Augmenting Gait in a Population Exhibiting Foot Drop With Adaptive Functional Electrical Stimulation

NCT05346640

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Statistical Analysis Plan

In this analysis, we plan to investigate whether the impact of FES on gait is statistically significant relative to unstimulated gait by pairwise comparison (single sample, pre-test post-test).

Power Analysis

An *a priori* power analysis was used to determine that we require eighteen or more participants to achieve 80% power to reject the null hypothesis, which states there is no difference between pre-test (noFES) and post-test (FES) conditions in a pairwise comparison with a significance level (alpha) of 0.05. An effect size of 0.7 was used for the power analysis based on a previous study of FES impact on post-stroke participants[1].

Reported Outcomes

For each metric of interest, we will take the average of each participant's metric values across steps for both noFES and FES walking. We will also report the 95% confidence interval for the differences between FES and noFES outcome metrics.

Tests of Statistical Significance

The Shapiro-Wilk test for normality will be used to assess the assumption of normality. If the outcome variable is approximately normally distributed, a paired t-test will be used to statistically compare noFES and FES outcome metrics. If the normality assumption is not met, the Wilcoxon signed rank test will be used as an alternative to the paired t-test for this statistical comparison. Bonferroni multiple hypothesis correction will be utilized (four outcome metrics), and our corrected significance level for comparison is 0.0125 (0.05 divided by the four hypotheses tested).

[1] N. Kapadia, B. Moineau, and M. R. Popovic, "Functional Electrical Stimulation Therapy for Retraining Reaching and Grasping After Spinal Cord Injury and Stroke," *Front. Neurosci.*, vol. 14, p. 718, Jul. 2020, doi: 10.3389/fnins.2020.00718.