

Prenatal Care: *Original Research*

Cognitive Behavioral Therapy for Prenatal Insomnia

A Randomized Controlled Trial

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OBJECTIVE: To evaluate the effectiveness of cognitive behavioral therapy for insomnia during pregnancy.

METHODS: Randomized, unmasked, 3-site controlled trial. Participants were randomly allocated to cognitive behavioral therapy for insomnia (a first-line, empirically supported psychosocial intervention that addresses sleep-related behaviors and cognitions) or a control intervention consisting of imagery exercises that paired patient-identified distressing nighttime experiences with patient-identified neutral images. Participants were eligible if they met diagnostic criteria for insomnia disorder and were between 18 and 32 weeks of gestation. Patients were ineligible if they met diagnostic criteria for major psychiatric disorders, including depression, or were receiving nonstudy treatments that could affect sleep (or both). The primary outcome was the Insomnia

Severity Index score, a validated brief questionnaire, with scores between 14 and 21 representing clinically meaningful insomnia of moderate severity, scores higher than 21 representing severe insomnia, and scores less than 8 representing no insomnia. Secondary outcomes included remission of insomnia (Insomnia Severity Index score less than 8), objectively measured and self-reported time awake (ie, total wake time), and the Edinburgh Postnatal Depression Scale score. All outcomes were measured weekly. Analysis included 48 participants who did not complete treatment. We estimated that 184 women would be required to have 80% power, with a two-tailed test, to detect a moderate Cohen's *d* effect size (.5) with $\alpha=.05$.

RESULTS: Between May 2013 and April 2017, 194 pregnant women were randomized and 149 completed treatment; 179 with available baseline data (92%) were ultimately analyzed, 89 in the cognitive therapy group and 90 in the control group. Women assigned to cognitive behavioral therapy for insomnia experienced significantly greater reductions in insomnia severity (scores decreased from 15.4 ± 4.3 to 8.0 ± 5.2 in the cognitive behavioral therapy group vs from 15.9 ± 4.4 to 11.2 ± 4.9 in the control therapy group [$P<.001$, $d=0.5$]). Remission of insomnia (to an Insomnia Severity Index score less than 8) disorder was attained by 64% of women in the cognitive behavioral therapy for insomnia group vs 52% in the control group. Women receiving cognitive behavioral therapy for insomnia experienced faster remission of insomnia disorder, with a median of 31 days vs 48 days in the control therapy ($P<.001$). Cognitive behavioral therapy for insomnia led to significantly greater reduction in self-reported but not objective total wake time and a small but significantly greater decline in Edinburgh Postnatal Depression Scale scores vs the control group.

CONCLUSION: Cognitive behavioral therapy for insomnia is an effective nonpharmacologic treatment for insomnia during pregnancy.

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Poor sleep during pregnancy is common and is a normal part of pregnancy.¹ However, difficulties initiating or maintaining sleep that result in significant distress and impairment in daytime function constitute an insomnia disorder that cannot be assumed to resolve without intervention.² Questionnaire-based estimates of prevalence of insomnia during pregnancy range between 40% and 60%.^{3–5} This is significant because 50% of women with probable insomnia during pregnancy continue to have symptoms at 2 years postpartum⁴ and because insomnia is associated with comorbidities.⁶

Cognitive behavioral therapy for insomnia is a nonpharmacologic insomnia-focused psychotherapy, whose strong empirical support lead to its designation as the first-line treatment for insomnia by the American College of Physicians.⁷ Cognitive behavioral therapy for insomnia has also been identified by pregnant women as their treatment of choice, compared with pharmacotherapy and acupuncture.⁸ However, little is known about its effectiveness for prenatal insomnia. Only two small nonrandomized studies have examined the effectiveness of approaches based on this therapy during pregnancy.^{9,10}

The aim of this randomized controlled trial (RCT) was to assess the efficacy of cognitive behavioral therapy for insomnia in an ethnically diverse sample of pregnant women who were not depressed and did not receive any other treatments for insomnia disorder. The primary outcome was the Insomnia Severity Index score,¹¹ commonly used as the primary outcome in contemporary RCTs of insomnia; secondary outcomes were rates of remission of insomnia disorder, objective and self-report measures of time awake at night (ie, total wake time), and the Edinburgh Postnatal Depression Scale.¹²

METHODS

Participants were recruited from university-based obstetric clinics (Stanford University) and county hospital-based obstetric clinics (Santa Clara Valley Medical Center) and through community advertising. The protocol was approved by institutional review boards at Stanford University and the Santa Clara Valley Medical Center and all participants provided signed informed consent.

To be eligible, participants needed to speak English or Spanish, be between 18 and 32 weeks of gestation at the screening visit and meet *Diagnostic and*

Statistical Manual for Mental Disorders (DSM) criteria for insomnia, which include complaints of difficulty initiating or maintaining sleep at least three times a week that is associated with dissatisfaction with sleep quantity or quality and leads to clinically significant impairment in social, occupational, educational, academic, behavioral, or other important areas of functioning, despite having adequate opportunity for sleep.² We used the Fifth Edition criteria; however, for the minimum duration criterion, we used the 1-month DSM-IV-TR rather than the 3-month DSM 5 criterion. This was done to broaden the clinical relevance of our findings. We reasoned that it is important to test the intervention in a sample that includes women whose clinically significant sleep difficulties emerge during pregnancy, even when the duration of the symptoms was less than 3 months. Participants were excluded if they had an uncontrolled thyroid or seizure disorder or met diagnostic criteria for major depressive disorder (current), bipolar disorder (lifetime), panic disorder (if symptoms included nocturnal panic attacks that occurred more than four times in the past month), posttraumatic stress disorder (current), any thought disorders (lifetime), or substance abuse or dependence disorders (during pregnancy). Exclusion criteria were concomitant use of substance for sleep, including prescription sleep medications, melatonin, and cannabis; use of stimulants; current ongoing nonpharmacologic treatments for insomnia (eg, massage or acupuncture); or having ever received cognitive behavioral therapy for insomnia. Additional exclusion criteria were comorbid sleep disorders that could better explain sleep problems based on a screening diagnostic interview¹³ and review of medical history, including obstructive sleep apnea (previously diagnosed, with apnea–hypopnea index greater than 15 that was not [or inadequately] treated, or suspected sleep apnea owing to presence of loud snoring or observed gasping or pauses in breathing), previously diagnosed periodic limb movement disorder with arousal index of at least 15, restless legs syndrome occurring three or more times per week with an onset before pregnancy and duration of at least 1 month, severe circadian rhythm sleep–wake disorders, and nightmare disorder or other parasomnias occurring more than once a week.

Participants were randomized with equal probability to one of two treatment groups: cognitive behavioral therapy for insomnia or a control insomnia therapy. Separate randomization lists were generated for each of the three recruitment sites. Randomization was performed using blocked randomization with random block sizes of 2, 4, and 6,¹⁴ from which

a person independent of the research team created sequentially ordered opaque envelopes containing assigned treatment condition. When a participant became eligible, the treatment coordinator (author N.S.) opened an envelope containing treatment assignment, assigned a participant to a treatment condition and a therapist, and coordinated scheduling of sessions. To keep the research team blinded to treatment condition, the treatment coordinator served as the interface between the research team and the therapists; additionally, participants were instructed to not discuss their therapy with the outcome assessors.

Both treatments (cognitive behavioral therapy for insomnia and control therapy for insomnia) consisted of five individual therapy sessions provided in English or Spanish, based on each participant's preference. We trained therapists who were naive to cognitive behavioral therapy for insomnia to competency in delivering this therapy or the control therapy. A different therapist provided cognitive behavioral therapy for insomnia and control therapy. Control therapists and patients were told that the study will test two nonpharmacologic interventions for insomnia, a standard treatment and an arousal-based treatment. Training consisted of didactic and experiential learning using standardized patient scenarios ("standardized patients"). Cognitive behavioral therapy for insomnia therapists' competency was ascertained by authors R.M. and N.S., who rated recorded practice sessions using the Competency Rating Scale for cognitive behavioral therapy for insomnia¹⁵; control therapists' competency was ascertained in a similar manner, using an adapted version of the Competency Rating Scale to assess the core skills of the control therapy. Sessions were recorded, and 10% of the recorded sessions from each therapist that were conducted in English were randomly selected and rated for fidelity.

