PROTOCOL TITLE: Does aberrant decision making prevent success in adolescent behavioral weight loss treatment?

Protocol Version Date: 1/26/2021

INSTRUCTIONS:

1) Protocol Title

Does aberrant decision making prevent success in adolescent behavioral weight loss treatment?

2) IRB Review History

Previously reviewed on 1/22/2021.

3) Objectives

Primary Aim 1: To test the hypothesis that baseline aberrant decision making is associated with weight loss outcomes.

Primary Aim 2: To test the hypothesis that baseline aberrant decision-making is associated with engagement in reward-driven overeating, loss-of-control eating, and rigid dietary restraint during intervention.

Primary Aim 3: To test the hypothesis that the association between baseline aberrant decision-making and subsequent weight loss outcomes is mediated by engagement in reward-driven overeating, loss-of-control eating, and rigid dietary restraint during intervention.

4) Background

Treatments for overweight and obesity in adolescence. Adolescent overweight and obesity (AOB; i.e., a body mass index (BMI) greater than 85th percentile for age, height, and gender) affects 34.5% of adolescents. Over 80% of obese adolescents will become obese adults and experience increased risk of cardiovascular disease, type 2 diabetes, gallbladder disease, and some forms of cancer. Because of contraindications and hesitations to pursue psychopharmacology or bariatric surgery, behavioral interventions are the first-line treatment for AOB. Unfortunately, adolescent outcomes from pediatric behavioral obesity treatments are poor. In fact, the modal weight loss in behavioral interventions is less than a single BMI point, and many participants lose no weight at all. Outcomes in adolescents are worse than those found in younger children and adults. Notably, the vast majority of existing interventions tested in adolescents are designed for younger children, which may preclude an adolescent's success in these interventions. Successful behavioral AOB interventions may require augmentations that address developmental concerns unique to adolescence. For example, research has shown that, in contrast to younger children, many adolescents are making their own food decisions and are thus more likely to engage in problematic eating behaviors during treatment. As a necessary step towards developing specialized interventions for AOB, it is critical to understand the underlying mechanisms of continued engagement in problematic eating behaviors during AOB interventions.

Problematic eating behaviors. Three types of problematic eating behaviors are strongly linked (cross-sectionally and longitudinally) with AOB. First, reward-driven overeating (i.e., frequently eating energy-dense foods) results in excess calorie intake, which, in turn, produces adiposity during childhood and adolescence. Second, loss-of-control eating

(LOC; the experience of not being able to stop eating once started) is an exceptionally strong predictor of excess weight gain, i.e., an additional 2.4kg per year compared to peers without LOC. Third, rigid dietary restriction involves skipping meals and cutting out food groups for the purposes of weight regulation, but instead results in intense feelings of deprivation. As a result, rigid dietary restriction has the paradoxical effect of calorie overconsumption, excess weight gain, and poor outcomes from pediatric obesity treatment. Taken together, findings indicate that elucidating the drivers of these three problematic eating behaviors is critical to improving AOB treatment outcomes.

Aberrant decision-making as a driver of problematic eating behaviors. An aberrant decision-making framework represents an attractive paradigm for understanding the above-described problematic eating behaviors, especially given that they all run counter to adolescents' intentions and well-being. There are several aberrant decision-making processes endemic to the adolescent developmental period. Three of these processes in particular appear to be directly linked to the three problematic eating behaviors described above. To the extent that aberrant decision-making produces problematic eating behavior, aberrant decision-making can also be hypothesized to predict poor weight loss outcomes. Below, we describe the three aberrant decision-making processes and their links to problematic eating behavior.

