**BROWN UNIVERSITY A-FRAME RCT CONSENT FORM**

**Consent Form Created:** 03/30/2024

**Official Title:** Daily personalized drinking feedback delivered via mobile phone

**Brief Title:** Alcohol Feedback, Reflection and Morning Evaluation (A-FRAME): Randomized Trial

**NCT number:** NCT05509218

**Date Consent Approved by IRB:** 05/30/2024

**BROWN UNIVERSITY**
**CONSENT FOR RESEARCH PARTICIPATION**

**Alcohol Feedback, Reflection and Morning Evaluation (A-FRAME)**
**Randomized Trial**
Version 2, 03/30/2024

**KEY INFORMATION**:
You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: The study is designed to further develop and test a program involving mobile delivery of personalized feedback sent to drinkers the morning after alcohol use. You are being asked to be in this study because you are between age 18 and 29 and endorsed recent alcohol use.
- PROCEDURES: After providing informed consent, you will be asked to complete a baseline questionnaire assessing your personal characteristics, alcohol use, and other substance use (less than 40 minutes). Then, you will be informed of your random assignment to one of three groups; each group will provide valuable information for this study. Two groups will be randomly assigned to complete one brief survey each morning on their smartphone for 28 days. When reporting drinking the day before, an electronic feedback report will be delivered to your phone, and you will be asked to review it. You will also receive a summary feedback report once in the middle and once at the end of the 28-day period. Participants selected to complete daily surveys and receive feedback will take part in an orientation session to learn more about these additional study procedures. Half of participants randomly assigned to the daily survey/feedback groups will be randomly selected to receive $1 per day for completing their daily surveys. Participants in all three groups will complete two 30-minute follow-up surveys, one month and 4 months after baseline.
- TIME INVOLVED: Participation will span four months. The study will involve (1) 60-90 minutes to complete a baseline questionnaire and study orientation, and (2) two 30-minute surveys 1 month and 4 months later. Some participants will be randomly assigned to complete 28 days of daily surveys and feedback reports (between 1 and 10 minutes per day).
- COMPENSATION: All participants will receive $30 for completing the baseline survey and orientation session, $35 for the 1- month survey, and $45 for the 4-month survey. The participants who are randomly selected to be paid $1 per day for completing daily surveys can receive up to an additional $28 during the 28-day period. The most participants in this group can receive for participation is $138.
- RISKS: It is possible that answering questions and reading the personalized feedback in this study could cause some discomfort.
- BENEFITS: You may not receive any direct benefits from this study. However, you will be contributing to research that may lead to better programs for young adults who use alcohol.

1. **Researcher:**

Jennifer Merrill, Ph.D., Associate Professor, Center for Alcohol and Addiction Studies, Brown University, Jennifer_Merrill@brown.edu

2. **What is this study about?**

You were selected for this study because you are age 18-29, and drink alcohol. The purpose of this study is to test and receive feedback on a mobile intervention that involves repeated, personalized feedback based on recent drinking events.

## 3. What will I be asked to do?

Overview of Procedures. After providing informed consent, you will be asked to complete a baseline questionnaire (~30 minutes). Then, you will be informed of your random assignment (determined by a procedure that is like the flip of a coin) to one of three groups; each group will provide valuable information for this study. Procedures applicable to each of the 3 groups are shown in the table below. Across groups, all participants will complete two 30-minute follow-up surveys, 1 month and 4 months later. Participants randomly assigned to Groups 1 and 2 will also complete one brief survey each morning on their smartphone for 28 days and will receive feedback about their drinking periodically. Participants randomly assigned to Groups 1 and 2 will take part in an orientation session to learn more about these additional study procedures.

| | **Group** | | |
|---|---|---|---|
| **Procedures** | 1 | 2 | 3 |
| Baseline and follow ups? | Yes | Yes | Yes |
| Orientation session? | Yes | Yes | No |
| Daily surveys? | Yes | Yes | No |
| Personalized report? | Yes | Yes | No |
| Pay for daily surveys? | Yes | No | n/a |
| Maximum compensation | $138 | $110 | $110 |

