

## **Research Protocol**

**Official Title | A pilot randomized controlled trial of cognitive behavioural therapy for insomnia in pregnancy**

**Brief Title | Sleeping for Two: RCT of CBT-Insomnia in Pregnancy**

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# **Sleeping for Two: A Pilot Randomized Controlled Trial of Cognitive Behavioural Therapy for Insomnia in Women during Pregnancy**

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## BACKGROUND AND RATIONALE

***Prevalence of sleep disturbances in pregnancy.*** Insomnia and poor sleep quality in pregnancy are common. During pregnancy, women experience a series of physiologic and emotional changes, ranging from alterations of hormonal secretions to fear of childbirth and parenthood. These changes can cause a series of somatic symptoms including sleep disturbances. In a study conducted with 486 pregnant women, the prevalence of insomnia was 52.2% (1). Interestingly, in a longitudinal evaluation, Facco, Kramer, Ho, Zee, and Grobman (2) found significant increases in insomnia from early (38%) to late pregnancy (54%). Higher rates of 61.9% were found in another study where 2,816 women who were 32 weeks pregnant completed self-report sleep quality assessments (3). Using a conservative prevalence estimate of 20%, numbers suggests that over 77,000 Canadian women experience insomnia during pregnancy each year (4).

***Insomnia and maternal and infant outcomes.*** Insomnia during pregnancy has consequences for maternal and child health. For example, insomnia in pregnancy has been associated with numerous pregnancy complications including: preeclampsia, preterm birth and growth retardation (5). Experiencing poor sleep quality in pregnancy has been shown to predict poor newborn sleep (6) and symptoms of maternal postpartum depression (PPD) (7, 8). In fact, experiencing a sleep trajectory characterized by consistent poor sleep quality in the perinatal period or development of poor sleep quality in the third trimester of pregnancy has been associated with ten to twenty-fold increases in the risk of experiencing symptoms indicative of PPD, even after controlling for robust predictors of PPD such as depression in pregnancy, and socioeconomic status (8). PPD is itself associated with numerous negative child outcomes (9).

***Treatment of insomnia in pregnancy.*** Treating antenatal insomnia with pharmacotherapy effectively improves sleep quality and confers a protective benefit against the onset of PPD (10); however, recent best practice guidelines advise against the use of sleep medications in pregnancy due to potential teratogenicity (11). Additionally, data suggests that the majority of pregnant women are reluctant to take prescribed medications due to their perception of risk (12, 13). Results from a recent study conducted in our lab, assessing patient perceptions, found that when presented with descriptions of pharmacotherapy versus cognitive behavioural therapy for insomnia (CBT-I), pregnant women rated CBT-I as significantly more credible and indicated that it was a preferable treatment for insomnia experienced in pregnancy when compared to pharmacotherapy (14).

***Cognitive Behavioural Therapy for Insomnia (CBT-I).*** CBT-I is an evidence-based psychotherapeutic intervention that combines cognitive and behavioural principles to provide psychoeducation about thoughts that contribute to the maintenance of sleep problems, and instruction in behavioural techniques to help participants decrease sleep onset latency and promote effective sleep maintenance. A large body of research has demonstrated that CBT-I is an effective treatment for insomnia, with short-term efficacy equivalent to medication, and long-term results suggesting that it outperforms medication. For example, in a review of

randomized controlled trials that assessed the comparative effectiveness of CBT-I and pharmacological interventions for insomnia, it was found that CBT-I was more effective than benzodiazepine and non-benzodiazepine drugs in the long term (15). Additionally, meta-analysis suggests that effect sizes of CBT-I range from medium to large both at post-treatment and follow-up assessments (15), prompting researchers to recommend primary care providers to consider CBT-I as the first treatment option for insomnia (16).

