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Complete Research Protocol (HRP-503)

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PROTOCOL TITLE:

Response: Protecting Allies In Risky Situations (PAIRS)

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VERSION:

Include the version date or number.

Response: March 20, 2020

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response: This IRB application will serve as JIT information for an R34 grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response: All electronic research related files will be stored on a hard drive in the research lab of Dr. Read, in Park Hall 386. This computer is password protected, and the computer itself is in a locked office.

Location: Alcohol Research Lab

Address: Park Hall 386

Department: Psychology

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research.

Response: The objective of the proposed study is to develop an innovative, friend-based motivational intervention (FMI) that encourages and prepares friends to reduce SA risk. Delivered to pairs of friends (dyads), the FMI will be designed to foster collaborative efforts to increase readiness

for, and decrease barriers to helping behavior, and to teach and plan together for assault prevention skills. As the role of alcohol has been under-addressed in SA prevention efforts, the FMI also will explicitly attend to how intoxication may serve as a barrier to friend intervention, and strategies for overcoming this barrier. The FMI will be developed in three stages (1. Development, 2. Implementation & Refinement, 3. Preliminary Testing). In the final stage of the project, the intervention will be tested in a randomized, controlled mini-trial (FMI vs. waitlist control). Friend dyads will be followed in bi-weekly online assessments for 3 months to examine changes in helping attitudes and behaviors. Feasibility, scalability, iatrogenic effects, and whether drinking influences intervention outcomes also will be examined. Findings will offer rich information about how best to incorporate friends into sexual assault prevention, and will lay the groundwork for the next steps for the FMI.

1.2 State the hypotheses to be tested, if applicable.

Response: . The first two studies are developmental and exploratory, and intended to be lay the foundation for the development and testing of the FMI intervention. Thus, no specific hypotheses are forwarded. For the third study, we do have hypotheses about how women will respond to our intervention. We expect changes in readiness and other barriers to be associated with implementation of FAPBs. We will also use our follow-up data to provide a rich description of the role of alcohol in implementing FAPBs, and whether the FMI reduces the impact of alcohol use. In exploratory analyses, we will examine how the FMI intervention may be associated with decreased assault risk, as well as decreased drinking.

2.0 Scientific Endpoints

2.1 Describe the scientific endpoint, the main result or occurrence under study.

Response: The scientific endpoint will be when we have the data to be able to better understand how women rely on friendships to prevent alcohol-involved sexual assault, and potential barriers to protective action. Another key scientific endpoint is the development and testing of a friend-based motivational intervention to be delivered to friend pairs in an effort to prevent sexual assault. Data for these endpoints will be derived from qualitative and quantitative assessments across three sequenced studies.

3.0 Background

Overview. The objective of this study is to develop and complete a preliminary test of a brief, dyad-based motivational intervention that empowers college women to protect themselves and one another from sexual assault (SA). Delivered to pairs of friends, this unique intervention will be designed to harness the power of friendships to arrive at a personalized, mutual, feasible, and effective approach to assault prevention.

The social context of college sexual assault: Engaging others in prevention: One of every five college women in the U.S. will experience a sexual assault, and as many as 1/2 of these assaults involve alcohol (Abbey, 2002; Calhoun et al., 2012; Testa & Livingston, 2009). Although some college sexual assaults occur in isolated settings, many - particularly those involving alcohol - develop from social occasions, where others are present (Banyard et al., 2004; Koelsch et al., 2012). Because of this, research efforts have begun to focus on understanding the ways in which others in the social context –sometimes referred to as bystanders - may be incorporated into intervention efforts (Banyard et al., 2007; Gidycz et al., 2011; Katz & Moore, 2013; Salazar et al., 2014). This literature has been informed by seminal theoretical work by Latané and Darley (1970), who recognized that in any risk situation, those present will have the choice to intervene, or not. Latané and Darley's model delineates a framework outlining five sequential steps that lead a bystander to a choice for intervention. These steps include (1) *noticing* the event; (2) *interpreting* the event as one that requires action; (3) making the *decision* to act; (4) *knowing how* to intervene; and (5) *implementing* intervention.

Fundamentals of prevention action: responsibility and relationship. In the years since investigators first began applying Latané and Darley's model to sexual assault prevention, two factors have emerged as being critical to intervention behavior: a sense of *personal responsibility* to the potential victim, and a *personal relationship* with her. A sense of personal responsibility is among the most reliable predictors of action to prevent interpersonal (including sexual) violence (e.g., Banyard & Moynihan, 2011; Burn, 2009). Likewise, a close personal relationship with the potential victim strongly predicts intervention action, with closer relationships linearly related to intervention likelihood (Banyard,

2008; Bennet & Banyard, 2014). In short, without relationship and responsibility, helping behavior is unlikely to occur. On a college campus, nowhere are relationship and responsibility more likely to be found than in a friendship. As such, it is friends who are most likely to intervene. Yet much of the extant literature has instead focused on the broader and more general social milieu, targeting bystanders. This misses important opportunities for assault prevention.

Those most likely to help are not bystanders, but friends. "Bystander" interventions typically are offered in group format to general audiences of students who may not socialize or even know one another. During the intervention, participants are presented with imaginal vignettes of sexual assault scenarios and/or didactic information about assault recognition and prevention. Such approaches tend to focus on providing broad-based information and skills in an effort to change the college culture around SA, and the likelihood of intervention by those within that culture (Banyard et al., 2004; Palm-Reed et al., 2015). Though these interventions have shown some efficacy in changing bystander intentions to intervene (Katz & Moore 2013; Kleinsasser et al 2015; Moynihan et al 2011; Salazar et al 2014), only one study has shown efficacy in reducing rates of sexual assault, and this was with high school students (Coker et al 2017). This may be because targeting broad groups of bystanders does not directly engage those with the strongest sense of relationship and responsibility to the potential victim. Shifting the focus to friends can change this, and can move the field in a new and impactful direction.

Friends are central to the drinking context of college women (Borsari & Carey, 2006) and to the context of sexual assault (Planty, 2002). Friends are most frequently in the social setting where sexual assault risk first begins to unfold, and when women disclose that an assault has occurred, it is most typically to friends that they share this experience (Campbell et al, 2015; Sabina & Ho, 2014). Relevant to Latané and Darley's model of helping behavior, because of their close personal relationships, friends are in an optimal position to identify risk as it emerges (Step 1). That is, a friend is most likely to notice when someone has become separated from the rest of the group or appears to be receiving unwanted advances, or to detect subtle changes in the potential victim's emotions or behaviors that may signal danger (Step 2). Further, women report greater intent to help and greater sense of personal responsibility (Step 3) to help when a friend rather than a stranger is at risk for SA (Katz et al., 2015). Indeed, individuals report being as many as three times more likely to act on behalf of a friend than they are a stranger to prevent violence (Bennett et al, 2013, see also **Preliminary Studies**). As such, friends are most likely to take action (Step 5). Clearly friends have the potential to play a crucial role in preventing sexual assault. Yet despite the centrality of friends to the assault risk context, no interventions have endeavored to explicitly include friends in SA prevention. This is a critical oversight. A motivational intervention can provide a way to effectively harness this potential.

Motivating friends to prevent sexual assault. Because motivational interventions (MI) are designed to capitalize on and cultivate existing personal and social resources to facilitate behavior change (Miller & Rollnick, 2012), an MI approach lends itself naturally to friend-based change efforts. Several studies have used MI in this way (Bourke et al., 2013; Monti, Colby, Mastroleo et al, 2014; Magill, Mastroleo et al., 2010; Shepard et al., 2016). In these interventions, the facilitator uses the interview to explore the ways in which the naturally existing strengths of the friend dyad can be leveraged to facilitate behavior change. The focus is on using the dyad to reaffirm and increase shared commitment for change, to jointly troubleshoot barriers, to provide concrete support for change efforts, and to identify specific change strategies. Research supports MI for dyads and groups, particularly in settings such as the college social environment, where the social context is a critical part of risk (e.g., Monti, Colby, Mastroleo et al., 2014; O'Leary-Tevyaw et al, 2007). Moreover, a friend-based MI is well suited to addressing several existing challenges to peer-based assault-prevention that have been identified in the literature. We describe these challenges below.

Existing challenges to helping behavior; Readiness, Barriers, and Alcohol. Friends are ideally positioned to protect one another against sexual assault. Moreover, they report both desire and intentions to do so (Banyard & Moynihan, 2011; Blayney et al., 2016; Bennett et al., 2014). Yet, in many cases they do not intervene, due to several key challenges that stand in the way (Labhardt et al., 2017; Pugh et al., 2016). For example, often, women do not feel ready to act to prevent sexual assault in others (Exner & Cumings, 2011), and perceive a number of barriers to preventive action. Primary among these barriers are low *self-efficacy* for knowing whether, when and how to intervene, and *interpersonal concerns* about peer reactions to intervention. Women also report skills deficits regarding appropriate and effective intervention steps.

Self-efficacy. When confronted with opportunities to intervene, women report lacking a sense of *self-efficacy* regarding whether, when, and how to offer such help (Exner & Cumings, 2011; Katz & Moore, 2013; see also Preliminary Studies). This appears to stem from a sense of ambiguity that women experience about recognizing potential assault situations, knowing how best to respond, and feeling confident regarding whether intervention is wanted or warranted (Pugh et al., 2016).

Interpersonal concerns are another key barrier to helping behavior. These concerns, pertaining to how others will respond to help efforts, or whether such efforts will damage the relationship, have been identified as among the strongest reasons given for failure to engage in peer-based intervention behavior (Armstrong et al., 2014; Bennett et al., 2014; Bennett et al, 2013). Our pilot data (see Preliminary Studies) are consistent with this; the majority of women in our sample report concerns about how friends may react to efforts to intervene to prevent assault, and highlight these concerns as a major barrier to preventive action.

