MOTIVATIONS, ATTITUDES, AND PERCEPTIONS STUDY

Protocol Number*: 21912

National Clinical Trial (NCT) Identified Number: NCT05873413

Principal Investigators*: David DiLillo, PhD & Sarah Gervais, PhD

Sponsor: University of Nebraska-Lincoln

Grant Title: RCT of a combined MI intervention to address bystander behaviors in the context of alcohol use

Grant Number*: 1R01AA029450-01A1

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13 January 2026

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

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STATEMENT OF COMPLIANCE

(1) [The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- **United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).**

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 5-27-2022

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1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title: Motivations, Attitudes, and Perceptions Study

Grant Number: 1R01 AA029450

Study Description: *During young adulthood, an estimated one in five women experience sexual assault. We seek to reduce this violence by motivating young adults to intervene with their peers to prevent sexual assault—an approach known as bystander intervention. Current bystander training is conducted in group sessions involving education about how to recognize and intervene in response to sexual risk situations. Although successful in changing knowledge and attitudes about sexual assault prevention, evaluations of these programs have rarely focused on changing actual bystander behaviors. Further, while bystander alcohol use is common in sexual risk situations, and undermines intervention attempts, alcohol consumption by bystanders is not explicitly targeted in existing intervention training programs. To address these gaps, we will conduct a RCT comparing the efficacy of: 1) our recently developed bystander intervention, Motivate-the-Bystander (MTB), 2) MTB with an MI alcohol component (MTB+ALC), and 3) an attention control condition for reducing alcohol use and increasing bystander behaviors in response to sexual risk. Bystander behaviors will be assessed observationally during a virtual reality-based house party at 1-2 weeks post intervention. Participants' bystander behaviors, alcohol use, and relevant contextual variables will be assessed weekly using electronic daily diaries immediately following the final virtual session until 9 months post intervention. We expect that, compared to MTB alone and the control condition, MTB+ALC will produce significantly greater reductions in overall drinking and increases in prosocial bystander behaviors in a diverse sample of 450 young adults who are heavy drinkers. If our hypotheses are confirmed, results will support the use of our combined MI-based bystander-alcohol intervention as an effective means of reducing drinking and motivating bystander behaviors among those at highest risk for sexual violence.*

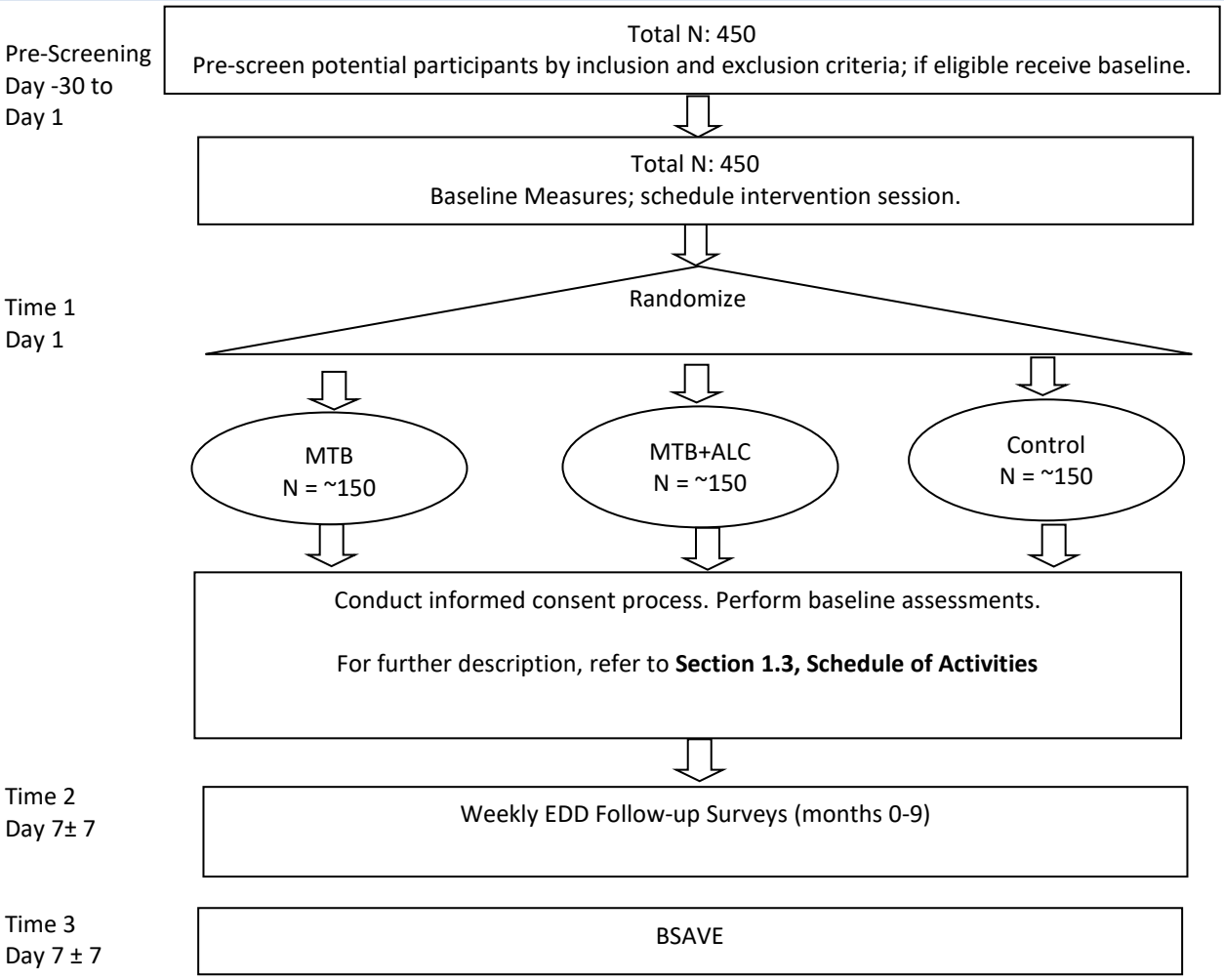
Objectives*: *The primary objective of the proposed project is to evaluate the efficacy of MTB+ALC in comparison to MTB and an attention control condition. The secondary objective is to assess self-reported individual differences in alcohol use and bystander outcomes and secondary endpoints.*

Endpoints*: *Primary study endpoints are: 1) reduced drinking, and 2) increased bystander behaviors. Secondary study endpoints are 1) SV perpetration, 2) SV victimization, 3) alcohol expectancies, 4) prosocial and personality traits, and 5) other theoretical and empirical factors related to primary outcomes.*

Study Population:	*The population for this study will be male and female young adult community members recruited from Lincoln, Omaha, NE and surrounding areas. Participants who are English speaking and ranging from ages 18-25 will be eligible for inclusion in the study.*
Phase* or Stage:	*Indicate Phase or Stage, as appropriate. Institutes and Centers may differ in their preferences for categorizing research. Consult with your Program Official (PO) This is a phase II trial.*
Description of Sites/Facilities Enrolling Participants:	*Once deemed eligible, participants will complete the baseline self-report measures via Qualtrics and then will be guided to schedule their intervention session via Calendly. The MTB, MTB+ALC and control sessions will then be completed via zoom. Participants will be instructed to find a private location for completing the session. Post-intervention participants will complete EDD follow up surveys (months 0-9) and be scheduled to complete self-report measures and the B-SAVE in the virtual reality lab (Burnett Room 12. Participants will be run individually, thus will not witness or have access to other participants identity or responses. During informed consent, participants will be notified that all information will be de identified and kept confidential.*
Description of Study Intervention/Experimental Manipulation:	*Participation will involve baseline survey, 1 virtual intervention session, one in-person lab visit and a series of 40 electronic daily diary (EDD) follow-up surveys. First, participants will complete various self-report measures via baseline. The baseline survey is expected to take approximately 1.5 - 2 hours. Then they will be scheduled and randomized to their virtual session to complete MTB, MTB+ALC, or a control condition which takes 60-180 minutes per session. Participants will then come to the lab 1-2 weeks later to complete self-report measures and the B-SAVE, a VR- based tool for assessing bystander behaviors in risky sexual situations. The BSAVE is expected to take approximately 1.5 hours. Immediately following the final virtual session participants will be sent EDD follow-up surveys to complete weekly via Qualtrics. The EDD surveys are expected to take 10 minutes weekly for months 0 through 9. In sum, participation in the entire study will take approximately 10 hours.*
Study Duration*:	*Estimated time is 48 months*

Participant Duration: *Approximately 9 months*

1.2 SCHEMA



1.3 SCHEDULE OF ACTIVITIES

	Pre-screening (Pre-consent)	Baseline Day 1	Virtual Intervention Session(s) Day 1 ±7	Weekly EDD Follow-up Surveys (months 0-9) Day 7 ±7	BSAVE Session Day 7 ±7
Review Eligibility	X				
Informed Consent	X	X	X		X
Demographics		X			
Outcome Evaluation					
Randomization		X			
Control & Experimental Interventions – MTB, MTB+ALC, & Control			X		
BSAVE Bystander Intervention Virtual Reality Simulation Task					X
Outcome Expectancies for Intervening		X			X
Bystander Efficacy Scale		X			X
DERS-SF		X		X	
Bystander Intention to Help Scale-Short Form					X
Urica		X			X
TSFP-short version (sexual assault measures)		X			
Social Reactions Questionnaire (Negative Reactions to Disclosure)		X			
Barriers to Sexual Assault Bystander Intervention		X			
The Revised Conflict Tactics Scale (CTS2)		X			
Childhood Trauma Questionnaire Short Form CTQ-SF		X			
ILLINOIS RAPE MYTH ACCEPTANCE – SUBTLE VERSION		X			
Toronto Empathy Questionnaire					X

	Pre-screening (Pre-consent)	Baseline Day 1	Virtual Intervention Session(s) Day 1 ±7	Weekly EDD Follow-up Surveys (months 0-9) Day 7 ±7	BSAVE Session Day 7 ±7
Big Five Inventory-10 (BFI-10)					X
Dirty Dozen Short Dark Triad (SD3)					X
Alcohol Use Disorder Identification Test		X			
The Alcohol Expectancies Regarding Sex, Aggression, and Sexual Vulnerability Questionnaire (AESAS)		X			X
Decisional Balance for Immoderate Drinking					X
Drinking Motives Questionnaire		X			
NIDA-Modified Alcohol, Smoking and substance Involvement Screening Test		X			
The Couples Satisfaction Index (CSI)					X
Individuality in Couples Questionnaire (ICQ)					X
The Experiences in Close Relationships-Short form					X
Experience of Dehumanization Measure (EDHM)					X
Interpersonal Sexual Objectification Scale		X			
Interpersonal Sexual Objectification Scale – Perpetration (ISOS-P)		X		X	
Interpersonal Sexual Objectification Scale – Victimization (ISOS-V)				X	
Self-Objectification Beliefs and Behavior Scale		X		X	
Daily Discrimination Scale				X	
Self-Compassion Scale Short Form (SCS-SF)					X
LEC-5		X			
PCL		X			
Drinking Norms Rating Form		X			
Sexual Assertiveness Questionnaire (SAQ)		X			
Sexual Norms Inventory-Perception of Bystander Intentions Subscale		X			
Urica-DV		X			X

	Pre-screening (Pre-consent)	Baseline Day 1	Virtual Intervention Session(s) Day 1 ±7	Weekly EDD Follow-up Surveys (months 0-9) Day 7 ±7	BSAVE Session Day 7 ±7
CDSES (Controlled Drinking Self-Efficacy Scale)					X
Bystander Decision Balance Scale (Baynard et al 2005)					X
CEMI (Client Experiences of Motivational Interviewing)					X
EDD Outcome Measures-Timeline Followback (TLFB)		X		X	
Competency Checklist					X
IGroup Presence Questionnaire (IPQ)					X
Adverse Events Reporting		x	x	x	
Phubbing Scale		x			

2 INTRODUCTION

2.1 STUDY RATIONALE

Existing bystander interventions to reduce sexual assault, and associated evaluations, are promising but suffer from significant limitations. First, psychoeducational approaches, which present identical material to all participants, may not be the most effective in prompting bystander behaviors. These interventions do not address factors, such as individual motivations and readiness to change, which may be crucial drivers of bystander behaviors. Second, current bystander intervention trainings do not address the adverse impact that bystander alcohol use may have on intervention attempts, even though bystanders often consume alcohol in SV situations. If bystanders are themselves drinking, and intoxication impairs bystander intervention attempts, then training efforts that fail to address bystander alcohol use will be of limited utility. Heavy drinkers, in particular, may have more opportunities to intervene because they frequent alcohol-laden situations where SV risk is common, yet they may have less SV interventions because alcohol consumption undermines bystander behavior. At the same time, if heavy drinkers could be motivated to drink less and intervene more, then they would be exceptionally well-positioned to prevent sexual assaults. Finally, prior evaluations of bystander trainings ask participants to report retrospectively about their bystander intervention attempts over periods ranging from 3 to 6 months. This is problematic because participants may not accurately recall details about sexual risk situations or their responses to them over such extended periods of time. Thus, key information about the impact of bystander training may be missed by the sole use of retrospective self-reports.

Our long-term goal is to reduce the prevalence of SV through evidence-based preventive interventions that can be easily adopted, implemented, and sustained across multiple settings. The present project represents a significant step toward that goal. Specifically, we propose to evaluate a promising new intervention to increase bystander behaviors, Motivate-the-Bystander (MTB), in combination with a proven motivational interviewing intervention to reduce alcohol use (ALC) with a sample of heavy drinkers. To our knowledge, this will be the first in-person intervention to explicitly target bystander motivations to intervene and bystander alcohol use as barriers to bystander intervention. This combined bystander-alcohol use intervention will be evaluated in a randomized controlled trial (RCT) that incorporates scientifically rigorous methods not found in prior bystander evaluation studies. In particular, rather than relying on long-term retrospective self-reports, we will assess key SV risk and alcohol-related outcomes multimodally with electronic daily diaries completed within a week of SV events and a validated virtual reality-based measure of observed bystander behaviors. We will test this combined MTB+ALC intervention with a community sample of young adults who are heavy drinkers. Our central hypothesis is that this novel MTB+ALC intervention will be superior to attention control and MTB alone in promoting bystander interventions in response to sexual risk.

