Cover page for Adolescent Assent Form

NCT03860077

Grant number: R01DA047356

Grant Title: Impact of Nicotine Reduction on Adolescent Cigarette Use, Alternative Tobacco Use, and Harm From Tobacco

Consent Document Approval Date: 9/28/20

BROWN

BROWN UNIVERSITY
ASSENT FOR RESEARCH PARTICIPATION

Impact of nicotine reduction on adolescent cigarette use, alternative tobacco use, and harm from tobacco

Version 10, 9.28.20

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

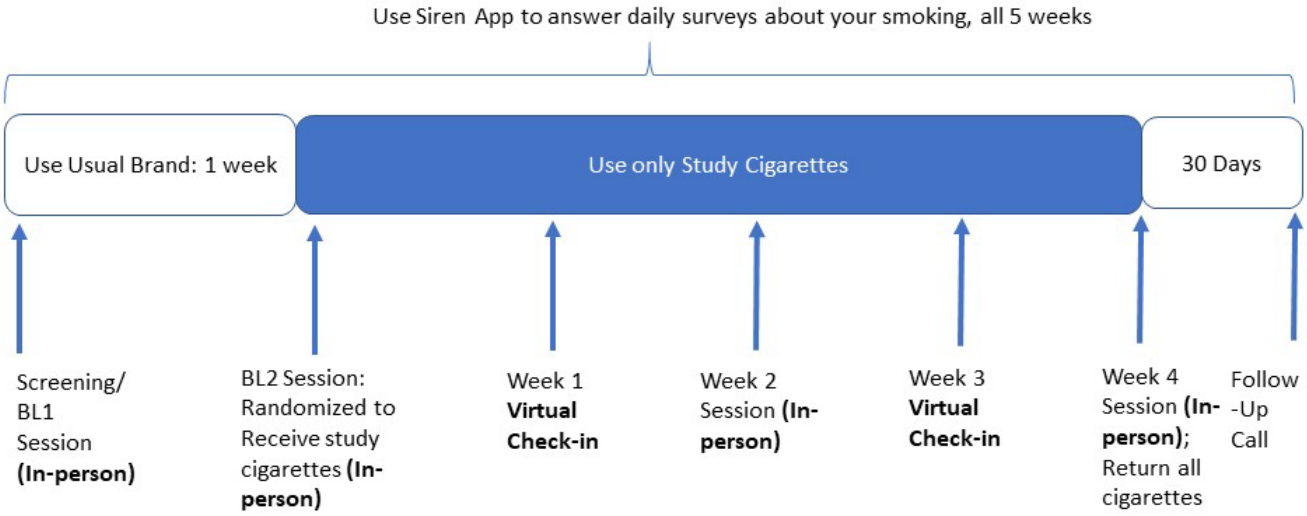
- PURPOSE*:* To look at the effect of different levels of nicotine in cigarettes on teen smoking behavior.
- PROCEDURES*:* We will ask you to come to our lab a total of 4 times (including today), to complete two virtual check-ins via Zoom, and complete several questionnaires each day on your smartphone for 5 weeks. You will also be asked to switch from using your usual brand cigarette to using a study cigarette that we will provide to you. You will be asked for a breath sample, urine sample, and pregnancy test, if able to get pregnant. You will also be asked to complete a questionnaire about your experiences related to COVID-19.
- TIME INVOLVED*:* You will be in this study for 5 weeks and completing the surveys will take up to 10-15 minutes per day. Lab visits will take between 45 minutes and 2 hours. Virtual check-ins will take up to 40 minutes.
- COMPENSATION: You will receive up to $523 for your time and effort, depending on how many surveys you respond to, cigarettes you return, and lab/virtual visits you complete.
- RISKS*:* Some of the questions may be about drug use or mental health, but you are free not to answer any questions you do not wish to answer. You may also experience nicotine withdrawal, but the study does not restrict your use of other nicotine-containing products that aren't cigarettes. If able to get pregnant and become pregnant during the study, you may experience emotional distress and you may be in need of a medical professional.
- BENEFITS: There are no direct benefits to you from participating in this research study.

