Medical University of South Carolina
Statistical Analysis Plan

PI Name: Michelle Woodbury, PhD, OTR/L

Study Title: Patient-Targeted Upper Extremity Rehabilitation After Stroke

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Statistical Analysis Plan

Aim 1: To test the effect of patient-specific targeted practice. <u>Rationale:</u> We hypothesize that task practice at the just-right challenge of difficulty will maximize post-stroke motor skill reacquisition. We expect that "targeted practice", will increase UE motor ability because the difficulty of task goals will be matched and systematically progressed according to patients' initial and evolving levels of ability. The Rasch UE motor ability measurement framework defines levels of UE motor ability by describing UE movement tasks (FMA-UE items) which patients in each level can easily perform, cannot perform (too hard), and are well-matched to ability level. This information is the basis for designing and progressing task-practice sessions to specifically target patient-specific movement abilities.

<u>Approach:</u> Dependent Variable: The dependent variable will be the Rasch FMA-UE person measure. Independent Variables: The independent variables are Group and Time. The between subjects factor "Treatment" has 2 levels (Targeted vs. Non-Targeted therapy) with 3 impairment levels nested within each level (mild, moderate, severe). The within subjects factor "Time" has 3 levels; Pre, Mid, Post. Data Analysis: A two-way mixed model ANOVA will be used to assess the main effect of Treatment. Significance for all comparisons will be alpha = 0.05. Covariate: intensity of training (averaged number of repetitions per session).

<u>Missing Data:</u> Since each patient will be observed over a 3-week period it is possible that the patient will miss a visit and/or drop out. If a patient misses a testing session, the session will be rescheduled to the next visit. If the patient drops out an intent-to-treat analysis will be applied and the missing data will be treated as missing at random (MAR). If missing occurs, multiple imputation methods will be used for data analysis (PROC MI and PROC MIANALYZE, in SAS version 9.3). This process will be overseen by the biostatistician Dr. Ramakrishnan.