- *Increased delay discounting*. Delay discounting refers to the tendency to discount greater, later rewards in favor of smaller, sooner rewards. A combination of greater sensitivity to reward and slow development of self-regulatory neural processes contributes to especially high discounting rates in some adolescents. Relatively higher discounting rates may produce reward-driven eating, i.e., frequent consumption of energy-dense foods (e.g., high-fat, high sugar foods), while discounting the future reward (e.g., weight loss) that would be derived from forgoing immediate gratification. Indeed, a recent meta-analysis concluded that higher discounting rates were strongly cross-sectionally linked with AOB. Although behavioral weight loss programs discourage consumption of energy-dense foods, psychological strategies for how to prioritize long-term over short-term rewards are not provided. Thus, delay discounting likely contributes to continued reward-driven eating during treatment. However, no studies have tested whether delay discounting predicts reward-driven overeating (and its effect on weight) during AOB treatment.
- *Affect-driven impulsivity.* Affect-driven impulsivity refers to a tendency to choose maladaptive behaviors geared towards the immediate cessation of a negative affective state, despite negative consequences. Affect-driven impulsivity likely drives continued LOC eating during treatment, precluding successful weight loss. Affect-driven impulsivity is a cross-sectional predictor of AOB, but it may be a particularly strong driver of LOC eating because compulsive eating serves the function of reducing distress. Although no studies have compared adolescents with and without LOC on affect-driven impulsivity, adolescents with LOC eating demonstrate overall higher levels of emotional reactivity and emotional eating. LOC eating resulting from affect-driven impulsivity may continue to occur during

treatment because little treatment content focuses on skills for tolerating negative affect. Dr. Manasse's work demonstrates that increased affect-driven impulsivity predicts poor outcomes from adult binge eating treatment. However, no studies have examined whether affect-driven impulsivity predicts (1) engagement in LOC during treatment or (2) poor AOB treatment outcomes.

- *Perseverative decision-making*. Perseverative decision-making is characterized by weakened ability to stop engagement in habitual behaviors despite changing contingencies. Highly perseverative decision-making may contribute to repeated engagement in rigid dietary restriction (i.e., setting rigid calorie goals, cutting out specific foods) that increase deprivation. This deprivation, in turn, leads to episodes of overeating that preclude successful caloric restriction. Those who show highly perseverative decision-making continue engaging in this rigid dietary restriction behavior despite the fact that it ultimately delivers the opposite of its intended effect. Indeed, perseverative decision-making and rigid dieting are associated with the presence of LOC eating, and perseveration is cross-sectionally associated with obesity in adolescence. Despite the established links between perseverative decision-making with unhealthy dieting and excess weight, no studies have examined whether perseverative decision-making underlies continued engagement in problematic dietary restriction during treatment and predicts poor outcomes.

The current study. To inform the development of tailored intervention approaches, the current study, funded by the National Institutes of Health, aims to elucidate the specific aberrant decision-making processes associated with three problematic eating behaviors and weight loss outcomes. Results from the study will provide specific direction for what components (e.g., strategies for tolerating emotional distress or promoting flexible thinking) should comprise a future decision-making intervention for AOB and for whom (e.g., those with LOC, those who engage in problematic restriction) certain components would be most relevant. Given that LOC eating is a robust predictor of excess weight gain but only 20-30% of those with AOB endorse LOC eating, we will oversample individuals with clinically significant LOC, i.e., we will recruit a total of 80 adolescents (ages 14-18) with overweight/obesity, half of whom (n=40) endorse clinically significant (i.e., at least once weekly) LOC eating and the other half of whom (n=40) endorse subclinical LOC or no LOC. All participants will receive a 16-week group-based, remotely delivered behavioral weight loss intervention and complete a 6-month follow-up. Decision-making measures will be administered at baseline. Problematic eating behaviors and weight will be assessed at all time points.

5) Inclusion and Exclusion Criteria.

The study will recruit 80 adolescent participants with overweight/obesity, half of whom (n=40) will endorse clinically significant (i.e., at least once weekly over the past 12 weeks) LOC eating and the other half of whom (n=40) will endorse subclinical LOC or no LOC. Information needed to determine whether participant meets eligibility requirements will be obtained during an initial phone-screen (see attached) and during a clinic visit to be conducted in person or by videoconference. If participants meet the

inclusion criteria based on the phone screening, they will be scheduled for an intake interview and initial clinical assessment, which will occur either in person or by videoconference. Participants will be included if they meet the following criteria:

Adolescent & Young Adult Inclusion & Exclusion Criteria

Inclusion Criteria:

1) Are between 14 and 18 years of age
2) Have a BMI between the 85th and 99th percentiles for sex and age as determined by the CDC growth charts
3) Are currently in high school and living at home with a parent or guardian
4) Have at least one parent or guardian who is willing to participate in the study
5) Are willing to complete baseline assessment tasks
6) Have a smartphone, are willing to download an app to track food intake and complete surveys on the phone for two seven-day periods throughout the course of the study, and are willing to wear a fitness tracker during these same two week-long periods
7) Are located in the US and wiling/able to participate in remote intervention and assessments

