

## Research paper

# Brief cognitive behavioral therapy for insomnia delivered to depressed veterans receiving primary care services: A pilot study



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## A B S T R A C T

**Background:** Depression and insomnia are treatable, often co-occur and are common among primary care patients. Treatments designed for primary care must be brief, effective and ideally have the potential to address multiple symptoms. A brief form of cognitive behavioral therapy for insomnia (CBT-I) was piloted among depressed primary care patients with insomnia some of whom endorsed suicidal ideation.

**Methods:** Veterans Affairs primary care patients were randomized to either CBT-I or sleep hygiene. CBT-I consisted of two, 20–40 min in-person sessions and two 15–20 min telephone sessions; SH consisted of one in-person and one telephone session. Participants were assessed at baseline, post-treatment, and a 3 month follow-up.

**Results:** Compared to SH ( $n = 14$ ), brief CBT-I ( $n = 13$ ) had large effects on insomnia severity, sleep efficiency, number of awakenings, and time awake after sleep onset with between group effect sizes ranging from .75 to 1.09 at post-treatment and .66–.89 at follow-up, though significance was not maintained at follow-up. Although both groups experienced significant reductions in depression severity, statistically significant group by time interactions were not observed for depression.

**Limitations:** Notable limitations include the small sample size, having excluded patients with the most severe suicide risk, and the absence of objective testing to detect presence of sleep disorders other than insomnia.

**Conclusions:** The effects observed for insomnia outcomes, corroborate support for using CBT-I in depressed patients and extend this support to a brief form of CBT-I structured for delivery in primary care. Whether a brief form of CBT-I delivered to patients in primary care who endorse suicidal ideation would have a significant effect on depressive symptoms and/or suicidal ideation remains to be tested in a fully powered trial.

## 1. Introduction

Insomnia frequently co-occurs with depressive symptoms (Tsuno et al., 2005) and both the presence of insomnia and depressive symptoms are independent risk factors for suicidal thought and behavior (Bernert et al., 2015; Bishop et al., 2013; Pigeon et al., 2012). Insomnia is also persistent in nature, does not tend to resolve without treatment (Ellis et al., 2012), and has been associated with the blunting of treatments aimed at reducing depression (Baglioni et al., 2011; Pigeon et al., 2008). Further, a majority of suicide decedents experience depressive symptoms and have been seen in primary care within a month prior to suicide (Luoma et al., 2002). With the increasing influx of integrated behavioral health providers in primary

care as a result of the implementation of medical home models (Nielsen, 2014; Pomerantz et al., 2014), behavioral treatments are needed that can help address the co-occurrence of depression and insomnia (Fig. 1).

Cognitive-behavioral treatments for depression and insomnia have both been found to be efficacious (Espie et al., 2007; Hofmann et al., 2012) with cognitive-behavioral therapy for insomnia (CBT-I) being supported by several meta-analyses (e.g., Trauer et al., 2015; Geiger-Brown et al., 2015). However, the capacity to deliver long behavioral interventions in primary care is limited. This is in part due to the fact that many integrated behavioral health providers work within a service delivery model devoted to maintaining access to services ultimately constraining treatments to be brief (e.g., 1–4 sessions of 15–30 min duration; Hunter et al., 2009; Robinson and Reiter, 2007; Rubenstein

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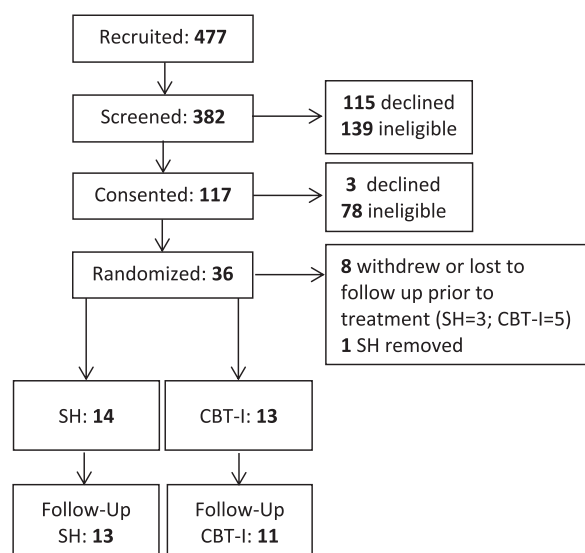


Fig. 1. Participant flow diagram.

et al., 2004). When patients present with co-occurring insomnia and depression, addressing insomnia using CBT-I may also be a more acceptable treatment goal within primary care as it is viewed as comparatively less threatening and carrying less stigma than depression (Pigeon, 2010). In addition, CBT-I has been demonstrated to be effective in improving sleep in the presence of comorbid depression (Manber et al., 2008) and may, in fact, be associated with reductions in suicidal ideation among depressed patients (Manber et al., 2011).