**Online CBT-I.** Despite an encouraging body of evidence supporting the use of CBT-I for treatment of insomnia and treatment with CBT-I is not easily accessible to all pregnant women. There are also a lack of well-trained CBT-I therapists and far fewer than would be needed to provide services to the vast number of North American women suffering from insomnia in pregnancy. To address this issue, researchers have turned to online administration of CBT-I (iCBT-I; 17). Two systematic reviews and meta-analyses suggest that iCBT-I is effective at reducing symptoms of both insomnia and depression (18, 19). For the treatment of insomnia, administration of iCBT-I has been shown to be comparable to face-to-face intervention (18, 19).

**CBT-I in the Perinatal Period.** Pregnant women have traditionally been excluded from intervention research and insomnia treatment is no exception, prompting calls for further development of interventions to treat insomnia in pregnancy and the postpartum (20). To our knowledge, there has only been one open pilot study examining the effectiveness of CBT-I in pregnancy, which was conducted by our lab. The intervention was delivered to thirteen pregnant women with insomnia and results suggest that CBT-I was effective and acceptable in reducing both subjective symptoms of insomnia and improving objective indices of sleep quality; in fact at the end of treatment 12/13 participants said they were no longer experiencing clinically significant symptoms of insomnia (21). Additionally, the intervention was acceptable to participants with 100% of women who began treatment successfully completing the 5-session protocol.

The majority of women entered the study reporting elevated depressive symptoms and experienced a significant decline in depressive symptoms in the follow-up period, a finding that has been observed in other populations (22, 23). These results are encouraging, as recent trajectory analyses from our group show that without intervention, disturbed sleep and depressive symptoms are relatively stable or increasing in the perinatal period (24, 25). Further, results from a systematic review and meta-analysis currently being conducted in our lab, which includes over 4,000 subjects, suggests that on average sleep quality declines significantly from early to late pregnancy; in contrast, group treatment with 5-sessions of CBT-I significantly improved sleep quality, even as pregnancy progressed.

## Objectives

The primary aim of the current project is to evaluate the impact of a 6-week in-person CBT-I versus iCBT-I versus a waitlist (WL) in reducing symptoms of insomnia (assessed subjectively by self-report and objectively with actigraphy) experienced in pregnancy. We hypothesize that

participants who receive a 6-week program CBT-I and iCBT-I (versus WL) will report fewer insomnia symptoms and have improved objectively assessed sleep as measured by at one-week (T2) post treatment. Based on previous research findings, we do not expect that there will be a difference between in-person CBT-I and iCBT-I administration.

The secondary aim is to investigate if CBT-I versus WL reduces symptoms of depression at T2 (one week post-treatment). We hypothesize that participants who receive CBT-I and iCBT-I (versus WL) will report fewer depressive symptoms as measured at T2.

## METHODS

### Trial Design

The proposed study is a randomized controlled trial of the efficacy of CBT-I for the treatment of insomnia experienced during pregnancy compared to WL. Assessments will occur at baseline, between 12-30 weeks of pregnancy (T1), and at one week posttreatment (T2).

### Recruitment Strategy

Participants will be recruited through Low Risk Maternity Clinics associated with Primary Care Networks, the Perinatal Mental Health Clinic, and the Foothills Medical Center Women's Mental Health Centre. Participants will also be able to self-refer to the study through several other methods including through posted announcements and pamphlets available in the main areas of family medicine clinics, midwifery clinics, ultrasound clinics, holistic/chiropractic clinics and other areas (community centres, libraries, and children's stores). Participants will also be recruited through advertising on Internet (Healthy Hearts Lab website, Healthy Hearts Lab accounts on Twitter and Facebook). Media releases about the study may also occur in print media, on the radio, and television. In any media releases, active recruitment will not occur; however, the study investigator would give general information about the study, potentially in an interview. A research assistant will explain the study protocols involved in the project to interested participants. If a participant meets the inclusion criteria and agrees to be involved in the study, a baseline assessment will be conducted in the two weeks prior to the start of the intervention.

