STUDY INFORMATION SHEET

Version Date: 05/01/2025.

UW HS-IRB # 2023-1025

NCT 06218823

“Tobacco Treatment Comparison for Cancer Care”

Principal Investigator: Danielle E. McCarthy, Ph.D. (608) 265-5949
Coordinating Center: UW-Center for Tobacco Research and Intervention (UW-CTRI)
Funding Sponsor: DHHS, PHS, National Institutes of Health (NIH)

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

Study Title for Participants: Smoking Treatment for Patients with Cancer

Formal Study Title: Comparative Effectiveness Trial of Tobacco Cessation Treatments among Cancer Patients who Smoke

Lead Researcher: Danielle E. McCarthy, Ph.D., 608-265-5949, 1930 Monroe St., Suite 200, Madison, WI 53711

Institution: University of Wisconsin-Madison Center for Tobacco Research and Intervention

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Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

Although research has identified several smoking treatments that help people quit smoking and improve their health, we do not yet know which treatments are most effective, efficient, or equitable in helping patients with cancer stop smoking. This study will compare two evidence-based smoking treatment approaches to see which works best at helping people quit smoking during cancer care.

We invite you to take part in this research study because your UW Health records suggest that you are an adult who may have received cancer care from the UW Carbone Cancer Center in the past year and may smoke cigarettes.

What will I need to do in this study?

The research team will ask you to participate in one of two smoking treatment programs. You will receive medication and phone calls with an experienced quitting coach to help you quit smoking. We will also ask you to complete 3 phone surveys and provide samples at the end of the study to check your smoking status.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment. You and your UW Health care team will be told which treatment you are getting.

We expect that you will be in this research study for 6-8 months.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you:	You may NOT want to be in this study if you:
• Don't know which treatment is best for you and you are comfortable being randomly assigned to treatment since doctors don't yet know which one will be best for you. • Are willing to help researchers find out which study treatment could better help people with cancer quit smoking. • Want the chance to get study treatment, even though it may have unwanted side effects and doctors don't yet know which one is better for patients with cancer. • Are comfortable having researchers ask questions about my smoking and health. • Are willing to try to quit smoking in the next 60 days, to talk with a quit coach by phone 3-7 times, and to use study medication for 2-12 weeks (if you are medically eligible for medication). • Are willing to complete 3 phone surveys with the research team and to give breath, urine, or saliva samples for research tests over the next 8 months.	• You want to make a decision about treatment with your own doctor and don't want to leave it to chance in a randomized study. • Do not want to try to quit smoking. • Do not want to talk with a quit coach about your efforts to quit smoking. • Do not want to answer survey questions or give breath, urine, or saliva samples to the University of Wisconsin research team. • Will not be able to take 15-20-minute study calls between 7:30 AM and 7 PM Monday-Friday.

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services

you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Instead of being in this research study, your choices may include: getting stop smoking treatment from your usual health care providers, from your state tobacco quit line, from SmokefreeTXT, or from your local pharmacy.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you go to a health provider for care, the provider focuses on how to help you as an individual. When you take part in a study, you are helping to answer a research question, like how safe or effective a treatment is, or what dose to use. Treatment is based on a study plan, not on you as an individual.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at 1930 Monroe St., Suite 200, Madison, WI 53711 or 608-265-5949.

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.

If I take part in the study, what will I do?

Step 1: Decide if this study is right for you. The first step in the study is to learn about the study and then decide if you want to be in it. Please feel free to ask the study team questions at any time before or after you make your decision to participate.

Step 2: Answer baseline questions over the phone. This will take about 10-15 minutes. We will ask you questions about yourself and your smoking. We will also ask you to choose a day to quit smoking within 60 days of the day you join the study. After you answer these questions, we will tell you which treatment you were randomly assigned to get, and then we will schedule your phone coaching sessions.

Step 3: We check to see if study medications are right for you. If you are eligible for study medication based on your baseline survey responses, we will reach out to your UW Health primary care and/or oncology providers to see if they have any concerns about you starting study medications.

Step 4: We ship you study medication. If you are medically eligible for study medication, the study team will mail you study medications and instructions for their use

ahead of your target quit-smoking date. You will receive either 2 or 12 weeks of medication, depending on your randomly assigned study treatment.

If you receive varenicline, you will be asked to start taking this one week before your quit date. You will start taking one 0.5 mg pill per day for 3 days, then take two 0.5 mg pills per day for 4 days, before stepping up to two 1 mg pills per day starting on your target quit-date and continuing for the next 11 weeks.

If you receive nicotine patches, you will be asked to start wearing one patch per day on your target quit date.

Step 5: Pre-quit coaching call. One week before your target quit-smoking date, you will complete a quit coaching call to get ready to quit smoking. This 20-minute call will give you instructions about how to use study treatments and focus on preparing for your quit date. You will also receive information about your state tobacco quit line services and about the National Cancer Institute texting program to help people stop smoking (SmokefreeTXT).

Step 6: Post-quit coaching calls. You will complete 2-6 more coaching calls, depending on the treatment you were randomly assigned in the study. These 10-20-minute calls will occur once every 1-4 weeks. Calls will focus on how your quit attempt is going, and what may help you prevent or deal with cravings to smoke or nicotine withdrawal symptoms. Quit coaches will also ask about how you are using study medications, and how these are affecting you. You will schedule these in advance with your quit coach, typically between 7:30 AM and 7 PM on weekdays (Mondays through Fridays). These calls will end either 1 week after your target quit date, or 12 weeks after your target quit date, depending on which treatment you are randomly assigned to receive.

Step 7: Follow-up calls. The study team will call you 12 and 26 weeks after your target quit-smoking date to collect follow-up data. These 15-20-minute surveys will ask about your tobacco use, experiences quitting, and treatment use and satisfaction.

Step 8: Smoking status check and end of study. In the 1-3 weeks following your 26-week post-quit phone call, we may ask you to come to the Madison research office to blow into a machine that tests for carbon monoxide 1-2 times, and to provide one urine sample for cotinine testing. Carbon monoxide and cotinine can tell us if you have been exposed to smoke and nicotine, respectively.

If you cannot come to the Madison office to provide breath and urine samples, we may mail you a kit that you can use to collect your saliva and then mail this sample back to us for cotinine testing. These tests will take about 10-15 minutes to complete.

Your participation in the study will end after either the 26-week follow-up phone survey or after you complete breath, urine, or saliva testing after this call.

All of these study activities are for research, and are not part of your health care at UW Health or Carbone Cancer Center. You can access your state tobacco quit line and SmokefreeTXT at any time.

As part of the study we may collect audio recordings of you during coaching calls to ensure that quit coaches are providing high-quality coaching and following the study protocol. We will only record these calls if you consent to recording. This is optional in the study. Recordings will not be used for purposes outside of the study or in any papers or publications.

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:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health
- 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 changes to your study medications by your care team or side effects you experience. We will get this information from your health care providers as we coordinate your smoking cessation care with them.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. 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.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

If you decide to leave the research, this may limit your access to study medications and quit-smoking coaching. If you decide to leave the research, contact the investigator so that the investigator can update study records to ensure you do not receive further study contacts and so your research record at UW Health can be updated to keep your care team informed.

If you stop being in the research, already collected data may not be removed from the study database.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. 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, Danielle McCarthy, Ph.D., at 1930 Monroe St., Suite 200, Madison, WI 53711.

Will being in this study help me in any way?

Being in this study may help you quit smoking by connecting you with evidence-based stop-smoking treatments. Both of the active treatments offered in this study have been shown to work better than no treatment in prior research. We do not yet know which treatment works best during cancer care, however, which is why we are comparing the treatments in this study.

Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about how best to treat smoking in people with cancer.

What are the study risks?

The medications to be used in the study are already approved by the FDA for treatment of smoking and the quit coaching to be provided carries minimal risks. The study is not free of risk, however. Here are the key risks of participation:

- Physical risks –you may experience side effects from study medications.
  - Nicotine patches can cause skin rash, insomnia, and vivid dreams.
  - Getting too much nicotine can cause nausea, vomiting, and other unpleasant symptoms.
  - Varenicline can cause nausea and disturbed sleep. Some individuals taking varenicline may experience more 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.
  - People can have allergic reactions to any kind of medication, including nicotine patches and varenicline. Signs of an allergic reaction include hives; difficulty breathing; and swelling of your face, lips, tongue, or throat.

- Psychological risks—you may find it difficult or unpleasant to quit smoking or to talk with a quit coach about your smoking or quit efforts. You may also find it difficult or upsetting to answer some study survey questions. Such difficulties and discomfort should be short-lived and you are free to skip study activities or questions you do not want to complete.

- Privacy risks—you may find some of the questions the study teams ask too personal, and we cannot guarantee that study data will not be accessed by unauthorized persons.

