Study Protocol for A Mobile Application to Address Cannabis Use Disorder Among Black Adults

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Table of Contents

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Abstract

Background: African American/Black (hereafter referred to as Black) adults who use cannabis use more frequently and are more likely to meet criteria for Cannabis Use Disorder (CUD) than both White and Hispanic/Latin individuals. Black adults may be more apt to use cannabis to cope with distress, which constitutes a false safety behavior (FSB; a behavior designed to reduce psychological distress in the short-term). Though FSB engagement can perpetuate the cycle of high rates of CUD among Black individuals, limited work has applied a FSB elimination treatment approach to Black adults with CUD, and no previous work has evaluated FSB reduction/elimination in the context of a culturally tailored and highly accessible treatment developed for Black individuals.

Objective: The current study aims to develop and pilot test a culturally tailored adaptive intervention that integrated FSB reduction/elimination skills for cannabis reduction/cessation among Black adults with probable CUD (CT-MICART).

Methods: Black adults with probable CUD (N = 50) will complete an online screener, enrollment call, baseline assessment, 3 daily ecological momentary assessments (EMAs) for 6 weeks, and a follow-up self-report assessment and qualitative interview The current study will provide a unique opportunity to provide healthcare providers and researchers a chance to further refine and provide low-cost and easily accessible treatment for a historically underrepresented and underserved population.at 6-weeks post-randomization. Participants will be randomized into one of two conditions post-baseline: 1) CT-MICART+EMAs for 6 weeks or 2) EMAs only for 6 weeks.

Results: The current study is open for enrollment and currently recruiting research participants and results have not yet been analyzed.

Conclusions: The current study will provide a unique opportunity to provide healthcare providers and researchers a chance to further refine and provide low-cost and easily accessible treatment for a historically underrepresented and underserved population.

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ABSTRACT

Introduction: African American/Black (hereafter referred to as Black) adults who use cannabis use more frequently and are more likely to meet criteria for Cannabis Use Disorder (CUD) than both White and Hispanic/Latin individuals. Black adults may be more apt to use cannabis to cope with distress, which constitutes a false safety behavior (FSB; a behavior designed to reduce psychological distress in the short-term). Though FSB engagement can perpetuate the cycle of high rates of CUD among Black individuals, limited work has applied a FSB elimination treatment approach to Black adults with CUD, and no previous work has evaluated FSB reduction/elimination in the context of a culturally tailored and highly accessible treatment developed for Black individuals. **Methods**: The current study aims to develop and pilot test a culturally tailored adaptive intervention that integrated FSB reduction/elimination skills for cannabis reduction/cessation among Black adults with probable CUD (CT-MICART). Black adults with probable CUD (N = 50) will complete an online screener, enrollment call, baseline assessment, 3 daily ecological momentary assessments (EMAs) for 6 weeks, and a follow-up self-report assessment and qualitative interview at 6-weeks post-randomization. Participants will be randomized into one of two conditions post-baseline: 1) CT-MICART+EMAs for 6 weeks or 2) EMAs only for 6 weeks. **Results**: Enrollment started in June 2023 and ended in November 2023. Data collected will be completed in January 2024.**Conclusion**: No culturally tailored, evidence-based treatment currently caters to the specific needs of Black individuals with CUD. The current study will lay the foundation for a new approach to CUD treatment among Black adults that is easily accessible and has the potential to overcome barriers to treatment and reduce practitioner burden in order to support Black cannabis users with probable CUD.

Keywords: Cannabis Use, False Safety Behaviors, Mobile Health, JITAI, Black/African American

1.0 INTRODUCTION

Cannabis has been among the most widely used substances for 30 consecutive years in the United States (US) [1] and rates of past-year use have consistently increased in the general population [2, 3]. Among individuals who use cannabis, African American/Black (hereafter referred to as Black) individuals exhibit more severe use patterns, including weekly use, and are more likely to meet diagnostic criteria for current Cannabis Use Disorder (CUD) than both White and Hispanic/Latin individuals who use cannabis [4-6]. These data are alarming as CUD is associated with more severe psychosocial risk profiles relative to cannabis users without CUD and non-users, including poly-substance use, psychiatric problems, and legal trouble [7]. Additionally, although Black individuals who use cannabis are more likely to report being ready to quit and making a recent quit attempt than both Hispanic/Latin and White individuals who use cannabis [8, 9], this population is less likely to seek in-person treatment relative to White individuals who use cannabis. Specific individual (e.g., beliefs about use) [10], community (e.g., neighborhood attitudes about use) [11], and institutional (e.g., healthcare access) [12], factors as well as institutionalized racism and discrimination (e.g., more likely to not be listened to by practitioners) [13], likely contribute to reluctancy to seek traditional treatments among Black individuals with CUD. Given treatment involvement has been shown to assist with cannabis use reduction and prolonged abstinence [14], addressing the lack of treatment engagement among this population is imperative to reduce the potential negative health and psychological effects of cannabis use among this group.

Psycho-sociocultural models of substance use posit that Black individuals may use cannabis and continue using despite cannabis-related problems to manage psychological distress associated with minority-related stress and daily stressors [15-18]. Using cannabis to cope with such distress reflects a false safety behavior (FSB), or a behavior designed to reduce psychological distress in the short-term, but paradoxically maintains or even exacerbates distress in the long-term [19, 20]. FSB is more frequent among Black compared to non-Hispanic/Latin White individuals and it is associated with

more anxiety, depression, and suicidal thoughts and behaviors among Black individuals [21]. Thus, FSB is an important behavioral vulnerability factor associated with mental health problems among Black individuals. These findings are concerning as problematic cannabis use is higher among those with mental health problems [22], and mental health problems interfere with changing cannabis use [23]. Moreover, the majority of individuals who use cannabis tend to engage in additional FSBs such as avoidance and avoiding social situations when cannabis is unavailable [24], and FSBs may contribute to cannabis-related problems due to tendencies to engage in maladaptive attempts to regulate negative affect [25]. As such, FSB engagement can perpetuate the cycle of high rates of CUD among Black individuals who use cannabis and increase risk for poor psychosocial outcomes and cannabis-related disparities [24, 26, 27].

Importantly, transdiagnostic treatments have been developed to eliminate FSBs to improve behavioral health outcomes. Specifically, cognitive-behavioral approaches to FSB elimination treatment that target the identification and elimination of FSBs have been designed and successfully employed for use across various anxiety disorders [20]. Furthermore, recent work has explored the potential of FSB elimination integrated with motivation enhancement therapy combined with cognitive behavioral therapy (MET-CBT) to address the co-occurrence among anxiety and cannabis use disorders, *Integrated Cannabis and Anxiety Reduction Treatment* (ICART) [28-30]. In a pilot test of ICART, individuals with CUD were randomized to either in-person ICART or MET-CBT for CUD [31]. Although participants in both study groups reported decreased cannabis use and related problems, patients in the ICART condition were more likely to be abstinent post-treatment than those in MET-CBT condition. Patients with more severe baseline cannabis use and use-related problems were especially likely to benefit from ICART [32]. These findings suggest that integrating FSB elimination with MET-CBT is at least as efficacious, if not more efficacious, as a gold-standard psychosocial CUD treatment (MET-CBT), especially for patients with more severe cannabis related pathology.

