



ORIGINAL ARTICLE

Preventing postpartum insomnia by targeting maternal versus infant sleep: a protocol for a randomized controlled trial (the Study for Mother-Infant Sleep “SMILE”)

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Abstract

Symptoms of insomnia are common during the perinatal periods and are linked to adverse parent/infant outcomes. Theories on insomnia development (e.g. 3P model) suggest that significant sleep disruption (e.g. nighttime infant care) can precipitate, while unhelpful sleep-related cognitions/behaviors can perpetuate parental insomnia symptoms. This study aims to examine how two interventions, one addressing infant sleep as the precipitator, the other targeting maternal sleep-related cognitions/behaviors as the perpetuator, might prevent postpartum insomnia. Participants are 114 nulliparous females 26 to 32 weeks gestation, with self-reported insomnia symptoms (Insomnia Severity Index scores ≥ 8). Participants are randomized to one of three conditions and receive: (1) a “responsive bassinet” used until 6 months postpartum, designed to boost/consolidate infant sleep and target infant sleep as a precipitator of insomnia, (2) therapist-assisted cognitive behavioral therapy for insomnia, addressing unhelpful sleep-related cognitions/behaviors as perpetuators of insomnia, or (3) a sleep hygiene booklet (control condition). The primary outcome is maternal insomnia symptoms. Secondary outcomes include maternal sleep duration/quality, mental health (e.g. depression, anxiety), and wellbeing-related variables (e.g. sleep-related impairment). Outcomes are assessed using validated instruments at 26–32 and 35–36 weeks’ gestation, and 2, 6, and 12 months postpartum. This study adopts an early-intervention approach and longitudinally compares two distinct approaches to prevent postpartum insomnia in an at-risk population. If interventions are efficacious, findings will demonstrate how interventions targeting different mechanisms mitigate insomnia symptoms in perinatal populations. This will provide empirical evidence for future development of multi-component sleep intervention to improve mother-infant wellbeing.

Clinical Trial Registration: The Study for Mother-Infant Sleep (The SMILE Project): reducing postpartum insomnia using an infant sleep intervention and a maternal sleep intervention in first-time mothers. <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377927>, Australian New Zealand Clinical Trials Registry: ACTRN12619001166167.

Statement of Significance

Sleep disturbance is a major concern in the perinatal period. Based on existing theories, this adequately powered randomized controlled trial investigates how two interventions targeting different mechanisms (i.e. infant sleep as a precipitator, and unhelpful sleep-related cognitions/behaviors as perpetuators) may ameliorate the development of postpartum insomnia. Findings will shed light on key treatment mechanisms to aid the development of multi-component perinatal insomnia interventions. The focus on prevention could support future early-intervention efforts.

Key words: insomnia; pregnancy; cognitive behavioral therapy; pediatrics—infants; women’s health

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Introduction

Insomnia and the 3P model

Symptoms of insomnia are experienced by approximately 23% of the adult population; these include difficulties initiating and maintaining sleep, early morning awakenings, and/or unrefreshed sleep despite adequate sleep opportunity and a sleep-conducive environment [1]. For approximately 10%–15% of adults who meet diagnostic criteria for Insomnia Disorder [2], these symptoms are significant, persistent, and cause impairments in daytime functioning [3].

The Spielman model [4], otherwise known as the 3P behavioral model of insomnia, is a widely accepted theory on how normal sleep can deteriorate into chronic insomnia [5]. The model proposes three central tenets of insomnia: predisposing, precipitating, and perpetuating factors. Predisposing factors increase one's vulnerability for sleep disturbances (e.g. genetic predispositions, variations in sleep-wake neurotransmitter systems, or a high capacity to ruminate/worry) [6]. Precipitating factors pose major challenges to sleep (e.g. stressful events, illness), triggering an acute period of sleep disturbance [5]. While individuals cope with these acute and often major disruptions to their sleep, they may develop unhelpful thoughts (e.g. worries about sleep, "if I don't sleep well I can't function the next day") and behaviors (e.g. increasing time in bed in attempt to increase sleep) [7], which become perpetuating factors of chronic insomnia, even after the initial triggering stressor/event is no longer present. Conceptualizing insomnia in this way has allowed researchers to direct treatments toward modifiable precipitating and perpetuating factors.

Insomnia in the perinatal context

A major risk factor for insomnia is being female (Insomnia Disorder ratio female:male 1.4–1.6:1), and moreover, being a female in the perinatal period [8, 9]. Approximately 50%–73% of gestational parents (i.e. females whose uterus is used to nurture a baby during pregnancy) [10] report changes to their sleep-wake patterns during pregnancy and postpartum, and estimated rates for self-reported insomnia symptoms range from 17% to 30% [11–16]. Further, approximately 50% of individuals with clinically significant insomnia symptoms during pregnancy have persistent symptoms at 2 years postpartum [15]. Importantly, perinatal sleep disturbances and insomnia have been associated with increased risk/symptoms of perinatal depression and anxiety, poor birth outcomes, fatigue, family dysfunction, and poorer mother-infant relationships [17–20].

The 3P model is well suited to understand the development of insomnia in the perinatal context. Precipitating factors for perinatal insomnia include sleep-disrupting physical changes in late pregnancy (e.g. fetus growth, hormonal changes, urination, nausea, and breathing difficulties), and these stressors are typically replaced by the numerous demands of infant nocturnal awakenings/feeding schedules postpartum, with 73.5% of maternal night-time awakenings due to infant-related factors [21–26]. As individuals cope with these significant sleep disruptions, they can develop unhelpful sleep-related thoughts and behaviors such as "I will never get a good night sleep" and napping in the evening, respectively. These can perpetuate sleep problems well into the postpartum period, and contribute to chronic insomnia. Therefore, (1) infant sleep as a precipitator, and (2)

unhelpful sleep-related cognitions and behaviors as perpetuators are sound therapeutic targets for reducing and preventing insomnia in perinatal populations.

Sleep interventions for parents and infants

Cognitive behavioral therapy for Insomnia (CBT-I) is a well-established treatment for insomnia that addresses maladaptive sleep-related cognitions and behaviors [27–29]. A small but growing body of research indicates that CBT-I is efficacious for prenatal insomnia symptom reduction [30, 31] and insomnia disorder remissions rates [32]; a recent study showed that for those with insomnia symptoms during pregnancy, CBT-I administered in pregnancy and early postpartum can lead to sustained benefits during the first 2 years postpartum [27]. While CBT-I is effective in reducing insomnia by altering sleep-related cognitions/behaviors as perpetuating factors, CBT-I does not address infant sleep as a primary source of sleep disruption.

Night awakenings are a normal feature of infant sleep due to feeding demands and immature circadian rhythms in newborns [33]. Newborns sleep for approximately 16–17 h in a 24-hour period [34], and the longest sustained sleep period at 4 and 8 weeks postpartum is approximately 4 and 6 h, respectively [35]. Videosomnography studies suggest that 1-month old infants wake approximately four times a night, and do not require parental intervention for 28% of these awakenings [34]. By 12 months postpartum, infants experience 2.6-night awakenings and put themselves back to sleep for 46.4% of these awakenings [34], suggesting that infants experience an increase in their capacity to self-soothe as they mature [26]. Therefore, the aim of infant sleep interventions is not to eliminate infant awakenings, but to provide infants with the opportunity to transition between sleep cycles without parental intervention, and reduce excessive wakefulness that is unrelated to feeding demands.

Of the few infant sleep studies that have documented behavioral intervention effects for gestational parents' sleep, increases in sleep quality were observed but effects were rather modest, most likely due to minimal changes in infant sleep characteristics [36–40]. For example, Hall et al. [36] reported that infants in the intervention condition had 0.5 fewer night-time awakenings than the control condition, and the longest stretch of infant night-time sleep was 16.3 min higher for the intervention condition. These differences, although statistically significant, may not translate into a meaningful increase in parental sleep opportunity. Further, infant sleep studies typically focus on infants > 6 months old with mild to severe sleep problems [37–39]. "Responsive bassinets" (i.e. a bassinet that automatically responds to the infant's cries) are designed for infants 0–6 months old, and internal data suggests the bassinets increase infant sleep duration by 1–2 hours' total sleep time per night [41]. This is a large effect compared to other interventions (educational/behavioral programs increase infant sleep by 29 minutes in a 24-hour period based on a systematic review [42]), suggesting that responsive bassinets could reduce parental exposure to infant-related sleep disruption from the birth of the infant. It remains unclear the extent to which insomnia symptoms could be mitigated by substantially reducing infant night-time awakenings as a major precipitating factor from the birth of the infant, and moreover, how two distinctive interventions targeting different potential mechanisms (i.e. infant sleep as a

precipitator versus unhelpful sleep-related cognitions/behaviors perpetrators) may reduce the development of postpartum insomnia.

Current study

There is a critical need for interventions that effectively reduce postpartum insomnia symptoms in gestational parents. Previous research suggests that insomnia symptoms in pregnancy are a risk factor for postpartum insomnia [43]. Further, addressing insomnia symptoms during pregnancy and early postpartum in individuals with existing insomnia symptoms (i.e. Insomnia Severity Index [ISI] [44] score > 7) can lead to sustained benefits 2 years postpartum [27]. Therefore, the current study focuses on gestational parents who experience subclinical symptoms of insomnia during pregnancy (i.e. score > 7 on the ISI), with the following aims:

1. To examine whether reducing exposure to a major precipitator of postpartum insomnia by increasing infant sleep continuity and duration from 0 to 6 months leads to lower insomnia symptoms in first-time gestational parents at risk of postpartum insomnia (i.e. gestational parents with sleep complaints in pregnancy).
2. To evaluate the efficacy of two interventions, one addressing infant sleep as the precipitator, the other targeting maternal sleep-related cognition/behaviors as the perpetrator, in ameliorating symptoms of postpartum insomnia in first-time gestational parents at risk of insomnia. In the context of the 3P model, this will allow us to examine the comparative benefits of addressing precipitating versus perpetuating factors in insomnia development. Group differences in secondary outcomes previously demonstrated to be associated with perinatal insomnia symptoms (i.e. sleep quality, sleep-related impairment, mental health, memory, quality of life, relationship satisfaction with partner, and attachment with infants) will be examined. Treatment mechanisms (e.g. examining whether infant sleep and sleep-related cognitions/behaviors mediated group differences in insomnia symptoms) will also be explored.

