

Restoring effective sleep tranquility (REST): A feasibility and pilot study

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Abstract

Introduction: The purpose of this pilot study was to establish the feasibility of completing a future controlled trial of a multi-component cognitive behavioral therapy for insomnia program for military veterans with sleep disturbance.

Method: This was a single-arm feasibility and pilot study. Participants were United States post-9/11 veterans with service-connected injuries, university students, and had self-reported sleep disturbances. Restoring Effective Sleep Tranquility was a multi-component cognitive behavioral therapy for insomnia intervention consisting of seven sessions of group therapy and eight 1:1 sessions delivered by occupational therapists. Feasibility and pilot indicators were process, resources, management, and scientific, including pre-post-assessments of sleep difficulties, dysfunctional sleep beliefs, participation, and pain interference.

Findings: Indicators were supportive of feasibility, including reduced sleep difficulties (for example Medical Outcomes Study Sleep Measure [$t = 3.29, p = .02$]), reduced nightmares: $t = 2.79, p = .03$; fewer dysfunctional sleep beliefs: $t = 3.63, p = .01$, and greater ability to participate in social roles: $t = -2.86, p = .03$, along with trends towards improved satisfaction with participation and reduced pain interference.

Conclusion: The Restoring Effective Sleep Tranquility program may reduce sleep difficulties and improve participation in US veterans with service-connected injuries, and evidence indicates a controlled trial would be feasible to deliver.

Keywords

Sleep, occupational therapy, group, self-management, veteran, cognitive behavioral therapy, meditation

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Introduction

Sleep is critical to health, and the consequences of poor sleep are multifaceted and can include fatigue, impaired memory, decreased mood and motivation, error proneness, and decreased school and work performance (Manber and Carney, 2015). Sleep is an essential aspect of daily life for which occupational therapy services may be warranted (Green and Hicks, 2015), and there is a great need to expand the profession's understanding of sleep-related interventions. Cognitive behavioral therapy for insomnia (CBT-I) is effective at reducing insomnia symptom severity, including in populations with comorbid conditions (such as posttraumatic stress and depression); however, there is a lack of professionals qualified to deliver

the intervention (Manber et al., 2012). The aim of the present study was to develop and deliver the Restoring Effective Sleep Tranquility (REST) program – an occupational therapy-led CBT-I intervention for military veterans in college with service-connected injuries – and to determine the feasibility of a future controlled trial through pilot study.

Literature review

For military veterans, sleep disturbances are an all too common sequela of stressors associated with training, deployment, and combat. United States military personnel

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have been engaged in conflicts in Afghanistan and Iraq since October 2001, and many have returned with mild traumatic brain injury (mTBI), posttraumatic stress disorder (PTSD), depression, pain, and anxiety, which commonly co-occur with insomnia in veterans (Pietrzak et al., 2010; Troxel et al., 2015). Sleep disturbance is the most frequently reported symptom of PTSD, occurring in as many as 90% of cases, and is associated with increased nighttime sleep disruptions such as nightmares, which in turn can exacerbate PTSD symptoms (Harvey et al., 2003). Lower estimates of sleep disturbances in veterans, such as insomnia, range from 20% to 42% (McLay et al., 2010; Mustafa et al., 2005), and insomnia is known to limit the efficacy of mental health treatments and contribute to poor daytime functioning (Manber and Carney, 2015). Furthermore, sleep disturbances have been associated with increased suicide risk in veterans (Pigeon et al., 2012).

Multicomponent CBT-I is indicated for the treatment of chronic insomnia and refers to a combination of strategies including: stimulus control therapy; sleep restriction therapy; cognitive therapy; psycho-education; and sleep hygiene (Bootzin and Manber, 2013). Researchers have developed substantial empirical support for multicomponent CBT-I as an effective treatment for insomnia (Geiger-Brown et al., 2015), and it is demonstrated to be effective in the presence of comorbid conditions such as PTSD, depression, pain, and anxiety (Manber and Carney, 2015; Manber et al., 2008). Growing evidence indicates that CBT-I improves sleep problems at equivalent rates compared to pharmacological interventions (Schutte-Rodin et al., 2008). Nonpharmacological behavioral therapies, specifically CBT-I, have therefore been recommended for treating sleep problems in veterans (Center for Integrated Healthcare, 2009).

Studies of multicomponent CBT-I in veterans have typically been conducted within the United States Veterans Health Administration (VHA) system and indicate the efficacy of the intervention for treating chronic insomnia (Trockel et al., 2014). However, there exists a significant shortage of VHA professionals capable of delivering CBT-I to the veterans it serves, despite initiatives to train its practitioners (Manber et al., 2012; Troxel et al., 2015). This issue is exacerbated by a dearth of professionals in the broader community appropriately trained to deliver CBT-I, thereby greatly limiting veterans' access to this treatment approach (Karlin et al., 2013). The community setting, especially the college environment, offers an ideal context for expanding veterans' access to care.

