Full Study Title: An App to Reduce Cannabis Use Among Emerging Adults

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Principal Investigator: Inbal Nahum-Shani. Ph.D.

MiWaves

Feasibility of a 2nd generation JITAI to reduce cannabis use among emerging adults

PI: Inbal Nahum-Shani, Ph.D. & Lara Coughlin, Ph.D.

Co-investigators: Erin Bonar, Ph.D., Susan Murphy, Ph.D. & Maureen Walton, Ph.D.

1. Introduction

Advances in mobile health (mHealth) not only allow for accessible and cost-effective intervention, but also offer novel opportunities for delivering personalized and adaptive interventions in real-time, in the real world. Analogous to personalized medicine, just-in-time adaptive interventions (JITAIs) are an emerging approach that operationalizes the personalization of the real time selection, and delivery of intervention strategies, based on real time data collection.[1, 2] This approach has had large clinical impact in managing cardiovascular disease and diabetes[3, 4] and JITAIs have been developed and evaluated for a wide range of behavioral health issues (e.g., mental illness,[5] smoking cessation[6, 7]).

mHealth interventions offer novel opportunities for delivering JITAIs based on real-time data collection to reduce substance use. Such approaches are lacking for substance use (SU; alcohol, cannabis, opioids) among emerging adults (EAs), which is critical because they are avid digital adopters. Also, SU is initiated in adolescence, reaches peak prevalence during emerging adulthood, and is associated with morbidity and mortality (i.e., injury, violence, suicide, overdose).

Critical challenges exist to developing evidenced-based, personalized, real-time mHealth interventions that can address youth SU. 1) Existing mobile interventions for SU primarily focus on adults, and/or individuals with substance use disorders (SUDs;<10% of EAs), missing youth and young adults with risky use. 2) Adequate engagement with mHealth tools is necessary for success;[1, 2] yet attrition in mHealth interventions is common,[8-10] including those targeting SU.[11] 3) There is high heterogeneity in response to mobile interventions targeting EA SU; many EAs do not benefit sufficiently from mHealth alone and require some level of human (e.g., coach) support to facilitate change.[12, 13] Addressing these challenges requires multidisciplinary effort, involving clinicians, engineers, methodologists, decision scientists, health economists, computer scientists and human-computer interaction (HCI) specialists.[1]

Current mHealth substance use interventions, including JITAIs, focus primarily on treatment seeking samples with substance use disorders (SUDs) and/or adults,[11, 14-18] which is a missed opportunity to intervene earlier in substance use trajectories by focusing on broader samples of non-treatment seeking EAs with risky use. Despite promising emerging data,[19] evidence-based JITAIs for cannabis use among EAs are lacking. Reducing cannabis and other drug use among EAs could have a major public health impact by preventing health consequences (e.g., injury), development of SUDs, and associated risk behaviors (e.g., drugged driving). [20-27] To address

this gap,[28] consistent with the Multi-Phase Optimization Strategy (MOST) approach, we conducted a series of pilot studies to inform the proposed JITAI. First, we developed an ecological momentary assessment app called SARA, which integrates gamification via an aquarium with scalable engagement strategies. A pilot micro-randomized trial (MRT) of SARA among 74 EAs with substance use showed excellent acceptability and 30-day engagement (*M* daily surveys=18.1, *SD*=9.2) despite much lower financial incentives (*M*=$6.24, *SD*=$3.83, range: $1-13) compared to previous daily self-report studies; further, inspirational messages increased daily survey completion.[29] Second, we integrated feedback from SARA into a prototype JITAI, and obtained acceptability data among 39 substance-using EAs, establishing a blueprint for future refinement of the MiSARA JITAI.

