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Approach Bias Modification for reducing Co-Occurring Alcohol and cannabis use among treatment-seeking Adolescents: Protocol of a randomized controlled trial

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ABSTRACT

Alcohol and cannabis are the first and second most used substances among adolescents. Adolescence is a period of considerable development, making the adolescent brain particularly vulnerable to negative effects of alcohol and cannabis use. Developing and testing interventions that target both alcohol and cannabis use during adolescence are vital to decreasing costly consequences. Biases in cognitive processing of drug-related stimuli play an important role in the development and maintenance of problematic substance use. The Approach-Avoidance Task (AAT) is a computerized program, effective in assessing implicit approach biases for both alcohol and cannabis, in which participants make approach or avoidance movements in response to an irrelevant feature of an image presented on a screen (e.g., push when in portrait, pull when in landscape). A modified version of the AAT is also used as an approach bias modification (ApBM) intervention, to retrain participants' implicit biases toward or away from stimuli by presenting the target stimuli predominantly in one format (e.g., push or pull). Despite research demonstrating the effectiveness of AAT interventions to reduce problematic alcohol and cannabis use, there is a dearth of research examining this intervention among adolescents. This protocol paper describes a NIDA-funded randomized control trial (RCT) to evaluate an integrated mobile ApBM intervention to target co-occurring alcohol and cannabis use among treatment-seeking adolescents. Outcomes will be measured from pre-treatment through a three-month follow-up. The sampling procedures, assessment protocol, description of the intervention, and planned statistical approaches to evaluating outcomes are detailed. Clinical and research implications of this work are also discussed.

Approach Bias Modification for Reducing Co-Occurring Alcohol and Cannabis Use among Adolescents: Protocol of a Randomized Controlled Trial.

Adolescent substance use poses a significant problem at both the individual and societal levels. Although adolescent substance use has demonstrated a slight decline over the past few decades [1], approximately half of adolescents reported lifetime marijuana use [2] and it is estimated that 60 % of adolescents consume alcohol [3,4]. Moreover, alcohol and cannabis are the first and second most commonly used substances among adolescents, respectively [5,6], and adolescent drinkers are twice as likely to develop an alcohol use disorder by age 26, while adolescent cannabis users are three times as likely to develop a cannabis use disorder [7]. Adolescence is a period of considerable cognitive and neurological development, making the adolescent brain particularly vulnerable to negative effects of cannabis and alcohol [8]. Exposure to cannabis and alcohol during this critical period is linked to greater lifetime rates of substance use disorders, psychiatric disorders, social deficits, poor school performance, and neurological problems [8,9]. Moreover, co-occurring cannabis and alcohol use has been associated with abnormal neurodevelopmental trajectories and diminished neurocognitive performance [10–12].

Interventions that aim to reduce or prevent co-occurring cannabis and alcohol use during adolescence are vital to decreasing such costly consequences. However, adolescent substance use interventions have tended to focus on deliberative processes (e.g., CBT, Motivational Interviewing, Motivational Enhancement) whereas implicit processes have largely been neglected. Although the aforementioned treatment approaches are evidence-based, room still exists to improve treatment outcomes (i.e., majority of adolescents do not sustain abstinence one year post-treatment, with many using during or shortly after completing

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treatment) [13]. The adolescent brain continues to develop well into young adulthood, especially with regard to the prefrontal cortex [14]. As such, the underdeveloped adolescent brain may impair an adolescent's ability to accurately evaluate the consequences and benefits associated with substance use, which may reduce the effect of interventions aimed at targeting explicit decision-making processes. Thus, incorporating implicit processes as an adjunct to existing evidence-based treatment and prevention approaches could significantly improve treatment outcomes, particularly as it presents a largely unrealized opportunity for improving public health [15].