Exclusion Criteria:

1) Acute suicide risk
2) Inability to engage in physical activity (defined as walking two city blocks without stopping)
3) Have diabetes or a history of bariatric surgery
4) Current medical or psychiatric condition that may pose a risk to the participant during intervention, cause a change in weight, or limit ability to comply with the program (i.e., bulimia nervosa, substance abuse disorder, psychosis, bipolar I disorder, and/or any condition prohibiting physical activity)
5) Are pregnant or planning to become pregnant in the next 2 years
6) Are taking oral contraceptives
7) Recently began or changed the dose of a medication that can cause significant change in weight
8) Have experienced weight loss ≥ 5% in the previous 6 months
9) Are planning to begin in the next 16 months, or are currently participating in, another weight loss treatment or psychotherapy for binge eating and/or weight loss
10) Are engaging in compensatory vomiting, other severe compensatory behaviors, or more than 12 of any compensatory behaviors in the previous 3 months

11) Are currently taking medication (e.g., Contrave, Alli, etc.) which is specifically intended for weight loss

After it is confirmed that adolescent participants meet the above criteria, they will be included in the LOC group (n=40) if they meet this additional criterion:

Inclusion Criteria:

1) Engage in at least one loss-of-control eating episode per week for the previous 12 weeks, as determined by the EDE interview

Participants who do not meet this additional criterion will be included in the non-LOC group (n=40).

Parent Inclusion and Exclusion Criteria

Inclusion Criteria:

1) Are able to speak, write, and understand English
2) Are willing to participate in the study, attend all required assessments, and complete surveys and computer-based tasks

Exclusion Criteria: None.

☐ *Adults unable to consent*
☒ *Individuals who are not yet adults (infants, children, teenagers)*
☐ *Pregnant women*
☐ *Prisoners*
☐ *Not Applicable*

6) Study Timelines

The study is expected to begin recruitment in January of 2021. An individual subject's participation in the study will last 16 months (16 weeks of intervention and a twelve-month follow-up period). In total, the project is anticipated to run for approximately 3.5 years, encompassing all study tasks from recruitment to data analysis. Of those 3.5 years, approximately 3 years are expected to enroll all study subjects. The investigators aim to complete the primary analyses for this study by April 2024.

7) Study Endpoints

The study will begin in January 2021, and we plan on having all data collected by November 2024. Data analysis and write up will occur during January-April 2025.

8) Procedures or Methods Involved

Screening and clinic visit

Graduate students and trained research coordinators will pre-screen parents/legal guardian of potential participants by phone to assess eligibility (e.g., frequency of binge

eating). If participants are ineligible for the current study, they will be offered the opportunity to be screened further for other currently ongoing WELL Center studies, which they may join if they meet a given study's criteria. Participants will also be given the option to have their screening information saved in a secure database (IRB # 3795) so that the WELL Center may contact them about future study opportunities; if they refuse this option, their screening data will be destroyed. Finally, ineligible participants will also be offered a list of referrals for treatment providers.

Once eligibility is determined, participants will then be scheduled for their clinic visit, which will be conducted by trained master's-level graduate students and research coordinators. Final eligibility will be assessed using the Eating Disorders Examination (EDE) and will be audio recorded. At the beginning of the assessment, informed consent and assent procedures will take place for all parents and participants. If participants or parents request a copy of the phone screen or consent/assent ahead of their screen or visit, a copy will be emailed. If a participant is 18 years old, he/she may consent for him/herself, but a parent/legal guardian must agree to also participate in the treatment and study. When available, consent will be obtained from both parents/guardians. Height and weight of the participant will be recorded. After eligibility is confirmed, participants be sent the self-report measures to be completed at their convenience between the clinic visit and baseline assessment. All other baseline measures will be completed during the baseline assessment.