### Inclusion and Exclusion Criteria

**Inclusion:** English speaking women over the age of 18, between twelve and thirty weeks of gestation, and identify as experiencing insomnia in pregnancy. Insomnia will be diagnosed using the Insomnia Interview Schedule (IIS).

**Exclusion:** Experiencing symptoms of other sleep disorders (i.e. restless legs syndrome, sleep-disordered breathing); history of untreated, serious psychiatric illness (i.e., bipolar disorder, schizophrenia); currently taking prescribed medications for sleep problems; smoking, drinking alcohol or drug abuse during pregnancy.

Pregnant women interested in study participation will contact the Healthy Hearts Laboratory and will receive additional information about the study protocols involved in the project. If a participant agrees to take part in the study, she will answer a series of questions during a phone-screening questionnaire (Insomnia Interview Schedule) (21). Potential participants who will not meet the inclusion criteria (e.g., reporting mild sleep problems) will be provided by email with a resource list of community services for pregnant women. Pregnant women excluded from the study for smoking, alcohol use, and/or drug use will also be provided with a list of community services, and referred to their primary care physician.

Prospective participants who agree to be involved in the study will meet with a member of the research team, who will explain the study procedures in full detail and obtain written consent. After consent has been obtained, participants will also be administered a diagnostic interview (Structured Clinical Interview for DSM-5; SCID) to assess if any exclusionary criteria are present and collect information about Axis 1 mood disorders (26). Assessments will be conducted by master's students in clinical psychology, under the supervision of a licensed clinical psychologist. Screening for Restless Legs Syndrome (RLS) and sleep-disordered breathing (SDB) will be conducted using the Cambridge-Hopkins questionnaire for Restless Legs Syndrome (CH-RLSq) and STOP questionnaire, respectively; women whose scores are suggestive of a sleep disorder other than insomnia will be referred to their primary care provider for further assessment.

## Procedures

**Week 1 (T1):** Eligible participants will meet with a member of the research team, who will explain the study protocols and obtain written consent. After completing a demographic and health practices questionnaire, women will be asked to read and complete self-report assessments of emotional and physical manifestations of fatigue, emotional health, social support, and sleep quality and quantity. Please see Figure 1 for a research design flowchart.

Once complete, participants will be provided with an actigraphy device and instructed on how to use it. They will be asked to wear the device for a period of 7 days during and send it back in a prepaid, stamped, envelope which will be provided at their study visit.

Participants will be randomly allocated to in-person CBT-I or iCBT-I or WL. Randomization will be determined using an online research randomization tool (27), which is not predictable and eliminates potential experimenter bias (28). Forty-five participants will be enrolled in the pilot RCT, with 15 randomized into each study group. A staff member who is not associated with the study will conduct the randomization and sequence generation and will put each participant assignment into opaque envelopes that contain the results of the randomization. After a baseline assessment is completed a study therapist will open an envelope and inform participants of their assignment.

Participants randomized to in-person or online treatment will be invited to participate in 6 sessions of CBT-I. Participants randomized to the waitlist group, will receive a pamphlet with information about community resources for pregnant women.

**Week 2- Week 7:** If randomized to the in-person treatment group, participants will be invited to attend 6 in-person sessions of cognitive-behavioural therapy for insomnia, which will take place at the University of Calgary in a newly renovated research space (*see Appendix A for the structure of each session*). Additionally, they will receive a manual which will include weekly readings relevant to the material being taught in the sessions and an informational pamphlet with helpful community resources for pregnant women. During this intervention, they will become familiarized with self-management approach for insomnia, sleep basics and sleep restriction, stimulus control, problem solving to cope with sleep disturbances and relapse prevention.

