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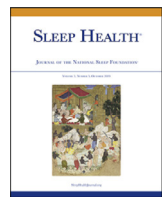
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## Racial disparities in treatment engagement and outcomes in digital cognitive behavioral therapy for insomnia among pregnant women

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## ABSTRACT

**Objectives:** In the United States, Black women are disproportionately afflicted with prenatal insomnia. Although cognitive-behavioral therapy for insomnia (CBTI) may represent a strategy to reduce disparities in insomnia, racial minorities attend fewer healthcare appointments and have poorer outcomes from prenatal care and mental health treatment relative to white patients. The present study examined differences in treatment engagement and patient-reported outcomes in non-Hispanic Black and white pregnant women receiving digital CBTI.

**Methods:** Secondary analysis of 39 pregnant women with clinical insomnia who received digital CBTI. Treatment engagement was operationalized as the number of sessions completed ( $\geq 4$  considered an adequate dose). Treatment outcomes were assessed using the Insomnia Severity Index (ISI; insomnia) and Pittsburgh Sleep Quality Index (PSQI; global sleep disturbance).

**Results:** Black women were 4 times more likely than white women to discontinue CBTI before receiving an adequate dose (8.3% vs. 33.3%). Regarding treatment outcomes, white women reported a mean reduction of 5.75 points on the ISI and a reduction of 3.33 points on the PSQI (Cohen's  $d_z = 1.10$ -1.19). By comparison, Black women reported reductions of 2.13 points on the ISI and 1.53 points on the PSQI, which were statistically non-significant. Differences in treatment engagement did not account for the disparities in patient-reported outcomes.

**Conclusions:** During pregnancy, Black women completed fewer CBTI sessions and experienced poorer treatment outcomes in response to digital CBTI relative to white women. Enhancements to insomnia therapy and its digital delivery may improve adherence and outcomes in Black pregnant women.

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## Introduction

In the United States, long-standing social and structural racism has put Black women at much higher risk for mental illness and adverse pregnancy outcomes—including hypertension and preterm birth<sup>1-6</sup>—than white women. Importantly, racism is associated with greater insomnia among Black Americans,<sup>7,8</sup> thus, it is unsurprising that Black women are 50% more likely than white women to endorse clinical insomnia during pregnancy.<sup>9</sup> As prenatal insomnia increases risk for maternal depression,<sup>10</sup> gestational hypertension,<sup>11</sup> preterm birth,<sup>12</sup> and other adverse outcomes, interest has grown in the role of poor sleep in perinatal complications.<sup>13,14</sup> Given the contribution of

sleep problems to racial disparities in perinatal complications, one strategy to reduce the disproportionate burden of insomnia for Black pregnant women is to identify insomnia treatments that are equally effective across racial groups in pregnancy.

The recommended treatment for insomnia disorder in the general patient population is cognitive-behavioral therapy for insomnia (CBTI).<sup>15</sup> Recently, data from randomized controlled trials (RCTs) support CBTI efficacy in pregnant women when delivered in-person<sup>16</sup> and digitally,<sup>17,18</sup> but about half of pregnant CBTI recipients do not adequately respond to therapy.<sup>16-18</sup>

A burgeoning literature highlights alarming racial disparities in mental health treatment outcomes among minoritized people in the United States, particularly Black Americans, who experience greater barriers to engage in and benefit from mental health treatment.<sup>19-21</sup> Despite racial disparities in mental health treatment engagement

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and outcomes, clinical research in insomnia disorder treatment suggests CBTI may be equally effective across races.<sup>22-24</sup> That is, race is not a reliable predictor of CBTI response in the general insomnia patient population. On the other hand, RCT data suggest that Black insomnia patients endorse higher levels of insomnia after treatment than white patients, even when race was not a significant moderator.<sup>24</sup> Race has not been thoroughly examined as a pretherapy factor associated with CBTI response in the pregnant population. This is an important gap in the literature as pregnancy is a stressful period in life that may exacerbate social determinants of health and potentiate racial disparities in treatment engagement and response. Given the high prevalence of insomnia among Black pregnant women,<sup>9</sup> available treatment options must be accessible and effective across racial groups.

The present study was a secondary analysis of an RCT that supported the efficacy of digital CBTI in pregnant women with clinically significant insomnia symptoms.<sup>18</sup> We analyzed data from CBTI patients who self-identified as non-Hispanic Black and non-Hispanic white (the only 2 racial groups with sufficient representation for analysis) to achieve 2 primary goals. First, we sought to determine whether treatment engagement differed by race. Consistent with the literature on racial disparities in treatment engagement,<sup>19-21</sup> we predicted that Black women would complete fewer sessions of digital CBTI than white women, and thus would be less likely to receive an adequate dose of CBTI (operationalized as  $\geq 4$  sessions<sup>25</sup>). Second, we tested for racial disparities in patient-reported outcomes of insomnia symptoms and sleep quality after CBTI. We predicted that Black women would have poorer response (operationalized as reduction in symptoms) to CBTI than white women. Notably, our team previously identified refractory cognitive arousal (cognitive arousal symptoms that do not alleviate with treatment) as a robust predictor of poor CBTI response.<sup>26</sup> As the present study examines racial disparities in CBTI response, we evaluated whether race-related differences were evident when controlling for refractory cognitive arousal.

