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Official Title: A social media intervention for high-intensity drinking in a national sample of emerging adults

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Study Protocol

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Study Title: SnappyHour

Grant Title: A social media intervention for high-intensity drinking in a national sample of emerging adults

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Background

Alcohol is the most prevalent substance of abuse consumed by U.S. citizens age 12+, costs the U.S. $249 billion per year[21], and is responsible for ~88,000 deaths per year.[22] Alcohol use often begins in adolescence (ages 12-17); emerging adults (EAs, ages 18-25) have the highest prevalence of past-month use at 57.1%.

The 2017-2021 NIAAA Strategic Plan notes increases in extreme binge drinking[23] (having 8+ drinks for women, 10+ for men, i.e., twice a traditional "binge" episode), also called high intensity drinking (HID), which increases risk for adverse consequences. Data from Monitoring the Future (MTF) show that 1 in 9 (11%) EAs reported a past 2-week HID episode of 10+ drinks, with 1 in 24 (4%) reporting episodes of 15+ drinks,[24] with higher rates of HID in men versus women. Peak prevalence of HID occurs around ages 21-22;[25] Among past-year drinkers, past 2-week HID ranges from 14% to 17% across ages 18 to 26.[26] HID is associated with simultaneous alcohol/cannabis use[27] and alcohol/non-medical prescription drug use (NMPDU),[28] increasing risk for overdose.

Excessive alcohol use is responsible for over 88,000 deaths in the U.S. per year[4] and poses a significant burden on public health and safety, with alcohol-related Emergency Department visits increasing an estimated 57% from 2001-2011. Alcohol consumption, particularly binge drinking (4+/5+ drinks), reaches peak prevalence in emerging adulthood (ages 18-25).[6] Emerging adults (EAs) comprise a high-risk group for short and long-term consequences of alcohol use such as increased risk for sexual assault, injury, risk-taking (e.g., unprotected sex, fighting), social/interpersonal problems, academic consequences, and risk for future alcohol use disorders.[7] High intensity drinking may intensify these risks.

There are no prior interventions for HID specifically, and EAs who engage in HID may not respond to traditional interventions, in part because cognitive factors (e.g., motives) associated with HID appear to differ from those related to traditional binge drinking. Thus, it is critical to identify optimal strategies for interventions that may build upon principles of efficacious BIs (e.g., motivational interviewing [MI] approaches, harm reduction), while reaching a broader population of EAs (outside of school/healthcare), and targeting the most extreme, acutely risky form of drinking, HID. Such interventions could disrupt high-risk alcohol use trajectories among the riskiest drinkers, preventing costly public health outcomes of HID for EAs.

With constant use of mobile social media (SM) by EAs, SM is a novel platform for intervening within EAs' daily lives, outside of school or healthcare settings. Mobile messaging apps (e.g., Snapchat) uniquely create a direct, private mode of communication to an individual allowing delivery of dynamic intervention content (e.g., videos, messages, photos) that is organic to EAs' daily lives and addresses the factors associated with high- risk drinking (e.g., motivations, peer influences). EAs commonly interact with similar-aged peers on SM, thus we seek to leverage peers as health coaches for intervention delivery to act as positive prosocial influences, facilitating and encouraging rapport and connection in a highly-used, widespread, and scalable platform. As of 10/2018, Snapchat had 186 million daily active users, an increase of 8 million over the past year.[17] For EAs in the U.S., ~80% use Snapchat, with users under age 25 spending M=40 min/day on the app.[18,19]

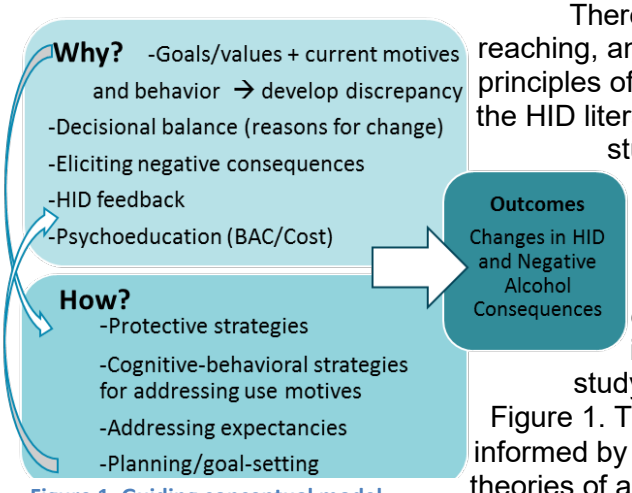

Figure 1. Guiding conceptual model

There is an urgent need to create tailored, scalable, wide-reaching, and cost-efficient interventions for HID that build upon principles of efficacious alcohol interventions and empirical data from the HID literature.[8] HID is not a drinking pattern specific to college students, and occurs among non-college EAs as well. Interventions that harness technologies such as SM that have individual, private delivery features (e.g., auto-delete) to intervene within EAs' daily life contexts could have high impact, unconstrained by setting. Thus, we are seeking to develop and test a peer coach delivered SM based intervention for EAs engaging in High Intensity Drinking. The study will be guided by a conceptual framework, as illustrated in Figure 1. The "Why, How"[20] model of Motivational Interviewing is informed by Self-Determination Theory[49,50] in concert with motivational theories of alcohol use.[51,52] We are implicitly guided by the trans-theoretical model[53,54], strengths and resiliency approaches,[55,56] principles of

harm reduction,[57] and social ecological approaches,[58-60] including SM influence.[61]

We propose to iteratively develop and pilot test, in a RCT design, a peer-led SM intervention for HID among male and female EAs. We will use national online recruitment and bachelor's-level peers trained in MI and cognitive behavioral strategies to deliver dynamic intervention content via Snapchat over 8 weeks, focusing on the "Why, How"[20] model of MI to address HID. Given that EAs with HID may have experienced consequences, but are likely to be ambivalent about ceasing alcohol use, engaging EAs focused on reasons for change (Why, eliciting benefits/consequences) and use of protective strategies (How) using a participant-centered MI-based approach to reduce negative consequences and overall consumption is needed.

In summary, we propose developing a theory-driven MI-based SM intervention for HID using Snapchat due to: 1) the modest efficacy of prior BIs for EAs' alcohol consumption, which have not targeted HID; 2) the ability to harness peer coaches to promote intervention engagement; 3) the frequency of Snapchat use by EAs, a highly used, relatively private medium; 4) the ability to include messages in varied formats (e.g., video, images, text) by which intervention content can stay novel over time; and 5) the use of auto-deleted private Snapchat messaging, wherein EAs may be more comfortable engaging with coaches about intervention content.

Objective

In this project, there are two specific aims:

Aim #1: Develop a SM mobile-messaging peer coach intervention for EAs with HID. With iterative focus testing, we will develop intervention content via crowdsourcing (mTurk), an EA advisory panel, student research assistants, and iteratively focus test it with up to 50 EAs (25 male/25 female) recruited online nationally.

In this aim, our goal is to recruit 50 participants, who will meet the eligibility criteria, provide consent, and complete a baseline survey, inclusive of the intervention content provided by other EAs through crowdsourcing, the advisory panel, and research assistants. The 50 EAs will help further curate the intervention content by providing feedback in preparation for Aim 2.

Aim #2: Conduct a randomized clinical trial of the SM intervention (*SnappyHour*), where we will examine its feasibility and acceptability as our primary outcome measures. As exploratory, other outcomes we will examine the preliminary efficacy of the SM intervention versus control (referral to NIAAA's Rethinking Drinking guide; N=50-52 per group) on HID episodes and consequences. Assessments will occur after intervention-start at a 2-month post-test and a 4-month follow-up to also examine other exploratory outcomes, including secondary effects on other substance use, and measurement of potential moderators (e.g., sex) and mediators (e.g., drinking motives). We will also quantify engagement with content (e.g., *type*: videos, images; *topic*: benefits, protective strategies; dose) and costs to guide future implementation.

After iteratively developing intervention content (Aim 1) using national crowdsourcing, feedback from an EA advisory group, and focus testing with EAs recruited via SM nationally, we will recruit (Aim 2) 102 EAs with HID for a pilot RCT. Our approach is guided by prior work on BIs for adolescent/EAs alcohol use, use of SM to recruit EAs, MI training protocols for peers, and packaging interventions for translation.

Aim 1 Methods: Intervention Development

We will iteratively develop SM content for the 8-week intervention via multiple sources, using a participatory action approach and user ratings during focus testing with EAs with HID recruited nationally (Fig. 2). We will have workers from a crowdsource platform (mTurk; a workforce where workers are paid token amounts for brief tasks) create a library of potential content. A diverse advisory group, consisting of approximately 5 Research assistants (RAs) and 5 community members will first provide feedback on content acceptability and intervention preference. Thus, content will be selected for user focus testing based on fit with our conceptual model, appropriateness (e.g., no images glamorizing use, offensive jokes) and ratings of receptivity by EAs. Up to 50 EAs will be recruited from social media ads online to further refine and develop intervention content. All Aim 1 participants will receive a resources list and link to Rethinking

Drinking at the conclusion of participation.

Enrollment: We aim for a target enrollment of up to 50 EAs (targeting ~50% male/female) nationally, ages 18-25, who report past-month HID and Snapchat use, in two waves of approximately 25 each.

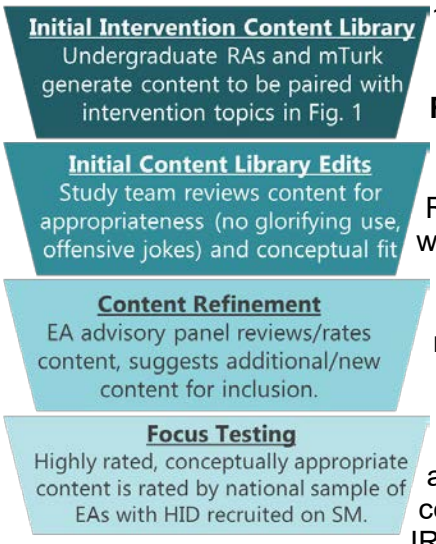

Figure 2. Developing and refining intervention content

Recruitment and Study Procedures: 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 oversample 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 1 race and 20% Hispanic.

Participants will be nationally recruited from advertisements on SM platforms (e.g., Snapchat, Facebook, Instagram). The advertisement will re-direct users to an online privacy notice page (required by Snapchat) and an online informed consent page (waivers of documentation and parental consent [for states where 18 is not age of majority] will be obtained from the IRB), participants will be invited to print or save a copy of the informed consent before moving onto a brief online screening survey on Qualtrics to determine eligibility for Aim 1.

Following determination of eligibility, negative screens will receive a thank you page ending their participation in the study. This page will also include the study's website which will include a resource list with contact information for national organizations that can provide assistance in the areas of substance use and physical/mental health and well-being. No identifying information will be collected from participants who are not eligible for the study, although the IP address of the device used to complete the survey will be automatically recorded by Qualtrics.

Eligible participants will be notified of their eligibility and asked to provide contact information for verification purposes and to contact them with the baseline survey. After completing the contact information form, participants will see a "Thank You" message.

From the pool of eligible and verified participants, study staff will select participants to receive an invitation to continue to the next part of the study (baseline). Screening items will be used to select participants representing a variety of characteristics (e.g., gender, race/ethnicity) to ensure that intervention content is widely acceptable among individuals in the study's target age group.

Selected participants will receive an email containing a link to the consent and baseline survey in Qualtrics. Participants who indicate that email is not their preferred method of communication will receive a text/social media notification (depending on their preferred contact method) directing them to the email with their consent and survey link. We will send reminders via different contact methods (e.g., email, private message on social media, text) to encourage completion of this survey.

After completing the baseline survey, participants will be redirected to a separate Qualtrics form and asked to indicate their payment preferences. Upon completing this form, participants will again see a "Thank You" message that includes the study's website which includes a resource list, including Rethinking Drinking. Participants who fully consent and successfully complete the baseline survey to rate user acceptability and intervention preference on the proposed intervention content will receive a $35 electronic gift card as compensation.

Based on ratings from the first wave of ~25 people (Wave 1), we will archive, modify content, add new content as needed, and recruit Wave 2 in the same manner to rate revised content. In both waves, participants will also rate their preferences (e.g., time of day, number of messages per day, days received, etc.) for delivery of intervention snaps.

Study Eligibility Criteria. Screening inclusion criteria includes: (1) be age 18-25 (2) reside in the U.S. (3) being able to read English. Additional eligibility criteria for baseline includes (1) self-reported past-month HID (using an item based on MTF[144]) and (2) regular Snapchat use (at least 3 days/week), consistent with our proposed intervention structure to send snaps on approximately 3 days/week. Participants will be excluded if they fail identity verification based on: 1) IP addresses, 2) survey time completion, 3) repeat

attempts or 4) survey responses. We will turn on the "Prevent Ballot Box Stuffing" option in Qualtrics to prevent repeated attempts from the same IP address.

Measures.

Screening Survey. Study eligibility will be assessed through a screening survey using items adapted from prior work or created specifically for this study. The screening survey includes questions inquiring about participants' demographics based on national surveys, (e.g., the Youth Risk Behavior Survey[146]), past-month HID (eligibility criteria) based on MTF[144], and social media involvement.[147] Screening measures will also query participants' other substance use.

Baseline Survey. Participants will respond with individual and descriptive characteristics regarding their demographics information and background characteristics using items based on national surveys (e.g., Youth Risk Behavior Survey[146]). Additional questions include gathering feedback on snapchat intervention preferences (e.g., when to share content, frequency of snaps to send, additional content that they would like to see). Next, participants will review and rate content for potential inclusion in the intervention, based on feedback received from the advisory panel and research assistants. Participants will also have the opportunity to suggest additional intervention content that may be relevant to this topic.

Data Analysis

Intervention development will involve identifying content with superior ratings by participants, and does not involve formal statistical inference. We will conduct descriptive analyses of participants' ratings to inform refinements of the intervention content.

This protocol initially focused on the methods for Aim 1 of the study. As we prepare to commence Aim 2, below we are submitting an amendment to reflect protocol changes to Aim 2 as a result of the formative work conducted in Aim 1.

Aim 2 Methods: Pilot RCT

Starting in Year 2, in a 2-arm RCT, we will pilot the *SnappyHour* intervention versus a control group (n=50-52 per group) among EAs with HID (balanced on sex and age group). Screened, eligible participants will complete baseline measures, their assigned condition for 8 weeks, a 2-month (after intervention-start) post-test after the active intervention period (to measure intervention acceptability, changes in outcomes during the intervention period, and mechanisms of change), and a 4-month (after intervention-start) outcomes assessment.

Enrollment: Target enrollment is 102 EAs (approximately 50% males and 50% females) between the ages of 18-25. We will conduct a 2-arm pilot RCT of the Snapchat intervention versus a control group (n=50-52 per group) among EAs with HID (balanced on sex and age group). We will enroll participants in 3-4 waves to allow breaks between 8-week intervention periods for staff.

Recruitment and Study Procedure. Recruitment and enrollment procedures will follow those used in Aim 1 above. 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 oversample 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 1 race and 20% Hispanic.

Study participants will be recruited via SM advertisements that appears on social media applications (e.g., primarily Snapchat, but Instagram, Facebook etc., as needed). Ads will be targeted to U.S users ages 18-25. When users swipe up or click on an advertisement, they will be redirected to a privacy notice (as required by Snapchat, our primary recruitment modality), and subsequently, a screening informed consent page. After indicating their agreement to the consent online (with a waiver of parental consent for states with age of majority >18 and a waiver of documentation of consent given our online procedures) and completing a captcha (to protect against bots), participants will complete a ~5-min eligibility survey.

Participants will have the option to print or save a copy of the screening informed consent form before moving on to the online screening survey. Prior to conclusion of the screening survey, regardless of their eligibility, participants will view a page within the survey that includes crisis information and the study's website which will include a resource list with contact information for national organizations that can provide assistance in the areas of substance use and physical/mental health and well-being. Participants will click a button to acknowledge they have viewed this information.

Individuals who screen negative will receive a thank you page ending their participation in the study. No identifying information will be collected from participants who are not eligible for the study, although the IP address of the device used to complete the survey will be automatically recorded by Qualtrics. IP address will be used to verify participant's location to confirm that they reside in the U.S. Aim 1 participants are excluded from Aim 2. IP address will be referenced to ensure that Aim 2 participants have not completed Aim 1's baseline survey. Eligible participants will be notified of their eligibility and asked to provide contact information for verification purposes and to contact them with the baseline survey. After completing the contact information form (stored separately from their study data), participants will see a "Thank You" message and link to the study resources.

From the pool of eligible and verified participants, study staff will select participants to receive an invitation to continue to the next part of the study (baseline). Screening items will be used to select participants representing a variety of characteristics (e.g., gender, race/ethnicity) to ensure that the intervention is widely acceptable among individuals in the study's target age group. Selected, verified participants will be invited to view and agree to the RCT consent in Qualtrics, followed by an online baseline survey. Selected participants will receive an email containing a link to the consent and baseline survey in Qualtrics. Participants who indicate that email is not their preferred method of communication will receive a text/social media notification (depending on their preferred contact method) directing them to the email with their consent and survey link. We will send reminders via different contact methods (e.g., email, private message on social media, text) to encourage completion of this survey and completion of study enrollment.

Those who complete baseline measures will be randomized to their assigned condition for 8 weeks, and will later be asked to complete a 2-month post-test after the active intervention period, and a 4-month outcomes assessment. Compensation at baseline will be a $35 electronic gift card (e.g., Amazon.com, Target, etc.) for participants who complete all baseline activities. Compensation will be a $35 electronic gift card for the 2-month post-test and a $40 electronic gift card for the 4-month follow-up.

Inclusion/Exclusion Criteria. For screening, participants must: be age 18-25, reside in the U.S., be able to read English, view, and click on a social media ad. Eligibility criteria for baseline and randomization is self-reported past-month HID (using an item based on MTF[144]) and regular Snapchat use (at least 3 days/week). Participants will be excluded if they fail identity verification (see prior studies[132,133]) based on: 1) IP addresses, 2) survey time completion, 3) repeat attempts, and 4) survey responses. Aim 1 participants are excluded from Aim 2.

Randomization and Consideration of Key Biological Variables. Randomization to conditions will be balanced based on sex and age (18-20, 21-25 years) using urn randomization in blocks of 4. After completing the baseline survey, participants will be informed which condition (intervention, control) they were randomized into via Qualtrics.

Intervention condition. Overview: Participants randomized to the intervention will be initially provided with a link to the NIAAA's guide Rethinking Drinking website, a list of national resources located on our study website, and the study's Snapchat user safety agreement. Participants in the intervention group will be instructed on how to add our study's account as a Snapchat contact. Participants will be invited to accept the friend invite from our study account. Participants may be contacted by a study team member via phone, email, or their preferred method of communication to aid them in adding peer coaches on Snapchat. Once we confirm participants as contacts, peer coaches will send a test/welcome "snap" to confirm the connection. They will also be directed to an orientation video (up to 3 mins) that provides an introduction to how *SnappyHour* works (e.g., frequency and types of "snaps"/ stories to expect, duration, coach availability),

introduces peer coaches, and notes that coaches are not available 24/7 and in the event of crisis the participants should contact 911 or the crisis text line (text "HOME" to 741741). Pre-selected intervention content will be sent to participants up to 7 days a week on Snapchat. Snapchat involves 2-way messaging; when participants in the intervention condition reply to messages, coaches will discuss content, in a MI-consistent manner using reflections, open ended questions, and affirmations to participants during their scheduled shifts.

Intervention Content. Participants will receive pre-selected snaps (e.g., coach-initiated snaps, snapchat stories, engagement cues) up to 3 times per day (with the number and type varying across days to increase novelty), from peer coaches over 8 weeks. Based on our Aim 1 pilot work, we have revised our plan and content for the intervention. Sample content based on iterative participant feedback is available in the uploaded "Aim 2 Snapchat Messaging Description". A variety of snaps and stories will be used to prompt participants to review and discuss intervention themes (see Table 1) and to promote engagement. Snaps and stories sent by coaches include a variety of multi-media messages (pictures, text, gifs, videos, links to articles or coping exercises with screenshots, etc.). The initial content is stored in a content library accessible to staff, but wording will be tailored to the individual participant, consistent with motivational interviewing (MI)

Table 1. Intervention Themes

Dealing with stress	Explore stress management, address coping motives for alcohol use, enhance self-efficacy and behavioral intentions to manage stress
Free time activities	Engage in developing free-time activities that promote healthy and valued activities and avoid/reduce use
What young adults do	Explore online/offline norms for alcohol use, strategies for managing use (e.g., refusal skills), social/conformity motives
Relationships	Engage in developing strategies for managing situations with peers, significant others, and parents; healthy social support
Staying out of trouble	Discuss risk perceptions, protective behavioral strategies (e.g., avoid drunk driving), planning ahead (e.g., safe rides)
Staying healthy	Address physical/health motives (e.g., sleep, pain), long-term health impacts, avoiding risky behaviors, mental health
Handling tricky situations	Address motives in healthier ways; managing temptations with cognitive/behavioral skills
Getting support	Explore benefits of change, planning, and cognitive/behavioral strategies for making changes if desired

Our content involves MI consistent coach greetings that are consistent with the Why/How model of MI. Peer-coaches will encourage discussion of content by eliciting discussion around theoretically-determined intervention topics shown above. Snaps will also be used to encourage engagement. Coaches will reply to comments with MI strategies (e.g., reflection, affirmation), including managing sustain talk (e.g., come alongside, agree with a twist), and eliciting protective behavioral strategies for drinking less. Messages address 1) Why (evoking reasons for change), and/or How (Tools for change). Based on our ongoing cannabis intervention on Snapchat, we have developed a peer coach guidelines outlining basic MI principles, protocols for posting, risk assessment, and peer-coach professionalism. We have also revised the User Safety Agreement from our cannabis Snapchat intervention (HUM00139068) for use in this study which outlines guidelines for participants (e.g., privacy, no snapping opportunities to buy or receive drugs with peer-coaches; no racial or political slurs, respect and confidentiality). Once participants in the intervention group are informed of the group they are randomized to, they are directed to a Qualtrics page containing the User Safety Agreement and they will be sent an additional copy of it via email. Snaps will be monitored during the 8-week period by scheduled peer-coaches who can contact rotating on-call supervisors (all highly experienced in MI) who

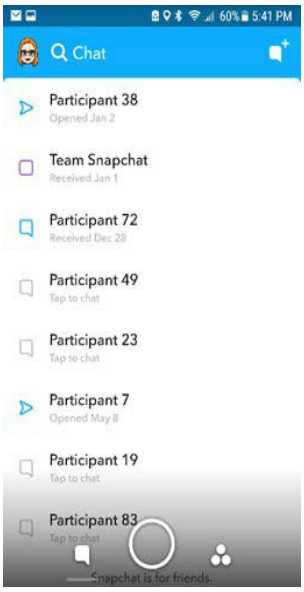

Figure 3. Snapchat screenshot of messages received/opened

include the investigators, study coordinator, and our lab network of clinical post-docs, and clinical social workers, who work as a team across studies address potential participant risk situations. We will note in the orientation video that we cannot monitor snaps 24/7, and include crisis numbers.

Tracking Engagement with Intervention Content. Coaches will track messages in an electronic log, noting whether snaps were known to be viewed (Fig. 3 shows messages sent/opened) and types of content discussed to quantify engagement. Coaches monitor Snapchat to determine if messages were viewed and send periodic reminders (e.g., via SMS) to prompt engagement when messages go unopened; these messages will be recorded on a log.

Coach Responses and Risk Management. If participants respond to snaps of intervention content, coaches will use MI skills[68] (e.g., reflections, open questions, affirmations) to reply during shifts, which will primarily be in the afternoon and evening, based on participant feedback in Aim 1. Coaches will be trained in collaborative MI strategies to manage sustain talk, if any arises. Coaches will have access to on-call supervisors experienced in MI, including Drs. Bonar and Fernandez, the study coordinator, and our lab network of clinical post-docs and social workers. All on-call supervisors have experience managing risk assessments (e.g., suicidal ideation) using procedures from our current online intervention study, where staff private message and talk by phone to participants in high risk situations. See DSMP for more details.

Table 1. Measures

Descriptive Information, Individual and Social Influences	
Demographics (from Youth Risk Behavior Survey[146])	S, B, P, F
Social media involvement[147]	S, P,F
Drinking Motives Questionnaire Revised Short Form[148]	B,P,F
Alcohol Expectancy Questionnaire Adolescent Brief [149]	B,P,F
Perceived risk of HID modified from MTF[144]	B,P,F
Readiness to change alcohol use[150,151]	B,P
Mental health: Patient Health Questionnaire-8 Generalized Anxiety Disorder-7	B,P,F
Protective Behavioral Strategies Scale-20[158]	B,P,F
Peer use of alcohol/HID based on MTF[144]	B,P,F
Alcohol online norms and exposure[74,159]	B,P,F
AUDIT-C	S,P, F
Short-Form PCL-5	B,P,F
UCLA Loneliness Scale	B,P,F
Berkman-Syme Social Network Index (SNI)	B,P,F
COVID-19	B,P,F
Choices for Intervention Topics	B
Strengths and Goals	B
Minute Discounting Task	S,P,F
Brief Assessment of Alcohol Demand	S,P,F
Activity Level Questionnaire	B,P,F
Other Outcomes	
Past-Month HID (eligibility criteria) based on MTF[144]	S, P, F
Brief Young Adult Alcohol Consequences[165]	B,P, F
Alcohol-impaired driving[166]	B,P,F
Daily Drinking Questionnaire	B,P,F
Tobacco and Nicotine use	S,P,F
Cannabis frequency (by modality)	S,P,F
Frequency of Illicit Drugs	B,P,F
Frequency of Rx Drug Misuse	B,P,F
Feasibility/Acceptability of Intervention	
Intervention acceptability ratings	P
Control acceptability ratings	P
S=*Screening, B=Baseline, P=2 month post-test, F=4-month follow-up*	

Control condition: Control participants will be provided with a link to and be asked to review NIAAA's guide Rethinking Drinking.[145] Additionally, participants will be provided with a list of national resources located on our study website. To balance receipt of this information across groups, we will provide the intervention condition participants with a link to review Rethinking Drinking at baseline as part of study resources.

Follow-Up Procedures. Self-report surveys will be self-administered online via Qualtrics at 2-month post-test ($35 compensation) and at the 4-month follow-up ($40 compensation). 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 provided in their

screening survey.

Study Measures. Whenever possible we will use reliable and valid measures from prior studies with emerging adults (Table 1).

Screening survey**.** To assess study eligibility and characterize the study sample, participants will be asked about their demographics, social media involvement, and health behaviors, including alcohol use. The screening survey should last 5 minutes.

Baseline and Follow-up Assessments. Participants will be asked to self-report measures including demographics; SM use; alcohol expectancies, consequences, and motives; protective strategies, etc. Although trial outcomes focus on feasibility and acceptability, the main behavioral dependent measures of interest for related to the intervention are alcohol consumption (e.g., HID episodes, daily drinking questionnaire, AUDITC) and alcohol-related negative consequences. Other measures include: age and sex as potential moderators; and peer influences, risk perceptions, discounting rate mental health symptoms as potential mediators; and feasibility/acceptability (adapted from prior work). The baseline and follow-ups are expected to last 30-40 minutes. The 2- and 4-month surveys will mirror the baseline survey measures with the inclusion of acceptability measures at 2-months and removal of baseline measures of intervention topic preferences and strengths and goals which can be used by peer coaches to tailor intervention content.

Data Management and Analysis

Please see Aim 2 Data Analysis Plan in the DSMP below.

Human Use Considerations and Protections (Aims 1 and 2)

Eligibility and study informed consent will be administered online (**a waiver of documentation of consent is requested**) as the first pages of the screening and baseline surveys, respectively. The consent document will include information on the general nature of the study, privacy rights, expectations for participation, the voluntary nature of participation, and that participation can be withdrawn at any time. Because of the sensitive nature of the information collected, as an added protection for subjects, this research is covered by a Certificate of Confidentiality from NIH. Study documents will make explicit the voluntary nature of the subjects' participation as well as potential situations for breaking confidentiality (see below for more information about limitations to confidentiality). Participants will be informed that their answers to the screening questions will be used to determine their eligibility for a research study. No identifying information will be collected from those who complete the screen and are ineligible or choose not to participate in the study, although the IP address of the device used to complete the screening survey will be automatically recorded in Qualtrics.

Since the age of majority varies across states (i.e., age 18 in most states, age 19 in Alabama and Nebraska, and age 21 in Mississippi), **a waiver of parental consent is also requested** for those participants who are in the study's target age group but are under the legal age of consent in their state of residence (i.e., AL, NE, MS). The same consent document described previously will be used for minors and adults. According to the Federal regulations governing research (45 CFR 46),163 Section 116(d) allows a waiver of the parental permission requirement for informed consent when (a) the research involves no more than minimal risk, (b) the waiver would not adversely affect the rights and welfare of the participants, (c) the research could not practicably be carried out without a waiver, and (d) whenever appropriate, the participants will be provided with additional pertinent information after participation.

a) This study involves no more than minimal risk. Every effort will be made to ensure that study participants are protected from risk. For screening eligibility, we will not collect any identifiers from participants unless they screen eligible for and are interested in enrolling in the main study. Screening data will be anonymous for those participants who are not eligible or interested in the main study. Participants will be informed in the consent document about the procedures taken to maintain and protect their confidentiality, including assigning unique ID, securing data on secure UM servers, and that this study is covered by a Certificate of Confidentiality.

b) The waiver of parental consent does not adversely affect the rights and welfare of the subjects (age 18-20 in certain states). Screening data will be anonymous for those participants who are not eligible, as well as those who are eligible but choose not to enroll in the baseline studies. To the extent possible given legal requirements on information required in the informed consent, the consent form is written in simple terms that should be understandable to individuals of varying ages and education levels. Participants will be able to download a copy of the consent form which contains contact information for research study staff should questions arise following enrollment. Participants who are eligible for the study and are interested in continuing will provide contact information and can indicate the method they prefer for being contacted.

c) The research could not practicably be carried out without a waiver. This research could not be practicably conducted without a waiver of parental consent because we would not be able to ensure confidentiality around the participant's substance use if parental consent were required for participants under the age of majority in their state (age 18-20 in certain states). Lack of a waiver of parental consent would hinder recruitment, particularly of young adults engaging in high-risk behaviors, and more importantly, have the potential to severely limit the generalizability of the findings. Research shows lower rates of young adult enrollment when parental consent is required, and that participants with lower risk (less substance use) are disproportionally enrolled (higher risk/greater use less likely to participate).

d) Whenever appropriate, the participants will be provided with additional pertinent information. After completing the screening and baseline surveys, participants will receive an electronic link which contains resources with contact information for national and community resources, including suicide hotlines, mental health and substance use treatment, etc.

We also request a **waiver of consent for re-consent of minors** (in states where the age of majority is greater than 18) who reach the age of majority in their state while participating in the study (between screening completion and baseline invitation). As described above, this study involves no more than minimal risk to subjects. Given the brief length of time in which a participant is part of this study, it will not be feasible to obtain immediate consent for any minors (age 18-20 in certain states) who reach the age of majority during the study. Furthermore, we anticipate that all study assessments will be completed online.

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 screening and baseline assessment procedures, the risk of violation of confidentiality exists because human participants are giving personal information. Consent documents will contain a statement explaining mandatory reporting requirements for information regarding child abuse and intention to harm self or others. We do not expect that participants will disclose such information in the context of this study, since our assessments do not inquire about these behaviors. However, we will notify participants when/if we must make any mandatory reports based on information they disclose and we will only disclose the minimum information necessary. Participants will be informed in the consent about the procedures taken to maintain and protect their confidentiality.
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.

Unique identification numbers will be assigned to participants. All computerized databases with survey data will identify participants by this number and will be saved on a secure, encrypted, password-protected server. For participant tracking, one electronic document will be maintained linking participants' ID numbers to their names. This password-protected document will be kept in a restricted-access folder on a secure research server. This document will be deleted as soon as the study is completed. All data will be collected specifically for use on this project.

Participants' Snapchat IDs can be viewed on study cell phones/ipads; however, we will change the front page of coaches' Snapchat apps to display generic participant IDs (see Figure 3). Study cell phones and

tablets will be password-protected and only accessed by study staff who have completed and maintain mandatory training in the protection of human subjects and good clinical practices.

For the online surveys, participants will be reminded that they may refuse to answer any questions that make them uncomfortable and that they may terminate the assessment at any time. However, some questions that relate to eligibility and specific outcomes will require response in order to continue in the study and receive payment for the survey. As described above, all participants will also receive substance use and mental health resources via a website link after completing the screening and baseline surveys. 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.

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 screening and baseline 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 not disclose such information regarding suicidality, homicidality, or child abuse as in the context of an online study, but should information to this effect be shared in any interactions with or messages to study staff, we will provide appropriate referrals to national hotlines and follow appropriate reporting procedures. We will notify participants when/if we must make any mandatory reports based on information they disclose and we 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. Consent forms will explain that although intervention Snapchat messages will be sent/received only by study staff, that their activity on Snapchat is still accessible to Snapchat and subject to the app's terms of use. We will inform participants that during their participation that the Snapchat messages received from them are saved for tracking purposes within the study's Snapchat account. We will inform participants that messages are also stored in password-protected computer logs by ID number, not names stored on our internal servers in password protected databases and they will be deleted from study accounts after participation. Text of messages to/from participants may be temporarily copied to a file on the password-protected local device (only accessible by study staff) prior to transfer to the secure drive. For example, this is necessary given frequent VPN network outages, times when we are temporarily kicked off the VPN, or times of shift overlap when multiple staff are logging study interactions. Note that identifiers are not included in temporary logging of these messages. The consent will also state that we cannot guarantee protection of Snapchat data from third-party access. At baseline, participants in the intervention group will be asked acknowledge a User Safety Agreement that includes guidelines for interactions with peer coaches (e.g., agreeing not to send graphic images) based on a procedure used in our prior and ongoing social media-based studies. Although young people post publicly about illegal behaviors such as underage drinking and drug use and on social media[74-79,185-188] and may not be concerned about joining a study discussing alcohol and other drug use, we will remind participants of potential risks.

Participants could potentially experience emotional discomfort as a result of being asked very personal questions or because of intervention content. Because the study takes place solely online via mobile devices and computers, all eligible and verified participants will receive crisis/referral information as part of the emailed informed consent and via a national resource listing from the study's website that will be linked for all participants at baseline and at 2- and 4-month assessments. Intervention participants will be made aware during consent, in the User Safety Agreement, and in the study introduction video that coaches will be "snapping" in shifts and thus may not be available in the event of a crisis. On the closing page of each survey they will be reminded of crisis hotlines/text-lines and national substance abuse and mental health resources should they experience discomfort that they wish to address with a professional. The electronic resource page on the website (sent to all participants at baseline and assessments) will include national resources including suicide hotlines/text-lines, mental health and substance use treatment, etc. 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. If a participant shares specific information about their own dangerous behaviors (e.g., driving impaired, self-harm), we will privately message them to express concern, provide safety plans, and discuss referral information, using protocols established in our prior and ongoing work.

Participants will be informed that we will take steps necessary to secure their data. Online data collected as part of screening and baseline assessments and analysis of intervention interactions will also be stored in secure, password-protected databases on the secure U-M network. Participants will be instructed at the close of each web-based survey (e.g., screening, baseline, post-test, follow-up) of steps they can take to further protect their privacy (e.g., clear browser history). In Aim 2, peer coaches sharing content via Snapchat 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 iPads (which have apple encryption) used to send and store Snapchats will have strong password protection and will only be accessed by study staff in private locations.

These risks will be noted as a possibility in the informed consent document with a statement encouraging participants to not leave their mobile devices or computers open/unlocked (i.e., they will be encouraged to use a passcode), and not to leave study webpages open and viewable when not using them. 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, participants will choose how they wish to be contacted by the study for surveys and reminders (e.g., email, text message, social media messages) and in any of these contacts we will not include sensitive information about substance use.