Participants randomized to online cognitive behavioural treatment (iCBT-I) will complete a series of 6 modules, where the main learning components are included in video and audio materials. To log onto the CBT-I intervention website, participants will be given login information through an anonymized email address, which will be used only for the duration of the study. Like the in-person intervention, the iCBT-I intervention includes instruction and homework on sleep hygiene and relaxation strategies. Participants will be contacted regularly by a member of the study team to ensure that there are no issues with accessing online readings and audio/visual materials (29).

Participants in the waitlist group will receive regular obstetric care provided according to the needs and current regime of the patient. The amount of contact with health care professionals outside of the study will be reported, as well as any treatment for insomnia (e.g., medication use) that the control participant engages in.

**Week 8 (T2):** After 8 weeks, all the participants will be invited to complete the same set of questionnaires from the baseline assessment. Additionally, they will be provided with an actiwatch and asked to wear it for seven days during weekdays. WL participants will be offered the opportunity to access the iCBT-I treatment.

**3-Months Postpartum (T3):** At 3-months postpartum, all participants will be invited to a web-link with the same set of questionnaires from the previous points of assessment, as well as one additional questionnaire assessing infant sleep quality. The web-linked questionnaires are expected to take approximately 30 minutes to complete.

## Equipment

Participants will be provided with an actigraphy device (Actiwatch II, Phillips, USA) and asked to wear it for 7 consecutive days at each assessment point.

## Outcome Measures

*Complete descriptions of outcome measures are provided in Table 1.*

### **Primary Outcome Measures**

**Insomnia Interview Schedule (IIS)**, Insomnia diagnosis will be confirmed using the IIS, which produces reliable and valid insomnia diagnoses, and provides information about developmental course and impact (21).

**Insomnia Severity Index (ISI)** (21, 30, 31). The ISI is a 7-item questionnaire designed to identify cases of insomnia and evaluate treatment outcomes. The ISI assesses severity of sleep onset, sleep maintenance and early waking problems, sleep dissatisfaction and perceived distress caused by sleep problems and it was found to be a clinically useful tool in assessing changes in insomnia symptoms in insomnia treatment research (31).

**Pittsburgh Sleep Quality Index (PSQI)**. The PSQI instrument is used in assessing one's sleep quality during the previous month. It consists of 19 self-rated items and 5 questions rated by the roommate or bed partner. There are seven components of the PSQI and these are subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications and daytime dysfunction. A score higher than 5 suggests poor sleep quality (32).

For assessing sleep quantity and quality, actigraphy (Actiwatch II, Phillips, USA) and sleep daily logs will be used in this study. Actigraphy monitoring provides objective information on circadian rhythm amplitude, acrophase, and mesor as well as indices of sleep efficiency, sleep latency, total sleep time, and number and frequency of awakenings (33). Participants will be asked to wear the actigraph for a period of 7 days at each assessment point.

### **Secondary Outcome Measures**

**Edinburgh Postpartum Depression Scale (EPDS)** (34). Symptoms of depression in pregnancy and the postpartum will be assessed by the EPDS. The EPDS consists of 10 items and is a reliable and valid tool for identifying symptoms of depression experienced in pregnancy and the postpartum (35).

### **Additional Measures and Questionnaires**

Additional questionnaires include the Multidimensional Fatigue Symptom Inventory-Short Form (MFSI-SF) (36), Dysfunctional Beliefs and Attitudes about Sleep Questionnaire (DBAS-16) (37), Sleep Self-Efficacy Scale (SES) (38), Sleep Hygiene Index (39), Pre-Sleep Arousal Scale (40), Glasgow Sleep Effort Scale (41), Sleep-Related Behaviors Questionnaire (SBRQ) (42), Epworth Sleepiness Scale (ESS) (43), Edinburgh Postnatal



Depression Scale (EPDS) (88), Generalized Anxiety Disorder (GAD-7) (44), Couple Satisfaction Index (CSI-16) (45), the Big Five Inventory (BFI-44) (46), the Extended Brief Infant Sleep Questionnaire (BISQ) (47), the Pregnancy-Specific Anxiety Measure (48), the PROMIS Adult Version 1.0 Pain Interference Short Form 8a (49), and the PROMIS Adult Version 1.0 Pain Intensity Short Form 3a (49).

