Title: Targeting Maladaptive Eating Behaviors with Mindfulness-Based Training to Prevent Weight Regain

NCT Number: NCT04847843

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Consent and Authorization Document

BACKGROUND

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

The purpose of the study is to learn about how mindfulness-based training may influence weight management following weight loss. You will also undergo a screening to determine eligibility, baseline assessments, and post intervention measurements. We will explain each of these procedures in this Consent Form. You are being asked to participate in this research because, as you have told us, have lost greater than or equal to 7% of your body mass via intentional weight loss within the past 6 months via lifestyle (diet/exercise) and/or medical/pharmaceutical; and/or are 12 to 18 months post bariatric surgery. This study is being conducted by Tanya M. Halliday, PhD, RD, a faculty member at the University of Utah.

STUDY PROCEDURES

Summary of the study: After screening, eligible participants that elect to continue will complete baseline evaluations. You will then complete 8 weeks of a mindfulness-based training program or a healthful lifestyle behavior program. Post-intervention testing will take place following the 8-week study period, and follow-up testing will take place at month 6 (4-months following the completion of the 8-week study phase). An additional 1 year (6-months following the completion of the 6 month testing) virtual follow-up evaluation will be optional to participants.

If you join the study, you will be asked to undergo the following steps:

1. Complete an interview to determine your eating habits and mood. This will be over Zoom and you will be asked to complete online questionnaires. We will also go over the consent form with you during this time.

2. You will be asked to come to the University of Utah's department of Health and Kinesiology to have your level of body fat measured using a special BodPod device. For this test you will be asked to wear spandex-like apparel and sit inside a small chamber. The chamber will fill with air while you are inside of it, this test takes approximately 10 minutes and there is no pain associated with this test. We will also provide you with a WiFi enabled digital scale to measure your weight at home over the course of this study.

a. If you are a woman of childbearing potential, you will be asked to complete a pregnancy test. Research study staff will provide you with a pregnancy test and you will be asked to take the test in our lab.

3. Complete online diet questionnaires that will give us information about your eating behaviors and habits. You will also be asked to complete an online diet recall to list what you ate and drank on three separate days, including 2 weekdays and 1 weekend day.

4. Complete a 1-day diet food record the day before your meal test. We encourage you to eat a diet that is easy to repeat because we will ask you to replicate this 1-day diet for the post-intervention meal test. During this time, we also ask that you do not change your usual activity level.

5. Participate in a meal test. On the morning of your meal test you will be asked to come to the Human Performance Laboratory at the University of Utah (located in HPR Complex, directions and a parking pass will be provided to you) in the fasted state (nothing to eat or drink except water since your evening snack). This study day will last about 4 hours. You will be asked to complete the following:

a. Body weight measurement.
b. Questionnaires will be given to assess food cravings before and after the breakfast. a.
c. You will also be asked to rate your appetite. You will be asked 3 questions regarding appetite before your breakfast meal and every 30 minutes after for the duration of 3 hours.
d. Eat all contents in the provided breakfast meal over 20 minutes.
e. Appetite ratings will be repeated 30, 60, 90, 120, 150, and 180 minutes after the test meal.
f. You will then be asked to eat the provided lunch. For this meal you will be allowed to eat as much or as little as you like.

6. You will be randomly selected to go into one of two groups. One group involves learning stress management techniques (like mindfulness), the other group involves learning and discussing healthy lifestyle behaviors and goals. What random selection means is that a computer will “flip a coin” so you will be randomly assigned to one of the two groups. You will not be able to choose which group you join.

7. Participate in 8 sessions of your assigned intervention. Each intervention is designed to help people with weight management to prevent weight regain. Each session will be about 2 hours long, held online in a group zoom session. You will attend each session with up to 15 other persons who have recently lost weight. After each session, you will fill out two brief questionnaires (they will take 5-10 minutes to complete). All group sessions will be audio recorded. The purpose of the audiotaping is to ensure that the interventionist leading the group is doing a good job. We may also use the tapes to learn about the experience of participants in these intervention groups. The recording will be focused on the interventionist, not you. Your identity will be kept completely confidential and no one will view these tapes besides the researchers.

8. Practice homework assignments for 15 minutes a day between group treatment sessions.

9. Weigh yourself weekly using the WiFi-enabled scales provided to you by the research study staff. Your weight and body composition will be uploaded automatically and only visible by you and the research study staff.

10. You will have to do #1-5 when the study begins. Then you will do #3-5 after the 8-week period is over.

11. At 6-months (4 months after the intervention is over), you will be asked to complete #3-5 again.

12. At 1-year (6 months after your 6 month follow up testing [#11]), you will be contacted and asked i) to fill out brief questionnaires about your experience in the study and ii) to provide your current weight.

RISKS

Risks, side effects, and discomforts you may experience while in this study include:

- **Questionnaires:** You will be asked questions that may make you feel uncomfortable or embarrassed.
- **Confidentiality:** There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed. Subject information will be kept in locked filing cabinets in locked offices and/or stored on password-protected and encrypted computers.
- **Group Setting:** There is a risk of confidentiality within a group setting. In order to reduce this risk all study participants will be briefed on group confidentiality and all study participants will be expected to not repeat any identifying or personal information outside of the group setting.

REPRODUCTIVE RISKS

Pregnant women must not take part in this study, nor should women who plan to become pregnant during the study. Women who are at risk of pregnancy will be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. If you become pregnant while taking part in the study, you must immediately tell the research team, and you will be withdrawn from the study

BENEFITS

This study is designed for the researcher to learn more about weight loss maintenance. We cannot promise any benefits to you from your being in the study. However, possible benefits may include: receiving information about your health which can be discussed with your primary care physician; possible reduction in weight regain. This could result in benefits to your health if you continue to healthful lifestyle interventions and mindfulness-based training following participation in this trial.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, please contact Dr. Tanya Halliday at 801-213-1364 or tanya.halliday@utah.edu

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. We will still answer any questions you have. Your decision will not affect your relationship with your doctor or the study team in any way.

COSTS AND COMPENSATION TO PARTICIPANTS

You will not be charged, nor will your insurance company be charged, for any test or visit that is completed solely for the purpose of this study.

You will be compensated up to a total of $230.00 for participation on this study. Compensation will be prorated as follows:

- $50.00 for completion of baseline assessments
- $50.00 for completion of post-intervention assessments @ 8 weeks.

- $50.00 for completion of post-intervention assessments @ 6 months.
- $10.00 for completion of each of the eight (8) intervention sessions each week, for a total of $80.00 compensation provided.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address telephone number, and email address
- Related medical information about you like family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure readings and lab results

All tests and procedures that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- 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 website at any time

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and University of Utah Health Sciences Center

- The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights

- If we share your information with groups outside of University of Utah Health Sciences Center, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date

NATIONAL INSTITUTES OF HEALTH
Reporting Race and Ethnicity Data

Date of Birth	Sex/Gender □ Male □ Female

Ethnicity

1. Do you consider yourself to be Hispanic or Latino? (See definition below.) Select one.
Hispanic or Latino*. A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."*

□ **Hispanic or Latino**
□ **Not Hispanic or Latino**

Race

2. What race do you consider yourself to be? Select one or more of the following.

□ **American Indian or Alaska Native**. A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

□ **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

□ **Black or African American.** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or "African American."

□ **Native Hawaiian or other Pacific Islander**. A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

□ **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

□ Check here if you do not wish to provide some or all of the above information.