

Daily Habits & Consumer Preferences Study Protocol with SAP

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Study Protocol

Objectives

Over 70% of U.S. adults are classifiable as overweight or obese, and weight stigma, defined as the negative attitudes, prejudice, and discrimination directed at heavier individuals, is highly prevalent. Our long-term goal is to understand and ultimately mitigate the negative behavioral effects of weight stigma that pose risk for obesity and cardiovascular disease. In order to achieve this goal, we must first gain a fundamental understanding of the causal processes of weight stigma and how it functions in people's lives to promote obesity. Therefore, the focus of this basic experimental study in humans (BESH) is to use an experimental manipulation as a probe in order to gain a fundamental causal understanding of the obesogenic nature of weight stigma. Much of the available evidence tying weight stigma to poor health outcomes is observational, precluding conclusions regarding causality. The few existing experimental studies that can infer causality only assess immediate outcomes in artificial lab settings. Moreover, the literature has thus far focused on documenting the negative effects of weight stigma, without attending to resilience factors that could confer protection against them.

Therefore, our overall objectives are to (1) test the central hypothesis that weight stigma causes decrements in health behaviors in everyday life using ecological momentary assessment (EMA) and actigraphy, and (2) identify resilience factors that could, in future work, be targeted in weight stigma interventions. The central hypothesis is based on existing literature and our 8 preliminary studies, which include a study of 2,000 participants census-matched to U.S. population demographics demonstrating associations between greater weight stigma and binge eating and sleep disturbance. Our focus on health behaviors is important because behaviors account for 40% of preventable deaths and are strongly protective against obesity and cardiovascular disease. Moreover, there is evidence that the COVID-19 pandemic is detrimentally impacting diet, exercise, and sleep. Using a true experimental design, we will therefore pursue the following

aims that capitalize on our deep experience manipulating weight stigma in laboratory experiments and our demonstrated expertise in ecological momentary assessment and actigraphy studies. This research will provide a fundamental understanding of weight stigma to potentially identify a future intervention target to ameliorate unfavorable health consequences for the hundreds of millions of Americans at risk for weight stigma, obesity, and cardiovascular disease.

Aim 1: Test the causal effects of weight stigma on diet, physical activity, and sleep in everyday life—we will randomly assign participants to a weight stigma vs. control manipulation and measure changes health behaviors in their everyday lives (3-day diet as captured by EMA food diaries, objectively measured physical activity captured by 24-hour actigraphy, and sleep, captured objectively by overnight actigraphy and subjectively self-reported sleep measures).

Aim 2: Identify resilience factors that confer protection against the causal effects of weight stigma—we will test moderators drawn from two sources of theory (identity/belongingness and stress/coping).

Design

Our approach consists of a one-way between-subjects experimental design, randomizing participants to weight stigma vs. control. We will measure immediate effects on objective eating behavior, and in addition engage in EMA to measure diet, physical activity, and sleep using actigraphy for 3 days pre- and post-manipulation.

Methods

Inclusion criteria are as follows [with justification in brackets]: (1) Age 18 and older [because children do not largely make their own diet/eating choices]; (2) BMI 28 or above [because heavier individuals are those who are most at risk for weight stigma and our preliminary data demonstrate our manipulation is effective in those with BMI 28 or higher]; (2) English-speaking [as the interaction task takes place in English]. Exclusion criteria include: (1) Recent (<1 year) diagnosis of major mental disorders including any eating disorder, mood disorder, schizophrenia, or PTSD [because weight stigma manipulations may impose undue risk for those with these conditions]; (2) Recent (<1 year) diagnosis of major physical conditions that limit physical movement [in order to avoid floor effects due to lack of physical activity]; (3) Recent (<1 year)

diagnosis of sleep disorder [in order to avoid ceiling effects due to disrupted sleep]; (4) Allergy to any of the foods in the food buffet [to guard participant safety].

Recruitment strategies will consist of a variety of methods including online postings, some targeted to specific demographics to match our planned enrollment table (for example, Facebook offers specification of populations for ads to reach), physical flyers around the UCLA community, listings on clinicaltrials.gov, clinicaltrials.ucla.edu, and other study recruitment portals such as researchmatch.com, and the psychology subject pools for our university. We have found in the past that recruiting to match the demographics of LA County is not difficult for White, Asian, and Latinx populations. However, recruiting 9% African American participants may be a challenge. Therefore, we will activate our existing database of churches and beauty salons/barber shops that enabled us to successfully recruit a 50% African-American sample in a prior study funded by the Robert Wood Johnson Foundation. We will also conduct in-person recruitment at community centers and events in areas represented by a large proportion of ethnic/racial minority individuals.

