Cessation Screening Project

NCT04188873

8/8/2023

Cessation Oral Consent Script

Description of Study from Phone Screen: *Thank you. This is a 1-year research study to compare different stop-smoking treatments. All participants will be assigned to a stop smoking treatment on a random basis (like flipping a coin). Everyone will get at least 12 weeks of either varenicline, which is a non-nicotine pill, or nicotine patches and nicotine mini-lozenges. The nicotine patch gives you a slow, steady release of nicotine and the mini-lozenges give you a way to deal with urges to smoke. You might also be asked to use your medication for a month before your quit date or receive 24 weeks of your assigned medication. Everyone will also get 2 or 4 sessions of quit-smoking coaching. All of these treatments are free to you. These medications have been shown to at least double the chances of quitting in past studies.*

Consent Script:

Now I would like to tell you more about the study, answer any questions you have, and ask if you consent to be in the study. If you do consent, the next step will be to collect more information before we end this call.

In addition to the free smoking cessation coaching and medication, everyone will be asked answer 9 more phone calls over the course of a year where we would ask you about your smoking, use of study medications, and your health. These calls may last up to 30 minutes. If you report quitting, you may be asked to provide a saliva sample at 6 or 12 months after your quit day. Your participation in the study will end 1 year after you enroll, but we may collect data from <UW Health/AdvocateAurora> electronic health records from one year ago and up to 4 years from now so we can see how study treatments affect people's health and use of health care. We keep information about you confidential and use it just for research. Your participation in this study is voluntary.

Here are some reasons you may want to be in the study:

> *The study will give you opportunities to get effective treatments to stop smoking.*
> *Everyone in the study will be given coaching and FDA-approved, non-experimental quit smoking medication, at no cost, for at least 12 weeks.*
> *You will help researchers learn how to offer stop smoking treatments in a way that helps more people quit smoking and improve their health.*
> *We value your time, so you will be paid for each study call or visit you complete, up to a total of $220 over one year.*

Here are some reasons you might NOT want to take part in this study:

> *You won't get to choose which quit smoking treatment you get. A computer will assign you at random (like flipping a coin) to one of the treatments we are studying.*
> *The study collects information about you and your health. You might be uncomfortable providing some of this information, and you have the right to refuse to answer any question.*
> *We will protect your information from unauthorized use and disclosure, but there is still a risk that your information could become known to someone not involved in this study.*

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There are also possible side effects from stop-smoking medications, which is why we will check with your primary care provider to make sure these medications are right for you.

- *The main risks of the nicotine patch are skin rash, insomnia, and vivid dreams.*
- *The main risks of nicotine mini-lozenges are heartburn, hiccups, and nausea.*
- *The main risks of too much nicotine are nausea, vomiting, and dizziness.*
- *Varenicline, can cause nausea, sleep disruption, and, in some people, negative moods such as anger, agitation, depression, or suicidal thoughts. Varenicline may also be associated with an increased risk of heart problems in people with heart and blood vessel disease. Rarely, people may have an allergic reaction or serious skin reactions including rash, swelling, redness, and peeling of the skin, with some of these reactions being potentially life threatening.*
- *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.*

If you quit smoking nicotine withdrawal can cause unpleasant side effects like problems sleeping, hunger, craving cigarettes, difficulty concentrating, irritability, and bad mood.

According to the FDA and the manufacturers of varenicline and the nicotine patch and mini-lozenge, these medications should not be used by pregnant women. The risks of these medications to an unborn child are not fully known. We ask study participants who are able to get pregnant or who believe that it is possible to get pregnant to agree to avoid pregnancy while taking study medication. Do you agree to avoid pregnancy while taking study medication?

YES Continue

NO Not eligible to participate

Now let's talk about how this study treatment differs from your usual medical care. The study treatment is not part of your usual health care. Study treatment will be delivered by UW Madison researchers, not your usual providers at <UW Health/AdvocateAurora Health>. We will let your primary care team know which treatments you are getting and if you have severe side effects from the medication. If you decide you don't want to use study treatment, you can ask your primary care provider for help or receive help quitting from the Wisconsin Tobacco Quit Line.

If you get sick or hurt during this study, please get the help you need right away. Costs for any medical care will be billed to you or your insurance, just like any other medical costs. No other compensation (such as lost wages or damages) is usually available.

Any questions so far? YES _____ NO Answer questions

I mentioned we will collect information about you. This information will come from you, and from your <UW Health/AdvocateAurora> health record for up to 5 years. We will use this information to see how our treatments affect smokers' ability to quit smoking and overall health. We will let your primary care team know you are in the study, and coordinate your stop-smoking treatment with your primary care team. We will document this in your electronic health record so your healthcare team will know what treatment you are receiving, if you have to stop the

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medication due to side effects, and if you quit smoking. Collecting information from <UW Health/AdvocateAurora> will not affect your relationship with <UW Health/AdvocateAurora> or the services you receive in any way.

<UW Health/AdvocateAurora> and the UW Madison have strict rules to protect your personal and protected health information. We limit who has access to your name, address, phone number, and other information that can identify you. We also store this information securely. The UW-Madison may publish and present what we learn from this study, but none of this information will identify you directly without your permission. We also have a Certificate of Confidentiality from the National Institutes of Health that prohibits us from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

We cannot promise complete confidentiality, however. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study, and to the National Cancer Institute, which is funding the study.

For this study, the main people who will use your information are researchers at the UW-Madison Center for Tobacco Research & Intervention, and researchers at other institutions who are helping with the project.

Any questions so far? NO YES _____Answer questions

Taking part in this study treatment is voluntary. This means that you can stop study treatment at any time. Your choice will not affect your relationships with <UW Health/AuroraAdvocate Health>, UW Madison, 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. By agreeing to use study treatment, you are not giving up any legal rights. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

If you decide to take part in the study, I will send you a written summary of all the information we discussed about this study. It will include contact information for the study team and instructions for what to do if you decide you want to leave the study, have any questions about your rights as a research participant, or have any complaints you cannot resolve with the research team.

Do you have any questions about the study? NO YES _____Answer questions

DO YOU CONSENT TO PARTICIPATE IN THE STUDY AND ALLOW FOR THE USE OF YOUR HEALTH INFORMATION? YES NO

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YES Continue

NO *OK. Would you like the number of the Wisconsin Tobacco Quit Line?* YES NO

YES *Their toll free number is: [1-800-784-8669]. Their staff are available 7 days a week, 24 hours a day.*

NO *Thank you for your time.*

Great! I'm so glad you've decided to join the study! We'll send you a welcome letter in the mail. This will have a summary of what we just talked about and additional information about the study. It will also give you the phone number of our research partners at UW Madison.

If participant wants to get contact numbers now, provide these over the phone:
Project Principal Investigator: 608-262-8673 (questions about study)
UW Health Patient Relations: 608-263-8009 (complaints about study or team)

As part of the study coaching sessions will be audio recorded. These recordings are being collected for quality assurance purposes to train health counselors and to ensure that treatment is consistent for everyone. Recordings will be stored on a secure server and 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.

We are requesting your email address and text messaging number so we can send you reminders about study calls, links to video calls, and reminders about refilling your study medication. Please note that if you want to be able to conduct your visits via video call, you will need to supply your email address. 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. Please tell me which of these statements about messages are true for you:

Email

____ *Yes, you may use email to contact me for this study.*
- *What is your email address?* _____

____*No, I do not want to be contacted by email or have video visits.*

Text

____*Yes, you may use text messages to contact me for this study. I know that I will be responsible for all texting charges.*
What number would you like us to use for text messages? _____

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____*No, I do not want to be contacted by text messages.*

[This invitation will be extended to all participants until we recruit 20 participants. To be offered to participants starting in 2021]
We are also asking up to 110 participants to answer additional questions about your experiences with telephone vs. video calls during your next call (a week before the scheduled quit day) and the call 3 months after the scheduled quit day. These extra questions will take about 5 additional minutes. We will audio record and transcribe your answers and they will be kept confidential for research purposes. If you agree to and complete these additional surveys, you will receive an extra $10 per call ($20 total). Do you want to participate in these extra surveys?

Additional Telehealth Satisfaction

_____*Yes, you may ask me additional satisfaction questions and audio-record my answers.*

____*No, I do not want to be asked extra satisfaction questions.*

I just have a few more questions.

Conduct baseline assessment

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