ClinicalTrials.gov ID: NCT03659032

Efficacy of Pediatric Manual Therapy in the Positional Plagiocephaly

Statistical Analysis Plan

Date: 09/01/2018
_STATISTICAL ANALYSIS PLAN SAP EFFICACY OF PEDIATRIC MANUAL THERAPY IN POSITIONAL PLAGIOCEPHALY_

**Statistical analysis**

The statistical analysis will be carried out with the software program SPSS v. 22.0 for Mac. Normality of the distribution of quantitative variables will be verified with the Lilliefors-corrected Kolmogorov-Smirnov test. Afterwards, a descriptive analysis of qualitative variables will be performed to obtain absolute and relative frequencies, as well as an analysis of quantitative variables to obtain the mean values ± standard deviation or median values (Q1-Q3), according to whether the distribution of the variables is normal or not, respectively.

Inter-group comparisons between the pre-intervention descriptive and dependent variables and the post-intervention dependent variables will be carried out with nonparametric tests for the qualitative variables (chi-squared test) and the quantitative variables without a normal distribution (Mann-Whitney U test). If the variables have a normal distribution, the inter-group comparisons will be carried out with Student’s t-test for independent samples. The effect size of the analyzed interventions will be calculated with Cohen’s $d$.

Intra-group comparisons between pre- and post-intervention dependent variables will be carried out with Student’s t-test for related samples with a normal distribution. If the distribution of the variables is not normal, the Wilcoxon signed-rank test will be used.

In the parametric analysis, a 95% confidence interval will be used, and a p-value $<0.05$ will be considered significant.