- Legal, social, or economic risks—there could be risks associated with unauthorized disclosure of information you share in the study. For example, if someone learned that you used tobacco or cannabis from unauthorized access to study records, this could lead to problems for you. We will take many steps to maintain your confidentiality to reduce this risk.

Study medications may also hurt a pregnancy or fetus in ways that are unknown. You should not be or become pregnant while using study medication. We will screen for pregnancy before issuing you study medication.

The research team will provide phone coaching and study medications (nicotine patches or varenicline) for you at no cost during participation in the study.

Taking part in this research study may lead to added costs to you. If you have limited cell phone minutes or data, completing study coaching calls, study surveys, or tobacco quit line calls, or SmokefreeTXT text messaging on your cell phone could cost you money for your cell service.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. The study is protected by a Certificate of Confidentiality from the National Institutes of Health. This means that even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study.

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 University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program, the Food and Drug Administration, and the Department of Health and Human Services.

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 in this form 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 confidentiality protections, we might use information that we collect during this study for other research, or share it with other researchers without additional consent from you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

Will information from this study go in my medical record?
A medical record may be created for you if you do not already have one. Your medical record might say that you participated in this study, and a copy of this consent and authorization form might go in your medical record. Some of the information we collect for this study will go in your medical record, including the stop-smoking treatments you receive through this study. Both you and your UW Health providers will be able to see these results. None of the information we collect for this study will go in your medical record.

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, the only test results we will share with you are for carbon monoxide levels in your breath samples, if you are asked to provide these 26-29 weeks after your target quit date. If you provide breath samples for this test, we can share the result immediately, if you would like this. This test will only tell us about your recent smoke or carbon monoxide exposure. It will not detect anything else about your health. You will not be informed of any other test results or unexpected findings.

The questionnaires you will complete in this study ask about symptoms of emotional distress such as depression, suicidal thoughts, 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.

Can I be removed from the research without my agreement?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- 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.

What else do I need to know?

Will I receive anything for participating?

If you agree to take part in this research study, you will earn $50 for each of the 3 phone surveys you complete, up to $150 for your time and effort. If you complete the final study visit for breath and urine testing, or return a saliva sample via the mail at the end of the study, you will earn another $75. You will be paid for each activity you complete.

How many people will be in this study?
We expect about 50 people will be in this research study.

Who is funding this study?
This research is being funded by the National Cancer Institute.

Will my data or samples be used for future research?
This study is collecting data and samples from you. We will not save any breath, urine, or saliva sample collected from you.

Because data from this research study can be useful for many different kinds of research, organizations like the National Institutes of Health (NIH) have created large databases that collect data from research studies. We will put data from this study in a federal database or in other public scientific resources to make the information broadly available. We cannot predict how this information will be used in the future. Because it can be used for many kinds of research, your information may be used for research that you disagree with or would not choose to be involved in.

We will share the following data from this study: de-identified (anonymous) data about your demographics, cancer, tobacco use, treatment use, treatment experiences and ratings, and data about the costs of treatment. These data will not contain your name or direct identifiers and will be shared under controlled access with other researchers who agree to protect the data from unauthorized use.

Sharing your data from this study is optional. We ask over the phone if you consent to share your data. You can change your mind later, but researchers might still use your data and samples if they have already been de-identified and shared. If you do not want your data used for other research studies, please tell the research team this.

Optional study activities

This part of the consent form is about additional research activities that you can choose to take part in. You can still take part in the main study even if you say “no” to these activities. The optional activities will not help you directly.

- **Audio recording:** In the study, we would like to collect audio recordings of coaching calls you complete in 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. We ask over the phone if you consent to audio recording. If you do not want your coaching recorded, please tell the research team.

- **Automated email or text reminders:** We will ask you if you consent to receiving automated mail or text messages reminders of study calls or visits to help you keep track of these appointments.
    - The study team will program automated reminders that can go to your email and/or cell phone so you know when to expect a call from the study team.
    - Email and text messaging are generally not secure ways to communicate about your health, as there are many ways for unauthorized persons to access email and text messages. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. You may not be able to reply to the automated messages you receive in the study. If you need to talk to someone immediately, please contact the study line at (608) 262-7527. You do not have to provide your email address or agree to text messaging to participate in this study.
    - Consenting to these automated emails or texts is optional in this study, and you can withdraw your consent for these reminders at any call by calling the study team at (608) 262-7527.
    - We will ask you over the phone if you consent to email and/or text message study reminders or not.