Exploring the Impact of a Sleep App on Sleep Quality: a Randomised Controlled Pilot Study

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Sleep App Study Analysis

Baseline characteristics: will be summarised overall and by randomised group using descriptive statistics.

Feasibility measures: Feasibility and acceptability are the primary focus. Follow-up rates at 1, 2 and 3 months will be reported overall and by randomised group. Engagement with the intervention, measured using the DBCI Engagement Scale weekly, will be summarised for the intervention group to show change in engagement score over time and overall engagement score.

Efficacy outcomes: Insomnia Severity Index (ISI) by group will be plotted. Between-group change in the mean ISI at postintervention will be the primary outcome. Analyses will be performed in SPSS, version 25 (IBM Corporation). Between-group contrasts in outcomes across the intervention period will be tested using generalized linear mixed modelling (MIXED command with full information maximum likelihood estimation to allow for analysis of participants with missing data) with pairwise comparisons, adjusted for preintervention levels of the outcome. Estimated mean differences and effect sizes (Cohen d with Hedges bias correction for small sample size) with their 95% CIs will be provided. We will assess whether data provides evidence of a benefit of using the sleep app vs not using it (control) on the ISI and on secondary outcomes from the core Consensus Sleep Diary, such as wake after sleep onset (WASO), sleep latency, sleep duration and method of awakening. Baseline ISIs between those with vs without missing data at postintervention will be compared using t tests. All analyses will be conducted under intention-to-treat principles. These analyses are exploratory, but effect sizes will be reported in line with Consolidated Standards of Reporting Trials guidelines for reporting feasibility and pilot studies (http://www.bmj.com/content/355/bmj.i5239).

As a further secondary analysis, the level of engagement with the app in the intervention group will be included as a covariate to assess whether average engagement level with the app had an effect on sleep outcomes over time for both the ISI and the Consensus Sleep Diary.

Though the Oura ring follow-up could not be completed we will look at agreement between Oura ring measurements on bedtime, sleep latency, WASO, final awakening and sleep duration at baseline with the corresponding baseline sleep diary using the Bland-Altman method.

Qualitative interviews: Formal analyses will be conducted using Framework analysis at a later date. For the primary paper, top line themes will be summarised, and the full qualitative analysis will be the subject of a future paper.