Exercise as a buffer against stress induced overeating
ClinicalTrials.gov #: NCT02936076

Study Protocol
10.11.17

Study overview: Subjects will be recruited to participate in this study via advertisements in local newspapers, internet postings, and community newsletters. Interested individuals will be screened via the telephone to determine initial eligibility (see full eligibility criteria below). If deemed eligible via the phone screen, participants will be invited to an orientation session where they will learn additional details about the study, sign an informed consent document, and complete baseline assessment measures. Participants will then be randomized to a 12-week exercise training program or a delayed exercise condition (see below for more details). Assessments will take place at baseline and 12 weeks. Participants will not be compensated for the baseline assessment visit. At 12 weeks, they will be compensated $25 for completing study questionnaires, a food choice computer task, and measures of weight, fitness and body composition. Further, at baseline and 12 weeks, participants will be asked to respond to prompts via their smartphone 5x/day over a 14-day period while also wearing an armband that objectively measures physical activity. At week 12, participants will receive $0.50 for each EMA prompt responded to within 45 minutes and a completer's bonus of $30 if they have >80% compliance and wore the armband for at least 9 days for ≥10 hours/day.

Eligibility criteria: To be eligible for the study, participants must be female, aged 18-60, have a BMI of 25 to 40 kg/m^2, own a smartphone, and be willing to receive and respond to text message prompts for 14 days at baseline and 12 weeks. Exclusionary criteria include: shift workers, those who do not endorse stress-eating, recent weight loss or current enrollment in a weight loss program, women who are pregnant, those with any medical condition that would limit participation in physical activity, diabetes, or an inability to walk without an assisted device or inability to meet exercise recommendations. Participants with a previous history of heart disease or hypertension will be required to provide physician consent prior to participating in this study. Further, individuals with <80% compliance to the EMA monitoring at baseline or those with poor compliance to wearing the armband will not be eligible to participate.

Treatment conditions:

1. **Exercise condition:** Participants randomized to the exercise condition will participate in a 12-week exercise training program and asked not to alter their dietary habits during this time. The exercise intervention will consist of both supervised and unsupervised exercise sessions. The exercise prescription will start out at 100 minutes/week of moderate-intensity exercise and progress to 200 minutes/week. During the first 4 weeks, they will engage in 2 supervised exercise visits/week in which their heart rate will be monitored by a member of the research staff to ensure that exercise is within the prescribed intensity range. During Weeks 5-12, participants will engage in 1 supervised visit/week. At these supervised exercise visits, heart rate, ratings of perceived exertion and feeling state will be assessed periodically. The remaining exercise will be performed on their own. To help facilitate exercise adherence, participants will be required to have a gym membership and will be reimbursed up to $40/month depending upon the cost of their local gym. Further, 'exercise' participants will be given an armband to wear over the 12-week period during all exercise sessions in order to verify compliance to the exercise protocol. Since the goal of this study is to determine how exercise training influences eating behaviors and other psychological parameters, participants will be incentivized to exercise. They will receive $10 in cash for each week that they meet the exercise goal and a $50 bonus (in the form of a gift card) if they averaged >180 min/week over the 12-week period as verified via the armband. Thus, they can receive a total of $170 for performing the prescribed exercise.

2. **Delayed exercise condition:** Participants randomized to the delayed exercise condition will be asked not to change their exercise or eating habits over the 12-week period and will complete the same assessment measures as the exercise condition. However, following the completion of the 12-week assessment period, participants will be given two options: 1) receive a one-on-one session with an exercise physiologist at our center and receive a written exercise program, or 2) complete the identical exercise protocol as the 'exercise' condition. If participants choose option 2, they will receive the exact program outlined above and also complete additional assessments at 24 weeks (similar to those described for week 12).

Assessment measures:

In-person visit: Height will be assessed at baseline and weight and body composition will be assessed at baseline and 12 weeks. Body composition will be assessed via bioelectrical impedance analysis (RJL Systems Quantum II impedance machine). Participants will be asked to fast for 4 hours, refrain from alcohol for at least 12 hours, and to refrain from strenuous exercise or sauna for 8 hours prior to these measures. As part of these assessment visits, participants will also be given a series of questionnaires (see measures below), be equipped with an armband (used to measure physical activity), and will be instructed on how to respond to the EMA prompts over the 14-day EMA period.

EMA protocol: Participants will be asked to carry their smartphone for 14 days at baseline and 14 days at the end of the intervention. They will report on their stress, mood, hunger, physical activity, overeating episodes, and dietary temptations/lapses as they occur in their natural environment. All entries will be made in response to 5 semi-random prompts delivered throughout the day (between 8:00am and 10:00pm) via text message. Upon receiving the text message, participants will have 45 minutes to click on the link provided and this will direct them to an online questionnaire. Each set of questions will take 3-5 minutes to complete and individuals <80% compliant at baseline will be ineligible to participate in the study.

Sensewear Armband: Participants will wear a Sensewear armband (Body Media, Pittsburgh, PA) for 14 consecutive days (to coincide with the EMA monitoring period) at baseline and 12 weeks. This device is worn on the upper arm and provides valid and reliable estimates of exercise intensity and energy expenditure via a unique combination of sensors (accelerometer, galvanic skin response, heat flux, and skin temperature). Structured exercise bouts (≥10 minutes of activity ≥3 metabolic equivalents) will be identified and total daily energy expenditure will be computed to examine whether these variables influence stress levels or overeating-episodes. Participants in the exercise condition will also be asked to wear this armband during all exercise sessions as these data will be used to confirm participants self-reported physical activity over the 12-week intervention period.

Fitness testing: A graded exercise test (GXT) to 75% of age-predicted maximal heart rate will be conducted at baseline and 12 weeks. Participants will walk on a treadmill at 3.0 mph and the incline of the treadmill will increase every two minutes until the subject's HR reaches 75% of their age-predicted maximum. Time on the treadmill and the estimated MET value upon test completion will be used to assess changes in fitness over time.

Food choice decision-making computer task: Participants will complete the food choice decision making task as part of their 12-week assessment visit. Using the methods employed in Hare and colleagues (2009) each participant will provide health and taste ratings on 150 different food items using a 5-pt scale[1]. Foods include a range of unhealthy (e.g., chips or candy bars) and healthier (e.g., apples or broccoli) items. From these ratings a food rated as neutral in both taste and health will be selected for each individual participant as a reference item for the decision-making portion of the task. Participants then decide for each of the other food items if they would rather eat that target food or the reference item using a 4-pt scale (strong yes, yes, no, strong no) to note the strength of each choice. Special emphasis will be placed on these decisions by informing participants that one trial will be randomly selected and they must eat the food that they chose at the end of the experiment. In this way participants are encouraged to make honest, true-to-life judgments as any one trial could be the one selected. Ratings and decision data will allow us to determine the degree to which participants value health and taste in their decision-making (i.e., the extent to which ratings of food health and tastiness independently correspond to choices).

Questionnaires to be administered at baseline and 12 weeks:

- Three-Factor Eating Questionnaire (TFEQ)

- Eating Self Efficacy Scale (ESES)
- Perceived Stress Scale (PSS)
- Weight Bias Internalization Scale (WBIS)
- Distress Tolerance Scale (DTS)
- Pain Catastrophizing Scale (PCS)
- Barratt Impulsiveness Scale (BIS)
- Modified Trait Food-Cravings Questionnaire (FCQ-T)
- Power of food scale (PFS)
- Bull's Eye II
- Self-regulation Questionnaire for Exercise (SRQ-E)
- Food craving Inventory (FCI)
- Paffenbarger Physical Activity Questionnaire (PPAQ)