Study Protocol

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Study Title: SnapCoach

Full Study Title: Harnessing social media to reduce cannabis use among adolescents and emerging adults in an urban emergency department

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Background

In the United States, cannabis use peaks during emerging adulthood (ages 18-25)[1] and there is a national trend of increasing cannabis use among emerging adults (EAs).[2] Monitoring the Future (MTF) data show daily use increased from 2007 to 2014-- from 3.5% to 5.9%-- in both college and non-college EAs.[3] These rates coincide with shifting cannabis attitudes,[4] including decreasing risk perceptions,[5] and the belief among youth that cannabis is easy to obtain.[3] EAs living in urban, low socioeconomic areas comprise a population in need of focus due to their higher rates of cannabis use and cannabis use disorders.[2] In addition, interventions initiated at healthcare visits, where youth tend to have higher rates of risky behavior, could have higher impact than if the intervention was given in a different location (i.e. college campus).

Cannabis use is associated with health risks and negative consequences among EAs. Early use of cannabis increases risk for substance use disorders and other problems into adulthood, including increased mortality.[6] Cannabis use is related to higher risk for both short and long term negative physical, psychiatric, and social outcomes.[7] In addition, cannabis use may affect neuro-maturational development processes, causing adverse emotional and cognitive changes, [8, 9, 10] and it can compromise decision making and inhibitory control. [10,11,12] Escalating use is attributed to social ecological factors such as individual level factors (i.e. mental health, delinquency, sex), and social/environmental influences (i.e. peers, norms, parents, community).[13,14,15] However, acute use of cannabis also has alarming effects. Acute use alters executive function (i.e. attention, decision making, inhibition, impulsivity, risk taking, memory, concentration)[9,16] and increases propensity for risky behaviors (i.e. risky sex [17,18], impaired driving [19,20]). Reducing cannabis use is critical due to the high usage and potential negative impact of cannabis use for EAs, especially those in urban, underserved settings with disparities in access to services.

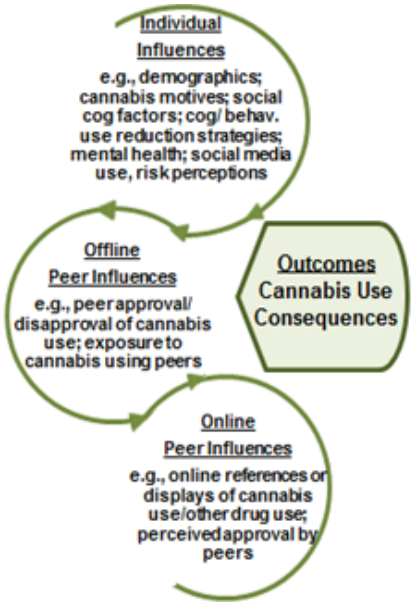

Figure 1. Guiding Framework for Intervention.

The conceptual framework (Fig. 1) guiding our intervention incorporates theories of initiation and escalation of cannabis use and behavior change, including, motivational, behavioral, social cognitive, social-ecological, and SM influence theories. We implicitly incorporate the trans-theoretical model,[79,80] strengths and resiliency-based approaches,[81,82] and principles of harm reduction,[83] with our intervention focus on eliciting alternatives to address motives for use in *SnapCoach*.

Given the role of peer influences in EAs' drug use,[21] harnessing peers for intervention delivery is a potentially viable strategy. Social media (SM) is an intervention platform which can extend healthcare interventions to EAs' individual, social, and environmental context especially because SM has infiltrated EAs' daily lives.[22] A pervasive form of SM for EAs is Snapchat [23,24,25]-- which is why we propose to harness this platform for intervention delivery to potentiate reach, engagement, and efficacy.

For these reasons, we seek to develop and test a social media based intervention for cannabis use among EAs, delivered by health coaches who will be similar age or slightly

older peers (i.e. clinical practicum students, bachelor's level psychology students, master's level public health and social work students). The guiding framework for this intervention can be found in Figure 1.

Objective

The specific aims of this clinical trial is to:

Conduct a randomized clinical trial of the SnapCoach intervention, where we will examine feasibility and acceptability of the SnapCoach Intervention as our primary outcome measures. As exploratory, other outcomes we will examine the preliminary efficacy of SnapCoach (vs. usual care control with attention-placebo; N=approximately 50 per group) on cannabis use (quantity, frequency) and consequences.

We will conduct a randomized clinical trial (RCT), to examine the feasibility, acceptability, and initial efficacy of the SnapCoach intervention. Our goal is to recruit N = 100 participants (as our target N) meeting eligibility criteria, who will complete baseline measures, and be randomized to receive the SnapCoach intervention or a control condition. They will participate in the 4-week intervention/control condition, with a post-test administered at 1-month post-baseline (i.e., end of 4-week intervention period) and a follow-up assessment of outcomes at 3-months post-baseline.

Primary outcomes are feasibility and acceptability of the Snapcoach intervention. Other exploratory outcomes include measures of cannabis quantity and frequency and consequences measured at the 3-month follow-up, examining the effect of the intervention on other substance use (alcohol, other drugs), analyses of moderators and mediators (e.g., sex, cannabis use motives), identification of the most engaging intervention content, dose-response analyses, and measurement of intervention delivery costs.

Aim 2 Methods:

Enrollment

Target enrollment is 100 emerging adults (approximately 50% males and 50% females) between the ages of 18-25, in a 2-arm pilot RCT of SnapCoach compared to an enhanced usual care (EUC) with attention placebo for EAs with weekly cannabis use.

Recruitment Procedures

Participants will be recruited either during or post-emergency department (ED; including urgent care) visit at Hurley Medical Center (HMC) which is a public, academic, Level-1 Trauma Center located in Flint, Michigan. Enrollment will focus on recruiting approximately 50% males and 50% females. Potential participants will be screened for eligibility using a 5-10 minute screening survey. Randomization to conditions will be balanced based on sex (male, female), age (ages 18-20, ages 21-25), and more than once a day cannabis use, using urn randomization in blocks of 4.

Modifications to recruitment procedures for the purposes of remote recruitment are described here:

For remote recruitment, RAs will contact ED patients ages 18-25 who meet screening inclusion criteria (listed below in "Study Eligibility Criteria") within 60 days of discharge to invite them to consent and complete a web-based screening survey. RAs

will determine who to contact by viewing HMC's ED medical records (same records viewed as during in-person recruitment), they may send a text message to let the participant know we will be contacting them. Using contact information obtained from the medical record, RAs will follow a phone recruitment script for these procedures, obtain verbal informed consent prior to starting the screening survey and document RA name and date consent is obtained.

After consenting, interested participants may choose to self-administer the survey online or complete an RA-administered version over the phone. For verbally consented participants completing the survey online, a copy of the screening consent form will appear at the beginning of the survey. Other participants may prefer to interact with us via text message, in this case we may adapt the phone script for text messaging, and we will obtain electronic consent at the beginning of the screening survey. Participants recruited remotely will not receive a token gift for completing the screening survey.

Those meeting eligibility criteria (see below) on the screening survey will be eligible for enrolling in the trial and completing the baseline procedures. RAs will explain the study to participants during the baseline consenting process. Interested participants will be enrolled in the study after completing verbal consent over the phone and RAs will document their name and date consent is obtained. A copy of this consent form will also be shown online at the beginning of the baseline survey.

Briefly, because participants will be identified via reviewing the ED medical chart we are requesting an update to our **waiver of HIPAA authorization** to accommodate remote recruitment. We are also requesting an update to our **waiver of documentation** to accommodate remote recruitment. At screening, consistent with prior procedures, interested participants will be asked to complete an electronic informed consent or verbally consent to complete the screening assessment. In addition, this waiver will apply to remote completion of baseline procedures allowing for verbal consent obtained over phone**.**

Study Eligibility Criteria

Screening inclusion criteria: (1) Emerging adults (ages 18-25) presenting to the Emergency Department (including Urgent Care) on the day of in-person recruitment; presenting within 60 days of contact for remote recruitment and (2) owning a working smartphone. Additional baseline inclusion criteria: (3) weekly or more frequent non-medical cannabis use for the past 3 months; and (4) any Snapchat use in the past month. Exclusion criteria: (1) Does not understand English; (2) presenting to the ED for sexual assault or acute suicidality; (3) unable to provide informed consent due to medical/psychiatric reasons/having a legal guardian; (4) Aim 1 participant.

