

**Cover Page**

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**Official Title of the study:** RCT of a Combined MI Intervention to Address Bystander Behaviors  
in the Context of Alcohol Use

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Sexual violence (SV) is a significant public health problem particularly among 18-25 year olds. A major risk factor for SV is alcohol use, which via its negative impact on cognitive abilities and decision-making, acts as a barrier to intervening in situations at-risk for SV. The goal of this study is to determine the efficacy of a motivational interviewing (MI)-based intervention called Motivate-the-Bystander (MTB), combined with a MI to reduce alcohol use (ALC) to reduce drinking and increase prosocial bystander behaviors in SV situations. Primary study endpoints are: 1) reduced drinking, and 2) increased bystander behaviors. Drinking will be assessed with self-reports in electronic daily diaries (EDD). Bystander behaviors will also be assessed with EDD and observed directly with a VR-based measure of bystander behaviors called the Bystanders in Sexual Assault Virtual Environments (B-SAVE). In this study, 450 men and women aged 18-25 will be recruited from Lincoln, NE using passive methods. Potential participants will be screened, consented, and enrolled. After obtaining consent, the baseline survey will be administered and will assess self-reported individual differences in alcohol use and bystander outcomes and secondary endpoints (SV perpetration, victimization, alcohol expectancies, prosocial and personality traits, and other theoretical and empirical factors related to primary outcomes). Following completion of the baseline survey, participants will be randomized to one of 3 conditions: MTB, MTB+ALC, or attention control. Participants will then be given instructions for completing the weekly EDD surveys post B-SAVE through month 9. One week post-intervention, investigators will schedule a lab appointment for participants to complete the B-SAVE. The follow-up B-SAVE includes 5 risk scenes within a house party in which participants are prompted at two points in the conversation (with a flashing microphone icon) to verbalize their response in that situation, providing 10 opportunities to intervene in sexual risk situations. Responses are recorded and coded and reflect the presence or absence of intervention attempts (0=no, 1=yes) as well as the effectiveness of the attempt, using a scale from -5 (very ineffective; the action would likely facilitate sexual aggression) to +5 (very effective; the action would likely disrupt an instance of sexual assault). Sum intervention attempts and effectiveness scores are the primary outcomes of interest for assessing bystander behaviors. The main hypotheses are: MTB (vs. attention control) will increase prosocial bystander behaviors at each follow-up (Hypothesis 1); MTB+ALC (vs. MTB) will increase prosocial bystander behaviors and decrease overall alcohol use measured via B-SAVE and weekly EDD follow-ups; (Hypothesis 2); MTB+ALC (vs. MTB and attention control) (a) will reduce alcohol use in risky sexual situations and (b) lower proximal alcohol use will be a mechanism explaining why MTB+ALC increases prosocial bystander behavior (Hypothesis 3).

The overarching goal of the proposed project is to evaluate the efficacy of MTB+ALC in comparison to MTB and an attention control condition. This goal will be achieved in a large-scale randomized controlled trial (RCT) of 450 women and men, aged 18-25, who are heavy drinkers, with the following study components: 1) baseline, 1-week follow-up, and weekly EDD follow-up assessments that include measures of alcohol use and bystander behaviors (retrospective self-reports at baseline; weekly electronic daily diary post B-SAVE; the B-SAVE observational measure of bystander behavior at one week follow-up), 2) the MTB interventions (MTB or MTB+ALC) or a attention control. Participants will be 450 women and men aged 18-25 who speak English and are heavy drinkers. Women and men of this age range were selected because rates of heavy alcohol use are higher at this age than any other period of adult development and this age group is at heightened risk for SV victimization. Our sample will contain heavy drinkers based on NIAAA criteria (men who consume 4 drinks on any day or more than 14 drinks per week in the past month; women who consume 3 drinks on any day or more than 7 drinks per week in the past month). Relative to population-based estimates, this proportion is consistent with heavy alcohol use reported by 18-25 year olds.

