Examining the Appeal of Nicotine Pouches in Ohio Appalachia
NCT Number: NCT05236894
Consent Approval Date: 05/31/2022

The Ohio State University Consent to Participate in Research

Study Title: Examining the Appeal of Nicotine Pouches in Ohio Appalachia

Protocol Number: 2021C0199

Researcher: Brittney Keller-Hamilton, PhD, MPH

Sponsor: The Ohio State University

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Your participation in this research study will not impact your affiliation with The Ohio State University in any capacity. You may withdraw from the study at any time.

Purpose:

Nicotine pouches are new smokeless tobacco products that are marketed as substitutes for cigarettes and are gaining in popularity. They may make a big impact in regions of Ohio known as Appalachia and surrounding rural areas. There is little research on how nicotine pouches will be adopted by residents of Ohio Appalachia and rural Ohio. We want to better understand the appeal and potential impact of nicotine pouches on public health.

We ask participants to provide blood samples for nicotine content analysis, which will show us how much nicotine is absorbed by your bloodstream as you use nicotine pouches or smoke. This is very helpful for us to understand how nicotine is absorbed by the body. Additionally, the questionnaires you answer will help us understand how and when you became a smoker, how much you like or dislike the nicotine pouches, and also how you feel while using nicotine pouches or cigarettes. There are two groups enrolling into this study. Participants enrolled in Aim 1 are from Ohio Appalachia and surrounding rural areas and participants enrolled into Aim 2 can be from anywhere in Ohio. You are enrolling into Aim 1, which focuses on the differences between nicotine pouches and cigarettes. Participants can only enroll in one aim and not both.

Procedures/Tasks:

This study will enroll 40 adult cigarette smokers from Ohio Appalachia and surrounding rural areas in Ohio.

We invite participants to visit our lab for 3 study visits. If transportation to our lab is a challenge, transportation via Lyft services may be available to you for two out of threeof your study visits. You will be asked to abstain from all tobacco products for 12 hours before each visit to provide the study team with a baseline value of the nicotine levels in your blood. During each visit, you will be randomly assigned to smoke your usual brand of cigarettes or try a nicotine pouch provided by the study. You will smoke for 5 minutes or keep the nicotine pouch in your mouth for 30 minutes. During this time, research staff will ask a series of questions and perform 7 blood draws.

During each visit, you will have an IV placed in one of your arms to make the series of blood draws less invasive. 3mL, or a little less than 1 teaspoon, of blood will be drawn at 7 intervals over the course of 90 minutes. The IV will be placed and blood draws will be performed by a trained research nurse.

At the beginning of each visit, participants who are capable of becoming pregnant will be asked to take a urine pregnancy test. If you are found to be pregnant, you will be withdrawn from the study.

Duration:

This study involves 3 study visits. The study timeline for each participant will vary, however, each visit will take place 2 or more days after the previous visit and ideally within 2 weeks. We ask participants to complete all 3 visits within two months of enrollment.

Each study visit is expected to take about 3 hours.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits:

Every attempt will be made to reduce risk to you. Nicotine pouches are no more harmful than cigarettes and may even be less harmful. Questionnaires and blood collection involve minimal risk to you. The IV placed is similar to a routine blood draw that would be performed for a clinic visit. Potential risks are as follows: risk of using nicotine pouches, use of cigarettes, loss of confidentiality or privacy, potential for interrupting your plans to quit smoking, and slight risk of discomfort, bruising and infection with blood draw.

You are not expected to directly gain any benefits from this study. Through your contributions to science, you provide insight into a new tobacco product that has potential to impact tobacco use in Ohio Appalachia and surrounding rural areas. Moreover, data collected will inform public health efforts, policy, and clinical care in this region.

While this trial is not without risk, every effort will be taken to reduce risk and undue burden on participants.

Participating in this study might make it harder to quit smoking. If you plan to quit smoking in the next 3 months, you should not enroll in this study. We do not want to ask smokers who want to quit to continue smoking. Please ask our PI about any questions you may have about nicotine pouches, smoking, or smoking cessation.

Study product or cigarette use: It is important to note that nicotine pouches are no more harmful than cigarettes. If at any point you are uncomfortable with using the nicotine pouch, please notify study staff immediately.

Slight risk of bruising, discomfort and infection with blood draw: Blood will be collected by trained research staff. Sterile instruments will be used and for blood draws, the participants skin will be cleaned with an alcohol wipe at the venipuncture site.

Breach of confidentiality: All information linking your name to the study will be stored in our secure platform, REDCap or in a locked filing cabinet. You will be given a participant ID and all information collected will be stored under that ID. Your study information will be stored in the secure database, REDCap. Only trained members of the study team will have access to your data. Moreover, any paper documents regarding your visit will be stored in a locked filing cabinet with keys kept by the study PI and manager. Finally, your blood samples will be deidentified – meaning including your participant ID and not your name - and stored in a freezer in a locked room. While a breach of confidentiality is possible through hacking or another means of forced entry, we believe the risk is low.