1. **Researchers:**
   Questions about the study should be directed to Dr. Rachel Cassidy at 401-863-6621 or Dr. Suzanne Colby at 401-863-6655. Questions about the rights of a research participant should be directed to the Human Research Protections Program at 401-863-3050.

2. **What is this study about?**
   This study is investigating the effects of different levels of nicotine in cigarettes on teen tobacco use, health, attitudes, mood and other outcomes. **This study is not going to ask you to quit smoking, or help you quit smoking**. You are being invited to take part in this research study because you are a teen smoker.

3. **What will I be asked to do?**
   If you agree to participate, you will be asked to attend a total of six individual sessions (including today). If you are eligible, we will start your first session (Baseline 1 [BL1]) today after this

screening session. You will be asked to attend five more sessions. There will be seven days in between each session. We call these sessions: Baseline 2 (BL2, a lab visit), Week 1 (W1, a virtual check-in session), Week 2 (W2, a lab visit), Week 3 (W3, a virtual check-in session), and Week 4 (W4, a lab visit). This study can be completed in five weeks. Lab sessions will occur in our research lab. Virtual check-in sessions will be conducted remotely via Zoom.



On each day of the study, starting tomorrow, you will receive notifications throughout the day from the app [PiLR Health] that will ask you to conduct a short survey in the app. The surveys will ask you about the cigarettes you smoked, any other tobacco products that you used, and questions about how you're feeling and what you're doing. You will also be asked to complete surveys in the app several times each day. We will show you how to download the app onto your phone and how to complete the surveys in the app later today if you are eligible. If you do not have a phone, we can lend you one to use during the study. You will do several types of surveys on your phone during the first two weeks and the last week of the study. During weeks 3 and 4, you will only need to complete one survey on your phone per day.

If you are eligible and assent to participate today, I will then take a breath sample that will show me how much you've been smoking recently. I'll also ask you some questions, and you will complete some questionnaires about yourself and your history of smoking. You may also be asked to provide a urine sample today so we can check to see how much nicotine is in your system.

IF ABLE TO BECOME PREGNANT: Smoking during pregnancy can lead to miscarriage, preterm delivery, stillbirth, birth defects, and other problems. To avoid these risks, it is important that you are not pregnant during this study. For that reason, you will be tested for pregnancy at this and every in-person lab visit. If you test positive for pregnancy, we will provide you with a referral to a doctor and/or encourage you to seek medical attention from your current primary care physician, if applicable. You will also be provided with local pregnancy resources. You will not be able to be in the study if you are pregnant, and if you become pregnant during the study, you will have to withdraw from the study. If you are ineligible due to pregnancy today, you will still be paid $25.

You will be asked to switch from your usual cigarettes to research cigarettes for four weeks. During each of your next two in-person study visits, you will receive research cigarettes to last you for the

following two weeks. You will be asked to smoke only those cigarettes and none of your usual brand or any other brand of cigarettes. However, you may choose to use other tobacco products during this time, such as e-cigarettes and little cigars.

We will ask you to keep track of all your research cigarettes and to bring back any empty packs, unopened packs, and unsmoked cigarettes to the lab. Do not share research cigarettes with anyone else. They are only for you. You will receive a payment for bringing in your unsmoked cigarettes and/or unopened packs of up to up to $5 per week, for a total possible amount of $20.

You will be randomly assigned to one of two study conditions. Random assignment is a procedure similar to flipping a coin. You have an equal chance of being in one condition or the other. If you are assigned to one condition, you will be trying cigarettes that contain a different amount of nicotine than what is found in most brands. If you are assigned to the other condition, you will be trying cigarettes that have levels of nicotine that are similar to cigarettes available in stores. You will not be told the nicotine content of your study cigarettes until after the study has been completed.

During lab sessions, you will be asked to complete questionnaires on the computer about any recent health changes, recent use of tobacco products, alcohol and marijuana, and about how you are feeling. At the BL2 and W2 sessions, we will also ask you to smoke one research cigarette in the lab, and to complete questionnaires about how you feel before and after smoking. You will also be asked to give a breath sample before and after smoking, to measure how much smoke you are exposed to from the cigarette. We will also ask you to rate the cigarette after smoking it (e.g., how much you like the taste, etc.) and to complete some questionnaires that measure your preference for the research cigarette compared to other tobacco products. These lab sessions will take about an hour and a half to two hours to complete.

