Comprehensive Chronic Care Study

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University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Title of the Study: Comprehensive Chronic Care Study

Principal Investigator: Jessica Cook, Ph.D. (phone: 608-265-9775)

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 in this research because you are an adult who smokes and you told us over the phone that you are willing to get updates about smoking treatments that are available to you. You enrolled in the study over the phone.

The purpose of this study is to see whether a treatment called Comprehensive Chronic Care that provides support, information, and easy access to smoking treatment helps people make changes to their smoking when they feel ready. Comprehensive Chronic Care is being compared with another treatment approach called Standard Care. We are doing this research because we want to find ways to help more people use effective 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 1000 people will participate in this study. Funding for this study is provided by the National Cancer Institute.

What will happen in this study?

We already had a telephone call that included screening for study eligibility, consent, and a discussion about what happens in this study. People who qualify for the study and decide to participate are randomly assigned to receive either Standard Care or Comprehensive Chronic Care. For every 5 people enrolled, 3 will be assigned to the Comprehensive Chronic Care group and the other 2 will be assigned to the Standard Care group.

If you were randomly selected to receive Comprehensive Chronic Care, you will receive 4 brief outreach calls over the next 14 months from a study Health Counselor to remind you about smoking treatments that are available to you. You will receive these outreach calls about every 4 months and you will also receive 4 letters or texts offering you the

same treatments. If you were randomly selected to receive Standard Care, you will receive 1 call about a year from now offering you smoking treatment.

Everyone who wants to quit will have access to smoking cessation treatment through the study or the Wisconsin Tobacco Quit Line. The study and the quit line can provide stop-smoking medication to patients who are medically eligible for these medications. It is your choice whether or not you use treatment or make changes to your smoking.

What will the study assessments include?

All participants will receive assessment calls from study staff about every 6 months for a total of 3 calls. During these calls, you will be asked questions about your mood, your confidence about your ability to quit smoking, your motivation, any alcohol or marijuana use, and nicotine withdrawal symptoms you might be having. You will also be asked about how much you smoke, if you have used smoking treatment, and how many quit attempts you have made. The assessment call will last about 15-20 minutes. You may skip any questions that you do not wish to answer.

We may also ask you to complete a home saliva kit 1 or 2 times to test for signs of smoking. The study also involves gathering data from your UW Health or Advocate Aurora Health record for up to 5 years.

What will happen if I decide to use smoking treatment offered by this study?

You do not have to quit smoking or use any treatment to be in this study. However, if you decide you would like to use treatment to help you make changes to your smoking, you will receive counseling and will be given an option to use medication if you are medically eligible and interested in using it. The counseling and medication follow clinical care guidelines. If you were randomized to Comprehensive Chronic Care, treatment involves 4 counseling sessions over the telephone with a study Health Counselor. If you were randomized to Standard Care, your treatment involves being referred to the Wisconsin Tobacco Quit Line, where you will receive one telephone counseling call. You can call back to the Quit Line for additional counseling calls if you choose to.

All participants who decide to use treatment will be given the option to use nicotine patch and/or nicotine mini-lozenge. Before you start using the medication, we will first ask questions to make sure you are medically eligible to use nicotine patch and/or nicotine mini-lozenge. If you are not medically eligible or do not want to use medication, you can still receive counseling as part of your smoking treatment.

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 or Advocate Aurora Health.
Information from the Wisconsin Tobacco Quit Line regarding use of medications and counseling.

How long will I be in this study?

You will be in the study for 1 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 or Advocate Aurora Health 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. If you take part in this study, the main difference between your regular care and the study is that study team Health Counselors will work with you to let you know about your 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 or Advocate Aurora 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.

If you stop being in this research study, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

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. Jessica Cook, 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 is getting access to effective treatments for smoking. Everyone in this study will be provided information on proven stop-smoking treatments, including access to FDA-approved, non-experimental medications. You will also help researchers learn which types of smoking treatments help more people quit smoking and improve their health.

Will I receive the results of research tests?

Most tests done as part of a research study are only for research and have no clear meaning for health care. In this study, you will not be informed of any test results or unexpected findings.

The questionnaires you will complete in this study ask about symptoms of emotional distress such as depression and anxiety. We are using the questionnaires only for research, not to diagnose mental health issues. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.

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.

If you choose to use smoking treatment offered by this study, there is a risk of unpleasant symptoms related to nicotine withdrawal from quitting or reducing your 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 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.

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.

FOR ANYONE WHO IS CAPABLE OF BECOMING PREGNANT

According to the FDA and the manufacturer of the nicotine patch and mini-lozenge, these medications should not be used by pregnant people. The risks of these medications to an unborn child are not fully known. We ask female study participants who are able to get pregnant or who believe that it is possible to get pregnant (for example, people who have gone through menopause but a year has not passed since the last menstrual period) to agree to the statement below about avoiding pregnancy while receiving study medication. People who have had tubal ligation ("tubes tied") to prevent pregnancy do not have to agree to this statement if the tubal ligation occurred more than a year ago and no pregnancy has occurred.

By providing verbal consent, I have agreed to attempt to avoid pregnancy if I decide to use study medication. I will continue to employ medically acceptable means of contraception that have been approved by study staff. These methods include IUD, oral contraceptive, barrier methods, or abstinence. I will immediately contact study personnel if pregnancy is suspected. I am aware that I may decline to agree to this statement and my refusal to do so will have no effect on my further treatment; however, I cannot participate in the treatment portion of this research study. If this occurs, I understand I can still receive smoking treatment through my primary care provider of the Wisconsin Tobacco Quit Line.

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 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 UW 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 can earn up to $280 for participating in this study. You will receive $40 for hearing about smoking treatment resources during the initial screening phone call. You will receive up to $140 for completing all of the assessment calls. You may be asked to complete a home saliva collection kit to test your saliva for nicotine exposure at12 or 18 months after you enroll in the study, as well. You would earn $50 for completing each of these saliva collection kits ($100 total). 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.

How will researchers keep my research information confidential?

UW Health or Advocate Aurora 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 protects 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 or Advocate Aurora 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 counseling calls you complete during the study. These recordings are being collected for quality assurance purposes. Recordings will be kept for a minimum of 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

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, and your smoking status. If you use medication provided by the study UW Health or Advocate Aurora Health staff will add that to your medical record so your care team knows what smoking medication you use. If you quit smoking, UW Health or Advocate Aurora Health staff may note that in your medical record, as well. Both you and your UW Health or Advocate Aurora 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 Care Manager or Health Counselor. 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. Jessica Cook, at the University of Wisconsin at 608-265-9775. 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 participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

For Advocate Aurora Health Patients - If you have general questions, problems, concerns, information, input or complaints, and want to speak to someone at Advocate Aurora Health who is unaffiliated with the study, please contact the Human Protections Administrator in the AAH Research Subject Protection Office (RSPP) at 414-219-7744 (outside Milwaukee: 877-219-7744) or via email at irboffice@aah.org .