Insomnia Treatment and Problems (The iTAP Study)
University of Missouri IRB #2010684
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Protocol

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1. Abstract

Heavy alcohol use is prevalent among young adults and results in significant physical and psychological burden. Despite wide implementation of alcohol risk reduction efforts on college campuses, rates of heavy alcohol consumption remain high, with 35% of students reporting consumption of 5+ drinks on the same occasion in the past 2 weeks. Thus, additional strategies are needed to reduce the burden of heavy alcohol use among young adults. More than half of heavy-drinking young adults report symptoms of insomnia. In turn, insomnia symptoms have been associated with increased risk of alcohol-related problems. The proposed project aims to reduce the burden of heavy alcohol use by examining the efficacy of Cognitive Behavioral Therapy for Insomnia (CBT-I) in reducing alcohol use and related problems among heavy-drinking young adults. Twenty seven young adults who indicate risk for problem drinking on the Alcohol Use Disorders Identification Test (scores ≥4/5 for women/men) and meet DSM-5 criteria for Insomnia Disorder will participate in a 6-week pilot trial. Participants will complete six individual sessions of CBT-I. Outcomes will be assessed at the end of the active intervention period (6 weeks) and 1 month post-intervention. Primary outcomes of interest include insomnia severity, total wake time, sleep quality, drinking quantity and frequency, and alcohol-related consequences. The proposed research aims to reduce the harms associated with heavy alcohol use among young adults by improving the availability of efficacious treatment. It will impact our understanding of the benefits of CBT-I, and it is innovative because it evaluates improvement in insomnia as a mechanism for improvements in alcohol use disorder (AUD). This research is consistent with the National Institute on Alcohol Abuse and Alcoholism's initiative to evaluate and promote interventions that prevent the progression of AUD in diverse populations. It will enhance the stature of the university by improving our ability to compete successfully for federal funding to conduct high-quality research.

2. Objectives (include all primary and secondary objectives)

(1) To evaluate the effect of insomnia treatment on insomnia severity, total wake time, and sleep quality.
(2) To evaluate preliminary treatment efficacy in reducing alcohol use and alcohol-related problems.

3. Background

Heavy alcohol use is a problem on college campuses, where 35% of students report consumption of 5 or more drinks on the same occasion in the past 2 weeks (Johnston, O'Malley, Bachman, Schulenberg, & Miech, 2015). This form of heavy drinking has been associated with a range of

problems, from academic underperformance to sexual assault (Hingson, 2010). Given the prevalence and impact of heavy alcohol use within this population, evaluation and promotion of interventions that prevent the progression of alcohol use disorders among young adults is an ongoing focus of public health efforts.

Sleep problems have been identified as prospective predictors of alcohol use in epidemiological studies of children, adolescents, and adults. Specifically, sleep problems in childhood predict the onset of alcohol use among adolescents (Wong, Brower, & Zucker, 2009), sleep problems in adolescence predict alcohol use and related problems among young adults (Pieters et al., 2015), and sleep problems in adulthood predict the onset of substance use disorders (Weissman, Greenwald, Nino-Murcia, & Dement, 1997). Thus, prevention and early intervention in sleep problems may delay onset of heavy substance use and prevent progression to problematic use.

College is an important developmental time period in adolescent sleep, characterized by significantly later, more irregular bedtime, shorter sleep durations, and increased difficulty falling asleep (Gellis, Park, Stotsky, & Taylor, 2014; Lund, Reider, Whiting, & Prichard, 2010; Wolfson, 2010). In national studies, as many as 60% of young adults in college are classified as 'poor quality' sleepers (Lund et al., 2010), and 10% meet criteria for chronic insomnia (Taylor, Bramoweth, Grieser, Tatum, & Roane, 2013). Unfortunately, in the case of alcohol use, drinking has also been associated with more alcohol-related problems in the context of inadequate sleep (Kenney, LaBrie, Hummer, & Pham, 2012; Miller, DiBello, Lust, Carey, & Carey, 2016). Thus, post-high school years may be a critical time to intervene in both sleep and alcohol use patterns among young adults, as the establishment of healthy lifestyles in college may minimize the long-term harms associated with poor sleep and heavy alcohol use.

Given the association between insomnia symptoms and alcohol-related consequences, treatment of sleep problems is expected to reduce heavy drinking and alcohol-related problems among young adults. Two previous studies have examined the effects of insomnia on alcohol use. Hershner and O'Brien (2016) found that an online sleep education intervention significantly improved sleep hygiene and reduced the likelihood of risky drinking (>10 drinks per week) among college students. In a separate trial, Fucito and colleagues (2017) found that an online sleep intervention incorporating personalized feedback on alcohol use reduced sleep impairment, drinks per week, and alcohol-related consequences; however, the evidence-based intervention did not improve sleep or alcohol-related outcomes significantly better than the general health education control. Both of these studies provide evidence that improving sleep patterns will reduce risk for alcohol-related problems; yet neither specifically targeted individuals with insomnia, nor did they utilize an empirically supported treatment.