Despite the potential for FSB reduction/elimination treatments to assist with cannabis use reduction or cessation among individuals with problematic use, this work has been limited by its in-person design and lack of cultural tailoring to Black adults. Indeed, given the cannabis-related and FSB disparities experienced by Black adults [16, 21], it may be beneficial to evaluate FSB reduction/elimination integrated with CBT for CUD in the context of a culturally tailored and highly accessible treatment (i.e., a mobile health [mHealth] intervention delivered via a smartphone app) developed for this underserved group.

Extant literature has highlighted existing mHealth work for cannabis use and CUD [33], including mHealth interventions which have been culturally-tailored to treat specific populations such as individuals with psychosis [34], as well as individuals with co-morbid CUD and cigarette smoking [35]. However, no Mhealth interventions for cannabis use and CUD currently target specific psycho-sociocultural factors related to cannabis use and use-related problems among Black cannabis users with probable CUD. We have therefore developed and are currently pilot testing a culturally tailored intervention for Black adults with probable CUD through integrated FSB reduction/elimination with CBT for CUD (CT-MICART) using an accessible, adaptable, and highly scalable smartphone app. The goal is to examine the effects of CT-MICART on cannabis use, coping motives for cannabis use, and FSB engagement. We hypothesize that participants who are randomized into the CT-MICART condition will report better cannabis outcomes and less FSB compared to those who are randomized into the control condition at the 6-week follow-up. Furthermore, we will examine app engagement indicators and review qualitative data for methods to improve app content.

2.0 METHODS

2.1 Ethical Considerations

All participants provide written informed consent signed electronically after reviewing consent documents with research staff. To protect participant privacy and confidentiality, all phone

and zoom appointments are completed by trained research staff in a secure office. Additionally, participants are assigned an ID number that is used to identify their data throughout the study. Only trained research staff have access to the key that can match participant data to the participant's name. The key is password-protected on a secure server housed at the University of Houston. Participants are compensated up US $160 in Amazon electronic gift cards for participating in the study. The Institutional Review Board (IRB) at the University of Houston approved the study (IRB approval no. STUDY00003690).

2.2 Study Design

Fifty (N=50) Black adults with probable CUD are being recruited through national advertisements across different social media and online platforms to participate in the current study. Eligible participants are randomized into one of two conditions (CT-MICART+EMA vs EMA only). All participants are consented and are asked to complete 3 prompted daily ecological momentary assessments (EMAs) for 6 weeks. Only participants in the CT-MICART+EMA condition will receive intervention content. Participants are informed during the consent process that they have an equal chance of being assigned to each study condition. Moreover, participants are also informed that one of the study's treatment conditions consists of watching treatment videos and utilizing CT-MICART app features, while the other condition consists only of completing daily EMAs. Following the 6-week intervention period, all participants will complete a follow-up assessment survey in the app and a qualitative interview phone call. See Figure 1 for study flow.

2.3 Participants

Participants will include 50 individuals who identify as Black with probable CUD. Participants must meet the following eligibility criteria to participate: (1) at least 18 years of age; (2) self-identify as Black or African American; (3) meet criteria for probable CUD (assessed via the Cannabis Use Disorder Identification Test-Revised (CUDIT-R) with a score of ≥12) [36]; (4) Motivated to reduce cannabis (≥5 on a 10-point scale); (5) score ≥4 on the Short-Form Rapid

Estimate of Adult Literacy in Medicine (REALM-SF) indicating > 6th grade English [37]; (6) own an Android Smartphone for EMA completion; and (7) report cannabis use to manage anxiety/stress in the past month. Exclusion criteria include: (1) legal mandate of substance misuse treatment; (2) report of current or intended participation in a concurrent substance use treatment, including pharmacotherapy or psychotherapy for CUD not provided by the researchers; (3) ongoing psychotherapy of any duration directed specifically toward the treatment of anxiety or depression; (4) not being fluent in English; (5) pregnant or planning to become pregnant within the next 6 months (assessed via self-report); and (6) inability to provide a photo ID and valid address to verify identity.

2.4 Procedures

This study is funded by the National Institute on Minority Health and Health Disparities (NIMHD; U54MD015946) and is registered on clinicaltrials.gov (ID: NCT05566730). The Institutional Review Board (IRB) where the study takes place has reviewed and approved all procedures and study materials. Interested participants are asked to complete an online self-report screener survey via Qualtrics. Those deemed eligible at the screener are then scheduled for an enrollment zoom call of approximately 30 minutes. During the enrollment zoom call, participants are given detailed information on goals, purpose and procedures of the study, provide informed consent, show their photo ID to the research team, and complete a literacy test to confirm they are at > 6th grade English reading level [38]. Those found eligible during the enrollment zoom call are asked to download the Insight™ smartphone app onto their personal smartphone and to complete the 30 minute baseline survey via the app. Eligible participants who complete the baseline survey are then contacted by research staff so they can be randomized into a study condition (i.e., CT-MICART vs EMA only). During this randomization call, participants are oriented to app features for their assigned condition by the research team.

Following randomization, participants are prompted by the app to complete 3 EMAs daily.

EMAs take approximately 2-3 minutes to complete. The research staff monitors EMA completion rates of each participant on a weekly basis. When a participant's completion rate falls below 80%, a research staff member contacts the participant via text, phone, or email to remind them of the importance of completing their daily EMAs. Participants are informed that they can contact study staff at any point during the study by pressing the 'Call Staff' button at the top of the app screen should they experience technical difficulties. Please see Figure 2 for a screenshot of the CT-MICART features available via the app home screen.

All participants are also asked to complete a 6-week post-randomization assessment and a qualitative interview. Specifically, at the end of the 6-week EMA period, the follow-up assessment becomes available in the app home screen and takes approximately 30 minutes to complete. The qualitative interview is scheduled with a trained research staff member and focuses on the participant's experiences using the CT-MICART+EMA or EMA only app features. Participants can earn up to $160 in Amazon electronic gift cards for their participation. Specifically, eligible participants are compensated with a $20 gift card for completing the baseline assessment and a $50 gift card for completing the Week 6 follow-up, including the qualitative interview. Ineligible participants are not be compensated for completing the brief baseline zoom call. In addition to baseline and follow-up compensation, participants are compensated for their EMA completion based on their completion rate. Those who complete 50%-70% of all EMA assessments during the 6-week study period receive a $30 gift card, those who complete 71%-79% receive a $60 gift card, and those who complete 80% or more receive a $90 gift card. Thus, if a participant completes 80% or more of the assessment across the entire 6-week trial, they can earn up to $160 in electronic gift cards across all assessments.

2.5 Intervention Conditions

All participants have access to a "Call Staff" button that enables participants to easily call the study team. In addition, all participants have access to an "App Instructions" button that provides

detailed descriptions of each of the app functions. Lastly, all participants are informed that they can click the “Payment” button to view an up to the moment accounting of all EMAs prompted and completed, and current compensation based on EMA and assessment completion.

All participants are instructed to complete all smartphone assessments through Insight, an encrypted mobile application through which participants receive all study content. Encrypted data will be automatically password protected and saved to the University of Houston’s and the University of Oklahoma Health Science Center’s institutional server and will only be accessible to IRB approved research team members. Moreover, participants are informed during the consent process that they are responsible for any phone service costs related to the study.