The college environment represents a critical context for fostering the resilience and academic success of post-9/11 veterans with service-connected injuries (Eakman et al., 2016). Veteran enrollment in college in the United States is increasing substantially, with veterans comprising roughly 4% of university undergraduates and graduates as of 2008 (Radford, 2011). Between 2000 and 2012, nearly one million veterans and military service members received education benefits through the United States Department of Veteran Affairs, representing a minority (30%) of benefit-eligible student veterans and military

service members enrolled in college (Sherman et al., 2012). Unfortunately, nearly a quarter of veterans in college have reported severe depression and almost one-half have reported significant symptoms of PTSD which contribute to difficulties with sleeping, social relationships, and academics (Plach and Sells, 2013; Rudd et al., 2011). Insomnia in college students, including veterans, is highly prevalent and associated with elevated levels of depression, anxiety, and stress capable of limiting academic success (Tyler et al., 2013). Yet there have been no studies which have evaluated the delivery of CBT-I to veterans with service-connected injuries in the context of a college environment, despite calls for the study of CBT-I within community-based settings (Vitiello et al., 2013).

Occupational therapists are concerned with sleep as a cornerstone of health and wellbeing, and an important consideration for practice and research. Also, it has been suggested that CBT-I is within the profession's scope of practice given the nonpharmacological and behavioral nature of this approach for managing insomnia (AOTA, 2014; Leland et al., 2014). Working in this emerging area of practice, occupational therapists can administer sleep-related interventions such as CBT-I provided they have received appropriate training in its delivery (Manber et al., 2012). Specifically, within the present project, a multicomponent CBT-I program was developed and tested through pilot study to assess the feasibility of delivering CBT-I to post 9/11 veterans with service-connected injuries in community-based university settings.

To enhance the quality of sleep for veterans with sleep disturbances, we developed and pilot tested the REST intervention. REST was delivered by occupational therapists to post-9/11 veterans enrolled at a public American university. The intervention was based in multicomponent CBT-I (Carney and Manber, 2009; Manber and Carney, 2015; Perlis et al., 2008), occupational therapy theories related to meaningful activity (see, for example, Eakman et al., 2016) as an adjunctive method to improve sleep quality, and included therapy delivered by occupational therapists with advanced training in CBT-I in group and 1:1 settings.

Method

Study design

This was a pre-posttest single-arm pilot study that included feasibility and outcome data for the REST intervention. Feasibility and pilot study work is common preparation for a future randomized controlled trial (RCT). Recent literature indicates that pilot studies are an important and necessary subset of feasibility studies and that the terms are not mutually exclusive (Eldridge et al., 2016). In general, a feasibility study assesses whether the study and all of the components can be completed, and whether the researchers should proceed with the line of inquiry. The accompanying pilot study used to assess feasibility may be a non-randomized study, which may support future randomized and/or larger studies. A non-randomized pilot study may include testing an

intervention, but participants are not randomized to a control or intervention group. The current study was a feasibility study that included a non-randomized pilot study (Eldridge et al., 2016) in which we documented indicators of: process (for example recruitment and retention rates); resources (for example physical capacity and time to deliver REST); management (for example inter-departmental collaboration and data management); and scientific aspects (for example treatment effects, safety, and participant satisfaction) using the recommendations of Thabane et al. (2010) and Tickle-Degnen (2013).

Participants and procedures

Inclusion criteria for participation in the study were: post-9/11 US military veteran attending college; service-connected injury; self-reported difficulties with sleep quality; and commitment to completion of daily sleep diaries, group, and 1:1 sessions. Diagnosis of epilepsy or bipolar

disorder (I and II) were exclusion criteria as sleep restriction therapy can increase both seizures and manic episodes (Manber and Carney, 2015). All veterans were recruited via the ongoing veteran research programs and veteran services on the university campus. Human subject approval was received from Colorado State University (#15-5974H in 2015) and all participants provided written informed consent.

Veterans completed outcome measures addressing sleep problems and occupational performance using computerized tools delivered via the internet, with the exception of the Canadian Occupational Performance Measure (COPM), which was completed by the occupational therapist in 1:1 sessions; see Table 1. Demographics included age, gender, military branch, time since military discharge, duration of sleep problems, self-report of service-connected injuries, posttraumatic stress (Posttraumatic Stress Disorder Checklist – Civilian Version, 6-item (PCL-C-6); Lang and Stein, 2005), and depression (Patient Health

Table 1. Outcome measures.

