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ORIGINAL RESEARCH

Brief CBT for insomnia delivered in primary care to patients endorsing suicidal ideation: a proof-of-concept randomized clinical trial

Wilfred R. Pigeon,[1–3] Jennifer S. Funderburk,[2–4] Wendi Cross,[1,2] Todd M. Bishop,[1–3] Hugh F. Crean[1,2]

[1]VISN 2 Center of Excellence for Suicide Prevention, Canandaigua VA Medical Center, Canandaigua, NY, USA

[2]Department of Psychiatry, University of Rochester Medical Center, Rochester, NY, USA

[3]Center for Integrated Healthcare, Syracuse VA Medical Center, Syracuse, NY, USA

[4]Department of Psychology, Syracuse University, Syracuse, NY, USA

Corresponding to: Wilfred R. Pigeon, Wilfred.Pigeon2@va.gov

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Abstract

Insomnia co-occurs frequently with major depressive disorder (MDD) and posttraumatic stress disorder (PTSD); all three conditions are prevalent among primary care patients and associated with suicidal ideation (SI). The purpose of the article was to test the effects of a brief cognitive behavioral therapy for insomnia (bCBTi) and the feasibility of delivering it to primary care patients with SI and insomnia in addition to either MDD and/or PTSD. Fifty-four patients were randomized to receive either bCBTi or treatment-as-usual for MDD and/or PTSD. The primary outcome was SI intensity as measured by the Columbia-Suicide Severity Rating Scale; secondary clinical outcomes were measured by the Insomnia Severity Index, Patient Health Questionnaire for depression, and PTSD Symptom Checklist. Effect sizes controlling for baseline values and sample size were calculated for each clinical outcome comparing pre–post differences between the two conditions with Hedge's *g*. The effect size of bCBTi on SI intensity was small (0.26). Effects were large on insomnia (1.91) and depression (1.16) with no effect for PTSD. There was a marginally significant ($p = .069$) effect of insomnia severity mediating the intervention's effect on SI. Findings from this proof-of-concept trial support the feasibility of delivering bCBTi in primary care and its capacity to improve mood and sleep in patients endorsing SI. The results do not support bCBTi as a stand-alone intervention to reduce SI, but this or other insomnia interventions may be considered as components of suicide prevention strategies.

Keywords

Depression, Insomnia, Posttraumatic stress disorder, Primary care, Suicide, Veteran

Implications

Practice: Cognitive behavioral therapy for insomnia is effective when delivered in a small number (four) of brief duration (30 min) sessions to primary care patients endorsing suicidal ideation.

Policy: Health care systems may consider brief behavioral interventions for insomnia to address the underutilization of nonpharmacologic interventions for insomnia and to expand interventions available for insomnia patients who endorse suicidal thoughts, but are not at imminent risk.

Research: Future research should be conducted in large and varied populations to assess generalizability of brief insomnia intervention effects.

INTRODUCTION

Insomnia and suicidal thoughts and behaviors

In 2007, a pivotal review drew increased attention to the association of suicidal thoughts and behaviors to sleep disturbance [1]. A seminal meta-analysis has since borne out the increased relative risk of suicide outcomes posed by sleep disturbance in general, as well as for insomnia and nightmares specifically [2]. A second meta-analysis, including only studies of patients with psychiatric diagnoses, observed similar associations of sleep disturbance with suicidal behaviors [3]. Sleep disturbance has also been shown to precede suicide in veterans [4] and suicide attempts in military service members [5]. Despite this recent evidence, intervention work undertaken to determine whether improving sleep disturbance has an effect on suicidal thoughts and behaviors is limited. Instead, clinical research in suicide prevention has understandably focused on risk factors more commonly associated with suicide (e.g., depression).

There is a strong etiological link between behavioral health conditions and suicide [6,7]. In a study of over 3 million patients receiving care in the U.S. Veterans Health Administration, those with a psychiatric diagnosis were more than twice as likely to die by suicide as those without such diagnoses [8]. Bipolar disorder, substance use disorders, depression, posttraumatic stress disorder (PTSD), other anxiety disorders, and schizophrenia were all associated with greater risk of suicide. In psychological autopsy studies, ~90% of suicide decedents had one or more behavioral health conditions during their last weeks of life [9]. Moreover, approximately half of suicide decedents in a national cohort study had a history of one or more psychiatric conditions [10]. Major depression, for instance, is a potent risk factor for eventual suicide [10,11] and PTSD has been

found to predict thoughts of suicide in recent combat veterans [12]. Few interventions for these conditions have shown that they significantly affect suicidal thoughts and behaviors [13]. A meta-analysis of psychotherapy for depression, for example, found only a small effect on suicidal thoughts and behaviors for these interventions [14]. A critical gap in care exists, therefore, for patients with common conditions like depression and PTSD who may be experiencing suicidal ideation (SI).

Insomnia, in turn, is highly comorbid with many conditions that are associated with suicide, including depression and PTSD. When insomnia is present the effects of standard treatments for depression and PTSD are blunted and/or insomnia continues to be a residual problem [15–18]. Indeed, available data suggest limited efficacy of standard pharmacologic and nonpharmacologic PTSD treatments on insomnia [19–21], mirroring findings from the depression literature [22,23]. When comorbid with another condition, the additional burden of insomnia may exacerbate symptoms and diminish patients' capacities to manage those symptoms. It is not surprising, therefore, that insomnia is consistently found to be associated with SI and suicidal behaviors after controlling for other risk factors like depression [24].

Cognitive behavioral therapy for insomnia (CBT-I), in particular, has shown to be effective in reducing insomnia as well as mood and anxiety symptoms in several comorbid populations [25]. CBT-I is a multicomponent intervention typically delivered in 6–8 weekly face-to-face sessions. As described in treatment manuals [26,27], CBT-I consists of three core components (sleep restriction therapy, stimulus control therapy, and sleep-specific cognitive therapy) along with sleep psychoeducation and sleep hygiene. Stimulus control therapy is based on behavioral principles designed to extinguish learned associations between the bed and negative states, such as worry, frustration, and especially extended periods of wakefulness in bed by limiting activities that occur in the bedroom to sleep and sex. Most especially, stimulus control emphasizes leaving the bed and/or bedroom when wakefulness becomes prolonged and then returning to bed when sleepy. Sleep restriction therapy is designed to improve sleep consolidation by restricting the duration of the sleep period to approximately the reported average total sleep time for a period of time (typically 1 week). This represents the size of the prescribed sleep window. In each subsequent week that the average sleep efficiency (total sleep time divided by total time in bed) exceeds a predetermined threshold (e.g., 90%), the prescribed sleep period is increased by 15 min. Cognitive therapy, as applied in CBT-I, is focused on altering dysfunctional sleep beliefs and sleep-interfering thoughts by helping patients challenge the usefulness and validity of their negative beliefs and thoughts. Finally, sleep hygiene involves identifying health practices (e.g., alcohol prior to bed) and environmental factors (e.g. light, noise, temperature) that interfere with sleep and developing action steps to modify those factors.

CBT-I also represents an alternative to sedative-hypnotic management of insomnia, which has been associated with a greater incidence of depression, mortality and with increased suicidal thoughts and attempts [28,29]. There are no comparable risks associated with CBT-I, which has been successfully used in patients with depression and PTSD [30,31]. Most importantly, there is evidence from a small case series [32] and two uncontrolled studies of outpatient clinic patients [30,33] that CBT-I can reduce SI (based on a single-item measure). In addition, a large randomized trial of internet-delivered CBT-I was shown to reduce mean scores on a suicidality scale relative to the control condition in persons with depressive symptoms [34].

CBT-I in the primary care setting

As CBT-I is a portable intervention, the setting(s) for its delivery can be strategically considered. The primary care environment represents an ideal treatment venue for several reasons. First, sleep disturbances in general, and insomnia specifically, are highly prevalent among primary care patients [35–37]. In addition, patients with multiple comorbidities (e.g., PTSD, depression) often seek help for insomnia in primary care, rather than in mental health settings [38]. For these and other reasons, adaptations of CBT-I have been developed for delivery in primary care settings. These adaptations have consisted of fewer sessions than the traditional 6–8 sessions of CBT-I with some excluding the cognitive components of CBT-I (e.g., brief behavioral treatment for insomnia [39]) and others retaining the cognitive components, but reducing the duration of sessions (i.e., 4 or fewer ~30-min sessions) in order to be sustainable in a primary care practice (brief CBT-I [bCBTi] [40]). In a small, pilot randomized trial (N = 23) moderate-to-large effects of bCBTi on subjective insomnia ratings were observed among depressed primary care patients relative to a sleep hygiene control condition [41].

