Title: A Randomized Controlled Trial of Behavioral Weight Loss and Stigma Reduction for Long-Term Weight Loss

NCT03704064

IRB Approval: August 7, 2019

University of Pennsylvania
Informed Consent and HIPAA Authorization Form

Title of the Study:	**Social and Behavioral Intervention for Long-term Weight Loss**
Protocol Number:	**828274**
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24-Hour #:	215-746-6700 for the Penn Outpatient Psychiatry Center; For emergencies, call 911 or report to your nearest emergency room.

Research Study Summary for Potential Subjects
You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

This research is being conducted to examine the effectiveness of a new intervention that addresses social aspects of obesity, combined with behavioral weight loss (BWL) treatment, in facilitating long-term weight loss.

If you agree to join this study, you will be asked to complete the following procedures:

- Screening Visit
- Randomization Visit
- Follow-up Assessment Visits (week 20, week 46, and week 72)
- 20 weeks of weekly group weight loss sessions
- 6 months of monthly group weight loss sessions
- 6 months of every-other-month group weight loss sessions

This study may benefit society at large by providing information about the benefits of discussing social aspects of weight, combined with BWL treatment, in helping people

achieve long-term weight loss. In addition, your participation may benefit you in a number of ways including, but not limited to, weight loss, improvements in medical conditions made worse by excess weight, and the improvement of your thoughts and feelings about yourself and your weight. Despite all of these possible benefits, you cannot be guaranteed weight loss or any medical or psychological benefit from participating in this study. Possible risks of participation may include gallstones, pain and bruising at the puncture site of blood draws, and psychological distress.

Please note that this is only a summary and there are other factors to consider before agreeing to participate in this research study. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

What is the purpose of the study?
The purpose of this study is to examine the effectiveness of a new intervention that addresses social aspects of obesity, combined with behavioral weight loss (BWL) treatment, in facilitating long-term weight loss. Researchers at the University of Pennsylvania do not know whether the discussion of social aspects of obesity, combined with standard BWL, will lead to better long-term weight loss than standard BWL treatment alone. This study is designed to answer this question.

Why was I asked to participate in the study?
You are being asked to participate in the study because you have indicated that you are interested in losing weight and are agreeable to discussing social aspects of obesity, including negative views about excess weight sometimes encountered in media reports. You also reported that you have had experiences of being treated negatively or unfairly due to your weight, and you described having some negative thoughts and feelings about yourself and your weight. You are an adult over the age of 18 and have a body mass index (BMI) of at least 30 (or of 27 or above with a weight-related health risk factor).

Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in the study, and what will be required of you during the study. The research team is going to talk with you about the study, and a staff member will give you this consent form to read. You may wish to discuss it with your family, friends, or physician. You may find some of the medical language difficult to understand. Please ask the study staff if you have any questions. If you decide to participate, you will be asked to sign this form.

How long will I be in the study? How many other people will be in the study?
The program is divided into two parts: a 20-week weight loss phase followed by a 52-week maintenance phase. The total duration of the study will be 72 weeks. A total of 104 participants will be enrolled in this study. Participants will be randomly assigned to one of two groups. Half of participants will be assigned to the group that will receive standard BWL treatment, which may also include added discussion of cooking tips and recipes. The other group will receive BWL treatment in addition to discussing social aspects of obesity, such as societal attitudes and unfair treatment due to weight. All participants will spend 1 hour discussing lifestyle modification topics for weight loss and maintenance,

followed by 30 minutes of discussing the assigned topic (social aspects of obesity or cooking tips). Each meeting will last approximately 90 minutes, and there will be 10-12 participants in the group. Additionally, we will ask all participants to attend four assessment visits, monitor your physical activity with an accelerometer four times during the study, and spend 30-45 minutes completing questionnaires four times.

Where will the study take place?
The study will be conducted at the Center for Weight and Eating Disorders at 3535 Market Street, located at the corner of 36th Street and Market Street in Philadelphia.

Procedures
You will begin the study with an assessment visit (described in more detail below), which will also include completing questionnaires and monitoring your physical activity. For the first 20 weeks of the study, you will be expected to attend weekly group weight loss sessions (of 90 minutes total, with 10 to 12 participants and 60 minutes devoted to BWL treatment), led by registered dietitians (RDs) or behavioral psychologists. After the first 20 weeks, you will complete another assessment visit. You will then be expected to attend monthly weight loss maintenance sessions for six months (weeks 21 through 46), followed by every-other-month sessions for the remaining six months (weeks 47 through 72). You will be asked to complete questionnaires and monitor your physical activity once during the year-long maintenance phase. You will attend a final assessment visit by week 72. Body weight will be measured at all group sessions and assessment visits.