Variable	Construct	Number of items; possible score range	Interpretation
Sleep-related outcome measures			
Sleep Problems Index II of the Medical Outcomes Study Sleep Measure (MOS-Sleep)	Sleep-related dimensions of initiation, maintenance, quantity, perceived adequacy, and somnolence	12; 1-100	A score of ≥ 35 indicates a clinically significant sleep problem (Hays et al., 2005)
Patient-Reported Outcomes Measurement Information System – Sleep Disturbance (PROMIS-SD)	Sleep disturbances	8; 28-76.5*	Higher scores are associated with higher levels of sleep disturbances (Yu et al., 2012)
Pittsburgh Sleep Quality Index Addendum for PTSD (PSQI-A)	Disruptive behaviors associated with PTSD-related nightmares and sleep disturbances	7; 0-21	Higher scores are associated with greater levels of PTSD-related sleep disturbances (Germain et al., 2005)
Dysfunctional Beliefs and Attitudes about Sleep Scale – 10 (DBAS-10)	Dysfunctional beliefs and attitudes about sleep	10; 10-70	Higher scores are associated with higher levels of dysfunctional beliefs and attitudes about sleep (Espie et al., 2000)
Occupational therapy-related outcome measures			
PROMIS – Ability to Participate in Social Roles and Activities (PROMIS-AP)	Ability to participate in typical social roles and activities	4; 27.5-64.2*	Higher scores are associated with a greater degree of perceived ability to participate in social roles (Cella et al., 2010)
PROMIS – Satisfaction with Participation in Social Roles (PROMIS-SP)	Satisfaction with performance of typical social roles and activities	4; 27.9-63.8*	Higher scores are associated with greater levels of satisfaction with participation in social roles (Hahn et al., 2010)
PROMIS – Pain Interference (PROMIS-PI)	Pain interference with daily functioning	4; 41.1-76.3*	Higher scores are associated with a greater extent of pain interference (Cella et al., 2010)
Performance and Satisfaction sections of the Canadian Occupational Performance Measure (COPM)	Performance and satisfaction in the following areas of daily function: school performance; study skills; social relationships; sleep; and home responsibilities	5**; 1-10	Higher scores are associated with greater perceived occupational performance (Law et al., 1990)

PTSD: posttraumatic stress disorder

*Score ranges represent *T*-scores

**Items within each section of the COPM are summed and then divided by the number of areas of daily function that were rated.

Questionnaire-9 (PHQ-9); Kroenke et al., 2001). A PCL-C-6 score > 15 indicates probable PTSD and a PHQ-9 score > 10 indicates probable moderate depression. All outcome measures were completed twice before the intervention to assess for stability of the assessment without intervention in this population. After the intervention, post-assessments were completed within 48 hours of the last group occupational therapy session.

REST intervention

REST is a multicomponent CBT-I intervention with an emphasis on stimulus control and sleep restriction therapies (see Table 2). The intervention spanned a period of eight weeks. Of these, there were seven weeks in which group occupational therapy sessions and individual occupational therapist-led CBT-I (1:1 occupational therapy) sessions were scheduled within the same week for each participant (weeks 1, 2, 3, 4, 5, 6, and 8). For the remaining week (week 7), only 1:1 occupational therapy sessions were scheduled. The intervention was based on contemporary literature on CBT-I (Manber and Carney, 2015; Perlis et al., 2008) while emphasizing content from the sleep workbook *Quiet your Mind and Get to Sleep: Solutions to Insomnia for Those with Depression, Anxiety, or Chronic Pain* (Carney and Manber, 2009).

A group intervention approach was adopted for three principle reasons. Firstly, group intervention can be

therapeutic via establishing the cohesiveness of the group, instilling hope, and allowing for interpersonal learning (Dopke et al., 2004; Falk-Kessler et al., 1991). Secondly, veterans often face difficulties with campus integration, in large part due to their unique backgrounds and experiences when compared to traditional college students (Eakman et al., 2016). Therefore, a group approach could allow for the development of a sense of comradery and peer support throughout program delivery. Thirdly, group CBT-I has demonstrated promise as an effective method for treating insomnia comorbid with mental health conditions such as depression in veterans (Dopke et al., 2004; Perlman et al., 2008). The 1:1 occupational therapy was included within REST because 1:1 intervention is the gold standard in the delivery of CBT-I for chronic insomnia (Perlis et al., 2008).

Group sessions. The team developed the seven group intervention sessions using the sleep workbook (Carney and Manber, 2009), supporting literature (Manber and Carney, 2015; Manber et al., 2012; Perlis et al., 2008), and clinical reasoning. The group sessions were delivered by a registered and licensed occupational therapist who had received advanced training in multicomponent CBT-I. Group sessions included didactic education delivered with PowerPoint presentations addressing sleep architecture, models of insomnia, sleep drive, circadian rhythm, stimulus control, sleep restriction, nightmares and image rehearsal techniques, sleep beliefs, constructive worrying, and sleep hygiene. Group discussions addressed these topics, emphasizing dysfunctional sleep beliefs and the role of meaningful activity for improving sleep. Additionally, each session started and ended with a meditation practice, led by a yoga therapist and mindfulness expert. Meditation was included weekly because it is linked to relaxation and stress reduction, allowing for better sleep (Winbush et al., 2007). Each participant was provided with a copy of the Carney and Manber (2009) sleep workbook and assigned weekly readings from the book.

