

Official title: Research Evaluating Sleep & Trends for Universal Prevention

NCT number: NCT04783519

Document date: May 13, 2019

Document: Research Strategy

SPECIFIC AIMS

Alcohol misuse by young adults (YA) is associated with a range of consequences, including accidental injuries and deaths, unwanted/unprotected sex, and work and academic difficulties (ACHA, 2014; SAMSHA, 2014). Marijuana (MJ) use is associated with risk of addiction, diminished work and school performance and lifetime achievement, mental health issues, and cognitive impairments (Voklow, et al., 2014). Sleep impairment is common and problematic among YA and associated with risk of obesity, depression, and suicidality (Owens et al., 2014). While each of these problems is serious in its own right, the co-occurrence of these conditions is both common and particularly problematic for YA. Thus, the current application seeks to directly target this co-occurrence in order to reduce harmful consequences and improve YA health.

There is good reason to approach alcohol, MJ, and sleep problems using a cohesive intervention approach. Considerable evidence indicates alcohol use interferes with sleep quality and exacerbates daytime sleepiness (Roehrs & Roth, 2001; Vitiello, 1997). Nonetheless, ~12% of YA use alcohol as a sleep aid (Taylor & Bramoweth, 2010). Prevalence of sleep disturbance, including insomnia, is higher in those who drink alcohol (Morioka et al., 2013; Stein & Friedman, 2005), particularly frequent heavy episodic drinking (HED, Popovici & French, 2013). Heavy drinkers who also report poorer sleep quality have more alcohol consequences, including increased risk of alcohol-related driving accidents, vs. those with better sleep quality (Kenney et al., 2012; Vakulin et al., 2007). Sleep dysfunction is also a primary risk-factor for development of MJ use disorder, maintenance of ongoing problematic MJ use, and relapse following abstinence (e.g., Gates et al., 2016; Allsop et al., 2011). Our data suggest YA who use MJ have both poorer sleep quantity and quality (R01AA022087).

Despite research documenting the link between alcohol and MJ misuse and sleep difficulties, as well as higher risk for alcohol- and MJ-related negative consequences among YA with sleep impairment, relatively little work has addressed sleep problems among YA in the context of high-risk drinking. Even less research has been conducted with MJ use and associated sleep problems, despite physiological consequences of MJ on sleep. Brief motivational interventions (BMIs) for alcohol use have shown efficacy in reducing HED, and studies support BMIs for MJ use, but typically these do not directly address sleep. Further, consistent evidence supports brief, cognitive-behavioral interventions for insomnia (CBT-I) to improve sleep in populations ranging from adolescents to older adults (Geiger-Brown et al., 2015; Taylor et al., 2014), but these interventions are not typically implemented with YA nor with individuals currently engaging in high-risk drinking or MJ use, despite strong evidence that brief CBT-I is appropriate for use with comorbid insomnia (Geiger-Brown et al., 2015). The current research is designed to remedy these gaps through development, feasibility, and pilot testing of an integrated brief alcohol, MJ and sleep intervention building on Brief Alcohol Screening and Intervention for College Students (BASICS; Marlatt et al., 1998; Larimer et al., 2001; Dimeff et al., 1999), BMI for MJ use (Lee et al. 2013) and Brief Behavioral Therapy for Insomnia (BBTI; Buysse et al., 2011; Troxel et al., 2012). Following a multi-stage intervention development process, YA participants ($N=150$) will be randomly assigned to: a) BASICS + SLEEP intervention; b) BASICS only; or c) assessment-only control (AOC). Assessments will include survey (baseline, post-intervention, 3-month follow-up), daily diary measures, and actigraphy to provide preliminary models of average and daily impact of interventions on alcohol and MJ use and sleep. **Specific aims are:**

1. Evaluate feasibility, acceptability, and preliminary efficacy of BASICS + SLEEP in reducing alcohol use and consequences and improving sleep quality and quantity in YA who report alcohol misuse, MJ use, and sleep disturbance.

H1a: YAs will find the BASICS + SLEEP intervention both feasible and acceptable.

H1b: Both BASICS + SLEEP and BASICS only will be more efficacious than AOC at reducing alcohol use (HED, peak drinking) and consequences and improving sleep at post- and 3-month follow-up. Effect sizes will be larger for BASICS+SLEEP than BASICS when each is compared to AOC. MJ use & consequences will be evaluated as secondary outcomes.

H1c: To evaluate effects of interventions at the event level, daily and lagged next-day associations between alcohol and sleep will be examined. We expect these relationships will be weaker in the active intervention conditions than in AOC at follow-ups, especially for the BASICS + SLEEP condition.

2. Explore daily and lagged relations between alcohol use, MJ, and sleep quantity/quality to assess potential directionality of sleep/alcohol/MJ associations, as well as influence of and impact on contextual factors (e.g., work/class schedules, stress, technology use, compliance with CBT-I strategies, and use of Alcohol/MJ protective behavioral strategies) related to these relationships.

SIGNIFICANCE

Heavy Episodic Drinking (HED) and Marijuana (MJ) Use by Young Adults (YA) is a Public Health Problem. Over 63% of college students report drinking and 42% have been drunk in the past 30 days (Johnston et al., 2015). Historically, HED among college students has been higher than non-college peers, with up to 39% reporting 5+ drinks on an occasion in the past 2-4 weeks. Understudied and underserved non-college YA also engage in frequent HED, (Johnson et al., 2013; SAMHSA, 2013) and their rates of use have been increasing (Johnston et al., 2016; Hingson et al., 2017). HED is associated with a range of harmful consequences, including regretted decisions, work and academic problems, blackouts, unprotected sex, injuries, and death (ACHA, 2014; Hingson et al., 2009). MJ use among YA has increased in the past decade, and in 2015 34% reported using in the past year and almost 7% used daily (Johnston et al., 2016). Most YA who use MJ also drink alcohol, though the converse is not always true (e.g., Pape et al., 2009; Subbaraman & Kerr, 2015). Evidence suggests many people who use both substances do so simultaneously (Briere et al., 2011; Subbaraman & Kerr, 2015). MJ use is associated with risk of addiction, diminished work and school performance and lifetime achievement, mental health issues, and cognitive impairments (Voklow, et al., 2014). Thus, reducing HED and co-occurring MJ use and consequences among YA remains a public health priority.

Sleep Difficulties among YA are Common and Costly. Of over 79,000 students at 140 schools (ACHA, 2014), 61.2% felt tired, dragged out, or sleepy during the day on ≥ 3 days/week, and 16.8% stated sleepiness during the daytime was a “big/very big” problem. About 9.5% of undergraduates indicated 0 days and 29.3% indicated 1-2 days in the past week they got enough sleep. Sleep difficulties are the 3rd most identified factor impacting academic performance, endorsed by 21.0% of students, behind only stress (30.3%) and anxiety (21.8%) (ACHA, 2014). 27.1% of students reported their sleep difficulties were “traumatic or very difficult to handle” within the last 12 months. More than 1 in 4 YA are at-risk for a diagnosable sleep disorder (Gaultney, 2010) and ~6% are treated for insomnia or other sleep disorder each year (ACHA, 2014). Sleep dysfunction is related to behavioral and emotional consequences in YA. Delayed phase sleep syndrome, shorter sleep duration, later bedtimes, and later rise times are associated with lower grades among students (Kelly et al., 2001; Lack, 1986; Singleton & Wolfson, 2009; Trockel et al., 2000). Sleep disturbance is considered a cardinal feature of depression, and insufficient sleep can increase depressive symptoms and suicidal ideation and attempts in YA (Hershner & Chervin, 2014). Insomnia is the most prevalent sleep issue in older adolescents and YA (Johnson et al., 2006; Taylor & Bramoweth, 2010) with rates up to 24% (Hysing et al., 2013); insomnia is also persistent, with reoccurrence in 88% of adolescences with a prior history (Johnson et al., 2006). Insomnia is estimated to cost the U.S. workforce \$63.2 billion/year in lost productivity (Kessler et al., 2011).

Heavy Episodic Drinking and Sleep Difficulties. Research demonstrates bidirectional causal links between alcohol misuse and sleep difficulties. Alcohol interferes with sleep quality and exacerbates daytime sleepiness (Roehrs & Roth, 2001; Vitiello, 1997). Despite initial reductions in time to fall asleep (sleep onset latency; SOL) associated with alcohol use, tolerance to this effect accrues rapidly, which can lead to increased doses of alcohol in an attempt to promote sleep. Alcohol use also results in fragmented sleep, particularly in the second half of the sleep cycle due to suppression of REM sleep (and related REM rebound in subsequent nights) (Hershner & Chervin, 2014; Lund et al., 2010; Roehrs & Roth, 2001; Vitiello, 1997). Alcohol withdrawal is associated with sleep impairment, making sleep difficulties a risk for relapse among those attempting to abstain (Vitiello, 1997). However, alcohol’s impact on sleep is not limited to those with alcohol use disorders; among adolescents the prevalence of sleep disturbance is higher in those who use alcohol than those who do not (Morioka et al., 2013). There is a strong relationship between HED and sleep difficulties among adolescents and YA which increases in magnitude with frequency of HED (Popovici & French, 2013). Almost 12% of YA who consume alcohol also use alcohol as a sleep aid (Taylor & Bramoweth, 2010) and among students who report HED, those with poorer sleep quality also report more alcohol consequences than those with better sleep (Kenney et al., 2012). Of note, sleep-deprived individuals are at greater risk for vehicular accidents with even modest doses of alcohol (Vakulin et al., 2007). Sleep deprivation can be acute (e.g., pulling an all-nighter) or chronically getting insufficient amount or quality of sleep (Hershner & Chervin, 2014). Challenges relevant to YA include varying class or work schedules, leading to inconsistent sleep- and wake-times, and also late-night events (Hershner & Chervin, 2014), which can exacerbate poor sleep symptoms.

Marijuana Use and Sleep Difficulties. MJ use reduces REM sleep and appears to increase stage 4 sleep while producing faster sleep onset (Schierenbeck, Riemann, Berger, & Hornyak, 2008; Angarita, et al., 2016). People who stop using MJ after a period of regular use often report difficulty sleeping and strange dreams (Schierenbeck et al., 2008). One of the most commonly reported challenges for people experiencing MJ withdrawal is sleep dysfunction (see Gates, Albertella, & Copeland, 2016 for review), including insomnia (see DSM-5 cannabis withdrawal criteria). Trouble getting to sleep was the most distressing withdrawal symptom for

YA during two weeks of abstinence following regular MJ use (Allsop et al., 2011). Removing MJ from the system can lead to acute sleep-related distress that has historically been managed through MJ use (Gates et al., 2016). Sleep dysfunction is a primary risk-factor for development of MJ use disorder, maintenance of problematic use, and relapse (Allsop et al., 2011; Gates et al., 2014, 2016; Schierenbeck et al., 2008).

Efficacy of Brief Motivational Interventions to Reduce Alcohol and MJ Use. Predominantly separate lines of research have demonstrated efficacy of interventions to address either alcohol or MJ misuse or sleep disruption, however the comorbidity of these conditions has rarely been addressed directly in YA populations. Brief motivational interventions (BMIs) such as BASICS (Dimeff et al., 1999; Larimer et al., 2001; Marlatt et al., 1998) have efficacy in reducing college student alcohol use and consequences (Carey et al., 2007; Crouce & Larimer, 2011; Larimer & Crouce, 2002, 2007; NIAAA, 2015). BASICS includes both personalized feedback regarding drinking norms, consequences, and motives for drinking, as well as protective behavioral skills for reducing HED and related consequences. BASICS is delivered in a motivational interviewing (MI) style (Miller & Rollnick, 2002) to enhance intrinsic motivation to change drinking and implement protective behavioral strategies (PBS). BASICS reduces alcohol use and consequences among high-risk drinkers, with effects up to 4 years (Baer et al., 2004). Effect sizes across trials with different populations, intervention components, and implementation approaches have been small-to-moderate (d 's ranging from .19-.85). Although BASICS has been implemented electronically with evidence of efficacy (Crouce & Larimer, 2011), some evidence suggests in-person implementation may be associated with larger and longer-lasting effects (Carey et al., 2007; Huh et al., 2015; Mun et al., 2014; White et al., 2007). BMIs targeting YA MJ misuse have also shown promising effects (Lee et al., 2013; Walker et al., 2006, 2011). Thus, for individuals with significant comorbidity, such as insomnia or other sleep disorders as well as HED and MJ use, in-person BASICS has potential to improve both alcohol/MJ and sleep outcomes through directly reducing alcohol/MJ use, indirectly impacting sleep.

Cognitive-Behavioral Therapy for Insomnia (CBT-I) is efficacious for improving sleep. CBT-I has been repeatedly demonstrated to improve a variety of sleep outcomes among adult populations (Geiger-Brown et al., 2015; Morin, 2012; Morin et al., 1994), but has rarely been implemented in YA populations nor in the context of comorbid HED or MJ use. Recent reviews indicate interventions incorporating at least 4 sessions of CBT-I and including components on stimulus control and sleep restriction are consistently associated with large effects on insomnia symptoms assessed via the Insomnia Severity Index (ISI; Bastien et al., 2001) and sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI; Buysse, 1989) as well as moderate-to-large effects on daily sleep indicators such as Sleep Onset Latency (SOL; time taken to fall asleep after going to bed), wake after sleep onset (WASO), Total Sleep Time (TST) and Sleep Efficiency (SE; TST/Time In Bed) (d 's .42-1.09) (Geiger-Brown et al., 2015). These changes correlate well with actigraphy (measurement of movement during sleep) and polysomnography (Geiger-Brown et al., 2015; Morin et al., 2011), including in YA populations (Williams et al., in press). Similar results are obtained when CBT-I is implemented with adults with comorbid insomnia in the context of other physical or mental health conditions, including alcohol use disorders (Geiger-Brown, 2015; Wu et al., 2015); improving sleep in comorbid populations also results in small-to-medium benefit on physical and mental health disorders (Wu et al., 2015). These findings strongly suggest improving sleep will pay dividends for improving alcohol/MJ outcomes in YA with comorbid sleep problems, and provides evidence of potential population-level benefits of addressing this common and costly comorbidity.

