InferiorGood-18-290

Behavioral Economic Methods for Assessing Tobacco Product Abuse Liability: Study 7

Informed Consent

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APPROVED
Mar 29, 2018
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TITLE: Behavioral Economic Methods for Assessing Tobacco Product Abuse Liability: Study 7

PROTOCOL NO.: 18-290
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United States

INSTITUTION: Virginia Tech Carilion Research Institute

STUDY-RELATED PHONE NUMBER(S): Warren K. Bickel, PhD
540-526-2088 (office)

Purpose of the Study
You have been asked to come to the Virginia Tech Carilion Research Institute (VTCRI) or the Virginia Tech Corporate Research Center (VTCRC) because you may qualify for this study. This study will allow us to compare purchasing and use of cigarettes with and without ventilated filters.

Your participation in this research study will also help us learn more about potential harms associated with tobacco products, in order to help decrease harms associated with tobacco use.

Results of this study may be published.

Organization and Funding Source
This study is being conducted by the VTCRI and is funded by the National Cancer Institute.

Number of Participants
We will enroll up to 160 participants in this study.

Participation
To participate in this study, you must be 18 to 65 years of age, be a current cigarette smoker, and be willing to try unventilated cigarettes (i.e., your usual brand of cigarette with the ventilation holes in the filter blocked).

To determine if it is safe and appropriate for you to join this study, we will ask you to complete several tasks. We may stop your participation if there is evidence that you have a current unstable medical illness or an unmanaged psychiatric or neurological disorder. We will stop your participation if your answers or performance suggest that it is not safe and appropriate for you to continue in the study. Violation of research center policies may result in the research team withdrawing you from the

study. We may also stop your participation if you do not, or are unable to complete any of the study procedures. We may also stop an ongoing session, or end your participation in the study, because we have collected all the information we need.

You are free to stop your participation at any time. You may talk with other people about your decision to participate in this study. You do not have to answer any questions that make you feel uncomfortable. There are no "right" or "wrong" answers. We want you to answer the questions honestly and thoughtfully. If it is safe and appropriate for you to continue in the study, you will then complete questionnaires and computerized tasks that will measure some of your preferences and abilities.

Description and Procedures
This study will require you to complete approximately 4 visits to the VTCRI or VTCRC (including today's session). There is a possibility that you will be placed in a pilot group of participants, and will be asked to complete more or fewer than 4 study visits.

We will ask you some questions to make sure participation in the study is safe for you. We will also collect information (e.g. age, education) from you that we need to analyze our data. We will give you a detailed description of what it will be like to be in the study and answer any questions you have.

If you choose to participate, you will initially be provided with small samples of Marlboro Black and Gold Cigarettes. You will not be told which cigarette is which. You may take these samples home for use over a three-day period and smoke them as you would normally smoke your usual brand of cigarette. The purpose of this sampling period is simply to familiarize you with the effects of unventilated cigarettes. Depending on your assignment in the study, you may also be given alternative nicotine products to sample such as cigarillos or nicotine gum.

You will be asked to schedule your next study session to coincide with the end of this three-day period. For example, if today is a Friday, your next session should be scheduled for this Monday. At this next session, you will be required to return any unused cigarettes and any used cigarette filters ("butts"), and report on how frequently you used the samples.

At the beginning of every visit to VTCRI or VTCRC you will be asked to submit breath samples to measure your level of recent cigarette and alcohol use. You may also be asked to leave a urine sample, which will be tested for recent drug use and pregnancy, when applicable. All urine samples will be destroyed following receipt of test results. During the consent and additional sessions, you will also be asked to complete a number of computerized assessments and answer questions regarding cigarette and alcohol use.

You will also be required to complete 2 "purchase" sessions (one every two days), which will last approximately 30-60 minutes each. These sessions will be scheduled at your convenience at approximately the same time each session. During these sessions, you will be given the opportunity to purchase either Marlboro Black or Gold cigarettes. Depending on your assignment, you may also

be given the opportunity to purchase alternative nicotine products such as cigarillos or nicotine gum. You will be provided money to purchase these products. The amount you are provided may differ across the different tasks. At each of these sessions, you will be asked to purchase enough cigarettes so that you do not have to purchase any more cigarettes elsewhere in between sessions. In other words, you will be asked to only purchase tobacco products from these purchase sessions during this portion of the study.

In addition to the procedures described above, you may also be asked to complete daily phone interviews, which will last approximately 1-5 minutes each, during which we will ask you how many nicotine products you used the prior days. You can complete these phone interviews at your convenience.

Risks/Discomforts/Inconveniences
There will be no direct costs for your participation, although there are risks. One risk is possible embarrassment. This may result from answering questions that you consider sensitive. Some of our questions will ask for information about medical and psychiatric conditions and drug use. In addition, loss of confidentiality is another potential risk of participation. Additionally, you might experience adverse effects associated with the use of nicotine (e.g., nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat). Another risk of participation is throat irritation from use of unventilated cigarettes, as you may find that unventilated cigarettes are harsher than your usual ventilated cigarettes. We will make every effort to protect your confidentiality should you participate in this study.

Any expenses accrued for seeking or receiving medical or mental health treatment will be billed to you/your insurance and not to the research project, research team, or Virginia Tech.

Due to the investigative nature of this study, there may be other risks that are currently unknown.

If problems occur during the course of the study we will determine whether you should continue. If necessary, referrals will be provided. If you have questions concerning the study, concerns or complaints please contact Warren K. Bickel, the Principal Investigator at 540-526-2088 (office).

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

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Possible Benefits
You will not directly benefit from participating in this study. The current study, however, may help identify effective methods of assessing the abuse liability of tobacco products. The use of these assessment methods may prevent harmful (i.e., addictive) tobacco products from reaching the market; or at a minimum, proper warning labels may be provided for their products.

Voluntary Participation and Confidentiality
Your participation in this study is voluntary. You are free to decline participation in this study or withdraw from it at any time without penalty or loss of benefits to which you are otherwise entitled. We will act in accordance with the guidelines for the protection of human research participants issued by the Institutional Review Board (IRB) and Office of Research Compliance (ORC). Your identity on records relevant to this study will not be made public. Any publications resulting from this research will not mention your name or any other personally identifying information.

It is possible that health officials may review your records. This includes the U.S. FDA. Also the Institutional Review Board (IRB) may view this study's collected data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research. The source of funding, the National Cancer Institute, or their appointed designees as well as the IRB, ORC, or other institutional oversight offices will be granted direct access to your original research records for verification of data. If your record is used or distributed for government purposes, this will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agencies. You will be informed of any significant new findings that may relate to your continued participation in this study.

Compensation
You will receive compensation outlined below after completion of the relevant tasks.

- $20.00 for completion of consent session
- $40.00 for completion of each purchase session (2 total)
- $40.00 for completion of follow-up session
- $30.00 study completion bonus

The total compensation that can be earned from participation in this study is $170. Your compensation will be paid by check or reloadable prepaid card issued by Greenphire ClinCard (www.myclincard.com), an FDIC-insured payment provider that specializes in clinical trial stipend payments that comply with IRB privacy regulations and considerations. At the beginning of the study, you will receive a prepaid MasterCard debit card that can be used anywhere that accepts MasterCard. As payments are earned in the course of the study, additional funds will be added to your account. Funds are immediately available when added and you can check your balance as desired. If you receive compensation greater than $600.00, the amount received will be reported to the IRS and you will receive an IRS 1099 Form. We will collect social security numbers and retain them for IRS and auditing purposes.

In addition, you will receive an account balance (separate from the amounts listed above) that you can use to purchase tobacco/nicotine products during the purchase sessions.

If you receive compensation greater than $600.00, the amount received will be reported to the IRS and you will receive an IRS 1099 Form. We will collect social security numbers and retain them for IRS and auditing purposes.

Alternative to Participation
You do not have to participate in this study if you do not wish to. Your employment status, student status, grades, extra-curricular activities, or medical treatment will not be affected in any way.

The alternative to participating in this study is not participating.

Future Research Opportunities
If you would like to be contacted regarding future opportunities for research participation, please check the box below.

□ Yes, please contact me regarding future research opportunities.

Subject's Responsibilities
I voluntarily agree to participate in this study. I have the following responsibilities:

- Answer questions about health, and past and current substance use
- Provide breath samples to test for recent cigarette smoking and alcohol use
- Take home the freely provided product samples (today only) and return any unused cigarette samples and filters from used cigarette samples at the beginning of the next session.
- Complete 2 laboratory purchase sessions at a consistent time of day each session.
- Purchase and use only the products that are provided to me during laboratory purchase sessions (beginning with the first purchase session)
- At the session following each purchase session, return any unused purchased cigarettes and used cigarette filters from the products you purchased.
- Notify the researchers if experiencing any discomfort or desire to discontinue participation from the study
- Notify the researchers of any comments, questions or concerns regarding participation in the study

Subject's Permission/Statement of Consent

The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have read the Consent Form and conditions of the project. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the study team. I have been told that I will be given a copy of this consent form. I hereby acknowledge the above and give my informed and free consent to be a participant in this study. I recognize that I am not waiving any of my rights as a research participant by signing this consent form.

Participant's printed name	signature	date
Principal Investigator's or Designee's printed name	signature	date
Person Obtaining Informed Consent printed name	signature	date

If you have questions about this study, please contact: Dr. Warren K. Bickel, the Principal Investigator at 540-526-2088 (Telephone) or wkbickel@vtc.vt.edu (e-mail).

If you have any questions about your rights as a research subject /or questions, complaints or concerns about the study you can call Western Institutional Review Board® (WIRB®) at (800) 562-4789 or help@wirb.com or the Virginia Tech Institutional Review Board for the Protection of Human Subjects at 540-231-4991 (Telephone) or irb@vt.edu (e-mail).