Consent - RCT & In-depth Interviews (Aim 2 & 3)

Record ID _____

Columbia University Consent Form

Protocol Information Attached to Protocol: IRB-AAAT7031
Principal Investigator: Rebecca Schnall PhD, MPH, RN-BC, FAAN (rb897)
IRB Protocol Title: Development and Pilot Testing of the Sense2Quit App

NCT05609032

General Information Participation Duration: 12 weeks
Anticipated Number of Subjects: 60
Research Purpose: The purpose of the research study is to find out more about smoking behaviors in people living with HIV and the subsequent efficacy of tobacco cessation strategies.

Contacts

Contact Title Contact Information
Rebecca Schnall Principal Investigator Phone: 212-342-6886

Email: rb897@cumc.columbia.edu

Detailed Information on Research The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form is written to address a research subject. This consent form includes information about:

-why the study is being done;

-the things you will be asked to do if you are in the study;

-any known risks involved;

-any potential benefit;

-options, other than taking part in this study, that you have; and

-the way your health information will be used and shared for research purposes.

A member of the study team will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study. The purpose of this research and its procedures are described below in the 'What is Involved in This Study?' section of this consent form.

What is Involved in this Study?

At the time of enrollment, you have a 50/50 chance of being assigned to either the intervention or control arm. The intervention arm consists of items 3-8 listed below, in particular, nicotine replacement therapy (NRT), and access to a smartwatch and the Sense2Quit App (item 4) and participate in an in-depth interview regarding experience using those devices (item 7). The control arm consists of items 2, 3,6 and 8, meaning participants in the control arm will not receive NRT, access to a smartwatch nor the Sense2Quit App, and will also not participate in the in-depth You will be referred to the New York State Quitline, where you can receive access to smoking cessation counseling and/or NRT. At the baseline visit, both groups will complete a questionnaire on Qualtrics which includes questions about demographics, tobacco use, substance use, alcohol use, pharmacotherapy use, and psychosocial factors. You will also undergo smoking cessation You will be offered an 8-week supply of combination NRT; you will be offered all 3 forms of NRT (patch, lozenge, gum) and will be allowed to choose 2 forms (combination: patch/lozenge or patch/gum) to use. You will begin NRT the day of the baseline visit to coincide with your quit date. As part of a multi-component tobacco cessation intervention, you will receive a smartwatch and the Sense2Quit App on your smartphone that will help you monitor your smoking behaviors. If your smartphone is not compatible with the Sense2Quit app, you will be provided an Android smartphone to use for the duration of the study. Study staff will help you create an account with the Sense2Quit App by providing personal and identifiable information, such as your name, email address, and your responses to the study The Sense2Quit App will be paired with the smartwatch so that smoking will be detected by the smartwatch and be sent directly to the App. You will be asked to wear the smartwatch and use the App for 12 weeks. The Sense2Quit App will: Passively collect smoking data during the first 2 weeks, such as when a user smokes (time of day, day of week, before/after eating, after waking up/before going to sleep, before driving to/from work, while driving), where a user smokes, and who is nearby (based on the same Bluetooth static address, as Sense2Quit App does not collect identities). Send you personalized reminders and feedback via notifications related to your smoking behavior, track changes in smoking behavior and money saved in a cash spent graph. You will also have the option to communicate with study staff through the chat feature. Provide you with supporting tips and videos, as well as games to distract you from an urge to smoke. At 4 and 12 weeks after your baseline visit, you will return for follow-up visits. You will be asked to complete a tobacco cessation assessment, a questionnaire and provide a breath sample. However, you may also complete these visits remotely instead of an in-person visit, where you will be mailed a carbon monoxide monitor and complete the follow-up visits via video call. You will be asked to use the carbon monoxide detector to measure your tobacco use. At the 12-week follow-up visit, study staff will ask you to complete a 20-30 minute
in-depth interview that will ask questions regarding your experience with the Sense2Quit App and the We will obtain information from your medical records, like all prior diagnoses and symptoms, as well as confirm your HIV status through Epic records.

The study will take about 2-3 hours for the baseline visit, 1.5 hours for the 4-week follow-up visit, and 1.5-2 hours for the 12-week follow-up visit (includes the in-depth interview). A study team member will reach out to you via phone call on a weekly basis during the study period to check-in about your quitting process, confirm follow-up visits, and/or provide support for any questions you may have. Phone calls will last between 1-10 minutes.

Permission for Future Contact The researchers may want to contact you in the future for other studies. We would contact you only once to solicit your participation in any research associated with the current study.

Please indicate whether or not you give permission for future contact.

◯ I give permission to be contacted in the future for research purposes.
◯ I do NOT give permission to be contacted in the future for research purposes.

Risks General risks

Some of the questions and testing may make participants feel uncomfortable or upset, but participants can decline to answer any questions and are free to stop at any time.

Loss of confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy, including that associated with the app on your phone. Loss of confidentiality or privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the 'Confidentiality' section of this consent form.