To improve implementation and uptake of CBT-I in non-clinical settings, a brief version of CBT-I has recently been developed (Brief Behavioral Treatment of Insomnia; BBTI; Buysse et al., 2011; Troxel et al., 2012) focusing primarily on stimulus control and sleep restriction as well as sleep hygiene recommendations. BBTI involves 2 in-person sessions and 2 brief telephone boosters and is designed to be implemented by non-specialists in primary care or other non-clinical settings. The intervention is manualized, and clients utilize sleep diaries and workbook assignments to consolidate recommendations. Results of an initial trial with comorbid insomnia in older adults demonstrated similar effect sizes to CBT-I (Buysse et al., 2011), suggesting BBTI is a viable alternative and could be implemented in worksite, school, or college health settings to increase reach of effective interventions. Further, the brief format lends itself to integration with brief alcohol and MJ feedback interventions to address these important and often unaddressed comorbidities.

Existing interventions for sleep disorders in YA populations are limited. Despite the availability of highly effective CBT-I interventions and recent emergence of BBTI as a briefer alternative, the majority of sleep interventions in YA have focused solely or primarily on sleep hygiene (Hershner & Chervin, 2014). Similar to findings that information-based alcohol prevention programs do not result in behavior change (Crouce & Larimer 2011), knowledge about sleep and sleep hygiene alone typically does not translate into improved sleep (Hershner & Chervin, 2014). Only 9% of college students who saw a sleep media campaign with tips for better sleep (e.g., keeping regular bedtime/waking hours, sleeping in a dark, quiet bedroom), reported

improved sleep habits; those who implemented these tips did report falling asleep earlier, faster, and sleeping more than peers who did not use these skills (Orzech, Salsky, & Hamilton, 2011). A psychoeducational group targeting sleep hygiene (Sleep Treatment and Education Program for Students, STEPS) showed some improvement in sleep hygiene practices at six week follow-up, but a smaller impact on sleep quality. An 8-week emailed self-help CBT-I in students with poor sleep quality showed YA who received the intervention ($n=19$) versus a comparison intervention ($n=15$) reported greater improvements in sleep quality and reductions in depression (Trockel et al, 2011), but participants were not randomly assigned, the sample was very small, and follow-up duration was limited. More recently, Taylor & colleagues (2014) conducted a pilot study comparing CBT-I to waitlist control (WLC) in college students with primary insomnia. CBT-I was well-tolerated, with over 90% completing at least 4 sessions, and both self-report and actigraphy measures demonstrated improvement on a broad range of sleep outcomes relative to WLC, with effect sizes similar to those in studies with older adults. However, students with comorbid conditions were excluded, leaving a gap in the literature. Finally, Fucito et al. (2017) conducted a small pilot ($n=21$ per condition) comparing two web interventions for comorbid alcohol and sleep in a college sample. Both interventions included sleep hygiene recommendations and encouraged reduction of alcohol use to improve sleep; the experimental condition also included personalized alcohol feedback and advice regarding stimulus control and sleep restriction. Both conditions were associated with large improvements in sleep and moderate-to-large reductions in alcohol use over 3 months, with a trend toward sleep improvements mediating impacts on alcohol use, but there were no differences between conditions in sleep outcomes and only one alcohol outcome differed between conditions, not in the expected direction. Further, the study did not include an inactive comparison condition to evaluate natural changes in sleep and alcohol use over time, did not include non-student YA, did not evaluate daily patterns of alcohol use and sleep to explore directionality, did not assess compliance with intervention recommendations for sleep or alcohol use, and did not assess comorbid MJ use. Thus, although these results demonstrate progress, there is a clear need to develop and evaluate additional evidence-based interventions for sleep impairment in YA.

Rationale for the Current Study. The current research is designed to develop and evaluate feasibility and initial efficacy of integrating a brief sleep intervention (i.e., BBTI) with an effective brief alcohol and MJ intervention (i.e., BASICS), with the potential to increase magnitude and duration of effects on sleep and alcohol and MJ misuse. BMIs that utilize personalized feedback attempt to elicit personally relevant reasons to change behavior. It is often the case that a particular topic or area of feedback emerges as a “hook” (i.e., content most relevant and salient to the individual such that a desire to see improvement in this domain could prompt commitment to change). For YA who report significant sleep difficulties, improving onset, duration, and quality of sleep may serve as a very potent “hook” to engage them in alcohol and MJ interventions (Fucito et al. 2017). In addition, an integrated intervention directly addressing alcohol and MJ misuse and sleep would be an important resource for improving health of YA, given bidirectional influences between sleep impairment and alcohol and MJ misuse, which are among the most significant public health problems facing this population.

INNOVATION

The proposed research is well-aligned with the current NIAAA strategic plan and addresses the highly significant problem of alcohol/MJ misuse and sleep problems among YA using an innovative design, sophisticated analytic plan, and integration of two different programs of research to develop and implement a highly personalized and relevant intervention targeting co-morbid high-risk alcohol use, MJ use, and sleep disorders. The current proposal is innovative in several ways. First, sleep issues among YA are a documented chronic problem with implications for overall health and academic/work performance, yet have received relatively little attention to date. Alcohol's role in sleep disturbance as well as the role of sleep disturbance in continuation/relapse to excessive alcohol use has been understudied. Additionally, many YA use both alcohol and MJ, often at the same time; comorbid MJ use has also been understudied in the context of sleep disorders among YA. To date, no other intervention has been developed that directly addresses both HED and MJ use and sleep, a comorbidity particularly critical to address given bidirectional influences between sleep and HED/MJ use and evidence that interventions for sleep are necessary to promote change and prevent relapse in comorbid insomnia. The current study addresses important gaps by directly targeting co-occurrence to reduce alcohol and MJ use and improve sleep, with potential to increase both magnitude and duration of intervention effects. The diverse community sample of YA will address a limitation of much of the previous work that focused primarily on college students in regard to high-risk alcohol and MJ use and intervention. The intensive measurement burst design allows us to examine daily relationships between alcohol use and sleep in the context of comorbid MJ as well as contextual factors relevant to YA (e.g., academic/work demands and schedules, technology use, use of CBT-I or PBS strategies). The sequence of impacts on alcohol, MJ, and sleep and the extent of additive or synergistic effects on consequences in this population is novel to this study.

