Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Mobile Health Reaction Time and Behavior Study
NCT06624514
Version Date: 1/21/2025
Principal Investigator: Dr. Austin Hahn

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to study the how completing tasks on a mobile device is related to behavior among women age 18+ who have experienced unwanted sexual experiences in the past. The app involves pushing and swiping up or down in response to images on a smartphone screen, including some depicting alcohol and condoms. You will be asked to complete a survey. If eligible, you will then be randomized to one of two groups. Each group will swipe up and down the same amount of time, but the content of the images that are swiped up and down may differ between the two randomized groups. This application is investigational and is not used as a standard treatment.

If you choose to participate, your participation will last approximately 100 days. First, you will complete an initial baseline questionnaire before completing any of the tasks. During the initial baseline questionnaire, you will answer questions about your alcohol and sexual history, including condom use. We will also ask questions about the way you think about things, past life experiences that may be related to your substance use, and questions about how you feel about reducing your substance use. Then, if you are eligible, you will complete a series of tasks where you will swipe up or down in response to images that are presented on a smartphone screen. The risks of this study include possible discomfort due to being asked sensitive questions and the possibility of loss of confidentiality. You may not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because you will be helping us to better understand associations between life experiences and health behaviors.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

The purpose of this research is to examine the relationship between reaction time and behavior using a task on mobile devices among adult women who report recent alcohol use, are not in an exclusive sexual relationship, and have experienced past unwanted sexual encounters. The task will instruct participants to swipe up or down in response to the format (i.e., portrait or landscape) of an image presented on a mobile screen. The images will depict pictures of alcohol and condoms. Please read this consent form carefully and take your time making your decision. As study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. The investigator in charge of this study is Dr. Austin Hahn. The study is being conducted by faculty in the Addiction Sciences Division at the Medical University of South Carolina. Forty-six women will take part in this study. Portions of the research team's salaries will be paid by this grant.

B. PROCEDURES

General Overview: You are eligible to participate if you are a woman age 18 or older who has used alcohol recently, are not in an exclusive sexual relationship, have engaged in unprotected sexual intercourse with a casual partner in the past three months, and have experienced past unwanted sexual encounters. If you agree to participate in this study, the following will happen:

You will complete a baseline survey. After staff has reviewed all the information collected, you will be informed of your eligibility status. If you are not found eligible and/or do not wish to continue in the study, additional community resources will be made available to you upon request.

If you are eligible, you will complete six mobile tasks over the course of 100 days. All sessions are completed independently on a mobile device. A table is provided below to clarify the timeline of these sessions. All sessions will be completed on a mobile device, where you will complete survey measures and computerized tasks. To complete study tasks, you will download the Inquisit 6 application to your cellular device. The tasks will be completed through the Inquisit 6 application. Research staff will provide you with a URL that will initiate the tasks.

For the task, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice of which group to which you are assigned. The two groups will complete the same task with the same images and only the format of the images (i.e., portrait or landscape) will differ between the two groups.

Day 1	Day 2	Day 3	Day 4	Day 11	Day 100
Baseline Questionnaire Mobile Task (~30 minutes)	*Mobile Task (~5 minutes)*	*Mobile Task (~5 minutes)*	*Mobile Task (~5 minutes)*	*Mobile Task Brief Questionnaire (~10 minutes)*	*Follow-Up Questionnaire Mobile Task (~30 minutes*

During the first session, you will answer questions either independently on a smartphone, computer, tablet etc. about your life experiences and behavior. You will be asked questions about substance use, types of trauma you have experienced, and dating and sexual behavior. Your name will not appear on the questionnaires. Responses to questions will be kept strictly confidential. Exceptions to this are listed below under Risks and Discomforts. You can stop your participation at any time or decide not to answer any of the questions.

During all of six sessions you will complete a task on the mobile app called The Approach-Avoidance Task. This is a task where you are instructed to swipe either up or down based on the format of an image shown on a smartphone (i.e., whether it is wide or tall). The images will be in various categories, including some of condoms and alcohol.

C. DURATION

Participation in the study will take six sessions over a period of approximately 100 days.

D. RISKS AND DISCOMFORTS

1. Breaches of confidentiality are a concern with components of any study. We have outlined several steps to maintain confidentiality, including only using study id numbers to store and track data. Also, all collected data is stored on secure encrypted servers. Nevertheless, if our protocol for maintaining confidentiality were broken, there is a risk of potential loss of confidentiality.

2. Any new (i.e., previously unreported) disclosures of abuse may be reported to the appropriate authorities if it meets the standard for mandatory reporting (i.e., Mandated reporters must report abuse or neglect when, in their professional capacity, they receive information giving them reason to believe that a child's physical or mental health has been, or may be, adversely affected by abuse or neglect). If you disclose self-harm, we may need to inform other authorities, and you will be provided referral to appropriate services.

3. You could experience increased cravings or negative emotions from seeing images of alcohol and condom stimuli.

4. There is the potential that the assessments may produce small to moderate amounts of anxiety or sadness. Often, the anxiety or sadness effects of such assessments are rare and temporary.

5. Randomization: You will be assigned to one of two experimental groups by chance. For this reason, the condition you are assigned to may differ from the other study condition.

6. Unknown Risks: The mobile task may have unknown and unanticipated side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

E. MEDICAL RECORDS

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

You may not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because you will be helping us to better understand associations between life experiences and health behaviors.

G. COSTS

This research study involves the use of your personal cellular device, normal data usage and rates will apply.

H. PAYMENT TO PARTICIPANTS

You will receive financial compensation for your time participating in this research. You will have the opportunity to earn up to $150 in total compensation. You will receive $20 for completing the initial survey. If you are eligible you will receive $20 if you complete session one, $10 if you complete session two, $10 if you complete session three, $10 if you complete session four, $30 if you complete session five, and $50 if you complete session six.

In total, participants can be compensated up to $150. Payment will be made using Amazon gift cards, as outlined in the payment schedule above.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards,

personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

You may choose not to participate in this study.

J. DATA SHARING

No information about you that is collected as part of this research (whether or not it is identifiable) will be used or distributed for future research studies under any circumstances.

K. DISCLOSURE OF RESULTS

Clinically relevant research results will be shared with you upon request.

L. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

M. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

N. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities.

Please initial by your choice below.

____Yes, I agree to be contacted

____No, I do not agree to be contacted

O. CLINICAL TRIALS.GOV

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.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and

tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Austin Hahn. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

Please sign below.

_____
Signature of Person Obtaining Consent Date

_____
Printed Name of Participant

_____
Signature of Participant Date

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