

Title: A Multi-Component Alcohol and Sex Risk Intervention for College Students

NCT number: NCT05180539

Document Date: IRB Approval 8/23/21

Study Protocol and Statistical Analysis Plan

RECRUITMENT

Participants will be recruited from two universities in the USA. All participants will be between the ages of 18-24 and will be eligible to participate regardless of drinking or relationship status. Students will be recruited from a random sample of students provided by the Registrar's Office or Office of Research at each site, stratified by gender and class year. Approximately three weeks into the fall semester, students will receive an email with an invitation to participate and a link to an IRB approved consent form. Each participant receives a personalized link with a random, unique personalized identification number (PIN) embedded in the link. This PIN is used instead of identifying information to track participation, track incentive payments, and for creating ingroup materials (more details below). Before each in-person group session, participants will receive emails, phone calls and / or text messages about the time and location of the group meeting.

BASELINE DATA COLLECTION

After providing consent, participants will be asked to complete a brief survey assessing past drinking, sexual behaviors, protective behavioral strategy use, bystander behavior, intentions of engaging in protective behavioral strategy use, intentions of engaging in bystander behavior, and self-efficacy measures of protective behavioral strategy use and bystander behaviors.

As part of the consent form, participants will consent to take the survey and participate in the groups. After completing the survey questions, participants will be reminded about the content and format of the group meetings. They will then be asked to select a time to attend the group meetings, alternatively they can indicate that they are still interested but not available to attend any of the meeting times, or that they no longer wish to attend the group meetings. Participants who sign up for the groups or indicate they are still interested in attending will be redirected to an additional survey to input their contact information. At the end of the survey, participants will be provided with a link to resources related to sexual assault and alcohol use. Participants will receive a \$15 Amazon gift card for completing the survey. Participants will be randomized to the SPLASH intervention or the control condition (i.e., healthy eating and physical activity promotion).

IN-PERSON GROUP MEETING CONTENT

Both the SPLASH intervention and control condition comprise of two group sessions that will take place approximately two weeks apart. Each group session will take approximately two hours. Upon arrival to the session, each participant will be asked to sign an informed consent form that includes permission to audiorecord the meeting. During the preamble statement to the group, the facilitators will discuss the importance of anonymity of in-group responses, and

students will be asked to treat the group discussion as a privileged conversation. Participants will be asked to use a fictitious name to avoid the use of their real names during the discussion. Discussions will be audiorecorded.

SPLASH CONDITION

Session 1 will involve normative feedback and protective behavioral strategies training related to alcohol use and sexual behaviors. The normative feedback component of the intervention is interactive (i.e., using live anonymous polling software participants will be able to text their responses to questions related to other same-campus students' alcohol consumption, alcohol use before/during sex, and frequency of unprotected casual sex and immediately view the group's responses). Data collected through the system are anonymous and are not connected to student cell phone numbers or any other identifying information. Participation in the polling is voluntary and there are no questions about students' personal behaviors. The normative feedback will involve a discussion of, for example, why students hold normative misperceptions.

In addition to normative feedback, participants in session 1 will receive protective behavioral strategies (PBS) training in order to build skills for overcoming barriers and implementing PBS to reduce risky alcohol and drinking-related sexual behaviors. The methods we will utilize are based on our past research (Kenney, Napper et al., 2014; LaBrie, Napper et al., 2015). More specifically, prior to the intervention session students' responses to the baseline survey are used to populate a feedback sheet that describes how often they use a series of protective strategies. Each sheet is labeled with a unique participant ID number (the same PIN as that used to identify their survey data), and not student names (or any other identifying information). When students check into the meeting, their name will be verified and they will be given a folder containing their personal feedback sheet(s). The folder provides students with a method to keep their responses private if they wish.

During the intervention, students will be asked to review their responses on the feedback sheet(s). They will be asked, for example, to identify strategies they commonly use and strategies they would like to use more often. Participants will be encouraged to discuss as a group why they find strategies useful, how they use them, barriers to use (including heavy alcohol use), and how they overcome barriers to use. Participants will be encouraged to set personal goals about their use of strategies in the future and asked to write down these goals. The facilitators will encourage participants to provide suggestions and support for each other, and will utilize group process strategies (e.g., creative inquiries, circular questioning) to facilitate peer discussion and collective brainstorming. Students do not have to share their own personal experiences if they are not comfortable and instead they can talk more generally about college students' experiences or not participate in the group discussion. As noted above, participants will be encouraged to use a fictitious name for all discussions. Participants are able to take home their folder containing the feedback sheets and goals.

