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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