To achieve these aims, a single-blind randomized controlled trial (RCT) with the following three conditions (see details in Figure 1 and Methods section) will be conducted:

- A. Infant sleep intervention. This study uses a “responsive bassinet” (see details in Methods section) from 0 to 6 months postpartum to reduce parental exposure to infant-related sleep disruption from the birth of the infant.
- B. Maternal sleep intervention based on CBT-I addressing unhelpful thoughts, beliefs, and behaviors around sleep.
- C. Control condition receiving a sleep hygiene and information booklet without the active components of CBT-I.

Methods

This study is a three-arm, parallel-group, single-blind, superiority RCT. Outcomes are assessed at five time points: 26–32 weeks of gestation (T1), 35–36 weeks of gestation (T2), and 2 months (T3), 6 months (T4), and 12 months (T5) postpartum.

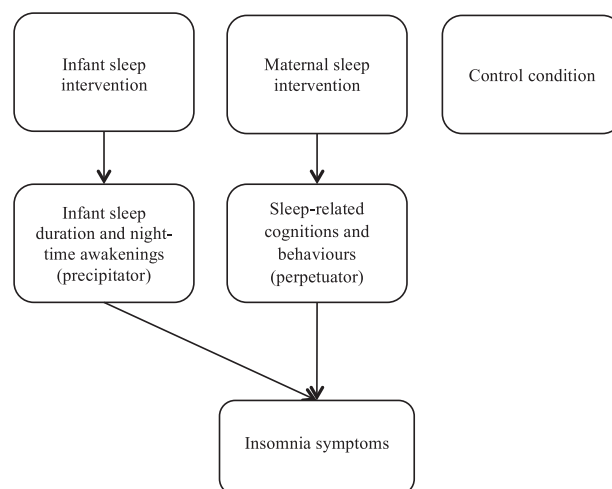


Figure 1. Conceptual framework for study design. A single-blind RCT with three conditions will be conducted, with an infant sleep intervention targeting infant sleep duration and night-awakenings as a precipitator of postpartum insomnia, and a maternal sleep intervention targeting sleep-related cognitions and behaviors as perpetrators of postpartum insomnia.

Methodologies are summarized below, and the trial was prospectively registered with Australian New Zealand Clinical Trial Registry (ACTRN12619001166167). This protocol article follows recommendations from the Template for Intervention Description and Replication (TIDieR) checklist and guide [45], and the SPIRIT-PRO Extension (Standard Protocol Items: Recommendations for Interventional Trials—Patient-Reported Outcomes) guidelines [46].

Participants

Participants are 114 pregnant individuals recruited from the general community in Australia, as well as a centrally located public hospital specializing in women’s health in Victoria, Australia. Inclusion criteria are: (1) nulliparous individuals in the third trimester of pregnancy (i.e. 26–32 weeks gestation and no older children); (2) singleton pregnancy; (3) age ≥ 18 years; (4) able to read and write in English; (5) have regular access to a smartphone, email, and internet; (6) score > 7 on the ISI [44]. Exclusion criteria are: (1) undertaking shift work during pregnancy or participation; (2) significant symptoms of the following sleep disorders based on Duke Structured Clinical Interview for Sleep Disorders (DSISD) [47]: narcolepsy, sleep apnea, periodic limb movement disorder, restless legs syndrome, circadian rhythm sleep disorders; (3) severe current psychopathology, including posttraumatic stress disorder, panic disorder (only if > 4 nocturnal panic attacks in the past month), substance abuse/dependence disorders; OR life-time bipolar or psychotic disorders; OR having high risk of harm to self or others; (4) use medications or substances that directly affect sleep; (5) medical conditions that directly affect sleep. Given that insomnia comorbid with depression or anxiety is responsive to CBT-I treatment [48, 49], participants with current/previous diagnoses of depression and/or anxiety are included to facilitate a representative sample and enhance the generalizability of our findings. Risk assessments (detailed below) will be used to determine whether participants meet exclusion criteria regarding high risk of harm to self or others.

Procedures

Recruitment and consent

Pregnant individuals enrolled in Childbirth Education at a public hospital in Victoria, Australia, are invited via email to participate in “a research project that evaluates different approaches to improving sleep for first-time mothers who currently experience sleeping difficulties.” The email invitation contains a link to an online Participant Information and Consent Form (PICF), and interested participants provide informed consent via a web-based survey form. The PICF includes comprehensive details of the project such as information regarding interventions, assessments, research procedures, potential risks, reimbursement, confidentiality, and freedom to withdraw participation.

To supplement recruitment, the study is also advertised in the general community in Australia (e.g. invitations to participate with an online link to the PICF are posted on relevant online forums and social media, and flyers are placed in appropriate public spaces).

Participants who consent to participate are asked to answer online screening questions to confirm whether they meet initial inclusion criteria (i.e. adult first-time parent with singleton pregnancy and a score > 7 on the ISI). Participants who do not meet inclusion criteria are thanked for their interest and encouraged to contact the research team if they have further questions regarding their eligibility; they are also encouraged to speak to a health professional if they are concerned about sleep. Participants who meet initial inclusion criteria are told that participation will be confirmed after an initial telephone interview and continue to complete the baseline questionnaires (see Measures section for details).

Telephone interview and screening

Respondents who meet the initial inclusion criteria and have completed the baseline questionnaires are contacted for a telephone interview to assess further eligibility. The interview contains the DSISD [47] and other questions related to mental/physical health to assess exclusion criteria. Participants who meet exclusion criteria due to a severe psychiatric condition are referred to the Women’s Mental Health Service at the Royal Women’s Hospital (where hospital patients are eligible for mental health care), or provided contact information of relevant professionals/services. Participants who meet exclusion criteria due to a severe sleep disorder are encouraged to discuss their conditions with their physician for further support.

Randomization and blinding

Eligible participants are randomized using a complete randomization scheme generated in advance. Block design with varying block sizes of 3 and 6 are used. Random seeds are generated to assure allocation concealment and pre-guessing of the allocation sequence at the end of each block. Randomization is stratified by baseline ISI (<15 and >14). The randomization scheme is generated and setup in REDCap by a member of the research staff who is (1) not involved in recruitment or delivery of intervention and (2) is not one of the study Principal Investigators. REDCap is a web application and back-end database model designed to support data capture for research studies. REDCap is an open-source tool developed by Vanderbilt University to build and manage online forms for data collection (www.project-REDCap.org). REDCap has developed specifically around the Health Insurance Portability and Accountability Act of 1996 security

guidelines with features such as data encryption. REDCap implements role-based security, which were used to limit access based on user function to certain forms, reports, and fields. To randomize a participant, an authorized research staff member logs in to REDCap enters eligibility and stratification data on the participant, and receives the group allocation. Follow-up measures are either self-completed or conducted by research staff who are blinded to the condition, which is achieved by limiting access to group-specific data on REDCap. In the event of accidental un-blinding for research staff undertaking clinical interviews, the event will be recorded and a sensitivity analysis will be conducted to determine whether results differ when the participant is included/excluded.

Timing of assessments and intervention

All participants undertake online questionnaires administered via REDCap at five time points: 26–32 weeks of gestation (T1), 35–36 weeks of gestation (T2), and 2 months (T3), 6 months (T4), and 12 months (T5) postpartum. As shown in previous data, sleep undergoes major changes during the postpartum period, the average scores on the ISI (primary outcome measure) across T3-T5 will be used as the primary endpoint to estimate cumulative, total symptom burden. Group differences at each time point will also be explored, including T2 as the pregnancy endpoint. [Table 1](#) contains a timeline of assessments and intervention material. All online questionnaires/telephone calls are delivered in English.

All participants receive a phone call from a researcher at T1 for orientation (varies in duration and content depending on condition), and at T3 for encouraging adherence and trouble-shooting (approximately 15 min). A final telephone call by a researcher blinded to group allocation is made to all participants to administer the DSISD Insomnia module at T4 (about 10 min). All telephone communication is audio-recorded, and this is explained in the PICF. Audio-recordings are used for assessing reliability and intervention fidelity and are stored securely with password protection. Trained researchers extract coded information from these recordings, and store these codes securely with other information participants provide for analysis.

To minimize missing data, participants will receive reminder emails/texts to prompt questionnaire completion. Following completion of assessments at T4 and T5, participants are sent a \$30 AUD gift voucher as a small token of appreciation for their effort in the study (i.e. \$60 AUD total in vouchers).

Adverse events

Adverse events are monitored during telephone contact at T1 and T3, and via questionnaire at T2, T4, and T5. Further, participants are asked to report to the research team immediately if they experience unwanted adverse effects during participation. These events are recorded and included in human research ethics reports.

Risk

A risk assessment is undertaken during the initial telephone interview (T1) and during the telephone calls at 2 months (T3) and 6 months (T4) postpartum. It assesses suicidal/homicidal ideation, plan, history of injurious behavior, and engagement with mental health care. During the initial interview, participants deemed to be at high risk, operationalized as current

Table 1. Timing of assessments and intervention

	Pregnancy		Postpartum				
	T1 26–32 weeks	T2 35–36 weeks	2 weeks*	T3 2 months	3 months*	T4 6 months	T5 12 months
Self-report questionnaires	X	X		X		X	X
Telephone (intervention)	X†			X‡			
Telephone (assessment)	X					X	
Intervention groups							
A: Infant sleep			X	X	X	X	
B: CBT-I	X	X	X	X	X	X	
C: Control	X						

*Intervention only.

Assessment at T1 is conducted before intervention commences. All participants undertake online questionnaires at T1–T5, and receive a telephone call from a researcher at T1, T3, and T4.

†Telephone call varies in content and duration depending on intervention condition.

‡Telephone call of 5–20 min for encouraging intervention adherence and trouble-shooting. Group A use the infant sleep intervention from the birth of the infant until approximately 6 months postpartum. Group B receive intervention materials one week before completing questionnaires. Group C receive control condition materials at T1.

suicidal/homicidal ideation with plan and/or history of harm, are excluded from the study and referred to relevant services for clinical care. Participants at medium risk, operationalized as experiencing current ideation to harm self/others but have no plan or previous history of harm, are included if no exclusion criteria have been met; these participants are encouraged to seek professional help for their mental health via general practitioner or psychologist, and will also be provided with details of relevant mental health services. Participants at low risk are included if no exclusion criteria are met.

Telephone calls at T1 and T3 are carried out by a provisional psychologist (N.Q.) who consults a clinical psychologist (B.B.) when any risk issues arise to decide on appropriate action. Risk assessments in the T4 telephone call are undertaken by research assistants who received training by a provisional (N.Q.) and clinical psychologist (B.B.). Research assistants contact the provisional psychologist (N.Q.) if any risk issues arise, who consults the clinical psychologist (B.B.) to decide on appropriate action. To support risk management, the PICF explains that a member of the research team may provide participant contact details to support services if potential risks are identified.