Skills. Critically, women lack either the knowledge of or the ability to implement specific, behavioral *skills* that are necessary for successful peer-based intervention (Bennett et al., 2013). Recent work by Banyard (2014) and Armstrong et al. (2014) has identified several peer-directed behavior strategies specifically geared toward assault prevention. These assault-specific protective behaviors are both conceptually and empirically distinct from behaviors geared toward preventing alcohol consumption. In contrast to more general alcohol protective behaviors (e.g., Martens et al. 2005), these peer-based strategies are designed for friends to use to help one another, and focus on shared behaviors that may prevent sexual assault. Strategies include such steps as formulating a pact or safety plan ahead of time, making sure that everyone from group stays together, having "signals" to friends when someone is making unwanted advances, or texting a code word to friends when assistance or interruption is needed. Increasing knowledge of, motivation for, and engagement in these friend-based, assault prevention behavior skills (FAPB) is one of the objectives of this study.

Alcohol and helping behavior. Alcohol is a major risk factor for SA and also a significant impediment to helping behavior. As intoxication increases, women are less likely to engage in peer-directed protective behaviors (Leone et al., 2017). This includes impairing willingness to intervene, and the ability to ascertain risk or to engage in helpful bystander behavior (Fleming & Wiersma-Mosley, 2015; Pugh et al, 2016). These data are consistent with our own preliminary focus group work (see **Preliminary Studies**), in which women identified alcohol consumption as a factor that may compromise their ability to recognize risk amongst their friends. Yet the role of alcohol has not been well addressed in peer-based intervention efforts, and examinations of alcohol's influence on intervention outcomes are rare (see Pugh et al., 2016, Leone et al., 2017). Our FMI will address this gap.

A friend-based MI can address these challenges. The literature reviewed above points to important but resolvable barriers to intervening that can be addressed within an MI framework. A friend-based intervention is especially well-suited to addressing and overcoming these barriers, cultivating the relationship and responsibility that already exist within friendships, and collaboratively addressing the challenges that stand in the way. Such an intervention also can target the ways that friends are uniquely relevant to all five steps of assault prevention according to Latané and Darley's model. Specific skills that incorporate friends can be discussed, agreed upon, and practiced together. Friends can work together toward a sense of self-efficacy for intervention, fostered through the collaborative processes of MI. Importantly, given that some of the most significant barriers to peer-based intervention pertain explicitly to social relationships (interpersonal concerns) and the social context, a friend-based dyad is an excellent mode of intervention, as it works within women's natural social environments, and can explicitly address interpersonal concerns. Finally, because women typically drink together and thus are together in high risk assault contexts, a friend based intervention is ideal for addressing how alcohol may impede assault prevention efforts, and ways to overcome this challenge.

The proposed Intervention: In this work, we propose to develop an intervention that use MI's, "collaborative conversation style for strengthening commitment to change" (Miller & Rollnick, 2012; p. 12), to motivate and prepare women to work together to reduce SA risk. Consistent with the peer-based MI literature (see Monti et al., 2014; Miller & Rose, 2010), this intervention will target ways that the friend dyad may support, encourage, and share responsibility with one another in protecting against SA. The Friend-based MI (FMI) will then use the responsibility and relationship of friends as a framework to foster collaborative efforts to **increase readiness** and **decrease barriers** to helping behavior. As part of this, the FMI will focus on the identification and implementation of **skills** friends can use to help one another prevent sexual assault. (**see C.2. Procedure** for details). We also will

incorporate a focused discussion of the ways drinking may impede helping efforts and we will examine how alcohol use may reduce implementation of helping behaviors. Moreover, the FMI will encourage women to identify specific strategies for reducing the effects of alcohol on helping. These potential strategies will be explored in Stage 1, and included in the FMI in Stages 2 and 3. This is important, given alcohol's role in the assault context, and innovative, as such a discussion is not a typical component of peer-based interventions (e.g., bystander interventions). Though decreasing drinking is not the objective of the intervention, it is plausible that our FMI will reduce consumption. Thus, we will examine drinking outcomes in secondary analysis.

3.1. Include complete citations or references.

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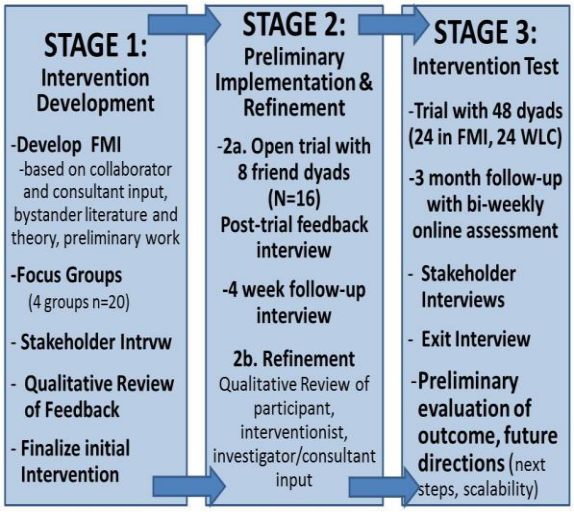
4. Study Design

4.1. ***Overview of the Proposed Research***

Figure 1. Three Stage Intervention Development Plan



Consistent with the objectives of the R34 mechanism, the current project will provide initial development and testing of a friend-based motivational intervention (FMI) designed to reduce SA risk. We also will address how to minimize the impact of alcohol on helping behavior, test whether drinking reduces intervention efficacy, and examine potential iatrogenic effects of the intervention.

We will use an iterative 3-stage approach to achieve this goal (Krueger & Casey, 2012; Figure 1). Across the three stages, we will develop a FMI that seeks **to increase readiness for intervention**, and **decrease barriers** to intervening, with a focus on collaboratively identifying appropriate friend-based assault prevention behavioral skills (FAPB). Finally, we will incorporate a discussion of and strategies to reduce alcohol's effects on helping. In Stage 1, we develop the initial intervention and then gather student feedback, with a focus on *feasibility* and *personal relevance* regarding the implementation of this intervention. We also will conduct stakeholder interviews. In Stage 2, we will deliver the FMI to a small sample of friend dyads in an open trial with a brief (4 week) follow-up. The FMI will then be refined based on participant feedback and research team input. Stages 1 and 2 thus will build a prototype intervention to be tested in Stage 3: a small-scale, randomized controlled trial.
We begin with our approach to screening, eligibility, and recruitment (consistent across all stages). We also describe interventionist selection, training, and supervision for Stages 2 and 3. Finally, procedures for all three stages are described, stage by stage (see also Timeline in **Personnel Justification**).

Screening, Eligibility, and Recruitment (All Stages)

Because women who drink heavily are at greatest risk for SA, we will recruit heavy drinking (i.e. 4 or more drinks in a single sitting [HED] 2 or more times monthly in past 3 months) women into our sample. These women will be recruited via campus and community-wide advertisements for a study of "women's social experiences". Telephone screens will be used to determine eligibility. For Stages 2 and 3, friend dyads will be recruited. Both women in the dyad must meet HED criteria. Additional eligibility criteria will be that each individual in the dyad reports going out (not necessarily drinking) together $\geq$ 1/week, and identifies the other dyad member a close friend. Eligible participants will be scheduled for a focus group session (for Stage 1) or for an initial intervention assessment session (for Stages 2, 3). Women must be college students, but can be from any of the greater Buffalo area's nine colleges. Thus, development will not be based on a single campus.

Recruitment Considerations: All kinds of friends could be valuable in helping to prevent SA. In the proposed study, we focus on female dyads with 2 heavy drinking members. We have chosen these dyad characteristics in this early phase of development for several reasons.

Stage 1: Intervention Development

Aim 1. (Development) Develop a brief, motivational intervention designed to enhance friend engagement in the prevention of SA (Friend-Enhanced MI; FMI).

We will draw from existing assault prevention literature, preliminary data, investigator and consultant input, and focus group feedback to develop an intervention designed to use the relationship context of the friend dyad to promote changes in the attitudes (*readiness*, *perceived barriers*), and *skills* (friend assault protective behaviors: FAPB) needed to act to ensure friends' safety. The intervention will address how *alcohol* may impede prevention behaviors.

Stage 1 Procedures

Intervention Development. Stage 1 will involve the development of the FMI intervention manual. Initially, co-Is Read, Livingston, Testa, and Katz, and consultant Mastroleo will meet regularly via conference calls and in-person meetings to determine the intervention's basic structure and content. These discussions will be guided by investigator/consultant expertise, our pilot data, the assault prevention literature, and by existing dyad-based MIs (e.g., Monti et al., 2014) that will help to provide a template for the intervention structure. Below, we provide a general description of what we expect will be the core features of FMI, though this intervention will evolve based on the results of our developmental work.

This two hour intervention will use MI techniques and principles to reaffirm a sense of commitment to the relationship, a shared sense of responsibility to protecting one another against sexual assault. The FMI protocol will include a discussion of the social context of SA, naturalistic efforts women report making to help their friends, and information (reviewed above) regarding how and why friends are well-positioned to help one another. The tone will be positive and affirming. The goal is to enhance a sense of shared commitment to one another's well-being, without engendering a sense of onus or liability.

The FMI will seek to enhance **readiness** for helping one another prevent SA (Steps 2, 3, 5 in Latané & Darley) and to **decrease barriers** to intervening (Steps 3 & 4). Barriers to be addressed include *interpersonal concerns* that may be of particular relevance in the context of a friendship, and the introduction and discussion of *friend assault prevention behavioral skills* (FAPB; Steps 4 and 5). These skills will be based on those identified by Banyard et al. (2014) and Armstrong et al., (2014; Step 4; see **Measures** for examples) and on pilot work from Stage 1. Another goal of the intervention will be to increase **knowledge about alcohol's effects on helping behavior** (Steps 4, 5) by discussing strategies for addressing these effects. The FMI also will include a discussion of how friends can recognize assault risk in one another (Steps 1 and 2 Participants will be instructed as to how to help without putting themselves in harm's way. During the intervention, friends will be encouraged to practice and to support one another in implementing these FAPB, enhancing self-efficacy. Lastly, the FMI will include a collaborative development of a prototype safety plan (Step 5) for risk situations, weighing the pros and cons of various plans, identifying potential barriers, and steps to overcome these barriers. Throughout, the interview will focus on peer support for behavior change, encouragement of one another in change efforts, and shared responsibility for overcoming barriers (e.g., Monti et al., 2014).

