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BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

A Peer Navigator Model to Improve Quit Attempts and Smoking Cessation Rates among HIV-positive Smokers
V.2. 08.01.19

KEY INFORMATION:
You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: This study will examine whether using a peer navigator to help smokers with smoking cessation will increase quit attempts among HIV-positive individuals.
- PROCEDURES: You will be asked to attend 4 study sessions with a research assistant. During these sessions, you will be asked to complete questionnaires and you will have your blood pressure, oxygen level, carbon monoxide level, and respiratory rate measured. In addition to these sessions, you will also meet once with a study nurse to discuss your current smoking habits, get advice that may help you quit smoking, discuss your readiness to quit, and assist you by providing resources for quitting smoking. This study will have 2 different groups of research participants. Both groups will meet with the nurse. In addition, one group will be assigned a peer navigator who will provide social support for smoking cessation. A peer navigator is someone who used to be a smoker and has successfully quit in the past. Participants assigned to the peer navigator group will receive weekly calls for 12 weeks from their peer navigator to discuss setting a quit date, adhering to smoking cessation medication therapy, utilizing the many available smoking cessation resources, and achieving, maintaining, or regaining abstinence from smoking.
- TIME INVOLVED: The study involves 5 total sessions (one with a nurse and 4 with a research assistant) over a period of 24 weeks. The first visit will take about 60 minutes and the rest of the sessions will take about 30 minutes each.
- COMPENSATION: You may receive up to $180 for your time.
- RISKS: Potential risks in the study are considered minimal and include: 1) potential discomfort related to completing questionnaires about sensitive information, 2) potential breach of confidentiality and/or privacy, and 3) potential discomfort in quitting smoking.
- BENEFITS: You may not directly benefit from being in this study. You may quit smoking which could improve your health.
- ALTERNATIVES TO PARTICIPATION: If you choose not to participate in this study, we can give you a list of other places that offer smoking treatments and you can talk with your doctor about what he or she recommends.

1. Researcher(s):

Dr. Patricia Cioe at (401) 863-6638

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2. What is this study about?

The purpose of the study is to examine whether using a peer navigator to help smokers navigate smoking cessation will increase quit attempts among HIV-positive individuals. We will enroll 72 HIV-positive smokers, regardless of their readiness to quit, into a 24-week study.

You are being asked to be in this study because you:

- are diagnosed with HIV
- are at least 18 years old
- smoke at least 5 cigarettes per day for longer than one year, and
- have an exhaled carbon monoxide level of greater than 5 (evidence of smoking).

3. What will I be asked to do?

In order to confirm your eligibility for the study, you will be asked to complete some brief questionnaires that will include questions about your medical history, alcohol and/or drug use, depressive symptoms, and tobacco use/smoking. You may refuse to answer any questions that you do not want to answer. You will also be asked to breathe into a tube that measures the amount of carbon monoxide in your lungs and you will have your blood pressure and heart rate checked. Women who are capable of becoming pregnant will also be asked to complete a pregnancy test. This will take about 60 minutes.

If you are eligible based on the baseline visit, we will schedule an appointment for you to meet with a study nurse the following week. The nurse will discuss your current smoking habits, give you advice to help quit smoking, assess your readiness to quit, and assist you by providing resources for quitting smoking. The nurse will also calculate and provide you with personalized feedback about your "lung age" (an estimate of your overall lung health) and provide you with helpful information on quitting smoking.

This study will have 2 different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. One-half of the study participants will meet with the study nurse. The other half of the study participants with be provided with a peer navigator, in addition to the meeting with the study nurse. If assigned to a peer navigator, the peer navigator will call you each week for 12 weeks to discuss whether you are ready to set a quit date, and whether you want to use smoking cessation medication (such as a patch or a pill) to help you quit. The peer navigator may also help you get a medication prescription, help you access smoking cessation resources, and may give you tips and strategies that may help you quit and stay quit.

Both study groups will be asked to come to the study center to meet with the research assistant and complete surveys 4, 12 and 24 weeks after your baseline. During those sessions, you will be asked questions similar to those asked today. You will be asked to breathe into a tube that will measure your carbon monoxide level. If you have quit smoking, you will also be asked to provide a saliva sample (drool method), which will be tested for the presence of cotinine, a by-product of nicotine.