Intervention conditions

All participants, regardless of group allocation, continue usual perinatal care. No participants are restrained from seeking treatment or support for sleep concerns. Treatment or support received outside of the study interventions are documented. Interventions are manualized and telephone scripts were developed by the research team to ensure consistency. A provisional psychologist undertaking doctoral training in clinical psychology (N.Q.) was trained in CBT-I and competence in delivering the intervention was assessed prior to trial commencement by a clinical psychologist (B.B.). The provisional psychologist (N.Q.) receives regular supervision throughout the trial. Audio-recordings will be used to quantify intervention fidelity at the end of the trial.

After group allocation, all participants receive a standardized telephone session from the provisional psychologist (N.Q.), who

introduces the rationale of each intervention, helps the participant to understand the intervention device/materials, and encourages consistent application of intervention. A follow-up call (5–20 min) is conducted by the provisional psychologist (N.Q.) at 2 months postpartum (T3) to trouble-shoot any difficulties in applying the strategies or using the infant sleep intervention. Participants in the infant sleep intervention and control condition are offered the maternal sleep intervention material following the completion of the final assessment.

A. Infant sleep intervention

The infant sleep condition receives a “responsive bassinet” to use from the birth of the infant until 6 months postpartum. The device is currently commercially available in Australia, United States, and Canada. The responsive bassinet is designed to calm crying and consolidate infant sleep by automatically responding to the infant’s cries. The bassinet is based on the soothing techniques called the “5S’s” (swaddling, side stomach, shushing white-noise, sucking, and swinging) developed by Karp [50], which has been shown to significantly reduce the frequency of infant nighttime awakenings, increase daily sleep duration, and facilitate infant soothing [51–53]. The bassinet employs the “5S’s” by (1) automatically emitting three-specially engineered white-noise sounds, (2) safely swaddling the infant, and (3) providing rhythmic “rocking” motions when crying noises are detected. Importantly, the bassinet employs the “5S’s” for a maximum of 3 min to provide the infant with the opportunity to transition between sleep cycles. If the infant does not settle within this time, the bassinet alerts adults for additional assistance (e.g. feeding, changing).

Participants receiving the bassinet will be asked to use a mobile application linked with the bassinet, which (1) provides daily sleep reports on the infant’s sleep progress, (2) alerts parents that the infant requires additional soothing if the infant does not settle after 3 min of crying, (3) allows parents to customize the motion and white noise settings for their infant’s individual needs, and (4) contains specialized settings to assist parents in transitioning their infant to a standard crib after 6 months of age. The mobile app collects the following data: diagnostic and performance-based information for the bassinet, status/

usage data, and sleep information for infants using the bassinet (e.g. sleep duration and number of night-time awakenings). All data is transmitted directly to the bassinet manufacturer, who will store the data in a password-protected online server. The manufacturer will provide our research team with access to the mobile app data on a per-participant basis. When using the mobile app, participants are provided with a daily report of their infant's sleep information. Researchers will compare averages from these daily sleep reports with the data provided from the manufacturer to ensure data is complete and has not been altered. These datasets are expected to be identical.

When using the mobile app for the first time, participants will be asked to enter their name, email address, password, and their infant's name and date of birth. To protect the privacy and confidentiality of participants, our research team will: (1) ask participants to enter a pseudonym for themselves and their infant when registering for the mobile app, and (2) provide each participant with an email address to use upon registration. Each email address will be assigned an ID number to ensure the manufacturer does not receive participants' personal/identifying information.

If participants require additional information or support for the bassinet, the manufacturer's customer care staff can provide telephone consultations as with any commercial purchase. The use of the bassinet in the current study will mimic what is currently available to Australian parents using the device. Therefore, engagement with the mobile application and customer support staff is expected to vary among participants so findings could approximate real-world use. Participants will be encouraged to use the bassinet every night for 6 months; however, participants are free to withdraw at any time. Use of the bassinet and mobile application will be measured using the Intervention Adherence and Usefulness questionnaire delivered at T2, T3, and T4 to examine roles in treatment response (see Measurements section below).

Participants in this condition will receive the bassinet directly from the manufacturer free of charge (usual retail price = \$1160.00 USD). They will be asked to return the bassinet before their infant reaches 7 months postpartum (i.e. within one month of completing use). If participants have logistical difficulties in returning the bassinet, the research team will arrange alternative transportation methods at no expense to the participants. Participants and the Royal Women's Hospital will not be held liable for hardware or software faults, or damages to the bassinet. The bassinet manufacturer is not considered a sponsor of this study because (1) the manufacturer has not been, and will not be involved in the development of the research question, study design, or other aspects of the study, except for providing the device free of charge; (2) publications from the current study do not require approval from the bassinet manufacturer and after study completion the manufacturer will be provided with the published manuscript, but no data collected from participants.

If participants are allocated to Group A, they will be given detailed information about the bassinet by a provisional psychologist (N.Q.), including its look and functionality; if they do not wish to use the bassinet, they are free to decline further participation in the study. If participants are allocated to Group B or C, they will be asked to use a conventional bassinet while participating in the study, unless otherwise advised by a health professional. This information is included in the PICF. The

bassinet is referred to as a "responsive bassinet" in all advertisements and in the PICF to reduce sign-ups of parents who are already planning to purchase the bassinet through retail.

