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Protocol

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1. Abstract

Heavy alcohol use is prevalent among returning Veterans and results in significant physical and psychological burden. One in five returning Veterans screens positive for probable past-year alcohol use disorder (AUD), and few hold positive beliefs about mental health treatment. Moreover, brief interventions for alcohol use demonstrate limited efficacy within this population. Thus, additional strategies are needed to engage and treat returning Veterans who may be at risk for AUD. More than half of returning Veterans who screen positive for hazardous drinking report clinically significant symptoms of insomnia. In turn, insomnia symptoms have been associated with increased risk of alcohol-related problems, perhaps due to insomnia-related impairments in executive functioning, negative emotionality, craving for alcohol, and use of alcohol as a sleep aid. The proposed K23 aims to determine the utility of the first line of treatment for insomnia (Cognitive Behavioral Therapy for Insomnia or CBT-I) in reducing alcohol use and related problems among Veterans of the Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) era. Forty-four Veterans who report heavy drinking (≥4/5 drinks per occasion for women/men) and have insomnia based on DSM-5 and research diagnostic criteria will participate in a randomized pilot trial. Participants will be randomly assigned to receive personalized normative alcohol feedback in the context of one of two treatment conditions: CBT-I (n = 22) or a sleep hygiene education control (SH; n = 22). Outcomes will be assessed at the end of the active intervention period (6 weeks), mid-treatment (after 3 sessions), post-treatment, and at 3 months post-intervention. Outcomes of interest include insomnia severity, total wake time, sleep quality, drinking quantity/frequency, alcohol-related consequences, executive functioning, negative affect, emotion regulation, craving for alcohol, and use of alcohol as a sleep aid.

2. Objectives (include all primary and secondary objectives)

(1) To evaluate the feasibility and acceptability of CBT-I among heavy-drinking Veterans.
(2) To evaluate the effect of insomnia treatment on insomnia severity, total wake time, and sleep quality.
(3) To evaluate preliminary treatment efficacy in reducing alcohol use, alcohol-related problems, and proposed mediators.

3. Background

Three out of four returning Veterans report heavy drinking in the context of poor sleep health (Swinkels, Ulmer, Beckham, Buse, & Calhoun, 2013). **The co-occurrence of these behaviors**, in combination with the anticipated stigma of mental health treatment (Vogt, Fox, & Di Leone, 2014), **represents a barrier to wellness among Veterans** (CDC, 2015; Fuehrlein et al., 2016). Symptoms of insomnia have been associated with elevations in alcohol use and related problems among returning Veterans (Luxton et al., 2011; Miller, DiBello, Carey, & Pedersen, 2017; Swinkels et al., 2013). While the precise mechanisms underlying these associations are unclear, we propose four distinct pathways. First, insomnia has been associated with (1) deficits in executive functioning (Alhola & Polo-Kantola, 2007; Benitez & Gunstad, 2012; Fortier-Brochu & Morin, 2014), which may lead to poor decision-making and increased risk of alcohol problems (Day, Kahler, Ahern, & Clark, 2015). Insomnia symptoms have also been associated with (2) negative emotionality (Pickett, Barbaro, & Mello, 2015; Sandru & Voinescu, 2014), which may exacerbate alcohol problems in the context of heavy drinking (Watkins,

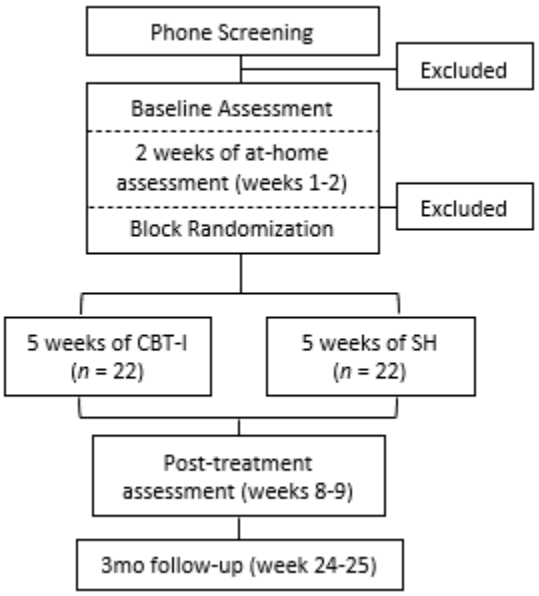
Franz, DiLillo, Gratz, & Messman-Moore, 2015), and (3) greater craving for alcohol (Mason, Light, Williams, & Drobes, 2009), which is a predictor of alcohol use (Bujarski & Ray, 2014). (4) Finally, insomnia may lead to use of alcohol as a sedative (Brower, Aldrich, Robinson, Zucker, & Greden, 2001).

