Sample size calculation

Information from previous studies [1] found a standard deviation of 2.4.

Design with two paired samples (Pre vs Post Treatment; Self-Controlled Trial)

To achieve a power of 80.00% to detect differences in the contrast of the null hypothesis H0: µpre = µpost by means of a bilateral Student’s T-test for two related samples, taking into account that the level of significance is 5.00%, an assuming that the average of the reference group is 0.00 units, the average of the experimental group is 1.00 units and the standard deviation of the difference variable is 2.40 units, it will be necessary to include 48 pairs of experimental units in the study. Given that the expected percentage of dropouts is 50.00%, it would be necessary to recruit 96 pairs of experimental units in the study.

Design with two independent samples (Treatment vs Placebo; Randomized Controlled Trial)

To achieve a power of 80.00% to detect differences in the contrast of the null hypothesis H0: µpre = µpost by means of a bilateral Student’s T-test for two related samples, taking into account that the level of significance is 5.00%, an assuming that the average of the reference group is 0.00 units, the average of the experimental group is 1.00 units and the standard deviation of the difference variable is 2.40 units, it will be necessary to include 92 experimental units in the reference group and 92 units in the experimental group, totalling 184 experimental units in the study. Considering that the expected percentage of dropouts is 50.00%, it would be necessary to recruit 368 experimental units in the study.

Clinical trial design for Mow-01-2017

Based on sample size calculated, the Self-Controlled Trial design is favoured for the MOW-01-2017 clinical trial.

1. McClurg, D., et al., *Abdominal massage for the alleviation of constipation symptoms in people with multiple sclerosis: a randomized controlled feasibility study.* Mult Scler, 2011. **17**(2): p. 223-33.