Randomization
At the start of the program, you will be assigned by chance, or randomized, to one of two groups. One group will be a standard BWL group, with added discussions of cooking tips and recipes (for 30 minutes per group meeting). Participants will be introduced to new healthy recipes and will be expected to find and share tips and recipes with other group members.

The second group will be a modified BWL group. This group will also include BWL, with additional discussions (for 30 minutes per group meeting) of societal attitudes about weight and experiences of unfair treatment due to weight. You will also be asked to discuss your own thoughts and feelings about yourself due to your weight. Group sessions will devote time to sharing your experiences, as well as learning new strategies to cope with negative experiences due to weight (described in more detail below).

BWL intervention. All participants will be provided with 20 weekly BWL sessions, based on the Diabetes Prevention Program (DPP) manual, followed by 6 monthly weight loss maintenance sessions and 3 every-other-month sessions (for a total of 29 visits over 72 weeks). A diet of 1200-1499 calories per day will be prescribed for participants < 250 lb, and 1500-1800 for those ≥ 250 lb. Participants will be instructed to eat a balanced deficit diet of protein, fat, and carbohydrates. Session topics during the first 20 weeks will include self-monitoring, emotional eating, social support, challenging negative thoughts, reducing portion sizes, and goal-setting. Sessions during weeks 21-72 will focus on continued self-monitoring and skills required for weight loss maintenance and relapse prevention. BWL sessions will last 60 minutes, with an additional 30 minutes devoted to discussing recipes and food preparation.

Physical activity will be prescribed at a level consistent with data showing that ≥250 min/wk is associated with improved long-term weight loss. Activity will begin at week 2 with 60 min/wk, and will gradually increase in small amounts over time. Participants will be instructed to spread the 150-250 minute doses of activity equally across at least 5 days, and to achieve structured physical activity for ≥10 minutes each time. Moderate intensity will be prescribed, with an emphasis on walking.

Social intervention (modified BWL). Participants in this group will receive the same BWL program described above, which will be combined with an intervention to address social aspects of weight. During the initial 20 weeks, the 60-minute BWL sessions will be followed by 30 minutes devoted to social content. Session topics will be based on those tested previously including: education about weight; challenging myths and negative thoughts related to weight; strategies for coping with negative experiences due to weight; and increasing empowerment and body esteem. The effects of negative weight-related experiences and thoughts on health behaviors will be discussed, and sessions will focus specifically on helping participants overcome social barriers to physical activity. In the monthly and every-other-month weight loss maintenance sessions from weeks 21-72, strategies for coping with negative weight-related experiences and thoughts will be reviewed, and participants will be encouraged to use these strategies specifically with physical activity.

Screening

Behavioral screening visit. Persons who are interested in the study first will attend a behavioral screening visit. You will meet with a psychologist (or other qualified staff member) who will inform you about the study, review this consent form with you, and obtain your written informed consent. The psychologist will assess your behavioral eligibility for the study, including but not limited to evaluating your willingness to participate in the research procedures and the presence of any major psychiatric illness (such as depression, use of psychiatric medications, or thoughts of harming yourself).

Medical screening. Following successful completion of the behavioral assessment, you will be asked to provide a medical history. This medical history will be reviewed by the study physician or nurse practitioner to determine whether you have any conditions for which weight loss or dietary changes would not be recommended. These conditions include but are not limited to: any major active kidney, liver, cardiovascular, or cerebrovascular disease; type 2 diabetes; or the use of any medications that significantly affect weight (weight loss or weight gain, including steroids). You will be referred to seek medical attention if the tests (described below) reveal any health concerns that require attention. You will be ineligible for the study if you are pregnant or nursing.

In order to participate in this study, you will be asked to have a primary care provider (PCP) who is responsible for providing routine medical care. If you have a history of coronary heart disease or other cardiovascular disease risk factors, you may be asked to provide a letter from your PCP giving medical clearance for you to participate in this study.

Outcome Assessment Visits

Regardless of which group you are assigned to, you will be asked to attend 4 outcome assessment visits, which will occur at baseline (prior to starting the program), at week 20

(following the initial weight loss phase of the program), at week 46 (halfway through the maintenance phase), and at week 72 (after completion of the program).

Blood tests, blood pressure, pulse, and waist measurement. You will undergo fasting blood tests at screening, week 20, and week 72. Tests will include a comprehensive metabolic panel (CMP), lipid panel, insulin, high sensitivity C-reactive protein (hs-CRP), and hemoglobin A_{1c} (a long-term measure of your blood glucose). These tests will require approximately 34 mls of blood. Blood pressure, pulse, and waist measurement will also be measured at all three outcome assessment visits.