B. Maternal sleep intervention

The maternal sleep condition uses therapist-assisted self-help CBT-I to address maladaptive sleep-related cognitions and behaviors. This intervention is based on the same intervention trialed by the research team [27] with infant soothing and settling component being removed to avoid overlapping content with the infant sleep intervention condition. The following evidence-based therapeutic components are included: (1) General skills for better sleep to promote resilience to sleep challenges: sleep hygiene, identifying and addressing unhelpful thoughts and beliefs about sleep, relaxation, and strategies for managing worries when trying to sleep; (2) Understanding the difference between symptoms of insomnia versus sleep deprivation, and managing sleep initiation and maintenance difficulty using stimulus control; time-in-bed restriction is not included in written materials, but administered over the phone if necessary (i.e. if an individual presents with insomnia symptoms and a sleep efficiency <80%). Time-in-bed restriction will be modified for pregnancy as per previous recommendations [32], with time in bed recommendations based on total sleep duration plus 30 min (and always greater than or equal to 5.5 h total); (3) Education about typical sleep patterns of new parents and infants to foster realistic expectations about sleep and normalize some sleep loss; (4) Mindfulness-based strategies targeting physical discomfort, pain, and cognitive arousal; (5) Encouragement to prioritize one's own need for sleep, rest, and self-care, and to use properly timed naps based on sleep and circadian rhythm principles [54]; (6) Skills for managing sleepiness/fatigue; (7) encouragement to enlist partner and family support.

Content of the intervention is delivered via the following two means, combined: (1) A 50-minute individual telephone session conducted by a provisional psychologist (N.Q.) at T1. The initial telephone call uses a protocol that is designed to introduce all core intervention components and tailor strategies based on the individuals' characteristics (e.g. identifying ways to promote morning light exposure based on a participant's daily routine). A follow-up call at T3 (approximately 15 min duration) is conducted to encourage adherence and troubleshooting; (2) A series of emails containing text, graphics, and/or audio-based intervention components delivered at T1–T4 (same time points as T1–T4 assessments), and in addition at 2 weeks and 3 months postpartum (see Table 1 above). In total, participants will receive 20 intervention-containing emails. At each pregnancy time point (i.e. T1 and T2), one daily email is sent over 5 days. Participants receive one daily email for 3 days at 2 weeks and 2 months postpartum (T3), and 2 days at 3 months and 6 months postpartum (T4). These 6 critical milestones are selected so sleep challenges are specific to each milestone (e.g. managing insomnia, physical discomfort, and expectation of postpartum sleep at T1 and T2, managing daytime sleepiness at 2 weeks postpartum). Each email is designed to be succinct and easy to read on a computer, tablet, or phone. Participants who have difficulty applying the intervention materials can request brief email or telephone clarification from the provisional psychologist (N.Q.) who conducted the initial session. Intervention usefulness/adherence will be measured using the

Intervention Adherence and Usefulness questionnaire delivered at T2, T3, and T4 (see Measurements section below).

C. Control condition

This condition accounts for the nonspecific effects of participating in a sleep-related research project (e.g. contact with health professionals, receiving health information, and expectations of benefit). Participants in the control condition receive an information booklet at T1 containing the psychoeducation and sleep hygiene information (e.g. healthy sleep habits regarding caffeine, light, and alcohol, and information about typical infant sleep patterns) from the maternal sleep intervention without other components. Sleep education and sleep hygiene are widely used in insomnia trials as a control condition with good face validity, because these two components on their own have shown substantially inferior effects on symptoms of insomnia [55].

Measures

A summary of the instruments used in this study can be found in the text below, and specific details on each measure (i.e. validity/reliability, instrument scoring) can be found in the [Additional file 1, Supplementary Materials. Table 2](#) describes when each measure is administered.

Self-report instruments with strong psychometric properties were selected for primary outcomes because insomnia is assessed and diagnosed based on self-report [2], and subjective sleep complaints (and not objectively assessed sleep parameters) share strong associations with other wellbeing outcomes [17].

Structured interview

The DSISD [47] is a structured clinical interview assessing DSM-5 defined insomnia-related disorders, excessive daytime sleepiness-related disorders, circadian rhythm sleep disorders, restless leg syndrome, and parasomnia disorders. The DSISD is administered in its entirety during the screening, and the Insomnia Module is repeated at T4 by a researcher blinded to group allocation.

Primary outcome

The primary outcome is symptoms of insomnia measured by the ISI [44], a 7-item self-report measure of Insomnia Disorder symptom severity. Items such as “*difficulty falling asleep*” and “*difficulty staying asleep*” are rated on a 5-point Likert-type severity scale (during the past 2 weeks), ranging from 0 = none to 4 = very severe. Scores range from 0 to 28, with 8–14 indicating subthreshold Insomnia Disorder, 15–21 moderate clinical Insomnia Disorder, and 22–28 severe clinical Insomnia Disorder [56]. A cut-off of 10 has demonstrated sensitivity of 97.2% and a specificity of 100% for detecting clinically significant insomnia, with high internal consistency (Cronbach’s $\alpha = 0.91$) at pretest [57].

