Cover Page

Type of Document: Statistical Analysis Plan

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

NCT number: Not yet assigned

Date of document: 04-27-2023

Statistical Analysis Plan

Given the rigorous retention strategies outlined in the Approach, a conservative expectation of 90% retention at the 1-week follow-up and 75% original sample retention for the 9-month EDD would result in 405 participants with B-SAVE outcome scores (135 per treatment group) and 336 participants with B-SAVE outcome scores and weekly EDD measures (112 per treatment group). The extensive baseline measures, high retention for the B-SAVE, and the weekly EDD design will provide a trove of information for all subjects, including those that may not contribute data to all follow-up measures. The richness of the observed data, even for those with some missing data across the nine months of follow-up, will increase the accuracy of a multiple imputation strategy for any missing data to preserve as many participants as possible for the Intention-to-Treat analysis framework. Multivariate imputation via chained equations (MICE)1 will be used to impute missing data on both predictors and outcome variables.

A unified statistical modeling framework will be employed to compare intervention groups on both BSAVE bystander scores and weekly EDD scores. All models will be estimated using the latent variable modeling software Mplus.2 Multigroup structural equation modeling (MG-SEM) will be used to explicitly test for differences in bystander intervention effectiveness between the MTB and attention control condition, and between MTB and MTB+ALC treatment groups. The outcomes will be intervention effectiveness scores coded from B-SAVE, burst-level aggregate scores of intervention effectiveness derived from coding the EDD bystander behaviors, and burst-level aggregate scores of alcohol use. We will also utilize the multigroup modeling approach with dynamic SEM (DSEM), a method for modeling intensive repeated measures (e.g., daily measures within each weekly EDD) in an SEM framework via Mplus. We will embed the weekly EDD DSEM into an MG-SEM to disaggregate within- and between-person effects of alcohol use proximal to bystander behaviors. This combined model will enable the use of random effects in the DSEM portion of the model as potential outcomes as well as sequential mediators. This full model will allow us to explicitly test if changes in alcohol use proximal to risky sexual situations account for differences in bystander behaviors. The model can be extended to compare the trajectory of bystander intervention effectiveness and the effects of alcohol use on bystander behaviors across the three treatment groups.

Analyses of pilot data suggest MTB is associated with improved bystander attitudes and likelihood to intervene with large effect sizes, with a Cohen's f of approximately 0.58 compared to attention control condition, which falls above the threshold large effect size under conventional rules of thumb (large effect = 0.40). Considering a more conservative expected medium effect size of f = 0.25 and 75% attrition by the 9-month follow-up (N=112 per group), the statistical power is over 0.80 to detect a mean difference between two groups (i.e., attention control vs. MTB, Aim 1) and over 0.90 to detect a mean difference among three groups (attention control vs. MTB vs. MTB+ALC, Aim 2). Greater retention and multiple imputation of missing data would be expected to further increase power in groupwise comparisons. Power calculations of the Sobel test for a sample of N = 336 were conducted for the indirect effect of MTB+ALC on bystander behaviors via reduction of alcohol use (vs. to MTB and attention control). Assuming a small effect size, the indirect effect would account for approximately 5.5% of the variance in the bystander outcomes (R2ab = 0.055). With a sample of 336 individuals, there is over 0.80 power to detect such an indirect effect. It is difficult to ascertain the power of an intensive longitudinal sequential mediation effect of the random effects in a multilevel DSEM, but one would expect that advanced modeling strategies would increase both the flexibility in the types of group comparisons that will be tested and the power to detect effects with a model that is more reflective of the complex data-generating process.