Consent to Participate in a Research Study

IRB Study # 24-0841
Title of Study: Little Cigar and Cigarillo Warnings to Reduce Tobacco-Related Cancers and Disease - Aim 3 Eye Tracking
Principal Investigator: Goldstein, Adam
Principal Investigator Phone number: (919)270-6491
Principal Investigator Email Address: aog@med.unc.edu
Study Contact: Kristen Jarman, jkristen@email.unc.edu, (919)966-3016
Version Date: 10/01/2024

Concise Summary

The purpose of this research study is to study how people react to health messages in order to improve them. You are being asked to take part in this research study because you are an adult that uses little cigars or cigarillos.

Being in a research study is completely voluntary. You can choose not to be in this research study. You can also say yes now and change your mind later.

If you agree to take part in this research, you will be asked to complete an eye tracking study appointment. During the study appointment you will answer survey questions and view health messages. As part of the appointment we will use an eye tracking camera to track where on a screen you are looking and use a sensor on your hand to measure how much your palm is sweating. Your participation in this study will take about 1 hour during your appointment.

You must be at least 21 years old to participate. If you are younger than 21 years old, please stop now.

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 choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. 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.

What is the purpose of this study? The purpose of this research study is to study how people react to health messages in order to improve them. You are being asked to take part in this research study because you are an adult that uses little cigars or cigarillos.

How many people will take part in this study? If you decide to be in this study, you will be one of approximately 120 people in this research study.

What will happen if you take part in the study? Your part in this study will last approximately 60 minutes. During the study appointment:

- You will sit down in front of a computer with an eye tracker attached to it. The eye tracker is a small camera on the front of the computer that records where your eyes are looking as you complete the study tasks. Study staff will help personalize it to you.
- Sensors will be placed on your hand to measure how much your skin is sweating.
- You will answer a baseline questionnaire to start the study session. It will ask about tobacco use, attitudes and demographics.
- You will see health messages and answer a few questions after each message.
- You will complete a questionnaire after the study session, which will ask about your response to the health messages and experience in the study.
- You can choose not to answer any question for any reason.

The study team will message you by email or text, however you may say "no" to receiving these messages and still participate in this study. These messages may include appointment reminders, requests to contact the study team, or reminders to complete study activities. The study team will ask you to provide your preferred email address or cell phone number. These messages may be sent by the study team's personal electronic devices. If you respond to the message, your message may be received by a study team member's personal device. This means there is the risk your information could be shared beyond you and the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device or email account, please notify the study team using the study contact information on the first page of this consent form.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study? We anticipate few risks in this study.

The possible risks to you in taking part in this research are:

- Statements or questions in the survey may make you feel uncomfortable or evoke emotional reactions. We anticipate this risk to be minimal and manageable.
- Survey questions may ask you about your opinions or behaviors that you would prefer to keep private. If you do not feel comfortable answering a question, you may skip it
- There is a risk of loss of confidentiality of the data, we will minimize these risks by using and enforcing appropriate data protection standards.

How will your privacy be protected? All of the data you provide will be stored without any identifying information. This means that there will be no way for anybody to ever link your data or the results of the study to your identity. To protect your identity as a research subject, the research data will not be stored with your name, and the researcher(s) will not share your information with anyone. In any publication about this research, your name or other private information will not be used. We will also obtain a Certificate of Confidentiality for this research study.

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.

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 and skip any question for any reason. The investigators also have the right to stop your participation if you have an unexpected reaction, have failed to follow instructions, etc. You can choose not to answer any question you do not wish to answer.

Will you receive anything for being in this study? Will it cost anything? If you complete the eye tracking study appointment, you will be given a $100 Visa gift card. You may incur costs associated with traveling to the study appointment.

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 any questions, please reach out to Kristen Jarman, jkristen@email.unc.edu, (919)966-3016. You may ask Kristen Jarman or the study staff conducting your appointment any questions that you may have.** Please let the Kristen Jarman or the study staff know about any questions, complaints, or concerns you may have.

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, or if you would like to obtain information or offer input, please contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Do you consent to participate?

[ ] Yes, I consent