PROTOCOL TITLE:

Decision Making Study

(Grant title: Mechanisms Explaining the Link Between Weight Discrimination and Poor Cardiovascular Health)

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	10/13/2022	The revised protocol addresses all issues raised in the initial pre-review including 1) following all clinical trial-related requirements and modifying sections in the protocol to include additional information, 2) asking all study team members to update their CAMS and 3) provide evidence of GCP training, 4) making requested revisions to the consent form, 5) uploading additional study documents referenced in the protocol, and 6) including information about the saliva sample on the debriefing form and verbal script. I am waiting for a few study team members to complete their required human subjects training (HSR and GCP). All members will have completed this training by Oct 21, 2022. All COI reports will also be submitted by this date.	yes

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1.0 Study Summary

Study Title	Decision Making Study (Grant title: Mechanisms Explaining the Link Between Weight Discrimination and Poor Cardiovascular Health)
Study Design	Randomized clinical trial
Primary Objective	• Identify early-stage cognitive, affective, behavioral, and physiological mechanisms activated by experimentally manipulated weight discrimination. • Identify psychological and demographic variables that moderate effects of weight discrimination.
Secondary Objective(s)	N/A
Research Intervention(s)/ Investigational Agent(s)	Experimental (weight discrimination) manipulation vs. Control manipulation
IND/IDE # (see section 5)	N/A
Study Population	Adults ≥ aged 18 years recruited from the local community
Sample Size	320
Study Duration for individual participants	135-140 minutes total
Study Specific Abbreviations/ Definitions	BMI = body mass index

2.0 Objectives

Specific Aims and Hypotheses

Our long-term goal is to develop interventions to minimize the negative health effects of weight discrimination. As a step toward this goal, we propose to conduct an experiment to identify mechanisms through which weight discrimination leads to poor cardiovascular health. A diverse sample of participants with obesity will be randomly assigned to experience weight discrimination vs. a control manipulation to test the following aims:

Aim 1: Identify early-stage cognitive, affective, behavioral, and physiological mechanisms activated by experimentally manipulated weight discrimination. We will manipulate exposure to weight discrimination to assess causal effects on cognitive (e.g., impaired self-regulation), affective (e.g., negative emotion), behavioral (e.g., comfort eating), and physiological (e.g., inflammation) outcomes in people with obesity (BMI $\geq$ 30 kg/m^2). We hypothesize that, relative to control participants, participants in the weight discrimination condition will display elevated responses on early-stage mechanisms that culminate in increased risk for poor cardiovascular health (e.g., more impaired self-regulation, higher negative emotion, lower positive emotion, more social withdrawal and comfort eating, and increased cortisol secretion).

Aim 2: Identify psychological variables that moderate effects of weight discrimination. Our pilot studies suggest that some individuals are more vulnerable to the adverse effects of weight discrimination than others. The proposed experiments will identify psychological individual differences (e.g., internalized weight bias, self-compassion) that moderate responses to the weight discrimination manipulation. We hypothesize that self-compassion and conscientiousness will be associated with resilience to the negative effects of weight discrimination, while internalized weight bias and neuroticism will increase risk for poor outcomes.

Aim 3: Identify demographic characteristics that moderate effects of weight discrimination. Given the paucity of studies recruiting diverse samples, coupled with methodological limitations of previous research, little is known about whether demographic characteristics moderate (amplify or mitigate) effects of weight discrimination. We will recruit a diverse sample and conduct exploratory analyses to assess whether the negative effects of weight discrimination differ by age, sex/gender, race, and ethnicity.

3.0 Background

Prior research and gaps in current knowledge.

Discrimination is a critical social determinant of health that underlies poor health outcomes.[1-4] One common but understudied form of discrimination is weight discrimination. Weight discrimination is the behavioral manifestation of weight stigma—the social devaluation of people with excess body weight.[5,6] Discriminatory actions toward people with obesity are perpetuated by widely held negative stereotypes.[6] Indeed, weight discrimination is a pervasive—sometimes daily—experience for people with obesity.[5,7-9] Encounters with weight discrimination range from inappropriate comments

and bullying to diminished opportunities for education, employment, and healthcare.[5-11] Findings suggest that the stress produced by weight discrimination prompts weight gain, creating a vicious cycle between weight discrimination and obesity.[12-14] Further, there is now well-documented evidence that experiencing weight discrimination is associated with cardiovascular health problems that culminate in increased risk of mortality.[15-22] Importantly, associations between weight discrimination and poor health persist when controlling for body mass index (BMI),[14,16-18] indicating that effects of weight discrimination do not merely reflect health risks associated with higher body weight.

This project will address several key gaps in the literature. First, although the association between weight discrimination and poor cardiovascular health is well documented,[15-22] far less is known about the mechanisms of this association. Identifying these mechanisms is critical because they are potential targets for intervention. Second, previous research has relied primarily on correlational data, and thus little is known about the causal effects of weight discrimination. We will use rigorous experimental methods to identify early-stage mechanisms that explain the link between weight discrimination and poor cardiovascular health. Third, previous studies have largely ignored the possibility that different people respond to weight discrimination in different ways. To address this gap, we will identify psychological factors (e.g., self-compassion) and demographic characteristics (e.g., race/ethnicity) that moderate the negative health effects of weight discrimination.

SIGNIFICANCE

Obesity is widespread and people with obesity are frequently subjected to discrimination. Currently, 42.4% of US adults meet criteria for obesity (BMI ≥ 30 kg/m^2).[23] By 2030, nearly 1 in 2 adults is expected to meet criteria for obesity and 1 in 4 will meet criteria for class II or III obesity (BMI ≥ 35 or 40 kg/m^2).[24] Obesity disproportionately affects minority populations, with the highest prevalence found in non-Hispanic Black adults (49.6%), followed by Hispanic adults (44.8%) and non-Hispanic White adults (42.2%).[23,25] Weight discrimination is a pervasive—sometimes daily—experience for people with obesity.[5,7-9] Encounters with weight discrimination range from inappropriate comments and bullying to diminished opportunities for education, employment, and healthcare.[5-11] A recent meta-analysis on the prevalence of weight discrimination found that 19% of individuals with class I obesity (BMI = 30-34.9 kg/m^2) and 42% of individuals with class II (BMI = 35-39.9 kg/m^2) or III obesity (BMI ≥ 40 kg/m^2) have experienced weight discrimination.[9]

Weight discrimination is a serious public health problem.[5,8] Weight stigma stems from the perception that body weight is highly controllable and thus people with obesity are personally responsible for their weight.[6] Although the etiology of obesity is complex and involves many factors (e.g., genetics, behavior, environment), the prevailing message that weight can be easily controlled through diet and exercise perpetuates negative stereotypes and prompts discrimination against people with obesity.[6] Such messages also contribute to the incorrect yet widely held belief that stigmatizing people for their weight will motivate them to lose weight. The reality is quite the opposite: Being stigmatized for one's weight is highly stressful and prompts further weight gain, resulting in a vicious cycle between weight discrimination, obesity, and poor health.[6,8,14,20,26,27]

Weight discrimination is associated with increased risk for poor cardiovascular health. Epidemiological studies link weight discrimination to increased risk for myocardial infarction and other forms of heart disease (e.g., angina pectoris, tachycardia),[17,18] as well as established risk factors for cardiovascular disease (CVD) including arteriosclerosis, diabetes, depression, hyperlipidemia, and obesity.[12-14,18,28] Weight discrimination is also associated with physiological processes underlying CVD such as high allostatic load, lipid/metabolic dysregulation, oxidative stress, and inflammation.[19-22,26] Importantly, many (though not all) of the associations between weight discrimination and CVD risk remain after controlling for BMI,[14,16-18,22] which indicates that harmful effects of weight discrimination are independent of health risks from excess body weight.

There is a critical need for interventions that mitigate the harmful effects of weight stigma. Reducing the public health burden of weight stigma requires multi-level interventions that address both the perpetrators and the targets of weight discrimination.[5,8,27] Little research has focused on reducing weight-based prejudice among perpetrators and the few interventions that do exist have been largely ineffective.[29] As weight discrimination continues to be a pervasive societal problem, there is a critical need for interventions to better support individuals who are the target of weight discrimination.

To inform such interventions, research is needed to identify *early-stage* mechanisms that underlie the adverse effects of weight discrimination, as well as moderators of those effects. Guided by our conceptual model (Figure 1), we propose that repeated

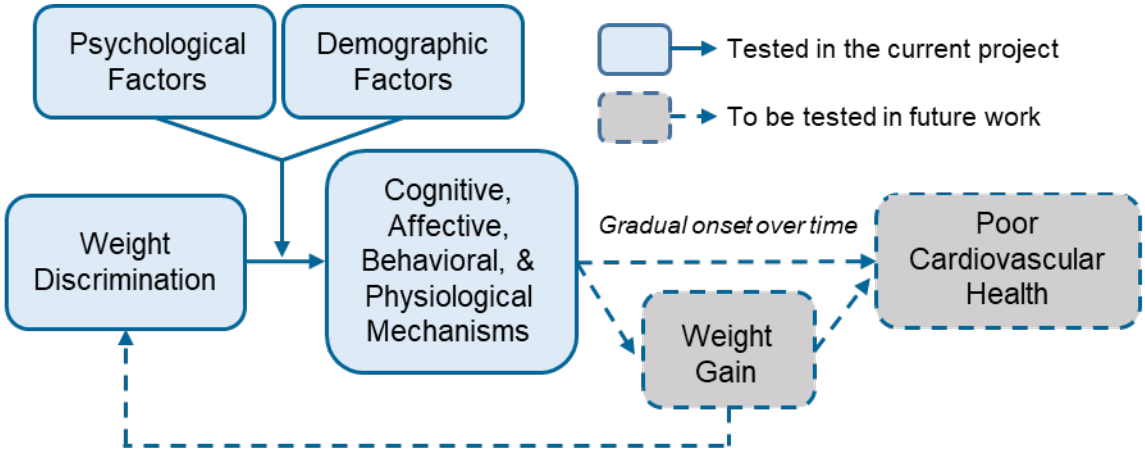

Figure 1. Conceptual model linking weight discrimination to poor cardiovascular health

exposure to weight discrimination results in a cascade of negative cognitive, affective, behavioral, and physiological processes that gradually culminate in poor cardiovascular health. These effects are expected to be moderated by psychological factors and demographic characteristics. Our model draws on the broader literature on interpersonal discrimination (e.g., due to race, gender, sexual orientation) and health [3,6,15,30,31] as well as Co-I Dr. Tomiyama's cyclic model of weight stigma,[26] which proposes that exposure to weight discrimination triggers a stress response that prompts physiological (e.g., cortisol secretion), emotional (e.g., feelings of shame), and behavioral (e.g., impaired self-

regulation, comfort eating) processes that promote weight gain, thus creating a vicious cycle between weight stigma and obesity.

Little is known about mechanisms that explain the link between weight discrimination and poor health. Previous studies have suggested mechanisms that may underlie the link between weight discrimination and poor cardiovascular health (e.g., overeating, cortisol secretion), yet most of this work relies on correlational studies, thus limiting the ability to make causal inferences.[19-22,32-35] For instance, correlational studies have documented an association between self-reported experiences with weight discrimination and unhealthy eating behavior (e.g., overeating, binge eating).[13,34,35] Our project will advance the literature by experimentally manipulating exposure to weight discrimination to identify causal mechanisms.

Identifying moderating variables will guide interventions to reduce the harmful effects of weight discrimination. Previous research has largely failed to examine variables that moderate effects of weight discrimination on poor health outcomes. To address this gap, we will identify both psychological variables (Aim 2) and demographic characteristics (Aim 3) that moderate responses to experimentally manipulated weight discrimination. Our pilot work identified several promising psychological moderators. For example, one candidate is internalized weight bias, or the extent to which people devalue and stigmatize themselves for their weight. In our pilot work, participants with higher internalized weight bias were more likely to view a negative social interaction as reflecting weight discrimination and, in turn, to display more negative affect, poorer self-esteem, and higher self-regulation failure. Replicating this finding in the current project would identify a valuable intervention target for mitigating the harmful effects of weight discrimination. Identifying demographic moderators (e.g., race, ethnicity, sex/gender) will also be useful for personalizing interventions to those groups with the highest need.

Using a rigorous experimental approach, we will identify moderators of and mechanisms through which weight discrimination undermines cardiovascular health. Identifying moderators and mechanisms is a critical first step for intervention development.[36] By intervening on early-stage mechanisms, we can prevent the cascade of downstream processes that contribute to poor cardiovascular health.

INNOVATION

We will use an experimental approach to manipulate weight discrimination. Previous studies documenting associations between self-report measures of perceived weight discrimination and poor health outcomes have relied almost exclusively on correlational designs.[15-22] Moreover, the few studies that have used experimental methods have either primed obesity stereotypes[37-39] or manipulated concerns that participants could be stigmatized for their weight (i.e., activated weight-based social identity threat).[40-44] Yet these manipulations lack the core component of weight stigma – personal devaluation for having excess body weight -- because the stereotypes primed were not personally directed at participants and the social identity threat manipulations never involved any actual devaluation of the participant. Reliance on these manipulations may underestimate the full impact of weight discrimination. We are aware of only one study (by Co-I Dr. Tomiyama) that experimentally manipulated exposure to weight discrimination by informing participants in the experimental condition that they could not participate in a shopping activity due to their shape and size.[45] Thus, to address the dearth

of causal evidence, we will manipulate exposure to weight discrimination by randomly assigning participants to experience vs. not experience personal devaluation on the basis of their body weight in order to test effects on mechanistic variables. Further, our manipulations were designed to reflect real-world contexts in which weight discrimination commonly occurs (e.g., the workplace).[5,7-9] In line with calls for research that examines the mechanisms of weight discrimination,[13,35] our approach will significantly advance the field by determining causal effects of weight discrimination on mechanisms hypothesized to underlie poor cardiovascular health. To our knowledge, the proposed study will be among the first to identify early-stage mechanisms activated by experimentally manipulated weight discrimination.

We will test whether racial and ethnic minorities are particularly vulnerable to weight discrimination. Despite the higher prevalence of obesity among Black and Hispanic adults compared to White adults,[23,25] most research on weight discrimination has been conducted with primarily White samples. Although findings are mixed, the few studies that have examined weight stigma in more diverse samples indicate that relative to Whites, racial and ethnic minorities experience equivalent rates of weight discrimination.[7] Whether effects of weight discrimination differ by race/ethnicity, however, is largely unknown. We will help fill this important gap by recruiting sufficient numbers of racial/ethnic minority participants to directly investigate whether race or ethnicity moderates effects of experimentally manipulated weight discrimination on early-stage mechanisms.

Preliminary Studies

Our preliminary studies provide valuable pilot data and demonstrate our team's ability to (1) conduct rigorous lab-based experiments that manipulate weight discrimination, (2) recruit sufficient numbers of adults with obesity, including racial and ethnic minority participants, and (3) work together in successful collaborations.

Pilot Study 1: *Qualitative Study on People's Experiences with and Responses to Weight Discrimination*. We conducted in-depth qualitative interviews with a diverse national sample of 32 adult men and women with obesity (BMI $\geq$ 30 kg/m^2) who had experienced mistreatment for their weight.[46,47] We identified common forms of weight-based discrimination (e.g., receiving offensive comments, being stereotyped, experiencing social rejection) and typical settings in which such discrimination occurred (e.g., health care, employment). For instance, weight discrimination was highly prevalent in employment settings. Participants were frequently labeled with derogatory obesity-related stereotypes (e.g., lazy, incompetent, unintelligent, lacking self-discipline) and regularly excluded from job-related opportunities for advancement (e.g., trainings, promotions). We also identified common cognitive (e.g., self-regulation deficits, self-acceptance); emotional (e.g., psychological distress, shame, anger); and behavioral (e.g., unhealthy eating behavior, social avoidance or withdrawal, social support seeking) responses to weight discrimination. These findings guided Aim 1 of the proposed research by suggesting contexts in which to manipulate weight discrimination in our experiments, as well as cognitive, affective, and behavioral processes (mechanisms) activated in response to weight discrimination.

Pilot Study 2: *Early-Stage Cognitive and Affective Responses to Manipulated Weight Discrimination*. This lab experiment demonstrated that perceptions of weight

discrimination evoke a number of negative responses.[48] Adults with obesity (N=109) participated in a "first impressions" study in which they received negative (vs. neutral control) feedback from a partner (a member of the study team). Participants who viewed the negative feedback as weight discrimination showed elevated negative emotions (shame, anger) and poorer performance on a self-regulation task (Stroop task).

Psychological moderators. Further, participants high in internalized weight bias (IWB) and neuroticism were more likely to view the negative feedback as reflecting weight discrimination and to report more negative emotions, whereas participants high in self-compassion and conscientiousness demonstrated the opposite pattern. Findings support Aim 1 by demonstrating effects of weight discrimination on negative emotions and self-regulation and Aim 2 by identifying psychological moderators.

Pilot Study 3: *Cognitive, Affective, and Behavioral Correlates of Expectations of Rejection*. This lab study identified individual differences associated with expectations of rejection during a novel social interaction and the implications of those expectations for psychological and behavioral outcomes. Before completing a task with a partner (a member of the study team), adults with obesity (N=111) reported the extent to which they thought they would be accepted vs. rejected by their partner. Participants who anticipated rejection by their partner reported more distress and anxiety. Expectations of rejection were also associated with social withdrawal, indicated by participants choosing to work by themselves to avoid further social interaction.

Psychological moderators. Participants high in internalized weight bias and neuroticism reported higher expectations of rejection, more distress and anxiety, and greater social withdrawal. In contrast, participants high in self-compassion demonstrated the opposite pattern. These findings demonstrate support for Aim 2.

Pilot Study 4: *Experiences with Weight Discrimination in Black, Hispanic, and Sexual Minority Women*. We recently conducted another qualitative study with 32 Black, Hispanic, and sexual minority (e.g., lesbian) women (BMIs $\geq$ 30 kg/m^2) to assess their lived experiences with weight discrimination. In addition to replicating several findings from Pilot Study 1, we observed additional sample-specific findings. Although higher body weight was perceived to be more acceptable within Black and Hispanic communities, women from these communities nevertheless reported facing high levels of weight stigma, which contributed to cumulative stress produced by discrimination based on race/ethnicity. Further, although levels of internalized weight bias varied, most of the women interviewed appeared to struggle with at least some degree of internalized weight bias. These findings support Aims 2 and 3 by identifying moderating variables.

Background: Scientific Rationale

Rationale for experimental manipulations. The proposed study will leverage rigorous methods from the extensive experimental social psychology literature on social exclusion. This literature has produced well-validated procedures for manipulating social rejection and personal devaluation in effective but ethical ways.[49,50] These manipulations produce immediate behavioral effects but, after thorough debriefing, no lasting distress or adverse effects. The proposed study relies on a controlled laboratory manipulation in which participants are led to believe that they were excluded from a group of "co-workers" who hold biased viewed toward people with higher body weight and apply

weight-based stereotypes to the participant. This approach simulates a "real-world" experience with weight discrimination in a way that is impactful and personally relevant.

Rationale for outcome measures (Aim 1). Selection of outcome measures (i.e., mechanisms) was guided by previous research,[6,15,20] theory, [3,6,15,26,30,31] and our pilot data.[3,30,31] Our central premise is that experiencing weight discrimination elicits a stress response that results in a cascade of cognitive, affective, behavioral, and physiological responses which, over time and with repeated exposure, lead to poor cardiovascular health (Figure 1 and Table 1).[6,15,20,26]

Cognitive mechanisms. We will assess self-regulation. We are interested in two aspects of self-regulation: executive control and delay discounting. Executive control reflects one's ability to exert control over one's thoughts, feelings, and behavior. It plays an essential role in the downregulation of stress[51] and is associated with a range of positive health behaviors relevant to cardiovascular health.[52] Anticipating that one may be stigmatized for one's weight has been shown to result in poor executive functioning.[40,42] Delay discounting reflects a tendency to delay gratification and prioritize long-term incentives,[53] and underlies behaviors such as healthy eating and exercise that bring long-term cardiovascular benefits.[54] Deficits in executive control and delay discounting can trigger processes (e.g., heightened stress, overeating) that contribute to poor cardiovascular health.[20] We hypothesize that weight discrimination will cause deficits in self-regulation (Aim 1).

Table 1. Outcome variables for proposed experiment

Mechanism	**Outcome measure/task**
Cognitive	
Self-regulation	Stroop task (executive control)
	Delay discounting task
Affective	
	Negative emotion (e.g., shame, anger)
	Positive emotion (e.g., self-assurance)
Behavioral	
	Social withdrawal
	Self-efficacy for weight control behavior
	Intentions for weight control behavior
	Comfort eating
Physiological	
	Cortisol

Affective mechanisms. We will assess negative and positive emotion triggered by exposure to weight discrimination. Negative, stress-based emotions include shame, anger, anxiety, and distress, which together reflect the broader construct of negative affect. Exposure to obesity stereotypes, *weight-based social identity threat*, and rejection have all been shown to produce high levels of negative affect among people with obesity.[15,26,40,42] Moreover, negative affect is a robust risk factor for CVD.[55,56] Further, specific negative emotional states (e.g., shame, distress) are associated with psychological (e.g., depression), behavioral (e.g., comfort eating, social withdrawal, sedentary behavior), and physiological stress responses (e.g., cortisol secretion) that can harm cardiovascular health.[26,57,58] Conversely, exposure to weight discrimination is linked with low levels of positive emotion. A recent study that used ecological momentary assessment found that more daily episodes of weight stigma were related to lower end-of-the-day positive emotions (e.g., happiness, pride), which in turn were associated with less motivation to diet, exercise, and lose weight.[59] With repeated exposure to weight discrimination, these affective mechanisms can become activated

chronically and lead to a pattern of harmful responses that increase CVD risk. We hypothesize that exposure to weight discrimination will increase negative emotion and decrease positive emotion (Aim 1).

Behavioral mechanisms. We will assess eating behavior, self-efficacy and intentions for weight control behavior, and social withdrawal. Numerous studies link weight discrimination to unhealthy eating behavior.[35] Exposure to weight discrimination is predicted to increase comfort eating as a means of immediate stress reduction.[13,20,26,35,38,60] If left unregulated, however, comfort eating can promote further weight gain and impair cardiovascular health.[61-64] Additionally, exposure to weight stigma undermines self-efficacy for engaging in effective weight control behavior (confidence in one's ability to resist eating in certain situations).[39,43,59,65] As these behaviors have important effects on weight,[12,14,35] we will assess self-efficacy for weight control behavior and intentions to engage in healthy weight control behavior. Discrimination and social rejection also promote social withdrawal, a tendency to avoid social interaction in favor of social isolation.[66,67] Although such isolation may bring temporary feelings of safety or relief, over extended periods, social withdrawal can promote loneliness, depression, and anxiety,[68-70] which adversely affect cardiovascular health.[71-73] We hypothesize that exposure to weight discrimination will increase comfort eating, reduce self-efficacy and intentions for weight control behavior, and increase social withdrawal (Aim 1).

Physiological mechanisms. We will assess salivary cortisol, a steroid hormone that regulates the body's response to stress. Experimental work has demonstrated sustained cortisol reactivity in response to weight stigma (vs. control).[44,45,74] Cortisol contributes to weight gain directly by promoting abdominal fat deposition and indirectly by promoting increased eating, especially hyperpalatable foods.[20] Over time, weight gain and obesity contribute to poor cardiovascular health.[75-77] We hypothesize that exposure to weight discrimination will lead to increased cortisol reactivity (Aim 1).

Rationale for moderators (Aims 2 and 3).

Psychological moderators (Aim 2). We will assess psychological individual difference variables as potential moderators of the effect of weight discrimination on primary outcomes. Guided by the literature[3,13,28] and our pilot work (see below), we identified psychological factors expected to moderate the negative effects of weight discrimination (Table 2). Internalized weight bias and neuroticism are expected to amplify the effects of weight discrimination on mechanisms, that is, effects of weight discrimination are expected to be stronger in individuals characterized by these traits. People high in internalized weight bias direct weight-based stereotypes at themselves and fear stigmatization due to their weight.[78-80] They are also more likely to use maladaptive strategies to cope with weight stigma (e.g., social isolation, overeating).[7,81] Neuroticism is a broad personality trait reflecting the tendency to experience negative emotions.[82] Thus, individuals high in Neuroticism may be more sensitive to and negatively affected by weight discrimination. Conversely, self-compassion and conscientiousness are hypothesized to be resilience factors, that is, effects of weight discrimination are expected to be weaker in individuals characterized by these traits. Self-compassion is the tendency to respond to painful and difficult experiences with self-kindness rather than self-criticism.[83] Thus, individuals with high self-compassion, may be less likely to display

negative outcomes when exposed to discrimination. Conscientiousness is a broad personality trait reflecting the tendency to be organized and disciplined.[82] People high in conscientiousness tend to interpret ambiguous situations as opportunities rather than threats[84] and thus may be less likely to view unfair treatment as discriminatory. Further, people high in conscientiousness may be less likely to engage in unhealthy behaviors following weight discrimination.[85]

Demographic moderators (Aim 3). We will examine whether age, sex/gender, race, and ethnicity moderate the effects of weight discrimination. Analyses will be exploratory given the lack of available data supporting robust predictions; most studies do not examine demographic moderators and those that have generally show mixed or null effects.[7,14,16-19,22,28,34] Further, previous studies have been limited by methodological constraints (e.g., correlational designs, use of self-report measures of weight discrimination, insufficient representation of racial/ethnic minorities). Thus, definitive tests of moderation are needed.

Table 2. Proposed moderating variables	
Risk Factors	Internalized weight bias Neuroticism
Resilience Factors	Self-compassion Conscientiousness
Exploratory Factors	Demographics (age, gender, race, ethnicity)

There are reasons to expect moderating effects. For instance, younger people are more likely to report experiencing weight discrimination than older people,[9] yet it is unknown whether weight discrimination has differential effects on health or putative mechanisms. With respect to sex/gender, women are more likely than men to report weight discrimination[9] and women randomly assigned to anticipate weight stigma sometimes display relatively worse outcomes (e.g., poorer self-regulation, more shame).[40] Nevertheless, weight discrimination is associated with adverse health outcomes in both men and women, and the magnitude of moderating effects of gender is unclear.[16,86,87] We considered competing predictions regarding moderation by race/ethnicity: On one hand, effects of weight discrimination could be amplified among Black and Hispanic/Latino participants relative to non-Hispanic Whites, based on evidence indicating that possessing multiple stigmatized identities places individuals at greater risk for more cumulative exposure to discrimination and in turn, worse health due to greater stress and reduced coping resources.[46,88,89] On the other hand, the effects of weight discrimination could be buffered among those minority groups, as some evidence suggests greater acceptance of higher body weight and less body dissatisfaction among Blacks and Hispanics relative to non-Hispanic Whites.[90-95]

To that end, we will test whether age, race (Black/African American vs. non-Black), ethnicity (Latino/Hispanic vs. non-Latino/Hispanic), or sex/gender (male/man vs. female/woman) moderate the effect of weight discrimination on proposed outcomes to determine whether certain demographic subgroups are more vulnerable to the negative effects of weight discrimination. Although these analyses will be exploratory, it is critical to evaluate whether effects are similar or different across sociodemographic groups because any differences would indicate that interventions need to be tailored to populations, or conversely, if similar, that interventions may be generalizable.

In summary, this research will identify novel and highly modifiable targets for interventions designed to reduce the adverse health effects of weight discrimination. In testing moderator variables, this work will identify individuals who display particular vulnerability vs. resilience to the harmful effects of discrimination. Information about

moderators will thus help future intervention efforts target those individuals who are most likely to benefit from intervention. Given the high prevalence of obesity and the millions of Americans affected by weight discrimination,[23] this work will address a critical public health issue. At a broader level, this research will also provide crucial insights into mechanisms that potentially underlie the adverse health consequences of other common forms of social stigma (e.g., discrimination due to race/ethnicity, sexual orientation, social class).

4.0 Study Endpoints

Outcome measures include cognitive (self-regulation); affective (emotional states); behavioral (social withdrawal, comfort eating); and physiological (cortisol secretion) responses to experimentally manipulated weight discrimination.

Measures to assess cognitive mechanisms.

Delay discounting task.[96] Delay discounting involves the subjective depreciation of an incentive based on its timing. The measure assesses the ability to delay gratification, that is, a tendency to prioritize larger long-term rewards over smaller short-term rewards. Participants will complete a well-validated task in which they choose short vs. long-term rewards from a set of five dichotomous choices (e.g., to receive $1 immediately or $10 in one month).[97] The task takes about 1 minute to administer, is highly reliable, and correlates well with longer and more extensive measures of delay discounting[97] (metric: discount rate (k) ranges from 0-1).

Stroop task. The Stroop task provides a measure of executive control by assessing the ability to inhibit an automatic response (reading) in favor of performing a more controlled task (color naming). The task is a classic, widely-used and well-validated measure of executive control.[98] Participants will perform 8 blocks of 20 trials that will take approximately 5 minutes to complete. Executive control scores will be calculated as a joint function of response accuracy and speed.[99]

Measures to assess affective mechanisms. We will use a modified version of the Positive and Negative Affect Scale-Expanded Form (PANAS-X)[100] to assess emotions in response to the experimental manipulation. The scale demonstrates good validity and reliability.[100] Emotions will be assessed with 46 adjectives (e.g., angry, confident). Participants will be asked to indicate the extent to which they feel each emotion at that moment (1=*very slightly or not at all* to 5=*extremely*). A composite score for positive and negative emotion will be created by taking the average of the relevant adjectives.

Measures to assess behavioral mechanisms.

Social withdrawal. Social withdrawal will be assessed with a measure from previous research,[50] in which participants indicate the extent to which they want to work on a task either by themselves, with one of their former group members, or with a new partner. Choosing to work by oneself reflects a desire to avoid social interaction. The details of the task will be tailored for the study to fit the study's narrative flow.

Comfort eating. Comfort eating will be assessed via an eating task to objectively measure hyperpalatable (high-fat, -sodium, -sugar, and -carbohydrate) food intake.[101] To avoid floor effects often observed in laboratory eating settings, the eating task will take place under the guise of a faux taste test.[102] Participants will be asked to rate each of the

foods/drinks to ostensibly guide the development of their food marketing campaign later during the study. To avoid ceiling effects and to allow participants to eat without fearing that the experimenter will negatively judge the amount they have eaten, large quantities of each food will be made available. Participants will have 10 minutes to complete the task alone in a private room. Bowls will be weighed (unobtrusively) before and after the task to compute the difference in grams, which will then be converted to kilocalories based on published nutrition information from the food maker.

Self-efficacy for weight control behavior. Self-efficacy (perceived confidence) in one's ability to engage in weight control behaviors (e.g., dietary restraint, physical activity) over the next six months will be assessed with items adapted from previous research. Self-efficacy for dietary restraint will be assessed with the short form of the Weight Efficacy Lifestyle Questionnaire[103] (e.g., I can resist eating … when I am depressed or down; 8 items). Self-efficacy for physical activity will be assessed with the Exercise Self-efficacy Scale[104] (e.g., I am confident I can participate in regular exercise when … I am tired; 5 items). To mask the study's focus, weight control items will be interspersed with items assessing self-efficacy for other health behaviors (e.g., flu vaccination, sleep, cancer screening). Participants will rate their self-efficacy for each behavior on an 8-point scale (0=*not at all confident* to 7=*very confident*). Items will be averaged to create a composite score.

Intentions for weight control behavior. Using the same health behaviors assessed for self-efficacy, we will also assess intentions for weight control behavior. Participants will be asked to rate the extent to which they intend to engage in each behavior over the next six months.[105] Each item will be rated on an 8-point scale (0=*strongly disagree* to 7=*strongly agree*). Items will be averaged to create a composite score.

Measures to assess physiological mechanisms.

Cortisol reactivity. We will measure cortisol secretion via saliva (passive drool) at three timepoints during the session: baseline, 20 minutes post-manipulation (to assess reactions to the manipulation), and 60 minutes post-manipulation (to assess recovery).[106] As in previous research,[106] participants will be asked to swish their mouths with water 2-3 times before the final sample is collected to avoid altering cortisol levels. Within 2 hours of collection, saliva samples will be frozen at -20°C. As in our previous work,[48] samples will be analyzed in duplicate with immunoassays. Participants will be instructed to refrain from eating, drinking, smoking, or exercising for 1 hour before the session. To reduce diurnal cortisol variability, sessions will be conducted between 1:00 and 7:00 p.m. During the session, we will assess factors that could potentially affect assay results (e.g., consumption of food, alcohol, nicotine within the past 12 hours; presence of oral diseases or injury; current medications), so that we can control for them in analyses if needed.

Measures to assess moderators (Table 2). Moderators will be assessed with an online survey completed at least one week before the experimental session. We will use reliable and well-validated measures to assess all psychological moderators. Internalized weight bias will be assessed with the 11-item Modified Weight Bias Internalization Scale.[79] Self-compassion will be assessed with the 26-item Self-Compassion Scale.[83] The 60-item Big Five Inventory-2[82] will be used to assess the five core personality domains (extraversion, agreeableness, conscientiousness, neuroticism, and openness). To mask the study's focus, the survey will include other measures unrelated to weight stigma (e.g., emotion

regulation),[107] plus demographic characteristics (e.g., education, biological sex) and health status (e.g., physical and mental health status, past medical history).

5.0 Study Intervention/Investigational Agent

The study intervention does not involve drugs or devices that are regulated by the FDA.

Participants will be randomly assigned to one of two conditions: experimental (weight discrimination) vs. control manipulation. The experimental manipulation will involve three components:

1. Learning that their groupmates are biased against overweight people
2. Receiving feedback that labels them with negative weight-based stereotypes (e.g., lacking self-discipline)
3. Not being selected as a partner for the remaining lab tasks (social exclusion).

In contrast, participants in the control condition will: 1) learn that their groupmates are very accepting of overweight people (i.e., they have positive attitudes toward people with higher body weight), 2) receive positive feedback about their personal attributes that are not consistent with negative weight-based stereotypes, and 3) will be told that one of their group members had to leave early for an emergency so the pairs cannot be assembled as usual (i.e., they will not experience social exclusion). In neither condition is any explicit reference to the participant's body weight, size, or shape included.

All three components of the planned experimental manipulation reflect common examples of weight discrimination reported by participants in our pilot data.[46,47] Moreover, all three manipulations have been used in previous IRB-approved experimental studies involving weight stigma or social exclusion. **Interacting with a confederate/partner who is biased against overweight people (component 1)** has been used in published studies[41] and is currently being used at UCLA for an NIH-funded study by Co-Investigator, Dr. Janet Tomiyama, in concert with direct interaction with a confederate who expresses (veiled) negative stereotypes about the participant (we will not use this latter procedure in our study). **Giving people bogus feedback about their personal attributes has a long history in social psychology (component 2)**. Classic and recent studies, for example, have provided participants with bogus negative feedback about their intelligence.[108,109] Similarly, studies have given participants bogus negative feedback about their level of competence to assess effects on psychological processes.[110] Finally, the **group exclusion manipulation (component 3)** in which participants interact with a group and then learn that nobody chose to work with them has been used in many published studies,[111] including studies conducted at FSU by Co-Investigator, Dr. Jon Maner.[50,112]

The study team used a combination of the second and third components a few years ago in a study in which participants received (bogus) negative feedback from their partner to manipulate weight stigma.[48] In (bogus) written feedback shared with the participant after viewing their video, a confederate (i.e., member of our study team who was pretending to be their partner for the study) indicated they were not looking forward to the face-to-face interaction with their partner (as indicated by a "2" on a 7-point scale ranging from 1 'not

at all' to 7 'very much'), and that they had a negative overall impression of their partner (as indicated by a "2" on a 7-point scale ranging from 1 'very negative' to 7 'very positive'). Their feedback also included the following hand-written note: "Her/His video was fine, but I guess I'm not that excited about talking face-to-face."

In summary, all components of the experimental manipulation used in the current study have been used in previous studies to produce immediate behavioral effects but, after thorough debriefing, no lasting distress or adverse effects have been reported.

Please see section 6.0 (Procedures Involved) for more detail about the experimental manipulation.

6.0 Procedures Involved

Describe and explain the study design.

The study uses a between-subjects experimental design. Participants will be randomly assigned to one of two conditions: experimental vs. control.

Research procedures, including procedures being performed to monitor subjects for safety or minimize risks.

The study involves two parts: a pre-session online baseline survey and an experimental session that will take place in the lab. Trained research assistants will guide participants through study procedures in the lab, including delivery of the intervention (manipulation), assessment of study outcomes, and study debriefing.

As identified in our pilot data and previous research,[5,7-9,46,113] employment is a common setting for weight discrimination. Negative employment outcomes (e.g., lower wages, fewer opportunities for promotion) often stem from negative stereotypes that cast employees with obesity as lazy, unintelligent, and incompetent.[5,8] To manipulate weight discrimination, this study will adapt manipulations widely used in previous experimental studies of social exclusion (conducted by Co-I Dr. Maner)[50,112] and weight stigma,[41] as well as our own pilot work.[48]

The study will be presented as an investigation of "decision making in the workplace," during which participants (adults with obesity) will "interact with" and receive initial impression ratings from three "co-workers" ("confederates," that is, research assistants posing as other participants). Participants will be told that the research team has partnered with the FSU marketing department to study how psychological factors affect decision making and that during the lab session they will work with their groupmates to develop a food product marketing campaign.

To begin, participants will create a 3-minute introductory "getting to know you" (GTKY) video, as in our pilot study.[48] To guide the creation of their video, participants will be provided with a list of "getting to know you" questions (please see attached video introduction questions) they can answer in their video. Participants will also complete a "getting to know you" questionnaire in which they will be asked to indicate their personal qualities (filler questions that assess self-monitoring practices) and social values where they will be asked to rate their attitudes toward elderly adults, overweight people, and

racial and ethnic minority individuals. Participants' videos and "getting to know you" questionnaire responses (averaged across the three members) will (ostensibly) be shown to their group members, and participants will view three similar videos created (ostensibly) by each of their group members. (Please see two sample confederate videos that were uploaded to IRB staff member Annette Allman's NiFTy account). After watching the videos, participants will provide impression ratings of each group member.

Participants will also be informed that, for the next portion of the session, the group will be divided into pairs to perform a taste-test task and develop ideas for the marketing campaign. Pairs will (ostensibly) be based on each person's preferences for whom they most want to work with based on the initial videos, and participants will be asked to indicate their preferences. The experimenter will say the following:

> "For the marketing task we want to partner people with someone they'd like to work with. Things work better that way. So please indicate here on this paper (at the bottom of the 'First Impressions Questionnaire' page 2) which one of your group mates (A, B, or C) you would most like to work with so we can try to partner you with them."

As described in Section 5.0 (Study Intervention), participants will be randomly assigned to one of two manipulations. In the experimental (weight discrimination) condition, participants will learn that their group members are biased against overweight people but not elderly or racial/ethnic minority individuals, as indicated by the GTKY summary ratings handout in which the three member's ratings will be presented in averaged form (experimental condition). Participants will also receive negative feedback about their personal attributes by being labeled with negative weight-based stereotypes (as indicated by the first impressions summary ratings averaged across the three members; experimental condition). Although some ratings will be positive (e.g., they will receive high ratings on being friendly and kind), participants will be rated poorly on attributes viewed as necessary to develop a strong marketing campaign (i.e., motivation to work hard, possessing self-discipline to persist at the task, and competence).

In the control condition, participants will learn that their group members have positive attitudes toward people with higher body weight, as well as elderly and racial/ethnic minority individuals, as indicated by the GTKY summary ratings handout (control condition). Participants will also receive positive feedback about their personal attributes, as indicated by the summary ratings averaged across the three members (control condition).

After (ostensibly) assembling the group's preferences, the experimenter will inform participants in the experimental condition that no one selected them to be their partner, thus they will perform the next few tasks alone. This manipulation has been shown to prompt feelings of social exclusion.[50] In contrast, participants in the control condition will be told that one of their group members had to leave unexpectedly for a family emergency, so pairs cannot be assembled as usual, thus they will perform the next few tasks alone. In sum, while participants in both conditions will perform the tasks alone, only those in the experimental condition should experience social exclusion. For the exact wording of the social exclusion manipulation, please see the attached script (social exclusion manipulation).

After the manipulation has been delivered, participants will complete a manipulation check (see lab survey). Participants will be asked to indicate their overall impressions of their groupmates and their perception of their groupmates' overall impressions of themselves. Participants will be also report the extent to which they think the impressions their group members formed of them thus far are based on various factors including their gender, race or ethnicity, weight, age, personality, and what they said in their video.[48]

Next, participants will complete primary outcome measures (Table 1). To assess comfort eating, participants will take part in a well-validated faux taste test from previous research (described below).[102] To provide a measure of social avoidance/withdrawal, we will use a previously validated measure[50] in which participants indicate the extent to which they prefer to complete the final task either by themselves, with a member of their previous group, or with a new partner (described below). Anthropometric measures (i.e., height, weight, waist and hip circumference) will be assessed at the end of the study following standard lab-based procedures.

To assess cortisol (a steroid hormone that regulates the body's response to stress), participants will be asked to provide three saliva samples during the lab visit. The first saliva sample will be collected at baseline (5-10 minutes after they arrive at the lab). The second and third saliva samples will be collected 25 and 60 minutes, respectively, after delivery of the experimental manipulation. If participants finish all study measures before it is time to collect the third saliva sample, they will be asked to watch a video about marketing strategies to presumedly help them prepare for the final task. Here's a link to the kind of video that will be shown to participants:
https://www.youtube.com/watch?v=0Ty64auIk_w
The experimenter will be instructed to stop the video when it's time to collect the sample.

We will use off-the-shelf foods for the taste test task. The following foods/drinks will be offered to participants: Lay's classic potato chips, Chips Ahoy cookies, milk chocolate M&M candies, and Sprite. During the taste test, participants will be provided with plentiful quantities of each food item (i.e., 80 grams of chips, 15 cookies, 300 grams of M&Ms) and 2 (355 mL) can of Sprite. These quantities were selected to circumvent both ceiling effects (i.e., participants eating all of the food available) and floor effects (i.e., participants eating no food at all) and are currently being used in a similar study being conducted by Co-I, Dr. Tomiyama. All food items will be stored according to package instructions (e.g., in airtight containers to preserve freshness). Cans of Sprite will be refrigerated. Participants will not be given food items that have become stale or are beyond their "best by" date. Any expired foods will be discarded. For sanitary reasons, any food or drink that is leftover after the taste test will be discarded as soon as the research assistant has logged the post-task weight for each item.

Participants will be screened for relevant food allergies on the screening survey (see attached). Those individuals who report being allergic to one or more of the products on the list will be excluded from the study. To take additional precautions, the consent form will remind participants of the food tasting and rating task that will take place during the lab visit. Participants will be instructed to alert a member of the study team if they have a relevant food allergy. If this occurs, the participant will be informed that they do not meet the eligibility criteria for the study and thus will not be scheduled for the lab visit (i.e., they will be withdrawn from the study for not meeting eligibility criteria). Further,

immediately prior to the food tasting exercise, the experimenter will remind participants of the ingredients contained in the foods they will be tasting. Participants will again be queried as to whether they have any relevant food allergies. If a participant admits to having a food allergy, any food items containing the specified ingredient(s) will not be offered to the participant during the taste test. In the unlikely event that a participant is allergic to all of the items of the food allergy list, the food tasting exercise will not be conducted.

The experimenter will bring the food to the lab room on a tray and will wear gloves while handling the food and presenting it to the participant. After setting down the tray, the experimenter will open a can of Sprite in front of the participant. To introduce the task the experimenter will say the following:

> "Okay, now it's time for the food tasting and rating task. These are the same foods that you'll be promoting in your food marketing campaign, so we wanted to give you a chance to try them. Please have at least a taste of each item so that you can rate them. Rate the foods using this form [hand participant food rating form; see attached food rating form]. You are welcome to have as much as want. It is important that you answer the questions on the form as accurately as you can, so if you need more food to answer the questions, please let me know. [Add off-handedly] And if you finish early, feel free to eat as much as you want. For sanitation purposes, we have to throw it away after you go anyway. You'll have about 10 minutes for this task. If you finish before I return, please feel free to review your ratings to make sure they are accurate."

To assess social avoidance/withdrawal, the experimenter will say the following after the participant has completed the food tasting task:

> "Next, you'll be sharing your ideas for the food marketing campaign. There are a few ways we can do it and it's up to you. You can do it by yourself, you can do it with one of the remaining people from your previous group—the same people in the videos you watched earlier—or there's someone else who showed up late for the study and you could do it with them. You haven't met them yet, but they'll be doing the marketing task as well so that's another option. Just so you know, the task will take the same amount of time whether you do it by yourself or with another person.
>
> So again, your options are by yourself, with a former group member, or with the new group member who showed up late. Please give it some thought. I'll be back in a few minutes and you can let me know your preference then."

Participants will be asked to indicate their response verbally to the experimenter, who will record their response.

Describe procedures performed to lessen the probability or magnitude of risks and source records

Our team is highly committed to the protection of participant welfare. We will work closely with our university's Institutional Review Board to ensure participant wellbeing and safety. Further, we will follow best practices for debriefing all study participants.

We will follow best practices for saliva sample collection. For example, participants will receive verbal instructions from the experimenter along with a written handout that

repeats the instructions and provides additional tips if they are having difficulty producing enough saliva (please see attached). Participants will also be given privacy and as much time as needed to provide the sample.

All participants will undergo a "funneled" debriefing process at the end of the study that begins with broad questions that narrow to probe for suspicion. The debriefing process will consist of an initial verbal debriefing with the research assistant, followed by receipt of a written debriefing form that provides additional information and psychological support resources. After receiving this information, participants will have the opportunity to discuss the study with the research assistant and ask questions. Here, we provide a brief summary of the verbal debriefing process and the information contained in the written debriefing form.

Debriefing Procedure Summary: The research assistant will begin by asking the participant a series of questions to assess prior knowledge of any aspects of the study (e.g., "Did anyone else tell you anything about what you would be doing in this study before your session today?") and gauge suspicion about study procedures (e.g., What do you think today's study was about? Was there anything we told you during the study that you didn't believe?"). Afterwards, the research assistant will explain the goals of the study and the nature of the two experimental conditions. All aspects of the procedure, including all elements of deception, will be explained clearly to participants. Participants will be assured that any feedback they received during the session from their ostensible partners was not real (i.e., the GTKY and first impression ratings from their "co-workers," being told that no one wanted to work with them on the partner task) and was developed by the research team to elicit particular types of reactions. Research assistants will emphasize this point until they are confident participants understand that none of the study procedures reflect any actual evaluation of the participant. The research assistant will apologize for not initially disclosing the purpose of the study and apologize for any discomfort that may have been experienced while completing the study measures or tasks.

Research assistants will be trained on how to assist participants who experience distress. Further, participants will be given a list of psychological support resources they can utilize (e.g., helplines) if they experience any lingering distress after the study has ended. Upon receiving full disclosure of the study goals, participants will be given the opportunity to withdraw their data from the study.

Participants will be thanked for their participation and given the written debriefing form. The debriefing form will provide a more detailed version of the verbal debriefing by outlining the study purpose and rationale underlying the current study. After receiving the verbal and written debriefing, participants will be given an opportunity to discuss the study with the research assistant and ask questions about the procedures and study goals. Participants will also be provided with several suggested readings if they are interested in learning more about weight discrimination and health, efforts that will be taken to protect their confidentiality, and a list of psychological support resources. The form will include contact information for the PI (Dr. Gerend) and the FSU human subjects committee should participants have any additional questions or concerns about the study. Participants will be instructed to contact the PI if they would like to receive a copy of the

study results.

Source Records: Please see attached documents for all surveys that will be used to collect data about participants (i.e., screening survey, baseline survey, lab survey).

Describe what data will be collected during the study and how that data will be obtained.

Outcome measures include cognitive (self-regulation); affective (emotional states); behavioral (social withdrawal, comfort eating); and physiological (cortisol secretion as indicated via saliva) responses to experimentally manipulated weight discrimination. Measures will be assessed with experimenter-administered and self-administered survey questions, computer-based tasks, a saliva sample, and a faux taste test. Please see previous description of outcomes for more detail.

Proposed psychological and demographic moderating variables will be assessed in the screening survey and baseline survey.

7.0 Data and Specimen Banking

N/A

8.0 Sharing of Results with Subjects

N/A

9.0 Study Timelines

The duration of an individual subject's participation in the study is a total of 135-140 minutes (15-20 minutes for the baseline survey; 120 minutes for the lab-based portion of the study).

We are aiming to recruit approximately 36 participants per month and will be recruiting for a 9 to 11-month period. If are not able to meet our recruitment goals, we will extend the recruitment window as necessary.

Our estimated date of completion is 9/30/2023. If we need more time to complete the study, we will request a no-cost extension.

10.0 Inclusion and Exclusion Criteria

Interested participants will be directed to an online screening survey via a link or QR code to assess eligibility criteria.

Eligibility criteria: (1) BMI $\geq$ 30 kg/m^2 (BMI criteria for obesity), (2) $\geq$ 18 years of age, (3) able to read and understand English, (4) have Internet access (to complete the baseline survey), and (5) able to come to FSU's campus to take part in a lab-based study.

Exclusion criteria: (1) having participated in any of our pilot studies on weight stigma, (2) diagnosed with a current major psychiatric disorder (e.g., major depressive disorder, eating disorder), (3) pregnant or nursing, diagnosed with Cushing syndrome, taking steroid-based medications, or (4) having allergies to ingredients in the foods being offered during the taste test (e.g., gluten, peanuts).

We will not be recruiting special populations (adults unable to consent, individuals who are not yet adults, pregnant women or prisoners).

11.0 Vulnerable Populations

N/A

12.0 Local Number of Subjects

Total number of subjects: 320

13.0 Recruitment Methods

Participants will be recruited from the local Tallahassee community and the surrounding area (e.g., Thomasville, Crawfordville). Following procedures used in our pilot work, we will use a variety of recruitment strategies (e.g., flyers, online ads, community outreach). Ads for the study will be distributed in the local Tallahassee community via flyers, online message boards (e.g., Craig's List), and social media sites (e.g., Facebook).

To facilitate recruitment of a racially/ethnically diverse sample, we have partnered with the FSU Center for Translational Behavioral Science's (CTBS) Community Engagement Core. The Community Engagement Core provides community liaison services, consults on engagement methodology, and facilitates the Community Advisory Council. The Council is a community advisory group comprised of area health care providers, professionals, and community members who have come together to enhance CTBS's mission toward effective community engagement in research. The Community Engagement Core is facilitated by Dr. Ennis and Dr. Pickett who serve as liaisons between investigators and the Council to engage relevant community partnerships needed to facilitate participant engagement and recruitment. As leaders of local community-based organizations, Council members also provide stakeholder input to facilitate recruitment. Participants will be recruited via direct outreach to locations such as local churches and community-based organizations.

Interested participants will be directed to an online screening survey to assess eligibility criteria.

The ads will provide a brief description of the study and the location where the study will take place. The ads will also mention that study participants will be compensated. Ads will include a link or QR code for the screening survey. Copies of the screening survey and advertisements are attached.

Participants will receive $75 cash upon completion of the lab-portion of the study.

14.0 Withdrawal of Subjects

The PI does not anticipate having to a) withdraw subjects from this research without their consent or b) terminate the study early. [46,47]

As described previously, the consent form will remind participants of the food tasting and rating task that will take place during the lab visit. Participants will be

instructed to alert a member of the study team if they have a relevant food allergy. If this occurs, the participant will be informed that they do not meet the eligibility criteria for the study and thus will not be scheduled for the lab visit (i.e., they will be withdrawn from the study for not meeting eligibility criteria).

If a participant arrives at the lab and does not appear to meet the minimum BMI criteria (BMI = 30 kg/m^2), the research assistant will be instructed to re-assess eligibility criteria to catch errors that were possibly made on the screening survey when reporting height and weight. Participants who may have entered inaccurate height or weight information on the screening survey (and thus do not meet the required BMI cutoff) will be told they cannot enroll in the study as they do not meet eligibility criteria. We do not anticipate having to do this very often, but it has happened a few times in our previous work, so we will have a procedure in place to address it.

