Modulation Effects of a Computer-based Multimodal Mind and Body Approach for Mild Cognitive Decline

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Biostatistical analysis plan

The intention-to-treat (ITT) population included all randomized participants who received at least one session of the assigned intervention and was used for all feasibility, exploratory efficacy, and safety analyses. The per-protocol (PP) and safety populations were identical to the ITT set, as all participants initiated the intervention and were monitored for adverse events throughout the study.

Consistent with NIH recommendations for feasibility studies, we will report the following feasibility outcomes: 1) recruitment: proportion of participants that are enrolled from the total number of patients screened; 2) retention: proportion of subjects who complete all assessments from the total number of subjects who received one intervention session; 3) fidelity: the proportion of completed/planned intervention sessions (cbMMBA or cbCFP control); 4) satisfaction: proportion of participants having therapy satisfaction scores above the midpoint; and 5) safety: symptoms and adverse events reported by the participants.

For exploratory analysis of secondary cognitive and clinical outcomes, we will: explore the effects of the cbMMBA and cbCFP using mixed-model regression. The regression model will include subject as a random effect; fixed effects will include treatment group, treatment time point (baseline, 6 weeks, 12 weeks, and 24 weeks), and their interaction. Covariates such as age, gender, and ERS scores will also be included in the model to reduce subject heterogeneity.