Official Title: Personalized Mobile Phone App Intervention: Challenging Alcohol Expectancies to Reduce High-risk Alcohol Use and Consequences

NCT number: NCT04213846

Document Date: May 24, 2024

STUDY PROTOCOL

The purpose of the study is to develop and test a smartphone/mobile app intervention to target high-risk alcohol use among young adult college students. The intervention incorporates three weeks of ecological momentary assessment (EMA, i.e., two brief surveys per day) and daily intervention messaging (2 messages per day). The intervention content mainly focuses on alcohol expectancies, alcohol use, and consequences and how these constructs are interrelated and includes personalized intervention messages based on participants' own event-level alcohol expectancies and experiences. Other psycho-educational alcohol-related content is also provided over the course of the three-week intervention.

The study design is a randomized clinical trial; participants are randomized to either the intervention condition or to an assessment-only condition. All participants completed an online or in-person informational/training session, an online baseline assessment, twice-daily surveys for 21 days, and online 1-month, 6-month, and 12-month follow-up assessments with additional twice-daily surveys for 14 days at each follow-up period.

College students were recruited from registrar's lists from three college campuses in the Seattle metropolitan area (i.e., two community colleges and one 4-year university) and sent initial information about the study via US mail. Students also received an email with an invitation to participate in an online screening survey to determine eligibility for the larger study. For those who went to the screening survey, they were first presented with an information statement and asked to electronically consent to participation.

To supplement these methods, recruitment also took place through social media, newspaper and other online advertisements and flyers posted around local colleges and nearby businesses. Interested individuals were directed to the study website to review an information statement and participate in a brief survey to obtain contact information and initial screening items. Participants who met initial criteria were contacted by study staff to verify their identity before proceeding to the full study screening process.

Participants who met eligibility criteria on the screening survey were presented with an information statement for the full longitudinal study. Upon providing electronic consent, participants completed a 30-35 minute baseline assessment. At the completion of the baseline survey, students were asked to schedule a training session conducted either in-person or virtually via Zoom. Prior to the training session, participants were randomized to one of two conditions (i.e., intervention condition or assessment-only control condition) by computer algorithm and stratified on biological sex, typical drinks per week, and college status. During the training session, participants were shown a PowerPoint presentation to aid in a discussion of the EMA survey process and study procedures, had the opportunity to ask study staff questions, and installed the web-based application on their mobile phone. Participants randomized to intervention condition had the capabilities within the app for EMA data collection and for viewing intervention content, whereas those randomized to the control condition only had the ability to utilize the app for EMA data collection. After completing the training session, participants were considered enrolled in the study.

The day after the training session, participants in both conditions completed twice daily surveys in the mobile app for 21 days. Morning assessments could be completed between 8am and 1pm. Afternoon assessments could be completed between 3pm and 7pm. Participants in the intervention condition also received intervention messages twice a day (timed to occur after completion of the assessment or generated at 1pm and 7pm, whichever was sooner).

Participants were asked to completed online follow-up assessments at 1-, 6-, and 12-months post-intervention. Follow-up assessments include both an online survey and 14 days of twice-daily EMA assessments. Participants received follow-up calls, emails, and text messages at each follow-up assessment.

Participants were compensated with Amazon.com eGift cards for completion of surveys with a total compensation of up to $435 if they completed all assessments. Participants received $20 for the Screening survey, $25 for the Baseline survey, $2 for each completed Daily EMA survey (2x/day for 21 days after baseline survey) with $84 possible, $20 for the 1-month follow-up survey, $30 for the 6-month follow-up survey, and $35 for the 12-month follow-up survey. Follow-up daily EMA assessments were compensated at the rate of $2 for each completed assessment (2x/day for each 14 days period) with total $168 possible. A bonus of $7 per week during the EMA periods was also received if 12/14 surveys are completed each week with $63 possible across the study period.