Cognitive Behavioral Therapy for Insomnia With Prolonged Exposure Compared to Sleep Hygiene and Prolonged Exposure:

A Randomized Controlled Trial

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Abstract

Objective: Co-occurrence of posttraumatic stress disorder (PTSD) and insomnia disorder is common and associated with greater psychiatric and functional problems than either condition alone. Evidence-based PTSD treatment often does not effectively decrease insomnia, and insomnia may interfere with the mechanisms underlying PTSD treatment. This study compared the efficacy of integrated cognitive behavioral therapy for insomnia (CBT-I) and prolonged exposure (PE; CBTI-PE) therapy to sleep hygiene and PE (hygiene-PE) in reducing insomnia and PTSD symptoms.

Methods: Ninety-four veterans with insomnia disorder (Insomnia Severity Index [ISI] ≥11) and PTSD (Clinician Administered PTSD Scale for *DSM-5* [CAPS-5] diagnosis) were randomized to CBTI-PE or hygiene-PE therapy for 12 weeks of treatment. Recruitment ran from January 2017 to March 2023. Planned outcomes were PTSD symptoms (CAPS-5; PTSD Checklist for *DSM-5*), quality of life (World Health Organization Quality of Life-BREF [WHOQOL]), and insomnia severity (ISI, subjective sleep efficiency [SE], total sleep time [TST]) between baseline, week 5, posttreatment, and 3-month follow-up.

Results: Randomized participants were 76.6% male, 52.1% white, and mean age was 40.0 years (SD = 11.6). Linear modeling showed PTSD symptoms significantly decreased for most participants, but there were no differences by treatment group ($P = .844$). While, on average, WHOQOL increased for all participants, there was greater improvement in perceived quality of life (QOL) in CBTI-PE relative to hygiene-PE. ISI decreased, and SE and TST increased for most participants but had statistically and clinically larger changes in CBTI-PE, compared to hygiene-PE ($P < .001$).

Conclusions: On average, participants had reductions in PTSD symptoms, with no differences between the groups. CBTI-PE produced greater reductions in insomnia symptoms and larger increases in QOL, SE, and TST than hygiene-PE. Together, CBT-I PE is an effective intervention for treating 2 highly co-occurring disorders, insomnia and PTSD.

Trial Registration: ClinicalTrials.gov identifier: NCT02774642.

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Difficulty in sleep onset and maintenance is the most frequently reported symptom of posttraumatic stress disorder (PTSD), with 65%–93% of individuals with PTSD meeting criteria for comorbid insomnia disorder.[1–3] For example, in a sample of 1843 veterans with PTSD newly enrolling for health care, 93.3% were positive for insomnia disorder.[3] While trauma-focused treatments have shown positive effects on sleep,[4] there is also evidence that even among responders to effective PTSD treatments, such as prolonged exposure (PE), approximately 70% still report clinically significant insomnia following treatment.[5–10]

Although sleep disturbances are symptoms of PTSD, insomnia may be best considered a co-occurring and independent disorder.[11,12] For instance, insomnia may precede the trauma and predict the development of PTSD.[13–17] This is especially true in military populations where short sleep duration and irregular sleep patterns are common.[18,19] Second, when insomnia initially occurs as a symptom of PTSD, it can become an independent disorder when the behavioral and cognitive responses to acute insomnia lead to perpetuating factors (eg, napping, sleeping pills) and conditioned arousal.[20] Additionally, nightmares and hyperarousal symptoms associated with PTSD may lead to the pairing of the bed with wakefulness (ie, conditioned arousal). Thus, the perpetuating factors and conditioned arousal are often responsible for the maintenance of insomnia even with trauma-focused PTSD, which only addresses the precipitating factors.[21] This suggests that insomnia needs to be assessed and treated separately from, or in conjunction with, PTSD.[22] This poor insomnia response rate is concerning given that insomnia disorder is associated with greater severity of PTSD symptoms, poorer quality of life and daily functioning,[23,24] and higher rates of suicide.[25] Treating insomnia in an integrated

Clinical Points

- Co-occurrence of posttraumatic stress disorder (PTSD) and insomnia disorder is common, PTSD treatments often do not effectively address insomnia, and untreated insomnia may interfere with the mechanisms underlying PTSD treatment.
- For patients with insomnia and PTSD, using an integrated cognitive behavioral therapy for insomnia with prolonged exposure effectively addressed both disorders.

protocol with PTSD treatment can help address 2 commonly co-occurring disorders collectively.[3,22,26]

Evidence suggests that insomnia negatively affects the mechanisms involved in PE treatment. A defining feature of PTSD is that environmental cues during trauma are associated with the traumatic event, and these cues generalize and continue to evoke strong fear reactions and trigger avoidance responses long after the initial trauma has receded. PE decreases avoidance of feared cues to allow fear extinction of over-generalized feared stimuli[27] through extinction learning recall and between session habituation,[28–33] the development of extinction memories,[34] and the ability to differentiate and recall safe and feared cues (ie, safety learning).[35] A growing body of research shows that sleep, particularly REM,[36] serves an important role in the acquisition, recall, and generalization/recall of extinction memories,[33,37–39] as well as effective safety learning (the ability to distinguish and recall safe from unsafe cues).[40,41] This implies that the sleep symptoms of insomnia could potentially interfere with both natural extinction and habituation (thus maintaining PTSD) and treatment-induced extinction (thus reducing the effects of PE) of PTSD-related fear.[42]

Cognitive behavioral therapy for insomnia (CBT-I) is an effective first line treatment of chronic and severe insomnia.[43–45] CBT-I has been shown to be effective in treating insomnia in individuals with co-occurring PTSD, increasing sleep efficiency (SE) and decreasing daytime PTSD symptoms.[46–48] However, one study showed no difference between CBT-I and waitlist control on decreases in PTSD symptoms.[47] Despite CBT-I being an effective treatment, insomnia treatment is rarely offered for individuals who have PTSD. There are only a few studies that examined CBT-I and PTSD treatment (eg, cognitive processing therapy).[49,50] They found that the integrated CBT-I groups, compared to the control groups, had lower insomnia, SE, and PTSD symptoms at follow-up. However, no randomized clinical trials (RCTs) have compared the efficacy and tolerability of CBT-I combined with PE[22] in addressing both disorders together.

To address these critical gaps, the current study compares integrated CBT-I and PE (CBTI-PE) therapy, using the 2NITE protocol,[22] to an active control of sleep hygiene (ie education about sleep best practices) followed by PE (hygiene-PE). We hypothesized that CBTI-PE, compared to hygiene-PE, would produce greater reductions in PTSD symptoms and insomnia severity and greater increases in quality of life, SE, and total sleep time (TST) at 3-month follow-up.

METHODS

Study Design

The study was a parallel-group, 2-armed RCT, whereby participants were randomized to either CBTI-PE or hygiene-PE for insomnia and PTSD. Participants gave written informed consent before enrollment. Independent evaluators were masked to treatment assignment for study duration. The study was approved by the Veterans Affairs (VA) local research review board and preregistered at ClinicalTrials.gov (NCT02774642). The study protocol can be requested from the corresponding author.

Participants

Participant recruitment took place from January 2017 to March 2023 through mental health PTSD clinics in a large, urban, VA hospital (see demographic characteristics in Table 1). Interested participants were provided an explanation of study procedures and completed a phone-based screening with verbal consent. Individuals screening positive for PTSD (PTSD Checklist for *DSM-5* [PCL-5] ≥33) and insomnia (Insomnia Severity Index [ISI] ≥11) and expressing interest in treatment were consented. Eligibility criteria was age over 19 years old and participants had current full or subthreshold PTSD (up to 1 symptom missing to be representative of treatment seeking VA PTSD clinics),[51] met diagnostic criteria for insomnia (ISI ≥11), were enrolled at the VA Healthcare System and living within 50 miles of the respective facility, and had English literacy. Exclusionary criteria were untreated obstructive sleep apnea (OSA), unmanaged psychosis or manic episodes in past year, substance/alcohol use disorder in past 6 months, severe medical or psychiatric illness, participation in concurrent psychotherapies targeting PTSD, or a history of moderate-to-severe cognitive impairment. Participants were financially compensated after each baseline, week 5, posttreatment, and follow-up assessment time point for a total possible of $175.

Procedures

Participants met with a study therapist (P.C., C.H., A.H., M.T., M.P.) to learn more about both therapies and ask any remaining questions about treatment. All study therapists delivered both treatments. Participants

Table 1.

Demographic and Baseline Characteristics of the Intent-To-Treat Sample[a]

Characteristics	Total (N = 94)	CBTI-PE (n = 52)	Hygiene-PE (n = 42)	*P* value
Age, mean (SD), y	40.2 (11.8)	39.4 (11.3)	41.2 (12.4)	.51
Sex, n (%)				.93
Men	72 (76.6)	40 (76.9)	32 (76.2)	
Women	22 (23.4)	12 (23.1)	10 (23.8)	
Marital status, n (%)				.58
Not married	41 (45.6)	24 (46.2)	17 (40.5)	
Married	53 (54.4)	28 (53.8)	25 (59.5)	
Education, n (%)				.42
High school/GED	9 (9.6)	5 (9.6)	4 (9.5)	
Some college	47 (50.0)	29 (55.8)	18 (42.9)	
College graduate	38 (40.4)	18 (34.6)	20 (47.6)	
Ethnicity, n (%)				.41
Hispanic	29 (30.9)	19 (36.5)	10 (23.8)	
Non-Hispanic	63 (67.0)	32 (61.5)	31 (73.8)	
Unknown	2 (2.1)	1 (1.9)	1 (2.4)	
Race, n (%)				.91
White	49 (52.1)	26 (50.0)	23 (54.8)	
Black	17 (18.1)	10 (19.2)	7 (16.7)	
Asian	7 (7.4)	5 (9.6)	2 (4.8)	
American Indian/Alaska Native	3 (3.2)	2 (3.8)	1 (2.4)	
Pacific Islander/Hawaiian	7 (7.4)	3 (5.8)	4 (9.5)	
Multiracial	11 (11.7)	6 (11.5)	5 (11.9)	
Subthreshold PTSD, n (%)	1 (0.01)	0 (0)	1 (0.02)	.26
Lifetime trauma exposure, no. of events, mean (SD)	9.5 (3.3)	9.7 (3.4)	9.3 (3.2)	.64
Event type, n (%)				
Combat trauma	68 (72.3)	36 (69.2)	32 (76.2)	.45
Sexual trauma	39 (41.5)	24 (46.1)	15 (35.7)	.31
Physical assault	75 (79.8)	42 (80.8)	33 (78.6)	.79
Disaster exposure	65 (69.1)	36 (69.2)	29 (69.0)	.99
Serious accident	64 (68.1)	36 (69.2)	28 (66.7)	.79
Life-threatening illness or injury	43 (45.7)	23 (44.2)	20 (47.6)	.74
Taking psychotropic medications, n (%)	57 (60.6)	33 (63.4)	24 (57.1)	.53
Mood medications	38 (40.4)	25 (48.1)	13 (31.0)	.09
Sleep medications	36 (38.3)	18 (34.6)	18 (42.86)	.41
Other medications	11 (11.7)	9 (17.3)	2 (4.8)	.06
Benzo/z-drug medications	2 (2.1)	1 (1.9)	1 (2.4)	.88
Medication adherence, n (%)	80 (85.1)	29 (83)	19(79)	.72
Baseline assessment scores, mean (SD)[a]				
Interviewer-rated PTSD severity (CAPS-5)	38.0 (8.1)	38.8 (6.7)	37.0 (9.5)	.31
No. of total sessions attended, mean (SD)	11.8 (4.4)	12.2 (4.2)	11.4 (4.6)	.85
Treatment dropout; <5 weeks of treatment, n (%)	11 (11.7)	5 (10)	6 (14)	

[a]For descriptions of score ranges, see the Methods section of the article.
Abbreviations: CAPS-5 = Clinician Administered PTSD Scale for *DSM-5*, CBTI-PE = integrated cognitive behavioral therapy for insomnia and prolonged exposure therapy, hygiene-PE = sleep hygiene and prolonged exposure therapy, PTSD = posttraumatic stress disorder.

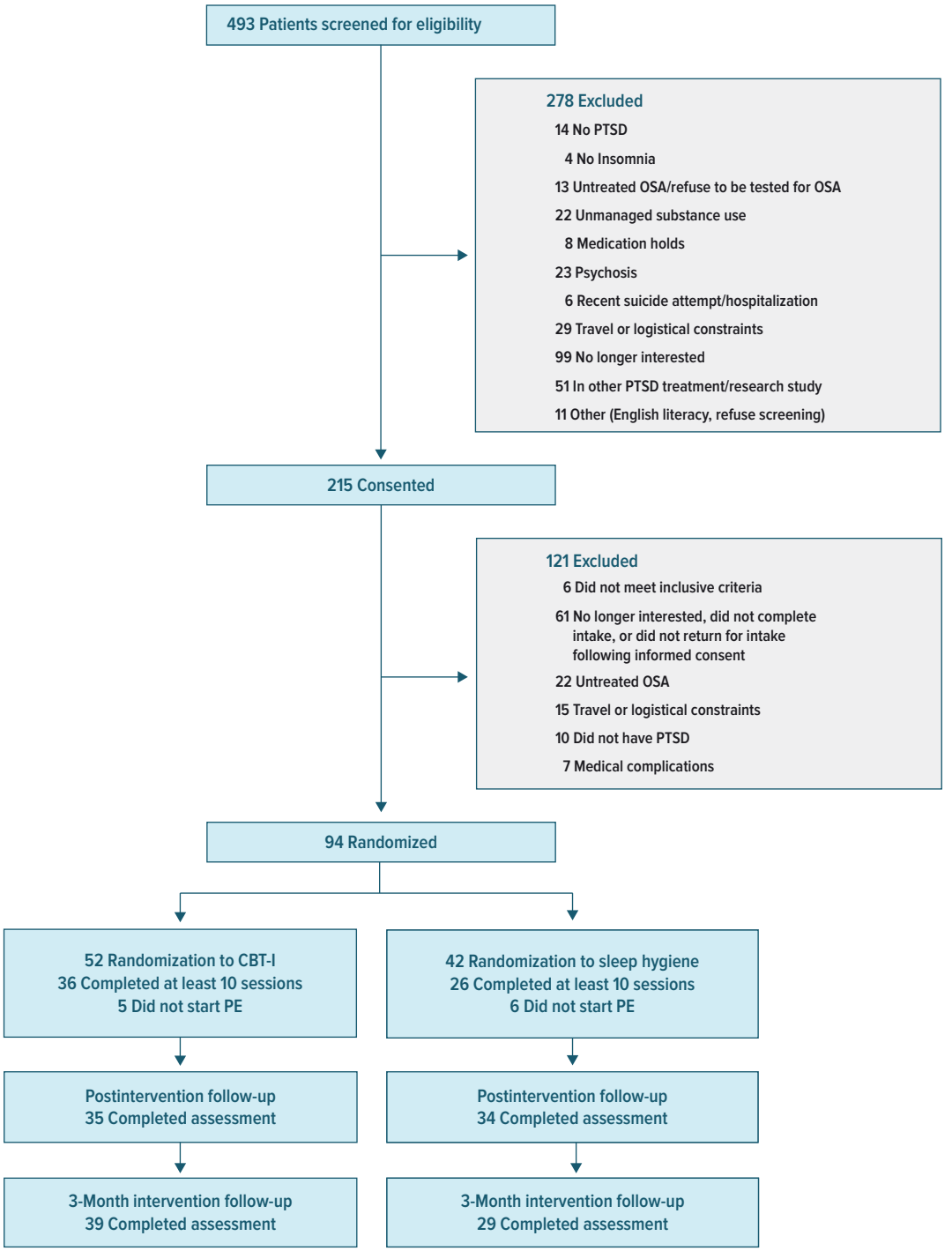
engaged in 12 to 16 sessions of psychotherapy. Measures were completed at baseline, week 5, posttreatment, and at 3-month posttreatment follow-up with compensation at each assessment point (see Figure 1 for CONSORT study flow diagram). Participants were asked not to engage in other PTSD psychotherapy during study treatment. Concurrent medication prescriptions and adherence were tracked.

Due to COVID-19 in March 2020, the study switched from delivering in-person treatment to telemental health (TMH) procedures per VA policy. CBT-I[52] and PE[53] have shown that TMH is noninferior to TMH. Our study showed no difference in key baseline variables between in-person and TMH procedures in our study.

Intervention

Integrated CBT-I and PE Treatment (2NITE protocol; CBTI-PE). We developed an integrated treatment of CBT-I[54] and PE.[55] The 2NITE protocol[22] is delivered in approximately 12–16, 90-minute weekly sessions and starts with CBT-I for the first 2 weeks with an added focus on the bidirectional relationship between PTSD and sleep. PE protocol (psychoeducation) begins on week

Figure 1.
CONSORT Flow Diagram



Abbreviations: CBT-I = integrated cognitive behavioral therapy for insomnia, ISI = Insomnia Severity Index, OSA = obstructive sleep apnea, PTSD = posttraumatic stress disorder.

3 of treatment, and both treatments overlap until week 6. Week 6 was specifically chosen to start PE exposures to allow sleep to consolidate from CBT-I based on our pilot data and CBT-I trials.[22] Over the course of PE, sleep diary review and sleep time adjustment continued until the end of treatment. The final session included reviewing treatment goals, discussing progress and skills to be used posttreatment, and discussing relapse prevention and handling reemergence of insomnia and PTSD symptoms.

Table 2.

Estimated Means of Key Variables by Treatment Arm[a]

	Baseline		Week 5		Posttreatment		3-Month follow-up	
	CBTI-PE	Hygiene-PE	CBTI-PE	Hygiene-PE	CBTI-PE	Hygiene-PE	CBTI-PE	Hygiene-PE
Primary								
CAPS	38.75 (6.69)	37.02 (9.54)	–	–	25.74 (12.34)	28.18 (11.62)	27.59 (12.68)	25.93 (12.61)
SE	70.94 (14.46)	74.87 (10.90)	–	–	88.71 (6.46)	78.44 (9.71)	86.46 (7.68)	78.23 (10.87)
Secondary								
ISI	21.26 (4.74)	19.67 (4.63)	15.13 (6.50)	17.70 (4.76)	9.46 (6.98)	12.93 (6.58)	11.77 (6.70)	12.37 (7.57)
TST	299.83 (94.21)	354.44 (74.32)	–	–	372.93 (82.14)	361.07 (75.18)	382.06 (83.40)	356.46 (79.58)
PCL-5	56.24 (12.97)	54.93 (12.15)	51.22 (14.61)	47.92 (11.29)	35.91 (19.09)	32.15 (18.35)	35.93 (18.41)	33.33 (19.05)

[a]Values expressed as mean (SD).

Abbreviations: CAPS-5 = Clinician Administered PTSD Scale for *DSM-5*, CBTI-PE = integrated cognitive behavioral therapy for insomnia and prolonged exposure therapy, hygiene-PE = sleep hygiene and prolonged exposure therapy, ISI = Insomnia Severity Index, PTSD = posttraumatic stress disorder, SE = sleep efficiency, TST = total sleep time.

Hygiene and PE treatment (hygiene-PE). To match CBTI-PE for total session, hygiene-PE was used as an active control condition to match for both session and treatment length. While sleep hygiene is shown not as effective as CBT-I, it still has significant pre-posttreatment improvements with small and medium effect sizes on insomnia.[56] Hygiene-PE consisted of 2 sessions of sleep education before starting the PE protocol on session 3 and thus starting in vivos/imaginals on session 6. Sessions 1 and 2 reviewed psychoeducation on the relationship between PTSD and sleep, as well as a review of lifestyle factors that influence sleep (eg, caffeine and alcohol intake, napping, exercise, creating a bedtime ritual). Hygiene homework assignments were set and reviewed only during sessions 1 and 2.

Treatment fidelity. Treatment fidelity rating scales were adapted from previously used PE[57] and CBT-I studies.[58,59] We used 2 adherence scales, one for the CBTI-PE protocol and one for the hygiene-PE protocol manual. Therapist adherence to published manuals was defined as 90% adherence to the items on the adherence checklist. Feedback was given on a weekly basis, if needed.

Therapist treatment fidelity. Study therapists were 2 licensed psychologists and 3 postdoctoral fellows. To mitigate therapist bias, therapists received training in study protocols through didactics, videos, and practice sessions with a supervisor before treating a participant. The first time that therapists administered both CBTI-PE and hygiene-PE interventions, sessions were rated for fidelity. Henceforth, other sessions were recorded, and 10% were rated within 2 weeks and delivered to the study therapist. All study therapists rated other therapists for fidelity scores. 52 CBTI-PE and 43 hygiene-PE therapy session recordings were rated for fidelity. Both treatment fidelity scores (mean [SD], 89.3% [12.6%]) and therapist factors (mean [SD], 99.35% [3.15%]) were strong.

Treatment termination. Participant termination decisions were based on (*a*) no more than 20 therapy session; (*b*) 2 assessment weeks in a row of PCL-5 below 33; (*c*) max subjective units of distress during PE imaginals below 40/100; and (*d*) mutual agreement to terminate based on clinical goals met.

Randomization and Masking

Participants were randomly assigned to either a CBTI-PE intervention or hygiene-PE using a blocked randomization sequence stratified by gender. The randomization sequence was created at the beginning of the study by the biostatistician and kept by the research coordinator who assigned participants strictly in the temporal order of baseline completion. Due to the nature of the behavioral intervention, participants were not blinded to the intervention and were aware of their group allocation.

Masked independent evaluators completed training and achieved at least 90% agreement on Clinician Administered PTSD Scale for *DSM-5* (CAPS-5) item scores before conducting assessments. Interrater reliability, conducted on 11.26% of randomly selected CAPS-5 assessments, was excellent ($\kappa = 0.98$) for severity and $\kappa = 0.97$ for symptoms intraclass correlation coefficients.[60]

Measures

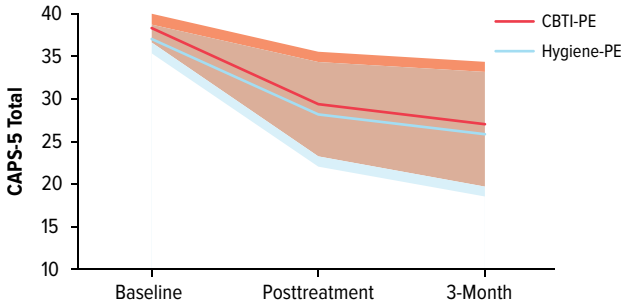
PTSD. The CAPS-5, a 30-item structured interview[61] considered to be the gold standard for diagnosing PTSD, was the primary measure of PTSD symptoms and diagnosis. CAPS scores range from 0 to 80, with 0 indicating no PTSD symptoms and 80 indicating extreme ratings across all symptoms. The presence of PTSD used *DSM-5* scoring rules. CAPS-5 severity scores had strong internal consistency ($\alpha = .84$).

