Official Title
Examining Motivations for and Quality of Alcohol and Marijuana Protective Behavior Strategy Use: Improving Prevention of Hazardous Young Adult Substance Use

Brief Title
Enhancing Quality in Protective Strategies (EQUIP)

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Protocol Synopsis for Research Project Involving Human Subjects

PROTOCOL INFORMATION

Title of Project: Enhancing QUality In Protective strategies (Project EQUIP) (Phase II)

Name of Principal Investigator: Dr. Zhengyang Zhou

Institution: University of North Texas Health Science Center, Fort Worth, TX

Department: Health Behaviors and Health Systems, School of Public Health.

Funding Agency / Company (if applicable): NIH/NIAAA

Funding Agency Proposal / Protocol Number (if applicable): R34AA028730A1

A. Purpose of the Study – *State the specific scientific objectives of the research, and, if applicable, outline the specific aims.*

Please note that this IRB application is being made only for the Phase 2 Online and Text Message Intervention (Aim 2) of the associated grant proposal. A separate IRB application (IRB approval 2020-139) was submitted and approved for the Phase 1 focus group and cognitive interview portion (Aim 1). Phase 1 was launched in January of 2022, and the results/findings of the focus groups and cognitive interviews are informing the content of the Phase 2 intervention being developed in this proposal.

The proposed research will (1) collect pilot data to establish feasibility and acceptability and test the interactive online and text message (TM) protective behavioral strategy (PBS) intervention (baseline, 2-month) while also (2) collecting event-level data to examine daily-level associations among PBS motivation/quality, PBS use and non-use, alcohol and/or marijuana use, and negative consequences with a focus on how PBS may differ on concurrent alcohol and marijuana (CAM; use of both substances on the same day, but not so their effects overlap) use or simultaneous alcohol and marijuana (SAM; use of alcohol and marijuana at the same time so that their effects overlap) use days compared to alcohol-only days.

The proposed research will conduct a pilot study with young adults (N=240; ages 18-24), who typically use alcohol and cannabis at least 3 times per month, to determine feasibility, acceptability, and preliminary effect sizes (to inform a future R01 application). Participants will be randomized to either the intervention or assessment-only control.

B. Background and Significance – *Briefly sketch the background leading to the present proposal, using documentation from the literature, where appropriate. Although it is helpful for the Board to have a decent understanding of the basis for conducting a research project, it is not necessary to have a full-blown literature review or extensive background and rationale for the proposed research plan of activity.*

The most successful young adult alcohol or cannabis interventions involve the provision of accurate, nonjudgmental personalized feedback (College Alcohol Intervention Matrix (CollegeAIM), NIAAA, 2019), but notably the inclusion and effectiveness of PBS content is inconsistent (Miller et al., 2013). Moreover, active components of brief interventions are not well understood (Gaume et al., 2014), and findings have

been inconclusive regarding whether PBS mediates intervention efficacy of college student personalized feedback interventions (PFIs), with only some studies showing evidence of mediation (Reid & Carey, 2015). One possible reason for these findings is that we often do not know young adults' motivations for using (or not using) PBS or the quality of PBS use across individuals or across drinking occasions. The proposed study will provide an in-depth examination of which PBS young adults are motivated to use (including implementation quality) and reasons that young adults may or may not use PBS. Understanding why young adults are choosing not to use PBS on specific occasions or do not engage in effective or high-quality PBS use on certain occasions has significant clinical implications, whereby interventions may need to spend more time increasing motivations to use PBS in an effective manner or work on reducing perceived barriers (i.e., reasons individuals are not using PBS). Clinicians may then be better able to work with young adults in various settings to reduce or prevent excessive alcohol and cannabis use and related consequences. The proposed research has high potential for making a substantial impact on the field and public health (particularly as more states permit legal access to cannabis for those over 21) as it will address a problem of high importance (alcohol and cannabis use) by being the first to develop and refine a PBS intervention that specifically focuses on motivations for alcohol and cannabis PBS use and non-use as well as quality of use, which is an overlooked aspect of current PBS-related intervention approaches. The development of more efficacious interventions to reduce the proportion of young adults who engage in excessive alcohol use and who experience consequences is a key priority of the NIAAA. Related, development of more effective interventions to reduce risk from cannabis use is an area of great importance for the NIDA.

C. Preliminary Studies – *Summarize preliminary studies conducted by the investigator pertinent to this proposal (e.g., You have completed a pilot project in preparation for this study, etc.). State "none" if applicable.*

Our work has shown that individuals who tend to use more PBS also report experiencing fewer negative consequences (e.g., Gilmore et al., 2018; Grazioli et al., 2018, 2019; Litt et al., 2013; Lewis et al., 2010). In our recent work (Fairlie et al., 2021), we found that descriptive norms for reasons to use PBS (i.e., perceptions that close friends use PBS to reduce drinking/consequences) were positively associated with perceived usefulness of PBS and personal PBS use for limiting/stopping and to some extent manner of drinking. Our work also shows on days when participants used more limiting/stopping PBS, fewer manner of drinking PBS, and more serious harm reduction PBS than usual, they experienced more negative consequences (Lewis et al., 2012, 2015). In addition, we have found that on days college students planned to drink more than usual, planned heavy episodic drinking, and planned high intensity drinking, they reported fewer plans to use limiting/stopping and manner of drinking strategies that night (but not plans of serious harm reduction strategies) (R21AA024156; Fairlie et al., 2019).

Drs. Lewis and Kilmer have previously worked together to develop, program, and pilot test PBS TMs to be used in an intervention for high-risk drinking among community college students (R34AA023047; Lee et al., 2021; Lewis et al., 2018). They conducted 6 focus groups with community college students around the content, frequency, types, and dosage of TMs students would find useful and interesting. Drs. Lewis and Kilmer developed a library of TMs and conducted a usability study where students received TMs in real time across two weeks and rated them for usefulness (Lewis et al., 2018). This study asked participants to rate how useful each TM was when the text was received. More than three-quarters (72% to 88%) of the queries to rate the TMs on "usefulness" were answered, indicating willingness to respond to the TM even if drinking (Lewis et al., 2018). Overwhelmingly, students liked the TMs, thought they were useful, and provided feedback for how to make the TMs even more personalized. The pilot study evaluating the TM intervention found that the combination of a web-based brief alcohol intervention with PBS TMs was feasible, acceptable, and resulted in reductions in alcohol consumption and consequences, relative to controls at 3-month follow up (Lee et al., 2021). This work is directly built upon in this application.

D. Investigator Experience – *Provide a brief synopsis of the principal investigator's expertise, experience, and capability to perform this research. Submit a copy of the curriculum vitae of the principal investigator in IRBNet.*

Dr. Lewis has over 20 years of adolescent and young adult alcohol research experience that has provided expertise in PBS, EMA methodology, recruitment and retention of adolescent and young adult populations, intervention development and testing, and longitudinal data analyses. Dr. Lewis' publication and grant record demonstrate her expertise and experience in substance use research, research among adolescent and young adult populations, and in studies with a PBS focus. Dr. Lewis has assembled a team of Co-Investigators with relevant expertise and with whom she has an established history of fruitful collaboration. Her program of research has been funded by numerous grants from the National Institute on Alcohol Abuse and Alcoholism, the Alcohol and Drug Abuse Institute, and the Alcohol Beverage Medical Research Foundation. Dr. Lewis has written over 140 articles, books, and book chapters.

Please see Dr. Melissa Lewis' CV for additional information.

E. Experimental Design and Methods:

1) *Methods and Procedures* - *Describe the procedure (s) in sequential detail. Describe the methods. Clearly identify any experimental elements of the study. Include a thorough description of any investigational drugs, therapeutic procedures, monitoring techniques, test procedures or medical devices.*

We will utilize a multi-method approach to reach a wide cross-section of young adults from Texas, including in-person recruitment, flyers in businesses and community centers, community outreach, online and electronic newspaper ads, electronic flyers, bus ads, and social media. In-person recruitment may consist of tabling at local events where young adults will be located. Flyers advertising recruitment for a local research study of 18-24 year olds will be placed in businesses (e.g., bars) with general, brief information about the study and links to the study website, email address, and phone number. Online, print, and bus ads may be placed in local areas and social media outlets frequented by those age 18-24. Bus ads will use the same content as approved flyers. Please see Appendix D for sample advertisements.

We will use paid ads on Twitter, Instagram, Facebook, etc. Social media outreach will also consist of an online Facebook, Twitter, and Instagram Fan page. Social media outreach will be from the **ST**udying **A**lcohol and **R**elated **R**isks (STARR) lab account and a specific Project EQUIP Facebook account. Because STARR Lab research is aimed at varying ages, the EQUIP Facebook page will be geared towards advertising and updates specifically to young adults, the focus of recruitment for Project EQUIP. Drs. Lewis and Litt are co-directors of the STARR lab. Using STARR lab social media accounts for our lab in addition to the specific Project EQUIP Facebook account allows additional protection for participants as interaction with our social media accounts will not indicate that a participant is in a specific study since multiple studies are conducted by the STARR lab. Moreover, there are additional individuals other than study participants, who will interact with STARR lab social media and Project EQUIP Facebook accounts, such as co-investigators, collaborators, and current and future graduate students. Researchers will interact with STARR lab social media by answering inquiries about the study and promoting other research studies pertaining to STARR lab. Researchers will interact with the EQUIP specific Facebook account by answering inquiries about the study and sharing general information about the STARR lab and related social media. This will allow additional protection to study participants as it will not indicate study participation in a particular study or any study at all. Private messages can be sent to the research team or people can call the research team. Only research staff have access to STARR social media and EQUIP Facebook accounts and the lab phone numbers used for Project EQUIP. Thus, only those on this IRB protocol will respond to participant inquiries. Researchers will direct interested participants to the online survey link that they can find on the STARR lab and EQUIP social media accounts and to the project website. Screening will only occur online so any interested participants will be directed to the online screening survey when calling. Researchers will also answer any questions interested participants might have about the study. There will be an active post for the online screening survey on STARR lab and EQUIP social media accounts for Project EQUIP. This will be the only screening survey for Project EQUIP Phase 2. This survey will begin steps for study eligibility for Project

EQUIP only. There will be no generic screening survey related to all projects, only the screening survey specific to Project EQUIP Phase 2. The posts for Project EQUIP will only be about Project EQUIP and eligibility for Project EQUIP. Individuals can like or share STARR lab or Project EQUIP related accounts and posts. Research articles shared on the STARR lab and Project EQUIP social media accounts are for information purposes for the team and their areas of research, **not** recruitment purposes. Individuals will not be able to post on the Facebook fan page without administrator approval by the research team and comments will be disabled. Online recruitment ads (e.g., Craigslist, Twitter, Instagram, Facebook, online newspapers, etc.) will provide a hyper-linked website address (URL) for more study information and eligibility screening. Other research projects that may recruit though the fan page will only be those approved by IRB beforehand and only those pertaining to STARR lab. In addition to other study information, there is a section on the study website that will lead individuals to the online consent statement and the online screening survey.

Links to our social media accounts are below. See Appendix D for the printouts of the social media accounts and website language.

Project EQUIP website: https://www.unthsc.edu/school-of-public-health/starr/equip/

- Please note that we will keep information pertaining to Phase 1 (IRB #2020-139) of the project available on the website until that phase has ended, and Phase 2 content will be posted only after receiving IRB approval and Phase 1 is complete.

STARR Lab Facebook: https://www.facebook.com/starr.unthsc/

Project EQUIP Facebook: https://www.facebook.com/Project-EQUIP-100141438822463

STARR Facebook: https://www.facebook.com/starr.unthsc/

STARR Lab Instagram: https://www.instagram.com/starrlab.unthsc/?hl=en

STARR Lab Twitter: https://twitter.com/STARRLab_UNTHSC

Study Reminders.

For all elements of this study, once the requested task (i.e., screening survey, baseline survey, follow-up survey, etc.) has been completed by a participant, all reminders to complete that specific task will stop.

Recruitment Methods.

1. **Online advertising**
   a. *Social Networking Sites.* We target ads to show up in newsfeed of individuals age 18-24 in Texas. We pay for ads to show up in newsfeeds and sponsored stories on Facebook, Instagram, and Twitter, etc. We do not buy ad space. Ads for this study will show up by age and/or birth sex to those in Texas. Ads do not appear based on any keywords. We submit ads directly via Facebook for both Facebook and Instagram and directly to Twitter. We do not use a recruitment agency. Ads in newsfeeds cannot be seen by anyone other than the individual. They are not permanent to newsfeeds. Because these ads are not permanent and cannot be seen by anyone other than the participant they do not increase or pose additional risk. Participants will have the option to hide or not see any ads from the STARR Lab that will promote Project EQUIP on Facebook, Instagram, and Twitter if they so choose. This is always an option for any ad on Facebook, Instagram, and Twitter. Project EQUIP ads from the STARR lab would not trigger any other ads related to alcohol or drugs as we do not use these keywords for ads. Ads in newsfeeds are not visible to anyone other than the participant. The use of a Facebook Fan page for study communications is included in the consent documents. Participants will not be able to post on the Facebook Fan page without administrator approval by the research team. In all consent documents, we inform participants that if they “like” our Facebook Fan page and/or follow our Instagram or Twitter, they may see

posts by the study research team. Liking the Facebook Fan page and/or following the Instagram or Twitter, is optional, is not required for study participation, and is not an indication of study participation as anyone who is a member of Facebook can like the study Facebook fan page or follow the study Twitter or Instagram. Posts on Facebook, Instagram, and Twitter will not refer to specific compensation amounts.

b. *Other Online Channels.* Online advertising will also be administered through Craigslist and other online newspapers (e.g., online version of the Star-Telegram, Dallas Observer, etc.).

2. **Future Contact List**
   a. Individuals that previously participated in The Freshman Experience Project (Phases I & II) (IRB #2018-128; IRB #2019-148) will receive one email invitation to participate in this study. They will only receive this invitation if they indicated that they wish to be contacted for future studies in the online screening survey they initially completed. Participants were only asked this question if they were 18-19 years of age. For eligible and ineligible individuals that indicated "yes" to being contacted for future research studies, all personal contact information was kept separate from their non-identifiable survey data. The email invitation will include information about Project EQUIP as well as a link to the consent form and screening survey. It will be sent to the email they provided in The Freshman Experience Project screening survey.
   b. Individuals that previously completed the screening survey for but did not participate or whose participation has concluded in Project PATH (IRB #2018-077) will receive one email invitation to participate in this study. They will only receive this invitation if they indicated that they wish to be contacted for future studies in the online screening survey they initially completed. For eligible and ineligible individuals that indicated "yes" to being contacted for future research studies, all personal contact information was kept separate from their non-identifiable survey data. The email invitation will include information about Project EQUIP as well as a link to the consent form and screening survey. It will be sent to the email they provided in the Project PATH screening survey.
   c. Individuals ages 18-20 that previously participated in Project PRISM (Phase I) (IRB #2019-035) or that will participate in Project PRISM (Phase II) (IRB#2021-124) will receive one email invitation to participate in this study. They will only receive this invitation if they indicate that they wish to be contacted for future studies in the online screening survey they initially completed. For eligible and ineligible individuals that indicate "yes" to being contacted for future research studies, all personal contact information was/will be kept separate from their non-identifiable survey data. The email invitation will include information about Project EQUIP as well as a link to the consent form and screening survey. It will be sent to the email they provide in Project PRISM Phase 1 or Project PRISM Phase 2 screening survey.
3. **Community Organizations**
   a. Study staff will contact Texas community organizations to share study information (e.g., via email, in meetings). If the contacts agree to share the study's information with individuals in their organization, we will share with them approved flyers and handouts and the study's consent link and the study's QR code for easy access. Any information shared will be currently approved language (e.g., summary of the study) and study materials (e.g., flyers, consent link). We are willing to get any special authorizations required. We will follow the policies they have in place in respect to sharing information with individuals in their organization.
4. **In-person recruitment and flyering**
   a. Study staff will go to community areas (i.e., businesses and community centers) to hand out study flyers. Flyers will contain a brief description of the study, contact information, website link, and link to the online screening survey.
   b. Study staff will also post flyers in community areas (i.e., business and community centers).

Online Screening (see Appendix B)

Participants age 18-24. After receiving information about the study and being presented with the online informed consent statement that covers both the screening survey and the online and text message intervention, if eligible (Appendix A), individuals will be asked to complete an electronic signature before being directed to participate in the online screening survey, which will determine whether or not they are

a good fit for the study. The electronic signature will be requested via a text box where participants can draw their signature. This electronic signature would include a date and time stamp. Only those participants who sign both the online consent form and HIPAA Authorization Form will be routed to the online screening survey. Participants who do not provide consent for themselves as well as HIPAA authorization forms for themselves will be routed to the screening decline page and will never view the screening survey.

Participants who provide consent will receive demographic questions (i.e., birth sex, race, ethnicity,) and items that assess crucial eligibility questions such as “Are you willing to participate in a study that involves an interactive online and text message program and a series of daily online surveys for eight weeks?”, etc. Participants will be asked to enter their email to receive an online copy of the signed consent form when completing the consent statement. Participants that do provide a valid email address will receive an email with an embedded link to a page that contains two additional links. One link will send them to their consent form copy, while the second link will send them to their HIPAA form copy, if relevant. Participants will be able to access and view their copies of their forms using the links for the duration of the study. In the case that a participant fails to give consent, thus does not access nor reviews the HIPAA authorization form, they will be redirected to an error page. Research staff will receive all copies of Consent/HIPAA forms e-mailed to a project-specific inbox (equip@unthsc.edu), so participants can also ask for a printed copy at any time and request to be mailed their copy. In addition, confirmation emails will be sent to participants to indicate receipt of their online screening survey. If a participant consents, but does not complete the online screening survey, they will receive up to 3 reminder email notifications to complete screening. If participants are deemed ineligible on any of the inclusion/exclusion criteria, they will be routed to an ineligible end page that will thank them for their time and inform them that they are not a good fit for the present study. They will also receive an email informing them that they are not eligible for the study. Any minor under the age of 18 who completes screening will automatically be routed to the Ineligible End Page (Appendix C) and receive the Ineligible Email Notification (Appendix C). Screening information provided by minors will not be retained and will be deleted 120 after the study has ended.

Online screening data will be collected via Rivulent Web Design, Inc. and saved on the HIPAA compliant LabArchives. Both Rivulent Web Design, Inc. and LabArchives meet HIPAA security regulations. To maintain the confidentiality of data submitted over the internet, participants are assigned a PIN at the start of the online screening survey. This PIN will be embedded in all communications in which a link to surveys is sent. The PIN embedded in the survey link means that the link is specific to that individual and their survey data will be connected to that PIN. Thus, participants will not ever need to enter their PIN for purposes to complete study surveys. Participants are further protected by having an embedded PIN. An embedded PIN is more secure than emailing the PIN to participants as participants do not have to worry about keeping this information private. There is also less participant burden with the use of an embedded PIN as emailing the non-embedded PIN would require doing so in a separate communication than the survey link, thus doubling any communications that would involve a PIN.

Screening survey data will be collected via Rivulent Web Design, Inc. survey software and be saved on a dedicated secure server provided by Rivulent Web Design, Inc. Data stored on the provided secure server is encrypted, password protected, and HIPAA compliant. To maintain the confidentiality of data submitted over the internet, participants will log in to a secure website using a link with an encrypted PIN created for study purposes. Data transfer will be protected using Transport Layer Security (TLS) version 1.2 or higher. The TLS encrypted session will ensure that data moving from the participant to the server (i.e., participant responses) will be encrypted in transit using a 2048-bit minimum encryption key. This is the same level of encryption used for most banking transactions and offers the highest degree of protection available for data transfer. Rivulent treats all data with the same level of encryption and security that would be expected for HIPAA-protected data, even if that data does not fall under HIPAA. Rivulent does not keep copies of data anywhere other than the secured, encrypted systems. Survey data will be transferred from the survey provider to secure file storage using this same TLS encryption. Secure storage within LabArchives is located in a managed datacenter. The datacenter is protected by two-step verification, configured sharing permissions, monitoring of activity, disabled

permanent deletions, and conduction of regular access reviews. LabArchives has strict policy and technical access controls that prohibit employee access except in rare circumstances when legally obligated to do so. In addition, they use a number of physical and electronic security measures to protect user information from unauthorized access. To determine levels of socioeconomic disadvantage using the Area Deprivation Index, we will utilize the United States Census Bureau Geocoder. To maintain the confidentiality of data, this tool uses unique ID numbers to link participants' addresses provided at screening with their corresponding geocodes and block codes.

Future Research Opportunities

We ask all participants in the online screening survey if they would like to be contacted for future research opportunities. Participants that agree to be contacted for future research activities will NOT be required to participate in these future research opportunities, they are only giving permission to be informed of future IRB-approved research activities/studies conducted by the STARR Lab. For eligible and ineligible individuals who indicate “yes” to being contacted for future research opportunities, all personal contact information is kept separate from the remaining non-identifiable survey data. Contact and demographic (age, sex, date of birth) information from eligible and ineligible participants who provide permission will be kept indefinitely. Dr. Lewis has used these procedures for their studies since 2005 and has never experienced any adverse events. She has been using these procedures at UNTHSC since 2018 without any adverse events.

Future research activities/studies conducted at UNTHSC by Drs. Lewis and/or Litt would be the only studies that would have access to this contact list. Future IRB submissions would describe the use of the list in detail and would not be used without IRB approval.

Consent Documents

Consent documents and consent status are stored in our secure, HIPAA compliant database. We will easily have access to documentation that contains the typed signature and the electronic signature that is date and time stamped to verify written consent was given or not given. Individuals will receive a copy of the signed consent document via email whenever a consent document is signed and can request to be mailed a printed copy of their signed consent forms. Consent and HIPAA documentation for the full study will be obtained during the screening survey.

Participant Consent

We are requesting informed consent for the screening survey and online/text message intervention to be obtained online with an electronic signature because the entire study is administered online. The electronic signature will be requested via a text box where participants can draw their signature. Participants will provide informed consent for the screening survey and online/text message intervention with electronic signatures. Participants who do not provide consent for themselves will be moved to the end page.

Survey programming will be done such that participants cannot advance to the HIPAA Authorization from until consent to participate has been provided. Survey programming will be done such that participants cannot advance to the survey items until both consent to participate and HIPAA Authorization has been provided.

In order to reduce participant burden, consent will be obtained for both screening and the online/text message intervention (if eligible) and follow-up surveys for all participants before commencing the screening survey. Thus, a separate consent form will not be signed after verifying eligibility.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by US law and is posted on the online consent form.

Online Training Session

Upon completion of the screening survey, eligible participants will schedule a time to complete a brief online training session via Zoom related to the daily portion of the study (see below). Participants will automatically be forwarded to an online scheduler upon completion of the screening survey, where they can schedule their online training session. Participants will also receive a scheduler invitation text message and email notification upon completion of the screening survey containing a link to our scheduler page. Participants will also have the option to schedule over the phone with study staff. If they do not schedule their online session, we will periodically send reminders – via email (up to 8), text (up to 8) and/or phone/voicemail (up to 6). Once a participant schedules an online training session, they will receive confirmation and reminder notifications via email (up to 2), text (up to 3), and/or phone call/voicemail (1). If a participant who has scheduled an online session misses their appointment, they will receive notifications to reschedule via email (up to 9), text (up to 9), and/or phone call/voicemail (up to 6). Participants will be paid $20 on a Greenphire MasterCard to compensate for their time, which they will be mailed after they complete the online baseline survey. Once a participant receives their card, they will be asked to contact us via email or phone so that we can load their card with a total of $40 ($20 for the online session, and $20 for the online baseline survey, which participants will receive an invitation to upon completion of the online session).

Participants will schedule a time to participate in an online training session hosted via Zoom Video Communications. After scheduling for an online session, participants will receive a confirmation email that will provide them with detailed instructions on how to download the Zoom software. This confirmation email will also provide participants with a “Meeting ID” URL link that will direct them to the designated Zoom online conference session. Participants will be asked to install/launch the Zoom application on their device when they click on this link. This installation will only occur the first time on any device. The Zoom application is free and participants are not required to sign up for a Zoom account to download/launch the application. Since the “Meeting ID” is embedded in the URL, once the application has been successfully installed on their personal device, participants will be able to join the online session via the link contained in the confirmation email. Participants will then click the “Join” button and will automatically join the online session. At this point, the online session will be locked and no one else will be allowed to join the online session. The digital recording feature in Zoom will not be used by the facilitator and participants will not have access to it. Participants will then be asked to show a current photo ID (i.e., driver’s license, state issued ID, etc.) to verify age and identity. The facilitator of the online session will verify that the information provided online is accurate and that it matches screening survey responses, including address to mail payment, and to give the participant additional details about the study. The facilitator will answer any questions participants may have and explain the daily survey portion of the study. Participants will also receive information regarding the randomization process and online intervention and TM portion of the study. This training will occur in a private Zoom meeting room. The session will last approximately 30 minutes and participants will be paid $20 to compensate for their time, loaded onto a Greenphire Mastercard, which will be mailed to them after they complete the online baseline survey. After they receive their card, participants will be asked to contact us via email or phone to load their card with a total of $40 ($20 for the online session, and $20 for the online baseline survey, which participants will receive an invitation to upon completion of the online session). If a participant does not confirm receipt of their card within 10 business days of it being mailed, they will receive 1 text message and 1 email notification reminding the participant to confirm receipt of their card. We will also periodically contact them over the phone to confirm receipt of their card. In the event they have not received it after a prolonged period of time, we will re-send them another Greenphire MasterCard to their preferred mailing address. In the event that a participant’s Greenphire MasterCard expires during the course of their participation, or shortly after their participation has concluded, we will send an email alerting the participant of the expiration of their card with instructions for the steps to take to request a replacement card. Participants who complete the online training session, but do not wish to continue their participation in the study will still be compensated the $20 for completion of the online training session, and will be opted out of the study.

During this online training session, the participant will meet with a staff member for a brief training on the next phase of the study and review the consent form, so that participants have the opportunity to ask any consent-related questions. During the online session, participants will be notified of the daily assessment design and information regarding the randomization to condition, daily text messages and online intervention. Facilitators will explain the daily surveys, which captures the subject's alcohol and cannabis use, as well as protective behavioral strategy use and motivations. We will emphasize in the online session, as outlined in the Facilitator Training Manual that researchers will not share this information with anyone outside the research team.

Please see Appendix C for the facilitator guide and online session slides.

Baseline Assessment and 2-Month Follow-Up Assessment

Baseline Assessment. Participants who meet inclusion criteria, complete the online training session, and express interest in continuing participation in the study during the online training session will be emailed and texted a study link to the baseline survey. The baseline survey will include questions about demographics, alcohol use, cannabis use, and related consequences, PBS use and motives, and other health behaviors and will take approximately 30 minutes to complete. Participants will be paid $20 to compensate for their time that will be loaded onto their Greenphire MasterCard. If they do not complete the baseline survey, we will periodically send reminders via email (up to 8), text (up to 8) and phone call (up to 5). Participants will have 30 days to complete the survey.

2-month follow-up assessment. After completion of the 8-week text message intervention, participants will be invited to complete a 2-month follow-up assessment to assess short term effects of the intervention on PBS use (or non-use), motivations for PBS use, quality of PBS use, alcohol use, CAM and SAM use, and related consequences. Participants will be invited via text message and email containing a link to this 2-month assessment. Participants will receive an email shortly before the 2-month follow-up assessment, letting them know that the assessment is approaching. The 2-month follow-up assessment will take approximately 30 minutes to complete. Participants will be paid $30 to compensate for their time that will be loaded onto their Greenphire MasterCard. If they do not complete the 2-month follow-up survey, we will periodically send reminders via email (up to 8), text (up to 8) and phone call (up to 5). Participants will have 30 days to complete the survey.

Baseline and 2-month follow-up measures (30 minutes). While the baseline and 2-month follow-up surveys will contain overlapping content, we may decide to include or exclude a measure over the course of the study, with IRB approval via a modification. Thus, we are electing to not indicate in the consent form that the two surveys will be the same. Overlap in surveys is indicated by the overall content areas of surveys that are provided in the consents. Demographics will include, but are not limited to, birth sex, gender, age, height, weight, and living situation. Eating patterns will be assessed in the baseline survey using the Eating Attitudes Test (EAT; α=.63; Garner & Garfinkel, 1979). **Alcohol Measures**: Drinking will be assessed with the Daily Drinking Questionnaire (DDQ; α = .73; Collins et al., 1985), the Quantity-Frequency Index (Dimeff et al., 1999; Lewis & Neighbors, 2004) and the Alcohol Use Disorders Identification Test (AUDIT; α=.85; Babor et al., 2001). Negative drinking consequences will be assessed with the Young Adult Alcohol Consequences Questionnaire (YAACQ; α=.79; Read et al., 2006) and evaluations of negative drinking consequences will be assessed with a modified version of the YAACQ. Alcohol PBS will be assessed with an adapted version of the Protective Behavioral Strategies Survey-20 (PBSS-20; α=.63-.81; Treloar et al., 2015). Motives for drinking will be assessed by the Drinking Motives Questionnaire (DMQ) - Modified (α = .66-.91; Grant et al., 2007). Readiness to Change Questionnaire (Treatment Version Revised) will be used to assess readiness to change drinking (Heather & Hönekopp, 2008; SAMHSA, 2019). The Alcohol-Induced Blackout Measure (α = .91; Miller et al., 2019) will assess frequency of inability to remember large stretches of time among young adults due to the consumption of alcohol. Family history of alcohol use problems will be assessed with the Family History Measure from the Brief Drinker Profile (Miller & Marlatt, 1984). Descriptive norms will be assessed by asking the perceived frequency and quantity of drinking and cannabis use (α = .80; Baer et al., 1991; Lewis & Neighbors, 2004; Neighbors et al., 2008) among typical men/women their age. **Cannabis Measures**:

Cannabis use will be measured with a parallel DDQ measure that will assess typical days used and typical number of hours high each day (α=.97, Lee et al., 2013). The Marijuana Consequences Questionnaire and a modified version (Lee et al., 2021) will measure a broad range of negative cannabis consequences and evaluations of negative cannabis consequences (α=.89). Motives for cannabis use will be assessed by a modified version of the Comprehensive Marijuana Motives Questionnaire (C-MMQ) (Lee et al., 2009).To assess risk for substance use disorder, we will use the Cannabis Use Disorders Identification Test-Revised (CUDIT-R; Adamson et al., 2010; α=.80). Cannabis PBS will be assessed using an adapted version of the Protective Behavioral Strategies for Marijuana Scale (PBSM-36; Pedersen et al., 2017; α=.93). Concerns related to alcohol or cannabis use will be assessed in the baseline survey using the Card Sorting Task from the Brief Drinker Profile (Miller & Marlatt, 1984). Simultaneous substance use will be assessed with the Other substance use will be assessed for lifetime and past month frequency using the Customary Drinking and Drug Use Record (CDDR; α=.70-.94; Brown et al., 1998; Schafer & Brown, 1991) as well as an adapted version that assesses co-use of substances. Readiness to Change Questionnaire (Treatment Version Revised) will be adapted to assess readiness to change cannabis use (Heather & Hönekopp, 2008; SAMHSA, 2019). SAM use: Questions regarding SAM use will be adapted from the Monitoring the Future measure (Johnston et al., 2015): "Within the past 2 months, how often did you use alcohol at the same time as cannabis – that is, so that their effects overlap?" We will use similar items to assess simultaneous substance use with alcohol and other drugs. CAM use: CAM use is determined from the alcohol and cannabis measures (i.e., endorsement of both alcohol and cannabis use within the same timeframe; Lee et al., 2013). The Consideration of Future Consequences scale (α = 0.80; Strathman et al., 1994) will assess the level to which participants weigh immediate and distant outcomes due to their consequences. Anxiety and depression will be measured using the PROMIS Anxiety v1.0 and PROMIS Pediatric Anxiety v1.1 Short Form (α=.96; Cella et al., 2010). Participants will be asked to report their intentions for using both alcohol and cannabis over the next 2 months. Concerns relating to alcohol and cannabis use will be selected and ranked in the Card Sorting Task in the Baseline survey (Marlatt & Miller, 1984). **Usability Items:** At the 2-Month Follow-Up Survey, participants assigned to the intervention condition will receive items to assess the usability of the online and text message program. Please refer to Appendix B for measures.

Online and Text-Message Intervention

Randomization to Condition. Immediately upon completion of the baseline survey, participants will be randomized to either the online and text message intervention group (n=120) or an assessment only control group (n=120). Randomization to condition (online and TM intervention or assessment-only control) will use a stratified, blocked randomization procedure, where assignment will be balanced across biological sex, and alcohol and cannabis use (Hedden et al., 2006).

Intervention Condition.

Link to Online Intervention Program Modules:

https://www.figma.com/file/kXRFcvowiklC00MXEEsWoj/EQUIP2-Intervention?node-id=0%3A1&t=FkUlzz1k6i7u9V75-1

The online and TM intervention, and its delivery, will be designed and adapted based on the results of the formative focus groups and cognitive interviews (Aim 1, IRB approval 2020-139) and is meant to be non-confrontational in tone, seeks to increase motivation to increase the quality use of PBS and decrease motivations for non-use of PBS. The aim of the intervention content is to focus on targeting the reasons (motives) why one might use PBS and not only how to use PBS, which traditional interventions focus on. The specific content of these TMs will be derived and finalized based in part from Aim 1 findings (i.e., TMs that are rated the most acceptable, PBS that are most likely to be used by this sample, targeting motives for use and non-use) and in part from previous TM interventions.

Upon completion of the baseline survey, participants assigned to the intervention condition will receive a link through text and email to the brief interactive online intervention focusing on self-selected and

personalized alcohol and cannabis PBS messages (Lewis et al., 2018) and reasons for using alcohol and cannabis PBS. The online intervention component will focus on increase motivation to change alcohol and cannabis use and to increase motivations to use PBS in a higher quality and more consistent manner. For example, the online intervention will seek to increase motivations to use PBS by exploring consequences that young adults might wish to avoid as a result of their alcohol and/or cannabis use and then provide suggestions on ways they can reduce consequences. Further, participants will be guided through informational modules related to the role of alcohol and cannabis as it relates to concerns with aggression, legal issues, sleep, boredom, relationship issues, finances, eating and appetite, anxiety and depression, social interaction, sexual behavior, cognitive impairments (i.e., attention, concentration, memory), work or school related issues, as well as other physical health impacts including risk of dependence. These modules will be personalized based on responses participants provide in the baseline survey so that they will only see modules pertaining to concerns that they selected. Information on other reasons that young adults may wish to reduce harms from alcohol and cannabis use will also be shared with the intention of using these topics as potential motivators for change among participants.

Participants will be asked to rate each topic in the online intervention by responding to 2 items that address how useful the information is to that participant and how much the participant enjoyed the content. Participants will then be provided specific information on how to minimize consequences they may wish to avoid by using PBS in a more consistent and quality manner for those specific topics that were most relevant to them. Thus, we can tailor remaining online intervention content directly to what is the most relevant and motivating for each individual participant.
Our prior research shows that young adults perceive TMs with personally, self-selected alcohol PBS as more useful than PBS chosen at random or selected by researchers (Lewis et al., 2018). Thus, it is beneficial to tailor PBS interventions to optimize perceived relevance and to increase motivation to use PBS and to implement PBS with high quality. As such, participants will be asked in the online program evaluation survey to choose 12 alcohol PBS and 12 cannabis PBS that they are motivated to use (from a list of possible PBS for alcohol and cannabis). Participants will also identify whether they prefer to receive that alcohol or cannabis PBS content during the week and/or on the weekend, and at what time of day they would like to receive the PBS. For each self-selected PBS, the interactive online intervention will prompt them to provide information about why they selected that particular PBS. Participants may also receive a series of interactive text messages related to the PBS text messages they receive (i.e., On a scale of 1-5, how useful did you find the strategy that you received?).

Finally, participants will receive information about the daily surveys they will be receiving for the 8-week intervention survey.

The expected length of time to complete the online intervention is 20-30 minutes.

Participants will be asked to provide brief feedback on the personalized information by responding to 2 items presented after each module that will assess how useful and enjoyable the content was.

If participants do not complete the online intervention and feedback on personalized information, we will periodically send reminders via email (up to 6), text (up to 6) and phone call (up to 5). Participants will have 30 days to complete the online intervention and feedback on personalized information.

Next, the self-selected personalized intervention content will be delivered via text messages (TMs) three days a week (Friday, Saturday, random day [i.e., Sunday through Thursday]) over eight consecutive weeks, to begin the first Friday following completion of the interactive online program and feedback. Participants will report on PBS use and non-use, including motivations and quality of PBS use, and alcohol and cannabis use in daily online surveys timed to occur the day after the intervention messages (Saturday, Sunday, morning after random day). Intervention content will be linked with the data entry module for the baseline and daily assessments, allowing data to be imported into the intervention content (online or TM). Please see Appendix C for a bank of the alcohol and cannabis PBS text messages.

On days intervention group participants will be receiving TM intervention content, they will respond to items in the daily survey assessing readiness to change, willingness to use PBS, and which types of PBS they are interested in receiving that day. Survey items will ask participants to complete a readiness ruler assessing importance of "at this moment" making a change in their alcohol use and cannabis use. Then, a second series of survey items requests a response to a modified readiness ruler assessing willingness to use PBS in general, willingness to use PBS to reduce use, and willingness to use PBS to reduce consequences, separately for alcohol and for cannabis (e.g., "How willing are you to use a tip or strategy related to your alcohol use today (Not at all Willing-Extremely Willing"). Later that day, the PBS content they receive will be personalized and matched to their importance/willingness ratings and reasons to use PBS, such that intervention TM content is stage-appropriate and for reasons related to lower use or lower risk.

Participants in the intervention group will be given two opportunities to review a personalized monthly summary of alcohol use, cannabis use, and protective behavioral strategy use. The first personalized report will summarize weeks 1-4 of their daily surveys and will be delivered via email and text message on the day after the 12th daily survey window closes. The second personalized report will summarize weeks 5-8 of their daily surveys and will be delivered via email and text message on the day after the 24th daily survey window closes. The reports will include a past month summary page for both alcohol and cannabis that provides details on the past four weeks. The alcohol use summary page will display the number of drinks participants had and the number of alcohol PBS they used on Friday, Saturday, and the random day on which they received personalized PBS text messages. The cannabis use summary page will display the number of hours participants spent high and the number of cannabis PBS they used on Friday, Saturday, and the random day on which they received personalized PBS text messages. A separate summary page will display the number of days in the past month that participants reported using both alcohol and cannabis simultaneously with overlapping effects. The last page of the monthly summary report invites them to review alcohol and cannabis PBS and ways they can use these PBS most optimally. This page routes back to a module in the intervention titled "Tips and Strategies" which outlines a list of high-quality PBS examples for alcohol use (e.g. "Refuse to ride in a car with a driver who you know has been drinking") and a list of high-quality PBS examples for cannabis use (e.g. "Consider alternate activities instead of using cannabis to cope with emotions such as sadness or depression, or decide to only use cannabis when not feeling sad or depressed.") Participants are not required to interact with their monthly summaries and will not be compensated for doing so. However, the aim of the monthly summaries is to encourage participants to reflect on their total number of drinks and hours high per day, week, and month and their PBS use over the time that they have received daily surveys and personalized PBS text messages.

Assessment-only control condition. The assessment-only control condition will not receive any intervention content (online or text message) during the 8-week period of data collection to support testing primary aims. Assessment-only participants will complete all surveys: baseline, 2-month, and daily surveys according to the same schedule as the intervention group.

Online Program Evaluation survey. The intervention condition participants will provide their feedback on the interactive online program. After viewing the online program, they will first be prompted to select which specific PBS they are interested in receiving, will be shown quality and consistency examples of each strategy, and will select which days/times they are interested in receiving a text message relating to each type of strategy. A modified System Usability Scale (Brooke 1996, 2013; Sauro, 2011) and Website Analysis and Measurement Inventory (WAMMI; Danielson et al., 2016) will assess perceived usability of the online intervention and TMs, perceived favorability of the online design, ease of navigation and use, convenience, relevance and usefulness. Perceived viewing, engagement and appeal of the intervention and TMs will be assessed (Lewis & Neighbors, 2015; Li et al., 2019; Shrier et al., 2018). Intervention participants will complete items to evaluate the online portion's: content (thought-provoking, easy to understand, relevant, useful), format (attention-grabbing, interesting, enjoyable) and next steps (motivation to change self/others, open-ended question on most useful and engaging portion of the online feedback session). PBS use intentions, as well as alcohol and cannabis use intentions will be assessed. We will assess if participants were under the influence of alcohol or cannabis while completing

the interactive online program or feedback on personalized information. Please refer to Appendix B for measures.

Daily assessments. For the intervention condition, the 8-week period for daily surveys and TM intervention content will begin the first weekend after completion of the interactive online program and feedback. Participants will receive up to 2 emails prior to their first daily survey alerting them of the start date for the approaching daily surveys. For the assessment-only control condition, the 8-week period for daily surveys will begin the first Saturday after completion of the interactive online program and feedback. Participants will complete daily assessments online via computer or smartphone. For each survey window, the participant will receive an email and TM indicating the beginning of the 4-hour survey period and a hyperlink to the survey. Those who do not complete the assessment will be emailed and sent a TM reminder 2 hours prior to the close of the window, and again 30 minutes prior to the close of the window. Each daily survey will take 9-10 minutes to complete regardless of reported substance use that day. Participants will earn $4 for each daily assessment completed that will be loaded onto their Greenphire MasterCard at the end of the study, upon completion of the 2-Month Follow-Up survey. Participants can earn a $10 bonus if they complete at least 90% of the daily surveys (21 out of the 24 total surveys) during the 8-week period, for a total of up to $106 that can be earned for the daily surveys. Participants will receive check-in calls by study staff on or after the 10th day of daily assessments to see if they are experiencing any issues or have any questions. For participants who miss several surveys, non-compliance phone calls will be made, and non-compliance emails and text messages will be sent to assess for any potential issues and keep retention rates high. Please refer to Appendix C for scripts.

Surveys will be set up to match local time zone: Central Standard Time. Participants will also be able to identify periods within set windows for weekday and weekend assessments. Participants can choose a 4-hour window beginning between 6am-11am to complete their daily assessment, separately for weekdays and weekends. To account for differences in schedules, participants will identify their preferred 4-hour daily assessment time prior to the start of their daily surveys.

Daily survey measures. Our strategy is to collect daily reports each morning after intervention participants received TM content (intervention group). Assessment-only control participants will receive daily surveys on the same schedule as intervention condition participants. **Yesterday's alcohol/cannabis use:** Participants will report the number of standard drinks consumed the previous day, the number of hours they spent drinking, whether they used cannabis, number of sessions used cannabis, and how long they were high. SAM use will be assessed by asking "Yesterday, did you use alcohol and cannabis at the same time-that is, so that their effects overlapped?" (Patrick et al., 2019). **CAM use** will be identified by the endorsement of alcohol and marijuana use the previous day, but responding "no" to the SAM use item. **Substance-related consequences** experienced the previous day will be assessed with items from alcohol and cannabis consequences scales. **Motives to use alcohol and cannabis** will be assessed via modified versions of the Drinking Motives Questionnaire and the Marijuana Motives Questionnaire, respectively (Bonar et al., 2018). For **alcohol**, we will administer items used in our previous daily diary study of alcohol use (Lewis et al., 2020). A modified Marijuana Consequences Questionnaire (Lee et al., 2021) will assess **cannabis consequences**, selecting acute items appropriate for daily-level measurement (Linden-Carmichael et al., 2020). We will assess **behavioral risks** not included above (e.g., other substance use). **PBS use and quality** the previous day will be assessed by having participants report which, if any, alcohol and/or cannabis PBS they used the previous day, and for those they report using, how well they implemented the PBS (i.e., quality) and how helpful they perceived the strategy to be. **Motivations to use PBS** will be assessed by asking why they selected to use those strategies that day, or why they did not select to use the strategies they reported not using. **Quality of PBS use** will be assessed by a series of items demonstrating examples of low, medium, and high quality use of each strategy, with participants being instructed to select which scenario best reflects how they utilized the strategy. **Readiness to change** (Miller & Rollnick, 2013; SAMHSA, 2019) will be assessed with "At this moment, on a scale of 0 to 10, how important is it for you to change your current drinking/cannabis use if you decided to?". Finally, we will assess if participants are currently **under the influence** of alcohol or cannabis when completing daily surveys.

Daily Survey Filler Measures. For days when participants do not report drinking or cannabis use the previous day, they will be asked alternative questions to balance the length of the assessments and to reduce participant boredom with the surveys. Alternative questions will be programmed such that a new filler measure will be shown to a participant on each non-drinking and non-cannabis use day. We will assess participants motives and reasons for either limiting alcohol/cannabis use or not using alcohol/cannabis on a given occasion via the Motives for Abstaining from Alcohol Questionnaire (α = 0.88; Stritzke & Butt, 2001), the Reasons for Limiting Marijuana Use Scale (Epler et al., 2010; Huang et al., 2011; Johnson & Cohen, 2004), the Reasons for Not Drinking Scale (O'Hara et al., 2014), and the Reasons for Alcohol and Cannabis Nonuse Scale (Stevens et al., 2021). The Fear of Missing Out scale (FoMO; α = .90; Przybylski et al., 2013) will assess the level to which one perceives that others are having rewarding experiences while one is absent. The Consideration of Future Consequences scale (α = 0.80; Strathman et al., 1994) will assess the level to which participants weigh immediate and distant outcomes due to their consequences. Self-compassion will be assessed using the Self-Compassion Scale (α = 0.88; Raes et al., 2011). The Self-Monitoring Scale (α = 0.71; Snyder & Gangestad, 1986) will assess the extent to which one is willing and able to influence how one's image is perceived. The Social Lives Scale (α = 0.76; Deri et al., 2017) will assess participants' perception of other and their own social lives. The Locus of Control Scale (α = .70; Rotter, 1971; Kourmousi et al., 2015) will assess participants' internal and external control of reinforcement. The Social Avoidance (α = .84) and Social Fear scales (α = .85; Heimberg et al., 1999; Liebowitz, 1987) will assess social phobia. Participants' level of satisfaction with life will be assessed by the Satisfaction with Life Scale (α = .87; Diener et al., 1985). The Network of Relationships Inventory subscales (Emotional Support, Companionship, Companionship; α = .92-.93; Furman & Buhrmester, 1985) will assess positive and negative features of participants' relationship with a best friend.

Feasibility and acceptability for TM content. <u>This information is subject to change based on the feedback collected from the focus groups/cognitive interviews being conducted in Phase 1.</u> TMs will consist of a two-way dialogue, to assess whether participants read the message, participant response after reading TMs, whether alcohol or cannabis was being used when TMs were sent/read. Adherence will be calculated by the percentage of TMs that prompted a participant response (Lewis et al., 2018). Participants will respond by indicating helpfulness, likeability, thought-provoking, and clarity (e.g., 1 = not at all to 5 = very). We will track message timing, response, recall, and content of messages to determine factors that may impact intervention efficacy as well as alcohol or cannabis use. We will examine response rates to intervention TMs on days alcohol and/or cannabis use were reported.

2) <u>*Data Analysis and Data Monitoring*</u> - *Describe plans for statistical analysis of data when appropriate. If a data safety monitoring committee is appropriate to protect the safety and/or welfare of subjects, describe its operation (e.g., membership, stopping rules and frequency of review).*

Data Analysis and Power.

Prior to any inferential statistics, univariate and bivariate descriptive statistics will be used to examine distributions and simple associations among variables. Preliminary analyses will include nature of missing data and identification of extreme values. Baseline equivalence on PBS, alcohol, and cannabis measures and demographic representation across conditions in Phase 2 will be examined. Feasibility and acceptability will be the primary outcomes for Aim 2. Behavioral alcohol and cannabis outcomes (PBS use, PBS motivation, PBS quality, alcohol use, alcohol consequences, cannabis use, cannabis consequences, CAM use, SAM use) will provide estimates of base rates and variance in outcomes to determine power for a R01 application as this program of research transitions to a Stage II study.

H2a: We hypothesize that the intervention will be feasible (achieve recruitment goal and do so within acceptable timeframe, high study retention, high time spent on online intervention, high interaction with online intervention, high participant responses to intervention TMs, high responses to intervention TMs including when using alcohol or cannabis) and acceptable (enroll high proportion of eligible participants; favorable participants' ratings of intervention components as well as ratings of accessibility, usability, convenience, thought-provoking, enjoyable, and relevance as measured at the feedback on personalized

information and post-text message assessments).

Feasibility of the intervention will be established by achieving the recruitment goal (N=240), achieving the recruitment goal within 6 months, and the rate of study retention being 90% or higher, including the proportion of young adults who complete the intervention and respond to intervention TMs, the proportion of daily surveys completed, and the 2-month follow-up retention. Study retention rates will also be examined by condition and baseline drinking status. These statistics are necessary as a basis for sample size/power calculations for the future R01.

As additional assessments of intervention feasibility, we will track time spent viewing the online intervention and which components of the online intervention had more viewing time and/or interaction with intervention content (Lewis & Neighbors, 2014, Lewis et al., 2018; Li et al., 2019). Because TMs will consist of a two-way dialogue, we will also examine feasibility related to whether participants read the intervention message, participant response after reading intervention TMs, whether alcohol or cannabis was being used when intervention TMs were sent/read, and participant recall of intervention messages. Adherence will be calculated by the percentage of intervention TMs that prompted a participant response (Lewis et al., 2018). We will track intervention message timing, participant response, participant recall of intervention TMs, and content of intervention messages to determine factors that may impact intervention efficacy as well as alcohol or cannabis use. We will examine response rates to intervention TMs on days alcohol and/or cannabis use were reported as another measure of feasibility. Participants will respond to intervention content by indicating helpfulness, likeability, thought-provoking, and clarity (e.g., 1 = not at all to 5 = very) as a measure of acceptability and/or palatability of the content.

Acceptability of the intervention will also be determined by: (1) proportion of eligible young adults enrolled (80% of eligible young adults agreeing to participate); (2) young adult participants' ratings of individual intervention components including both online and text message content (rating content as favorable overall, attention-grabbing, interesting, enjoyable), (3) young adult participants' ratings of accessibility (acceptable length of intervention, acceptable timing of intervention delivery), usability (ease of viewing and navigating intervention online and via TM), convenience (mode of intervention delivery), and relevance of intervention content (engaging and helpful content, thought-provoking), and (4) the proportion of young adults who would recommend the program (outside of a paid research study). Acceptability will be achieved if 80% of responses in each domain are rated a 4 or higher (out of 5). For the System Usability Scale, scores below 4.0 on the 5-point items indicate a need to re-examine intervention features, and scores of 68 or higher of the 100-point total support overall usability. In the case that intervention areas do not meet these criteria, the investigative team will revise intervention components prior to a future large-scale randomized trial. The Website Analyses and Measurement Inventory (WAMMI) consists of 20 validated statements used to evaluate websites or intervention programs. We will use this measure to assess acceptability of our online and text message intervention. Each statement is rated on a 5-point scale from strongly agree to strongly disagree and scores are calculated for Attractiveness, Controllability, Efficiency, Helpfulness and Learnability as well as an overall global usability score. All scores are automatically calculated by the WAMMI website and compared to large international database of scores for other projects. A global usability score of 50 or higher indicates that a given website or intervention program is above average (50) for usability and accessibility according to a large international database maintained by the creators of the Website Analyses and Measurement Inventory.

H2b: We expect that receiving the intervention will be associated with short-term (2-month) increases in PBS use, motivations for PBS use, and quality of PBS use as well as decreases in motivations for PBS non-use and reductions in past 2-month alcohol use, CAM and SAM use, and related consequences.

Given the repeated measures design, generalized linear mixed models (GLMM; Hox, 2010; Snijders & Bosker, 2012) will be used. GLMM (i.e., hierarchical generalized linear models) allow for non-normal outcomes (e.g., count outcomes such as number of days high or number of negative consequences) and missing data, handle varying timepoints, and accommodate time-varying and time-invariant covariates. Models include two repeated measures (baseline, 2-month), yielding up to 600 observations (Level 1:

repeated-measures) across 240 individuals (Level 2: people; n = 120 per condition). Time (2-month) will be coded as a dummy variable that compares the 2- month follow-up to baseline (reference category). To test intervention effects for H2b, Intervention Condition will be a dummy variable that compares the intervention condition to the assessment-only control condition (reference category). Of particular interest are parameters that reflect the interaction between intervention condition and Time. For count outcomes (e.g., alcohol use and consequences), the outcome is connected to covariates through a log link function, which is the standard link function for Poisson GLMM. Covariates can be exponentiated to yield Rate Ratios (RRs) that describe the proportional change in the count outcome associated with a 1-unit increase in the covariate. If data show over-dispersion where the variance exceeds the mean, the model will be extended to include a scale parameter to fit an over-dispersed Poisson, or we will consider zero-altered models to ensure accurate inferences (Atkins & Gallop, 2007). Biological sex, age, and baseline readiness to change will be included as covariates in all analyses. We will also consider (a) adding baseline covariates to improve precision or in the case that evidence suggests an imbalance in the distribution of the covariate(s) across conditions and (b) adding baseline covariates related to the COVID-19 pandemic if deemed necessary.

H2c: Using the event-level data (from daily surveys), we expect that on days when individuals' motivations to use PBS are elevated (i.e., higher than their own average level) or the quality of their PBS use is elevated (i.e., higher than their own average level), they will report lower alcohol use, be less likely to report CAM or SAM use, and report fewer negative consequences. These effects will be stronger among those in the intervention group compared to the assessment-only control group.