The present study

On the basis of these results and the need for interventions that can address modifiable risk factors for suicide in settings that can reach large numbers of vulnerable patients, we designed the present study. Given the relatively low base rate of suicide and nonfatal suicide attempts, we focused our examination on SI, which is a potent risk factor for suicidal behavior that confers prospective risk for suicide attempts and suicide [42,43]. The approach is consistent with current suicide prevention recommendations to target the prevention and treatment of SI as well as the prevention of suicidal behavior

[44]. The objectives of the study were to test the feasibility and acceptability of delivering the bCBTi intervention to primary care patients with SI, to assess the intervention's effect on the severity of SI and to test the possible mediating role of insomnia improvement on SI. Feasibility and acceptability data are presented in detail elsewhere (*reference information removed to keep reviewer blinding*). Here, we present study results related to SI and the mediating role of insomnia; we also present the interventions' effect on the severity of insomnia, depression, and PTSD symptoms.

METHODS

Study design and participants

This randomized clinical trial (*NCT no. blinded*) was funded by (*Grant no. blinded*) and conducted at the Department of Veterans Affairs (VA), and approved by the local VA Institutional Review Board. Participants were recruited from VA primary care clinics and assessed for further eligibility if they endorsed SI, insomnia, and co-occurring PTSD and/or depression. Eligible participants were randomized to either treatment-as-usual (TAU) for depression or PTSD or TAU plus bCBTi. There were two assessments, which occurred at baseline and at a posttreatment follow-up (6 weeks).

To identify potential participants, the electronic medical record was used to identify those patients who had an encounter in primary care where PTSD or major depressive disorder (MDD) was a diagnosis or they screened positive for depressive or PTSD symptoms on the Patient Health Questionnaire-2 (PHQ-2) or Primary Care PTSD screens [45,46] in the 3 months prior to the encounter. The names of patients that met these initial criteria were then submitted to their primary care provider. Patients whom the primary care provider deemed suitable for participation were mailed a signed letter describing the study. Research staff contacted these patients by telephone 7–10 days later and asked if they were interested in participating and, if so, conducted an initial phone screen. Initial eligibility criteria included absence of potential untreated sleep apnea as assessed by three questions from the STOP-Bang questionnaire [47] (frequent loud snoring, awakened by choking or gasping, and bed partner noticing pauses in breathing); a score of ≥10 on the Insomnia Severity Index (ISI [26,48]); and endorsing SI on the first two items of the Columbia-Suicide Severity Rating Scale (C-SSRS) [49]) in the past 6 months. Those meeting initial eligibility criteria and still wishing to participate were scheduled for a full, face-to-face informed consent and baseline assessment visit.

Eligibility

Inclusion criteria included English-speaking veterans aged 18–70; demonstrate an understanding of the informed consent; seeking or receiving services at a local VA primary care clinic; endorse SI on the C-SSRS [49]; either (i) a current diagnosis in their medical record of MDD, depression not otherwise specified, PTSD, or (ii) evidence of current depression as indicated by a score of ≥10 on the Patient Health Questionnaire-9 (PHQ-9 [50]) *or* current PTSD as indicated by a score of ≥38 on the PTSD Symptom Checklist-Military version (PCL-M [51]); an ISI score of ≥10 with trouble sleeping ≥3 months, and at least 1 insomnia-related daytime consequence (score of ≥1 on the ISI item no. 3).

Exclusion criteria included a history of serious mental illness, such as schizophrenia, bipolar I or II disorder, or current psychiatric conditions, such as psychosis, mania, dementia, cognitive impairment, or SI with plan and intent, a report of a suicide attempt in the past 6 months in the electronic medical record or via self-report, or a score of ≥4 on the C-SSRS; currently engaged in inpatient or partial hospitalization programs or ongoing or pending medical procedures that could inhibit sleep; recent substance dependence disorder with <3 months in remission or abstinence; suspicion of or evidence of untreated sleep apnea; diagnosis of a circadian rhythm disorder or narcolepsy; and history of seizures.

