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Impact of cognitive behavioral therapy for insomnia disorder on sleep and comorbid symptoms in military personnel: a randomized clinical trial FREE

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Sleep, Volume 41, Issue 6, June 2018, zsy069, https://doi.org/10.1093/sleep/zsy069
Published: 29 March 2018 **Article history ▾**

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Abstract

Study Objectives

To compare the efficacy of cognitive behavioral therapy for insomnia (CBTi) disorder and a Control condition on reducing insomnia and comorbid symptoms in a sample of active duty military personnel.

Methods

Randomized clinical trial of 151 active duty US Army personnel at Fort Hood, Texas.

Results

This study replicated Original ($n = 66$) findings (CBTi outperformed Control) in a follow-on sample ($n = 85$) on diary-assessed sleep efficiency ($d = 1.04$), total sleep time ($d = 0.38$), sleep latency ($d = -0.93$), number of awakenings ($d = -0.56$), wake time after sleep onset ($d = -0.91$), sleep quality ($d = 1.00$), and the Insomnia Severity Index ($d = -1.36$) in active duty soldiers. CBTi also outperformed Control in the combined sample ($N = 151$) on four of the five subscales of the Multidimensional Fatigue Inventory ($d = -0.32$ to -0.96) and the mental health subscale on the Veterans RAND 12-Item Health Survey ($d = 0.37$). Exploratory analyses also showed CBTi outperformed Control on nicotine ($d = -0.22$) and caffeine ($d = -0.47$) use reduction. Significant within-group differences were found for both groups on depression, anxiety, and posttraumatic stress disorder symptoms, but there was no group by time interaction for these symptoms or for use of hypnotics or alcohol.

Conclusions

CBTi was an effective treatment for insomnia and comorbid symptoms including daytime fatigue, general mental health, nicotine, and caffeine use.

Clinical Trial Registration

Clinicaltrials.gov; Identifier: NCT01549899; "Comparing Internet and In-Person Brief Cognitive Behavioral Therapy of Insomnia"

insomnia, cognitive behavioral therapy, military, caffeine, nicotine, randomized clinical trial

Statement of Significance

Cognitive behavioral therapy for insomnia (CBTi) disorder has the potential to improve military operational readiness through improvements in sleep, fatigue, and general mental health along with reductions in the use of nicotine and caffeine. Future studies are needed to examine the effectiveness of CBTi in other military settings (e.g. primary care, predeployment, during deployment) and in comorbid populations (e.g. depression, anxiety, posttraumatic stress disorder).

Introduction

People with insomnia disorder (hereafter referred to just as insomnia) often have comorbid depression, anxiety, and posttraumatic stress disorder (PTSD) [1–4]. It is plausible that the stress of insomnia, disruption of circadian rhythms, or coping methods adopted to manage the insomnia (e.g. alcohol or medications to help sleep; caffeine or nicotine to increase daytime alertness; social isolation; decreased activity) may actually instigate or exacerbate these comorbid symptoms [5, 6]. One way to test this hypothesis is to experimentally assign participants with insomnia to treatment or no treatment, and then measure if the treatment group has a significantly greater reduction in those conditions closely related to insomnia.

Recommendations for a Standard Research Assessment of Insomnia [7] considered assessment and reporting diagnosis of insomnia and comorbid conditions, sleep and insomnia severity, and waking correlates and consequences of insomnia (i.e. medications and substances [i.e. caffeine, alcohol, tobacco], fatigue, mood [i.e. depression and anxiety], and quality of life) essential elements of efficacy and effectiveness studies. The stated intention of these recommendations was to provide greater standardization and comparability across insomnia research studies. To date, few efficacy and effectiveness studies have met the above recommendations by comprehensively assessing and reporting on *all* of these variables. More typically, studies assess sleep outcomes comprehensively, then focus on *only one* comorbid outcome (e.g. PTSD, anxiety and/or depression, alcohol abuse) and sometimes one to two related outcomes [8–12]. Furthermore, although several studies have now shown that it is possible to treat insomnia successfully in patients with other psychiatric and medical problems, these studies have generally focused on civilian populations with only one comorbidity [8–12]. One recent systematic review of this literature found that cognitive behavioral therapy for insomnia (CBTi) is generally effective for insomnia in civilians and veterans with comorbid depression, anxiety, PTSD, and alcohol abuse disorders, and in some cases, CBTi also improved the comorbid disorder [8]. However, the results were often mixed, possibly because the improvement of insomnia comorbidities was secondary aims of these studies, and the studies may have been underpowered to find smaller effect sizes.

More studies are needed to investigate the secondary benefits of treating insomnia, such as reduction in depression, substance abuse, and PTSD symptoms. Our recently completed randomized trial ($N = 100$) found in-person and Internet-delivered CBTi resulted in significantly greater improvements in sleep and insomnia symptoms than the Control group, with the in-person group consistently showing better effect sizes than the Internet group [13]. The effect sizes found were similar to those found in civilian samples comparing in-person and Internet-delivered CBTi versus Control groups [13]. The purposes of the current paper were to (1) replicate those findings in a follow-on sample of an additional 85 participants (to gain adequate power to test secondary effects) randomized to either CBTi or Control and (2) examine the impact of CBTi on comorbid symptoms in the combined ($N = 151$) sample.

We hypothesized that, similar to previous studies, the CBTi group would report greater improvement than the Control group on insomnia variables as well as symptoms of depression, anxiety, and PTSD, and of hypnotic use [8, 14, 15]. Exploratory analyses also examined the effect of CBTi on use of alcohol, caffeine, and nicotine.

Methods

Participants

The participants were 151 active duty US Army soldiers stationed at Fort Hood, Texas, recruited between April 2012 and December 2014. Inclusion criteria included the following: (1) active duty, activated Reservists, or activated National Guard; (2) at least one military deployment in or around Iraq or Afghanistan (per the Fiscal year 2009 Psychological Health/Traumatic Brain Injury Research Program request for "post-deployment evidence-based preventive and early intervention"); (3) diagnosis of persistent insomnia disorder [16]; (4) stable on psychotropic and hypnotic medications for at least 1 month; (5) stable on continuous positive airway pressure therapy for sleep apnea for at least 1 month; (6) <85 percent sleep efficiency; and (7) correct utilization of actigraphy and sleep diaries (described in procedures section). Exclusion criteria were as follows: (1) <3 months since returning from deployment (to ensure they meet the 3 month duration criteria for "persistent" and not "situational/acute" insomnia due to being deployed) [16]; (2) suicidal risk meriting crisis intervention; (3) inability to comprehend or read English; (4) pregnancy; (5) serious mental health

diagnosis such as bipolar disorder or psychosis; (6) hypersomnia, chronic sleep deprivation, or circadian rhythm disorders; and (7) working rotating shifts or shifts requiring that the service member report to work earlier than 6 am or later than 9 pm. Participants were not excluded for other comorbid mental health conditions such as anxiety, depression, PTSD, alcohol use, head injuries, or medication use.

The study was approved by the Institutional Review Boards at Brooke Army Medical Center, the University of Texas Health Science Center at San Antonio, and the University of North Texas. The study was also approved by the US Army Medical Research and Materiel Command Human Research Protection Office.

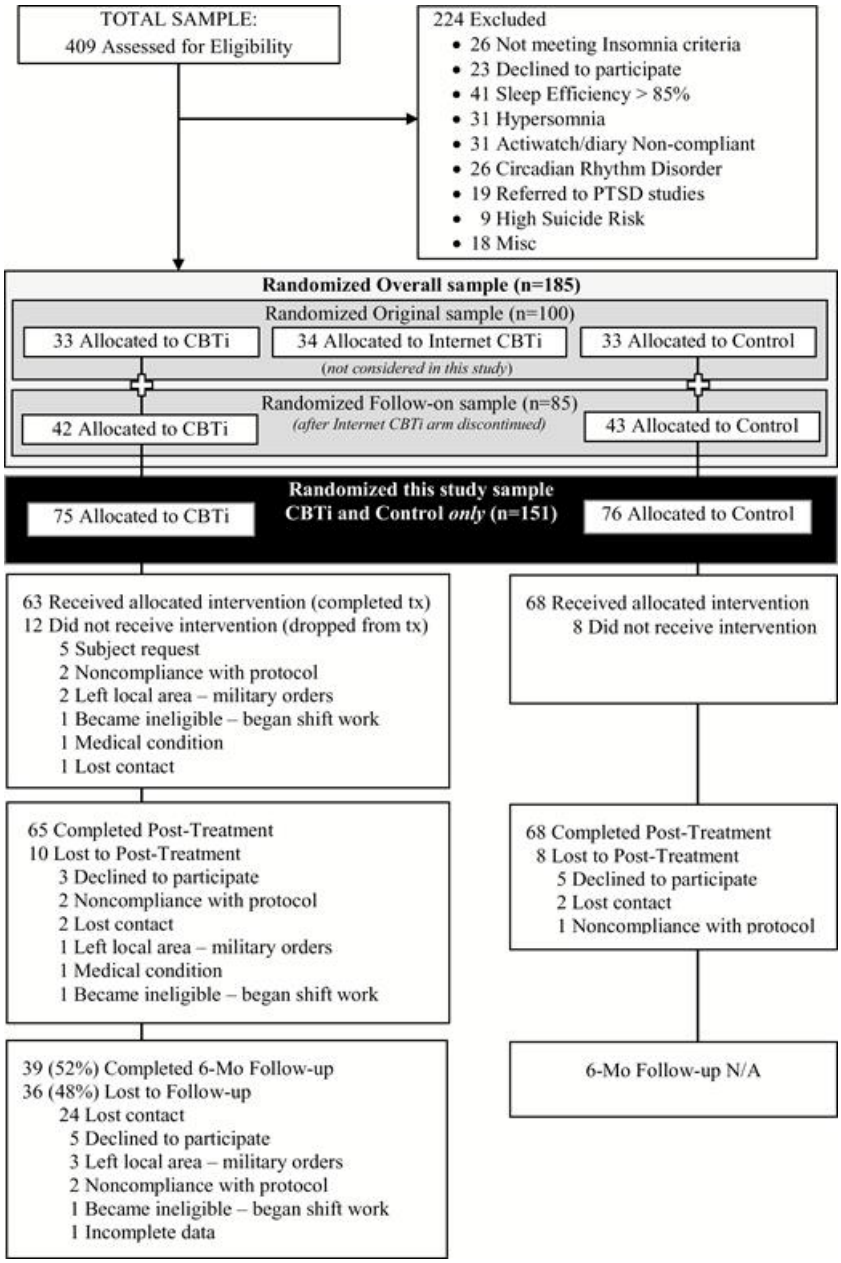
Research design

The current study was an extension of recruitment from a recently completed randomized clinical trial comparing in-person (n = 33) and Internet (n = 34) CBTi to a minimal contact (Control) condition (n = 33) on improvements in sleep [13]. Randomization was stopped to the Internet condition when that sample reached 34, but randomization continued into the in-person (additional n = 42) and Control (additional n =43) conditions, so there would be sufficient power (0.8) to test the effects of CBTi on comorbid symptoms (e.g. depression, anxiety, PTSD symptoms, and hypnotic medication use). As described in detail in the statistical analyses, the replication of the Taylor and colleagues study [13] compared the sleep outcomes of 42 participants randomized into the in-person CBTi intervention and 43 participants randomized into the Control condition. Then, the data from the Original sample (n = 66) and the above follow-on sample (n = 85) were combined (N = 151; 75 randomized to in-person CBTi and 76 randomized to the Control) to investigate secondary outcomes.

Procedures

A telephone screen was conducted as an initial evaluation of basic eligibility criteria (see Figure 1 for CONSORT chart). Eligible volunteers were then scheduled for a baseline evaluation in which they provided informed consent to participate in the study, completed a battery of questionnaires, and underwent structured clinical interviews by trained evaluators. Participants determined to be eligible then completed 1 week of sleep monitoring with Actiwatches and sleep diaries over a typical week (e.g. not during holidays, convalescent leave, vacation). Eligible participants were randomized using a random number generator with randomly permuted blocks provided by the biostatistician.

Figure 1.



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CONSORT chart showing participant flow through a randomized clinical trial with an Original sample comparing in-person CBTi, Internet CBTi, and a minimal contact control (Control) condition and then a follow-on sample of only in-person CBTi and Control.

Treatment

Cognitive behavioral therapy of insomnia

The CBTi intervention consisted of six weekly 60 min sessions and included the following components: stimulus control [17], sleep restriction [18], sleep hygiene [19], relaxation training [19], and cognitive restructuring [20]. CBTi was administered by civilian-licensed clinical psychologists, clinical psychology postdoctoral fellows, and a licensed clinical social worker. Therapists completed a 2 day training workshop and treatment of at least two clinical cases to fidelity prior to treating patients enrolled in the study. Weekly supervision of therapy was provided. Two clinicians with expertise in treating insomnia in active duty military populations and who were otherwise independent of the study reviewed audio of therapy sessions and rated a random sample of 18 percent of the treatment sessions using adherence and competence rating forms developed for the treatment manual used in this study. Other than requiring hypnotic medication to be stable at baseline (see inclusion/exclusion criteria above), we did not address hypnotic use during the course of treatment. If a patient expressed a desire to discuss or withdraw from a prescribed medication, we directed them back to their prescribing physician.

Control

Those assigned to the Control group were contacted for a brief (5 min) check-in call every other week for 6 weeks. At the end of 6 weeks, they completed the baseline assessments again. This served as the posttreatment assessment for the Control period.

Instruments

All participants completed the same measures at baseline and posttreatment or post-control. A more thorough description of the measures and procedures (e.g. treatments) can be found in the Original study [13].

Health interview

Key variables from the participants' health interview analyzed as part of the current study included use of medications for sleep, as well as caffeine, nicotine, and alcohol usage. Using standard conventions [21], we calculated average mg/day of caffeine over the prior 7 days based on participants' reported daily consumption of 8 ounce cups of coffee (150 mg/cup) and tea (50 mg/cup), 12 ounce cans of soda (40 mg/can), 16 ounce energy drinks (160 mg/can), caffeine tablets (200 mg/tablet), and pieces of caffeinated gum (100 mg/piece). Similarly, we calculated average weekly alcohol consumption using participants' self-reported daily consumption of 12 ounce cans of beer, 5 ounce glasses of wine, and 1.5 ounce drinks of liquor [22]. Finally, we calculated average mg/day of nicotine over the prior 7 days based on participants' reported daily number of cigarettes (1.5 mg each) [23], large cigars (1.4 mg each) [23], and cans of smokeless tobacco (11.9 mg/g) [24].

Sleep diaries

Daily sleep diaries were used to prospectively derive average sleep parameters (total sleep time, sleep latency, number of awakenings, wake time after sleep onset, sleep quality, and sleep efficiency [total sleep time/time in bed × 100]) over the course of a week [25].

Insomnia Severity Index

The Insomnia Severity Index (ISI) is a 7-item commonly used self-report measure of insomnia symptoms, with total scores ranging from 0 to 28, where higher scores indicate greater severity [19]. The ISI had an internal consistency α coefficient of 0.74 in a large ($N = 4101$), similar sample of active service members at Fort Hood [26], and α was 0.78 at pretreatment and 0.91 at posttreatment assessment in the current study.

Beck Anxiety Inventory

The Beck Anxiety Inventory (BAI) is a 21-item measure of anxiety symptoms, with total scores ranging from 0 to 63, where higher scores indicate greater severity [27]. The Cronbach's α for the BAI was 0.94 in a similar sample [26] and 0.94 at pretreatment and 0.95 at posttreatment assessment in the current sample.

Beck Depression Inventory-II

The Beck Depression Inventory-II (BDI-II) is a 21-item measure of depression symptoms, with total scores ranging from 0 to 63, where higher scores indicate greater severity [28]. The Cronbach's α for the BDI-II was 0.94 in a similar sample [26] and 0.94 at pretreatment and 0.96 at posttreatment assessment for the current sample.

PTSD Checklist-Military Version

The PTSD Checklist-Military Version (PCL-M) is a 17-item measure of PTSD symptoms indexed to military experiences, with total scores ranging from 17 to 85, where higher scores indicate greater severity [29]. The Cronbach's α for the PCL-M was 0.95 in a similar sample [26] and 0.94 at pretreatment and 0.96 at posttreatment assessments in the current sample [13].

Multidimensional Fatigue Inventory

The Multidimensional Fatigue Inventory (MFI) is a 20-item self-report measure of fatigue symptoms, designed to index five dimensions: general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity [30]. Total scores on the dimensions ranged from 4 to 20, with higher scores indicating greater fatigue. Cronbach α's at pretreatment and posttreatment assessments were as follows: general fatigue (0.70, 0.78),

physical fatigue (0.80, 0.82), reduced activity (0.81, 0.84), reduced motivation (0.76, 0.79), and mental fatigue (0.83, 0.87).

Veterans RAND 12-Item Health Survey

The Veterans RAND 12-Item Health Survey (VR-12) was derived from the Veterans RAND 36-Item Health Survey (VR-36), historically called the Veterans SF-36 [31, 32]. The VR-36 has been widely used, distributed, and documented in the Veterans Health Administration (VHA), with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales [33]. The VR-12 utilizes a complicated scoring algorithm that produces a physical component summary (PCS) score and mental component summary (MCS) following published procedures. Corresponding PCS and MCS scores are scaled from 0 to 100, with a mean of 50 and standard deviation of 10 [34], for comparison to a normative population, with higher scores reflecting greater physical and mental health.

Alcohol Use Disorders Identification Test

The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item measures of physiological and psychological dependence on alcohol as well as negative consequences associated with drinking [35]. Individuals endorse different items depending on the extent of their alcohol usage. Total scores can range from 0 to 40, where higher scores indicate a greater likelihood of an alcohol use disorder and scores greater than or equal to 8 indicate the likely presence of alcohol use disorder.

Statistical analysis

To replicate earlier published findings comparing the sleep outcomes following an in-person CBTi intervention to Control, the primary hypothesis was that CBTi would result in better sleep outcomes (e.g. greater sleep efficiency improvement, less insomnia) from pretreatment to posttreatment relative to the Control group. Outcomes were examined using linear mixed model regressions (intent-to-treat) with unstructured covariance matrices examining group (CBTi [$n = 42$] and Control [$n = 43$]) by time-point (pretreatment to posttreatment) main effects and interactions on each of the outcomes. Consistent with earlier published findings, the effect size (Cohen's d) for each variable was calculated as the between group difference in pretreatment to posttreatment change divided by the pooled pretreatment standard deviation. These effect sizes were compared with those from the previous study to determine whether the size of any observed effects varied across the two samples/analysis phases. This comparison was made by dividing the difference in Cohen d values across phases by an estimate of their pooled standard deviation. The resulting z score, when squared, is equivalent to the Q statistic one would obtain from a meta-analytic test of homogeneity; values greater than ±1.96 would indicate that the observed effect sizes differed across the two study phases. We then combined the data from the previously published study [12] with data from participants recruited and treated later using linear mixed model regressions (intent-to-treat) to compare group (CBTi [$n = 75$] and Control [$n = 76$]) by time (pretreatment to posttreatment) by time (Original sample vs. Follow-on sample) main effects and interactions on each of the sleep outcomes. Effect sizes for these models were calculated as described above.

To determine the effect of treatment on the comorbidities of depression, anxiety, PTSD symptoms, and substance use of alcohol, caffeine, and nicotine, specified mixed models were used to examine group by time point main effects and interactions. Because the counts of hypnotic medications were largely categorical, the data were dichotomized (i.e. on medication vs. not on medication) and tested group by status relationships separately at each assessment using chi-square tests. Similarly, change in medication use was examined. Effect sizes are reported for all analyses to put statistically significant results in context of clinical significance.

Results

Table 1 shows the demographic characteristics for the total sample and each of the groups, collapsed across samples. Overall, 151 participants were randomized into the CBTi ($n = 75$) and Control ($n = 76$) groups. The mean age of the total sample was 32.44 years, 82 percent were male, and 45 percent were Caucasian. There were no baseline differences in groups on any demographic characteristic. There was not a statistically significant difference between the groups in attrition over the course of the study (CBTi = 19%; Control = 14%), $\chi^2 = 0.48$, $p = .49$. The average time from pre- to posttreatment/control was 11 weeks.

Table 1.

Demographic characteristics

Characteristic	Total Sample	CBTi ($n = 75$)	Control ($n = 76$)	χ^2	p
Age	32.44 ± 7.57	32.21 ± 7.18	32.67 ± 7.97	0.37	0.71
Male	124 (82%)	62 (83%)	62 (82%)	0.03	0.86
Married/cohabitating	101 (67%)	46 (61%)	55 (72%)	2.07	0.15
Number of marriages	1.11 ± 0.78	1.04 ± 0.82	1.18 ± 0.73	1.14	0.25
Number of children	1.75 ± 1.68	1.55 ± 1.58	1.88 ± 1.76	1.23	0.22
Ethnicity				4.31	0.23
African American	46 (30%)	19 (25%)	27 (36%)		
Hispanic	26 (17%)	14 (19%)	12 (13%)		
Caucasian	69 (45%)	39 (52%)	30 (40%)		
Other	10 (7%)	3 (4%)	7 (9%)		
Education				0.19	0.90
High school	36 (24%)	19 (25%)	17 (22%)		
Some college/associate degree	92 (61%)	45 (60%)	47 (62%)		
College/graduate degree	23 (15%)	11 (15%)	12 (16%)		
Typical duty				0.96	0.62
Combat arms	52(35%)	25 (33%)	27 (36%)		
Combat support	41 (27%)	23 (31%)	18 (24%)		
Combat service support	58 (38%)	27 (36%)	31 (41%)		
Number of deployments				3.61	0.61
1	58 (38%)	27 (29%)	31 (29%)		
2	49 (33%)	26 (35%)	23 (30%)		
3	26 (17%)	14 (19%)	12 (16%)		
4+	18 (12%)	8 (10%)	10 (13%)		

Tests for all categorical variables are with *df* = 1–5 depending on the variable. Tests for variables presented with means and standard deviations are with *df* = 1.149.