Preliminary/Pilot Studies. Drs. Larimer, Lee, and Kilmer have conducted numerous studies of YA alcohol/MJ use and related risk behaviors, which provide key background and methodology for the proposed research. Dr. Vitiello brings particular expertise in assessment of and interventions to improve sleep. Our consultants bring experience conducting sleep intervention trials with YA college students (Taylor) and veterans with MJ comorbidity (Babson). Relevant work includes:

1) Etiology and prevention of YA alcohol and substance use. Biosketches of the research team show their extensive experience in etiology and prevention of alcohol, MJ and other substance use and high risk behaviors in YA. Drs. Larimer, Lee, and Kilmer have been PI/Co-I of numerous NIH and foundation grants which provide conceptual, clinical, and methodological support for the proposed intervention development study (e.g., R01AA018292; R01AA012529; R01AA018276; R01DA025051; R01AA016979; R01AA016099; R01AA018276). Many involved recruiting YA to attend in-person brief MI and skills-based sessions of similar or longer duration than proposed. Much of our research has involved web-based recruitment/assessment, and we have refined strategies over time, incorporating new technologies (e.g., text messages, Facebook notifications) and developing responsive systems for tracking to maintain high levels of retention (80-90%). For example, in our RCT of a web-based MJ intervention, 351 students were recruited in 1 month, and completed 3, 6, & 9 months follow-ups with >90% retention (Lee et al., 2010). Similarly, for an etiologic study of a diverse sample of community YA (R01AA025037; Lee PI, Larimer Co-I), over 779 YA were recruited in one year using online advertising. Retention in monthly assessments averaged 85% across 2 years.

2) Methods for daily diary studies. Drs. Larimer, Lee, and Fairlie have served as PIs/ Co-Is on several projects using intensive daily measurement of alcohol/MJ use across time (e.g., R21AA016211, R01AA018292, R21AA024156), demonstrating high retention and completion rates for similar or longer diaries using similar incentives as proposed. For example, we assessed YA 3 times/day for 56 days across 1 year via mobile phones (R01AA016979), examining prospective influence of alcohol expectancies, use, and negative consequences (resulting in 18,364 days of data). At least one daily interview was completed on 91.5% of days; mean number of interviews (out of 3 per day for 56 days) was 141 of 168 possible (84%); 88% of participants were retained through one year, with minimal assessment reactivity. Drs. Vitiello, Babson, & Taylor similarly have extensive experience using daily sleep diaries, and will contribute this expertise to the team.

3) Experience with longitudinal analytic methods. We have experience analyzing and interpreting findings using proposed methods for longitudinal designs. Various publications utilized generalized linear mixed models to examine intervention effects in multi-arm and other complex RCTs, mediational hypotheses, moderation, and daily-level risk factors using intensive longitudinal designs (e.g., Larimer et al., 2001; 2012; Neighbors et al., 2010; Lee et al., 2014). Dr. Fairlie has particular expertise in proposed analytic methods, including analyses to test efficacy of YA alcohol interventions (Ichiyama et al., 2009; Wood et al., 2010) and multilevel modeling to test daily associations (Fairlie et al., 2015). Drs. Lee and Fairlie have numerous publications analyzing longitudinal data using hierarchical linear modeling (HLM) including intensive daily and weekly diary designs (e.g., Fairlie et al., 2015; Lee et al., 2010; Patrick & Lee, 2010, 2012).

4) Experience with assessment of and interventions for sleep difficulties. Dr. Vitiello is a national leader in sleep research, with extensive experience in assessment, diagnosis, and treatment of sleep disorders in populations including individuals with comorbid medical, psychological, and addictive disorders (Vitiello, 1996; Vitiello et al., 2013; Vitiello et al., 2014). Dr. Vitiello's research demonstrated the value of CBT-I in improving both chronic pain and sleep among a comorbid older adult sample, whereas pain treatment alone did not result in long-term improvements in sleep (Vitiello et al., 2013; Vitiello et al., 2014). Dr. Vitiello's expertise in sleep assessments, CBT-I and RCTs, while historically focused on older adults, will integrate well into the rest of the research team's expertise in AOD interventions for YA. Dr. Taylor has similarly demonstrated feasibility and initial efficacy of CBT-I among college students with primary insomnia, demonstrating moderate-to-large effect sizes on a broad range of sleep outcomes (Taylor et al. 2014).

5) Pilot data on YA sleep problems, comorbid alcohol and MJ use, and CBT-I for sleep and MJ use. The Transitions project (R01AA022087; Lee PI, Larimer Co-I) included items on sleep and alcohol and MJ use in a diverse sample of 644 YA. Among YA who used alcohol in the past month, 59% scored 5+ on the PQSI, indicative of sleep dysfunction. Alcohol-related consequences from the Brief YAACQ were correlated with Global PQSI score as well as Daytime Dysfunction, Sleep Aid, Sleep Latency, and Sleep Disturbance subscales. Peak BAC, total weekly drinks, average drinks per day, and frequency of drinking were also correlated with the Sleep Aid subscale; 12% reported using alcohol as a sleep aid in the past month. Similarly, among those who used MJ at least monthly, 63.9% reported PQSI global scores above 5. Global PQSI and all subscales were correlated with MJ frequency. Dr. Babson also has expertise in bidirectional associations between sleep and MJ among YA Veterans, directly relevant to our hypotheses. Poor sleep quality among

veterans prior to a MJ cessation attempt was a risk for early lapse/relapse to MJ (Babson, Boden, Harris et al., 2013). Veterans with poor sleep quality had greater MJ frequency at baseline, and less reduction in MJ frequency over a 6-month cessation attempt (Babson, Boden, & Bonn-Miller, 2013). Dr. Babson conducted a small pilot of CBT-I for sleep among veterans with CUD, and found reduced MJ frequency and improved sleep quality compared to placebo control (Babson et al., 2015). This pilot informed a recently completed RCT (IK2 CX001023-01A1; PI: Babson), examining impact of CBT-I on MJ use in veterans with CUD and insomnia. CBT-I resulted in reduced MJ frequency and improved sleep quality compared to placebo control at post-treatment. Taken together, our prior work supports bidirectional relations between sleep and alcohol and MJ use in YAs, provides evidence that directly targeting sleep improves both sleep and substance use, and supports potential benefits of integrating alcohol & MJ BMI with sleep interventions to maximize impact.

Summary of Preliminary Studies. Our team has experience in longitudinal prevention outcome research in YA samples; intervention development with CBT, MI, and integrated interventions for a variety of risk behaviors; research on risk factors and prevalence of AOD use in YA; assessment of sleep disorders and interventions to improve sleep in YA and adult populations; bidirectional influences between sleep and alcohol/MJ use; daily diary research, analyses of daily and longitudinal data, and retention strategies for daily assessment procedures; and experience utilizing the web for recruitment and assessment in a variety of populations including community samples of YA. This experience has influenced the current proposal conceptually and methodologically, and yielded specific implementation strategies incorporated into the current research. Collectively, we represent a qualified research team to conduct this intervention development study.