Sleep diary. Each individual was required to record their sleep on a daily basis in line with best practice standards for CBT-I (Perlis et al., 2008). Participants recorded their daily sleep starting two weeks prior to the intervention. This was done electronically as each participant received a daily email with a link to their electronic sleep diary, which included questions based upon consensus sleep diary recommendations (Carney et al., 2012). Key sleep diary variables were: time in bed; time individual tried to sleep; amount of time it took to fall asleep; number of awakenings per night and total duration of awakenings; last awakening; time out of bed; alcohol and caffeine use. Daily sleep diary data were then used to calculate variables such as total time in bed (TIB), total sleep time (TST), and sleep efficiency (SE). This allowed the occupational therapist to work with each participant during 1:1 sessions to enhance adherence to sleep prescription (that is, sleep restriction therapy). Additionally, all participants received a commercially available electronic activity monitor

Table 2. Multi-component cognitive behavioral therapy for insomnia (CBT-I) intervention.

Intervention:	Key components of Intervention:
1. Sleep Restriction Therapy (SRT)	<ul style="list-style-type: none"> A. Wake up at the same time every day (Decided together with occupational therapist). B. Go to bed at the same time every night. (Decided by occupational therapist based on average veteran TST plus 30 minutes. TST based upon student veteran baseline sleep diary data.) C. No naps.
2. Stimulus Control (SC)	<ul style="list-style-type: none"> A. Only sleep and sex in bed. B. If in bed for more than 10-15 minutes not sleeping, get out of bed, go to another room and do something enjoyable. C. Go back to bed only when sleepy. D. No clock-watching. E. Get out of bed within five minutes of alarm sounding.
3. Sleep Hygiene	<ul style="list-style-type: none"> A. Keep room cool (62-68 degrees), quiet, and dark. B. Limit alcohol and caffeine. C. Quit using nicotine. D. Exercise and eat healthy. E. Keep daytime routine consistent. F. Stay active/engaged throughout the day.

TST: total sleep time

(Fitbit Flex) and were encouraged to wear it daily throughout the intervention period.

Individual occupational therapist-led CBT-I (1:1 occupational therapy). Each participant was scheduled to meet weekly for eight weeks with a registered and licensed occupational therapist who had also received advanced training in CBT-I. These sessions differed substantially from the group occupational therapy sessions in that they were used to develop, monitor, and reach personalized sleep-related goals based upon sleep restriction and stimulus control therapies and sleep hygiene recommendations (see Table 2). A component unique to the 1:1 occupational therapy sessions includes calculating SE to monitor an individual's progress, and for the occupational therapist to use in clinical reasoning for adjustments in weekly sleep restriction therapy (SRT) goals. SE was calculated as $(TST/TIB) \times 100$, and indicates the percentage of time an individual was actually asleep (TST) while in bed (TIB) based upon weekly averages. Additionally, 1:1 occupational therapy sessions were used for: goal setting around stimulus control and sleep hygiene; discussing participant-specific daily routines used for building sleep drive and adhering to stimulus control; brainstorming ideas to stay awake and to arise at the set wake time in adhering to SRT; and addressing personal issues not appropriate for the group sessions. The occupational therapist who led the group sessions and the occupational therapist who provided 1:1 support met weekly to discuss issues related to participants' progress. Consultation in reviews of participants' response to treatment was obtained from a clinical psychologist with extensive expertise in CBT-I delivered to veterans.

Data analyses

Two baseline assessments of the outcome variables (Baseline 1 and Baseline 2) were collected one week apart immediately prior to delivery of the REST pilot intervention. We used a one-week period to account for statistical noise not associated with the intervention as a test of the stability of the assessments. Paired *t*-tests revealed no statistically significant differences in baseline assessments. Therefore, as a test of treatment effect, the average baseline value was compared to the posttest value for each outcome using paired *t*-tests. An alpha of 0.05 was set to evaluate significance, and pooled Cohen's *d* was used to establish treatment effect sizes. Cohen's *d* effect sizes were used as indicators of the magnitude of difference in the outcome variables between pooled baseline and posttest. Effect sizes were interpreted as 0.20 = small, 0.50 = medium, 0.80 = large, and 1.30 = very large (Maher et al., 2013). Inferential statistics were conducted using R (R Core Team, 2015) and descriptive statistics were generated using IBM SPSS Statistics (IBM Corporation, 2015).

Results

Process indicators

Recruitment took approximately two months. Overall, 13 individuals completed an online screening to determine their eligibility for the study. Five people did not meet inclusion criteria (Insomnia Severity Index score below 10). In total, a convenience sample of eight veterans, which was deemed an ideal number for facilitating an

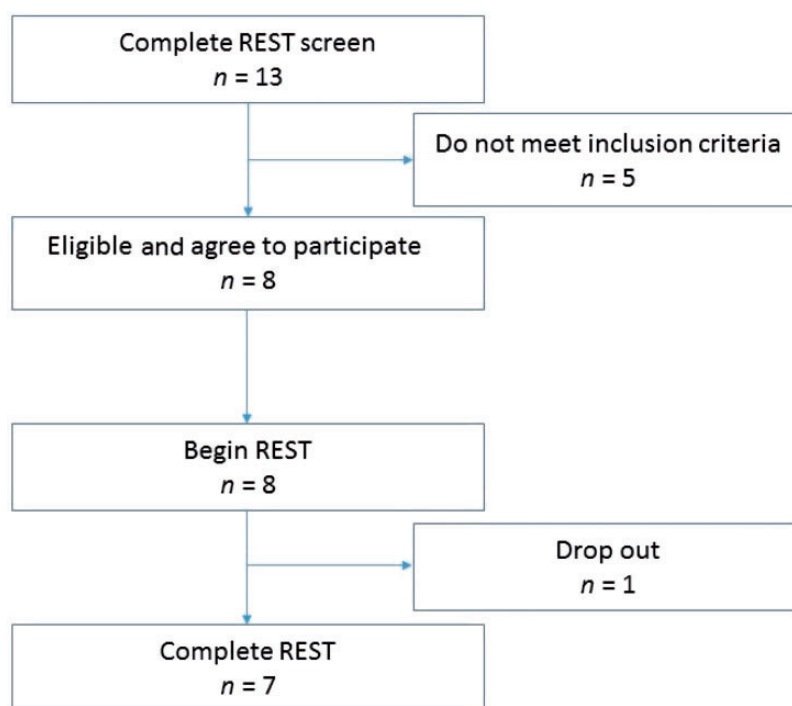


Figure 1. Process flow.

REST: Restoring Effective Sleep Tranquility.

effective group process, completed the baseline assessments and seven completed the intervention and post-assessments. On average, participants who completed the intervention attended 5.9 of the seven group sessions and 6.8 of the eight total 1:1 occupational therapy sessions. Missed classes were due to schedule conflicts. The online data collection tools and processes (for example Qualtrics for daily online sleep diary, pre- and post-test assessments) and data analytic software were sufficient for data collection, use in 1:1 occupational therapy sessions to monitor response to treatment, and analyses of treatment effects.

Resource indicators

The physical space required for group meetings, 1:1 occupational therapy sessions, and study personnel was accessible and available for all aspects of the REST pilot study. The time allotted for recruitment and program delivery was sufficient, with one minor exception. The group intervention was planned for one hour per week; however, most sessions lasted up to 10 minutes longer due to conversation and socialization. All aspects of the group and 1:1 occupational therapy sessions were delivered as planned, including effective cooperation of study personnel within and outside of the occupational therapy department.

Management indicators

The sufficiency of project processes and resources supported the effective management of the REST pilot intervention. The REST principal investigator (first author) coordinated and implemented planning meetings to assure timely participant recruitment, staff training, intervention development and delivery, data management, and analyses in collaboration with the multi-disciplinary team, which included occupational therapists, a mindfulness expert, a statistician, and a consulting psychologist, physician, and veteran. Data collection, management, and analyses were effective with the support of a graduate research assistant. Sleep diary data were reviewed approximately twice weekly and email notifications were sent to participants who were tardy in diary completion. All individuals received a reminder the morning of their 1:1 occupational therapy session. Multiple individuals required rescheduling of the 1:1 occupational therapy sessions due to schedule conflicts with classes or forgetting about the appointment.

Scientific indicators

Of the participants beginning the intervention ($n=8$), the average age was 35.6 ± 7.4 years (range: 29–52 years). All were male, White/Caucasian, and college students. The participants had a mean of 51.1 ± 31.6 months since separation from service (range: 9–91 months) and a mean 78.9 ± 56.2 months' duration of sleep difficulties (range:

Table 3. Baseline demographics and self-reported injuries ($n=8$).

Demographic variables	
Age in years (mean \pm SD)	35.6 \pm 7.4
Gender (male)	8 (100%)
Race (white)	8 (100%)
Months since separation from service (mean \pm SD)	51.1 \pm 31.6
Months of self-reported insomnia (mean \pm SD)	78.9 \pm 56.2
Prior medical treatment for insomnia	4 (50%)
Posttraumatic stress (PCL-C-6) (mean \pm SD)	16.5 \pm 5.1
Depression (PHQ-9) (mean \pm SD)	12.0 \pm 6.2
Self-reported injuries	
Posttraumatic stress	6 (75%)
Mild traumatic brain injury	4 (50%)
Orthopedic injury (for example knee, vertebrae)	4 (50%)
Tinnitus	3 (38%)
Shrapnel wound	2 (25%)
Anxiety	2 (25%)
Acute lymphoblastic leukemia	1 (13%)
Hearing loss	1 (13%)

SD: standard deviation; PCL-C-6: six-item version of the Posttraumatic Stress Disorder Checklist - Civilian Version; PHQ-9: Patient Health Questionnaire - Depression

12–180 months). The average number of service-connected injuries reported per participant was three but varied from one to five injuries. Four participants reported receiving prior treatment for insomnia before enrolling in the study. Demographic information can be found in Table 3.

All outcome measure data are found in Table 4. Statistically significant benefits were found in terms of reduced insomnia symptom severity by the Medical Outcomes Study Sleep Measure (MOS-Sleep) ($t=3.29$, $p=.02$) and Patient-Reported Outcomes Measurement Information System - Sleep Disturbance (PROMIS-SD) ($t=3.21$, $p=.02$), reduced sleep disturbances and nightmares (Pittsburgh Sleep Quality Index Addendum for Post-Traumatic Stress Disorder (PSQI-A): $t=2.79$, $p=.03$), and fewer dysfunctional sleep beliefs (Dysfunctional Beliefs and Attitudes About Sleep Scale - 10 (DBAS-10): $t=3.63$, $p=.01$). Effect sizes for the sleep-related variables were medium to very large, ranging from 0.73 (PSQI-A) to 2.20 (DBAS-10). Participants reported greater ability to participate in social roles and activities (Patient-Reported Outcomes Measurement Information System - Ability to Participate in Social Roles and Activities (PROMIS-AP): $t=-2.85$, $p=.03$), along with trends towards improved satisfaction with participation in social roles and reduced pain interference.

There were no intervention-related adverse events. However, one participant dropped out of the study due to poor adherence and attendance. A second participant disclosed a diagnosis of bipolar disorder; SRT was

Table 4. Change in pretest to posttest outcome measures ($n = 7$).

Variable	Baseline 1 <i>M (SD)</i>	Baseline 2 <i>M (SD)</i>	Difference between baselines <i>t(p)</i>	Posttest <i>M (SD)</i>	Pooled baselines-to-posttest difference <i>t(p)</i>	Cohen's <i>d</i> , pooled baselines to Posttest
Sleep-related outcome measures						
MOS-Sleep	55.16 (9.14)	51.83 (11.54)	2.37 (0.06)	28.65 (19.68)	3.29 (0.02)**	1.58
PROMIS-SD	60.07 (3.82)	59.00 (3.57)	1.24 (0.26)	46.67 (9.35)	3.21 (0.02)**	1.82
PSQI-A	6.57 (4.43)	8.14 (6.28)	-1.62 (0.16)	4.14 (3.29)	2.79 (0.03)**	0.73
DBAS-10	4.84 (0.67)	4.63 (0.59)	0.79 (0.46)	2.67 (1.22)	3.63 (0.01)**	2.20
Occupational therapy-related outcome measures						
PROMIS-AP	41.66 (7.31)	43.21 (7.53)	-2.00 (0.09)	47.09 (6.07)	-2.86 (0.03)**	0.69
PROMIS-SP	40.61 (5.64)	41.79 (2.90)	-0.53 (0.61)	45.07 (5.79)	-1.26 (0.25)	0.81
PROMIS-PI	59.79 (9.08)	58.44 (8.92)	0.88 (0.42)	54.21 (12.59)	1.46 (0.19)	0.45

MOS-Sleep: Medical Outcomes Study Sleep Measure; PROMIS-SD: Patient-Reported Outcomes Measurement Information System - Sleep Disturbance; PSQI-A: Pittsburgh Sleep Quality Index Addendum for Post-Traumatic Stress Disorder; DBAS-10: Dysfunctional Beliefs and Attitudes About Sleep Scale - 10; PROMIS-AP: Patient-Reported Outcomes Measurement Information System - Ability to Participate in Social Roles and Activities; PROMIS-SP: Patient-Reported Outcomes Measurement Information System - Satisfaction with Participation in Social Roles; PROMIS-PI: Patient-Reported Outcomes Measurement Information System - Pain Interference

** $p < 0.05$.

withheld from this participant due to increased risk of a manic episode (Manber and Carney, 2015). All other participants were able to successfully complete all aspects of the intervention and engage in both the group occupational therapy and 1:1 occupational therapy.

In regard to the Canadian Occupational Performance Measure employed during 1:1 occupational therapy, participants on average showed a total increase of 8.50 in performance across the five areas of occupation and a total increase of 6.86 in satisfaction with performance across the same five areas. Of all occupations, sleep performance improvements (4.00) and sleep satisfaction improvements (5.14) were greatest. All participants who completed the intervention indicated they were "satisfied" or "very satisfied" with group sessions, individual sessions, and the REST program overall.

Discussion

The present feasibility and pilot study indicates that REST, a sleep improvement program based upon multi-component CBT-I and led by occupational therapists, is feasible to deliver within a college setting and capable of reducing insomnia symptom severity in military veterans with service-connected injuries. Feasibility was evaluated in line with recommendations from Thabane et al. (2010) and Tickle-Degnen (2013) to assess for successful implementation of prospective intervention studies and to reduce threats to the validity of those studies. One key process indicator of feasibility is adequate recruitment, because it ensures participant characteristics and sample sizes sufficient for future study implementation. Recruitment in the present study was facilitated because a majority of REST participants were receiving services through the New Start for Student Veterans (NSSV) program (Eakman et al., 2016), a post-secondary supported education program for veterans with service-connected injuries housed in the university's occupational therapy

department, and all authors were affiliated with the department. Also, the NSSV program has affiliations with other university-based veteran service providers and veteran-related programs in the community at large, which facilitated recruitment. Together, these factors offer a relatively high level of assurance for successful recruitment in future REST interventions.

