

Official Title:	An mHealth Mood Management Tool to Improve Population-Level Cessation
NCT number:	NCT04525222
Document Type:	Informed Consent Form
Date of the Document:	June 26, 2022

Informed Consent Form

Fred Hutch

Consent to take part in a research study: An mHealth mood management tool to improve population-level smoking cessation

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Funding: This study is funded by the National Institute on Drug Abuse

To help you decide if you want to take part in the study, this form tells you about the study and its activities. You can also email us to ask any questions you have about the study to help you decide whether or not you want to take part.

What is the purpose of the study?

We are conducting this research study to learn how well a new investigational smartphone application (app) helps adult smokers quit smoking.

If you agree to join the study, you will receive access to a smartphone app designed to help you quit smoking.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty if you say no or if you change your mind later.

We plan to enroll 240 people in this study. Although the study may or may not benefit participants directly, the information we learn will help us design better smoking cessation programs in the future.

Below is a more complete description of this study. Please read this description carefully. If you join this study, we will email you a copy of this form for your reference.

What are you asking me to do?

For this study, we will ask that you use a quit smoking app on a smartphone and fill out 3 surveys. Specifically, if you join this study, you will be asked to:

- Fill out a survey, called the *Baseline Survey*. It is a confidential, web-based survey that takes 15-20 minutes to complete and includes questions about:
 - Your current smoking habits and your smoking history
 - Demographics (for example, education, and employment)
 - Your personality and mood
 - Your current alcohol use
- Use a smoking cessation app on your smartphone. We will electronically record information on your use of the program (for example: how many times you open

- the app and if you view certain parts of it). Study staff will reach out to you via telephone to help you download the app/or provide technical assistance if you have not successfully logged into the program 7 days after joining the study.
- Fill out follow-up surveys after 2- and 6-months of being in the study. These surveys can be filled out online, by telephone, or by mail and will help us learn about your overall experiences with the app. The follow-up surveys should take about 10-20 minutes to complete.
 - We may call you on the phone and ask that you to briefly confirm some of your answers for any of the study surveys.
 - After completing the 2- and 6-month follow-up survey, you may be asked to verify your smoking status by completing a saliva cotinine test and a carbon monoxide test via your smartphone.

These details are described further below.

Smoking Cessation App

You will be randomly assigned (like a coin toss) to one of two programs designed to help people quit smoking. Both are smartphone apps.

Smoking Cessation App A (120 participants)

If you are assigned to Group A, you will receive a smartphone application based on Behavioral Activation Therapy to help you quit smoking. This app helps you explore your personal values, teaches you about smoking triggers, helps you create and track your smoking cessation progress and your activities, and helps you manage your cravings. You will also receive notifications providing helpful and encouraging information.

Smoking Cessation App B (120 participants)

If you are assigned to Group B, you will receive a smartphone application based on current clinical practice guidelines for tobacco cessation to help you quit smoking. This app helps you with quit advice, tracking your progress on quitting smoking, and managing your cravings. You will also receive notifications providing helpful and encouraging information.

Research Surveys

You will be asked to complete three study surveys:

1. At the time you start your participation in the study.
2. Two-months after enrollment in the study.
3. Six-months after enrollment in the study.

Surveys may take 10-20 minutes to complete. You will be asked about your smoking history, current smoking status, mood, alcohol use and interest in quitting. At the 2-month survey, you will also be asked to give us feedback about the app you used.

Saliva Cotinine and Carbon Monoxide Testing

At the 2- and 6-month surveys, you may be asked to confirm your smoking status by completing a saliva cotinine test kit and an app-based carbon monoxide (CO) test and sending us a picture of your result.

How long will I be in this study?

The total length of participation is 6 months. This includes your time using the app-based quit smoking program (i.e., 2 months) and completing the 2-month and 6-month surveys.

If you leave the study, your survey results and information cannot be removed from the study records.

Will you pay me to be in the study?

Yes. You will receive up to \$124 for your participation based on the following:

- You will be mailed \$2 cash in a reminder letter for each follow-up survey (for a total of \$4)
- You will be mailed a \$25 electronic gift card to Amazon after you complete the 2- and the 6-month surveys (for a total of up to \$50). If we have questions about your survey responses, payment will be delayed until we are able to reach you to confirm your answers.
- If you complete the follow-up surveys online within 24 hours of the first survey invitation being sent by email, we will give you an additional \$10 for each survey (for a total of up to \$20).
- If you are asked to confirm your smoking status at 2-months and/or at 6-months, we will give you an additional \$25 after you send us your results (for a total of up to \$50).

