Official Title: Development and Preliminary Examination of Two Brief Personalized Feedback Interventions Focused on Lab-based and EMA Alcohol Cues to Reduce Hazardous Young Adult Alcohol Use

Brief Title: Testing Brief Personalized Feedback Integrating Lab-based Alcohol Cue Information (Project ACE)

NCT number: NCT05873556

Document date: February 15, 2025

STUDY PROTOCOL

Given the role of cue reactivity in eliciting alcohol-related cravings that can lead to increased alcohol use, the current study develops and tests a novel intervention strategy that may ultimately increase the strength of Personalized Feedback Intervention (PFI) effects to reduce young adult alcohol misuse. We developed a novel Cue Reactivity PFI based on an *in vivo* cue reactivity session that includes personalized feedback regarding the extent to which young adults' desire to drink varied in response to an alcohol cue (i.e., alcoholic beverage of their choice) presented during a lab session. We anticipate that this feedback will increase young adults' awareness of their drinking, consequences, and cues that may increase their desire to drink. The intervention aims to equip young adults with strategies for reducing exposure to factors that increase their desire to drink, how to cope with an increased desire to drink, and how to reduce potential harms from drinking.

The study design is a randomized clinical trial that includes an in-person *in vivo* cue reactivity session at the study office and online baseline, 2-week, and 3-month surveys. Participants are randomized to either a PFI condition or an assessment-only condition. The study tests initial development of the PFI intervention, which is in the form of personalized feedback and is delivered online to the intervention group. All participants complete the cue reactivity session and baseline, 2-week and 3-month surveys.

Individuals who agreed to participate in the screening survey (Information Statement presented) and who were eligible based on the screening survey were contacted by research staff to verify their identity (e.g., name, date of birth). Participants were then sent a link to complete the informed consent process (Consent Form) and baseline survey. In the baseline survey, participants identified their preferred beverage from a list of alcoholic beverages that are commonly consumed by young adults and that cover a range of alcohol types (e.g., beer, wine). After participants completed the baseline survey, they were scheduled for an in-person *in vivo* cue reactivity session with a research staff member.

All participants complete the lab-based cue reactivity protocol that involves an *in vivo* alcohol cue exposure task. At the start of the lab session, participants were randomized to either a cue reactivity PFI condition or assessment-only condition. In the lab session, participants first confirmed their identity by showing either a drivers license or ID card. To enhance the personalization of the cues, the cue reactivity protocol for each participant involves exposure to their preferred alcoholic beverage. During the lab session, participants complete a series of questionnaires, both before and after the cue exposure. Participants undergo a 3-minute block in which they are instructed (by audio delivered via headphones) to hold and smell a glass of their preferred alcoholic beverage. Participants follow the audio-taped instructions about picking up and smelling the beverage.

After the cue reactivity protocol, participants in the control condition complete several additional questionnaires to increase comparability of session time. Participants in the PFI condition view the online personalized feedback and complete a brief survey to assess reactions to their feedback. Intervention participants are also emailed a link to their personalized feedback so the participant can view it again after the lab session. The personalized feedback consists of pre-programmed content viewable on either a computer or mobile phone. The personalized feedback uses participants' responses from the baseline survey and from the lab-based cue reactivity protocol. The aim of the intervention is to increase young adults' awareness of how alcohol cues may affect their desire to drink, mood, willingness to drink, and alcohol demand both in relation to lab-based exposure to an alcohol beverage of their choice and also more broadly in everyday life.