If you experience any bad reactions or issues as a result of this study, please report to our trained research nurse and study staff and, if severe, seek treatment immediately. Any treatment you seek as a result of this study will be covered by you.

Confidentiality:

We will work to make sure that no one sees your online responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Confidentiality will be maintained by numerically coding all data, disguising identifying information, and keeping data locked in file drawers or in a secure, password protected database. All biospecimen samples are kept in a locked freezer and also will be deidentified. Names of participants will be kept separate from participant data. Only study staff will have the information that connects participants' names and ID numbers. All electronic data will be numerically coded and stored in a password-protected database, on a password-protected computer in a secure research space. Participant information will be accessible only to

research staff, who are pledged to confidentiality and have completed training in the ethical conduct of research. Identifying information will not be reported in any publications.

Also, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information; and
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Your de-identified information may be used or shared with other researchers without your additional informed consent. Your deidentified blood samples may be sent to an outside lab for analysis. Your name would never be connected with the sample.

We will not recontact you every time we use your sample or data from the questionnaires for analysis.

Future Research:

You will be given the option to be contacted for future, related studies.

Your selection for being contacted about related studies will not impact your eligibility for this study.

Incentives:

By law, payments to participants are considered taxable income. You may receive up to $500 for your participation. After each visit, you will receive $150 on a pre-paid ClinCard. If you complete all of your visits in a month, you will receive a $50 bonus at the end of your third visit. If you complete baseline surveys but do not complete the blood draw portion of the visit, we will provide a $50 pre-paid ClinCard to thank you for your time.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

Additionally, if at any point you decide to quit tobacco and/or nicotine products, please let us know and we will withdraw you from our study. If you wish to withdraw from the study, please contact the program manager Hayley Curran by phone or email and state your desire to withdraw from the study. Our phone number is 614-366-9693 and our lab email is BKH-Lab@osumc.edu If you withdraw, data you previously provided to the study may have already been used for analyses or publication; however, no new information will be accessed or analyzed from the time of withdrawal onward.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By agreeing to participate, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for research involving human subjects at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants

Contacts and Questions:

For questions, concerns, or complaints about the study you may contact our study manager at 614-366-9693 or directly contact the Principal Investigator, Brittney Keller-Hamilton, at 614-366-9652.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251 or hsconcerns@osu.edu.

Providing consent

I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate.

Do you agree to be contacted about future research studies? Please select one option:
[Yes] [No]

This document will be provided to you for your records.

Please click the button below to proceed and participate in this study. If you do not wish to participate, please close out your browser window.

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Purpose:

Nicotine pouches are new smokeless tobacco products that are marketed as substitutes for cigarettes and are gaining in popularity. They may make a big impact in Ohio. There is little research on how nicotine pouches will be adopted. We want to better understand the appeal and potential impact of nicotine pouches on public health. There are two groups enrolling into this study. Participants enrolled in Aim 1 are from Ohio Appalachia and participants enrolled into Aim 2 can be from anywhere in Ohio. You are enrolling into Aim 2, which focuses on the differences between tobacco-derived and synthetic nicotine pouches. Participants can only enroll in one aim and not both.

We ask participants to provide blood samples for nicotine content analysis, which will show us how much nicotine is absorbed by your bloodstream as you use nicotine pouches. This is very helpful for us to understand how nicotine is absorbed by the body. Additionally, the questionnaires you answer will help us understand how and when you became a smoker, how much you like or dislike the nicotine pouches, and also how you feel while using nicotine pouches.

Procedures/Tasks:

This study will enroll 20 adult cigarette smokers from Ohio.

We invite participants to visit our lab for 3 study visits. You will be asked to abstain from all tobacco products for 12 hours before each visit to provide the study team with a baseline value of the nicotine levels in your blood. During each visit, you will be randomly assigned to

try a nicotine pouch provided by the study that contains either tobacco-derived or synthetic nicotine. All nicotine pouches used in this study can be purchased online or at stores. In other words, we did not make the nicotine pouches. You will keep the nicotine pouch in your mouth for 30 minutes. During this time, research staff will ask a series of questions and perform 7 blood draws.

During each visit, you will have an IV placed in one of your arms to make the series of blood draws less invasive. 3mL, or a little less than 1 teaspoon, of blood will be drawn at 7 intervals over the course of 90 minutes. The IV will be placed and blood draws will be performed by a trained research nurse.

At the beginning of each visit, participants who are capable of becoming pregnant will be asked to take a urine pregnancy test. If you are found to be pregnant, you will be withdrawn from the study.

You will be asked to try a nicotine pouch during each visit. As a participant, you will be asked to try 3 different types of nicotine pouches in random order. They are all FDA-approved and available in stores. Products include: Zyn wintergreen 3mg (tobacco-derived nicotine), a Fre wintergreen 3mg (synthetic nicotine), and a Niin wintergreen 3mg (synthetic nicotine).

Duration:

This study involves 3 study visits. The study timeline for each participant will vary, however, each visit will take place 2 or more days after the previous visit and ideally within 2 weeks. We ask participants to complete all 3 visits within two months of enrollment.

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