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Sleep replication analyses

The replication analyses (Table 2) in the Follow-on sample showed a significant group (CBTi vs. Control) by time (pretreatment to posttreatment) interaction for sleep efficiency assessed with sleep diaries, with the CBTi group showing significant improvements in sleep efficiency from pretreatment to posttreatment compared with the Control group ($d = 1.10$). Similar effects were found for the components of sleep efficiency, with the CBTi group showing significant improvements compared with the Control group in sleep latency ($d = -1.09$), number of awakenings ($d = -0.64$), and wake after sleep onset ($d = -0.97$). A significant group by time interaction was also found for total sleep time, with the CBTi group showing significant improvements over time compared with the Control ($d = 0.61$).

Table 2.

Replication of Original (n = 66) [12] mixed linear model (intent-to-treat) analyses of pretreatment to posttreatment changes on primary outcome measures in a Follow-on sample (n = 85) of participants

		Follow-on sample									
		CBTi		Control							
		Pre: (n = 42) Post: (n = 30)		Pre: (n = 43) Post: (n = 36)		Group x time interaction		Effect size comparison			
M	(*SE*)	*M*	(*SE*)	*F*	*P*	$d_{Follow-on}$	$d_{Original}$	*z*	$d_{combined}$		
Sleep efficiency	Pre	70.46	2.07	70.12	2.04						
	Post	86.50	2.35	71.44	2.14						
	Within Group Δ,*d*	16.04*	1.22	1.32	0.10	32.61	<.001	1.10	0.89	−0.60	1.04
Total sleep time (hr)	Pre	5.15	0.19	5.03	0.19						
	Post	5.96	0.22	5.08	0.22						
	Within Group Δ,*d*	0.81*	0.65	0.05	0.04	9.18	.004	0.61	0.03	−1.75	0.38
Sleep latency (min)	Pre	46.04	3.68	45.16	3.64						
	Post	20.31	3.81	45.38	3.51						
	Within Group Δ,*d*	−25.73*	−1.16	0.22	0.08	18.59	<.001	−1.09	-0.68	1.19	−0.93
Number of awakenings	Pre	2.51	0.22	2.53	0.22						
	Post	1.38	0.28	2.33	0.26						
	Within Group Δ,*d*	−1.12*	−0.76	−0.21	−0.14	7.71	.007	−0.64	-0.42	0.66	−0.56
Wake time after sleep onset (minutes)	Pre	55.80	5.86	49.31	5.79						
	Post	22.95	6.62	53.16	6.23						
	Within Group Δ,*d*	−32.85*	−0.88	3.85	0.10	25.58	<.001	−0.97	-0.88	0.26	−0.91
Sleep quality	Pre	1.65	0.09	1.59	0.09						
	Post	2.28	0.11	1.72	0.10						
	Within Group Δ,*d*	0.62*	1.04	0.13	0.21	11.54	<.001	0.90	0.97	0.20	1.00
Insomnia Severity	Pre	17.71	0.78	18.00	0.77						
	Post	8.52	0.88	16.37	0.81						
	Within Group Δ,*d*	−9.20*	−1.86	−1.63	−0.33	36.67	<.001	−1.51	-0.98	1.48	−1.36

Δ = Within group change; CBTi = Cognitive behavioral therapy for insomnia; *d* = Cohen's *d*; pre = Pretreatment; post = Posttreatment;

sleep efficiency equals total sleep time/time in bed × 100.

*Indicates that the within-group change was significant from pretreatment to posttreatment for designated group. *Z* values greater than 1.96 would indicate that the effect sizes varied across the samples. Also, note that mixed models containing Group, Visit, and Analysis Phase all included nonsignificant three-way interaction terms, consistent with the “Effect Size Comparison” results above.

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Analyses of the global sleep quality ratings from the sleep diary and the ISI also revealed significant group by time interactions, with the CBTi group realizing significantly greater improvements compared with the Control group over time ($d = 0.90$ and -1.51, respectively).

Comparison of Original and Follow-on sleep results

Comparison of effect sizes between samples (Original vs Follow-on) indicated that there were no significant differences on any of the above sleep variables. Additionally, alternative models for all of the sleep-related outcomes were tested including a group (CBTi vs. Control) by time (Pre vs. Post) by sample (Original vs. Follow-on) interaction term. Consistent with the conclusions drawn from the effect size comparisons, none of the three-way interactions in these models were significant, indicating that the observed effects did not differ by sample. For comparability to other studies and use in future quantitative reviews, the last column of Table 2 contains the effect sizes on each of the main sleep-related variables for the combined sample of 151, which was subsequently used to analyze the effect of treatment on comorbid symptoms.

Comorbid symptoms

Given that the samples did not differ on the sleep-related outcomes, a single sample of 151 (75 CBTi and 76 Control) was used to assess the effects of treatment on common comorbid symptoms of sleep disturbance, specifically fatigue, health status, symptoms of depression, anxiety, and PTSD, and of hypnotic use and use of alcohol, caffeine, and nicotine. Results of these linear mixed model regression analyses (Table 3) showed that the group by time interaction was significant on four of the five subscales of the MFI, with the CBTi group showing significantly larger improvements over the course of treatment in general fatigue ($d = -0.96$), activity ($d = -0.32$), motivation ($d = -0.43$), and mental fatigue ($d = -0.56$), but not physical fatigue ($d = 0.04$), over time. A significant interaction was also found for the mental health subscale of the VR-12 ($d = 0.37$), with the CBTi group showing significantly greater improvements over time (Figure 2), but not for the physical health subscale ($d = 0.07$). Significant interactions were also not found for symptoms of depression, anxiety, and PTSD or alcohol use.

Table 3.