Data will also be collected regarding demographic and psychosocial variables known to impact sleep. Demographic information collected will include age, family socioeconomic status, and number of children at home. Health practices assessed include smoking, alcohol consumption, and level of habitual exercise. Assessment of previous mental health problems, sleep disorders and psychotropic medication use will be assessed via interview.

## ANALYSIS PLAN

### Sample Size Power Calculation

The primary response variable, change in symptoms on the Insomnia Severity Index (ISI) between baseline (T2) and post treatment follow-up (T2), will be analyzed with using Repeated Measures Analysis of Variance (ANOVA) with a linear distribution specified at a significance level of  $\alpha = 0.05$ . Using data from our pilot study, and insomnia symptoms on the ISI, we found that pre-post treatment yielded a  $d = 3.07$ . Prior studies of CBT-I for patients with insomnia have found large between-group effect sizes in a range from  $d = 1.1$  to  $d = 1.6$ , even in patients with comorbid mental illness; however, we completed our power calculations using a more conservative effect size estimate, which showed that 18 patients are required to have a 95% chance of detecting a between-group effect size of  $d = 0.8$  at a significance level of  $\alpha = 0.05$  on the ISI. Although we had no attrition from our pilot study, we added a potential attrition rate of 20%, resulting in 14 participants to detect group differences in our pilot RCT.

Based on previous research, we do not expect to see differences in iCBT-I versus in person CBT-I; however, we expect that both conditions will outperform the WL group. Although we had no attrition from our pilot study, we calculated a potential attrition rate of 20% based on previous research in this area, resulting in 45 participants in our pilot RCT. Across 3 arms, this will allow 14 participants in each group and will provide a power of more than 90% to detect a difference of 8 points on the ISI, which is indicative of a clinically significant change (30).

### Primary Aims

*Hypothesis 1) Participants who receive in-person and online CBT-I (versus WL) will report fewer insomnia symptoms as measured by Insomnia Severity Index (ISI) at the post treatment assessment point (T2).*

Primary aims will be assessed using Generalized Estimated Equations (GEE) and an intent-to-treat (ITT) basis, including data for each participant who was randomized, regardless of their

adherence to the intervention or whether they withdraw from the study. Analyses including only patients fulfilling the treatment will also be conducted.

## Secondary Aims

*Hypothesis 2.1) Participants who receive in-person and online CBT-I (versus WL) will experience fewer symptoms of depression as assessed by the Edinburgh Postpartum Depression Scale (EPDS) and will be less likely to be diagnosed with depression as assessed using Structured Clinical Interview for the DSM-IV (SCID) at T2.*

*Hypothesis 2.2) Participants who receive online and in-person CBT-I (versus WL) will be less likely to be diagnosed with insomnia, as measured by the Insomnia Interview Schedule (21), at T2.*

*Hypothesis 2.3) Participants who receive in-person and online CBT-I (versus WL) will experience better objective sleep as assessed by actigraphy (higher sleep efficiency and lower sleep onset latency) at T2.*

Secondary aims including changes in actigraphy parameters, diagnosis of insomnia, symptoms of and diagnoses of depression will be examined. Changes in binary outcomes will be tested using Generalized Estimated Equations (GEE) with a binary outcome specified.

## RESEARCH MANAGEMENT

Dr. Tomfohr-Madsen, as the Primary Investigator will be responsible for the overall management of the project. She received extensive training in cognitive behavioral interventions and will be responsible for training clinical psychology master's students in the delivery of in-person cognitive behavioural therapy for insomnia adapted for pregnant women.

