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Main Title

OHI--RANDOMIZED CONTROL TRIAL TO EVALUATE EFFICACY, ACCEPTABILITY, AND PERCEPTION OF BENEFIT OF AN INNOVATIVE CUSTOM ANKLE FOOT ORTHOSIS

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Supplementary Document – Details of Statistical Analytical Plan

Data analysis will be done to determine if efficacy points are met and to compare different measurements against others (Intervention group (IG) v. Control Group (CG)). Baseline group differences will be compared using a one-way analysis of variance (ANOVA) for continuous variables that were normally distributed or the Mann-Whitney U test if they were not normally distributed. For categorical variables, the $\chi 2$ test will be used to compare baseline group differences. Normality will be assessed using Shapiro-Wilk tests ($p > 0.05$). To assess the effect of intervention, multiple linear mixed models (LMMs) will be used to first examine group (2 levels: IG and CG) × time (2 levels: baseline and 6-month follow-up) interaction effects. The LMM will be selected because it can account for missing data (to prevent entire subject data from being removed due to lack of a measurement at a specific time point). The LMMs will be also used to assess the main effect of time within each group. For all statistical analysis, $p < 0.05$ will be considered statistically significant.