Aim 1: Compare the impact of MTB to an attention control condition on bystander intervention behaviors. Hypothesis 1: MTB (vs. attention control) will increase prosocial bystander behaviors at measured via B-SAVE and weekly EDD follow-ups (months 0-9).

Aim 2: Compare the impact of MTB+ALC to MTB on bystander intervention behaviors. Hypothesis 2: MTB+ALC (vs. MTB or attention control) will (a) increase prosocial bystander behaviors, and (b) decrease overall alcohol use measured via weekly EDD follow-ups (months 0-9).

Aim 3: Compare the impact of MTB+ALC to MTB on alcohol use proximal to opportunities for bystander intervention. Hypothesis 3: MTB+ALC (vs. MTB or attention control) will reduce alcohol use in risky sexual situations; lower proximal alcohol use will be a mechanism explaining why MTB+ALC increases prosocial bystander behavior.

2.2 BACKGROUND

Sexual violence (SV) is a major public health problem among young adults in the U.S (Breiding et al., 2014; Cantor et al., 2017). Bystander intervention programs, which train witnesses to intervene to diffuse risky sexual situations (Banyard, 2008), are a common approach to sexual assault prevention. Typical bystander intervention trainings consist of group psychoeducational presentations about risk factors for sexual assault, taking responsibility for intervening, and how to intervene (Banyard et al., 2007). Evaluations of these interventions have focused primarily on attitudinal and intent-to-intervene outcomes, which are positively impacted by bystander training. The few studies to examine actual bystander behaviors in response to sexual risk show increases in self-reported intervention attempts following training.

We will test the efficacy of a new bystander intervention (MTB) in conjunction with a well-established motivational enhancement intervention (ALC) to reduce alcohol use. Strengths of this RCT include recruitment of a diverse community (rather than college) sample of heavy drinkers, multimodal assessment of bystander behaviors using a virtual reality paradigm, which allows for direct observation of intervention attempts, and weekly electronic daily diaries, to provide unprecedented detail about proximal associations between bystander alcohol use, opportunities for bystander intervention, intervention behaviors, and key contextual variables surrounding those behaviors. With evidence of its efficacy following this RCT, MTB+ALC could be quickly disseminated to enhance alcohol reduction and SV prevention efforts among young adults.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Potential risks to participants are most likely to arise in relation to the following aspects of our study: (1) participation is not anonymous; (2) participants will be asked potentially sensitive questions about alcohol use, recent sexual victimization experiences, and sexual violence intervention opportunities and behaviors with the battery of questionnaires at baseline as well as with the EDDs; (3) participants complete MI interventions in which they discuss sexual risk situations (MTB; MTB+ALC) and alcohol use (MTB+ALC); (4) participants will engage in the B-SAVE, which involve fictional, but realistic and immersive sexual risk scenarios; (5) participants will complete the B-SAVE in which they wear an oculus rift and navigate a virtual environment while occupying physical space in the real environment (i.e., walking around). Safeguards to manage the risks associated with breaches of confidentiality, emotional distress, and virtual reality are detailed in the Protection Against Risks section below.

The first concern, which is associated with all research that is not anonymous, is breach of confidentiality. Realization of this risk could cause negative social consequences. Given that data will be linked to participants' identities in between the baseline assessment to 9-month follow-up, this is an important risk to consider. We believe that the risk is very low, given that most data are collected electronically and all data will be stored securely and separately from identifying data. Further, all self-report data will be collected through Qualtrics, a secure online survey service. Several safeguards and procedures for protecting data will be in place.

The second concern is that participants may feel uncomfortable answering potentially sensitive questions. For example, some people may experience distress when providing self-reports of sexual victimization. Likewise, participants may experience discomfort when providing self-reports of sexual violence intervention opportunities and behaviors, particularly if they failed to intervene or help. Finally, participants may experience embarrassment when reporting alcohol use, especially heavy drinking. Participants will be reminded that they have the right to refuse to answer any question during the study (baseline, daily diary follow-ups) or to discontinue participation at any time. All self-report measures are programmed to allow participants to skip any question, but still complete the survey.

The third concern relates to participation in the MTB and MTB+ALC interventions. Participants may experience some adverse psychological reactions such as feeling upset or discomfort as they undergo the intervention. For example, a potential risk is that a participant may gain a new awareness of a situation in which a woman was at-risk for sexual violence and the participant did not previously intervene. Likewise, participants may learn that their drinking behaviors are not normative, which may make them feel uncomfortable. Although these instances represent some degree of risk, we have designed the procedures to minimize adverse reactions. For example, MI interventions are delivered in a non-judgmental, supportive manner.

Regarding the fourth concern, it is possible that completing the B-SAVE with fictional, but highly realistic and immersive sexual risk scenarios (depicting objectifying commentary, unwanted touching, and coercive tactics for sex), may induce emotional distress. Furthermore, people with victimization experiences may be particularly likely to experience distress when engaging in the B-SAVE. Relevant to these concerns are a number of recent articles specifically examining whether participation in trauma-related research causes distress or "re-traumatizes" participants. This work does not support the conclusion that participating in trauma-related research, including studies that involve disclosing traumatic or abusive experiences, results in lasting psychological distress or harm to participants (Black & Black, 2007; Ullman, 2007; Becker-Blease & Freyd, 2007; Cromer et al., 2006). Additionally, although the visual displays and dialogue used in the B-SAVE may be upsetting to some due to their sexual content, none of the scenes involve sexual threat directed toward participants. Moreover, the party environment and interactions depicted in the virtual environment are situations that young adults are exposed to in their daily life (Banyard et al., 2007). Researchers who have exposed participants to sexual content in the form of self-reported descriptions, vignettes, audio or video recordings, or through virtual reality have not found long-term adverse reactions (Jouriles et al., 2009; Jouriles et al., 2016; Messman-Moore & Brown, 2006; Parks et al., 2016).

The fifth concern specific to the proposed study is exposing participants to virtual reality, which raises the possibility of cybersickness, physical injury, and aftereffects. Virtual reality can create conflict in some participants because sensory cues from a variety of modalities (e.g., auditory, visual, vestibular, proprioceptive) are incongruent between the virtual environment and the real-life physical environment. Thus, what the participant senses in the virtual environment is different than what is expected by the

body based on prior real-life experiences (e.g., the visual displays provide information to the brain that one is walking more quickly through the virtual environment than the actual physical environment). This conflict is unlikely with the virtual reality technology we are using because the virtual reality parameters closely approximate the physical reality (e.g., a 20' X 20' house is depicted in a 20' X 20' lab room; sensors track the participants' movements in real time, so that the physical displays correspond to bodily expectations). Nonetheless, the B-SAVE could still cause cybersickness (Stanney et al., 1997) in some individuals. Cybersickness is thought to resemble motion sickness and result in similar symptoms such as nausea, vomiting, eyestrain, disorientation, ataxia, and vertigo (Kennedy et al., 1994; Rizzo et al., 2002). Additionally, because people are walking in a real life physical environment when they are navigating the virtual environment, there can be increased risk for injury (e.g., falling, bumping into walls on the perimeter). A final issue is aftereffects or difficulties with reorienting to the real world following immersion in virtual reality. There can be a lag between leaving the virtual environment and adjusting to the sensorimotor requirements of the real world. Thus, participants can have disturbed locomotion, changes in postural control, or perceptualmotor disturbances because they have adapted to the sensorimotor requirements of the virtual reality. A number of procedures are in place to allow participants to safely complete the virtual reality B-SAVE measure.

2.3.2 KNOWN POTENTIAL BENEFITS

Participants who complete the MTB intervention may benefit from increased knowledge and skills related to bystander interventions, and those who complete the MTB+ALC intervention may additionally benefit from increased knowledge about problematic drinking. All participants will receive monetary compensation for involvement in the study. Participants who complete the MTB+ALC intervention may reduce their drinking, which could have several positive health benefits. Additionally, although not a direct benefit to participants, those who complete the MTB or MTB+ALC interventions may demonstrate increased behaviors to prevent others sexual assault, therefore helping potential sexual assault victims. Further, the proposed investigation will provide data that is critical to developing an evidence base for interventions (MTB and MTB+ALC) on decreasing drinking and increasing bystander behaviors, leading to dissemination and valuable information for future heavy drinking as well as sexual violence prevention efforts. The risks associated with this study are expected to be outweighed by the potential benefits of these findings.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Rationale for Exposing Participants to Risk
Given our aim to reduce sexual assault, it would not be possible to conduct the MTB intervention without exposing participants to potentially upsetting content. Similarly, for a rigorous assessment of bystander outcomes, it is necessary to supplement traditional self-report measures with VR, which is not subject to social desirability bias.

Minimization of Risks
Upon arriving at each scheduled appointment (baseline, intervention and B-SAVE), and before beginning any part of the study, the informed consent process will take place. All participants will read a written copy of the Informed Consent Form (ICF) and be able to ask questions before signing. The ICF will clearly

state that participation is voluntary and that participants can withdraw from the study at any time without penalty. Participants will have the opportunity to ask questions prior to consenting, and may withdraw from the study at this or any other point. The informed consent form will explicitly state that the B-SAVE may contain sexually aggressive cues, and that some study procedures and questionnaires may induce negative feelings (e.g., reporting on alcohol use; reporting on sexual victimization). The ICF will also explicitly state that some participants may experience cybersickness and/or aftereffects when participating in virtual reality research. In the event that a potential participant seems ill at ease or shows any behavioral signs of ambivalence in the lab (e.g., taking an inordinately long time to read the consent form, hesitating before signing the form, asking questions revealing concern about the study tasks), that individual will be reminded that participation is not required and that he or she may choose not to consent without penalty. In short, the informed consent protocol is structured to ensure that individuals understand the full nature of the study and feel comfortable agreeing to participate before providing consent.

In addition to informing participants of the nature and associated risks of the study, a number of precautions will be implemented. Protection against risks associated with confidentiality breaches. Several procedures that have been used previously by the MPIs will be followed to ensure confidentiality of all research participants. Following our established procedures, all research staff will be trained in the importance of maintaining confidentiality and will complete the required NIH training in protection of human research participants. They will be informed that breach of confidentiality may result in termination of employment and will sign a pledge attesting to their commitment to maintaining subject confidentiality. All presentations of the project data will report findings in terms of groups; no individual identifying information will be presented. All computers that will store data for this project are in locked rooms when users are not present.

All computers, servers, and Cloud storage files (i.e., restricted SharePoint folders) are password-protected. Only individuals with a correct password can gain access to individual computers, servers, or restricted SharePoint folders. To protect individual computers from unauthorized intrusion, computer users do not have administrative privileges on workstations and servers, and therefore are unable to install unauthorized applications and services or modify critical system files that could create vulnerabilities. In addition, firewalls protect each individual computer, server, and SharePoint folders from intrusion. Further, the University of Nebraska-Lincoln has additional firewalls and other security devices to protect the network infrastructure from outside their campus. Auditing and password security policies are enabled on computers, servers, and SharePoint folders to track login attempts and restrict unauthorized access.

Consent forms will not be stored with any data and will be secured in another location from the primary study data. The central list of subject IDs and names will also be stored in a locked cabinet at a separate location and/or in a separate SharePoint folder.

MTB and MTB+ALC interventions will be video recorded and the digital file downloaded for transcription. The video file will be transcribed verbatim and coded for fidelity; participants will be identified numerically only. The digital files will then be destroyed to protect confidentiality following transcription and coding. Transcribed files will be stored on a restricted SharePoint folder on password protected computer in a locked room. All data will be stored securely and separately from identifying data. Paper consent forms for all the in-person data collection sessions will be stored in locked file cabinets in the laboratory, separate from the data. A code key which links participant names to the unique ID number and any hard

copies of participants' data will be kept in separate locked filing cabinets. Upon completion of the follow-up B-SAVE session and EDDs, the code key that links participants' identity to their data will be destroyed.

Protection against risks associated with experience of emotional distress as a result of answering sensitive questions about heavy drinking, sexual victimization, or sexual violence intervention behavior. This project includes the potential risk that participants may fear repercussions for (1) reporting underage or heavy drinking to the research team, (2) reporting an incident of sexual violence to the research team, (3) reporting the type of sexual violence intervention behavior in which they engaged, or (4) reporting that they did not engage in any sexual violence intervention behavior after witnessing a sexual violence event or a situation at-risk for sexual violence. For instance, participants may fear that researchers will review their responses and render some negative judgment (e.g., if the participant is under 21 and reports drinking alcohol; if the participant did not intervene in a sexually risky situation). To protect against this potential risk, participants will be clearly told in the consent process that some of the questions asked may be distressing. They will also be reminded that they have the right to refuse to answer any question during any study phase (i.e., baseline, follow-up B-SAVE, follow-up electronic daily diaries) or to discontinue participation at any time. All instruments are programmed to allow participants to skip any question but still complete the survey. In addition, participants will be informed that all responses are confidential and are submitted directly to a secure database housed on a non-university, secure web-based server. They will be further reminded during the informed consent process that members of the research team do not monitor their responses. Thus, during the period in which participants' responses are identifiable, the research team will not access the data. These procedures will not only minimize participants' fear of potential repercussions, but they also maximize the reliability and validity of data obtained during the project.

Protection against risks associated with distress during the MTB and MTB+ALC interventions. Our MTB and MTB+ALC interventions are constructed in a manner such that participants themselves detail their values and recall their previous experiences with bystander interventions and drinking. As such, it is unlikely that participants will report situations they themselves are unwilling to discuss and may have adverse reactions too. However, participants in the MTB+ALC intervention condition will receive normative feedback on drinking and they may feel distress or embarrassment for heavy drinking. Furthermore, discussing sexual risk situations and previous bystander opportunities during MTB and MTB+ALC could still cause participants emotional discomfort. If a participant experiences an adverse psychological reaction, MI interventionists will be available for counsel and will use active listening techniques (e.g., reflection, empathic understanding) and administer a distress protocol to help alleviate participant distress. To further safeguard this risk, Dr. David DiLillo (MPI), a licensed clinical psychologist in the state of Nebraska, will train, supervise, and consult with MI interventionists to implement procedures to minimize risks and protect participants in the event an adverse reaction occurs. Dr. DiLillo will also be "on call" to consult about unforeseen issues that may arise, as well as speak to participants who might experience intense distress. In addition, the Psychological Consultation Center, which provides services to the community of Lincoln and is staffed by numerous doctoral student therapists and doctoral-level psychologists, is housed in Burnett Hall at the University of Nebraska-Lincoln where study sessions will take place. This permits quick access to a counselor, if needed.

