Informed Consent/Authorization for Participation in Research

Title of Research Study: Smartphone-delivered scheduled smoking with compliance facilitation as an adjunct cessation therapy: a feasibility study

Study Number: 2022-0772

Principal Investigator: Yong Cui, Ph.D.

_____ _____
Participant's Name Medical Record Number or Study ID

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you are a current smoker who is interested in quitting or reducing your smoking.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

There are 2 parts to this study. You will take part in Part 1 or Part 2.

The goal of Part 1 of this research study is to collect user experience data for a smartphone app that is designed to help people reduce or quit smoking.

The goal of Part 2 of this study is to learn if the app, combined with nicotine patches, can help people quit smoking.

How long will the research last and what will I need to do?

You are expected to be in this research study for about 6 weeks (Part 1) or up to 4 months (Part 2).

You will be asked to provide personal health information and download a smartphone app that you will interact with that describes and schedules your smoking activity.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

There are no expected physical risks to you for taking part in this study, though nicotine patches can cause mild irritation. When you reduce or quit smoking, you may experience withdrawal symptoms due to changes in your smoking behavior.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

It cannot be promised that there will be any benefits to you or others from your taking part in this research. However, participation may help you reduce your smoking activity or quit completely. People in the future may benefit from what is learned.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate.

Detailed Information

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

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-792-2265.

This research has been reviewed and approved by an Institutional Review Board ("IRB" - an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected that about 75 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

If you agree to take part in this study, you will be asked about your demographics (such as your age and sex), smoking history, and other health-related questions. If you are found to be eligible after the first step, we will mail you a study kit to complete the second step. The kit contains the needed materials for completing the study procedures, including a device to measure breath carbon monoxide (CO, a gas associated with smoking) levels, help brochures on quitting smoking, and nicotine patches if you are in the Part 2 of the study. The study staff will schedule a phone call with you after the study kit is delivered to discuss with you the contents of the kit and help you with setting up the app and completing the required breath sample.

You will then be asked to install the study app on your smartphone. You may be lent a smartphone by the study staff if you do not have one that is compatible with the app. You will be instructed on how to use the app, including a few tests to determine your final eligibility.

Your responses in these tests will be reviewed by the study staff. In some cases, further assessment may be conducted by a qualified health professional.

If you are in Part 1, you will use the app for 4 weeks, during which you will follow a smoking schedule on the app to help you reduce your cigarette consumption. You will be asked to record your smoking and complete online surveys each day, including submitting daily CO readings via the Bluetooth iCO device included in your screening kit and your smartphone. After these 4 weeks, you will be asked to provide your feedback regarding the app by completing an online survey and a brief telephone interview. This will not be recorded.

If you are in Part 2, you will be randomly assigned to one of two groups; Group 1: Usual Care or Group 2: COSSR Intervention. Both groups will be asked to use the app for the duration of the study. You will be asked to record your smoking using the app and complete online surveys, including submitting weekly CO readings via the Bluetooth iCO device included in your screening kit and your phone (or study phone if applicable).

Group 1: Your study participation will last approximately 3 months. You will only submit weekly CO readings for about 1 week, and additional CO readings before each counseling session and at the end of treatment (EOT).

Group 2: Your study participation will last approximately 4 months. You will only submit weekly CO readings for about 4 weeks, and additional CO readings before each counseling session and at the end of treatment (EOT). You will be provided with pre-cessation patches (14 mg) to use during the 3-week intervention period, in addition to the 8-weeks of patches during the main portion of the study, for a total of 11 weeks. During this time, you will also be asked to create a smoking schedule before you begin using the nicotine patches. This will be done using your personal information (such as the time you wake up and the time you usually have your first cigarette).

Both groups will receive the usual care treatment, and you will be provided nicotine patches to help you quit smoking, which will be provided at no cost to you. You will use these for 8 weeks. The study staff will provide you with instructions on how to use them.

During the 8-week period that you will use nicotine patches, both groups will also have 3 smoking cessation counseling sessions at Weeks 2, 4, and 6 by phone with the study staff. Each will last about 15 minutes. You will discuss your quitting progress. The sessions will not be recorded. At the end of the 8-week period, you will have a brief telephone visit with the study staff to check on how you are doing, as well as a final telephone call approximately 30 days after you stop your nicotine patches to check in on side effects.

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

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the study doctor so that the study doctor can help you safely withdraw. If you withdraw from this study, you can still choose to be treated at MD Anderson.

Is there any way being in this study could be bad for me? (Detailed Risks)

Nicotine Patch Side Effects

It is not known how often the following side effects may occur.

• high blood pressure • fast heartbeat • difficulty concentrating • depression • dizziness • headache • difficulty sleeping • nervousness • skin rash • sweating • increased saliva	• bleeding gums • swollen tongue • dry mouth • mouth blisters/sores (possible difficulty swallowing) • abnormal taste • constipation • gas • diarrhea • upset stomach	• nausea • pain (joint/muscle/jaw) • abnormal sensation (such as pins and needles) • hiccups • cough • infection • allergic reaction • application site reaction (such as skin rash, redness, swelling, and/or irritation)

To lower the risk of skin reactions, you should put the patch on a different skin area each day. To lower the risk of difficulty sleeping and abnormal dreams, you can remove the patch when you are sleeping and put on a new patch in the morning. To avoid possible burns, you should also remove the patch before having any magnetic resonance imaging (MRI) procedures.

Keep the patches out of the reach of children and pets. Unused and used patches have enough nicotine to poison children and pets. Be sure to fold the sticky ends together when you are done using the patch. In case of accidental overdose, call your doctor or a poison control center right away.

You should discuss the risks of **questionnaires/interviews** with the study chair. The known risks are listed in this form, but they will vary from person to person. Some questions may make you feel upset or uncomfortable. You may refuse to answer any question. If you have concerns after completing the questionnaires or interview, you are encouraged to contact your doctor or the study chair.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

Taking part in this research study may lead to added costs to you. All study materials and supplies, such as all the items in the screening kit and for those in part 2 as well as the nicotine patches, will be provided at no cost to you.

You will be compensated for your time and effort in taking part in this study by way of a reloadable debit or gift card.

Aim 1: You will receive $25 for completing the baseline (that is, producing a CO measure to determine a participant's eligibility), $50 for completing the end of treatment (EOT) survey and interview, and $1/day for completing the daily CO measure and the diary survey for up to $28 total (28 days). In total, participants in Aim 1 can receive a total of up to $103.

Aim 2: If you are randomly assigned to Usual Care, you will receive $25 for completing the baseline, $1/day for completing the EMA daily diary survey for up to $7 total (7 days), $20 for completing Visit 1 and associated assessments, $25 for completing each of the three counseling sessions and their associated assessments, and $40 for the End of Treatment (EOT) call. In total, participants in the usual care group can earn up to $167.

If you are randomly assigned to the Intervention group, you will earn $25 for completing the baseline, $1/day for completing the EMA daily diary survey for up to $28 total (28 days), $20 for completing Visit 1 and associated assessments, $25 for completing each of the three counseling sessions and their associated assessments, and $40 for the End of Treatment (EOT) call. In total, participants in the Intervention group can earn up to $188.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

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 but are not limited to, providing false information and not following the study procedures without justifiable reasons.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- call the study doctor (Dr. Cui, at 713-792-2265) or 713-792-2121 (24 hours)

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to

deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law).

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT