Sleep-SMART for Veterans with MCI and Insomnia: A Pilot Study

Statistical Analysis Plan

NCT05016960

July 21, 2021

Data Analytic Plan

General data considerations: Our goal is to collect important data regarding the development of the new integrated Sleep-SMART intervention as well as test the feasibility, adherence, and acceptability of the treatment and its measurements for future large-scale clinical trials. We will analyze data for participants who provide outcome data, regardless of their compliance with treatment; and as described above, reasons for dropout will be studied to help identify potential factors that may need to be addressed in future iterations of the intervention. We would like to emphasize that although we will estimate effect sizes to assist in future power calculations, this is not our major focus. Studies have identified important limitations of hypotheses testing and sample size estimation using pilot feasibility studies due to the large standard error surrounding the pilot study effect size. As a result, we will focus our analyses on a feasibility of conducting a larger study and report our findings with this limitation in mind.

Qualitative data: Interview and focus group data will be independently coded by two project team members using a rapid qualitative analytic approach described by Hamilton and colleagues[70]. A third team member will assess coding quality and resolve conflicts. Using a mixed-methods convergent design approach, the qualitative data will be used to explain and support/refute the quantitative data and to inform treatment refinement as well as future implementation efforts.

Quantitative data: Descriptive statistics will be obtained for all quantitative variables, including distributions, means, medians, variances, standard deviations, skewness, kurtosis, ranges, and quartiles. We will calculate estimated effect sizes to assist in future power calculations and explore changes from baselines to end of the study for sleep (PSQI, ISI, sleep efficiency), rehabilitation outcomes (WHODAS 2.0), quality of life, and subjective and objective cognitive functioning, in the context of a 95% confidence interval according to procedures described by Cohen (1988). Due to our small sample size our statistical analytical finding would be interpreted with caution. SPSS Version 27 will be used for all quantitative analyses.

Power and sample size: Due to feasibility nature of this pilot study and small sample size we will not be testing the efficacy of the intervention. We are confident that the proposed sample size will provide us with sufficient number of subjects to evaluate these feasibility and acceptability outcomes.