Title: Piloting a Novel Intuitive Eating Intervention for College Women With Disordered Eating

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Piloting an Intuitive Eating Intervention for College Women

VCU INVESTIGATOR: Suzanne Mazzeo, PhD

SPONSOR: Academy for Eating Disorders

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 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 pilot test a new intervention that helps young adult women learn adaptive eating and exercise strategies, increase their body acceptance, decrease unhealthy weight control behaviors and prevent future eating and problems. This intervention is experimental, and the study will test its feasibility, acceptability, and effectiveness. You are being asked to participate in this study because you are a woman between the ages of 18-25, you report engaging in some unhealthy weight control behaviors, and are an undergraduate student at Virginia Commonwealth University.

You will be randomly assigned (like the flip of a coin) to participate in either a group program with 6-10 other young women or guided self-help, where you have phone calls with a member of the study team. Both programs occur weekly for 8 weeks. You have an equal chance of being assigned to the group or guided self-help.

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

All Participants:

1. Complete ~30-minute online surveys before the program, immediately after the program (8 weeks), and 2 months after the program. Questions will ask about your eating and exercise behaviors and attitudes, level of body appreciation, body awareness, feelings of weight stigma, and satisfaction with life.
2. Complete weekly ~5 minute online surveys after each session on your satisfaction with the program.

3. Have the chance to participate in an *optional*, brief, in-person ~30-minute interview at the end of the program where you provide feedback about the program. This interview is voluntary, conducted by a member of the study team, and occurs at 800 W Franklin Street on the Monroe Park campus.

Group Participants:

1. Visit the Wellness Resource Center on the Monroe Park campus eight times for group sessions, lasting 1.5 hours each. Sessions are led by trained study staff under the supervision of Dr. Mazzeo. They will be audio-recorded to ensure all groups receive the same information. We'll ask all participants to only use first names.
2. Complete homework assignments between sessions that will take about 30 minutes/week.
3. Be contacted through phone, email, or text message (your preference) to remind you of each group session.
4. If you miss a session, arrive 15 minutes early to the next session to discuss key points from the session you missed with the group leaders.

Guided Self-Help Participants:

1. Spend about 1.5 hours/week for 8 weeks on your own reading and completing 1-2 chapters in a workbook provided for you.
2. Have 8 weekly, ~20 minute scheduled phone calls with a member of the study team. These sessions will be audio-recorded to be sure all participants receive the same information. Only first names will be used.
3. Be contacted through phone, email, or text message (your preference) to reschedule missed sessions.

Your participation in this study will last up to 18 weeks. Approximately 60 individuals will participate in this study.

If you do not wish to participate, you can find alternative help from other available resources on campus that can support behavioral change, such as University Counseling Services, Student Health, Recreational Sports, and The Wellness Resource Center.

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

Most Common Risks and Discomforts	Benefits to You and Others
• 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. • The study questionnaires ask personal questions that are sensitive in nature and may make you feel uncomfortable.	There is no guarantee that you will receive any benefits from being in this study. However, there are several possible benefits, including: • You might develop a healthier and more compassionate relationship with food and your body.

• If in the group condition, you might experience limited respect or judgment from group members, discomfort when sharing personal experiences with others, or loss of privacy when participating in a group. • If in the guided self-help condition, you might feel embarrassed to discuss your eating and exercise attitudes and behaviors with the interventionist.	• You might develop a greater awareness of your hunger and full signals, learn to eat more intuitively, trust your body, and accept your natural, healthy body size. We hope the information learned from this study will provide more information about how to improve eating habits and body image and reduce eating and weight-related disorders in young adult women

In general, we will not give you any individual results from the study. However, you may contact the researchers (contact information below) if you would like a summary of study results at the completion of the study.

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 ARE THE COSTS?

There are no costs for participating in this study other than the time you will spend in the groups and filling out questionnaires.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You may receive a total of $30 in Amazon gift cards during this study if you complete all online questionnaires ($5 for completing the pre-test, $10 for completing post-testing, $15 for completing the two-month follow-up testing). You will receive electronic gift cards to your preferred email address within one week upon your completion of questionnaires.

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.

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 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

A description of this clinical trial will be available on http://www.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 anytime.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

Future Research Studies

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.

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:

Suzanne Mazzeo, PhD, Professor of Psychology (semazzeo@vcu.edu), 804-827-9211
or
Blair Burnette, MS, Graduate Student (burnettecb@vcu.edu), 615-308-4769

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

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.

Instructions: This consent question should be set up so that if the potential participant selects "No," then they will not proceed to the survey.

Do you consent to participate in this research study?

YES
NO