Behavioral decision making is impacted by a dynamic interaction between prior learning, reflective processing, and affective-motivational processes [16,17]. Affective-motivational processes, such as implicit behavioral biases [18], are particularly salient in substance use contexts. Among both adult and adolescents, larger approach bias toward alcohol stimuli is associated with greater rates of alcohol consumption and perceived difficulty controlling drinking [19–23]. Similarly, among adult and adolescent cannabis users, greater cannabis use is associated with a larger approach bias toward cannabis stimuli [24]. Incentive-salience models of substance use indicate that approach biases can strengthen as a result of repeated substance use and altered dopaminergic systems, leading to increased reactivity to substance-related stimuli [15,25]. Interventions that can address these biases may be particularly fruitful.

Time-dependent processes are theorized to play an important role in the balance between deliberative processing and automatic biases [16,26,27]. While behavioral biases are often automatic, it takes more time, and cognitive resources, for one to engage in reflective processing and access prior learning. This is compounded by possible competing cognitive pressures such as the immediate physical and social gratification of both alcohol and cannabis use weighed against the more delayed negative consequences of impaired judgement, engagement in risk behaviors, and legal/social consequences. Thus, the immediate benefits of substance use may overpower the costs of latent and probabilistic negative outcomes, particularly in the short time in which these decisions are often made. Cannabis and/or alcohol intoxication might further impact adolescent decision-making processes by impairing basic decision-making processes [28]. Interventions aimed at modifying implicit tendencies to reduce approach bias for substance-related stimuli can decrease use, and subsequently reduce the likelihood of substance-related consequences.

Recent work has applied the approach and avoidance movement paradigm to computerized assessment and intervention approaches. Stimuli presented on a computer screen can elicit a motivational orientation and subsequent behavioral response similar to a physical object [29]. The Approach-Avoidance Task (AAT) [30], is a computerized program in which participants push or pull a joystick in response to the format of an image presented on a computer screen (e.g., push when in portrait, pull when in landscape). The AAT features a zooming effect to simulate the sensation of approaching when pulling the joystick and avoiding when pushing the joystick, such that the images increase in size when the joystick is pulled and decreases in size when the joystick is pushed. With participants' explicit attention focused on the format of an image (i.e., portrait or landscape), the implicit bias can be measured through calculating the difference between approach (i.e., pulling/arm flexion) and avoidance (i.e., pushing/arm extension) movements during trials with a specific stimulus category. The AAT is effective in assessing implicit approach biases for various stimuli, including alcohol [23], cannabis [24], gambling [31], sexual [32,33], and condom stimuli [33].

A modified version of the AAT is also used as an approach bias modification (ApBM) intervention to retrain participants' implicit biases toward or away from stimuli by presenting the target category of stimuli predominantly in one format (e.g., push or pull) [34–38]. Given the associations between arm flexion and positive evaluations and arm extension and negative evaluations [30], training an individual to respond to certain stimuli with arm flexion or arm extension can subsequently change their approach or avoidance biases, respectively. ApBM interventions using the AAT are emerging as effective treatment tools for many disorders and problematic behaviors. Namely, if an individual is trained to attend toward or attend away from specific information, symptoms may be reduced, and behavior may be changed. Specifically, ApBM interventions have demonstrated preliminary effects increasing positive health behaviors [21] and reducing substance use and rates of relapse [34,35,37–40]. However, effects have been inconsistent, especially among those receiving the intervention within the context of a proof-of-principle study [41,42].

There have been two primary approaches used to evaluate the AAT in approach bias retraining. First, proof-of-principle studies have been conducted to evaluate the hypothesized relationships between bias and behavior among participants who are not necessarily motivated to change their behavior [37]. For example, a previous study conducted by the research team successfully modified participant action tendencies away from alcohol stimuli and toward condom stimuli, and the effects of the training generalized to subsequent behavior, such that individuals who were trained to approach condoms showed increases in condom use and condom-related attitudes [36]. However, participants in the aforementioned, and most proof-of-principle studies, were unaware that they were participating in an intervention, potentially limiting the effect of the intervention. The second approach to evaluating the effects of ApBM is via randomized controlled trials (RCTs) among clinical samples in which participants have an objective to change behavior, often demonstrating stronger effects than proof-of-principle studies. RCT studies have demonstrated success in retraining participants' implicit action tendencies away from alcohol among participants at inpatient treatment facilities [34,35,38,43,44]. Among large scale RTCs using this methodology (e.g., four training sessions) one found a medium effect with significant effects at one-year follow-up [38] and two others found up to 13 % less relapse one year post-treatment [34,44].

