

Support2Quit Study Informed Consent

March 6, 2024

Informed Consent for Participation

Study Title: Support2Quit Study

Principal Investigator: Dana Smith, Ph.D. and Herb Severson, Ph.D.

Sponsor: CDC 1 R44DP006495-02-00

You are invited to participate in a research study that will test a new program designed to provide support to adults who smoke and want to quit smoking. This study is being conducted by Dana Smith, Ph.D. and Herb Severson, Ph.D. of Influents Innovations in Springfield, Oregon and is funded by the Center for Disease Control and Prevention (R44DP006495). We want everyone in the study to understand what it is about. Please read this form and ask any questions you may have before agreeing to participate in the study.

What You Will Be Asked to Do

If you decide to participate, you will be asked to complete an initial survey. This survey will take about 20 minutes and can be done on your cell phone. The survey consists of questions about your past and current use of cigarettes and your motivation to stop smoking. There are also questions about you, such as your age, living situation, education and employment.

In the month following the first survey, you will be asked to use the Support2Quit app on your mobile device and make an effort to quit smoking. Support2Quit takes about 1 month to complete. There are two versions of the program. The version of the app that you receive will be determined randomly.

- Version 1 contains supportive daily messages and interactive features that you complete independently within the app. Please enable notifications for the app so you receive the messages.
- Version 2 contains supportive daily messages, interactive features, and also 5 short videos of a facilitator introducing activities designed to help you stop smoking. Every few days, you will be asked to watch a video, complete the activity (for example, writing a short letter to a family member about your decision to stop smoking), record a video of yourself related to the activity (for example, reading the letter) and upload it to the video feed within the app. You will be connected to an online support group of 6 or 7 other study participants whose videos will appear in the same video feed. These videos can only be seen by study staff and other adults in your online support group. Group members will watch others' videos and provide encouraging comments. There is a brief survey to answer after uploading each video. Please enable notifications for the app so you receive the messages and reminders.

You will be asked to complete surveys at about 1 month and about 3 months after the first survey. These questions will ask about your current cigarette use and your thoughts and behavior involving smoking. You will also be asked how much you like the app and if you find it helpful and easy to use. These surveys will each take about 20 minutes to complete.

Once you answer all three surveys and complete the study, you will receive a check or gift card for \$125, which is \$25 for each completed survey and a \$50 completion bonus. If you do not complete all 3 surveys, you will receive \$25 for each completed survey and no bonus. You will select the gift card from tangocard.com, which offers cards from hundreds of retailers and restaurants, including Visa, Target, Amazon, Walmart and Starbucks.

Use of Video-recordings

If you are using the version of the app with the video activities, you will be part of an online group of adults who can support and encourage each other around their shared goal of reducing or stopping their use of cigarettes. You will be connected to 6 or 7 other adults who are also in this study. Study activities include the group members making and sharing videos that focus on avoiding cigarettes. Study staff will control access to these groups and monitor activity for appropriateness and confidentiality. Videos must be appropriate for public viewing and respectful of diverse people and their views. Videos may not contain any other people, offensive language, profanity or sexual references.

Risks and What Will Be Done to Reduce the Risks

There are some possible risks involved for participants.

We will be asking you questions about your thoughts and actions related to tobacco use and asking you to share some of these thoughts and actions with other adults who are also working to reduce their tobacco use. We will also ask for your opinion about the app after you use it. You might feel a little embarrassed or uncomfortable sharing information about yourself or your opinions. Remember, you are not required to answer any questions or complete any activity.

We will be getting personal information from you. There is always the possibility that someone who is not authorized might see it. We take the following precautions to prevent any unauthorized person from having any access to the information you give us:

- Any information you give us will be kept strictly confidential. All information will be kept in locked electronic files. We will remove all names from all the information we get (except the Informed Consent). ID numbers will be assigned to the information you give us and only authorized staff will have access to the locked electronic file that links your name to your ID number.
- We will do all we can to protect your confidentiality. However, because you will be using your phone to answer questions, take videos and watch videos, others near you might be able to figure out that you are in a study related to tobacco use.
- We have a “Certificate of Confidentiality” which is a legal assurance from the federal government, which will help us protect your privacy even if the records are subpoenaed. We will not give any information about you to anyone unless you give us your written permission to do so.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the research results. At the very end of the project, we will post a study consent form to the same website. The consent form will not have names on it. You can search this website at any time.

Storage & Future Use of Your Information

We may keep information about you forever. We do not know what studies we might do in the future. We would like your permission now to use or share your personal information without having to ask you again in the future. We will only use your information in other studies about smoking cessation. We will remove your name and any other information that identifies you before we use it in a new study. There is still a chance that someone could figure out that the information is about you.

Benefits to You for Your Participation

There are some benefits to you for taking part in this research project. You will contribute to the design of an app that will help efforts to reduce dependency on tobacco. Using this app may help you quit smoking, which could have significant health benefits.

Alternative Procedures

There are other programs available to help you stop smoking. This study is testing a new program. You could explore other methods of reducing your use of tobacco instead of being in this study.

Your Right to Withdraw from the Project

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits you might otherwise receive. If you decide to participate, you can stop participating any time without penalty. You will receive checks or gift cards for each survey that you complete.

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please call Holly Chedester or Erika James at 541-484-2123. If you have questions about your rights as a research subject and/or research-related injury, call Kathryn Madden in the Office for the Protection of Human Subjects, Oregon Research Institute, 541-484-2123. You will receive a copy of this form via email.

Your signature below indicates that you:

- have read and understand the information provided above
- willingly agree to participate
- may withdraw your consent at any time and stop participating at any time without penalty

Name: _____

Signature: _____

Date: _____