Informed Consent

Randomized Clinical Trial Evaluating the Impact of E-cigarette Device Warnings

NCT05714982

8/11/2023

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Participants

IRB Study 21-0469, Consent Form Version Date: August 11, 2023

Title of Study: Informational labels for e-cigarettes
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CONCISE SUMMARY.

The purpose of this research study is to better understand perceptions about informational labels for e-cigarettes. Participants in this research study will attend two in-person appointments at our study office scheduled 2 weeks apart. The first appointment lasts about 60 minutes; the second appointment lasts about 30 minutes. For each appointment, you bring in the vapes that you use regularly. We also ask that you bring in 2 weeks' worth of refills (e-liquid bottles, cartridges, pods, or disposable vapes) that you plan to use over the next 2 weeks. For the 4 weeks of the study, you use only the labeled vaping device. At these in-person visits you take a survey about vaping. We also e-mail you 3 more surveys to complete online at home. Risks of being in the study may include completing surveys with sensitive items, a change in tobacco use, and an accidental breach of confidentiality. There are no direct benefits to study participants. If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty. Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will receive a copy of this consent form. You can ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to better understand how vapers respond to informational labels on their devices and refill materials. We asked you to be in the study because you indicated that you are a current e-cigarette user, are over age 21, and are willing to let us apply a sticker to your e-cigarette device and refill materials.

Are there any reasons you should not be in this study?
You should not be in this study if you are currently pregnant, under age 21, do not use an e-cigarette that contains

nicotine, live with someone currently enrolled in this study, are concurrently enrolled in any research studies about smoking or using other tobacco products. You should only be in this study if you are willing to use and have your main e-cigarette device and refill materials labeled with a study warning sticker. Also you should not be in this study if you cannot perform the required tasks of the study (take survey on computer or on paper in English, have an e-cigarette that can be labeled with study sticker, bring in and only use your main e-cigarette device, bring in 2 weeks' worth of e-cigarette refills and attend 2 in-person appointments and complete 3 surveys online from home).

How many people will take part in this study?

If you decide to be in this study, you will be one of about 3,000 people in this study.

How long will your part in this study last?

Your participation in this study will last for 4-weeks. The study consists of two in-person appointments at our study office, scheduled two weeks apart. The first appointment will take about 60 minutes. The second appointment will take about 30 minutes. You will also be sent three surveys to complete online at home over the course of a month.

What will happen if you take part in the study?

For each in-person appointment, we ask that you bring in the main e-cigarette devices that you own and use most regularly. We also ask that you bring in 2 weeks' worth of refills (e-liquid bottles, cartridges, or disposable e-cigarettes) that you plan to use over the next two weeks. We will assign you to a study group by chance, like flipping a coin. We will apply informational labels to your device and refills. We will ask that you use only the labeled e-cigarette device and refills while you are enrolled in the study. At each appointment, we will ask you to fill out a survey about your e-cigarette use habits, reactions to the label and experience being in the study. We will also take a picture of your e-cigarette device and refills at each visit. At week 2, 3, and 5 we will e-mail you a survey to take online at home.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. One benefit is that you might be encouraged to reduce or quit smoking or vaping as a result of new information you learn through the study.

What are the possible risks or discomforts involved from being in this study?

Your tobacco use may or may not change as a result of being in this study. You may use less, more, quit, or use the same amount. We will minimize any risk of increased tobacco use by providing information to you about tobacco cessation programs at the end of the study. We will also refer you to community services if you experience health problems as a result of changes in tobacco use during the study. Some survey questions may be embarrassing to answer. You may have the option to skip questions you do not feel comfortable answering. Some of the informational label sticker or adhesive could remain on your device or refills. The only other known risk of harm could come from an accidental breach of confidentiality. You should report any problems to the researcher.

How will your privacy be protected?

Your responses to interview questions will be confidential. We will assign you a unique numerical identifier to be used on all study documents (e.g., completed surveys). We will shred the paper copy of your contact information and maintain an electronic version of your name, identifier, and contact information on a secure, password-protected server that can only be accessed by study personnel. The only individuals who will have access to the information are the Principal Investigators, the Study Director, and Research Associates. We will delete your personal information from the computer six months after the study ends. If you indicated that you were interested in hearing about future research studies, we will maintain your contact information indefinitely, separate from any other study data.

Participants ***will not*** be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research

study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Your information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped. If you withdraw from the study, you will receive the weekly incentive each week that you participated in the study.

Will you receive anything for being in this study?

Yes. You will receive giftcards in the following amounts: $75 (visit 1), $30 (visit 2), $75 (visit 3), $30 (visit 4), and $75 (visit 5) for a total of $285.

Will it cost you anything to be in this study?

No. You will need to buy the amount of e-cigarette devices and refills you would normally use between study appointments *before* coming to your appointments. This will not cost you any extra money, as you are only buying what you would usually buy anyway. You may have to pay for parking at or transportation to the study office. You will not be reimbursed for these costs.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, payment-related questions or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

UNC Principal Investigator: Noel Brewer, PhD
E&W Study Director: Katrin Ewald, PhD

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent