Statistical Analysis Plan

Study Title:

A Randomized Controlled Trial of Cognitive Control Training for Urgency in a Naturalistic Clinical Setting

Date: 2/19/2021

NCT#: NCT03527550

The statistical analysis plan for primary outcome measures is as follows:

1. Change in Average Score on Negative Urgency Scale:

A 2 (condition: TAU, TAU + cognitive training) x 2 (time) repeated-measures Analysis of Variance (ANOVA) will be used to test change in negative urgency at time 1 (admission) and time 2 (discharge), and whether participants differ in their average change in negative urgency as a function of condition (interaction of condition X time).

2. Change in Average Score on Positive Urgency Scale:

A 2 (condition: TAU, TAU + cognitive training) x 2 (time) repeated-measures Analysis of Variance (ANOVA) will be used to test change in positive urgency at time 1 (admission) and time 2 (discharge), and whether participants differ in their average change in positive urgency as a function of condition (interaction of condition X time).

Statistical Analysis Plan for Secondary Outcome Measures:

1. Change in Estimated Stop-Signal Reaction Time (SSRT) on Stop-Signal Task (ms):

A 2 (condition: TAU, TAU + cognitive training) x 2 (time) repeated-measures Analysis of Variance (ANOVA) will be used to test change in SSRT at time 1 (admission) and time 2 (discharge), and whether participants differ in their average change in SSRT as a function of condition (interaction of condition X time).

2. Feasibility of assessing change in event-related potentials (ERPs) during a Stop-Signal Task in a partial hospital population:

This will be tested using descriptive statistics assessing the percentage of participants who are able to complete and provide ERP data for the stop-signal task.

3. Completion Rates:

This will be tested using descriptive statistics assessing the percentage of enrolled participants who complete the training intervention and the discharge session. This will be compared to an a priori benchmark of a 75% completion rate, based on previous studies.

4. Average Perceived Helpfulness of Training

This will be tested using descriptive statistics assessing the average rating of overall perceived helpfulness of the intervention, as rated by participants using a self-report form at the discharge session. This average rating will be compared to an a priori benchmark of an average rating of 4.0 or greater for each of the two training tasks (PASAT and Go/NoGo).