Focus group feedback. It is critical that this intervention be feasible for implementation within the context of real friendships and naturalistic socializing patterns – a context that often includes drinking. To this end, we will present the FMI to focus groups (approximately 4 groups, 5 per group, *n*=20) to gather feedback regarding how our intervention may be received by college women. Specifically, we will use these focus groups to gather information on the degree to which critical aspects of the intervention are seen as: (1) personally relevant to the risks and barriers women confront and (2) feasible to implement, and (3) potential iatrogenic effects (e.g., personal safety concerns, relationship concerns, guilt about looking after others).

Stakeholder interviews. To gather information about the need, feasibility, and acceptability of the FMI from a campus perspective, and with consideration for next steps (scalability, generalizability) for the FMI, 5 interviews will be conducted with campus administrators at several Buffalo-area colleges. Drs. Read and Livingston will consult with Deans and other upper administrators to identify faculty and staff who promote student wellness via campus programming. The objective is to see the FMI through the eyes of those most likely to implement or recommend the intervention on the campus. In these interviews, a detailed overview of the FMI will be presented to obtain feedback regarding benefits and

limitations of the FMI, including cost, broader dissemination, and overlap with existing campus programs.

Remuneration. Women will be compensated for focus group participation with $50 in cash. Stakeholders will receive a $25 in cash as a gesture of appreciation.

Finalization of the FMI. At the end of Stage 1, we will review initial focus group and stakeholder feedback to make additional modifications to the intervention to enhance feasibility, personal relevance (focus groups) and campus appeal (stakeholders). Once the FMI's preliminary structure and content are complete, it will be ready for a first-round implementation with the target population, Stage 2

Stage 2: Preliminary Implementation and Further Refinement

Aim 2. Conduct an initial open trial of this intervention with short-term (4-week) follow-up, and then modify based on feedback and outcomes.

1. We will conduct an open trial of our FMI intervention (friend dyads n=10, 20 women) and comprehensively evaluate the intervention via multiple methods (investigator observations, open-trial sessions, feedback interviews) during and post-intervention.
2. We will use feedback from the open trial to further refine the FMI intervention.

Stage 2: Specific Procedures for Preliminary Implementation and Evaluation

a. Open Trial & Short-Term Follow-Up

Open Trial: We will conduct an open trial (N=10 dyads) of the FMI. Open trial eligibility will be determined using procedures outlined above (**see Screening & Recruitment**).Trained clinical Ph.D. students will conduct these sessions. At the end of each session, participants will give both structured (self-report measures) and semi-structured (interview) feedback regarding their impressions of the intervention. Note that the facilitator who gathers feedback will be different from the FMI interventionist. Participants will have the option to complete all the online questionnaires prior to coming in for their session (within a week of their session).

Immediately following the completion of the intervention, doctoral-student facilitators will present open-ended questions to the friend dyad about each of the content domains of the intervention. The goal will be to stimulate a conversation between dyad members about their perceptions of the intervention. Specifically, these dyad interviews will be used to gather information on two critical aspects of the intervention that we have developed: (1) whether the intervention is seen as personally relevant with regard to the risks women confront and how they may minimize these risks and (2) whether the FMI material is perceived as being feasible to implement in a real world risk environment. As part of this, we will elicit feedback on the extent to which the intervention adequately addresses barriers to helping, including effects of alcohol consumption. We will also solicit information on additional potential barriers to helping behavior not currently addressed in the FMI. This feedback data will be used in concert with investigator and consultant input to further refine the FMI.

Short-term Follow-up. Participants in the Open Trial also will be asked to implement the skills and safety plan developed in the intervention over a four-week period. After which they will participate in a follow-up interview. Prior to completing the follow-up interview, participants will complete online self-report measures. These measures may be completed prior to the session (within a week of the session). Dyad members will be interviewed first separately, then together. The objective of this follow-up will be to evaluate participant experiences of implementing the intervention material. All interviews will be conducted by a doctoral-level trainee. This feedback will be semi-structured, and will ask largely about issues pertaining to the implementation of intervention skills in a real-world setting, whether friends used any strategies to protect one another that were not covered in the intervention and how effective they perceived these strategies to be. We also will discuss how alcohol consumption may have influenced implementation of skills learned in the FMI. Finally, we will query about potential iatrogenic effects. Participants who are unable to come in for an in-person follow-up (due to extraneous circumstances), will be offered the opportunity to complete the follow-up via teleconferencing (using Zoom).

We also will elicit systematic feedback from interventionists regarding the implementation of the intervention (e.g., perceptions regarding participant response, etc.). This feedback will be derived from group-based interviews with interventionists, conducted at the end of the open trial.

Remuneration. Open Trial participants will be paid $50 for participating in the intervention and feedback sessions. They will receive an additional $10 bonus if the pair is scheduled for an appointment within 72 hours of being contacted for scheduling. For pairs who are completing the follow-

up via teleconferencing, they will be paid using the phone application Venmo or with an Amazon gift card (depending on their choice).

b. Further Refinement

In this stage, feedback from assessment and the post-session interviews will be aggregated, analyzed, and used to refine the FMI intervention. All intervention sessions in the open trial will be digitally recorded and transcribed. Transcripts of the post-session semi-structured interviews will be created by an RA within a week of the interview. An encrypted audio file will be distributed to investigators to enable them to review feedback independently and then meet to discuss impressions. Three sessions will be selected randomly and distributed to consultant Mastroleo, who will review sessions and provide written feedback regarding modifications.

Information gathered from the Open Trial will be used to refine intervention elements as well as procedures for training, recruitment, and adherence materials. Investigators and consultant Mastroleo will continue to meet monthly to discuss emerging impressions, reactions to feedback, and ideas for modification. When all open trial and follow-up sessions are completed, we will hold an Investigator and Consultant meeting. At this meeting, we will synthesize qualitative and quantitative feedback and finalize plans for revising the FMI protocol. If warranted, based on participant feedback and the extent of the revisions, a second open trial with new dyads will be carried out to further refine the FMI intervention protocol.

Stage 3: Intervention Testing

Aim 3. Conduct a mini-trial with 3-month follow-up via weekly assessments to examine changes in target attitudes (readiness, barriers) and behaviors (friend-based assault prevention behavior skills). We also will examine knowledge and strategies pertaining to the role of alcohol in helping behavior, and will test whether drinking influences the implementation and efficacy of this intervention.

Twenty-four friend dyads will participate in the FMI along with 24 wait-list control dyads (total of 48 dyads). We will compare groups on outcomes at post-intervention and at bi-weekly 3 month follow-ups, and also examine within subjects change. Given the pilot nature of the R34 mechanism and the smaller sample size, we will focus on whether effects are in the expected direction and whether the strength of effect sizes are of practical magnitude. We expect participants receiving the FMI to demonstrate significant increases in readiness, and engagement in FAPBs and alcohol strategies, and decreases in perceived barriers (improved self-efficacy, relationship concerns), at post-intervention and over the 3-month follow-up. We will also use our follow-up data to provide a rich description of the role of alcohol in implementing FAPBs, and whether the FMI reduces the impact of alcohol use. In exploratory analyses, we will examine whether the intervention may be associated with decreased assault risk, as well as decreased drinking (see **Data Analysis Plan).**

Stage 3 Procedures:

Intervention: FMI Mini-Controlled Trial with Intensive Follow-Up

In this stage, we will test the finalized FMI (see **Screening, Eligibility, and Recruitment** above). To do this, we will contrast outcomes among those in this trial (N=24 dyads) with 24 pairs of friend dyads (total dyad N=48) who are randomly assigned to a wait list control condition.

The FMI will consist of a single session. Sessions will be offered on many days and times across the week to accommodate variability in student schedules. Each session will begin with a baseline assessment. In this session, women will be provided with the refined intervention protocol and will have the opportunity to role play and practice implementing the skills and strategies. Following the intervention, participants will be encouraged to utilize the skills and strategies presented in the intervention over the next 12 weeks, whenever they are out with their friend in a social context.

Dyad pairs assigned randomly (stratified on drinking levels, sexual assault history, and age) to the wait list control condition will be assessed once at baseline and again 12 weeks post-baseline. Assessment measures (baseline, 12 weeks) will mirror those administered to women in the FMI condition. At the completion of the 12 week "wait list," participants will be administered the FMI and followed for 12 weeks. Comparison of outcomes across conditions will allow for stronger inferences about the efficacy of the intervention, will allow for examination of measurement reactivity, and will increase our sample size to examine within person change.

Follow-up Assessments. We will conduct bi-weekly online post-intervention assessments (with the first assessment to occur within 2 weeks of FMI completion) for 12 weeks. The bi-

weekly structure will optimally capture women's experiences applying strategies from the intervention. Participants will be reminded of follow-up assessments by phone, text, and email prompt. Individual members of the dyad will be interviewed in the unlikely event that the other member is lost to follow up over the brief follow-up period. At the end of the 12 weeks, participants will be contacted for an exit interview.

Stakeholder interviews. In this second set of stakeholder interviews, we will gather information to inform next steps for the FMI intervention. To this end, a series of 5 interviews (2 randomly selected from prior interviews, 3 new to the project) will be conducted with campus administrators at Buffalo-area colleges. Selection will follow procedures outlined in Stage 1. In these interviews, the final FMI manual will be presented, and feedback would be solicited regarding ideas for scaling the FMI to other populations and contexts.

Remuneration. Students will receive electronic gift card payments of $40 for the baseline assessment (which occurs just prior to the intervention) and $20 for each post-intervention assessment. To encourage participant retention, participants who complete at least 4/6 bi-weekly assessments will receive a $20 bonus. Stakeholders will receive $25 in cash as a gesture of appreciation for participation.

Selection, Training and Supervision of Interventionists (Stage 2 & 3)

Selection. Interventionists will be doctoral trainees. Training and supervision procedures are detailed below.

Training. Interventionists will receive intensive training which will consist of (a) a 2-day training workshop on MI with Drs. Mastroleo and Read, (b) reviewing tapes and model BMI sessions from previous research, (c) individual reading of the intervention manual, (d) digitally recorded mock interviews followed by individual feedback and evaluation, and (e) weekly group supervision and tape review with Dr. Read. Therapists will be deemed ready after completing a mock session rated as acceptable by Consultant Mastroleo.

