

3.03.2017

The Effect of Vest Type Dynamic Elastomeric Fabric Orthosis (DEFO) on Sitting Balance and Gross Manual Dexterity in Children With Bilateral Cerebral Palsy: A Feasibility and Randomized, Single-blinded, Pilot Study (NCT03191552)

(Unique Protocol ID:09.2013.0351)

STATISTICAL PLAN

IBM SPSS Statistics for Windows, Version 20,0 (Armonk, NY, USA) will be used to perform all of the analysis. Statistical significance is accepted as $p < 0.05$. Descriptive statistics will be used to determine mean \pm SD of data. Chi-square and t-tests will be used to compare demographic findings. The histogram and normality plots and Shapiro-Wilk normality test were used for data distribution analysis. Between group analysis will be performed using ANOVA if data followed normal distribution. But if not Kruskal-Wallis test will be performed. Mann-Whitney U test was performed to test the significance of pairwise differences using Bonferroni correction (post-hoc test) to adjust for multiple comparisons. For Bonferroni correction, a p value of less than 0.017 ($0.05/3$) was determined as the level of statistical significance

Depending on the distribution analysis, Wilcoxon and dependent t-test will be utilized to detect within group analyzes. To assume changes over time with treatment Friedman and repeated measures analysis of variance will be conducted.

Mann Whitney u and independent sample t-tests will be applied to compare SPIO 2 hours and 6 hours group. To compare groups in pairs in terms of parent satisfaction questionnaire results chi square test will be done.

To evaluate feasibility, recruitment and retention rates will be calculated and percentages will be reported.