Cognitive behavioral therapy for insomnia is a skill-based, nonpharmacologic treatment for insomnia. The treatment protocol included general education about sleep and sleep during pregnancy, as well as information about healthy sleep habits; sleep restriction therapy,¹⁶ modified for pregnancy with initial time in bed recommendations equal to average total sleep time plus 30 minutes (and never less than 5.5 hours); stimulus control¹⁷; strategies for reducing cognitive and somatic hyperarousal; and relapse prevention. Cognitive therapy¹⁸ was provided throughout the intervention to address sleep interfering thoughts as needed. Therapy also included education about infant sleep development and elements from *Tips for Improving Postpartum Sleep*.¹⁹

The control therapy was a modified pseudo-desensitization therapy for insomnia, which has been previously and successfully used as a credible control treatment in RCTs of cognitive behavioral therapy for insomnia that produces low remission rates (eg, between 8% and 29%)²⁰⁻²² and low percent reduction in wakefulness.²⁰ This control therapy offers control for attention and passage of time. Pseudo-desensitization therapy for insomnia includes general education about sleep and sleep during pregnancy, as well as information about healthy sleep habits (but not sleep restriction or stimulus control recommendations); creating a hierarchy of sleep-related distressing situations and a list of neutral situations; and desensitization exercises based on the created hierarchy. Therapy also included education about infant sleep development.

Screening measures included the Duke Structured Interview for Sleep Disorders and the MINI International Neuropsychiatric Schedule.^{13,23} The primary outcome was the Insomnia Severity Index score, a validated brief questionnaire, with scores between 14 and 21 representing clinically meaningful insomnia of moderate severity, scores higher than 21 representing severe insomnia, and scores less than 8 representing no insomnia.^{11,24} Consequently, insomnia remission was defined as an Insomnia Severity Index score of less than 8. The Insomnia Severity Index score was collected at baseline and weekly thereafter. Following recommendations for a standard research assessment of insomnia,²⁵ sleep outcomes included actigraphy (Actiwatch ACT2) and the Consensus Sleep Diary,²⁶ from which we derived objective and self-reported total wake time, defined as time (minutes) awake during the sleep opportunity period. Participants were asked to complete the sleep diary daily and wear the Actiwatch continuously on their nondominant hand from baseline until 1 week after the end of treatment. They also completed the Edinburgh Postnatal Depression Scale¹² weekly. The Edinburgh Postnatal Depression Scale has been validated for use during pregnancy, with positive screen cutoffs ranging between 10 and 15 depending on the sample studied and the balance between specificity and sensitivity.²⁷⁻²⁹

All analyses were conducted on all randomized participants who provided baseline data. Women who did not provide baseline data dropped out before learning what treatment they would receive. The Cox proportional hazards model was conducted to examine whether time to insomnia remission differed significantly between cognitive behavioral therapy for insomnia and the control therapy. We also

reported the number of patients needed to treat (NNT) to have one patient whose insomnia remitted by the end of the treatment. Changes in continuous outcomes, including weekly Insomnia Severity Index score and Edinburgh Postnatal Depression Scale score (without the sleep item, to reduce symptom overlap), and nightly total wake time measured by sleep diary and actigraphy were examined using mixed effect models with auto-regressive error structures. The time variable (days since baseline) was set to be 0 for baseline, then log-transformed to accommodate non-linear change after treatment began. Based on a priori analytic plan, primary analyses included time, group, site, and their two- and three-way interactions. A significant time by group interaction indicates a significant difference in the change of outcomes over time between treatment groups. We further examined whether outcomes differed by treatment language (English or Spanish), Hispanic ethnicity (yes or no), and gestational week at the first treatment session by testing their main and interaction effects with time and group, controlling for site. In all analyses, the independent variables were centered following procedures recommended by Kraemer and Blasey.³⁰ Examining residuals of random effects and multivariate normality identified a few (up to 4 for any variable) influential cases. Sensitivity analysis revealed that removing such cases did not change findings. Data were analyzed in R 3.5.³¹ Effect sizes for continuous variables were quantified using Cohen's *d*, with values higher than 0.2, 0.5, and 0.8 suggesting small, moderate, and large effect sizes, respectively.³² We estimated that 184 women would be required to have 80% power to detect a moderate Cohen's *d* effect size (.5) across the treatment period, with $\alpha=.05$, using two-tailed tests.

RESULTS

From May 2013 to April 2017, 254 participants completed screening and 194 were randomized (See Fig. 1 for details on reasons for exclusion); of these, 15 did not provide baseline data for the primary outcome measure and were therefore excluded. The 15 participants who discontinued participation before providing baseline data on clinical measures did not differ demographically from participants who were analyzed for testing a priori hypotheses. Thus, the analyzable sample consisted of 179 pregnant women, of whom 71 (90%) in the cognitive therapy group and 63 (79%) in the control group completed the assigned intervention (Fig. 1). The two groups had similar baseline characteristics except that the cognitive behavioral therapy for insomnia group had higher

Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *Individual participant data will be available, after de-identification, beginning 12 months and ending 5 years after article publication to researchers who provide a methodologically sound proposal.*

What data in particular will be shared? *The data to be shared will be for the purpose of achieving the aims in the approved proposal and will be available through Stanford Digital Repository (SDR).*

What other documents will be available? *Other documents available will include data dictionaries and the time points at which measures were collected.*

When will data be available (start and end dates)? *Not applicable.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Not applicable.*

baseline Edinburgh Postnatal Depression Scale scores (Table 1).

On average, participants who completed the baseline phase and began treatment received 4.6 ± 1.0 sessions.³³ Cognitive behavioral therapy for insomnia participants received 4.8 ± 0.7 sessions and control therapy participants received 4.4 ± 1.2 sessions. Treatment fidelity was high. Among the 10% of recorded sessions randomly selected for fidelity rating by an independent rater, there were no instances in which elements of control therapy were detected in cognitive behavioral therapy for insomnia sessions, and there was only one instance in which a single cognitive behavioral therapy for insomnia element was observed in a control therapy session. There were no unanticipated serious adverse events related to either of the two treatments, as determined by the Data Safety and Monitoring committee and the study investigators.

Participants who received cognitive behavioral therapy for insomnia had greater improvement in insomnia symptom severity (the primary study outcome) than those assigned to control therapy ($P < .01$; $d = 0.5$, Table 2, Fig. 2). Model statistics are in Appendix 1, available online at <http://links.lww.com/AOG/B328>. We found no statistically significant differential treatment effects on insomnia severity for women of Hispanic ethnicity ($P = .17$), for those who chose to receive treatment in Spanish ($P = .28$), or by gestational week on commencing treatment ($P = .74$).

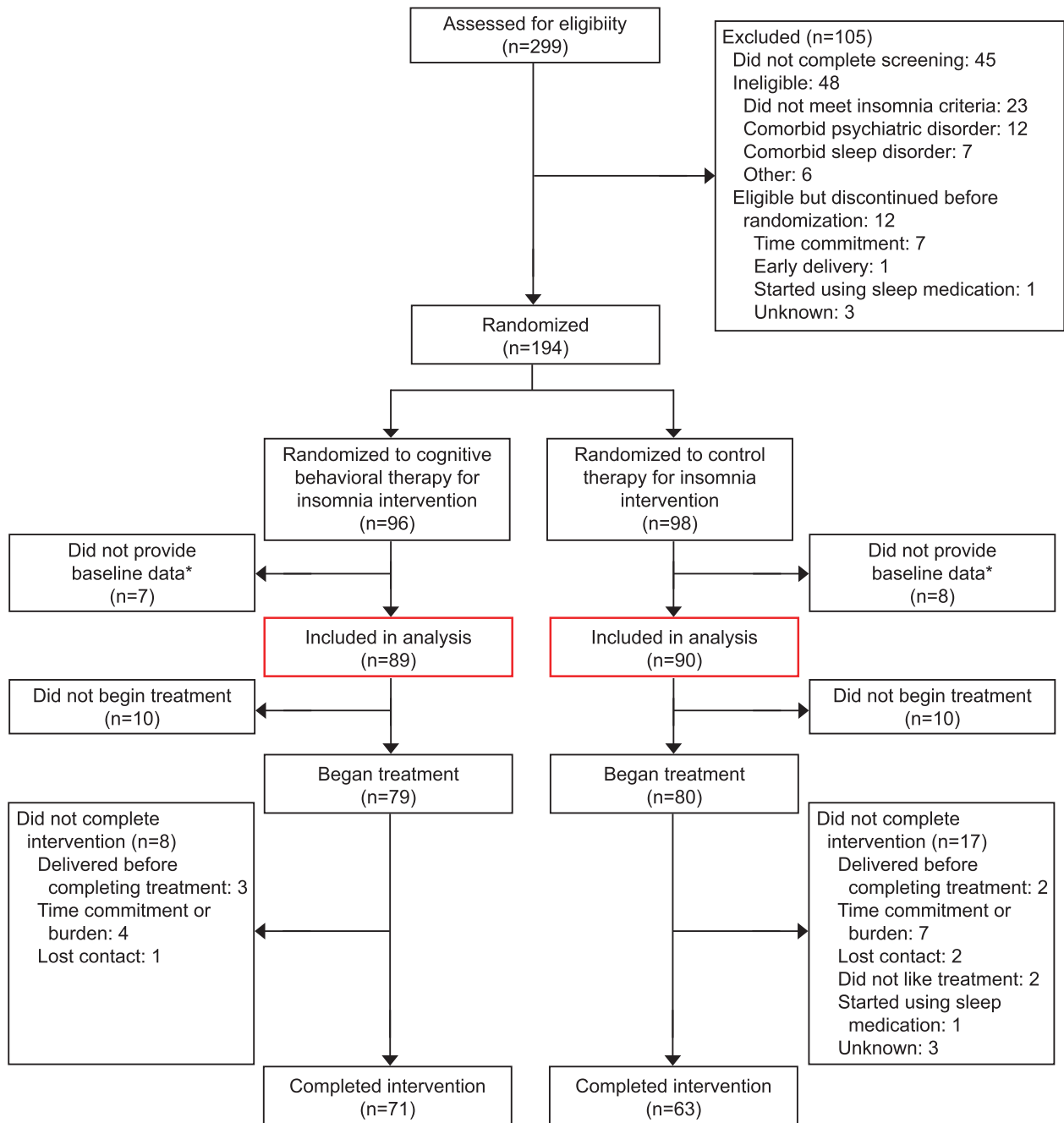


Fig. 1. Participant flowchart. Red boxes indicate that women who did not start or complete treatment were included. *Women who did not complete baseline data dropped out before learning which treatment they were assigned. Manber. *Nondrug Therapy for Prenatal Insomnia. Obstet Gynecol* 2019.

The Cox proportional hazards model revealed a significantly shorter time to remission of insomnia (Insomnia Severity Index score less than 8) among those assigned to cognitive behavioral therapy for insomnia (31 days) compared with control therapy (48 days; $P < .001$), with 63.8% of participants assigned to cognitive behavioral therapy for insomnia attaining remission by

the end of treatment, compared with 51.9% of control therapy participants (Fig. 3). The hazard ratio is 2.55 (95% CI 1.51–4.32), $P < .001$. The NNT for the difference between rates of remissions is 8. The NNT for the Cox proportional hazards model, taking into account the fact that the final remitting event occurred at different times for the two groups, is 3.05 (95% CI 1.53–4.57).

Table 1. Descriptive Statistics of Sample Characteristics at Baseline

Characteristic	CBTI (n=89)	CTRL (n=90)
Age (y)	33.4±5.2	32.6±4.9
Race		
White	44 (49.4)	42 (46.7)
Black	4 (4.5)	2 (2.2)
Asian	12 (13.5)	14 (15.6)
Other	25 (28.1)	26 (28.9)
Unknown	4 (4.5)	6 (6.7)
Hispanic ethnicity	30 (33.7)	38 (42.2)
Gestational age (wk)	24.5±4.9	25.0±5.0
Nulliparous	50 (56.2)	52 (57.8)
Therapy in Spanish	22 (24.7)	21 (23.3)
ISI score	15.9±4.3	15.4±4.4
EPDS score	9.2±4.6	7.9±4.2

CBTI, cognitive behavioral therapy for insomnia (intervention group); CTRL, control therapy; ISI, Insomnia Severity Index; EPDS, Edinburgh Postnatal Depression Scale. Data are mean±SD or n (%).

For both groups, self-reported total wake time reduced significantly over time ($P<.001$), with cognitive behavioral therapy for insomnia participants experiencing significantly greater reduction compared with control therapy participants ($P<.001$; $d=0.50$). Changes over time in objective total wake time were not statistically significant ($P=.74$) and the effect size for difference between treatment groups was small ($d=.18$). Means appear in Table 2 and model statistics in Appendix 1, <http://links.lww.com/AOG/B328>. We did not detect statistically significant differences in treatment effects on self-reported or objective total wake time, controlling for ethnicity, treatment language, or gestational week on commencing treatment (all P -values $>.44$).

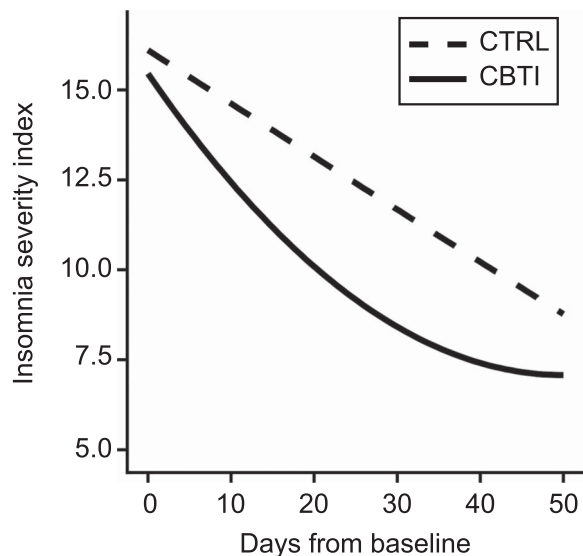


Fig. 2. Model estimated changes in insomnia symptom severity for the intervention (cognitive behavioral therapy for insomnia [CBTI]) and control therapy for insomnia groups (CTRL).

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There was an overall statistically significant reduction in EDPS scores over time ($P<.001$), but the effect size for difference between treatment groups was small ($d=0.15$) (Table 2 and Appendix 1, <http://links.lww.com/AOG/B328>).

DISCUSSION

Women assigned to cognitive behavioral therapy for insomnia experienced significantly greater reductions in insomnia severity and faster remission of insomnia disorder, with 64% of participants receiving cognitive

Table 2. Descriptive Statistics of Outcome Variables and Effect Sizes of Group Differences in Change

Outcome Variable	CBTI (n=89)		CTRL (n=90)		Cohen's d
	Baseline	Postintervention	Baseline	Postintervention	
ISI score (primary outcome)	15.4±4.3	8.0±5.2	15.9±4.4	11.2±4.9	0.50
Remission [% (95% CI)]	63.8 (44.6–75.4)		51.9 (23.6–69.8)		—
Median time to remission (d)*	31		48		—
Actigraphy TWT (min)	98.5±39.7	95.2±51.2	90.8±26.3	94.6±33.0	0.18
Sleep diary TWT (min)	84.2±50.2	47.8±32.8	99.9±61.1	86.6±58.4	0.50
EPDS (no sleep item)	7.2±3.7	3.8±3.6	8.2±3.8	5.5±4.0	0.15

CBTI, cognitive behavioral therapy for insomnia; CTRL, control therapy; ISI, Insomnia Severity Index; EPDS, Edinburgh Postnatal Depression Scale; TWT, total wake time.

Data are mean±SD unless otherwise specified.

Remission is defined by an ISI of no greater than 8.

Values in the table are based on all participants who attended at least one session ($n=159$). Last available observation (for actigraphy and sleep diary, the mean over the last available 7 days) were used for postintervention values.

* The number needed to treat (NNT) for the difference between rates of remission is 8; the NNT effect size for the model, taking into account the fact that the final remitting event occurred at different times for the two groups, was 3.05 (95% CI 1.53–4.57).

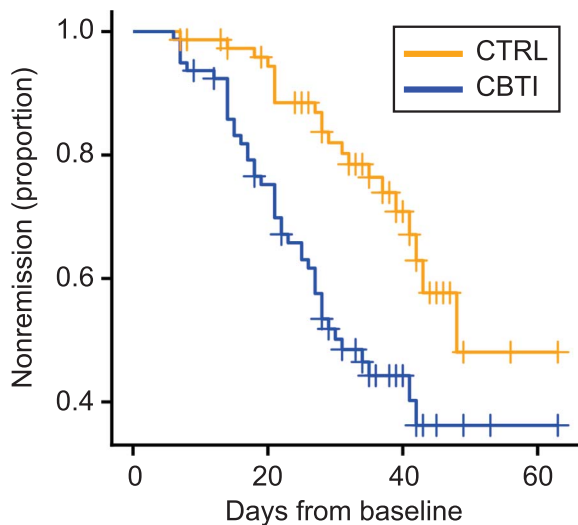


Fig. 3. Survival curves derived from Kaplan-Meier analysis. Time to insomnia nonremission for the intervention (cognitive behavioral therapy for insomnia [CBTI]) and control conditions (CTRL). The analysis was based on all participants who provided at least one postbaseline Insomnia Severity Index score; remission is defined by Insomnia Severity Index score less than 8. Hazard ratio=2.55 (95% CI 1.51–4.32). Number needed to treat for the difference between rates of remissions was 8. Number needed to treat effect size for the model, considering the fact that the final remitting event occurred at different times for the two groups, was 3.05 (95% CI 1.53–4.57).

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behavioral therapy for insomnia experiencing remission of insomnia at the last available observation. Improvements in insomnia over the course of pregnancy are particularly notable because sleep typically worsens later in pregnancy.⁸ Moreover, because cognitive behavioral therapy for insomnia led to a 17-day faster remission of insomnia disorder (median days to remission=31), it offers an effective treatment option even late in pregnancy. Notably the remission rate in control therapy (52%), though lower than in cognitive behavioral therapy for insomnia, was higher than previously reported in samples with comorbid depression and insomnia.^{21,22} This suggests a stronger placebo effect during pregnancy than is seen for comorbid insomnia and depression.

There was a moderate effect size for improvement in self-reported time awake at night. Women in the cognitive behavioral therapy for insomnia group reported a baseline-to-end-of-treatment reduction in

time awake at night of 37 minutes and those in the control therapy group reported a reduction of only 13 minutes. However, the actigraphs detected an average of only 3 minutes' reduction of total wake time from baseline to end of treatment in each treatment group. Discrepant findings in subjective compared with objective changes in sleep are not surprising given previous reports of low agreement between actigraphy and self-reported sleep among pregnant women (39% overestimated and 23% underestimated their sleep duration by more than an hour.³⁴) The observed discrepancy may be related to different levels of attention to, and distress about, sleep difficulties. It is possible that cognitive behavioral therapy for insomnia helped women be less distressed about sleep problems, including those caused by increased pregnancy related discomfort with increased gestational week. Self-reported sleep is clinically relevant because it guides health seeking behaviors and appears to be a stronger predictor of maternal mental health than objective sleep.³⁵

Our adequately powered RCT had a few notable strengths that support its generalizability, including rigorous methodology and sample heterogeneity. To promote sample heterogeneity, we recruited participants from the community, university-based obstetric clinics and public hospital-based obstetric clinics, where 78% of the recruited participants were of Hispanic ethnicity. To promote and facilitate participation of women of Hispanic ethnicity, who comprised 38% of the total sample, we offered treatments in both English and Spanish.

Our study also had some limitations. First, 15 randomized participants dropped out of the study before completing the baseline assessment and were therefore not included in the analysis. This dropout was an artifact of our protocol implementation, whereby participants were randomized as soon they became eligible, and usually before their baseline assessment. It is unlikely that this limited the generalizability of the results both because these women did not know what treatment they would receive when they dropped out and also because they did not differ demographically from the rest of the sample. Also, only 75% of participants completed their assigned intervention. A second potential limitation is that actigraphy has not yet been validated for use during pregnancy. This is important because the actigraphs might register fetal movement and leg movements as wakefulness. It is possible that the reason for the small change in actigraphy-based wake time results from continued negative effect of pregnancy on maternal sleep (eg, through increased physical discomfort

during sleep). Exclusion of women with comorbid psychiatric conditions is another potential limitation, as these conditions are often comorbid with insomnia.⁶ Finally, we note that we cannot infer from these results whether cognitive behavioral therapy for insomnia will be effective for prenatal sleep disturbances that do not rise to the diagnostic threshold for insomnia disorder.

We hope that our findings will lead to increased use of cognitive behavioral therapy for insomnia among pregnant women through referrals to trained therapists. Although cognitive behavioral therapy for insomnia is covered by health insurance, access is currently limited. However, access is gradually increasing through greater availability of trainings and of health insurance coverage for tele-mental-health, and development internet-based versions of cognitive behavioral therapy for insomnia,³⁶ though their use during pregnancy has not been tested.

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Letters

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