abstract presents data from a decentralized, open-label, single-arm real-world clinical trial of the Somryst prescription digital therapeutic for insomnia, which provides insight on who seeks care for insomnia using virtual research methods.

Methods: In alignment with FDA guidance, the DREAM trial began enrolling patients in March, 2020 with an expected final sample size of 350 adults (Clinical Trial # NCT04325464). This abstract presents data from participants seeking enrollment into the trial via an online screening. Demographic and sleep variables were collected to confirm eligibility.

Results: Of 1,063 respondents, the majority were female (62%) and the most common age brackets were ages 30–39 (22%); 40–49 (20%); and 50–59 (20%). Most respondents (63.8%) did not report being under the care of a healthcare provider for their insomnia. Respondents reported sleep problems for an average of 12.9 years; sleep problems 5 nights/week; and sleeping an average of 5.4 hours/night. Geographic diversity was high with respondents from 45 states and Washington DC. Of those passing initial screening (N=270), 5.5% reported having another diagnosed sleep disorder, 14.4% reported a comorbid psychological condition, 58.9% reported taking a medication for insomnia, and 30.7% reported taking a medication for depression. Using the Insomnia Severity Index, 16.7% had subthreshold/mild insomnia (score 8–14), 60.0% had moderate insomnia (score 15–21), and 23.7% had severe insomnia (score > 21).

Conclusion: Respondents to this decentralized trial reported moderate-severe, long-lasting insomnia with high rates of medication use for sleep and depression. Results demonstrate that virtual trials can quickly draw a highly geographically diverse research population, overcoming logistical challenges inherent in a pandemic and resulting in recruiting appropriate, but more geographically diverse, samples than those typically observed in randomized trials of cognitive behavioral therapy for insomnia (CBT-I).

Support (if any):

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INSUFFICIENT SLEEP AND MORTALITY AMONG PERSONS WHO INJECT DRUGS (PWID)

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Introduction: Insufficient sleep is associated with all-cause mortality in the general population. Illicit drugs have pronounced effects upon sleep, and insomnia symptoms are common among people with HIV (PWH), suggesting persons who inject drugs (PWID) with HIV may be at higher risk of adverse outcomes from insufficient sleep.

Methods: Participants in the AIDS Linked to the IntraVenous Experience (ALIVE) study, a cohort of PWID with or without HIV, completed the Sleep Adequacy subscale of the Medical Outcomes Study (MOS) semi-annually from 2005-present. Two questions queried participants about the frequency over the past four-weeks of: 1. getting sufficient sleep to feel rested on awakening; 2. obtaining needed amount of sleep. Six-Item responses ranged from "all of the time" to "none of the time". Participants with mean subscale scores below the sample median were considered to have insufficient sleep. Mortality data were obtained through the National Death Index through 2018. Hazards of all-cause and cause-specific mortality were evaluated using Cox-regressions accounting for repeated measurements of insufficient sleep, respectively. Models were adjusted for sociodemographics, HIV and HCV infection, severe depressive symptoms (Center for Epidemiological Studies Depression [CESD]≥23), number of comorbidities (0, 1, ≥2), active injection drug use, current tobacco and alcohol use.

Results: Of 2612 participants (33% HIV+), mean age at baseline was 45.8 years, 32.4% were female, 75% Black, 45% had ≥high school education, and 33% had an annual income >$5,000. At baseline, the majority were current smokers (84%), alcohol drinkers (59%), or actively injecting drugs (56%), while 25% had severe depressive symptoms and 21% had ≥2 comorbidities. After adjustment for covariates, insufficient sleep was associated with a 37% increased hazard of all-cause mortality (HR: 1.37, 95% confidence interval [CI]: 1.13–1.65). Insufficient sleep was associated with a 93% increased hazard of death from HIV or infectious disease-related deaths (HR: 1.93, 95% CI: 1.26–2.97).

Conclusion: Insufficient sleep was independently associated with all-cause mortality and specifically with death from HIV or infectious diseases-related causes among PWID. Interventions consider targeting sleep behaviors among PWID hold promise for improving health and longevity in this population.

