Health Systems Reach Interventions Project

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Study Information Sheet

Title of the Study: Health System Reach Interventions Study

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Thank you for joining this study. This sheet goes over the information we talked about on the phone when you enrolled.

Why are researchers doing this study?

We asked you to take part because you are an adult who smokes and because when you enrolled in the study over the phone you said you were not interested in quitting smoking in the next 30 days.

The purpose of this research study is to see which ways of offering support best help people get into stop-smoking treatment. We are doing this research because only a small proportion of the people who try to quit smoking use both medication and coaching to help them quit, and we want to find ways to connect more people with stop-smoking treatment. This study is being done by the Center for Tobacco Research and Intervention at the University of Wisconsin – Madison (UW-Madison). Up to 2600 people will participate in this study.

What will happen in this study?

This is a 2 to 2 ½ -year study in which we will send you 5 letters (one is included in this mailing) and ask you to complete 5 to 10 phone calls lasting 10 to 20 minutes each. We may also ask you to come to your <UW Health/AdvocateAurora Health> clinic 1 or 2 times for a brief visit to give breath, urine, and/or saliva samples to test for signs of smoking. The study also involves gathering data from your <UW Health/AdvocateAurora Health> record for up to 5 years.

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

After answering those questions, I told you about the support and stop-smoking treatments you were assigned in the study. Everyone in the study was assigned randomly to a stop-smoking support and treatment program. This means that the type of support you will receive was selected by chance, like by a coin flip.

Over the next 2 years, everyone in this study will be mailed 5 letters about resources available to quit smoking. (One of these letters is included in this mailing.) If you are active in MyChart, we may send this information to your MyChart inbox, as well. Everyone who wants to quit will have access to smoking cessation treatment through the tobacco quitline or their primary care provider. Both the quitline and primary care providers can provide stop-smoking medication to patients who are medically eligible for these medications.

Everyone in the study was asked to answer questions at enrollment and earned $20 by completing this part of enrollment. In addition, everyone will be asked to answer follow-up questions by phone 6, 12, 18, and 24 months from now and will be paid $20 for completing each of these 10-20 minute calls. Everyone in the study will have this chance to earn $100 by answering these questions over the phone.

Also, everyone who decides to try to quit smoking and sets a date to quit with a Tobacco Care Manager in the next 2 years will be asked to complete 10-20 minute telephone follow-up interviews 3, 12, and 26 weeks after their smoking quit date. Everyone who completes these calls will be paid $10 for each of these calls, for up to $30 per quit attempt. You will be paid for completing follow-up interviews for up to 2 quit attempts a year and up to 4 quit attempts total in the study. That means that everyone in the study could earn up to $120 for completing these follow-up calls about their quit attempts. These follow-up ups could end as late as 2 ½ years from now.

Once a year, we may also ask you to come to an <UW Health/AdvocateAurora Health> clinic near you to blow your breath into a carbon monoxide tester and/or to give us a urine sample (like you would at a doctor's office). We may also ask you to provide a sample of saliva. We use breath, urine, and/or saliva to test for signs of smoking. This helps us make sure our results are correct. People who complete these tests will earn $50 per year ($100 total possible).

Some people were randomly assigned to receive more support to encourage them to quit smoking. The extra support that some will get includes: additional information in letters about smoking cessation treatment, 5 phone calls from a Tobacco Care Manager to talk about quit-smoking options, rewards for using stop-smoking coaching, and access to extra medication and coaching.

All payments for study activities will be checks or gift cards mailed to you within 6 weeks of a completed call or visit.

You may skip any question in any phone interview or visit that you do not wish to answer.

Protected health information (PHI) used in the study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like

your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

Results of tests or procedures done as part of the study
Things you tell the researchers about yourself, your health, and your history of tobacco use
Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history; your diagnosis; and billing records. We will get this information from your health care providers such as UW Health and AdvocateAuroraHealth.

How long will I be in this study?

You will be in the study for 2 to 2 ½ years, and the study will end after your final phone call or visit, if you are asked to take part in that visit. In addition, we may collect data from your <UW Health/AdvocateAurora> electronic health record for as long as 5 years, from up to 1 year before your enrollment and up to 4 years after your enrollment in the study.

The researchers may take you out of the study, even if you want to continue, if

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

How is being in this study different from my regular health care?

- People who smoke usually are asked about their smoking and advised to quit smoking, and are sometimes offered help quitting. In this study, everybody will get offered help in quitting. Some people will get the standard treatment to quit smoking from the Wisconsin Tobacco Quit Line, or help from their primary care provider, and others will get intensive treatment with counseling and medication from the study team instead.

  If you take part in this study, the main difference between your regular care and the study is that a Tobacco Care Manager will work with you over to let you know about your stop smoking treatment options and help you start treatment when you are ready.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, AdvocateAurora Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Dr. Michael Fiore, at 1930 Monroe St., Suite 200, Madison, WI 53711.

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get stop-smoking treatment. If you decide not take part in the study, you have other choices. For example:

You can call the Wisconsin Tobacco Quit Line at 1-800-QUIT-NOW (1-800-784-8669) to access their toll-free services.
You may talk to your primary care provider about stop-smoking treatments.
You may purchase nicotine medications like the patch, lozenge, and gum over the counter, without a prescription.

Will being in this study help me in any way?

The main benefit of this study for you is getting access to effective treatments to stop smoking. Everyone in this study will be provided information on proven stop-smoking treatments, including access to FDA-approved, non-experimental drugs offered by the Wisconsin Tobacco Quit Line. You will also help researchers learn how to offer stop smoking treatments in a way that helps more people quit smoking and improve their health.

Will I receive the results of research tests?

Participants will not receive results of research tests.

What are the risks?