Study Procedures

After enrolling in the study, EAs will complete a 15-20 minute baseline survey, a 15-30 minute RA administered semi-structured Timeline Follow-Back calendar (TLFB), and a urine drug screen (UDS) (for in-person recruitment), before they are randomized to condition (*SnapCoach* or EUC). They will also complete a 3-minute immediate post-test and provide contact information. For these activities participants will receive $40. When a participant is recruited

remotely, they will not complete the UDS during the baseline procedures. For these remote participants, and when an in-person participant does not complete the UDS during baseline procedures for any other reason, those participants will still be compensated a total of $40. Our consents do not reflect that a participant will still receive $40 if they do not complete the UDS because doing so could adversely affect UDS completion rates among participants who would otherwise be willing to complete the test. Participants will also complete their assigned condition (i.e., *SnapCoach* initial session or EUC: review of health and community resources, with the same information contained in a paper brochure or electronic format depending on type or recruitment). Enrolled participants may also receive small items such as candy, water bottles, notebooks, etc., or small tchotchkes with project logo and phone number (e.g., lanyard or pen) during the study. These tokens are not used as a contingency of study participation.

For those assigned to the intervention condition, the *SnapCoach* initial session is an intervention delivered in the ED and/or remotely (e.g., facetime, bluejeans, vidyo, or Skype for Business) by research health coaches using a computer. The health coaches will use a computerized guide and Motivational Interviewing (MI) to engage EAs and understand their cannabis use. Sessions will be followed by reviewing a health and community resources that the participants keep (provided electronically or on paper, dependent on type of recruitment). This session will take about 30-45 minutes and will be audio-recorded.

Participants will receive pre-selected snaps, up to 3 per day, from health coaches over 4 weeks. The final Snapchat content was created based on focus testing participant ratings and feedback and/or engagement data, and uses the Why/How model of MI. Messages address 1) Why (evoking reasons for change), and/or 2) How (Tools for change). We also send encouraging greetings/affirmations to enhance engagement.

For those assigned to the control condition, they will receive a brochure and review health and community resources that the participants keep (provided electronically or on paper, dependent on type of recruitment), exceeding current standard of care for drug using EAs at HMC. As an attention-placebo, participants will add coaches on Snapchat, and receive messages that do not contain intervention content (e.g., entertainment, trending content such as memes or gifs, weather, current events]). Coaches will thank participants for any responses via 2-way messaging, but will not engage in MI.

As additional enrollment activities, all participants will watch brief introduction videos of the health coaches, who they will be communicating with on Snapchat, welcoming them to the project and introducing themselves. Participants will also “add” the coaches on Snapchat via their mobile phones and the RA will send a snap to confirm the connection. Snapchat involves 2-way messaging; when participants in the intervention condition reply to messages, coaches will discuss content, in a MI-consistent manner[91] using reflections, open questions, and affirmations to participants during designated shift times. Participants who are unable to complete the baseline procedures and intervention while in the ER may be able to complete those activities within 72 hours by returning to the study site or remotely using telephone/video conference and web-based surveys. Likewise, participants who join remotely will have up to 30 days after providing consent to complete baseline procedures. Coaches will use an electronic log to track ingoing/outgoing messages and metrics such as whether messages were viewed by the recipient and types of content discussed to quantify engagement. Coaches will monitor Snapchat to determine if messages were viewed and send periodic reminders (e.g., via SMS) to

prompt engagement when messages go unopened; these reminder messages will also be recorded on a log.

There will be two follow-up assessments, at 1-month and 3-months post-baseline assessment. After the 4 weeks of interacting with health coaches on Snapchat, participants will be completing a 20-minute online, video, phone or in-person (depending on participant preference) 1-month follow-up assessment ($25), and an in-person, online, video or phone (depending on participant preference) 3-month follow-up assessment which includes a web-based survey, the RA-administered TLFB, and a UDS (if in-person) to encourage accuracy of substance use reporting. Participants will receive $40 for the 3-month assessment. When a participant is recruited remotely, they will not complete the UDS for the 3-month assessment. For these remote participants, and when an in-person participant does not complete the UDS at the 3-month assessment for any other reason, those participants will still be compensated a total of $40. Follow-up assessment reminders will be sent in a variety of ways which may include via e-mail, private Snapchat messaging, SMS text message, mail and/or phone call and other social media, based on contact information participants provide at the enrollment assessment. Three-month follow-up assessments completed in-person may be done at the HMC, or other community locations for participant convenience. During the RA-administered TLFB, the participants will view pictures and response cards either on paper (when in person) or given the option to view them electronically when completed over the phone (sent to the participant via preferred method, e.g., email, text, or in a shared online document, etc.). The RA-administered TLFB and intervention sessions will be audio-recorded. Whenever possible, follow-up staff completing assessments will be blinded to condition assignment.