Finally, we conducted exploratory analyses to disentangle effects of race and treatment engagement in treatment response. We hypothesized that race-related differences in CBTI response would be non-significant after accounting for differences in treatment engagement.

## Methods

### Study design

The trial was registered at ClinicalTrials.gov (#NCT03596879). We invited women within our 6-hospital health system who were nearing or entering the third trimester of pregnancy (identified via ICD codes in electronic medical records) to participate in an RCT comparing the efficacy of digital CBTI vs. digital sleep education control. Women interested in participating were screened for eligibility via an online survey. Eligible participants were randomized to digital CBTI or control. Full details on study methods and primary efficacy results are reported elsewhere.<sup>18</sup> This study was approved by the Institutional Review Board at the study site. All patients provided written informed consent.

In this secondary analysis of racial disparities in CBTI engagement and patient outcomes, we analyzed only data from women who self-identified as non-Hispanic Black ( $n = 15$ ) and non-Hispanic white ( $n = 24$ ); the only 2 racial groups with sufficient representation for comparison. See Fig. 1 for study enrollment diagram.

### Study intervention

**Digital CBTI.** Patients randomized to CBTI completed the Sleepio program, which is efficacious in pregnancy,<sup>17,18,27</sup> via the internet ([www.sleepio.com](http://www.sleepio.com), Big Health Inc). Sleepio is led by a virtual therapist avatar who is depicted as a white male and involves 6 sessions that cover behavioral sleep strategies, cognitive therapy, relaxation,

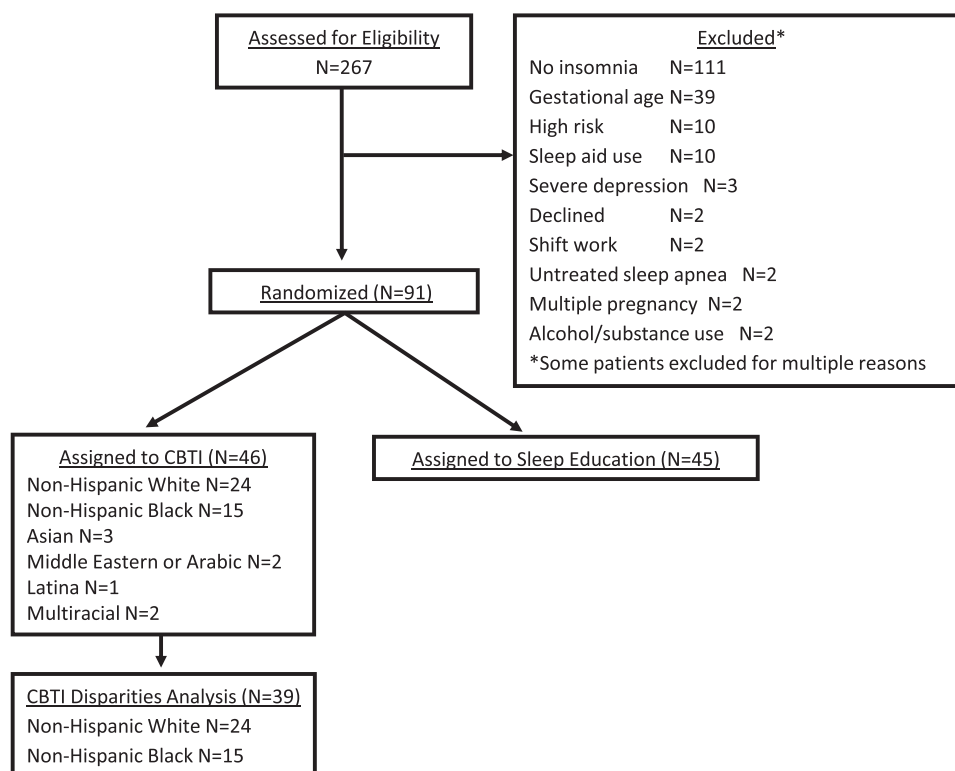


Fig. 1. Patient enrollment flow diagram

and sleep hygiene. To avoid excessive sleepiness, we modified the program so that time in bed could not be prescribed < 6 hours in sleep restriction.

### Study variables

All study variables were assessed during pregnancy via online surveys in Qualtrics at pre-treatment assessment (1-2 weeks before CBTI) and post-treatment assessment (1 week after completing or discontinuing CBTI).

Sociodemographics, health information, and perinatal health. At screening, patients provided sociodemographic and health information, including age, race, marital status, poverty (annual income <\$20,000), and parity. Patients reported whether they snore (Yes/No). Body mass index (BMI) was derived from electronic medical records: we analyzed BMI recorded at initial obstetrics appointment, which is a more robust predictor of prenatal sleep problems than BMI later in pregnancy.<sup>9</sup>

Treatment engagement was operationalized as number of sessions completed, which was derived from the Sleepio clinician portal. As a previous study evaluating CBTI dose-response showed that attending  $\geq 4$  sessions is adequate, we used this dose to define completion (referred to as “CBTI completers” below).<sup>25</sup>

Patient-reported outcomes. As we treated women in the third trimester (mean gestational age when completing CBTI was 36 weeks), we assessed post-treatment outcomes 1 week after treatment to minimize likelihood that patients would deliver before the post-treatment assessment. As such, post-treatment surveys were oriented to measure symptoms over the previous week.

