

Sample size estimation Introvision Study for headache

Randomized comparison of Introvision vs. waiting group in relation to headache days after Introvision (approx. 5 months after the study was started) or at the time of entry into Intervention phase (Waiting list group)

Specifications: Comparison of average headache days per month at survey time between Introvision group (experimental group) and waiting list group (control) by means of T-test for independent samples

Values assumed:

Introvision group:

Mean value 6, 5.5, or 5 headache days per month, standard deviation: 4.5, 5, 6, 7 days

Control group:

Average 8.5 headache days per month, standard deviation: 4.5, 5, 6, 7 days

Difference (effect): 2.5, 3, 3.5 headache days per month, standard deviation: 4.5, 5, 6, 7 days

Statistical test: T-Test for independent samples (analysis also with Mann-Whitney-U-Test)

Significance level: 5% double-sided (maximum probability of having a significant result in the event of a lack of effect); statistical power 80% (minimum probability of detecting an actual effect in the assumed order of magnitude)), 1:1 randomization

Result of the sample size estimation: See table

| Medium effect (Headache days per month) | Standard deviation (Headache days per month) | Sample size group | Total sample size |
|---|--|-------------------|-------------------|
| 2.5 | 4.5 | 52 | 104 |
| 3 | 4.5 | 36 | 72 |
| 3.5 | 4.5 | 27 | 54 |
| 2.5 | 5 | 64 | 128 |
| 3 | 5 | 45 | 90 |
| 3.5 | 5 | 33 | 66 |
| 2.5 | 6 | 91 | 182 |
| 3 | 6 | 64 | 128 |
| 3.5 | 6 | 47 | 94 |
| 2.5 | 7 | 124 | 248 |
| 3 | 7 | 86 | 172 |
| 3.5 | 7 | 64 | 128 |