Dr. Campbell is an experienced clinician and will provide clinical support regarding the establishment of therapy protocols and ongoing consultation regarding fidelity to the CBT treatment protocol. Dr. Madsen will be responsible for supervising master's students in administering diagnostic interviews for Axis I mood disorders. Dr. Vincent will be responsible for supervising the research assistant at the University of Manitoba who will be coordinating the online portion of the intervention.

## RESEARCH ENVIRONMENT

All assessments and in-person CBT-I sessions will take place at the University of Calgary in a newly renovated research space designed specifically for conducting and evaluating evidence-based interventions which is located in suite 292 of the Education Classroom Building.

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## TABLES AND FIGURES

Figure 1: Research Design Flowchart

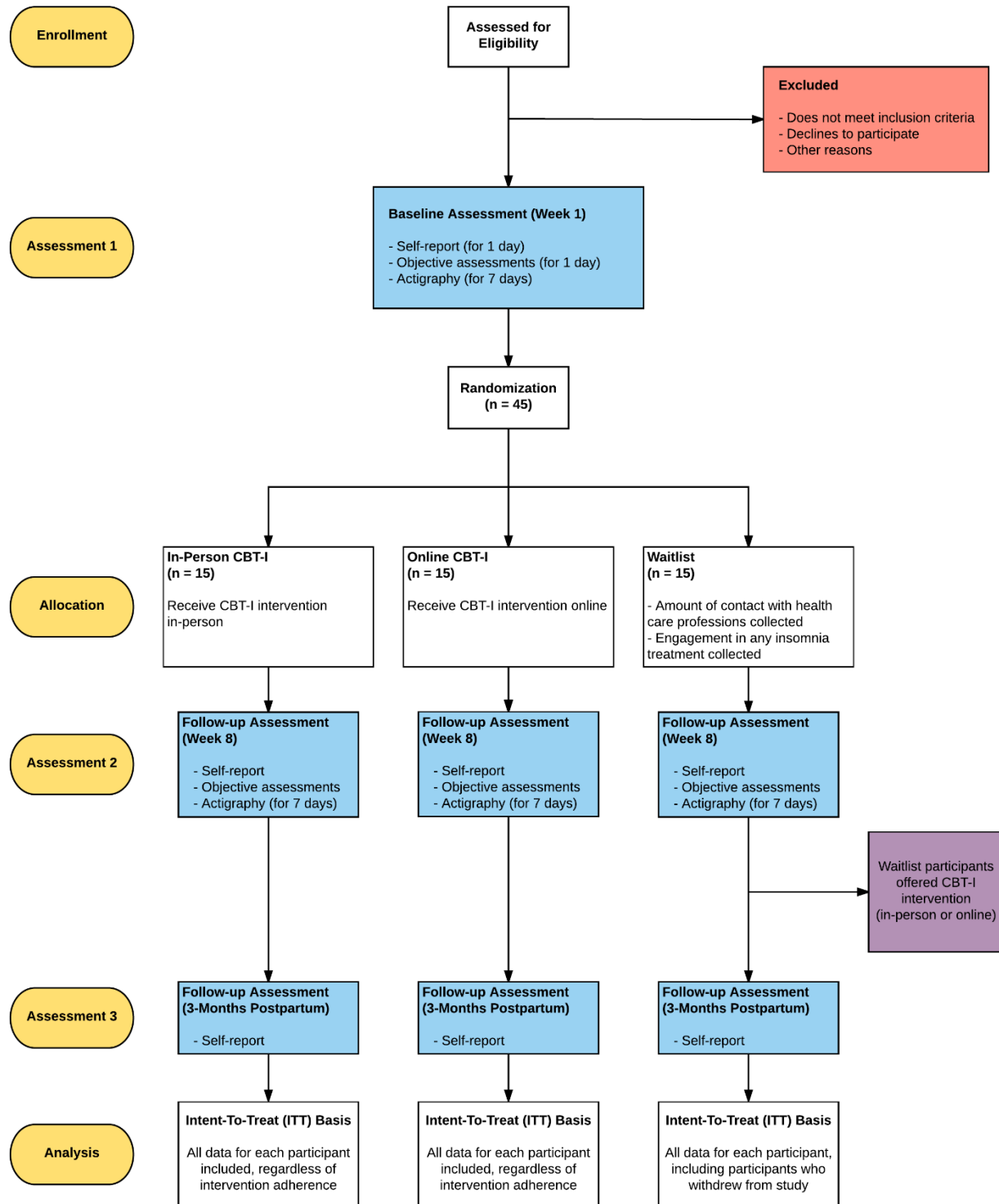




Table 1: Measurement Reliability and Validity

Measure	Description	Reliability and Validity
Insomnia Interview Schedule	Semi-structured interview, used to assess sleep history and insomnia complaints among participants. Gathers wide range of information about nature and severity of sleep problems. Assesses impact of insomnia on daytime functioning and quality of life [46].	Provides all relevant clinical information for assessment of insomnia, produces reliable and valid insomnia diagnoses [46].