The Insomnia Severity Index (ISI) measured insomnia symptom severity.<sup>28,29</sup> The original assessment window for the ISI is the prior 2 weeks. Scores range from 0 to 28, with higher scores indicating greater severity. ISI  $\geq 10$  has excellent sensitivity (.842) and specificity (.812) for detecting DSM-5 insomnia disorder in pregnant women.<sup>30</sup> Moreover, ISI scores  $\leq 7$  represent remission in clinical trials<sup>29</sup> and yield adequate sensitivity (.700) and excellent specificity (.889) for detecting good sleep in pregnancy.<sup>30</sup>

Global sleep disturbance was measured using the Pittsburgh Sleep Quality Index<sup>31</sup> (PSQI), which assesses a wide range of sleep parameters over the previous month, including sleep duration, sleep latency, sleep aid use, and sleep difficulties related to insomnia, breathing difficulties, environmental stimuli, and other factors. A global cutoff score of PSQI > 5 differentiates poor sleepers from good sleepers, which has been supported in pregnancy.<sup>30</sup> In addition to measuring global sleep disturbance, we used the PSQI to assess habitual sleep duration (item #4a). Short sleep was operationalized as  $\leq 6$  hours of nightly sleep.

Nocturnal cognitive arousal was measured using the Pre-Sleep Arousal Scale's Cognitive factor (PSASC),<sup>32</sup> which has been validated for use in pregnant women.<sup>30</sup> PSASC scores range from 8 to 40, with higher scores indicating greater cognitive arousal while trying to fall asleep at night. Refractory cognitive arousal—that is, PSASC scores that do not alleviate with treatment—is a robust predictor of poor CBTI response.<sup>26</sup> In the present study,  $\Delta$ PSASC represents change in PSASC and is operationalized as PSASC<sub>post-treatment</sub> – PSASC<sub>pre-treatment</sub>. Thus,  $\Delta$ PSASC scores  $\geq 0$  indicate refractory cognitive arousal (ie, PSASC scores do not decrease with CBTI). PSASC is included to rule out any potential confound between race and refractory cognitive arousal on CBTI response.

### Analysis plan

Analyses were performed in SPSS version 26 (IBM Corp) with alpha set at .05. Given the small sample size, we acknowledged test results approaching statistical significance ( $.05 < p < .10$ ) in the

Results section when consistent with the overall pattern of study findings. We analyzed data from 39 CBTI patients who self-identified racially as non-Hispanic Black or non-Hispanic white. We report sociodemographics and pre-treatment clinical symptoms for the full sample and separately by race.

The first study goal was to examine whether treatment engagement differed by race; the primary endpoint was number of sessions completed. We conducted an independent samples t-test comparing number of sessions completed between white and Black women and then a  $2 \times 2$  chi-square analysis comparing rates of CBTI completion ( $\geq 4$  sessions) by race.

The second study goal was to determine whether treatment outcomes differed by race; the primary endpoints were changes in ISI and PSQI from pre-treatment to post-treatment. Using independent samples t-tests, we compared changes in ISI/PSQI to evaluate whether symptom reductions differed between Black and white CBTI patients. We then conducted post hoc paired samples t-tests separately by race to explore whether reductions in ISI/PSQI were significant within white and Black CBTI patients and to estimate effect sizes within each racial group. Effect sizes for paired samples t-tests accounted for the correlated nature of the data, reported as Cohen's  $d$ .<sup>33</sup>

We then conducted an exploratory analysis of interrelationships among race, treatment engagement, and CBTI response. Using multivariate regression, we regressed post-treatment ISI onto race and sessions completed while controlling for pre-treatment ISI, refractory cognitive arousal, marital status, poverty, BMI, short sleep duration. The goal of this analysis was to determine whether race predicted post-treatment ISI even after accounting for the effects of treatment engagement. This exploratory model was then repeated for change in PSQI as the primary endpoint.

## Results

### Sample characteristics

Of the 39 participants included in this secondary analysis, 24 self-identified as non-Hispanic white, and 15 self-identified as non-Hispanic Black. The median gestational age at the start of CBTI was 29 weeks. Although pre-treatment insomnia severity did not differ between groups, Black women were nearly twice as likely to report short sleep duration ( $\leq 6$  h/night) than white women (73.3% vs. 37.5%). See Table 1 for baseline characteristics for the full sample and by race.

### Treatment engagement

Treatment engagement was high overall, as indicated by a mean, median, and mode of 6 sessions completed (ie, the maximum available); 32 of 39 (82.1%) received an adequate CBTI dose ( $\geq 4$  sessions). In support of our hypothesis regarding treatment engagement, we observed differences in session attendance by race: Black women completed, on average, 1.34 fewer sessions than white women ( $4.20 \pm 2.24$  vs.  $5.54 \pm 0.93$ ;  $t [37]=2.61$ ,  $p = .013$ , Cohen's  $d = .78$ ). Consequently, Black women were 4.1 times more likely than white women to discontinue CBTI before receiving an adequate dose (33.3% vs. 8.3% premature discontinuation rate,  $p = .048$ ; Table 1). Notably, gestational age after CBTI did not differ by race ( $p = .504$ ). See Table 1 for number of sessions completed and CBTI completion rates for the full sample and by race.

### Treatment outcomes

Insomnia (ISI). An independent samples t-test showed that mean reductions in insomnia symptoms were over twice as large for white

**Table 1**  
Patient characteristics and engagement metrics for digital CBTi patients

	All subjects	White	Black	
Sample size	39	24	15	
Age in y (M ± SD)	28.95 ± 4.51	29.46 ± 4.72	28.13 ± 4.17	t (37) = -0.89, p = .379
Gestational age when starting CBTi	29.20 ± 1.00	29.00 ± .98	29.53 ± .92	t (37) = 1.70, p = .098
Poverty (n;%)	7; 17.9%	4; 16.7%	3; 20.0%	$\chi^2 = 0.07, p = .792$
Obesity (BMI ≥ 35) (n;%)	2; 7.1%	2; 11.1%	0; 0.0%	$\chi^2 = 1.20, p = .274$
Marital status (n;%)	26; 66.7%	21; 87.5%	5; 33.3%	$\chi^2 = 12.19, p < .001$
Multiparous (n;%)	16; 41.0%	11; 45.8%	5; 33.3%	$\chi^2 = 0.60, p = .440$
Snore (n;%)	19; 48.7%	12; 50.0%	7; 46.7%	$\chi^2 = 0.04, p = .839$
Gestational onset of insomnia (n;%)	9; 23.1%	4; 16.7%	5; 33.3%	$\chi^2 = 1.44, p = .229$
ISI	14.51 ± 3.35	14.79 ± 3.34	14.07 ± 3.43	t (37) = -0.65, p = .518
PSQI	9.41 ± 2.60	9.38 ± 2.75	9.47 ± 2.45	t (37) = 0.11, p = .916
Sleep duration (h)	6.35 ± 1.12	6.67 ± 1.08	5.83 ± 1.03	t (37) = -2.39, p = .022
Short sleep (≤6 h; n;%)	20; 51.3%	11; 73.3%	9; 37.5%	$\chi^2 = 4.74, p = .029$
Number of sessions completed (M ± SD)	5.03 ± 1.68	5.54 ± 0.93	4.20 ± 2.24	t (37) = -2.61, p = .013
CBTi completers (≥4 sessions; n;%)	32; 82.1%	22; 91.7%	10; 66.7%	$\chi^2 = 3.92, p = .048$
ΔPSASC (change in cognitive arousal; M ± SD)	-6.33 ± 8.12	-7.38 ± 7.98	-4.00 ± 8.36	t (37) = 1.26, p = .215

Note: BMI, body mass index; ISI, insomnia severity index; M, mean; n, number; PSQI, Pittsburgh Sleep Quality Index; SD, standard deviation; Sleep Duration, assessed via PSQI item 4a, reported in hours (h); Short Sleep, reported ≤ 6 hours per night on the PSQI item 4a; %, percentage; ΔPSASC, post-treatment PSASC minus pre-treatment PSASC.

women relative to Black women after CBTi (-5.75 ± 5.04 vs. -2.13 ± 5.74; t [37] = -2.07, p = .046, Cohen's d = .67; See Fig. 2). A paired samples t-test showed that ISI reductions in white women were very large (t [23] = -5.59, p < .001, Cohen's dz = 1.19), whereas ISI scores did not significantly change among Black women (t [15] = -1.44, p = .172, Cohen's dz = .42). Post hoc descriptives showed that the post-treatment ISI mean ± standard deviation for white women was 9.04 ± 5.12, which is slightly below the threshold for detecting DSM-5 insomnia disorder in pregnancy. By comparison, Black women had a post-treatment ISI mean of 11.93 ± 6.61, which is above the cutoff for DSM-5 insomnia disorder in this population. Descriptive data showed that 41.7% of white women reported remission on the ISI (≤ 7) after CBTi, compared with 26.7% of Black women. These rates suggest that white women may be 1.56 times more likely to remit from insomnia after digital CBTi than Black women.

Sleep disturbance (PSQI). An independent samples t-test comparing changes in PSQI between groups revealed a statistical trend suggesting that white women may respond more favorably to CBTi than Black women (-3.33 ± 3.03 vs. -1.53 ± 3.34; t [37] = 1.74, p = .091, Cohen's d = .56; See Fig. 3). A paired samples t-test showed that the PSQI reduction in white women was very large (t [23] = -6.31, p < .001, Cohen's dz = 1.10), whereas PSQI scores do not significantly change in Black women (t [15] = -1.78, p = .097, Cohen's d = .41). After CBTi, mean PSQI scores for both white women (6.04 ± 2.80) and Black women (7.93 ± 3.37) remained above the PSQI >5 cutoff indicating poor sleep quality. Along these lines, 12/24 (50.0%) of white women

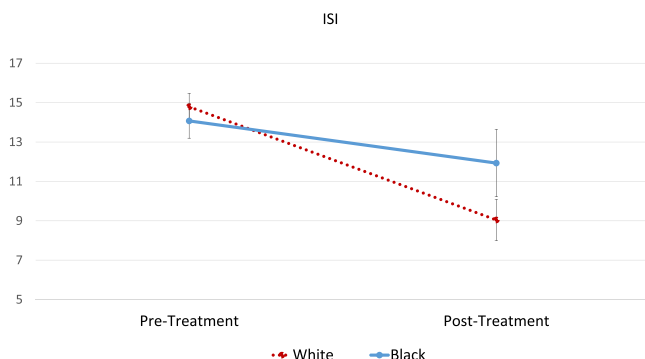
reported good sleep after CBTi (PSQI ≤ 5), whereas only 5/15 (33.3%) of Black women reported good sleep after CBTi.

#### Disentangling effects of race and treatment engagement in treatment response

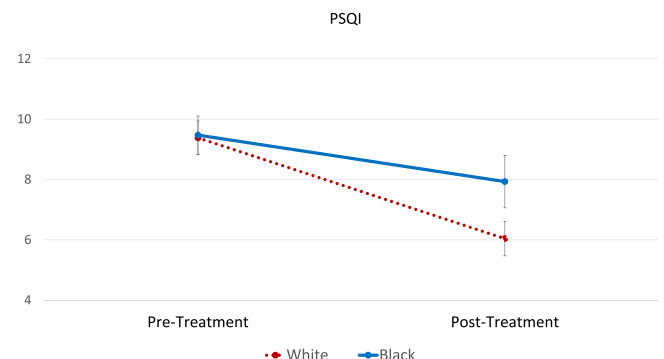
Next, we examined associations among treatment response, session attendance, and race. A comparison of CBTi completers and non-completers suggested that completers may experience greater reductions in ISI than non-completers (-5.09 ± 5.47 vs. -1.00 ± 4.90; t [37] = -1.82, p = .076, Cohen's d = .79). As race, treatment response, and treatment engagement were interrelated, we conducted multivariate regression analyses controlling for potential confounders known to associate with insomnia and race.

Insomnia (ISI). A multiple regression model showed that Black women reported ISI scores 5.52 points higher than white women after CBTi when controlling for adequate dose, refractory cognitive arousal, pre-treatment ISI, poverty, short sleep, marital status, and BMI ≥ 35 (Table 2). Notably, patients with refractory cognitive arousal reported ISI scores that were 7.82 points higher after treatment relative to patients whose cognitive arousal decreased with CBTi (p = .001).

Insomnia Post hoc. Among patients with an adequate dose of CBTi, a paired samples t-test showed that white women who completed ≥ 4 sessions of CBTi had a mean ISI reduction of 6.18 ± 4.90, which was



**Fig. 2.** Mean (and 95% CI) Insomnia Severity Index (ISI) scores at pre-treatment and post-treatment for non-Hispanic white (n = 24) and Black (n = 15) pregnant CBTi patients



**Fig. 3.** Mean (and 95% CI) Pittsburgh Sleep Quality Index (PSQI) scores at pre-treatment and post-treatment for non-Hispanic white (n = 24) and Black (n = 15) pregnant CBTi patients

**Table 2**

Regressing post-treatment sleep symptoms on race, treatment engagement, and relevant covariates

	b (SE)	$\beta$	t-statistic	p-value
<b>Insomnia Severity Index</b>				
Race (Black)	5.52 (1.61)	.51	3.42	.003
Completed $\geq 4$ sessions	-2.77 (1.80)	-.21	-1.54	.141
ISI, pre-treatment	1.04 (.19)	.71	5.45	<.001
Married	1.29 (1.74)	.11	0.74	.466
Poverty (< \$20,000)	-3.73 (2.10)	-.22	-1.78	.091
BMI $\geq 35$	3.81 (2.71)	.19	1.41	.175
Short sleep ( $\leq 6$ h/night)	-1.39 (1.37)	-.13	-1.02	.321
$\Delta$ PSASC $\geq 0$	7.82 (1.90)	.53	4.12	.001
<b>Pittsburgh Sleep Quality Index</b>				
Race (Black)	4.33 (1.07)	.72	4.06	.001
Completed $\geq 4$ sessions	.46 (1.17)	.06	0.40	.695
PSQI, pre-treatment	.41 (.20)	.39	2.09	.050
Married	3.73 (1.13)	.56	3.31	.004*
Poverty (< \$20,000)	1.14 (1.37)	.12	0.83	.415
BMI $\geq 35$	-1.14 (1.76)	-.01	-0.08	.937
Short sleep ( $\leq 6$ h/night)	-.06 (1.15)	-.01	-0.05	.958
$\Delta$ PSASC $\geq 0$	4.51 (1.23)	.55	3.67	.002

Note: b (SE), unstandardized beta coefficient and standard error; ISI, insomnia severity index; p-value, significance value for each predictor; PSQI, Pittsburgh Sleep Quality Index; Sleep Duration, assessed via PSQI item 4a, reported in hours (h); Short Sleep, reported  $\leq 6$  hours per night on the PSQI item 4a; t-statistic, significance test for each predictor;  $\beta$ , standardized beta coefficient;  $\Delta$ PSASC  $\geq 0$ , refractory cognitive arousal.

\* Significant p-value interpreted as erroneous.

a very large effect ( $t [21] = -5.92, p < .001$ , Cohen's  $d_z = 1.32$ ). By comparison, we observed a non-significant change in ISI scores among Black women who completed  $\geq 4$  sessions of CBTI ( $-2.7 \pm 6.15; t [9] = -1.39, p = .198$ , Cohen's  $d_z = .49$ ).

Sleep disturbance (PSQI). We repeated this multivariate model for PSQI, which revealed that Black women reported higher PSQI scores after CBTI relative to white women when controlling for session attendance, refractory cognitive arousal, pre-treatment PSQI, poverty, short sleep, and BMI  $\geq 35$  (Table 2). Once again, refractory cognitive arousal was associated with poorer CBTI response as indicated by PSQI outcomes ( $b=4.51, p = .002$ ). Although marital status was a significant predictor, this was interpreted as an erroneous finding based on a null bivariate analysis examining changes in PSQI between married and unmarried women ( $p = .745$ ) and its inconsistency with the ISI model described above.

Post hoc. A paired samples t-test showed that white CBTI completers had a mean PSQI reduction of  $3.09 \pm 3.04$ , which was a very large effect ( $t [21] = -4.77, p < .001$ , Cohen's  $d_z = 1.02$ ). By comparison, a non-significant change in PSQI scores was observed among Black CBTI completers ( $-1.80 \pm 3.94; t [9] = -1.45, p = .182$ , Cohen's  $d_z = .47$ ).

## Discussion

In a sample of 39 non-Hispanic Black and white pregnant women with insomnia living in the United States, we observed racial disparities in treatment engagement and outcomes when treated with digital CBTI. White pregnant women had high treatment completion rates in digital CBTI and reported large reductions in insomnia symptom severity and global sleep disturbance. By comparison, Black pregnant women completed fewer sessions of digital CBTI and did not report significant treatment benefits for either insomnia symptom severity or global sleep disturbance. Importantly, racial disparities in CBTI outcomes were robust and remained significant even when accounting for refractory cognitive arousal, which our team has reliably linked to CBTI non-response.<sup>26,34,35</sup> Overall, these findings indicate that patient uptake and treatment efficacy of digital CBTI may be reduced for Black pregnant women in the United States.

## Racial disparities in digital CBTI engagement

Pregnant women carry significant burden for healthcare appointments—even women with healthy pregnancies—which include routine prenatal care, imaging, and tests among other wellness appointments not directly related to pregnancy. Of course, healthcare appointments are often more numerous for women with prenatal complications, which require engagement in specialty clinics such as maternal-fetal medicine. As pregnant women with untreated insomnia are at elevated risk for complications,<sup>10–12</sup> it is critical to prioritize easy access to insomnia care for these patients. Unfortunately, a paucity of trained providers with uneven geographic distribution severely limits access to CBTI.<sup>36</sup> To increase CBTI access, our group and Felder's team<sup>17,37</sup> delivered CBTI digitally to maximize treatment access for pregnant women who can easily feel over-taxed by healthcare appointments and tests.

Although digital CBTI engagement was high overall, the premature discontinuation rate for Black pregnant women was 4 times higher than for white pregnant women (33.3% vs. 8.3%). Important to emphasize here is that the observed racial disparities in treatment engagement was unique to digital CBTI in the present study. By comparison, we explored racial differences in engagement in the sleep education control intervention in this clinical trial, which revealed equal engagement between Black and white pregnant women (see supplementary materials). Thus, race-related differences in treatment engagement in this study were specific to digital CBTI. This finding was different from a prior digital CBTI RCT in the non-perinatal patient population, which did not reveal differences in CBTI engagement between Black and white insomnia patients.<sup>24</sup> Importantly, these 2 trials were conducted using the same digital CBTI program and sampling from the same geographic location.<sup>24</sup> In other words, key aspects of the 2 RCTs were consistent across studies with the main difference being the patient population, suggesting that these racial disparities may be more significant in a perinatal population. Even so, the racial disparity in digital CBTI engagement we observed in pregnancy is highly consistent with the broader literature for mental health and behavioral interventions showing reduced engagement for non-white patients.<sup>19–21</sup>

Along these lines, prenatal care utilization in the United States is much lower for racial minorities as compared with white women. Non-white pregnant women are less likely to initiate prenatal care or access timely and affordable care, and they are also more likely to delay prenatal care, attend fewer prenatal medical appointments, and receive inadequate care.<sup>38–40</sup> Moreover, inadequate healthcare utilization is also reflected by reduced engagement in mental health treatment (eg, perinatal depression and substance use disorders) for non-white pregnant women.<sup>41–43</sup> Given the low utilization of mental health treatment among Black pregnant women, efforts to increase minority treatment engagement in behavioral sleep interventions—via digital format or otherwise—will play a critical role in closing the racial gap in prenatal insomnia burden. Future research may focus on comparing patient factors and social determinants between treatment completers vs. those who prematurely discontinued, which may identify targets for enhancing patient uptake and engagement in digital health intervention.