The PCL-5[62] was used as a screener questionnaire and a biweekly assessment tool to track PTSD symptoms. The measure maps directly onto *DSM-5* diagnostic criteria. The PCL-5 total scores had strong internal consistency ($\alpha = .82$).

Insomnia. The ISI[63] was used to measure insomnia with well-established reliability and validity. The ISI

Figure 2.

Posttraumatic Stress Disorder Symptom Severity Estimated Means by Treatment Condition at Each Time Point, With Standard Deviations



Abbreviations: CAPS-5 = Clinician Administered PTSD Scale for *DSM-5*, CBTI-PE = integrated cognitive behavioral therapy for insomnia and prolonged exposure therapy, hygiene-PE = sleep hygiene and prolonged exposure therapy.

consists of 7 items, 3 of which assess severity of insomnia (ie, degree of difficulty falling asleep, staying asleep, and waking too early). The remaining items address satisfaction with sleep pattern, effect of sleep on daytime and social functioning, and concern about current sleep difficulties. A total score of ≥11 was used on the ISI to indicate the presence of insomnia *disorder*.[64] Scores range from 0 (no insomnia) to 28 (severe insomnia). ISI showed strong internal consistency ($\alpha = .81$).

Sleep diaries. Patients completed a daily sleep diary throughout the course of treatment. The sleep diaries were used to assess subjective measures (bedtime, wake time, sleep latency, number and duration of awakenings, and total time in bed) and 2 calculated variables (TST and SE).

Quality of life. World Health Organization Quality of Life-BREF (WHOQOL-BREF) uses 26 items to measure the following domains: global quality of life (1 item), global general health (1 item), physical health (7 items), psychological health (6 items), social relationships (3 items), and environment (8 items). Higher scores indicate higher quality of life.

Obstructive sleep apnea (OSA). A type-3 home sleep test (NOX T3) was used to rule out OSA, with veterans positive for OSA referred to the VA sleep clinic to get fit for positive airway pressure treatment prior to the start of randomization.

Other. Modified Adherence to Medications[65] is a questionnaire that inquires about names, dosages, and adherence of all the psychiatric medications, and the participant is currently prescribed. The Client Satisfaction Questionnaire[66] is an 8-item self-report scale (score range, 8–32, with 8 indicating extremely poor satisfaction and 32 indicating extremely high satisfaction). The average across all treatment sessions was computed to ascertain satisfaction.

Dropout. Treatment dropout was defined as any participant who did not start PE protocol on week 6.

Statistical Analysis

Sample size was determined to ensure adequate statistical power to detect between-group differences in PTSD and insomnia after treatment (using G*power). While we anticipated a large effect size for PE on PTSD (average effect size of 2.5)[67,68] and a large effect size for CBT-I on insomnia (eg, ES = 2.15),[69] there were no published studies examining CBT-I effects on PE outcomes. As such, we examined 3 studies' reported effect sizes of CBT-I on PTSD symptoms with an average effect size of 1.8[46,47,69] and agreed upon an effect size of 0.8 for CBT-I on PTSD treatment outcomes (N = 68 to be detected with 90% power and a 2-tailed test with α at .05). We increased the total sample size to be randomized to N = 94 in anticipation of study attrition by the 3-month assessment.[70,71]

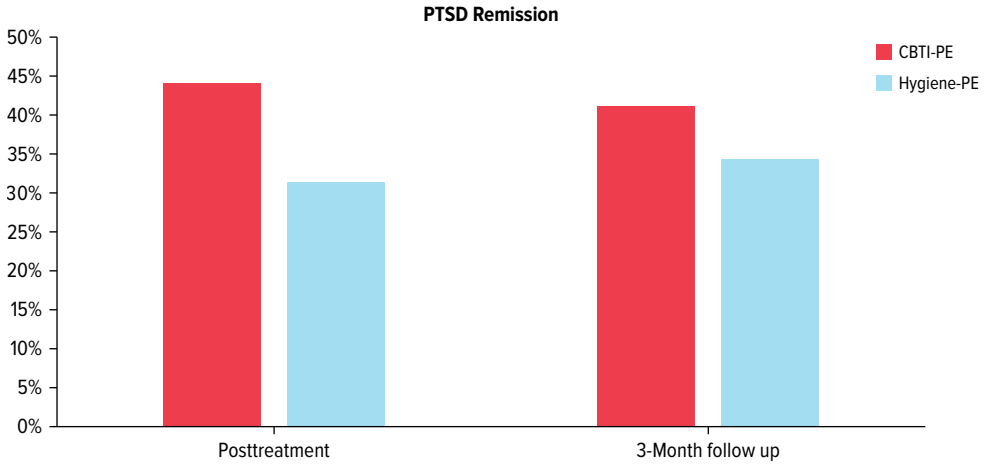
Mixed-effects models (MEMs) were used to analyze changes in CAPS-5, ISI, SE, TST, and WHOQOL-BREFs single-item scores over time and between groups using SPSS version 28.[72] These models allow data from randomized participants to yield unbiased estimates under the missing at random assumption. We began by testing different combinations of random effects (intercept, slope, and intercept-slope covariation) and different definitions of time (linear and logarithmic) and retained the best-fitting/most parsimonious combination for each outcome. Within the best-fitting model for each outcome, we tested treatment condition, time, and their interaction as fixed effects. Time was coded such that it reflected the change in the outcome collapsed across both treatment groups, whereas the time × group interaction reflects the extent to which changes in the outcome were different between treatment groups with 3-month follow-up being our primary outcome. For a measure of effect size, we computed a d value for each effect according to the formula $d = t(2/n)^{1/2}$, which can be applied to any test that yields a t statistic.[73]