Session 2 will address alcohol use and bystander skills training. At the beginning of the session participants will be reminded about the audiorecording and to use fictitious names. Any participants who missed session 1 will be asked to sign consent forms. Participants will receive interactive normative feedback on the prevalence and acceptability of bystander intervention

using the same polling software as in Session 1. Participants will also be presented with bystander scenarios related to excess alcohol use and sexual assault situations. In small groups, participants will be asked to identify possible dangers in the scenarios and specific strategies that could be used to intervene. The session will end with a group discussion on the intersection of alcohol use and bystander behaviors (e.g., how alcohol use inhibits intervention). At the end of both Session 1 and 2 participants will be offered an information sheet with information about alcohol and sex-assault related resources.

CONTROL CONDITION

The procedures for the control condition are the same as those described above; however, the content of intervention focuses on promoting healthy eating and physical activity. For example, during Session 1 participants receive interactive normative feedback regarding healthy eating behaviors, review and discuss strategies for eating healthily. In Session 2, participants receive interactive normative feedback related to physical activity, discuss barriers to exercise and strategies to promote physical activity. They are presented with scenarios about other students who are struggling to exercise and asked how they could intervene to promote a healthy college community.

DATA COLLECTION DURING IN-PERSON MEETINGS

At the end of each session participants will complete post-intervention assessment measures in order to determine participants' perceptions of the helpfulness of the intervention and acceptance of the intervention content. Participants will receive a \$20 gift card for attending each in-person group session and completing post-session measures.

MITIGATING RISK

Participants will be informed that their participation is voluntary, that they can decline to answer any questions they do not feel comfortable answering, and that they can withdraw from the study at any time without penalty. In addition, efforts will be taken to ensure all participant data is kept confidential. While some of the topics in the survey are sensitive in nature, the questions do not fall outside of the bounds of questions that might come up during a routine doctor's visit, and thus do not pose more than a minimal risk. During group meetings, participants will not be required to share personal alcohol or sex related information. During the group discussions, participants will be asked to use a fictitious name. Participants will be reminded that it is their choice what they disclose during group discussions. At the end of the group, students will be offered information about alcohol and sex-assault related resources.

STATISTICAL ANALYSIS PLAN

Preliminary analyses will examine patterns of missing data, dropout rates, and differences between the two sites. Before commencing analyses, variable distributions will be assessed and outliers dealt with appropriately when necessary. We will assess the effectiveness of the randomization procedure by comparing groups on relevant variables. If meaningful differences are observed between conditions, individual-level covariates will be used.

Study Feasibility and Treatment Feasibility/Acceptability. We will assess the feasibility of procedures by examining study recruitment, refusal rates, follow-up rates. We will assess the feasibility and acceptability of SPLASH and the general health promotion control by examining rates of session attendance, completion (attending both sessions, drop-outs), and descriptive analysis of satisfaction data.

Intervention Effects: In examining preliminary intervention effects, we will investigate the effect of condition on outcomes (i.e., alcohol use, safe sex behaviors, use of PBS and bystander behaviors, perceived norms, self-efficacy, and willingness). Given that effect size estimates may be unreliable for small pilot studies we will assess effect size ranges (e.g., 95% CIs) and direction of effects between conditions. We will explore correlations among condition, alcohol and sex-related outcomes.

Between-Group Comparisons and Power: Given the pilot nature of the study and the smaller sample size, our focus will be on ascertaining whether the direction of the results are consistent with proposed hypotheses, and whether the strength of effect sizes for differences between conditions (e.g., Cohen's d and its 95% CIs) are of practical magnitude. In addition, we will conduct a series of independent t tests, as a function of treatment vs. control group, on dependent measures for each of the post-intervention time points. If relevant baseline covariates are identified, analyses of covariance (ANCOVA) will be used instead.

While our primary goal is to test feasibility and acceptability of interventions and to generate data supporting the direction of effects to indicate the potential for a large-scale randomized trial, we will use mixed models (normally distributed variables) and generalized estimating equation analysis (count / binary outcomes) to examine longitudinal differences in outcomes between conditions.