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

NCT05065918

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STATISTICAL DESIGN AND POWER

Aim 3: Conduct a pilot randomized 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.

Exploratory Hypotheses: The multi-target intervention will result in: a) greater decrease in alcohol use, and b) greater increase in the use of SV harm reduction behaviors, when compared to the alcohol use reduction condition

Primary Outcomes:

1) number of drinking days per month,
2) number of binge drinking days per month,
3) use of SV harm reduction strategies,

Secondary (Intermediate) Outcomes:

4) knowledge of SV harm reduction behaviors,
5) self-efficacy to use SV harm reduction behaviors

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 adherence 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, will be used as the basis for sample size considerations in a larger R01-scale study. 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 $\beta = 0.2$ and two-sided $\propto = 0.05$ 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 to detect statistically and clinically significant results, we have provided preliminary sample size calculations for our outcomes of interest. We estimated within-subject correlations to be between 0.2 and 0.6 between baseline and follow-up assessments.

Alcohol use (Number of drinking days, number of binge drinking days): Assuming a within-person correlation of 0.4 in alcohol use between baseline and follow up assessment, analyzing 70 students per arm (total n=140) would provide 80% power at $\propto$=0.05 to detect a standardized difference of 0.395 between intervention and control. This translates to a 2-day greater reduction (SD=5.1 days) in number of drinking days in the past 30 days compared to a reduction seen with the control arm program. Given initials results of the control arm program, this would bring the total change needed to 3 fewer drinking days in the past 30 days from baseline

(150% greater efficacy compared to control program messaging). Assuming a 1-day greater decrease is possible with this intervention (2 days overall), 410 participants would need to be enrolled per arm (820 total), given 30% attrition.

SV Harm Reduction Strategy Use: Estimating a baseline prevalence of using at least one strategy at 25%, We believe a meaningful increase in any use is 30%. To achieve 80% power at an $\propto$=0.05, and assuming a within-subject correlation of 0.4 between baseline and follow-up assessment, we would need 876 participants in each arm at follow-up; with 30% attrition, we would need to enroll over 2,500 total participants, at baseline. This sample sizes, however, are beyond the scope of the project. We believe enrolling 200 at baseline is feasible, providing 80% power at $\propto$=0.05 to detect a 75% increase in any use of SV harm reduction strategies after accounting for attrition.

References

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2. Strauss A. *Qualitative Analysis for Social Scientists.* New York: Cambridge University Press; 1987.
3. Crabtree B MW. *Doing qualitative research.* 2 ed. Thousand Oaks, CA: Sage Publications; 1999.