Full Study Title: An App to Reduce Cannabis Use Among Emerging Adults

IRBMED #:HUM00222194

ClinicalTrials.gov ID: NCT05824754

Principal Investigator:
Inbal Nahum-Shani Ph.D

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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: MiWaves

Company or agency sponsoring the study: National Institutes of Health

Principal Investigators: Inbal Nahum Shani, Ph.D., Institute for Social Research, University of Michigan & Lara Coughlin, Ph.D., Department of Psychiatry, University of Michigan

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. 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 sign this form 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 certain 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 time required. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's behaviors may have an effect on health behaviors such as cannabis, alcohol, and other substance use. The purpose of the study is to learn more about different ways that surveys and health information can be shared with 18-25 year olds via a mobile phone app. If you choose to participate, you will be asked to complete several online surveys: one survey when you join the study, four weekly surveys during the 30-day intervention period, a post-test at the end of the 30-day intervention period, and a follow-up survey two months after you joined the study. You will also be asked to download the MiWaves app on your smartphone and interact with the app for 30 days. Your involvement in the study will end after you complete the two-month follow-up survey.

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 feelings of unease after

answering personal questions about sensitive topics, and the potential for information about you to be accidentally shared with others. More detailed information will be provided later in this document.

This study may not benefit you directly, but may benefit others in the future by allowing us to better understand how to deliver appealing and helpful interventions using a mobile phone app. More detailed information will be provided later in this document.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

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

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to learn more about how cell phone apps can be used to collect and share health information. We are asking 18-25 year olds to help test a new phone app named MiWaves and provide feedback about the app's features and usability. This feedback will be used to refine and improve the app.

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 the ages of 18– 25 years old and have qualified for the study based on your eligibility survey answers about your health behaviors and the type of cell phone you have.

3.2 How many people are expected to take part in this study? We expect about 150 people to take part in this 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 ask you to complete a 25-35 minute baseline survey and provide additional contact information. The survey will ask questions about how you cope with stress, your health behaviors (e.g., smoking, other substance use) and social relationships.

From here, you will receive instructions about how to download and use the MiWaves app on your personal phone during the 30 days after you join the study (called the 'intervention period'). During the

intervention period, you will be asked to complete four short (5-10 minutes) weekly surveys and brief (1-3 minutes) twice-daily surveys within the app. You can earn money for completing these tasks. The amount earned will vary by chance and how many tasks you complete. You will receive daily push notification reminders about completing surveys, and we may also contact you by phone, email, and/or social media with reminders. You will also receive notifications, messages, and images from the MiWaves app that include references to health behaviors, including cannabis, alcohol and other substance use. The MiWaves app will automatically collect data about your interaction with the app, movement and may also collect GPS location. App responses are not monitored 24/7 and staff may not be available to respond immediately in case of emergency. You will receive information about resources and crisis lines, as explained in section 5.4.

You'll then be asked to complete two additional surveys after the intervention period: a 20-25 minute post-test assessment at the end of the intervention period and a 35-45 minute follow-up assessment two months after you enroll in the study. These surveys will ask about your health behaviors, experience using the app, and feedback about app content. You will have the option to complete the assessments online or over the phone with a study team member.

4.2 How much of my time will be needed to take part in this study? The baseline survey will take about 25-35 minutes to complete. Each weekly survey will take 5-10 minutes and each twice-daily survey will take 2-5 minutes to complete. The amount of time you spend using the app during the intervention period is up to you. The post-test will take about 20-25 minutes and the 2-month follow-up survey will take about 35-45 minutes.

4.3 When will my participation in the study be over? Your participation in the study will be over after you complete the 2-month follow-up survey. Although certain features of the app will be deactivated after the end of the intervention period, you may keep the app installed on your phone after the study ends if you would like.

4.4 What will happen with my information used in this study?
Your collected information may be shared with the National Institutes of Health, who is the sponsor of this study.

