Statistical Analysis Plan Cover Page

Official Title of the study: A Pilot Chronotherapeutic Intervention to Improve Sleep Following Acute Coronary Syndrome: The SleepWell Study

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Statistical Design and Power

Below we outline the statistical approach we will use to investigate the specific aims and associated hypotheses for this pilot study.

Primary Aim: *Determine the feasibility of administering the combined chronotherapy (CC) intervention in individuals who experiences acute coronary syndrome (ACS). We will assess a) feasibility, b) acceptability, c) appropriateness, d) usability, and e) adherence of the 4-week CC intervention in ACS survivors with poor sleep.*

Aim 1 will be tested by assessing the following measures:

(1) proportion of participants who complete the outcome assessments at study conclusion;

(2) proportion of participants who report scores ≥4 for their final rating of the intervention's feasibility;

(3) proportion of participants who report scores ≥4 for their final rating of the intervention's acceptability;

(4) proportion of participants who report scores ≥4 for their final rating of the intervention's appropriateness for improving sleep;

(5) proportion of participants who report total scores ≥68 for their final rating of the intervention's usability.

(6) proportion of who report administering the intervention (i.e., morning BLT and evening BLB) on ≥50% (and ≥75%) of the days throughout the 4-wk treatment period.

Statistical approach for Primary Aim. In addition to computing the proportions listed above, we will conduct secondary analyses regarding measures 2, 3, and 4 (feasibility, acceptability, appropriateness) as follows. First, the final assessment for each scale (feasibility, acceptability, and appropriateness) will be identified for each participant (i.e., at study conclusion for participants) to compute a mean for each of the three scales. Second, the mean across participants will be computed for each scale (feasibility, acceptability, and appropriateness). A one-tailed t-test will be conducted comparing the mean for each scale against the comparison value of each 5-point scale's midpoint of 3.

Secondary Aim 1: Determine whether the CC intervention engages its target mechanism: sleep. *We will assess insomnia, sleep quality, and sleep duration at baseline and at the end of the 4-week intervention period, and will evaluate whether the CC intervention leads to greater changes in sleep-related outcomes relative to the control condition.*

Secondary Aim 1 will be tested by assessing the following measures:

(1) Baseline-to-study conclusion change in insomnia severity (measured as the within-person difference in the total score of Insomnia Severity Index);

(2) Baseline-to-study conclusion change in global sleep quality severity (measured as the within-person difference in the total score of Pittsburgh Sleep Quality Index [PSQI]);

(3) Baseline-to-study conclusion change in sleep duration (measured as the within-person difference in the sleep duration subscale of the PSQI);

Statistical approach for Secondary Aim 1. We will test this aim by evaluating the change scores in measures listed above. We hypothesize that the pattern of means will reveal a reduction in insomnia symptom severity, an improvement in global sleep quality, and an increase in self-reported sleep duration in the CC intervention group. As mentioned above, this Phase-I trial is not powered to test the significance of these sleep-related changes.

General Approach. For descriptive statistics, categorical data will be presented as percentages and continuous data will be presented as means with standard deviations for normally distributed measures and as median with interquartile range for measures that are not normally distributed. Checks of assumptions (e.g., normality) underlying statistical procedures will be performed and corrective procedures will be applied (e.g., log transformation or nonparametric tests).