Program attendance and ability to complete the REST intervention was on par with other studies delivering CBT-I to veterans. Our withdrawal rate was 12.5%, which compares favorably to withdrawal rates in veteran clinical samples, ranging from 20% to 24% (Perlman et al., 2008; Trockel et al., 2014). The intervention resulted in no adverse events, indicating its relative safety within the sample under study. Unique to the present study, however, was the delivery of the intervention to veterans with service-connected injuries in a community-based university setting utilizing both group and individual occupational therapist-led CBT-I. The prevalence of mTBI and PTSD in the present sample, in addition to accommodating varied class schedules, added a level of challenge in assuring group occupational therapy and 1:1 occupational therapy service delivery. Meeting reminders sent by electronic text messaging, flexibility in rescheduling 1:1 occupational therapy meetings, and weekly face-to-face reminders appeared to be useful in garnering a high level of attendance for those who completed REST across the eight weeks of implementation. Participant report of satisfaction with the program was also relatively high, indicating the combined group and 1:1 occupational therapy approach was well received as delivered, and therefore future interventions based upon the REST model could expect completion rates comparable to the present study.

An electronic daily sleep diary was developed exclusively for the present study and allowed for email invitations to be sent each morning to participants' smart-phones and home computers to complete daily

sleep diaries. This, in combination with manual reviews of daily sleep diary completion rates twice per week, with an additional email prompt for diary completion when indicated, appeared to result in very few days of missed sleep diary data, and therefore enabled effective monitoring and progress of SRT within weekly 1:1 occupational therapy sessions. Beyond this, use of an internet-based survey tool to collect pretest and posttest outcome data provided automated reminder prompts, resulting in no missing data.

In sum, the adequacy of REST pilot processes, resources, and management enabled effective program delivery and afforded reliable data in determining that the REST intervention may be capable of reducing insomnia symptom severity in veterans with service-connected injuries. Notably, the large majority of REST participants in the sample indicated the presence of mTBI, PTSD, and/or orthopedic injuries associated with military service. Furthermore, participants on average reported probable PTSD based upon the PCL-C-6 and probable moderate depression based upon the PHQ-9 at the outset of REST, indicating the presence of significant mental health issues as comorbid conditions associated with their chronic insomnia. This finding was anticipated given that elevated insomnia symptom severity in veterans is often associated with service-connected injuries and persisting mental health complaints (Wright et al., 2011).

The scientific aspects of the REST intervention were most favorable, including very large treatment effect sizes in both subjective assessments of insomnia (MOS-Sleep and PROMIS-SD) when comparing pretest to posttest data. Subjective assessments of sleep difficulties are recommended as indicators of treatment efficacy within CBT-I studies because they reflect subjective complaints associated with insomnia such as difficulties falling asleep and maintaining sleep (Geiger-Brown et al., 2015). MOS-Sleep baseline scores indicated the presence of severe insomnia, whereas baseline PROMIS-SD *T*-scores indicated participants' sleep complaints were one standard deviation higher than found in the general population. Following the completion of REST, participants on average fell below the clinical threshold for insomnia in the case of MOS-Sleep and below the national average for sleep complaints in the case of PROMIS-SD, indicating substantial reductions in insomnia symptom severity. The very large effect sizes evidenced by MOS-Sleep and PROMIS-SD also indicate that as few as 10 participants per condition could be sufficient for detecting a treatment effect within a controlled trial using these indicators.

Sleep disturbances associated with PTSD are of significant concern for veterans due to the high incidence of PTSD and associated nightmares which are characteristic of this population (Harvey et al., 2003). Within the present study, a medium effect size in PTSD-related sleep disturbances as assessed by the PSQI-A was found, indicating the REST intervention may serve a role in decreasing sleep disturbing factors such as nightmares, nighttime terrors, panic, and anxiety. Though participants in our study were

briefly exposed to information on image rehearsal therapy for nightmares, it is likely that the combined use of stimulus control and SRT employed as part of REST's approach to multicomponent CBT-I was the more salient factor given findings of CBT-I's efficacy in reducing nightmares (Manber and Carney, 2015). Nonetheless, we are unable to identify the relative contributions of each component of the REST intervention, an issue common to multicomponent CBT-I studies (Vitiello et al., 2013).

Of the sleep-related outcome measures, REST participants demonstrated the greatest improvement in their dysfunctional beliefs about sleep (Cohen's $d=2.20$). Dysfunctional sleep beliefs are associated with the development and perpetuation of insomnia in both behavioral and cognitive models of chronic insomnia (Carney and Edinger, 2006). Sleep beliefs within behavioral models are posited to motivate behaviors that can worsen insomnia, such as taking naps to make up for lost sleep. Naps are viewed within the military, however, as a critical tool for maintaining service members' operational readiness in the face of extended periods of sleep loss (Troxel et al., 2015) and this was therefore a belief REST participants endorsed highly at the onset of treatment.

Within cognitive models of insomnia, beliefs that a poor night's sleep will result in poor functioning the next day can lead to sleep-related anxiety, thereby extending sleep onset latency and decreasing total sleep time. A substantial component of REST was challenging and reframing dysfunctional sleep beliefs through ongoing group education and discussions and 1:1 occupational therapy goal setting and monitoring. We believe this emphasis played an instrumental role in veterans' beneficial response to REST. Nonetheless, future study is needed to determine if reframing dysfunctional sleep beliefs in veterans serves a mediating role in the effectiveness of multicomponent CBT-I. Also, it will be important to discern if the combination of group and 1:1 CBT-I was a significant factor in generating the very large effect size found in the present study.

Unique to the present study was the assessment of occupational performance using PROMIS measures and the COPM. These indicators of participation reflect a broader range of daily life activities than the insomnia-related outcomes. A large effect size was found in participants' ability to participate in social roles and activities (such as leisure, family, and work activities), indicating REST may have been of benefit to participants in this regard. Though trends towards improvement were seen in satisfaction with participation in social roles and pain interference, these indicators did not achieve statistical significance. One explanation may be that we adopted the four-item short versions of these measures, and therefore the scores may be limited in their sensitivity to change. Future testing of the REST intervention should benefit from longer (for example, eight-item) or computer-adapted test versions of these assessments, as well as increasing the size of the sample under study to detect a treatment response.

Limitations and lessons learned

A limitation of the present study is that we did not have direct access to participants' medical records and therefore relied solely on self-report in terms of medication use. There were two participants who indicated a physician-prescribed medication change during REST. Though those medications are not indicated in the treatment of insomnia, we cannot rule out medication change as a possible factor influencing treatment effects upon insomnia in the two cases.

Feasibility and pilot studies are done to support the preparation of future larger randomized trials to determine the efficacy and then effectiveness of the intervention (Eldridge et al., 2016). From the current pilot study, we did identify processes we intend to modify in planning for a controlled clinical trial. Firstly, we will incorporate a structured approach to weekly mindfulness training, encourage daily practice, and embed an item within the online daily sleep diary to monitor mindfulness practice. Secondly, we will modify the daily sleep diary by trimming some content (such as caffeine use) and incorporate mid-day and evening reminders to better ensure timely sleep diary completion. Thirdly, we will build in additional time before and after group sessions to allow for unstructured socialization as this appeared to positively affect the group process amongst the veterans. An additional limitation is with regard to the feasibility testing. While we recorded information regarding REST processes, resources, management, and scientific indicators, we did not set a priori criteria to indicate whether or not each item should be identified as feasible or not feasible. Any future study will include such pre-identified criteria.

Future research

In addition to the suggestions for future research indicated above, the development and delivery of REST offers avenues for future inquiry. Firstly, given the intimate nature of sleep and sleep-related routines, qualitative research designs could address the ways in which participants' significant others might support or hinder adherence to the behavioral changes required for stimulus control and SRT. For example, SRT often requires modifications to participants' time to bed, which may affect couples' nightly routines. Secondly, REST utilized an eight-week protocol, which is in line with other CBT-I interventions, though this may not be sufficient time to establish an ideal amount of total sleep time for some individuals. An extended CBT-I protocol could therefore be tested. Thirdly, because of page limitations, this paper did not report subjective response to treatment indicators such as TST, SE, sleep onset latency, and waking after sleep onset, or follow-up indicators of treatment outcomes. Such indicators will be important to report in future publications and to include within controlled clinical trials. Lastly, given occupational therapists' concern for sleep difficulties in other populations (such as older adults), additional feasibility and pilot studies are needed

in order to develop and test effective sleep-promoting interventions (Leland et al., 2014).

Conclusion

This was a single-arm feasibility and pilot study to assess REST, an occupational therapist-led program to reduce insomnia symptom severity in United States post-9/11 veterans with service-connected injuries in college. Pilot study indicators of process, resources, and management were supportive of the feasibility of delivering the REST intervention as a controlled trial. Scientific indicators were favorable, including statistically significant benefits in terms of reduced insomnia symptom severity (MOS-Sleep and PROMIS-SD), reduced nightmares (PSQI-A), fewer dysfunctional sleep beliefs (DBAS-10), and greater ability to participate in social roles and activities (PROMIS-AP), with trends towards improved satisfaction with participation in social roles, reduced pain interference, and improved performance and satisfaction in occupation, especially sleep. Preliminary evidence indicates REST may reduce sleep difficulties and improve participation in US military veterans with service-connected injuries attending college.

Key findings

- It is feasible to deliver a controlled trial of a multi-component CBT-I intervention consisting of group and 1:1 sessions delivered by occupational therapists to veterans in college with service-connected injuries who have chronic insomnia.
- REST resulted in reduced sleep difficulties, nightmares, and dysfunctional sleep beliefs, along with improved ability to participate in social roles and activities.

What the study has added

Findings from this study indicate that appropriately trained occupational therapists can feasibly deliver a CBT-I program capable of reducing insomnia symptom severity.

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Research ethics approval

Human subject approval was received from Colorado State University (#15-5974H in 2015) and all participants provided written informed consent.

Declaration of conflicting interests

The authors confirm that there is no conflict of interest.

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