Insomnia Severity Index	This 7-item questionnaire was designed to detect cases of insomnia and evaluate treatment outcomes. ISI can be used to assess the severity of sleep onset, sleep maintenance and early wakening problems, sleep dissatisfaction and one's perceived distress caused by the sleep problems [55, 74].	Researchers recommended the use of ISI for detecting cases of insomnia in the population and for examining treatment responses in clinical patients [55, 74].
Cambridge Hopkins Questionnaire for Restless Legs Syndrome	Validated, self-report assessment of restless legs syndrome. Includes questions designed to exclude common health issues that are similar to RLS symptomatology [51].	High specificity (94.4%) and sensitivity (87.2%) [51]. Previously used among pregnant women with good predictive value [75].
STOP Questionnaire	The 4-item measure includes questions about snoring, tiredness during the day, stopped breathing during sleep time, and hypertension [52].	Varied sensitivity of 76-96%, good negative predictive value among moderate to severe obstructive-sleep-apnea [52]. Used in previous research with pregnant women with great predictive value during last two trimesters [76].
Pittsburgh Sleep Quality Index	Used to assess sleep quality during previous month. 19 self-rated items, 5 questions rated by roommate or bed partner. Seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, daytime dysfunction. Score > 5 suggests bad sleep quality [26].	Excellent internal consistency (Cronbach $\alpha$ of 0.90 and 0.91). 86.1% sensitivity and 87.7% specificity for a cut-off score of 10. Validity confirmed by polysomnographic findings and sensitivity in discriminating patients from controls. Diagnostic sensitivity of 89.6% and specificity of 86.5% [26].