Therefore, you can receive up to \$124 in the mail for participating in this study. Payment will be sent to you after you complete the 2- and the 6-month study surveys and the saliva and carbon monoxide testing (if asked).

If you agree to join the study, there is no cost to you for participating.

What are the benefits of being in this study?

- Participating could help us learn how to better help adult smokers quit smoking, which could improve care options in the future.
- Participation in this study may help participants quit or cut back on how much they smoke.
- Some people feel good when they help with research like this.

What are the possible risks or discomforts of being in this study?

- If you quit smoking, you may experience some short-term discomfort associated with nicotine withdrawal including irritability, depressed mood, restlessness, difficulty sleeping, headaches, difficulty concentrating, and cravings to smoke. These symptoms typically last a few weeks and then go away.
- You may feel discomfort from some sensitive survey questions (e.g., questions asking about your mood).
- People not working on this study could learn your identity or learn information about you from your surveys. We will do everything we can to keep this risk small and to

protect all study participants against this risk in the following ways: (1) All of your identifying information will be kept in a password protected, secure database behind Fred Hutch firewall for 7 years after the study is over and will then be destroyed, (2) your connection to the treatment smartphone apps as well as where you fill out the surveys will be password restricted and protected by secure-socket-layer (SSL) encryption; and (3) the study server will be kept at Fred Hutchinson Cancer Research Center behind a hardware firewall.

Do I have other options besides this study?

You do not have to join this study. You are free to say yes or no. If you decide not to take part in this study, you can still receive treatment to help you to quit smoking. Your other choices may include:

- Talking to your doctor
- National Cancer Institute's smoking cessation websites, apps, and text messaging programs: see www.smokefree.gov
- Your state quitline (available in all 50 states) by calling 800-QUIT-NOW

Protecting your privacy as an individual and the confidentiality of your personal information

Some organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers and research staff involved with this study.
- Datatope LLC, the company that maintains the study data related to the utilization of the smartphone applications and other study outcomes
- The Fred Hutchinson Cancer Research Center Institutional Review Board (IRB). An IRB is a group that reviews the study to protect your rights as a research participant.
- The study sponsor, National Institute of Drug Abuse (NIDA), The Office of Human Research Protections (OHRP), and other agencies as required.
- Food and Drug Administration (FDA)

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality.

We will not use identifiable information about you in any reports about this study, such as journal articles or presentations at scientific meetings.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.

- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others. For example, if you tell us you have plans to harm yourself or others, we may have to share this information.

A description of this clinical trial will be available on <http://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 I get sick or hurt during this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact us when the medical emergency is over or as soon as you can.

Study staff will not be monitoring your survey responses, and this program is not intended to deliver medical or mental health care. Should you experience suicidal thoughts during the study, seek assistance from a healthcare provider or crisis line:

- National Suicide Hotline: 1-800-273-TALK (8255)
- National Crisis Text: Text GO to 741741 (crisistextline.org)

For all other problems related to the study, please contact the project manager at 206-667-2428. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

Your rights

You are free to join this study and it is up to you whether you choose to participate or not. If you join this study, you do not have to stay in it. You may stop at any time (even before you start).

There is no penalty for stopping.

If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.

What else should I know

The study investigator may decide to stop your participation in this study at any time if:

- it is not in your best medical interest to continue;
- you do not follow study procedures (e.g., if study staff is unable to reach you to confirm any of your survey answers)

- funding is stopped, or
- new information becomes available that requires a change in your participation

Should the information we learn during this study lead to a commercial product or a patent, you will not receive any compensation.

For more information

Be aware that by agreeing to participate in this study, your information could be used for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information. If you do not want your information to be used for future research studies without your consent, you should not participate in this study.

If you have any questions or concerns about this study you would like answered before deciding to participate, please email us at Actify@fredhutch.org. We are committed to answering your questions within 2 business days. Other people you can talk to are listed below.

If you have questions about:	Call:
This study (including complaints and requests for information)	206-667-7314 or jheffner@fredhutch.org (Dr. Jaimee Heffner, Principal Investigator)
If you get sick or hurt in this study	206-667-2428 or eserfozo@fredhutch.org (Project Manager)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)

- I consent to participate in this study
- I do not consent to participate in this study