## Racial disparities in digital CBTI treatment response

After CBTI, white pregnant women reported very large reductions in insomnia and global sleep disturbances, whereas Black pregnant women did not report statistically significant changes in these symptoms. Indeed, symptom reductions were twice as large for white pregnant women relative to Black pregnant women. Consequently, descriptive data suggested that white pregnant women may be 1.56 times more likely to remit after CBTI than Black pregnant

women. These observed racial disparities in digital CBTI response are highly consistent with the extant literature showing poorer mental health treatment outcomes for racial minorities.<sup>19–21</sup>

Contrary to our hypotheses, the observed racial disparities in treatment outcomes were not attributable to differences in session completion. Rather, racial disparities in CBTI outcomes persisted when accounting for dosage. Even Black pregnant women who received an adequate dose of CBTI did not report significant reductions in insomnia or global sleep disturbance. By contrast, white pregnant women who completed CBTI reported very large reductions in these symptoms. These data strongly suggest that poorer treatment outcomes for Black pregnant women are not entirely attributable to differences in the number of sessions completed.

Along these lines, racial disparities in CBTI response were observed despite controlling for poverty status, obesity, and patient-reported short sleep duration. Prior research shows that Black pregnant women, relative to white pregnant women, report higher levels of poverty and perinatal obesity, and report shorter sleep duration.<sup>9</sup> Moreover, our team has shown that elevated rates of prenatal insomnia among Black women are attributable to these risk factors, such as the disproportionate number of Black women affected by poverty.<sup>9</sup> But, despite these other factors contributing to elevated insomnia rates for Black pregnant women, these factors did not account for the insufficient response to CBTI for Black pregnant women. More research is needed to better understand barriers to insomnia treatment response for Black women during pregnancy, which can guide enhancing the delivery of insomnia therapy to this population. It is important to emphasize that we captured patient-reported short sleep, but Black women have shorter objective sleep duration than white women.<sup>44</sup> Importantly, objective short sleep is a potential barrier to CBTI response.<sup>45,46</sup> Studies are needed to evaluate the prevalence of the short sleep insomnia phenotype in pregnancy, and whether objective short sleep duration predicts CBTI response in this population.

#### *Enhancing digital CBTI to improve treatment engagement and reduce disparities*

Social and structural determinants of insomnia. Pregnancy is a stressful life event,<sup>47</sup> and disproportionately so for Black Americans who report higher levels of psychosocial stress, pregnancy-related stress, and perceived racism relative to white Americans.<sup>6</sup> By extension, pregnancy may exacerbate the pre-existing stress and limited resources of underserved populations in the United States. And further compounding these issues is structural racism in prenatal care in the United States that contributes to racial disparities in adverse pregnancy and delivery outcomes.<sup>48</sup> One potential avenue to improve these racial disparities is to target social and structural determinants of health and treatment engagement driving reduced effectiveness/efficacy of CBTI.

Social and structural determinants of health and treatment engagement are complex, and many cannot be addressed by insomnia therapy. Rather, CBTI predominantly targets mechanisms on the individual level (eg, sleep homeostasis), but not social and structural factors such as the sleeping environment (eg, noise and light contamination, pollutants that impact breathing), familial arrangements (eg, bed sharing with children, or sleeping on uncomfortable surfaces), sleep-interfering work schedules (eg, shift work, unpredictable schedules, multiple jobs), and stress and other psychological factors (eg, financial strain, increased vigilance due to neighborhood crime). The COVID-19 pandemic has highlighted the need to address social determinants of sleep disorders, which has influenced calls for structural interventions, such as increasing access to and engagement in individual-level treatment, and including culturally relevant material in sleep interventions (see Jackson and Johnson's letter to the editor for more potential roles and responsibilities for researchers and

clinicians to address social determinants of sleep health).<sup>49</sup> Although CBTI certainly cannot address all social determinants of health, any modifications to CBTI that address social determinants of health, particularly those that may interfere with the ability to adhere to specific CBTI components, may enhance its efficacy in Black pregnant women. To illustrate, a recent RCT supported good patient engagement and treatment outcomes for a digital CBTI platform tailored to Black women, which involved several changes for this population such as modifying stimulus control for crowded living environments<sup>50</sup>; we explore this RCT further in the next section.