At the BL2 and W4 sessions, you will also be asked to give a urine sample, which we will have tested to tell us how much nicotine and other toxicants related to tobacco use you have in your system. During these two sessions, you will also be asked to blow into a device that measures your lung function.

At virtual check-in sessions (W1 and W3), we will ask you about recent changes in your health, and ask your about your recent use of tobacco products, alcohol, and marijuana.

During session W4, the final session, we will collect any remaining research cigarettes from you. You will answer some final questions anonymously on your experience in the study, and we will schedule a phone call for 30 days from then so we can check in on you and your recent smoking. If you feel comfortable, we will also ask you to participate in an open-ended audio interview regarding the COVID-19 pandemic where you can share how this pandemic has affected you. This audio interview is optional and will be recorded on a device that is stored in a locked drawer that only research personnel has access to. The audio file will be transferred from the device and onto a secure sever that only the research staff has access to and deleted from the device. There will be no personal identifying information obtained in this interview (i.e., you will be referred to as your participant ID number and not your first or last name).

It is very important for you to attend your appointments for this study. Throughout the study, if you reschedule your sessions more than 3 times for any reason, you may be withdrawn from the study.

The study can be completed in five weeks. The daily surveys will take about 90 seconds per survey to complete each day. Each lab session will vary in length but will not take more than two hours.

4. Will I be paid?

You will be paid for completing each of the sessions as follows: $25 for today; $50 for BL2; $15 each for W1 and W3, $50 each for W2 and W4. You will be paid up to $5.00 for every day that you interact with the phone app during weeks 1, 2 and 5; and up to $2 for completing one phone survey per day during weeks 3 and 4. You will also be eligible to earn up to $40 in random bonuses if you interact with the app, for a maximum total of $173. A bonus payment of $50 will be paid if you complete 80% or more of the surveys you're supposed to fill out on your phone app. A completion bonus of $75 will be given if you attend all 4 lab sessions. A maximum of $20 possible compensation is available for returned cigarettes and packs (up to $5 per week). The total amount that you can earn for participating in the study, if you complete all sessions and app surveys, is $523.

Payments for each of the sessions will be paid to you at the end of each session. Bonuses will be paid to you at the end of the study. All study payments will be made on a ClinCard. This pre-paid card works like a bank debit card. You will receive further information about how to use this card. If you decide to withdraw from the study before completing it, we will add the money to your ClinCard for the number of sessions and daily app surveys that you completed before stopping. If you decide to quit smoking during the study, you may still be paid for any remaining study procedures that you complete.

We will pay for your transportation expenses to in-person lab sessions as follows: If you drive to the study, parking in the garage at our research building will be paid for by the study. If you prefer to take a bus, bus tickets will be provided to you at each visit. We can also pay if you take Uber to your appointment if you send us the receipt from your phone. If none of these options works for you, we can arrange for a taxi bring you to the study and back; when you schedule your appointment the study staff will also schedule a taxi.

Completion of the surveys using the app will incur normal data and texting rates from your phone service provider that the study does not specifically compensate for.

5. What are the risks?

Discomfort from nicotine withdrawal: You may experience nicotine withdrawal symptoms during this study. Symptoms can include irritability, frustration, anxiety, sadness, craving to smoke, difficulty concentrating, muscle pain, fatigue or difficulty sleeping, and increased hunger. These feelings can be uncomfortable, but they are normal, temporary, and are usually mild.

Discomfort from interview procedures: We will ask you questions about whether you are experiencing psychological symptoms and about your background and smoking/drug use history. Answering these questions could cause you some minor discomfort. However, the questions we ask are commonly used in research and clinical practice and you will not be required to answer any

question you are not comfortable answering. All answers to these questions will be kept confidential.

Risks related to smoking cigarettes: All cigarettes are bad for a person's health and can lead to heart disease, lung diseases, cancer, and death. However, exposure to smoke and nicotine in this project is not significantly more than what you are exposed to on a daily basis. You do not have to smoke more than you normally would. The study cigarettes do not provide any less risk than your usual brand cigarette. Only those teenagers who smoke cigarettes daily, and have smoked this much for 6 months or longer, will be allowed to participate. Because some of the cigarettes in the study may have less nicotine in them, you may use other nicotine-containing products in response. The type of product you chooses to use may result in increased risk.