Baseline Survey. After reading this form, if you agree to participate, you will be asked to complete a baseline survey on your own computer or phone. This survey will ask basic questions about you (e.g., your age, gender) and your drinking behavior. If you are randomized to Group 1 or 2, you will be asked to set goals related to your drinking, such as maximum drinks you want to limit yourself to per drinking occasion; this information along with self-report behavior during the daily surveys will be referred to in personalized feedback reports. If you are randomized to Group 1 or 2, at the beginning of the baseline survey, you will be asked to enter a study password. We will retain a record of this password, which you will use to enter your daily surveys, in order to ensure that it is you that is accessing each survey.

Once you start the survey, you will be asked to provide a response to all questions. You have the right to refuse to complete the survey. However, answers to these questions are essential to the study goals. Therefore, an inability to answer these questions may affect your eligibility to participate in this study.

Orientation. If you are randomized to Group 1 or 2, you will be asked to complete an orientation session today on this Zoom call. It is possible this will be done in a group setting; however, we will honor requests to complete it individually. During the orientation, you will complete an example daily report. A research staff member will review this survey and an example feedback report with you. The staff person will explain study expectations (i.e., keep phone on and charged, have data or Wi-Fi on at all times, respond to as many morning surveys as possible), and answer any questions you may have. This orientation will take ~30 minutes.

Completing daily surveys. For 28 days, participants randomly assigned to Group 1 or 2 will be asked to complete a web-based survey prior to 6pm. A link to each survey will be sent via text message each day and you will be asked to complete this report as soon as you get up each morning. If you have not completed the survey, will send you a reminder via text message at noon, 3pm and 5:15pm. If at any point during the study you decide you do not want to receive your survey notifications via text message, you may email us at a-frame@brown.edu to let us know. However, inability to receive text messages from the study will impact your eligibility to continue.

Your password provided at baseline will be used to unlock all daily surveys. This survey will ask you to provide information about any previous day alcohol use. If you drank the previous day, you will be asked questions about your experiences, for example, the number of drinks you had, how much you spent on alcohol, consequences you experienced from your alcohol use, and strategies you used to avoid negative alcohol related consequences. If you did not drink, we will ask reasons for not drinking, current mood, and whether you used marijuana. Daily surveys should take no more than 3 minutes. When you start a daily survey, you will be asked to respond to all questions. If there is a question you do not want to answer, you can exit the report. However, answers to these questions are essential to the creation of your personalized feedback. Some of your feedback may involve a summary of what you report across days (e.g., drinks per week), and this information will not be accurate if you have not completed all daily surveys.

Reviewing personalized feedback reports. For participants randomly assigned to Group 1 or 2, on mornings that you report that you drank alcohol the prior day, after submitting your daily survey, you will receive a personalized feedback report that you will be asked to review. During each report you will be provided with the choice to receive feedback about your drinking, such as your blood alcohol concentration from the prior day and how your drinking compares to peers. Similar feedback reports, but that include a summary of your drinking across days, will be delivered at the midpoint and end of your 28 days of daily surveys. Data will automatically be collected on the time you receive and the time you finish reviewing the feedback report, as well as which topics you choose to view.

Follow-up surveys. At one month and four months after your baseline survey, participants in all groups will be asked to complete follow-up surveys. We will ask you to complete these surveys within one week of receiving them. These surveys will take approximately 30 minutes and will be completed remotely from your own computer or phone. Questions will be similar to those administered at baseline. At the 1-month follow-up, participants randomly selected for Groups 1 and 2 will answer additional questions about their experience in the study.

Additional contact. If needed, we may contact you during the study, by email or phone, to clarify answers to your surveys, or to follow up on your compliance with completing them.

4. **Will I be paid?**

All payments will be made in the form of electronic Amazon gift cards. You will receive $30 for the baseline survey, $35 for the 1-month survey, and $45 for the 4-month survey. As such, all participants can earn up to $110. Additionally, some participants will be randomly selected to be paid based on their compliance with the daily surveys. If selected for this condition, based on the number of surveys you complete, you can receive up to $7 each week during the 28-day period. The most participants in this randomly selected group can receive for participation is $138. If you end participation early, you will be paid for the parts of the study you completed.

**5. What are the risks?**

The risks in this study are minimal.

a. It is possible that answering questions and/or (for those randomly selected into Groups 1 or 2) reading the personalized feedback in this study might cause some discomfort. You do not have to answer any question that you do not feel comfortable answering. While many questions will be required for us to create your personalized feedback, you can exit out of the survey at any time. You may withdraw from the study at any time without penalty. In the event that participation in this study triggers the desire to further discuss your health behaviors or other issues with a professional, a referral list containing contact information for resources will be provided to all participants in this study.
b. It is possible that a participant could be identified as being a part of our research study or that data could be breached. However, a breach of confidentiality is highly unlikely because the investigative team will strictly adhere to the guidelines for research outlined by the Brown University Institutional Review Board (IRB), Rhode Island State law, and the DHHS Federal Policy for the Protections of Human Subjects (45 CFR, Part 46). More information on how your information is protected is outlined below (section 7).
c. It is possible that questions about alcohol use on the daily survey will increase drinking. You do not have to consume alcohol at any time to receive any type of compensation in this study. You only need to submit your surveys, regardless of your drinking behavior.
d. You could get in trouble with your instructors/employers if you engage with the mobile platform during class or work. We ask that you complete the survey and view feedback reports in private (from home) first thing in the morning. We also ask that you put your phone on vibration mode if the 7am prompt for survey completion will occur during a time when it would be inappropriate to receive audible survey prompts.

**6. What are the benefits?**

You may not receive any direct benefits from this study. However, you will be contributing to research that may lead to better programs for other young adults who drink alcohol.

**7. How will my information be protected?**

All of the information you provide will be used strictly for research purposes. Any identifying data collected (e.g., name, email address, phone number) will be kept separate from your data, which will be linked only by a numeric code. The researchers will protect the privacy of the information you provide in the following ways:

(a) No information that could be used to identify you as a participant will be shared with other research programs, your university, or law enforcement agencies. Your name will not appear on any recordings, questionnaires, or forms. All data reported in publications or reports will be based on group responses, and

no individuals will be identified. All researchers are required to protect the confidentiality of the information you provide.

(b) Data, including the study password that you use to access your surveys, will be kept in a locked and/or password-protected file at the research office and will be kept separate from this signed document.

(c) For those participants who will complete surveys on their smartphone, we advise that you keep your smartphone protected with a password that you do not share with anyone. To further protect participant privacy, SMS texts for study surveys will include generic text (e.g., "complete a survey") and participants will be required to select and enter a password to access surveys (and therefore to receive feedback reports). No identifying information (such as name, date of birth, etc.) will be included in the feedback report.

(d) All identifying information (e.g., your name, email address) will be destroyed upon your completion in the study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you*, except as explained below.*

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers cannot use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of harm to yourself or anyone else or child and elder abuse.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

**8. What if I want to stop?**

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. If you refuse to participate in or leave the study, your current or future relationship with Brown University will not be affected.

**9. Who can I talk to if I have questions about this study?**

If you have any questions about your participation in this study, you can call Dr. Jennifer Merrill at 401-863-5165 or email jennifer_merrill@Brown.edu.

**10. Who can I talk to if I have questions about my rights as a participant?**

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

**11. Consent to Participate**

The entry of your name and today's date below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

____ I have read and understand this consent form, and I agree to participate

____ I do not wish to participate

First Name: _____
Last Name: _____

Date: _____