Protections Against Risks

To minimize the risk of violating confidentiality, RAs will make every effort to ensure that study data are always kept confidential. Research staff will sign a pledge of confidentiality. 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. 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., Snapchat message logs) will be coded with this number, rather than with a name. Computer data files (e.g., screening/baseline/ follow-up data, message logs, contact information database) will be saved with passwords on a secured network, and will not contain names, birthdates, etc. For participant tracking, one list will be maintained linking participants' ID numbers to their names. This list will be kept in a password-protected restricted folder on a secure research server. This list will be deleted as soon as the study is completed. In accordance with NIH rules, we will also receive 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. All data will be collected specifically for use on this project

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 ipads (which use apple encryption) used to send Snapchats will be password protected and only accessible to study staff, as commonly done in our research studies.

Research staff will be trained to handle (i.e., discuss and refer as needed) unexpected issues that may arise. Because this is an online study, participant contact with research staff is limited, but participants could disclose this information via Snapchat messages or to staff who contact them for follow-up reminders. 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 board at UM will be informed of any incidents as appropriate (see Data and Safety Monitoring Plan). Of note, the investigators have substantial prior clinical and research experience with at-risk populations, including online research with at-risk drinkers.

For the online surveys, participants will be reminded that they may refuse to answer any questions that make them uncomfortable and that they may terminate assessments at any time. All participants are free to terminate the assessment or intervention at any time or refuse to respond to questionnaire items. However, some questions that relate to eligibility and specific outcomes will require response in order to continue in the study and receive payment for the survey. As described above, all participants will also receive substance use and mental health resources via links to the study's website. Furthermore, Aim 2 participants will be explicitly instructed during the consent process that, although there will be study staff (peer coaches) interacting with them via Snapchat in designated shifts (if assigned to this condition), no one will be monitoring messages continuously (24/7). The integration of motivational interviewing techniques into intervention interactions is non-confrontational and helps to eschew any form of coercion or threat. The investigators of this project will use established protocols from prior and current work to guide staff in responding to crisis or harm situations via Snapchat or during follow-up contacts. In current and prior social media-based online interventions, we have developed procedures for managing these situations when communicating with participants via social media. As described above, all participants will also receive a link to substance use and mental health resources in a community resource listing on the study's website.

Regarding Snapchat messages, content of new messages do not appear on a participant's phone 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 participant 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 coaches where they cannot be seen or heard and also to consider using a password/passcode on their cell phone. Snapchat messages are typically automatically deleted after both parties have viewed the snaps. However, features within the settings portion of the Snapchat app allow participants to manually change the chat settings to "delete after 24 hours after viewing", instead of the usual chat deletion "after viewing" option. Further, users may choose to save a message at the moment of viewing. We will save messages in our study app during study participation to facilitate responding to participants in the app and our study documentation. Participants will be informed that they still risk having messages viewed by others if anyone else accesses their cell phone or has access to their Snapchat account. Messages during the intervention Snapchats sent by the study team will not directly mention details obtained from assessments about participants' own reports of illegal behaviors, instead they will be theoretically grounded statements based on MI behavior change (e.g., weighing pros/cons of alcohol use in relation to goals and motives). During informed consent, participants will be informed that the researchers do not control Snapchat's access to their messages and that they are still subject to Snapchat terms of use. Furthermore, participants will be explicitly instructed during the consent process that, although there will be study staff interacting with them via Snapchat (if assigned to this condition), no one will be monitoring messages continuously (24/7) and that in the event of a crisis they should call 911 or utilize the crisis resources in the community resource listing, from the study's website. Supervisors (Drs. Bonar, Fernandez, and Walton) and members of our lab network of clinical research post-docs and social workers will be on call to assist study staff in the event a participant discloses risk for self-harm or other crisis situation.

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 via a Snapchat message or other study-related interaction. Regarding disclosure via social media, we have protocols in place, and we had only 1 participant describe suicidality out of 955 risky drinkers ages 16-24 in a recently completed study. Protocols were followed and the participant was deemed moderate risk and given appropriate resources. In our clinical trials with patient populations in the emergency department and substance use treatment settings, we also have experience dealing with these issues. Thus, 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. If the participant discloses suicidality or homicidality, staff will attempt to contact the participant to assess risk level and provide appropriate follow-up (e.g., suicide hotline numbers, safety check, 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 inform participants when we must make a mandatory report. Staff will also be trained to manage responses to potentially inappropriate messages from participants (e.g., asking on dates, sending explicit images) and participants will also acknowledge our User Safety Agreement to avoid misuse of Snapchat with study staff.

In addition, the IRB board at UM will be informed of any incidents as appropriate (see Data and Safety Monitoring Plan). Of note, the investigators have substantial prior clinical and research experience with at-risk populations, including online research with at-risk drinkers.

Potential Benefits

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 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 questions that prompt participants to consider their risky 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.[191,192] Second, all baseline participants in both Aims will receive a link to the NIAAA interactive and evidence-based resource Rethinking Drinking, with information resources and referral information for substance use and mental health treatment. In addition, participants in the intervention group may be helped by participating in the intervention. In sum, potential benefits for the research outweigh the risks for the participants.

Importance of Knowledge to be Gained

Given that risky alcohol 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 with risky drinking patterns do not seek help for their drinking, the development of effective targeted prevention interventions is clearly needed. Given the current penetration of social media into the lives of young people, the potential reach for interventions using this medium, and the ability to harness peers 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 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 high intensity drinking among emerging adults.

Data Safety Monitoring Plan (Aims 1 and 2)

Below, please find the information contained in the DSMP solicited and approved by NIAAA during the funding process, which is being updated for Aim 2.

1. A description of the entity(ies) responsible for monitoring the trial (e.g., an independent monitoring group or person, DSMB, etc.) and procedures for monitoring subject safety.

The investigators will be responsible for monitoring the trial and data quality and safety. All research projects involving human participants require approval from the University of Michigan Medical School's Institutional Review Board (IRBMED). A Certificate of Confidentiality will be issued for this study per NIH procedures.

Dr. Bonar (PI) will ensure that all relevant IRBMED policies, procedures and stipulations are being followed and she will be responsible for ensuring that project staff adhere to the UM IRBMED policies including the following: (1) All participants will understand, agree to, and provide consent before participating; (2) Strict adherence to a participant's right to withdraw or refuse to answer questions will be maintained; (3) Assessments and interventions will be confidential and no names will be associated with the obtained research data; (4) Identifying information will be kept separate from the coded participant data; (5) All identifying information will be kept locked at all times and computer files will be saved with passwords on secure servers; and (6) Participants will be informed in writing in the consent form on how to contact the PI and IRBMED office with any questions and/or concerns. In directly supervising research staff, the investigators will be responsible for monitoring these confidentiality

procedures. Quality control and reliability of screening, baseline and follow-up data will be monitored via regular meetings where data frequencies are examined. Drs. Bonar and Goldstick will also monitor the quality of the data files via supervision of the data manager.

2. **Name of the responsible party (e.g., Principal Investigator, Study Physician if different than PI) who will distinguish a serious adverse event (SAE) from a non-serious adverse event (AE) and provide attributions (causality and severity). Provide a detailed accounting of how SAEs, AEs, and unanticipated problems will be managed consistent with local IRB guidelines (e.g. reporting requirements).**

Dr. Bonar (PI) will be responsible for distinguishing severity of and reporting adverse events. We will adhere to UM IRBMED policies regarding the timing of reporting adverse events to the IRB. The timing of the reporting of any at least possibly study-related adverse event to the UM IRBMED will be dependent on the severity of the event, and whether such adverse events were expected (included in the informed consent) and/or related or unrelated to the research. According to UM IRBMED, all adverse events must be reported for those defined as: "An adverse event is any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio." Per the "NIAAA Data and Safety Monitoring Plan Requirements for NIAAA-Funded Clinical Trials," serious adverse events (e.g., hospitalization for suicidal ideation uncovered during study interaction) and unanticipated events related to the study will be reported to IRBMED and NIAAA within 48 hours of learning of the event. Non-threatening potentially serious adverse events that are causally related to the research will be reported to the IRBMED within 7 days of learning of the event. A summary of adverse events that occurred during the previous year will be included in the annual progress report to NIAAA.

3. **A description of the follow-up plans for SAE and unresolved unanticipated problems.**
The PI will be responsible for follow-up on all SAEs and unresolved unanticipated problems until resolution or stabilization.

4. **Risks associated with study participation.**
   a) Although it is not expected that there will be any risks to participants because of online screening and baseline assessment procedures, the risk of violation of confidentiality exists because human participants are giving personal information.
   b) Although intervention Snapchat messages will be sent/received only by study staff, participants' Snapchat accounts are still accessible to Snapchat and subject to the app's terms of use. Further, we cannot guarantee protection of Snapchat data from third-party hackers.
   Participants could potentially experience emotional discomfort as a result of being asked personal questions or because of intervention content.

   Procedures to address these risks are detailed in the Protection of Human Subjects portion of the grant application [note for IRBMED: and these are detailed in the above human use section and throughout the IRBMED electronic application]

Confirmation that SAEs and unanticipated events which are considered "at least possibly related" during the treatment and follow-up phases will be reported to the local IRB and to NIAAA within 48 hours of knowledge of the SAE and all other SAEs and unanticipated events must be reported within the time period mandated by the local IRB.

SAEs and unanticipated events which are considered "at least possibly related" during the intervention and follow-up phases will be reported to NIAAA within 48 hours of knowledge of the SAE and reported to UM IRBMED per UM guidelines depending on severity.

5. **A statement confirming that the Annual Report will include the following: a summary of all AEs, confirmation of adherence to the DSMP, a summary of any data and safety monitoring issues**

since prior reporting period, a description of the changes in the research protocol or DSMP and all new and continuing IRB approvals.

The annual RPPR will contain the following:
-a summary of all AEs
-confirmation of adherence to the DSMP
-a summary of any data and safety monitoring issues since the last RPPR
-a description of changes in the research protocol or DSMP
-new/continuing IRB approvals

6. **Study inclusion and exclusion criteria**

These inclusion/exclusion criteria apply to both Aim 1 and Aim 2 studies.

For screening, participants must: be age 18-25, reside in the U.S., and be able to read English (as they are recruited via advertisements written in English). Eligibility criteria for baseline and randomization is self-reported past-month HID and regular Snapchat use (at least 3 days/week). Participants will be excluded if they fail identity verification based on: 1) IP addresses, 2) survey time completion, 3) repeat attempts, and 4) survey responses. Aim 1 participants are excluded from Aim 2.

A statement confirming that trained clinical staff will be present or on call when study procedures take place, based on level of risk and consistent with approved protocol, policies and guidance from the local IRB and/or other regulatory and monitoring entities. Examples include (but are not limited to) the administration of alcohol, other drugs and/or medications; invasive or other study procedures or testing; etc. The types of trained personnel (e.g.: nurse, nurse practitioner, physician assistant, physician, etc.) should be stated.

Drs. Bonar and Fernandez will be responsible for providing regular supervision to research staff who have contact with participants. The investigators will provide training to all research staff (e.g., bachelor's level health coaches and research assistants, master's level study coordinator) who are interacting with participants via the intervention regarding procedures for identifying, managing, and responding appropriately to acute warning signs of distress (e.g., messages to peer coaches that reflect distress). Staff will receive training in risk assessment and management procedures in the event that participants reveal via study-related interaction any suicidal and/or homicidal ideation or child abuse.

If staff becomes aware of any of these issues, they will follow written guidelines to assess level of risk and will immediately page Dr. Bonar, Dr. Fernandez, or Dr. Walton for consultation in moderate or high/acute risk cases. If necessary, authorities will be notified and participants will be notified of reporting requirements.

7. **For studies in which alcohol is administered, provide assurance that NIAAA guidelines for the administration of alcohol will be followed. These guidelines can be found here: Alcohol Administration Human Laboratory Studies.**

Not applicable

8. **Describe the plan for referral to treatment during follow-up phases for any research participant who requires additional intervention due to significantly increased alcohol consumption or serious psychiatric/medical symptoms.**

All participants will receive link to a webpage containing a resource list (e.g., substance use disorder treatment, mental health, crisis lines) at baseline and follow-ups and all will receive a link to NIAAA's Rethinking Drinking as part of participation. Crisis resource information is also provided prior to the close of study surveys. During study interaction, if we believe a participant could benefit from additional treatment services we will email/private message them a link to locate treatment in their area (SAMHSA

treatment locator) as well as contact information for 24/7 crisis lines. We have done this in prior work with online interventions via social media.

9. Describe procedures for data quality assurance and protecting confidentiality of participant data (e.g., Certificate of Confidentiality).

Quality Assurance Plan

Quality assurance will be accomplished in several ways listed below under supervision of the Study Coordinator and Data Manager, overseen by Drs. Bonar/Goldstick.

Recruitment. We have experience identifying fraudulent cases by examining data for integrity, falsification, multiple attempts, IP addresses, etc. We will use procedures currently employed in ongoing research.

Screening Survey. During each screening wave, the Data Manager will print frequency data from screening surveys and examine for out-of-range values; the Study Coordinator will look at eligibility criteria and randomization tables to determine they are correct; the Study Coordinator and Data Manager will ensure all screening data are backed-up; the Study Coordinator will ensure that all screening participants are accounted for in tracking database and update the study flow chart to ensure accurate numbers recorded as screened, baseline, refused, or withdrawn.

Baseline Assessments. During each recruitment wave, the Data Manager and Study Coordinator will review baseline data for accuracy and out of range values; ensure that all baseline data are backed-up; ensure that all baseline participants are accounted for in tracking database; update flow chart to ensure accurate numbers of baselines recorded as completed or refused. Assessments (baseline and follow-up) will contain an item unique to participants that will assist in ensuring that the participant and not someone else is completing their surveys (e.g., name of street they grew up on, name of high school mascot).

Intervention period. The Study Coordinator will review Snapchat message logs for accuracy and consistency after close of each intervention wave; note weekly supervision with Dr. Bonar/Dr. Fernandez will also include review of message logs.

Follow-up Assessments. Monthly, the Data Manager and Study Coordinator will review follow-up data for accuracy and out of range values; ensure that all follow-up data are backed-up; insure that all follow-up interviews are accounted for in the tracking database; update flow chart to ensure accurate numbers of follow-up assessments recorded as completed, missed, refused, or withdrawn.

Protecting Confidentiality

To minimize the risk of violating confidentiality, RAs will make every effort to ensure that study data are always kept confidential. Research staff will sign a pledge of confidentiality and will understand that violation of confidentiality is reason for dismissal. 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. 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., Snapchat message logs) will be coded with this number, rather than with a name. Computer data files (e.g., screening/baseline/ follow-up data) will be saved with passwords on a secured network, and will not contain names, birthdates, etc. Message logs may be temporarily recorded on the local study device, without identifiers, prior to saving in the secure log on the secure drive. The contact information database will be password protected and securely stored and will not be attached to participants' survey or message data and only accessible to study staff. For participant tracking, one list will be maintained linking participants' ID numbers to their names. This list will be kept in a password-protected document on a secure research drive folder only accessible to study staff. This list will be deleted as soon as the study is completed. In accordance with NIH rules, we will also receive 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. All data will be collected specifically for use on this project. All data will be collected specifically for use on this project.