2. Objectives

Given that cannabis use peaks among EAs and changing norms and policies have led to increases in availability and reductions in perceived risks of cannabis use,[30, 31] we aim to develop a JITAI to reduce cannabis use among non-treatment seeking EAs who use cannabis thrice weekly. Using a transdisciplinary approach, the JITAI will integrate empirically based intervention strategies for reducing substance use (e.g., motivational interviewing and mindfulness) with engagement strategies grounded in areas such as basic psychology, human computer interaction (HCI), and marketing, which are necessary for efficacious mHealth interventions.[32-34]

In this study, we will innovatively build on the results from our prior MRT optimizing app engagement (SARA) and prior feasibility/acceptability pilot of a prototype JITAI (MiSARA JITAI). In Aim 1, based on participant feedback, we will refine the MiSARA JITAI app environment to improve engagement by increased interactivity and personalization to maintain novelty throughout the intervention period. Then, we will test the feasibility, acceptability, and preliminary efficacy of a person specific JITAI called MiWaves for reducing cannabis use in this critically important EA population.

3. Project Aims

The **specific aims** of this project are to:

Aim 1: Refine the MiSARA JITAI to reduce cannabis use among EAs.

Aim 2: Conduct a pilot trial to test the feasibility and acceptability of MiWaves, a 2nd generation MiSARA JITAI with continually optimized population-based decision rules.

The achievement of the proposed aims addresses a significant public health problem, namely the increases in cannabis use among EAs. The innovation is grounded in the development of a real-time, real-world, personalized, and scalable intervention approach to reduce substance use among EAs. This work is highly innovative since, despite promising results, evidence based JITAIs for cannabis use among EAs are lacking. Reducing cannabis and other drug use among EAs could have a major public health impact by preventing adverse health consequences (e.g., injury), development of SUD, and associated risky behaviors (i.e., drugged driving).

4. Methods

Aim 1: Refine the MiSARA JITAI to reduce cannabis use among EAs.

This aim does not include human subjects. Instead, it includes the development of (a) therapeutic content and (b) engaging content and human computer interfaces. Using a participatory action approach, we will integrate EA feedback from our formative studies with consultation from a new EA advisory board to create the MiWaves JITAI app.
Refinements may include:

- increased interactivity and personalization of the app,
- integration of data into personalized feedback graphs,
- personalization of messages based on behavioral trends to increase novelty, and
- archiving intervention content in a virtual toolbox and creating 'on-demand' pulls for additional messages.

A collection of empirically- and theoretically-grounded therapeutic content will be identified and developed by multiple intervention experts to maximize engagement. Therapeutic content will harness a variety of mediums and may include: a) messages (targeting goals, strengths; benefits to change, tools to address motives); b) brief videos (e.g., focusing on goal setting and attainment, protective behavioral strategies, safe driving, overdose prevention, other strategies); and c) life-insights visualizations -- feedback capitalizing on Ecological Momentary Assessments (EMAs) to visually integrate information about behaviors, risk and protective factors. Intervention content will be reviewed by an advisory board of EAs and selected based on fit with evidenced-based intervention content (e.g., motivational interviewing) and appropriateness (e.g., no images glamourizing use, offensive jokes). Intervention experts on our team will collaborate with engagement experts, machine-learning experts and HCI experts to further develop and refine various types of visualizations to specifically address cannabis use related risk.

Aim 2: Conduct a pilot trial to test the feasibility and acceptability of MiWaves, a 2nd generation JITAI with continually optimized population-based decision rules.

This aim includes human subjects. Specifically, it includes the following: a) conduct EA enrollment and obtain feedback, and b) software refinement. Based on prior work and Aim 1 feedback from EA advisors, the MiWaves app will be iteratively refined among a total of 150 EAs (ages 18-25). Participants who report cannabis use three or more times per week in the past month (see Inclusion/Exclusion criteria below for more information) will be recruited online to use the MiWaves JITAI for 30 days. Enrollment will occur in multiple waves, with the first two waves beta testing proposed trial procedures with small groups of n≈10 participants and n≈20, and the final wave(s) involving a pilot trial with up to 150 EAs. Feasibility will be defined by the percentage of participants who consent to the study who ultimately download the MiWaves app.

Participants

The subject population comprises of emerging adults ages 18-25 years-old, residing in the US, who use cannabis, and report motivation to change their cannabis use habits. To ensure representation of both sexes, we will recruit approximately 50% males and 50% females. Using a similar approach to the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), we will attempt to represent minorities who are African American and Hispanic (~20%). Thus, we expect approximately 67% Caucasian, 20% African American, 3% Asian, 1% Native American/Alaskan Native, 1% Hawaiian/Pacific Islander, and 8% more than one race.

