UW Withdraw from Tobacco Study

NCT04969198

8/26/2021

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

Study Title for Participants: UW Withdraw from Tobacco Study

Formal Study Title: UW Withdraw from Tobacco Study: Enhancing and Evaluating Tobacco Withdrawal Assessment Psychometrics and Validity

Lead Researcher: Timothy B. Baker, PhD (608) 262-8673

Where Lead Researcher works: University of Wisconsin-Madison School of Medicine and Public Health; Center for Tobacco Research and Intervention

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Invitation

We invite you to take part in a research study about the health effects of tobacco withdrawal and how the quit smoking medications nicotine patch and nicotine mini-lozenge affect tobacco withdrawal to help people quit smoking. We are inviting you because you smoke cigarettes and are interested in quitting. Your participation is voluntary.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research study is to 1) identify important health effects of tobacco withdrawal and 2) understand how the quit smoking medications nicotine patch and nicotine mini-lozenge affect tobacco withdrawal to help people quit smoking. Everyone in the study will try to quit smoking without any medication for the first week after their quit day. Everyone will receive 8 weeks of quit smoking medications, the nicotine patch and nicotine mini-lozenge, starting 1 week after quitting. We are doing this research to

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University of Wisconsin – Madison

understand how people experience tobacco withdrawal symptoms and how to measure them accurately. We will do this using data gathered over the first week after quitting when people are not using medications and during the following weeks when they are using them. The surveys used to evaluate the effects of tobacco withdrawal have not been updated in many years and this study is evaluating new and improved surveys.

This study is being done at the Center for Tobacco Research and Intervention, University of Wisconsin-Madison (UW-Madison) offices in Madison and Milwaukee, WI. A total of about 200 people will participate in this study.

Funding for this study is provided by the National Institutes of Health (NIH).

What will happen in this study?

If you are eligible and decide to participate in this research study, you will receive quit smoking medications (nicotine patch and nicotine mini lozenges) and 4 coaching sessions to help you quit smoking. You will set a date to quit smoking and try to quit without using medications for the first week. You will receive 8 weeks of medications starting 1 week after your quit date.

Nicotine patches and mini lozenges are medications that help you quit smoking. They are approved by the Food and Drug Administration (FDA) for use in quitting smoking, but have not been approved to start after the quit day so its use in this way is considered experimental. The quit smoking treatments will be provided at no cost to you. You will start using the patch and lozenges 1 week after your quit date. You will use the 2 mg mini lozenge at least 5 times per day (but not more than 20 mini lozenges per day) until the end of the study. You will use the patch 1 time per day until the end of the study. You will start using either the 14 mg or 7 mg patch for 4 weeks (depending on if you smoked during the first week after your quit date), followed by 7 mg patch for 4 weeks. We will give you instructions and written information about how to use the patch and mini lozenge (for example: allow the lozenge to slowly dissolve, do not chew or swallow it). We ask you not to use any other quit smoking treatments (for example: varenicline/Chantix or bupropion/Zyban) or electronic/e-cigarettes/vaping while you are using the study medications.

You will be asked to attend 1 study visit and 3 phone calls before your quit day and attend 2 visits and 2 phone calls after your quit day. In total, over the course of about 3 months, study participants will be asked to complete 3 study visits (2 with quit coaching) and 5 phone calls (2 with quit coaching). At these visits and calls the researchers will ask you complete questionnaires and answer questions about your smoking habits, medication use and side effects, withdrawal symptoms, emotions, daily experiences, and changes to your physical health or mental health. You may be asked the same

questions at different study visits/calls and you may skip any question on the questionnaire that you do not wish to answer. At each visit you will also complete a test to look at the amount of nicotine and carbon monoxide in your body (by a breathing into a machine or providing a urine sample) and check your blood pressure. Most study visits will last about 1 hour, although some visits may last up to 2 hours (3-5 hours total over the whole study). The study assessment calls will last about 25-60 minutes.

You will also be asked to answer questions on your mobile phone several times per day (3-6x/day) for 29 consecutive days, starting 2 weeks before the date you plan to quit smoking. These questions ask about your smoking, withdrawal symptoms, and daily experiences (such as moods, stressors, alcohol use, etc.) and will take less than 10 minutes to complete.

