UNIVERSITY OF WASHINGTON
Lab CONSENT FORM
Project ACE

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

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RESEARCHER'S STATEMENT

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent."

PURPOSE OF THE STUDY

The purpose of this study is to conduct a randomized clinical trial that tests the effect of an online personalized feedback intervention that contains information about participants' own drinking behaviors, alcohol-related cues, desire to drink, and mood. To do so, we ask all young adults to come into our lab to view and smell an alcoholic beverage and report on their experiences so we can better understand how exposure to alcohol cues affects young adults. Participants in the study will be randomly assigned (like rolling a dice or flipping a coin) to a condition in which they receive an online personalized feedback intervention or a condition where they do not receive this feedback intervention.

STUDY PROCEDURES

Participation in this research is completely voluntary and confidential. If you decide to participate in this study, you could earn up to $100 in electronic Amazon.com gift cards. Details about the study are described below.

- You will complete an online baseline survey that takes 30-45 minutes to complete. This survey includes a number of questions about your personality and health behaviors like alcohol use. For example, we will ask you about the number of negative consequences you've experienced because of your alcohol use in the past 3 months. Some questions may reveal illegal activities around drug and alcohol usage.
- You will come to our lab (located on the University of Washington, Seattle campus in the Health Sciences Building) for a single visit lasting approximately 30-45 minutes ($40 electronic Amazon.com gift card upon completion). During this visit we will ask you to view and smell an alcoholic beverage in addition to completing a number of survey questions. You will not be permitted to consume any alcohol presented. While viewing and smelling the alcoholic beverage, research staff will observe you from another room via camera; however, neither audio nor video from this camera will be recorded.
- You will complete a 2-week online follow-up survey ($30 electronic Amazon.com gift card upon completion).
- You will complete a 3-month online follow-up survey ($30 electronic Amazon.com gift card upon completion).
- Payment for the 2-week, and 3-month surveys is expected to occur within 3-5 business days of completion for each survey. Payment after the lab session is expected to occur within 3-5 business days of completing this visit.
- In total, you can earn up to $100 in electronic Amazon gift cards for completing all elements of the entire study.
- Some participants will be randomly assigned (like rolling a dice or flipping a coin) to receive an online personalized feedback intervention that contains information about their own drinking behaviors, alcohol-related cues, desire to drink, and mood as reported during the lab visit. Other participants will be randomly assigned to a condition that includes the lab session, but does not include the online personalized feedback intervention. Participants that are randomly assigned to receive the personalized feedback will also be asked to complete a very brief survey so that we can see if participants found the feedback to be helpful.
- Following completion of all study elements, all participants will be provided with a resource list for services intended to provide support for substance-related issues as well as general counseling resources to help with mood management, stress, anxiety, or other life challenges. This list will also be available upon request for all participants prior to completing all study elements.

Some of the most personal and/or sensitive questions in the surveys include:

- During the past week how difficult would it have been to resist taking a drink if you had known a bottle were in your house?
- How willing would you be to drink something when you are unsure of how much alcohol is in it?
- Have you ever used Hallucinogens (PCP, LSD, mushrooms, peyote, mescaline, etc.)?

Please click "Next" to confirm you have read the information above.

RISKS, STRESS, OR DISCOMFORT

The risks associated with participation in this study are primarily related to the loss of privacy and unintentional release of private information. This could occur if data from a participant, or the information that he or she was participating in a study of alcohol use, were to be released to anyone outside the study. Should the data be breached, this could potentially include parents, friends, current or future teachers, and current or future employers being aware of a participant's reported alcohol use or illegal drug usage, which could result in negative consequences. For example, a future employer could hold this information against you when making a hiring decision about you. These risks are unlikely and have not occurred with this study team in the many years that our research team has been doing research at UW. We, the research team, will do our best to protect your confidentiality, but we cannot guarantee it. Additionally, the potentially sensitive nature of some of the survey questions may make you feel uncomfortable or feel as if you should share information you may not want to share. We will review survey responses and may contact you by email or telephone if we become concerned about your alcohol use and inform you about the risks of alcohol and services available on campus or in the local community.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to participate in the study but have questions about alcohol, or other psychological issues, we can provide you with a list of information and referrals within the community.

BENEFITS OF THE STUDY

There may be no direct benefit to you for participating in this research. However, it's possible that reporting on your drinking behavior and desire to drink in the study may help you increase your own awareness of these behaviors and feelings. Also, if you're randomly selected to receive personalized feedback, it may help you to better understand your drinking desires and related experiences. Benefits to society include the evaluation and testing of a personalized feedback intervention that may (or may not) be beneficial for young adults interested in reducing their alcohol use or consequences. We have no plans to provide research study findings directly to participants; however, if you are interested you can contact the research team to request access to future publications that result from this study.

SOURCE OF FUNDING

The study team is receiving financial support from the National Institutes of Health (NIH).

Please click "Next" to confirm you have read the information above.

CONFIDENTIALITY OF RESEARCH INFORMATION

We have taken steps to protect you from the risks mentioned above. Identifying information such as names or contact information will not be stored with other data including items regarding substance use. Your name and contact information will be accessible to research staff for the purpose of contacting you in regard to study participation and will be stored on computers with password protection. We will retain your name and contact information until the end of the records retention period required by state law, after which all identifying information will be destroyed.

Participation in this research is voluntary, and you are free to not answer any survey questions you do not want to answer or to stop participating at any time without any penalty or loss of benefits. All of the information collected from the online surveys will be kept confidential to the best of our abilities. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. In addition, government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your data may be examined. The reviewers will protect your privacy. The study data will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institute Institutes of Health (NIH). The Certificate helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you

even if we are asked to by a court of law. We will use the Certificate to resist any requests for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the federal government who needs it in order to evaluate the research
- Individuals at the University of Washington, NIH, and other groups involved in the research, if they need the information to make sure the research is being done correctly
- The federal Food and Drug Administration (FDA), if required by the FDA
- Individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form
- Proper authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is 08/31/2023. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

Please click "Next" to confirm you have read the information above.

OTHER INFORMATION

This study meets the definition of a "clinical trial," which refers to a type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the intervention on a health condition. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Research staff may also withdraw or exclude you from participating in the study at any point for any reason. If you become concerned about your alcohol use, or experience discomfort as a result of participation, you can contact one of the investigators listed above to discuss this and receive a list of resources. In addition, you are free to participate in other substance-related programs such as support groups, treatment, therapy, etc. while involved in the study.

FUTURE STUDIES

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

Please click "Next" to confirm you have read the information above.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can contact Florence Williams, Project Research Coordinator, at fwilli2@uw.edu. In the event of research-related injury, I can contact Jason Ramirez, Principal Investigator, at jjramirz@uw.edu, or Anne Fairlie, Principal Investigator, at afairlie@uw.edu. If I have questions about my rights as a research participant, I can call the Human Subjects Division at (206) 543-0098. I have the option to download a copy of this form for my records by clicking here [insert pdf link here].

- ○ I have read this consent form, and I volunteer to participate in this study.
- ○ I do NOT want to participate in this study.