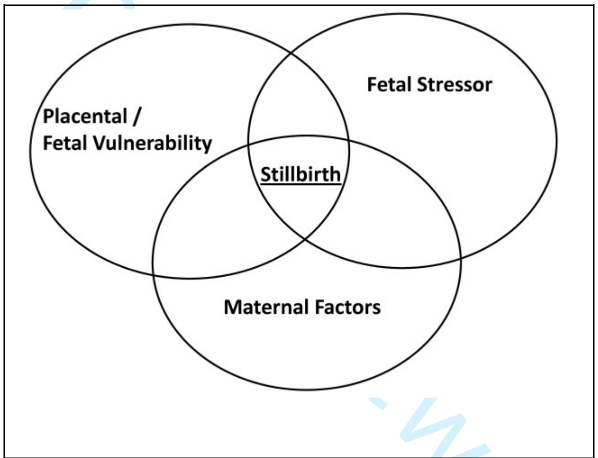


Figure 2. Triple risk model for unexplained late stillbirth **[25]**.

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].

Maternal sleep position has recently been implicated as a potential modifiable risk factor for LBW and SB [14] [15] [16]. Hence, a simple, low-cost, and easily-implemented device has been developed for use by pregnant women to mitigate this risk factor. We anticipate that using this device will remove the need for the woman to make a conscious effort to avoid the supine sleeping position. The device name is 'PrenaBelt'. The PrenaBelt is currently at the prototype stage of development, and as such, this proposal is a proof-of-concept/feasibility project.

The PrenaBelt is a belt-like, positional therapy device designed specifically for pregnant women. While the PrenaBelt does not prevent the user from lying on her back or right side during sleep, it is expected to significantly decrease the amount of time she spends in these two positions via the mechanism of positional therapy. Positional therapy is a simple, non-invasive, inexpensive, long-established, safe, and effective intervention for preventing people with positional-dependent snoring or mild to moderate obstructive sleep apnea from sleeping on their back [27] [28] – a position that exacerbates their condition [29] [30] [31] [32].

The PrenaBelt is worn at the level of the waist. By virtue of its design and position on the user's body, the PrenaBelt affects subtle pressure points around the midriff (back and right side) of the user when she lies on her back or right side, respectively. These subtle pressure points activate her body's natural mechanism to spontaneously reposition itself to relieve discomfort [33] [34] [35], thereby reducing the amount of time she remains on her back or right side. Alternatively, the PrenaBelt can be worn at the level of the thorax with the back of the device centered at the mid-back, in which case the front of the device would sit just below the breasts at the level of the fundus (upper abdomen).

The PrenaBelt is also designed for adjustability and comfort. As such, its configuration can be easily adapted by the user to only help her avoid sleeping on her back if she requires the option of sleeping on her right side as well as her left for comfort reasons.

Members of our team at Global Innovations for Reproductive Health and Life (GIRHL, Cleveland) have developed a Body Position Sensor (BPS) to be integrated into the PrenaBelt. The BPS is a small, electronic data acquisition device developed for research purposes only and in accordance with the original proposal to our funder, Grand Challenges Canada. The BPS fits into a pocket on the PrenaBelt and uses a three axes accelerometer to detect orientation of the PrenaBelt, and thus the user, in three-dimensional space. The accelerometer data is collected and stored on the BPS hard drive and can be accessed via connecting it to a computer.

The PrenaBelt only comes into contact with intact skin and, as such, is a non-invasive medical device. As per Rule 7, subrule (1) in the Government of Canada's Medical Devices Regulation – Classification Rules For Medical Devices, the PrenaBelt is classified as a Class I medical device [36]. The BPS is a research-use only device and, as such, does not fall under medical device regulation.

Per the Government of Canada's Medical Devices Regulation – Part 3: Medical Devices For Investigational Testing Involving Human Subjects, Section 80, Subsection (3), "A manufacturer or importer of a Class I medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer possesses records that contain all the 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 acceptable[1] 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

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[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 outcomes[2].
- **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

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[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