A total of 581 potential participants were identified from medical records and received a recruitment letter from their current treatment provider (see Fig. 1) in 2015. From this total, 420 participants were screened by phone with 71 meeting initial eligibility criteria and ultimately completing written informed consent and a full baseline interview. Of these, 54 participants met all eligibility criteria and were randomized to bCBTi or a control TAU condition. Sample characteristics are displayed in Table 1.

Randomization and blinding

Subjects were randomized at a 1:1 ratio to one of the two experimental conditions. Randomization was stratified by gender and by diagnostic group (PTSD only, depression only, and both PTSD and depression). A randomization table with condition assignment was generated prior to the study by the statistician and participants were assigned sequentially to condition within each of the six possible substrata (two gender × three diagnoses). One assessor conducted all follow-up assessments and remained blinded to condition. A separate assessor conducted the baseline assessments prior to randomization, but was not subsequently blinded.

Measures

Several unpublished instruments were used to characterize the sample and assess eligibility: the Demographic and Veteran Information Form, a Medication and Treatment History Questionnaire, a Medical Chart Review form, and Sleep Disorders Screening Questionnaire.

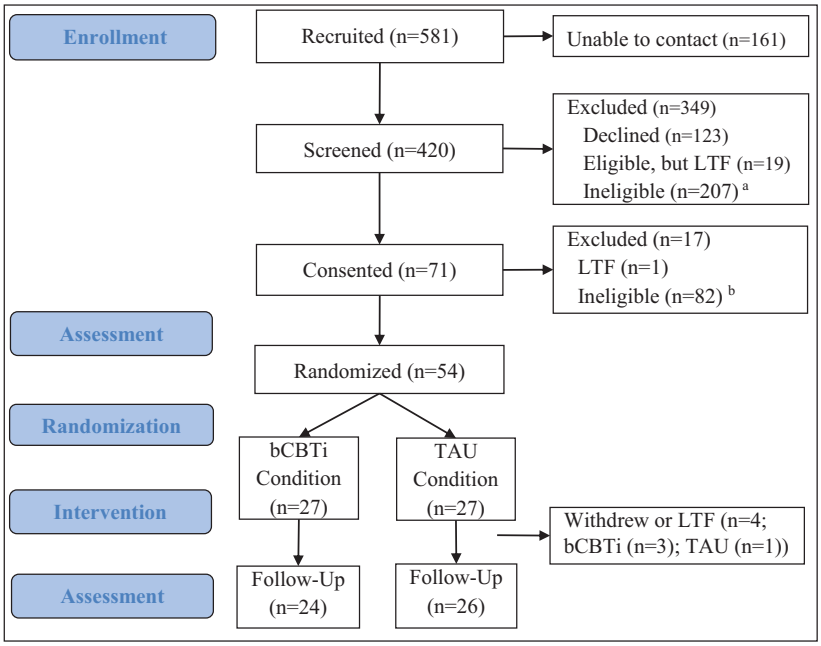

Fig 1 | Participant flow diagram. *bCBTi* brief cognitive behavioral therapy for insomnia; *LTF* lost to follow-up; *TAU* treatment-as-usual. [a]Reasons for ineligibility at screening: no suicidal ideation (*n* = 65); no insomnia (*n* = 54); untreated sleep apnea (*n* = 34); severe suicidal ideation (*n* = 12); deemed inappropriate for study by primary care provider (*n* = 12); severe psychiatric illness (*n* = 9); no depression or PTSD (*n* = 8); severe medical condition (*n* = 7); various other (*n* = 6). [b]Reasons for ineligibility at baseline assessment: no suicidal ideation (*n* = 3); untreated sleep apnea (*n* = 2); severe/unstable medical condition (*n* = 2); alcohol use disorder (*n* = 2); unstable medication dosages (*n* = 2); cognitive impairment (*n* = 1); deployed/return to active duty (*n* = 1).