Potential Discomfort Related to Electronic Cigarette Use: The FDA has not regulated electronic cigarettes to date and electronic cigarettes have not been fully studied. We currently don't know all risks of electronic cigarettes when used as intended, how much potentially harmful chemicals are being inhaled during use, or whether there are any benefits associated with using these products. The studies to date indicate that electronic cigarettes are likely less harmful than regular cigarettes. The most common discomfort from electronic cigarettes is that some people find the vapor irritating. The most frequently reported discomforts are mouth irritation, throat irritation, and dry cough. Other possible effects may include: nausea, sore throat, or headache. No serious health effects have been clearly due to electronic cigarettes in any study. 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.

What are the benefits?

There are no immediate benefits from participating in the study. You will have the chance to learn more about the effects of smoking. Also, you will help us learn more about how nicotine in cigarettes affects teen smoking.

6. **How will my information be protected?**

Participation in this study and information gathered from the study will be kept confidential to the extent allowable by law. All information that you give us will be identified only by a code number, not your name. Your answers and test results are confidential and will not be shared with your parents, or anyone else who is not involved in conducting, overseeing, or monitoring the research. There are two exceptions to this. The first is if you report any plans to hurt yourself or anyone else. The second is if you report any physical or sexual abuse of yourself, other minors, or elderly people. If you report these things, then we are ordered by law to report them to the proper agency, to help keep you and other people safe. Also, if you report plans to harm yourself, we will share that information with our medical provider, who will talk with you about it, to help keep you safe.

Participation in this study may require a sign-in or download for using Zoom and will require that you have internet access or access to WiFi. You should schedule your interviews with appropriate times to ensure privacy.

In addition to the investigators listed on the first page of this assent form and their research staff, organizations that oversee this research may ask to review information we collect that may identify you. These organizations include the Brown University Research Protections Program and the National Institute on Drug Abuse. The findings of the study may be published but individual participants will not be identified.

Additionally, authorized representatives from any governmental agency that regulates the study may also have access to your identifiable information. Agencies include the Food and Drug Administration (FDA), the U.S. Department of Health and Human Services (DHHS) and Office for Human Research Protections (OHRP).

A description of this 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.

Certificate of Confidentiality

To help us protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health. We can use this certificate to legally refuse to provide information about you, even if there is a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The Certificate cannot be used to refuse to provide information to the U.S. Government or the Federal Food and Drug Administration (FDA). The U.S. Government or the FDA can require us to provide information so that they can audit or evaluate this federally funded research project.
You should understand that a Certificate of Confidentiality does not prevent you or a family member from voluntarily releasing information about you and your involvement in the research. If an insurer, employer or other person obtains your parent's written consent and your written assent to receive research information, then we may not use the Certificate to withhold that information.
The Certificate of Confidentiality will not be used to prevent us from contacting state or local authorities if you report child or elder abuse, or plans to hurt yourself or others.

The medical monitors of this study may decide to withdraw you from the study if they feel it is necessary to protect your health.

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

Your decision whether to be in this study is completely up to you and your parent. Participation is voluntary. If you decide now to participate, you will be able to change your mind and withdraw from the project at any time without any consequences. We will keep the data and specimens we collected from you prior to your withdrawal.

8. **Who can I talk to if I have questions about this study?**

Please ask any questions you have now. You can email us at ProjectSiren@brown.edu with any general study questions, or call Jasmine at 401-863-6645 (jasminette_dilorenzo@brown.edu).

Any further questions about the study should be directed to Dr. Rachel Cassidy at 401-863-6621 (Rachel_cassidy@brown.edu) or Dr. Suzanne Colby at 401-863-6655 (Suzanne_Colby@brown.edu).

9. **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.

10. Assent to Participate

Your signature below shows that you have read and understood the information in this document, and 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
Research Staff Signature and Date	/	PRINTED NAME

Optional

The researcher may contact me in the future to see whether I am interested in being in other studies by researchers working at the Center for Alcohol and Addiction Studies at Brown University.

I agree _____ **I disagree** _____