Active Condition (CT-MICART+EMAs). The CT-MICART+EMA condition consists of access to the CT-MICART content in the Insight™ app and 3 prompted daily EMAs. The morning EMA is delivered 30 minutes after preset waking time; the lunch EMA is delivered at 12:15pm; and the evening EMA is delivered 1 hour and 15 minutes before the participant’s preset sleep time. The core components of the CT-MICART condition include FSB elimination training and CBT for CUD with culturally-tailored content. The CT-MICART+EMA content includes: (1) treatment on a ‘schedule’ that is culturally adapted (i.e., 12 different 3-5 minute treatment video files); (2) interactive, automated, individually tailored treatment messages (e.g., tailored to each participant’s daily goal of reducing cannabis use, abstaining from cannabis, or no daily goal); (3) ‘on demand’ features (i.e., Coping Toolkit, Help Me Reach My Goal); and (4) end of day FSB elimination training exercises.

Process to culturally adapt treatment: We followed the Cultural Adaptation Process [39] model of treatment adaption to culturally tailor CT-MICART. All treatment videos include depictions of Black adults and accompanying audio is voiced by Black voice actors who worked closely with our research team. Moreover, all app content was reviewed by a diverse Community Research Advisory Board (CRAB) at the Health Research Institute at the University of Houston. The CRAB

was consulted and provided feedback during the app development process and appropriate modifications were made based on their feedback.

Treatment on a schedule*:* To provide automated intervention content that is tailored to each participant's current goals and delivered in a manner that is best matched to their schedule, the app asks participants if they would like to watch 1 of 12 different 3-5 minute treatment videos (i.e., 2 videos per week) over the 6-week intervention period. Scheduled video sessions are cued (i.e., the phone rings and vibrates) at the scheduled time and every 15 minutes (up to 2 times) after the scheduled time until the participant acknowledges the cue. Participants have the option to delay/reschedule videos or watch them after the scheduled day/time (i.e., the next unwatched video populates [in order] in the app after the previous video is viewed). Videos can be watched as many times as desired. The phone records the date/time when each video is watched (i.e., both initiation and completion). The 12 brief (3-5 minute) CT-MICART videos provide psychoeducation on: 1) the nature of cannabis use and negative affect (e.g., anxiety, stress) and the FSB model; 2) the emotional processing model of negative affect (and how it relates to cannabis) and cannabis-related coping strategies (e.g., avoiding people, places, and things); 3) relations between FSB and racial discrimination, negative affect, and cannabis use; 4) cannabis (and other substance) use as a FSB and understanding cannabis use patterns; 5) countering phobias (i.e., exposure to anxiety- and stress-provoking stimuli without engagement in FSB, including cannabis) and coping with cravings; 6) fading other FSBs (e.g., checking, reassurance seeking, companions, avoidance of bodily sensations) and managing thoughts related to cannabis use; 7) fading other FSBs (avoidance) and managing negative moods; 8) fading other FSB (cognitive avoidance) and seemingly irrelevant decisions; 9) problem-solving; 10) managing social influences (refusal skills, assertiveness); 11) planning for emergencies and coping with lapse; and 12) preventing relapse.

Tailored, interactive, real-time treatment messages*:* Participants receive personally tailored messages that are based upon each day's cannabis cessation/reduction goal (i.e., reduce cannabis use

today, abstinent from cannabis today, no cannabis use goal today). Thus, the app "meets participants where they are" and provides messaging that is in line with their current goal. On days when the participant has no goal to reduce/abstain from cannabis, the app offers primarily "gain-framed" messages that aim to increase motivation for cannabis cessation/reduction. Importantly, the type of message that is delivered at the end of each EMA is recorded in the database so we may analyze the effect of messages on currently present cannabis use triggers.

***On demand features**:* Hundreds of unique messages were developed for the current study to address various use risk triggers and to reduce repetition. Messages are consistent with MET-CBT approaches (including ICART) [40] and address identified cannabis use triggers. On-demand content is available through two buttons on the app home screen. First, the *Coping Toolkit* feature contains a menu of resources that become available once this button is pressed (see Figure 3), including: Ways to Cope with Urges; Challenge Unhelpful Thoughts (see Figure 4 for a list of automatic thoughts that can be challenged via the app); I've Slipped, Now What?; How to Cope with Stress; Coping with Discrimination; Coping with others Using Marijuana; Motivate Me to Stay on Track; and Eliminate False Safety Behaviors (see Figure 5 for menu options). Second, the *Help me Reach my Goal* feature contains a menu of resources that also become available once this button is pressed (see Figure 6), including: Benefits of Reducing or Quitting; Harms of Marijuana Use; Relaxation Exercises; Give Me Something to Do and I'm Bored, Distract Me. Finally, all participants are instructed to click the "Record Stress or Urge," "I'm About to Use," and "I just used" buttons (see Figure 2) when appropriate. CT-MICART+EMA participants receive a tailored intervention message at the completion of each of participant initiated EMAs.

Control Condition (EMAs only). Participants randomized to EMA only condition receive the baseline, follow-up, qualitative interview, 3 prompted daily EMAs for 6 weeks, and they have access to the participant-initiated "Record Stress or Urge," "I'm About to Use," and "I Just Used" buttons. However, they do not receive tailored messages or access to the CT-MICART intervention

content.

2.6 Assessments

See Table 1 for schedule of data collection and measures list. All measures have been utilized among samples of Black adults.

Study Screening and Demographics Questionnaire. All participants are asked to answer questions related demographics characteristics during the Qualtrics screener (e.g., race, ethnicity, age, sex, education, marital status). In addition, participants answer questions related to previous substance use, discrimination experiences, acculturation, anxiety, depression, motivation to quit or reduce cannabis use (i.e. “On a scale from 1-10 with 1 being "not at all motivated" and 10 being "extremely motivated" how motivated are you to reduce your marijuana use in the next month?”), legal status to engage in substance use treatment, use of cannabis in the past month to cope with anxiety/stress, and ongoing treatment of substance use, anxiety, or depression.

Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF) [38]. The REALM-SF is designed to determine if participants have at least a 6th grade literacy level through a 7-item assessment taken with the help of a research assistant. The REALM-SF is utilized in the current study by the research staff to determine if participants can read the EMA items and intervention content.

Cannabis Use Disorder Identification Test-Revised (CUDIT-R) [36]. The CUDIT-R is an 8-item self-report measure designed to identify the likelihood of cannabis use disorder (CUD). Items are rated on a 5-point Likert-type scale where higher scores indicate higher likelihood of CUD. Scores of 12 or greater indicate probable CUD and it is used as eligibility criteria for the current study [36].

Safety Aid Scale (SAS) [24]. The SAS is an 80-item measure that is designed to assess FSBs in participants. Examples of items and FSBs include “Avoid being far from home” and “Fiddling with an object (e.g., pen).” Items are rated based on how frequently participants endorse the behavior

on a scale from 0 (never or rarely) to 4 (almost always). Items are summed to form a total score of FSB use. This measure has demonstrated excellent internal consistency among Black adults [21]. For the current study, item reduction analysis was used among to reduce the number of items to 22 [41].