Table 1 | Baseline characteristics of sample by experimental condition (bCBTi = 24; TAU = 26)

	bCBTi	TAU	Total		
	n (%) or mean (*SD*)	*n* (%) or mean (*SD*)	*n* (%) or mean (*SD*)	χ^2	*p*
Gender (female)	5 (20.8%)	5 (19.2%)	10 (20.0%)	0.020	.887
Minority	8 (33.3%)	7 (26.9%)	15 (30.0%)	0.244	.621
Hispanic	1 (4.2%)	1 (3.8%)	2 (4.0%)	0.003	.954
Marital status					
Single	4 (16.7%)	3 (11.5%)	7 (14.0%)		
Widowed	1 (4.2%)	1 (3.8%)	2 (4.0%)		
Divorced/separated	9 (37.5%)	10 (38.5%)	12 (46.2%)		
Married/cohabitating	10 (41.7%)	19 (38.0%)	22 (44.0%)	0.298	.960
Education					
High school equivalency	4 (16.7%)	1 (3.8%)	5 (10.0%)		
High school diploma	8 (33.3%)	6 (23.1%)	14 (28.0%)		
Associate/technical degree	6 (25.0%)	11 (42.3%)	17 (34.0%)		
Four-year college diploma	2 (8.3%)	4 (15.4%)	6 (12.0%)		
Master's degree	4 (16.7%)	4 (15.4%)	8 (16.0%)	4.150	.386
Combat exposure	11 (45.8%)	13 (50.0%)	26 (52.0%)	0.086	.768
MH treatment	17 (70.8%)	18 (69.2%)	35 (70.0%)	0.02	.902
Insomnia medication	6 (25.0%)	6 (23.1%)	12 (24.0%)	0.03	.874
Continuous measures					
Age (in years)	52.79 (14.45)	56.81 (10.95)		1.24	.271
Depression (PHQ-9)	15.64 (5.10)	16.27 (5.47)		0.18	.674
Insomnia (ISI)	18.51 (4.31)	18.23 (4.82)		0.05	.832
PTSD (PCL-M)	51.60 (15.55)	55.00 (15.54)		0.60	.444
SI intensity (C-SSRS-SI)	13.04 (3.57)	12.00 (2.59)		1.41	.241

bCBTi brief cognitive behavioral therapy for insomnia; *C-SSRS-SI* Columbia-Suicide Severity Rating Scale—Suicidal Ideation Intensity subscale; *ES* effect size (Hedge's *g*); *ISI* Insomnia Severity Index; *MH treatment* receiving outpatient mental health services; *PCL-M* PTSD Symptom Checklist-Military version; *PHQ-9* Patient Health Questionnaire-9; *TAU* treatment-as-usual.

The latter's items are based on the diagnostic criteria for sleep disorders, including insomnia, sleep apnea, narcolepsy, restless legs syndrome, and circadian rhythm disorders which was used in conjunction with self-report and chart review to assess for sleep disorders.

The C-SSRS is a clinician-administered interview designed to assess SI and suicidal behaviors [49]. The first section of the C-SSRS assesses severity of SI and has five categories with increasing levels of severity (1 = suicidal thoughts or wishing to be dead to 5 = suicidal thoughts with a plan and intent to carry it out). The C-SSRS intensity of ideation scale consists of five items that assess frequency, duration, controllability, deterrents, and reasons for SI. Depending on the intensity of the response, each item can receive up to 5 points yielding a maximum total score of 25. Studies have found it is correlated (with *r*'s ranging from .51 to .69) with other suicide severity measures [52].

The ISI is a validated 7-item scale that assesses difficulty initiating and maintaining sleep, daytime consequences, worry about sleep, and satisfaction with sleep quality on a scale of 0–4 [26,48]. The summed score on the instrument can be categorized into no, mild, moderate, and severe insomnia or a cutoff of ≥10 can be used to demonstrate clinically meaningful insomnia. We used this cutoff as an inclusion criteria and the total score (Cronbach's α in this study = .78) to assess treatment effects on symptom severity.

The PHQ-9 is a validated 9-item scale developed for use in primary care settings that assesses how much respondents have been bothered by MDD symptom criteria on a 4-point scale (0 = "not at all" to 3 = "nearly every day") [50]. We used a cutoff of ≥10 as an inclusion criteria and the total score (minus the sleep item; α = .80) to assess treatment effects on symptom severity.

The PCL-M is a validated 17-item scale developed for veterans that asks respondents to rate how much they have been bothered by PTSD symptoms on a 5-point scale (1 = "not at all" to 5 = "extremely") [51]. We used a cutoff score of ≥38 as an inclusion criterion and the total score (minus the insomnia item; α = .93) to assess treatment effects on symptom severity.