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?
Some of the topics discussed in the surveys and app health content may feel sensitive or personal, such as mood, smoking and other substance use. These topics may make you feel uncomfortable or nervous. You may skip any survey questions you don't want to answer; however, some questions require a response to continue in the study and receive payment for your survey. You are free to leave the study at any time.

It is possible that, if you download the MiWaves app or remotely complete your surveys on a device that others can access (e.g., a shared phone or a public computer), the next person who uses the device could unintentionally see your app messages or survey answers. To protect your privacy, please clear your browsing history after completing each web-based survey and use a strong password (with a mix of upper/lower case letters, numbers, symbols) on any mobile devices and email accounts which are used for participating in the study.

Because this study collects information about you, one of the risks of this research is a loss to confidentiality or privacy. It is important that you know we will not share your survey answers with anyone outside of our research team. When replying to questions in the app, please avoid use of names or other information that might allow someone to determine who you or others are. No guarantees can be made regarding third-party access to data sent via internet or phone. Additionally, there may be a risk of loss to confidentiality or privacy. 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 have 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, 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?
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. Some people may find that answering survey questions is helpful. By viewing the app content, you may learn more about substance use and other health behaviors. You will also receive information for national and community resources, including crisis hotlines and substance use and mental health treatment services. We hope this study will help us better understand how to deliver appealing and helpful interventions using a mobile phone app.

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?
Taking part in this research project is voluntary. You do not have to participate and you can stop at any time.

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 there would be any harm 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. 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 $40 for completing the baseline procedures. You can earn up to $120 in additional compensation for completing all four weekly surveys ($15/survey) and twice-daily surveys ($0.50 - $3.00 for each completed survey). You will be paid at the end of the intervention period for all money earned from completing weekly assessments and interacting with the app. You will also receive $40 for completing the post-test survey and $50 for completing the 2-month follow-up survey. You will be paid electronically (e.g., e-gift card via Amazon) within about 7 days after you complete the study activities at each time point.

8.3 Who could profit or financially benefit from the study results?
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. The investigators and University of Michigan may eventually license and sell the app. This means that they and the University of Michigan might one day gain financially from this study. 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, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

You may be worried about the privacy of your answers. We won't share your answers with anyone except the researchers of this study. If you qualify for the study and are interested in participating, we will ask for your contact information so that we can contact you about the study and send your electronic payments. This personal information will not be connected to any of your survey answers. Your surveys will be coded with a unique ID number and stored in a file that is separate from your name, email address, or any other contact information. Computer data files will be kept in password-protected folders on secure servers that only authorized research staff can access. Any reports or articles that we write will not contain any information that could allow somebody to identify you.

The computerized surveys are designed and administered using Qualtrics Research Suite through the University of Michigan (http://www.qualtrics.com/). Qualtrics is dedicated to protecting 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. 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 data collected through the MiWaves app will be regularly uploaded to a secure computer server. These data will rest on your phone within the app when internet connection is not available. Data will be encrypted before being stored locally on your phone and/or transmitted to the server. We strongly encourage you to set a security passcode or TouchID on your phone in order to protect all locally stored data. The MiWaves app will not collect or store your full name or contact information with your survey answers; all data stored on the server will instead be coded with your unique ID number. Data will be stored on the server until we complete the study. The MiWaves app was created for research purposes only so all data collected from the app will only be accessible by the researchers in the study. Your d-identified data may be shared with other outside researchers as indicated in section 4.4.

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 DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). 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 study 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?

Signing 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
- 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.

We may use or share your research information for future research studies. If we share your information with other researchers, it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

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

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.

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 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
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Inbal Nahum Shani, Ph.D
Email: inbal@umich.edu
Phone: 734-763-7562

Principal Investigator: Lara Coughlin, Ph.D.
Email: laraco@med.umich.edu
Phone: 734-764-0231

Study Coordinator: Maya Campbell, B.S.
Email: camaya@med.umich.edu
Phone: (734) 707-6907

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: irbmed@umich.edu

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 signature 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.)*

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. 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. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Do you agree to participate in MiWaves?

☐ YES - I have read and understand the information above and I agree to take part in this study.

Legal Name: _____