

**Cover Page**

Official Title: Morning Light Treatment at Home to Reduce PTSD Symptoms

Document Type: Study Protocol with Statistical Analysis Plan (SAP)

Document Date: 04/19/2018

NCT Number: NCT03513848

## **Study Protocol**

The study will take 36 days and consist of the following:

WEEK 1 (Days 1-7):

- A home sleep section with a wrist monitor that records motion and light.
- Daily logs of activities, sleep, nightmares, and medications.

WEEKS 2 – 6 (Days 8-36):

- Daily logs of activities, sleep, nightmares. and medications
- A home sleep section with a daily morning light treatment the participant self-administers using the Re-timer light device. Participant is randomized (assigned by chance) to a placebo (inactive) Re-timer or active Re-timer. Participant continues to wear the wrist monitor that records motion and light.
- Weekly lab visits to complete questionnaires on days 8, 15, 22, 29, and 36. During these visits, participants are breathalyzed and we review the data from daily logs and wrist monitor. We will also review if participants followed the light treatment schedule.

During the home sleep sections of the study, you will sleep at your usual sleep times and fill out a few daily questionnaires.

The lab visits will consist of setting up or downloading data from the wrist monitor, completing questionnaires on a computer, and training sessions on how to best use the Re-timer light device for light therapy every morning.

## **Statistical Analysis Plan**

- We will conduct a t-test to evaluate difference in PTSD symptom changes from pre- to post-treatment between the active and placebo group. We will calculate the effect size of the difference between the groups.
- We will conduct a t-test to evaluate difference in depression symptom changes from pre- to post-treatment between the active and placebo group. We will calculate the effect size of the difference between the groups.
- We will evaluate actigraphy data to provide descriptive information regarding treatment compliance.