APPROACH

Overview. Although alcohol's negative impact on sleep has been established, there is a lack of attention to targeted alcohol and sleep interventions to reduce this comorbidity among YA. MJ as a complicating factor in the alcohol-sleep relationship has also been overlooked, despite evidence that both alcohol and MJ have bidirectional relationships with sleep disturbance, and many YA use both MJ and alcohol concurrently (and often simultaneously). Most research on alcohol and MJ interventions for YA has ignored the "forgotten half" of YA who do not attend 4-year universities. The current study proposes to address these gaps through development, feasibility testing, and pilot-testing an integrated alcohol, MJ, and sleep intervention, in a community sample of YA who score above a 10 on the Index of Insomnia Symptoms (ISI; Morin et al., 2011), report heavy episodic drinking (5/4 drinks per occasion) at least once in the past two weeks (Fucito et al. 2017), and MJ use at least once in the past month. Assessments will be online, including baseline, daily diary (up to 8 weeks), and follow-up at post-intervention and 3 months. Participants will be randomized to BASICS + SLEEP, BASICS alone, or Assessment-Only Control (AOC).

Intervention Adaptation and Beta Testing. The first 9 months of Year 1 will be a multi-stage, iterative process to adapt intervention protocols to finalize the BASICS + SLEEP intervention. This process will involve four stages—initial development, rapid prototyping, beta-testing, and a small open trial with cognitive interviews.

Development. We will develop visual (i.e., graphics, display) and content (i.e., therapist manual, prevention messages for personalized feedback, handouts/worksheets) prototypes (Moggridge, 2007; Rudd et al., 1996; Takayama et al., 2002). We will first conduct a thorough review and summary of existing materials (including the BASICS, MJ BMI, and CBT-I/BBT-I manuals) and update our literature review relevant to alcohol, MJ, and sleep in YA to ensure the most recent findings and innovations are incorporated. We will also gather input from 3-5 undergraduate research assistants at CSHRB within the target age-range who will review materials, address potential issues with comprehension and persuasiveness of the messages, and identify potential barriers to implementation with YA. Dr. Larimer will convene a 2-day meeting, working with investigators and consultants to discuss critical aspects of content, display, messaging, and personalization of the materials, incorporating key theoretical perspectives, empirical findings, and practical issues identified. The members of the clinical research team (Drs. Larimer, Lee, Kilmer, Vitiello) will take responsibility for modifying specified components of the manual and/or personalized feedback and handouts/worksheets, which will then be distributed to the full team and consultants for further edits. Through this process, we will adapt the integrated intervention and produce initial prototype manuals, handouts, feedback, and worksheets for further refinement.

Rapid Prototyping. Once initial prototypes of the intervention materials are produced, we will review and revise them using a rapid iterative testing and evaluation (RITE) approach (Medlock et al., 2005). We will bring in 3 participants per day who meet eligibility criteria for the later pilot study (see Recruitment) for a total of 3-5 days over a three week period. Participants will be asked to imagine receiving this information personalized to them, review the materials, and provide feedback on how engaging, appropriate, and informative they find it (Svanaes & Seland, 2004) and how likely they would use the skills and strategies. During these sessions, participants may annotate prototypes with problems, useful content, or suggested changes, and may sketch

their own designs for improving display or clarity of information; this has been found to promote more reflection from participants (Tohidi et al., 2006). We will audio record and transcribe all interviews, and retain any sketches or annotations. We will focus on mockups and simulated interaction and thus be able to explore a broad design space, rapidly refine ideas, and eliminate those that are unfeasible, unappealing, or ineffective before substantial time and resources are spent on implementation. Between participants, the study team will revise materials based on the feedback. We have used this process to develop complex intervention materials and protocols in short timeframes, which have been positively received and efficacious (see prelim studies).

Beta-testing. The next stage of development involves programming and beta-testing the personalized feedback components of both BASICS + SLEEP and BASICS-only. We will also program online measures and work with our programmer to finalize the web-based daily diary system, based on an existing diary platform. Following programming, all components of screening, assessment, randomization, diaries, and intervention feedback will be extensively beta-tested in-house to ensure items and skip patterns are working appropriately, randomization correctly allocates individuals to condition, feedback algorithms are working properly and feedback matches input from sample survey data, and to more closely estimate time to complete diaries and assessments and potentially refine assessments to minimize burden and maximize data quality if necessary.

Open Pilot Trial. Following beta-testing, we will implement a small (n=10) open pilot to establish therapist adherence and competence, further test technological interfaces, assessment, and intervention materials for language and graphics, and obtain additional feedback from the target population prior to the pilot study.. Eligible and recruited open trial participants (see Screening and Recruitment) will complete baseline and daily assessment protocols, including 14 days of daily diary assessment, and keep a daily log of any difficulties with the procedures. Participants will attend BASICS + SLEEP intervention sessions, complete 3 weeks of monitoring during the intervention and an additional week post-intervention. They will complete post-assessment measures, and be contacted for a telephone interview to discuss the intervention and any difficulties they experienced. Participants will be compensated up to \$298 for their time during the open trial. Post-intervention phone interviews will be conducted based on Cognitive Interviewing (e.g., Beatty & Willis, 2007; Willis, 2005) and our similar intervention trials. For example, the interviewer will ask participants to state their perception of the meaning, purpose, and utility of each major component of the BASICS + SLEEP intervention and recommendations for revisions. Analysis of interviews will occur through systematic review of interviewer notes. Comprehension and interpretation of components will be reviewed in 3 categories: (1) unclear meaning or main points, (2) limited applicability or utility, and (3) difficulties with wording or explanations. Investigators will meet throughout to review notes and feedback, but will formally meet after the first 3 interviews are conducted to determine whether immediate changes need to be made prior to conducting additional open trial sessions. After all interviews are conducted, revisions will be made to intervention content and process, and assessments, if warranted, based on interview findings. The open trial will also provide initial information regarding feasibility of the intervention, and allow us to refine estimates of recruitment rates and generalizability, intervention completion, and trouble-shoot feasibility of procedures prior to the full pilot study.

Pilot Study. Following completion of the multi-stage intervention development process, beginning in month 10 we will implement a pilot RCT to further establish feasibility and initial efficacy of the BASICS + SLEEP intervention in comparison to BASICS alone and AOC, for reducing alcohol and MJ use and improving sleep quality and quantity in a community sample of YA. We will also use data from this pilot trial to address our final aim exploring daily and lagged relationships between alcohol and MJ use and sleep, compliance with recommended sleep and protective alcohol/MJ strategies, as well as contextual factors that might promote or impede improvements in sleep and substance use outcomes. This information is necessary to support a larger longitudinal trial, as questions regarding compliance of YA with sleep restriction and stimulus control, as well as response of sleep indicators to alcohol/MJ only interventions and direction of sleep/substance use effects in integrated interventions, currently limit our knowledge to proceed forward with a large-scale RCT in this area.

