

Improving Quitline Support (IQS) Study

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Study Information Sheet

Title of the Study: Improving Quitline Support (IQS) Study

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Description of the study

Thank you for your interest. This sheet goes over the information we talked about on the phone when you enrolled.

The purpose of this study is to test ways to improve Quit Line services for people who want to quit smoking in the next two weeks. This study will test four ways to add to current Quit Line services to help more people quit smoking.

This study is being done by the Center for Tobacco Research and Intervention at the University of Wisconsin - Madison. About 1600 people will participate in this study.

We asked you to take part because you reside in Wisconsin and you were interested in quitting smoking within two weeks.

The first step in the study was to answer some questions about your use of tobacco and stop-smoking aids, mental and physical health, cell-phone use, employment, and family income over the phone. You have already completed this step.

After answering these questions, I told you what kind of support we will give you to help you quit smoking. Everyone in the study was assigned randomly to a set of smoking support services. This means that the type of support you are receiving was selected by chance, like by a coin flip.

Everyone in the study is receiving Quit Line coaching at no cost, like the support you had before. People who are medically able to take nicotine medication are also getting this treatment at no cost. The Quit Line coaching call and nicotine medication that everybody will get will take the place of usual Quit Line services for about 6 months. This means you will not be able to receive the usual state Quit Line benefits while also receiving study treatment for the 6 months you are in the study.

Some people were assigned randomly to receive more support.

The extra support that some will get includes more coaching calls; an extra two weeks of nicotine medication, including both nicotine lozenges and patches, for those who are medically able to use nicotine medication; 6-8 weeks of SmokefreeTXT text messages with tips and support for quitting; and additional gift card payments for using coaching and text treatments. Only some people in the study will get each of these extra treatments.

Everyone in the study will be asked to answer follow-up questions by phone about 3 and 6 months from now and will be paid \$30 for completing each of these 10-15-minute calls. Everyone in the study will have this chance to earn \$60 by answering questions over the phone.

In about six months, we may also ask you to come to a research office near you to blow your breath into a carbon monoxide tester and to give us a urine sample (like you would at a doctor's office). Or, we may ask you to complete a test at home using a special breath-testing machine we would send you, or a kit you would use to collect your spit (or saliva). If you do the test at home, you will email or mail the result to us. We will use breath, saliva, and urine to test for signs of smoking. This helps us make sure our results are correct. People who complete these tests will earn \$40. Payments will be sent after completing each call or visit and can take up to four weeks to reach you.

You will be in the study for a about 6 months and it will end after your final phone call or the 6 month follow-up visit if you are asked to take part in that visit.

How is this study different from usual QuitLine services?

For many people, the study offers as much or more support as usual QuitLine services. For some people who have access to intensive QuitLine programs, the study may offer less than the QuitLine.

If you are American Indian or Alaskan Native, the American Indian Commercial Tobacco Cessation program offers more medication and more calls with specially trained Quit Coaches than the study. You cannot be in both the study and the American Indian QuitLine program at the same time. I can help you enroll in the American Indian program if you do not want to be in the study. Of, you can enroll in the American Indian program after your study participation ends in 6 months.

If you are 18-24 years old, the QuitLine offers the Text2Quit program, a year-long text-message program similar to SmokefreeTXT. Only half the people in the study will be offered SmokefreeTXT, so you may not get a text-message program if you enter the study. I can help you enroll in the study or QuitLine Text2Quit, but not both programs at the same time.

What are the risks and benefits of being in the study?

A risk if you participate in the study is that your study information could become known to someone who is not involved in performing or monitoring this study. All your information will be kept on secure, password-protected computers and will be sent to the University of Wisconsin Center for Tobacco Research and Intervention securely to protect your information from unauthorized use and disclosure.

You may experience side effects from nicotine medication if you use this. For the nicotine patch, the most common side effect is irritated skin. In very rare cases, some patch users may have an allergic reaction that would require medical attention. If you were assigned to a group receiving nicotine lozenges, they may cause heartburn, hiccups, coughing, sore throat, and cold-like symptoms. Most smokers are used to nicotine due to smoking and, because of this, using nicotine medications should not be a problem. However, it is possible that you might get too much nicotine and experience nausea, vomiting, and other unpleasant symptoms. If you have such symptoms, you can reduce your use of patch and/or lozenges.

There is also a risk of unpleasant symptoms related to nicotine withdrawal because of quitting smoking. These symptoms may include problems sleeping, hunger, craving for cigarettes, difficulty concentrating, irritability, and bad mood. Your Quit Line coach will talk with you about how to manage such symptoms.

It is important for you to know that Quit Line coaching and text messages will be delivered over the phone and may cost you cell phone minutes. There will be no other costs for participating in this study.

The main benefit of this study for you is getting treatment that could help you stop smoking. The researchers also hope that the information they learn from you will help other smokers quit.

What happens if I am injured or get sick because of this study?

Being injured during this research is very unlikely. However, accidents can happen. If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

If it is an emergency, call 911 right away or go to the emergency room.

For non-emergency medical problems, contact your regular health care provider. You may also call your Quit Coach at the Wisconsin Tobacco Quit Line at 1-800-QUIT-NOW.

Call the Lead Researcher, Danielle McCarthy, at 608-262-8673 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.

Your health insurance company may or may not pay for this care.

No other compensation (such as lost wages or damages) is usually available.

UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.

By taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

What health information will be collected for this study?

The information collected will include your background (such as your name, phone number, age, race, and county), your health, and your history of tobacco use that was shared when you registered for the Quit Line. It will also include the answers to the questions you provided on the day you enrolled in the study. This information will be used by the researchers to determine how well study treatments work for particular groups of smokers.

Information about your use of Quit Line coaching and the SmokefreeTXT support program will be used by the researchers to see how much support you actually received. Information about your use of the Quit Line coaching calls includes how many calls you complete and how long they last, but the things you discuss during coaching calls will not be used for this study. If you are assigned to use the SmokefreeTXT program, the study will gather information about how much you use the program and about the texts you send to the system about your smoking, mood, and cravings to smoke.

Information about your use of tobacco and stop smoking treatments and your beliefs about quitting smoking will be collected by researchers 3- and 6-months from now to see how the treatments changed these.

Who will use your health information from this study?

The information collected from you during this study will be used by the researchers at the UW-Center for Tobacco Research & Intervention. It may also be shared with others at the UW-Madison. Whenever possible your health information will be kept confidential

The Quit Line, which is helping the researchers at UW-Madison complete this study.

The information collected during this study may be shared with researchers at other institutions helping with the project. Whenever possible we will not share any information that could identify you directly.

UW-Madison regulatory and research oversight boards and offices

How Will Your Privacy Be Protected?

Both Quit Line and the University of Wisconsin-Madison researchers have strict rules to protect your personal information and protected health information. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. The UW Madison may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

The information collected from you during this study will be used by the researchers and research staff of the UW-Madison for this study. It may also be shared with others at the UW-Madison. Whenever possible your health information will be kept confidential.

People outside of UW- Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. This study, however, does not involve sharing any of your health information with individuals outside of the UW-Madison.

How long will your permission to use your health information last?

By agreeing to participate in the study you gave permission for your health information to be used for the study and be shared with the individuals and institutions described in this form. Unless you withdraw your permission to stop the use of your health information, there is no end date for its use for this research. You can withdraw your permission at any time by contacting the research team by phone at 1-888-497-0920 or in writing at 1930 Monroe St., Suite 200, Madison, WI 53711.

Once you withdraw your permission, no new health information will be used. Any health information that was shared before you withdrew will continue to be used. If you decide to withdraw your permission, you can no longer take part in this study.

Is participating in the study voluntary?

Your participation is voluntary. You don't have to participate in this study and you may refuse to do so. If you refuse to give your consent, you cannot take part in this study. You can still get support from the Quit Line, but will not be able to participate in any of the study activities or receive any payments related to the study. Any relationship you have with the Quit Line or the University of Wisconsin-Madison will not be affected by your decision whether or not to participate. You may completely withdraw from the study at any time.

When we ask you questions for the study, you can choose to skip any question that you do not feel comfortable answering. You will not be punished or penalized for choosing not to answer study questions.

If You Have Questions

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.

If you have any questions about your treatment or compensation, you can call the Wisconsin Tobacco QuitLine at 1-800-QUIT-NOW.

If you have for questions about your follow-up interviews, how your information will be used, or results of the research you can call the researchers at the University of Wisconsin – Madison at 1-888-497-0920.

If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team, contact UWHC Patient Relations Representative at 608-263-8009.