Informed Consent Document

Study Title: Development of a Just-in-Time Adaptive Intervention to Reduce High-Intensity Drinking among Young Adults

ClinicalTrials.gov ID: NCT07126613

IRB Approval Date: 9/11/25

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 9/5/25
IRB Study # 25-1872
Title of Study: Randomized Controlled Trial of mHealth Intervention to Reduce High Risk Alcohol Use Among Young Adults
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CONCISE SUMMARY

The purpose of this study is to learn about the accessibility and feasibility of a text message intervention that targets alcohol use among young adults.

As a participant in this study, you will be asked to attend an introductory session via Zoom with a member of the project staff and then respond to surveys sent via text message on your cellphone for four weeks. You will be assigned to one of two groups and may receive more or fewer text message surveys depending on which group you are assigned to. You will have an equal chance of being assigned to either group, like flipping a coin. You will be asked to complete one online survey 30 days following completion of the four-week study.

Taking part in this research study may involve telling us your opinions or behaviors that you consider private, that caused you embarrassment, or that are illegal (such as using substances that are not approved for use at your age). We will take steps to keep your information safe and private.

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this study.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people

in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this study is to learn about the accessibility and feasibility of a text message intervention that targets alcohol use among young adults.

You are being asked to be in the study because you are between the ages of 18-25 and have reported consuming 8+/10+ drinks in a single occasion at least once in the past 30 days.

Are there any reasons you should not be in this study?
You should not be in this study if you are not between the ages of 18-25, have not consumed alcohol in the past 30 days, do not speak English, are currently enrolled in high school, are seeking treatment for substance use disorder, or do not consent to receive text messages to your personal cellphone.

How many people will take part in this study?
Up to 40 people at this institution will take part in this study.

How long will your part in this study last?
You will attend a 60-minute introductory, online video session in which we will ask you to complete a survey and our project staff will explain general study procedures. Then, you will receive multiple prompts throughout the day beginning on Wednesday through Sunday for four consecutive weeks. Finally, you will complete one 30-minute online survey 30 days following the end of the four-week trial. In total, your participation in the study will last 2 months.

What will happen if you take part in the study?
You will complete one 60-minute online introductory session with a member of the study staff. During this session, you will complete an introductory survey and learn about general study procedures. You will receive surveys sent via text message to your cellphone beginning on Wednesday through Sunday for four consecutive weeks. You will complete one 30-minute online survey 30 days following the last text message prompt you receive.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?
Taking part in this research study may involve telling us about your opinions or behaviors that you consider to be private, or that cause you embarrassment. We will also ask about your

substance use, which may be an illegal activity in general, or if you use substances that are not legal based on your age. We will take steps to keep your information safe and private.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. All information you provide to us will be stored on a password-protected server. Any identifying information will be deleted as soon as we complete the study. Only approved research staff will have access to the data. During the course of the study, your data will be kept separate from your identifying information (such as your name) and a unique ID will be used to link your information. We may use de-identified data and/or specimens from this study in future research without additional consent. Every effort will be taken to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. Your name will not appear on any transcripts; instead, you will be given a code number. The list which matches names and code numbers will be kept in secure computer file that only approved members of the research team may access. The recording will be destroyed, and the list of names and numbers will also be destroyed, within two years of study completion.

The study team will message you by email and/or text. These messages may include appointment reminders, requests to contact the study team, or reminders to complete study activities. The study team will ask you to provide your preferred email address or cell phone number. These messages may be sent by the study team's personal electronic devices. If you respond to the message, your message may be received by a study team member's personal device. This means there is the risk your information could be shared beyond you and the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device or email account, please notify the study team using the study contact information on the first page of this consent form.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions or because the entire study has been stopped.

Will you receive anything for being in this study?
You receive payment via an online gift card distributed by Tango Rewards for taking part in this study. Payment amounts are commensurate with your level of participation, up to $200.
In order to process payments, the University may share certain identifiable information about you, such as name and contact information where required with third parties that the University retains to process payments on its behalf. If you do not want to agree with sharing your information with these third parties, then you will be unable to receive payment/compensation for participating in the study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights

and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness