

Cognitive Behavioral Therapy to  
Increase CPAP Adherence in Veterans  
with PTSD

Statistical Analysis Plan

NCT02641496

October 6, 2023

## DATA ANALYTIC PLAN

**Hypothesis 1. (Primary Outcome) Effect of CBT on CPAP usage.** We hypothesize that the CBT-OSA group will use CPAP more hours per night on average than the Education group. An ANOVA will be used to compare performance on the primary measure (CPAP mask-on time, a continuous variable) by Group (CBT-OSA versus Education group) at the end of the 1-year RCT (Day 365) adjusting for baseline CPAP mask-on time values. The analyses will be an intention to treat design in which drop-outs after the baseline evaluation will not be replaced. Their last CPAP mask-on time score will be considered their final score. Potential covariates (e.g., AHI prior to treatment, daytime sleepiness) will be considered in the analysis. In a RCT, we assume that the groups will be apportioned relatively equally on relevant background variables such as age, but we will verify this by presenting descriptive statistics on such variables. We do not propose to enter all possible background variables as covariates into this analysis.

**Hypothesis 2-4. (Secondary Outcomes) Effect of CBT on Self-reported Everyday Activities, Mood and Quality of Life, Cognitive Outcomes and PTSD.** Secondary analyses will be conducted to compare performance between groups at Day 365 on relevant measures listed in Table 4 using the same statistical approach as Hypothesis 1.

**Hypothesis 2. Effect of CBT on Self-reported Everyday Activities, Mood and Quality of Life.** We hypothesize that after initiating CPAP treatment, Veterans in the CBT-OSA group will report more improvement in the ease of performing everyday activities compared to that reported by those in the Education group. An ANOVA will be used to compare performance on the FOSQ Total Score (continuous variable) by Group at Day 365. Potential covariates: sleep efficiency.

**Hypothesis 3. Effect of CBT on Cognitive Outcomes.** We hypothesize that the CBT-OSA group will have better cognitive outcomes than the Education group over time. An ANOVA will be used to compare performance on CVLT-II Delayed Recall Score (continuous variable) by Group at Day 365. Potential covariates: education.

**Hypothesis 4. Effect of CBT on PTSD.** We hypothesize that the CBT-OSA group will have fewer PTSD symptoms than the Education group over time. An ANOVA will be used to compare the PCL-5 Total Score (continuous variable) by Group at Day 365. Potential covariates: type of trauma, PTSD treatment, gender.

**Other Secondary Analyses.** Other secondary analyses will also examine Group effects at the cessation of the 4-week treatment (Day 21). Complementary analyses will be conducted using all available time points with mixed modeling and regression techniques, however, after extensive discussion with our statistical advisors, we felt that the easily interpretable ANOVA approach should be the primary statistical approach for this RCT.