Title: Evaluating the acute effect of vaping on food intake

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Evaluating the acute effect of vaping on food intake

VCU INVESTIGATOR: Dr. Caroline Cobb, Associate Professor of Psychology

SPONSOR: National Institutes of Health

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study that is being conducted by VCU Dr. Caroline Cobb. **It is important that you carefully think about if being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide to not participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

The purpose of this research study is to examine the effect of electronic cigarette (e-cigarette) use or vaping on food intake during an ad libitum (free access, all you can eat) buffet meal.

In this study, you will be asked to do the following things:

1. When you arrive to the study site, you must wear a mask at all times except when directed by study staff. Before and/or upon arrival to the study site, we will ask you questions about possible COVID-19 symptoms/exposure and take your temperature (on your forehead).
2. We will be using Zoom, as an intercom system, for the majority of communications during screening and sessions. At some points, we may use the camera feature to explain tasks/procedures. We will make you aware before turning your camera on.
3. Before you join the study, we will ask you to fill out some forms about yourself, your medical history/physical activity/eating behavior, tobacco/alcohol/drug use and we will use a urine pregnancy test to make sure that women qualify to participate in the study. Pregnant women are not eligible to participate in this study. At this visit we will also ask to see a form of identification with your date of birth. This is to verify your age. We will also check your heart rate and blood pressure and measure your height and weight. We will include a brief menstrual cycle/birth control use questionnaire as well.
4. If eligible, following the in-person screening session, we will ask you to complete **two sessions,** each taking 3 hours, at the Behavioral Health Research Laboratory/Center for the Study of Tobacco Products. Each session will begin at about the same time each day (must be in the morning before 11am), and will be

separated by about 1 week. If applicable, sessions will be timed based on menstrual cycle.

5. Before each session, we will ask you to abstain from (refrain from eating or using) **all food and tobacco/nicotine products** (like the gum or patches) for at least 12 hours. We also ask that you refrain from drinking any beverages other than water for at least 12 hours. We will ask you to sign a form stating whether or not you have been abstinent from food and tobacco/nicotine for at least 12 hours. We will also ask you to take a simple breath test to make sure that you have followed these restrictions. Our tests are not perfect, but they will be the only measures that we can accept to make certain that you have followed the no tobacco/nicotine restrictions.
6. At the beginning of each session, you will complete some additional pre-session measures and then start a 1-hour rest period. The 1-hour rest period will take place in the session room, this will help you get used to the setting. During this waiting period you will not be allowed to use your phone, eat food, or drink outside beverages, however, we will provide you with water to drink and a book/magazine to read.
7. After this 1-hour rest period, you will either be asked to: **take 20 puffs from a JUUL (pod-mod style e-cigarette) containing nicotine** or **you will be asked to sit with an uncharged JUUL loaded with an empty pod for 20 minutes**. You will only vape in one of the sessions and the other session will involve no vaping. The order of the activities will be randomly assigned (like the flip of a coin) and each will take about 20 minutes.
8. You will then complete an additional 35-minute rest period which will be followed by access to a buffet meal (e.g., crackers, cookies, cheese, chicken, carrots, chips, etc) for 30 minutes. You may eat all you like. During the meal, researchers will observe you with a camera linked to a computer to ensure you follow study procedures but this data will not recorded or stored for future use.
9. During each session, you will be asked to complete questionnaires that measure how you feel and how you would behave in certain situations at several time points.

Your participation in this study will last up to 8 hours in-person in the laboratory (1.5 - hour screening; two 3-hour long sessions). About 34 individuals will participate in this study.

WHAT ALTERNATIVES ARE AVAILABLE?

You have the alternative not to participate. If you are unable/unwilling to complete study tasks on the computer, you are will be offered the alternative of completing study tasks on paper.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

There are both risks and benefits of participating in research studies.

Physical Risks

1. You may experience some mild discomfort during the 12-hour food and tobacco/nicotine abstinence period before each session. Side effects from abstaining from food can include dizziness, nausea/indigestion, and fatigue. Side effects from tobacco/nicotine abstinence

can include irritability, anxiety, restlessness, excessive hunger, difficulty concentrating, and sleep disturbance. Though uncomfortable, these feelings are not medically dangerous.