Procedures

Safety

A procedure to assess and manage safety was implemented at each study contact for all participants. At baseline this included review of any existing suicide safety plans or the development of a safety plan if none existed. At each subsequent study contact, current SI and any plan or intent were assessed. Safety plans were reviewed or modified as appropriate. Procedures were in place to manage any immediate safety concerns.

Treatment conditions

All participants in the TAU condition were encouraged to begin or continue treatment for their co-occurring condition(s) as recommended by treatment providers. Treatment could occur within the primary care teams, through behavioral telehealth, and/or specialty outpatient mental health and could consist of any pharmacologic or nonpharmacologic interventions. Participants randomized to TAU could also receive pharmacotherapy for insomnia.

All participants in the bCBTi condition were encouraged to begin or continue TAU per above with the exception of insomnia interventions. In addition, participants received four individual sessions of bCBTi. Sessions were audiotaped. Behavioral health providers (n = 3) with at least a master's degree in mental health counseling, social work, or psychology were trained to deliver bCBTi. Sessions typically occurred weekly for the first 3 weeks, with 2 weeks between the third and fourth sessions. bCBTi consisted of standard, structured, multicomponent CBT-I intervention containing sleep education, sleep hygiene, sleep restriction, stimulus control, and cognitive therapy [27]. Participants completed a daily sleep diary for the week prior to treatment initiation and throughout the intervention period. This subjective self-report measure includes the times participants went to bed and rose for the day as well as minutes to fall asleep, additional minutes awake during the night, number of awakenings, and total sleep time. Sleep efficiency (total sleep time divided by total sleep opportunity) is calculated by the therapist each week and is used to guide the sleep restriction portion of bCBTi. Values are summed and averaged over a 1-week period to guide bCBTi treatment.

The bCBTi therapists received weekly supervision, which included review of session audio recordings. Therapist fidelity to the bCBTi manual was confirmed by two independent, fidelity raters who rated 20% of sessions from audio recordings against reliable therapist fidelity measures developed for the current study (*Fidelity manuscript reference blinded*).

Analytic procedures

Sample size was based on having 80% power to detect effects of ≥0.60 with α set at .05 and assuming covariates explaining 50% of the variance in mean differences at posttreatment. Accordingly, we sought to accrue a sample of 48 participants with complete data, assuming ~15% completely missing data from 56 randomized participants.

Consistent with reporting pilot trial findings, rather than statistical tests of significance for primary and secondary outcomes, effect size estimates with 95% confidence intervals were calculated. There were based on marginal means and adjusted for sample size bias using Hedge's g to provide a more conservative effect size estimate than Cohen's d

[53]. This approach was applied to test the effect of bCBTi on the primary outcome of SI intensity as measured by the C-SSRS-SI intensity subscale and the effects of bCBTi on the secondary outcomes of severity of insomnia (ISI), depression (PHQ-9 minus sleep item), and PTSD (PCL-M minus insomnia item) symptoms. An intent-to-treat framework was followed [54].

To provide additional information about SI, we compared the proportion of participants in each condition that experienced at least a one category decrease in SI severity on the first section of the C-SSRS. To test the mediational portion of the study aims, path analysis was applied to a model of insomnia severity mediating the intervention effect on SI intensity.

RESULTS

Fifty of the 54 randomized participants completed the study (a 93% retention rate). There were no differences between completers and dropouts on baseline characteristics. There were three dropouts in the experimental condition and one in the control condition for which no follow-up data were available. The analyzed sample included 24 bCBTi participants and 26 TAU participants and no significant baseline differences were observed, including the number using a sleep medication or insomnia severity score at time of randomization (see Table 1). In addition, no additional participants were started on any insomnia medication during the intervention period and none reported discontinuing their sleep medication. There were no important harms.

As detailed in Table 2, the effect size of bCBTi on SI was in the expected direction, but small (ES = −0.26; CI: −0.81, 0.30). Compared to the control condition, large effects were observed for bCBTi on insomnia severity (ES = −1.91; CI: −2.58, −1.24) and depression severity (ES = −1.16; CI: −1.76, −0.56) with no effect on PTSD severity (ES = −0.17; CI: −0.73, 0.38).