Recruitment

We will employ a variety of recruitment sources on this project. Recruitment options may include:

1. We may use social media ads (e.g., Facebook, Instagram, Snapchat, X [Twitter]) to target 18–25-year-olds in the United States. When users click on our ad, they will be redirected to the online (Qualtrics) screening informed consent (with waiver of documentation of consent and waiver of parental consent requested for states where the age of majority is over 18).
2. We may recruit potential participants through flyers displayed within the community (at locations such as coffee shops, gyms, community centers, clinics, restaurants, libraries, stores or small businesses, pharmacies, churches, etc.).
3. We may recruit potential participants through a page on UMHealthResearch.org, a website hosted by the Michigan Institute for Clinical and Health Research (MICHR). Participants who learn of the study through UMHealthResesearch.org may be redirected to the study website and/or the direct link to the screening survey through the study's description. If someone with a UMHealthReserach.org account finds the study and expresses interest in participating, they may be contacted by research staff by phone or email.
4. We may partner with third-party recruitment companies (e.g., BuildClinical) to generate additional leads for our study staff to follow up with.
5. With appropriate regulatory approval from the necessary IRBs, we may contact participants from other studies that consented to recontact for future research participation. In these situations, we will receive approval from that study's investigative team and IRB, and list the IRB number in section 8-1.1 of our application.
6. We may provide sample emails with recruitment resources to distribute to venues (with appropriate approval) such as the UM Registrar email list or other community Listservs.
7. We may recruit potential participants through a study specific website, which may include an embedded eligibility survey.
8. We also may contact interested participants via email or in person with appropriate follow-ups.

Participants will be invited to print or save a copy of the informed consent before moving on to the screening survey. After giving online screening consent and completing a CAPTCHA to protect against bots, participants will complete a 2-3-minute eligibility survey. Following determination of eligibility (see eligibility requirements outlined in inclusion and exclusion criteria section below), negative screens will receive a thank you page ending their participation. No identifying information will be collected from those participants who are not eligible for the study.

<u>Inclusion/Exclusion Criteria</u>

Individuals will be eligible to continue if they: 1) reside in the US; 2) speak and read English; 3) are 18-25 years of age; 4) have a smartphone on which the app can be downloaded; 5) screen positive for cannabis use 3 or more times each week over the past month; 6) report motivation to change cannabis use as a 1 or higher (using a scale of 0-10); and 7) meet study verification criteria (i.e., use of CAPTCHA, IP address checks, repeat attempts, social media checks).

Participants may be excluded if they report current medical marijuana use and/or fail identity verification procedures (see prior study[1]) based on IP addresses, survey time completion, repeat attempts, social media checks or survey responses. Potential participants may also be excluded based on participant best interest (e.g., if the participant has plans to travel outside of the country during the app use period, or if study staff know the participant or their family personally, in order to fully ensure participant privacy), with PI approval.

Baseline Assessment

Eligible participants will be notified of their eligibility and sked to provide contact information. Following completion of the screening assessment, participants will be verified for authenticity. We have experience with methods related to identification and handling of fraudulent cases using internet-based research via use of a Completely Automated Public Turing test to tell Computers and Humans Apart (CAPTCHA) and checking for duplicate IP addresses.

Once verified, eligible participants will be redirected to an online baseline consent housed in Qualtrics (waiver of documentation and waiver of parental consent requested for states where the age of majority is over 18). After giving online baseline consent and completing a CAPTCHA to protect against bots, eligible participants will complete a 25-35 minute baseline survey and another contact information form in Qualtrics. In the rare event and at the participant's request, participants may also have the option to complete the consent and surveys over the phone where the research assistant will read the questions and record responses.

After completion of the baseline assessment, eligible participants will receive information about how to download and enroll into the MiWaves app. Eligible participants will have one month from screening consent to complete the baseline assessment and download the MiWaves app. To begin the 30-day pilot trial, participants will be activated to begin receiving notifications. After this step, participants will be enrolled in the study and begin the pilot trial.

