**Brief introduction to the pilot trial**

From January 2019 to July 2019, a randomized controlled clinical trial was conducted at Yueyang Hospital of Integrated Traditional Chinese and Western Medicine and Shanghai Hospital of Traditional Chinese Medicine to observe the efficacy of electroacupuncture for constipation in Parkinson's disease. So far, a total of 45 patients (23 in the intervention group and 22 in the waitlist control group) have been enrolled. There were 3 and 2 patients dropout in the intervention group and the control group, respectively. Finally, 40 patients completed the efficacy evaluation in week 8.

**The brief raw data on primary outcome**

Table 1 Brief raw data on primary outcome

| The change in mean weekly spontaneous bowel movements from baseline to 8-9weeks | |
|---|---|
| Intervention group(n=20) | Waitlist control group(n=20) |
| -2.50 | 0.50 |
| -2.00 | -1.50 |
| 1.50 | 1.00 |
| -1.00 | 0.00 |
| -1.00 | 0.00 |
| -1.00 | 0.00 |
| 0.00 | -2.50 |
| 4.50 | 0.00 |
| 1.50 | 0.00 |
| 2.50 | 0.00 |
| 0.50 | -0.50 |
| 1.00 | -1.50 |
| -1.50 | 0.00 |
| 0.00 | -0.50 |
| 3.00 | 1.00 |
| 0.00 | -1.50 |
| 4.00 | -0.50 |
| 2.00 | 2.00 |
| 0.00 | 0.00 |
| 0.50 | -2.50 |

## Statistical analysis

**Group Statistics**

| | 1=waitlist control group; 2=intervention group | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| SBMs | 1 | 20 | -.3250 | 1.12712 | .25203 |
| | 2 | 20 | .9250 | 1.87276 | .41876 |

**Tests of Normality**

| 1=waitlist control group; 2=intervention group | | Shapiro-Wilk[a] |
|---|---|---|
| | | Sig. |
| SBMs | 1 | .110 |
| | 2 | .586 |

**Independent Samples Test**

| | | Levene's Test for Equality of Variances | | t-test for Equality of Means | |
|---|---|---|---|---|---|
| | | F | Sig. | t | df |
| SBMs | Equal variances assumed | 7.589 | .009 | -2.558 | 38 |
| | Equal variances not assumed | | | -2.558 | 31.168 |

**Independent Samples Test**

| | | t-test for Equality of Means | | | |
|---|---|---|---|---|---|
| | | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% Confidence Interval of the Difference |
| | | | | | Lower |
| SBMs | Equal variances assumed | .015 | -1.25000 | .48876 | -2.23943 |
| | Equal variances not assumed | .016 | -1.25000 | .48876 | -2.24661 |

**Independent Samples Test**

| | | t-test for Equality of Means |
|---|---|---|
| | | 95% Confidence Interval of the Difference |
| | | Upper |
| SBMs | Equal variances assumed | -.26057 |
| | Equal variances not assumed | -.25339 |

SBMs, the change in mean weekly spontaneous bowel movements from baseline to weeks 8 and 9.

# Sample size

## Two-Sample T-Tests Assuming Equal Variance

**Numeric Results for Two-Sample T-Test Assuming Equal Variance**
Alternative Hypothesis: H1: δ = μ1 - μ2 ≠ 0

| Target Power | Actual Power | N1 | N2 | N | μ1 | μ2 | δ | σ | Alpha |
|---|---|---|---|---|---|---|---|---|---|
| 0.90 | 0.90493 | 49 | 49 | 98 | -0.3 | 0.9 | -1.3 | 1.9 | 0.050 |

**References**
Julious, S. A. 2010. Sample Sizes for Clinical Trials. Chapman & Hall/CRC. Boca Raton, FL.
Chow, S. C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research (Second Edition). Chapman & Hall/CRC. Boca Raton, FL.
Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, MA.
Zar, Jerrold H. 1984. Biostatistical Analysis (Second Edition). Prentice-Hall. Englewood Cliffs, New Jersey.

**Report Definitions**
Target Power is the desired power value (or values) entered in the procedure. Power is the probability of rejecting a false null hypothesis.
Actual Power is the power obtained in this scenario. Because N1 and N2 are discrete, this value is often (slightly) larger than the target power.
N1 and N2 are the number of items sampled from each population.
N is the total sample size, N1 + N2.
μ1 and μ2 are the assumed population means.
δ = μ1 - μ2 is the difference between population means at which power and sample size calculations are made.
σ is the assumed population standard deviation for each of the two groups.
Alpha is the probability of rejecting a true null hypothesis.

**Summary Statements**
Group sample sizes of 49 and 49 achieve 90.493% power to reject the null hypothesis of equal means when the population mean difference is μ1 - μ2 = -0.3 - 0.9 = -1.3 with a standard deviation for both groups of 1.9 and with a significance level (alpha) of 0.050 using a two-sided two-sample equal-variance t-test.

**Dropout-Inflated Sample Size**

| | Sample Size | | | Dropout-Inflated Enrollment Sample Size | | | Expected Number of Dropouts | | |
|---|---|---|---|---|---|---|---|---|---|
| Dropout Rate | N1 | N2 | N | N1' | N2' | N' | D1 | D2 | D |
| 20% | 49 | 49 | 98 | 62 | 62 | 124 | 13 | 13 | 26 |

**Definitions**
Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as "missing").
N1, N2, and N are the evaluable sample sizes at which power is computed. If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power.
N1', N2', and N' are the number of subjects that should be enrolled in the study in order to end up with N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2' are calculated by inflating N1 and N2 using the formulas N1' = N1 / (1 - DR) and N2' = N2 / (1 - DR), with N1' and N2' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., and Wang, H. (2008) pages 39-40.)
D1, D2, and D are the expected number of dropouts. D1 = N1' - N1, D2 = N2' - N2, and D = D1 + D2.

## Two-Sample T-Tests Assuming Equal Variance

**Procedure Input Settings**

**Autosaved Template File**
C:\Users\king\Documents\PASS 15\Procedure Templates\Autosave\Two-Sample T-Tests Assuming Equal Variance - Autosaved 2019_8_16-12_7_11.t388

**Design Tab**

| | |
|---|---|
| Solve For: | Sample Size |
| Alternative Hypothesis: | Two-Sided |
| Power: | 0.90 |
| Alpha: | 0.05 |
| Group Allocation: | Equal (N1 = N2) |
| Input Type: | Means |
| μ1: | -0.325 |
| μ2: | 0.925 |
| σ: | 1.873 |