We also examined proportions of each condition achieving some improvement on the categorical SI severity scale of the C-SSRS (baseline sample range of 1–3). Here, 78% of the bCBTi participants experienced at least a one category reduction in severity compared to 59% of control participants. In the mediational analysis, treatment condition had a strong effect on insomnia severity ($\beta = -.62$, $p < .001$). Insomnia severity had a marginal positive relationship with suicide intensity ($\beta = .37$, $p = .060$). The Sobel test (to determine mediation effect) was marginally significant ($\beta_1\beta_2 = -.23$, $p = .069$). As a form of sensitivity, we also examined if participating in other forms of mental health treatment (outside of those offered in the intervention) during the study intervention period had an effect on the findings. Here, many of the participants received some mental health treatment outside of the study (35 of the 50 participants, 70%) with no difference across conditions ($\chi^2_{(1\ df)} = 0.015$, $p = .90$). Nor were there any differences in the amount of sessions attended (bCBTi mean sessions attended = 1.54, $SD = 1.59$; control mean = 2.12, $SD = 2.52$; $F_{(1\ df)} = .91$, $p = .34$, ES = 0.26). When accounting for participation in mental health services, there were no to negligible differences in the patterns and strengths of the effects reported.

DISCUSSION

This study was a proof-of-concept trial to test the feasibility and effect of delivering a brief from of CBT-I to primary care patients experiencing thoughts of suicide. The bCBTi intervention was constructed for, and successfully delivered in, a real-world primary care setting among patients endorsing SI. The bCBTi intervention was associated with large effects on insomnia and depression severity, but with small effects on SI intensity and PTSD severity. These clinical outcomes suggest that bCBTi is an effective form of treatment for insomnia in the presence of SI with depression and/or PTSD.

The observed effect size of bCBTi compared to the control condition for SI intensity, however, was modest at best. This finding is similar to effects on SI observed in a study of dialectical behavior therapy for women veterans with borderline personality disorder [55], for depression psychotherapies [14,56],

Table 2 | Posttreatment marginal means and effect sizes (bCBTi = 24, TAU = 26)

	bCBTi	TAU		
	Adj mean (*SD*)	Adj mean (*SD*)	ES[a]	95% CI
C-SSRS-SI	6.14 (6.76)	7.83 (6.36)	−0.26	−0.81, 0.30
ISI	8.16 (5.49)	17.93 (4.60)***	−1.91	−2.58, −1.24
PHQ-9[b]	6.60 (4.59)	12.37 (5.16)***	−1.16	−1.76, −0.56
PCL-M[b]	46.09 (16.08)	48.91 (16.07)	−0.17	−0.73, 0.38

Covariates include gender, age, white/minority status, ethnicity, and baseline value of the dependent variable. *adj mean* analysis of covariance adjusted mean; *bCBTi* brief cognitive behavioral therapy for insomnia; *CI* confidence interval; *C-SSRS-SI* = Columbia-Suicide Severity Rating Scale—Suicidal Ideation Intensity subscale; *ISI* Insomnia Severity Index; *PCL-M* PTSD Symptom Checklist-Military version; *PHQ-9* Patient Health Questionnaire-9; *TAU* treatment-as-usual.

[a]Effect size (ES) presented as Hedge's *g* based on marginal means and adjusted for sample size.

[b]PHQ-9 and PCL-M are with insomnia items omitted.

***$p < .001$, **$p < .01$, *$p < .05$.

and an internet-delivered intervention for SI [57,58]. There was a 50% mean reduction in SI intensity in the bCBTi condition of this study, which compares favorably to suggestions that a 43% reduction in SI severity (albeit on a different scale) is clinically significant [58]. Although, the mediation results also suggest that the level of insomnia severity following treatment may mediate the relationship of bCBTi on SI intensity, in sum the study results as they pertain directly to the effect of bCBTi on SI are not as convincing as the intervention's effect on insomnia and depression severity. It is possible that the use of safety assessments and safety planning dampened the between-group effects on SI as participants in each condition were closely monitored throughout their study involvement.

