

Informed Consent Cover Page

A social media intervention for high-intensity drinking in a national sample of emerging adults

NCT: NCT04721925

Study ID: HUM00162416

IRB: IRBMED

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UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: SnappyHour

Agency sponsoring the study: National Institutes of Health

Principal Investigator: Erin E. Bonar, PhD, University of Michigan Department of Psychiatry

Study Coordinator: Joey Tan, LLMSW, University of Michigan Department of Psychiatry

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. All of the information in this form is important. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to provide your consent before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about health conditions and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of direct benefit. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study, such as the amount of time required. In your decision to participate in this study, consider all of these matters carefully.

This research collects health-related information to better understand young people's own health behaviors, substance use, and social media use. This research is studying new ways of sharing health and wellness information with young adults. Researchers want to understand how to share this information so it will be interesting to people your age. If you choose to take part, you will be first asked to complete an online survey. Then, you will be randomly assigned to one of two groups:

If you are assigned to Group 1, you will be provided with links to an interactive website (National Institute on Alcohol Abuse and Alcoholism [NIAAA] Rethinking Drinking) and our study website with resource information.

If you are assigned to Group 2, you will also be provided with a link to the Rethinking Drinking website and our study website with resource information. You will also be sent an invitation to

add our study Snapchat account as a friend, where you will receive and exchange messages with a team of peer health coaches over the next 8 weeks.

Next, everyone in both groups will be asked to complete two follow-up surveys, at 2 and 4 months from the time you enrolled in the study. These surveys will be similar to the first survey. Information about things such as your background, stress, substance use, and mood will be collected for this research study. You can earn up to \$110 in electronic gift cards and your participation in the study will end when you complete your 4-month follow-up survey.

This study involves a process called randomization. This means that the group you are assigned to is not chosen by you or the researcher. The study design divides study participants into separate groups based on chance (like the flip of a coin), to compare the different programs. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include loss of confidentiality or feelings of discomfort as a result of being asked personal questions. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by sharing new health information that could be helpful. More information will be provided later in this document

You can decide not to be in this study. Participation in the study is voluntary.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

We're doing a study to learn more about ways to share health and wellness information with people your age. The purpose of the study is to test prevention methods to promote wellness and reduce risky behaviors, including the use of substances such as alcohol and other drugs. The study will help us to learn about ways of delivering this information that is both appealing and helpful to young adults.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

To take part in this study, you must be between 18 to 25 years old and qualified by completing the screening survey.

3.2 How many people are expected to take part in this study?

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Approximately 100 total people are expected to participate in this research study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to join the study, we will first ask you to complete a 30-40 minute online baseline survey. The questions included are about your background, social media use, interactions with your friends, and health behaviors including alcohol and drug use, as well as questions about your health. From here, you will be randomly assigned (like tossing a coin) to one of two study groups. The two study groups are:

Group 1: After completing today's baseline survey, you will be informed of the group you are in, group 1. We will provide you with a link to the Rethinking Drinking interactive website, as well as information so you can access the list of national resources on our study website that offer tools and information.

Group 2: After completing today's baseline survey, you will be informed of the group you are in, group 2. We will provide you with a link to the Rethinking Drinking interactive website, a list of national resources located on our study website, and provide you a copy of our study's user safety agreement. Additionally, a copy of the user safety agreement will be emailed to you. You will be sent a friend request through our study Snapchat account. A study team member will reach out to you via your preferred method of contact. You will be asked initially to test *SnappyHour* messaging on Snapchat to ensure that the study's account friend request went through. You will receive no more than three different Snapchat messages per day over the next 8 weeks initiated by our team. The *SnappyHour* team will deliver health information focused on increasing well-being and reducing risky behaviors. This information will be sent by study peer coaches. You can interact with the peer coaches on your account and we will temporarily save these messages within Snapchat.

While snapping with the *SnappyHour* team over the next eight weeks, we encourage you to reply to *SnappyHour* messages. We'll send you reminders to check out the snap messages and stories from the *SnappyHour* team during the 8 weeks. The *SnappyHour* team will only be available at certain times to respond to you – if you have a crisis, do not contact *SnappyHour* because we may not reply immediately. Please contact 911 or other emergency services listed in a resource list we will provide to you.

Then, about 2- and 4-months after you first enrolled in the study, we will ask you to complete the follow-up survey, with questions similar to those in today's baseline survey. When it's time for your online follow-up survey, you'll receive invitations via email, text, or other preferred methods of contact with a link and password to access the surveys.

4.2 How much of my time will be needed to take part in this study?

Today's baseline survey will take 30-40 minutes to complete in total. The amount of time you spend reviewing the Rethinking Drinking website and resource list, and *SnappyHour* messages (if applicable) during the 8 weeks is up to you. The 2- and 4-month follow up survey will each take about 30-40 minutes of your time.

4.3 When will my participation in the study be over?

Your participation in this study will be over after you complete your 4-month follow up survey.

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4.4 What will happen with my information used in this study?

Your collected information may be shared with the National Institutes of Health.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are loss of confidentiality and feelings of discomfort as a result of being asked personal questions.

Some of the questions that will be asked are about sensitive or personal information such as your alcohol or drug use or mental health. These questions may make you feel uncomfortable or nervous. You may skip questions you don't want to answer, however, some questions require response in order to continue in the study and receive payment for your survey. You are free to leave the study at any time.