Regarding Snapchat messages, content of new messages do not appear on a participant's phone 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 participant 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 coaches where they cannot be seen or heard and also to consider using a strong password/passcode on their cell phone. Snapchat messages are automatically deleted after viewing, unless a user manually changes their settings to "delete after 24 hours after viewing" or manually chooses to save a message. Participants will be informed that they still risk having messages viewed by others if anyone else accesses their cell phone or has access to their Snapchat account. Messages during the intervention Snapchats sent by the study team will not directly mention details obtained from assessments about participants' own reports of illegal behaviors, instead they will be theoretically grounded statements based on MI behavior change (e.g., weighing pros/cons of alcohol use in relation to goals and motives). During informed consent, participants will be informed that the researchers do not control Snapchat's access to their messages and that they are still subject to Snapchat terms of use.

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 via a Snapchat message. Regarding disclosure via social media, we have protocols in place, and to date we have had only 1 participant describe suicidality out of 955 risky drinkers ages 16-24. Protocols were followed and the participant was deemed moderate risk and given appropriate resources. In our clinical trials with patient populations in the emergency department and substance use treatment settings, we also have experience dealing with these issues. Thus, 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. If the participant discloses suicidality or homicidality, the facilitator will attempt to contact the participant to assess risk level and provide appropriate follow-up (e.g., suicide hotline numbers, safety check, 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 inform participants when we must make a mandatory report.

10. Provide a statement indicating certification of IRB approval(s) of the study protocol will be provided to NIAAA prior to screening study participants. IRB approvals should be submitted (preferably electronically) to the NIAAA Grants Management Officer (GMO) before initiating a proposed clinical trial. For multi-site studies, the Data Coordinating Center (DCC) and associated study sites must submit certification of IRB approval as well as assurance that IRB approvals have been obtained for all study sites, are on file at the clinical site and DCC, and are available to the NIAAA upon request.

We will provide documentation of IRB approval for all study procedures prior to beginning screening participants.

11. Provide the analysis plan including the power calculation(s). There should be discussion of any planned interim and/or futility analyses, including adjustments for allocating "alpha" on "multiple looks" at the data.

Specific Aim 1. Intervention development will consist primarily of identifying preferences for content delivery and content with superior ratings, and thus will not involve formal statistical inference. We will conduct descriptive analyses of participants' data regarding preferences, leading to refinements in intervention content.

Specific Aim 2. 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). To examine other outcomes related to estimating intervention efficacy, in Aim 2, randomized participants will be included in intent-to-treat analyses, regardless of engagement. By design, groups will be balanced on sex and age; we will validate randomization by evaluating covariate balance between groups. If significant differences that could confound treatment effect estimates emerge, we will adjust for those variables or stratify analyses. *Testing for Intervention Effects.* We will first compare groups outcomes of HID frequency and alcohol-related consequences using basic two-sample comparisons, operating on the pre-post differences (e.g., 4M-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. We will use generalized linear mixed models (GLMMs) to jointly study the 2M and 4M outcomes while adjusting for correlations between data points (e.g. repeated measurements on individuals). While baseline adjustment is important for guarding against regression to the mean in RCTs, such adjustment at every time point may overestimate the treatment effect when there are multiple follow-ups. Baseline adjustment at only the first follow-up (2M in this case) corrects this overestimation while also guarding against regression to the mean, which will be our approach. Within this framework, the treatment effect is estimated by the treatment group indicator in the regression model. We will conduct exploratory sub-analyses of whether the intervention effect is accumulating or weakening over time, by including time-by-group interactions. If we ascertain the need, we will control for confounders through their inclusion in the model as covariates. Overall, this approach is effectively the same as the ANCOVA method of RCT analysis, but modified to account for multiple follow-ups and possibly inhomogeneous treatment effects (e.g. time-varying or modified by other factors, see secondary aims, below). 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 we will scrutinize this choice by examining model diagnostics. If we ascertain the need, we will examine other distributional choices (e.g., Poisson, Negative Binomial) and more complex random effects structures (e.g., autoregressive). *Effect Size Estimation*: This pilot will provide critical data necessary to inform power analyses for a later efficacy trial. While effect sizes from pilot studies can have large standard errors and be unstable, we can use pilot data to estimate point estimates and confidence intervals for treatment effect sizes using the R package MBESS. The effect size of choice will be the standardized regression coefficient corresponding to the treatment group indicator in a model adjusted for the baseline measurement, which will have the same interpretation as the standardized mean difference (commonly referred to as Cohen's D). This analysis will provide a basis for calculating the minimal sample size required for a fully powered study while accounting for uncertainly in the effect size estimate.

Other exploratory analyses. *Other Outcomes:* We will use the framework described above for alcohol outcomes to analyze other behavioral outcomes (cannabis, NMPDU). *Moderation:* To assess potential moderators (e.g., sex, age) we will include interactions with treatment group in the GLMM models above. *Mediation:* To test if alcohol motives and other variables (e.g., mental health) mediate treatment effects, we will use Imai's causal mediation analysis framework, implemented in the R package *mediation.* Traditional mediation analysis is limited by the class of statistical models (e.g. the linear structural model of Baron and Kenny) that can be accommodated. Under technical assumptions of sequential ignorability, mediation effects are identifiable using Imai's framework when models for the mediator and outcome are non-linear, have discrete or continuous outcomes, include random effects, or are non-parametric. *Engagement:* Counts from Snapchat message logs (e.g., content viewed, replies), will be assessed descriptively to see types of content with high response and to measure dose. We will test for sex and age differences in engagement. *Cost:* 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 and clinical supervision. As with Dr. Walton's 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 intervention cost vs. control divided by difference in mean effectiveness between intervention and control). Change in health benefits will be quantified as the difference in alcohol consequences per month for the

intervention vs. 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 ways to generate confidence intervals that do not rely on a normal distribution (e.g., non-parametric boot-strapping).

Power Analysis.

For exploratory analyses regarding intervention efficacy, our inferential target (the regression coefficient corresponding to treatment group) is effectively equivalent to the comparison of two means, for which Cohen's D is the typical effect size (0.2: small; 0.5: medium; 0.8: large). Under the expected sample size (n = 50-52 per group), we will have sufficient power (>80%) to detect effects on outcomes at a single time point if D > 0.56, a medium effect size. In analyses involving multiple follow-ups, the effective sample size cannot be smaller than the nominal sample size (n = 50-52 per group), and so the effect size of D = 0.56 is conservative in that case.

12. Provide the study stopping rules part of the study protocol. Generally, stopping rules reflect one of the following conditions: 1) there is clear evidence of harm; 2) there is no likelihood of demonstrating treatment benefit (futility); 3) there is overwhelming evidence of the benefit of treatment.

The PI will work directly with NIAAA, in the case that project discontinuation is necessary. Should there be clear evidence of harm to the participants due to this trial we will cease the trial. Given this is a no more than minimal risk study as deemed by our IRB, we do not anticipate evidence of harm. As this is a pilot/feasibility trial, we may not be able to detect a treatment effect and thus do not anticipate stopping the trial due to evidence of futility or benefit.