Marijuana Motives Measure (MMM) [42]. The MMM is a 25-item questionnaire that assesses 5 motives for cannabis use including enhancement, coping, social, conformity, and expansion regarding motives for, frequency of, and problems associated with cannabis use. Items are rated on a 5-point Likert-type scale where 1= almost never/never, 2= some of the time, 3= half of the time, 4=most of the time, and 5=almost always/always.

System Usability Scale (SUS) [43]. The SUS is a 10-item questionnaire that is used in the current study to evaluate participants' perceived usability of the app. The SUS includes items related to app engagement, frequency of use, complexity of the app, and thoughts about using the app.

Credibility/Expectancy Questionnaire (CEQ) [44]. The CEQ is a 6-item measure that assesses treatment expectancy and rationale credibility. It derives two predicted factors including cognitively based credibility and affectively based expectancy. In the current study, it is used to gauge participants' thoughts on the credibility of the intervention and assessment content assigned to them (CT-MICART+EMA or EMA only), and their expectations regarding the intervention (i.e., "How successful do you think this intervention will be in helping you quit or reduce marijuana?").

Ecological Momentary Assessments (EMAs). Throughout the 6-week intervention period, participants complete 3 daily EMAs occurring at specific times (one 30 minutes after self-selected wake time, one 60 minutes before self-selected sleep time, and one at 12:15pm). Items include questions about cannabis use, duration of being high, urges/cravings, motivation, and confidence to reduce/quit cannabis, negative affect, social support, and other substance use. Each EMA also gauges the CT-MICART+EMA participants' cannabis goal for the day (i.e., wanting to avoid using cannabis today, reduce use today, or no cannabis use goal today). All participants are also instructed to access the app's on demand assessment features including the "Record Stress or Urge," "I'm About to Use,"

and “I just used” buttons when they experience increased stress or an urge to use cannabis as well as anytime they think they might use or after actual cannabis use. Each time participants click these buttons, they are asked to complete a brief set of questions pertaining to their current situation.

Qualitative Interview. After completion the 6-week follow-up assessment in the app, study staff are notified via an encrypted email to contact the participant to complete the qualitative interview phone call. Participants are asked to assess their satisfaction with their assigned app content and ways it could be improved via a semi-structured interview. This 30 minute interview assesses participant engagement with the app, and specific thoughts about app features including EMA items, intervention content, and why they did or did not use certain features.

3.0 RESULTS

3.1 Data Analysis

General Overview. Given the current pilot study is likely underpowered to detect statistical significance, conclusions will primarily be based on effect sizes and associated confidence intervals (CIs) which will be used to guide future, larger, fully powered trials of comparative efficacy. Prior to data analysis, we will assess the equivalence of groups on key baseline variables. Variables on which the groups differ will be used as covariates in the final analyses.

Hypothesis Testing. We will examine treatment effects on cannabis use (derived from EMA data) using multilevel models (MLMs). We will focus on two cannabis use outcomes: (1) use on a given day, and (2) frequency of use within a given day. We will account for baseline covariates and time since the start of intervention. We will also employ appropriate random effects and residual constraints. For coping motives for cannabis and FSB engagement, we will conduct a linear regression analysis wherein we will regress treatment condition on each outcome assessed at the 6-week follow-up while adjusting for baseline scores of the specific outcome and baseline covariates.

Triangulation mixed methods quantitative/qualitative data analysis [45] will be employed to evaluate quantitative and qualitative data. Quantitative Data. The app’s feasibility and utility will be

examined by quantifying the use of CT-MICART features (e.g., number of assigned videos that are watched), and by evaluating participant opinions about the helpfulness of CT-MICART features (e.g., treatment videos, automated treatment messages that follow EMAs, exercises). Quantitative data analysis will focus on (1) behavioral markers of engagement with the app; (2) overall evaluations of the app and evaluations of each app feature, including usefulness/helpfulness and likelihood to recommend the app to a friend; and (3) data from the CEQ and SUS [46-48]. Data will be compared across conditions. Qualitative Data. The week 6 qualitative interviews will prompt information on what participants liked about CT-MICART, how it could be improved, and what barriers currently limit app engagement. Individual interviews will be transcribed following the completion of participant treatment and then reviewed by the research team to ensure data quality. Transcribed interviews will be coded using NVivo v.12 and decisions regarding the appropriateness of suggested changes into potential future versions of CT-MICART will be evaluated using a team-based approach. Consistent with the Systematic and Reflexive Interviewing and Reporting method [49], this approach will help to systematically organize collected qualitative data and thus guiding improvements to CT-MICART. Moreover, content analysis will be employed to analyze collected qualitative data [50]. Participant responses will be integrated with quantitative usage data to identify inconsistencies in the participant's perceptions and actual engagement with the app [51, 52].

Missing Data. Some participant attrition is anticipated to happen during the current study. We will assume a missing-at-random (MAR) mechanism if missing data occurs. This will allow us to increase statistical power and provide more accurate estimates of model parameters and standard errors, as they are the recommended intent-to-treat approach for clinical trials. We will compare this approach and the intent-to-treat approach as a sensitivity check of the influence of missing data on the statistical conclusion.

Data Availability. De-identified data from this project will be provided to interested individuals 1 year after this project's aims have been achieved (conceptualized as the publication of the main

outcome paper). All data will be clearly labeled, provided in digital format, and released directly by the investigators. Interested parties will be asked to provide documented approval for planned analyses of the data from their institution's institutional review board. The study team will be available to answer any queries.

3.2 Study Status

The current study is open for enrollment and currently recruiting research participants. The estimated study completion date is January 2024.

4.0 DISCUSSION

Black adults evince significant cannabis-related health disparities compared with non-Black populations [13, 15, 53]. Thus, the primary goal of the current study is to develop and pilot test a culturally adapted mobile app for Black adults with probable CUD to help mitigate these disparities. We have culturally tailored this mobile intervention following the Cultural Accommodation Model [39], incorporating knowledge from the current research team, published literature, expert opinion, and feedback from the CRAB. As a next step, we seek to obtain data on the initial efficacy and qualitative evaluation of the app with the target population (i.e., Black adults with probable CUD). To our knowledge, this is the first culturally tailored mHealth intervention to integrates FSB and CBT for CUD for Black adults with a probable CUD. We hypothesize that the culturally tailored mobile app CT-MICART will lead to reduced cannabis use and related problems and reduce use of FSBs.

Though extant literature has highlighted existing mHealth work for cannabis use and CUD [33], including mHealth interventions tailored to treat specific populations (i.e., individuals with psychosis, co-morbid substance use) [34, 35], this study is the first to target specific psycho-sociocultural factors related to cannabis use and use-related problems among Black cannabis users through a mobile intervention. Should the CT-MICART app prove efficacious in reducing cannabis use, it will provide healthcare officials and researchers a unique opportunity to further refine and

provide low-cost and easily accessible treatment for a historically underrepresented and underserved population. The success of the CT-MICART app would also provide the foundation to further refine and culturally inform better implementation of the app through qualitative interviews of all participants. Overall, the CT-MICART app and its development provides a potential to address the dearth of literature that exists for mobile health development and Black Americans who use cannabis.