Assessment procedure

Subseuent assessments will occur at baseline (pre-intervention), mid-intervention (after 6 weeks of intervention), post-intervention (16 weeks after intervention begins), 6-month follow up (40 weeks after intervention begins), and 12-month follow-up (64 weeks after intervention begins). All assessments will take place remotely via HIPAA-compliant Zoom videoconferencing software. The measure of binge eating (EDE) will be conducted by trained blind-raters who will be trained until they reach 100% agreement on diagnosis and acceptable reliability (> 0.80) on EDE scoring.

Ecological Momentary Assessment

As a way of tracking participant's eating behaviors, we make use of Ecological Momentary Assessment (EMA), an assessment technique which reduces recall biases by repeatedly assessing behaviors in their real-world context. Participants will be asked to fill out self-initiated reports whenever they engage in disordered eating behaviors and in response to prompts throughout the day. Data will be collected through an online survey (that they can fill out either on their phone or computer). These questions will be similar in structure and content to questions used in several other IRB-approved protocols, including Protocol 16030043 (PI Dr. Juarascio).

These data will be collected during two periods: 1) at baseline (one week before intervention), and 2) at post-intervention (during the 17th week, the first week after intervention). Participants will be shown how to complete the EMA surveys.

FitBit Charge 4

Participants will be given a *FitBit Charge 4*, a consumer-grade wrist-worn activity tracker utilized in numerous other studies, during the periods of EMA assessment (outlined above). The FitBit will be used to track physical activity (PA) and sleep. PA will be measured in minutes per week of moderate-to-vigorous physical activity (MVPA). Previous studies have demonstrated that adherence to a wrist-worn Fitbit (which can be worn continuously) is superior to hip-worn accelerometers (which must be put on each morning). The Fitbit is sufficiently well-validated for steps and minutes of PA to support its role in this study and has demonstrated high inter-device reliability (crucial for obtaining accurate within-person change in PA).

Measures: Adolescents

Note, all of the below measures have been well-validated and show strong psychometric properties in clinical populations and in children and adolescents.

Measured/Rater-Administered:

- **Eating Disorder Examination (EDE)** is a widely utilized, semi-structured interview for the assessment of eating disorder symptoms. The EDE interview will be audio recorded and will be used to confirm patient eligibility. Participants will undergo this interview at their clinic visit and post-treatment. In the case of remote assessments, this examination will still be administered.
- **Eating Disorder Examination – Binge Module** is a shortened version of the EDE which uses only the binge eating module of the questionnaire. This module has been used in previous protocols by our group (e.g., 1906007227). This interview will be audio recorded. Participants will undergo this interview at mid-treatment and at each follow-up assessment.
- **Body Mass Index (BMI)** and **Tri-Ponderal Mass Index (TMI).** Height (via stadiometer) and weight (via medical-grade, digital scale) will be assessed at each assessment point. These data will be used to calculate BMI and TMI. In the case of remote assessments, participants will weigh themselves at home using digital scales and take their heights using yard sticks or measuring tape.
- **Body fat percentage** will be assessed using air-displacement plethysmography with a *BodPod*. The BodPod uses the principles of whole-body densitometry to determine body composition. This technique relies on a mass measurement from a scale and a volume measurement inside the BodPod chamber. Once body density (Density = Mass/Volume) is determined, the BodPod measures Thoracic Gas Volume and then uses known densitometric equations to calculate percent fat and fat-free mass. This measurement will be taken at each assessment point. In the case of remote assessments, this measurement will not be collected.

Behavioral tasks:

- **Delay Discounting Task (DDT).** This is a computerized task that asks participants to choose between hypothetical monetary choices provided at different time intervals. Because this is a computerized task, a copy of the measure has not been included. DDTs have been used in binge eating samples to measure choice impulsivity. Participants will complete this task

at baseline only. In the case of remote assessments, this task will still be administered. Participants will also complete a shortened version of this task twice daily during EMA periods.