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SLEEP ARCHITECTURE IN THE INTENSIVE CARE UNIT AS REVEALED VIA BREATHING AND HEART RATE VARIABILITY

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Introduction: Sleep in the intensive care unit (ICU) is difficult to measure by conventional polysomnography. We investigated the feasibility of assessing sleep state from readily available ICU signals: heart rate variability (HRV) from electrocardiography and breathing from a wearable respiratory band. We compared findings with an age and sex matched sleep laboratory group.

Methods: As part of a clinical trial, 102 adult non-ventilated patients in three ICUs in the Massachusetts General Hospital wore a respiratory band. Both heart rate variability (RR-intervals) from ECG, and breathing (respiratory effort waveforms) data for up to seven days per patient were obtained. 220 age- and sex-matched subjects from a sleep lab cohort who wore the same respiratory effort band and ECG were selected for comparison. We staged sleep from the HRV and breathing data using previously published deep neural network models. We defined discordant sleep epochs as those where HRV- and breathing-based models disagreed. Agreement was computed for the following pairs: (R,R),(N1,N1),(N2,N2),(N3,N3),(N1,W),(N1,N2),(N2,N3).

Results: Demographics: Mean(STD) age: ICU 68(9), sleeplab 68(9); BMI: ICU 27(6), sleeplab 31(6); ICU 40% female, sleeplab 44% female; race: ICU%:Sleeplab% 90:69 White, 5:4 Black, 2:7 Asian. 34% of ICU-subjects were in a medical ICU, 66% in a surgical ICU. Mean total sleep duration in the ICU was 8.9 hours (4.5h concordant, 4.4h discordant sleep). We observed increased amounts of discordant sleep in the ICU compared with the sleeplab cohort (4.4h vs. 1h, $p<0.01$). We found different REM sleep distributions ($p<0.01$) with reduced median (10% vs. 20%) but elevated 90% quantile (45% vs. 26%), elevated N1(%) (41% vs. 26%, $p<0.05$), reduced N2(%) (19 vs. 44, $p<0.01$), and reduced N2+N3(%) (34 vs. 59, $p<0.05$). We further observed higher mean respiratory rate (17.4 vs. 15.9 breaths per minute,

p<0.01), lower inter-breath-intervals (3.9 vs. 4.7 seconds per breath, p<0.01), and more breathing variability than in sleeplab AHI<5 group but less than in AHI>15 group.
Conclusion: HRV and respiratory-based measures can assess sleep in the ICU. The findings of increased discordant sleep in the ICU might stem from limitations of the models, fundamental changes in sleep biology during critical illness, pharmaceutical drugs, sleep fragmentation, and/or associated pathology in the ICU.
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EFFECTS OF SLEEP-EXTEND ON GLUCOSE METABOLISM IN WOMEN WITH A HISTORY OF GESTATIONAL DIABETES: A PILOT STUDY

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Introduction: Experimental and epidemiological data have linked insufficient sleep to increased diabetes risk. Women with a history of gestational diabetes (GDM) have a 7-fold greater risk of developing type 2 diabetes. This pilot study explored the feasibility of a sleep extension intervention in women with a history of GDM and short sleep, and the effects on glucose metabolism.
Methods: Women age 18–45 years with a history of GDM (at least 1 year postpartum) and actigraphy confirmed short sleep duration (<7h/night) on weekdays were randomized at a ratio of 1 control (healthy living information) to 2 cases (6 weeks of "Sleep Extend" intervention: use of a Fitbit, weekly digital content, interactive tools, and coach delivered feedback in order to increase sleep duration). An oral glucose tolerance test (OGTT), 7-day actigraphy recording and questionnaires were obtained at baseline and 6 weeks (at the end of the intervention).
Results: Twelve women (mean (SD) age 40.3 (4.5) years) participated (n=8 Sleep Extend, n=4 control). Compared to baseline, nightly sleep duration increased in Sleep Extend group (+30.6 (48.8) minutes) but decreased in the control group (-6.8 (22.9) minutes). Both fasting and 2-h glucose levels from OGTT increased in both groups but were greater in the control group (Sleep extend vs. healthy living: fasting glucose +2.1 (9.8) vs. +12.8 (7.3) mg/dL; 2-h glucose +8.2 (21.9) vs. +20.0 (19.4) mg/dL). Self-reported sleep quality improved in both groups. When compared controls, Sleep Extend participants reported improved fatigue symptoms (Promis fatigue score change -5.1 (9.3) vs. 7.0 (1.0), p=0.008), and self-reported physical activity tended to increase (+1614 (3659) vs. -2900 (3922) MET-minutes/week). Combining all participants, an increase in sleep duration correlated with a decrease in fatigue (r= -.62, p=0.04) and anxiety symptoms (r= -.69, p=0.02).
Conclusion: Sleep extension through coaching and use of remote monitoring is feasible in women with a history of GDM. It appears to decrease fatigue and may improve glucose metabolism and physical activity.
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UTILIZING RISK SCORE ASSESSMENT TO MAXIMIZE SLEEP RESEARCH PARTICIPANT SAFETY DURING THE COVID-19 PANDEMIC

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Introduction: Research study recruitment has been profoundly affected by the COVID-19 pandemic, demonstrated by significant delays or pauses. Various guidelines pertaining to in-person visits have applied to research. Some call for exclusion of participants that the CDC has labeled "at increased risk".1 For obstructive sleep apnea (OSA) studies, these guidelines have caused a sharp decrease in the number of new participants. This decrease is due to high rates of OSA comorbidities including obesity and diabetes. New evidence-based risk scores have been developed using individual- and community-level factors. The use of more refined COVID-19 risk scores can help protect patient safety while allowing research to continue.
Methods: The risk score assessment used for this study (COVID-19 Mortality Risk Calculator; Johns Hopkins University, Baltimore, MD)2 is evidence-based and uses a set of risk factors and community-level pandemic dynamics in the state of residence.3,4 It was compared to the list of CDC medical conditions that are considered to put an individual "at increased risk." Both measures were calculated retrospectively on current participants to determine how many could safely attend in-person visits based on each risk assessment method.
Results: Sample characteristics of the 110 participants were: mean age: 49.5±13.7(24–76); mean BMI: 32.3±5.3(20.9–46.1); mean AHI: 24.3±21.4(5.1–110). Mortality Risk Calculator scores were: 91(82.7%) close to/lower than average [Level 1]; 12(10.9%) moderately elevated; 6(5.5%) substantially elevated; 1(0.9%) high; and 0(0%) very high [Level 5]. Using CDC guidance, 63 (57.3%) had at least one at-risk condition and 47 (42.7%) had 0. Using only Level 1 of the Risk Calculator would allow an additional 28 (25%) participants to attend in-person visits; using Levels 1 and 2 would allow an additional 40 (37%) participants.
Conclusion: Policies based on CDC at-risk conditions resulted in higher levels of participant exclusion in research during the COVID-19 pandemic than use of an evidence-based Mortality Risk Calculator. This analysis shows that researchers can use risk-adjusted scores to make informed decisions about study participation that balances both participant safety and research study progress.
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INCREASED NIGHTMARES DURING THE COVID-19 PANDEMIC: EXPLORING THE ROLE OF RESILIENCE AND EMOTIONS

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Introduction: COVID-19 had a tremendous impact on many aspects of our lives and has caused an increase in stress and mental health issues in many people. We have recently found that there was an increase in nightmares during the pandemic in young adults. Since emotions have been associated with both resilience and nightmares, the objective of this study was to investigate the role of resilience and emotional changes in the increase in nightmares observed during the pandemic, in a group of young adults.
Methods: Resilience, emotions and nightmares were assessed using the Connor-Davidson Resilience Scale-10, the Differential Emotions Scale-IV and an adapted version of the Pittsburgh Sleep Quality Index. Measures were administered to 209 young adults (18–25 years old, 76.1% females). Hierarchical multiple regression models were computed to examine the unique contribution of changes in positive and negative emotions during the pandemic to the increase in nightmares during the pandemic. Analyses were controlled for nightmares and emotions prior to COVID-19, and for gender. The sample was separated in two groups: resilient and less resilient young adults.