4.1 Limitations

The current study has several limitations which warrant comment. First, this pilot randomized controlled trial will only offer intervention content and collect data for 6 weeks. As such, future research should examine the efficacy of similar, but longer-term interventions. Second, because the study will only enroll participants that are motivated to quit or reduce their cannabis use. Future work should determine if participants who are not currently motivated to quit or reduce their cannabis use can benefit from this type of culturally tailored cannabis cessation/reduction app. Thirdly, only Android smartphone users will be enrolled in the current study due to limitations of the Insight™ smartphone platform. Future studies will utilize the updated Insight™ platform that works on Apple and Android smartphones. Additionally, it is possible that the EMA only condition will have potentially therapeutic benefits to participants due to self-monitoring of behaviors, though EMA studies on substance use have found such effects to be limited [54-56]. Thus, a waitlist control should be included in future study designs to isolate the effect of CT-MICART beyond the potential influence of behavior monitoring or tracking behavior. Finally, although the sample size will be adequate to achieve study aims/hypotheses, future fully-powered studies will be needed to test intervention efficacy and effectiveness.

4.2 Conclusions

This study will address a significant gap in the literature. Specifically, this pilot RCT will offer initial insights on the utility of an mHealth intervention that is tailored for Black Americans

who use cannabis. Smartphone interventions like CT-MICART have incredible potential to provide low-cost, scalable treatments to diverse populations. Moreover, the CT-MICART app has the potential to help Black Americans who use cannabis achieve and maintain higher rates of cessation and reduction and help narrow health disparities that have negatively impacted this underserved population.

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Data Availability: The data sets generated and analyzed during this study will be available from the corresponding author on reasonable request following the completion of the trial and publication of the main outcomes paper.

Declaration of Interests: Dr. Businelle is the primary inventor of the Insight mHealth Platform, which was used in the current study. He receives royalties related to its use. Dr. Obasi is the founder and sole owner of HEALTH Equity Empowerment, LLC.

Table 1. Measures and schedule for data collection

Measure Name	Screener	Baseline	6-week Follow Up	EMA Items
Demographics/Background information	X			Cannabis use assessment (outcomes)
Motivation to quit cannabis (eligibility)	X			Alcohol consumption
Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF; eligibility)	X			Motivation regarding cannabis use
Cannabis Use Disorder Identification Test (CUDIT-R; eligibility)	X		X	Watch treatment videos (CT-MICART condition only)
Legal mandate status (eligibility)	X			Cannabis use goal assessment (CT-MICART condition only)
Report of cannabis use to manage anxiety/stress in the past month (eligibility)	X			Negative affect
Assessment of ongoing substance use treatment/ anxiety and depression (eligibility)	X			Confidence in reducing/quitting
Safety Aid Scale (outcome)		X	X	Urges/cravings
Qualitative Interview (outcome)			X	Social support and daily interactions
System Usability Scale (outcome)			X	Coping motives for cannabis and consequences/benefits of using.
Credibility/Expectancy questionnaire (outcome)		X	X	False safety behavior elimination engagement.
Marijuana Motives Measure (outcome)		X	X	

Figure 1. Study Flowchart

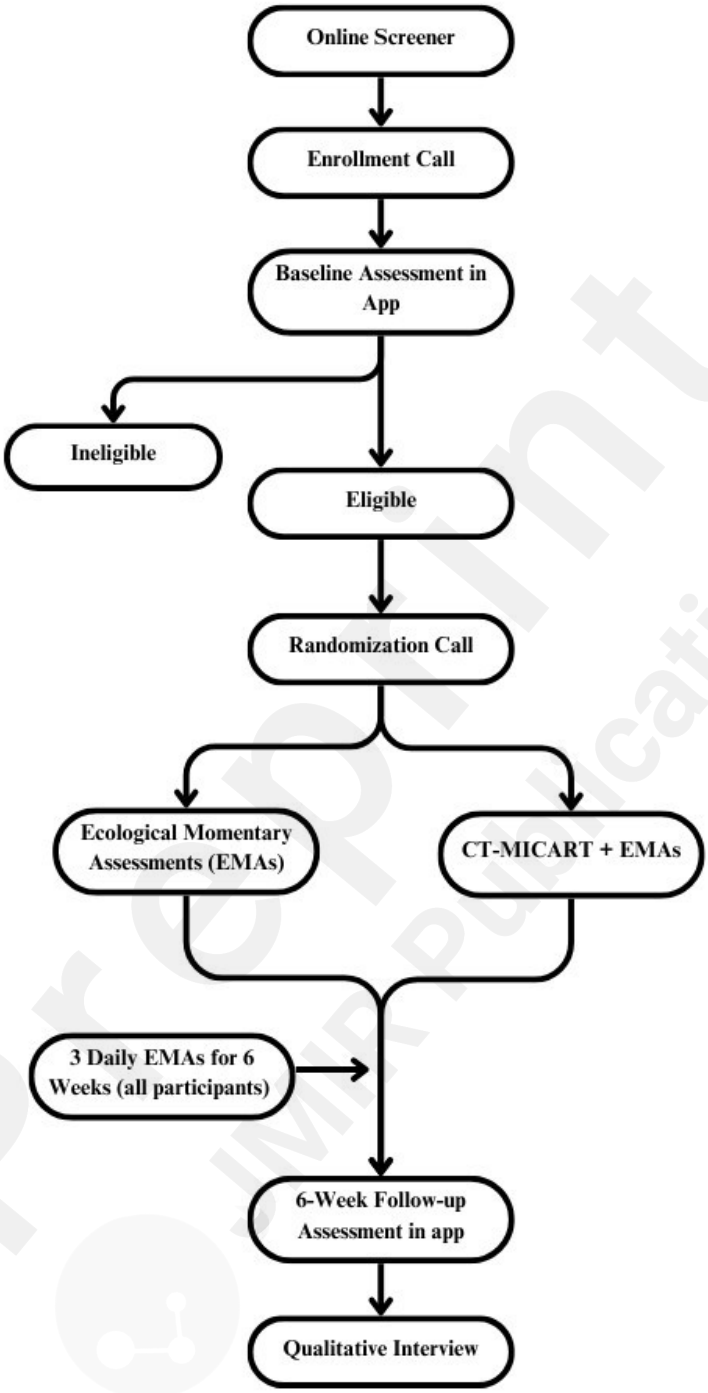


Figure 2. Main Menu of CT-MICART Features

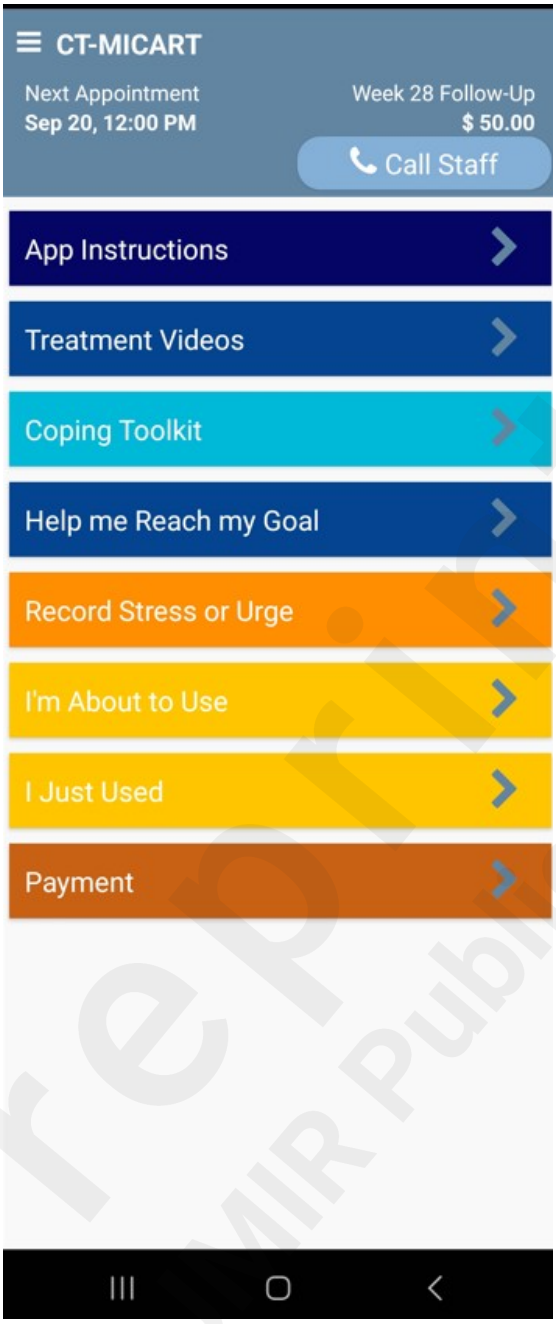


Figure 3. ***Coping Toolkit*** **CT-MICART Feature**

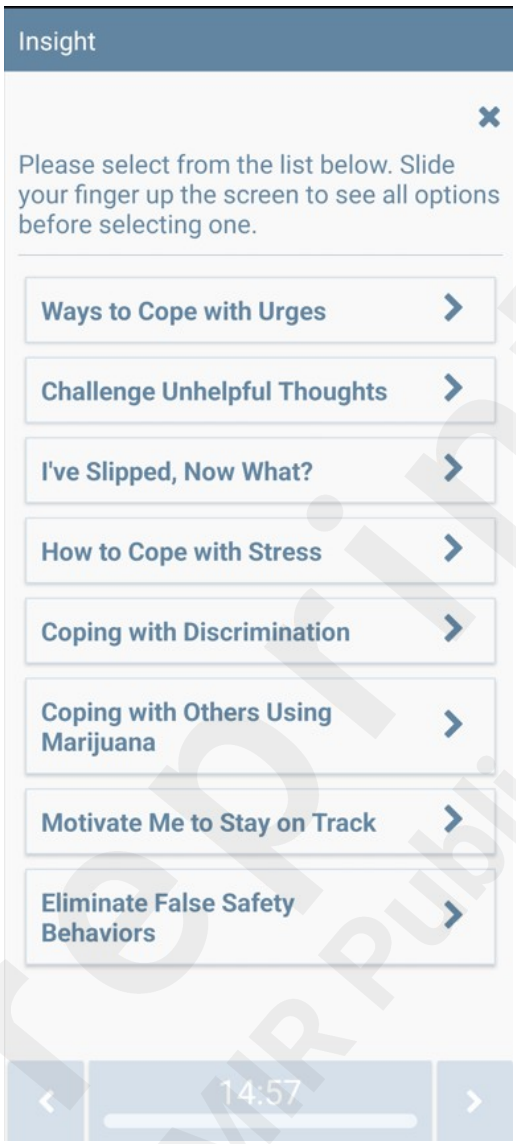


Figure 4. ***Challenging Unhelpful Thoughts*** **CT-MICART Feature**

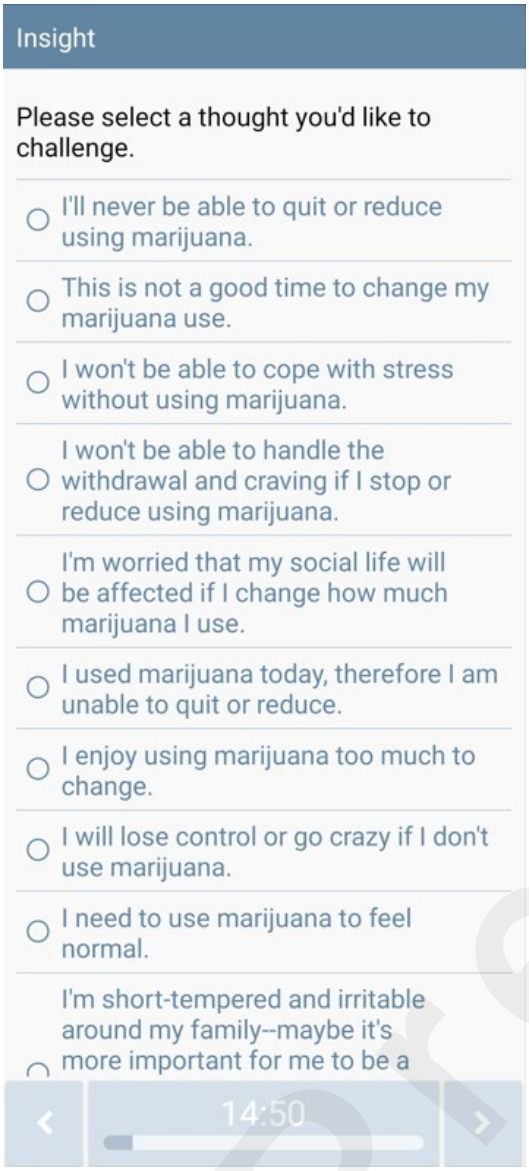


