Text Message Intervention for Alcohol Use and Sexual Violence in College Students

NCT05065918

June 29, 2023

Study Protocol

A randonmized control trial to assess the full trial protocol and to generate estimates of multi-target intervention efficacy compared to an alcohol use reduction TM intervention. This aim will also explore gender and SV exposure as potential moderators of the intervention's effects.

Scientific Premise: Data from Aim 2 student participants will be used to systematically review message content and decision trees by the mentorship team and SAG. Study procedures will also be reviewed and revised using data obtained from campus faculty/staff during Aim 2. The pilot randomized trial will examine the potential efficacy of the multi-target TM-delivered intervention among college students seeking care from campus health centers. We will also begin to explore two hypotheses, that the multi-target intervention will show: 1) greater decrease in alcohol use than the alcohol use reduction condition and 2) greater increase in the use of SV harm reduction behaviors than the alcohol use reduction control condition. Intermediate outcomes of SV harm reduction behavior knowledge and self-efficacy will also be assessed. Exploratory analysis will be conducted to examine potential moderation effects of gender and SV history on the intervention's effectiveness. To achieve this aim, we will recruit 200 students from campus health centers. Findings from this aim will inform an R01-scale RCT of the multi-target TM intervention. Following intervention completion, a sub-group of participants will be invited to participate in semi-structured interviews to elicit feedback on their experiences participating in the intervention.

Setting: This phase of the intervention will continue to build on existing relationships from Dr. Miller's campus health center work (See stakeholder letter of support). Student recruitment, eligibility requirements, screening and consent procedures will be as described in Aim 2 (the addition of recruitment sites will be used, as needed, to achieve the proposed sample size). Eligible students will complete baseline measures and be randomized via computer to the intervention (multi-target SV/alcohol use messaging) or control (alcohol use reduction messaging alone) condition. To examine potential moderators of intervention effect, stratified randomization will be used to ensure an equal distribution of students by gender and SV history.

Intervention condition: The multi-target intervention will use a similar model to the alcohol use reduction intervention developed by Dr. Suffoletto.13-15 Students will be: 1) queried via TM prior to planned drinking days regarding both alcohol use and SV harm reduction goal setting; 2) provided with goal reminders during drinking period; and 3) assessed for goal attainment and given feedback following drinking episodes. Message library tailoring based on gender and prior SV victimization is anticipated, and will be developed and modified with feedback obtained during Aim 1 focus groups and from the SAG. Gender-based tailoring will likely include addressing risks/fears that are associated with or specific to different sex/gender categories (e.g. risk of pregnancy for women, fear of being accused of SV among men, gender-specific statistics). Development of gender neutral bystander intervention, help seeking, and harm reduction behavior language is anticipated. Prior SV victimization tailoring is anticipated to include messaging regarding coping with trauma and sharing of campus and community resources, while SV perpetration history tailoring will remain focused on universal

education regarding consent, and risk reduction techniques such as alcohol use reduction and use of social support mechanisms to monitor behavior while drinking (e.g. planning with friends how the group will get home after a night out).

Control condition: The control condition will be the TM-delivered alcohol use reduction intervention developed by Dr. Suffoletto.13-15 This intervention has been tested in young adults (age 18-25) recruited from Emergency Department and college settings, and will be used to provide an attention control group for efficacy testing. Prior to typical drinking occasions, individuals planning a drinking event are prompted to consider committing to a drinking limit goal, i.e.: "Would you be willing to set a goal to drink less than X drinks when drinking?". Based on willingness to commit to the goal, a feedback message is provided. During typical drinking periods, individuals receive a goal reminder. The following day, the program provides goal success/failure feedback or drinking quantity feedback. For example, those occasions where an individual committed to a drinking limit goal triggers either messages to reinforce goal successes or reframe goal failures. When an individual did not commit to a drink limit goal, they are provided feedback based on alcohol quantity (e.g. abstinence feedback, high risk drinking feedback).

Sample, data collection, and measures: Inclusion criteria, data collection time periods and measures for the efficacy pilot will occur as detailed in the Aim 2 feasibility pilot, with the addition of a third time point three months following the end of the intervention (T3).

Analysis: Assessment of the full trial protocol will be conducted using descriptive statistics, including proportion of those recruited who are willing to be randomized, proportion adherent to the intervention and control treatments, and proportion who are retained three months post-intervention. These estimates will be crucial to design and success of a larger R01-scale study. In addition to descriptively assessing the full RCT protocol, we will conduct analyses of the specified exploratory outcomes, which serve as the basis for the full-scale study. Each exploratory outcome: 1) number of drinking days per month, 2) number of binge drinking days per month, 3) use of SV harm reduction strategies, 4) knowledge of sexual violence and alcohol risk, 5) self-efficacy to obtain sexual consent, and, will be tested for differences between the intervention and control conditions at T2 and T3 using generalized linear modeling. All models will be adjusted for age, SV history, and gender. Imbalances between groups on additional baseline characteristics (e.g., relationship status, residence, other substance use) will be assessed, and if differences are noted, variables will be included in multivariable models. Following intention-to-treat principles, analyses will be conducted on all who were randomized to a condition regardless of degree to which they interacted with the intervention. The estimates found in these analyses, including baseline prevalence estimates and confidence intervals, will be used as the basis for sample size considerations in a larger R01-scale study. Due to the small sample size of this pilot study, we do not expect to be powered at $\propto$ of 0.05, and will thus consider interactions terms at $p<0.2$ worth exploring in stratified analyses. To assess the impact of missing data, we will compare the primary models (maximum likelihood) to full information maximum likelihood models; differences in results between the two models will be described. Participation biases and attrition analyses will be completed to inform future study design. The

effect sizes calculated from these data will be used to estimate sample size needed for each outcome at of 0.2 and two-sided ∝ of 0.05 for subsequent study.

Sample size considerations: Assessing 70 students per arm (total n=140) that have completed the program and follow up would provide sufficient data on the full RCT protocol across multiple campuses as well as estimates of intervention effects. Assuming a conservative retention rate of 70% for the three-month post-intervention follow up, we would need to enroll 200 participants at baseline. While we do not anticipate having sufficient power in this pilot to detect statistically and clinically significant results, preliminary sample size calculations for each outcome of interest is provided in the Statistical Design and Power attachment.