InferiorGood-18-290

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

Study Protocol

3/16/2018

Protocol

Introduction

The 2014 Surgeon General's Report on the Health Consequences of Smoking concludes that changes in the physical design of cigarettes have caused an increased risk of developing lung cancer. One prominent cigarette design feature is filter ventilation, which has become increasingly common since the 1960s. Now, ventilated cigarettes now dominate the tobacco market. Filter ventilation alters cigarette burn rate and smoking topography. Ventilated cigarettes increase how much smoke is inhaled and therefore exposure to carcinogens. Moreover, because ventilated cigarettes most frequently feature low nicotine yield, smokers of highly ventilated cigarettes also smoke more cigarettes per day to compensate for reduced nicotine; this, in turn, further increases exposure to mutagens and carcinogens in tobacco smoke.

The Food and Drug Administration has the authority to ban filter ventilation. However, we currently don't know what such a ban would do to consumption of unventilated cigarettes--that is, whether smokers would switch to unventilated cigarettes and demonstrate similar levels of consumption, or whether smokers would reduce cigarette consumption or quit entirely. We also do not no if such a ban would result in the substitution of other nicotine procucts (e.g., electronic cigarettes, cigarillos, etc.). One way of understanding the effects of ventilation bans on tobacco consumption is to investigate unventilated cigarettes as an inferior good. An inferior good is an inferior substitute for a preferred product. This can be established by manipulating the account balance of a cigarette smoker. A good is determined inferior if its consumption decreases as the account balance for tobacco products increases. Thus, in the present studies, we will examine the behavioral economic demand for unventilated cigarettes in participants who normally smoke highly ventilated cigarette varieties (i.e., "ultra light" and "light" cigarettes). Using an account balance we provide, participants will purchase ventilated and/or unventilated cigarettes in three separate sessions across a range of prices (e.g., $0.12, $0.25, $0.50. $1.00, $2.00 per cigarette). For some participants, some participants may also have access to alternative nicotine products such as cigarillos, gum, or lozenges. Participants will be asked to make these purchases under six different account balance conditions. From each session, purchases from one price will be randomly selected and participants will take home all cigarettes purchased at that price. Participants will later return to the lab to return any unused cigarettes and receive reimbursement for these unused products.

Participants

Up to 160 smokers will participate in this study. To participate, smokers must:

1) provide written informed consent,

2) be 18-65 years of age,

3) be an active smoker,

4) report smoking daily in the past month,

5) have stable self-reported mental and physical health,

6) be willing to try unventilated cigarettes or alternative nicotine products.

7) report that their usual brand of cigarettes features >~20% filter ventilation (i.e., "ultra light" and "light" varieties).

Individuals will be excluded from participating if they are trying or have immediate plans to quit smoking, are currently using prescription medication that might affect smoking or nicotine metabolism (e.g., varenicline, bupropion), have plans to move away from the area, or report regular use of electronic cigarettes, nicotine replacement therapy, or other alternative tobacco products (e.g., chewing tobacco). Females of childbearing age who report not having gone through menopause will be excluded from participating if they are pregnant (through urine screen at the time of consent) or lactating. Participants who meet DSM criteria for other substance dependence will be evaluated for eligibility on a case by case basis.

Recruitment

Participants will be recruited using a separate IRB protocol to screen cigarette smokers into a variety of smoking studies in our lab (see IRB #17-870), as well as study flyers.

To the extent possible, we will attempt to minimize obstacles to participation. For example, travel barriers may be addressed by providing transportation or parking costs for participants, and scheduling barriers will be minimized by offering a flexible study visit schedule. Compensation may be provided for travel costs and time. We have a history of successful recruitment of cigarette smokers into research programs. All participants will enroll on a voluntary basis.

Consenting Process

Potential participants will be provided with the written consent form prior to visiting VTCRI or the Virginia Tech Corporate Research Center (VTCRC) (e.g., by email), if they wish. They will also be given additional time in a quiet room at VTCRI or VTCRC to read the form. VTCRI research staff will review each element of the written consent form with the potential participant. The potential participant will be given the opportunity to ask questions and will have as much time as they need to decide whether they would like to participate in the study. They will be encouraged to speak with whomever they wish before making this decision. Staff will reiterate that the potential participant can choose to decline participation in the study at that time or at any time thereafter without consequence. The potential participant and person obtaining consent will sign the consent form after the potential participant verbally states that s/he understands the conditions of the study, has no more questions, and chooses to participate.

Procedures

The study will take place over approximately four experimental sessions (one consent session, two purchase sessions, and one follow-up session) at the VTCRI's Addiction Recovery Research Center or the Virginia Tech Corporate Research Center. The initial consent session will last approximately two hours; the two purchase sessions and the final follow-up session in which subjects report consumption of, and/or return for reimbursement, their purchased cigarettes will last approximately 30 minutes to 1 hour each. Participants may also complete a brief (5-10 minutes) phone interview daily throughout participation, during which they will be asked to provide the number of study and non-study products they have used the previous day(s). They will be asked about their tobacco consumption at the laboratory sessions for days in which the data from the phone screen was not collected. Participants will also be asked to provide a breath sample for recent alcohol use at each session.

During the consent session, participants will provide informed consent (see section 4, above, for details), provide a baseline CO breath sample, and may also be asked to leave a urine sample. This sample may be tested for recent drug use and pregnancy, when applicable. During the consent sessions, and throughout the study, participants will also be asked to complete one or more of the following: the AUDIT questionnaire, questionnaires about cigarette use, craving withdrawal, delay-discounting tasks, cigarette demand, and ETM tasks.