Culturally tailored digital insomnia therapy. Along the lines of including culturally relevant material in sleep interventions, it is important to emphasize that Black Americans have positive appraisals of engaging in digital health treatment.<sup>51</sup> Unfortunately, very few digital health programs are developed using racially diverse patients, which results in a severe lack of culturally tailored digital health interventions.<sup>52</sup> An emergent literature suggests that culturally tailored digital health tools may enhance treatment engagement and outcomes in minority women.<sup>50,53–55</sup>

Indeed, a recent study examined the efficacy of a digital CBTI program tailored for Black women, relative to one that was not tailored. The tailored version included Black men and women in all visual content, modifications for stimulus control in a crowded living environment, and addressed neighborhood noise.<sup>50</sup> Patients who received the culturally tailored version were more likely to complete treatment than those without the tailored version (78% vs. 65% completion rate), and program completion was associated with greater alleviation of insomnia symptoms.<sup>50</sup> This study strongly supports culturally tailoring digital health interventions to enhance patient engagement and treatment outcomes by offering a more inclusive experience for patients. These findings are relevant to the present study as the digital CBTI platform utilized here includes a cartoon therapist avatar that is depicted as a white male. It is unclear whether the avatar's depicted race or sex may have influenced treatment engagement among Black pregnant women in our study.

Going forward, the field should adopt an equity lens in developing and tailoring digital CBTI programs, which can include utilizing (1) a diverse selection of virtual therapists for programs that utilize avatars, (2) visual and presentation features that represent a diverse patient population, (3) content (eg, case vignettes) that reflect the target patient population, and (4) modifies aspects of the intervention to address social determinants of health (eg, environmental noise).<sup>50,56</sup> Future studies may evaluate whether culturally tailored digital CBTI programs may improve treatment engagement and outcomes relative to the presently widely available standard programs that are more geared to white patients. As treating prenatal insomnia reduces risk for future maternal complications, including postpartum depression and anxiety,<sup>37</sup> then reducing racial disparities in prenatal insomnia via insomnia therapy may consequently contribute to reducing disparities in related outcomes such as postpartum depression and anxiety.

#### *Study limitations and future directions*

Study findings should be interpreted in the context of important methodological limitations. The primary limitation for this study is our inability to determine the extent to which group differences observed here were related to the CBTI intervention vs. its digital delivery. Future research is needed to determine whether these disparities are observed when CBTI is delivered to pregnant women by a clinician (in-person or telemedicine). These data will be important for guiding improvement for delivering insomnia therapy to non-white pregnant women. If racial disparities are observed for CBTI irrespective of treatment delivery, then we must determine how to make CBTI equally efficacious across all races of pregnant women. However, if racial disparities are only observed for digitally delivered



CBTI, then these results would further support the need to create diverse digital health intervention platforms.

Another important limitation concerns the assessment of treatment engagement. While session completion is an important indicator, several other engagement-related metrics can provide valuable insight. Future investigations of racial disparities in treatment engagement may evaluate adherence to prescribed sleep-wake schedules, adherence to stimulus control, and completion of homework (eg, cognitive therapy and relaxation homework).

Third, as outlined above, Black Americans, and especially Black pregnant women, are less likely to seek out and engage in treatment, which has been linked to distrust in healthcare.<sup>57</sup> Future studies examining racial disparities in insomnia treatment engagement may consider evaluating potential motivational factors associated with treatment-seeking and engagement. Even so, it is important to highlight that we observed racial differences in digital CBTI response even after accounting for treatment engagement in our multivariate model, which indicates that future inquiry into improving CBTI engagement and outcomes for Black pregnant women must go beyond simply increasing engagement.<sup>56</sup>

Fourth, our study sample was small and only 2 racial groups had sufficient representation for analysis. Future research should explore racial disparities in CBTI engagement and response in larger patient samples, which may also allow for evaluation of treatment engagement and response in other racial groups that were insufficiently represented in the present study. Along the lines of generalizability, we want to emphasize that it is unclear whether these observed racial disparities are specific to the United States, or whether these results generalize to other countries.

## Conclusions

Insomnia symptoms affect approximately half of all women by the end of pregnancy, but Black women are at substantially higher likelihood of experiencing prenatal insomnia than white women in the United States. Although CBTI—when delivered by clinicians or via digital format—is efficacious in pregnancy, results from the present study support racial disparities in treatment engagement and patient-reported outcomes among pregnant women treated with digital CBTI. Relative to white pregnant women, Black pregnant women completed fewer sessions of digital insomnia therapy. Yet, even among patients with high treatment engagement, Black pregnant women did not report therapeutic benefits from digital CBTI. By comparison, white pregnant women reported large sleep symptom reductions. Future research is needed in 3 key areas: (1) determine whether these study findings replicate in larger digital RCTs and in trials using clinician-led CBTI treating pregnant women, (2) examine whether treatment engagement and patient-reported outcomes differ for other racial groups in pregnancy, (3) enhance insomnia therapy and its digital delivery to improve treatment engagement and outcomes for Black pregnant women with insomnia.

## Declaration of conflicts of interest

OW is CEO of Arascope, a mobile software development company for circadian rhythms. CLD has received research support from Apnimed and Proctor & Gamble. No other financial or non-financial interests exist. The other authors declare that they have no conflict of interest.

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## Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.sleh.2022.10.010.

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