There is a possibility that others may see or hear your open smart phone or device communications when accessing and sending study messages when you are not alone. In addition, it is possible that private messaging from a mobile device may be spied on, intercepted or hacked during transmission. We encourage you to use headphones if possible when you are opening up Snapchat messages sent by the peer coaches. We also encourage you to use a strong passcode on your devices and to avoid letting anyone else access your device or your Snapchat account.

As with any research study, there may be additional risks that are unknown or unexpected. It is important that you know we will not share your survey answers with any authorities, however no guarantees can be made regarding third-party access to data sent via internet or phone.

See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any problems that you have during this study.

5.3 If I take part in this study, can I also participate in other studies?

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Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Some people may find that answering the survey questions is helpful. We will share information about national resources and provide a link to a NIAAA interactive website, Rethinking Drinking, with you which you may find to be beneficial. We hope to learn more about ways to deliver health information to young people and adults as a result of this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Participation in the study is entirely voluntary. If you decide not to take part, your access to your Snapchat account will not be affected in any way.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

It is not expected that any harm would be done to you if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. As with any cell phone, depending on your text/data plan, you may be charged for text/data use on your personal phone bill.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive these amounts for completing each survey and activities listed. You will get an electronic card within about 14 days after you complete the study activities for each time point.

Study Activity	Gift Card Amount
Today's baseline survey and add back <i>SnappyHour</i> on Snapchat (if applicable)	\$35
2-month survey	\$35
4-month survey	\$40
	Total: \$110

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of this study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?

You may be worried about the privacy of your answers. The researchers will try to minimize loss of confidentiality in the following ways. Every effort will be made to protect your identity. We won't share your answers with anyone except the researchers of this study, but if we learn about child abuse, or that you are at risk of harm to yourself (e.g., suicide) or others (e.g., homicide), we may have to notify the authorities. We will ask for contact information so that we can contact you about the study and to send your electronic gift cards. This personal information will not be connected to any of your survey answers.

To protect your information, research records will be kept in a separate research file that does not include names, or other information that is likely to allow someone other than the researchers to link

the information to you. Your surveys will be coded with a unique number and stored in a different location from your name, email address, or any other contact information, which will be collected only to contact you about the study. Computer data files will be kept on secure servers at the University of Michigan and saved with password protection. Any reports or articles that we write won't contain any information that could allow somebody to identify you.

The online surveys are designed and administered using Qualtrics Research Suite (<http://www.qualtrics.com/>) through the University of Michigan. Qualtrics is dedicated to protect all customer data using industry best standards. There are security precautions in place to protect against unauthorized access, but there is still a small risk of unauthorized access. There are systems in place that prevent the survey from being taken more than once. No identifying information is directly linked to your answers. For more information, Qualtrics security and privacy statements can be found at <http://www.qualtrics.com/security-statement> and <http://www.qualtrics.com/privacy-statement>.

All study devices used to communicate with participants will be password-protected and only be accessed by study staff. We encourage you to close out from your devices when viewing the study webpages and NIAAA Rethinking Drinking website when you are not viewing it. Your activity on Snapchat is still accessible to Snapchat and subject to the app's terms of use, including use of the feature that allows saving snaps for 24 hours. We will change the front page of coaches' Snapchat apps to display your assigned number for identification and confidentiality purposes, instead of your usual Snapchat account username. Peer coaches will also communicate with you from a private location. We encourage you to use a strong password/code on your phone (mix of lower case and upper case letters, numbers, and symbols) and to view the study messages in private spaces. No guarantees can be made regarding interception of Snapchat, video chat, and/or other online communications or information by any third parties. We also encourage you to use a strong password/code on the email accounts you provide for study contact.

Here is additional information about Snapchat and Privacy information:

- The snaps delivered will be secret and confidential, meaning only you and the SnappyHour team can view the snaps. No one else will be able to view the snaps or know that you are snapping with us.
- We encourage you to close out of your Snapchat app when you are not using it; although you will not be able to add other people into the conversation, leaving the webpage or device open could unintentionally show the content to others.
- Information on Snapchat Privacy Policies can be found at: <https://www.snap.com/en-US/privacy/privacy-policy>

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder

abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>. 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.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Consenting to this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
 - Make sure the study is done safely and properly
 - Learn more about side effects
 - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

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As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have left the study or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my information expire?

Your permission will not expire unless you cancel it.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report a problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Erin E. Bonar, PhD
Mailing Address: 2800 Plymouth Road

Ann Arbor, MI 48109-2800

Telephone: 734-764-7936

Study Coordinator: Joey Tan, LLMSW
Mailing Address: 2800 Plymouth Road
Ann Arbor, MI 48109-2800
Telephone: 734-647-8674

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmmed@umich.edu

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If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your consent to participate in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (Note: *In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.*)

[Please click here to save or print a copy of this consent form.](#)

12. SIGNATURES

Sig-A

Consent/Accent to Participate in the Research Study

I understand the information printed on this form. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request.

Do you agree to participate in SnappyHour?

YES – I have read and understand the information above. I CONSENT to participate in this study.

NO – I do not wish to participate in this study.



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