Measures

We will use reliable, valid measures from prior work with EAs, reflecting our conceptual model: demographics; SM involvement; cannabis use, motives, and consequences; and protective strategies, etc. (Table 1). Some measures (e.g., intervention ratings) were created for use in this study.

Table 1. Measures. (S=Screening, B=Baseline, I=Immediate Post-test, 1M=1-month follow-up, 3M=3-month follow-up	
Individual Level and Descriptive Characteristics	
Demographics: Age, Sex, Race, Ethnicity (adapted from national surveys, e.g., the Youth Risk Behavior Survey [39])	S
Demographics: Gender identity, Sexual Orientation, School Status, Employment, Living Situation, Children, Marital Status, Pregnancy (adapted from national surveys, e.g., the Youth Risk Behavior Survey [39])	B,3M
Demographic: Parents and Personal Income [86,87]	B
Service Utilization: ER and Urgent Care [86,87]	B,3M
1-minute delay discounting task [84]	S,1M,3M
Snapchat involvement (modified) [22,40,41,42]	S
Comprehensive Marijuana Motives (modified) [43]	B,3M
Perceived risk of cannabis (modified for different cannabis modalities) [44]	S,1M,3M
Importance, Self-Efficacy, Intention Rulers [45,46]	B,I,1M,3M
Cannabis acquisition, strain, and medical marijuana[47,48,49,50,51,74] Cannabis acquisition Preferred Marijuana Strain Medical Marijuana	 B,1M,3M B S,3M
NIDA modified ASSIST [65,66,85]	S,3M
Alcohol use frequency (AUDIT-C) [73]	S,3M
Tobacco and Nicotine use (modified) [65]	S,1M,3M
Mental health: Patient Health Questionnaire-2; Generalized Anxiety Disorder-2 [52,53,54,55,56,57,58,59,60,61]	B,1M,3M
Protective Behavioral Strategies for Marijuana (modified) [77]	B,3M
Gun Carriage [75,76]	B
Hope [78]	B,1M,3M
Peer/Social Influences	
Cannabis online norms and exposure [64,41]	B,1M,3M
Exploratory Outcomes	

Cannabis use method, frequency and quantity [74] (modified) Smoke, Vape, and Dab (frequency, quantity) Drink and all methods combined (frequency, quantity) Number of days all methods combined Number of days vaped	 S,3M B,3M B,1M,3M 1M
Cannabis and Other Drug Use Frequency, Alcohol Quantity/Frequency(TLFB)[67,68,69,70]	B,3M
Brief Marijuana Adolescent Consequences Questionnaire (modified)[71]	B,3M
Impaired driving (modified) [72]	B,3M
Primary Outcomes: Feasibility/Acceptability of Intervention	
Brief Intervention acceptability ratings (created for this study)	I
Snapchat acceptability ratings (created for this study)	1M
Brief intervention feasibility (e.g., % of participants completing brief intervention)	I
Snapchat health coaching feasibility (e.g., % of participants who complete process of adding health coach on Snapchat, % of participants who reply to at least 1 Snapchat message)	I,1M

Data Management and Analysis

Randomized participants will be included in intent-to-treat analyses, regardless of group engagement. By design, groups will be balanced based on sex, age, and more than once a day cannabis use, using urn randomization in blocks of 4; we will validate randomization by evaluating covariate balance between groups. If significant differences that could be confounding emerge, we will adjust for those variables or conduct stratified analyses.

Analyses pertaining to primary outcomes of feasibility and acceptability of the intervention are primarily descriptive in nature (e.g., % completing the assigned intervention condition, % engaging in Snapchat messaging, ratings of intervention satisfaction).

For analyses of other exploratory outcomes pertaining to cannabis use, alcohol, and drug use, we will first compare groups on cannabis quantity and frequency using basic two sample comparisons, operating on the pre-post differences (e.g., 3M-Baseline) to test for treatment effects. Our first choice will be a two-sample *t*-test to compare the pre-post differences between groups; considering non-parametric alternatives as needed. To assess changes in the dependent measures (e.g., use days, quantity, cannabis consequences) over follow-up we will use generalized linear mixed models (GLMMs) to jointly study the 1M and 3M outcomes, where possible, while adjusting for correlations between data points (e.g. repeated measurements on individuals). While adjustment for the baseline measurement is important for guarding against regression to the mean in RCTs[195], using this baseline adjustment at every time point can result

in overestimation of the treatment effect when there are multiple follow-up points. It has been shown that baseline adjustment at only the first follow-up (1M in this case) corrects this overestimation while also guarding against regression to the mean, which will be our approach. Within this framework, we will conduct exploratory sub-analyses of whether the intervention effect is accumulating or weakening over time, by including time-by-group interactions. If the need is ascertained, we will control for confounders through their inclusion in the model as covariates. Our initial specification will be a linear mixed effects model (with Gaussian error distribution) with only a random intercept to capture within-individual dependence, but this choice will be scrutinized by examining model diagnostics and evaluating the veracity of modeling assumptions. As the need is ascertained, we will examine other distributional choices (e.g., Poisson, Negative Binomial) and more complex random effects structures (e.g., autoregressive).

Other analyses**.** *Moderation:* To assess potential moderators we will include interactions with treatment group in the GLMM models above. Potential effect modifiers will include sex and age. *Mediation:* To test if cannabis motives and other variables (e.g., mental health symptoms) mediate treatment effects, we will use Imai's causal mediation analysis framework, that is robustly implemented in the R package *mediation*. Traditional mediation analysis can be susceptible to bias; one source of this bias is the limitation to the classes of statistical models (e.g. the linear structural model of Baron and Kenny), that can be accommodated in traditional mediation analysis. Under technical assumptions of sequential ignorability, mediation effects are identifiable using Imai's framework when models for the mediator and for the outcome that are non-linear, have discrete (nominal or ordinal) or continuous outcomes, include random effects, or are non-parametric. *Engagement:* Daily content ratings assessed by tallies from Snapchat messages logs (e.g., content, messages sent/received) will be calculated for different content areas (e.g., free time, stress, drug/alcohol-related) and assessed descriptively to see types of content with high response rates. *Cost:* To estimate intervention we will calculate summary statistics for the total intervention-specific costs and mean costs per participant, with confidence intervals. Costs will be reported with/without start-up and development, for example, including costs for recruiting and training coaches as well as their clinical supervision. As with prior work, net costs (savings) will be calculated by subtracting mean costs per participant in the control group from costs per participant for the assigned condition, also calculating the incremental cost effectiveness ratio (difference in mean cost of intervention vs. control divided by difference in mean effectiveness between intervention and control). Change in health benefits will be measured as the difference in cannabis consequences per month for the intervention vs. the control, expressed in dollars per consequence averted. Sensitivity analyses to evaluate alternate assumptions for estimated costs will be conducted. Given likely skewness, we will identify appropriate methods for generating confidence intervals that do not rely on the normal distribution (e.g., non-parametric boot-strapping).

Power calculation and sample size

Aim 2: The sample size is N = 100 (approximately 50 per group). For our primary analytic goal – examining feasibility and acceptability this is acceptable. With regard to other exploratory analyses estimating treatment effects – we are comparing two groups of size n = 50. Assuming no substantial covariate adjustment is needed, testing the significance of the treatment effect at a single time point will be equivalent to the comparison of two means, for which we use Cohen's D (0.2: small, 0.5: medium, 0.8: large) as an effect size. Under the expected sample size, we will have sufficient power (>80%) to detect effects on both our cannabis and other substance use outcomes if d > 0.56, a medium effect size. Although the required effect size is non-negligible, the proposed pilot will provide the critical data necessary to inform the power analyses for a subsequent efficacy trial. While effect sizes from pilot studies

can have large standard errors and be unstable,[202] we can use these pilot data to estimate point estimates and confidence intervals for our treatment effect sizes using the R package MBESS[203].

Data Confidentiality Plans

Our study team will take the following steps to minimize potential confidentiality breaches. As done in prior research and deemed HIPAA compliant by the IRBs at University of Michigan (UM) and HMC by use of a waiver of HIPAA authorization, minimal clinical data will be collected on ED patients who refuse to participate in the screening survey, and on ED patients who the research assistants fail to approach or contact (for remote recruitment). ED-based intervention, TLFB assessment sessions and any phone interviews (e.g., in the event a person cannot attend a follow-up in person, or during remote recruitment, we can administer the TLFB by phone) will be audio-recorded and will be destroyed after the conclusion of the study.

For each stage of the proposed research investigation, participants' names and contact information will be stored in a secure, password-protected database, separate from their study data and only accessible to members of the research team for research purposes. Paper copies of signed consents and completed contact information forms will be stored in locked file cabinets only accessible to study staff, separate from study data. Any additional documents with identifying information linked to individual ID numbers will be only accessible by study staff and stored separate from study data, and in locked file cabinets or in restricted access folders on a secure server and destroyed at study completion.

Participants' Snapchat IDs can be viewed on study cell phones; however, we will change the front page of coaches' Snapchat apps to display generic participant IDs. Study cell phones and tablets (devices used for data collection and participant communication) will be password protected, use UM encryption (e.g., Hub) whenever possible, and only accessed by study 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. The major risk for participants in this study is the violation of confidentiality. This risk is due to the disclosure of personal information regarding the use of an illegal substance, and is heightened due to the audio recording and use of social media. The informed consent will contain a statement about exceptions to confidentiality which include if the participant expresses suicidality, homicidality, or the physical or sexual abuse of a child. We expect that participants will not disclose such information in the context of Snapchat messaging, but should information to this effect be shared, we will provide appropriate referrals to resources and follow appropriate reporting procedures. Coaches will review limits of confidentiality at enrollment, will always notify participants when mandatory reporting or breaking of confidentiality is required, and will only disclose the minimum information necessary as required by law.

Consent forms will also explain that participants' activity on Snapchat is still accessible to Snapchat and subject to the app's terms of use. We will also encourage participants to use a password/code on their phones and to view study messages in private spaces. Messages received on the Snapchat app are not viewable until the phone is unlocked, the app is opened, and the message is clicked on. Thus message content will <u>not</u> be viewable: when a phone's

screen is locked, in the notification bar, or without opening the app and choosing to look at the message.

Participants will be informed that we will take steps necessary to secure their data. Survey data collected will be stored in secure, password-protected databases on the secure U-M network. When sending Snapchat messages, coaches will do so in private spaces using privacy screens where others who are not part of the research team could not see the data. Study cell phones and tablets used to send Snapchats will be password protected and use UM encryption (e.g., Hub) whenever possible, which is required of all mobile devices accessing the U-M network. Encryption programs used by UM enables safeguards against data compromise, malware, and ransomware and have a user portal to manage devices in case of theft, loss, or forgotten passwords. The computerized surveys are designed and administered using Qualtrics Research Suite through the University of Michigan (http://www.qualtrics.com/), which meets the HIPAA standards, and is where data will be stored based on study ID securely and separate from any identifying information.

Protections Against Risk

To minimize the risk of violating confidentiality, RAs 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 U-M Program for Education and Evaluation in Responsible Research and Scholarship system and will complete CITI Good Clinical Practice Training. Staff will be trained to conduct assessments and the initiation session where no one can overhear the conversation. Participants engaging in remote recruitment or follow-up activities will be encouraged to complete interviews and assessments in private locations where no one can overhear. Consent documents will fully explain the study procedures, potential risks, and potential benefits. At baseline, participants will also be asked to sign (for in-person recruitment) or verbally agree (for remote recruitment) to a User Safety Agreement that includes guidelines for interactions with coaches (e.g., agreeing not to send graphic images) based on a procedure used in our recently completed Facebook study.

Unique identification numbers will be assigned to participants. Any data forms will be coded with this number, rather than with a name. Computer data files will be saved with passwords on a secured network, and will not contain names, birthdates, etc. See “Data Confidentiality Plan” above for further information on protection of participants’ data. Furthermore, as is standard practice, this study is covered by 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 for use outside of research purposes. All data will be collected specifically for use on this project; however, de-identified data may be used for future research studies or distributed to another researcher for future research studies.

Research staff and health coaches will be trained to respond to any emotional distress and to refer participants to appropriate resources as necessary. All participants are free to terminate the study at any time or refuse to respond to any questionnaire item. The integration of motivational interviewing techniques will be non-confrontational and eschew any form of coercion or threat. Further, the risk of potential coercion is minimized by using standard

recruitment scripts to avoid undue influence. All enrolled participants will also receive a substance use and mental health resources at baseline and follow-up.

Regarding Snapchat messages, content of new messages do not appear on a participant's notification screen and are only viewable when opened by the participant, taking at least 2-3 clicks before content is viewable. Because Snapchat use is common among emerging adults, it is unlikely that others will know that the youth is in a research study just by seeing Snapchat or a new notification on their phone. We will instruct participants to view messages from the study Snapchat account where they cannot be seen and to consider using a password/passcode on their cell phone. Snapchat messages are automatically deleted after viewing, with the exception of immediately re-viewing one message per day or if a participant chooses at the moment they receive it to save certain messages. Participants will be informed that they still risk having unread or saved messages viewed by others if anyone else accesses their cell phone or has access to their Snapchat account.

Participants' confidentiality will be breached by the research study only to protect the safety and welfare of research participants and only in accordance with state and federal law. Participants will be informed that coaches are not monitoring Snapchat 24/7 and that it should not be used for crisis situations, however staff will receive training in crisis assessment and risk management procedures in the unlikely event that participants reveal suicidal and/or homicidal ideation, or child physical/sexual abuse during study interactions (including Snapchat). If staff becomes aware of any of these issues, they will follow our standard risk assessment guidelines for in-person encounters and our standard written guidelines for attempting to contact participants remotely in the Snapchat messaging phase (e.g., message/text/email hotline number and by phone). In cases of psychiatric distress, staff are trained in strategies that include privately messaging/contacting the individual using MI and empathically encouraging use of referral information or other coping skills. Staff will immediately page on-call supervisors (including Dr. Bonar, Dr. Walton, or Dr. Carter) for consultation in cases where participants express moderate or high/imminent risk. Staff will also be trained to manage responses to potentially inappropriate messages from participants (e.g., asking on dates, sending explicit image).

Regarding reporting of adverse events, we will follow the following procedures for UM IRBMED and the National Institute on Drug Abuse (NIDA), as specified in the Data Safety Monitoring Plan approved by the NIDA Project Officer (PO). Life-threatening serious adverse events (e.g., hospitalization as a result of suicidal ideation uncovered during study interaction) related to the study will be reported to IRBMED, NIDA, and the Medical Monitor no later than 72 hours after learning of the event. All other SAE's (regardless of study relatedness) will be initially reported to the NIDA PO by phone/email no later than 72 hours after learning of the event. Non-threatening potentially serious adverse events that are causally related to the research will be reported to the IRBMED within 14 days of learning of the event. A summary of the serious adverse events that occurred during the previous year will be included in the annual progress report to NIDA. We will follow the Hurley IRB guidelines for reporting both protocol deviations and adverse events to Hurley IRB, as well as follow the UM IRBMED guidelines for reporting protocol deviations to UM IRBMED.

Potential Benefits

We believe the potential for benefits outweighs the minimal risks associated with this study. It is possible that the assessments may be beneficial to all 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 interviews regarding risky behaviors). Indeed, participants in our previous investigations have commented that they have found the questions to be helpful. Second, all participants will receive health and community resources (that will be updated from our prior studies), with referral information including suicide hotlines, and resources for substance use and mental health treatment.

Importance of Knowledge to be Gained

Given that cannabis use behaviors often begin and reach a peak during adolescence and 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 may not receive traditional preventive services or access treatment, the development of effective targeted prevention programs is clearly needed. Given the current penetration of social media into the lives of young people, the potential reach provided by extending clinical-care interventions through a popular and widely used medium is significant. In addition, the ability to harness peer influences to create behavior change and the knowledge to be gained from this research is also significant. The risks to participants are reasonable 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 at-risk emerging adults.

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