BROWN

TITLE: Preloading with Nicotine Replacement Therapy in Smokers with HIV to Improve Self-Efficacy and Quit Attempts
NCT04994444
V.2. 08/12/2021

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BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Preloading with Nicotine Replacement Therapy in Smokers with HIV to Improve Self-Efficacy and Quit Attempts
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KEY INFORMATION:
You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: To examine whether starting nicotine replacement therapy prior to the quit date (called preloading) will help smokers with HIV, who are struggling with urge to smoke (craving) and low self-confidence as barriers to quitting, which may help smokers quit successfully.
- PROCEDURES: You will be asked to attend 6 study sessions with a research assistant (RA), who will ask you to complete questionnaires.
- You will have one (1) in-person smoking cessation counseling session with a nurse 1 week after your initial session. You will have another nurse session at week two (this session may be done in-person, on Zoom, or on the phone based on your preference. Following this session, the study nurse will call you 3times: once on your quit day, and then 1- and 2-weeks after your quit day. These calls are to discuss with the nurse how your quit attempt is going and to answer any questions you may have.
- This study will have 2 different groups of research participants. One group will be asked to start wearing a nicotine patch daily for 3 weeks before their quit date. The second group will start the patch on their quit date. Both groups will receive an 8-week supply of nicotine gum or lozenge, and an 8-week supply of the nicotine patch stating on quit date at no cost. Both groups will be asked to complete a daily medication calendar indicating whether they used the nicotine patch each day.
- TIME INVOLVED: The study involves attending a baseline interview, and then 6 brief study sessions over a period of 16 weeks. The first baseline visit will take about 60 minutes and the others will take about 20 minutes each. Participants will also receive a 30-minute session with a nurse and 4 phone calls from the nurse.
- COMPENSATION: You may receive up to $200 for your time.
- RISKS: Potential risks in the study are considered minimal and include: 1) potential discomfort related to completing questionnaires about sensitive information such as psychological and alcohol/drug problems, 2) potential breach of confidentiality and/or privacy, 3) risk of adverse effects related to nicotine patch use.
- BENEFITS: We cannot and do not guarantee or promise that you will receive any benefits from this study. You may quit smoking which could improve your health.
- ALTERNATIVES TO PARTICIPATION: 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.

1. **Researcher(s):**

Dr. Patricia Cioe at (401) 863-6638; Dr. Christopher Kahler, PhD at (401) 863-6651

2. What is this study about?

This study is examining a new way to help smokers with HIV quit smoking successfully. We will enroll 60 smokers with HIV.

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

- diagnosed with HIV;
- at least 18 years old;
- smoking at least 5 cigarettes/day and a Carbon Monoxide level greater than 5 at Baseline;
- willing to use nicotine patch;
- ready to quit in the next 30 days.

3. What will I be asked to do?

In order to confirm your eligibility for the study, you will be asked to complete a medical screening questionnaire. This will assess your medical and psychiatric histories, current use of antiretroviral therapy (ART), and whether you have medical conditions that may make it unsafe for you to use nicotine patches. You will also complete questionnaires, about self-confidence for quitting, and craving for cigarettes. Women will be asked if they are pregnant, or are nursing; all women who are able to become pregnant will complete a urine pregnancy test. Participants will be withdrawn from the study if they are found to be pregnant. Participants should contact the study team if they become pregnant during the course of the study. Medical resources will be offered to any participant who is found to be pregnant.

Your smoking will be confirmed via a carbon monoxide breath sample, which requires breathing into a tube. Lastly, we need to confirm your CD4 T-cell count and HIV viral load. At the initial visit, the Research Assistant will ask you to bring a copy of your most recent HIV viral load and T-cell count from your health care provider or clinic. **This initial appointment will take about 60 minutes.**

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 start to wear the nicotine patch daily for 3 weeks prior to their quit date. The other half of the study participants will start the nicotine patch on their quit date. Both groups will receive an 8-week supply of nicotine gum or lozenge, and an 8-week supply of the nicotine patch stating on quit date at no cost. You will be asked to complete a daily medication calendar indicating whether you used a nicotine patch each day.

Both study groups will be scheduled for study appointments with the Research Assistant at weeks 2, 4, 8, 12, and 16, following the Baseline session. **These follow-up study sessions will last about 20 minutes.** You will complete questionnaires about your smoking, how confident you are about quitting smoking, your cravings to smoke, your experiences with alcohol and drugs, your use of other kinds of tobacco products, and any symptoms of depression. You may refuse to answer any questions that you do not want to answer. You may skip any question that is asked of you. You will have your blood pressure checked, and have your breath sample checked for carbon monoxide.

At the week 4 session, the nurse will ask you to quit smoking. On your quit date, you will have a phone counseling session with the study nurse. You will receive smoking cessation counseling, and tips and strategies to stay quit. Resources for quitting and a 2-week supply of nicotine replacement therapy (your

dose based on your current level of smoking) will be given to you by the Research Assistant prior to the quit date. The nurse will call you again 1 week and 2 weeks after your quit date. You will be encouraged to continue to use the nicotine replacement therapy. You will be instructed in its proper use. You will also be provided with nicotine gum or lozenge (your choice) to use daily, along with the patch, when you are having cravings to smoke. Nurse sessions will last for 20-30 minutes each.