Figure 5. ***False Safety Behavior Elimination*** **CT-MICART Feature**

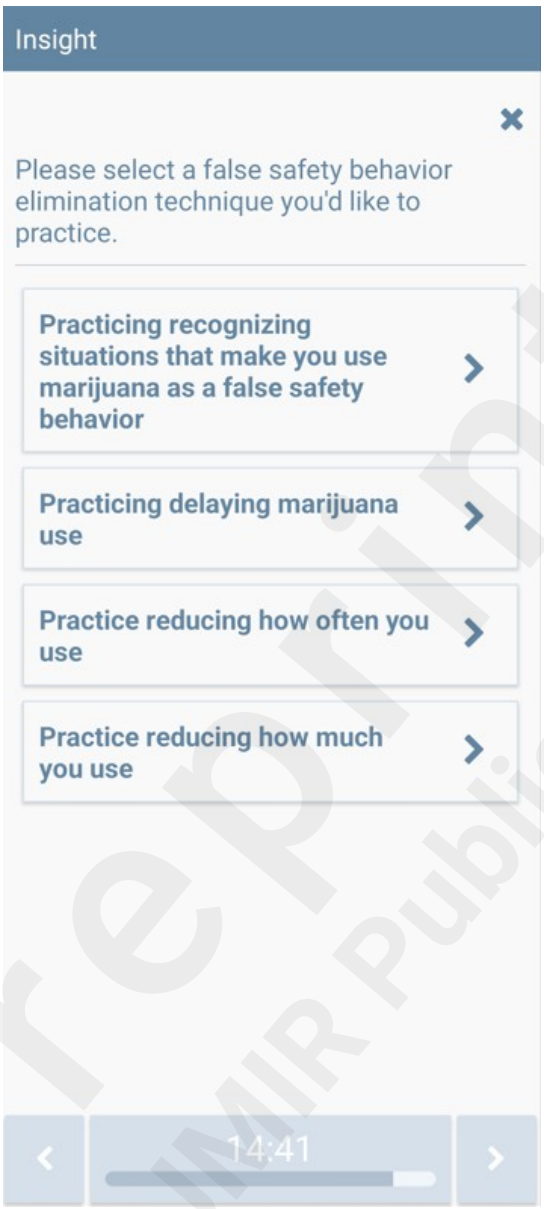
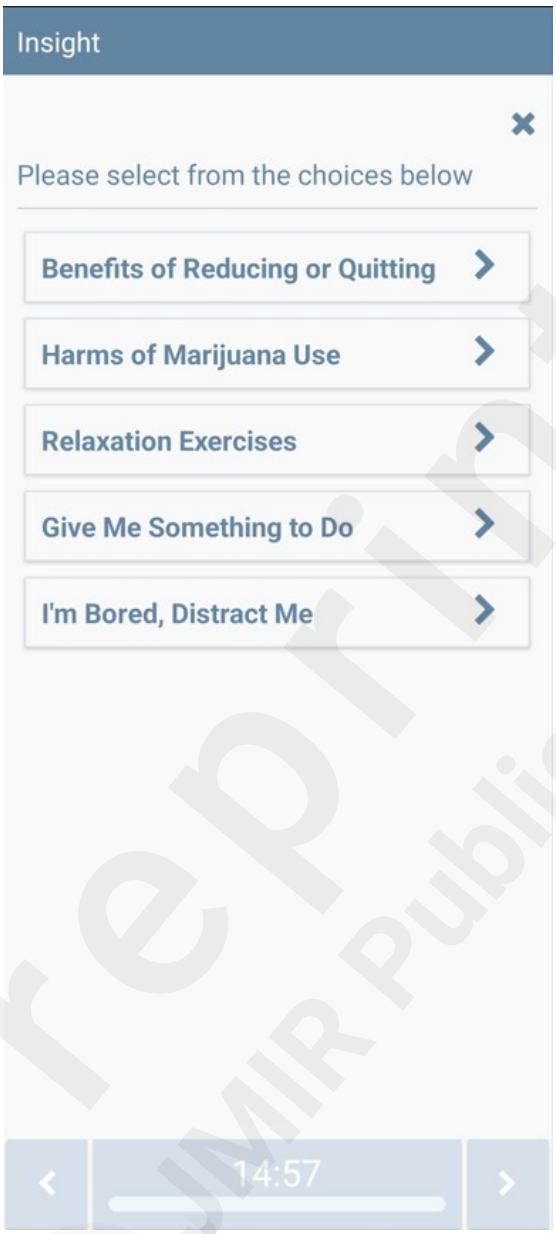


Figure 6. ***Help me Reach my Goal*** **CT-MICART Feature**



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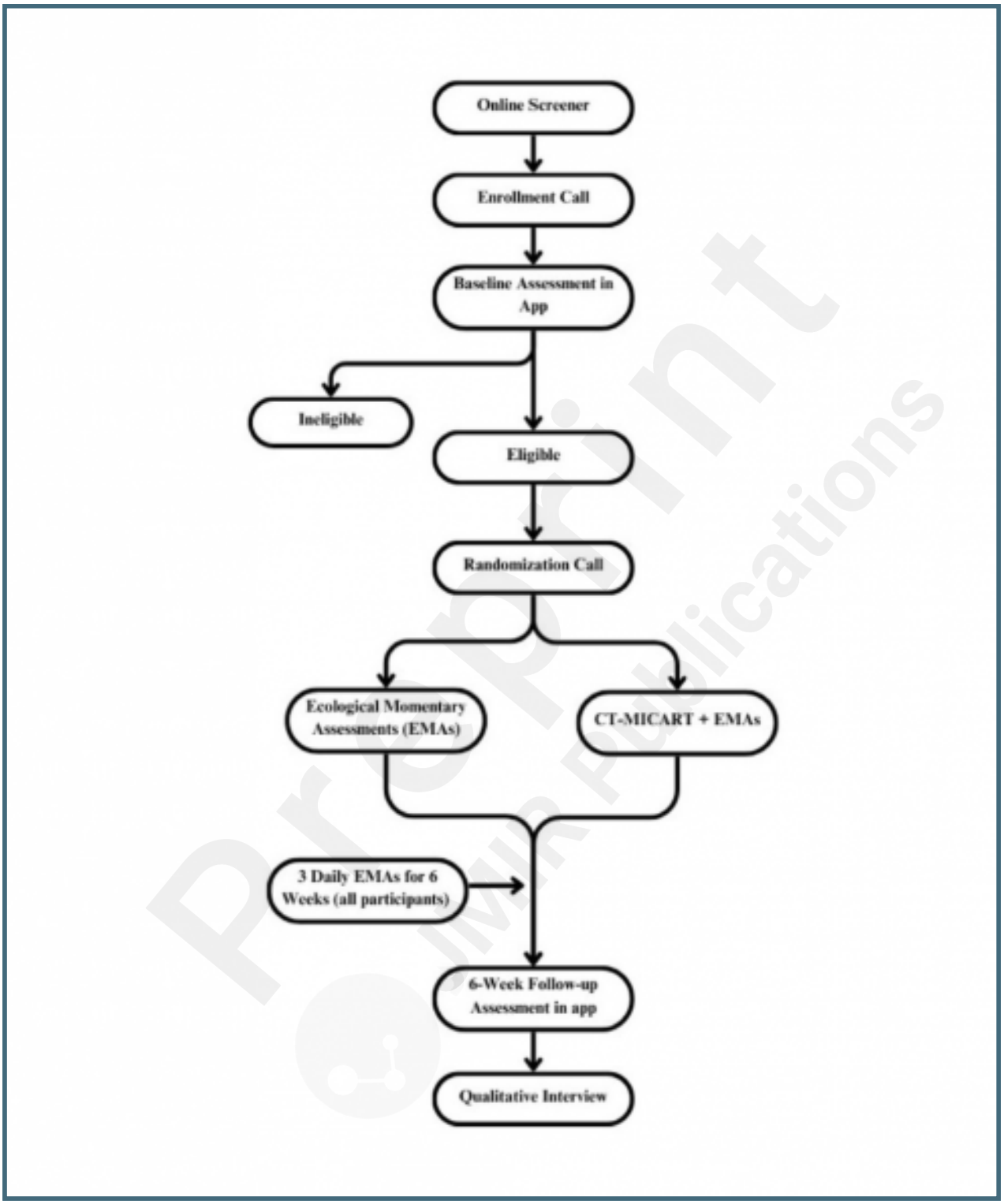
Supplementary Files