There are several limitations of this study. The eligibility criteria included the presence of either (i) a medical chart-based diagnosis of depression or PTSD, (ii) a PHQ-9 score of ≥10 and/or a PCL-M score of ≥38. Given, that diagnoses in the medical record may not be current or accurate it is possible that the aforementioned criteria may have led to the inclusion of participants based only upon a diagnosis that might not be accurate. Although it could have been otherwise, in this study, all participants scored either ≥10 on the PHQ-9 or ≥38 on the PCL-M. The study design also allowed for all participants to receive TAU interventions for PTSD and/or depression during the intervention period to provide a real-world test of bCBTi as an addition to TAU. Here, although the number of participants using outpatient mental health services during the intervention period was not different between conditions, diagnostic coding in the medical record did not allow us to discern they types of outpatient services received keeping the possibility open that some forms of treatment were unequally distributed. Another limitation is that there was no follow-up assessment beyond the immediate posttreatment period, making any estimation of durability of effects impossible. In addition, the study was powered to detect a moderate effect of 0.60 on continuous outcomes which was not achieved for the primary outcome of SI intensity. It is, of course, unknown whether other forms of CBT-I may have had superior effects on the main outcome given the study design. The study findings may not be generalizable to other populations experiencing SI due both to the veteran population studied and to the eligibility criteria which required both a meaningful level of insomnia and the presence of either PTSD and/or major depression. Similarly, the findings do not generalize to patients with MDD and/or PTSD who do not endorse SI or to patients outside of primary care settings. Finally, this study did not address the sizable knowledge gap that exists with respect to the effect of sleep interventions on suicide attempts and suicide.

Notwithstanding these limitations, the study is one of the few randomized trials of any insomnia intervention to exclusively enroll participants with SI and to test its impact on insomnia severity. The size of observed effects on insomnia severity is similar to those achieved by other forms of CBT-I in other samples. The study also joins an increasing number of trials that have demonstrated an effect of a CBT-I intervention on depression. The findings support the contention that insomnia is a modifiable risk factor for suicide among those experiencing thoughts of suicide. Finally, the study findings can inform sample size estimates for the development and conduct of fully powered trials to determine the effects CBT-I on SI.

Several observations and suggestions follow from this study findings. First, given the effect size of bCBTi on SI observed, the design of CBT-I clinical trials where SI is an outcome need to be powered based on these smaller effects as opposed to the larger effects of CBT-I typically observed for insomnia and depression severity. Second, this study supports the inclusion of patients with insomnia and SI (that is not at the most severe levels) in clinical trials and/or in behavioral sleep medicine practices assuming very standard safety procedures are in place. Third, although isolating insomnia as a single variable to target for suicide prevention is antithetical to a multifactorial issue the findings suggest that adding bCBTi to usual care may enhance overall care by improving both sleep and mood. In fact, as insomnia is a common denominator across several populations at increased risk for suicide, insomnia interventions could be critical features of existing suicide prevention efforts and should continue to be evaluated as such. Fourth, with respect to behavioral insomnia interventions, we strongly believe that for patients experiencing insomnia and a comorbid condition(s), combining or sequencing insomnia treatment with an evidence-based treatment for the comorbid condition(s) is an optimal strategy, which has been accomplished (with good results) in several conditions [59,60]. We are not aware of examples of combining a behavioral insomnia intervention with a behavioral suicide prevention intervention, but support any efforts to assess this strategy. Fifth, with respect to the format of CBT-I tested in this study, due to its brevity bCBTi may represent an optimal choice for an insomnia intervention that is combined with a suicide prevention intervention. A related observation is that brief interventions for other common conditions that are themselves risk factors for suicide (e.g., chronic pain, PTSD) may be equally viable candidates for being combined with suicide prevention interventions. Sixth, whether brief insomnia treatments are combined with suicide prevention interventions or as an adjuvant to other mental health TAU, primary care is an ideal setting in which to take either or both approaches

given that patients at elevated risk for suicide so often present there. Finally, although this study was focused on suicide prevention, a significant value of the intervention may reside in its potential to improve overall population health while conserving the limited resource of more intensive CBT-I.

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Compliance with Ethical Standards

Conflict of Interest: Author W.R. Pigeon has received consulting fees from CurAegis Technologies, Inc. There are no other conflicts to report.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. IRB approval was obtained from the Syracuse IRB of the Department of Veterans Affairs.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

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