Pilot Trial

As part of the pilot trial, participants will interact with the app for a 30-day period. During this intervention period, participants will be asked to complete four short (5-10 minutes) weekly surveys online and brief (1-3 minutes) twice-daily surveys within the app. Participants will receive daily push notification reminders about completing surveys which will not include sensitive information (e.g., about substance use) or other information that may identify the individual as a study participant. The MiWaves app can also passively collect data regarding participants' interaction with the app, movement, context, and may also collect GPS location. Beta testing will occur in the first two waves of n=10 per wave to aid in the development of the app and algorithm creation. Participants involved in beta testing waves will interact with the app for only 10 days including the twice-daily surveys during those 10 days and then complete only one weekly survey.

Since novelty is well understood to enhance user engagement with technology[35], additional features of the app can be intermittently turned on to maintain participant engagement during the intervention period. These features may include: 1) life insights feedback, or graphs of survey responses/app engagement over a window of time; 2) inspirational messages which harness the theory of reciprocity to encourage survey completion; 3) financial incentives of varied amounts which are tied to survey completion; and 4) active tasks, which are brief games that capture cognitive performance (e.g., reaction time, spatial memory). In instances where the app is not able to display how many surveys have been completed and how much money participants have earned during the pilot trial (e.g., due to technical difficulties), participants will receive a message each week from the study team that informs them: 1) how many

assessments they completed during the past week; and 2) the total amount of money earned to date.

Participants will likewise receive therapeutic content via the app during the pilot trial. Twice per day (morning and afternoon), intervention messages may be delivered. MiWaves will use reinforcement learning algorithms to learn whether and in which context it is best to deliver these messages for each EA. The message will target content areas such as daily goals to reduce use, upstream factors (e.g., coping with negative affect), reasons and tools to reduce use, potential consequences of use, and identification of alternative activities. Messages will vary by the amount of effort required by the EA to engage with the content (e.g., messages with a 'pick' list or text entry box will be considered higher effort, whereas messages with only visual content will be considered lower effort), as a potential moderator of intervention effects. Furthermore, harm reduction messages can be delivered when the EA enters a high-risk location (e.g., dealer's/dispensary location). These high-risk locations will be prespecified during app set-up. Note that all content participants receive directly on their phone as push notifications will not contain any confidential information. All intervention messages will include user ratings (e.g., thumbs up/down, star rating) to inform future content refinement.

Post-Test and Follow-Up Assessments

At the end of the 10-day or 30-day intervention period, all participants will be invited to complete a 20-25 minute post-test about their experience using the app, feedback about intervention content, and recent cannabis use (with questions mirroring those asked in earlier surveys).

Then, two months after the start of the app intervention, all pilot trial participants will be invited to complete a 25-35 minute follow-up assessment containing questions that mirror those asked in the screening, baseline, weekly and daily surveys. Participants will have the option to complete both assessments online or over the phone with a RA if preferred.

Incentives

Participants will be compensated $40 for completing the baseline assessment and downloading and enrolling in the MiWaves app. During the pilot trial, all participants can earn up to $60 for completing the four weekly surveys ($15/survey) and between $0.50 - $3.00 for each completed daily survey, with the possibility of earning up to $60 for completing all twice-daily surveys. All incentives earned for completing the daily surveys and weekly surveys will be disbursed at the end of the intervention period. Participants will then receive $40 for completing the post-test and $50 for completing the follow-up assessment. Over the course of the study, participants could receive up to $250 for completing study activities and assessments. Earned financial incentives will be disbursed electronically (e.g., via a gift card of the participant's choice).

Participant involved in the beta-testing waves will receive the above rates of compensation for the activities completed. Total potential compensation for beta testing participation is $117.

Measures

Self-administered measures are reliable and valid among emerging adults. Please see Table 1 for more information about the domains queried at each assessment timepoint, the timeframes asked about for each domain at each timepoint, and references for the questions capturing each

domain. All the outcomes listed in Table 1 are exploratory, except for the bolded primary outcomes concerning feasibility and acceptability.

