Bright Light Treatment At Home To Manage Chronic Pain In U.S. Veterans

NCT02373189

Document Date: 12/23/22

Data Analysis

Aim 1. To determine the feasibility and acceptability of bright light treatment in a sample of US veterans (n=30) experiencing chronic low back pain. For Aim 1 we will track the number of US veterans who express interest in the study, the number that meet our inclusion criteria, the number that enroll, the number of mornings that bright light is self-administered and the duration of the exposure, and we will collect treatment expectancy and treatment satisfaction ratings. Hypothesis 1: We expect reasonable feasibility in that (i) we will be able to enroll 2 US veterans per month, (ii) ≥75% of those enrolled self-administer at least 30 mins of morning bright light on at least 50% of treatment days (this light should still be somewhat effective, as per winter depression studies [125, 126, 131]). Research Strategy Page 54 Contact PD/PI: Burgess, Helen, Julia Hypothesis 2: We expect reasonable acceptability in that (i) at least 1 in 4 US veterans who are eligible for the study agree to participate, (ii) average expectancy rating at start of bright light treatment is ≥6/10, (iii) the attrition rate is ≤ 30%, and (iv) average treatment satisfaction at end of bright light treatment is ≥6/10. Aim 2. To examine the effects of 6 days and 13 days of bright light treatment on chronic pain intensity and sensitivity in US veterans (improved PTSD symptoms, mood and sleep are secondary outcomes).

For Aim 2 we will plot daily diary ratings of pain intensity expressed as percentage change from baseline pain intensity (mean intensity over the 7 days of baseline). The point where the mean change for the whole sample achieves 30% ("moderately clinically meaningful effect" p.239, [137]) will reveal a potential candidate for an optimal treatment dose. We will also examine pain sensitivity (ischemia, heat) changes over the 4 lab visits. Hypothesis 3: We expect (i) a ≥30% reduction in pain intensity ratings and (ii) a ≥30% reduction in pain sensitivity (ischemia and thermal pain) by the 13th day of morning bright light treatment. As a preliminary analysis, we will examine these data with a within-subjects ANOVA to determine: a) effect size of change over 13 days of treatment; b) statistical significance of this change; c) whether there is significant non-linearity indicating that response to treatment reached a plateau. In an effort to understand a plateau effect, we will use a piecewise linear mixed model with a fixed change point occurring at the 30% change level. Random effects for time before the change point and time after change point will be included in the model. We will use graphical analyses to investigate violations of the model assumption. Secondary analyses for daily ratings of mood and sleep will be conducted similarly. For additional secondary analyses involving PTSD, depressive and anxiety symptoms, and sleep questionnaires, we will subject data to withinsubjects ANOVAs to determine: a) effect sizes of changes over 13 days of treatment; b) statistical significance of these changes; c) whether there is significant non-linearity indicating that treatment response plateaued.

Aim 3. To determine time course of decay of treatment response (decreased pain intensity) after cessation of light treatment. For Aim 3, we will plot daily diary ratings of pain intensity expressed as percentage change from the mean of pain ratings over the last 3 days of bright light treatment. The point where the mean change for the whole sample achieves 20% (less than a "moderate" decrease [137]) will reveal a potential candidate time for a maintenance dose of bright light. Second, we will subject these data to a within-subjects ANOVA to determine: a) effect size of erosion over 4 weeks of follow-up; b) statistical significance of this change. A change point modeling strategy similar to Aim 2 will be used here, but the change point will be set at a 20% level rather than a 30% level. Secondary analyses involving daily diary ratings of sleep and mood will be conducted as described above. Hypothesis 1: A mean increase of 20% in pain ratings is expected to occur within the first week post treatment (as per winter depression studies [125, 126, 131]). Hypothesis 2: Pain intensity is expected to return to baseline by 1 month post treatment (as per winter depression studies [125, 126, 131]).

We will also examine effects of other factors on treatment response. We will determine whether analyses must be adjusted for confounding factors including but not limited to age, BMI, race/ethnicity, employment, physical workload, any comorbidity (including depression and anxiety), history of traumatic brain injury, time from onset of chronic pain, current psychotropic and analgesic medications, and other treatments being received for chronic pain and/or PTSD. These analyses may involve treating these factors as time-varying covariates. We will also determine whether key factors moderate treatment response. We plan to test whether men or women

and those with low vs. high psychiatric symptoms (e.g., PTSD) show evidence of differential treatment response. These analyses will involve testing Sex or Psychiatric Symptom x Time interactions on pain intensity during and following treatment. In other exploratory analyses we will examine the correlations between change in DLMO and DLMO to midpoint of sleep interval and change in pain, mood and sleep.