- **Stop-signal inhibitory control task (SST).** This is a computer-based, well-validated behavioral measure of impulsivity. The task measures one's ability to cancel an initiated behavioral response. The outcome measure used for the SST is the stop signal reaction time (SSRT), which is calculated by subtracting the average reaction time on normal trials from the average stop signal delay. SSRT scores will capture ability to withhold responses in the context of negative affect. Participants will complete this task at baseline only. In the case of remote assessments, this task will still be administered. Because this is a computerized task, a copy of the measure has not been included.
- **Go/No-Go Task (GNG).** This task involves repeated trials in which participants respond to food-related or non-food-related images by pressing the designated key on the keyboard. Participants will complete a brief version of this task twice daily during EMA periods.
- **Wisconsin Card Sort Task (WCST)** is a widely-used and validated paradigm assessing perseverative decision-making. The WCST asks participants to sort cards by a rule (e.g., color, shape, number of objects) derived by trial-and-error and feedback. The rules change throughout the task; number of perseverative errors (i.e., trials in which they used an old rule after given the feedback that the choice was incorrect) will be used as the outcome measure. Participants will complete this task at baseline only. In the case of remote assessments, this task will still be administered. Because this is a computerized task, a copy of the measure has not been included.
- **Food-specific Cued Color-Shape Switching Task (FCCST).** Food-specific cognitive flexibility will be assessed with a novel food-specific FCCSST that is identical to the CCSST (see below), except with respect to the stimuli. Rather than using plain figures as stimuli, the food-specific CCSST will present images of food that are primarily a single color and fit a triangular or round shape. Two of the stimuli will be unhealthy foods (a yellow triangular wedge of cheese and a red round donut) and the remaining two will be healthy foods (a red triangular watermelon slice and a yellow round lemon slice). Participants will be cued to alternate between reporting whether a food presented is (1) red or yellow or (2) a circle or triangle. This paradigm has been approved for use in previous protocols (e.g., #2003007690 and #2004007769). Participants will complete this task at baseline only. In the case of remote assessments, this task will still be administered. Because this is a computerized task, a copy of the measure has not been included.

- **Cued Color-Shape Switching Task (CCSST).** General cognitive flexibility will be assessed with the CCSST. This general task-switching paradigm assesses cognitive flexibility by cuing participants to alternate between reporting whether a shape presented is (1) red or green and (2) a circle or triangle. The cue for the color task is a color gradient, while the cue for the shape task is a row of black shapes. This paradigm has been approved for use in previous protocols (e.g., #2003007690 and #2004007769). Participants will complete this task at baseline only. In the case of remote assessments, this task will still be administered. Because this is a computerized task, a copy of the measure has not been included.
- **Ideal Portion Size Task** is a validated, computer-based measure designed to predict in laboratory meal size consumption. In this task, participants are asked to select a photograph of their ideal portion size of three typical American meals. Each meal has been photographed 51 times, with the amount of food in each picture increased systematically. Participants will complete this task at each assessment point. In the case of remote assessments, this task will still be administered. Because this is a computerized task, a copy of the measure has not been included.

Self-Report Measures. All self-report measures will be administered regardless of whether assessments occur remotely or in person.

- **Adverse Childhood Experiences Questionnaire (ACEs)** will be used to measure adverse childhood experiences (e.g., witnessing or experiencing abuse or neglect, violence, substance abuse, divorce) with the ACEs as higher ACEs may have an impact on decision-making and problematic eating. These data will be collected at baseline only to help control for potential confounds.
- **Sexual Maturation Scale** will be used to measure pubertal stage, in order to control for any effects of pubertal status on results. These data will be collected at baseline only to help control for potential confounds.
- **Demographics Questionnaire (DQ).** The Demographics Questionnaire will assess information such as age, sex, and ethnicity. This questionnaire will be administered at baseline only.
- **Dieting and Weight History Questionnaire (DWHQ).** The DWHQ evaluates weight suppression, weight history, current and previous dieting history. This questionnaire will be administered at baseline only.
- **Beck Depression Inventory-II** (BDI-II). Measures depression symptomatology over the past 2 weeks. This questionnaire will be administered at each assessment point.
- **UPPS Impulsive Behavior Scale – Negative Urgency Subscale**. The UPPS measures impulsive behavior based on a four-factor personality model assessing Urgency, Premeditation, Perseverance, and Sensation Seeking. Only the Negative Urgency subscale will be used in this study. This questionnaire will be administered at baseline only.

