Title: A Novel Approach to Reducing Adiposity Among Young Men

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: A novel approach to reducing adiposity among young men

VCU INVESTIGATOR: Jessica G. LaRose, Associate Professor, 804-628-7521

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether 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.**

Your participation is voluntary. You may decide not to 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

Why is this study being done?

The purpose of this research study is to find out whether a primarily self-guided program can produce changes in physical activity, diet and weight among young men. We think that this self-guided lifestyle intervention may help men to reduce weight and improve heart health because it has been adapted to meet the possible weight loss needs of young men. We anticipate that young men will experience reductions in body weight after enrollment in the intervention, but this is unknown and what we are testing. We hope to learn about men's experience participating in this self-guided lifestyle intervention, as well as effects of the program on changes to diet, physical activity, and perceived risk for cardiovascular disease and obesity.

What will happen if I participate?

Study participation lasts approximately 3 months. We anticipate enrolling approximately 32 young men. If you choose to participate, you will schedule your first virtual data collection visit (Assessment 1), where you will weigh yourself using a study issued scale and fill out electronic questionnaires about current lifestyle practices (diet, physical activity, risk behaviors). For this visit, you will be asked to attend a virtual meeting via Zoom wearing light clothes. Prior to this

visit, you will be asked to refrain from eating and drinking (with the exception of water) for 8 hours. The virtual assessment will last approximately 1 hour. Staff will meet with you via Zoom to obtain your current weight via video, medical events, and medication use within the last 3 months to see if you are eligible to be in the study. If you qualify for the study, you will be randomly assigned (like the flip of a coin) to the self-guided lifestyle intervention group or delayed treatment control group. You have an equal chance of being assigned to one of the two groups described below. About 2 weeks after you are randomly assigned to a group, we will ask you to complete a brief 10-minute questionnaire online.

Self-Guided Lifestyle Intervention Group

If you are randomly assigned to this group, you will be asked to:

1. Complete a follow-up virtual assessment (3-months following enrollment), where your current weight will be obtained via video using a study issued scale and electronic surveys will be administered. This visit will last approximately 1 hour. You will receive feedback on your measures after each virtual assessment.
2. Participate in 1 virtual group meeting that will last 60-minutes.
3. Review the Intervention Toolkit, which will include: a scale for self-weighing; handouts that will include free self-monitoring apps and strategies for no-cost exercise, sample meal plans and meal planning tips, and tips for healthy living that emphasize risk areas for young adults
4. Read 12 weekly text messages related to men's health risk and strategies for avoiding these health risks
5. Participate in an approximately 30-minute interview via Zoom (using audio only; no video) that asks about your personal experience and satisfaction with the lifestyle intervention, as well as your motivations for joining the study. This interview will be audio recorded to allow us to transcribe and code the conversation, which will help us improve future programs for young men.

Delayed Treatment Control Group

If you are randomly assigned to this group, you will asked to:

1. Complete a follow-up virtual assessment (3-months following enrollment), where your current weight will be obtained via video using a study issued scale and electronic surveys will be administered. This virtual assessment will last approximately 1 hour. You will receive feedback on your measures after this virtual assessment.
2. Following the 3-month assessment visit
    a. Participate in 1 virtual group meeting that will last 60-minutes.
    b. Review the Intervention Toolkit, which will include: a scale for self-weighing; handouts that will include free self-monitoring apps and strategies for no-cost

exercise, sample meal plans and meal planning tips, and tips for healthy living that emphasize risk areas for young adults

c. Read 12 weekly text messages related to men's health risk and strategies for avoiding these health risks

What alternative treatments or procedures are available?

If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes talking with your doctor or other community providers about weight loss, participating in a commercially-available weight loss program, and/or exercising on your own or with a personal trainer. The study staff will provide a referral list to you if you are interested in these alternatives. You do not have to participate in this study to pursue weight loss, healthy eating, or physical activity.

What are the risks and benefits of participating?

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

Risks and Discomforts	Benefits to You and Others
1. There is a risk that the self-guided lifestyle intervention may not lose as much weight as a more intensive behavioral weight loss program. 2. There is also a risk that you may not lose weight or improve cardiovascular risk factors 3. There may be some risks that the investigators do not know about yet, so we will let you know of any new findings. 4. Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue. 5. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study	There is no guarantee that you will receive any benefits from being in this study. However, possible benefits include weight loss, decreases in cardiometabolic risk, improvements in diet and physical activity. We hope the information learned from this study will provide more information about effective strategies for engaging young men to lose weight.

could see and misuse information about you. 6. The study questionnaires and interview ask questions that you might find sensitive in nature and may make you feel uncomfortable or upset. 7. Randomization means you cannot pick the group to which you're assigned, which means there is a risk you will not be assigned to the group you desire.	

Unknown or Unforeseeable Risks

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study. In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

WHAT ARE THE COSTS?

The sponsor is paying for the virtual assessment and intervention materials. You will have to pay for the following items, which are done for research purposes only and are not covered by the study. This includes:

- The cost of the cell phone used in this study
- Any memberships or costs associated with physical activity
- Any costs associated with healthy dietary practices

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $25 following completion of the second virtual assessment. If you are randomly assigned to the intervention group, you will receive the same payment as described above. In addition, you will receive $10 for completing the 30-minute interview during the second virtual assessment. The delayed treatment control group will receive up to $35 for participation. The self-guided group will receive up to $45 for participation. All payments will be made via electronic gift cards; you will be given the choice between multiple options (e.g., amazon).

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 virtual assessment, please write to Jessica G. LaRose, VCU Department of Health Behavior and Policy, 830 East Main Street, 4th floor, Richmond, VA 23219 or Jessica.larose@vcuhealth.org to officially terminate your participation.

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
- 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.

Data is being collected only for research purposes. Your data will be identified by an ID number only (not names or birth dates, or other identifiable information), and stored separately from medical records in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted as soon as the data is collected and cleaned. Your research record / file, which will be identified by an ID number only and contains the results from your assessment visits, will be kept in a locked file cabinet for 5 years after the study ends and will be destroyed at that time. Access to all data will be limited to study personnel.

Each participant assigned to the intervention group will complete a semi-structured interview which will be audio-recorded. The audio files will be stored in password protected files which

can only be accessed by authorized study personnel. Once the information on the recordings has been coded and analyzed for research and quality control purposes, or within 5 years of study completion, the files will be destroyed.

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:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

A description of this clinical trial will be available on clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

If, as part of this research, we learn about real or suspected child or elder abuse, the law says that we have to let people in authority know so they can protect the person(s) at risk. Similarly, if something we learn through this research indicates that you may intend to harm yourself or others, we are obligated to report that to the appropriate authorities.

Once study identifiers have been removed, findings from this study may be presented at meetings or published in papers, but your name will never be used in these papers or presentations.

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.

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

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Jean Reading
Phone: 804-827-2250
Email: jean.reading@vcuhealth.org
and/or
Dr. Jessica G. LaRose
Phone: 804-628-7521
Email: Jessica.larose@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157;
http://research.vcu.edu/human_research/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 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