ApBM is a novel intervention that has been effective in reducing alcohol and cannabis behavior among adults [34,35,37,38,40]. Despite research demonstrating the effectiveness of ApBM interventions using the AAT to reduce problematic alcohol [34,35,38] and cannabis use [40], there is a dearth of research examining this intervention with adolescents. To date, no study has examined an ApBM intervention targeting adolescent alcohol use. Moreover, only one study examined this intervention for adolescent cannabis use [39] and demonstrated preliminary support in reducing subsequent adolescent cannabis use, but also found an increase in post-intervention alcohol use among participants in the treatment condition. Additionally, few studies have explored mobile AAT (mAAT) [45–48], which reduces participant burden of in-person sessions under the supervision of study staff by enabling flexible, remote administration from a personal smartphone. Altogether, these findings establish the promise of this type of brief intervention, while also highlighting the need to develop an integrated intervention for co-occurring alcohol and cannabis use among adolescents in an accessible format.

1. Method

1.1. Study overview

This trial employs a 2 (Training: training/sham) × 4 (Time: pretest/posttest/one-month follow-up/three-month follow-up) mixed design. Participants are randomized to a training or sham condition. The intervention and sham-intervention (i.e., control) will occur over the course of four days.

1.2. Participants

Recruitment. Treatment-seeking adolescents are recruited nationally based on interest in participating in a clinical study testing an intervention for co-occurring alcohol and cannabis use among adolescents. Participants are also recruited locally from an outpatient adolescent treatment program at the investigating institution. Eligible participants are (a) between the ages of 13 and 17; (b) seeking treatment for either cannabis or alcohol use; (c) reporting co-occurring alcohol and cannabis use during the previous three months (regardless of if the use was simultaneous or concurrent); and (d) have a caregiver willing to provide consent. Eligible families of the prospective participants are contacted by the research staff to discuss the experimental portion of the study. Informed consent was obtained prior to data collection.

Retention. All participants receive $160 for the experimental portion ($20 for each of the first five session days; $30 for each of the 1- and 3-month follow-up sessions). Participants are also awarded a $25 bonus for completing the first five sessions on time (i.e., Sessions 1–4 on Days 1–4, and Sessions 5 on Day 11). For the EMA portion, participants receive $1 for each random or morning assessment they complete. Thus, participants are compensated up to $150 total for the EMA portion. Participants who complete 90 % or more of the morning assessments receive a $25 bonus. Participants who complete 75 % or more of the random assessment receive a bonus of $40. In total, between the experimental appointments and the EMA portion of the study, participants are compensated up to $400.

Randomization. Once enrolled, participants are randomized by study personnel to either the training or sham-training using a stratified random block design. The randomization is stratified by gender, weekly cannabis use, and weekly alcohol use to distribute covariates equally between treatment conditions. Moreover, participants are counter-balanced to image-format in the Approach-Avoidance Task.

1.3. Procedure

All participants complete baseline self-report measures and the Timeline Followback with a trained member of the research staff. Baseline approach biases are then assessed with the approach avoidance task (AAT) in the Inquisit programming environment, which was developed and first implemented for alcohol use by Wiers and colleagues [23] as an assessment-tool and subsequently as a training program [37]. All participants complete the assessment mAAT, then the ApBM, which vary depending on study condition. Biases are assessed at one-week, one-month, and three-months post-intervention. See Fig. 1 for procedural timeline of study tasks.