Mixed linear model (intent-to-treat) pretreatment to posttreatment analyses of secondary outcome measures in overall sample ($N = 151$)

		Combined (Original + Follow-on) Samples						
Secondary outcomes		**CBTi**		**Control**				
		Pre: (*n* = 75) Post: (*n* = 65)		**Pre: (*n* = 76) Post: (*n* = 61)**		**Group × time interaction**		
		M	***(SE)***	***M***	***(SE)***	***F***	***P***	***d***
MFI-general fatigue	Pre	14.99	0.35	14.76	0.34			
	Post	11.41	0.50	14.05	0.49			
	Within group Δ,*d*	−3.58*	−1.04	−0.71	−0.21	**23.13**	**<.001**	**−0.96**
MFI-physical fatigue	Pre	10.77	0.47	11.16	0.47			
	Post	9.77	0.51	10.01	0.50			
	Within group Δ,*d*	−1.00	−0.38	−1.15	−0.28	0.08	.78	0.04
MFI-reduced activity	Pre	10.32	0.47	10.07	0.47			

		Combined (Original + Follow-on) Samples						
Secondary outcomes		**CBTi**		**Control**				
MFI-reduced motivation	Pre	**Pre: (*n* = 75)**		**Pre: (*n* = 76)**		**Group × time interaction**		
	Post	**Post: (*n* = 65)**		**Post: (*n* = 61)**				
		M	***(SE)***	***M***	***(SE)***	***F***	***P***	***d***
	Within group Δ,*d*	−2.23*	−0.38	−0.59	−0.15	**9.40**	**.003**	**0.43**
MFI-mental fatigue	Pre	13.75	0.45	13.01	0.44			
	Post	11.13	0.56	12.53	0.54			
	Within Group Δ,*d*	−2.62*	−0.64	−0.49	−0.12	**11.35**	**<.001**	**-0.56**
VR-12 Mental Health Subscale	Pre	54.78	2.48	60.99	2.46			
	Post	65.99	2.86	64.32	2.81			
	Within group Δ,*d*	11.22*	0.51	3.32	0.15	**7.57**	**.007**	**0.37**
VR-12 physical health subscale	Pre	63.11	2.80	64.99	2.78			
	Post	68.85	2.85	68.92	2.80			
	Within group Δ,*d*	5.74*	0.25	3.91	0.17	0.39	.53	0.07
PCL-M total	Pre	34.83	1.67	35.96	1.66			
	Post	31.15	1.83	31.52	1.80			
	Within group Δ,*d*	−3.68*	−0.26	−4.44*	−0.31	0.29	.59	0.05
BAI-anxiety	Pre	14.57	1.42	14.05	1.41			
	Post	12.05	1.38	11.37	1.35			
	Within group Δ,*d*	−2.52*	−0.22	−2.69*	−0.23	0.01	.91	0.01
BDI-II-Depression	Pre	15.48	1.29	13.59	1.28			
	Post	11.19	1.48	10.52	1.45			
	Within group Δ,*d*	−4.29*	−0.38	−3.07*	−0.27	0.87	.35	−0.11
AUDIT	Pre	4.12	0.52	5.22	0.51			
	Post	3.44	0.48	3.91	0.47			
	Within group Δ,*d*	−0.68	−0.16	−1.31*	−0.32	0.79	.38	0.14

Δ = Within group change; AUDIT = Alcohol Use Disorders Identification Test; BAI = Beck Anxiety Inventory; BDI-II = Beck Depression Inventory-II; CBTi = Cognitive behavioral therapy for insomnia; *d* = Cohen's *d*; MFI = Multidimensional Fatigue Inventory; PCL-M = PTSD Checklist-Military Version; pre = pretreatment; post = posttreatment; VR-12 = Veterans RAND 12-Item Health Survey.

*Indicates that the within-group change was significant from pretreatment to posttreatment for designated group.

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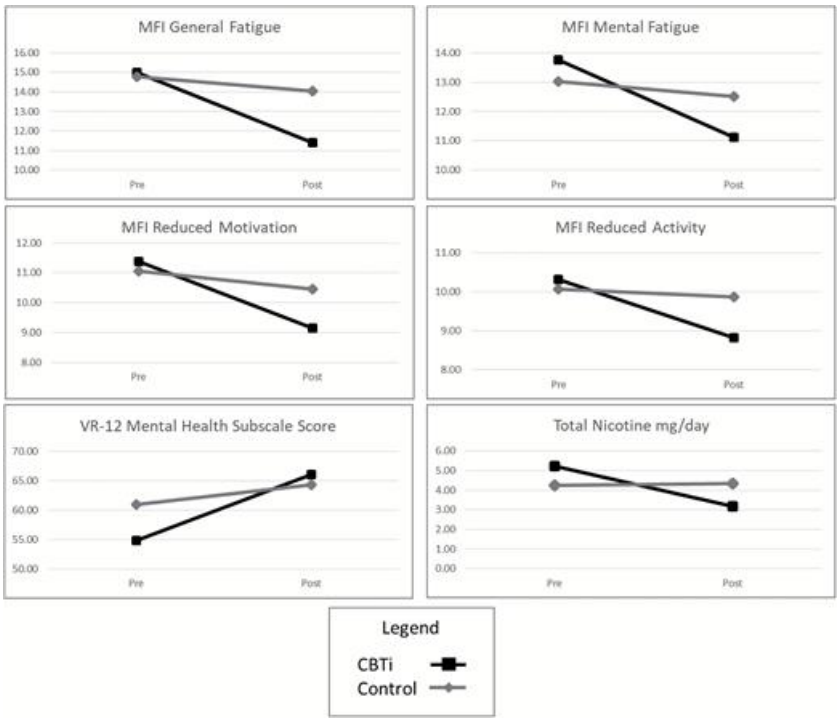
Figure 2.