These eligibility criteria are initially assessed by an online screening. Upon contacting the lab, ad respondents will receive a short description of the study and complete the initial online Qualtrics to determine eligibility. Those who meet study inclusion criteria and are interested will be scheduled for a lab visit to complete the baseline assessment and complete the randomly assigned intervention (MTB, MTB+ALC, or attention control).

We will use a broad recruitment strategy that includes advertising online (e.g., Craigslist, Facebook), in newspapers, and via community flyers that target young adults who are heavy drinkers in Lincoln, NE. Ads will ask respondents to contact the laboratory online, via e-mail, or by phone to complete an initial eligibility screening. Using conservative estimates from past studies conducted by Drs. DiLillo and Gervais, the above recruitment efforts will generate approximately 26 calls per month. We estimate that 13 (50%) will be deemed eligible, provide EDD data, and return for the follow-up session (B-SAVE VR assessment). These data indicate that we will be able to meet or exceed our target sample size of N = 450.

**Participants and procedures.** Participants will be recruited from Lincoln, Nebraska in Lancaster County, which includes a racial makeup of 15% non-Caucasian. Hispanic/Latino residents of any race make up 6.5% of the population. The recruitment strategy will ensure that the final sample will exceed these figures (estimated 36%) of minority representation. The baseline survey will be administered using Qualtrics. The 60-minute assessment will include measures of demographic variables (age, race/ethnicity, SES, relationship status, sexual orientation, gender identification, etc.), the primary outcome variables (alcohol use and bystander behavior), and secondary outcomes (SV perpetration, SV victimization, alcohol expectancies, prosocial and personality traits, etc.). Data will be stored on Qualtrics until it is downloaded. Once individuals complete the baseline survey, they will be randomized to an automated stratified block randomization program. This procedure ensures equal numbers of participants across 3 intervention groups (MTB, MTB+ALC, control). As our recruitment approach will ensure that 36% of our sample are from racial or ethnic minority groups, we will first stratify by race/ethnicity, resulting in two strata: non-minority and minority. We will also use this approach for gender and sexual orientation. For each stratum, a separate block randomization sequence will be used to assign people to one of 3 intervention groups: 1) MTB, 2) MTB+ALC, 3) Attention control.

### **Intervention Conditions**

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

MI-consistent use of confidence and importance rulers. Throughout the MTB session the interventionist uses tailored open-ended questions, reflections, and strategic summaries to elicit and enhance change talk related to bystander behaviors. To ensure that MTB is equivalent in length to the other interventions, participants will also receive a 60-minute attention and relaxation intervention following MTB, so the MTB intervention will be 120 minutes long.

**MBT+ALC.** Participants in MTB+ALC will receive an additional MI session with personalized feedback to address alcohol use and alcohol-related consequences. The ALC portion of MTB+ALC follows a traditional manualized format following MTB. The session begins with rapport building and exploration of personal values and goals related to alcohol use. The interventionist explores both the positive and negative aspects of drinking and provides a personalized feedback report tailored to the participant's alcohol use and alcohol related consequences. This computer-generated feedback report summarizes: 1) past-month frequency and quantity of drinking and heavy drinking; 2) normative comparisons for past-month frequency and quantity of drinking and heavy drinking; 3) past-month typical and peak BAC; 4) BAC interpretation guides; 5) alcohol-related consequences and risk factors for alcohol problems (past year); and 6) other alcohol-related outcomes (i.e., calorie intake, cost of alcohol use, and time allocated to alcohol consumption in comparison to other activities). The interventionist presents each topic in a non-judgmental style and invites discussion and reflection. The interventionist uses MI techniques throughout the discussion (i.e., respecting autonomy, open-ended questions, reflective listening, eliciting change talk, providing feedback that supports self-efficacy). Following the presentation of the personalized feedback report, the interventionist explores the participant's interest in changing drinking behavior. All participants are also provided with a menu of options of potential changes in alcohol use. Participants who identify an interest in change collaboratively set goals with the facilitator and identify a change plan. MTB+ALC lasts 120 minutes.