Supervision. Treatment providers will attend weekly supervision meetings with Dr. Read. These meetings will be supplemented with monthly phone supervision with Dr. Mastroleo. All sessions will be digitally recorded. The PI will listen to 30% of the sessions, randomly selected, and will review for use in ongoing supervision. In addition, Dr. Mastroleo will listen to one randomly chosen session per interventionist per month and complete the Motivational Interviewing Treatment Integrity Code (MITI) and relevant adherence questionnaire. During individual phone supervision sessions, Dr. Mastroleo will provide feedback to interventionists based on her review of session tapes. This follows fidelity procedures that we have used previously (R01AA016564; Read).

5.0 Local Number of Subjects

5.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: The total number of participants across the three studies will be 128.

5.2 If applicable, indicate how many subjects you expect to screen to reach your target sample.

Response: 175

5.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: Participants will be recruited from the nearly a dozen colleges in the greater Buffalo area. The University at Buffalo alone has over 30,000 students, approximately ½ of whom are women. Given the large student population from which we will draw from, and the fair financial remuneration that participants will receive for participation, achieving our target N within the proposed timeframe is highly feasible.

6.0 Inclusion and Exclusion Criteria

*6.1 Describe the criteria that define who will be **included** in your final study sample.*

Response: We will recruit heavy drinking (i.e. 4 or more drinks in a single sitting, 2 or more times monthly in past 3 months) college women who are between 18 and 24 years old, enrolled in a part or full-time in a 4-year degree program. For Studies 2 and 3, women will be recruited in dyads, and both members of the dyad must be willing to participate. The friends in the dyad must go out together at least once a week. Women must be proficient in the English language. This is unlikely to pose a challenge, as they are enrolled in U.S., English-speaking universities. There are no other inclusion or exclusion criteria.

*6.2 Describe the criteria that define who will be **excluded** from your final study sample.*

Response: See above. There are no other exclusion criteria.

6.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response: No members of these special populations will be targeted to enrollment.

*6.4 Indicate whether you will include non-English speaking individuals in your study. **Provide justification if you will exclude non-English speaking individuals.***

Response: All participants in the study must will be proficient in English.

7.0 Vulnerable Populations

*If the research involves special populations that are considered vulnerable, **describe the safeguards included to protect their rights and welfare.***

☒ **N/A**: This research does not involve pregnant women.

*7.1 For research that involves **neonates of uncertain viability or non-viable neonates,** safeguards include:*

NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

☒ **N/A:** This research does not involve non-viable neonates/neonates of uncertain viability.

*7.2 For research that involves **prisoners**, safeguards include:*

NOTE CHECKLIST: Prisoners (HRP-415)

☒ **N/A:** This research does not involve prisoners.

*7.3 For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*

NOTE CHECKLIST: Children (HRP-416)

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*7.4 For research that involves **cognitively impaired adults**, safeguards include:*

NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

☒ **N/A:** This research does not involve cognitively impaired adults.

*7.5 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. **Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response: There is no specific targeting of any population in this study. The original sample was a community sample, drawn to be representative of the greater-Buffalo community.

8.0 Eligibility Screening

*8.1 Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

We will recruit heavy drinking (i.e. 4 or more drinks in a single sitting [HED] 2 or more times monthly in past 3 months) women into our sample. For phase 2 and 3, members of the dyad must also go out together at least once a week. These women will be recruited via campus and community-wide advertisements for a study of "women's social experiences". Telephone screens will be used to determine eligibility.

9.0 Recruitment Methods

9.1 Describe when, where, and how potential subjects will be recruited.

Friend dyads will be recruited in pairs via campus and community-wide advertisements for a study of women's social experiences. Those interested will call in for a telephone screening to determine eligibility. To be eligible for the study, both women in the dyad must report heavy episodic drinking (i.e. 4 or more drinks in a single sitting, HED) at least twice monthly for the past 3 months. In addition, the friends must report that they go out together regularly (at least once weekly). Eligible participants will be scheduled for a focus group session (for Stage 1) or for an intervention session (for Stages 2,3). At the focus group or intervention session, women will be provided with an overview of study procedures and what their involvement will entail. They then will be given the opportunity to ask questions. Following this, informed consent will be obtained.

9.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

Response: All potential participants will be contacted privately, via email and/or phone. All screenings will be conducted over the telephone.

9.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response: See attached advertisement/recruitment flyer.

Facebook Ads will be posted on Facebook using stock/royalty-free images downloaded from Shutterstock (https://www.shutterstock.com/), a website that provides stock photography.

Each ad that posted on Facebook has three components: 1) Headline (25-character limit), 2) Image, and 3) Text (125-character limit). For the proposed recruitment campaign, each image that will appear on Facebook will be accompanied using the headlines and study descriptions detailed below, or using equivalent language.

1. Ad Headlines

Due to the character limit, headlines will not be used

2. Ad Images

3. Compliance with Advertising Standards
The images that will be used will not be targeting minors, and are compliant with Facebook policy (https://www.facebook.com/policies/ads/prohibited_content).

4. Ad Recruitment Information

Each ad will use equivalent language to communicate that:

The University at Buffalo is recruiting women ages 18-24 who are in college.

Investigators from the Department of Psychology at the University at Buffalo are looking for women to help us evaluate a new program designed for friends to help protect one another against sexual assault. Participation will take approximately 4 hours of your time (across four weeks) and you will each earn up to $50 in cash.

INTERESTED?? Please Call (716) 645-0252 or email us at PAIRSProject@buffalo.edu

10.0 Procedures Involved

*10.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

Response: See procedures described above.

10.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response: Please see description provided above.

10.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Instruments & Measures (For Stage 3)

Data collection will occur at baseline and bi-weekly assessments, and a final evaluation that will be administered at the end of the last bi-weekly assessment. At baseline, we will collect demographic data, as well as drinking and sexual victimization history, and descriptive information regarding the relationship of the friends in our dyads. Other self-report measures will be administered both at baseline and then weekly during the follow-up periods (as denoted below). In the final (exit interview) evaluation, we will obtain feedback on participants' perceptions of the intervention and potential iatrogenic effects. All self-report measures may be completed prior to the session.

The proposed intervention will be designed to use relationship and responsibility in friend dyads as the basis for decreasing perceived barriers to intervention, improving readiness for helping friends, increasing knowledge about alcohol's effects on helping and strategies for overcoming or working around these effects, and imparting friend-based helping skills. These attitudes and behaviors will be the target intervention outcomes. Sexual assault will be examined as a secondary outcome. Changes in drinking also will be examined though this is not the principal focus of the intervention.

Baseline Assessment

Demographic (baseline). Demographic variables will be assessed, including sex, age, ethnicity, sexual orientation, family history of alcohol problems, living situation (with family, friends, alone, etc), work status, year in school, romantic relationships, and weight (for BAC calculations).

Sexual Assault (baseline). A revised version of the Sexual Experiences Survey (RSES; Koss et al, 2007; will be used to measure a spectrum of sexual victimization experiences. At baseline, lifetime experiences will be assessed. This will enable us to examine whether SA history affects intervention efficacy, or intervention response (e.g., guilt, blame, other possible iatrogenic effects) in exploratory analyses.

Drinking history (baseline). A variety of alcohol behaviors and related outcomes will be assessed. Using a grid-based average assessment measure, participants will report on typical weekly alcohol consumption over the past week (for relevant comparison of follow-up data) and past year (for descriptive purposes), including the average number of drinks consumed per occasion, and the average time over which drinks were consumed (for blood alcohol calculations). Harmful drinking outcomes will be assessed with the 48-item Young Adult Alcohol Consequences Questionnaire (YAACQ; Read et al., 2006, 2007). We will also assess frequency of drinking in various contexts including parties, bars, etc. to assess patterns of exposure to high risk contexts.

Relationship information (baseline). We will assess the duration and origin of the friendship, as well typical amount of time spent together. Note that at baseline we will assess level of closeness to confirm eligibility. Dyads who do not identify one another as a "close friend" will be excluded from participation.

Bi-Weekly Follow-Up Assessment

Overview: Bi-weekly, participants will report on any occasion since the last assessment that the participant was out with the target friend in a social setting. For each such occasion, we will collect information about the context of these occasions (i.e., bar, party, out to dinner), whether there was alcohol, who was present, and whether there was an opportunity for intervention.

Friend-Based Assault Prevention Behavior Skills (FAPB)

Peer-Directed Bystander Behaviors for Sexual Assault Prevention (Baseline, bi-weekly). We will use the 49-item Bystander Behaviors Scale for Friends (Banyard et al., 2014), which includes 4 subscales (1) the identification of sexual assault risk situations, (2) accessing resources, (3) planning ahead for risk situations, and (4) safety behaviors in risk settings. This measure will be adapted to include a broader

range of protective behaviors based on findings at Stage 1, and some of the items that refer to intimate partner violence will need to be reworded to assess sexual violence. Participants will complete this measure with respect to their target friend (i.e., did they do this for their friend) and also for themselves (i.e., did their friend do this for them?).

Sexual Assault-Related Protective Behaviors (baseline, bi-weekly for all drinking occasions). A measure developed by Armstrong et al., the Women's Peer-Directed Protective Strategy questionnaire (WPPS) will be used to evaluate assault-specific protective behaviors. This 24 item measure includes items such as, "*I try to be aware and monitor where my friends are at all times*," and, "*I watch out for my friends in an attempt to keep them away from (risk) situations*". Participants will complete this measure for their target friend (i.e., did they do this for their friend?) and also for themselves (i.e., did their friend do this for them?). Participants will be asked to rate frequency and how effective they perceived each behavior to be. They also will rate how they felt about it when they or their friend engaged in the behavior or did not engage in the behavior (when there was an opportunity) using a brief checklist of positive and negative feelings (e.g., good, relieved, safe, guilty, angry, scared). This will be based on information from qualitative participant interviews at earlier stages.

We also will assess whether the intervention resulted in unanticipated or adverse consequences, such as placing undue stress on a member of the dyad, or straining the friendship.

Readiness

Readiness to Intervene (baseline, bi-weekly). Participants will rate readiness for intervening on a 10-point likert-type scale, modeled after the Readiness Ruler (CEBP, 2010). This scale will be used in the FMI discussion, and also will be examined over follow-up *(Moyers et al., 2009).*

Decisional Balance (baseline, bi-weekly). The 10-item Decisional Balance Scale (Banyard et al., 2007) will be used to assess ambivalence about intervening in a potential assault situation. Responses regarding the decision about whether to intervene are rated along a 5-point Likert-type scale. Scores are computed for pros, cons, and negative consequences of intervention for each social occasion with the target friend.

