

Study Protocol and Statistical Analysis Plan

Official Title: Decisions During Drinking: Phase 3 Feasibility Study

NCT number: NCT06978140

Unique Protocol ID: STUDY00021311

Date: 9.14.2026

Objectives: Assess the feasibility, acceptability, and preliminary effects of an online brief intervention titled *Decisions During Drinking (D3)* that aimed to reduce alcohol-related consequences in young adults by increasing awareness of personal cues and building skills to address those cues through adaptive approaches.

Procedures: Participants were recruited through social media advertisements on Instagram, Facebook, and Reddit. Interested individuals were directed to the consent form followed by a brief screener. Initial eligibility included: 1) 18-24 years old, 2) lived in Washington State, 3) ≥ 3 past-month alcohol-related consequences on the Rutgers Alcohol Problems Index (White & Labouvie, 1989), 4) ≥ 1 past-month heavy episodic drinking and 5) indicated they wanted to change their drinking experiences. Participants who reported a peak blood alcohol content level of .30 or higher were excluded. Participants were reviewed and scheduled for an identification verification over Zoom (see Hultgren, Guttmanova, et al., 2022). A flag system was used to remove possible fraudulent responses; individuals who had two or more flags were excluded. The flags were regularly updated if additional information to indicate fraud was learned. Verified participants were sent the link to the baseline survey (~25 minutes), which included questions about alcohol use, expectancies, motives, and more comprehensive questions on consequences. Participants received \$20 to complete the baseline and were randomized to receive the D3 Intervention or Assessment only Control (AOC). Randomization was conducted using URN randomization where participants were stratified by sex at birth and college status (i.e. enrolled in 4-year university vs not enrolled in 4 year university). The intervention group could receive 5-7 modules over the course of 30 days. The intervention group also received 1-2 booster text messages after each module. At the completion of the last module, or if incomplete on day 37, participants were invited to the post-assessment which included a limited number of alcohol-related items and items assessing acceptability and satisfaction of either the intervention, for the intervention group, or the survey items, for AOC. All participants were invited to complete a 1-month follow-up which included items similar to baseline. Participants received \$35 and \$50 for completing post-assessment and 1 month follow-up, respectively. All procedures received approval from the university's Institutional Review Board.

Primary outcomes:

1. *Usability of the intervention.* Assessed using the System Usability Scale among the intervention group at post assessment (i.e. immediately after the completion of the intervention). Score of 70 or higher indicates high level of usability.

2. *Acceptability of the intervention.* Assessed using 11 items in the intervention group at post assessment. Items with an average of 4.5 or higher were deemed acceptable.
3. *Feasibility of the intervention.* Assessed by the percentage of participants randomized to the intervention that complete the intervention and the 1 month follow-up assessment

Secondary outcomes:

1. *Alcohol consumption.* Measured in typical weekly drinks by the Daily Drinking Questionnaire at baseline and 1 month follow up.
2. *Alcohol related consequences.* Measured at baseline and 1 month follow up by 49 items from several alcohol consequences scales including the Rutgers Alcohol Problems Index, Young Adult Alcohol Problems Scale, and the Alcohol-Related Sexual Consequences. All questions except the Alcohol-Related Sexual Consequences are answered on a scale of 0 "Never" to 4 "More than 10 times". Alcohol-Related Sexual Consequences responses are 0 "No" and 1 "Yes" to indicate any occurrence in the past month.

Statistical Analysis Plan:

- To assess usability, the mean of the usability score was compared to the cut off 70.
- To assess acceptability the mean of the 11 items were compared to the 4.5 cutoff.
- To assess feasibility the percentage of the individuals in the intervention retained at 1 month follow up was compared to the cut off of 70%
- To assess preliminary effects of the intervention, negative binomial regression models examined group differences in the number of alcohol-related consequences and typical weekly drinks at 1-month follow-up. Separate models were implemented for each outcome. Negative binomial models were selected due to the presence of count data with overdispersion. Each model included the corresponding centered baseline value (i.e., number of drinks or alcohol-related consequences) as a covariate to adjust for baseline differences. Model estimates were exponentiated to support interpretation as incidence rate ratios (IRRs), with $IRR < 1$ indicating fewer consequences/drinks in the intervention group relative to control. Due to the pilot nature of the study and small sample size, results were utilized to examine potential signal of effects rather than significant *p*-values.