Cognitive Behavioral Therapy (CBT-I) is the first line of treatment for insomnia (Rybarczyk, Lund, Mack, & Stepanski, 2009; Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008; Siebern & Manber, 2011). It has moderate to large effects among Veterans, with improvements documented up to 6 months (between-group effect sizes=0.5-0.8; 10-11% more time asleep in bed at post-treatment and 6mo) (Edinger et al., 2009; Germain et al., 2014; Karlin, Trockel, Taylor, Gimeno, & Manber, 2013; Taylor et al., 2018). Research with college students (Fucito et al., 2017; Hershner & O'Brien, 2016) and animal models (Vengeliene, Noori, & Spanagel, 2015) suggests that improvements in insomnia may reduce heavy alcohol use, and pharmacological treatment of insomnia has been found to delay relapse among individuals with alcohol use disorder (AUD) (Anton et al., 2011; Brower et al., 2008). Based on this research, **CBT-I is expected to reduce insomnia symptoms among heavy-drinking Veterans**, thereby resolving insomnia-related deficits in executive functioning, negative emotionality, and craving for alcohol, as well as use of alcohol as a sleep aid. **These improvements, in turn, are expected to reduce alcohol use and related problems.** This line of research is particularly promising for Veterans, as Veterans generally perceive stigma toward mental health treatment (Vogt et al., 2014) but indicate interest in treatment for insomnia (Hom et al., 2016; Plach & Sells, 2013; Shepardson, Funderburk, Pigeon, & Maisto, 2014).

4. Study Procedures

This research will examine the efficacy of CBT-I in improving sleep and alcohol use outcomes among heavy-drinking OEF/OIF/OND-era Veterans. Forty-four Veterans will be randomized to receive sleep hygiene or to participate in five sessions of individual Cognitive Behavioral Therapy for Insomnia (CBT-I). Outcomes will be assessed at baseline, mid-treatment (3 weeks), post-treatment, and 3-month follow-up (see Figure 1).

Figure 1. Flow diagram



Recruitment. Participants will be recruited through community advertising for treatment of insomnia in Veterans. Flyers will be posted around campus and in local primary care and sleep clinics. We will recruit using Facebook and, if needed, other digital marketing sites (e.g., Google, Amazon, Hulu). We will also recruit using radio advertisement and local mail distribution lists for the University of Missouri and (if possible) the Truman VA. (Notably, researchers will not have access to these mail lists, but will provide information about the study to the university/VA, who will send out the information.) Efforts will be made to ensure that traditionally underrepresented groups are aware of this research. These include posting flyers and printed advertisements at Black- and Latinx-owned businesses and through local churches, newspapers, and community organizations (e.g., MU's Veterans Center, MU's Multicultural Center, the local library, coffee shops with internet access). If needed, research assistants will set up recruitment booths at local events and career fairs to inform people about the study and answer any questions they may have. Sign-up sheets will be made available for individuals who would like us to contact them in the future (e.g., if they are moving to the area in the next couple of months or currently active duty but will be getting out in a few months). PI Miller will also inform local providers and community leaders about the study. Per provider request, providers will be given handouts detailing the eligibility/exclusion criteria and contact information for the study. To facilitate easy access to the screening assessment, a text message service will be used so that participants who text "sleepy" to 21000 will be sent a direct link to the screening survey. Many recruitment materials will also include a QR code link to screening.

Participants who are not eligible for this study – but do screen eligible for other ongoing studies in the Department of Psychiatry – will be referred to those studies as appropriate.

Snowball sampling will also be implemented in March/April of 2021. Specifically, the research team will send a letter asking existing participants to inform anyone they know who might be eligible about the study. All participants will be mailed $5 preemptive compensation for their time and effort.

As of April/May of 2022, BuildClinical will manage all digital marketing recruitment for this study. BuildClinical is a data-driven digital marketing company that helps academic researchers recruit participants for research studies more efficiently using social media, software, and machine learning. They will ensure that all IRB-approved guidelines and procedures are followed during recruitment. They use study-specific advertisements to engage participants on digital platforms such as Facebook, Google, WebMD, etc. Participants who click on the advertisements will be redirected to a study-specific landing page. On the landing page, the person can complete an online pre-screen questionnaire. Pre-screening data is then routed to BuildClinical's Secure Socket Layer (SSL) software, which encrypts all information to keep it private and HIPAA compliant. Their backend servers are stored in secure data centers in the USA.

Interested individuals will have the option of (a) completing the screening survey online, either via Qualtrics or BuildClinical, or (b) calling project staff to learn more about the study. In CBT-I trials with Veterans, attrition rates have ranged from 19 to 38% (Edinger et al., 2009; Germain et al., 2014; Karlin, Trockel, Spira, Taylor, & Manber, 2015). Estimating an attrition rate of 35%, we will recruit 68 participants over 34 months to obtain a final sample of **44 participants**. Approximately 9% of Veterans are women and 12-15% have PTSD; therefore, randomization will be stratified by gender and PTSD.

Screening. Individuals who are interested in the study will complete a brief eligibility screen online from remote locations and provide their first name, phone number, and email.

A research assistant will contact those who provide this information to explain the study in more detail and, if they are still interested, schedule them for the baseline assessment. Interested individuals whose only barrier to participation is travel/in-person appointments will be scheduled for a remote baseline visit.

Initial baseline assessment visit. Individuals who are eligible and interested will be scheduled for the baseline assessment, during which they will provide informed consent. Mailing addresses will be collected during the consent process to allow us to send written communication (e.g., thank you notes, reminder letters). If participants come in person, they will provide a urine drug sample to verify self-reported illicit drug use. Redwood Toxicology 5-panel urine drug screens test for cocaine, THC, methamphetamine, opiates, and benzodiazepines. Cups come with test strips in the specimen lids, allowing for safe and efficient drug screening. A trained research assistant will take the participant's height and weight. Participants will then complete parts of the Mini International Neuropsychiatric Interview (MINI) and a Timeline Followback (TLFB) with a graduate research assistant who has been trained in clinical interviewing and assessment. Participants will complete self-report baseline measures by computer. If participants are in person, they will also wear a holter monitor/electrocardiogram, which will be used as an index of autonomic nervous system regulation, in two separate 5-minute sessions. After assessments are complete, the research assistant will orient participants to the actiwatch (Philips Respironics) and sleep diary. Procedures for remote visits will differ as follows: (a) participants will provide written consent electronically using Qualtrics, (b) participants will be unable to provide a urine drug sample, complete computerized cognitive tasks, or wear the holter monitor, and (c) an actiwatch will be mailed to participants who agree they will send it back, along with pre-stamped and addressed return postage.

If participants endorse suicidal ideation during the baseline assessment (or at any assessment throughout the protocol), the research assistant will assess their suicidal ideation using the Columbia Suicide Severity Rating Scale. All risk information will be shared in real time with the supervising licensed clinical psychologist, who will make a clinical judgment regarding the continued level of care required. If the participant endorses active suicidal ideation with current intent and plan and is meeting with research staff in person, they will be escorted to the Psychiatric Center's Emergency Room for an in-person, comprehensive evaluation. If they endorse active suicidal ideation with current intent and plan during a remote meeting (phone call or video conference), then research staff will call 911 and provide the participant's current address to help ensure their safety. Participants who report passive thoughts of suicide (i.e., thoughts of death/dying without intention or plans for suicide) will be included in the study if they meet all other eligibility criteria.

Individuals who become emotionally distressed during assessments will remain with the trained graduate research assistant or on-site licensed clinical psychologist until they are calm. If they are included in the study, they will be encouraged to contact their interventionist or the licensed supervising psychologist if they experience emotional distress while participating in the study.

All participants who are excluded from the study will be provided with feedback on their sleep, recommendations on the treatments that might be appropriate for them (e.g., individuals reporting circadian rhythm disorders will be encouraged to maintain a consistent sleep/wake schedule), and a list of community and online resources for sleep and mental health treatment (see section 12 of the protocol below).

At-home assessment. Participants who report symptoms of sleep apnea and attend baseline in person will be asked to wear the holter monitor/electrocardiogram (SpaceLabs Healthcare EVO device) for one night in their own homes and in their own bed to rule out diagnosis of sleep apnea. The research assistant will prepare eligible participants who screen positive for sleep apnea for this assessment using SpaceLabs Healthcare EVO devices. Monitoring will be completed in accordance with recommendations for sleep assessment (Stein & Pu, 2012). HRV monitoring will provide an index of autonomic arousal (which has been linked to sleep impairment) and an apnea hypopnea index (a measure of sleep apnea). Participants who demonstrate an apnea hypopnea index greater than 15 will be referred for polysomnography and treatment of sleep apnea.

All participants will also be asked to wear the actiwatch 24/7 and complete two full weeks of daily sleep diaries to confirm diagnosis of insomnia (>30min sleep onset latency or wake after sleep onset 3+ nights per week). Sleep diaries will be collected electronically and time-stamped each morning using the Qualtrics data management system. Participants will be asked to complete the diary each morning before noon. Those who have not completed the diary by noon will receive a reminder text or phone call from study staff.

Table 1. Assessment, therapy, and payment schedule

Week	Assmt	CBT-I	Paymt	Bonus
1	BL		30	
2		S1	20	20
3		S2		
4	Mid-tx	S3	20	
5		S4		
6	Post-tx	S5	20	
7		(S6)	30	30
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20	3mo		50	
21			40	40

Note. 1mo = 1-month. Assmt = assessment. BL = baseline. Bonus = bonus payment (for completion of all previous 14 days of sleep diaries). Paymt = standard payment. Tx = treatment.

Randomization. Participants who are eligible based on the at-home assessment will be randomized to the CBT-I or sleep hygiene only conditions.

Return baseline assessment visit. Participants will be informed of their condition following the two weeks of at-home assessment. During their return visit, one of the research assistants will also provide all participants with a one-page handout on sleep hygiene, which will include personalized normative feedback on their alcohol use. The research assistant will walk the participant through the sleep hygiene handout and answer any questions they may have about the information.

Cognitive Behavioral Therapy for Insomnia (CBT-I). Participants assigned to the CBT-I condition will attend 1-hour individual sessions of CBT-I once a week for five weeks. A sixth week of treatment will be included – and scheduled for the same date as the post-treatment assessment – if the participant and research team agree that it would be beneficial (e.g., if a participant has difficulty grasping cognitive therapy concepts). Zoom video service will be utilized for remote appointments when necessary. Consistent with clinical guidelines (Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008), treatment will include stimulus control (e.g., limit use of bed to sleep or sexual activity, get out of bed if lying awake for more than 20 minutes), sleep restriction (limit time in bed to amount of time spent sleeping on a typical night), sleep hygiene (e.g., avoid exercise within 2 hours of bedtime, create cool and dark sleep environment), relaxation training, and cognitive restructuring. All patient interactions will be conducted under the weekly supervision of PI Miller, a licensed clinical psychologist who specializes in addiction treatment. In turn, PI Miller will be supervised by Dr. McCrae, a licensed clinical psychologist who is board certified in behavioral sleep medicine.

Sleep hygiene. All participants will receive a one-page handout on sleep hygiene that includes personalized normative feedback on their alcohol use. This is the only intervention that participants assigned to the Sleep Hygiene condition will receive and is consistent with what may be expected as standard care in a doctor's visit with a primary care physician. A sleep coach will then call to check in on sleep hygiene participants' progress each week for five weeks. We did not include a control condition that was matched with CBT-I for time and content, given our focus on preliminary outcomes.

Personalized normative feedback on alcohol use. As part of the sleep hygiene recommendations, participants will receive personalized normative feedback on their alcohol use. Normative feedback will be modeled after previously utilized, efficacious interventions (Pedersen, Parast, Marshall, Schell, & Neighbors, 2017). Feedback will portray a bar graph and explanatory text comparing personal drinking quantity to that of same-sex peers.

Follow-up assessments. To enhance follow-up rates, participants will receive up to $300 for completion of all phases of this study. The proposed payment schedule is as follows:

Baseline		**Up to $70**
Clinical interview (Zoom)	60-90min	$0
Online survey	30-45min	$30
14 days of actiwatch	---	$20
14 *consecutive* diaries	2-3min/day	
-7 in a row to be eligible		needed for eligibility, $0 bonus
-10 in a row		$10 bonus
-14 in a row		$20 bonus
Mid-Treatment		**Up to $20**
Online survey	10-15min	$20
Post-Treatment		**Up to $80**
Online survey	30-45min	$20
-phone only	5min	$10
14 days of actiwatch	---	$30
14 *consecutive* diaries	2-3min/day	

-7 in a row		$10
-10 in a row		$20
-14 in a row		$30
3-Month Follow-Up		**Up to $130**
Online survey	30-45min	$50
-phone only	5min	$20
14 days of actiwatch	---	$40
14 *consecutive* diaries	2-3min/day	
-7 in a row		$10
-10 in a row		$20
-14 in a row		$40

Participant retention. To enhance follow-up rates, participants will receive up to $70 for completion of the baseline, $20 for the mid-treatment assessment, up to $80 for the post-treatment assessment, and up to $130 for the 3-month follow-up; for a total of up to $300. They will also receive reminder texts/calls, have access to free parking outside the research lab, receive immediate payment, and have access to after-hours 'on-call' support. We will also send all participants a personalized "thank you" note following study completion.

Blinding. PI Miller will not be blinded to block size or participant assignment because she will inform study therapists of participant assignment to conditions. However, PI Miller and study therapists will be blinded to assessment outcomes, and the assessment RA will be blinded to participant condition. All participants will be told that they are receiving treatment for insomnia in order to blind them to condition assignment (sleep hygiene will be described as "brief" insomnia treatment, and CBT-I will be described as the "most intense" treatment).

Treatment integrity. Treatment integrity will be assured in three steps. (1) Delivery. The study therapist will receive training in use of the treatment manual via audio-recorded mock therapy sessions. PI Miller and co-I McCrae, both of whom are licensed clinical psychologists, will evaluate audiotapes of mock sessions and provide corrective feedback. All intervention sessions will be audio-recorded, given participant permission. PI Miller and Dr. McCrae, who is board certified in behavioral sleep medicine, will review session audiotapes for ongoing training and supervision. PI Miller will score five randomly selected tapes to assess treatment fidelity using a checklist of treatment elements. Descriptive analyses will be used to determine the proportion of intended treatment elements covered in intervention sessions. (2) Comprehension. Participants will be provided with a workbook detailing treatment instructions, rationale, and handouts and encouraged to ask questions. (3) Enactment. Workbooks will contain written instructions on home assignments, and therapists will encourage assignment completion.

Early termination. All participants will receive sleep hygiene recommendations and personalized feedback on their alcohol use immediately following baseline assessment, so every participant who attends baseline will receive some form of treatment for insomnia and heavy drinking. However, participants may decide to stop participating in the study at any time without penalty. If they decide to withdraw their participation, therapy will be terminated. This will be discussed as part of the informed consent process.

5. Inclusion/Exclusion Criteria

Eligible participants will (a) be OEF/OIF/OND-era Veterans, defined as military service after September 11, 2001; (b) report either 1+ heavy drinking episode, defined as 4/5+ drinks for women/men, or 1+ alcohol-related consequence in the past 30 days; and (c) meet DSM-5 and research diagnostic criteria for Insomnia Disorder. Criteria for insomnia include difficulty (>30min) falling asleep, staying asleep, or waking up too early on 3+ nights per week for 3+ months that occurs despite adequate opportunity and circumstances for sleep and results in daytime impairment (impairment operationalized as Insomnia Severity Index scores ≥ 10).

Individuals will be excluded if they are unable to provide informed consent, report contraindications for CBT-I (mania or seizure disorder), work on a rotating shift schedule, have a severe or untreated psychiatric disorder that requires immediate clinical attention (e.g., psychosis, suicidal ideation with intent and plan), or are already receiving behavioral treatment for insomnia.

6. Drugs/ Substances/ Devices
N/A

7a. Primary Outcomes
Recruitment. Completion of 1+ session of CBT-I will be used to indicate recruitment.

Retention. Completion of all sessions of CBT-I will be used to indicate retention.

Client Satisfaction Questionnaire. The Client Satisfaction Questionnaire (Larsen, Attkisson, Hargreaves, & Nguyen, 1979) is an 8-item measure of satisfaction with treatment that has been validated in substance use treatment settings (Kelly et al., 2018). Items are scores from 1 to 4, with higher scores indicating greater satisfaction with treatment. For example, response options for the item, "How would you rate the quality of services you received?" range from 1 (poor) to 4 (excellent).

Timeline Followback. The Timeline Followback (TLFB) will be used as a face-valid measure of change in drinking quantity and frequency from baseline to follow-up (Sobell & Sobell, 1996). Using a calendar-based form, participants will indicate how many standard drinks they consumed on each day over the past 6 weeks. Holidays and significant historical events will be labeled to enhance memory recall. The TLFB will be used to estimate percentage of abstinent days and percentage of heavy-drinking days (4/5+ drinks for women/men).

Brief Young Adult Alcohol Consequences Questionnaire. The Brief Young Adult Alcohol Consequences Questionnaire (BYAACQ) is a 24-item measure of alcohol-related problems that has demonstrated reliability and concurrent validity among young adults who drink alcohol (Kahler, Hustad, Barnett, Strong, & Borsari, 2008; Kahler, Strong, & Read, 2005). Participants indicate (yes/no) if they have experienced consequences such as saying/doing embarrassing things, taking foolish risks, drinking on nights they had planned not to drink, or passing out from drinking in the past 30 days. Possible total scores range from 0 to 24.

Insomnia Severity Index. The Insomnia Severity Index (Morin, Belleville, Belanger, & Ivers, 2011) will be used as a 7-item measure of insomnia severity in the past two weeks. Items assess difficulty falling or staying asleep, satisfaction with current sleep pattern, interference with daily functioning, the extent to which others notice their sleep problems, and worry/distress related to sleep problems. Response options range from 0 (not at all worried) to 4 (very much worried), with possible total scores ranging from 0 to 28. Participants scoring 10 or higher will be classified as screening positive for insomnia (Morin et al., 2011). Notably, self-report is the recommended method of assessment for symptoms of insomnia in adults (Schutte-Rodin et al., 2008).
Actiwatch 2. The Actiwatch 2 (Philips Respironics) is a watch-like device that monitors body movement. Actigraphy data will be used in conjunction with self-report data to estimate sleep onset latency, wake after sleep onset, and total sleep time. Data will be analyzed by proprietary software using 30s epochs. Actigraphy provides valid estimates of nighttime awakenings, wake after sleep onset, total sleep time, and sleep efficiency when compared to polysomnography (Kushida et al., 2001; Lichstein et al., 2006).

Daily Sleep Diary. The sleep diary used in this study includes all elements of the consensus sleep diary used in sleep studies across the nation (Carney et al., 2012). Participants will estimate what time they got into bed, what time they tried to go to sleep (bedtime), how long it took them to fall asleep (sleep onset latency), the total duration of nighttime awakenings (wake after sleep onset), the time of their final awakening (waketime), and what time they got out of bed for the day. Sleep onset latency and wake after sleep onset will be summed to

estimate total wake time. Total wake time will be subtracted from time in bed to estimate total sleep time. Participants will also rate sleep quality on a scale from 0 (very poor) to 4 (very good). Finally, they will be asked to report the number of standard drinks consumed; if they used alcohol (yes/no), marijuana (yes/no), or other illicit drugs (yes/no) to help with sleep; and the name, dose, and time of any sleep medication they used to help with sleep.

7b. Secondary Outcomes

Behavior Rating Inventory of Executive Function for Adults (BRIEF-A). The BRIEF-A (Rabin et al., 2006) is a 75-item measure of executive function comprised of two index scores: the Behavioral Regulation index (BRI) and the Metacognitive Index (MI). In turn, the BRI is comprised of four subscales (inhibit, shift, emotional control, and self-monitor), and the MI is comprised of five subscales (initiate, working memory, plan/organize, task monitor, and organization). Consistent with the measure detailed on the Science of Behavior Change website and the theoretical model of executive function detailed in this proposal, we will use the initiate, working memory, plan/organize, and task monitor subscales of the MI index to assess self-reported executive function. Participants will indicate how often in the past month statements such as, "I make careless mistakes when completing work," and, "I start work (such as cooking, projects) without the right tools," have applied to them. Response options range from 1 (never a problem) to 7 (always a problem).

Monetary Choice Questionnaire. The Monetary Choice Questionnaire (Kirby, Petry, & Bickel, 1999) will be used as a self-report measure of delay discounting. In 27 trials, participants will be asked to choose between a smaller, immediate reward or a larger, delayed reward. For example, "Would you prefer $54 today or $55 in 117 days?" Data will be used to calculate participants' discounting-rate parameter (k).

Positive and Negative Affect Schedule. Participants will indicate the extent to which they feel each of 20 mood states (10 positive and 10 negative) on a scale from 1 (*very slightly or not at all*) to 5 (*extremely*).

Difficulties in Emotion Regulation Scale. The 16-item Difficulties in Emotion Regulation Scale has demonstrated good convergent and discriminant validity in clinical and community samples (Bjureberg et al., 2015). On a scale from 1 (almost never) to 5 (almost always), participants will indicate how often in the past 6 weeks they would endorse items such as, "I have difficulty making sense out of my feelings," and, "When I am upset, I become out of control."

Penn Alcohol Craving Scale. The Penn Alcohol Craving Scale is a 5-item measure of alcohol craving in the past week. Participants rate the intensity, frequency, and duration of cravings, as well as their ability to resist acting on those cravings and their overall "average alcohol craving" for the past week. This measure has demonstrated good internal consistency and construct validity (Flannery, Volpicelli, & Pettinati, 1999).

8. Study Statistics

Power analysis. We chose to utilize G-Power, rather than a power analysis specific to multilevel modeling (MLM, sometimes referred to as mixed modeling) because powering for ANOVA will ensure we are adequately powered for MLM analyses, which will increase power to detect significant effects. Based on previous studies, the expected effect size is large for insomnia outcomes (based on trials with Veterans) (Germain et al., 2014; Talbot et al., 2014), medium for alcohol use outcomes (based on trials with college students) (Fucito et al., 2017), and medium for executive functioning outcomes (based on trials with fibromyalgia patients) (Miro et al., 2011). We used G-Power to determine the sample size needed for an a priori repeated measures ANOVA, within-between interaction ($\alpha = .05$, power = .95, groups = 2, repetitions = 4, correlation = .40). Based on these calculations, the sample size required to detect a small effect ($f = .10$) is 260; a medium effect ($f = .25$) is 44; and a large effect ($f = .40$) is 18. Assuming 2/month recruitment and 35% attrition, we plan to recruit 68

participants over 34 months to obtain a final sample of 44 participants. This will provide us with an adequate sample size to detect moderate to large group by time interactions.

Data analysis. All questionnaire and behavioral task data will be scored according to published conventions. We will test for group equivalence in gender, age, race/ethnicity, use of sleep medication (# LRD), use of other drugs, and perceptions of peer drinking quantities (descriptive norms) at baseline. Group differences are unexpected in the context of randomization; however, if one of these variables is associated with both group and a given outcome variable, we will include it as a covariate in the prediction of that outcome. Data will be screened for integrity, outliers, missing values, and violations of the assumptions of MLM. Outliers will be replaced with the value that is 3 standard deviations +1 unit above the mean (Tabachnick & Fidell, 2007), and missing values will be handled in MLM using full maximum likelihood estimation.

Cohen's *d* and 95% CIs will be used to examine the magnitude of between-group differences mid-treatment, post-treatment, and at 1-month follow-up. We chose MLM over other statistical approaches because it requires fewer assumptions and has superior ability to handle missing data. In each model, the Level 1 variable will be time. Level 2 portions of the model will include the effect of condition and necessary covariates. The impact of CBT-I on insomnia symptoms will be tested by regressing condition on the Level 1 intercept and time effect. We will examine whether attrition is associated with any baseline variables and control for such variables when necessary. We will also explore CBT-I effects on alcohol use and proposed mediators, though we will be underpowered to detect small to moderate effects. We will use MLM to examine the within-individual associations between insomnia symptoms and alcohol use.

Early stopping rules. PI Miller will monitor adherence to the study protocol and adverse events on an ongoing basis and discuss these issues with the research team during weekly meetings. All serious and unexpected adverse events will be reported to the IRB within 24 hours of receipt of information. Other adverse or potentially adverse events will be monitored and reported at annual continuing reviews. After discussion with the IRB, we will discontinue the trial if there is (a) compelling evidence from this or another study of a serious adverse effect of CBT-I that has potential to override potential benefit, (b) compelling evidence from this or another study of a significant beneficial effect of CBT-I, such that continued denial to other groups would be unethical, or (c) low probability of addressing study aims within a feasible time frame.

8. Risks

We believe the risks associated with completing assessments and participating in the intervention are minimal. Potential risks include: temporary daytime fatigue (due to restriction of time in bed), subjective discomfort from answering questionnaires, coercion, and the possibility of a breach of confidentiality. Participants will not incur financial risk. There are no other known iatrogenic effects of CBT-I or completion of sleep diaries. However, if any emerge, they will be addressed immediately by research and/or clinical staff.

The following safeguards will be implemented to protect participants from risks related to study participation:

Temporary fatigue. Participants will be informed as part of the consent process that restricting their time in bed may increase daytime fatigue for the first few weeks of treatment (although this will be temporary, as time in bed will be expanded as sleep efficiency improves). Consistent with standard insomnia treatment procedures, time in bed will never be restricted to less than 5 hours in order to avoid impaired vigilance and significant daytime sleepiness. Participants will also be provided with recommendations on ways to increase alertness and counter daytime fatigue (e.g., staying active, engaging in social activities, strategic use of caffeine and water).

Discomfort. All measures used in this study are well-validated clinical measures that have been used extensively with this and/or similar populations of patients. Participants will be informed of the types of questions that they will be asked to answer as part of the informed consent process, and they will have the opportunity to skip questionnaire items or discontinue participation in the study at any time without penalty. In

addition, referrals will be provided to participants during the consent and throughout the study, in the event that participants report experiencing distress.

Coercion. Participants will be provided with modest compensation for their participation in the study. Specifically, participants will receive up to $50 for completion of the baseline, post-treatment, one-month, and three-month assessments ($10 for the in-person assessment, $20 for returning the actiwatch, and $20 for completing all 14 daily diaries). We believe these compensation rates are commensurate with the time and effort involved in these tasks, and the amounts are consistent with compensation provided for other clinical insomnia studies. Participants are free to discontinue at any time and will receive compensation for any and all assessments that they complete.

Confidentiality. Several steps will be taken to ensure that data remain confidential. Study data will be handled only by research staff and will be used strictly for research purposes. All research staff will be trained in responsible research conduct and the handling of private and confidential information. Identifying information will not be recorded on computerized or paper-and-pencil assessments; rather, assessment instruments and related study data will be identified and tracked using a unique study identification number. The database containing identification numbers and contact information will be stored separately from study data and will be used to link data from each assessment. This database will be stored on a password-protected computer accessible only to research staff and will be destroyed immediately upon completion of the study. Identifying information (e.g., names and dates) will appear only on consent forms, payment receipts, and the contact information form. All paper forms containing identifying information will be kept in a locked filing cabinet in a locked room in the Department of Psychiatry, separate from any data. Only research staff will have access to these filing cabinets. Audiotaped treatment sessions, which will be used in fidelity coding, will not be labeled with identifying information and will be deleted permanently once fidelity coding is complete.

In the screening survey, contact information is linked to the data provided. That will not be the case for any subsequent data collected in this study. For the remainder of the study, self-report assessment data collected using computer software will be stored electronically and identified by unique study number only. No personally identifying information will be included in the data. A password will be required to access data that are stored electronically, and only personnel involved with the project will have access to the electronic data. The computer-administered surveys provide an additional layer of confidentiality protection relative to paper and pencil surveys where staff would see a participant's data as they were entering or storing it.

Participants will be informed verbally and in writing during the consent process that mandatory reporting laws will be followed. Subjects who indicate current danger to themselves or others during the study will be escorted to the emergency room or Urgent Care services, both of which are located in the same building as the Department of Psychiatry.

Given the sensitive nature of information being collected, all data will be protected by a Certificate of Confidentiality and identified using unique ID numbers assigned to participants specifically for this project. Names and identifying information required for follow-up reminders will always be kept separate from research data and will not be used as study data. Text messages will only be sent with participant permission. To protect participants' privacy, communication sent via text message will be limited to scheduling [e.g., "We have you scheduled for a research appointment tomorrow (date) at (time). To confirm, text YES. To decline, text NO."]; participants' phone numbers will not be stored on research staff phones; research assistants will permanently delete all texts and calls at least once per month; and the name of the study will not be mentioned in any text. Informed consent papers will be stored in a locked filing cabinet in a locked office that is accessible only to project staff. Computerized survey data will be stored electronically on a password-protected server. Digital audio recordings of treatment sessions, which will be used to determine treatment fidelity, will be stored on password-protected computers to which only project staff will have access. All research staff will be trained in procedures for maintaining data and participant confidentiality.

Data safety and monitoring plan. PI Miller will monitor procedures to ensure that they conform to the approved protocol. Specifically, she will monitor (a) the progress of the research, including participant recruitment and retention and assessments of data quality; (b) adverse events and procedures for making determinations that

there may be a change to the benefit-to-risk ratio of research participation; and (c) procedures to protect participant privacy and confidentiality. She will monitor all serious, unexpected, and other adverse or potentially adverse events. Serious adverse events include those resulting in death, inpatient hospitalization, a threat to life, persistent or significant disability or incapacity, congenital anomalies/birth defects, or serious health risk. Unexpected adverse events are those that were unforeseen based on the anticipated potential risks outlined in the study protocol and informed consent. Other adverse or potentially adverse events include those that may be causally related to study participation and lead to participant distress or drop-out.

PI Miller will monitor data quality and adverse events on an ongoing basis and discuss these issues with the research team during weekly meetings. All serious and unexpected adverse events will be reported to the IRB within 24 hours of receipt of information. Other adverse or potentially adverse events will be monitored and reported at annual continuing reviews.

An independent, four-member Data Safety Monitoring Board (DSMB) will also be assembled to oversee the study. The DSMB will include investigators, a medical monitor, and a biostatistician who are independent of the study. Members will include those with expertise in AUD, chronic insomnia, sleep medicine, and cognitive-behavioral therapy. All DSMB members must attest that they have no conflicts of interest. The DSMB will meet once via conference call at the beginning of the study to review the study protocol, informed consent form, and monitoring plan, with emphasis on data integrity and patient safety issues. Following this initial meeting, the DSMB will meet every 6 months to review progress reports. DSMB reports will include interim statistical analyses. Any changes to these procedures that are recommended by the DSMB will be adopted. The DSMB will review adverse events and monitor study results, focusing on efficacy, recruitment progress, randomization, compliance, retention, protocol adherence, operating procedures, forms completion, intervention effects, participant safety, and minority inclusion. The DSMB will ensure adequate protection of human subjects and address ethical concerns based on Federal Guidelines. It will also make recommendations to NIH and the PI to continue or conclude the study. Discontinuation of any component of the study could be recommended for any of the following reasons: (1) compelling evidence from this study or another study of a serious adverse effect of study treatment that has potential to override potential benefit, (2) compelling evidence from this or another study of a significant beneficial effect of study treatment, such that continued denial to other groups would be unethical, and (3) low probability of addressing study aims within a feasible time frame.

9. Benefits

Participants in the CBT-I and Sleep Hygiene conditions may benefit from the sleep-related information provided. Participants may also appreciate the opportunity to engage in research that may help others benefit from treatment. Beyond these potential benefits to subjects, this research is expected to inform future research and clinical efforts to treat insomnia and reduce the consequences associated with alcohol use among returning Veterans. As noted above, we believe the risks of this research to participants are minimal and the overall benefits of this research to subjects and society outweigh these risks.

10. Payment and Remuneration

To enhance follow-up rates, participants will receive up to $300 for study completion. Specifically, participants will receive up to $70 for completion of the baseline, $20 for the mid-treatment assessment, up to $80 for the post-treatment assessment, and up to $130 for the 3-month follow-up. Participants who choose not to complete an assessment will not receive payment for that assessment; however, they will be invited to participate in any subsequent assessments (e.g., if they decline the post-treatment assessment, they will still be invited to complete the one-month follow-up). Notably, participants who fail to return an actiwatch will not be compensated for that assessment and will not be provided an actiwatch at subsequent assessments; however, they will be asked to complete and compensated for subsequent assessments.

11. Costs

Participants will be expected to travel to the Department of Psychiatry for assessment and therapy appointments. It is unlikely that the expense of this travel will be a burden to participants, as the Department of Psychiatry is located in downtown Columbia and is easily accessible by foot, car, public transportation, and the University of Missouri shuttle system. However, participants will be expected to cover the cost of these expenses. Participants will not be charged for other study procedures or for insomnia treatment.

12. Referral list

On-Campus Sites

- MU Counseling Center (MU students only): 573-882-6601
- MU Student Health Center—Behavioral Health (MU students only): 573-882-1483
- Psychological Services Clinic: 573-882-4677
- Integrated Behavioral Health Clinic: 573-882-2428

Off-Campus Sites

- Counseling and Psychological Services: 573-446-5034
- Counseling Associates: 573-874-8818
- Mayer, Flanagan, Scott and Associates: 573-443-1177
- Lawrence Oliver & Associates, LLC: 573-214-0436
- MU Hospital
  - Missouri Psychiatric Center: 573-884-1300 (Tiffany Sanford-Martens provides CBT-I)
  - Sleep Disorders Center: 573-882-1515
- Truman VA Hospital
  - Behavioral Health: 573-814-6486
  - Sleep Lab: 573-814-6470

Self-Guided / Online Resources

- Online CBT-I: http://www.myshuti.com/ (does cost money)
- Self-guided book (Amazon): http://www.amazon.com/Quiet-Your-Mind-Get-Sleep/dp/1572246278/
- App (free): "CBT-I Coach"

Crisis/Emergency

24-Hour Services

- National Suicide Prevention Lifeline: 800-273-8255
- The Trevor Lifeline: 866-488-7386
- Veteran Crisis Line: 800-273-8255

After-Hours Services

- MU Counseling Center: 573-882-6601
- Missouri Crisis Line: 888-761-4357

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