Device Malfunction

Intervention group - It is possible that the Sense2Quit app or smartwatch may malfunction, or function incorrectly, during the period of the study. Possible malfunctions or issues may include the smartwatch gets disconnected (typically a Bluetooth issue), the smartwatch keeps dying or will not charge (battery life issue or charging cable stops working) or Sense2Quit app keeps logging you out (typically due to an internet connection issue or the app is undergoing maintenance). If you run into any issues or malfunctions with any of your device(s), please contact our research study team at 212-305-8198.

Risks of Nicotine Replacement Therapy

Intervention group - You will be given a NicoDerm CQ Patch and may experience any of the following side effects: skin irritation, itching, dizziness, headache, rapid heartbeat, and nausea. If these persist, please discontinue use and contact the study team and/or your current healthcare provider.

Benefits You may or may not receive personal (direct) benefit from taking part in this study. As an active smoker in this study, you will receive various resources as someone who is seeking to quit smoking. You will receive an 8 weeks supply of combination nicotine replacement therapy (NRT) if you are placed in the intervention group, as well as a one-time session of smoking cessation counseling, that may be of direct benefit to your health.

Alternative Procedures The alternative is not to participate. You are free to refuse to participate or withdraw from this research at any time.

Confidentiality Columbia University is conducting this study. The study is funded by the National Institutes of Health/National Cancer Insitute.

To help us protect your privacy, we received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we cannot be forced to provide information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate of Confidentiality does not stop you or a member of your family from telling others about yourself or your involvement in this research. If an insurer, employer, or other person gets your written consent to receive research information, then we cannot use the Certificate to withhold that information. The Certificate cannot be used to resist a demand for information from representatives of the United States Government that is used for auditing or evaluation of projects they are responsible for overseeing. You should also know that this Certificate does not protect you from our responsibility to report to appropriate state or local authorities any information obtained in the research of suspected child abuse, or intent to hurt self or others. Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems such as a stolen

computer may occur, although it is highly unlikely.

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. Your participation in this research study will be documented in your electronic medical record in Epic and can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and NYP affiliate institutions who are involved in your health care. The health information that we may collect and use for this research may include medical history that may be considered sensitive. This will include information relating to HIV and your smoking behaviors.

Your results will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a password-protected computer and only the investigator and authorized study staff will have access to the file.

The following individuals and/or agencies will be able to look at and copy your research records:

The Investigators, Columbia University Irving Medical Center study staff and other medical professionals who may be evaluating the study Authorities from Columbia University including the Institutional Review Board ('IRB') The Office of Human Research Protections ('OHRP') Our sponsor, the National Institute of Health/National Cancer Institute ('NIH'/'NCI') You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Rebecca Schnall 212-342-6886. However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor may continue to use and disclose the information they have already collected.

Compensation Compensation for participating in the study will be provided in the form of a pay card or Amazon gift codes. You are eligible to receive up to $180 for participating in the study:

$40 for completing the baseline visit $50 for completing the 4-week follow-up visit $60 for completing the 12-week follow-up visit $30 for the completing the in-depth interview There are no costs to you for participating in this study.

Voluntary Participation Your participation in the study is voluntary. You may decide not to participate in the study. If you decide to participate, you are free to withdraw from the study at any time. Your refusal to participate, or your early withdrawal, will not affect the care provided by the members of your care team or status with this investigator.

Additional Information 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.

If you have any questions or concerns about the study, you may contact:

Dr. Rebecca Schnall at (212) 342-6886 or rb897@cumc.columbia.edu

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact:

Human Research Protection Office, Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 2nd Floor
New York, NY 10032
Telephone: (212) 305-5883 Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

Recordings We are asking for your permission to allow us to audiotape your voice as part of the in-depth interviews in this research study.

The recording will be used for analysis by the research team. The recording will be stored on a password protected computer in a locked office in the Columbia University School of Nursing and will be destroyed upon publication of the results. Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording for any other reason than that/those stated in the consent form without your written permission.

Statement of Consent

I have read the consent form HIPAA authorization and talked about this research study including the purpose, procedures, risks, benefits and alternatives with the researcher. I understand my role in taking part in the research and volunteer to participate. Any questions I had were answered to my satisfaction. If I have questions later about the research, I can ask the investigator listed above or the study team. I agree to cooperate with the study investigator/staff and will report any unusual symptoms from my use of the nicotine patches. I understand that I may refuse to participate or withdraw from participation at any time and that the investigator may withdraw me at his/her professional discretion. If I have questions about my rights as a research participant, I can call the Institutional Review Board office at CUMC (212)-305-5883. I certify that I am 18 years of age or older and freely give my consent to participate in this research. I am aware that by signing this consent and HIPAA authorization form, I am agreeing to take part in the research study and that I can stop being in the study at any time. I am not giving up any of my legal rights that I would have if I were not a participant in the study. I will be able to receive a copy of this consent and HIPAA authorization form to keep for my records.

Signatures

Study Participant's Full Name:

_____

Study Participant's Signature:

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Date:

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