1.4. Measures and instrumentation

Baseline and Outcome Self-Report Measures. All participants complete a Timeline Followback (TLFB) [49] interview at baseline and a three month follow up. The TLFB is used to assess cannabis and alcohol use during the previous 90 days.

Alcohol and Cannabis Approach Bias. Approach bias for alcohol and cannabis are assessed using the mAAT. For this study, 20 alcohol images are paired with 20 non-alcoholic beverage images and 20 cannabis-related images are paired with 20 psychophysically matched neutral images (e.g., pens, straws, etc.). The instructions for completing the mAAT are automated. The assessment mAAT consists of 160 trials (i.e., each image in portrait and landscape format) requiring participants to make push or pull swipe movements in response to the orientation (landscape or portrait, or vice versa) of an image presented on a mobile device. The assessment procedure was created such that when presented with images in any stimulus category (i.e., alcohol, cannabis, non-alcohol beverages, and neutral images), participants approached 50 % of the time and avoided 50 % of the time. The picture format to response assignment is counterbalanced, such that half of participants pull landscape pictures and half pull portrait pictures. This counterbalance remains consistent across all procedures. Research on approach and avoidance tasks indicates that positive and negative stimuli elicit pulling and pushing motions, respectively [18]. Thus, the automated instructions state that when swiping up and down on the screen, participants should imagine pulling the image toward them or pushing the image away (See Fig. 2). The task features a zooming effect to simulate the sensation of approaching when swiping down and avoiding when swiping up. If a participant responds incorrectly a large red 'X' is displayed until the participant corrected the error. These procedures have been used successfully in previous research [23,32,38]. *D* scores are calculated for each participant based on the procedures of Greenwald and colleagues [50]. Participants' mean reaction times during the approach cannabis trials were subtracted from the mean avoid cannabis trial RTs. These scores were then divided by the *SD* across all cannabis trials. Positive scores indicated an approach bias for cannabis stimuli. This procedure was repeated for alcohol stimuli.

Mobile ApBM Training Intervention Procedure. The format of the ApBM training task, uses the same instructions and format as the mAAT assessment. However, for individuals in the training condition, the task is designed to pair cannabis and alcohol stimuli with an avoidance action tendency and the neutral/non-alcoholic stimuli with an approach action tendency. As such, for participants in the training condition, all cannabis and alcohol images are in avoid format and all non-alcohol beverage images and neutral stimuli are in approach format. All participants, regardless of experimental condition, complete 400 trials during each "training session." The sham-training task has the same number of trials, however 50 % of each stimuli category are presented in portrait and 50 % in landscape format. Those in the sham condition equally approach and avoid all stimuli categories (i.e., alcohol, non-alcohol, cannabis, neutral). Thus, the sham-training task is like the assessment task and does not attempt to modify response tendencies though manipulating the pairings and controls for mere exposure effects. Regardless of experimental condition, each participant swipes up and down an equal number of times. Participants complete four training sessions on consecutive days [38].

EMA. To assess cannabis- and alcohol-related behavior in real-time, EMA methodology is used to obtain a more accurate representation of participants' true behavior. EMA data has been successfully collected with adolescents and is feasible [51,52]. Participants are assessed via EMA during the time they were engaged in the ApBM intervention (~5–10 days) and 30 consecutive days following the intervention.

The EMA application is programed via llumivu and randomly alerts participants to complete a brief questionnaire (approximately one to 2 min) on the device four times per day between the hours of 10:00 a.m. and 10:00 p.m. Each random assessment occurs at a random time within four 3-h blocks. Using this schedule, each participant provides up to 160

		Day 1		Day 2	Day 3	Day 4	Day 11 (Posttest)	Day 40 (1-Mo. Follow-up)	Day 100 (3-Mo. Follow-up)
Training Condition			Training	Training	Training	Training			
All Participants	Eligibility Screen	Informed Consent Baseline Assessments Assessment AAT					Assessment AAT	Assessment AAT	Follow-up Assessments AAT Assessment
		All participants complete EMAs during the intervention period and for 30 days following the intervention							
Control Condition			Sham-Training	Sham-Training	Sham-Training	Sham-Training			

Fig. 1. Procedural timeline for study tasks.

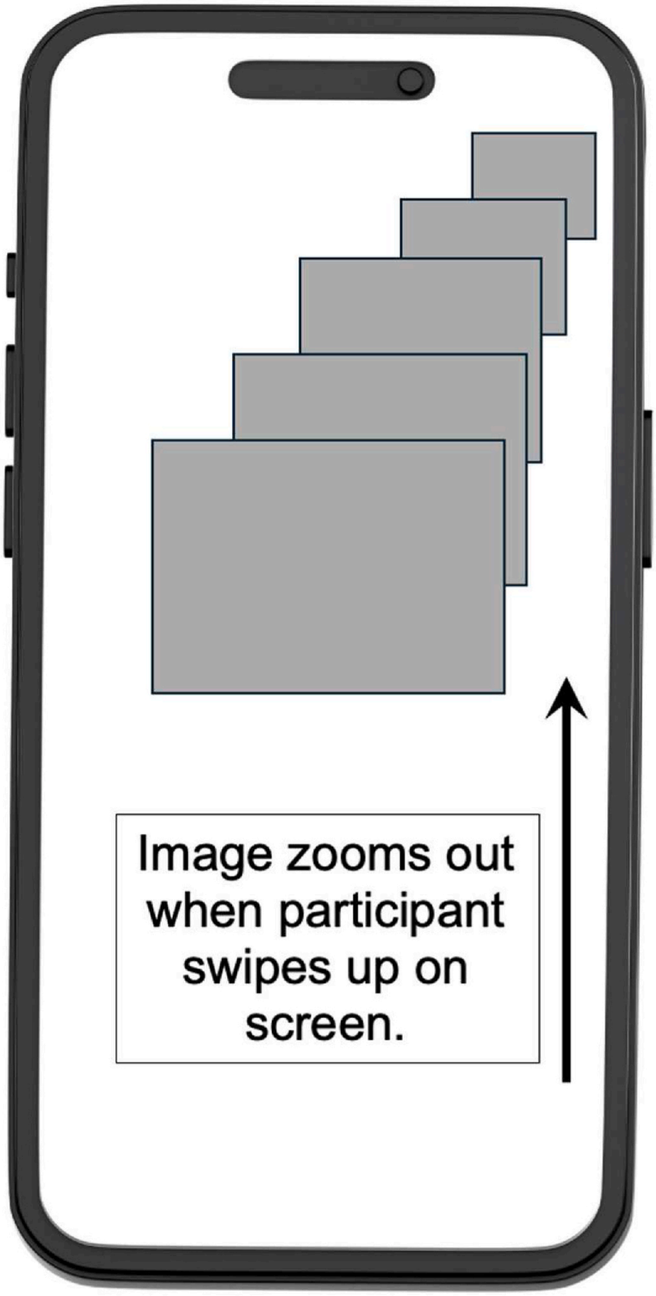

Fig. 2. mAAT Zooming Effect Render.

EMA reports (i.e., four times per day for up to 40 days). Random assessments inquire about behavior since the last EMA report. Participants are asked to respond to as many prompts as possible, excluding situations where it may be dangerous or inappropriate to do so (e.g., while driving, in class, etc.). In addition, participants are instructed to self-initiate a morning assessment each day to assess behaviors that may not have been captured during the random assessments the previous evening (i.e., substance use behaviors occurring after 10:00 p.m.). The EMA questionnaires assess participants' intentions to use, cravings, cannabis use, and alcohol use since the previous assessment.

1.5. Planned data analysis strategy

Descriptive analyses will be used to describe the sample. Self-reported substance use behavior will be verified using biological data collected within the clinic. Clinical outcomes of interest are defined as: (1) change in approach biases for cannabis and alcohol stimuli from baseline to post-treatment as measured by the AAT; and (2) change in frequency and amount of cannabis and alcohol use from baseline to post-treatment as measured by the TLFB [49]. We will test associations between the implicit approach-avoidance bias for substance-related stimuli and substance use behavior at baseline. Subsequent analyses will test (1) the effects of the intervention on cannabis and alcohol approach bias and (2) the effects of the intervention on cannabis and alcohol use. To test whether the training affected implicit approach-avoidance tendencies, we will use a 2 (Training: experimental/sham) x 4 (Time: pretest/posttest/1-month follow-up/3-month follow-up) mixed ANOVA. Gender, age, and substance use treatment received prior to enrollment will be included as covariates. Planned comparisons will be tested to see whether there was significant effect of the intervention on biases one-week post-intervention and if effects were sustained at the 1- and 3-month follow-up assessments. Additionally, we will use the same 2 x 4 mixed ANOVA to examine the effect of the intervention on alcohol and marijuana use. Additionally, we will test if intention and cravings mediated the relationship between treatment condition and daily use using multilevel structural equation modeling (MSEM) using Mplus 8.4 [53]. MSEM will permit for a simultaneous test of the influence of the mobile ApBM training on intention and craving, and the influence of intention and craving on subsequent use. Analyses will control for treatment participation and engagement (i.e., did the participant receive concurrent outpatient SUD treatment?; Number of treatment sessions completed).

2. Discussion

The objective of this paper was to describe the rationale and methods for a NIDA-funded RCT to rigorously evaluate the efficacy of a mobile Approach Bias Modification intervention for reducing alcohol and cannabis use among treatment-seeking adolescents. By targeting implicit mechanisms that are not currently leveraged in existing, explicit interventions, this study may identify a powerful avenue for improving outcomes for adolescents seeking treatment for cannabis and alcohol use. Given the high relapse rates of current substance use interventions among adolescents [12,54] and the deleterious long-term impacts of adolescent substance use [55], identification of ways to enhance treatment outcomes has important clinical implications.

The prefrontal cortex, responsible for higher-level cognition and deliberative processes (e.g., decision making, problem solving, etc.), is less developed in adolescents than the subcortical structures responsible for motivation, affect, and impulses [16]. Current gold-standard treatment approaches for adolescent substance use (e.g., CBT, MI, ME) focus on deliberative processes and may include identifying adolescents' values and evaluating whether their substance-related behaviors are consistent with these values, weighing the risks and rewards of their behaviors, identifying healthy coping skills and replacement behaviors, and learning ways to regulate their emotions and manage triggers. All these skills are highly valuable yet may not adequately address the powerful implicit processes that drive risk behaviors. In other words, adolescents experience urges and desires that their prefrontal cortex may not be prepared for countering, thus enhancing vulnerability for behaviors that reap immediate gratification and reward [16]. Thus, existing treatments that target deliberative processes may benefit from a supplementary component targeting implicit processes as well. One reason for this is that it may provide more time for the deliberative behaviors to activate (e.g., refusal skills, risk and reward evaluation, etc.). Adolescent cannabis and alcohol use are highly time-dependent activities, with the impulse to approach a substance-related stimulus the highest immediately after presentation [56]. In other words, delaying an approach behavior even a small amount may provide enough time for an adolescent to reflect on the deliberative skills and knowledge learned in treatment.

Existing research provides support for the use of AAT as a CBM in retraining adult approach biases away from alcohol and cannabis [24, 34,35,37,38,40,44]. These studies found that pairing previously attractive substance-related stimuli with an avoidance behavior led to an alteration in substance related behaviors and attitudes. Initial evidence exists for approach bias modification effectiveness in retraining adolescent cannabis users [39], though this study did identify an increase of alcohol use following treatment conclusion. It is possible that this is because, in the absence of a more explicit intervention (e.g., CBT), individuals were seeking new coping mechanisms without the tools to identify more positive/adaptive strategies. Thus, the present study aims to build upon proof-of-principle studies and RCTs to explore the possible supplementary role AAT can have in adolescent substance use treatment to target the impulsive processes contributing to adolescent substance use, jointly exploring cannabis and alcohol use. Indeed, other studies have discussed the role of AAT as a supplementary treatment component rather than an intervention on its own [57]. The focus on implicit processes is a particular strength of the present study, as these are rarely considered in clinical interventions and may have great value in augmenting existing adolescent substance use treatments.

It is important to note that most studies demonstrating positive effects using ApBM were among adult inpatient samples participating in abstinence-only treatment. These studies use time-to-relapse as the primary outcome, due to the emphasis on abstinence. In fact, a meta-analysis found no significant effect of ApBM on reducing the quantity of substance use compared to placebo trainings in non-abstinence adult samples [58]. Although adolescents in our study are not necessarily enrolled in abstinence-only, inpatient programs, our recruitment criteria target those who have recently entered or are in the process of initiating outpatient treatment. However, adolescent treatment-seekers often face challenges with engagement, and a notable portion may have limited or no sustained treatment involvement, which our analyses will control for.

We anticipate that adolescents randomized to ApBM and actively engaged in outpatient treatment will show the most significant reductions in alcohol and cannabis use. However, we hypothesize that ApBM may also positively affect those with lower levels of treatment engagement. While comparisons to adult studies are inevitable, there are critical distinctions between adult and adolescent populations regarding brain chemistry, cognitive development, and patterns of substance use. The theoretical foundation of approach bias modification (ApBM) suggests that prolonged use leads to automatic approach tendencies toward substance-related stimuli. Given that the adolescent brain is more malleable than the adult brain, sustained exposure to substances such as alcohol and cannabis poses heightened risks for developmental impacts. This malleability also supports the potential for intervention impact in adolescents, where automatic responses to substance cues may be more readily modifiable.

Notably, regulatory, financial, and logistical challenges often lead researchers to avoid studying adolescents ages 13–17, resulting in studies that define adolescent populations to include individuals up to 25 years old. We believe that by focusing specifically on younger adolescents, we can identify how ApBM might benefit a particularly vulnerable population, potentially achieving lasting changes at a critical point in their neurodevelopment and substance use trajectories.

Other strengths are also worth noting. One is the integration of EMA, which enables an assessment of real-time changes in substance use behaviors. As compared with clinic-based studies that assess behaviors at baseline and follow-up, the present study will have a more granular data set with information about substance use throughout intervention, providing insight into the number of sessions beneficial for impact as well as other valuable data. Another strength is the mobile delivery format of mAAT. Smartphones are ubiquitous [59], and digital interventions have proven to be feasible and efficacious [12]. The ability to engage in the intervention remotely without a clinician present and in a flexible manner removes significant barriers to care, including transportation costs, time, and enhanced privacy, among others [47,60]. Additionally, not all individuals with substance use difficulties seek or receive clinic-based treatment, limiting the impact such treatments can have. Mobile interventions may capture those individuals whose substance use is sub-clinical or those who are not yet ready to seek clinic-based treatment [61].

In sum, the present study has the potential to elucidate a valuable supplemental component to substance use treatment. Implicit processes are largely neglected in gold-standard substance use treatments yet may capture those individuals for whom extant treatments do not result in significant long-term improvement. The mobile delivery of such interventions may further support treatment gains by enhancing flexibility and accessibility, thus improving outcomes.

CRediT authorship contribution statement

Austin M. Hahn: Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Funding acquisition, Conceptualization. **Erin Corcoran:** Writing – review & editing. **Carla Kmett Danielson:** Writing – review & editing, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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