Executive Function Training Intervention for Chronic Traumatic Brain Injury

October 8, 2018

1 Data and Statistical Analysis Plan

1.1 Power Analysis

We performed a sample size analysis to determine the appropriate number of subjects to enroll in order to assure that we would achieve adequate statistical power. For an alpha level of .05, and an anticipated effect of 0.5 (medium), and a power of .8, we need a total of 102 (50 in each rehabilitation group) for a one-tailed (Strategic Advantage > Informational Advantage) directional hypothesis. Based on these analyses we plan to enroll 100 participants. These individuals will be randomized into the two intervention arms.

1.2 Statistics for Primary Outcome Measures

Virtual Multiple Errands Test (VMET): We will evaluate intervention efficacy by comparing the performance of the VR-EFT group to that of the VR-BHT group on performance-based measures of executive function ability related to daily life. This first test will evaluate near-transfer of intervention skills to the VMET, a test of executive functions evaluated in a computerized format. VMET requires working memory, planning, coordinating, and prioritizing, thus is serves as a global, performance-based measure of executive function. We will evaluate change on total number of errors from the pre-intervention baseline using a 2 (group) x 2 (testing session) repeated-measures ANOVA followed by Bonferroni-correct post-hoc tests to evaluate the significance of simple mean comparisons. We predict a significant time-by-group interaction in which the VR-EFT group will perform more accurately relative to the VR-BHT group at the post-intervention test, but not at the pre-intervention test. In the event that this measure proves insensitive, we will compute and analyze sub-scores based on strategy errors, completion errors, and rule-violation errors applying an additional Bonferroni multiple comparison correction for the use of three sub-measures.

TBI Awareness Questionnaire: We will evaluate far-transfer to overall Awareness score, which is a reflection of actions carried out in a real life setting. Performance (averaged over sub-domains) will be evaluated using a 2 (group) x 2 (testing session) repeated-measures ANOVA, followed by post-hoc tests corrected for multiple comparisons. We predict a time-by-group interaction with superior life outcomes reported by the Strategic Advantage group over the Informational Advantage group at the post-intervention time point only with no reliable differences expected at the pre-intervention phase.

1.3 Secondary Outcome Measures

In addition to evaluation of near and far transfer of executive function training skills, we will evaluate a series of subcomponents that are expected to be actively improved by the intervention.

1.3.1 Performance on Neuropsychological Tests

The neuropsychological tests will be evaluated according to the procedures outlined for the use of the ANAM and the relevant scoring procedures for each additional test in the planned battery. These scores will be organized by primary domain and analyzed using 2 (group) x 2 (testing session) ANOVAs. The domains of interest for the neuropsychological battery are as follows: working memory, goal maintenance, verbal fluency and general cognition. These same groupings will be applied to the ANAM data as well with the exception of verbal fluency, as this domain is not examined in our ANAM battery.

Analysis of Game Performance Data Acquired During Intervention

Data from the Strategic Advantage and Informational Advantage weekly modules will be analyzed by total number of task errors and by completion times for each task in order to determine the degree of individual improvement on tasks from Day 1 to Day 5 during each of the four weeks. For the long term memory module we will also analyze total recall scores across the week. We will apply this same analysis to the overall recall scores obtained in Week 4 during the composite game-based simulation.