At the end of today's Orientation study visit, you will be asked to schedule your remaining study visits and calls approximately along this timeline:
Call 1 (12 days before your quit day, 0.5 hour)
Call 2 (1 week before your quit day, 1 hour)
Call 3 (1-3 days before your quit day, 0.5 hour)
Call 4 (1-2 days after your quit day, 1 hour)
Visit 2 (1 week after your quit day, 1-2 hours)
Visit 3 (2 weeks after your quit day, 1 hour)
Call 5 (9 weeks after your quit day, 1 hour)
Visit 4 (>9 weeks after your quit day, 0.5 hour, only if you are not smoking at Call 5)

Protected health information (PHI) used in this 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:

- Your answers to questionnaires and interviews about your smoking and other tobacco use, demographics, emotional and physical health, your use of alcohol, your use of study medications, withdrawal symptoms, and your mood.
- The names, addresses, and phone numbers of 3 people who will know how to contact you during your participation in this study. If we have been unable to get in touch with you (for example, if mail is returned or your phone is disconnected or no longer in use), we will ask these people how to contact you – we will not share anything about your participation in the study with these contacts.
- Audio recordings of your counseling/coaching sessions.
- Urine and/or carbon monoxide breath tests to verify nicotine abstinence.

How long will I be in this study?

You will be part of the study starting about 2 weeks before your quit day and for about 9 weeks after your quit day while you are taking study medication and coming in for study visits or calls. The total amount of time you'll be in the study is about 3 months.

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 wanting treatment to quit smoking from health care providers usually receive either brief coaching and a single prescription for medicine lasting 8-12 weeks or a referral for brief coaching and a starter package of medication from a telephone quitline. During this study, you will receive medication for up to 8 weeks, complete in-person pre- and post-quitting study visits, complete pre-and post-quitting phone calls, and complete questionnaires.

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 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 Project Director, Jesse T. Kaye, PhD, at 1930 Monroe St # 200, Madison, WI 53711.

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

You do not have to participate in this study to get help with quitting smoking. If you decide not to participate in this study, you can get help from your primary care provider at your health clinic. Also, you can receive help from the Wisconsin Tobacco Quit Line by calling the toll-free number 1-800-QUIT-NOW (1-800-784-8669).

Will being in this study help me in any way?

The nicotine patch and nicotine mini lozenge are FDA-approved smoking cessation treatments and have been shown to help people quit smoking, especially when used in combination. Quit smoking counseling has also been shown to help people quit. We don't know if being in this study will make it easier for you to quit smoking, but it may. All participants in this study will receive free quit-smoking medication and 4 counseling sessions to help them quit smoking.

What are the risks?

The most common side effects associated with the nicotine patch are headache, skin irritation, difficulty sleeping, vivid dreams, nausea, upset stomach, and dizziness. The most common side effects associated with nicotine mini-lozenge are heartburn, hiccup, nausea, upper respiratory tract infections, coughing, and sore throat. If you are taking a prescription medicine for depression or asthma you should talk to your doctor or pharmacist because your prescription dose may need to be adjusted. Study staff will be checking your physical and mental health symptoms at every visit. You should notify

study staff immediately and stop taking the study medication if you experience any significant emotional or heart-related symptoms, a seizure, symptoms of an allergic reaction (such as difficulty breathing), or symptoms of nicotine overdose (such as nausea, dizziness, rapid heartbeat). You should notify study staff and stop taking the medication if skin redness caused by the patch does not go away after four days, or if you skin swells, or you get a rash. If you experience symptoms of nicotine overdose, the study staff may recommend you stop the study medications or make adjustments to the dose or how often you use the medications. If you do report significant, unresolved emotional issues or thoughts of suicide, you will be asked to speak to a licensed psychologist or medical doctor who will evaluate your symptoms and help connect you to appropriate psychiatric services.

According to the FDA and the manufacturer of the nicotine patch and nicotine mini-lozenge these medications should not be used by pregnant women. The risks of this medication 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 to agree to the statement below about avoiding pregnancy while taking study medication.

People who quit smoking may experience unpleasant symptoms as part of the nicotine withdrawal syndrome. These symptoms may include the following: anger, frustration, irritability, craving for nicotine, anxiety, difficulty concentrating, restlessness, decreased heart rate, increased appetite or weight gain. Since you will not start using nicotine patches or mini-lozenges until one week after your quit day, you may experience more severe withdrawal symptoms. In addition, smoking cessation can increase the likelihood of depression in some individuals, and this is the reason we ask about depression and thoughts of hurting yourself during the study. Coaching received in the study may help you cope with symptoms such as these.

Some of the topics discussed in interviews or in questionnaires may cause temporary embarrassment or emotional discomfort for some people. If this happens to you, please let study staff know about your discomfort. You may choose not to answer any questions that make you uncomfortable. This study involves asking questions about illegal substance use (e.g., cannabis use). There is a chance that someone outside the study could find out about answers to your questions or your study information. If this happens, this could expose you to legal risks or damage your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job. We will try to keep others from getting this information by asking these questions in private and storing your information securely (see section on confidentiality below).

