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

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

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1. STUDY OBJECTIVE

To evaluate, in a 72-week randomized controlled trial, the efficacy of a psychological intervention to reduce weight bias internalization (WBI) on enhancing long-term weight loss.

2. BACKGROUND

2.1 The Problem of Obesity

Obesity, defined by a BMI ≥ 30 kg/m² (or ≥ 27 kg/m² with a weight-related comorbidity), is the most common nutritional disease in the United States, affecting about 36% of adults age 20 years and over. An additional 33% of American adults are overweight, as judged by a BMI of 25.0-29.9 kg/m². Obesity is associated with a number of co-morbidities including type 2 diabetes (70% of people with type 2 diabetes have obesity) and cardiovascular disease. Losing as little as 5% of initial weight improves co-morbid conditions including insulin resistance, dyslipidemia, and hypertension.

A program of diet, physical activity and behavioral therapy is the first line treatment for obesity. This approach produces significant weight loss (≥5%) but is often followed by weight gain. Patients regain about 35% of their initial weight loss in the first year and 50% or more have returned to their baseline weight by 5 yr. It is therefore, highly desirable to identify effective interventions, which would improve long-term maintenance of prior weight loss.

2.2 Benefits of Weight loss

A 5–10% reduction in body weight in obese individuals improves several risk factors for cardiovascular disease (CVD) including blood pressure, triglyceride levels, low-density-lipoprotein cholesterol, blood glucose, and sleep apnea.[1-3] The Diabetes Prevention Program (DPP) revealed that a 7% reduction in initial weight, combined with 150 minutes of activity, reduced the risk of developing type 2 diabetes by 58%, compared with placebo, in at-risk overweight/obese individuals at an average of 2.8 years follow-up.[4] Losses ≥10% are associated with greater improvements in CVD risk factors[5] and are more consistent with obese individuals' desired weight loss goals. [6]

2.3 Current Status of Behavioral Weight Loss Treatment for Obesity

Behavioral weight loss (BWL) treatment is the cornerstone of treatment for most obese individuals, as recommended by the NHLBI's Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.[7] In trials conducted in academic medical centers, persons treated by a 1200-1500 kcal/d diet, combined with regular exercise and a comprehensive program of group or individual BWL, lose approximately 7-10% of initial weight in 20-26 weeks.[4,8,9]

2.4. Role of Physical Activity in Facilitating Long-Term Weight Loss

Physical activity is the most reliable predictor of long-term weight loss.[9,10] Studies consistently show that participants are more likely to achieve and maintain significant long-term weight loss (e.g., ≥10%) when they engage in high levels (e.g., ≥ 200-250 minutes per week) of physical activity.[10-15] For example, in secondary analyses of a randomized controlled trial evaluating the effects of different doses of exercise on weight loss, Jakicic et al showed that participants who reported exercising ≥ 200 min/wk had significantly greater weight loss at month 12 (by 6.3 kg) than participants who exercised <150 min/wk.[13] Another study found that participants who maintained a 10% weight loss 24 months after treatment reported engaging in an average of 275 min/wk of physical activity.[12] These observational data are supported by findings from some but not all randomized trials.[12,16]

One pathway to increasing physical activity is by boosting exercise self-efficacy. Self-efficacy – which refers to individuals' confidence in their ability to engage in goal-directed behavior – robustly predicts initiation and maintenance of health behavior change,[17] including weight-loss behaviors such as adherence to diet and physical activity recommendations.[18-20] Greater weight-related self-efficacy is associated with greater short- and long-term weight loss[20-24] and, in comparison to dietary self-efficacy, self-efficacy to exercise is a stronger predictor of weight loss.[25] Self-efficacy may naturally decrease during long-term weight-loss maintenance.[23] A recent study found that an intervention designed to increase self-efficacy (combined with standard BWL) resulted in significantly less weight regain from months 12 to 18 of follow-up than BWL alone.[26]

2.5 Weight Stigma as a Barrier to Weight Loss

2.5.1. Weight stigma is pervasive.

The term *weight stigma* refers to societal scorn and devaluation of individuals with overweight and obesity.[27] This includes discrimination (e.g., being denied employment), bullying/teasing, social exclusion and avoidance (e.g., rejection from peers), and other forms of unfair treatment due to excess weight. Common stereotypes and prejudicial (or *weight-biased*) beliefs include perceptions that persons with obesity are lazy, incompetent, weak, and lacking willpower.[11] These beliefs lead individuals with obesity to be mistreated across multiple settings in their daily lives, including: disparagement in educational settings from students and educators;

discrimination in hiring, firing, and promotions; social avoidance (e.g., on public transportation); criticism from family members, spouses, and friends; and negative representation in media.[28-32]

The high rates of obesity and overweight in the US population are accompanied by high rates of weight-based stigmatization. Estimates indicate that rates of weight-based discrimination have increased by 66% from 1995 to 2006 and, among women, are comparable to rates of discrimination based on race and age.[33,34] Due to the pervasiveness of weight bias in daily life, some individuals may internalize stigmatizing attitudes; this occurrence is referred to as weight bias internalization (WBI), or self-directed stigma.[35] Internalizing stigma involves: 1) awareness of and agreement with stereotypes; 2) applying of those stereotypes to oneself; and 3) devaluing oneself due to the stigmatized trait (i.e., weight).[36] For example, someone who is unable to successfully maintain weight loss may attribute weight regain to laziness and weakness, and have lower self-esteem due to assigning these stereotypical characteristics to oneself.

2.5.2. Weight stigma impedes weight control.

Individuals with obesity who experience and internalize weight stigma may benefit from weight loss to improve their health, yet may face stigma-specific barriers to weight loss. In two longitudinal studies, individuals who reported experiencing weight discrimination at baseline were three times more likely to remain obese[37] and gained 1.7 more kg than individuals who did not report weight discrimination.[38] Recent studies have also illustrated that patients who have experienced and/or internalized weight stigma, in comparison to those who have not, have poorer long-term weight loss outcomes with both behavioral and surgical weight loss interventions.[39-42] For example, in a study of 49 adults with BMI $\geq$ 27 kg/m^2 who received behavioral weight loss (BWL) treatment, higher frequency of receiving weight-stigmatizing comments from others was associated with less weight loss and less physical activity.[39] In another study, participants who consciously or unconsciously endorsed negative weight stereotypes (one aspect of WBI) also lost less weight and reported less physical activity.[46] Proposed pathways for these effects include a combination of physiological stress responses that increase inflammation and appetite, and maladaptive behavioral coping responses such as increased caloric intake and avoidance of physical activity.[34]

Acute and long-term studies have shown that weight stigma (particularly WBI) is associated with reduced self-efficacy for dietary control,[43] with increased caloric consumption (particularly of unhealthy foods),[43-45] and with worse dietary adherence following bariatric surgery.[46] In addition, individuals who experience weight stigma feel more self-conscious in fitness settings and are more prone to anticipating future stigmatization in these settings, thus increasing avoidance of physical activity.[47-49] In prior work, my colleagues and I have also shown associations between WBI and reduced self-efficacy to engage in physical activity, along with reduced exercise motivation and engagement.[50] In other words, if individuals with obesity believe that they are lazy and lack willpower (internalized stereotypes), they lose confidence in their ability to follow through on their physical activity goals and are, thus, less likely to engage in their planned physical activity.[50,51]

2.5.3. Addressing weight stigma in weight loss interventions

Weight stigma-specific barriers are not addressed in current weight loss programs. As stated above, cognitive-behavioral treatments for weight loss produce clinically meaningful losses in the short-term,[52] which reduce cardiometabolic risk.[53-55] However, these losses are not maintained, on average, in the long-term,[52,56] highlighting the need to develop novel treatments to sustain weight loss. Adherence to high levels of physical activity predicts long-term weight loss.[57] Given the evidence reviewed that individuals who have experienced and/or internalized weight stigma have reduced self-efficacy for and engagement in physical activity, an intervention targeting weight stigma may improve long-term weight loss.

An intervention that combines traditional BWL with a program to reduce WBI could produce clinically meaningful short- and long-term weight losses, as well as reductions in self-stigmatization. The intervention to reduce WBI is expected to increase long-term exercise self-efficacy and adherence, thus, facilitating long-term weight loss. An intervention that incorporates elements from both approaches could provide patients with multifaceted health benefits.

3. SPECIFIC AIMS

Aim 1. To test, in a randomized controlled trial, the effects of a novel 29-session cognitive-behavioral weight stigma intervention, combined with BWL (in comparison to standard BWL alone), in producing long-term weight loss (at week 72) in a total of 104 individuals with obesity who have experienced weight stigma.

H1: Patients who receive the stigma + BWL intervention will achieve significantly greater weight loss at week 72 than patients assigned to standard BWL (9% and 5% of initial weight, respectively).

Aim 2. To assess whether the stigma + BWL intervention significantly increases physical activity and self-efficacy (as compared with BWL alone).

H2: Patients who receive the stigma + BWL intervention will achieve significantly greater levels of physical activity and exercise self-efficacy at weeks 20, 46, and 72 than patients assigned to standard BWL.

Secondary Aims

3. To compare changes in cardiometabolic risk factors (e.g., metabolic syndrome) in patients assigned to the stigma + BWL intervention versus BWL alone.

H3: Patients who receive the stigma + BWL intervention will achieve significantly greater reductions in cardiometabolic risk at week 72 than patients assigned to standard BWL.

4. To evaluate changes in psychological distress (e.g., WBI) in the stigma + BWL intervention compared to BWL alone.

H4: Participants who receive the stigma + BWL intervention will have greater reductions in WBI and psychological distress at weeks 20, 46, and 72 than participants receiving BWL alone.

5. To compare short-term weight change in patients assigned to the stigma + BWL intervention versus BWL alone.

H5: Participants who receive the stigma + BWL intervention will achieve significantly greater weight loss than patients assigned to standard BWL at weeks 20 and 46.

4. STUDY DESIGN

4.1 General Design

This is a randomized controlled trial to test the effects on long-term weight loss of a novel stigma-reduction intervention combined with standard BWL treatment, as compared to BWL alone. Participants will be a total of 104 men and women seeking weight loss, ages 18years and older, with a body mass index (BMI) of 30 kg/m^2 or above (or 27 kg/m^2 or above with an obesity-related comorbidity), a history of experiencing weight bias, and elevated levels of WBI. Participants will attend a screening visit in which they will complete a behavioral evaluation with a psychologist and a medical history that will be reviewed by a nurse practitioner or physician. Questionnaires assessing experiences and internalization of weight bias, with confirmation by interviewer assessment during the behavioral evaluation, will be used to determine whether participants meet criteria for having high levels of WBI. Eligible consenting participants will be randomly assigned to the standard BWL intervention (n = 52) or the stigma + BWL intervention (n = 52). All participants will attend weekly, 90-minute group meetings for 20 weeks (20 visits). In the stigma + BWL treatment group, beginning at week 5, 60 minutes will be devoted to BWL and 30 minutes to weight stigma. In the standard BWL treatment group, the additional 30 minutes will be devoted to sharing recipes and food preparation tips. Following 20 weeks of weight loss treatment, participants will attend group meetings focused on weight loss maintenance, monthly from weeks 21-46 (6 visits), and every-other-month from weeks 47-72 (3 visits). Maintenance sessions in the stigma + BWL group will continue to incorporate discussion of WBI and stigma-related barriers to physical activity. Assessments – which include questionnaires, blood draws, and measurements of body weight and physical activity – will occur at baseline and weeks 20, 46 (no blood draw this week), and 72. Weight will be measured at every group meeting for clinical purposes.

Other Therapy:

Participants will be expected to use medications (prescribed by their primary care providers) to control traditional cardiometabolic risk factors (e.g., hypertension, hypercholesterolemia, etc) and other co-morbid conditions. Subjects will be asked at the study's outset to keep medication dose constant throughout the study, whenever possible. Participants will be expected to have been on their medication regimen (including the dose) for 3 months prior to entering the dietary group lifestyle modification program.

5. SUBJECT SELECTION

5.1 Subject Recruitment

Participants will be recruited from advertisements in local media outlets (newspapers, radio, television, social media), as well as flyers and public transportation in the surrounding area. Online and print media outlets at the University (such as newsletters) will also be used to advertise the study. We also will advertise the study to health care providers who work in Penn's Clinical Care Associate practices, with whom we have collaborated previously.[58]

5.2 Inclusion/Exclusion Criteria

Key Inclusion Criteria

Eligible participants will be men and women ages 18 years and older. Participants must have obesity, defined as a BMI $\geq$ 30 kg/m^2 or $\geq$ 27 kg/m^2 with an obesity-related comorbidity. Obesity-related comorbidities (which confer added CVD risk) will include: coronary heart disease; other atherosclerotic disease; sleep apnea; hypercholesteremia (i.e., high cholesterol, as diagnosed by doctor and/or if taking medication to lower cholesterol); and components of the metabolic syndrome, including hypertension (SBP $\geq$130, DBP $\geq$80 mm Hg, diagnosed by doctor and/or if taking anti-hypertensive medication); fasting blood glucose of 100-125 mg/dL (or prediabetes, diagnosed by doctor); low HDL cholesterol (<40 mg/dL in men, <50 mg/dL in women), elevated triglycerides (>150 mg/dL, i.e., dyslipidemia diagnosed by doctor or taking medication to treat dyslipidemia), or elevated waist circumference ($\geq$40 in for men, $\geq$35 in for women). Eligible participants must also report a history of experiencing weight bias as assessed by self-report questionnaire and in-person interview, and have elevated levels of WBI as indicated by an average score of 4 (midpoint) or above on the Weight Bias Internalization Scale (WBIS) and by in-person interview. Participants must be seeking weight loss. If currently taking medications, dosages must be stable for at least 3 months. Participants will be eligible to participate if they exhibit mild to moderate severity of depression, anxiety, or binge eating disorder, as determined by the behavioral evaluation and the screening measures (Beck Depression Inventory-II and Questionnaire for Eating and Weight Patterns; see below for details). Elevated WBIS scores are often associated with these variables.[19] Participants taking anti-depressant medication will be eligible if their dose has been stable for a minimum of 3 months.

Eligible female patients will be:

- non-pregnant and non-lactating
- surgically sterile or postmenopausal, or they will agree to continue to use a method of birth control during the study

Participants must:

- have a PCP who is responsible for providing routine care
- have reliable telephone service and/or email access with which to be in contact with the study team
- understand and be willing to comply with all study-related procedures and agree to participate in the study by giving written informed consent

Key Exclusion Criteria:

Applicants will be excluded if they have: a diagnosis of type I or II diabetes (for type II diabetes, blood glucose ≥126 mg/dL or A1C ≥6.5); uncontrolled hypertension (blood pressure ≥ 160/100 mm Hg); experienced a cardiovascular event (e.g., stroke, myocardial infarction) in the last 12 months; lost and maintained ≥ 5% of their initial weight in the last 3 months or ≥ 10% in the past 2 years; or have participated in individual or group psychotherapy related to weight in the last 3 months (due to the potentially confounding effects of receiving a simultaneous cognitive-behavioral intervention). Participants who have recently received or are currently receiving therapy for a pre-existing mental health issue unrelated to weight (e.g., psychotherapy for depression or anxiety, or marriage, grief, or career counseling) may be eligible if the therapy is deemed by the Principal Investigator to be unlikely to affect weight, eating habits, or physical activity. Applicants with *severe* symptoms of mood (BDI-II score ≥ 29), anxiety, or binge eating disorder, and any severity of thought or substance use disorders will not be accepted into the study, as these symptoms may interfere with individuals' ability to adhere to a weight loss program. Clinician judgment will be used to determine severity of mood disorder symptoms independent from obesity-related concerns and complications (e.g., fatigue), and decisions about applicants' eligibility based on psychiatric symptoms will fall within the Principal Investigator's discretion. Individuals with bulimia nervosa will not be eligible to participate, because weight loss may be contraindicated. Applicants with current, active suicidal ideation, and/or a suicide attempt within the past year will be excluded from the study and referred to psychiatric treatment facilities in the greater Philadelphia area. Applicants will not be eligible if they have a history of bariatric surgery. Women who are nursing, pregnant, or planning to become pregnant in the next 16 months are not eligible to participate. Applicants who report obtaining 150 minutes or more of structured physical activity per week (e.g., 30 minutes 5 days per week) will not be eligible, as they will already be obtaining the recommended amount of physical activity and may not be able to further increase their activity as part of the study.

6. STUDY PROCEDURES

6.1 Screening Procedures

All applicants will be screened by phone to determine whether they potentially meet eligibility criteria. We will obtain a waiver of written documentation of consent for the telephone screen. Those who remain interested in the trial will be scheduled for an in-person interview. The Weight and Lifestyle Inventory (WALI), an assessment of general eating and lifestyle behaviors, the Weight Bias Internalization Scale (WBIS), and the Beck Depression Inventory (BDI) will be mailed or emailed to eligible participants following the phone screen and completed by them prior to their screening/informed consent visit. The in-person interview will be conducted by a psychologist, who will obtain informed consent and evaluate participants' behavioral eligibility (i.e., willingness and appropriateness to participate). This will include our assessment of the applicant's mood (as measured by interview and the BDI) and suicidality (including history of suicidal ideation and behavior). Applicants who report active suicidal intent will be escorted to the emergency room at the Hospital of the University of Pennsylvania. (If applicants report suicidal intent while being screened by phone, they will be instructed to report to their nearest emergency room and/or to call the suicide hotline, for which the phone number will be provided

during the call. If applicants reporting suicidal intent by phone refuse to seek immediate help, a wellness check may be requested from the local police department.)

Applicants who remain interested and pass the behavioral assessment will proceed to provide a medical history, which will be reviewed by the study physician or nurse practitioner to determine medical eligibility. Medical eligibility will be confirmed with blood test results. Applicants with a history of cardiac events or other significant CVD risk factors may also be asked to provide written verification from their primary care physician stating that they are healthy enough to participate in a weight loss program.

Following completion of the screening visit, applicants will be required to complete food records for one week. Applicants will be provided with booklets or assisted in downloading a free mobile app to monitor their food intake over the course of the week. Applicants must return their completed food records (via mail or email) before being provisionally accepted into the study. Participants will be officially accepted into the study and randomized during a subsequent randomization visit that will occur within one month of beginning the study intervention.

6.2 Study Visits

Screening visit. The following procedures will be completed at the screening visit as discussed above: informed consent, medical history, weight, height, and meeting with psychologist whose assessment will be used as a part of determining the subject's eligibility for the study. This medical history will be reviewed by the study physician or nurse practitioner to determine whether there are any contraindications to weight loss. These contraindications 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). Female participants will be ineligible for the study if they are pregnant or nursing. Applicants with a history of cardiac events or other significant CVD risk factors may also be asked to supply a letter from their primary care physician providing medical clearance for them to participate in this study. Applicants will be required to monitor their food intake following the screening visit and return their food records before being provisionally accepted into the study.

Randomization visit. Within one month of the start of the group intervention, participants will attend a visit in which their weight and blood pressure will be measured and, if they still meet all study criteria, they will be randomized to their treatment group. Accelerometers will be given to participants to monitor their activity for 7-10 days. Participants will return their accelerometers in person, at which time their activity for the past week will be assessed with a structured interview. Participants may be held financially responsible if the accelerometer is lost, stolen, or not returned.

If a participant is randomized but no longer able to attend groups as scheduled, it may be available to them to begin the group intervention, in the same treatment condition as assigned at randomization, in a subsequent cohort. In this case, baseline measurements will be repeated within one month of the start of treatment.

BWL intervention. Participants in this group will be provided with 20 weekly BWL sessions, based on the Diabetes Prevention Program (DPP) manual,[59] 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.[59,60] Participants will be instructed to eat a balanced deficit diet with approximately 15-20% of kcal from protein, 20-35% from fat (less than 10% from saturated fat), and the remainder from carbohydrates.[59] Session topics during the first 20 weeks will include self-monitoring, stimulus control, slowing eating, social support, cognitive restructuring, portion sizes, and goal-setting.[59] Those during weeks 21-72 will focus on continued self-monitoring and skills required for weight loss maintenance and relapse prevention. BWL sessions will last 90 minutes. Beginning at week 5, 60 minutes of the group session will be devoted to BWL content, 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.[12-14,61] Activity will begin at week 2 with 60 min/wk, and will gradually progress by 10 minutes over 2-4 week intervals until achieving 150 min/wk by week 20, 200 min/wk by week 46, and 250 min/wk by week 72. Participants will be instructed to spread the 150-250 minute doses of activity equally across at least 5 days, and to accumulate their structured physical activity in bouts that are ≥10 minutes in duration. Moderate intensity will be prescribed with an emphasis on walking; the vast majority of our research participants self-select this form of activity.

Participants who cannot attend any given group session will be offered a brief (10-20 minute) make-up session (in person or by phone) during the week with the group leader or a study staff member. Participants may also meet briefly with the group leader individually, outside of group sessions, up to 3 times during the initial 20-week study period if they have not lost at least 1% of their body weight by week 4, report difficulty controlling their eating, or describe other challenges preventing them from adhering to the program that cannot be fully covered during group sessions.

Stigma + BWL intervention. Participants in this group will receive the same BWL program described above, which will be combined with a stigma-reduction intervention. Beginning at week 5, the 60-minute BWL sessions will be followed by 30 minutes devoted to stigma-related content. Session topics will be based on those tested in a previous pilot study, including: psychoeducation about weight and weight stigma; challenging myths and cognitive distortions related to weight; strategies for coping with instances of stigma; and increasing empowerment and body esteem. The effects of weight stigma on health behaviors will be discussed, and sessions will focus specifically on helping participants overcome stigma-related barriers to physical activity. For example, they will be given strategies to cope with anticipated stigma while exercising in public spaces (e.g., while walking), as well as to challenge self-critical beliefs (e.g., that they are lazy) which may otherwise lead them to avoid exercising. These concrete strategies, along with reducing WBI and improving self-confidence, are intended to increase participants' self-efficacy for and engagement in physical activity. In the monthly and every-other-month weight loss maintenance sessions from weeks 21-72, strategies for coping with weight stigma and challenging internalized beliefs will be reviewed, and participants will be encouraged to use these strategies specifically with physical activity.

As with the BWL Intervention, participants who cannot attend group sessions or are experiencing difficulties adhering to the program will be eligible for brief individual meetings with the group leader or study staff (as described above).

Adjustments to treatment sessions due to COVID-19. During the pandemic, all group sessions will be conducted virtually on the platform BlueJeans. Group members who do not have access to video technology will be invited to join the meeting by phone. Makeup sessions will continue to be offered by phone. Treatment session handouts will be sent to participants by email. Since weight will no longer be measured in person at group meetings, all participants will be sent an EatSmart Precision Digital Scale. Prior to group meetings, participants will be asked to email the study coordinator their weight. This will allow the group leader and study team to continue to monitor participant weight loss for clinical purposes.

Outcome assessment visits

Participants will be expected to attend 4 assessment visits throughout the course of the study: at baseline, week 20, week 46, and week 72 (or within 4 weeks of each assessment period). Three of these assessment visits (baseline, week 20, and week 72) will include a fasting blood test, which will include a comprehensive metabolic panel (CMP), lipid panel, insulin, high sensitivity C-reactive protein (hs-CRP), and hemoglobin A_{1c}. These tests will require approximately 34 mls of blood. Blood pressure, pulse, and waist measurement will also be measured at these outcome assessment visits, and weight will be measured at all assessment visits.

Participants will also be asked to monitor their physical activity and complete questionnaires at baseline, week 20, week 46, and week 72. Questionnaires will be completed online or administered/returned via mail or at scheduled group sessions. Accelerometers will be administered at scheduled group sessions or assessment visits and returned in person or by mail, with an accompanying brief interview to assess activity over the past week (in person or by phone).

Adjustments to outcome assessment visits due to COVID-19. During the pandemic, in-person assessment visits will be replaced with remote assessments whenever possible. Specifically, all week 46 assessment visits will be conducted remotely for the duration of the pandemic. If permitted by the city, institution, and funding sponsor, week 20 and week 72 assessment visits will be offered in-person, in order to allow for the measurement of blood pressure and a fasting blood test. All local and institutional safety regulations will be followed when conducting in-person visits. Participants with safety concerns or other barriers that prevent them from attending in-person assessment visits will be offered remote assessments without penalty.

Remote assessment visits will be scheduled during the morning and will involve a brief phone call with the study coordinator, measurement of weight (and for weeks 20 and 72, measurement of waist circumference), monitoring of activity with an accelerometer device, and completion of online questionnaires. As described above, all participants will be sent an EatSmart Precision Digital Scale (with a tape measure included in the package). For remote assessments, participants will be asked to use the EatSmart scale to weigh themselves in duplicate, in kilograms, in the morning before eating anything. Participants will be asked to send

their weights to the study coordinator; when possible, they will be asked to take pictures of their weight with their phone, and then weigh their phone and send all information/pictures to the coordinator. For weeks 20 and 72 assessments, participants will also be provided with instructions to measure their waist circumference in duplicate with the EatSmart tape measure and will send their measurements to the study coordinator by email. For all remote assessments, accelerometer devices will be delivered to each participant's home, and participants will be asked to begin to wear the device on the morning of their scheduled remote assessment. Participants will also be asked to complete their online questionnaires by the morning of their remote assessment. The study coordinator will have a brief phone call with each participant on the morning of their remote assessment to confirm that the weight/waist measurements have been received, the participant is wearing the accelerometer, and all questionnaires are completed. The coordinator will also conduct a brief assessment by phone of any changes in the participant's health and medications since the last study visit, and the study nurse practitioner will follow up with participants about these changes as needed. Participants who complete either in-person or remote assessments will be able to return their accelerometers by mail using a prepaid shipping label. The study coordinator will schedule an additional phone call to instruct participants when to return the device and to conduct a brief interview assessing their physical activity over the past week.

6.3 Outcome Measures

Primary outcome. Percent weight loss from baseline to week 72 is the study's primary outcome. At week 72, participants in the stigma + BWL intervention are predicted to maintain their 9% reduction in initial weight, as compared to a significantly smaller 5% reduction in the BWL alone group. Duplicate measures of height (with a wall-mounted stadiometer; Veeder-Root, Elizabethtown, NC) will be obtained at screening, and weight (with a digital scale; Detecto, model 6800A) will be measured at screening, randomization (baseline), and at weeks 20, 46, and 72. Weight will also be measured at all group sessions. Percent weight loss from baseline to weeks 20 and week 46 will be assessed as secondary outcomes, along with categorical weight loss at weeks 72, 46, and 20 (loss of ≥5% and ≥10% of initial body weight at each time point). Participants in the BWL group are predicted to lose 8% of their initial weight at week 20. Participants in the stigma + BWL group are expected to lose 1% more of their initial weight (9%) at week 20 due to greater engagement in physical activity.

Secondary outcomes.

Physical activity. All participants will be given triaxial accelerometers (ActiGraph GT9X) to wear on their wrist for a 1-week period within 4 weeks of each assessment period (baseline and weeks 20, 46, and 72). Accelerometry has been used in numerous clinical trials,[62-65] and the ActiGraph to be used in this study was adopted in the 5-year extension of the Look AHEAD study. Established activity counts will be used to identify thresholds of physical activity (sedentary, light, moderate, vigorous).[66] Self-reported physical activity will be assessed with the Paffenbarger Physical Activity Questionnaire[67] to obtain specific information on the types of activity participants engage in, and a brief questionnaire used in prior studies[68] to collect data on sedentary behavior. Self-efficacy will be assessed with the Self-Efficacy for Exercise Scale[69] Exercise Outcome Expectations and Barriers Scale (perceived barrier items only),[70] and Weight and

Lifestyle Efficacy (WEL),[71] which measure individuals' confidence in their ability to overcome barriers to exercising and controlling their weight. Greater physical activity by objective and self-report assessment is expected in the stigma + BWL intervention vs. BWL alone group at weeks 20, 46, and 72. Based on prior research,[13] we predict that participants in the stigma + BWL group will engage in approximately 250 min/wk of physical activity at week 72, as compared to approximately 150 min/wk in the BWL alone group, thus contributing to the 4% difference in weight loss at week 72.

Cardiometabolic risk. Blood pressure, waist circumference, and blood samples (measures: triglycerides, cholesterol, and glucose) will be obtained at screening and weeks 20 and 72 to assess changes in cardiometabolic risk factors, particularly in the components and diagnosis of metabolic syndrome. Blood pressure also will be assessed at randomization. Blood pressure will be measured using an automated Dinamap monitor (Johnson & Johnson, XL model 9300) at three, 1-minute intervals after ≥ 5 minute rest, using measures described previously.[72] Waist circumference will be measured (to the nearest 0.1 cm) in duplicate with flexible tension-controlled measuring tape midway between the iliac crest and lowest rib. Blood samples will be drawn after an overnight fast to obtain plasma glucose levels and a lipid panel (triglycerides and HDL cholesterol), along with inflammatory markers of cardiometabolic risk (e.g., C-reactive protein). Samples will be sent to Quest Diagnostics (Horsham, PA) for analysis. Additionally, the study nurse practitioner or physician will review current medication use. Improvements in triglycerides, HDL cholesterol, and glucose are expected at week 20 in both treatment groups because of acute weight loss and calorie restriction. Due to higher levels of physical activity, greater weight loss, and reduced WBI, the magnitude of improvement is expected to be greater in the stigma + BWL intervention vs. BWL alone group at week 72.

Weight bias coping and internalization. Participants will complete the WBIS (described previously) at screening and weeks 20, 46, and 72. In addition to scoring this measure on its continuous scale, the percentage of participants who do and do not meet the eligibility criterion cutoff score (4 or above) will be calculated at weeks 20, 46, and 72, as a measure of "remission" from elevated WBI. Participants will also complete additional measures of stigma, quality of life, stress, and depression at randomization and all subsequent assessment times. Stigma questionnaires will include the Weight Self-Stigma Questionnaire (WSSQ; an alternative measure of WBI),[73] Fat Phobia Scale (a measure of stereotype endorsement),[74] and the Everyday Discrimination Scale (an assessment of unfair treatment in daily life for a variety of reasons, including weight).[75] The WBIS, WSSQ, Fat Phobia Scale, and Everyday Discrimination Scale are widely used and well validated.[37,76-81] Additionally, an assessment of weight stigma coping strategies[82] will be completed to assess the frequency with which participants engage in adaptive and maladaptive behaviors (e.g., exercising more vs. avoiding physical activity) in response to weight stigma. At baseline only, participants will complete the Weight Stigma Timing of Life Questionnaire to assess their history of weight-stigmatizing experiences, and the Adverse Childhood Experience Questionnaire to assess experiences of childhood trauma.[83] Participants will also complete the Impact of Weight on Quality of Life Questionnaire-Lite (IWQOL),[84] which contains five subscales that include items assessing distress due to weight-stigmatizing situations and weight-based discrimination. Participants will complete the Perceived Stress Scale (PSS)[85] to determine self-reported daily stress, the Questionnaire for Eating and Weight Patterns (QEWP)[86] to assess disordered eating, and the Patient Health Questionnaire (PHQ-9)[87] to assess

symptoms of depression. Participants will complete the Body Appreciation Scale[88] to assess changes in body positivity. Additionally, participants will complete a brief questionnaire assessing the frequency with which they self-monitor their weight and eating (along with food records which will be collected from participants at all group meetings to assess days of recorded food intake and activity), and treatment acceptability will be assessed at weeks 20 and 72. Participants in the stigma + BWL intervention group are predicted to show greater reductions in all measures of stigma and distress than participants in the BWL group at weeks 20, 46, and 72.

6.4 Safety Measures

Risks
The risk of adverse medical or psychiatric events should be minimized by the careful screening procedures to be used. The principal risks during the group lifestyle modification program include:

Risk of gallstones. Rapid weight loss may increase the risk of gallstones. 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. Participants may become distressed by learning about and discussing their experiences with weight-based discrimination and stigma.

Confidentiality and loss of privacy. All efforts will be made to protect participant confidentiality and privacy. We cannot guarantee total privacy. Personal information may be given out if required by law.

Ongoing medical visits and safety measures
A physician/nurse practitioner will be available if participants notice any side effects of weight loss. Participants who lose 15% or more of their initial body weight may be advised to inform their PCP of their weight loss, particularly if taking medications that may need to be adjusted due to weight loss (e.g., anti-hypertensive medications). Participants who report significant depression or emotional distress 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).

7. STATISTICAL ANALYSIS

Sample size calculation
Using a sample size equation for longitudinal clustered samples,[84] a power analysis was conducted for the **primary outcome: percent weight change at week 72**. Estimated group means, attrition rate, intraclass correlation (ICC), and variances were derived from data from prior studies

conducted at our Center.[72] Specifically, we predict a 72-week weight loss of 9% in the stigma + BWL group and 5% in the BWL group, with expected standard deviations of 7%.[72] Based on these estimates, a baseline sample size of 104 participants (52 per group), assuming a 20% attrition rate, an ICC of .80, and 4 assessment points, will give us 80% power to detect a between-treatment group difference at week 72 of 4% (effect size: 0.57) to be significant at alpha = 0.05. The power analysis was conducted using PASS v14. All secondary outcomes will be considered exploratory and will provide valuable findings that will help to inform larger studies. This study has not been powered to detect differences in changes in physical activity, cardiometabolic outcomes, or psychosocial variables.

Analysis plan

Data quality and integrity will be checked by assessing the data for missing and out-of-range values with basic statistical procedures, including univariate statistics and visual graphical displays (e.g., scatter plots). We will investigate all questions of data quality and integrity prior to performing any statistical modeling. To test the adequacy of randomization, preliminary analyses will include a comparison of all participant demographic and baseline characteristics by randomized treatment groups (t-tests or Wilcoxon rank sum tests for continuous variables and Chi-Square test or Fisher's Exact test for categorical data). If imbalances are observed, the relevant variables will be included as covariates in the final analyses.

All data will be analyzed with a modified intention-to-treat principle. Participants who attend at least one group meeting (i.e., receive a dose of treatment) will be included in the analyses; participants who do not attend a single group meeting will not be included in the analyses. Analyses will be two-tailed with a significance level of 0.05, and will be conducted using SPSS version 24.0 or SAS version 9.4. To assess the primary outcome of percent weight change by treatment group, a mixed effects model will be fit with Treatment Group (*stigma+BWL, BWL*) as a between subjects factor and Time (*Weeks 20, 46, 72)* as a categorical within-subjects factor. We will use the group x time interactions with the time main effect to estimate and test treatment group differences at each time point, with the 72-week time point as our primary test. In fitting a mixed effects model with residual maximum likelihood (REML), a variance-covariance structure must be selected. The criteria for selecting the best form of the variance-covariance structure will be based on criteria such as the Akaike's Information Criterion (AIC). We will include as baseline covariates any variables that differ significantly between the treatment groups at baseline and show significant relationships with the outcome. The results from the mixed model will be summarized by mean(SE) for each treatment group at each time point. Residual analyses will be conducted to check for outliers and influential points and violations in the normality assumption. If violations are detected, variance-stabilizing transformations will be considered. Logistic regression will be used to test for between-group differences in categorical weight loss (≥5% and ≥10% of initial body weight) at weeks 72, 46, and 20.

The second aim of assessing changes in physical activity and self-efficacy, and the secondary aims of comparing changes in cardiometabolic risk factors and psychological well-being (including WBI), will be analyzed using the same methods as described above for the mixed effects model used for the primary aim. Changes in all outcomes will be summarized by mean(SE) for each treatment group at each time point. Logistic regression will be used to test for between-group

differences at weeks 20, 46, and 72 in the percentage of participants who have remitted from elevated WBI, as indicated by no longer having a score of 4 or above.

This study will consider death, pregnancy, bariatric surgery, amputation, and other major medical events or procedures that require a participant to terminate treatment as "censoring events." For primary analyses, participants experiencing these events will be censored at the last measured weight before the event occurred. As discussed above, the primary analysis techniques being employed (i.e., linear mixed models) can accommodate incomplete participant response profiles, so these participants will still be included in the analyses. Additional sensitivity analyses may be conducted in which data will be censored due to other factors that directly affect weight (e.g., change of medication that affects weight, receipt of additional weight-related treatment, change in smoking status, or other major medical changes that occur within 3 months of an assessment visit).

Additional analyses may be conducted to explore potential effects of cohort, time of group meeting, and group leader on weight loss and changes in WBI. Analyses may also explore potential differences in attendance between groups and the effects of attendance on weight loss and changes in WBI.

8. SAFETY AND ADVERSE EVENTS

At each contact with participants, the study personnel will seek information on adverse events by specific questioning and, as appropriate, by physical examination. Information on all adverse events will recorded immediately in the source document, and also in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedures results will be recorded in the source document, though should be grouped under one diagnosis.

All adverse events occurring during the study period will be recorded. The clinical course of each event will be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause. Serious adverse events that are still ongoing at the end of the study period will be followed up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to the study treatment or study participation will be recorded and reported immediately. All serious adverse events will be reported to the IRB within 10 working days.

9. DATA HANDLING AND RECORD KEEPING

Information about study participants will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- Protected health information (PHI) collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of research participants to revoke their authorization for use of their PHI

- View of PHI will be limited to individuals at the University of Pennsylvania directly involved in the study. The company donating the study product will not have access to PHI.

In the event that a participant revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For participants who have revoked authorization to collect or use PHI, attempts will be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

10. STUDY MONITORING, AUDITING, AND INSPECTING

The investigator will permit study-related monitoring, audits, and inspections by the EC/IRB, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data, etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

A Data Safety and Monitoring Board (DSMB) consisting of at least one external (non-Center) reviewer will be assembled to provide additional study oversight. Members of the DSMB will meet twice per year to review the study's progress, enrollment, and de-identified group-level data for differential rates in key outcomes and Adverse Events (AEs). This team will be responsible for monitoring the safety and efficacy of this trial, executing the data safety and monitoring (DSM) plan, and complying with Public Health Service (PHS) reporting requirements. Review of the rate of subject accrual and adherence to inclusion/exclusion criteria will occur at this time.

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

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