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Mixed linear model (intent-to-treat) pretreatment to posttreatment comparisons of CBTi and Control mean scores on the MFI subscales, VR-12 mental health subscale, and Nicotine usage.

Hypnotic medication and substance use

The CBTi and Control groups did not differ in their likelihood of using sleep medications at pre- or posttreatment, nor were those in either of the groups more or less likely to have changed their medication use over the course of treatment. Of those individuals who were on hypnotic medications at baseline and completed follow-up, 43 percent of the CBTi group and 40 percent of the Control group were no longer taking medication at posttreatment, χ^2 (1, n = 29) = 0.024, p = .88, despite our not making any recommendations to this effect.

The CBTi and Control groups differed in the amount of change in total nicotine usage over time (d = −0.22), with the CBTi group showing significant reductions with treatment (Table 4 and Figure 2). There was no evidence of differential increases or decreases in the total amount of weekly alcohol consumed. The two groups differed significantly at baseline in terms of caffeine intake, with the CBTi group (M = 306.63 mg/day) using significantly more caffeine per day than the Control group (M = 218.75 mg/day). Because of this baseline difference, an ANCOVA was conducted on posttreatment scores, controlling for baseline scores. This analysis revealed that, when controlling for baseline caffeine usage, the CBTi group (M = 197.98 mg/day) used significantly less caffeine per day compared with the Control group (M = 220.08 mg/day) at the posttreatment assessment, F(1,123) = 6.68, p = .01, d = 0.47.

Table 4.

Substance usage and hypnotic medication status over time

		CBTi (n = 75)		Control (n = 75)		Group × time interaction		
		M	*(SE)*	*M*	*(SE)*	*F*	*P*	*d*
Total Nicotine mg/day	Pre	5.22	1.11	4.25	1.10			
	Post	3.15	0.92	4.32	0.90			
	Within group Δ,*d*	−2.07*	−0.24	0.07	0.01	**4.31**	**.04**	**−0.22**
Total alcoholic drinks/week	Pre	14.99	2.26	14.31	2.25			
	Post	15.08	3.05	16.42	2.96			
	Within group Δ,*d*	0.08	0.00	2.11	0.10	0.21	.64	−0.10
		N	*%*	*N*	*%*	χ^2	*P*	*Odds Ratio**
Hypnotic Medication	Pre	17	22.70	16	21.10	0.06	0.81	1.09
	Post	11	18.00	11	11.30			

CBTi = Cognitive behavioral therapy for insomnia; pre = Pretreatment; post = Posttreatment.

Nicotine and alcoholic beverage analyses were mixed linear model, but hypnotic medications were chi-square (not intent-to-treat).

*Odds Ratio indicates how many more times likely CBTi group was to be on designated medication relative to the Control group, only calculated for 2 × 2 cross-tabulations.

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Discussion

Consistent with previous studies testing CBTi in civilian [36, 42] and military [13] samples, the current study found that CBTi was highly effective at improving sleep (i.e. efficiency, duration, quality, and ISI) in active duty military personnel when compared with a Control condition. CBTi was also more effective than the Control at reducing mental fatigue as well as improving activity, motivation, general mental health, and nicotine use. Significant differences were not seen in PTSD symptoms, depression symptoms, anxiety symptoms, hypnotic medication use, or alcohol use.

The sleep diary-assessed sleep efficiency (primary outcome) effects in the Follow-on sample were higher than found in meta-analyses of CBTi (Follow-on sample = 1.10 vs. meta-analysis = 0.89) [36]. The results were also better than a recent meta-analysis of nonbenzodiazepine hypnotics on sleep diary-assessed sleep latency (CBTi =1.10 vs. nonbenzodiazepines = 0.33) and sleep quality (CBTi = 0.90 vs. nonbenzodiazepines = 0.30) [43]. These results replicate results from the Original sample [13], strongly suggesting that CBTi should be the first-line treatment of insomnia in active duty military.

Self-reported ISI was also higher than reported in a meta-analysis of CBTi (Follow-on sample = 1.51 vs. meta-analysis = 0.93) [36]. The within-group ISI results (d = 1.86) were slightly lower, however, than those reported in the recent VHA rollout of CBTi (d = 2.2 [44] to 2.3 [45]). However, the magnitude of ISI change was similar (Follow-on sample = −9.2; VHA rollout = −9.7 [44] to −9.8 [45]). Baseline scores in the ISI in the current study were slightly lower (17.7 in the CBTi group to 18.0 in the Control group) compared with those previous studies (20.7 [44] to 19.7 [45]), which may have resulted in a floor effect for the current study in that service members in this study did not have as severe insomnia symptoms.

The results of the current study were consistent with previous studies using CBTi to treat insomnia and fatigue. Compared with a study of CBTi in college students [46], the current study demonstrated less improvement in general fatigue (current study d = 0.82 vs. college sample d = 1.10), physical fatigue (current d = 0.04, college d = 0.44), and mental fatigue (current d = 0.52, college d = 0.33), but slightly better effects (small to medium) for activity (current d = 0.32, college d = 0.75) and motivation (current d = 0.42, college d = 0.31).

As with this study, previous studies have also shown mixed results of the effect of CBTi on daytime functioning, with some showing improvements in anxiety, depression, fatigue, and quality of life [36–38, 47], whereas others have found no differences [39, 40, 48]. One possible explanation for the lack of change in daytime functioning in this study is that both groups were relatively healthy, reporting near-normal daytime functioning, creating a

floor effect. There was no evidence of symptomatic depression (sample $M = 14.5$, $SD = 11.2$; typical cutoff for the BDI ≥ 20), anxiety (sample $M = 14.3$, $SD = 12.2$; typical cutoff for the BAI ≥ 16), PTSD (sample $M = 35.4$, $SD = 14.4$; typical cutoff on the PCL-S ≥ 50), or alcohol use disorders (sample $M = 4.7$, SD 4.5; typical cutoff on the AUDIT≥ 8). Therefore, the nonsignificant changes in comorbid symptoms with treatment were likely due to a floor effect. However, as seen in Supplementary Table 1, comparisons were still nonsignificant when we analyzed just those participants who were above cutoff on baseline depression, anxiety, PTSD, and alcohol measures.

In addition, only 22 percent were taking a medication for insomnia. Of those participants using hypnotic medications at baseline, 43 percent of the CBTi group and 40 percent of the Control group had stopped using these medications by posttreatment, despite no tapering intervention. These data are better than 28 percent found in our previous studies in a clinical case series sample [14] and only slightly lower than the 53%–54% found in studies where tapering was implemented with CBTi [15, 41].

Interestingly, the one mental health measure that did show significant results, the VR-12 Mental Health Subscale, also showed clinically or nearly significant scores (see description of measure above) [34] on this measure of mental health at baseline. It is not clear what to make of this result. It is plausible that because the measure attempts to more broadly assesses mental health, which might more broadly assess general mental health than the specific measures above (i.e. depression, anxiety, PTSD). The measure, for instances, assesses decreases in accomplishments or conscientiousness "…as a result of any emotional problems (such as feeling depressed or anxious)," as well as feeling "calm and peaceful," "a lot of energy," or "downhearted and blue" over the previous 4 weeks. In addition, it asks "Compared to one year ago, how would you rate your emotional problems (such as feeling anxious, depressed or irritable) now?" This varied approach to assessing mental health might in turn increase the variance of this measure making it more sensitive to change (i.e. CBTi = 11.22 point improvement vs Control = 3.32 point improvement). Ongoing studies in this population will attempt to replicate these results.

Collectively, these results demonstrate that CBTi is an effective intervention for insomnia in active duty military personnel and that it results in significant improvements in sleep characteristics (sleep efficiency, sleep latency, number of awakenings, wake time after onset, sleep quality, and insomnia severity), general mental health, fatigue, nicotine use, and caffeine use. These results support the training of behavioral health providers across all branches of the military to deliver CBTi and provide an alternative to medication for the treatment of insomnia.

Additional research is needed to test the effects of CBTi on work safety and operational readiness. Future studies are needed to examine the effectiveness of CBTi in other military settings (e.g. primary care, predeployment, and during deployment) as well as in service members with comorbid PTSD, depression, and substance abuse. Studies are also needed to determine the best methods for the dissemination and implementation of CBTi in military settings.

Supplementary Material

Supplementary material is available at *SLEEP* online.

Funding

This study was conducted with support from the US Department of Defense through the US Army Medical Research and Materiel Command, Congressionally Directed Medical Research Programs, Psychological Health and Traumatic Brain Injury Research Program award W81XWH-10-1-0828 (PI: Dr. Taylor). The funding source had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication.

Acknowledgments

We would like to thank Gregory Gahm, PhD, Robert Ciulla, PhD (National Center for Telehealth and Technology) and the afterdeployment.org Web site for their scientific and technical support of the Internet portion of the study. We would like to thank Jamie Anderson, BS, Michelle Barrera, BS, Julia Garza, BA, Amanda Hasselle, BA, Nicholas Holder, BS, Sonia Holloman, BS (University of Texas Health Science Center at San Antonio [UT Health San Antonio]), Jessica Dietch, MS, Jade Francetich, MS, Katherine Marczyk, PhD, and Allison Wilkerson, PhD (University of North Texas), who supported this study as study coordinators and research assistants; Katherine Dondanville, PsyD, Brooke Fina, LCSW, Brittany Hall-Clark, PhD, Kristi Pruiksma, PhD, Edward Wright, PhD, Alma Molino, PhD, and Jacob Williams, PhD (UT Health San Antonio), who served as therapists;

Charity Wilkinson, PsyD (UT Health San Antonio), who served as a therapist supervisor; Lucas Brilliott, MS, Monica Gauna, MS, Dana Larson, MS, and Susan Paschall, MS (UT Health San Antonio), who served as independent evaluators; Jeffrey Goodie, PhD (Uniformed Services University of the Health Sciences) and Ann Hryshko-Mullen, PhD (Wilford Hall Ambulatory Surgical Center, Joint Base San Antonio-Lackland), who served as therapy fidelity evaluators; Susan Deason, BA, Gary Burk, MA, MBA, and Deanne Hargita, MPA (UT Health San Antonio), who served as part of the STRONG STAR Administrative Core; Raymond Aguilar, BS, Ivan Negovetic, PhD, and Kevin Muenzler, BS (UT Health San Antonio), who served as part of the STRONG STAR Data and Biostatistics Core; Crystal Mendoza, MA (UT Health San Antonio), Christopher Harte, PhD, Alex Jordan, PhD, and Erik Shumaker, PhD (VA Boston Healthcare System), who supported this study as part of the STRONG STAR Assessment Core; Kimberly Del Carmen, PhD and Holly Campbell-Rosen, PhD (DoD-Congressionally Directed Medical Research Programs), who supported this study as grant officer representatives; and Julie Collins, BA (UT Health San Antonio) who provided editorial support for this manuscript.

Notes

Conflict of interest statement. The views expressed in this article are solely those of the authors and do not reflect an endorsement by or the official policy or position of the US Army, the Department of Defense, the Department of Veterans Affairs, or the US Government. No off-label or investigational drugs were used in this study.

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