- **Loss of Control Over Eating Scale.** This survey measures LOC dimensionally rather than dichotomously, like the EDE does. This questionnaire will be administered at each assessment point.
- **GI Symptoms Questionnaire.** This 10-item questionnaire assesses gastrointestinal symptoms and the severity of symptoms experienced.
- **EDFLIX.** The EDFLIX is a well-validated measure examining behavioral flexibility, both generally and with regard to eating disorder symptoms.
- **Family Meal Environment.** The FME assesses family meal environment in three specific domains: priority of family meals, atmosphere during family meals, and structure of family meals. It will be completed at all assessment timepoints.
- **Expressed Emotion.** This brief questionnaire assesses caregiver expressed emotion (both positive and negative) towards their child. It will be used to evaluate both the teen's perception of their parents' expressed emotion towards them, as well as the parents' perception of their own expressed emotion towards their child. It will be completed at all assessment timepoints.
- **Power of Food Scale (PFS).** The PFS measures valuation of food as a rewarding or motivating stimulus. This questionnaire will be administered at each assessment point.
- **Three Factor Eating Questionnaire (TFEQ).** The TFEQ evaluates dietary restraint, disinhibition and hunger. This questionnaire will be administered at each assessment point.
- **MacArthur Scale of Subjective Social Status – Youth Version**. This is a well-validated adaptation of a widely used measure of subjective social status. Participants are asked to rate their family's social status in society and their personal social status in school. This questionnaire will be administered at baseline only.
- **60-Minute Moderate to Vigorous Physical Activity Screening Measure**. This well-validated measure assesses the number of days in the past week and in a usual week in which participants are physically active for >= 60 minutes/day. This questionnaire will be administered at each assessment point.
- **Brief social cohesion measure.** This validated, 4-item measure assesses different aspects of social cohesion in one's neighborhood. This questionnaire will be administered at baseline only.

Measures: Parents

Note, all of the below measures have been well-validated and show strong psychometric properties in clinical populations.

Measured/Rater-Administered:

- **Body Mass Index (BMI)**. Height (via stadiometer) and weight (via medical-grade, digital scale) will be assessed at each assessment point. These data will be used to calculate BMI. In the case of remote assessments, participants will weigh themselves at home using digital scales and take their heights using yard sticks or measuring tape.

Self-Report Measures. All self-report measures will be administered regardless of whether assessments occur remotely or in person.

- **Socioeconomic status (SES)** will be assessed by obtaining parent report of household members' highest educational attainment because it is the most stable indicator of SES and is more linked to obesity than family income. These data will be collected at baseline only to help control for potential confounds.
- **Demographics Questionnaire (DQ).** The Demographics Questionnaire will assess information such as age, sex, and ethnicity. This questionnaire will be administered at baseline only.
- **Beck Depression Inventory-II** (BDI-II). Measures depression symptomatology over the past 2 weeks. This questionnaire will be administered at each assessment point.
- **Eating Disorders Examination – Questionnaire** (EDE-Q)**.** This self-report adaptation of the EDE is well-validated and widely used. This questionnaire will be administered at each assessment point.
- **Family Meal Environment.** The FME assesses family meal environment in three specific domains: priority of family meals, atmosphere during family meals, and structure of family meals. It will be completed at all assessment timepoints.
- **Expressed Emotion.** This brief questionnaire assesses caregiver expressed emotion (both positive and negative) towards their child. It will be used to evaluate both the teen's perception of their parents' expressed emotion towards them, as well as the parents' perception of their own expressed emotion towards their child. It will be completed at all assessment timepoints.

Below are assessment schedules for children and their parents.

Child

Measures	**Clinic Visit (2 hours)**	**Baseline (3 hours)**	**Mid-treatment (2 hours)**	**Post-treatment (3 hours)**	**6 month follow-up (1 hour)**	**12 month follow up (1 hour)**
EDE	X			X		
EDE (Binge module only)			X		X	X
Height & weight	X		X	X	X	X
DDT		X				
Food-specific SST		X				
FCCSST		X				
CCSST		X				
WCST		X				
Ideal Portion Size Task		X	X	X	X	X
Adverse Childhood Experiences Questionnaire		X				
Sexual Maturation Scale		X				
Demographics Questionnaire		X				
TFEQ		X	X	X	X	X
PFS		X	X	X	X	X
BDI-II		X	X	X	X	X
UPPS (Neg. Urg. scale only)		X				
LOC Scale		X	X	X	X	X
MacArthur Scale of Subjective Social Status – Youth Version		X				
EDFLIX		X		X	X	
GI Symptoms Questionnaire		X		X	X	
Brief social cohesion measure		X				
60-minute MVPA screening measure		X	X	X	X	X
Family Meal Environment		X	X	X	X	X

