

Statistical Analysis Plan

Official Title: Strategy Training for People with Aphasia After Stroke

ClinicalTrials.gov ID (NCT number): NCT03593876

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Statistical Analysis Plan

As this is a small descriptive case series study minimal statistical analyses are planned.

To assess feasibility, we will calculate descriptive statistics (means and standard deviations) of the Measure of Participation in Conversation Interaction Score. We established a priori that a mean of 2 or greater would indicate feasibility (Kagan et al., 2004).

To assess change in disability, we will calculate descriptive statistics (means and standard deviations) of Functional Independence Measure change scores between study baseline and at inpatient rehabilitation discharge. We will also calculate Cohen's d_{rm} effect sizes using the repeated measures method described by Lakens (Lakens, 2013). We established a priori that a Cohen's d_{rm} effect size of 0.5 or greater would indicate feasibility and would warrant further investigation in a larger trial. A moderate effect size of 0.5 would be smaller than the effect sizes seen in a previous strategy training trial ($d=1.06$) (Skidmore et al., 2015) but would still suggest meaningful improvement in outcomes. We will compare mean change scores and Cohen's d_{rm} effect sizes of change with data from previously published clinical trials to assess whether people with aphasia make similar changes with strategy training.