Secondary outcomes

1. *Sleep quality*, measured using (1) self-reported sleep behaviors over the past week (e.g. sleep duration, onset latency, wake after sleep onset, daytime naps [58]), and (2) the PROMIS Sleep Disturbance [59], a computer adaptive test [60] assessing sleep disturbance.
2. *Sleep-related impairment*, measured using the PROMIS Sleep-Related Impairment (CAT version) [59].

Table 2. Timing of measurements

Name of measure	Pregnancy		Postpartum		
	T1	T2	T3	T4	T5
Screening: Duke Structured Interview for Sleep Disorders	X			X*	
Primary outcome					
Insomnia Severity Index	X	X	X	X	X
Secondary outcomes					
Perinatal Sleep Questions (sleep timing, duration, quality)	X	X	X	X	X
PROMIS Sleep Disturbance	X	X	X	X	X
PROMIS Sleep-Related Impairment	X	X	X	X	X
Prenatal Attachment Inventory	X	X			
Mother to Infant Bonding Scale			X	X	X
PROMIS Depression	X	X	X	X	X
PROMIS Anxiety	X	X	X	X	X
Cross-Cutting Symptoms Level 1	X			X	X
Dyadic Adjustment Scale-4	X	X	X	X	X
AQoL-4D	X	X	X	X	X
Prospective and Retrospective Memory Questionnaire	X	X	X	X	X
Other factors					
Demographic and Obstetric Information	X	X	X	X	X
Brief Infant Sleep Questionnaire			X	X	X
Perceived Stress Scale	X	X	X	X	X
PROMIS Instrumental Support	X	X	X	X	X
PROMIS Emotional Support	X	X	X	X	X
Ford Insomnia Response to Stress Test	X				X
Maternal Efficacy Questionnaire			X	X	X
Dysfunctional Beliefs and Attitudes about Sleep Scale	X	X	X	X	X
Glasgow Sleep Effort Scale	X	X	X	X	X
Reduced Morningness and Eveningness Questionnaire	X	X	X	X	X
Credibility Expectancy Questionnaire	X				
Intervention Adherence (0–3) and Usefulness (0–3)		X	X	X	
Client Satisfaction Questionnaire, Program Feedback				X	
Medical Records Extraction				X	
COVID-19 Questionnaire				X	X

X, measure administered at that time point.

*Insomnia module only; T1 occurs before randomization.

3. *Mother-infant relationship*, measured with (1) Prenatal Attachment Inventory [61], and (2) Mother to Infant Bonding Scale [62].
4. *Mental health*, measured with (1) PROMIS Depression (CAT version) [63], (2) PROMIS Anxiety (CAT version) [63], and (3) Cross-Cutting Symptoms Level 1 [2].
5. *Relationship satisfaction*, using the brief Dyadic Adjustment Scale [64] for participants who have a partner.
6. *Health-related quality of life*, measured with the AQoL-4D [65].
7. *Memory*, measured using the Prospective and Retrospective Memory Questionnaire (PRMQ) [66].

Other factors

1. *Demographic, medical conditions, and obstetric information* are collected using self-report at baseline (T1) and changes are

monitored at T2, T3, T4, and T5 (e.g. infant-feeding method and feeding difficulties, medical conditions of gestational parent/infant, engagement in therapy, medication). With the participant's consent, medical and obstetric information including health conditions during pregnancy (e.g. hypertension, preeclampsia), blood pressure and weight during pregnancy, blood pathology, delivery information (e.g. gestation at time of delivery, duration of labor), and infant information (e.g. birth weight) are also extracted from medical records at the Royal Women's Hospital.

2. The following are assessed and examined as covariates: *perceived stress* (Perceived Stress Scale [PSS-10]) [67] and *social support*, assessed using the PROMIS Instrumental Support and PROMIS Emotional Support (CAT versions) [68], as well as questions created specifically for this study to assess *night-time assistance with the baby*, *partner sleep*, and *infant feeding method and feeding difficulties*.

The following constructs are also measured and examined for their potential roles in treatment responses:

1. *Infant sleep duration and quality*, measured with the original Brief Infant Sleep Questionnaire (BISQ) [69]. The original scale has been revised (BISQ-R) [70], and this study includes five additional items from the BISQ-R to allow for calculation of subscores regarding infant sleep patterns and parents' perceptions of their infant's sleep, as suggested by Mindell et al. [71].
2. *Vulnerability to insomnia under stress*, using the Ford Insomnia Response to Stress Test (FIRST) [72].
3. *Maternal self-efficacy*, assessed using the Maternal Efficacy Questionnaire [73].
4. *Beliefs and attitudes about sleep*, using the Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS-16) [74].
5. *Sleep effort*, using the Glasgow Sleep Effort Scale (GSES) [75].
6. *Patients' perceived credibility and expectancy of treatment*, via the Credibility Expectancy Questionnaire (CEQ) [76].
7. *Chronotype*, via the Reduced Morningness Eveningness Questionnaire (rMEQ) [77].
8. *Intervention adherence* (assessing frequency and usefulness of each intervention component).
9. *The impact of COVID-19 (Coronavirus) on project participation*, using the COVID-19 Questionnaire. Due to ongoing data collection during the COVID-19 pandemic, questions related to personal experiences with COVID-19 and potential impact on participation are asked to all participants who completed assessments after July 2020. This is intended to assist with interpreting findings from this trial following completion.

