Individually Tailored Lighting System to Improve Sleep in Older Adults

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Statistical Analysis

We will determine whether the lighting treatments significantly affect the primary outcomes, the nighttime sleep measures (minutes of sleep, sleep onset latency, sleep efficiency, and circadian rhythmicity from actigraphy data; PSQI score; MALSQ score) and safety measures, as well as the secondary endpoints. The primary analytic strategy for the efficacy analyses will employ linear mixed models with measures from the actigraph data (a fourteen-day baseline, plus two seven-day intervention data collection periods for each treatment condition) or one of the survey sleep measures (two observations per treatment condition) as the dependent variable, a random effect for study participant, and a fixed effect for treatment (i.e. a dummy variable for the experimental condition, with the control condition as the reference category). These analyses allow for different numbers of observations for different participants. As part of data cleaning prior to analysis, actigraph data recorded while the monitor is not worn will be identified and removed from the analyses. This will include periods identified as such in the subjects' sleep logs, in addition to actigraphy data in which no activity is present for more than 30 consecutive minutes, and days that contain more than 10% of missing data, and data sets with fewer than 2 days of valid data. The balanced assignment of the two intervention sequences is designed to minimize any adverse impact with respect to period and carryover effects, as is use of a washout period in the experimental design. However, we can explicitly test for a period effect by including a dummy variable in the linear mixed model (with period one as the reference). We will also adjust for covariates that may be may be found to be associated with night-time sleep, such as gender, age, cognitive status, functional status, baseline sleep disturbance and sedative medication load; however, because of the crossover

nature of the study, in which participants serve as their own controls, it is not expected that covariate adjustment will markedly alter estimates of treatment effect.