Body weight. Body weight will be measured at all group sessions, as well as the 4 outcome assessment visits. Body weight measurements will be used to test the effects of modified BWL program on weight loss.

Physical Activity. You will be provided with an accelerometer to monitor your physical activity at 4 times during the study: at baseline, at week 20, at week 46, and at week 72. An accelerometer is a small device that is worn (e.g., on your wrist) to measure the amount and intensity of your physical activity. You will be expected to wear your device consistently for one week in order to measure your engagement in physical activity. For your baseline assessment, you will be required to come in to our Center twice, to pick up and return your accelerometer. Upon return, you will also be interviewed by a staff member to assess your physical activity over the previous week. At weeks 20, 46, and 72, your accelerometer will be distributed during group sessions, and you will be required to attend an assessment visit to return your device and report your physical activity over the previous week. You are accountable for the accelerometer and may be held financially responsible if the device is lost, stolen, or not returned.

Questionnaires. You will be asked to complete several questionnaires at 4 times during the study: at baseline and weeks 20, 46, and 72. These questionnaires are designed to assess your negative experiences and thoughts and feelings related to weight, along with your mood, quality of life, eating behavior, and physical activity. You will have the opportunity to examine the questionnaires before you complete them.

Summary of outcome assessments

	Screening/Baseline	Week 20	Week 46	Week 72
Blood draw	x	x		x
Blood pressure, pulse, waist circumference	x	x		x
Physical activity monitoring	x	x	x	x
Questionnaires	x	x	x	x
Weight measured	x	x	x	x

Questionnaires will be completed online or sent/returned by mail or during scheduled group sessions. Accelerometers will be sent/returned in person or at group sessions.

What are the risks?

Risk of gallstones. Rapid weight loss may increase the risk of gallstones. Symptoms of gallstones include abdominal pain, nausea, vomiting, fever, and chills. The risk of gallbladder disease will be reduced by limiting weight loss to no more than 3 pounds per week for 4 consecutive weeks. Weight loss will be monitored at all group sessions. Patients will be asked to slow or stop their weight loss if there are concerns about the rate of their weight loss.

Blood draw. Risks of drawing blood include pain, bruising at the puncture site, swelling, feeling faint or lightheaded, and rarely infection.

Psychological distress. Discussing weight-related criticism or negative thoughts and feelings due to weight may be upsetting. You may also become upset by something another group member says. Measures will be taken to promote an atmosphere of support, respect, and confidentiality within the group. If you become concerned or distressed, you may discuss your concerns with your group leader or the Principal Investigator.

Loss of confidentiality risk. Because information about your identity is collected and stored for research purposes, there is a chance that the information could be viewed by others not associated with the research team and therefore, there is a potential for loss of confidentiality. We will, however, make every effort to keep your personal information confidential.

Ongoing medical and safety measures. A physician/nurse practitioner will be available if you notice any changes in your health during the program that you believe may be associated with weight loss. Participants who report significant symptoms of depression or other mental health symptoms will be evaluated by the study's psychologist or psychiatrist and referred to their PCP for further evaluation and treatment. Participants will be referred to their PCP if their mood is significantly disrupting their normal function (as reflected by symptoms that include feeling blue, not enjoying usual activities, trouble sleeping or concentrating, or having thoughts of dying or harming oneself).

How will I benefit from the study?

This study may benefit society at large by providing information about the benefits of discussing social aspects of weight, combined with BWL treatment, in helping people achieve long-term weight loss. In addition, your participation may benefit you in several ways. First, based on the results of previous studies, participants tend to lose, on average, 5-10% of their initial weight during the 20-week group weight loss program. Weight losses of this size are associated with improvements in medical conditions made worse by excess weight, including type 2 diabetes, high blood pressure, and high cholesterol. Second, all participants will receive a 52-week behavioral weight loss maintenance program, which has been shown to improve the maintenance of weight loss as compared with no further treatment. The addition of discussing social aspects of obesity and weight to this program may or may not further improve the maintenance of lost weight as compared with the program alone. Third, you will undergo repeated assessment and monitoring of several health factors, including blood pressure, cholesterol, and blood sugar. The results of these assessments will be made available to you and your health care providers. Finally, by participating in this study, you may learn

more about your own and others' weight-related experiences. You may also improve your thoughts and feelings about yourself and your weight. Additionally, your participation could help psychologists understand how to help other people cope with negative experiences and thoughts and feelings due to weight. Despite all of these possible benefits, you cannot be guaranteed weight loss or any medical or psychological benefit from participating in this study.

What other choices do I have?
Your alternative to being in the study is to not participate. Our staff can recommend other programs for weight control in the community. We can also recommend other programs for psychological issues related to weight.

What happens if I do not choose to join the research study?
You may choose to join the study or you may choose not to join the study. Deciding not to join will not affect any care you might receive at Penn Medicine. Your participation is voluntary.