Ethics considerations

Ethics approval was obtained from the Royal Women's Hospital Human Research Ethics Committee (Project number: 19/17). All participants provide informed consent for the participation of themselves and their infants. The consent clarifies that the decision whether or not to participate in the study will not affect usual care, and that participants are free to withdraw from the study at any time. Participants excluded due to current psychiatric condition are referred for treatment at the Women's Mental Health Service of the Royal Women's Hospital, and/or encouraged to speak to their doctor about their mental health

needs. Any changes in protocol are reported to and approved by the Royal Women's Hospital Human Ethics Committee before implemented, and are updated on trial registration. Given the scope of this study, a Data Safety Monitoring Board is not utilized.

For security of information collected, each participant is assigned an identification (ID) number. Participants' identifiable information is only stored in REDCap, which has role-based secure access, and researchers working on this project have different levels of access (e.g. full access, de-identifiable information only). Access can also be immediately revoked if required. Outside REDCap (e.g. dataset for analyses, interview notes), participants are only identified using the numeric ID. All hard copies of data collected are kept in secure locked filing cabinets at Monash University and/or Women's Mental Health Service at the Royal Women's Hospital. Only the researchers involved in the project have access to the data. 7 years after the final publication, data will be de-identified by removing names, date of birth, addresses/contact details, and any information that may link the data to individual participants. These personally identifying data will be completely erased and destroyed. The de-identified database will be made publicly available to maximize the potential benefit to the scientific and research community.

Results will be disseminated in peer-reviewed publications, scientific conferences, and via community media outlets (e.g. newspaper articles, social media). Opportunities to further disseminate will be sought out, such as by contacting healthcare professionals and organizations (e.g. perinatal professionals, maternal and child health centers) with the aim of accelerating further intervention development. All participants who had expressed interest in receiving trial results will be provided with a summary of findings following trial completion, including any resulting publications that may arise.

Statistical analysis

All analyses will be conducted on an intention-to-treat basis. Missing data is expected in a longitudinal design, and will be addressed using mixed effects models, full information maximum likelihood when structural equation modeling frameworks are applied, and multiple imputation in other analyses. Deviations from the assigned intervention protocol will also be documented and a sensitivity analysis will be conducted.

Descriptive statistics will be used to characterize baseline demographic characteristics, rates of missing data over time, and outcomes over time. Exploratory analyses and graphs will be used to identify univariate or multivariate outliers as well as to evaluate normality assumptions for primary and secondary analyses. Extreme outliers will be winsorized.

To examine group differences in primary and secondary outcomes at baseline and each endpoint or specific time point, multiple regression analyses will be conducted with treatment conditions (along with relevant covariates) as independent variable, and the outcome of interest as dependent variable. Effect sizes along with 95% confidence intervals will be calculated for group differences. The proportion of participants meeting diagnostic criteria for Insomnia Disorder at each time point will also be described.

To examine intervention mechanisms, path analyses will be conducted, with the presence of either intervention as predictors, infant sleep duration/quality and maternal sleep-related

cognition and behaviors as mediators, and insomnia symptom severity as the outcome.

Assuming 10% missing data at each follow-up, randomizing 38 participants to each group will give the study 80% power (two-tailed $\alpha = 0.05$) to detect a medium to large effect size ($d = 0.7$). The effect size estimation is based on our previous trial using the CBT-I intervention [27].

Discussion

Despite high prevalence rates of insomnia symptoms during the perinatal periods [13, 15], longitudinal research on interventions for parental sleep is limited. Research to date has overlooked the impact of infant sleep on parental insomnia during the early-postpartum period, and it is unclear how postpartum insomnia symptoms could be mitigated or prevented by reducing infant night-time awakenings as a major precipitating factor from the birth of the infant. It is also unclear how two distinctive interventions targeting different mechanisms (i.e. infant sleep as a precipitator vs. unhelpful sleep-related cognitions/behaviors as perpetuators) may ameliorate or prevent the development of postpartum insomnia. This study is a first step toward filling these gaps.

This study focuses on early intervention during pregnancy and the first 6 months postpartum, and will allow us to longitudinally compare two distinct approaches to treating and preventing insomnia. This proactive approach could build our understanding of how to best support expecting/new parents presenting with risk factors for insomnia. By examining key treatment mechanisms, findings could provide empirical evidence to support the development of multi-component interventions. Given the adverse effects of poor sleep on mental health [17, 18], these findings have the potential to improve wider family functioning.

Finally, pharmacological treatments for sleep disturbances are often avoided during the perinatal periods [31]. This study serves to increase awareness of non-pharmacological treatment among healthcare professionals and the public, and efforts could be made to increase the availability of non-pharmacologically based interventions in the general community (e.g., rental schemes for bassinets, hospitals offering CBT-I materials).

Supplementary Material

Supplementary material is available at *SLEEP Advances* online.

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Authors' Contributions

NQ and BB led the design of this randomized-controlled trial and NQ wrote the first draft of the protocol. NQ and BB are responsible for the patient-reported outcomes of this protocol. LT contributed to the design of infant sleep measurements. LS contributed to the study aims and design. JF provided input on

rationale/clinical significance. NQ, BB, LT, LS, and JF all provided input to the write-up, and approved the final manuscript.

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Data Availability Statement

De-identified data from this trial will be shared on reasonable request to the corresponding authors.

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