Figures

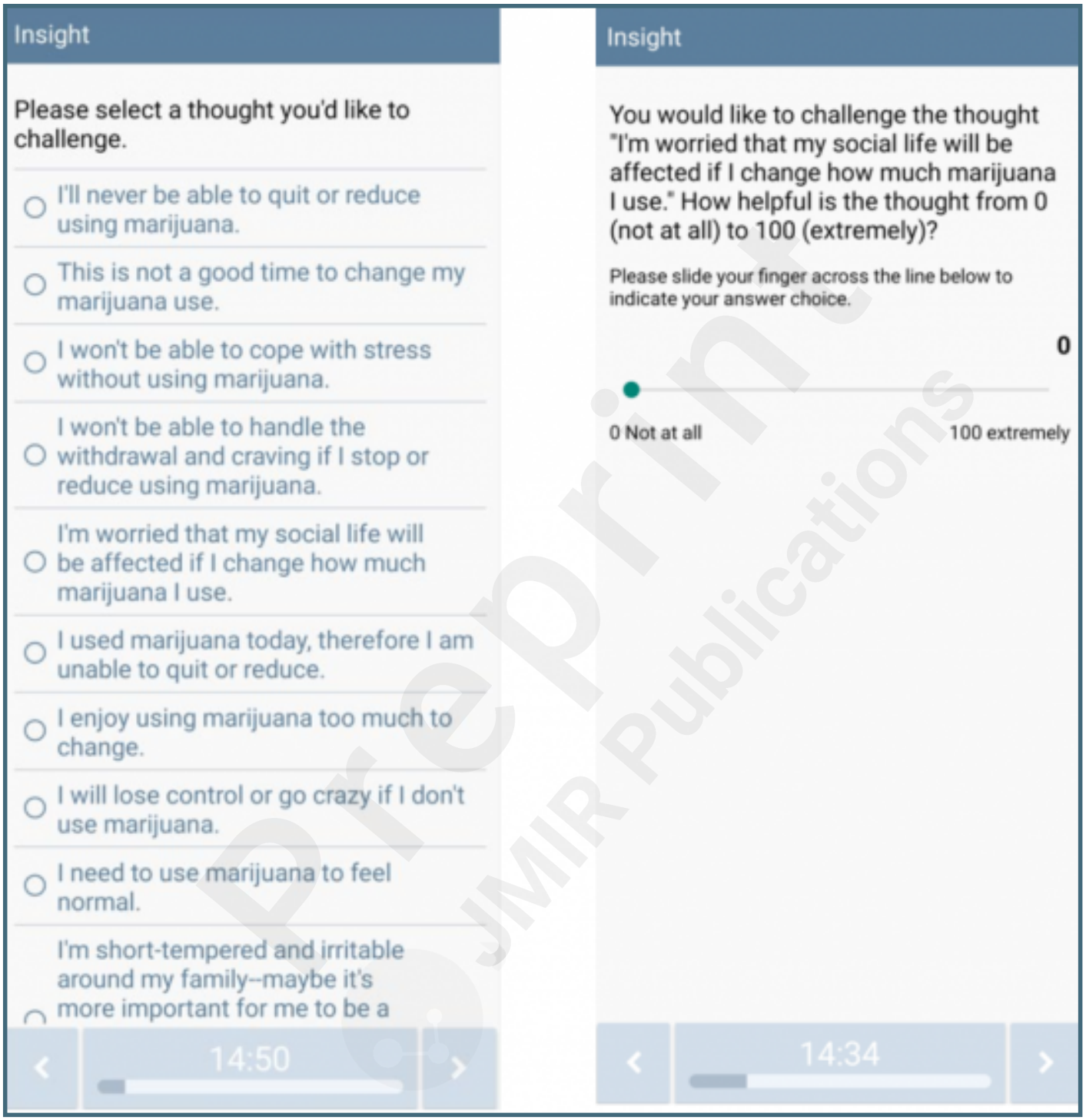
Study Flowchart.



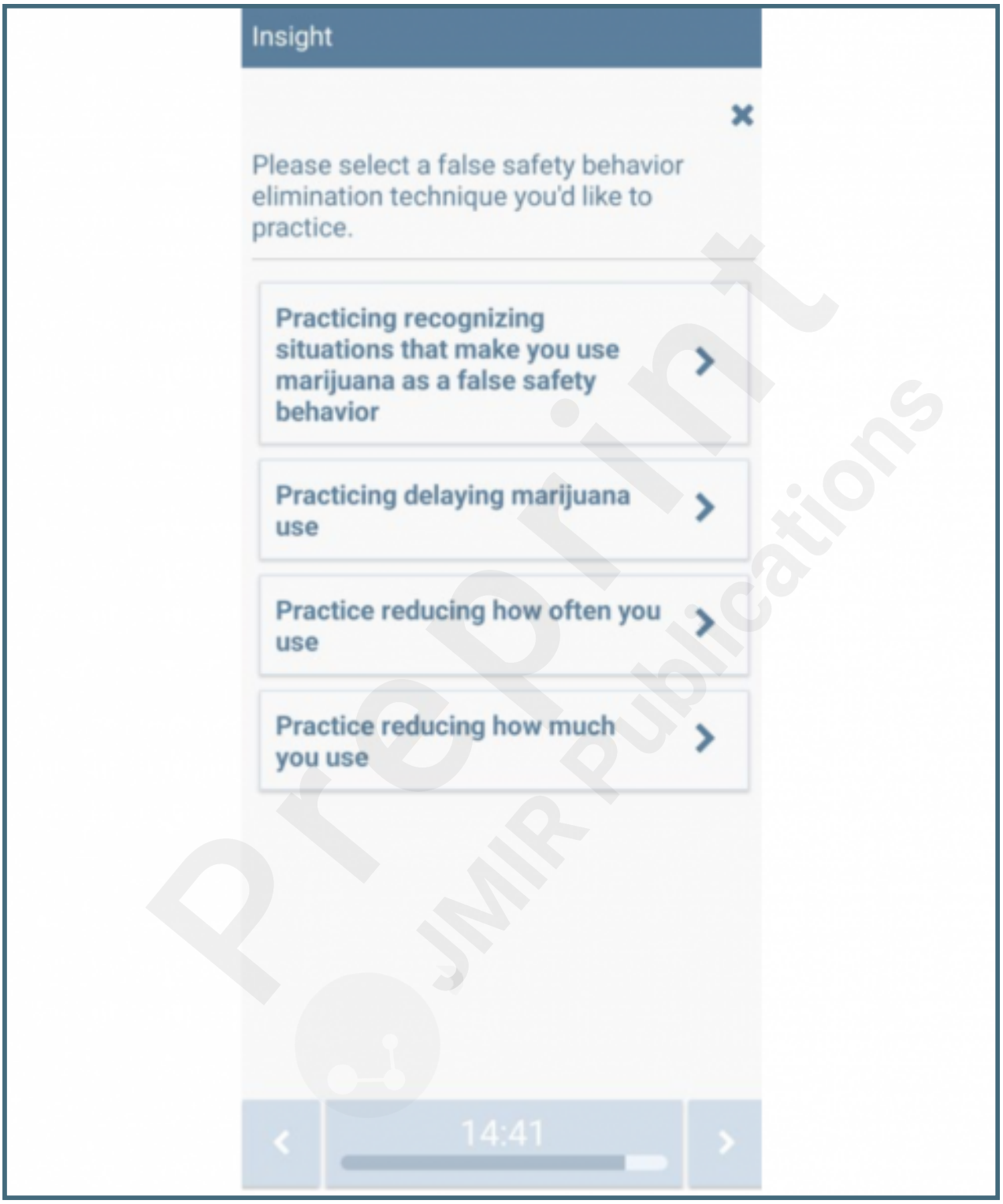
Main Menu of CT-MICART Features.

Coping Toolkit CT-MICART Feature.

Challenging Unhelpful Thoughts CT-MICART Feature.



False Safety Behavior Elimination CT-MICART Feature.



Help me Reach my Goal CT-MICART Feature.