Sleep disturbance likely exerts both direct (Pigeon et al., 2012) and indirect effects on suicide risk. For example, insomnia may indirectly impact suicide risk through its association with depression, which itself is a primary driver of suicide risk. In addition to blunting response to depression focused treatments, presence of insomnia has been associated with both the onset of new major depression (Ford and Kamerow, 1989) and the recurrence of depressive episodes (Perlman et al., 2006). Further, the frequent co-occurrence of insomnia and depression has been suggested to be the result of several overlapping neurobiological and psychological processes some of which may include: stress hormone secretion (e.g., cortisol), insomnia's impact on mood and cognition (e.g., reduced ability to cope with stressors), and feelings of hopelessness or a sense of loss of control often associated with insomnia (Pigeon and Perlis, 2007) and with suicidal thoughts and behaviors (Pigeon et al., 2012).

CBT-I has been condensed into briefer formats, making it more practical for use in the primary-care setting (e.g., Edinger and Sampson, 2003). Brief Behavioral Therapy for Insomnia (BBTI) is a two-session variant of CBT-I that focuses on the behavioral components of CBT-I (Buysse et al., 2011). Most recently, a trial examined the efficacy of another two session, CBT-I influenced intervention among general practice patients in New Zealand (Falloon et al., 2015). The intervention focus was on a modified version of sleep restriction therapy delivered by general practitioners over two sessions with instructions for patients to continue adjusting their sleep schedules at subsequent two week intervals. Six month follow-up revealed modest, yet statistically significant, improvements in sleep efficiency, sleep quality, and insomnia severity scores for patients who received the intervention. However, patients with co-occurring psychopathology, including depression, were excluded from participation in this study. In contrast, the current study specifically enrolled participants with depression including those experiencing suicidal ideation. In addition, the current study tested a brief form of CBT-I delivered in two 30–40 min sessions and two 20 min phone sessions. The feasibility of delivering the intervention in a primary care setting has been reported (Pigeon and

Funderburk, 2014).

Here we address the remaining study aims, which were to: (1) describe the prevalence of suicidal thoughts and gather effect size data of the brief sleep intervention on suicidal ideation; (2) test the hypothesis that brief CBT-I, compared to a two-session sleep hygiene (SH) control condition would be associated with decreased insomnia severity; and (3) test the hypothesis that brief CBT-I, compared to SH, would be associated with decreased depression severity. Study approval was granted by the Department of Veterans Affairs (VA) Syracuse VA Medical Center Institutional Review Board.

## 2. Method

### 2.1. Participants

Individuals were eligible to participate if they were a veteran seen within VA primary care within the past year, carried a diagnosis of major depressive disorder (MDD), reported trouble initiating or maintaining sleep which had persisted for 3 months and contributed to at least one insomnia-related daytime consequence, had an Insomnia Severity Index (ISI; Morin, 1993) total score  $\geq 10$ , and were free of (or willing to discontinue the use of) hypnotic medications prior to beginning the study intervention. Potential participants were excluded from the study if they reported active suicidal ideation with either the intent to act or a suicide attempt within the past 6 months. Participants were also excluded if they had a history of seizures, schizophrenia, mania, or bipolar disorder, moderate or severe traumatic brain injury, or a mild brain injury occurring within the previous 6 months. Additionally, if participants were substance dependent or reported a partial remission of less than 3 months, exhibited psychotic symptoms, gross intellectual impairment, narcolepsy, circadian rhythm disorders, or untreated sleep apnea, they were excluded from study participation.

Participants were recruited from two VA primary care clinics in Western New York state, one in a large urban medical center and the other in a community outpatient clinic. Patients with elevated scores on their annual depression screener ( $\geq 3$  on the 0–6 point PHQ-2 scale; Kroenke et al., 2003; Lowe et al., 2005) were recruited via referral from primary care providers. Providers either signed a letter introducing them to the study or introduced the participant directly to study staff in person.

A total of 477 patients were recruited and 382 were able to be reached for the phone screening. Of those reached, 115 declined to participate, 139 were ineligible, and 128 were eligible with 11 eligible subjects who were subsequently lost to follow-up prior to informed consent. Reasons for ineligibility at the phone screening included no sleep problem=41, medical conditions=24, inpatient treatment or nursing home resident=20, cognitive deficits=16, untreated sleep apnea=11 serious mental illness or substance dependence=8, and various other reasons=19. Among participants consented to participate ( $n=117$ ), three individuals declined to participate any further and 78 were deemed ineligible (did not meet criteria for MDD=26, serious mental illness=18, suspected sleep apnea=14, other=20). Thus a sample of 36 participants were randomized to either the CBT-I ( $n=18$ ) or SH ( $n=18$ ) conditions. The remaining sample was predominantly male (89%) and White (82%) with many having had exposure to combat (56%). Following randomization and the collection of initial baseline data, five participants from the CBT-I condition and three from the SH condition withdrew or were lost to follow-up prior to the start of the intervention. One subject in the SH condition was removed from analysis as review of therapy tapes revealed that the participant had received some components of CBT-I. This left a total sample of 27 participants (CBT-I=13; SH=14). There were no significant differences between the analyzed sample and those 9 participants who withdrew or were excluded from analysis in terms of gender, race, insomnia severity (mean ISI scores of 16.7 and 17.1, respectively) or depression severity (mean PHQ-9 scores of 20.9, and 19.8 respectively); the study sample

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