Head-Mounted Vibrotactile Prosthesis for Patients With Chronic Postural Instability

NCT03330262

Statistical Analysis Plan

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Study Hypotheses

Overview: The overarching study hypotheses is that use of the BALCAP device provides significant assistive and/or rehabilitative benefit.

Dynamic Gait Index (DGI) and Gait Speed null hypotheses: The analyses of the Dynamic Gait Index (DGI) and the Gait Speed were focused on testing the following null hypotheses: H_0 -- The mean pre-therapy score is the same for the BALCAP and No BALCAP test conditions.

Activities-specific Balance Confidence Scale (ABC), Dizziness Handicap Inventory (DHI), and Computerized Dynamic Posturography (CDP) null hypotheses: These analyses were focused on testing the null hypothesis that the mean pre- to post-intervention change in score after 6-weeks of therapy, in which the participant was required to wear the BALCAP (BALCAP condition), is the same as the mean per- to post-intervention change in score after 6-weeks of therapy, in which participant was required not to wear the BALCAP (Control condition).

Statistical Methods

Dynamic Gait Index (DGI): The average of the week 1 DGI scores of three trials the participant underwent represents the response variable data, and a Linear Mixed Model (LMM) was used to estimate the mean intra-subject difference between the DGI score when the subject wore the BALCAP and the DGI score when the subject did not wear the BALCAP. The LMM random effect was a subject-specific intercept, which allowed the between test-condition comparison of the DGI scores to be a within-subject comparison, and thus eliminated the between-subject variability from the residual error that was used in hypothesis testing. A two-sided $p \leq 0.05$ decision rule was used as the null hypothesis rejection criterion.

Gait Speed: The Gait Speed data were also analyzed via a LMMs. The parametric analysis was conducted in the same manner as the DGI analyses above.

CDP Equilibrium Score: The CDP Equilibrium scores were analyzed via LMMs. The average score of the three replicate trials at weeks 1, 6, and 12 served as the outcome data. For the analysis, the CDP Equilibrium scores represented the response variable data, and a linear mixed model (LMM) was used to estimate the mean intra-subject change in the score. The LMM was specified in accordance with a two treatment by two period crossover design ANOVA model in which the two treatments were the BALCAP and Control interventions and the two periods were the week 1 to week 6 period and the week

6 to week 12 period. The LMM was specified so that the variability in the response due to the sequential order in which the participant underwent the BALCAP and Control interventions (Control→BALCAP, or BALCAP→Control) could be separated out from the variability in the response due to the test condition. To account for any disparities in pre-intervention scores, the pre-intervention scores served as a covariate adjustment variable to standardize the between-intervention and between-trial conditions comparisons to a common pre-intervention score. The LMM random effects were subject-specific and sequence-specific, which allowed the comparisons to be within-subject comparisons, and thus eliminated the between-subject variability from the residual error used in hypothesis testing. A two-sided $p \leq 0.05$ decision rule was used as the null rejection criterion.

Activities-specific Balance Confidence (ABC): The parametric analysis was conducted via an LMM that was specified in accordance with a 2 x 2 crossover design ANOVA model. The model specification was similar to the CDP Equilibrium LMM specification above, in which the sequential order of the interventions and the assessment period represented fixed effects along with the intervention condition (i.e., BALCAP and Control). As in the CDP analysis, the pre-intervention ABC scores served as a covariate adjustment variable to standardize the between-intervention comparisons of the mean pre- to post-intervention change in the ABC score to a common pre-intervention ABC score.

Dizziness Handicap Inventory (DHI): The parametric analysis was conducted via an LMM that was specified in accordance with a 2 x 2 crossover design ANOVA model. The model specification was similar to the CDP Equilibrium analysis, in which the sequential order of the interventions and the assessment period represented fixed effects along with the intervention condition (BALCAP, Control). As in the CDP parametric analyses, the pre-intervention DHI scores served as a covariate adjustment variable to standardize the between-intervention comparisons of the mean pre- to post-intervention change in the DHI score to a common pre-intervention DHI score.