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. This study involves asking broad questions about illegal substances. There is a chance that someone outside of the study could find out about the answers to your questions or information from your electronic health record. If that happens, this could expose you to legal risks or damage your reputation. We will try to keep others from getting this information by using the following procedures. 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. We also have a Certificate of Confidentiality from the National Institutes of Health that prohibits us from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

Should you decide to quit during this study, there is also a risk of unpleasant symptoms related to nicotine withdrawal from quitting smoking. These symptoms may include problems sleeping, hunger, craving for cigarettes, difficulty concentrating, irritability, and bad mood.

If you use medication to stop smoking, you may have side effects from the medication. The main risks of **varenicline** are nausea and disturbed sleep. Some individuals taking varenicline may experience worsening of psychiatric conditions or symptoms such as anger, agitation, depression, or suicidal thoughts. Varenicline may be associated with a small, increased risk of certain heart problems in people with heart and blood vessel disease. There are rare cases of allergic reactions or serious skin reactions to varenicline including rash, swelling, redness, and peeling of the skin, with some of these reactions being potentially life-threatening.

The main risks of the **nicotine patch** are skin rash, insomnia, and vivid dreams. In rare cases, a more severe allergic reaction may occur involving hives (raised, itchy areas of skin), difficulty breathing, and swelling of the face, lips, tongue, or throat. If you have symptoms of a severe allergic reaction, get emergency care right away.

For **nicotine mini-lozenges** the main risks are heartburn, hiccups, sore throat, and nausea. The main risks of too much nicotine are nausea, vomiting, diarrhea, weakness, rapid heartbeat, and dizziness.

Other, non-nicotine medications for quitting smoking, such as bupropion, also have side effects such as nausea, dry mouth, and headache. There may be other side effects we don't know about yet. If you decide to quit smoking and get stop-smoking treatment from us, we will go over possible side effects with you before you start using a medication. If you get stop-smoking treatment from the Wisconsin Tobacco Quit Line or your doctor, they will go over side effects of their treatments with you and you should let them know if you have side effects.

Will being in this study cost me anything?

- There will be no cost to you for any of the study activities or procedures.
- There will be no cost to you for Wisconsin Tobacco Quit Line treatment, or for intensive medication and counseling done for research purposes only and not part of your regular care.
- You or your insurance company will have to pay for all costs for medical care from UWHealth or AdvocateAurora Health providers related to participation in this study, including co-payments and deductibles for care you receive. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.
- If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

Will I be paid or receive anything for being in this study?

You will be paid up to $480 over 2 to 2 ½ years for completing study calls and visits. Everyone in the study will receive $20 for completing questions at enrollment and for follow-up phone interviews every 6 months, for a total of $100 over 2 years. People who try to quit smoking in the study will be paid $10 for each of 3 follow-up phone interviews they complete 3, 12, and 26 weeks after each quit attempt ($30 per quit attempt). Because you can quit 2 times per year for 2 years, you could earn up to $120 during the study for these post-quit follow-up calls. You may be asked to complete a clinic visit to test your breath, urine, and/or saliva 1 or 2 years after you enroll in the study, as well.

You will earn $50 for each of these visits ($100 total). Some people will also be able to earn up to $120 in rewards for using quit coaching. Payment will be mailed to you within 6 weeks of each call or visit. If you choose to leave or we take you off the study for any reason, you will receive payment for whatever activities you have completed up to that point.

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

If you are injured or get sick because of this study, medical care is available to you through your local provider, UW Health, 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.
Call the Lead Researcher, Dr. Michael Fiore, (608-262-8673), to report your sickness or injury.

How will researchers keep my research information confidential?

<UW Health/AdvocateAurora Health>, UW-Madison researchers, and the Wisconsin Tobacco Quit Line have strict rules to protect your personal information and protected health information (PHI). 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 study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

As part of the study, researchers may collect audio recordings that could identify you during coaching calls you complete during the study. These recordings are being collected for quality assurance purposes. Recordings will be kept for up to 7 years after the end of the study and destroyed following completion of the study. Recordings will not be used for purposes outside of the study or in any papers or publications. Agreeing to recording is optional in this study; you do not need to agree to recording to be in the study. At the time you enrolled, you <agreed/did not agree> to allow recordings of your coaching calls that could identify you.

Who at UW-Madison can use my information?

Members of the research team
Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

U.S. Office for Human Research Protections
The U.S. Food and Drug Administration (FDA)
The study sponsor, the National Cancer Institute, National Institutes of Health
Collaborating researchers outside UW-Madison, including researchers at the University of Illinois-Chicago, the University of Colorado-Denver, and Pennsylvania State University.

Will information from this study go in my medical record?

Some of the information we collect for this study will go in your medical record. This includes the fact that you are enrolled in the study, the stop-smoking treatment you use in the study, any serious adverse reactions you have to stop-smoking medication, and your smoking status. <UW Health/AdvocateAurora Health> staff will ask your doctor to review any requests you make for study medication to quit smoking, to make sure the medication is right for you. If you use medication or coaching to quit smoking, or have to stop medication due to side effects, <UW Health/AdvocateAurora Health> staff will add that to your medical record so your care team knows what stop smoking medication you use and if you have problems with the medication. If you quit smoking, <UW Health/AdvocateAurora Health> staff may note that in your medical record, as well. Both you and your <UW Health/AdvocateAurora Health> providers will be able to see these results.

The following information from research procedures will **NOT** go in your medical records: your answers to questions about anything other than tobacco use or medication side effects, or information you discuss with your Tobacco Care Manager or Quit Coach. The researchers are not required to release health information to you if it is not part of your medical record.

What if I 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 questions about this research, please contact the Lead Researcher, Dr. Michael Fiore, at the University of Wisconsin at 608-262-8673. In case of an emergency, please contact your primary care provider or call 911.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.