

NCT# 05227027



UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO BE IN RESEARCH

Study Title: Feasibility and Acceptability of Smartphone-Based Gamification to Promote Smoking Cessation

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This is a research study about quitting smoking. Participation is voluntary. If you have any questions, please ask the researchers using the email address listed below.

You are being asked to take part in this study because you smoke cigarettes, want to quit, and have downloaded the Smoke Free smartphone app.

Why is this study being done?

The purpose of this study is to learn how to help people to quit smoking using a smartphone app. The study is paid for by the National Cancer Institute, National Institute on Aging, the Hellman Foundation, UCSF, and University of California, Berkeley.

How many people will take part in this study?

About 500 people will take part in this part of the study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

- You will be asked take an initial 15-minute online survey. We will send a link to the survey by e-mail today or tomorrow.
- You will use the Smoke Free app in whatever way you like for 8 weeks (56 days) after the quit date you select. You may continue to use the app after 8 weeks, but it is not part of the study.
- At the end of the 8 weeks, you will be asked to take a 10-minute online survey.
- We may ask you to complete an at-home saliva test that measures nicotine in your body. The test kit would be mailed to you. The test involves a saliva swab that gives results in 10 minutes. We will ask you to take photos of the testing process and test results, and to send us the photos as an e-mail attachment.
- **Study location:** The surveys will be completed online. You may use the Smoke Free where you like. The saliva test will be completed at your home.

There is no requirement for you to use the Smoke Free app during the study.

How long will I be in the study?

Participation in this study will take a total of about 45 minutes over a period of 9 weeks (up to 1 week before your quit date and 8 weeks after your quit date), plus the time you decide to use the Smoke Free smartphone app. Smoke Free will share with the research team de-identified information on your app use for 6 months after your quit date.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just send a message to the e-mail address below if you wish to stop being in the study.

What risks can I expect from being in the study?

- If you try to quit smoking, you will likely experience nicotine withdrawal symptoms, such as anxiety, difficulty concentrating, drowsiness, increased appetite, and irritability. The symptoms may start 2-3 hours after quitting and are typically strongest 2-3 days later. Some symptoms may last for 8-12 weeks. The Smoke Free app will give you some suggestions for dealing with these symptoms.
- Some of the survey questions may make you feel uncomfortable. You are free to skip any question you do not wish to answer.

Are there benefits to taking part in the study?

If you choose to be in the study, you may benefit in a few ways:

- Get free access to several paid features in the Smoke Free app, which will assist with quitting smoking.
- Learn more about quitting smoking.
- Increase your chances of quitting smoking in the future, even if you do not succeed in this study. Smokers who make a serious attempt to quit are more likely to succeed in future quit attempts.

If you quit smoking successfully, you may benefit in several other ways. You will:

- Improve your and your family's health.
- Avoid cravings for tobacco and dependence on tobacco.
- Save money that can be used for other purposes.

The information that you provide may help researchers to understand more about how to help smokers to quit smoking.

Can I say “No”?

Yes, you can say “No.” You do not have to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still use the Smoke Free app without penalty.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The photos of your saliva test will be stored on an encrypted computer server separately from your name, and the photos will be destroyed after the study is published.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the National Institutes of Health

Are there any costs to me for taking part in this study?

There are no costs of taking part in this study. Your phone plan may charge you for data usage of the Smoke Free app, depending on your data plan.

Will I be paid for taking part in this study?

You will get up to \$100 for taking part in this study.

- \$20 for completing the initial survey
- \$40 for completing the 8-week survey
- \$40 for completing a saliva test, if requested. Not all participants will be asked to complete a saliva test.

Participants will be able to choose from hundreds of gift cards (for example, from Amazon.com) or a Visa® prepaid card. Payments will occur after each survey is completed and, if requested after the saliva test has been received and reviewed.

In addition, you will get free access to several paid features in the Smoke Free app, worth about \$10.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher about any questions, concerns, or complaints you have about this study. Contact the researcher Dr. Justin White [REDACTED].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at (415) 476-1814.

CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY.

If you agree to participate, you will be sent a copy of this consent form to your email address.

Would you like to participate?

- 1 Yes, I agree to participate in the study
- 2 No, I do not agree to participate in the study