

Statistical Analysis Plan

Community-based *Brain Health Program* to Address Dementia Risk (C-BBHP)

Protocol Number: PSC-0318-22

NCT05529706

Document Date: June 16, 2023

The trial is a single arm open label usability/feasibility study, enrolling older adults with AD risk factors in a public health, community-deployed, group-based and individualized multimodal Brain Health Program (targeting, among other domains, diet, exercise and cognitive exercise), with a set of baseline assessments intended to characterize the population, and outcome measures intended to evaluate the usability/feasibility of the program, as well as preliminary efficacy to reduce dementia risk factors. The primary outcome measure is the Net Promoter Score (NPS); all other measures are secondary outcomes.

Number of participants: n=80, comprised of 4 groups of 20 participants each. Because this is a usability/feasibility pilot study, sample size is not determined from statistical tests of outcome measures. Sample size justification is based on a balance of having a sufficient number of participants to ensure diversity of participant experience against having a number that exceeds the ability of a user-experience designer to effectively debrief participants and synthesize their diverse experiences into actionable guidance for a next round of product improvements. In our experience, usability/feasibility trials are most effective with at least 6 and no more than 20 participants, for a total for n-size for the project at n=80.

Baseline Characterization Measures

Demographics Survey

- Age
- Gender
- Education

Screening

- *Inclusion and Exclusion Criteria*
- *Cognitive Abilities Assessment*
 - The Cognitive Abilities Screening Instrument-Short (CASI-Short) will be used to assess cognitive abilities and identify severity of dementia in individuals. This assessment is a 4-item measure which includes repeating three words, temporal orientation, generating animal names, and recalling three words that do not involve reading, writing, drawing, or arithmetic, which is particularly suitable for individuals with little or no formal education.

Outcome Measures

Primary Outcome

The Satisfaction Measure:

- Net Promoter Score (NPS): NPS is a single question – “How likely is it that you would recommend this product to a friend or colleague?” – on a scale of 0-10. NPS score is calculated by subtracting the fraction of detractors (rating 0-6) from

the fraction of recommenders (rating 9-10). NPS is a commonly employed measure in commercial enterprises, and has generally been associated with customer satisfaction, word- of-mouth marketing, and business growth. Net promoter score of >20 would lead us to conclude that the usability/feasibility study had been successful.

Secondary Outcomes

Feasibility and Acceptability Measures:

- Program Completion Rate: Percentage of participants who attended 80% of intended sessions.

Usability Measures:

- Quantitative program-specific questionnaire with Likert scales on questions
 - Understanding of the program
 - Relevancy of the program
 - Program satisfaction