Participants will then be given samples of the ETM cigarettes and/or alternative nicotine products (if that participant is assigned to ETM conditions that have more than cigarettes). Commercially available cigarettes will be used. Specifically, Marlboro Black 100's (~1.5% ventilation) and Marlboro Gold 100's (~28% ventilation). For participants that typically smoke menthol cigarettes, they will be given menthol versions of the Marlboro cigarettes. Importantly, the cigarettes will be labeled as "Cigarette A" or "Cigarette B." While both cigarettes are labeled with the Marlboro logo, they are not explicitly labeled as ventilated or unventilated. If participants are assigned to conditions where they will also purchase alternative nicotine products, they may be given samples of those products as well. Popular flavors of the alternative nicotine products will be made available. Participants will then take these samples home to use over approximately the next three days. The end of this sampling period will coincide with the first purchase session, at which time participants will return any unused samples.

Participants will then begin reporting to the laboratory approximately once every 2 days at a consistent time of day. Breath samples will be collected at each visit to measure CO. Participants will be informed that during the study they will be expected to only use products that we provide to them, but that the use of other products will not disqualify them from the study if they are accurately reported to us. This approach is intended to discourage the use of products that are not provided within the study while encouraging accurate self-reporting of such use. We will use a timeline follow-back procedure, or structured interview of recent product use to assess the use of other products outside of the laboratory.

At each of two purchase sessions, participants will "purchase" two days' worth of either the Marlboro Blacks or Golds in one session. Here, they will report the number of cigarettes they would like to purchase across increasing prices (e.g., $0.12, $0.25, $0.50, $1.00, $2.00 per cigarette). In one session, the price of both ventilated and unventilated cigarettes will increase in tandem across trials. In the other session, only the price of ventilated cigarettes will increase across trials. They will complete this task 6 times at each session. Once with the account balance that reflects what they typically spend on tobacco products (100%). The full range of account balances will be 140%, 120%, 100%, 80%, 60%, and 40%. At the end of each session, one price from one of the six times they complete the task will be drawn randomly and the participant will take home all cigarettes purchased at this price. Participants may also complete hypothetical purchase tasks. For some participants, alternative nicotine products such as cigarillos, gum, or lozenges may be available as well in both the real and hypothetical purchase tasks.

In each of the purchase sessions, participants will be able to purchase as many cigarettes (or alternative nicotine products) as their account balance allows, with the total price of the products purchased deducted from their account balance. Participants will be informed that the price of any unused products that are returned to the laboratory at their next visit will be refunded to their account. Thus, the number of cigarettes used outside of the laboratory will be calculated from the amount that is provided minus the amount that is returned. Before and after each session, participants may be asked to complete product evaluation surveys to measure changes over the course of the study. Participants will also be asked to return used cigarette filters (and cigarillo butts, depending on their availability) following each purchase session and the sampling period in order to qualify for the next session so that we may detect tampering or alteration of our method of ventilation blocking.

Participants will also complete a series of computerized and/or paper assessments (see attached task files for examples) during the consent session, purchase, and/or follow-up sessions. Likewise, in all sessions, participants may also be asked to leave a urine sample. This sample may be tested for recent drug use and pregnancy, when applicable.

To allow for payments that are both convenient and rapidly available, we may pay participants with reloadable prepaid cards through Greenphire ClinCard (www.greenphire.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, the participant 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 the account for that participant. Funds are immediately available when added and participants can check their balance as desired. This system will allow frequent, immediately available payments. Payments may also be made via check, however remote debit card payments and checks will be used most often.

Risks and Benefits

One risk of participation is embarrassment that may come from answering sensitive questions related to medical, psychiatric, and/or drug use history. Loss of confidentiality is another risk of participation. Additionally, because the present experiment allows and sometimes involves participants self-administering cigarettes or other alternative nicotine products, participants might experience adverse effects associated with the use of nicotine products (e.g., nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat) or withdrawal from nicotine (e.g., anxiety, irritability, difficulty concentrating). However, the amount of nicotine consumed is not expected to be different from what participants normally consume.

Data Protection

The linked code and identifying information document will be stored in a locked cabinet separate from the coded data, accessible only by members of the research team who have completed VT Human Subjects Training. The electronic version (REDCap) requires a VTC-issued user name and password and access is again limited to members of the research team who have completed VT Human Subjects Protection Training.

All data and participant binders will be stored in a safe place to protect confidential participant information. Safe places will include locked filing cabinets or locked rooms accessible only to study personnel. The full names of participants will not be listed on the outside of binders to protect confidentiality of study participants. Electronic data will be saved in secure, limited access shared drives on password-protected computers accessible only to the research team.

Access to study data will be limited to study personnel who have completed the Virginia Tech IRB Human Subjects Tutorial and who have been delegated the responsibilities of data collection, management, or analyses by the PI. Data collected from this study will be retained and destroyed in accordance with the center's policy that requires a 3-year retention period following final publication of the data.

Participant Compensation

Compensation for participation will be as follows:

$20.00 for completion of informed consent

$40.00 for completion of each purchase session (3 total in Study 1 and 2 total in Study 2)

$40.00 for completion of the follow-up session

$30.00 study completion bonus

Combined, the subjects could earn up to approximately $210 in Study 1 and $170 in Study 2 by completing all aspects of the experiment.

In addition, participants will receive approximately $5 to $40 each purchase session to purchase cigarettes. The amount each participant receives will be proportional to his/her real-world cigarette expenditure. In Study 2, it may also be smaller or larger depending on the account balance condition drawn. Account balances provided as part of the study to purchase study tobacco products will not be advertised as or considered compensation.