When is the study over? Can I leave the study before it ends?
The study is expected to end after all participants have completed all visits, and all information has been collected. The study may be stopped without your consent for the following reasons:

- The Principal Investigator or your physician feel it is necessary for your health or safety. You will be informed if such a decision is made and the reasons for the decision.
- You have not followed study instructions.
- The Principal Investigator or the Office of Regulatory Affairs at the University of Pennsylvania has decided to stop the study.

Your participation in this study is voluntary. You may withdraw from the study at any time without penalty or loss of any benefits to which you are otherwise entitled. Withdrawal will not affect your future care at the University of Pennsylvania Health System. If you wish to withdraw, you should contact the Principal Investigator listed on page 1 of this form.

Will information about this study be available to the public?
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

What information about me may be collected, used or shared with others?
The following personal health information will be collected, used for research, and may be disclosed during your involvement with this study:

- Name, address, telephone number, and date of birth
- Social security number
- Personal and family medical history
- Electronic mail address
- Medical record number
- Current and past medications or therapies

- Information from a physical examination that generally also includes blood pressure reading, heart rate, weight, height, and waist measurements
- Results of tests and procedures you will undergo during this research study as described in the informed consent form

Why is my information being used?
Your personal health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care.

Your information is used by the research team to contact you during the study. Your social security number is used to process any reimbursement payments. Your information and results of tests and procedures are used to:

- Conduct the research
- Oversee the research
- Determine if the research was executed properly

How will confidentiality be maintained and my privacy be protected?
Personal information is anything that can be used to identify who you are. Examples include your name, address, telephone number, medical record number, social security number, or electronic mail address. We will do our best to make sure that the personal information obtained during the course of this research study will be kept confidential. Privacy will be protected by conducting group sessions in private rooms with only study staff and group members present. Assessment visits will also be conducted in private rooms. However, we cannot guarantee total confidentiality or privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What may happen to my information and samples collected in this study?

Collection of Identifiable Specimens
Your blood samples will be discarded after processing. Your blood samples will not be used to create any products. Whole genome sequencing will not be conducted on your samples. (Whole genome sequencing involves analyzing your entire personal genetic code.)

Future Use of Data and/or Specimens
Your blood samples will not be stored or shared for the purpose of future research studies. Your information and data could be stored and shared for future research. Data will be de-identified if stored or shared for use in future research. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected in this study.

Who may use and share information about me?
The following individuals and organizations may use or disclose your personal health information for this research study:

- The Principal Investigator and the research team associated with the study
- The University of Pennsylvania Institutional Review Board (the committee responsible for overseeing research on human participants) and the University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.)

Who, outside of the School of Medicine, might receive my information?

- Those working under the direction of the investigator for the study, (e.g. under subcontracts).
- All research centers participating in the study, even if they are not part of the School of Medicine
- The funding sponsor and organizations supporting the sponsor

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.
The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
You may withdraw your permission to use and disclose your health information at any time. You do this by sending written notice to the Principal Investigator of the study. Even if you withdraw your permission, the Principal Investigator may still use your personal information that was collected prior to your written withdrawal request. If you withdraw your permission to use your personal health information, you will not be able to remain in the study.

What if I decide not to give permission to use and give out my health information?
You will not be able to participate in this study if you do not give permission to use your personal health information.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes, as described above.

Will I receive the results of research testing?
Weight measurements will be shared with you regularly. Results from other measurements, such as height, blood pressure, and waist circumference, will be shared upon request. Research results from fasting blood tests at screening, week 20, and week 72 will be disclosed to you. We will not provide any results to your primary healthcare provider without a signed HIPAA release form.

What happens if I am injured from being in the study?
The University of Pennsylvania will offer you the care needed to treat injuries directly resulting from taking part in this research study. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of the costs.

If you have an illness or injury during this study that is not directly related to your participation in the study, you and/or your insurance company will be responsible for the cost of the medical care of that illness or injury.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for an injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, you should contact the Principal Investigator listed on page 1 of this form.

Will I have to pay for anything?
There is no cost or financial risk for participating in this study. All study devices, assessment measures, and BWL counseling will be provided at no cost. However, you will be responsible for purchasing all food and covering your costs of transportation.

Will I be paid for being in this study?
You will receive, at no cost, a version of the weight loss and maintenance interventions that our Center offers to the public at a cost of over $1000. You will be compensated $25 for each of the 3 assessment outcome visits you complete during the course of the study (excluding baseline assessments). Payment will come in the form of a Greenphire ClinCard (a debit card), paid after each visit. You will only receive payment for the visits you complete.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member

of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

You will receive a copy of this consent document.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date