STUDY SCHEDULE:

VISIT:	YOU MEET WITH:	TIME INVOLVED:	ACTIVITY:	PAYMENT:
Baseline	Research Assistant	60 minutes	Surveys, blood pressure, breath test, pregnancy test (for females)	$40
Week 1	Nurse	30 minutes	Counseling	$20
Week 2	Research Assistant	20 minutes		$20
Week 2	Nurse (in-person, phone call or Zoom)	30 minutes	Counseling	None
Week 4	Research Assistant	20 minutes	Surveys, blood pressure, breath test	$20
Week 5	Nurse (phone call)	20-30 minutes		None
Week 6	Nurse (phone call)	20-30 minutes		None
Week 8	Research Assistant	20 minutes	Surveys, blood pressure, breath test	$25
Week 12	Research Assistant	20 minutes	Surveys, blood pressure, breath test	$25
Week 16	Research Assistant	20 minutes	Surveys, blood pressure, breath test	$50

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 that we can contact in the event that your phone number or address changes and we are unable to locate you. This individual would be asked to provide your updated phone or mailing address. We will not share any information with them that you have provided to us.

4. Will I be paid?

You will be paid $40 for the baseline assessment; $20 for the nurse visit at week 1, $20 for the week 2 assessment, $20 for the week 4 assessment, $25 for the week 8 assessment, and $25 at week 12, and $50 at week 16.

This will add up to a total of $200, if you complete all of the visits. This amount is the same for both groups of participants. 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.

Payment for participating in this study will be made using a pre-paid card that works like a bank debit card. We will give you the debit card. You will be issued one card for the duration of your participation

and this card may be used to pay you in any future Brown University studies you choose to participate in. You will also receive information about how to use this card and who to call if you have any questions. Be sure to read this information, including the cardholder agreement.

Money will be added to your card according to the study's payment schedule. You may use this card at any store that accepts Mastercard. You may also use an ATM with the Mastercard logo to withdraw cash. If you use the card to withdraw cash, or if the card is not used within any six (6) month period, you will be charged a fee that will reduce the total amount of money left on the card. Please read the FAQ information sheet we will give you for full details about fees.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call 401-863-6638 or ask the Research Assistant for a replacement card. You may be charged a fee if you request a replacement card from Greenphire directly.

If you leave the study early, or if we have to take you out of the study, you will only be paid for the visits you completed.

If you are found to be ineligible for the study at the baseline appointment based on any reason, you will be paid $10 (cash or money order) 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:

a. 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. 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. You may stop an interview at any time.

b. There is always a risk of loss of confidentiality, yet it is highly unlikely to occur during this study. This is because all information will be identified with a numeric code only and stored in a Brown University secure file. A database linking names and study identification numbers will be kept in a secure file separate from other subject data sources and will be used to facilitate the collection of follow-up data. Only study staff will have access to this database. All staff are fully trained in relevant ethical principles and procedures, including confidentiality. All assessments and procedures will be closely supervised by the Principal Investigator.

c. **The nicotine patch should be avoided, or used with caution, by people with certain medical conditions.** In particular, it is important that you share with study personnel whether you have had any of the following conditions: recent myocardial infarction (heart attack), angina pectoris (chest pain), cardiac arrhythmia (irregular heartbeat), uncontrolled high blood pressure, or skin disease.

d. **Nicoderm has been classified for pregnancy by the FDA as a category D drug**, indicating that it should not be used during pregnancy.
e. We will ask study participants about nicotine withdrawal symptoms and adverse effects of the nicotine patch at all study visits, and the study staff will provide advice on minimizing these symptoms. Study staff will be available to answer questions and concerns regarding the nicotine patch, lozenge, and gum during the study period. Participants will be advised to contact the study staff with any questions related to the nicotine replacement therapy, potential side effects, or general concerns. The Nicoderm nicotine patch and Nicorette patch and gum are regulated by the FDA. The Nicoderm patches and gum/lozenge are being used as approved/regulated. Confidentiality of these records will be maintained to the extent of Rhode Island law. Since this study uses nicotine replacement therapy, the FDA may inspect our records.
f. During the study, we will notify officials, as mandated by law, if a participant reports intention to harm him/herself or others, or reports child abuse or abuse of an elder.

6. What are the benefits?

We cannot and do not guarantee or promise that you will receive any benefits from this 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. As part of their participation in the study, subjects will receive nicotine replace therapy at no cost, for either 8 week or 11 weeks (depending on which study group you are in). Furthermore, subjects will be provided with smoking cessation information and resources that they may choose to use.

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.

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 gathered from people who are screened 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, and call with session reminders, 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.

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."

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects 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 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.

Clinical Trial:
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.

9. **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, or leave the study, your current or future relationship with Brown University will not be affected.

10. **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. They will answer any questions you may have.

11. **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.

12. **Consent to Participate**

    Your signature below means that you have read the information on this form, asked any questions you have about the project, and agree to participate in this study, as indicated above.

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.

Participant's Signature and Date / PRINTED NAME

Research Staff Signature and Date / PRINTED NAME