Pregnant people who abuse illegal drugs or alcohol may be reported by members of the research team to county social services under Wisconsin state law. Although this rarely

happens, county social services may decide to place pregnant people found abusing drugs or alcohol to a severe degree in custody to protect the fetus.

Will being in this study cost me anything?

The study medication (nicotine patch and nicotine mini-lozenge), all clinic visits, physical tests, and quit smoking coaching will be provided at no cost to you. You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities. 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 receive up to $280 for participating in this study. You will receive $20 for completing today's visit ($20 total). You will receive $30 for completing each study visit during the first 2 weeks after your quit day ($60 total). You will receive $10 for completing each study phone call ($50 total). If you are asked to come for the in-person visit at Week 9 (Visit 4), you will receive $50 if you attend this visit. If you complete 80% or more of the mobile/cell phone surveys, you will receive $100. We will issue checks in the following schedule:

Visit Number:	Call 1	Visit 2	Visit 3 (Smartphone Survey Bonus)	Call 5	Visit 4
Weeks from your quit day:	-2 week	+1 week	+2 week	+9 week	>9 week
Maximum Payment:	$30	$60	$30-130	$10	$50

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 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 first. Then contact the study team to discuss possible changes to your study medication use and/or study participation.

Call the Project Director, Jesse T. Kaye, PhD, 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 signing this consent form and 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.

How will researchers keep my research information confidential?

We 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 protect your confidentiality by assigning a participant number to most of the information that you provide. We will also store this information securely. The study team has a Certificate of Confidentiality from the National Institutes of Health for this study. 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.

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. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records. 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 and biospecimens 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.

Who at UW-Madison can use my information?

Members of the research team
Offices and committees responsible for the oversight of research
Accounting and billing personnel at the UW-Madison

Who outside the UW-Madison may receive my information?

U.S. Office for Human Research Protections
The National Heart, Lung and Blood Institute (NHLBI; the study sponsor)
The U.S. Food and Drug Administration (FDA)
The OSF (Open Science Framework)

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

As required by the study sponsor, after the conclusion of the study, ALL information that can identify you will be removed from the health information collected in this study and the data will be deposited in the NHLBI data repository. At that time, it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information without anything that identifies you could be used or shared for reasons other than the ones described in this form (for example, use by a researcher from another university).

While there will probably be scientific publications and presentations as a result of this study, your name or identity will not be used. Some of the information you provide may be shared publicly on the OSF (https://osf.io) to support open and transparent science practices. This will not include any information that can identify you. Data shared with OSF will be totally de-identified, meaning this information will not be linked to your name or identity.

Will information from this study go in my medical record?

None of the information we collect for this study will be put in your medical record.

What if I have questions?

If you have questions about this research, please contact the Project Director, Jesse T. Kaye, PhD, at (608) 262-8673.

We are requesting your email address and text message number so we can send you reminders and instructions for your study visits and reschedule your study visits, if necessary. Email and texting is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email and text messages. You should avoid sending sensitive, detailed personal information by email or text. Email and text messages should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the Project Director, Jesse T. Kaye, PhD, at (608) 262-8673. You do not have to provide your email address to participate in this study.

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.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____
Printed Name of Research Participant

_____
Signature of Research Participant Date

_____
Signature of Person Obtaining Consent and Authorization Date

****You will receive a copy of this form****

VOLUNTARY STATEMENT OF INTENT TO AVOID PREGNANCY

According to the FDA and the manufacturer of the nicotine patch and nicotine mini-lozenge these medications should not be used by pregnant women. The risks of this medication 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 to agree to the statement below about avoiding pregnancy while taking study medication. Women who are menopausal and have not have a menstrual period in more than one year are not required to sign. Male participants are not required to sign this statement.

I, _____(print name), agree to attempt to avoid pregnancy while I am taking study medication. I will continue to employ medically acceptable means to avoid pregnancy that have been approved by study staff. These methods include abstinence from sex with men, condoms, diaphragm, birth control pills, injectable contraceptive (e.g., Depo-Provera), contraceptive implant (e.g., Implanon), IUD, have had hysterectomy or tubal ligation, vasectomy of sex partners, or are more than 2 years post-menopausal. I will immediately contact study staff if pregnancy is suspected. I am aware that I may decline to sign this statement and my refusal to sign will have no effect on my further relationship with the University of Wisconsin; however, I cannot participate in this research study.

_____ _____

Signature of Participant **Date**