H2d: We will examine whether days when young adults use alcohol alone, compared to both CAM and SAM use days, are associated with greater use of alcohol PBS, greater motivation to use alcohol PBS, less motivation for non-use of alcohol PBS, and higher quality of alcohol PBS use. Similarly, we will examine event-level associations between PBS use and consequences (alcohol and marijuana) to determine whether PBS are as effective at reducing consequences when CAM or SAM use occurs.

H2c and H2d utilize event-level data and can be tested with GLMM, which is also used for H2b. The 2-level model accounts for the clustering of observations whereby daily surveys (Level 1: day-level) are nested within individuals (Level 2: person-level). GLMM can accommodate unequal observations per person. We will employ an appropriate modeling distribution for all outcomes (e.g., zero-inflated Poisson distribution for count outcomes like consequences; normal distribution for PBS motivation). We will evaluate whether model assumptions are met (e.g., normality of error terms) so that data are modeled appropriately (Atkins & Gallop, 2007). Centering of predictors and controlling for the associated higher-level effects will be done based on standard practice and current recommendations. Biological sex and age will be person-level covariates in all analyses, and daily-level covariates will be alcohol use, cannabis use, weekend, and readiness to change in all analyses. We will also consider adding daily-level covariates related to the COVID-19 pandemic if deemed necessary. Due to the large number of models, p-values will be adjusted (Benjamini & Hochberg, 1995).

Event-level designs using daily surveys produce rich and complex data sets that permit the examination of different types of associations among constructs, and these complex associations can be tested with GLMM. For instance, H2c specifies that on days when individuals' motivations to use PBS are elevated (i.e., higher than their own average level), they will report lower alcohol use. Here, PBS motivations is the predictor (person-centered) and number of drinks consumed that day is the outcome. A cross-level interaction between the predictor (Level 1) and condition (Level 2) can be tested to determine whether this effect is stronger among those in the intervention condition compared to the assessment-only control condition. GLMM specifications can easily be modified for the event-level data to test all the hypotheses specified by H2c and H2d. For instance in H2d, each day will be coded as: neither alcohol nor marijuana, alcohol alone, marijuana alone, CAM, or SAM. Then dummy codes will be created to make specific comparisons (e.g., alcohol alone days versus SAM use days).

3) <u>Data Storage and Confidentiality</u> – *Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data. This*

includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data. State who will have access to the data. If data with subject identifiers will be released, specify the person (s) or agency to whom the information will be released and the purpose of the release. For specific language, please refer to the NTR IRB's Data Storage and Security Guidance document.

Screening, Baseline, Feedback, and 2-month follow-up Data. Survey data will be identified only by a seven-digit PIN (personalized identification number) randomly generated for research purposes, and will not be identified by participants' names. Participants are assigned a PIN at the start of the online screening survey. This PIN will be embedded in all communications in which a link to surveys is sent. The PIN embedded in the survey link means that the link is specific to that individual and their survey data will be connected to that PIN. Thus, participants will not ever need to enter their PIN for purposes to complete study surveys. Participants are further protected by having an embedded PIN. An embedded PIN is more secure than emailing the PIN to participants as participants do not have to worry about keeping this information private. There is also less participant burden with the use of an embedded PIN as emailing the non-embedded PIN would require doing so in a separate communication than the survey link. The participant's PIN is kept separate from their personal information, so that without their PIN, none of their answers can be linked to anything that might identify them. Only the researchers will know the PIN. Participants will not be identified in any research reports, data sharing/online research, databases, or presentations of the research. Their name and contact information will be accessible only to research staff for the purposes of contacting them to complete the study, and will be stored separately from their data on computers with password protection and in locked file cabinets. Screening, baseline, feedback, and 2-month follow-up surveys will be completed online via Rivulent Web Design, Inc., which provides the highest available level of protection for their confidentiality. The survey data will be retained indefinitely and will identified only by the PIN. The master list of identifiable data (with the exception of those consenting to the re-contact provision) from screening forms will be destroyed by the end of the study for all participants. Identifiable data that will be kept separate and destroyed by the end of the study includes name, contact information, city, state, and zip code of residency, with the exception of those consenting to the re-contact provision. To determine levels of socioeconomic disadvantage using the Area Deprivation Index, we will utilize the United States Census Bureau Geocoder. This tool uses unique ID numbers to link participants' addresses provided at screening with their corresponding geocodes and block codes maintaining data confidentiality. Screening, baseline, and 2-month follow-up survey data will be collected via Rivulent Web Design, Inc. and be saved on a dedicated Rivulent Web Design, Inc. server for STARR lab (Drs. Lewis and Litt) projects. Project EQUIP data will also be saved by the research team on LabArchives. Rivulent Web Design, Inc. and LabArchives are both HIPAA compliant. Rivulent Web Design, Inc. and LabArchives data are encrypted, password protected, and HIPAA compliant. To maintain the confidentiality of data submitted over the internet, participants will log in to a secure website using their unique PIN created for study purposes. Data transfer will be protected using Transport Layer Security (TLS) version 1.2 or higher. The TLS encrypted session will ensure that data moving from the participant to the server (i.e., participant responses) will be encrypted in transit using a 2048-bit minimum encryption key. Data downloaded from the dedicated Rivulent Web Design, Inc. server will be stored by the research team with secure storage within LabArchives network, and is located in a locally managed datacenter. The datacenter is protected by two-step verification, configured sharing permissions, monitoring of activity, disabled permanent deletions, and conduction of regular access reviews.

EMA/Daily Data. EMA survey data will be collected via Rivulent Web Design, Inc. and be saved on a dedicated Rivulent Web Design, Inc. server for STARR lab (Drs. Lewis and Litt) projects. Project EQUIP data will also be saved by the research team on LabArchives. Rivulent Web Design, Inc. and LabArchives are both HIPAA compliant. Rivulent Web Design, Inc. and LabArchives data is encrypted, password protected, and HIPAA compliant. To maintain the confidentiality of data submitted over the internet, participants will log in to a secure website using their unique PIN created for study purposes. Data transfer will be protected using Transport Layer Security (TLS) version 1.2 or higher. The TLS encrypted session will ensure that data moving from the participant to the server (i.e., participant responses) will be encrypted in transit using a 2048-bit minimum encryption key. Data downloaded from

the dedicated Rivulent Web Design, Inc. server will be stored by the research team with secure storage within LabArchives network, and is located in a locally managed datacenter. The datacenter is protected by two-step verification, configured sharing permissions, monitoring of activity, disabled permanent deletions, and conduction of regular access reviews. The EMA data/study information is immediately sent to the secure, HIPAA compliant server via the internet. All survey links have security features to keep all data confidential. This data security information has been added to all consent forms.

If a participant agrees to be contacted for future research opportunities, their personal contact/demographic information will be stored on our secure LabArchives network which is protected by two-step verification, configured sharing permissions, monitoring of activity, disabled permanent deletions, and conduction of regular access reviews. Personal contact/demographic information will only be retained for participants who give permission to be contacted for future research opportunities. This information will be kept separate from the raw research data and will only be used to inform consenting participants of future research opportunities. The master list which connects identifiers to research data will be destroyed at the close of the study, preventing any connection between the future contact information and the raw research data. In order to monitor enrollment and prevent participants from enrolling multiple times, we will keep contact information for all participants until the end of the study (or indefinitely for those who agree to be contacted for future/additional research opportunities).

In addition to the above-described data safeguards, all members of the research team have received or will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project (including research assistants and study staff) will complete the required NIH training in protection of human research participants. All staff will sign confidentiality statements. In addition, we have been automatically issued a federal Certificate of Confidentiality through the Department of Health and Human Services. This certificate offers the highest protection available by law for research data. We previously used these certificates in our work with high school students, college student gamblers, drinkers, cannabis users, and those who engage in risky sexual behavior. Participants will be informed of these risks and protections in the informed consent process. All recruitment contacts will emphasize the voluntary nature of participation, to reduce risks of experienced coercion. Finally, participants will be notified of the potential risk that the information provided may not be helpful, and will be provided with information about where else they might seek information about alcohol or drug use, or receive alcohol and drug-related services if desired.

4) *Setting* - *Describe briefly where the study will be conducted (e.g., private outpatient clinics, physicians' offices, etc.).*

The entire study will be conducted online.

Data collection will only occur at the University of North Texas Health Science Center. The University of Washington will not be a site for data collection. Participant data and safety monitoring plan, data analyses, and manuscript preparation will occur at the University of Washington.

We will comply with the NIH policy on the use of IRB for Multi-Site Research. The University of North Texas Health Science Center will serve as the IRB of record. The University of Washington will agree to rely on the University of North Texas Health Science Center to serve as the IRB of record. If any additional sites are added after the award, these sites will rely on the University of North Texas Health Science Center as the IRB of record.

The University of Washington determined this study to be "human research not engaged" and that review and approval by the University of Washington IRB was not required. Please see new document (University of Washington IRB determination).

5) *Laboratory methods and facilities* - *Indicate where specific laboratory tests will be performed (e.g., hospital chemistry laboratory, investigators' laboratory, radiology clinic, etc.). If None, state "N/A".*

N/A

6) *Estimated Period of Time to Complete the Study – Describe the stages and total time of subject participation as well as overall time for the entire study (start to completion). Also, if the study involves more than one visit, describe time range estimates for each visit (e.g., 20-30 minutes; 2 – 3 hours, etc.). Where possible, use a table or "bullet-point" format to clearly illustrate the flow of activities and procedures.*

- Start to finish: Approximately 8 weeks
- Online screening survey: 5-10 minutes
- Online Training Session: 30 minutes
- Online baseline survey: 30 minutes
- Online intervention (intervention condition only): 20-30 minutes
- Feedback on personalized information (intervention condition only): 10-15 minutes
- Daily surveys: 9-10 minutes each (24 surveys total)
- Online 2-month follow-up survey: 30 minutes

F. Human Subjects - *Describe the characteristics of the research population:*

1) *Sample Size: Specify the approximate number of subjects to be enrolled in this study at this site.*

Approximately __240 (120 intervention group participants; 120 assessment-only control participants)__ subjects at __1__ sites in the U.S. will be enrolled/randomized in the study overall.

2) *Describe both Inclusion AND Exclusion Criteria. BE SPECIFIC! Include physical, mental, cognitive, medical, and other relevant Inclusion and Exclusion criteria.*

1) Provide first and last name
2) Age 18-24
3) Live in Texas
4) Valid email address
4) Valid cell phone number
5) Own a cell phone with text messaging capabilities
6) Have a schedule that allows for daily surveys
7) Have a device that supports Zoom system requirements to participate in online training session
8) Willing to receive study notifications and messages

9) Typically drink at least 3 days in the past month

10) Typically use cannabis at least 3 days in the past month

11) Report having at least 1 alcohol-related or 1 cannabis-related consequence in the past month

12) Report being in contemplation or action stage based on readiness to change scale for alcohol or cannabis (i.e., not in precontemplation stage)

13) If female, not pregnant or trying to become pregnant

14) Not currently in treatment for alcohol or substance use

15) Willing to participate in online/text message based intervention

16) Not having participated in a Phase 1 focus group or cognitive interview

17) Must correctly answer attention check questions (i.e., select 2 for "what is 4 minus 2?")

18) Be willing to participate in a 30-minute online training session via Zoom Video Communications

19) Owns a valid photo ID to present in online training session

The initial screening is conducted online to determine eligibility. Eligibility questions will be embedded in demographic and behavioral questions so as to not make criteria obvious. Rolling recruitment will be used for the proposed study. We will track participants' personal information (home address, phone numbers, date of birth) to ensure that individuals do not participate multiple times. Upon completion of screening and verification procedures, eligible participants will be sent an email with a link to the baseline survey with an embedded PIN unique to that participant. Aim 1 participants cannot participate in Aim 2.

Exclusion criteria include not meeting inclusion criteria, unwillingness to participate, failure to provide consent (e.g., declining participation in the study), providing inconsistent responses (e.g., age) identified by the survey, and having already participated in the study as identified by overlap or consistency in email addresses, contact information, and demographics. There are no other inclusion or exclusion criteria for the longitudinal portion of Aim 2 other than participants being excluded if they report that they are no longer interested in continuing their participation.

This proposal includes age-appropriate inclusion of individuals across the lifespan (ages 18-24) as this specific age range provides the best sample to address study aims. Alcohol and cannabis use are prevalent and problematic in this age range and thus age-appropriate inclusion is warranted and preferable. All participants will be 18 or older and thus are not considered children by NIH definition.

3) *Describe intended gender, age range, intended racial and ethnic distribution. If any vulnerable subjects are involved in this study (e.g., those with limited autonomy or decision-making capabilities),a justification must be provided.*

We will stratify recruitment based on biological sex and alcohol and cannabis use, aiming to recruit equal numbers of participants in each of the categories and targeting equal numbers of males and females in each group. We will recruit all minority participants to be above local census estimates. For the randomization to conditions (intervention or assessment-only control) we will use a stratified, blocked randomization procedure, where assignment will be balanced across biological sex and alcohol and cannabis use (Hedden et al., 2006). We will stratify recruitment based on biological sex, alcohol and cannabis use to aim for equal numbers of males and females at each group.

4) *Identify the source(s) from which you will obtain your study population.*

Participants will be selected by targeted online (Facebook/Instagram/Twitter; Craigslist and online newspapers) advertisements as well as in-person recruitment approaches (i.e., leaving flyers at local businesses, etc.)

5) *Describe plans for recruitment of subjects. All materials (e.g., flyers, ads, emails, letters, postings, handouts, social media language, website link, etc.) that will be used for recruiting subjects must be submitted to the IRB for review. For specific guidance, please refer to the NTR IRB Recruitment Guidance document.*

We will utilize multiple recruitment methods to reach a variety of participants ages 18-24 from Texas. Our experience has demonstrated success in recruiting participants using the proposed methods. Online ads will be placed in media outlets. In-person recruitment may consist of tabling at local sites and study staff handing out study flyers and study information businesses. Flyers advertising recruitment for a research study of 18-24 year olds will include information about the study and links to the study website, email address, and phone number. Website links and QR codes provided to individuals (in flyers and online recruitment ads) will lead them to the consent/assent forms. Online, print, and bus ads may be placed in local media outlets and city buses. Community organizations may be contacted via email requesting them to share the study's information with individuals in their organization. Social media outreach will consist of a Facebook Fan page that will provide a brief study description and links to the study website. We will use Facebook's advertising platform to also show our ads on Instagram. The Facebook Fan page is open to the public. Liking the Fan page is not an indicator of study enrollment. The communication for the Fan page is a one-way communication platform whereby communication will come from the study staff via Facebook. Individuals will not be able to post or comment within the Fan page. They can share posts from the page on their newsfeed. We ask participants to like or share our Fan page, but we do not ask them to post anything on the Fan page. Additionally, we created Twitter and Instagram accounts. We will use paid Facebook, Twitter, and Instagram sponsored ads, stories, and promoted boosts on our Fan page/Twitter/Instagram accounts to increase our online presence. We will also advertise in local online versions of newspapers and in high school newspapers. Online (e.g., Craigslist, Facebook, Twitter, Instagram, newspaper) recruitment ads will provide a hyper-linked website address for more information and eligibility screening. Print advertisements in local newspapers will contain a brief description of the study and various methods of contact for the study (website, phone number, email).

We are targeting ads to show up in newsfeeds of individuals age 18-24 in Texas. We pay for ads to show up in newsfeeds in Facebook and Instagram. We do not buy ad space. Ads for this study will be targeted by age and/or by birth sex to those in Texas. Ads do not appear based on any keywords. We submit ads directly via Facebook for both Facebook and Instagram as well as directly to Twitter. We do not use a recruitment agency. Ads in newsfeeds cannot be seen by anyone other than the individual. They are not permanent posts to newsfeeds. Because these ads are not permanent and cannot be seen by anyone other than the participant they do not increase or pose additional risk. Participants will have the option to hide or not see any ads from Project EQUIP on Facebook, Instagram, and Twitter if they so choose. This is always an option for any ad on Facebook, Instagram, or Twitter.

Study materials related to Project EQUIP will include the following HSC logo:

hsc
THE UNIVERSITY of NORTH TEXAS
HEALTH SCIENCE CENTER at FORT WORTH

G. Risk/Benefit Assessment

1) *Describe any **potential RISKS OR DISCOMFORTS** in detail. Please note that potential risks include informational risks (such as breach of confidentiality) as well as other risks, such as physical risks (direct injury or harm to the subject), reputational injury, and emotional risks. Describe the procedures for protecting against or minimizing potential risks. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Be sure to describe any anticipated adverse events that might occur during the course of the study, and describe the methods for detecting adverse reactions.*

The study procedures involve more than minimal risk to participants. The consent procedures will make clear all of the potential risks of study participation. Psychological risks posed by the research are primarily related to the sensitivity of some of the survey items. These items include thoughts, feelings, and personal difficulties that may be private and personal behavior such as alcohol and cannabis use and related negative consequences. These questions may make participants uncomfortable, or be perceived as an intrusion on their privacy. In addition, participants are asked to report on potentially illegal behaviors, such as drinking under the legal drinking age and using illegal substances. Answers to these questions could pose a risk if the information were known and linked to identifiable individuals. We have automatically been issued a Certificate of Confidentiality from NIH to prevent disclosure of sensitive or illegal behaviors. We have been using similar procedures on multiple NIH-funded studies with no adverse events or loss of confidentiality on any project. We have taken steps to protect participants against potential risks posed by their participation in this research. Participants will be fully informed of the range of items and the most sensitive and personal topics in the consent form, and will be informed that they are free not to answer any question they wish not to answer, and can refuse to participate or withdraw from participation at any time without penalty. Psychological risks of experienced invasion of privacy or increased awareness or concern about one's behavior as a result of completing the surveys and potential loss of confidentiality will be addressed as a risk in the consent documents. Participants are encouraged to contact the investigators at any time to discuss any concerns they might have. Participants who express interest in seeking help for substance-related problems or for psychological distress will be offered referral information and will be emailed a copy of the Resource List (see Resource List Email). Participants will not be restricted from seeking other alcohol or mental health education, prevention, or treatment opportunities, and we will assess for use of other services at each assessment.

We do not ask any survey items that assess suicide, child abuse, or child neglect, so we would have no data related to these topics to report. However, if a participant discloses this information we will report it to the appropriate official/agency according to Texas State Law.

We have taken steps to protect participants against potential risks posed by their participation in this research. Participants will be fully informed of the range of items and the most sensitive and personal items in the consent forms, and will be informed that they are free not to answer any question they wish not to answer, and can refuse to participate or withdraw from participation at any time without penalty. Psychological risks of experienced invasion of privacy or increased awareness or concern about one's behavior as a result of completing the surveys and potential loss of confidentiality will be addressed as a risk in the consent documents. In order to protect against risks posed by a potential loss of confidentiality, we will take the following steps: First, all data will be identified only by a unique identifier, which will be randomly generated for study purposes. These unique identifiers will be embedded in individual survey links such that they do not need to be entered by participants or known by participants. Identifiable information entered online (such as contact information) will be downloaded and stored separately from participants' responses, but will be identified by the unique identifier. A master list of names and unique identifier will be stored in a password-protected database, on a password-protected computer with restricted access, and will be available only to senior research staff and the PI on this project. Electronic data will be stored on password-protected secure computers only accessible to study personnel. Second, all members of the research team have received or will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project (including research assistants and study staff) will complete the required NIH training in protection of human research participants. All staff will sign confidentiality statements. Third, to maintain confidentiality

of data submitted over the internet, participants will be required to log into a secure and HIPAA compliant servers using a link with an encrypted unique identifier created for study purposes. The PI has extensive experience with conducting online recruitment and assessment with no adverse events ever occurring from this method of data collection or stated procedures. Fourth, NIH issues a federal Certificate of Confidentiality through the Department of Health and Human Services. This certificate offers the highest protection available by law for research data. We previously used these certificates in our work with high school students, college student gamblers, drinkers, cannabis users, and those who engage in risky sexual behavior. Participants will be informed of these risks and protections in the informed consent process. All recruitment contacts will emphasize the voluntary nature of participation, to reduce risks of experienced coercion. Fifth, to maintain confidentiality through using Zoom, connection to the online session will be protected using 256-bit Transport Layer Security (TLS). The use of TLS encryption will provide safety against the online training session being intruded. Additionally, session facilitators will use Zoom's locking session feature to preclude others from joining the session and to minimizing the possibility of the Zoom server being hacked and the loss of confidentiality. The digital recording feature in Zoom will not be used by the facilitator and participants will not have access to it. Finally, participants will be notified of the potential risk that the information provided may not be helpful, and will be provided with information about where else they might seek information about alcohol use, or receive alcohol-related services if desired.

A plan is in place for identifying and referring individuals who report significantly worsening alcohol or cannabis use trajectories as well as consumption of potentially lethal doses of alcohol (estimated peak BAC's above .35%) and potential for dependence as measured on the AUDIT and CUDIT-R. Specifically, baseline survey data will be screened immediately upon submission, for indication of significant risk based on criteria established in our prior trials of this nature and the research literature (i.e., a score of 8 or more on the AUDIT or CUDIT-R on baseline in combination with a peak estimated BAC in the past month exceeding .35%; Adamson et al., 2010; Chung et al., 2000; 2002). The AUDIT total score is used to assess the risk of alcohol use disorder. The CUDIT-R total score is used to assess the risk of cannabis use disorder. A score of 8 or more is suggested for identifying hazardous drinking behaviors and hazardous cannabis use among adults. Thus, cutoffs of 8+ on the AUDIT and 8+ on the CUDIT-R will be used to assess hazardous alcohol and cannabis use for referral in combination with .35% peak estimated BAC from the baseline survey. Once identified, these individuals will be emailed referral resources. All emails will be noted in the tracking database. In our ongoing trials, we have used this procedure without incident and have provided referrals for both alcohol and mental health treatment. Information regarding the potential for a follow-up contact by the investigators to clarify responses or provide information is included in the consent documents. Participants are also informed in the consent form that they are free to seek other services for their alcohol or cannabis use. This structure is currently in place and approved at both the local and federal level on all our existing drinking and health-risk behavior studies. **All participants, at the end of study participation (following the completion of the 2-month survey), will be emailed referral resources available locally and nationally.**

Please see Appendix C for the Clinical Referral Email and Referral Information Email scripts.

Participants are encouraged to contact the investigators at any time to discuss any concerns they might have. Participants who express interest in seeking help for substance-related problems or for psychological distress will be offered referral information. Participants will not be restricted from seeking other alcohol or mental health education, prevention, or treatment opportunities.

Participants are encouraged to contact the investigators at any time to discuss any concerns they might have. Participants who express interest in seeking help for substance-related problems or for psychological distress will be offered referral information. Participants will not be restricted from seeking other alcohol or mental health education, prevention, or treatment opportunities.

2) *Describe the **level of risk.** (Either **Minimal** or **More than Minimal**; note that the federal regulations define minimal risk as, "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the*

performance of routine physical or psychological examinations or tests".)

This study is considered more than minimal risk and is not designed to directly benefit participants, although there may be some benefit attained as described below.

3) *Describe the **proposed benefits** of the study, whether they are direct benefits to study participants and/or benefits to society/science. (If there is NO direct benefit to subjects, please include such a statement in this document as well as in the consent document(s), if any.)*

There may be no direct benefit to individuals for their participation. However, participants may benefit from the intervention in that preliminary data suggest that interventions like the one proposed here will reduce alcohol and cannabis use. Any study that involves an intervention could have an anticipated direct benefit as participants will receive an intervention that they would not otherwise receive. In addition, this research has the potential for reducing the serious public health problem of high-risk drinking and cannabis use in young adults. Given the high rates of hazardous alcohol and cannabis use, risk for future use, and consequences in this population, development and dissemination of efficacious brief prevention strategies has the potential for significant societal benefits.

All participants may directly benefit through the provision of resources on a variety of topics including alcohol use, substance use, mental health, etc. In addition, we have a plan for identifying and referring individuals who report significantly worsening alcohol and cannabis use trajectories as well as hazardous consumption of alcohol and cannabis as reported on their baseline and 2-month survey assessments. This screening process is also a potential direct benefit for participants as they have the opportunity to learn more about their drinking and cannabis use and potentially be referred to services, if needed. **All participants at the end of participation, will be provided with referral resources available both locally and nationally, which is a direct benefit of participating in the proposed study.**

The process of completing alcohol and cannabis assessments is often illuminating for participants. Reactivity is the possibility that the research methods themselves affect the behavior under study. Research has shown that there is reactivity to substance use assessments for longitudinal surveys (McCambridge & Kypri; 2011; Walters et al. 2009) and ecological momentary assessments studies (Hufford et al., 2002), such as those proposed in Project EQUIP. Reactivity to substance use assessment occurs when completing surveys is associated with changes in substance use. Thus, participants in Project EQUIP have the potential to benefit from completing longitudinal surveys (baseline, 2 month) and ecological momentary assessments over two months in that they may reduce their substance use as a result of completing Project EQUIP assessments.

4) Describe **how the anticipated benefit justifies the risk**. Additionally, explain how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects.

Given the potential individual and societal benefits described above, we believe that the more than minimal risks of the study are reasonable in relation to the importance of the knowledge gained.

If the participant chooses not to participate in the study but has questions about alcohol or other substances, we can provide them with a list of information and referrals within the community. See Clinical Referral Email (Appendix C).

H. Payment/Compensation – *Describe any payments for subject participation (e.g., compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Recall that payments cannot be perceived as coercive (overpayment for time and effort). **Remember: payments are NOT benefits.***

Compensation. Each participant will compensated in the form of a Greenphire MasterCard that will be mailed to the provided address, to be sent after completion of the online baseline survey. Mailing address for each participant will be confirmed during the online training session. See Appendix C what a Greenphire MasterCard looks like. The card will be sent with no payment loaded onto it yet. Participants will be instructed that they will need to contact study staff to load their cards with their first payment of $40 ($20 for completing the online training session, and $20 for the online baseline survey). Participants will also be provided with this information as part of their Greenphire MasterCard FAQs along with information on how the Greenphire MasterCard can be used via mail to be sent upon completion of the online training session. If a participant does not confirm receipt of their card within 10 business days of it being mailed, they will receive 1 text message and 1 email notification reminding the participant to confirm receipt of their card. We will also periodically contact them over the phone to confirm receipt of their card. In the event they have not received it after a prolonged period of time, we will re-send them another Greenphire MasterCard to their preferred mailing address. Participants will receive a confirmation text message and email each time a payment is uploaded to their card to alert them a payment was loaded, and the amount of the payment that was loaded.

Each Greenphire MasterCard has a unique identifier. In monthly Greenphire reports, this identifier will indicate payment amount and payment date for each payment to participants. This monthly Greenphire report will verify each and every payment for compliance purposes. Greenphire has an option to request or not request social security numbers for payment. We do not request this information as it is not a requirement for Greenphire or for study purposes.

Compensation Schedule:

Online screening survey: 5-10 minutes, no incentive

Online training session: 30 minutes, $20 loaded onto a Greenphire MasterCard

Baseline Survey: 30 minutes, $20 loaded onto a Greenphire MasterCard

Online Intervention (intervention condition only): 20-30 minutes, no incentive

Feedback on Personalized Information (intervention condition only): 10-15 minutes, no incentive

Daily Surveys: 9-10 minutes, up to $106 loaded onto a Greenphire MasterCard at end of daily survey period ($4 per survey, 24 surveys total, with a $10 90% completion bonus)

2-Month Follow-Up Survey: 30 minutes, $30 loaded onto a Greenphire MasterCard

Total Possible Over the Course of Study: $176 loaded onto a Greenphire MasterCard

I. Subject Costs - *Describe any anticipated costs to research subject, whether they be financial or something else. If none, state such.*

The use of a participant's phone during the entire study (including the use of the text message links to complete study surveys) may contribute to the participant's data use/data plan. This information has been provided in the consent form.

J. List of KEY PERSONNEL - *List all individuals directly involved in the conduct, design or reporting of research involving human subjects in this study, including anyone who may be consenting subjects. This list will include the Principal Investigator, Co-Investigators, collaborating investigators, study coordinators, etc. Please describe the roles/responsibilities of each person who is listed as key personnel on this project.*

Name & Degree: Zhengyang Zhou, PhD

Department: Population and Community Health in the School of Public Health at the University of North Texas Health Science Center
Role:
Principal Investigator
Responsibilities: Dr. Zhou will manage daily project upkeep from the University of North Texas Health Science Center as well as assist in data analysis and will collaborate with the research team in the dissemination of research findings.

Name & Degree: Melissa A. Lewis, Ph.D.
Department: School of Social Work, University of Texas Arlington
Role: Co-Investigator
Responsibilities: Dr. Lewis will be responsible for the overall scientific direction of the research, including design and development of protocols, assessments, materials, participant recruitment and retention, personalized feedback intervention development and refinement, human subjects compliance, data analysis, and dissemination of results. In particular, Dr. Lewis will be responsible for intervention development, measurement of alcohol use and cannabis use, as well as the development of the recruitment and retention procedures, procedures for assessment reminders, and development and implementation of participant tracking protocols. She will also take the lead in the data analysis and dissemination efforts, being responsible for first authoring several papers, conducting data analyses, and supporting co-authors in dissemination efforts. Dr. Lewis will lead all communications and efforts between investigators at the University of North Texas Health Science Center and the University of Washington. Dr. Lewis will be responsible for following the data and safety monitoring plan and monitoring and reporting all adverse events. Dr. Lewis will conduct regular staff and investigator meetings and closely monitor all project activities to ensure that the project is completed efficiently and on time. Dr. Lewis has demonstrated success in working with each of the Co- Investigators as evidenced by several co-authored papers and/or collaboration on currently funded projects (see Biosketches for research team).

Name & Degree: Dana M. Litt, PhD
Department: School of Social Work, University of Texas Arlington
Role: Co-Investigator
Responsibilities: Dr. Litt will assist Dr. Lewis in supervising the participant recruitment and retention activities of the Research Assistant. Dr. Litt will work closely with Dr. Lewis and other investigators and staff members. Dr. Litt will attend weekly meetings with the research team to ensure that the project is carried out appropriately and efficiently. She will collaborate with the research team in the dissemination of research findings and assisting in the preparation of scientific reports.

Name & Degree: Jason Kilmer, PhD
Department: Psychiatry and Behavioral Sciences in the School of Medicine at the University of Washington
Role: Co-Investigator
Responsibilities: Dr. Kilmer will have the primary responsibility to provide expertise on intervention development pertaining to protective behavioral strategy use and the content of the motivational interviewing adherent text messages. Dr. Kilmer will attend weekly meetings with the research team (via Zoom and/or phone) and will share responsibility in preparing scientific manuscripts for peer review.

Name & Degree: Anne Fairlie, PhD
Department: Psychiatry and Behavioral Sciences in the School of Medicine at the University of Washington
Role: Co-Investigator
Responsibilities: Dr. Fairlie will be responsible for data collection and data management for the pilot study in which daily surveys for protective behavioral strategy and substance use are collected across 8 weeks. Dr. Fairlie will lead data analyses to test the aim of the pilot study. She will also be responsible for providing input on assessment materials and procedures and dissemination of the findings. Dr. Fairlie will attend weekly meetings with the research team (via Zoom and/or phone) to ensure that the project is carried out appropriately and efficiently. She will collaborate with the research team in the dissemination of research findings and assisting in the preparation of scientific reports.

Name & Degree: Scott Graupensperger, PhD
Department: Psychiatry and Behavioral Sciences in the School of Medicine at the University of Washington
Role: Co-Investigator
Responsibilities: Dr. Graupensperger will assist in data analysis and will collaborate with the research team in the dissemination of research findings.

Name & Degree: Allison Cross, MS
Department: Population and Community Health in the School of Public Health at the University of North Texas Health Science Center
Role: Graduate Student Research Assistant
Responsibilities: Allison will assist the Research Assistants as needed in the coordination of project tasks, scheduling of team meetings with investigators, monitoring participant email and phone communications, participating in meetings with study investigators, and coordination of recruitment materials. She will also assist the Research Assistants in preparation, review, and modification of human subjects forms and scripts; preparation of materials to be mailed to participants; and subject payments. She will also assist in facilitating focus groups. This individual will assist with the preparation of timely status reports and updates for the investigators. In addition, she will assist in dissemination of research findings through assistance with manuscript preparation.

Name & Degree: Emma Kannard, BS
Department: Institute for Sexual and Gender Minority Health and Wellbeing, Feinberg School of Medicine, Northwestern University
Role: Graduate Student Research Assistant
Responsibilities: Emma was involved in the original development of this intervention during my previous role at UNTHSC. Emma will now be conducting an analysis using the deidentified intervention data and redesign of the intervention as part of her capstone project for her graduate studies at Northwestern University.

K. Literature Cited - *If any, the references should be limited to relevant and current literature pertinent to the proposed research.*

Adamson, S. J., Kay-Lambkin, F. J., Baker, A. L., Lewin, T. J., Thornton, L., Kelly, B. J., & Sellman, J. D. (2010). An improved brief measure of cannabis misuse: The Cannabis Use Disorders Identification Test-Revised (CUDIT-R). *Drug and Alcohol Dependence*, *110*, 137-143. https://doi.org/10.1016/j.drugalcdep.2010.02.017

Atkins, D. C., & Gallop, R. J. (2007). Rethinking how family researchers model infrequent outcomes: A tutorial on count regression and zero-inflated models. *Journal of Family Psychology*, 21(4), 726-735. https://psycnet.apa.org/doi/10.1037/0893-3200.21.4.726

Babor, T. F., Higgins-Biddle, J. C., Saunders, J. B., Monteiro, M. G. (2001). *AUDIT- The alcohol use disorders identification test: guidelines for use in primary care* (Research Report No. (WHO/MSD/MSB/01.6a). Retrieved from: World Health Organization website: http://whqlibdoc.who.int/hq/2001/WHO_MSD_MSB_01.6a.pdf

Baer, J. S., Stacy, A., & Larimer, M. (1991). Biases in the perception of drinking norms among college students. Journal of studies on alcohol, 52(6), 580-586. https://doi.org/10.15288/jsa.1991.52.580

Benjamini, Y., & Hochberg, Y. (1995). Controlling the false discovery rate: a practical and powerful approach to multiple testing. *Journal of the Royal Statistical Society*, *57*(1), 289-300. https://doi.org/10.1111/j.2517-6161.1995.tb02031.x

Bonar, E. E., Cunningham, R. M., Collins, R. L., Cranford, J. A., Chermack, S. T., Zimmerman, M. A., Blow, F. C.,... & Walton, M. A. (2018). Feasibility and acceptability of text messaging to assess daily substance use and sexual behaviors among urban emerging adults. Addiction research & theory, 26(2), 103-113.

Brooke, J. (1996). SUS: A quick and dirty usability scale. In Jordan PW, Thomas B, Weerdmeester BA, McClelland IL (Eds.), Usability evaluation in industry (pp. 189-194). London, England: Taylor & Francis.

Brooke, J. (2013). SUS: A retrospective. Journal of Usability Studies, 8(2), 29-40.
Brown, S. A., Myers, M. G., Lippke, L., Tapert, S. F., Stewart, D. G., & Vik, P. W. (1998). Psychometric evaluation of the Customary Drinking and Drug Use Record (CDDR): A measure of adolescent alcohol and drug involvement. *Journal of Studies on Alcohol and Drugs*, *59*, 427. https://doi.org/10.15288/jsa.1998.59.427
Cella, D., Riley, W., Stone, A., Rothrock, N., Reeve, B., Yount, S., ... & Cook, K. (2010). The patient-reported outcomes measurement information system (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. Journal of clinical epidemiology, 63(11), 1179-1194.
College AIM Alcohol Intervention Matrix. (2019). National Institute on Alcohol Abuse and Alcoholism [PDF File]. https://www.collegedrinkingprevention.gov/CollegeAIM/Resources/NIAAA_College_Matrix_Booklet.pdf
Collins, R. L., Parks, G. A., & Marlatt, G. A. (1985). Social determinants of alcohol consumption: The effects of social interaction and model status on the self-administration of alcohol. *Journal of Consulting and Clinical Psychology, 53,* 189-200. https://doi.org/10.1037/0022-006X.53.2.189
Chung, T., Colby, S. M., Barnett, N. P., Rohsenow, D. J., Spirito, A., & Monti, P. M. (2000). Screening adolescents for problem drinking: performance of brief screens against DSM-IV alcohol diagnoses. *Journal of studies on alcohol*, *61*(4), 579-587.
Chung, T., Colby, S. M., Barnett, N. P., & Monti, P. M. (2002). Alcohol use disorders identification test: factor structure in an adolescent emergency department sample. *Alcoholism: Clinical and Experimental Research*, *26*(2), 223-231.
Danielson C. K., McCauley J. L., Gros K. S., Jones, A. M., Barr, S. C., Borkamn, A. L., … & Ruggiero, K. J. (2016). SiHLE Web. com: Development and usability testing of an evidence-based HIV prevention website for female African-American adolescents. *Health Informatics Journal, 22*(2), 194-208. doi:10.1177/1460458214544048
Deri, S., Davidai, S., & Gilovich, T. (2017). Home alone: Why people believe others' social lives are richer than their own. *Journal of Personality and Social Psychology, 113*(6), 858.
Diener, E., Emmons, R.A., Larsen, R. J., Griffin, S. (1985). The satisfaction with life scale. *Journal of Personality Assessment, 48* (1), 71-75.
Dimeff, L. A., McDavid, J., & Linehan, M. M. (1999). Pharmacotherapy for borderline personality disorder: A review of the literature and recommendations for treatment. Journal of Clinical Psychology in Medical Settings, 6, 113-138. doi:10.1023/A:1026259431809
Epler, A. J., Sher, K. J., & Piasecki, T. M. (2010). Reasons for abstaining or limiting drinking: A developmental perspective. Psychology of Addictive Behaviors,23(3), 428-442. doi:10.1037/a0015879 PMCID:PMC2777643
Fairlie, A. M., Cadigan, J. M., Patrick, M. E., Larimer, M. E., & Lee, C. M. (2019). Unplanned heavy episodic and high-intensity drinking: Daily-level associations with mood, context, and negative consequences. *Journal of Studies on Alcohol and Drugs, 80*(3). 331-339. https://dx.doi.org/10.15288%2Fjsad.2019.80.331
Fairlie, A. M., Lewis, M. A., Waldron, K. A., Wallace, E. C., & Lee, C. M. (2021). Understanding perceived usefulness and actual use of protective behavioral strategies: The role of perceived norms for the reasons that young adult drinkers use protective behavioral strategies. *Addictive Behaviors, 112*, 106585. https://doi.org/10.1016/j.addbeh.2020.106585
Furman, W., & Buhrmester, D. (1985). Children's perceptions of the personal relationships in their social networks. *Developmental Psychology*, *21*, 1016–1024.
Garner, D. M., & Garfinkel, P. E. (1979). The Eating Attitudes Test: An index of the symptoms of anorexia nervosa. Psychological medicine, 9(2), 273-279. https://doi.org/10.1017/S0033291700030762
Gaume, J., McCambridge, J., Bertholet, N., & Daeppen, J. (2014). Mechanisms of action of brief alcohol interventions remain largely unknown — A narrative review. *Frontiers in Psychiatry, 5*, 108. https://doi.org/10.3389/fpsyt.2014.00108
Gilmore, A. K., Bountress, K. E., Selmanoff, M., & George, W. H. (2018). Reducing heavy episodic drinking, incapacitation, and alcohol-induced blackouts: Secondary outcomes of a web-based combined alcohol use and sexual assault risk reduction intervention. *Violence Against Women, 24*(11), 1299–1313. https://doi.org/10.1177%2F1077801218787934
Grant V.V., Stewart S.H., O'Connor R.M., Backwell E., & Conrod P.J. (2007). Psychometric evaluation of the five-factor Modified Drinking Motives Questionnaire-Revised in undergraduates. *Addictive Behaviors, 32*(11), 2611-2632. Doi: 10.1016/j.addbeh.2007.07.004

Grazioli, V. S., Lewis, M. A., Fossos-Wong, N., & Larimer, M. E. (2018). Attitudes towards protective behavioral strategies: Do they predict use of strategies and alcohol outcomes over time? *Addictive Behaviors, 87*, 190-195. https://doi.org/10.1016/j.addbeh.2018.07.017

Grazioli, V. S., Studer, J., Larimer, M. E., Lewis, M. A., Marmet, S., Lemoine, M., … Gmel, G. (2019). Protective Behavioral Strategies Scale-20: Psychometric properties of a French and German version among young males in Switzerland. *International Journal of Methods in Psychiatric Research, 28*(3). https://doi.org/10.1002/mpr.1777

Heather, N., & Hönekopp, J. (2008). A revised edition of the Readiness to Change Questionnaire [Treatment Version]. *Addiction Research & Theory, 16*(5), 421-433. https://doi.org/10.1080/16066350801900321

Hedden, S. L., Woolson, R. F., & Malcolm, R. J. (2006). Randomization in substance abuse clinical trials. *Substance Abuse Treatment, Prevention, and Policy, 1*(6). https://doi.org/10.1186/1747-597X-1-6

Heimberg, R., Horner, K., Juster, ,H., Safren, S., Brown, E., Schneier, F., & Liebowitz, M. (1999). Psychometric properties of the Liebowitz social anxiety scale. *Psychological Medicine, 29*(1), 199-212.

Hox. J. J. (2010). *Multilevel analysis: Techniques and applications* (2nd ed.). Routledge: New York, NY.

Huang, J., DeJong, W., Schneider, S.K., & Towvim, L. G. (2011). Endorsed reasons for not drinking alcohol: a comparison of college student drinkers and abstainers. Journal of Behavioral Medicine, 34, 64-73. doi:10.1007/s10865-010-9272-x

Hufford, M. R., Shields, A. L., Shiffman, S., Paty, J., & Balabanis, M. (2002). Reactivity to ecological momentary assessment: an example using undergraduate problem drinkers. *Psychology of addictive behaviors*, *16*(3), 205.

Johnson, T. J., & Cohen, E. A. (2004). College students' reasons for not drinking and not playing drinking games. Substance Use and Misuse, 39(7), 1137-1160. doi:10.1081/JA-120038033

Johnston, L. D., O'Malley, P. M., Miech, R. A., Bachman, J. G., & Schulenberg, J. E. (2015). *Monitoring the Future national survey results on drug use: 1975-2014: Overview, key findings on adolescent drug use: 1975-2014* [PDF File]. Ann Arbor: Institute for Social Research, The University of Michigan. https://deepblue.lib.umich.edu/handle/2027.42/137913

Kourmousi, N., Xythali, V., Koutras, V. (2015). Reliability and validity of the multidimensional locus of control IPC scale in a sample of 3668 Greek educators. *Social Sciences, 4*(4), 1067-1078.

Lee, C. M., Cadigan, J., Kilmer, J, Cronce, J., Suffoletto, B., Walter, T., Fleming, C., & Lewis, M. A. (2021). Brief Alcohol Screening and Intervention for Community College Students (BASICCS): Feasibility and preliminary efficacy of web-conferencing BASICCS and supporting automated text messages. *Psychology of Addictive Behaviors, 35*(7), 840-851. https://doi.org/10.1037/adb0000745

Lee, C. M., Kilmer, J. R., Neighbors, C., Atkins, D. C., Zheng, C., Walker, D. D., & Larimer, M. E. (2013). Indicated prevention for college student marijuana use: A randomized controlled trial. *Journal of Consulting and Clinical Psychology, 81*, 702-709.

Lee, C. M., Kilmer, J. R., Neighbors, C., Cadigan, J. M., Fairlie, A. M., Patrick, M. E., & White, H. R. (2021). A marijuana consequences checklist for young adults with implications for brief motivational intervention research. *Prevention Science*, *22*(6), 758-768. https://doi.org/10.1007/s11121-020-01171-x

Lee, C. M., Neighbors, C., Hendershot, C. S., & Grossbard, J. R. (2009). Development and preliminary validation of a comprehensive marijuana motives questionnaire. Journal of studies on alcohol and drugs, 70(2), 279-287. https://doi.org/10.15288/jsad.2009.70.279

Lewis, M. A., & Neighbors, C. (2015). An examination of college student activities and attentiveness during a web delivered personalized normative feedback intervention. *Psychology of Addictive Behaviors, 29*(1), 162-167. https://doi.org/10.1037/adb0000003

Lewis, M. A., & Neighbors, C. (2004). Gender-specific misperceptions of college student drinking norms. Psychology Of Addictive Behaviors, 18, 334-339. doi:10.1037/0893-164X.18.4.334

Lewis, M. A., Cadigan, J. M., Cronce, J. M., Kilmer, J. R., Suffoletto, B., Walter, T., & Lee, C. M. (2018). Developing text messages to reduce community college student alcohol use. *American Journal of Health Behavior, 42*(4), 70-79. https://doi.org/10.5993/AJHB.42.4.7

Lewis, M. A., Litt, D. M., & Neighbors, C. (2015). Chicken or the egg: Examining temporal precedence among attitudes, injunctive norms, and college student drinking. *Journal of Studies on Alcohol and Drugs, 76*, 594-601. https://dx.doi.org/10.15288%2Fjsad.2015.76.594

Lewis, M. A., Litt, D. M., King, K. M., Fairlie, A. M., Waldron, K., A., Garcia, T. M., LoParco, C. & Lee, C. M. (2020). Examining the ecological validity of the prototype willingness model for adolescent and young

adult alcohol use. *Psychology of Addictive Behaviors, (34)*, 293-302. https://psycnet.apa.org/doi/10.1037/adb0000533

Lewis, M. A., Neighbors, C., Geisner, I., Lee, C. M., Kilmer, J. R., & Atkins, D. C. (2010). Examining the associations among severity of injunctive drinking norms, alcohol consumption, and alcohol-related negative consequences: The moderating roles of alcohol consumption and identity. *Psychology of Addictive Behaviors, 24*(2), 177-189. https://doi.org/10.1037/a0018302

Lewis, M. A., Patrick, M. E., Lee, C. M., Kaysen, D. L., Mittmann, A., & Neighbors, C. (2012). Use of protective behavioral strategies and their association to 21st birthday alcohol consumption and related negative consequences: A between- and within-person evaluation. *Psychology of Addictive Behaviors, 26*(2), 179-186. https://doi.org/10.1037/a0023797

Li, X., Lewis, M. A., Fairlie, A. M., & Mun, E. Y. (2019, June). Participants come back to see web-delivered personalized feedback aimed at reducing alcohol-related risky sexual behavior among young adults. Poster presented at the annual meeting of the Research Society on Alcoholism, Minneapolis, MN.

Liebowitz, M. R. (1987). Social phobia. *Modern problems of pharmacopsychiatry*.

Linden-Carmichael, A. N., Van Doren, N., Masters, L. D., & Lanza, S. T. (2020). Simultaneous alcohol and marijuana use in daily life: Implications for level of use, subjective intoxication, and positive and negative consequences. *Psychology of Addictive Behaviors. 34*(3), 447-453. https://doi.org/10.1037/adb0000556

Litt, D. M., Lewis, M. A., Blayney, J. A., & Kaysen, D. L. (2013). Protective behavioral strategies as a mediator of the generalized anxiety and alcohol use relationship among lesbian and bisexual women. *Journal of Studies on Alcohol and Drugs, 74*, 168–174. https://doi.org/10.15288/jsad.2013.74.168

McCambridge, J., & Kypri, K. (2011). Can simply answering research questions change behaviour? Systematic review and meta analyses of brief alcohol intervention trials. *PloS one*, *6*(10), e23748.

Miller, M. B., Leffingwell, T., Claborn, K., Meier, E., Walters, S., & Neighbors, C. (2013). Personalized feedback interventions for college alcohol misuse: An update of Walters & Neighbors (2005). *Psychology of Addictive Behaviors, 27*(4), 909-920. https://doi.org/10.1037/a0031174

Miller, W. R., & Marlatt, G. A. (1987). The Brief Drinker Profile. Odessa, FL: Psychological Assessment Resources.

Miller, W. R., & Rollnick, S. (2013). *Motivational interviewing: Helping people change* (3rd ed.). New York, NY: Guilford Press.

Miller, M. B., DiBello, A. M., Merrill, J. E., & Carey, K. B. (2019). Development and initial validation of the alcohol-induced blackout measure, Addictive Behaviors, https://doi.org/10.1016/j.addbeh.2019.106079

National Institute on Alcohol Abuse and Alcoholism (2019). Planning alcohol interventions using NIAAA's College Alcohol Intervention Matrix (CollegeAIM). Bethesda, MD: National Institutes of Health, (NIH Publication No. 19-AA-8017, Updated December 2019).

Neighbors, C., O'Connor, R. M., Lewis, M. A., Chawla, N., Lee, C. M., & Fossos, N. (2008). The relative impact of injunctive norms on college student drinking: the role of reference group. Psychology of Addictive Behaviors, 22(4), 576. https://doi.org/10.1037/a0013043

O'Hara, R. E., Armeli, S., & Tennen, H. (2014). College students' daily-level reasons for not drinking. *Drug and Alcohol Review*, *33*(4), 412-419.

Patrick, M. E., Fairlie, A. M., Cadigan, J. M., Abdallah, D. A., Larimer, M. E., & Lee, C. M. (2019). Daily motives for alcohol and marijuana use as predictors of simultaneous use among young adults. *Journal of studies on Alcohol and Drugs*, *80*(4), 454-461. https://doi.org/10.15288/jsad.2019.80.454

Pedersen, E. R., Huang, W., Dvorak, R. D., Prince, M. A., Hummer, J. F., & The Marijuana Outcomes Study Team. (2017). The Protective Behavioral Strategies for Marijuana Scale: Further examination using item response theory. *Psychology of Addictive Behaviors*, *31*(5), 548–559. https://doi.org/10.1037/adb0000271

Przybylski, Murayama, DeHaan, & Gladwell (2013). Motivational, emotional, and behavioral correlates of fear of missing out. *Computers in Human Behavior, 29,* 1841-1848.

Raes, F., Pommier, E., Neff, K. D., & Van Gucht, D. (2011). Construction and factorial validation of a short form of the Self-Compassion Scale. *Clinical Psychology & Psychotherapy, 18*, 250-255.

Read, J. P., Kahler, C. W., Strong, D. R., & Colder, C. R. (2006). Development and preliminary validation of the Young Adult Alcohol Consequences Questionnaire. *Journal of Studies on Alcohol*, *67*, 169-177. https://doi.org/10.15288/jsa.2006.67.169

Reid, A. E., & Carey, K. B., (2015). Interventions to reduce college student drinking: State of the evidence for mechanisms of behavior change. *Clinical Psychology Review, 40*, 213-224. https://doi.org/10.1016/j.cpr.2015.06.006

Rotter, J. B. (1971). Locus of control scale. *Psychology Today, 42*.

Sauro, J. (2011). A practical guide to the system usability scale: Background, benchmarks, & best practices. Denver, CO: Measuring Usability LLC.

Schafer, J., & Brown, S. A. (1991). Marijuana and cocaine effect expectancies and drug use patterns. *Journal of Consulting and Clinical Psychology*, *59*, 558-565. https://doi.org/10.1037/0022-006X.59.4.558

Shrier, L. A., Burke, P. J., Kells, M., Scherer, E. A., Sarda, V., Jonestrask, C., ... & Harris, S. K. (2018). Pilot randomized trial of MOMENT, a motivational counseling-plus-ecological momentary intervention to reduce marijuana use in youth. Mhealth, 4. doi:10.21037/mhealth.2018.07.04

Snijders, T. A. B., & Bosker, R. J. (2012). *Multilevel analysis: An introduction to basic and advanced multilevel modeling* (2nd ed.). Thousand Oaks, CA: Sage Publications, Inc.

Snyder, M., & Gangestad, S. (1986). On the nature of self-monitoring: Matters of assessment, matters of validity. *Journal of Personality and Social Psychology, 51*(1), 125-139.

Stephens, R. S., Roffman, R. A., and Curtin, L. (2000). Comparison of extended versus brief treatments for marijuana use. *Journal of Consulting and Clinical Psychology, 68*(5), 989-908. https://doi.org/10.1037/0022-006X.68.5.898

Stevens, A. K., Blanchard, B. E., Sokolovsky, A. W., Gunn, R. L., White, H. R., & Jackson, K. M. (2021). Forgoing plans for alcohol and cannabis use in daily life: Examining reasons for nonuse when use was planned in a predominantly white college student sample. *Alcoholism: Clinical and Experimental Research*, *45*(10), 2167-2178

Strathman, A., Gleicher, F., Boninger, D. S., & Edwards, C. S. (1994). The consideration of future consequences: weighing immediate and distant outcomes of behavior. Journal of Personality and Social Psychology, 66(4), 742-752. doi:10.1037/0022-3514.66.4.742

Stritzke, W. G., & Butt, J. C. (2001). Motives for not drinking alcohol among Australian adolescents: Development and initial validation of a five-factor scale. *Addictive Behaviors*, *26*(5), 633-649.

Substance Abuse and Mental Health Services Administration. Enhancing Motivation for Change in Substance Use Disorder Treatment. Treatment Improvement Protocol (TIP) Series No. 35. SAMHSA Publication No. PEP19-02-01-003. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019.

Treloar, H., Martens, M. P., & McCarthy, D. M. (2015). The Protective Behavioral Strategies Scale-20: improved content validity of the Serious Harm Reduction subscale. *Psychological Assessment, 27*(1), 340–346. https://doi.org/10.1037/pas0000071

Walters, S. T., Vader, A. M., Harris, T. R., & Jouriles, E. N. (2009). Reactivity to alcohol assessment measures: an experimental test. *Addiction*, *104*(8), 1305-1310.

White, H. R., Labouvie, E. W., Papadaratsakis, V. (2005). Changes in substance use during the transition to adulthood: A comparison of college students and their noncollege age peers. *Journal of Drug Issues, 35*(2), 281-306. https://doi.org/10.1177%2F002204260503500204