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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: A Novel Integrated Treatment Program to Reduce Obesity and Inflammation among Emerging Adults

VCU INVESTIGATOR: Dr. Jessica LaRose, Associate Professor [p] 804-628-7521

SPONSOR: Massey Cancer Center

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.** 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 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 examine the effects of a newly-developed treatment program on diet, physical activity, sleep, emotional well-being, and weight loss among emerging adults ages 18-25. Emerging adulthood is an important time to consider these factors because during these years, many people experience weight gain, increased stress and depression, poor dietary quality, reduced physical activity, and poor sleep habits. The treatment program being tested in this research study aims to address all of these behavioral and psychological factors and we hypothesize that this will produce weight loss. In order to test this hypothesis, participants will receive the treatment program and data will be collected throughout the treatment program and at 2 data collection visits. These data will be analyzed to determine whether this approach produces positive changes in the expected health indices. In addition, we will collect feedback

from you throughout the treatment program in order to make changes and improve similar programs in the future.

What will happen if I participate?

Participants will be asked to do the following **at 2 time points** (baseline, and 4 months):

- Attend in-person data collection visits where we will measure your height, weight, and blood pressure. In addition, you will complete questionnaires that ask about your mood, stress level, diet, physical activity, sleep habits, and weight history. These visits will take place at One Capitol Square (830 East Main Street).
- In addition, **at baseline only**, participants will be asked to complete a finger stick to test their fasting glucose. This value (in addition to the other measures taken during your visit) will determine your eligibility for the study.

As a part of the treatment program, participants will also be asked to do the following:

1. Attend weekly virtual (Zoom) group sessions for 8 weeks
2. Attend virtual (Zoom) group sessions every other week for 8 weeks
3. Monitor what you eat and drink, your physical activity, your weight, and your mood
4. Provide weekly feedback about the group sessions

Your participation in this study will last up to 4 months. Approximately 20 individuals will participate in this study.

This study will not use your samples to sequence all or part of your DNA.

What alternative treatments or procedures are available?

If you decide not to enter this study, you can pursue the usual care available to you even if you were not in the study. This includes talking to your doctor or other community provider about weight loss, participating in a commercially-available weight loss program, and/or meeting with a psychologist or therapist to discuss stress management. The study staff will discuss these options with you. You do not have to participate in this study to pursue weight loss, healthy eating, physical activity, or stress management.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others
1. You may experience temporary discomfort during blood pressure recordings due to the constriction of the blood pressure cuff on your arm. 2. You may experience temporary discomfort including pain and soreness during the finger stick for the blood glucose measurement. 3. 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. 4. You may experience temporary increased distress from tracking your mood and stress. 5. There may be some risks that the investigators do not know about yet, so we will let you know of any new findings. 6. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. 7. Some of the study questionnaires ask questions that are sensitive or potentially upsetting in nature and may make you feel uncomfortable.	1. There is some evidence that the program we have developed is effective in producing weight loss. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you. 2. There is no guarantee that you will receive any direct benefits from being in this study. We hope that what we learn from this study will provide more information about the relationship between mood/stress, healthy lifestyle behaviors, and weight among emerging adults.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

Baseline Assessment (Visit 1)

Your first study visit (Visit 1) will take place in person at One Capitol Square (830 East Main Street) and last approximately 45 minutes. This visit will require you to fast and refrain from alcohol use and caffeine for 12 hours and to refrain from any strenuous physical activity for 8 hours prior to your appointment. At this visit, we will measure your blood pressure, height, and weight. We will also conduct a finger stick to assess your glucose (a diabetes risk assessment). This finger stick is similar to one that you could do at home if checking your own blood sugar and requires only a small droplet of blood. In addition, you will complete questionnaires that ask about your mood, stress, demographic information (e.g., race, occupation), financial strain, typical diet, physical activity, and sleep habits. Visit 1 provides information that study staff will use to determine your final eligibility for the study. You will receive $20.00 for completing Visit 1 in addition to $5.00 to cover any parking/transportation costs associated with the visit. If you are found to be eligible, you will receive the treatment program outline below:

Treatment

As a part of the treatment program, you will be asked to attend weekly virtual (Zoom) group sessions for 8 weeks followed by attending sessions every other week for 8 weeks (total of 12 groups spanning 4 months). These sessions will last approximately 75 minutes each, and will involve a combination of education, discussion, and applied activities to help you learn evidence-based skills and strategies for weight loss, stress management, and mood regulation. Throughout the treatment program, you will be asked to apply these strategies to help you:

- increase your physical activity
- decrease your intake of high-fat, high-sugar, and highly processed foods
- reduce your stress level
- improve your mood
- establish a consistent sleep routine

Each group will be led by your coach, who has received extensive training in principles of weight loss and stress/mood management.

In addition to attending these groups, you will also be asked to track your weight, eating, physical activity, sleep, and mood each day. Your coach will use this information to provide weekly feedback to you and to help facilitate group discussions. Following completion of each assessment visit (Visit 1 & Visit 2), you will receive a personalized report with your physical measurements and feedback on health behaviors.

Follow-up Assessment (Visit 2)

Visit 2 will take place approximately 4 months following Visit 1 and will entail collection of the same data as described in Visit 1 but without the finger stick. You will receive $20.00 for completing Visit 2 in addition to $5.00 to cover any parking/transportation costs associated with the visit.

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

You may not lose weight, and there is a possibility that you may gain weight while you are in this study.

Possible Risks Associated with Data Collection

Frequent

- None

Occasional

- Physical discomfort
- Fatigue

Rare

- None

Possible Risks Associated with Treatment

Frequent

- None

Occasional

- Accidental injuries such as falling
- Sore or pulled muscles
- Physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue associated with increased physical activity

Rare

- Development of excessively restrictive eating habits
- Prolonged worsening of stress level and/or negative mood

Non-Physical Risks

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

Questionnaires may contain questions that are sensitive and personal in nature. You may refuse to answer any question that makes you feel uncomfortable.

We will be asking you to monitor your stress and mood. You may notice a temporary increase in stress and negative mood as a result. You may discontinue self-monitoring at any time if it becomes excessively distressing.

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.

WHAT ARE THE COSTS?

The sponsor is paying for everything in this study. You will not be charged for any study visits, tests, or procedures.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $20.00 in cash for each completed study visit in addition to $5.00 in cash for any parking or transportation costs associated with these visits. If you complete all scheduled study visits and measures, you will have received a total of $50.00.

Total payments within one calendar year that exceed $600.00 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income.

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.

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 (prior to treatment launch only)
- 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 identifiable information in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted within 3 years after the study is over. 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.

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

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. 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 that you intend to harm yourself or others, or we learn about actual or suspected child or elder abuse, we are required by law to let people in authority know about this.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples 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 named below is the best person to contact if you have any questions, complaints, or concerns about your participation in this research:

Dr. Jessica LaRose
[p] 804-628-7521
[e] 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; https://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 participate in this research study. I will receive a copy of the consent form for my records.

_____	
Participant Name (Printed)	
_____	_____
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