The informed consent form will clearly spell out that the MTB and MTB+ALC interventions and some of the questions are of a personal nature and may cause some degree of distress. We will also provide mental health referral information to each participant and participants will complete the Alcohol Use Disorders Identification Test (AUDIT) and given appropriate referrals if requested. Specifically, we will provide the Nebraska Crisis and Suicide hotline which provides 24/7 crisis counseling and the SAMHSA National

Helpline (1-800-662-4357) which provides 24/7 mental and/or substance use disorder counseling. We will also refer to a local mental health facility, the UNL Psychological Consultation Center, 325 Burnett Hall, 402-472-2351, which serves community members on a sliding fee basis and treats substance use, anxiety, depression, PTSD, and trauma. Although unlikely, if a participant expresses intent to harm himself or herself, or another individual, project staff will take immediate steps to ensure the safety of participants or other individuals (e.g., by calling 911).

Protection against risks associated with experience of emotional distress as a result of the BSAVE. To address the risk of emotional distress related to completing the B-SAVE, participants will be reminded that they can withdraw from the study or skip any measures or tasks at any time. Additionally, during the debriefing process, participant's responses will be discussed in a nonjudgmental way (e.g., participants will be reminded that people have a variety of responses on the B-SAVE including intervening and not intervening). Furthermore, during informed consent and debriefing, participants will receive contact information for local mental health agencies that provide affordable (sliding fee) services (i.e., the UNL Psychological Consultation Center, 325 Burnett Hall, 402-472-2351) as well as a local and national 24-hour crisis hotlines (i.e., Voices of Hope, 402-475-7273; RAINN National Sexual Assault Hotline, 1-800-656-4673), should they experience any emotional difficulties resulting from participating in the study. To manage potential risks arising during the lab-based portions of the study, trained graduate research assistants will staff the in-lab data collection sessions. The research assistants will closely monitor research participants for behavioral signs of distress (e.g., taking an exceptionally long time to complete portions of the study, asking questions revealing concern about the B-SAVE), in which case participants will be offered a break and reminded of the option to withdraw from the study at any point. Furthermore, to determine if distress increases over the course of the B-SAVE, we will assess distress at the beginning of the study and at the end. In the event of continued distress, Dr. David DiLillo (MPI), a licensed clinical psychologist in the state of Nebraska, will be available in person or via telephone to consult with the research assistant and/or speak with the participant until distress levels abate. In the event that distress persists (but there is no threat of imminent harm) participants will be referred to local agencies providing counseling services on a sliding scale basis (see above). Although unlikely, if participants express intent to harm themselves, or another individual, project staff will take immediate steps to ensure the safety of participants or other individuals (e.g., by calling 911).

Protection against concerns related to cybersickness, potential injury, and aftereffects. Several protections will be in place to address these concerns. First, our motion tracking system reduces the chances for cybersickness because it is calibrated to synchronize real-life, three dimensional movements with virtual reality movement, so that the visual displays that participants see as they navigate the virtual environment closely resemble the physical sensations they feel as they navigate the real world physical environment. Furthermore, participants will be in the virtual environment for a relatively short period of time (approximately 15 minutes), further reducing the chances of cybersickness (Kennedy et al., 1995) Anyone who reports experiencing such symptoms such as cybersickness will be immediately removed from the virtual environment and offered to sit in a quiet space until symptoms subside (they tend to subside very quickly once someone is removed from the virtual environment). They will be reminded that they can withdraw from the study at any time without penalty. They will also be told that should any of the symptoms arise, they should tell the research assistant immediately. If symptoms persistent, we will end the study and participants will be monitored until the symptoms completely subside. A sickness bin will be kept in the VR lab in case a participant vomits. To ensure participants do not bump into walls while wearing the VR headset, research assistants will be trained to shadow participants as they walk around the room during the B-SAVE. They will redirect the participant if the person comes within three feet of a wall or other object. Once the study has ended, participants will be led to a quiet space where they can

sit and walk around. Participants will be reminded that if they experience any symptoms they should seek medical attention right away. Although very unlikely, if a participant experiences medical symptoms, project staff will take immediate steps to ensure the safety of participants or other individuals (e.g., by calling 911).

Why the value of the information to be gained outweighs the risks

The results of the proposed research are expected to provide initial evidence for the MTB+ALC intervention and additional evidence for the MTB intervention on increasing individuals' behaviors to prevent sexual assault. Previous bystander interventions provided to large groups of individuals have shown limited success in engaging bystanders to actually act to prevent assault, and the results of this proposed study may provide evidence for the efficacy of an individualized, value-driven approach to motivate potential bystanders. Further, this work addresses a significant gap in the literature, as previous bystander interventions have typically relied on retrospective self-reported behavioral and attitudinal measures for assessment. By using virtual reality, our results maximize both internal and ecological validity, and we will be able to assess actual bystander behaviors as they unfold in simulated sexual risk scenarios. Furthermore, by using EDDs, we will assess self-reported bystander behaviors that are strong in external validity shortly (within 1 week) after they occur. This should allow us to examine bystander behaviors in potentially unprecedented detail. These novel measurement approaches may provide valuable evidence for the potential efficacy of the intervention and can guide future prevention efforts. The risks of this study are expected to be minimal, and, as heavy drinking and sexual assault pose significant psychological and physical risk to individuals, potential benefits outweigh the potential risks to participants.

3 OBJECTIVES AND ENDPOINTS

Primary study endpoints are: 1) reduced drinking, and 2) increased bystander behaviors. Drinking will be assessed with self-reports in electronic daily diaries (EDD). Bystander behaviors will also be assessed with EDD and observed directly with a VR-based measure of bystander behaviors called the Bystanders in Sexual Assault Virtual Environments (B-SAVE). In this study, 450 men and women aged 18-25 will be recruited from Lincoln, NE using passive methods. Potential participants will be screened, consented, and enrolled. After obtaining consent, the baseline survey will be administered and will assess self-reported individual differences in alcohol use and bystander outcomes and secondary endpoints (SV perpetration, victimization, alcohol expectancies, prosocial and personality traits, and other theoretical and empirical factors related to primary outcomes).

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary			
The overarching goal is to evaluate the efficacy of MTB+ALC in comparison to MTB and an attention control condition.	*1) reduced drinking 2) increased bystander behaviors*	*Briefly identify the hypothesized role that each measure plays in the study objectives, e.g., moderator, mediator, causal mechanisms, covariate.* *These endpoints serve as the outcome variables necessary*	*This column is optional and can be included when appropriate.*

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
		for evaluating the goals of the intervention.	
Secondary			
The secondary objective is to assess self-reported individual differences in alcohol use and bystander outcomes and secondary endpoints.	*1) SV perpetration,* *2) SV victimization,* *3) alcohol expectancies* *4) prosocial and personality traits* *5) other theoretical and empirical factors related to primary outcomes*	*Briefly identify the hypothesized role that each measure plays in the study objectives, e.g., moderator, mediator, causal mechanisms, covariate.* *These endpoints are understood to serve as potential moderators.*	

4 STUDY DESIGN

4.1 OVERALL DESIGN

Our first hypothesis is that MTB (vs. attention control) will increase prosocial bystander behaviors at each follow-up. Our second hypothesis is that MTB+ALC (vs. MTB) will increase prosocial bystander behaviors and decrease overall alcohol use measured via B-SAVE and weekly EDD follow-ups. Our third hypothesis is that MTB+ALC (vs. MTB or attention control) (a) will reduce alcohol use in risky sexual situations and (b) lower proximal alcohol use will be a mechanism explaining why MTB+ALC increases prosocial bystander behavior.

This is a Phase II trial. It will be a single site trial. A futility analysis is planned when 75% of the sample has been recruited (refer to details in **Section 9.4.6, Planned Interim Analysis).** Stratifications are planned based on racial and ethnic identity (refer to details in **Section 9.4.7, Sub-Group Analyses).** No sub-studies are planned.

Our study will use a randomized design. Once individuals complete the baseline survey, they will be randomized to an automated stratified block randomization program. This procedure ensures equal numbers of participants across 3 intervention groups (MTB, MTB+ALC, control). As our recruitment approach will ensure that 36% of our sample are from racial or ethnic minority groups, we will first stratify by race/ethnicity, resulting in two strata: non-minority and minority. We will also use this approach for gender and sexual orientation. For each stratum, a separate block randomization sequence will be used to assign people to one of 3 intervention groups: 1) MTB, 2) MTB+ALC, 3) Attention control.

The first study intervention, MTB, is an individual, face-to-face, MI session designed to enhance bystander intervention behavior in sexual risk situations. MTB is grounded in principles of motivational interviewing and is informed by brief interventions for other behaviors such as alcohol use (Miller et al., 1988). MTB

begins with brief psychoeducational information, presented in an MI-consistent manner according to the elicit-provide-elicit framework (Miller & Rollnick, 2002). MTB sessions are individually-tailored and incorporate personalized feedback from online measures of participant attitudes and current bystander behaviors. Consistent with MI-principles, MTB incorporates an exploration of a participant's values and goals (e.g., being a good friend, being an advocate for women) in relation to bystander behavior, and emphasizes individual autonomy with respect to potential behavior change. One key feature of MTB is an exploration of possible bystander behaviors a participant may be willing to initiate over the course of the study. The participant selects one or more of these behaviors to focus on over the next 9 months, and the interventionist reinforces the choice through the MI-consistent use of confidence and importance rulers. Throughout the MTB session the interventionist uses tailored open-ended questions, reflections, and strategic summaries to elicit and enhance change talk related to bystander behaviors.

Participants in MTB+ALC will receive MTB and an additional MI session with personalized feedback to address alcohol use and alcohol-related consequences. The ALC portion of MTB+ALC follows a traditional manualized format following MTB. The session begins with rapport building and exploration of personal values and goals related to alcohol use. The interventionist explores both the positive and negative aspects of drinking and provides a personalized feedback report tailored to the participant's alcohol use and alcohol related consequences. This computer-generated feedback report summarizes: 1) past-month frequency and quantity of drinking and heavy drinking; 2) normative comparisons for past- month frequency and quantity of drinking and heavy drinking; 3) past-month typical and peak BAC; 4) BAC interpretation guides; 5) alcohol-related consequences and risk factors for alcohol problems (past year); and 6) other alcohol-related outcomes (i.e., calorie intake, cost of alcohol use, and time allocated to alcohol consumption in comparison to other activities). The interventionist presents each topic in a non-judgmental style and invites discussion and reflection. The interventionist uses MI techniques throughout the discussion (i.e., respecting autonomy, open-ended questions, reflective listening, eliciting change talk, providing feedback that supports self-efficacy). Following the presentation of the personalized feedback report, the interventionist explores the participant's interest in changing drinking behavior. All participants are also provided with a menu of options of potential changes in alcohol use. Participants who identify an interest in change collaboratively set goals with the facilitator and identify a change plan.

The attention control condition begins with an introduction and general rapport building. The interventionist reviews the rationale for treatment, stating that life transitions during young adulthood may be stressful. Next, an exploration phase addresses the participant's typical level of daily stress and reviews current participant-employed coping behaviors. To promote treatment expectancies, a rationale and instructional exercise for progressive muscle relaxation is provided. The session concludes with a recommendation that the participant practice these techniques regularly.

At T2, participants will complete self-report measures (see measures) and the BSAVE. The B-SAVE virtual house party was developed by PIs DiLillo and Gervais using virtual reality software and hardware. This setting was selected because parties: (1) often involve heavy drinking; (2) are a high risk setting for SV, and; (3) are bystander intervention-appropriate (i.e., unwanted sexual advances are visible to onlookers, see Figure 3). The virtual environment for the party consists of a house including a front porch, a living room, a kitchen, and a bedroom. The overall dimensions are approximately the same (20 x 20 feet) as the room that houses the VR lab, thus enabling users to walk and move freely in the VR environment. MPIs DiLillo and Gervais programmed the B-SAVE using state-of-the-art virtual reality software and hardware (Worldviz LLC), creating a fully immersive experience. The virtual house is populated with individuals and small groups of same- and mixed-gender avatars who are racially diverse (33% representing racial/ethnic minority groups) from different sexual orientations (heterosexual, lesbian/gay), casually dressed, and

appear to be young adult aged. Non-verbal cues from the avatars (e.g., smiling, leaning toward or away from someone) as well as environmental cues to bolster immersion in the overall party setting (e.g., party music, a cooler with beer, a keg, red Solo cups) are present in the environment. Following a practice period to acclimate to VR, participants proceed through the 10 scenes of the BSAVE (5 risk, 5 neutral). In each scene, participants are prompted at two points in the conversation (with a flashing microphone) to verbalize their response in that situation, providing 10 opportunities to intervene in sexual risk situations. The VR system simultaneously records non-verbal behaviors (e.g., location: moving toward or away from avatars; gaze: head movements). If no verbal response is provided for 3 seconds, the scene automatically continues. Each neutral scene contains two response opportunities (not analyzed) to reduce demand characteristics. Following each scene, participants are directed to the next scene with an arrow. Risk scenes encountered in the B-SAVE contain both subtle and blatant sexual risk cues and show: a man sharing a nude photograph of an ex-girlfriend without her consent to another man; a woman experiencing unwanted sexual touching while dancing with a male acquaintance; two men making rape supportive jokes and talking about a drinking woman in sexually derogatory ways; the female victim of the revenge porn (from the earlier scenario); and a man pressuring an obviously intoxicated woman to remove her clothes against her will in a bedroom. These risk scenes are interspersed among the following neutral (i.e., non-risk) scenes: a man greeting the participant at the front door; two women and one man recounting a recent night of heavy drinking; two women engaging in small talk by a keg; an intoxicated man talking with his girlfriend; and two women planning to leave the party for a consensual hook-up.

T3 will consist of a series of weekly follow-up surveys immediately post final virtual intervention session until 9-months after T1. We will employ a prospective electronic daily diaries (EDD) approach in which participants report their prosocial bystander behaviors and alcohol use each day. Study participants will receive a prompt to provide past-week reports of bystander and drinking-related outcomes. Morning was chosen as the ideal time because SV situations and drinking can occur well into night; querying participants in the morning is therefore the best time to capture the prior day's activities in their entirety. Drinking and bystander-related outcomes will be assessed, each with a yes-no screening question, followed by drop down and open-ended responses options (see Weekly Electronic Diary). Alcohol consumption will be assessed as the number of standard drinks consumed over the past 24 hours on a 1-25 scale (with definitions of standard drinks provided). The time of the first and last drink will be collected as well, to examine drinking in relation to sexual risk and bystander opportunities. Responses to these items will provide unique and rich data addressing the occurrence of bystander behaviors in alcohol vs. nonalcohol contexts (i.e., when others are consuming alcohol) and bystander alcohol use in relation to interventions targeting the perpetrator, victim, or other bystanders. Finally, because of the high co-occurrence between alcohol and other substance use (e.g., cannabis, opioids, sedatives, stimulants, psychedelics) we will also assess the timing and levels of any other substances participants may have used on each occasion (refer to ***Section 1.3, Schedule of Activities***).

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

We selected the relaxation attention control condition because it is similar to prior control conditions used in prior evaluations of the MI-based ALC intervention and is designed to control for nonspecific factors by providing equivalent levels of attention. There are no known potential problems associated with the control group.

4.3 JUSTIFICATION FOR INTERVENTION

MTB is an individual, face-to-face, 60-minute MI intervention designed to enhance bystander intervention behavior in sexual risk situations. MTB is grounded in principles of MI and is informed by brief interventions for other behaviors such as alcohol use and weight loss. MTB sessions are individually-tailored and incorporate personalized feedback to address bystander attitudes and previous bystander behaviors. Following MTB, participants in the MTB+ALC condition will receive a 60-minute MI intervention with personalized feedback to address alcohol use and alcohol-related consequences. Several factors led us to select MI as the unifying framework for our combined bystander-alcohol intervention. First, MI has proven to be efficacious in helping individuals change a variety of behaviors related to other forms of interpersonal violence (e.g., intimate partner violence) and for reducing substance use, including drinking. Second, MI is flexible; rather than comprising a single set of techniques, it represents a style of interaction with a client and is rooted in the several interrelated principles, including: expressing empathy through reflective listening; identifying discrepancies between clients' goals or values and their current behavior; avoiding direct confrontation; adjusting to resistance; and supporting client self- efficacy and optimism. Thus, although MTB and ALC target different behaviors for change, they share hallmark features of MI; therefore, each intervention serves to reinforce principles promoted in the other. Further, providing content tailored to the individual's values, goals, and abilities may boost intervention efficacy by enhancing message impact and perceived relevance to participants, rather than presuming a "one size fits all" group format. Finally, our selection of a brief evidence-based preventive intervention is intended to ensure that our intervention can be easily adopted, implemented, and sustained across multiple settings.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if they have completed the baseline assessment, the randomly assigned intervention or control condition (i.e., MTB, MTB+ALC, control), 1-week B-SAVE follow-up, and weekly EDD follow-up assessments.

The end of the study is defined as completion of the 9-month follow-up assessment shown in the Schedule of Activities (SoA), **Section 1.3**.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:
1. Individuals ages 18-25
2. Heavy drinkers (as defined by using the AUDIT, see measures)
3. English fluency
4. Community members from Lincoln, Omaha, NE and surrounding areas
5. Signed and dated consent form
6. Stated willingness to comply with study procedures

5.2 EXCLUSION CRITERIA

This project does not have any pre-determined exclusion criteria beyond the need to meet inclusion criteria for the study.

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

Individuals who do not meet the criteria for participation in this trial (screen failure) because of not meeting one or more inclusion criteria that are likely to change over time may be rescreened.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment: Our targeted sample size is N = 450 women and men between 18 and 25 years of age (n ≈150 per condition). Initial recruitment will take place on a rolling basis over a 36-month period. Recruitment for this clinical trial will utilize methods used previously by the research team with advertisements via multiple media outlets to ensure we have adequate reach of our targeted population. We will use a broad recruitment strategy that includes advertising online, in local newspapers, and via community flyers (in buses, bars, liquor stores, etc.) and that will target young adults who are heavy drinkers in Lincoln, Omaha, NE and surrounding areas. Ads will ask respondents to contact the laboratory via a QR code, e-mail, or phone to complete an initial eligibility screening. To enhance the generalizability of our results, we will use a broad recruitment strategy that includes advertising online (e.g., Craigslist, social media), in newspapers, and in places in the community via flyers that target young adults who are heavy drinkers in Lincoln, Omaha, NE and surrounding areas. In doing so, we will use strategies from Co-Is Orchowski and Parrott and our own research to recruit heavy drinkers (e.g., posting fliers in bars; outside liquor stores). We will also utilize a list of students from the UNL Bursar's office as needed. Ads will ask respondents to contact the laboratory via an online survey, email, or phone, to complete the initial eligibility screening. Eligibility screening will take place using a Qualtrics form (see Eligibility Screening). The link to this form will be provided to

participants either through email (for those who email the lab) or via a QR code on advertisements. Individuals who call the lab may be screened on the phone.

To increase sample size, participants will also be recruited through BuildClinical—a recruitment service used for NIH-funded research—to advertise the study. BuildClinical is a data-driven platform that helps academic researchers recruit participants for research studies more efficiently using social media, software, and machine learning. They work with IRBs in the United States to adhere to all the appropriate guidelines and procedures. They utilize study-specific advertisements to engage participants on digital platforms such as Facebook, Google, WebMD, etc. and redirect them to a study-specific landing page should they click it. On the landing page, the person can complete a brief online questionnaire (called the "Screening Form" in the above link) that gets routed into BuildClinical's platform to enhance recruitment (e.g., to ensure the correct populations are being reached and to inform adjustments to the algorithm) before being directed to the study team's Qualtrics screening survey to determine eligibility. (Importantly, the brief questionnaire/screening form used by BuildClinical is for recruitment purposes only and those data will not be accessed by the investigative team.) BuildClinical's Secure Socket Layer (SSL) software encrypts all inputted information and keeps the information private and HIPAA compliant. The backend servers are stored in the United States at some of the most secure data centers in the world.

To be eligible, participants must be between 18 and 25 years old and meet NIAAA criteria for heavy drinking via alcohol screening items. Those who meet inclusion criteria and provide informed consent will be provided a link to the baseline assessment and later scheduled for a virtual lab visit to undergo one of the three treatment conditions. Using conservative estimates from past studies conducted by MPIs DiLillo and Gervais as well as Co-Is Orchowski and Parrott, including substantial samples of heavy drinkers, the above recruitment efforts will generate approximately 26 calls per month. We estimate that 13 (50%) will be deemed eligible, provide consent, and be randomly assigned to intervention condition (N = 450). (See table below for a month-by-month schedule of baseline and follow-up sessions.)

***Retention*:** Our team has had significant success in retaining large, community-based cohorts including heavy drinkers. We conservatively estimate a 25% attrition rate from baseline to the last 9-month EDD, which is greater than other longitudinal research including MI-interventions with heavy drinkers (attrition at 9- to 12-month follow-ups = 15-20%). To maximize retention, we will employ several proven strategies successfully used in previous studies involving community-based samples of heavy drinkers. We will collect and verify extensive contact information after informed consent using a data collection form adapted from MPI DiLillo and colleagues. We will attain contact information for people from participants' differing social networks (e.g., non-drinking and drinking family and friends), to ensure retention across the 9-month period (e.g., a subset of our sample might enter alcohol use disorder rehabilitation programs and thereby have more contact with non-drinkers than drinkers compared to when they were initially recruited). Qualtrics will be used to automatically send text messages and email reminders about pending follow-up assessments (i.e., VR B-SAVE lab session; EDD surveys). For EDD surveys specifically, participants will receive daily email and/or text message reminders until each survey is completed; once a survey is completed, reminders for that survey will stop. We will use multiple additional strategies to boost

retention, including: 1) maintaining cell phone, address, email and other records (e.g., social media handles); 2) sending email "meeting" invites; 3) emailing and texting reminders prior to each EDD period; and 4) holding incentives until several tasks have been completed. Finally, participants will be paid $30-$40 for completion of online baseline measures (1.5– 2 hours).They will also receive $20 per hour for 1 virtual intervention session (1-3 hours). They will be paid $40 for the lab visit when they complete the B-SAVE (1.5 hours). In addition to this standard compensation, participants will be eligible for two bonuses: a $15 bonus if they complete the baseline online measures within 2 days of providing consent, and another $15 bonus if they complete your Zoom session within 3 weeks of finishing the online measures. Participants will be paid $5 for each follow-up survey. Participants will also receive a $2 bonus for each follow-up survey they complete on Sundays.

STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

5.6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

5.6.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

Participants in this study will be randomly assigned to receive one of three interventions: MTB, MTB+ALC, and attention control. Intervention conditions will last approximately 60-120 minutes and will be administered by a trained interventionist.

MTB: MTB is an individual, face-to-face, MI session designed to enhance bystander intervention behavior in sexual risk situations. MTB is grounded in principles of motivational interviewing and is informed by brief interventions for other behaviors such as alcohol use (Miller, Sovereign, & Krege, 1988) and weight loss (Smith West, DiLillo, Bursac, Greene & Gore, 2007). Because the concept of bystander intervention may not be familiar to some participants, MTB begins with brief psychoeducational information, presented in an MI-consistent manner according to the elicit-provide-elicit framework (Miller & Rollnick, 2002). MTB sessions are individually-tailored and incorporate personalized feedback from online measures of participant attitudes and current bystander behaviors. Consistent with MI-principles, MTB incorporates an exploration of a participant's values and goals (e.g., being a good friend, being an advocate for women) in relation to bystander behavior, and emphasizes individual autonomy with respect to potential behavior change. One key feature of MTB is an exploration of possible bystander behaviors a participant may be willing to initiate over the course of the study. The participant selects one or more of these behaviors to focus on over the next 9 months, and the interventionist reinforces the choice through the MI-consistent use of confidence and importance rulers. Throughout the MTB session the interventionist uses tailored open-ended questions, reflections, and strategic summaries to elicit and enhance change talk related to bystander behaviors.

MTB+ALC: Participants in MTB+ALC will receive an additional MI session with personalized feedback to address alcohol use and alcohol-related consequences. The ALC portion of MTB+ALC follows a traditional manualized format following MTB. The session begins with rapport building and exploration of drinking-related personal values and goals. The interventionist explores both the positive and negative aspects of drinking and provides a personalized feedback report tailored to the participant's alcohol use and alcohol related consequences. This computer-generated feedback report summarizes: 1) past-month frequency

and quantity of drinking and heavy drinking; 2) normative comparisons for past-month frequency and quantity of drinking and heavy drinking; 3) past-month typical and peak BAC; 4) BAC interpretation guides; 5) alcohol-related consequences and risk factors for alcohol problems (past year); and 6) other alcohol-related consequences and risk factors for alcohol problems (past year; and 6) other alcohol-related outcomes (i.e., calorie intake, cost of alcohol use, and time allocated to alcohol consumption in comparison to other activities). The interventionist presents each topic in a non-judgmental style and invites discussion and reflection. The interventionist uses MI techniques throughout the discussion (i.e., respecting autonomy, open-ended questions, reflective listening, eliciting change talk, providing feedback that supports self-efficacy). Following the presentation of the personalized feedback report, the interventionist explores the participant's interest in changing drinking behavior. All participants are also provided with a menu of options of potential changes in alcohol use. Participants who identify an interest in change collaboratively set goals with the facilitator and identify a change plan. ALC lasts 90-150 minutes.

Attention control: The attention control condition is designed to control for nonspecific factors by providing equivalent levels of contact time and attention. Like the active treatment conditions, the attention control condition begins with an introduction and general rapport building. The interventionist reviews the rationale for treatment, stating that life transitions during young adulthood may be stressful. Next, an exploration phase addresses the participant's typical level of daily stress and reviews current participant-employed coping behaviors. To promote treatment expectancies, a rationale and instructional exercise is provided. Specifically, progressive muscle relaxation is introduced and practiced. The session concludes with a recommendation that the participant practice these techniques regularly. The entire Attention control session lasts approximately 90 minutes.

5.6.2 ADMINISTRATION AND/OR DOSING

The study intervention will be administered individually, in two face-to face sessions (60-120 minutes).

5.7 FIDELITY

5.7.1 INTERVENTIONIST TRAINING AND TRACKING

Interventionists will then complete a two-day intensive training program with Consultant Nadine Mastroleo, Ph.D., in which prescribed and proscribed behaviors are enumerated and practiced through group and didactic instruction as well as role- playing techniques. Following training, interventionists will complete practice sessions and provide self-ratings of competence and adherence. Once interventionists feel ready, they will record two sessions with pilot participants (who meet study inclusion criteria). Interventionists will be certified when they are deemed proficient in accordance with the Motivational Interviewing Treatment Integrity scale (MITI; Moyers et al., 2005) MPIs DiLillo and Gervais and Co-Is V. DiLillo and Orchowski are or will be certified on the latest version of the MITI.

Co-I V. DiLillo, a licensed psychologist who oversaw the implementation of MTB during the pilot RCT, will employ treatment integrity/fidelity checks for MTB. Co-I Orchowski, also a licensed clinical psychologist, will implement these procedures for ALC. Twenty percent of sessions will be randomly reviewed and rated for adherence to protocols using the MITI Coding Manual 4.2.1 on an ongoing basis. The MITI is a behavioral coding system that is the most commonly used treatment integrity measure in clinical trials of MI. If someone does not meet the requirements of the MITI, they will receive remedial training and complete practice sessions until adequate levels of adherence and competence are achieved.

5.8 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Once individuals complete the baseline survey, they will be randomized to an automated stratified block randomization program. This procedure ensures equal numbers of participants across 3 intervention groups (MTB, MTB+ALC, control). As our recruitment approach will ensure that 36% of our sample are from racial or ethnic minority groups, we will first stratify by race/ethnicity, resulting in two strata: non-minority and minority. We will also use this approach for gender and sexual orientation. For each stratum, a separate block randomization sequence will be used to assign people to one of 3 intervention groups: 1) MTB, 2) MTB+ALC, 3) Attention control.

Interventionists must know which participants are receiving which intervention, precluding them from being blinded to conditions. However, coders will be blind to condition when coding the electronic daily diaries and responses to the VR B-SAVE for the primary endpoints (e.g., bystander outcomes, alcohol use). This should reduce any bias related to coding endpoints.

5.9 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

N/A

5.10 CONCOMITANT THERAPY

N/A

5.10.1 RESCUE THERAPY

N/A

6 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

If a clinically significant finding is identified (including, but not limited to changes from baseline) after enrollment, the investigator or qualified designee will determine if any change in participant management is needed. Any new clinically relevant finding will be reported as an adverse event (AE).

The data to be collected at the time of study intervention discontinuation will include the following: The reason(s) for discontinuing the participant from the intervention, and methods for determining the need to discontinue.

6.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
- Lost-to-follow up; unable to contact subject (see **Section 7.3, Lost to Follow-Up**)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are discontinued from the study, will not be replaced.

6.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she or they does not complete any of the follow-ups. The following actions must be taken if a participant fails to complete study protocols at each of the time-points:

- For participants who fail to complete any of the follow ups, the study personnel will contact them (e.g., phone call, text message) 6 times for each follow up.
- Should the participant continue to be unreachable for all of the follow ups, he, she, or they will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Primary study endpoints are: 1) reduced drinking, and 2) increased bystander behaviors. Drinking will be assessed with self-reports in electronic daily diaries (EDD). Bystander behaviors will also be assessed with EDD and observed directly with a VR-based measure of bystander behaviors called the Bystanders in Sexual Assault Virtual Environments (B-SAVE). In this study, 450 men and women aged 18-25 will be recruited from Lincoln, Omaha, NE and surrounding areas using passive methods. Potential participants will be screened, consented,
and enrolled. Determinations of eligibility will be based on an initial eligibility screening via an online survey, e-mail, or phone. Individuals will be eligible to participate if they meet the following criteria:

1. Individuals ages 18-25
2. Heavy drinker (For men, 5+ drinks on a single occasion or more than 15 drinks per week during the last month. For women, 4+ drinks on a single occasion or more than 8 drinks per week)
3. Lincoln, Omaha, NE and surrounding areas community members
4. Signed and dated consent form
5. Stated willingness to comply with study procedures

After obtaining consent, the baseline survey will be administered and will assess self-reported individual differences in alcohol use and bystander behavior, as well as other theoretical and empirical factors related to primary outcomes. Participants will then be given instructions for completing the weekly EDD surveys post final intervention through month 9. Participants will self-report the number of standard drinks consumed in the past week (our primary alcohol use endpoint), as well as whether they intervened as a bystander if there was an opportunity to do so (our primary bystander behavior endpoint). One-week post-intervention, investigators will schedule a lab appointment for participants to complete the B-SAVE. The follow-up B-SAVE includes 5 risk scenes within a house party in which participants are prompted at two points in the conversation (with a flashing microphone icon) to verbalize their response in that situation, providing 10 opportunities to intervene in sexual risk situations. Responses are recorded and coded and reflect the presence or absence of intervention attempts (0=no, 1= yes). Along with the intervention attempts from the EDD, sum intervention attempts during the B-SAVE is the primary outcome of interest for assessing bystander behaviors.

7.2 SAFETY ASSESSMENTS

The MI interventionists or trained graduate research assistants will be present during all study sessions and will be responsible for ensuring participants' safety on a daily basis. The MPIs, Dr. DiLillo and Dr. Gervais, will be available in the building or by phone during all study sessions. Throughout data collection, the MPIs will meet with the MI interventionists and graduate research assistants weekly and the rest of the study team (i.e., Co-Is) monthly to monitor participant safety, among other aspects of the study (e.g., evaluating progress, reviewing procedures).

7.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.3.1 DEFINITION OF ADVERSE EVENTS

7.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

This protocol uses the definition of serious adverse event from *HRPP Policy 13.001*: an event resulting in any of the following outcomes:

A. Death
B. A serious threat to life, health, safety or welfare of the subjects
C. Inpatient hospitalization (for a person not already hospitalized) or prolongation or hospitalization (for a patient already hospitalized)
D. Persistent or significant disability or incapacity
E. Required intervention to prevent permanent impairment or damage
F. Congenital anomaly and/or birth defects
G. An event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes
H. The rights, safety, or welfare of subjects is seriously jeopardized.

7.3.3 CLASSIFICATION OF AN ADVERSE EVENT

7.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

7.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by the study team based on temporal relationship and his/her judgment. The degree of certainty about causality will be graded using the categories below.

- **Related** – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
- **Not Related** – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

7.3.3.3 EXPECTEDNESS

The study team will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

7.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during the intervention, VR B-SAVE lab session, or any of the electronic daily diary follow-up surveys.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a determination), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

The study team will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. Events will be followed for outcome information until resolution or stabilization.

7.3.5 ADVERSE EVENT REPORTING

Per our Data and Safety Monitoring Plan, the DSMB will receive quarterly reports of any adverse events, and an annual report summarizing all AEs will be provided to the NIAAA Project Officer. The report will include confirmation of adherence to the data and safety monitoring plan, b) a summary of any data and safety monitoring issues that occurred since the previous reporting period, c) a description of any changes in the research protocol or in the data and safety monitoring plan that either does or potentially affect risk, and d) all new and continuing IRB approvals. Finally, the PI will report any adverse events to the UNL IRB within 48 hours of when any of the research team members become aware of the incident.

7.3.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event (SAE). Per our Data and Safety Monitoring Plan, SAEs will be reported within 48 hours (via telephone and/or e-mail) to the University of Nebraska IRB, the DSMB, and the NIAAA Project Officer.

7.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

7.3.8 EVENTS OF SPECIAL INTEREST

N/A

7.3.9 REPORTING OF PREGNANCY

N/A

7.4 UNANTICIPATED PROBLEMS

7.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the Data Coordinating Center (DCC)/lead principal investigator (PI). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the DCC/study sponsor/funding agency within 48 hours of the investigator becoming aware of the event
- Any other UP will be reported to the IRB and to the DCC/study sponsor/funding agency within 48 hours of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 48 hours of the IRB's receipt of the report of the problem from the investigator

7.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

8 STATISTICAL CONSIDERATIONS

8.1 STATISTICAL HYPOTHESES

- Primary Endpoint(s):

The main hypotheses are: MTB (vs. attention control) will increase prosocial bystander behaviors measured via B-SAVE and weekly EDD follow-ups (months 0-9; Hypothesis 1); MTB+ALC (vs. MTB) will increase prosocial bystander behaviors and decrease overall alcohol use measured via weekly EDD follow-ups (months 0-9; Hypothesis 2); MTB+ALC (vs. MTB and attention control) (a) will reduce alcohol use in risky sexual situations and (b) lower proximal alcohol use will be a mechanism explaining why MTB+ALC increases prosocial bystander behavior (Hypothesis 3).

A formal statistical analysis plan will not be completed. Thus, relevant information is provided below in each subsection.

- Secondary Endpoint(s):

n/a

8.2 SAMPLE SIZE DETERMINATION

Primary study endpoints are: 1) reduced drinking, and 2) increased bystander behaviors. Drinking will be assessed with self-reports in electronic daily diaries (EDD). Bystander behaviors will also be assessed with EDD and observed directly with a VR-based measure of bystander behaviors called the Bystanders in Sexual Assault Virtual Environments (B-SAVE). Specifically, our main outcome variable for testing Hypothesis 1 will be bystander intervention attempts during the B-SAVE and from electronic daily diary reports (EDD; 0 = no, 1 = yes). Our main outcome variables for testing Hypothesis 2 will be bystander intervention attempts, as well as alcohol use from the EDD (number of standard drinks consumed over the past week. Our main outcomes for Hypothesis 3 will be bystander intervention attempts from the EDD.

The null hypotheses are: (1) there will be no difference between MTB and the control condition on bystander intervention attempts across the B-SAVE and EDD, (2) there will be no difference between MTB, MTB+alc, and the control condition on bystander intervention attempts across the B-SAVE and EDD or on the number of standard drinks reported on the EDD, and (3) changes in alcohol use proximal to risky sexual situations will not account for differences in bystander intervention attempts.

Cohen's f effect sizes and Sobel test statistics (R^2_{ab}) were used to determine power sufficient for the current study. Power estimates were conducted in G*Power (Faul et al., 2007). The alpha's examined were .05 for at least 80% power. Analyses of data using pilot data suggest that MTB is associated with improved bystander attitudes and likelihood to intervene with large effect sizes (Grandgenett, 2021), with a Cohen's f of approximately 0.58 compared to attention-control group, which falls above the threshold large effect size under conventional rules of thumb (large effect = 0.40). Considering a more conservative expected medium effect size of f = 0.25 and 75% attrition by the 9-month follow-up, the statistical power is over 0.80 to detect a mean difference between two groups (i.e., MTB vs. control, Aim 1) and over 0.90 to detect a mean difference among three groups (MTB vs. MTB+ALC vs. control, Aim 2). Power calculations of the Sobel test for a sample of N = 336 were conducted for the indirect effect of MTB+ALC on bystander behaviors via reduction of alcohol use (vs. MTB and control; Aim 3). Assuming a small effect size, the indirect effect would account for 5.5% of the variance in bystander outcomes ($R^2_{ab} = 0.055$). With a sample

of 336 individuals, there is over 0.80 power to detect such an indirect effect. These calculations indicate that our sample size is sufficient for addressing all endpoints and accounts for attrition.

We will have one dichotomous outcome: bystander intervention attempts (measured across B-SAVE and EDD). In the B-SAVE, participants have 5 opportunities to intervene. In daily life, participants have varied opportunities to intervene. Specifically, our pilot data from the MTB RCT showed that young adults from the community reported approximately two SV intervention opportunities in a 1-month period (*M* = 2.26, *SD* = 1.55). Thus, we expect that participants will report 9-18 SV bystander intervention opportunities over the 9-month period. The rate of intervention attempts during these opportunities is exploratory, given lack of prior EDD data. Further, based on our eligibility criteria, we expect that men will report 2-4 drinks per day and women will report 1-3 standard drinks per day.

Given our use of rigorous retention strategies, we expect 95% retention at the 1-2-week follow-up and 75% original sample retention for the 9-month EDD. This would result in 405 participants with B-SAVE outcome scores (135 per treatment group) and approximately 336 participants with B-SAVE outcome scores and complete EDD weekly measures (112 per treatment group). Multivariate imputation via chained equations (MICE) will be used to impute missing data on both predictors and outcome variables. MICE is a flexible and widely used method that builds prediction models for variables with missing data using all other variables in the dataset and draws randomly from the predictive distribution.

We will not be conducting qualitative analyses, a cluster-randomized or individually randomized group-treatment trial, or using a Bayesian approach.

8.3 POPULATIONS FOR ANALYSES

We are using a modified intention-to-treat analysis population (i.e., all randomized participants who complete the intervention).

8.4 STATISTICAL ANALYSES

8.4.1 GENERAL APPROACH

We will not be using qualitative data. For quantitative data, categorical data will be presented as percentages and *n*'s. Continuous data will be presented as means with standard deviations. For inferential tests, we will consider statistical significance based on p-values < .05 and confidence intervals that do not cross zero. These will be two-tailed inferential tests. We will check our data for normality and corrective procedures (e.g., transformation, predictive mean matching) will be applied.

8.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

Primary study endpoints are: 1) bystander intervention attempts, 2) bystander effectiveness, and 3) drinking. Bystander behaviors will be assessed with weekly EDD (electronic daily diaries) and observed directly with a VR-based measure of bystander behaviors called the Bystanders in Sexual Assault Virtual Environments

(B-SAVE). Drinking will be assessed with self-reports in weekly electronic daily diaries (EDD). Scores on the B-SAVE will be taken at 1-week post-intervention. Scores on the EDD measures will be taken weekly for 9 months post-intervention.
The outcomes will be intervention effectiveness scores coded from B-SAVE, aggregate scores of intervention effectiveness derived from coding the weekly EDD bystander behaviors, and aggregate scores of alcohol use from the weekly EDD bystander behaviors. Bystander intervention attempts is a binary variable where 1 = intervention attempt occurred and 0 = no attempt. Bystander effectiveness is an interval variable ranging from -5 (very ineffective; the action would likely facilitate sexual aggression) to +5 (very effective; the action would likely disrupt an instance of sexual assault). Drinking is an interval variable that represents the number of standard drinks consumed each day for the past week.

A unified statistical modeling framework will be employed to compare intervention groups on both B-SAVE bystander scores and weekly EDD scores. All models will be estimated using the latent variable modeling software Mplus. Multigroup structural equation modeling (MG-SEM) will be used to explicitly test for differences in bystander intervention effectiveness between the MTB and attention control condition, and between MTB and MTB+ALC treatment groups, on all primary endpoints while controlling for pre-intervention bystander behaviors, alcohol use, and other relevant variables (e.g., SV victimization, polysubstance use). We will also utilize the multigroup modeling approach with dynamic SEM (DSEM), a method for modeling intensive repeated measures (e.g., daily measures within each weekly EDD) in an SEM framework via Mplus. We will embed the weekly EDD DSEM into an MG-SEM to disaggregate within- and between-person effects of alcohol use proximal to bystander behaviors. This combined model will enable the use of random effects in the DSEM portion of the model as potential outcomes as well as sequential mediators. This full model will allow us to explicitly test if changes in alcohol use proximal to risky sexual situations account for differences in bystander behaviors. The model can be extended to compare the trajectory of bystander intervention effectiveness and the effects of alcohol use on bystander behaviors across the three treatment groups.

This is not a cluster-randomized or individually randomized group-treatment trial.

Variances and covariances across repeated measures will be estimated using MG-SEM and DSEM. Specifically, DSEM is a dynamic multilevel modeling approach that involves specifying the form of intraindividual longitudinal trajectories or time series models while allowing for quantitative differences in the parameters of the trajectories between subjects.

