Cover Page

Study Title: Using ANDS to Reduce Harm for Low SES Cigarette Smokers. (Tri-PEC study)
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CONSENT FOR RESEARCH PARTICIPATION

Three Arm Trial: Pouch, E-cigarette, Control (Tri-PEC)
Version 6, date: 01/27/2022

KEY INFORMATION:

You are invited to take part in a Brown University research study if you meet final eligibility for this study. Your participation is voluntary.

- PURPOSE: This study is about the potential effects of electronic cigarettes and oral nicotine pouches on health and switching away from cigarettes among people who smoke.

- PROCEDURES: If eligible for this study, over the course of this visit and six future visits, you will be asked to complete assessments of your medical and mental health and give samples of your breath and urine. During Visits 1-6, you may receive free electronic cigarettes (VUSE Alto) or free oral nicotine pouches (on!) and complete assessments, or you may just complete the assessments. You will fill out questionnaires and provide breath samples at each visit. During Visits 1 (this visit) and Visit 6 at week 8, you will be asked to give additional urine samples.

- TIME INVOLVED: There are 7 visits in total. Today's visit will take up to 2 hours. Visits 2,3 and 5 will take approximately 30 minutes and will be done over the phone. Visits 4 will take approximately 30 minutes and will be done in person. Visit 6 will take approximately 1 hour and will be done in person. Visit 7 will take approximately 45 minutes and will be done over the phone.

- COMPENSATION: You will receive up to $275 for your time and effort if you complete all measures.

- RISKS: Although your information is kept confidential, there is some risks to your privacy. There is a risk of discomfort answering questions about your use of substances. Risks of using e-cigarettes or nicotine pouches are mild throat and mouth irritation and increased smoking.

- BENEFITS: You are not likely to benefit personally from this research. The outcome may increase scientific knowledge and help people in the future.

- ALTERNATIVES TO PARTICIPATION: You can speak to your doctor for more information about nicotine use and its relationship to your health. Additionally, you can choose to not participate in this study.

1. Researcher(s):

The principal investigator is Jasjit S. Ahluwalia, MD (401-863-6654). The Research Fellows are Jaqueline Avila, PhD (401-863-3901) and Dale Maglalang, PhD (401-863-3862)

2. What is this study about?

The purpose of the study is to see whether the use of electronic cigarettes and oral nicotine pouches will lead to reduced cigarette smoking and improvements in cardiovascular and respiratory health in smokers.

You are being asked to be in this study because you smoke cigarettes, are age 21 or older, meet an income requirement, do not use e-cigarettes or oral nicotine pouches, are not currently quitting or planning to quit smoking, and are willing to substitute cigarette for electronic cigarettes or nicotine pouches.

3. What will I be asked to do?

Your participation will involve 7 visits, including today's visit. Your participation in the study will last up to 2 hours at today's visit (Visit 1). Subsequent visits will last approximately 30 minutes (Visits 2,3,4 and 5) or 1 hour (Visits 6 and 7) depending on the visit. Participants who report pregnancy at any point during Visits 2-7 will be withdrawn from further participation.

VISIT 1 (Baseline)

The study consent will be reviewed with you. Your final participation in the study will be confirmed with a breath sample and a pregnancy test (if woman). If the smoking test is negative or the pregnancy test is positive your participation in the study will end and you will receive $25.

If the smoking test is positive and the pregnancy test is negative you will be asked questions about your medical history, mental health, experiences of trauma or discrimination, alcohol, tobacco, and drug use. You will also complete questionnaires about your social and medical history. For example, you will be asked whether you have used marijuana recently and whether you have had symptoms of serious mental illness. You will also be asked about physical or emotional trauma experienced as a child. You may skip any questions that you do not wish to answer.

Your height, weight, blood pressure and breath will be measured. A urine sample will be taken for testing of clinical data. For women, the urine sample will be tested for pregnancy hormones. You will be told if you have high blood pressure or a positive pregnancy test.

The study will have **three different groups of research participants.** After completing all assessments during Visits 1, the first group will receive free electronic cigarettes (VUSE Alto) , the second group will receive free oral nicotine pouches (on!), and the third group will not receive anything. Those who will receive free electronic cigarettes will be allowed to sample different commercially available flavors and will receive one electronic cigarettes device and four weeks' worth of electronic cigarettes cartridges. Those who will receive free nicotine pouches will also be allowed to sample different commercially available flavors and will receive four weeks' worth of pouches. Those who receive free electronic cigarettes or nicotine pouches will receive a number of electronic cigarette cartridges or boxes of pouches equal to 1.5 times the number of weekly packs of cigarettes smoked, rounded to the nearest number. For example, those smoking two packs of cigarettes per week will receive 3 electronic cigarette pods or boxes of nicotine pouches (2 x 1.5 = 3) while those smoking seven packs per week will receive 11 cartridges or boxes of pouches (7 x 1.5 = 10.5, rounded up to 11). To decide which group you are in, we will use a method of chance. This method is like flipping a coin or rolling dice. Although you will know which group you are in, some members of the research team might not know. This information needs to be kept secret so that the study is based on scientific results, not on people's opinions. However, we will give this information to all members of the research team should medical needs occur.

At the conclusion of Visit 1 we will schedule for Visit 2. You will be paid $50 for Visit 1.

VISIT 2, 3 and 5 (Weeks 1, 3, and 7)

These visits will be done over the phone. You will answer questions about your use of tobacco over the past week. If you are in a group receiving free electronic cigarettes or nicotine pouches you will be asked about the use of these products. At the conclusion of these visits we will schedule your next visit. You will be paid $25 for Visits 2, 3 and 5.

VISIT 4 (Week 4)

When you return for this visit, your breath carbon monoxide will be measured. You will answer questions about your use of tobacco over the past week and other assessments similar to Visit 1. If you are in a group receiving free electronic cigarettes or nicotine pouches, you will receive an equal number of free electronic cigarette cartridges or pouches as you received during Visit 1 in the commercially available flavor of your choice after completing all assessments. No matter which group you are in, you will be paid $50 for Visit 4.

VISIT 6 (Week 8)

This visit is similar to Visit 4 with the addition of several questionnaires about your tobacco use, mental health, and a urine sample for testing of clinical data. This visit will also include an interview about the study. At the conclusion of this visit we will schedule your next visit. You will be paid $50 for Visit 6. If you were in a group receiving electronic cigarette cartridges or nicotine pouches, you will not receive these products at this Visit or any future visits.

VISIT 7 (Week 16)

This visit is similar to Visit 6 but will not involve a urine collection or an interview. This last visit will be done by phone. You will be paid $50 for Visit 7. At the end of Visit 7 you will have the opportunity to ask questions about the study. After the conclusion of Visit 7 your participation in this study will end.

Nicotine is regulated by the FDA. Those who are provided with electronic cigarettes and nicotine pouches are being encouraged to use these products in place of their cigarettes, as they would if they purchased these products on their own. Electronic cigarettes and nicotine pouches are not approved/regulated as a smoking cessation aid.

4. **Will I be paid?**

If eligible for the study, you will receive $50 for completing Visits 1, 4, 6, and 7. You will receive $25 for completing Visits 2,3 and 5. This will add up to $275 if you complete all visits. If during Visit 1 you are not eligible for the study you will receive $25 at the end of Visit 1.

You also may receive up to $10 as reimbursement for transportation per visit. The study will reimburse you for the cost of transportation if you use a taxicab, a ride-sharing service such as Uber, or public transportation.

Payment for participating in this study will be made using ClinCard, a pre-paid Mastercard that works like a debit card.

We will give you the card. You will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that uses ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn $600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

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 the study coordinator for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

5. What are the risks?

There are risks of being in this study. If you experience a study-related injury, illness, or distress, call the Principal Investigator, Dr. Ahluwalia at 401-863-6654.

- **Sensitive information**: This study asks questions about sensitive subjects, including drug use, medical problems, and psychiatric symptoms. We take many precautions to protect the privacy of your information. Section 7 includes details about privacy protections.

- **Risk of smoking**: This study will provide some participants with free ELECTRONIC CIGARETTES or ORAL NICOTINE POUCHES. It is possible that participation in the study could result in increased smoking for those who receive these products. However, this risk is low based on previous research.

- **Risk from electronic cigarette device:** When used as intended, serious risks related to electronic cigarettes are rare but it is important to use the electronic cigarette and e-liquid provided by the study as intended and to not alter the device or e-liquid. It is important to follow all the study instructions regarding the electronic cigarette and e-liquid, since there have been cases of serious injury, including burns and explosions. The FDA has become aware that some people have experienced seizures, with most reports involving teens or young adult users. Seizure activity is a known potential side effect of nicotine toxicity. There are no known interactions of electronic cigarettes with any medications.

- **Irritation from electronic cigarettes vapor**: It is possible that using electronic cigarettes could cause mild irritation to the throat and mouth. In this study, we are not providing flavors that have been shown to cause irritation most frequently. Those who do experience irritation from electronic cigarettes vapor can choose to switch to a different flavor or stop participating in the study.

- **Irritation from oral nicotine pouches**: It is possible that using oral nicotine pouches could cause mild irritation to the throat and mouth. In this study, we are not providing flavors that have been shown to cause irritation most frequently. Those who do experience irritation from nicotine pouches can choose to switch to a different flavor or stop participating in the study.

The study can be stopped at any time if you tell us that you do not want to continue.

6. What are the benefits?

You may not directly benefit from being in this research study. You may benefit by switching form cigarettes to these nicotine products, or you may quite nicotine entirely. You may benefit from becoming more aware of your own patterns of smoking, which could lead to changes in your tobacco use behaviors. You may also benefit from receiving results of clinical tests when such results indicated that medical attention is warranted (e.g., high blood pressure). The outcome may increase scientific knowledge and help people in the future.

7. How will my information be protected?

Your study data, including biological samples, will be coded with an ID number so that it cannot be linked directly to you without knowing the code. Coded study data and your personal information are kept in separate, locked filing cabinets. The file linking the code to personal information is password-protected and accessible only to study staff. This file will be destroyed after data collection is complete so that there will no longer be a link between coded data and your personal information. Interviews will be audio recorded, transcribed, and the original audio recordings destroyed. The audio recorder will be stored in a locked filing cabinet.

The consent process and all study procedures are conducted in private locations. Paper files and computer files are accessible only to study staff. Computer files are stored on Brown University's encrypted, secure servers. Your information is kept confidential, meaning that it is not shared with anyone outside of the study except under the circumstances below:

- Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

If you report imminent risk of harming yourself or others, or abuse or neglect of a child or elderly person, these events will be reported to the appropriate authorities.

De-identified data will be kept and used for future research on chronic disease (for example, asthma, diabetes, or heart disease) and substance use. This includes your biospecimens. We may share your de-identified data and biospecimens with researchers at Brown or other institutions (other universities, non-university research entities such as Rand, and researchers at the National Institutes of Health). The recipients of de-identified data from Brown will agree to not transfer the data to other users, that the data are only to be used for research, and that the recipient will return or destroy the data at the conclusion of data analysis. If you allow for the use of your de-identified data for future research, you will not be able to withdraw that data from future use.

It is unlikely but possible that biospecimens may be used to generate discoveries or other applications for commercial profit. You will not share in any profit arising from such uses.

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 government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. 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 child abuse or neglect, or harm to self or others.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

8. **Are there any alternatives to this study?**

One alternative to participating in the research is to speak to your doctor for more information about smoking and its relationship to your health. Additionally, you can also choose to not participate in this study.

9. **What if I want to stop?**

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 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. Ahluwalia at 401-863-6654, or Dr. Jaqueline Avila the Research Fellow at 401-863-3901.

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. **May we contact you for further studies?**

Yes _____ No_____ Initial_____

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13. May we store your de-identified urine samples (biospecimens) for future studies?

Yes _____ No_____ Initial_____

14. <u>Consent to Participate</u>

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

The signature below indicates that the research assistant or principal investigator reviewed this signed consent form with the research participant.

_____

Research Assistant or Principal Investigator Signature / DATE