For each participant, identical measurements (below, collectively referred to as "sleep variables" in Section 1.4.1.6) will be recorded on both nights using the same methods, equipment, and software. The sleep tests will be set up and monitored by a research assistant trained in polysomnography and under the supervision of a sleep technologist except on Friday and Saturday evenings. On Friday and Saturday evenings, either two research assistants will be present or one research assistant and one authorized study personnel will be present and a sleep technician will be on call. The sleep tests will be scored by a sleep technologist holding board certification in sleep technology (RPSGT). Scoring will be according to the current American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated Events. The sleep tests and scores will be interpreted and reported by a sleep specialist physician. Note that the measurements, methods, equipment, and software employed will be non-invasive:

a. Maternal position: direct observation by the sleep technologist through real-time or recorded audio/video and by an electronic Body Position Sensor incorporated into the PrenaBelt
b. Chest and abdominal respiratory movement: respiratory inductance plethysmography (RIP) via Pro-Tech zRIP DuraBelt with Sandman PSG software
c. Nasal and oral airflow and presence of snoring: Braebon nasal pressure transducer. If the participant is a total mouth breather, Braebon thermistor will be available as a back-up.
d. Arterial blood oxygenation: pulse oximetry (SpO_2) via Embla Sandman
e. Heartbeat rate and regularity: via electrocardiography (EKG)
f. Sleep staging: via electroencephalography (EEG), electromyography (EMG), and electrooculography (EOG). Note that if a participant is uncomfortable or cannot tolerate some of the EEG, EMG, or EOG electrodes/leads, e.g., EMG electrodes/leads on arms and legs, these electrodes/leads may be removed.

In the morning following each sleep test, before each participant is discharged home, she will be asked to complete the approved PrenaBelt User Feedback Questionnaire and seal it in a provided envelope for the researchers. Participants will be asked:

a. What position she adopted upon settling down last night
b. What position she fell asleep in last night
c. What position she woke up in this morning
d. If she changed position during night
e. If she remembers changing positions
f. Her level of satisfaction with the PrenaBelt as it relates to the quantity and quality of her sleep last night
g. Her level of comfort while wearing and sleeping with the PrenaBelt
h. Her intention to use the PrenaBelt for the remainder of her pregnancy if it was available to her
i. Any suggestions of changes/ modifications/ improvements she may have for the 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 (SpO_2)
- 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 SpO_2 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, Respirologist, 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-five[3] (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.

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[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, Respirologist, 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 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 discuss her results with her at her next antenatal care appointment. We have found in previous studies that most women appreciate this.

If severe OSA is identified for a given participant, she and her maternity care physician will be notified immediately, given the sleep test results, and advised to discuss this issue together at earliest opportunity to ensure proper management and care. Proper management of her OSA may result in instant and long-term benefits for her and her baby.

In addition, the opportunity to assist in the advancement of sleep-in-pregnancy knowledge and the possibility of benefiting other pregnant women globally in the future may be a source of immediate satisfaction to participants.

2.1.2 Others

Note: the following section refers to the WHO definition of stillbirth and not the definition used by Statistics Canada (see Section 1.1).

In Canada, three babies are stillborn every day (≥1000g birthweight or ≥28 weeks completed gestation) [1]. This is a largely unrecognized national tragedy yet pales in comparison to Ghana, where 47 babies are stillborn every day [1] (Note: in Ghana, the birth rate is 2 times greater than that in Canada, but the stillbirth rate is more than 15 times greater). In addition, every day, 61 Canadian babies are born with low birthweight (≤2500g) [48], and 232 Ghanaian babies are born with low birthweight [49] – many of whom will die in infancy or suffer lifelong consequences. These statistics and disparities are unconscionable, yet even they pale when compared to regions of further impoverishment where the state of affairs has been aptly described by one author as 'obstetric carnage' [50].

Maternal supine sleep has recently emerged as a potential risk factor for SB and LBW [14] [15] [16]. If supine sleep has a causative role in LBW and subsequently SB, the population attributable risk (PAR%) suggests that up to 17% of LBW, and consequently 26% of SB, might be averted by changing maternal sleep position [16] – this translates to the aversion of 3.7 million LBW and 676,000 SB annually [1] [5]. Since LBW is a major contributor to stillbirth [4], morbidity [5] [11] [12], and neonatal mortality (60-80%) [6] [7] [8] [9], further benefit may be realized.

This study will test a novel approach to reducing the global incidence of SB and LBW by determining whether this potential risk factor can be mitigated via treatment with a simple, positional therapy device. Demonstrating that maternal sleep position is, in fact, amenable to positional therapy will be a valuable contribution to existing knowledge and may be a key component to reducing the rates of SB and LBW in Canada and worldwide.

Currently, research is underway to determine whether a causal relationship between maternal sleep position and SB and LBW exists and collect a robust evidence base from which to advise whether a public health intervention should be considered (dissemination of research findings expected by August 2016) [24]. If a public health intervention is advised, our study will be at the forefront of scientific investigation into one possible intervention, i.e., positional therapy.

Following successful completion of this proof-of-concept (Phase I) study, there is potential for transition-to-scale (Phase II) funding from Grand Challenges Canada (contingent on 50% matching through partnerships) of up to $1,000,000 CAD for up to 2-3 years. In addition to this funding, other grant options in the area of maternal, newborn, and child health (MNCH) are available, e.g., Bill and Melinda Gates Foundation, Saving Lives at Birth. Such grants would enable exploration of the effectiveness of this intervention in populations that have very high perinatal mortality rates.

