University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: The Options Study

Formal Study Title: Understanding the real-world impact of the use of three alternate nicotine-delivery products on combustible cigarette use

Lead Researcher: Megan E. Piper, PhD, (608) 265-5472

Where Lead Researcher works: Center for Tobacco Research and Intervention

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Invitation

We invite you to take part in a research study about people's use of cigarettes and other forms of tobacco or nicotine. We are inviting you because you expressed an interest in sharing your experiences as a smoker.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Important things to know about any research study:

- Taking part in research is voluntary. You can choose not to be in this study, or stop at any time.
- If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights.

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More information about this study

Why are researchers doing this study?

The purpose of this research study is to understand how well electronic and low nicotine cigarettes can serve as a replacement or substitute for someone's regular cigarettes. We also want to know whether nicotine from a nicotine patch can help make these a better substitute. We are doing this research because the Food and Drug Administration needs more information on how different cigarettes are used in the real world.

This study is being done at the University of Wisconsin Center for Tobacco Research and Intervention offices in Madison and Milwaukee. A total of about 225 people will participate in this study.

Funding for this study is provided by the National Cancer Institute and the Food and Drug Administration.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to come to the research office 8 times over the next 4 weeks. At each of these office visits you will complete different surveys. The surveys will include questions about your smoking and your use of study products, how dependent you are on nicotine, your mood, your thoughts about cigarettes and e-cigarettes, your health, your use of alcohol and marijuana, and basic demographic information (age, gender). You may skip any questions on the surveys or during interviews that you do not wish to answer.

We will also ask you for a breath sample to measure carbon monoxide (a substance contained in cigarette smoke). You will take a breath test that measures carbon monoxide in your lungs, which helps measure how much you smoke. After inhaling deeply and holding your breath for 15 seconds, you will breathe out into a disposable cardboard tube that will be placed over a sensor. Finally, we will ask you give us a urine sample for us to test to see how much nicotine is in your body. We will ask you to urinate into a cup at the visit and we will use a test strip to measure the nicotine levels. Once the test is over your sample will be thrown out.

At your second study visit you will be randomly assigned (like flipping a coin) to get a JUUL e-cigarette, a low nicotine cigarettes, or no study product. You will be able to use your study product for 4 weeks, if you are assigned a product. You will be asked to return unused product as well as the JUUL, if you receive one, at the end of the study. Two times during this study you will be asked to not smoke your regular cigarettes for a

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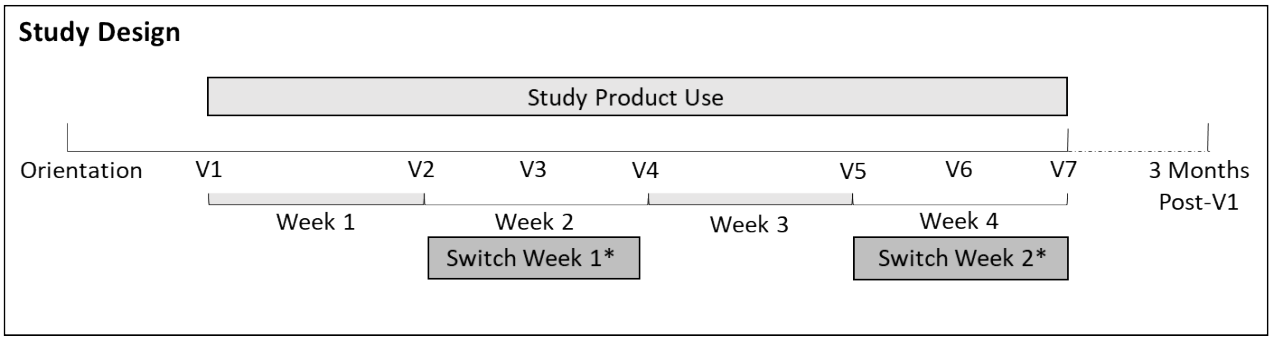
week. We call these switch weeks. You can use your study product (if you have one) during switch weeks. You will also get a patch to wear each day during the switch weeks. One week the patch will have nicotine in it and the other week it won't (a placebo patch). Neither you nor the staff will know whether you are getting a nicotine or a placebo patch the first week or the second week.



For the 4 weeks when you are on the study, we will ask you to record each time you smoke one of your cigarettes or use a study product (if you have one) in a smartphone app. At certain times the app will ask you to answer a few questions about your smoking or product use such as where you are and how you are feeling. You will also be asked to answer questions each evening about your use of study products, number of your cigarettes you've smoked, and how you feel. The app will be provided to you as part of your study participation. If you have a smartphone with the Android operating system, you may choose to have the app installed on your phone but you will be responsible for the minimal data use. If you do not have an Android smartphone, or do not wish to use your own smartphone, the study will provide you with a smartphone. The study smartphone will only provide limited service and should only be used to complete the study assessments. You will not be responsible for the cost of the study smartphone data plan if you use a study smartphone. You will need to return the study smartphone once the study is complete.

Finally, you will be asked to complete a 3-month follow-up phone call that will include answering questions about your smoking, your mood, your health, and your plans to quit smoking in the future.

Your participation during this first visit will last about 90 minutes and then future visits will last 30-60 minutes and the follow-up call will last about 15 minutes. The smartphone assessments should take about 5 minutes per day. This should result in about 18 hours of total participation time over the next 3 months.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Information about you, such as your birth date, home address, phone numbers (cell, home, work), email address and Social Security number (which is required by the IRS for participant payment)
- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health

How long will I be in this study?

You will be part of the study for about 1 month while you are using study products and coming in for study visits. After that, we would like to check on your smoking and health by calling you 3 months after you start the study. During this follow-up call we will collect information about your smoking, health, mood, and thoughts about smoking, electronic cigarette use and quitting.

The researchers may take you out of the study, even if you want to continue, if

- your health changes and the study is no longer in your best interest; this would include a significant increase in carbon monoxide or the number of study cigarettes smoked
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers
- you become incarcerated

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Megan Piper, at 1930 Monroe St., Suite 200, Madison, WI 53711.

Will being in this study help me in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about how well electronic cigarettes and low nicotine cigarettes can substitute for regular cigarettes. This is important information for the Food and Drug Administration as they try to develop public health regulations of the tobacco industry.

This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

Will I receive the results of research tests?

All of the tests that are part of this study are for research purposes only. Because of this, we will not tell you or your doctors the results of these research tests.

What are the risks?

The main physical risks of this study are:

- Withdrawal symptoms during the switch weeks such as craving, difficulty sleeping, negative mood, and hunger.
- Common side effects from the nicotine patch such as skin irritation, trouble sleeping, and vivid dreams.
- A rare risk of nicotine patch is an allergic reaction. The allergic reaction could be life threatening.
- Getting too much nicotine could cause nausea and vomiting (throwing up).
- Some people using e-cigarettes have experienced seizures.

There is also a risk that your information could become known to someone not involved in this study. This study involves asking questions about illegal substances / drug use. There is a chance that someone outside of the study could find out about the answers to your questions. If that happens, this could expose you to legal risks or damage your reputation. We will try to keep others from getting this information by storing all of your information securely and limiting the number of people who have access to this information.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures. You would be responsible for any data costs that you incur if you decide to use your own smartphone during the study.

Will I be paid or receive anything for being in this study?

You will receive up to $380 over the course of this 3-month study. You will be paid:

- $20 for completing each of the 8 study visits ($160 total if you complete all visits).
- $20 for completing the 3-month follow-up call
- $200 for completing 80% of the EMA prompts and nightly assessments OR $150 for completing 75% of the EMA prompts and nightly assessments.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular health care provider.

- Call the Lead Researcher, Megan Piper, PhD, at 608-262-8673 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

A description of this clinical trial will be available on http://www.ClinicalTrials.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.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health

information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The U.S. Food and Drug Administration (FDA)
- The study sponsor, the National Cancer Institute

Will information from this study go in my medical record?
None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Megan Piper, PhD., at 608-262-8673. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Printed Name of Research Participant

_____

Signature of Research Participant Date

_____

Signature of Person Obtaining Consent and Authorization Date

VOLUNTARY STATEMENT OF INTENT TO AVOID PREGNANCY

According to the FDA and the manufacturers of the nicotine patch, this medication should not be used by pregnant women. The risks of these medications to an unborn child are not fully known. We ask study participants who are able to get pregnant or who believe that it is possible to get pregnant to agree to the statement below about avoiding pregnancy while taking study medication.

I, _____ (print name), agree to attempt to avoid pregnancy while I am taking study medication. I will continue to employ medically acceptable means of contraception that have been approved by study staff. These methods include abstinence from sex with men, condoms, diaphragm, birth control pills, injectable contraceptive (e.g., Depo-Provera), contraceptive implant (e.g., Implanon), IUD, hysterectomy, tubal ligation, sterilization, vasectomy, or being more than 1 year post-menopausal. I will immediately contact study staff if pregnancy is suspected. I am aware that I may decline to sign this statement; however, I cannot participate in this research study.

_____ _____
Signature of Participant Date

****You will receive a copy of this form****

Email and Text Use

We are requesting your email address and text messaging number so we can send you reminders about study visits. Email and texting is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email and text messages. You should avoid sending sensitive, detailed personal information by email or text. Email and text messages should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Project Principal Investigator Megan E. Piper, PhD at 608-265-5472. You do not have to provide your email address or text messaging number to participate in this study.

Email

Yes, you may use email to contact me for this study.

No, I do not want to be contacted by email.

Text

Yes, you may use text messages to contact me for this study. I know that I will be responsible for all texting charges.

No, I do not want to be contacted by text messages.

****You will receive a copy of this form****