The cover story for this study will be that we are studying the relationship between health habits and consumer preferences. This cover story ties together the disparate elements of the study, including the health behavior measurement and taste test task. All participants will be scheduled between 3:00 and 5:00 pm. This time frame was chosen because we want the manipulation to occur late in the day to be proximal to sleep, but not so late that dinnertime hunger levels create ceiling effects for eating.

All participants will provide written, informed consent. Eligibility will be confirmed by measuring potential participants' weight and height in the lab. The other inclusion/exclusion criteria will be confirmed through a questionnaire. Participants will complete the resilience measures. They will then be given instructions on actigraph use and will affix the physical activity actigraph to their leg (the sleep actigraph is a wrist device that they will put on like a normal watch before sleep). They will also be trained on the food diary, along with serving size estimation training [1], [2]. To ascertain that the participants have successfully understood how

to estimate portion sizes, all participants must pass a pop quiz estimating serving sizes with real food in varying portions.

Participants will then undergo 3 days of food diaries to capture baseline food intake and 3 days of actigraphy to capture baseline sleep and physical activity. Then, participants will return to the lab to undergo the weight stigma or control manipulation. After the manipulation, participants will taste and rate a variety of snack foods under the guise of a Consumer Preferences task (our measure of objective food intake).

They will then undergo another 3 days of food diary and actigraphy measurement. Finally, they will return to the lab, at which point they will return the devices and receive compensation. They will be fully debriefed, which will include a funneled debrief to probe for suspicion of the manipulation.

Our team is deeply committed to engaging in ethical research that protects participant welfare. Across the entire time that the PI has been utilizing weight stigma manipulations, zero adverse events have occurred. Moreover, a peer reviewer for the PI's first weight stigma manipulation (developed with Co-I Hunger) noted: "The manipulation that was developed to create this active stigma context was a considerable strength, as it was grounded in theory and effective without crossing ethical boundaries—something that is challenging when designing weight stigma studies." All research will receive human subjects approval from the UCLA Human Research Protection Program. We also have an extensive debriefing protocol in place.

Weight stigma will be manipulated using a protocol we have successfully used previously [3] in which participants are led to believe that their interaction partner (always a trained confederate) endorses anti-fat attitudes. Participants will be told that they will complete consumer rating tasks, some with partners and some alone (to bolster the overall cover story). Participants will complete a "Getting to Know You Questionnaire" to ostensibly exchange with their "partner" (the trained confederate) before meeting in person to conduct the rating task. The questionnaire asks about demographic information (age, gender, and ethnicity) and attitudes toward several groups including "fat people." We will then deliver the confederate's questionnaire to the participant.

In the weight stigma condition, the confederate agrees or strongly agrees with five items from Crandall's [4] Anti-Fat Attitudes Scale (e.g., "Some people are fat because they have no willpower," "Fat people make me somewhat uncomfortable"), resulting in an average of 5.6 out of 6. In the control condition, the partner disagrees or strongly disagrees resulting in an average of 1.4 out of 6. In both conditions the confederate reports low levels of bias against other social groups. Participants are given 2 minutes to review their partner's responses [5] and respond to a manipulation check that ensures that they are aware of their partner's anti-fat attitudes (embedded among questions about attitudes toward the other groups, to maintain blinding; [6], [7], [8]).

In both conditions, participants will then work with the confederate to rate consumer items for the ostensible consumer ratings task. This will bolster the cover story, paving the way for the food rating task, which is our measure of objective eating behavior. Confederates will have standardized scripts so that their responses, and thus the interaction, will be the same across conditions.

Stratified block randomization will be used to ensure equal participant N in the two conditions. Two stratification factors of gender and race/ethnicity will be used to ensure balanced enrollment as defined by our Enrollment table. The randomization will be conducted by the Co-I/Biostatistician Tseng, and the block size will not be disclosed to the PI or study team.

The cover story blinds participants to treatment condition. To preserve equipoise, we will maximize researcher blinding by using standard methods such as ensuring all assessment personnel are blinded to condition. Furthermore, assessors, research assistants, and participants will be blinded to study hypotheses and the arms will be labeled with neutral labels (e.g., Blue vs Green). We anticipate no emergency unblinding procedures will be necessary.

We have chosen resilience factors that have strong theoretical foundations and rigorous empirical literatures. Within each resilience factor, we have chosen specific measures that are widely researched and validated. To measure the cognitive reappraisal aspects of emotion regulation, we

will use the Emotion Regulation Questionnaire subscale that captures habitual cognitive reappraisal [9]. A sample item is, “I control my emotions by changing the way I think about the situation I’m in,” administered on a Likert scale where 1 = Strongly disagree and 7 = Strongly agree. To measure emotional support, we will use the Patient-Reported Outcomes Measurement Information System (PROMIS) [10] emotional support scale [11]. A sample item is, “I have someone who will listen to me when I need to talk,” administered on a Likert scale where 1 = Never and 5 = Always. To measure emotional approach coping, we will use the coping through emotional approach scale [12]. A sample item is, “I let my feelings come out freely,” administered on a Likert scale where 1 = I usually don’t do this at all and 4 = I usually do this a lot. A sense of social belonging will be measured with the General Belongingness Scale [13]. A sample item is “I feel connected with others,” administered on a Likert scale where 1 = Strongly disagree and 7 = Strongly agree. The tendency to engage in self-affirmation will be measured with the Spontaneous Self-Affirmation Measure [14]. A sample item is, “When I feel threatened or anxious by people or events I find myself thinking about my values,” administered on a Likert scale where 1 = Disagree completely and 7 = Agree completely. Group identification will be assessed using the Leach In-Group Identification Measure [15]. A sample item is, “The fact that I am heavier is an important part of my identity,” administered on a Likert scale where 1 = Strongly disagree and 7 = Strongly agree.

Before and after the randomization to condition, we will measure 3 days of physical activity, sleep, and self-reported eating behavior (we will also have an objective measure of eating; see below). We carefully considered the length of this assessment period. Too short and the health behaviors may not be captured reliably. Too long and the effects of the manipulation may not be detectable across several days. Thus, the assessment period of 3 days was chosen because it represents a balance between reliable measurement of health behaviors and feasibly capturing the effects of our manipulation. Moreover, 3 days would represent the longest existing follow-up, to our knowledge, of experimental effects of weight stigma or indeed any form of social stigma. Therefore, this study is anticipated to have high impact on the field.

Eating: We will use objective and self-reported measures of eating behavior. We chose the tasks we describe next based on the expertise of PI Tomiyama and Co-I Hunger, who have extensive

experience measuring eating behavior in the lab and outside of the lab. In the 3 days pre- and post-manipulation, participants will self-report their food intake using food diaries [16] that were designed by a registered dietitian [1]. To control for weekday/weekend variability in diet [17], we will ensure that the pre- and post- manipulation days will have the same makeup (all weekdays, 1 weekend day, 2 weekend days). This may necessitate a gap between their baseline 3-day measurement and their lab visit for the manipulation, but follow-up measurement will begin immediately after the manipulation. These food diaries will be coded using Nutrition Data System for Research (NDSR) software (University of Minnesota Nutrition Coordinating Center). Our primary eating outcome for the food diaries will be kilocalories because calories drive obesity, although exploratory analyses will be conducted using macronutrients such as % sugar and % trans fat, as these are foods recommended to be avoided according to the 2015-2020 USDA Dietary Guidelines for Americans [18]. Adherence to food diaries will be maximized by providing daily reminders, and monitoring the diaries remotely to nudge those who are not completing them.

Given known weaknesses with self-reported food intake [19], we will also objectively measure food intake in the lab. Food consumption of the following items will be measured: Cookies, chocolate candies, potato chips, and Sprite. These foods were chosen because the 2015-2020 USDA Dietary Guidelines for Americans recommend limiting foods with saturated fats, trans fats, added sugars, refined starches, and sodium [18]. To avoid floor effects that can threaten the validity of laboratory eating paradigms, the eating will take place under the guise of a “consumer preferences” faux taste test task [20]. Participants will be asked to rate each of the foods for taste, texture, etc. 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.

Physical activity: Physical activity quantified as Metabolic Equivalent of Task (MET) units will be assessed using an ActivPAL4 actigraph (PAL Technologies) affixed to the thigh. We chose this device on the recommendation of Consultant Eli Puterman, an expert in physical activity research, who has had successful experience using it in his own studies. The ActivPAL4 is lightweight (9 g) and small (23.5 mm x 42 mm x 5 mm) device that is a triaxial (measuring in

vertical, anterior-posterior and mediolateral planes) accelerometer. It provides objective measurement of free-living lying, sedentary, upright and ambulatory activities. According to Google Scholar, over 2,500 published papers have used ActivPAL actigraphs, including over 150 NIH-funded clinical trials. Adherence considerations are relatively mild, as the actigraph is attached to participants' thighs with Tegaderm dressing film (3M), with which they can shower and do all daily activities. We will provide additional film and instructions in case a participant removes the actigraph. In addition, each day of actigraphy will be individually compensated.

Sleep: Sleep duration, onset latency, and efficiency will be assessed using an Actiwatch-2 (Philips Respironics) affixed to each participant's non-dominant wrist. We chose this device based on the recommendation of Co-I Aric Prather, an expert in sleep science who has successfully used it in his own studies. Wrist actigraphy is a well-validated tool for quantifying sleep behavior in healthy, community samples [21], [22]. Data will be captured in 30-second epochs and validated. Actiware 6.0.9 software algorithms will be used to estimate sleep parameters with the following sleep/wake algorithm: $D = A - 2*(1/25) + A1*(1/5) + A*(1) + A + 1*(1/5) + A + 2*(1/25)$, where AX = accelerometer activity for that minute. Sleep onset is operationalized as after 10 consecutive minutes of $D \leq 40$ (as $D > 40$ indicates participants are awake). In addition, in the 3 mornings following the lab protocol participants will complete a questionnaire assessing self-reported measures of the past night's sleep quality, bedtime, number of minutes it took to fall asleep, number of minutes awake during the night, and the present morning's wake time using a well-validated consensus sleep diary [23]. Adherence will be maximized by sending reminders each evening to participants to remind them to put the actigraph on their wrist, and sending reminders each morning to complete the self-report measures. As with physical activity, each day of sleep actigraphy will be individually compensated.

To maximize retention, we will have a prorated subject payment schedule so that each component of the study (baseline visit, 3 days of actigraphy/food diary, lab visit [experimental manipulation], 3 more days of actigraphy/food diary, and follow-up visit) is associated with payment. Participants will receive \$225 in total: \$25 for each of 3 lab visits and \$150 for the 6 days (\$25 per day) of actigraphy/food diary measurement. We will engage in a thorough

informed consent process so that participants are well-informed regarding the procedures in the study. Our staff will reflect the diversity of the LA community. Moreover, to protect against loss of power due to participant dropout, we have accounted for a 10% dropout rate in our sample size calculations.

Statistical Analysis Plan

Descriptive statistics will be generated for the demographic, mediating, and outcome variables, in aggregate and by randomized assignment (weight stigma vs. control). Eating behavior is often skewed, and if kilocalorie intake evinces skew greater than 3.0 we will conduct transformations (either square root or natural-log) to normalize the data. In addition, all other variables with skew greater than 3.0 will be natural-log transformed. Cronbach's α will be computed to confirm internal consistency for self-reported outcomes. Values will be averaged over the 3 pre- and post-manipulation days, respectively. With this randomized study, intention to treat analysis will be performed to ensure causal inference. Analysis of variance will test main effects of the weight stigma manipulation on the outcome measures. As we are utilizing randomization, we do not anticipate a priori that covariates will be necessary. However, we will test for potential failure of randomization and include necessary covariates in the models.

Moderation analyses to test resilience buffering will be conducted using the PROCESS macro, Model 1 [24], testing whether the effect of the weight stigma condition on the three outcomes is moderated by the resilience variables. We will additionally control for exposure-outcome (e.g., socioeconomic status, operationalized as recommended by the MacArthur Network on SES and Health [25]) and moderator-outcome (e.g., depression, measured by the Center for Epidemiologic Studies Depression Scale [26]) confounding. As we are engaging in primary data collection in the laboratory, missing data will occur at relatively low levels in our experience. However, in consultation with Co-I/Biostatistician Tseng, we will use missing data/imputation methods if necessary.

Our lowest-powered test will be the resilience factor*condition interaction tests. Because no published research has examined such a hypothesis, we base our power analysis on the smallest effect size we observed in our preliminary studies and simulated interaction power at differing levels of effect sizes at different N. Table 2 depicts the results of power simulations. The interaction effect size column is not a Cohen's d but rather refers to the % change in the relationship when the moderator is 1 SD higher or lower than the average. Given the tradeoff between power and feasibility, we will have a sample size of 300 participants. We have reason to believe the effect size we observe will be larger than what was observed in in our preliminary studies, as the outcomes will be measured in ways that will minimize random error (repeated measurement and objective measurement). To account for ~10% dropout, we will recruit an additional 30 participants, bringing the total recruited to 330.

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