2. The e-cigarette liquid that we give you may contain more nicotine than you usually use, although many e-cigarette users report using these liquids. You may experience side effects from products that contain nicotine such as acute increases in heart rate/blood pressure, sweating, lightheadedness, dizziness, nausea, and nervousness. These effects are unlikely in individuals who use nicotine-containing e-cigarettes regularly. Inform the study staff immediately if you experience any discomfort.
3. The Centers for Disease Control and Prevention advises that e-cigarette, or vaping products are unsafe for youths, young adults, or women who are pregnant. Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products. If you use e-cigarette products, monitor yourself for all of these symptoms and promptly seek medical attention if you have concerns about your health.
    a. Some people who use e-cigarettes have reported experiencing seizures. Some of these individuals reported a prior history of seizures or using other substances at the same time as their e-cigarette.
    b. In some cases, e-cigarette use has led to respiratory illnesses such as difficulties breathing, shortness of breath, cough, and/or chest pain before hospitalization. In some cases, e-cigarette use has led to death, although most of these cases have been related to vaping THC.
    c. In some cases, symptoms of mild to moderate gastrointestinal illness such as nausea, abdominal pain, vomiting, diarrhea, or fevers or fatigue have been reported.
4. The use of e-cigarettes may include other side effects/risks such as a sore or scratchy throat and headache.
5. E-cigarette companies have to apply to the Food and Drug Administration (FDA) and be approved for sale in U.S. markets. In June 2022, the FDA denied the marketing application from JUUL, the manufacturer of the e-cigarettes used in this study. The FDA determined that JUUL did not provide enough evidence about the toxicity of its e-cigarette device and pods in its application. However, the FDA has not received clinical information to suggest an immediate hazard associated with the use of JUUL devices or JUUL pods. The FDA decision to ban the sale of JUUL is not final yet due to ongoing legal disputes. When and if the FDA's decision to ban JUUL is final, it will be illegal to sell JUUL products. However, it will still be legal for researchers to study these products and for participants to use them.
6. The foods that you will consume during the buffet meal are commercially available snacks such as cookies, wafers, crackers, chips, cheese cubes, etc. If you have a food allergy, there is a risk that you could have an allergic reaction. All participants with known life-threatening food allergies must inform staff of their allergies.
7. The researchers will let you know about any significant new findings (such as additional risks or discomforts) that may make you change your mind about participating in the study.

Non-Physical Risks

1. Participation in research might involve some loss of privacy. There is a small risk that someone outside the study could see and misuse information about you.
2. Some of the study questionnaires ask personal questions that are sensitive in nature. These questions might make you feel uncomfortable or be frustrating to complete. You have the right to refuse or not answer any study-related question.

Benefits

1. You will derive no personal benefit from this study.
2. However, your participation will help us in the future as we try to understand better how the effects of vaping nicotine on eating behavior.

In general, we will not give you any individual results from the study with the exception of a positive pregnancy test or high blood pressure readings.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid in cash for the time and inconvenience involved in participating in this study. You will be paid $15/hour for completing the in-person screening to determine your eligibility to participate. For the study sessions, you will be paid $75 for completion of the first session and $100 for session 2 for a total of $175. Thus, total potential compensation for this study is $198. Additionally, if lab parking is not available for the in-person screen or study sessions you will be reimbursed for parking expenses only.

Total payments within one calendar year that exceed $600 will require the University to annually report these payments to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately (contact information for Dr. Thokozeni Lipato, the medically responsible investigator, is included below). Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

If you leave the study before the final regularly scheduled visit, you will be able to keep any money that you have earned in the study up to that point. You will not be allowed to withdraw data that has already been collected about you.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- The investigator thinks it necessary for your health or safety
- You are found to not be eligible for the study
- The sponsor has stopped the study
- You have not followed study instructions

- Administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the Sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

A description of this clinical 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 but may contain an overall results summary. You can search this website at any time.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family 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.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints, or concerns about your participation in this research, contact:

Dr. Caroline Cobb at 804-827-3562 / email: cobbco@vcu.edu

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

The medically responsible investigator is Dr. Thokozeni Lipato at thokozeni.lipato@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	

Signature of Person Conducting Consent Discussion	Date
Principal Investigator Signature (if different from above)	Date