Expressed Emotion		X	X	X	X	X

Parent

Measures	**Baseline (1.5 hours)**	**Mid-treatment (1 hour)**	**Post-treatment (1 hour)**	**6-month follow-up (1 hour)**	**12-month follow-up (1 hour)**
Height and weight	X	X	X	X	X
Socioeconomic Status	X				
Demographics Questionnaire	X				
Family Meal Environment	X	X	X	X	X
Expressed Emotion	X	X	X	X	X
EDE-Q	X	X	X	X	X
DWHQ	X				
BDI-II	X	X	X	X	X

Intervention

This intervention is designed to facilitate induction and maintenance of a 5-10% weight loss, which is sufficient to produce clinically meaningful health benefits, and engagement in up to 250 min/wk of MVPA, which has health benefits independent of weight and which is the standard recommendation in lifestyle modification programs for adolescents. The intervention protocol will be adapted for group-based weekly weight loss coaching from manuals this team has used in previous weight loss studies, which were themselves adapted from the Look AHEAD and the Diabetes Prevention Program protocols. The intervention will consist of group-based, weekly or biweekly weight loss coaching (75 minutes per session), which will occur via HIPAA-compliant Zoom videoconferencing software. Participants will also be asked to download and utilize the smartphone app, FitBit, to track eating behavior. Participants will be given a non-identifiable login for the app. Clinicians will be experts in lifestyle modification who have graduate degrees in psychology or a related field. Participants will be given prescriptions for reducing calorie intake (using a balanced deficit diet) and gradually increasing PA. Participants will learn to set goals for diet, weight, and PA and to use stimulus control and problem-solving skills.

9) Data Banking

The final dataset will include anthropometric data (i.e., height, weight, waist circumference), demographic, behavioral data (e.g., dietary intake), and neurocognition data. This dataset will be stripped of identifying information of subjects, and no names or identifying information will be associated or published with any reports. We will make the data and associated documentation available to members of the research team only

under a data-sharing agreement that requires: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing data using appropriate computer technology (i.e., through a secure sever); and (3) a commitment to destroying or returning the data after analyses are completed. The information provided to users will not be used for commercial purposes and will not be redistributed to third parties. Only if required by law will subject identifiable data be disclosed to persons or organizations not directly involved in this research. With the exception of release of information required by law, no subject identifiable information will be released without the subject's explicit permission.

10) Data Management

All electronic files will be stored on a research lab computer in an encrypted password protected directory that can only be accessed by specific, trained users. Data is de-identified and will not contain PHI, and is stored on Redcap, an encrypted backend server (a unique subject identification number will be used in place of participant names to identify input from the app). Our server utilizes industry-standard encryption techniques (e.g., secure sockets layer; SSL) to facilitate secure data transfer from subject device to study repository). For data analysis purpose, data from our server will be downloaded to research lab computers. All data will be stored on research lab computers with encrypted storage in password-protected files. Access to subject data will be limited to project staff, on an as-needed basis and as determined by the PI.

All paper surveys (if any) will be labeled with non-identifiable information and stored in a locked filing cabinet in a limited access, password protected office at the Drexel University Laboratory for Innovations in Health-Related Behavior Change. All data will be erased or shredded in the standard 3 years from the date of study completion.

Participant confidentiality. As per policy of the IRB, all participant data, including the fact of their participation, will be treated confidentially and will be safeguarded according to the practices described above. To ensure participant confidentiality, training will be provided to all staff regarding responsibilities for maintaining and protecting participant confidentiality. Unique identifiers will be used to identify participants in the database, and all written measures and transcripts will be solely identified with a participant identifier. All data will be housed in locked files to which only the study staff will have access. The master list linking participant names and unique identifiers will be stored in a locked file cabinet in a location physically distant from the data. Laptops used for data collection will be password protected and stored in locked file cabinets when not in use. Baseline and follow-up measures will be linked by the unique identifiers employed (which will be stored in the locked files). Participant consent forms will stipulate the research activities and intervention services they can anticipate and the protections they will receive. Study findings will

make use of aggregate data only and no publication or presentation will involve any use of individual or personalized information.

