Statistical Analysis Plan

Timing Personalized Feedback After Alcohol Health Education (TIME)

NCT04453007

11/13/2020

Statistical Analysis Plan

Prior to hypothesis testing, the data will be examined for normality and outliers. Histograms and values for skewness and kurtosis will be examined. Positively skewed variables will be natural log transformed, unless paired with an excessive number of zeroes. If there are an excess of zeroes in an outcome, the variable will be dichotomized if other values are not well represented, or appropriate modeling techniques will be used (e.g., hurdle models) if other values are well represented. Boxplots will be used to check for outliers. Extreme values will be winsorized (i.e., cases retained in the sample, but values made less extreme). Cases with missing data will be compared to complete cases across major study variables to identify if there are systematic differences in missingess. If significant associations are identified, these variables will be used as covariates in later analyses.

To address the major aim of the study, the data will be analyzed using latent growth models within a structural equation modeling framework. Separate models will be conducted for each alcohol outcome: alcohol consumption (e.g., quantity), and alcohol-related problems. It is not known the exact trajectory across time (baseline, 1 month, 3 months, 6 months, 9 months), so a few models will be compared to identify which best captures the shape of change over time. A simple model that reflects change to 1 month (slope 1; initial change post-intervention) and longer-term maintenance (slope 2; linear growth to 9 months) will be compared to models with additional piecewise slopes or curvilinear components in case longer-term maintenance is not a linear process. Study condition (6 groups) will be dummy coded across 5 variables with "no booster" as the category of reference, and will serve as a predictor of each latent variable (latent intercept, each slope). All models will be conducted using maximum likelihood estimation, and will control for gender. The model for problems will also control for alcohol quantity.

Given prior findings that emailed booster feedback containing personalized normative feedback and protective behavioral strategies (PBS) was significantly more effective for select groups (i.e., those lower in PBS use [Braitman & Henson, 2016], legal age drinkers [Braitman & Lau-Barraco, 2018]), we will examine potential moderators of booster efficacy as a supplementary exploratory analysis. Legal drinking status by age (coded as 1 = *age 21-24* [legal], 0 = *age 18-20* [underage]) and baseline PBS use (in its original continuous metric) will be explored as potential moderators. For each outcome, two additional models will be conducted (one for each moderator). The moderator will be added as a predictor of each latent factor (latent intercept, slope 1, and slope 2). Multiple interactions terms will be created to capture the interaction with condition (dummy coded across 5 variables). These interaction terms will also be included as predictors of each latent factor. Thus, the outcome at baseline and change over time will be predicted by condition, the moderator, and the interaction between the two, controlling for relevant covariates.

References:

Braitman, A. L., & Henson, J. M. (2016). Personalized boosters for a computerized intervention targeting college drinking: The influence of protective behavioral strategies. *Journal of American College Health*, *64*(7), 509-519. http://doi.org/10.1080/07448481.2016.1185725

Braitman, A. L., & Lau-Barraco, C. (2018). Personalized boosters after a computerized intervention targeting college drinking: A randomized controlled trial. *Alcoholism: Clinical and Experimental Research*, *42*(9), 1735-1747. http://doi.org/10.1111/acer.13815