**Attention control.** The attention control condition is designed to control for nonspecific factors by providing equivalent levels of contact time and attention. Like the active treatment conditions, the attention control condition begins with an introduction and general rapport building. The interventionist reviews the rationale for treatment, stating that life transitions during young adulthood may be stressful. Next, an exploration phase addresses the participant's typical level of daily stress and reviews current participant-employed coping behaviors. To promote treatment expectancies, a rationale and instructional exercise is provided. For example, progressive muscle relaxation and related techniques are introduced and practiced. The session concludes with a recommendation that the participant practice these techniques regularly. The entire Attention control session lasts 120 minutes.

**Weekly electronic daily diaries months 0-9 post intervention.** Once a week for 9 months, participants will receive a morning prompt via a cell phone app (i.e., Qualtrics) to provide past-week reports of bystander and drinking related outcomes. Bystander-related outcomes will be assessed, each with a yes-no screening question, followed by an open-ended response. 1) Did you witness an SV event? If yes, what occurred (open-ended text box)? When did it occur (open-ended text box)? Where did it occur (open-ended text box)? Who was involved (drop-down menus for gender, race, age, sexual orientation, drinking status [1=very sober-7=very drunk] of perpetrator[s], victim[s] and witnesses[s])? 2) Were you drinking? If yes, when did you start drinking (drop-down menu with time)? How many standard drinks (1-25 scale) did you consume to that point (drop-down menus with number, type and definition/ image of standard drinks)? How intoxicated were you (1=very sober, 7=very intoxicated)? 3) Did you say or do anything in response to the SV event? If yes, what

did you do (open-ended text box)? 4) Did you successfully prevent the potential SV event? If yes, explain (open-ended text box)? Alcohol consumption will be assessed as the number of standard drinks consumed over the past 24 hours on definitions of standard drinks provided during the baseline session. The timing of the first and last drink will be collected as well, in order to examine drinking in relation to SV and bystander opportunities.

**B-SAVE at 1-week follow-up.** Participants proceed through the 10 scenes of the B-SAVE (5 risk, 5 neutral). In each scene, participants are prompted at two points in the conversation (with a flashing microphone icon) to verbalize their response in that situation, thus providing 10 opportunities to intervene in sexual risk situations. The VR system simultaneously records their non-verbal behaviors (e.g., location: moving toward or away from avatars; gaze: head movements). If no verbal response is provided for three seconds, the scene automatically continues. Each neutral scene also contains two response opportunities (not analyzed) to reduce demand characteristics. Following each scene, participants are directed to the next scene (i.e., group of people) in the party with an arrow. The risk scenes encountered in the B-SAVE contain both subtle and blatant sexual risk cues and show: a man sharing a nude photograph of an ex-girlfriend without her consent to another man (2); a woman experiencing unwanted sexual touching while dancing with a male acquaintance (3); two men making rape supportive jokes and talking about a drinking woman in sexually derogatory ways (6); the victim of the revenge porn in scenario 2 and (7); and a man pressuring an obviously intoxicated woman to remove her clothes against her will in a bedroom (10). These risk scenes are interspersed among the following neutral (i.e., non-risk) scenes: a man greeting the participant at the front door (1); two women and one man recounting a recent night of heavy drinking (4); two women engaging in small talk by a keg (5); an intoxicated man talking with his girlfriend (8); and two women planning to leave the party for a consensual hook-up (9).

Participants' EDDs of bystander behaviors, as well as transcriptions of their audio recorded responses to the BSAVE risk scenes are coded using a bystander coding manual developed by MPIs DiLillo and Gervais. A team of undergraduate research assistants will code each response for the presence or absence of an intervention attempt (0 = no, 1 = yes) and effectiveness of the intervention (-5 = least effective, 5 = most effective).