RESULTS

Ninety-four veterans (mean [SD], age 40.2 [11.8] years; 76.6% male) were randomized (see baseline characteristics in Table 1 and means by treatment arm in Table 2). The CBTI-PE and hygiene-PE arms did not significantly differ on any background variables or baseline measures of the primary outcomes, medication use, or number of treatment sessions. TST did differ at baseline where the hygiene-PE group had significantly longer sleep time than the CBTI-PE group. Out of the 94 veterans randomized, 16 participants (17%) only had 1 data point (17.3% for CBTI-PE, 16.7% for hygiene-PE). Since MEMs require a minimum of

Figure 3.

CAPS-5 Percent Without PTSD Diagnoses by Treatment Condition at Posttreatment and 3-Month Follow-up



Abbreviations: CAPS-5 = Clinician Administered PTSD Scale for *DSM-5*, CBTI-PE = integrated cognitive behavioral therapy for insomnia and prolonged exposure therapy, hygiene-PE = sleep hygiene and prolonged exposure therapy, PTSD = posttraumatic stress disorder.

2 data points for model estimation, we compared participants with multiple data points vs a single data point on condition randomization, baseline ISI and CAPS-5, and demographic variables to ensure that there was no bias in the intent-to-treat data we utilized for analyses. There were no differences between individuals with 1 or 2 time points on any variables at baseline ($P > .05$).

Primary Analyses

Changes in all outcomes were better approximated with logarithmic models. There was no difference by treatment for the average number of sessions (CBTI-PE mean = 12.2, SD = 4.2; hygiene-PE mean = 11.4, SD = 4.6).

PTSD. For CAPS-5, there was a significant effect of time, $b = -8.07$, 95% CI, −10.10 to −6.05, $P < .001$, $d = 1.18$, but not a time-by–treatment group interaction $b = 0.02$, 95% CI, −4.01 to 4.09, $P < .001$, $d = .003$. Thus, both treatment groups were estimated to experience similarly large reductions in CAPS-5 scores of approximately 11 points (see Figure 2). Chi-square analyses were run to examine the percent of participants with PTSD remission at posttreatment (CBTI-PE = 45%; hygiene-PE = 32%; χ^2 [1, N = 69] = 1.3, $P = .261$) and 3-month follow-up (CBTI-PE = 42%; hygiene-PE = 35%; χ^2 [1, N = 68] = 0.3, $P = .56$). There were no differences between the groups (see Figure 3).

Sleep efficiency outcomes. For SE, the effect of time was significant (SE: $b = 8.06$, 95% CI, 5.83 to 10.28, $P < .001$, $d = 1.04$), indicating improvement in SE following treatment for both groups. Additionally, the time-by–treatment group interaction was also significant (SE: $b = -9.70$, 95% CI, −14.15 to −5.26, $P < .001$, $d = 0.65$), which in each case reflected greater sleep improvement within the CBT-I-PE group (SE = 27.77% increase) relative to the hygiene-PE group (SE = 0.81% increase; see Figure 4).

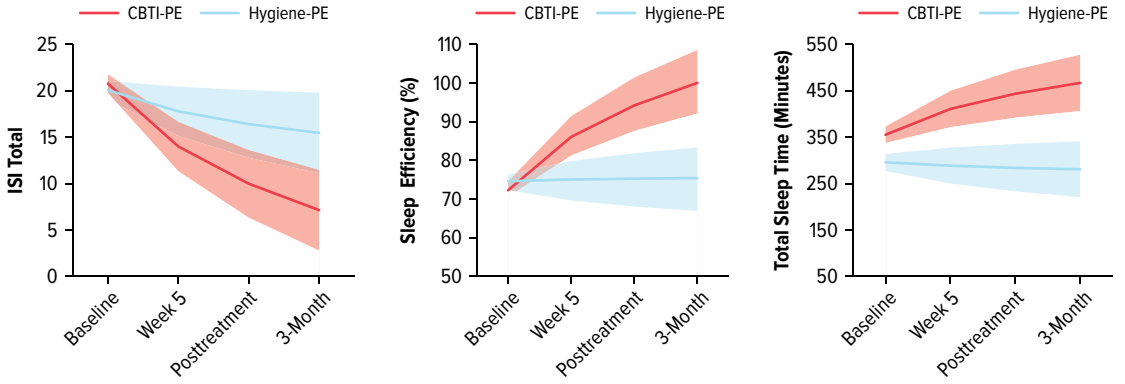
Secondary Analyses

Quality-of-life outcomes. For WHOQOL-BREF overall, there was once again a significant effect for time, indicating improved perceptions of quality of life following both treatments, $b = 0.30$, 95% CI, 0.18 to 0.43, $P < .001$, $d = 0.74$. The time-by-treatment group interaction was significant as well, $b = -0.29$, 95% CI, −0.54 to −0.05, $P = .019$, $d = 0.36$, which reflected greater improvement in perceived quality of life in the CBTI-PE group (0.63 point increase) relative to the hygiene-PE group (−0.18 point decrease; see Figure 5). Additionally, time was significant for all four WHOQOL-BREF subdomains (ds ≥ 0.56, Ps ≤ .001), while the time-by-treatment group interaction was significant for the WHO-QOL physical domain, $b = -6.00$, 95% CI, −10.63 to −1.37, $P = .011$, but not for the psychological health, social, or environmental domains (ds ≤ 0.25, Ps ≥ .10).

