Protocol NX-31380

Cover Sheet

Official Title: Boost Study 31380 (mHealth)

ClinicalTrials.gov ID (NCT number): NCT05757453

Document Date: March 30, 2022

Document Description: Statistical Analysis Plan

1. Study Design and Power

A targeted enrollment of 30 patients is projected as adequate to evaluate the primary endpoint of technical feasibility. Given expected drop-off (up to 66%), a requirement for 30 patients enrolling will lead to expected completion yielding an opportunity to demonstrate both statistical and clinical significance of null hypothesis rejection, with an estimated 10 to 15 patients completing the study.

Based upon a review of published reports of neurostimulation interventions for cognitive dysfunction, a power analysis (observed power > 0.8 at an alpha level of .05) indicates that a sample of 8 participants is sufficient to show a cognitive treatment effect outcomes; such that with large drop-off in the sample, we estimate retained power to measure a medium-large effect size (>0.2).

Participants who disenroll during the study period are not expected to specifically be replaced by any procedure other than ongoing recruitment in rolling fashion, until the end of the recruitment period.

2. Analysis Methodology

Upon completion of the study, a comprehensive analysis will include pre-specified analyses:

A. Technical Feasibility, or Task Completion, is the primary endpoint and will be evaluated as median reported platform interactions, evaluated at the close of week 8, including range and optional summary statistical measures which may inform distribution or skew of results.

B. Intervention Usability Rating is a secondary endpoint and will be calculated as whole-number median and range at week 8 of participation, for all subjects. Summary statistical measures will be reported if robustness checks are qualified.

C. Treatment Progress Measure as assessed by TEA score is a secondary endpoint and will be calculated as whole-number median and range at the close of week 8 of participation (with optional collection without required reporting of scores weekly), for all subjects. Summary statistical measures will be reported if robustness checks are qualified.

D. Recordation and qualitative assessment of adverse events and actions taken by the investigators in response to AEs or SAEs, per IRB requirements.

3. Archival

This study is to be performed in full compliance with the protocol and applicable oversight body and regulatory requirements. All required study documentation and data records will be archived in accordance with preauthorized policies and procedures.

Paper-based and electronic documentation and records will be stored and archived in a secure format for at least 2 years and for the duration required by the Sponsor and collaborating study site.