Finally, this project may bring beneficial opportunities to members of the research team. For example, it may cultivate future research collaboration with other teams worldwide through publication in journals and presentations/networking at global health conventions. Another example is that the inventors of the PrenaBelt (Mr. Borazjani, Mr. Kember) plan to establish or partner with a social enterprise organization to ensure sustainability and maximum benefit to mothers and their babies globally.

2.2 Potential Harms to Participants and Others

This study is minimal risk. Participants in this study are at no greater risk of harms when completing the activities of this study than those risks they encounter in their everyday life.

The PrenaBelt device is a non-invasive medical device of Class I designation (see section 1.1.3). Pregnant women typically sleep with many pillows supporting their body, including a pillow behind their back to avoid the supine position. The PrenaBelt is a positional therapy device that may assist pregnant women to avoid supine sleep. Positional therapy devices have been shown to be safe and approved for use by humans by the US Food and Drug Administration [37]. In addition, maternal body pillows, regular pillows, and pelvic belts (lumbar support) have been used by pregnant women during sleep without reports of serious adverse effects for the mother or neonate [51].

In Halifax, wearing the PrenaBelt and sleep monitoring equipment may be uncomfortable for a participant and disturb her sleep. Each participant will be told that she can remove these devices at any time overnight if she becomes too uncomfortable.

In order to ensure the monitor electrodes remain adhered to participant’s skin, the research assistant will need to prepare the area of skin, which involves cleaning and slight abrasion with an abrasive skin preparation gel. In the morning, after the monitors are removed, participants may experience slight discomfort and redness on the regions of their skin that were in contact with the electrodes. Rarely, a person will have a minor skin reaction on the area of his/her skin that was in contact with the electrodes. This reaction is not dangerous and usually goes away on its own within 24 hours to a few days.

Since personal information will be collected from participants, there always exists the potential harm should breach of confidentiality inadvertently occur.

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.

Upon enrolment in the study, each participant will be assigned a random, six-digit, alphanumeric code. All data collected from participants during the studies will be collected only in association with this code, thus automatically de-identifying the data and minimizing the risk of identification. The key to the code, which links the codes to patient names and contact information, will be kept in a secure location away from the de-identified study data, thus minimizing the risk of re-identification. The de-identified data in forms (paper) and files (electronic) will be secured in a locked filing cabinet and in password-protected files on a password-protected computer, respectively, in a locked office with limited access.

For all study activities, all data collected from participants will be protected from unauthorized access to safeguard participant privacy and confidentiality in accordance with TCPS2, PHIPA, and PIPEDA and personal information policies at the IWK Health Centre.

There is a reasonable foreseeable risk that the Unexpected Events Contact Form for a given participant (contains participant's first name, name of contact, phone numbers of contact, and relationship of contact) could be matched with her Data Collection Form, PrenaBelt User Feedback Questionnaires, or sleep recording files (which contain her alphanumeric code) and be used to re-identify her de-identified information. To mitigate this risk of re-identification, the research assistant will be the only person who will have access to the Unexpected Events Contact Form and will be instructed to keep it in a separate secure location and shred it in a cross-cut shredder after the second sleep test is complete. In addition, the research assistant will not have access to the Data Collection Form or PrenaBelt User Feedback Questionnaires, which will be delivered and retrieved from each participant in a sealed envelope.

Study data will only be exchanged in de-identified form and between authorized research team members per the approved EAS Form. Data will be protected in electronic transfers through password protection and encryption if deemed necessary.

After study closure, study data will be stored securely (locked cabinets, password-protected files, password-protected computers, locked offices) in de-identified form for five years, after which it will be destroyed in a secure manner (e.g., incineration and cross-cut shredding).

2.5 Process for Seeking Consent

1. **Ethical Approval and Training:** The study requires approval from the Review Ethics Board at the IWK Health Centre (Halifax, Canada). All study personnel will be trained to the approved Research Protocol by Mr. Allan Kember (Sub-investigator, Project Lead).

2. **Recruitment:**

   - The IWK OB/GYN will review charts of her/his patients scheduled for their routine antenatal visit at the clinic to identify potential participants. These patients will then be screened by the OB/GYN within their circle of care using the Screening Inclusion Form to determine if they meet the inclusion/exclusion criteria for this study.
   - Patients who meet the inclusion/exclusion criteria will be invited to participate in the study by their OB/GYN at the end of their antenatal care visit via the approved Flyer. The Flyer will

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

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.