Participants may decide to withdraw from the study at any time. No additional data will be collected after a participant withdraws. If a participant shares their intent to withdraw, the investigator will ask if the information that has already collected can be used or whether it should be destroyed.

15.0 Risks to Subjects

Potential Risks: Participants may experience psychological distress in response to the experimental manipulation. The manipulation used in this study is like other commonly used procedures designed to produce acute short-term distress in a laboratory setting [49,50,114-119] without affecting long-term mental or physical health. Distress is expected to be no stronger than what participants might experience in response to a single instance of day-to-day weight discrimination outside the lab. These risks are considered to be minimal as both the probability and magnitude of discomfort are not anticipated to be greater than those ordinarily encountered in daily life. It is also important to note that the negative effects of weight discrimination on health are presumed to be cumulative over the life course and develop only after repeated exposure to the chronic stress of weight discrimination experienced over time. Our manipulations simulate a single instance of weight-based discrimination and thus should have measurable acute effects in the lab without contributing to long-term risk.

Potential risks also include those associated with providing the three saliva samples (e.g., disgust with the procedure, difficulty producing enough saliva). Overall, these risks are considered to be minimal as the probability and magnitude of harm or discomfort anticipated in this study are not greater than those ordinarily encountered in daily life.

Information about the study's actual purpose will be withheld from participants until the debriefing process, which will take place at the end of the lab-portion of the study. During the consent process the experimenter will provide participants with a statement to the effect that participants may not be made aware of some features about the study and will be provided with additional information about the study at the end of their participation or at any time they withdraw. All participants will take part in the funneled debriefing process at the end of their participation or at any time they withdraw. Please

see attached for the full text of the verbal debriefing script and the written debriefing form.

16.0 Potential Benefits to Subjects

Potential benefits of the research for participants are minimal. Participants will learn (via debriefing) about the potential negative effects of weight discrimination on health and will be provided with links to several readings if they are interested in learning more about it.

17.0 Data Management and Confidentiality

Statistical Design, Power, and Analysis Plan
We designed this study to have very high power for the main effects of weight discrimination (Aim 1) and to ensure sufficient sensitivity for moderation effects of psychological (Aim 2) and demographic variables (Aim 3).

- **Aim 1: Identify early-stage cognitive, affective, behavioral, and physiological mechanisms activated by experimentally manipulated weight discrimination.** We hypothesize that, relative to participants in the control condition(s), participants in the weight discrimination (experimental) condition (vs. control) will display more impaired self-regulation, higher negative emotion, lower positive emotion, more social withdrawal and comfort eating, lower self-efficacy and intentions for engaging in weight control behavior, and increased cortisol secretion.

Aim 1 power and analysis. Nine outcomes are assessed for the study (Table 1), hence we adopt a conservative Bonferroni adjustment when evaluating the primary hypothesis and use significance level $\alpha = 0.005$ to maintain familywise Type I error rate of 0.05. We assumed conservative effect size estimates, which were among the smallest observed in our pilot data.[48] We plan to recruit 160 subjects per condition for the study, which yields 90% power ($\alpha = 0.005$) to detect the medium Cohen's $d = 0.50$ between the control and experimental conditions.

Aim 1 analyses will use unadjusted ANOVA followed by analysis of covariance and multiple regression methods that permit adjustment for age and other baseline characteristics that may exhibit imbalance across experimental conditions. To analyze effects of the manipulation on cortisol secretion (assessed at 3 timepoints), we will calculate the area under the curve (AUC) with respect to ground (AUCg).[120] For all Aims, residual diagnostics will assess model assumptions (e.g., normality, homogeneity) and responses will be transformed if necessary. Effect of experimental weight discrimination will be reported for both unadjusted and adjusted analyses.

- **Aim 2: Identify psychological variables that moderate effects of weight discrimination.** We hypothesize that the effect of weight discrimination (vs. control) will be stronger for individuals who score higher on certain psychological variables (i.e., internalized weight bias, neuroticism) and weaker for individuals who score higher on other variables (i.e., self-compassion, conscientiousness; See Table 2). In other words, possessing some traits will be protective, while possessing other traits may render individuals more vulnerable to the harmful effects of weight discrimination.

Aim 2 power and analysis. The very high power of these designs for the primary hypotheses of Aim 1 ensures sufficient power for Aim 2 and additional analyses.

Statistical analysis will use multiple regression with condition assignment, the moderator, and their interaction as predictors and focus on interpretation of the coefficient for the interaction.[121] With a continuous moderator, the coefficient for the interaction is the difference in the slope coefficients associated with the moderator in each of the treatment groups. Because these slopes are proportional to the correlation between the moderator and outcome in each group, respectively, the test of no moderation is equivalent to the test of equal correlation between moderator and outcome in all groups. Using Fisher's z transform of the correlations to approximate normality, The study (with 160 subjects in each of two conditions) provides 90% [80%] power (2-sided, $\alpha = 0.05$) to detect the change in correlation between moderator and outcome from 0.65 to 0.39 [0.43] associated with treatment assignment.[122] Additional statistical analyses will adjust for baseline characteristics by including these as additional predictors in the model; estimated moderation effects will be reported for both unadjusted and adjusted analyses.

- **Aim 3: Identify demographic characteristics that moderate effects of weight discrimination.** We will conduct exploratory analyses to assess whether the negative effects of weight discrimination are moderated by age, sex/gender, race, and ethnicity.

Aim 3 power and analysis. The power to detect a moderating effect of age is similar to continuous moderators described in Aim 2. Defining the effect of a binary moderator as the difference in the standardized effects of intervention associated with the two levels of the moderator, The study provides 88% power for a moderator effect of 0.70.[122] If the moderator is unbalanced (e.g., 60% of participants are female), then the power to detect a moderator effect of 0.70 is 86%. Power is maintained at 84% when there is a more severe imbalance (e.g., 1/3 Hispanic vs. 2/3 non-Hispanic).

All analyses will use the intent-to-treat data sets, meaning all participants will be included and associated with the experimental condition to which they were assigned. Missing outcomes will be addressed using multiple imputation or marginalization (i.e., maximum likelihood). Based on our pilot work, we anticipate little missing data. If the missingness exceeds 10%, however, we will evaluate the potential for nonignorability by including indicators for missingness throughout our analyses.

Participant privacy and data will be carefully protected. Participant information will be collected using a secure web-based application. The baseline survey will be as brief as possible and will be configured for easy completion on multiple platforms (e.g., cell phone, tablet, laptop). Participants will have the option to skip questions that make them uncomfortable. The experimental session will take place in a private laboratory on campus and will be guided through the study by a research assistant.

Data Security

Procedures to eliminate risks related to breach of confidentiality are as follows: Each participant will be given a unique identifier in the data set which will be stripped of all personal information to protect confidentiality. Data sets used for analysis will contain participant identification numbers but neither names nor any other identifying information. Identification information will be retained by the PI for the duration of the study and stored separately from the responses provided by subjects. Data will be stored in password-protected databases on secure servers, accessible only to project staff. Collaborators will receive data stripped of personal identifiers (de-identified data). To ensure complete confidentiality, access to the "key" linking personal identifiers to

participant usernames and passwords will be restricted to the PI. Dr. Gerend will oversee the data storage and reporting procedures. The "key" linking personally identifiable information to the participant's ID in the data set will be destroyed at the end of the study. Reports will only use aggregated data and will not identify individual participants. All study staff will be trained in security and confidentiality procedures before receiving access to any participant data.

Quality Control
The baseline and lab-based survey will include several data quality checks (e.g., attention checks) and a "speeding check" to identify any surveys that may be associated with poor quality.

Data Handling and Storage
All data will be stored on the PI's password protected computer in a secure folder on the College of Medicine server. Dr. Gerend will oversee data storage and handling procedures. Only members of the study team will have access to the data. De-identified data will be stored into perpetuity. Collaborators will receive data stripped of personal identifiers (de-identified data). Data transmission procedures will follow best practices to ensure data safety and security during transfer.

Saliva samples will be handled following standard laboratory procedures to ensure participant privacy and specimen protection. Saliva samples will be frozen at -20°C within 2 hours of collection and will be stored in a secure area (card-access only). Saliva samples will be stored until they are ready for analysis. Samples will be assayed for cortisol by an outside laboratory in small batches or once data collection is complete, depending on how quickly data collection takes place. Specimens will be shipped following standard protocols required by the processing lab.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This research constitutes a clinical trial and, as such, requires a Data Safety and Monitoring Plan (DSMP), but not a formal Data Safety and Monitoring Board.

Data and Safety Monitoring Plan
Potential Risks: Participants may experience psychological distress in response to the experimental manipulation. The manipulation used in this study is like other commonly used procedures designed to produce acute short-term distress in a laboratory setting [49,50,114-119] without affecting long-term mental or physical health. Distress is expected to be no stronger than what participants might experience in response to a single instance of day-to-day weight discrimination outside the lab. These risks are considered to be minimal as both the probability and magnitude of discomfort are not anticipated to be greater than those ordinarily encountered in daily life. It is also important to note that the negative effects of weight discrimination on health are presumed to be cumulative over the life course and develop only after repeated exposure to the chronic stress of weight discrimination experienced over time. Our manipulations simulate a single instance of weight-based discrimination and thus should have measurable acute effects in the lab without contributing to long-term risk.

Potential risks also include those associated with providing the three saliva samples (e.g., disgust with the procedure, difficulty producing enough saliva). Overall, these risks are considered to be minimal as the probability and magnitude of harm or discomfort anticipated in this study are not greater than those ordinarily encountered in daily life.

Any unexpected or serious adverse events that occur during the course of the study will be reported by the PI (Dr. Gerend) to the Florida State University Institutional Review Board (IRB) in accordance with current University guidelines for reporting adverse events.

Dr. Gerend will be responsible for monitoring data to ensure the safety of participants. The PI will provide close monitoring of each study to ensure steady progress of the trial and the safety of its participants. The PI will be in daily contact with study personnel and will actively oversee participant recruitment and enrollment, intervention administration, and all data collection activities. The research team will have weekly meetings to monitor the progress the study.

At the end of every experimental session, the research assistant will document whether 1) any problems that occurred during the lab session (e.g., session started late; computer problems; participant could not produce sufficient saliva; participant continued to experience psychological distress after the debriefing procedure), 2) whether the participant indicated that their data should be kept or discarded (and if so, why), and/or 3) if a participant decided to withdraw from the study (and if so, why). **The research assistant will be instructed to inform Dr. Gerend immediately after the lab session if a participant decides to have their data discarded, if a participant continues to exhibit psychological distress after the debriefing process, or if a participant decides to withdraw from the study.**

In order to assure privacy for participants and to minimize risk, we will be primarily using computer-based data collection procedures. This reduces the number of people who view the data and increases self-disclosure on sensitive topics. Access to the data will be password protected.

Each participant will be given a random unique identifier in the data set that will be stripped of all personal information to protect confidentiality. Data sets used for analysis will contain participant identification numbers but neither names nor other identifying information such as home address. Identification information will be retained by the PI for the duration of the project and stored separately from the responses provided by subjects. Collaborators will receive data stripped of personal identifiers (de-identified data). To ensure complete confidentiality, access to the “key” linking personally identifiable information to the participant’s ID will be restricted to the PI. Reports will not identify individual participants. Dr. Gerend will oversee the data storage and reporting procedures. De-identified data will be stored into perpetuity. The “key” linking personally identifiable information to the participant’s ID in the data set will be destroyed at the end of the project. Reports will only use aggregated data. All study staff will be trained in security and confidentiality procedures before receiving access to any participant data.

Adverse Events. The PI will review the progress of the project and data being collected to ensure that potential adverse effects are identified, if they occur, and reported to the

Committees for the Protection of Human Subjects. Any action recommended by these boards to the PI will be implemented immediately in order to determine actions to be taken to minimize further risk. The adverse event report will further be communicated to other entities (e.g., NIH) in a timely manner as appropriate based on their policies. The PI will also be responsible for reporting to the program director if the IRB or any other entity temporarily or permanently suspends an NIH-funded trial.

Unanticipated problems involving risks to subjects or others will be promptly reported by the PI to the IRB. The PI will also notify the project officer of any study modifications or suspension imposed by the IRB (in response to adverse events). All notifications will be done via email immediately followed with a certified letter.

19.0 Provisions to Protect the Privacy Interests of Subjects

Steps will be taken to protect subjects' privacy interests. During recruitment, potential participants will decide for themselves whether they would like to answer the questions in the online screening survey and/or provide their contact information to be enrolled in the study. Participants who are eligible for the study will be contacted by the project coordinator to take the baseline survey and schedule their lab-based session. Participants who are no longer interested in taking part in the study will be able to decline participation at any time.

Data collection procedures will take into account privacy interests by using computer surveys that will be completed in private and at the participant's own pace. We will follow best practices for survey design and ask sensitive questions in a respectful manner. Sensitive questions (e.g., annual income) will include a "prefer not to answer" option.

The research team will not be permitted to access any additional sources of information about subjects beyond data provided in their screening survey, baseline survey, or during the lab-based study itself.

20.0 Compensation for Research-Related Injury

It is not anticipated that participants in this study will experience research-related injury. In the event that a participant experiences a research-related injury the participant will be instructed to contact the investigator to report the issue and to contact their primary care physician for medical care. Generally, this care will be billed to the participant, their insurance, or another third party. In the event that a participant experiences a research-related injury, Florida State University is not able to offer financial compensation nor to absorb the costs of medical treatment.

21.0 Economic Burden to Subjects

N/A

22.0 Consent Process

Participants interested in taking part in the study will be sent a link to the baseline survey by the study coordinator. The baseline survey will begin with the informed consent form. Participants will be asked to 'sign' the e-consent form by typing their name. Participants

will not be allowed to complete any study procedures (including the baseline survey) until they have completed the informed consent form.

At the start of lab visit (which will take place approximately one week later), the experimenter will review key information about the study from the consent form and ask participants if they have any questions about the study or their rights as a participant. After all questions are answered to the participant's satisfaction, the study will begin.

The experimenter will follow SOP: Informed Consent Process for Research (HRP-090).

Alteration of Consent Process

As this research involves deception, the true purpose of the study will not be disclosed in the consent form. The true purpose of the study will be provided during the debriefing. The research could not practically be carried out without this alteration. To further mask the focus of the study, information that would traditionally be included the informed consent form for clinical trials such as circumstances that make a participant eligible (e.g., having a BMI $\geq$ 30) or ineligible for the study (e.g., having participated in one of our previous studies on weight stigma) will not be included. Further, the consent form will not mention that participants will be randomized to receive the experimental vs. control manipulation, however, this information will be revealed and discussed during the debriefing process.

ClinicalTrials.gov Requirements

The clinical trial proposed in this application will be registered on ClinicalTrials.gov. An unsigned copy of the IRB-approved consent form will be posted to the ClinicalTrials.gov site as required by NIH.

23.0 Process to Document Consent in Writing

As informed consent will be obtained electronically at the beginning of the baseline survey, participants will be asked to 'sign' the e-consent form by typing their name into the survey. Please see attached consent document for details.

Participants who would like a copy of the consent form will be informed they can print or save a copy of the screen. Additionally, participants can request a hard copy of the consent form from the experimenter during the lab visit. This information will be included at the end of the consent form.

24.0 Setting

Participants will be recruited from the local Tallahassee community and the surrounding area (e.g., Thomasville, Crawfordville). Following procedures used in our pilot work, we will use a variety of recruitment strategies (e.g., flyers, online ads, community outreach). Ads for the study will be distributed in the local Tallahassee community via flyers, online message boards (e.g., Craig's List), and social media sites (e.g., Facebook).

To facilitate recruitment of a racially/ethnically diverse sample, we have partnered with the FSU Center for Translational Behavioral Science's (CTBS) Community Engagement Core. The Community Engagement Core provides community liaison services, consults on engagement methodology, and facilitates the Community Advisory Council. The

Council is a community advisory group comprised of area health care providers, professionals, and community members who have come together to enhance CTBS's mission toward effective community engagement in research. The Community Engagement Core is facilitated by Dr. Ennis and Dr. Pickett who serve as liaisons between investigators and the Council to engage relevant community partnerships needed to facilitate participant engagement and recruitment. As leaders of local community-based organizations, Council members also provide stakeholder input to facilitate recruitment. Participants will be recruited via direct outreach to locations such as local churches and community-based organizations.

Participants will complete the online baseline survey at their own convenience in a location of their choosing.

The lab-based portion of the study will take place on campus at Florida State University. Data collection will take place in a private room in the lab of co-investigator, Dr. Jon Maner, Department of Psychology.

25.0 Resources Available

The investigative team has the necessary skills, experience, and resources to successfully carry out the proposed project. The team has a successful history of collaboration and experience conducting similar studies in a laboratory setting.

- As roughly two thirds of U.S. adults are overweight or obese, the team will have access to a large pool of potential participants for the study.
- Dr. Gerend will devote approximately 20% effort to this study to ensure timely completion of the project.
- Dr. Gerend will train all study staff and research assistants assisting with this research. Further, the PI will meet with the research team weekly to discuss study progress and any other important information relevant to conducting the study.

The study team consists of six FSU faculty members and one external faculty member from UCLA, Dr. A. Janet Tomiyama. Dr. Tomiyama will not be engaged with data collection (i.e., obtaining informed consent from participants, running participants through the study) and thus the FSU IRB does not need to serve as her IRB of record.

26.0 Multi-Site Research

The study is NOT a multi-site project.

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