Awareness and Strategies Regarding Alcohol Effects on Helping

Awareness of and strategies for alcohol's effects on helping behavior (baseline, post- and 12 weeks; strategies also assessed bi-weekly).We will assess participant understanding of the ways that alcohol may interfere with helping behavior. Questions will include levels at which alcohol is most likely to inhibit helping behavior (i.e., BACs of .08 or higher; Davis et al., 2009) and knowledge of alcohol's effects on risk recognition and responding. Based on focus group work (Stage 1) and collaborative discussions during the FMI, friends will generate a list of personalized strategies to be used to sustain helping motivation and behaviors during alcohol use, despite alcohol consumption (from Fillmore et al., 2000; Grattan & Vogel-Sprott. 2001). Strategies will include efforts such as sending pre-timed text reminders to check on friend, making plans for one member of the dyad to commit to moderate alcohol consumption, etc. In bi-weekly assessments, participants will be asked to what extent they engaged in these strategies during social occasions that involved alcohol.

Assault and Drinking Outcomes

Alcohol Consumption (bi-weekly, all drinking occasions). Using a grid-based average assessment measure based in the Daily Drinking Questionnaire (Collins et al., 1985), participants will report on alcohol consumption, on occasions when they were out with the target friend. See above for detailed description.

Sexual assault (bi-weekly). This intervention is designed to target risk for a full range of non-consensual sexual experiences, from unwanted sexual attention, to completed rape. Because lower-severity events are more frequent and may signify risk for higher severity events, it may be in lower-severity situations where there is greatest opportunity for intervention. Following Kelley-Baker (2008) for assessing assault-events for particular occasions, we will use the Revised SES to assess each social occasion with the target friend in the prior week. Each item will be coded 1(*yes*) or 0 (*no*), based on whether it happened to the woman/friend on each occasion that the pair socialized together.

Alcohol-Related Protective Behaviors (baseline, bi-weekly). Because one strategy women may use to decrease assault risk is to limit their own and friend's alcohol consumption, we will administer the Protective Behaviors Strategy Survey (PBSS; Martens et al., 2005).

Treatment Evaluation. (Used in Stages 2, 3; from Borsari et al., 2007)

End of Session Questionnaire. Completed at the end of the intervention session, this 6-item measure evaluates the participant's perceptions of the personal relevance of and engagement in the session. Participants also will complete a 1page survey that asks about their experiences in the session.

End of Treatment Questionnaire. This 48-item measure assesses participant perceptions of the helpfulness of each treatment component on a scale from -3 (*greatly harmful*) to +3 (*greatly helpful*). Participants will also be asked to elaborate on their perceptions of what was helpful and/or harmful (i.e., iatrogenic effects).

Therapist Assessment. (Used in Stages 2, 3)

Brief Intervention Adherence Checklist. Following prior MI studies (Barnett et al. 2007; Murphy et al., 2010), 25% of the interviews will be selected randomly for review by Dr. Mastroleo. Two aspects will be assessed, Content and MI Adherence. Dr. Mastroleo will complete a 52-item checklist based on the FMI components (*content*), to evaluate whether each intervention component was covered (Moyers et al., 2010), as well as the MITI (below) for each session to determine whether interventionists maintain MI proficiency.

Motivational Interviewing Treatment Integrity Code Version 3.1.1 (MITI 3.1.1; Moyers et al., 2010) The MITI evaluates interventionist adherence to MI principles. Randomly-selected 20-minute segments of the session are coded. The MITI contains global and behavior components. The global ratings are (a) evocation; (b) collaboration; (c) autonomy/support; (d) direction; (e) empathy; (f) acknowledging change talk; and (g) inviting change talk. The behavior counts assess (a) MI adherent (e.g., emphasizing self-efficacy) and MI non-adherent (e.g., confronting) behaviors; (b) the types of questions; (c) types of reflections, and (d) providing information. As the FMI is built on a MI framework, it is crucial to examine therapist interactions to evaluate the level of collaboration, empathy, and autonomy/support infused through the session interaction. As MI focuses on attaining high ratings in these areas as more predictive of behavior change (Miller & Rollnick, 2012), our ability to evaluate if and how well the therapists delivered these skills is a crucial aspect of intervention fidelity.

Relationship Quality

Effects on the relationship are among the primary concerns that women cite regarding intervening in potential assault situations. Thus, we will examine whether the intervention has any influence on the relationship quality. Further, given that relationship and responsibility are strong predictors of helping behavior, we also will examine these as potential moderators of intervention outcome in exploratory analysis.

Relationship Quality (baseline, follow-up). A brief 5-item version of the Network of Relationships Inventory (NRI, Furman & Buhrmester, 1985) will be used to assess relationship quality (companionship, reassurance of worth, intimate disclosure, reliable alliance, and affection). These items will be augmented with items that query about the sense of working as a team toward one another's safety, and to what extent they were supporting one another's change efforts (e.g., *"I felt like we worked together to follow our safety plans*.").

Responsibility (Baseline, bi-weekly). We will assess Responsibility using a 4-item measure developed by Banyard et al. (2007) that reflects taking responsibility for preventing sexual or other forms of interpersonal violence. This measure will be adapted to reflect a sense of responsibility to the target friend in the dyad.

Exit interview

Following the 12-week follow-up, women will be contacted by phone for a brief exit interview. At this time, women will be given the chance to share any last reactions to or thoughts about the intervention, to pose questions, or inquire about resources. At this interview we also will elicit ideas for application in other settings and populations, and other friend types (e.g., male friends, non-drinking friends, etc.). This

interview will give participants a chance to talk with project staff about anything that was distressing over the trial/12-weeks.

10.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response: N/A. No source records will be used in this study.

*10.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others*

Response: No individual results will be shared with participants or others.

*10.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: Study results will be shared with participants on our study website, as they are available.

11.0 Study Timelines

11.1 Describe the anticipated duration needed to enroll all study subjects.

Response: We expect that all study subjects will be enrolled within the first 2.5 years of the project, so by January of 2020.

11.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: Once enrolled, participants will be followed over a period of 3 months.

11.3 Describe the estimated duration for the investigators to complete this study.

Response: See timeline, below.

Funding Period	Staffing & Training	Stage I FMI Development	Screening and Recruitment	Stage I: Focus Groups (N= 6-8 per group)	Stage 1 Review and Modification	Stage 2: Open Trial (N= 16)	Short-term Follow-Up	Stage 2 Review and Modification	Stage 3 Intervention mini-RCT (N=92) Intervention WLC conditions	3 MO FU (weekly online assmts)	Data Analysis and Report Writing
Sept '18-Dec '18	X	X									
Jan 19-Mar '19		X	X	X							
April '19-June '19			X	X	X						X
July '19-Aug '19					X						X
Sept '19-Dec '19	X		X			X	X				X
Jan '20-March '20			X			X	X	X			X
April '20-June '20							X	X			X
July '20-Sept '20	X		X						X		X
Oct 20-Dec '20	X		X						X	X	X

Jan '21-Mar '21			X						X	X	X
April '21-June '21			X						X	X	X
July '21-Aug '21										X	X

Setting

11.4 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant.

Response: Data collection will be conducted via in person interviews and online. For online assessments, assessments will be completed by participants in their own local setting. Instructions for the online surveys will suggest to participants that they complete online surveys at a time and in a place where privacy can be ensured. In person assessments will be conducted on UB's North Campus, in Dr. Read's research lab.

For research conducted outside of UB and its affiliates, describe:

Response:

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

12.0 Community-Based Participatory Research

12.1 Describe involvement of the community in the design and conduct of the research.

Response:

☒ **N/A:** This study does not utilize CBPR.

12.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

13.0 Resources and Qualifications

*13.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

Response: Dr. Read's work has focused on the complex intersection of trauma (including sexual victimization) and alcohol misuse. She also has examined developmental pathways to risk behaviors from early to late adolescence and into young adulthood. These studies have employed longitudinal, web-based methods such as those that will be used in the proposed study. Dr. Read has assembled an outstanding team of investigators who are ideally suited to ensure the successful completion of this project's aims. All members bring unique and critical expertise to the project. All study staff will be well trained in research procedures, and in ethical treatment of human subjects. All members of the study will complete CITI training.

Describe other resources available to conduct the research.

13.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

Response: Dr. Read will contribute 1.5 months to the study. Dr. Colder will contribute .5 Dr. Livingston will contribute 1.5 montsh. The study also budgets for a ½ time project manager and also a graduate student line.

13.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

Response: All links to the study survey will include a referral list and contact information for participants to reach someone for additional support in the event that they find the reporting of psychosocial stressors/traumatic events stressful or upsetting. This referral list will explicitly include local and national resources for both trauma and also substance misuse. In addition, as we have done in the previous web-based studies, we have a "**Request for Contact**" button that appears at the end of the web survey. Participants are instructed to click on this button if they are distressed and would like to talk to a member of the project staff. Clicking this will generate an e-mail to our staff, and Dr. Read will contact the participant within two business days. This will give participants who are distressed and/or who have experienced a recent event to discuss both treatment and reporting options with a mental health professional.

13.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: See above and also the Study Timeline. There is time allotted for training of staff in study procedures, including necessary duties and functions.

14.0 Other Approvals

14.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

15.0 Provisions to Protect the Privacy Interests of Subjects

15.1 Describe how you will protect subjects' privacy interests during the course of this research.

Response: Participants will be assessed at three points annually, for three weeks each (a total of 9 weekly assessments per year). A more comprehensive baseline assessment will precede the first of the three weekly assessments. In an effort to prevent or minimize discomfort or embarrassment in responding to questions we will reiterate our procedures for protecting participant confidentiality in on-line questionnaires. Participants will be informed that study participation is entirely voluntary, and that they may choose not to participate without any consequence to them. Further, participants also will be informed that they may skip specific items within the online survey if they so choose. Detailed procedures for protecting electronic data are described within the body of this proposal, and include the creation of random ID numbers which are later hooked into a "hash ID". Thus, at no point are identifying information and participant data linked in cyberspace. We will further safeguard against breaches of confidentiality by coding participant data by ID number rather than by name and by keeping information linking these ID numbers to specific individuals in separate files (i.e., identifying information is stored in a separate electronic file with a separate password, accessible only to project staff). Further, no individuals will be identified by name nor will any identifying information be offered when presenting data in lectures, seminars, professional presentations, or papers. Finally, we will obtain a Certificate of Confidentiality from NIH for this study, as an additional protection of confidentiality of data. Participants will be informed that this is in place. All links to the study survey will include a referral list and contact information for participants to reach someone for additional support in the event that they find the reporting of psychosocial stressors/traumatic events stressful or upsetting.

Finally, participants may be concerned about the confidentiality of their responses. Data show that under-reporting of substance use is reduced when participants believe assurances of confidentiality

and you have cultivated a trusting relationships with them (Harell, 1997; Winters et al., 1991, Wish et al., 1997). Both of these necessary conditions will be in place. First, we will have a Certificate of Confidentiality in place, and will describe this to participants in the consent form. We expect that this will both minimize risk of any breach of confidentiality, and also ease any concerns that participants may have about the security of their data. Second, as we have followed this sample over approximately 10 years, assessing –among other things - illicit behaviors such as substance use and other risk behaviors (e.g., delinquency), we are confident that a strong rapport has been established with these participants.

15.2 Indicate how the research team is permitted to access any sources of information about the subjects.

Response: Participant information will be stored by participant study ID number, and not by any identifying information. The link between participant data and identifying information will be stored separately, in a "master list" that will be stored on a password-protected computer. The document itself also will have a password. Only project staff will have access to this information.

16.0 Data Management and Analysis

16.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Analytic Plan

Aim 2: The goal of the Stage 2 open trial is to evaluate the feasibility of the intervention, as well as to generate suggestions for improving and refining it. To this end, the feedback obtained through the Stage 2 open trial and dyad interviews will be analyzed primarily using qualitative data analysis. All qualitative data analysis will be transcript-based, using complete interview transcripts and observer notes as the original data sources. Given that our purpose is to make sense of participants' feedback and suggestions for improving the intervention, content and thematic analysis will be used to analyze transcript data (see Braun & Clarke, 2006; Hsieh & Shannon, 2005). The dyad and not the individual will be the unit of analysis (Krueger & Casey, 2012). We will use Nvivo software (22.nvivo.com) for data analysis. At least two coders will read through the transcripts and develop and refine a series of codes through an iterative process. Disagreements will be resolved through team discussion and final codes to be entered into Nvivo as "nodes". Node development will reflect the targeted areas of feedback and will organized around improving relevance and feasibility of the intervention (e.g., barriers, effects of alcohol, ease of implementation). Once entered, the Nvivo program will be used to sort and organize information chunks into thematic categories. Themes will be reviewed and discussed by the investigators and final kappa agreement will be computed. Using Nvivo, a series of headings will be generated, each corresponding to themes identified in the focus groups. We also will use Nvivo's "query" function to search interview data to examine respondents' reactions to content and feasibility domains of the FMI. In Stage 2, we also will review quantitative summary data from self-report assessments (ratings of feasibility, acceptability) for consideration of continued modification.

Aim 3:

Data preparation. We will examine patterns of missing data, research dropout rates, therapist adherence and competence, distributional properties of our measures, and correlations among outcome measures. Though we expect some missing data due to attrition, this will be minimal as we will be using rigorous participant retention procedures that have proven effective in our prior work. Importantly, our analytic approach (below) will allow us to include cases with missing data. Given the short follow-up and the fact that we are focusing on close friend dyads, we expect minimal missing data. However, we will attempt to follow up with everyone, and in the case of one friend dropping out we will attempt to determine whether the intervention played any role in study attrition. We will

examine for FMI and control group differences on baseline measures and demographics, and if differences emerge, we will include the relevant variables as covariates in analysis.

Treatment Feasibility and Fidelity. Descriptive analyses of adherence data, refusal rates, follow-up rates, and participant evaluations will be used to guide possible changes in the intervention and to provide information on feasibility and acceptability. Decisions about possible intervention changes will be made with consideration of qualitative data (analysis described above) and investigator input. As noted, we will collect data on fidelity to ensure that the FMI was administered according to protocol and consistent with MI spirit.

Outcome analyses. The primary goals of Aim 3 are to evaluate whether (1) FMI increases readiness, reduces perceived barriers, and increases alcohol knowledge and strategies post-intervention and over the follow-up (2) FMI increases the implementation of friend-based assault-protective behaviors (FAPB) in our 3-month follow-up, and (3) changes in readiness, perceived barriers, alcohol knowledge and strategies are associated with implementation of FAPDs at 3-month follow-up (potential mechanisms). We will also examine if quality of the dyad relationship changes as a function of the intervention. Increases would suggest strengthening of the relationship as a function of the intervention, and declines would indicate iatrogenic effects. Whether increases in implementation of behavioral strategies are associated with reduced rates of sexual victimization will also be examined. Examination of sexual victimization is exploratory, as victimization rates are expected to be relatively low over the short follow-up period (i.e., approx. 30% across 3 months; Parks et al., 2008). In secondary analyses, parallel analyses will also be done with alcohol use as an outcome variable. Given the pilot nature of the R34 mechanism and the smaller sample size, we will focus analysis on effect sizes and whether effects are in the proposed direction. Effect size estimates can be unreliable in small pilot studies (Kraemer et al., 2006); thus, we will report effect sizes ranges (95% confidence bands).

A prominent feature of our design is that individuals are nested within dyads, and this necessitates a data analytic approach that can accommodate nested data structures. Hence, our Aim 3 analyses are built around hierarchical linear models (HLMs). First, we will evaluate group differences on variables from our first post-intervention assessment (i.e. perceived barriers, readiness, alcohol knowledge and strategies, and implementation of FAPBs) using a two level model (individuals nested within dyads). Treatment will be dummy coded (FMI vs. waitlist control group) and included as a level two covariate. Second, we will utilize all data from our three month follow-ups and repeat these analyses using a three-level model (6 repeated measures nested within individuals, and individuals nested within dyads). In these models treatment will be included as a level three covariate. We will use f^2 to describe effect sizes (Cohen, 1988; Selya et al., 2012).

Our burst design provides a rich opportunity to examine whether changes in target constructs of interest (e.g., barriers, skills, alcohol knowledge and strategies) are associated with implementation of FAPBs. For these analyses we will combine the post-intervention data from our FMI and WLC groups after the latter has completed the intervention and follow-up assessments. Combining groups will increase our sample size and provide more stable estimates of effect sizes. For these analyses we will include reports of past week protective behavioral strategies just prior to the intervention and weekly aggregates of protective behavioral strategies from our three-month follow-up yielding 7 repeated measures nested within individuals and individuals nested within dyads. Using growth models, we will model change in readiness, perceived barriers, alcohol knowledge and strategies, and implementation of FAPBs. Effect sizes characterizing change will be computed in two ways: 1). Computing a difference score using baseline and the first follow-up divided by the standard deviation of the difference score, and 2). A difference score using baseline and the last assessment of the follow-up divided by the standard deviation of the difference score (Gibbons et al., 1993; Morris & DeShon, 2002). Individual level intercepts and slopes will be output from these growth models and this will allow us to examine correlations between slopes and intercepts. We expect that reductions in perceived barriers (better self-efficacy, fewer interpersonal concerns), and increases in readiness will be positively related to implementation of FAPBs. Our growth models will

also allow us to include individual characteristics (e.g. assault history, drinking history, relationship, responsibility) to examine their association with change in perceived barriers, skill implementation, etc. (e.g., prior history of sexual assault is related to more or less change in variables our intervention is expected to impact).

In exploratory analyses, we will examine whether increases in implementation of FAPB from baseline to follow-up are associated with rates of sexual victimization. For these analyses we collapse our follow-up data into dichotomous variable indicating whether sexual victimization occurred. Using a two-level HLM (individuals nested within dyads), this dichotomous outcome will be regressed on the intercepts and slopes from our growth models of FAPBs (described above). Steeper increases in FAPBs are expected to be associated with lower likelihood of sexual victimization at follow-up controlling for baseline levels of sexual victimization. Odds ratio will be used to describe the effect size. Data from stakeholder and exit interviews will be analyzed using qualitative data analytic techniques.

16.2 If applicable, provide a power analysis.

Power Estimates and Sample Size. This is an intervention development project. As such, the focus is on feasibility rather than on statistical significance. For this reason, as described above, our analyses will focus largely on the derivation of effect sizes to inform parameter estimates for future studies, and to gauge clinical significance of the intervention. Still, we will conduct inferential tests. For these, with a sample of 88 in Study 3, we will be powered to detect "moderate" to "large" intervention effects.

16.3 Describe any procedures that will be used for quality control of collected data.

Response: See above description of data management. In addition, we will follow procedures used in our lab previously for the assurance of quality online data. Specifically, we will review completion times and response patterns. Extremely brief (i.e., less than ½ of estimated) completion times for online surveys, or seemingly random response patterns (e.g., inconsistent or uniform responding) will prompt a reminder email to participants regarding study expectations.

17.0 Confidentiality

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*17.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response: For in-person interview and self-report assessments, data will be stored on a computer in the UB Alcohol Research Lab, and backed-up regularly. The computer itself is password protected, and the lab in which the computer is kept is locked. For online (electronic) data, detailed procedures for protecting electronic data include the creation of random ID numbers which are later hooked into a "hash ID". Thus, at no point are identifying information and participant data linked in cyberspace. We will further safeguard against breaches of confidentiality by coding participant data by ID number rather than by name and by keeping information linking these ID numbers to specific individuals in separate files (i.e., identifying information is stored in a separate electronic file with a separate password, accessible only to project staff). Further, no individuals will be identified by name nor will any identifying information be offered when presenting data in lectures, seminars, professional presentations, or papers. Additionally, as we have done in the past, we will obtain a certificate of confidentiality from NIH in order to enhance the protection of the data, and to minimize concerns about reporting on illegal drug use.

17.2 A. How long will the data be stored?

Response: Five years.

17.3 A. Who will have access to the data?

Response: Only study staff will have access to the data. At a later date, others may access the data for secondary data analysis. However, at this point, the data will be deidentified.

17.4 A. Who is responsible for receipt or transmission of the data?

Response: Drs. Read and Livingston are primarily responsible for the receipt and transmission of the data. Staff personnel such as the graduate student and the project manager will also be involved in this task.

17.5 A. How will the data be transported?

Response: Electronically, via the internet. Please see description above.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research.
(Skip to Section 19.0)

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

18.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response. For in-person assessments, all study staff, including interventionists and research assistants, will be trained to identify serious adverse events that may be subject to mandatory reporting guidelines. Related to this, staff also will be trained to identify any events that, though falling short of mandatory reporting requirements, may nonetheless warrant immediate clinical attention (e.g., recent sexual assault or assault-related distress, severe negative alcohol consequences). Any evidence that a participant may be in immediate and identifiable danger, or is experiencing other significant and acute distress (e.g., recent assault) will trigger an "emergency procedures" protocol (see description below). follow up interviews will have specific measures and interview questions that will serve as "flags" for our interventionists to assess for signs of distress. In cases where distress is indicated, interventionists and follow-up interviewers will have a protocol as to specific follow-up questions, and a link to referral resources. Finally, as we have done in previous work, our online assessments will have a "**REQUEST for CONTACT**" button. Participants are instructed to click on this button if they are distressed and would like to talk to a member of the project staff. Clicking this will generate an e-mail to our staff, and Dr. Read (UB), who is a clinical psychologist, will contact the participant within 24 hours. These procedures are described in greater detail, below.

Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: Please see response above.

18.2 Describe any safety endpoints.

Response: As described above, safety endpoints involve identified distress or danger to a participant. It is important to note that our procedures are designed to balance reasonable measures to maintain participant safety, while at the same time not discouraging accurate and truthful reporting on the part of participants. As described above, policies such as those involving the implementation of Title IX have been developed with this specific challenge in mind. Wanton reporting of every distressing event has

the potential not only to have a deleterious effect on the study, but also can be iatrogenic for the participants themselves.

18.3 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: See above.

18.4 Describe the frequency of safety data collection.

Response: As is outlined in the description of our study approach above, we will collect data pre- and post-intervention, and then at follow-ups. Data will be reviewed for safety concerns at each data collection occasion.

18.5 Describe who will review the safety data.

Response: Drs. Read and Livingston and associated project staff (project manager, graduate student) will review the safety data. Requests for contact will come to Dr. Read, and she will oversee these procedures.

18.6 Describe the frequency or periodicity of review of cumulative safety data.

Response: Safety reviews will be ongoing throughout the course of the study. Please see descriptions above.

18.7 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: There are no statistical tests to determine safety.

18.8 Describe any conditions that trigger an immediate suspension of the research.

Response: The research would be suspended if, in the highly, highly unlikely event, it was determined that the research was leading to immediate and identifiable distress or danger to participants.

19.0 Withdrawal of Subjects

*19.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: A participant could be withdrawn without his or her consent in the event that it was determined that s/he was doing something purposefully to undermine the project. Such circumstances are hard to imagine, but might include mistreating project staff or other participants. This is not expected, both because such behavior is very unusual in study participants, and in 15 years of acting as the PI of the Alcohol Research Lab, Dr. Read has never encountered an event so serious that it would call for termination of research participation. Still, it is possible, however unlikely.

19.2 Describe any procedures for orderly termination.

Response: Participants would first be contacted about the event, and efforts to resolve the problem would be made. The goal would always be to keep the participant enrolled in the study. If it were determined that this was not possible, the participant would be told of her or his removal, and compensated for any time that he/she had already put into the study. No future compensation would be offered, and no further contact would be initiated by study staff.

19.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: Participants can withdraw from the study at any time. If a participant withdraws, no efforts at future contact (e.g., follow-up assessments) would be initiated by the project staff.

20.0 Risks to Subjects

20.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research.

Response: Risks posed to participants in the present study are minimal. Evidence shows that assessments of sexual assault and related experiences may be conducted without serious deleterious psychological effects. Some participants may experience minor emotional discomfort or embarrassment in responding to questions pertaining to potentially sensitive topics such sex or sexual assault, or even substance use. This could occur during completion of self-report assessments, or during individual interviews. However, such discomfort is relatively rare, and is almost always mild and transient. Our labs have been conducting both in-person and online assessments of these phenomena for more than a decade and are well equipped to manage participant needs in the event that distress occurs (see below).

As this dyad-based intervention focuses on motivating a sense of agency for action, through enhancement of personal responsibility and relationship between friends, another potential risk pertains to inadvertent, iatrogenic effects of the intervention. For example, in cases where sexual victimization occurs to one of the dyad members – or even if it doesn't- the other member of the dyad may believe that somehow she is to blame. We plan to assess such effects carefully, with an eye toward both (1) modification of the intervention to decrease such iatrogenic effects, and also (2) ensuring the wellness of the participants enrolled in our study. Efforts to address the first of these issues (future intervention modification) are described in the body of the proposal. To address specific participant wellness concerns, here we outline several steps that we will take in the "Adequacy of Protection Against Risk" section, below.

Lastly, because our study focuses on high-risk (i.e., heavy drinking) women, it is possible and perhaps even likely that women will experience some kind of event that falls along the spectrum of assault behaviors during the course of follow-up. Though this assault would not be as a result of the intervention itself, it is a risk that our participants could incur during the period of follow-up and as such, is something that we have planned to address in our procedures. These procedures are described below.

20.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: In an effort to prevent or minimize discomfort or embarrassment in responding to questions we will reiterate our procedures for protecting participant confidentiality in on-line questionnaires. Additionally, as a precautionary measure, all web surveys will be accompanied by a treatment referral list, as well as by contact information for study clinical staff in the event that they become distressed by reporting on traumatic events and would like to speak further with a mental health professional. Detailed procedures for protecting electronic data are described within the body of this proposal, and include the creation of random ID numbers which are later hooked into a "hash ID". Thus, at no point are identifying information and participant data linked in cyberspace. We will further safeguard against breaches of confidentiality by coding participant data by ID number rather than by name and by keeping information linking these ID numbers to specific individuals in separate files (i.e., identifying information is stored in a separate electronic file with a separate password, accessible only to project staff). Further, no individuals will be identified by name nor will any identifying information be offered when presenting data in lectures, seminars, professional presentations, or papers. Additionally, as we have done in the past, we will obtain a certificate of confidentiality from NIH in order to enhance the protection of the data, and to minimize concerns about reporting on illegal drug use.

First, as part of the intervention, we will explicitly discuss the ways in which a sense of responsibility to someone, is different from a sense of responsibility for someone, and that though there are ways in which friends may help one another to decrease sexual assault risk, this does not mean that they alone are responsible for one another'. Second, all participants will receive as part of the general study debriefing procedure, a description of possible iatrogenic intervention effects, including

guilt and blame. Participants will be encouraged to discuss these concerns with interventionists at follow-up, with one of the two PIs, or to seek out additional support, available through our referral list. Third, as follow up interviews now have specific measures and interview questions that will serve as "flags" for our interventionists to assess for signs of distress. In cases where distress is indicated, interventionists and follow-up interviewers will have a protocol as to specific follow-up questions, and a link to referral resources. Finally, as we have done in previous work, our online assessments will have a "**REQUEST for CONTACT**" button. Participants are instructed to click on this button if they are distressed and would like to talk to a member of the project staff. Clicking this will generate an e-mail to our staff, and Dr. Read (UB), who is a clinical psychologist, will contact the participant within two business days.

Assessment and Management of Adverse Events. Our procedures for managing adverse events are informed by the collective experience of our team in conducting research with women at risk for assault and other adverse, alcohol-related outcomes, including Dr. Read's training as a Clinical Psychologist and her experience as the Director of the Clinical Psychology program, including the Psychological Services Clinic. All study staff, including interventionists and research assistants, will be trained to identify serious adverse events that may be subject to mandatory reporting guidelines. Related to this, staff also will be trained to identify any events that, though falling short of mandatory reporting requirements, may nonetheless be warranting immediate clinical attention (e.g., recent sexual assault or assault-related distress). Any evidence that a participant may be in immediate and identifiable danger, or is experiencing other significant and acute distress (e.g., recent assault) will trigger an "emergency procedures" protocol. In these cases, the PI (Dr. Read) will be notified by telephone and text of such an event. In cases where this "triggering" occurs via online assessment, Dr. Read will make immediate phone contact with the participant to further evaluate safety and other concerns. In cases where the triggering takes place during in-person assessments, Dr. Read will be contacted and will speak with the participant either by phone (if Dr. Read is off-site) or in person to provide further assessment and to formulate an action plan to ensure the participants safety and wellbeing. In the unlikely event that Dr. Read cannot be reached within the hour, either the Campus Psychological Services Center (PSC) or if outside of business hours, Campus Security will be contacted. In cases where the threat is determined not to be imminent, Dr. Read will work with the participants to connect them to services at either the PSC or the university-based Counseling Center. At both of these facilities, students may receive either free or reduced rate services. Drs. Read, Livingston, and Testa have close ties to these facilities. This will ensure a seemless pathway of care.

***Application of Title IX Reporting*.** In addition, we have carefully reviewed reporting requirements for Title IX, consulted with our UB Title IX representative (Ms. Sharon Nolan-Weiss, Director of Equity, Diversity, & Inclusion (EDI); https://www.buffalo.edu/equity/obtaining-assistance/sex-discrimination-and-sexual-harassment/title-ix.html), and read a number of opinions and discussions regarding responsible adherence to these requirements as they pertain to campus life, and how they may pertain to research (e.g., http://www.chronicle.com/article/Mandatory-Reporting-for-Title/141785; https://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf;). Based on these investigations, it appears that, because mandatory reporting among researchers may act as a deterrent to research participation and thus may interfere with understanding of the very problem that such research is intended to address https://cola.unh.edu/sites/cola.unh.edu/files/departments/Prevention%20Innovations%20Research%20Center/pdf/Prevention_Innovations_Research_Center_Title_IX_Human_Subject_Research_White_Paper_Nov_5_2015docx.pdf), the reporting of assault events that may occur in the context of research such as the proposed project would not meet the standard of mandatory reporting as outlined by Title IX (Note that our research still would be subject to other mandatory reporting demands, as described above). Still, guidelines around Title IX adherence change with time, and as such, we will continue to work closely with our Title IX officer to arrive at procedures that maintain the rights, confidentiality, and protections of our participants, while still complying with reporting laws.

Further, because "Best Practices" of Title IX procedures facilitate understanding on the part of students as to who may or may not be a mandated reporter, we will include in our informed consent a description of Title IX and its parameters. We will explicitly note that research reporting does not fall under mandated reporting guidelines, and will provide information for how to get in contact with the EDI offices for further information and guidance about reporting and assistance.

*20.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response: To our knowledge, there are no procedures which may have risks that are unforeseeable.

20.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: Our research procedures carry no risks for an embryo or fetus.

20.5 If applicable, describe risks to others who are not subjects.

Response: To our knowledge, there are no risks associated with our study procedures to others who are not research subjects.

21.0 Potential Benefits to Subjects

21.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

Response Individuals participating in this research may gain insight through the data collection/assessment process which involves providing thoughtful answers to questions about sexual victimization experiences, the social environment, friendships, and alcohol use. This information will be made available through the dissemination of study findings. In addition, we will post findings on the UB lab websites so that participants may go to that site to read about findings as they come out.

22.0 Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

23.0 Economic Burden to Subjects

23.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response: There are no costs for which participants in this study are responsible.

24.0 Compensation for Participation

25.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Study 1 Remuneration. Women will be compensated for focus group participation with $50 in cash. Stakeholders will receive $25 in cash as a gesture of appreciation.

Study 2 Remuneration. Open Trial participants will be paid $50 in cash for participating in the intervention and feedback sessions. They will receive an additional $10 bonus if the pair is scheduled for an appointment within 72 hours of being contacted for scheduling.

Study 3 Remuneration. Students will receive electronic gift card payments of $40 for the baseline assessment (which occurs just prior to the intervention) and $20 for each post-intervention assessment. To encourage participant retention, participants who complete at least 4/6 bi-weekly assessments will receive a $20 bonus. Stakeholders will receive $25 in cash as a gesture of appreciation for participation.

25.0 Consent Process

25.1 Indicate whether you will be obtaining consent.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 27.0)*

25.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response: For the first study, consent will be obtained in person, when participants come in for their first session. For Study 1 participants, this will be the focus group. For Study 2 &3, participants will consent online when they complete the self-report measures. For these studies, participants will be directed to an online consent form, which provides information about the study. Participants will consent by clicking a button that reads, "I consent". Participants who provide consent will then be directed to a series of questionnaires online Qualtrics.com (see measures table for a complete list).

25.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

Response: All participants will be scheduled for a lab visit. This will occur at least a week in advance, which should give them ample time to consider whether they wish to participate. Further, when participants are consented, they will be informed that there is no pressure to consent, and that if they would like to take time to think it over, they can come in at another date to complete the consent and initial session.

Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response: There is no process for ongoing consent. The participant's participation in the study is voluntary. As such, completion of the online surveys effectively functions as continued and ongoing consent.

25.4 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response: We have reviewed the SOP and there will be no substantial deviations from these procedures.

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects.
(Skip to Section 26.8)

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 26.9)

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 26.13)*

25.5 *Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.*

Response: All participants in our study will be over the age of 18. As such, there will be no role for a legally authorized representative.

☒ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

25.6 ***For research conducted outside of New York State**, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response: Though participants may be outside of NY state when they complete online surveys, the research itself is being conducted only in NY state.

25.7 *Describe the process for **assent of the adults**:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.*

Response: No assent will be collected. All participants are adults. Consent procedures described above will be used.

- *If assent will not be obtained from some or all subjects, provide an explanation of why not.*

Response: N/A

25.8 *Describe whether **assent of the adult** subjects will be documented and the process to document assent.*

Response: N/A. All participants will be able to provide consent.

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults.
(Skip to Section 27.0)

25.9 *Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

Response: All participants will be asked to bring a driver's license or other government issued ID into the session. This is what will be used to confirm that they are over the age of 18.

25.10 ***For research conducted outside of New York State****, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response: See above. This research is being conducted in the state of NY.

25.11 Describe whether parental permission will be obtained from:

25.12 Describe whether permission will be obtained from individuals ***other than parents****, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response: N/A

25.13 Indicate whether assent will be obtained from all, some, or none of the ***children****. If assent will be obtained from some children, indicate which children will be required to assent.*

Response: N/A

25.14 When assent of children is obtained, describe how it will be documented.

Response: N/A

26.0 Waiver or Alteration of Consent Process

☐ **N/A:** A waiver or alteration of consent is not being requested.

This project is eligible for the waiver of written documentation of consent because participation presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context.

27.0 Process to Document Consent

27.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response: See attached consent forms. (3 forms, 1 for each study)

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

28.0 Multi-Site Research (Multisite/Multicenter Only)

☒ **N/A:** This study is not an investigator-initiated multi-site study. Does not apply.

29.0 Banking Data or Specimens for Future Use

☐ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

30.0 Drugs or Devices

☒ **N/A:** This study does not involve drugs or devices. This section does not apply.

31.0 Humanitarian Use Devices

☒ **N/A:** This study does not involve humanitarian use devices. This does not apply.

Statistical Analysis Plan

Data preparation. We will examine patterns of missing data, research dropout rates, therapist adherence and competence, distributional properties of our measures, and correlations among outcome measures. Though we expect some missing data due to attrition, this will be minimal given the short follow-up, the focus on close friend dyads, and employment of rigorous participant retention procedures that have proven effective in our prior work. Importantly, our analytic approach (below) will allow us to include cases with missing data. In the case of one friend dropping out, we will attempt to determine whether the intervention played any role in study attrition. We will examine for FMI and control group differences on baseline measures and demographics, and if differences emerge, we will include the relevant variables as covariates in analysis.

Treatment Feasibility and Fidelity. Descriptive analyses of adherence data, refusal rates, follow-up rates, and participant evaluations will be used to guide possible changes in the intervention and to provide information on feasibility and acceptability. Decisions about possible intervention changes will be made with consideration of qualitative data (analysis described above) and investigator input. As noted, we will collect data on fidelity to ensure that the FMI was administered according to protocol and consistent with MI spirit.

Outcome analyses. The primary goals of Aim 3 are to evaluate whether (1) FMI increases readiness and reduces perceived barriers to intervene, and increases alcohol knowledge and strategies post-intervention and over the follow-up (2) FMI increases the implementation of friend-based assault-protective behaviors (FAPB) in our 3-month follow-up, and (3) changes in readiness and perceived barriers for protective behaviors, and alcohol knowledge and strategies are associated with implementation of FAPDs at 3-month follow-up (potential mechanisms). We will also examine if quality of the dyad relationship changes as a function of the intervention. Increases or decreases in relationship quality as a function of the intervention would suggest either a positive impact on dyadic relationships or iatrogenic effects of the intervention, respectively. Whether increases in implementation of behavioral strategies are associated with reduced rates of sexual victimization will also be examined. Examination of sexual victimization is exploratory, as victimization rates are expected to be relatively low over the short follow-up period (i.e., approx. 30% across 3 months; Parks et al., 2008). In secondary analyses, we will also consider alcohol use as an outcome variable to examine potential intervention effects on drinking. Given the pilot nature of the R34 mechanism and the smaller sample size, we will focus analysis on effect sizes and whether effects are in the proposed direction. Effect size estimates can be unreliable in small pilot studies (Kraemer et al., 2006); thus, we will report effect sizes ranges (95% confidence bands).

A prominent feature of our design is that individuals are nested within dyads, and this necessitates a data analytic approach that can accommodate nested data structures. Hence, our Aim 3 analyses are built around hierarchical linear models (HLMs). First, we will evaluate group differences on variables from our first post-intervention assessment (i.e. perceived barriers, readiness, alcohol knowledge and strategies, and implementation of FAPBs) using a two level model (individuals nested within dyads). Treatment will be dummy coded (FMI vs. waitlist control group) and included as a level two covariate. Second, we will utilize all data from our three month follow-ups and repeat these analyses using a three-level model (6 repeated measures nested within individuals, and individuals nested within dyads). In these models treatment will be included as a level three covariate. We will use f^2 to describe effect sizes (Cohen, 1988; Selya et al., 2012).

Our burst design provides a rich opportunity to examine whether changes in target constructs of interest (e.g., barriers, skills, alcohol knowledge and strategies) are associated with implementation of FAPBs. For these analyses we will combine the post-intervention data from our FMI and WLC groups after the latter has completed the intervention and follow-up assessments. Combining groups will increase our sample size and provide more stable estimates of effect sizes. For these analyses we will include reports of past week protective behavioral strategies just prior to the intervention and weekly aggregates of variables of interest from our three-month follow-up yielding 7 repeated measures nested within individuals and individuals nested within dyads. Time will be included as a level-1 covariate, and we will

examine change in readiness, perceived barriers, alcohol knowledge and strategies, and implementation of FAPBs. Effect sizes characterizing change will be computed in two ways: 1). Computing a difference score using baseline and the first follow-up divided by the standard deviation of the difference score, and 2). A difference score using baseline and the last assessment of the follow-up divided by the standard deviation of the difference score (Gibbons et al., 1993; Morris & DeShon, 2002). Individual level intercepts and slopes will be output from these models and this will allow us to examine correlations between slopes and intercepts. We expect that reductions in perceived barriers (better self-efficacy, fewer interpersonal concerns), and increases in readiness will be positively related to implementation of FAPBs. Our models will also allow us to include individual characteristics (e.g. assault history, drinking history, relationship, responsibility) to examine their association with change in perceived barriers, skill implementation, etc. (e.g., prior history of sexual assault is related to more or less change in variables our intervention is expected to impact).

In exploratory analyses, we will examine whether increases in implementation of FAPB from baseline to follow-up are associated with rates of sexual victimization. For these analyses we collapse our follow-up data into dichotomous variable indicating whether sexual victimization occurred. Using a two-level HLM (individuals nested within dyads), this dichotomous outcome will be regressed on the intercepts and slopes of FAPBs (described above). Steeper increases in FAPBs are expected to be associated with lower likelihood of sexual victimization at follow-up controlling for baseline levels of sexual victimization. Odds ratio will be used to describe the effect size. Data from stakeholder and exit interviews will be analyzed using qualitative data analytic techniques.