Table 1. Overview of MiWaves Measures, Assessment Timepoints, and Question Timeframes

Domain	Assessment Timepoint					
	Screen	*Baseline*	*Weekly*	*Daily*	*Post-Test*	*2M FU*
Background Characteristics						
Demographics[36-47]	Current	Current				Current
Cell phone characteristics[48-50]	Current					
Substance Use Frequency, Quantity and Methods of Use						
Nicotine use[47, 51-54]	1M	1M			1M	1M
Nicotine methods of use[47, 51-54]		1M			1M	1M
Alcohol use QxF[55-61]	1M	1M		Yesterday	1M	1M
Alcohol TLFB[59, 60, 62, 63]		7D	7D			7D
Cannabis use QxF[39, 47, 59, 60, 62-67]	1M	1M	7D	12h	1M	1M
Cannabis TLFB[59, 60, 62, 63]		7D	7D			7D
Cannabis methods of use[39, 47, 64-67]		1M			1M	1M
Illicit drug use[47, 64, 68]		1M			1M	1M
Prescription drug misuse[45]		1M			1M	1M
Precursors of Cannabis Use						
Cannabis use motives[69-71]		Current		12h		Current
Cannabis cravings[72, 73]		Current		Current		Current
Perceived risk of cannabis[74]		Current				Current
Social influences[45, 54]		Current				Current
Mood/Affect[75, 76]			7D	Current		
Stress[76]				Current		
Energy[76]				Current		
Readiness to Change Substance Use						
Importance rulers (nicotine, alcohol, cannabis)[77]	Current	Current			Current	Current
Likelihood and confidence rulers (cannabis)[78, 79]		Current				Current
Substance Use Outcomes and Consequences						
Marijuana Adolescent Consequences Questionnaire[80]		1M			1M	1M
Young Adult Driving Questionnaire[81]		1M			1M	1M
DSM Symptoms Checklist[82]		1M			1M	1M
Protective Factors						
Protective Behavioral Strategies for Marijuana[83]		1M	7D		1M	1M
Social Support[84]		Current				Current
Behavioral Economic Measures						
Cannabis Purchase Task[85-88]		Current	Current			Current
Activity Level Questionnaire[89, 90]		1M			1M	1M
Delayed Discounting Task[91]		Current	Current			Current
Brief Relative Reinforcement*			7D			
Mediators						
Social context of cannabis use[92, 93]		7D	7D			7D

Domain	Assessment Timepoint					
	Screen	*Baseline*	*Weekly*	*Daily*	*Post-Test*	*2M FU*
Satisfaction with social events[94]				Current		
Distress[92, 95]				Current		
Positive outlook[76]				Current		
Health Status, Outcomes and Service Utilization						
Service Utilization[45]		Lifetime				2M
Mental Health						
Global Measure[94]		Current				Current
PHQ-2[96]		2W	7D		2W	2W
GAD-2[97]		2W	7D		2W	2W
ASI-3[98]		Current				
Mindfulness Attention Awareness Scale[99]		Current				Current
PCL-5 short form[100]		1M				1M
Physical Health						
Global Measure[94]		Current				Current
Pain Intensity[101]		7D				7D
Pain Interference[101, 102]		7D				7D
Sleep Quality[101, 103]		7D				7D
Sleep*				12h		
Exercise[104]				12h		
Acceptability and Feasibility (Primary Outcome Measures)						
Acceptability[105,*]					Current	
Feasibility						

*Items were created for this study

Notes: In the table above, 1M = Past Month, 2W = Past 2 weeks, 7D = Past 7 days, 12h = Past 12 hours.
Bolded items indicate Primary Outcome Measures. All other outcomes are exploratory.
Table cells which are blank indicate that the domain was not assessed at that timepoint.

5. Analysis

Quantitative data will be analyzed using a statistical software package (e.g., SAS, STATA, SPSS). Descriptive statistics (frequencies) will be employed to understand the distributions of question responses. Appropriate bivariate and multivariate techniques will be used to explore trends in the data. Open-ended responses will be analyzed manually and coded into themes and subthemes when possible.

6. Human Use Considerations and Protections

This research is covered by a Certificate of Confidentiality from the NIH. All hired members of the research team will complete training and receive certification in Human Subjects Research Protection and HIPAA regulations, including Good Clinical Practice, and the investigators will keep current certifications up to date.

Aim 1. There will be no human subjects' involvement in Aim 1 of this proposal as it is focused on app and content refinement.

Aim 2. In this aim, we will conduct a pilot trial to test the feasibility and acceptability of a 2nd Generation just-in-time adaptive intervention (JITAI) with continually optimized population-based decision rules.

Identifiable Information. For each stage of the proposed research investigation, participants' names and contact information will be stored in a secure database, separate from their study data. Names will be linked to individual ID numbers *only* in a study database, which will be kept in a restricted access location only accessible to study staff. All study devices will be password protected, use UM encryption (e.g., Hub) whenever possible, and only accessed by study staff. UM encryption enables safeguards against data compromise, malware, and ransomware and has a user portal to manage devices in case of theft, loss, or forgotten passwords. All information collected will be accessible only to research staff who have completed and maintain mandatory training in the protection of human subjects and good clinical practices.

Potential Risks. Every effort will be made to ensure that study participants are protected from risks. Although it is not expected that there will be any risks to participants because of online assessment procedures, the risk of violation of confidentiality exists because human participants are giving personal information. Consent forms will contain a statement explaining mandatory reporting requirements for information regarding child abuse and intention to harm self or others, should this be disclosed in the context of the research, although we will not be collecting any assessment data on these topics.

We expect that participants will <u>not</u> disclose such information in the context of an app-based study. Should information to this effect be shared as part of assessment data collection or study interactions (e.g., phone follow-up, reminder messages), we will provide appropriate referrals to national hotlines and follow standard reporting procedures. We will notify participants when/if we must make any mandatory reports based on information they disclose and will only disclose the minimum information necessary. Participants will be informed in the consent documentation about the procedures taken to maintain and protect their confidentiality. Also note in a study conducted by our team using mobile phone assessments of EAs' illegal drug use, participants reported (98%) that they were well-informed about potential study risks and most used a password/code on their phone during the study, as advised.[106]

Participants could also potentially experience emotional discomfort as a result of being asked personal questions or because of intervention content. Because the study takes place solely via mobile devices, participants will receive a national resource list. Our prior studies have involved phone and web-based follow-ups; thus, we will use established protocols for addressing any crisis or harm situations that may arise, including having national hotline phone and text numbers.

Participants will be informed that we will take steps necessary to secure their data. Electronic data files will be stored in a restricted-access folder in a secure U-M web-based location (e.g., U-M Dropbox, U-M network) only accessible to study staff. Participants will be instructed at the close of each web-based survey (e.g., screening, baseline) of steps they can take to further protect their privacy (e.g., clear browser history). In the baseline consent, participants will be encouraged not to leave their mobile devices or computers open/unlocked (i.e., they will be encouraged to use a passcode). In addition, to limit inadvertent disclosure of participation in the study to family or others, we will suggest that participants use strong passwords (mix of upper/lower case letters, numbers, symbols) on their mobile devices and email accounts that they give the study for contact. Further, study contacts and reminders will not include sensitive information about substance use.

<u>Protections against risk</u>. To minimize the risk of violating confidentiality, research staff will make every effort to ensure that study data are always kept confidential. Staff training procedures will include information about the importance of confidentiality and techniques to maintain

confidentiality of all information reported by research participants. Staff will maintain human subjects and confidentiality certifications through the UM Program for Education and Evaluation in Responsible Research and Scholarship system and will complete Good Clinical Practice Training. Consent documents will fully explain the study procedures, potential risks, and potential benefits.

Unique identification numbers will be assigned to participants. Any data forms (e.g., app-based survey response logs) will be coded with this number, rather than with a name. Computer data files (e.g., screening/baseline/ follow-up data, survey logs,) will be saved with passwords in a restricted-access location, and will not contain birthdates, etc. For participant tracking, a list will be maintained linking participants' ID numbers to their names. This list will be kept in a restricted access location and deleted after the study is completed. We have also received a Certificate of Confidentiality from the NIH to protect the confidentiality of our data from legal requests. Finally, specific information collected during this research study will not be available to family or friends or others outside of the study team.

Research staff will be trained to handle (i.e., discuss and refer as needed) unexpected issues that may arise. Because this is an online, app-based study, participant contact with research staff is limited, but participants could disclose this information to staff who contact them for the phone-based follow-up assessment or in response to reminder messages. In all instances, staff will follow a written protocol regarding reporting these incidents to the PI and taking appropriate referral or legal action as indicated. In addition, the IRB at UM will be informed of any incidents as appropriate (see Data and Safety Monitoring Plan).

Because smartphone and app use are common among emerging adults, it is unlikely that others will know that the participant is in a research study just by seeing a new notification on their phone. We will instruct participants to interact with the in private and to consider using a password/passcode or other security features (e.g., biometrics, face recognition log in) on their phone. Participants will be informed that they still risk having content viewed by others if anyone else accesses their phone or has access to their MiWaves app account. Intervention content included in the MiWaves app pilot study will not directly mention details obtained from assessments about participants' own reports of illegal behaviors, instead they will be theoretically grounded content based on MI behavior change (e.g., weighing pros/cons of cannabis use in relation to goals and motives). Furthermore, participants will be explicitly instructed during the consent process that in the event of a crisis they should call 911 or utilize the crisis resources in the resources page of the MiWaves app.

Participants' confidentiality will be breached by the research team only to protect the safety and welfare of research participants and only in accordance with state and federal law. The exceptions to confidentiality include if the participant reports acute suicidality, homicidality, or the physical or sexual abuse of a child— this could happen during a phone-based follow-up assessment. Staff will receive training in crisis assessment and management procedures in the unlikely event that participants reveal suicidal and/or homicidal ideation, or child physical/sexual abuse during some type of study interaction. If the participant discloses suicidality or homicidality during study interaction, staff will attempt to assess risk level and provide appropriate follow-up (e.g., suicide hotline numbers, etc.). Although study assessments will not ask about child abuse, in the unlikely event that a participant self-discloses the abuse of a child, staff will be trained to report this information to local child protective services/family independence agencies via anonymous report. This exception to breaking confidentiality – the case where a participant reveals child abuse, suicidality, or homicidality – will be explained in detail to participants in the consent forms and

prior to completing the reporting process. We will always attempt to inform participants when we must make a mandatory report.

Vulnerable subjects. We will enroll 18-25 year-old emerging adults with regular (3 times weekly or more) cannabis use. Per the NIH definition, children under 18 will not be enrolled; however, a few US states list the age of majority as 19, 20, or 21. For those states where age of majority is greater than 18 years, we have requested a waiver of parental consent and these participants are still considered adults, thus not vulnerable subjects, under NIH guidelines. The age range is critical for this research because rates of cannabis use peak during this developmental period, and interventions delivered during this time can potentially prevent future escalation and consequences associated with use, which could have enormous public health impact. It is important to study this vulnerable population because they are at risk for negative outcomes, and they could experience possible benefits if effective, accessible interventions can be developed.

Potential Benefits of the Proposed Research to Human Subjects and Others. Participation in the proposed study could potentially benefit participants in a few important ways. First, it is possible that the assessments may be beneficial to participants by asking them to review their substance use. Therefore, these assessments may actually serve as a very minimal intervention (as could any study with questions that prompt participants to consider their behaviors). Indeed, participants in our previous investigations have commented that they have found the questions to be helpful; participants in human subjects research focused on substance use for EAs have previously reported benefits of participation such as helping their communities and peers.[106] In addition, participants may be helped by the intervention. In sum, potential benefits for the research outweigh the risks for the participants. With regard to benefits to others, in the event that the intervention tested in the present study is efficacious, the potential benefits to society involve reducing the public health burden associated with cannabis use by way of healthcare expenditures, reductions in impaired driving/motor vehicle crashes, etc.

Importance of the Knowledge to be Gained. Given that cannabis use often reaches a peak during emerging adulthood, as well as the correlation with other substance use, the individual and societal cost of these behaviors, and the fact that many emerging adults do not seek help for their cannabis use, the development of effective and targeted prevention interventions is clearly needed. Given the current penetration of smartphone usage into the lives of young people, the potential reach for interventions using this medium, and the ability to engage emerging adults in interventions that may facilitate behavior change, the knowledge to be gained from this research is significant. The risks to participants are minimal in relation to the importance of this knowledge to be gained and potential public health impact of developing an effective program to reduce the use of and consequences associated with cannabis use among emerging adults.

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