The Effects of Dual Task Training on Motor and Non-Motor Function in Individuals with Parkinson's Disease

NCT02538029

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Statistical Analysis Plan

Phase 1:

Baseline participant demographics and outcome variables will be summarized by group using mean ± standard deviation for normally distributed variables, median [25th percentile, 75th percentile] for data that is not normally distributed, or N (%) (categorical data). Paired sample t-tests will be used to detect differences in cognitive scores between single and dual-task conditions. A repeated measures analysis of variance (ANOVA) model will be used to determine the effects of the different cognitive dual tasks and single-task on gait performance as measured by the spatial-temporal parameters of gait. When the ANOVA model results in significant differences in comparison from single to dual-task, a post hoc pairwise comparison will be performed to identify which tasks were significantly different from each other. The p-values in multiple comparisons will be adjusted using the Bonferroni correction. All statistical testing will be performed at the 5% level of significance.

Phase 2:

Baseline participant demographics and outcome variables will be summarized by group using mean ± standard deviation for normally distributed variables, median [25th percentile, 75th percentile] for data that is not normally distributed, or N (%) (categorical data). The intervention effects on outcomes will be assessed using separate linear mixed effects models, each including a random intercept, main effects for group, time, and a group-by-time interaction term. Given a significant group by time interaction, post hoc pairwise comparisons will be performed between groups at each follow-up. In the absence of a group-by-time interaction, the overall change across collapsed groups between each evaluation will be estimated (i.e., change from Baseline to End of Treatment and Baseline to End of Treatment + 4 weeks). All comparisons will be performed at the 0.05 significance level. Within each outcome, pairwise comparisons will be Bonferroni corrected to maintain a 5% type I error rate per outcome.