Multidimensional Fatigue Symptom Inventory-Short Form	30-item short form version of MFSI consists only empirically derived subscales, designed to assess general, physical, emotional and mental manifestations of fatigue [77].	Acceptable psychometric properties, can be safely used as substitute for the 83-item original version. Validity confirmed by correlation coefficient with relevant instruments (-0.21 to 0.82, $p<.001$ ), [77].
Dysfunctional Beliefs and Attitudes about Sleep Questionnaire	Cognitive scale used for assessing problematic levels of unhelpful beliefs about sleep. 16 items, 10-point Likert scale ranges from 0 (Strongly Disagree) to 10 (Strongly Agree). Captures four factors: perceived consequences of insomnia, worry/helplessness about insomnia, sleep expectations, and medication [78].	Total scores correlate with insomnia severity, anxiety, and depression, as measured by ISI and Beck Depression and Anxiety Measures, with adequate temporal stability ( $r=0.83$ ) [78].
Sleep Self-Efficacy Scale	9-item scale used for measuring one's level of confidence in carrying out specific sleep-related behaviors [79].	Has been found to predict response to CBT treatment for insomnia [80, 81].
Sleep Hygiene Index	13-item self-report items used for assessing presence of behaviors thought to compromise sleep hygiene. Assesses how frequently behaviors engaged in (always, frequently, sometimes, rarely, never). Higher total scores indicative of more maladaptive sleep hygiene status [82].	Adequate reliability (Cronbach's $\alpha$ of 0.66); superior to previously published sleep hygiene instruments. Good validity - positively correlated with the Epworth Sleepiness Scale ( $r(269)=0.244$ , $p<0.01$ ) and the Pittsburgh Sleep Quality Index total score ( $r(269)=0.481$ , $p<0.01$ ) [82].
Pre-Sleep Arousal Scale	16-item self-report measure assessing two subscales of pre-sleep somatic and cognitive arousal. Five-point Likert scale (1, "not at all" to 5, "extremely") used to rate extent to which each item is experienced [83].	Adequate internal consistency ( $\alpha = .76$ and $.81$ for somatic and cognitive scales, respectively), and elevated PSAS scores associated with sleep onset difficulties [83].
Glasgow Sleep Effort Scale	Measure of sleep-related effort. Example of an item: "I put off going to bed at night for fear of not being able to sleep" (Very much/To some extent/Not at all) [84].	Cronbach's $\alpha$ of 0.77, can discriminate between insomnia patients and "good sleepers". Good predictive value of presence of insomnia [84].

Sleep-Related Behaviors Questionnaire	Designed to assess use of safety behaviours to promote sleep and cope with tiredness, which are associated with impairment in sleep and daytime functioning. Scale will help determine effectiveness of treatment in reducing the use of unhelpful safety behaviours [85].	Good internal consistency, able to discriminate normal sleepers from those with insomnia [85].
Epworth Sleepiness Scale	It is a self-report 8-item questionnaire producing scores from 0 to 24. The scale is designed to assess the tendency to fall asleep in situations such as while working or driving. Scores greater than 10 suggest significant daytime sleepiness [86].	The Epworth Sleepiness Scale has good psychometric properties [86] correlates with objective measures of sleepiness, and has been shown to differentiate between individuals with and without sleep disorders [87].
Edinburgh Postnatal Depression Scale	Useful in identifying women at risk for depression. Scale items assess depressive symptoms including sleep disturbance, low energy and suicidal ideation [59].	Sensitivity and specificity varies by cut score, however, established as useful tool in field of perinatal mental health [88].
Generalized Anxiety Disorder	Brief measure for assessing symptoms of generalized anxiety disorder. Cut scores of 5, 10 and 15 considered to reflect mild, moderate and severe anxiety [89].	In perinatal research, sensitivity of 61.3% and specificity of 72.7% at cut score of 13. Researchers deemed scale useful in detecting perinatal anxiety symptomatology [90].
Couple Satisfaction Index	The CSI-16 scale will be administered to assess participants' relationship satisfaction. Consists of 16 six-point Likert Scale statements [91]	In comparison with relevant instruments, has higher precision of assessment, superior sensitivity for detecting satisfaction differences. Strong convergent and construct validity, Cronbach's $\alpha$ of .98 [91].
Big Five Inventory	Used for assessing five broad dimensions of personality traits (openness, conscientiousness, extraversion, agreeableness, neuroticism). Includes 44 five-point Likert scale items [92].	Review demonstrates good reliability and acceptable discriminant and convergent validity across several studies [92].

Actigraphy	Provides objective information on circadian rhythm amplitude, acrophase, and mesor as well as indices of sleep efficiency, sleep latency, total sleep time, and number and frequency of awakenings. Less costly and intrusive than polysomnography (gold standard in sleep measurement)	Satisfactory accuracy (high sensitivity, low specificity), recommended as reliable and useful method for assessment of sleep (de Souza et al., 2003). Actigraphic estimates for sleep percentage and sleep latency correlated 0.82 and 0.90 ( $p < .0001$ ) compared to polysomnography [93].
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