Results of statistical procedures will be presented as estimates with standard errors and/or confidence intervals from our MG-SEM and DSEM models.

Participants will be 450 women and men aged 18-25 who speak English and are heavy drinkers. Our sample will contain heavy drinkers based on NIAAA criteria (men who consume 5 drinks on any day or more than 15 drinks per week in the past month; women who consume 4 drinks on any day or more than 8drinks per week in the past month).

Multivariate imputation via chained equations (MICE) will be used to impute missing data on both predictors and outcome variables. MICE is a flexible and widely used method that builds prediction models for variables with missing data using all other variables in the dataset and draws randomly from the predictive distribution.

Although we have two endpoints for Hypothesis 2, we did not adjust statistically for Type I error criteria because we are interested in whether MTB+ALC improves bystander behavior and reduces alcohol use – two separate outcomes.

8.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

n/a

8.4.4 SAFETY ANALYSES

n/a

8.4.5 BASELINE DESCRIPTIVE STATISTICS

We will monitor demographic variables throughout recruitment (i.e., race/ethnicity, sexual/gender identity, education, SES) using descriptive statistics (e.g., percentages). Further, we will test for efficacy across racial/ethnic groups by testing for a subgroup by treatment group interaction effect at the α=.05 level. If the interaction is not statistically significant, following the guidelines in Rothwell (2005), Schulz and Grimes (2005), and Friedman et al. (2010), no further testing will be conducted for individual subgroups. In the event of a significant interaction test, we will conduct statistical testing of efficacy for each individual subgroup.

8.4.6 PLANNED INTERIM ANALYSES

Power analyses have been conducted to assure that we have a sufficient number of participants (n = 450) to detect differences between MTB, MTB+ALC, and control intervention conditions. We will conduct a futility analysis in accordance with the recommendations of Sully et al. (2014). Based on their recent analysis of publicly funded RCTs, Sully and colleagues (2014) recommended that a futility analysis be conducted when 75% of the target sample had been recruited using a boundary of γ = 0.3. Based on this approach, if we have less than 0.3 observed power to detect the hypothesized effects, the trial will be stopped. Notably, this approach does not require any alpha adjustment. Co-Investigator Dr. Katherine Masyn will be responsible for overseeing the interim analyses.

The overall project will be stopped if there is evidence of harm, if there is no likelihood of benefit, or if there is overwhelming evidence of treatment benefit. Given the nature of the intervention, it is unlikely that participants will experience adverse events. However, DSMB meetings will be held every 12 monthsbeginning in Year 1 of the study to evaluate these possibilities. SAEs will be reported to the DSMB Chair
as soon as they occur. The DSMB Chair will determine whether an in-person meeting or teleconference is needed. Prior to the meetings, a written report containing descriptions of any AEs or SAEs as well as any preliminary findings will be sent to DSMB members. Preliminary findings will not be made available to individuals outside of the DSMB. Each meeting will include time to review the progress of the study and to answer questions from members of the DSMB. During the meeting, the DSMB will review reports of AEs and SAEs. If we have reached 75% of our targeted sample for the futility analysis, then we will review these analyses of outcome data to determine whether the current study needs to be changed or terminated depending on whether there is clear evidence of harm, futility, or benefit. A determination will be made as to whether the trial should continue as designed, should be changed, or should be terminated based on the data and make recommendations to the NIH and the Institutional

8.4.7 REVIEW BOARD CONSIDERING CONCLUSION OR CONTINUATION OF THE STUDY.SUB-GROUP ANALYSES

We have proactively decided to adopt a conservative power analytic approach to subgroup analyses for racial and ethnic groups aimed at safeguarding against multiplicity concerns. The first step in the subgroup analysis will be to test for a subgroup by treatment group interaction effect. There are two general schools of thought regarding whether an adjustment to the power calculation be made for such a test of interaction. One possible approach is to make a change to the power analysis to increase the sample size needed for the interaction test. Another is to power the study on efficacy of its primary outcome and avoid further adjustment for an interaction test. We have chosen this second approach to conservatively protect against a false positive finding.

Subgroup analyses will proceed with first testing for efficacy across the racial/ethnic groups by testing for a subgroup by treatment group interaction effect at the α=.05 level. If the interaction is not statistically significant, following the guidelines in Rothwell (2005), Schulz and Grimes (2005), and Friedman et al. (2010), no further testing will be conducted for individual subgroups. This approach is analogous to requiring a significant overall F-test in an ANOVA analysis before proceeding to conduct multiple comparison tests. Interaction tests provide proper caution and consider the limited information available in subgroups. Ceasing to continue on to test for individual effects in the absence of a significant interaction test is the most effective statistical approach for avoiding inappropriate subgroup findings.

In the event of a significant interaction test, we will conduct statistical testing of efficacy for each individual subgroup. Rothwell (2005) suggests the use of an alpha spending function with testing efficacy of individual subgroups to adjust for the multiplicity problems that ensue as a result of multiple statistical tests on the same outcome. Alpha spending functions were developed to address multiplicity concerns that occur with multiple statistical tests performed on the same primary outcome in a randomized controlled trial. Alpha spending functions are used to avoid an inflated number of false positives that results with multiple statistical tests (Todd et al 2001). Many types of alpha functions have been developed to support different analysis strategies. We will use the Pocock alpha spending function to implement an equal alpha level across subgroups, which suggests an alpha level for each subgroup analysis of α=0.01 (Pocock et al., 2002). We have adjusted these levels to account for the sample size differentials between subgroups.

8.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data will be listed by measure and time point.

8.4.9 EXPLORATORY ANALYSES

We do not have planned exploratory analyses at this time.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

9.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study intervention. The following consent materials are submitted with this protocol: Informed Consent 04.21.22, ICH-GCP consent form.

9.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Upon arriving at each scheduled appointment (baseline, intervention and B-SAVE), and before beginning any part of the study, the informed consent process will take place. All participants will read an online copy of the informed consent form (see Informed Consent Form 4.21.22, ICH-GCP consent form), and a member of the lab (e.g., research assistant) will be available to answer questions via email or phone. During virtual and lab-based sessions lab members will verbally review the information provided in the form. The participant will have ample opportunity to ask questions and decline participation if they so choose. If participants agree to participate, they will click on an I agree button on the informed consent form. There will also be a text box on the Informed Consent Form where participants will type their name so that the researchers are able to keep track of each participants informed consent document between each timepoint (T1-T3). The participant will also be provided a copy of the informed consent form for their records. At T2, a member of the lab (e.g., research assistant) will verbally review the informed consent form. Participants will again have the opportunity to ask questions and decline participation if they so choose.

In addition to providing consent to participate in the study as a whole, the consent form will provide participants with information about sharing their study data with the National Institute of Mental Health Data Archive (NDA) and ask if they consent to data sharing. Individuals can participate in the study regardless of whether or not they provide consent for NDA data sharing. Individuals are informed they can revoke consent for data sharing at any time. No new data will be shared with NDA, but already shared data cannot be removed.

We request to waive parental consent for those who are 18 years old. All participants--including those under the age of 19--will review a copy of the informed consent form and sign the form if they agree to participate.

9.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigators, NIAAA, and regulatory authorities (e.g., DSMB). If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (ie, significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies (OHRP, DSMB).]

9.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the National Institute of Alcoholism and Alcohol Abuse. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or organizations supplying the product, may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participants' contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored on a secure, restricted Microsoft SharePoint site. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and on the secure, restricted Microsoft SharePoint site will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the NIAAA Data Archive ($NIAAA_{DA}$).

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate and consistent with the NIAAA Data Archive Sharing Plan.

Certificate of Confidentiality
To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.]

9.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored on a secure, restricted Microsoft SharePoint site. After the study is completed, the de-identified, archived data will be transmitted to and stored at the $NIAAA_{DA}$, for use by other researchers including those outside of the study. Permission to transmit data to the $NIAAA_{DA}$ will be included in the informed consent.

When the study is completed, access to study data and/or samples will be provided through $NIAAA_{DA.}$

9.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Principal Investigator**
David DiLillo, PhD, Willa Cather Professor and Department Chair	Sarah Gervais, PhD, Susan Rosowski Professor
University of Nebraska - Lincoln	University of Nebraska - Lincoln
238 Burnett Hall	238 Burnett Hall
402-472-3297	402-416-6287
ddilillo@unl.edu	sgervais2@unl.edu

There are no study leadership committees. PIs DiLillo and Gervais will be responsible for the conduct, management, and oversight of the trial. Other study team members include the co-investigators Dominic Parrott, PhD, Lindsay Orchowski, PhD, Vicki DiLillo, PhD, and Katherine Masyn, PhD, as well as consultant Nadine Mastroleo, PhD.

Study staff and participants can report study misconduct directly to the UNL IRB. Participants are provided the UNL IRB contact information in the informed consent form.

9.1.6 SAFETY OVERSIGHT

Safety oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of individuals with the appropriate expertise. A Chair with no conflicts of interest who has been the Principal Investigator of NIAAA funded projects on alcohol use and violence will be identified. The Chair will recruit at least two other members with complementary expertise in the areas relevant to the proposed project (e.g., alcohol use, including by people who are heavy drinkers, bystander intervention, sexual aggression/victimization). The NIH Project Officer will serve as an ex-officio member of the DSMB. All members of the DSMB will be voting members and be appointed for the life of the project. Members of the DSMB will be independent from the study conduct and free of conflict of interest. The DSMB will meet at least annually to assess safety and efficacy data from each year of the study. Prior to the meetings, a written report containing study information (see below) will be sent to DSMB members. Each meeting will include time to review the progress of the study and to answer questions from members of the DSMB. Any serious adverse events (SAE) or unanticipated problems will be reported to the DSMB within 48 hours and the DSMB will receive quarterly reports of any adverse events (AE).

Members of the DSMB will perform the following activities:

a. Review the research protocols, the DSMP, and informed consent documents.
b. Review progress of the trial, including analysis of data quality and timeliness, participant recruitment, accrual, and retention, participant risk versus benefit ratio, and other factors that may affect outcomes.
c. Review unanticipated problems, serious adverse event reports, and adverse events, provide feedback, and provide oversight to ensure that reports are relayed to the IRB and to NIAAA whether there is an effect on participant safety.
d. Review analyses of outcome data and review reports of related studies to determine whether the
current study needs to be changed or terminated. Preliminary findings will not be made available to individuals outside the DSMB. All data in the report will be confidential.
e. Determine whether the trial should continue as designed, should be changed, or should be terminated based on the data and make recommendation to the NIH and the IRB considering conclusion or continuation of the study.
f. Review proposed modifications to the study prior to their implementation.
g. Protect the confidentiality of the trial data and the results of the monitoring as appropriate.
h. Determine whether and to whom outcomes results should be released prior to reporting of study
results.
i. Following DSMB meetings, provide appropriate NIH staff with written information concerning their findings.

9.1.7 CLINICAL MONITORING

N/A

9.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

All data collection will occur on UNL's campus. PIs DiLillo and Gervais will perform internal quality management of study conduct, data collection, documentation and completion.

Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Data will be initially captured on source documents (see **Section 10.1.9, Data Handling and Record Keeping**) and will ultimately be entered into the study database. To ensure accuracy site staff will compare a representative sample of source data against the database, targeting key data points in that review.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section 6.2.1, Interventionist Training and Tracking**.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.]

9.1.9 DATA HANDLING AND RECORD KEEPING

9.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial staff at UNL under the supervision of PIs DiLillo and Gervais. The investigators will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

We will have paper (e.g., consent forms, compensation records) and electronic source documents (e.g., measures completed by participants in Qualtrics, audio recorded responses to the B-SAVE). All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. Paper source documents will be stored in a locked file cabinet, while electronic data will be stored securely on the restricted SharePoint site and a password-protected computer.

Hard copies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant consented/enrolled in the study.

9.1.9.2 STUDY RECORDS RETENTION

Upon completion of the study, the list linking participant names to their numerical identifier will be deleted. Video files and all data will be kept for seven years in accordance with recommendations by the American Psychological Association (APA).

9.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within two working days of identification of the protocol deviation, or within two working days of the scheduled protocol-required activity. All deviations will be addressed in study source documents and reported to our NIAAA Program Official. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

9.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers after the completion of the primary endpoint by contacting PIs DiLillo and Gervais or $NIAAA_{DA}$. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.
In addition, this study will comply with NIAAA Data Sharing Plans. All deidentified data will be shared with NIAAA for inclusion into the NIAAA Data Archive following the template provided by NIAAA.

9.1.12 CONFLICT OF INTEREST POLICY

Any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The University of Nebraska Lincoln has an established Conflict of Interest in Research Policy that will be followed and complies with Public Health Service requirements.

9.2 ADDITIONAL CONSIDERATIONS

N/A

9.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
CFR	Code of Federal Regulations
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DSMB	Data Safety Monitoring Board
EC	Ethics Committee

EDD	Electronic Daily Diaries
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Council on Harmonisation
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
MOP	Manual of Procedures
MTB	Motivate-the-Bystander
MTB+ALC	Motivate-the-Bystander with Alcohol Component
NCT	National Clinical Trial
NIAAA	National Institute of Alcoholism and Alcohol Abuse
$NIAAA_{DA}$	National Institute of Alcoholism and Alcohol Abuse Data Archive
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

9.4 PROTOCOL AMENDMENT HISTORY

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale
1.1	04/13/2023	1) We request to update the study title to Motivations, Attitudes, and Perceptions Study. 2) We request to revise the study timeline to have participants complete the BSAVE Virtual reality assessment (T2) approximately 1-2 weeks post-intervention instead of 2 months post-intervention. 3) We request to complete the follow-up retrospective surveys that assess alcohol use and bystander behavior from the previous week for a period of 9 months, rather in three 21-day bursts (see Weekly Electronic Diary for new measure to accommodate weekly follow-up assessment). 4) We request to revise payment for the follow-up surveys to be $5 per weekly survey. 5) We request to shift T1 intervention sessions to be held virtually over Zoom. 6) We request to update the Informed Consent Form to reflect the above changes (see Informed Consent Form 03.30.23 with tracked changes & Informed Consent Form 03.30.23 clean).	1) We would like to provide a more generic title that does not reveal the purpose of the study. 2) Having participants complete the BSAVE 1-2 weeks after intervention should allow us to better examine the short-term impact of our interventions on bystander behavior. 3) This will allow us to examine alcohol use and bystander behavior during the entire duration of the study, rather than only 63 days. 4) This update will allow us to allocate payment to participants in a way that matches the proposed follow-up survey timeline changes. 5) By holding T1 sessions virtually, this will allow participants greater flexibility to schedule these sessions. 6) The revised Informed Consent Form describes the above changes.
1.2	08/04/2023	Baseline Assessment: 1. Baseline Assessment: We request to have participants consent and complete the baseline questionnaires via Qualtrics prior to their first session.	1.This change will allow us to have time to review baseline measures prior to administering the first intervention content.