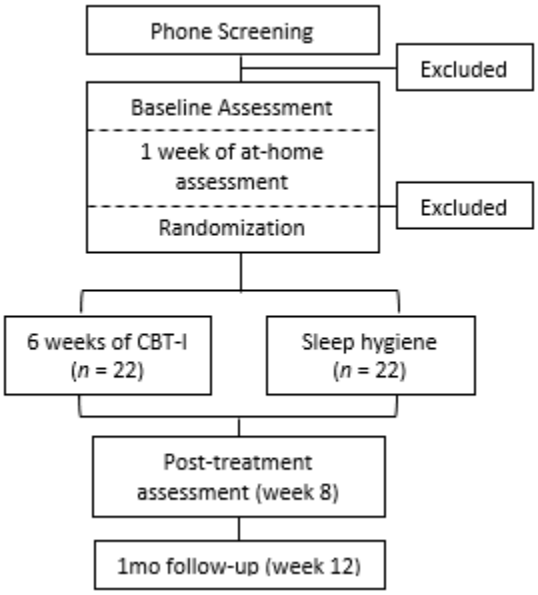
Cognitive Behavioral Therapy for Insomnia (CBT-I) is the first line of treatment for insomnia (Siebern & Manber, 2011). It has demonstrated efficacy in reducing symptoms of insomnia among young adults (Taylor et al., 2014), and effects are maintained in the presence of medical and psychiatric disorders (Smith, Huang, & Manber, 2005). However, no studies have examined the impact of CBT-I on alcohol-related outcomes among heavy-drinking young adults.

4. Study Procedures

This research will examine the efficacy of CBT-I in improving sleep and alcohol use outcomes among heavy-drinking young adults. Forty-four young adults will be randomized to receive sleep hygiene or to participate in six sessions of individual Cognitive Behavioral Therapy for Insomnia (CBT-I). Outcomes will be assessed at baseline, post-treatment, and 1 month follow-up (see Figure 1 below).

Recruitment. Participants will be recruited through community advertising for treatment of insomnia in young adults. Flyers will be posted around campus and in local primary care and sleep clinics. We will also recruit using monthly emails through the MU email system and Facebook. Participants will have the option of (a) completing the screening survey online via Qualtrics or (b) calling project staff to learn more about the study. In a previous trial examining the efficacy of CBT-I among young adult college students who were not heavy drinkers (Taylor et al., 2014), prevalence was 10% and attrition was 15%. Assuming a similar attrition rate, we will recruit 6 participants per month for 10 months (n = 52) to obtain a final sample of 44 participants.

Figure 1. Flow diagram



Baseline assessment. Individuals who are interested in the study will complete a brief eligibility screen. Those who are eligible and interested will be scheduled for an intake assessment, during which they will provide informed consent, complete the Mini International Neuropsychiatric Interview (MINI) for DSM-5 with the RA, and complete baseline measures. At the end of the baseline assessment, the RA will provide all participants with a one-page handout on sleep hygiene, which will include personalized normative feedback on their alcohol use. The RA will give the participant time to read the handout and will be available to answer questions, but will not engage the participant in unsolicited discussion about the information. The RA will then orient participants to the actiwatch (Philips Respironics) and the sleep diary.

If participants endorse suicidal ideation during the baseline assessment (or at any assessment throughout the protocol), research staff will assess their suicidal ideation using the Suicidal Ideation Attributes Scale (SIDAS). 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 supervising psychologist deems that the individual requires immediate on-site psychiatric evaluation, the participant will be escorted to the Psychiatric Center's Emergency Room (located in the same building as the Department of Psychiatry) for an in-person, comprehensive evaluation.

At-home assessment. Participants will be asked to wear the actiwatch 24/7 and complete one full week 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.

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

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 six weeks. The study therapist will follow the CBT-I protocol implemented in previous efficacious trials of CBT-I with college students (Taylor et al., 2014). 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 co-I 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. 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 (Neighbors, Larimer, & Lewis, 2004). Feedback will portray a bar graph and explanatory text comparing personal drinking quantity to that of same-sex peers.

Follow-up assessments. At the end of treatment and 1 month after treatment, follow-up assessments will be administered in person by the RA. To enhance follow-up rates, participants will receive $20 for completion of the baseline assessment, $5 for on-time completion of each week of daily diaries (potential to earn $30), $25 for the post-treatment assessment, $25 for the one-month follow-up.

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 received a promising treatment for insomnia in order to blind them to condition assignment.

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 co-I 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

Eligibility criteria include (a) age 18 to 30 years, (b) heavy episodic drinking, defined as 1+ heavy drinking episode in the past 30 days on the Timeline Followback, and (c) DSM-5 and research diagnostic criteria for insomnia. 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 in mood, cognitive, social, or occupational activities. Daytime impairment will be characterized as scores ≥ 10 on the Insomnia Severity Index.

Individuals will be excluded if they are unable to provide informed consent, began a new sleep medication in the past 6 weeks, report contraindications for CBT-I (mania or seizure disorder), have a severe psychiatric disorder that requires clinical attention (PTSD, major depression), or are currently receiving treatment for insomnia or alcohol use.

6. Drugs/ Substances/ Devices

N/A

7. Study Statistics

Outcome measures. Primary outcomes include insomnia severity, assessed using the Insomnia Severity Index (Morin, Belleville, Belanger, & Ivers, 2011); total wake time, assessed using sleep diaries and actigraphy; and sleep quality, assessed using daily sleep diaries (Carney et al., 2012); drinking quantity and frequency per week, assessed using the Timeline Follow-Back (Sobell & Sobell, 1996); and alcohol-related consequences, assessed using the Brief Young Adult Consequences Questionnaire (Kahler, Hustad, Barnett, Strong, & Borsari, 2008).

Secondary outcomes include delay discounting, assessed using the Monetary Choice Questionnaire (Kirby, Petry, & Bickel, 1999); negative affect, assessed using the Positive and Negative Affect Schedule (Watson, Clark, & Tellegen, 1988); emotion regulation, assessed using

the Difficulties with Emotion Regulation Scale (Gratz & Roemer, 2004); and alcohol craving, assessed using the Penn Alcohol Craving Scale (Flannery, Volpicelli, & Pettinati, 1999).

Power analysis. The expected effect size is large for insomnia outcomes (Taylor et al., 2014) and moderate for alcohol use outcomes (Fucito et al., 2017). We used G-Power to determine the sample size needed for an a priori repeated measures ANOVA, within-between interaction (α = .05, power = .95, groups = 2, repetitions = 3, correlation = .50). Based on these calculations, the sample required to detect a small effect (f = 0.1) is 260; a moderate effect (f = 0.25) is 44; and a large effect (f = 0.4) is 18. Assuming 5/month recruitment and 15% attrition, we will recruit 52 participants over 10 months to obtain a final sample of 44 participants. This will provide us with an adequate sample size to detect moderate group by time interactions in insomnia- and alcohol-related outcomes.

Data analysis. Data will be screened for missing values, outliers, normality, and homogeneity of variance before analysis. Assuming there are no significant group differences on baseline measures of each outcome, repeated measures analysis of variance with time (baseline to 1 month) as the within-subjects factor and randomized condition (CBT-I vs. sleep hygiene) as the between-subjects factor will be conducted. If there are significant differences between groups on baseline measures of an outcome, a one-way analysis of covariance, controlling for that variable at baseline, will be conducted.

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 be paid $20 for completion of the baseline assessment (60-90min), $5 for on-time completion of each of six weeks of daily diaries (~5min each), $25 for the post-treatment assessment (45-60min), and $25 for the one-month follow-up (45-60min). 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 baseline, post-treatment, and follow-up assessments. 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 (names and dates) will appear only on consent forms, payment receipts, and the contact information form. Participant addresses, which will be collected in order to allow research staff to follow up with participants who do not return the Philips Respironics Actigraphy device, will appear only on 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. 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.

Pending participant permission, participants will receive research appointment reminders via text or phone. Some text messages and phone calls may be made using Google Voice, which allows research staff to send texts and phone calls from their personal phones using a separate phone number. This separate phone number, which is provided free of charge, can subsequently

be unlinked from one's personal phone. We believe use of text messaging will improve our ability to contact and retain the young adults in our study, as they frequently decline to answer phone calls or respond to emails. This will allow research staff to contact and respond to participants while not in the office. We will take several steps to protect the privacy and confidentiality of participant information: (1) Google Voice will be downloaded and used only on password-protected phones by research assistants (RAs) who have been trained in responsible conduct of research. (2) Participant phone numbers will not be saved on the device; rather, RAs will enter the phone number manually each time they need to contact a participant. (3) Text messages will be used only for scheduling purposes (e.g., "We have you scheduled for a research appointment tomorrow (date) at (time). To confirm text YES. To decline text NO"). To protect participant privacy and confidentiality, we will not include the name of the study in the body of the text message. If participants ask about details regarding the study via text, we will follow up with them by phone call and explain that we are unable to disclose study information via text. (4) All text messages and phone calls will be deleted permanently from RAs' phones every week so that participant phone numbers are no longer accessible from the RA's phone. RAs will be reminded to do this in weekly research meetings.

Similarly, participants who have not returned a Phillips Respironics Actigraphy device and have not responded to electronic communication (i.e. calls, texts, emails) will be mailed a letter reminding them to return the device. To protect privacy and confidentiality, the letter will not include the name of the study or the university department.

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. 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.

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 young adults. 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 $20 for completion of the baseline assessment ($10 at the baseline assessment appointment and $10 when they return the actiwatch one week later), $5 for completion of each of six weeks of daily diaries, $25 for the post-treatment assessment ($10 at the post-treatment appointment and $15 when they return the actiwatch one week later), and $25 for the one-month follow-up ($10 at the post-treatment appointment and $15 when they return the actiwatch one week later). The total potential earnings would equal $100. 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).

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.

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