BREATHE 2 Clinic Outreach Study: Self-Guided Treatment Substudy

NCT05683821

2/22/2024

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

Study Title for Participants: BREATHE 2 Clinic Outreach Study: Self-Guided Treatment Substudy

Formal Study Title: BREATHE 2 Clinic Outreach Study: Self-Guided Treatment Substudy

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Institution: University of Wisconsin-Madison

Key Information

Thank you for joining this study. This sheet goes over the information we talked about on the phone or that you reviewed online when you consented to and requested self-guided treatment with a Smokefree.gov texting program and/ or nicotine medication.

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

Why are researchers doing this study?

The purpose of this research study is to see if connecting patients who smoke with texting programs and/or free samples of nicotine medications helps more people use treatment and change their smoking. We are doing this research because many people who try to quit smoking do not use treatment to help them quit, and we want to find ways to connect more people with treatments that can help people smoke less. This study is being done by the Center for Tobacco Research and Intervention at the University of Wisconsin – Madison (UW-Madison) in clinics at Aurora Health and UW Health. The study is funded by the National Cancer Institute.

We asked you to take part because you are an adult who is enrolled in the BREATHE 2 Clinic Outreach Study. You are eligible for this self-guided treatment substudy because you receive care at an Aurora Health or UW Health clinic that is working with researchers at the University of Wisconsin to give patients extra treatment options. These options include text-message programs provided by Smokefree.gov and free nicotine medications provided by the University of Wisconsin-Madison.

What will I need to do in this study?

This is a substudy that you can join at any time during the 18 months you are in the BREATHE 2 Clinic Outreach Study. You do not have to join this Self-Guided Treatment Substudy to remain in the BREATHE 2 Clinic Outreach Study. This part of the study is completely voluntary and optional.

The first step in the study was to learn more about Smokefee.gov texting programs and/or nicotine medications. In the case of nicotine medications, this also involved learning how the University of Wisconsin-Madison will use the information you shared when you requested medication. You also consented to registering for a Smokefree.gov texting program and/or to receiving medication from the University of Wisconsin-Madison. You answered some medication screening questions and/or text program registration questions. You have already completed these steps.

Because you receive care at an Aurora Health or UW Health clinic that is offering self-guided treatment options to adult patients who smoke, you can access the texting programs and 2-week nicotine medication starter kits during your 18 months in the BREATHE 2 Clinic Outreach Study. You can enroll in and repeat the Smokefree.gov texting programs as many times as you want. You can receive 2-week supplies of 1-2 nicotine medications a maximum of 6 times in the study. Medications will only be sent once in every quarter of the year (or once every 13 weeks). You will have to repeat the steps described above (consent, answer questions, begin treatment) each time you want to request a new texting program or medication.

We will only send you medication if you pass the health screening for use of study medications. If you do not pass the health screening, you can talk with your health care provider about other options that might work for you.

You do not have to request any more treatment in the study, and you do not have to answer any more questions if you do not want to do so.

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 stay in this study if you:	**You may NOT want to stay in this study if you:**
Want to try nicotine medications to see if they help you change your smoking. Want to try texting programs that can help you learn to cope with cravings to	Do not want to try nicotine medication or a texting program to help you change your smoking.

smoke, help you practice quitting smoking, or help you quit smoking for good. Are willing to share information about you, your smoking, and your health with the University of Wisconsin-Madison to get medication from them Are willing to share information about you and your smoking with Smokefree.gov so they can send you tailored text messages to help you change your smoking. Are interested in contributing to scientific knowledge even though you won't benefit directly from the study.	Do not want to share your information with the University of Wisconsin-Madison to get nicotine medication. Do not want to share your information with the Smokefree.gov text message programs. Do not want your use of nicotine medication or Smokefree.gov texting programs noted in your Aurora Health or UW Health medical records.

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:

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.

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. In this study, the research question is whether giving clinics extra treatment options to offer patients, including self-guided treatments like sampling nicotine products and Smokefree.gov texting programs, helps more patients use smoking treatment and change their smoking.

In this study, everybody will get offered free help in changing their smoking. Everyone will have access to state tobacco quitline services (through the Wisconsin Tobacco QuitLine for people who live in Wisconsin). Everyone in the study will also have access to their usual healthcare teams for support in quitting, but will be charged for this as they are for usual healthcare.

If you take part in this self-guided treatment study, the main difference between your regular care and the study is that a Tobacco Care Manager will work with you to let you know about your stop smoking treatment options and help you start treatment when you are ready (either on the phone or online).

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 your Aurora Health or UW Health Tobacco Care Manager or another member of the University of Wisconsin-Madison research team at 608-265-5949. Your Tobacco Care Manager contact information appears below:

Aurora Health: 414-219-4801

UW Health: 608-265-4561

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?

Nicotine medication.

If you requested nicotine medication samples, you first read or listened to a consent form to make sure you had information about the risks and benefits of these treatments before you requested them. You will have to do this and pass a health screening each time you request medications so we can make sure medications are right for you, and to see which dose you should receive. You then get to choose 1-2 of the medications that you are medically eligible to use.

The Tobacco Care Manager shares information about your medication requests, answers to screening questions, and medication choices with the University of Wisconsin-Madison who review the information and then send you medications in the mail along with instructions in how to use the medications, and this study information packet. The medications you may request (if medically eligible and in stock) include:

- Nicotine patches that release nicotine slowly over 24 hours, in either 7 mg, 14 mg, or 21 mg doses (depending on your smoking pattern)

- Nicotine gum or lozenges that release medication quickly and can be used every 1-2 hours to prevent and cope with cravings to smoke, in either 2 mg or 4 mg doses (depending on your smoking pattern):
  - Nicotine mint mini-lozenges
  - Ice mint coated lozenges
  - Nicotine gum with cinnamon flavor
  - Nicotine gum with fruit flavor
  - Nicotine gum with a mint flavor
  - Nicotine gum with original flavor

Texting programs.

If you chose a Smokefree.gov texting program, you read or listened to a consent form to make sure you had information about the risks, benefits, and costs of these texting programs, and about their terms of use and privacy policy. You will do this each time you want to start a texting program, and will then answer some questions that the Tobacco Care Manager will use to register your mobile number in the program through the Smokefree.gov enrollment portal. You then start receiving text messages from the program you selected. You can text STOP to the program at any time to stop receiving messages. You can text HELP at any time for help using the program. The texting programs you can choose from include:

If you are not ready to quit: The **Daily Challenges** program will help you learn to handle cravings to smoke or stress

If you are ready to practice quitting: The **Practice Quit** program will guide you through 1, 3, or 5 days of living smoke-free

If you are ready to quit smoking in the next 2 weeks: The **SmokefreeTXT** program will provide tips and support for up to 2 weeks before you quit and 6 weeks after you quit smoking

All the texting programs provide on-demand support via keywords at all times

You can stop getting text messages any time

The only cost of these programs is phone minutes or data (if you have a limited plan)

Both the nicotine samples and the Smokefree.gov texting programs are different from the smoking treatment normally available to you at Aurora Health or UW Health. Even if you do not take part in this or any other study, your Tobacco Care Manager and other care team members at Aurora Health or UW Health can refer you to the Wisconsin Tobacco Quit Line (or the quitline in your state if you live outside Wisconsin), or your primary care provider could give you help quitting smoking. These are all other options that you could pursue to get treatment to help you quit smoking.

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:

Things you tell the researchers about your health to see if medications are right for you
The information you share about you, your smoking, and your mobile phone to register for a texting program
Your name and address (if you request medication)

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, you will just lose access to the free nicotine medication samples and assisted enrollment in Smokefree.gov texting programs. You will still have access to quitline support and your current primary care team for support.

If you stop being in the research, 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) 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 texting or nicotine medication substudy.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Danielle McCarthy, Ph.D., at the Center for Tobacco Research and Intervention, 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 access free treatments to help you change your smoking, even if you are not ready to quit smoking permanently. You can use these

treatments even if you are not in the study, however. The study treatment might not work at all, or it might have bad side effects. If you do not use any of the nicotine medication or texting treatment offered, we do not expect you to get any additional health benefit from being in the 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 to connect more people who smoke with treatment to help them change their smoking patterns.

What are the study risks?

Physical risks of nicotine medication– you may have an allergic reaction or other negative reactions to nicotine patches, nicotine gum, or nicotine mini-lozenges. These include the following:

- Skin irritation from the patch that can be painful, itchy, or change the appearance of your skin
- Nicotine patches can also cause insomnia or vivid dreams that disrupt your sleep.
- Nicotine gum and mini-lozenges can cause heartburn, hiccups, nausea, coughing, sore throat, and cold-like symptoms.
- Nicotine gum can cause jaw pain
- Getting too much nicotine can cause nausea, vomiting, and other unpleasant symptoms.
- People can have allergic reactions to any kind of medication. Signs of an allergic reaction include hives; difficulty breathing; and swelling of your face, lips, tongue, or throat. Allergic reactions can be severe and life-threatening.

Physical risks of texting programs—you should never text while driving or in other unsafe situations like walking across the street or riding a bicycle. Texting can be distracting.

Psychological risks—using nicotine patches, gum, or mini-lozenges, or participating in texting programs are unlikely to cause distress or carry psychological risks.

Privacy risks—you may not want to share your information with the University of Wisconsin-Madison to obtain nicotine medication samples, and you may not want to share information with a texting program. Sharing your information in these ways may also increase risks that other people may access your private information.

Legal risks—We do not know of any legal risks related to using over-the-counter nicotine medication or texting programs sponsored by the National Cancer Institute.

Social risks—If information about your smoking were revealed to others, this might affect the way they treat you, your employment, or your insurance.

Economic risks—you may be charged for text messages by your mobile phone service provider.

Using nicotine during pregnancy is known to hurt a pregnancy or fetus in the following ways: exposing a fetus to nicotine in ways that can have lasting effects on their development. You should not be or become pregnant while using nicotine medication in this study.

Taking part in this research study may lead to added costs to you. These costs would be in the form of mobile phone service charges for using texting programs or talking with your Tobacco Care Manager.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. You remain responsible for all deductibles, co-pays, and balances under your insurance. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. A member of the study team can talk to you about what procedures would be considered standard of care and the coverage of those costs.

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 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.

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 the Department of Health and Human Services and the 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 (FDA), and the Department of Health and Human Services (DHHS).

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, 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.

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 will 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 what nicotine medications you receive and what texting programs you enter. Both you and your Aurora Health or UW Health providers may be able to see these results.

Will I receive the results of research tests?

The only tests done as part of a research study are screening you for eligibility for nicotine medication. You will be informed about your eligibility for nicotine medication right after you answer the screening questions. If you cannot use study nicotine medication, you can decide whether you want to talk with the quitline or your health care provider about other treatment options.

The questionnaires you complete in this study may show that you are experiencing symptoms of emotional distress such as suicidal thoughts. If the questionnaires show that you are experiencing symptoms of emotional distress such as suicidal thoughts, we will give you a list of places where you can get help. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional or the suicide prevention hotline (call or text 988).

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?

Participants will NOT be paid for participation in this study.

How many people will be in this study?
We expect about 4,000 people will be in this research study nationally.

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