In order for this study to have scientific value, it is important that we follow your smoking behaviors for the full study period. We will make every effort to contact you by phone for the follow-up interviews. We also will ask you to provide the name of one friend or relative whom we can contact in the event that

your phone number or address changes and we are not able to locate you. This individual would be asked to provide your updated phone or mailing address. We also will ask these individuals about your recent smoking, if any. We would not share any information with them that you have provided us.

Your participation in this study may last up to 60 minutes (for the first session). All other sessions (the nurse visit and 3 follow-up appointments) should last about 30 minutes.

4. Will I be paid?

You will be paid $40 for the baseline interview (today's visit), $25 for the nurse visit and the week 4 appointment, $40 for the week 12 appointment and $50 for the final 24-week appointment. This will add up to a total of $180, if you complete all of the visits. If you leave the study early, you will be paid only for the visits that you completed. Payment is not contingent upon your smoking status.

You are free to stop the study at any point. If you choose to stop participating before the session is complete, you will not receive payment for the session in which you stopped early.

If you are found to be ineligible for the study at the baseline visit based on any reason, you will be paid $10 for your time and effort.

5. What are the risks?

There are some risks to participating in this study of which you should be aware. Potential risks in the study are considered minimal and include:

a. Potential Discomfort Relate to Questionnaires: Some questionnaires ask about sensitive information such as psychological and alcohol/drug problems. The questionnaires and interviews are commonly used in research and clinical practice; however, some questions may be of an embarrassing or sensitive nature. Some participants may experience discomfort in disclosing or discussing HIV status. To minimize this potential discomfort, questionnaires will be completed in a private study room. Also, you may refuse to answer or skip any question asked of you. You do not have to answer any questions that you choose not to answer.

b. Potential Breach of Confidentiality and/or Privacy: There is always a risk of loss of confidentiality. This risk will be minimized by conducting study interviews in a private room, assigning you a study number and identifying your information only by this number, storing all study documents in a locked file cabinet in a locked office, and only using a password protected computer. Also, (if assigned to a peer navigator), it is important for you to know that the peer navigator is an employee of the clinic and is trained in maintaining confidentiality, similar to your doctor and nurse.

c. Potential Discomfort in Quitting Smoking: Quitting smoking can result in uncomfortable withdrawal symptoms including mood changes, irritability, and changes in sleep. The nurse will discuss quitting smoking with you and will recommend actions you can take to reduce any symptoms related to nicotine withdrawal.

6. What are the benefits?

You may not directly benefit from being in this research study. You may quit smoking, which could improve your health. You also have a chance to contribute to a scientific study that may help people

in the future.

7. How will my information be protected?

Participation in this study and information gathered from the study will be kept confidential to the extent of Rhode Island law.

Your answers are confidential. The findings of the study may be published, but individual participants will not be identified. Any reports related to child abuse/neglect or elder abuse will be reported by us to the appropriate authorities.

Certification of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information."

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of such as child abuse and neglect, or harm to self or others.

All data will be collected for research purposes only. All forms will be marked with only participant ID, session number and date. All records will be stored in locked files (physical or on computer) in locked rooms accessible only to research staff. Data collected will be stored on password-protected computers and marked with only participant ID, session number and date. Data gathered from people who attend the screening but do not meet inclusion criteria or decide not to participate will be stripped of personal identifiers or links and only the reason for study exclusion will be kept.

Personal information (participant name, address, telephone number, locator contact information) must be collected so that the Research Assistant can contact you to schedule assessments, call with session reminders and arrange transportation to sessions, if necessary. These data will be stored in a locked file that does not contain ID code numbers. All other data will be stored in files (physical or on computer) locked in a separate location with only code numbers identifying participants and no personal identifiers. A cross-index of code numbers and participant names will be kept in a separate, password-protected computer file that is available only to research staff.

Saliva specimens will be marked with a study ID number, stored in the locked laboratory suite, and sent to a commercial laboratory for analysis. We will track samples sent and analysis results received using a form stored on a password-protected computer.

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.

8. Are there any alternatives to this study?

If you choose not to be in this study, you may continue to receive medical care in your usual medical office or clinic. You may discuss alternatives to smoking or quitting smoking with your health care provider.

What if I want to stop?

Taking part in research is voluntary. You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with Brown University, Lifespan, or the Miriam Immunology Center will not be affected.

9. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call Dr. Patricia Cioe at (401) 863-6638.

10. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

11. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

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Participant's Signature and Date / PRINTED NAME

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Research Staff Signature and Date / PRINTED NAME