		Intervention Timelines: 2a. We request to administer MTB and ALC interventions on separate days rather than on the same day. 2b. We request to administer MTB and Control interventions on separate days rather than on the same day. 2c. We request to update the timing for completing the MTB and Control interventions to 1-1.5 hours 2d. We request to update the timing for completing the ALC intervention to 1.5-2 hours. 2e. We request to administer the weekly follow up surveys will be starting the weekend after final intervention. Control Condition: 3. We request to use progressive muscle relaxation as the activity that control participants will complete. Research assistants will guide participants through a recording of progressive muscle relaxation, where theyll be instructed to tense and relax certain muscle groups (see "Protocol-Control Condition and Recording.docx"). Updated Intervention Protocols: 4. We request to add a questionnaire assessing participants current alcohol use and consequences (see Measure-ALC Full Survey.pdf) to our previously approved ALC intervention protocol. Interventionists will guide the participant through completing this questionnaire and information the participant provides during this measure will be reviewed and discussed with participants during the ALC intervention. Measures: 5a. We request to replace the existing baseline measures(see "Measures-Baseline(Final).dox",), in person lab session measures (see "Measures-BSAVE(Final).dox"), and weekly timeline follow-back EDDs measures (see "Measures-EDD(weekly follow-up survey).docx"). 5b. We request to replace the existing VR Party Script with minor script changes and updated avatars (see "Measure-VR Party Script and Avatar Changes.docx") Distress Protocol: 6. We request to add a standardized distress and support protocol (see Protocol-Distress&Support Resources.docx) in the event that a participant becomes distressed during participation. This protocol includes chronological steps to take to reduce	2a. Separate intervention sessions will reduce significant participant burden associated with completing both interventions on the same day. 2b. Separate intervention sessions reduce significant participant burden associated with completing both interventions on the same day. 2c. As we finalize the interventions it has become clear this is how long it will take. 2d. As we finalize the interventions it has become clear this is how long it will take. 2e. This will allow us to assess reductions in alcohol use and increases in bystander behavior immediately after the final intervention 3. We previously indicated we were including the control condition but did not provide details about that condition. 4. In order to administer the ALC intervention, participants need to provide information on their current drinking behaviors, consequences, and strategies for reducing drinking. 5a. These measures will ensure we assess all relevant variables at each timepoint with the most appropriate measures 5b. To provide an updated version that represents minor language changes as well as updated avatars. 6. Although we foresee serious participant distress as being unlikely, we want to have this protocol in place just in case. This protocol will provide a set of pre-determined steps to minimize participant distress during the course of the study. 7a. This change will adequately represent changes to session

		participant distress, including ending the study early if necessary and provided local and nation support resources. Informed Consent: 7a. We request to update the consent form to match new session procedures and protocols. Specifically representing the updated intervention and session timelines (see #2 of change request). 7b. We request to increase participant payment to $20/hour for completing the baseline measures, $20/hour for completing each zoom session (1-2), $40 for completing the in-person lab session, and $5 for completing each weekly follow up survey. with a $20 bonus for completing 80% of the total weekly surveys. 7c. We request to update the overall time commitment for completing the study to approximately 10 hours Scheduling: 8a. We request to utilize Calendly, a scheduling website, to schedule all participant sessions. Participants will be provided with a scheduling link directing them to schedule their sessions. Available blocks of time will be added to the calendar and managed by study staff. Participants will not have access to or be able to view other calendar events and/or anyone elses session information. 8b. We request to obtain participants email address and study ID in Qualtrics (see 3 - Pre-Baseline Contact List Survey_07.15.22). These two questions will be is a separate survey administered during the baseline session in order to keep identifying information separate from participant data. Participant Eligibility Screening: 9a. We request to add brief introductory language to the eligibility screening. Participants will be directed to this page when clicking on the screening link (see Eligibility-Description Page (screening).docx) 9b. We request to add a question assessing participants previous participation in virtual reality studies. Question: Have you participated in a virtual reality study in the last 12 months? If a participant selects yes then an open text box will be provided for them to describe that study. If their description of the prior study matches our virtual reality BSAVE then they will no longer be eligible to participate. Participant Reminders:	procedures and will properly inform participant of study tasks. 7b. This change is in line with hourly rates for many types of employment and is intended to increase interest in the study. 7c. This change will adequately represent the overall time it takes to complete the entire study 8a. By allowing participants to schedule their sessions, we hope to increase the likelihood that participants will attend all study sessions, as well as reduce any inconveniences of scheduling via phone. 8b. This secure contact list will be used to send automated emails to participants with the weekly 9 months follow up surveys. Automating this process will facilitate adherence to the study timeline. 9a. This change will provide potential participants with easier access to study information and streamline the recruitment and eligibility screening process for both participants and study personnel 9b.Assessing participants prior participation in virtual reality studies will allow researchers to determine if participants prior experiences could bias data collection. 10. This change will increase the likelihood of participants completing sessions and study tasks. This change also reflects previously approved changes to study design and protocols. 11a. This method will allow us to recruit more participants into the study. 11b. This change will facilitate increased recruitment of participants by focusing our efforts on popular social media

		10. We request to add additional session reminders (see Reminders (participant)-Baseline, Virtual, In-person, & follow-up.docx) Recruitment: 11a. We request to obtain an email list from the UNL Registrar of UNL students who are between the ages of 18-25, which includes students (1) first and last name, (2) gender identity, (3) birthdate, and (4) race/ethnicity. Only approved personnel at UNL will have access to the email list. The research team will randomly select students from this list to contact via email and invite to participate in the study (see Recruitment Email to UNL Student Body_06.01.23.). The body of the email will include a link and QR code to see if they are eligible. Both the link and QR code will take them to the IRB approved Online Eligibility Survey. The research team will send a follow up email two weeks after initial contact, for people who do not complete the Online Eligibility Survey. The content of the follow up email will not change (re: Recruitment-Email to UNL Student Body_06.01.23). 11b. We request to advertise for our study using social media accounts associated with our lab (e.g., Map Study Facebook page). All advertisements will briefly describe the study and send interested participants to the eligibility screening. In addition, if potential participants message us through our social media accounts, we will respond with a link to the eligibility screening and communicate with them as necessary (e.g., scheduling). Social media ads will be posted to the lab page and will be shared using the social media platforms advertising features. The researchers will not share the advertisements on their personal pages. These ads will be set to only be shown to participants in the Lincoln area. In order to address confidentiality concerns that might arise if previous or potential participants interact with these posts (by liking or commenting), we will use a page moderation feature that will allow us to limit any comments to our posts. 11c. We request to use new images and associated captions (see Recruitment-Social Media Captions and Ads.docx) to be used for our social media advertising. 11d. We request to revise our craigslist recruitment ad and advertising posters with minor language changes regarding	platforms for the age-group of interest. 11c. This change will facilitate increased recruitment of participants by focusing our efforts on popular social media platforms for the age-group of interest. The new images are best suited (e.g., eye-catching, properly formatted) to be used on these platforms. 11d. This change will provide participants with updated and accurate study information. 11e. This change will provide participants with updated and accurate study information.

		our updated study name, screening link, and contact information. Some language has been removed in order to make the advertisements brief (removed information is now on the screening description page). Please see (Recruitment-Craigslist Advertisement .docx, Recruitment-Flyer Advertisement 06.01.23.docx). 11e. We request to add minor language changes to participant recruitment and eligibility phone/email templates/scripts that reflect changes in study procedures and sessions. (see Recruitment-Email & Phone Script (tracked changes7clean).docx, ,Eligibility-Email Template (tracked changes&clean).docx)	
1.3	12/1/2023	1. We request to add six additional measures, DERS-SF, ISOS-V, ISOS-P, Self-Objectification Beliefs and Behaviors Scale, and the Daily Discrimination Scale to our weekly electronic diary. See Measures-EDD(11.16.23 Tracked Changes) and Measures-EDD(11.16.23 Clean). These measures are only to be completed by participants who do not report any weekly instances of risk. 2. We request to implement minor language changes to the weekly electronic diary. See Measures-EDD(11.16.23 Tracked Changes) and Measures-EDD(11.16.23 Clean). 3. We request to add additional questions to our weekly electronic diary to further assess unwanted sexual behaviors and substance use, in addition to alcohol use. See Measures-EDD(11.16.23 Tracked Changes) and Measures-EDD(11.16.23 Clean). 4.We request to provide participants with a weekly follow up tips document that will be presented to participants at the completion of their final intervention (see Weekly Follow Up Survey Tips.docx). Interventionists will review this document with participants to guide/teach them how to accurately complete the weekly electronic diary. This document will also be emailed to participants so they can reference it at any time. 5. We request to add five additional measures, Urica-DV, TSFP-short version (sexual assault measures), Negative Reactions to Disclosure, Sexual Norms Inventory-Perception of Bystander Intentions Subscale, and SAQ to our Baseline measures. See Measures-Baseline (11.16.23 Tracked Changes) and Measures-Baseline (11.16.23	1. These measures have been added to ensure that participants who do not report any risk incidents that week will take approximately the same length of time to complete the weekly diary as participants who report risk incidents. This is intended to de-incentivize underreporting of sexual risk incidents. 2. These changes will provide participants with a clearer understanding of how to complete the measure and will decrease the likelihood of participants misinterpretation of specific measure items 3. These updates will better capture key variables of interest in the study. 4. This will increase the likelihood that participants report accurate data and will decrease any confusion participants may experience while completing the measures. 5. These measures will ensure we assess all relevant variables at each timepoint with the most appropriate measures. 6. These measures will be replaced with additional measures (see change request item 5) to better assess all relevant variables. 7. By allowing participants to schedule their own sessions, we hope to increase the likelihood that participants will attend all study sessions, as well as reduce any inconveniences of scheduling via phone. 8. These measures will ensure we

		Tracked Changes)". 6.We request to remove five measures (Bystander Intervention Scale, SES-F, SES-M, TSFP and the Sexual Assertiveness Scale) from our Baseline measures. See Measures-Baseline (11.16.23 Tracked Changes) and Measures-Baseline (11.16.23 Tracked Changes). 7. We request to add additional scheduling language to the end of the baseline measures. See Measures-Baseline (11.16.23 Tracked Changes) and Measures-Baseline (11.16.23 Tracked Changes) Once participants complete their baseline measures, they will be provided with language and a Calendly link to schedule their first intervention. 8. We request to add 12 additional measures (Urica-DV, Controlled Drinking Self-Efficacy Scale, Bystander Decisional Balance Scale, CEMI, Decisional Balance Scale for Immoderate Drinking, Interpersonal Reactivity Index, Big Five Inventory10, Short Dark Triad, The Couples Satisfaction Index, Individuality in Couples Questionnaire (ICQ), The Experiences in Close Relationships-Revised (ECR-Short Form) Questionnaire, Sexual Norms Inventory-Perception of Bystander Intentions Subscale, and the SAQ) to our BSAVE measures. See Measures-BSAVE (11.16.23 Tracked changes) and "Measures-BSAVE (11.16.23 Clean) 9. We request to add additional eligibility language to the end of the eligibility screening in Qualtrics (see Measures-Eligibility Screening 10.18.23 (tracked changes) and Measures-Eligibility Screening 10.18.23 (tracked changes). After completion of screening, participants will automatically be notified of eligibility. If participants are eligible, theyll be presented with language and link to complete the consent form. Participant screenings that require further review to determine eligibility, will be presented with language notifying them that a study staff will be in touch. 10a.We request to replace the current bonus amount for completing weekly electronic surveys from $20 for completing 80% of surveys to an additional $2 for every survey they complete on Sundays. This will increase the amount they earn for surveys completed on Sundays from $5 to $7	assess all relevant variables at each timepoint with the most appropriate measures. 9. This will aid in the inflow of consenting participants and minimize the amount of contact attempts 10a. This change will encourage participants to complete the weekly electronic diary when due on Sundays. This will also allow for less time/effort and contact attempts from staff. 10b. After finalizing the measure, this is how long the measure will take to complete. 11. These changes will accurately represent the amount a participant can earn for completing the weekly electronic diary, as well as the amount of time it will take them to complete it.

		(see Informed Consent Form 10.18.23 (tracked changes)" and Informed Consent Form 10.18.23 (clean)"). 10b. We request to update the amount of time it takes to complete the weekly electronic diary from 5 minutes to 10 minutes. (see Informed Consent Form 10.18.23 (tracked changes) and Informed Consent Form 10.18.23 (clean)"). 11. We request to update recruitment forms and participant reminders to reflect the changes made to the weekly electronic diary bonus as well as the amount of time it takes to complete the weekly electronic diary (see Recruitment-Craigslist Advertisement 10.18.23 (tracked changes & clean), Recruitment-Email & Phone Script 10.18.23 (tracked changes & clean), Recruitment-Flyer Advertisement 10.18.23(clean), Recruitment-Flyer Advertisement 10.18.23(tracked changes), Reminders (participant)-Baseline & Follow-up Reminders 10.18.23(clean), and Reminders (participant)-Baseline & Follow-up Reminders 10.18.23(tracked changes)).	
1.4	1.11.2024	1. Consent Form: a. We request to revise various aspects of the consent form to better describe the study's purpose and procedures. See Informed Consent Form 12.11.23 (tracked changes) b. We request to add in additional language informing participants of providing valid data and how they may no longer be eligible if they do not. To define valid data, participants must complete 80% of the surveys, respond correctly to 6 out of 8 attention checks, and take at minimum 30 minutes to complete the surveys. See "Informed Consent Form 12.15.23 (tracked changes)" and "Informed Consent Form 12.15.23 (clean)". c. We request to add additional language to the consent form describing the weekly follow-up surveys. 2. Revised Measures: a. We request to make minor language changes and add additional questions to our study measures. See "Measures-Baseline (FINAL-tracked changes 12.15.23)", "Measures-Baseline (FINAL-Clean 12.15.23)", "Measures-BSAVE (Final-Tracked Changes 12.15.23)", "Measures-BSAVE (Final Clean-12.15.23)", "Measures-EDD (FINAL-Tracked Changes 12.15.23)", "Measures-	1a. These changes describe study requirements more clearly and describe the purpose of the study in a manner that will not compromise participants responses during data collection (i.e., so responses will not be impacted by overly specific knowledge related to study aims). 1b. This will increase the likelihood that participants report accurate data and will decrease the likelihood that participants, will rush through the measures 1c. These changes will provide participants with a clearer understanding of study tasks and will decrease the likelihood of participants misinterpretation of what the study entails. 2a. These changes will ensure we assess all relevant variables with the most appropriate questions. These changes will also provide participants with a clearer understanding of how to complete the measures and will decrease the likelihood of participants misinterpretation of specific measure items. 2b. These items increase the likelihood that participants report accurate data and will decrease the

		EDD (FINAL-Clean 12.15.23)", "Measures-Eligibility Screening (FINAL-Tracked Changes 12.15.23)" and "Measures-Eligibility Screening (FINAL-Clean 12.15.23)" b. We request to add 8 attention check items throughout the baseline measures. See "Measures-Baseline (FINAL-tracked changes 12.15.23)", "Measures-Baseline (FINAL-Clean 12.15.23)"	likelihood that participants, will rush through the measures. These items will allow for study staff to remove those individuals that do not provide valid data from the study.
1.5	2.5.24	Participant Reimbursement: 1a. We request to update participant reimbursement for the baseline (online) measures from $20/hr to $40 total. Consent Form: 2a. We request to revise the participant reimbursement language for the baseline (online) measures from $20/hr to $40 in our consent form. See Informed Consent Form 1.23.24 (Clean) and Informed Consent Form 1.23.24 (tracked changes). 2b. We request to revise the timing language for completing the baseline (online) measures from 1.5 hours to 1.5-2 hours in our consent form. See Informed Consent Form 1.23.24 (Clean) and Informed Consent Form 1.23.24 (tracked changes). 2c. We request to revise the timing language for completing the zoom session from 1.5-3 hours to 1.5-4 hours. See Informed Consent Form 1.23.24 (Clean) and Informed Consent Form 1.23.24 (tracked changes). Participant Reminders: 3a. We request to revise the participant reimbursement language for the baseline (online) measures from $20/hr to $40 in our study reminders and advertisements. See Eligibility-Email Template 1.23.24 (tracked changes), Eligibility-Email Template 1.23.24 (clean), Recruitment-Email & Phone Script 1.23.24 (tracked changes & clean), Recruitment-Flyer Advertisement 1.23.24 (tracked changes), Recruitment-Flyer Advertisement 1.23.24 (clean), Reminders (participant)-Baseline 1.23.24(tracked changes), Reminders (participant)-Baseline 1.23.24(clean). 3b. We request to revise the timing language for completing the baseline (online) measures from 1.5 hours to 1.5-2 hours in study reminders and advertisements. See Eligibility-Email Template 1.23.24 (tracked changes), Eligibility-Email Template 1.23.24 (clean), Recruitment-Email & Phone Script 1.23.24 (tracked changes & clean),	1a. Due to the online structure of the baseline measures, it would make it hard for examiners to determine the exact time it took for participants to complete the baseline (online) measures. We have estimated that it will take approximately 1.5-2 hours to complete the baseline measures, so $40 will allow participants to be paid approximately $20/hour. Having a set reimbursement amount will cause less confusion and avoid possible conflicts with participants. 2a. This accurately describes what participants will now be reimbursed for completing the baseline (online) measures. 2b.This will accurately describe the time it will take participants to complete the baseline (online) measures. 2c. This will accurately describe the time it will take participants to complete the zoom sessions. 3a.This accurately describes what participants will now be reimbursed for completing the baseline (online) measures. 3b.This will accurately describe the time it will take participants to complete the baseline (online) measures. 4a. We may use the video-recorded interventions or intervention transcripts to develop future interventions (e.g., interventions involving artificial intelligence or machine learning).

		Recruitment-Flyer Advertisement 1.23.24 (tracked changes), Recruitment-Flyer Advertisement 1.23.24 (clean), Reminders (participant)-Baseline 1.23.24(tracked changes), Reminders (participant)-Baseline 1.23.24(clean). Data Usage for Future Studies: 4a. We request to add language to the consent form informing participants that videos/transcripts from the intervention may be used by research staff to create materials for future studies (e.g., AI-based interventions). Only researchersno other participantswill see the videos/transcripts.	
1.6	3.19.24	1. We request to add a question to assess whether potential participants are currently enrolled as a graduate student in the UNL Department of Psychologyand to exclude those who are current students in the department. See Measures-Eligibility Screening (Tracked changes 3.4.24) and Measures-Eligibility Screening (Clean 3.4.24)). 2. We request to add two questions to the screener so that we can exclude participants who are unable or unwilling to complete an in-person lab session within the next four months (see: Measures-Eligibility Screening (Tracked changes 3.4.24) and Measures-Eligibility Screening (Clean 3.4.24)). 3. We request to add a question assessing participants preferred pronouns. (see: Measures-Eligibility Screening (Tracked changes 3.4.24) and Measures-Eligibility Screening (Clean 3.4.24)). 4. We request to make minor changes to eligibility screening end of survey response. (see: Measures-Eligibility Screening (Tracked changes 3.4.24) and Measures-Eligibility Screening (Clean 3.4.24)). 5. We request to change the number of weekly drinks required for eligibility (as a "heavy drinker") from 7 to 8 for women and from 14 to 15 for men.	1. This will ensure that participant privacy is protected by removing the risk of a participant previously knowing an interventionist or study staff. 2. As stated in the consent form, participation requires attending one in-person lab session. Informing potential participants during the eligibility screening of the in-person lab session and assessing their ability to attend within four months will reduce the likelihood of participants missing that session or dropping out of the study altogether. 3. This will allow study staff to properly address participants by using their preferred pronouns. 4. This will provide participants with accurate instructions on how to complete the next steps of the study. 5. These figures represent the latest NIAAA guidelines.
1.7	8.29.24	1. Implemented minor revisions to our weekly follow-up surveys. Drafted an email to send participants reminding them about the importance of completing the weekly surveys. We plan to send this email periodically (e.g., monthly) as a reminder to participants. Implementedbroad recruitment methods (recruitment email to unl faculty, listserv	Minor revisions will streamline the weekly follow-up surveys for participants, by minimizing the amount of text they must read. Sending a reminder email will boost compliance with the weekly survey. Adding additional recruitment methods will allow us to recruit more participants.

		outreach through daily Nebraskan, student organization recruitment, snowball sampling, direct recruitment at public venues (eg., festivals, tailgate events, concerts, sports games, etc. To increase sample size, new participants will be recruited through BuildClinicala recruitment service used for NIH-funded researchto advertise the study	Build Clinical will allow us to expand our ability to recruit and increase recruitment.
1.8	10.22.24	1. Due to requirement by NIAAA, we'll provide information about NDA data sharing and ask if participants consent to it. If they agree, we will collect the following additional demographic information (legal first, middle, and last name, date of birth, city/municipality of birth). This includes adding email, text, and phone call templates to notify currently enrolled participants about the new survey to collect this additional information, including reminders. We will also update the informed consent form to provide information about NDA data sharing and ask if future participants consent to it. If they agree, the same demographic information as above will be collected, by adding these questions to the end of the Consent Form Qualtrics survey. 2. Implemented minor revisions to the Baseline survey, which involved changes to instructions and phrasing of some questions and the addition of a new measure to assess phone usage.	1. NIH requires this demographic information to be collected from all participants as part of its data archiving requirements. These variables will be used to create a GUID for each participant, which is a random alphanumeric code used by NIH to identify research participants without exposing their personal information. Variables not needed for other purposes after the GUID is created (middle name and city/municipality of birth) will be deleted after GUID creation. 2. These changes will improve clarity for participants and allow us to measure phone usage as a potential barrier to bystander intervention.
1.9	7.14.25	1.1 Request to Provide a $15 Incentive for Timely Completion of Baseline Measures We propose to offer a $15 virtual incentive to participants who complete the baseline measures within 48 hours of receiving the initial survey link (following consent). This incentive will be in addition to the previously approved $40 compensation. 1.2 Request to Add an Alternative $40 Virtual Compensation Option for Online Measures Currently, participants receive the $40 baseline compensation during their in-person lab session. We propose giving participants the option to receive this $40 virtually immediately after completing the Zoom session, instead of waiting for the in-person visit.	1.Participant Compensation: Providing compensation earlier, providing additional bonuses, and providing compensation for partial completion of baseline measures will help promote timely completion of study tasks, increase participant engagement and improve retention. 2. Participant Schedule: will streamline data collection, reduce participant burden and improve scheduling efficiency 3. Consent: to accurately represent participant payment schedules, time commitment, and ensure consistency with updated study procedures 4. Recruitment Materials: to accurately reflect current recruitment efforts, participant

		1.3 Request to Add a $15 Incentive for Timely Completion of the Zoom Intervention Session We propose offering a $15 virtual incentive for completing the intervention session within 3 weeks of completing the online measures. This is in addition to the previously approved $20/hour compensation. 1.4 Request to Add Partial Compensation for Baseline Measure Completion We request approval to offer $30 compensation to participants who complete at least 80% of the baseline measures. Currently, participants receive $40 for completing 100% of baseline measures. 2.1 Request to Update Zoom Session Schedule (from 1–2 sessions to 1 session) We request to update the participation schedule from the current protocol (participants may be randomly selected to attend 1–2 Zoom sessions) to a revised format where each participant will attend only one Zoom session (combining the MTB and ALC sessions). In the current design, participants assigned to the MTB+ALC condition complete two separate intervention sessions; under the revised format, these sessions will be combined into a single session. 2.2 Request to Allow Participants to Proceed to Intervention After Completing 80% of Baseline Measures We request IRB approval to allow participants who have completed at least 80% of baseline measures to move forward to the intervention phase of the study. Currently, participants are required to complete 100% of baseline measures before progressing. 3.1 Request to Update Compensation Language We request to update the consent form to reflect changes to participant compensation (items 1.1–1.3; see "Informed Consent Form 7.15.25 [tracked changes]"). 3.2 Request to Update Zoom Session Duration We request to revise the stated Zoom session time to reflect actual completion times (1–3 hours), based on participant	payment schedules and amounts, and study information 5. Participant Reminders: To maintain consistency across study material, clearly state compensation amounts and inform participants of next steps.

		experience (see "Informed Consent Form 7.15.25 [tracked changes]"). 3.3 Request to Update Consent Language Regarding Participation Schedule We request to update consent language to reflect the change from 1–2 Zoom sessions to a single session (see item 2.1 and "Informed Consent Form 7.15.25 [tracked changes]"). 3.4 Request to Add a Post-Consent Summary Page in Qualtrics After completing the consent form, participants will be directed to a brief summary page outlining the study's time commitment and schedule. This includes a table of study activities and three participation options (see "MAP_Consent_Confirmation").	
2.0	1.13.26	1. Request to Add Additional Daily Reminders for EDD Weekly Surveys We request to implement daily participant reminder messages, delivered via email or text, to encourage timely completion of the EDD weekly surveys (see "Daily EDD Reminders (Weekly Surveys)"). <u>Participants are informed prior to beginning the weekly surveys that they will receive daily reminders until the survey is completed. Each Sunday, for up to 40 weeks, participants are sent a link to complete that week's survey; if it is not completed on Sunday, daily reminders continue through the following Saturday. Once the weekly survey is completed, reminders stop immediately and do not resume until the next scheduled survey, ensuring messages are expected, time-limited, and tied directly to study participation.</u> 1.2 Request to Send Participant Progress Updates for Weekly Surveys We request to send periodic progress update messages to participants who are completing the EDD weekly surveys. These messages would notify participants of their current completion status and notify them how much compensation they can potentially earn by continuing to	1. Participant Reminders: to encourage participant engagement and promote continued participation. 2.Recruitment Procedures: broaden our reach and support ongoing recruitment efforts 3.Consent Form: to provide accurate and concise information consistent with previously approved changes to participant procedures and compensation. 4&5: Removed assessments that are not being collected.

		complete surveys (see “Weekly Survey Progress Texts”). 1.3 Request to Add Statement to Session Reminders Regarding Substance Use We request to add a brief statement to participant session reminders asking participants to refrain from alcohol use and other substances before and during their study sessions. Please see “MAP Study Session Reminders (Virtual & In-Person)_12.2.25 (tracked changes)” for the proposed language. 2. Request to Expand Snowball Recruitment to Include Email Communication With participants’ permission, we request to distribute the approved recruitment flyer to participants via email and encourage them to share the materials with friends or family members who may be interested and eligible to participate (see “Recruitment_UNL_Snowball Sampling Script (11.5.25)”). 2.1 2.1 Request to Revise the Approved Snowball Sampling Script to Include Maximum Compensation We request to update the currently approved snowball sampling script to include information about the maximum compensation available for study participation (see “Recruitment_UNL_Snowball Sampling Script (11.5.25)”). 2.2 Request to Revise the Approved Faculty Email Outreach Template to include maximum participation compensation We request to update the currently approved faculty email outreach template to include the maximum compensation participants can earn (see “Recruitment_UNL Faculty Email Outreach Template (tracked changes 11.5.25)”). 2.3 Request to Revise our previously approved Craigslist Advertisement We request to update the currently approved craigslist ad to include recent updates to study procedures and compensation (see Craigslist Advertisement 11.5.25 (tracked changes). 3.1 Request to Make Minor Revisions Using Already Approved Language We request minor revisions to the consent form to edit a statement regarding study sessions from “1–2 Zoom sessions” to “1 Zoom	

		session" and to include additional language regarding the previously approved bonus compensation. 4.Removed Simulation Sickness Questionnaire from protocol 5. Remove Clinical History and Height & Weight assessments from protocol	

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