Sleep outcomes. For sleep outcomes, the effect of time was significant for all outcomes (ISI: $b = -6.56$, 95% CI, −7.76 to −5.37, $P < .001$, $d = 1.62$; TST: $b = 34.78$, 95% CI, 19.33 to 50.22, $P < .001$, $d = 1.04$), indicating improvement in each sleep measure following treatment for both groups. Additionally, the time-by-treatment group interaction was also significant for each (ISI: $b = 3.25$, 95% CI, 0.85 to 5.65, $P = .008$, $d = 0.40$; TST: $b = -45.63$, 95% CI, −76.52 to −14.74, $P = .004$, $d = 0.44$),

Figure 4.

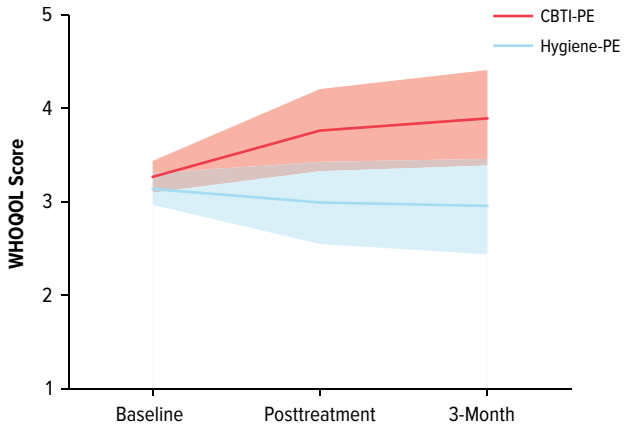
Insomnia Severity, Sleep Efficiency, Total Sleep Time Estimated Means by Treatment Condition at Each Time Point, With Standard Deviations



Abbreviations: CBTI-PE = integrated cognitive behavioral therapy for insomnia and prolonged exposure therapy, hygiene-PE = sleep hygiene and prolonged exposure therapy, ISI = Insomnia Severity Index.

Figure 5.

Quality of Life Estimated Means by Treatment Condition at Each Time Point, With Standard Deviations



Abbreviations: CBTI-PE = integrated cognitive behavioral therapy for insomnia and prolonged exposure therapy, hygiene-PE = sleep hygiene and prolonged exposure therapy, WHOQOL = World Health Organization Quality of Life.

which in each case reflected greater sleep improvement within the CBT-I-PE group (ISI = 13.64 points decrease; TST = 1.86 more hours of sleep) relative to the hygiene-PE group (ISI = 4.61 points decrease; TST = 0.25 hours less of sleep; see Figure 4).

Chi-square analyses were run to examine the percent of participants with insomnia remission (ISI <11) at week 5 (CBTI-PE = 20%; hygiene-PE = 5%; χ^2 [1, N = 81] = 3.6, P = .06), posttreatment (CBTI-PE = 57%; hygiene-PE = 44%; χ^2 [1, N = 62] = 1.0, P = .32), and 3-month follow-up (CBTI-PE = 50%; hygiene-PE = 37%; χ^2 [1, N = 63] = 1.1, P = .31). There were no differences between the groups (Figure 6).

Satisfaction and safety. No participants were discharged from the study because of serious adverse events, suggesting adequate levels of treatment safety. Satisfaction in CBTI-PE (mean = 28.4, SD = 2.9) and hygiene-PE (mean = 28.3, SD = 3.0) treatment was high and did not differ between conditions.

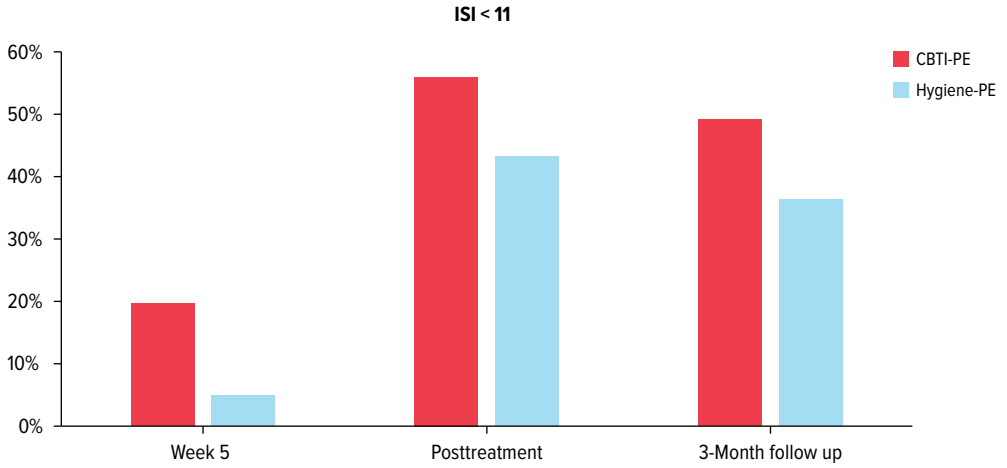
DISCUSSION

This RCT compared the relative efficacy of an integrated CBT-I and PE treatment (2NITE protocol; CBTI-PE)[22] to sleep hygiene and PE (hygiene-PE) on PTSD and insomnia symptoms. This study is based on the evidence that while insomnia and PTSD are highly co-occurring, insomnia does not remit following evidence-based treatments and may interfere with treatment mechanisms of PE.[5–10] As such, addressing both insomnia and PTSD may increase client-centered care by directly addressing 2 problems simultaneously.

