Official Title of the study: ADDRESS: Activity Dependent Rehabilitation via Transcutaneous Electrical Spinal Stimulation to Restore Upper Extremity Functions in Spinal Cord Injury
NCT number: NCT03184792
Date of the document: February 22, 2022

Statistical Analysis Plan:

For comparison of the functional changes occurring during each intervention phase, one-way repeated measures ANOVA will be used with post-hoc pairwise analysis as per Tukey LSD test (IBM SPSS version 26). A Shapiro-Wilk Test will be used to determine whether repeated measurements follow a normal distribution. Mauchly's test will be used to analyze the assumption of sphericity, and degrees of freedom will be corrected using Greenhouse-Geisser estimates of sphericity when the assumption is violated. We will directly compare the benefits of training alone and stimulation combined with training by calculating the cumulative changes in each outcome measure across the two intervention arms. These values will be normalized to baseline to control for individual variation in function at the beginning of the study and compared between the training and stimulation + training interventions using a paired-samples T-test.

Additionally, score changes relative to the preceding treatment block will be calculated to compare the improvement rates between intervention phases repeated monthly.
For all tests, $p < 0.05$ will be considered significant. All participants' data will be included in all analyses. Given the early stage of research and the lack of prior data on transcutaneous spinal cord stimulation for restoring upper limb function, power analysis and sample size calculations are not feasible.