Recruitment and Screening. To reach the target population of 150 YA (ages 18-24) with comorbid sleep, alcohol, and MJ problems, ads will be placed in online SNS (i.e., Facebook, Instagram), Craigslist, and other media outlets (newspapers, community ads) that attract a broad spectrum of YA. Online recruitment is appropriate for this age group, as nearly 93% of YA use internet and 83% have a SNS profile (Pew Internet & American Life Project, 2013, Pew Research Center, 2013). Online recruitment ads will provide a hyper-linked website address (URL) for more information and screening. Other methods of recruitment include ads in local university, community college, and trade school newspapers or flyers in public locations. We have had success using these procedures to recruit similar samples including large (N's 280-770) demographically diverse (40-50% minority) samples of HED and frequent MJ users (R01AA025037; R01AA022087; See human subjects recruitment plan). Nonetheless, we will also evaluate most effective ad strategies based on completed and

eligible screens from each source and representativeness relative to general and clinical samples of YA with sleep dysfunction and alcohol/MJ misuse, to plan for a subsequent large-scale trial. We expect approximately 60% will be enrolled in 2-year (community college, trade/vocational school) or 4-year college and 40% not in post-secondary school (SERC, 2006). Numbers are roughly equal by sex.

Interested YA clicking on the link or going to our website will be taken to an informed consent page that includes all elements of consent (see human subjects). Those who consent will be immediately routed to screening that includes demographic items, Quantity/Frequency/Peak alcohol use indices (Dimeff et al., 1999; Marlatt et al., 1998), MJ prevalence/frequency, ISI for sleep symptoms (Bastien et al., 2001) and use of alcohol and/or MJ to promote sleep (Taylor & Bramoweth, 2010). Based on prior experience, we anticipate screening approximately 750 YA to enroll 150 participants. We expect screening respondents will be demographically similar to the Greater Seattle Metropolitan Area (GSMA) YA population; however, we will compare respondents to demographics from the most recent census to evaluate potential response bias and provide information for refining recruitment for a future larger trial. *Eligibility criteria* for all phases include a score on the ICI of 10 or higher (Morin et al., 2011), at least one heavy drinking episode (4 or more drinks for women, 5 or more for men in a 2-hour period; NIAAA 2004) in the past two weeks, and MJ use at least once per month. We have previously used these criteria to identify a sample in need of brief alcohol and/or MJ interventions (Larimer et al., 2001, 2007; Lee et al., 2013). We estimate 20% of those screened will meet criteria and agree to participate in the RCT, based on rates of self-reported sleep impairment and sleep disorders in the YA and college population (ACHA, 2014; Hershner & Chervin, 2014), our preliminary data, rates of HED and MJ use among YA, and increased likelihood of insomnia symptoms given HED/MJ, for an eligible pool of 150 participants randomized to 1 of 3 conditions (n=50 per condition).



Figure 1. General intervention design. All conditions receive assessments in light and dark blue.

General Design: Baseline, Daily Monitoring, and Longitudinal Follow-Up Assessments. Participants who meet criteria will immediately be linked to the baseline survey online. Upon completion of baseline, they will be automatically randomized (programmed in DatStat Illume) to one of the 3 conditions using urn randomization (Wei & Lachin, 1988) to reduce disparities in baseline alcohol use and consequences, MJ use, and severity of sleep problems across conditions. Participants will be immediately routed to an online scheduling system listing multiple dates to choose to attend one (AOC) or two (BASICS + SLEEP, BASICS) in-person meetings. The first will be at least 2 weeks from baseline to enable sufficient time for baseline daily monitoring. Upon scheduling, an immediate email reminder will be automatically generated, including a link to a map to assist with locating the scheduled session. Participants will also receive a reminder call and email and text message the day prior to their meeting. Missed meetings will be rescheduled. Participants in all conditions will also receive a link to online daily diaries the morning after baseline, and a text message reminding them to log in the next morning to begin their first 14-day monitoring period (see diary procedures). Participants in all conditions will complete 4 additional weeks of daily monitoring corresponding with timing of interventions.

Daily, post-, and follow-up assessments for AOC will be yoked for timing to intervention for BASICS and BASICS + SLEEP, so assessments of alcohol, MJ, and sleep diaries will be at comparable times across groups. Three-month follow-up will replicate the email, text, and telephone reminders (see retention below and in human subjects), and participants will complete 2 weeks of daily monitoring at follow-up (see Figure 1). All participants will complete satisfaction scales at post-assessment as well as measures of outcomes and potential mediators to inform the future longitudinal RCT. Repeated daily assessments allow us to closely model the natural history of changes in alcohol, MJ, and sleep across the 3-month period, adding to sparse literature on this topic.

Daily Diary Procedures. Consistent with prior sleep research and interventions (Troxel et al., 2012; Taylor et al., 2014), participants will complete once daily web-based diary assessments/logs for 14 days pre-intervention, one week in relation to each intervention contact, one-week at post-assessment, and two weeks at 3-month follow-up, across all conditions. Each morning participants will receive an email and text with a link to the online assessment and instructions to fill it out within one hour of waking for the morning; however, it will be open from 6am to noon (2pm on the weekends and sanctioned holidays). Measures will consist of the Consensus Sleep Diary (CSD), Core sleep questions and items from the extended CSD (Carney et al., 2012) and supplemented with additional alcohol and MJ behavior and consequence questions, as well as positive and negative affect (PANAS, Watson et al., 1998) academic (e.g., exams, projects/essays, class schedule)

and/or work (e.g., work schedule, deadlines, work stress) and technology use. Alcohol items will assess total drinks consumed yesterday from the time they woke up to the time they went to sleep, timing of each drink, alcohol as a sleep aid, a short measure of alcohol consequences previously utilized in our daily diary research (R01AA016979; Lee et al., 2015), and use of protective behavioral strategies (PBS). MJ assessment will include frequency, timing, route of administration, quantity, daily consequences, use of MJ as a sleep aid, and MJ PBS. Sleep will be assessed with 9-items from Core CSD including time getting into bed, time attempted to fall asleep, sleep onset latency, number and duration of awakenings, time of final awakening, final rise time, perceived sleep quality, and an open-ended question for comments, validated with actigraphy using Actiwatch 2 (Williams et al. in press). Other sleep questions will assess estimated total sleep time, napping/dozing, use of caffeine and over the counter or prescription medications to help with sleep, and use of stimulus control or sleep restriction strategies. Participants will receive \$4/day completed (\$28/week) and a \$5 bonus for completing 90%+ each week (total up to \$33/week for 8 weeks). They will be paid \$15 for screening, \$30 for baseline, \$20 for post-assessment, and \$35 for 3-month.

Web-based assessment. All assessments will be conducted via internet, using a secure server and encryption. We have purchased DatStat Illume, a survey and data management system, which allows us to flexibly create and modify surveys and feedback. We will work with Rivulent Web Design to adapt a real-time tracking and management system interfaced with DatStat Illume to provide real-time reminders during the daily assessments that is responsive to whether participants complete daily assessment or not. The tracking system provides up-to-date information about completion rates and can alert us to when participants miss a day and need to be telephoned for a second level of reminders and reinforcement. We have utilized these complex tracking systems for intensive longitudinal studies, including studies with assessments up to 3x per day with excellent compliance and retention (80-90%) using similar incentives (e.g. R01AA016979).

Measures

Variable	Function	Measure	Assessment(s)
Alcohol use (quant., freq., BAC) Marijuana use (freq., high)	DV	Quantity/Frequency/Peak Alcohol Use Index (Baer, 1993; Marlatt et al., 1995); Daily Drinking Questionnaire (Collins et al., 1985; Kivlahan et al., 1990), Daily Marijuana Questionnaire (Lee et al., 2013),	Screening, Baseline, All LFU
Alcohol consequences Marijuana consequences	DV	Rutgers Alcohol Problem Index (White & Labouvie, 1989); Alcohol Use Disorders Identification Test (Babor et al., 2001); ¹ Daily Alcohol-related Consequences (Lee et al., 2015), Marijuana-related Consequences (R01AA025037); Cannabis Use Disorder Identification Test-Revised (CUDIT-R, Adamson et al., 2010)	Screening, All LFU, ¹ Daily
Sleep Symptoms; Sleep Quality; Expanded Consensus Sleep Diary; Actigraphy	DV; Mediator; Moderator	Insomnia Severity Index (Bastien et al., 2001), ¹ Expanded Consensus Sleep Diary (Carney et al., 2012), Pittsburgh Sleep Quality Index (PSQI, 1989; Buysse et al., 1989; Backhaus et al., 2002); Actigraphy (AW2; Williams et al. in press)	Screening, Baseline, All LFU, ¹ Daily
Perceived descriptive norms	Intervention; potential mediator	Drinking Norms Rating Form (Baer, Stacy, & Larimer, 1991)	Baseline, All LFU
Protective behavioral strategies	Intervention; potential mediator;	PBS Survey (Martens et al., 2005)	Baseline, All LFU, daily
Readiness to change	Intervention; potential mediator	Readiness to Change Questionnaire (Heather, Gold, & Rollnick, 1991).	Baseline, All LFU
Self-efficacy	Potential Mediator	Brief Situational Confidence Questionnaire-8 (BSCQ-8, Breslin, et al., 2000),	Baseline, All LFU
Sleep-related motivations; Drinking motives	Exploratory Moderators	Sleep-related motivations (Taylor & Bramoweth, 2010); Drinking Motives Questionnaire - Revised (Cooper, 1994)	Baseline, All LFU
Positive and Negative Affect	Aim 2	Positive and Negative Affect Scale (PANAS, Watson et al., 1988)	Daily
Daily Academic Demands; technology use	Aim 2	Investigator Generated	Daily
Other Drug Use & Consequences	Aim 2; Covariate	ASSIST (WHO, 2002)	Baseline, All LFU
Psychiatric Symptoms	Covariate	Brief Symptom Inventory (Derogatis & Melisaratos, 1983)	Baseline
Demographics	Covariate	Investigator generated items	Screening, All LFU
Social Desirability	Covariate	Balanced Inventory of Desirable Responding (Pauhus, 1984)	Baseline
Participant Satisfaction	Intervention Delivery	Investigator Generated	Post-assessment
Coding of Sessions	Intervention Delivery	Motivational Interviewing Treatment Integrity (Moyers et al., 2005); Yale Adherence and Competence Scale (Carroll, 2000)	

Participant Retention. At each assessment participants will update their contact information, and provide 2 alternate people we can contact to reach them. Consistent with recommendations regarding recruitment and

retention (Kypri et al., 2004; Tourangeau, 2004), we will use multiple reminders (text, email, phone), provide financial compensation, and send participants who complete assessments promotional items to encourage continued participation. These methods have been effective for retention in our prior studies (prelim studies; see Recruitment and Retention Plan in Human Subjects and Clinical Trials section for more detail).

Intervention Procedures. Upon completion of baseline assessment, participants will be immediately randomized (using urn randomization) to BASICS + SLEEP, BASICS, or AOC. The following sections describe procedures and interventions in more detail for the BASICS + SLEEP, BASICS, and AOC conditions.

BASICS. The BASICS condition will meet for 2 in-person sessions of 45-75 minutes in length to review and discuss feedback from baseline assessment. Length within these parameters and exact content of each session will depend on the degree to which participants discuss feedback with the facilitator, have questions about alcohol's effects, and/or explore a variety of behavior change options; BASICS is designed to be flexible to accommodate this MI process. Content and process will be based on our prior successful interventions (see prelim studies) developed and tested by Marlatt and colleagues for use for college student drinking (Larimer et al., 2001; Marlatt et al., 1998) described in detail in the BASICS manual (Dimeff et al., 1999). MJ feedback will also be fully integrated based on Lee and colleagues (2013). Therapists (see therapist training) review feedback components with participants, eliciting personally relevant reasons to change as feedback domains are explored (when values and goals of importance to the individual are in conflict with participants' current alcohol and/or MJ use and related consequences, contemplation and commitment to change are enhanced). When the participant is ambivalent about change, therapists will work with the participant to explore and resolve that ambivalence. The method is non-confrontational and utilizes exploration of personalized graphic feedback domains to increase motivation for change by highlighting ways in which alcohol and/or marijuana use could be inconsistent or incongruent with a person's goals or values (e.g., a YA explains that doing well in school is their most important goal, but sees feedback highlighting past instances of missing class because of hangovers; a participant states that avoiding drinking and driving is important, and stays at a friend's house to "sleep off" their buzz before driving, yet learns it takes 15 hours to bring their .240% BAC to .000%, meaning they actually are driving under the influence the next day). Personalized feedback includes a summary of frequency, quantity, and peak use alongside the presentation of perceived and actual norms for alcohol/MJ use. Beliefs, expectations, and motives for use are discussed as well as strategies to minimize risks and consequences. Ways in which reduced alcohol and/or MJ use might be related to reduced harms are elicited and reflected across multiple domains. Feedback will be given on personal high-risk situations that contribute to excessive drinking and MJ use and ways to respond to these situations (Marlatt & Gordon, 1985). A tips page covering these recommendations and highlighting other aspects of the skills content will be provided, and specific skills reviewed based on relevance and utility for the particular high-risk situations identified. Telephone booster sessions will be used to address any questions and highlight relevant aspects of the initial session (booster 1) and consolidate changes and problem-solve any challenges that have arisen since the second in-person session (Booster 2), providing comparable time and contact with the counselors across the BASICS and BASICS + SLEEP conditions (see below). The BASICS intervention is kept brief through the skillful introduction and exploration of skills elements in the context of a motivational discussion of drinking and MJ behaviors and beliefs, guided by graphic feedback produced from the assessment materials. Thus, although BASICS content is relatively broad, depth of coverage of skills elements is adjusted to be appropriate to needs and existing skills of participants, and overall emphasis is on supporting motivation and self-efficacy. In our past research, we have effectively delivered personalized feedback and brief skills content in 45-90 minutes, with and without additional booster material, targeting behaviors ranging from heavy alcohol use and MJ use to binge eating and purging behaviors, in populations ranging from college students to middle school youth to employees of a large food & retail services company, with significant effects maintaining up to 4 years post-intervention. Thus, both the specific BASICS protocol to be implemented in the current trial and our previous work indicates brief intervention can be efficacious for producing long-lasting reductions in high-risk behavior and consequences. Importantly, Hingson (2010) proposed that systematic screening and referral of students to efficacious brief interventions such as BASICS in college populations could "achieve population-level benefits" (p. 1695); recent epidemiologic research provides some evidence of this, in that alcohol-related harm has begun to decline in college populations, where such interventions have been extensively implemented, compared to non-college YAs (Hingson et al., 2017) who have been relatively understudied and underserved. Thus, extending this research to a community sample of YAs experiencing comorbid alcohol, MJ, and sleep problems has potential to extend this public health impact in several ways.

BASICS + SLEEP Intervention. BASICS + SLEEP will integrate BASICS feedback and MI process described above with Brief Behavioral Therapy for Insomnia (BBTI; Troxel et al., 2012) content and materials.

BASICS + SLEEP intervention will also be implemented in 2 in-person sessions of 45-75 minutes in length, as well as 2 telephone booster sessions. We will follow BBTI procedures described by Troxel et al. (2012), including provision of a physiological rationale for insomnia and the importance of behavioral strategies to regulate sleep; introduction of sleep hygiene and discussion of factors that can impede duration and quality of sleep; introduction of sleep restriction and stimulus control strategies and negotiation of an initial sleep restriction schedule; and follow-up evaluation of success of the sleep restriction and stimulus control schedule and continued refinement to achieve sleep efficiency goals. Telephone booster contacts serve as opportunities to adjust the sleep restriction schedule, problem-solve challenges, further build motivation to implement behavioral strategies, and consolidate gains. The integration of BASICS and BBTI will be accomplished through maintaining MI style, retaining all core elements of BASICS and BBTI, introducing sleep disturbance as a possible motivation for and consequence of alcohol use and MJ use, and discussing their bidirectional relationships, as a rationale to further target both sleep and amount and pattern of alcohol and MJ use. Integrating the alcohol and MJ content with BBTI content, highlighting bidirectional relations between and among these outcomes throughout the discussion rather than simply adding these components together, allows for relatively comparable time between conditions without sacrificing any core content, and further increases synergy of the integrated intervention. For example, feedback likely relevant to participants will be: (1) time to bring typical and peak BAC down to .000% (examining how much of their night is spent trying to sleep with a positive BAC), (2) endorsement of anxiety, irritability, or daytime sleepiness (all associated with REM deprivation that could be lessened if changes are made in alcohol and MJ use), (3) motives/reasons for drinking or using MJ related to reducing anxiety or helping with sleep onset, bridging to the SLEEP intervention to explore substance-free ways to enhance sleep, and (4) protective behavioral strategies that will also be conducive to end-of-the-evening decisions (e.g., planning to end or leave a bar/party at a set time).

AOC Condition. Participants in AOC will complete all assessments (including survey, daily, actigraphy) at the same time as participants in the 2 active interventions. AOC will also attend an in-person meeting to verify identity, provide rationale for daily monitoring, control for time/attention, and participants in all conditions including AOC will receive referrals for community services to address alcohol and MJ use, sleep, and other mental health concerns. No participants will be deprived of services; use of outside services will be tracked to assist with interpretation of outcomes. AOC condition will be offered BASICS + SLEEP after 3-month follow-up.

Selection, Training, and Supervision of Therapists. Therapists will be clinical psychology graduate students and postdoctoral fellows who participate in a practicum for course credit. Selection of therapists will be based on interest, willingness, and availability to commit to training and intervention. Continued participation will be based on demonstration of adequate adherence and competence (see below), as measured by warmth, empathy, communication style consistent with MI, and knowledge of the interventions (Forrest et al., 2002; Jemmott et al., 1998). Three-day didactic workshops will be provided by Drs. Larimer, Kilmer, and Vitiello, consisting of complete manual review, videotaped examples of BASICS and BASICS + SLEEP interventions, and practice exercises covering both MI skills (open-ended questions, simple and complex reflections, strategies for resistance) and content and feedback directly related to the BASICS and integrated BASICS + SLEEP interventions. Therapists will participate in supervised practice, followed by completion of a role-play with Drs. Larimer, Kilmer, and/or Vitiello to demonstrate competency. After completing the role-play, each therapist will be assigned at least one case during the open trial, which will be videotaped, adherence coded, and reviewed by Drs. Larimer, Kilmer, and the CSHRB Coding Team (See Adherence/Competence) who will provide detailed guidance. Weekly group supervision by Drs. Larimer or Kilmer will involve discussion of sessions, problems of adherence, questions regarding implementation, and MI practice/boosters.

Monitoring adherence/competence. All sessions will be audio-taped and rated for adherence and competence by trained coders supervised by the investigators. Sessions will be coded on 3 aspects: 1) Motivational interviewing/process skills as assessed by the MITI developed at the University of New Mexico (Moyers et al., 2005). 2) CBT skills delivery using a modification of the YACS (Carroll, 2002); and 3) Content covered, using a content checklist incorporating each component of the interventions. Therapists will also complete the adherence checklist after each session, to indicate which components they covered. Therapists will not begin seeing participants until they have achieved a minimal score of 5 on global ratings for the MITI and exhibit no MI non-adherent behaviors in a pilot session. They will receive feedback on MITI and YACS scores at minimum every 3rd session to prevent drift. We have an existing team of supervised undergraduate coders who evaluate BMIs and behavioral interventions across projects. Coders were trained to reliability, meet weekly for supervision to prevent coder drift, and have high reliability across coders and with codes assigned by experts to standardized patient tapes. In addition to measures of therapist adherence/competence, all participants will complete a Participant Satisfaction Survey, which for intervention

participants will include questions specific to rating of therapists and in-session process as well as intervention materials/content. Scores on these measures will be evaluated in relation to intervention efficacy.