DESCRIPTION: You are invited to participate in this research study on MindCotine's virtual reality smoking cessation program as a treatment option among cancer center patients who smoke cigarettes. The MindCotine program will be used according to labelling. Your participation will inform whether this 6-week treatment option is feasible and acceptable. There are two short questionnaires involved for this study: The first is the screening questions you went through, and the other will be after the 6-week program. This is for seeing changes pre- and post- treatment. This form will go over what's involved and cover potential risks such as loss of confidentiality, simulation sickness, and discomfort in answering questions. It will also cover potential benefits such as reducing or quitting smoking. You can decide at any point not to participate, and you may use tobacco treatment options such as nicotine replacement therapy and counseling services.

The Stanford research team will be mailing MindCotine's Virtual Reality (VR) kit to you. The kit will contain an activation code that will allow you full access to MindCotine's VR app. The VR kit will be yours to keep; Nothing to return. If the cardboard headset needs replacement, please contact the research team.

You will be asked to register a user profile with the app, and this is where the activation code will be used. MindCotine will ask for an email as part of the intervention process. You do not have to provide your real name to them. MindCotine's app will have a privacy policy page to read and accept before the app can be used. MindCotine can also provide tech support with the VR program.

The MindCotine program includes audiovisual content, cognitive behavioral therapy based self-reflective questions, setting a quit date, and notifications. The audio-visual content includes are based on formal mindfulness exercises involving breathing techniques, body awareness, thought recognition, emotions, and smoking impulses. VR therapy exercises include the following topics: The Act of Smoking; RAIN meditation; Stress at work; Bodily sensations; Deep emotions; Nicotine anonymous; Alcohol as a trigger. Each content consists of a 2 minute animated environment to induce meditative states of mind, 6 minutes of exposure with real people, and 2 more minutes of an animated environment to induce a meditative mindset.

After the 6-week intervention period, the Stanford research team will contact you to do a short survey asking about your tobacco use and satisfaction with the VR program. You will still have access to the app after your study participation. The VR program can be accessed for up to a year since you started. After a year, the information you provided to the app will be deleted.

<u>Data analysis portion of the study</u>:
After the 20 participants in the study finish their intervention, MindCotine will provide the Stanford research team with app user frequency data. This is data on how often was the MindCotine app used throughout the intervention.

The Stanford research team will combine this data with the survey data, including the screening questions, and demographic data. Demographic data (age, gender, ethnicity)

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will be obtained from your medical record so the study sample can be described. After the data is combined, identifying information such as names and emails will be removed, and each row of data will be coded with a number for analysis.

The Stanford research team will provide a summary of results to MindCotine. No individual can be identified from the summary. Results from analyses will inform whether MindCotine's VR program would be a good treatment option to offer as part of Stanford's Tobacco Treatment Services.

TIME INVOLVEMENT: You have completed the phone screen, which was estimated to be about 5 minutes. The VR kit will be mailed to your address, and will take 3-5 business days to arrive. After the 6-week intervention, you'll be asked to complete a short survey that is estimated to be 5 minutes long. The intervention involves up to 10 minutes per day to learn skills for smoking cessation. Your study participation ends after the short survey at the end of the intervention is completed.

RISKS AND BENEFITS: The risks of participation include possible discomfort in answering sensitive questions and the potential for health information to be leaked. The survey questions will involve questions your about tobacco use. MindCotine will require an email when registering with the app. To protect your privacy, the research team will store data in Stanford encrypted and password protected computers and will train staff in how to handle confidential data.

There is a small chance that you may experience simulator sickness during the virtual experience. Symptoms include dizziness, nausea, disorientation, sweating, or headache. If there is any change in the way you are feeling during the simulation, remove the headset to stop interacting with the virtual environment.

There are no other foreseeable risks.

Potential benefits include reduction of tobacco use and quitting smoking. We cannot and do not guarantee or promise that you will receive any benefits from this treatment option.

CONFIDENTIALITY:
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. Your participation in this pilot study, tobacco use, and tobacco cessation resources used will be noted in your medical record.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this research study without your authorization. If you verbally approve, it will provide that authorization. This is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization and the informed consent and as required or allowed by law. Please listen carefully before making a decision.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of the study is to test whether MindCotine's VR program is feasible and acceptable if offered as a treatment option for cancer center patients who smoke. We will be asking you questions about your health behaviors and personal history, including tobacco use. Your name will not be used in any published reports from this study.

Do I have to sign this authorization?

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You do not have to sign to this authorization. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment.

Signing this authorization is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Judith Prochaska, 1265 Welch Road, Stanford, CA 94305-5411 or email tobaccotx@stanford.edu.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your medical record number, name, telephone number, electronic mail address, tobacco use, and demographic information (age, sex/gender, ethnicity), and survey/assessment responses, which will also be collected for study purposes. To use MindCotine's app you will be asked for an electronic mail address and IP address will be collected temporarily.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Judith Prochaska

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- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- MindCotine
- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institutes of Health
- The U.S. Food and Drug Administration (FDA)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2045 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

PAYMENTS: You will not receive payment for your participation.

FUNDING: The National Cancer Institute is providing financial support and/or material for this study.

WITHDRAWAL FROM STUDY: The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:
o Failure to follow the instructions of the Protocol Director and study staff.

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o The Protocol Director decides that continuing your participation could be harmful to you.
o The study is cancelled.
o Other administrative reasons.
o Unanticipated circumstances.

SUBJECT'S RIGHTS: If you have decided to participate in this project, please understand your **participation is voluntary** and you have the **right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled**. **The alternative is not to participate.** You can withdraw from the study and still have access to the MindCotine app for up to a year since starting. If you wish to withdraw your data from the app, you can request to have your data removed. Information provided to MindCotine's app will be deleted after a year. You have the right to refuse to answer particular questions. Your individual privacy will be maintained in all published and written data resulting from the study. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed. Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Any of your data which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, research participants do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Bill of Rights:
As a research participant you have the following rights. These rights include but are not limited to the participant's right to:
*be informed of the nature and purpose of the experiment;
*be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
*be given a description of any attendant discomforts and risks reasonably to be expected;
*be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
*be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
*be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
*be given an opportunity to ask questions concerning the experiment or the procedures involved;
*be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
*be given a copy of the signed and dated consent form;
*and be given the opportunity to decide to consent or not to consent to a medical

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experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

CONTACT INFORMATION:
Questions: If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact the Protocol Director, Dr. Judith Prochaska, (650) 724-3608. You can also reach the research team at tobaccotx@stanford.edu.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University,1705 El Camino Real , Palo Alto, CA 94306.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

Best number to call: _____
Email: _____
Mailing address: _____

Please print or save a copy of this consent form for your records.

[ ] Please check this box if you would prefer an email or mailed copy of your signed consent form.

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent