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IMPROVING MATERNAL SLEEP VIA COGNITIVE BEHAVIORAL INTERVENTION: A RANDOMISED CONTROLLED TRIAL FROM PREGNANCY TO 2 YEARS POSTPARTUM

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Introduction: Maternal sleep disturbance is common during pregnancy and postpartum periods. This study evaluated the feasibility and efficacy of a scalable cognitive behavioural therapy (CBT) sleep intervention tailored for these periods.

Methods: This is a two-arm, parallel-group, single-blind, superiority randomised controlled trial. Nulliparous women without major medical/psychiatric conditions were randomised 1:1 to CBT or active control of equal frequency/duration. All participants received a 1-hr telephone session and automated multimedia emails from the 3rd trimester until 6 months postpartum. Outcomes were assessed with validated instruments at gestation weeks 30 (baseline) and 35 (pregnancy endpoint), and postpartum months 1.5, 3, 6 (postpartum endpoint), 12, and 24.

Results: 163 eligible participants (age M +/- SD = 33.35 +/- 3.42) were randomised. The CBT intervention was well accepted, with no reported adverse effect. Intention-to-treat analyses showed that compared to active control, receiving CBT was associated with lower insomnia severity and sleep disturbance (two primary outcomes), and lower sleep-related impairment at the pregnancy endpoint (p-values ≤ .001), as well as at 24 months postpartum (p ranges .012-.052). Group differences across the first postpartum year were nonsignificant. Women with elevated insomnia symptoms at baseline benefitted substantially more from CBT (vs control), including having significantly lower insomnia symptoms throughout the first postpartum year. Group differences in symptoms of depression or anxiety were nonsignificant.

Conclusion: A scalable CBT sleep intervention is efficacious in buffering against sleep disturbance during pregnancy, with long-term benefits to maternal sleep, especially for women with sleep complaints during pregnancy. The intervention holds promise for implementation into routine perinatal care.

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ACUTE EFFECTS OF SELTOREXANT, A SELECTIVE OREXIN-2 ANTAGONIST (JNJ- 42847922), ON DRIVING AFTER BEDTIME ADMINISTRATION

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Introduction: Seltorexant (JNJ-42847922), a potent and selective antagonist of the human orexin-2 receptor, is being developed for the treatment of major depressive disorder. Seltorexant also has sleep-promoting properties. Investigating the effects of sleep-promoting medications on driving is important because some of these agents (e.g. GABAA receptor agonists) may be associated with increased risk of motor vehicle accidents. We evaluated the effect of seltorexant on driving after forced awakening at night, using a validated driving simulator.

Methods: This double-blind, placebo and active-controlled, randomized, 3-way cross-over study was conducted in 18 male and 18 female healthy subjects. All subjects received seltorexant 40 mg, zolpidem 10 mg, or placebo 15 minutes before bedtime. Eighteen subjects were awakened at 2- and 6-hours post-dose, and the other 18 at 4- and 8-hours post-dose. At those timepoints, pharmacokinetics, objective (standard deviation of the lateral position [SDLP]) and subjective effects (using Perceived Driving Quality and Effort Scales) on driving ability, postural stability and subjective sleepiness were assessed.

Results: For seltorexant, the SDLP difference from placebo (95% confidence interval) at 2-, 4-, 6- and 8-hours post-dose was 3.9 cm (1.26, 6.60), 0.9 cm (-1.08, 2.92), 1.1 cm (-0.42, 2.63), and 0.6 cm (-2.75, 1.55), respectively vs. 9.6 cm (6.97, 12.38), 6.6 cm (3.53, 9.60), 4.7 cm (1.46, 7.85), and 1.3cm (-1.16, 3.80), respectively for zolpidem. The difference from placebo was significant at 2-hours after taking seltorexant, while the difference from placebo was significant at 2, 4 and 6-hours after zolpidem. Subjective driving quality was decreased for both drugs at all time points and driving effort was increased up to 4-hours post-dose for both medications. Subjective sleepiness showed a significant increase compared to placebo 2- and 4-hours after administration of either drug. Postural stability was decreased up to 2-hours after administration of seltorexant, and up to 4-hours after administration of zolpidem.

Conclusion: Compared to zolpidem, objective effects on driving performance were more transient after seltorexant administration and largely normalized by 4–6 hours post-dose.

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CBT-I HAS SUSTAINED EFFECTS ON INSOMNIA VERSUS HEART-FAILURE SELF-MANAGEMENT EDUCATION AMONG ADULTS WITH CHRONIC HEART FAILURE

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Introduction: Insomnia is common among adults with chronic heart failure (HF), often not explained by sleep apnea (SA), and associated with daytime symptoms and poor daytime function. The purpose of this randomized controlled trial was to evaluate the sustained effects of cognitive behavioral therapy for insomnia (CBT-I) on insomnia severity and sleep characteristics over 6 months among adults with stable chronic HF.

Methods: We included adults with HF who had at least mild insomnia [Insomnia Severity Index (ISI) > 8] and no more than mild SA or SA treated with continuous positive airway pressure. We randomized in groups to 8 weeks of group CBT-I (Healthy Sleep: HS) [4 group sessions + calls on alternate weeks] or attention control (Healthy Hearts: HH) [HF self-management education + brief sleep hygiene] in