Contrary to our hypotheses, while, on average, participants had statistical and clinically meaningful decreases in PTSD severity over time, there were no statistical differences found between conditions for PTSD. Our hypothesis was based on research suggesting that better SE may increase the emotional memory learning necessary for effective PE.[74] Even in our own sample, we found that better SE during the week predicted a greater reduction in distress to the trauma memory at the next imaginal exposure and a greater reduction in PTSD symptoms at the following assessment.[75] These contrary findings could be due to several factors. First, and most likely, our study was underpowered to examine comparative changes of 2 active sleep treatments on PE outcomes. While sleep hygiene is shown not as effective as CBT-I, it

Figure 6.

ISI Percent Below 11 by Treatment at Week 5, Posttreatment, and 3-Month Follow-up



Abbreviations: CBTI-PE = integrated cognitive behavioral therapy for insomnia and prolonged exposure therapy, hygiene-PE = sleep hygiene and prolonged exposure therapy, ISI = Insomnia Severity Index.

still has significant pre-posttreatment improvements with small and medium effect sizes on insomnia[56] that decreased our ability to see group interactions in PTSD outcomes. In a post hoc reanalysis of power, using a small effect size of 0.4 (compared to 0.8 we originally used for the funded study), we would require a sample size closer to 260 participants. Other studies that showed that CBT-I was more effective than the control condition on decreasing PTSD used either attentional control[49] or no-sleep treatment added.[50] Second, it is possible that the effect we hypothesized on PTSD would be seen further downstream beyond 3-month follow-up. Third, PE is an effective treatment and, given enough time, may result in significant PTSD decreases regardless of sleep intervention. Fourth, evidence suggests that sleep hygiene is more effective in addressing insomnia than originally anticipated[76] and may not be compared to solo PE studies.[6–10]

As hypothesized, CBTI-PE, when compared to hygiene-PE, had significantly greater improvement in perceived quality of life and physical domain (eg, increased daily activities, increased energy). However, there were no significant differences between groups in psychological health (eg, self-esteem, positive feelings), social relationships (eg, social support), or environmental domains (eg, recreation, financial stability). These findings make sense given the changes seen in PTSD and sleep noted below; the positive effects of SE and TST seen in the CBTI-PE group only translate to global quality of life and daytime energy.

As hypothesized, CBTI-PE, when compared to hygiene-PE, had significantly larger decreases in insomnia symptoms and larger increases in SE and TST at 3-month follow-up. These differences were both statistically and clinically meaningful, suggesting that addressing sleep directly with CBT-I, in the context of trauma-focused treatment, is effective at decreasing insomnia disorder. These results suggest that the 2NITE protocol is more effective in addressing sleep than sleep hygiene and PE treatment and seems to show better sleep response than previously published PE only studies.[6–10] We believe that the 2NITE protocol is a viable treatment option for clinicians when working with patients presenting with insomnia and PTSD.

Our study expands on the pilot study[22] and suggests that among individuals with PTSD and insomnia, the integrated CBT-I and PE 2NITE protocol effectively addresses insomnia and PTSD together. There are several key implications of the novel integrated CBTI-PE 2NITE protocol. First, our trial is critical in showing that integrated CBT-I and PE protocol was beneficial to both insomnia symptoms and PTSD with a single provider. CBT-I and PE delivered separately likely requires 16–20 sessions and may need referrals to 2 clinics (eg, a sleep and PTSD clinic referral). The full-course 2NITE protocol was delivered in an average of 11.8 sessions (SD = 4.4 sessions), with significant decreases in both insomnia and PTSD symptoms. The minimal number of sessions is of critical importance to facilitating access to evidence-based treatments in mental health settings. Third, the combined 2NITE protocol also showed significant increases in TST from baseline to the end of treatment. Many CBT-I studies only show increases in SE, and not TST, in the 6–8 week protocols.[43,77,78] Tracking sleep for another 8–10 weeks may allow

further opportunity to reinforce positive sleep/wake habits and titrate wake and sleep times using the sleep diary.

Limitations

Although the present study represents the most comprehensive investigation of CBT-I and PE to date, it does possess several limitations. First, our study is limited in generalizability by an all-veteran, majority male sample and may not fully generalize to a civilian sample. Although we expect any client with PTSD and sleep disorders to show a similar response to PTSD and insomnia as shown in our study, future studies will need to address this overlap directly. Second, we only had a 3-month follow-up, and extending the follow-up timeline would offer important insight into the stability of our findings. Third, as noted above, we have been underpowered to examine comparative difference between 2 groups in PE. Fourth, we had therapists deliver both treatments, which has the potential to introduce therapist bias (eg, allegiance to either CBT-I or sleep hygiene); we did not measure therapist bias to assess for allegiance. To mitigate this issue, we utilized robust protocol training, supervision, feedback, and treatment fidelity. Fifth, the blocked randomization sequencing created at the start of the study was created on 134 participants which resulted in unequal groups. Finally, treatment fidelity was scored by study therapist, and not by an external treatment fidelity team.

Future Directions

Future research should examine testing sleep-relevant and PTSD treatment mechanisms of change. For instance, incorporating objective measures of sleep such as polysomnography during PE could shed light on whether the positive benefits of sleep are really driven by enhanced consolidation of extinction memories by assessing whether clinical outcomes are predicted by time spent in later sleep stages (ie, N3, REM). These data would allow researchers to more confidently infer whether fragmentation in sleep stages relevant to memory consolidation truly contribute to reduced clinical outcomes during PE. Future research should also examine designs that examine PE alone to the 2NITE-integrated protocol on PTSD outcomes to better understand the effects of insomnia treatment on trauma-focused treatment outcomes. Finally, future studies can further examine other common sleep and PTSD co-occurring disorders such as traumatic brain injury and substance use.

CONCLUSIONS

This study provides evidence that integrated CBT-I and PE, when compared to sleep hygiene and PE, is efficacious in treating insomnia disorder and PTSD among individuals with insomnia and PTSD.

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