11) Provisions to Monitor the Data to Ensure the Safety of Subjects

Participants' medical histories will be taken into account during screening, and no participants with conditions that are known to pose a risk during weight loss or physical activity will be enrolled. Of note, the dietary and physical activity prescriptions, as well as provided weight loss goals, are fully consistent with guidelines for the general public published by the Center for Disease Control, American College of Sports Medicine, NHLBI and NIDDK. As such, risk is minimal. Even so, staff will respond proactively (including offering medical referrals as needed) to any participant report of medical changes, or discomfort, soreness, or injury that may be related to the program. In order to minimize the risks of medical complications related to overly-rapid weight loss (in particular, gallstones), all participants will be instructed to achieve weight loss in a gradual fashion (0.5-1.0 kg per week) in order to give the body sufficient time to accommodate changes. If a patient shows signs of high risk behavior (e.g., overly-rapid weight loss), he or she will be provided additional individual counseling by the interventionists, and referred to his/her physician, as needed; study staff will also relay data directly to the participant's primary care physician if necessary. Participants taking any medication will be instructed to carefully coordinate the oversight of these medications with their primary care physicians to make any necessary adjustments of dosage necessary as weight loss occurs.

Physical activity will increase gradually. Participants will be trained in measuring exercise intensity, in order to monitor activity intensity and calibrate it accordingly. Brisk walking will be recommended as the activity of choice because of its safety, low cost, and easy access. The importance of consistency will be emphasized, and participants will be cautioned against abrupt increases in exercise duration or intensity. Protection against risks related to physical activity is enhanced by limiting participation to those without overt contraindications to 250 min/week of MVPA (e.g., likelihood of aggravation to existing injury). Participants will be taught the U.S. Department of Health and Human Services (USDHHS) Physical Activity Guidelines for Americans and in particular guidelines for increasing PA for inactive people and those with low levels of physical activity. These guidelines include:

- Instructions to start with relatively light- and/or moderate-intensity aerobic activity, and information about the types of activities that are unsafe (e.g., shoveling snow or running)
- Instructions on calibrating and increasing the duration and frequency of moderate-intensity activity
- Instructions on gauging the safety of the relative size of increases in duration of physical activity each week
- Suggestions for exercise that is least likely to result in musculo-sketelal injury and cardiac events

Several precautions will be taken to guard against psychological risks to participants. A methodical process of intervention development will be carried out to ensure that participant needs are met in a sensitive and caring way. In addition, an automated warning will be generated for the research coordinator if a participant completes an assessment and levels of depression exceed preestablished thresholds. Similarly, coaches will notify research coordinators if they become concerned about a participant's mental health. The research coordinator will then arrange a clinical evaluation of the participant by Dr. Manasse, and the necessary precautions will be taken to ensure safety or medical attention as appropriate. These steps might include additional assessment, referral to treatment, removal from the study or referral to a higher level of care, and/or hospitalization. All coaches will have had prior training and experience delivering lifestyle modification. In addition, coaches will receive specialized training in the delivery of the intervention programs, in particular how to monitor, respond to, and prevent participant feelings of shame or embarrassment. Training will be conducted by Drs. Manasse and Forman.

Consistent with mandated reporting laws, if any reportable events (e.g., physical abuse) that have yet to be reported are discovered (e.g., via the Adverse Childhood Experiences questionnaire), we will report it to the appropriate authorities (i.e., the Department of Human Services).

12) Withdrawal of Subjects

Participants will be withdrawn from the study if they no longer meet the study criteria and/or they experience any acute life-threatening incident, hospitalization, suicidal or homicidal ideation, or serious self-harm behavior. If termination is found necessary, the participant will be contacted by the project coordinator immediately and the necessary precautions will be taken to ensure safety or medical attention as appropriate. The participant will then be provided with referrals to other programs or studies if applicable and the data will be destroyed/barred from use.

13) Risks to Subjects

The procedures and intervention proposed in this project pose few known risks to the subjects' physical or psychological well-being. Weight loss and increases in physical

activity are recommended for individuals who are overweight or obese. Intervention provided to subjects should be safer than that offered by commercial organizations or self-guided weight loss attempts because of our screening and monitoring. However, some risk remains. One risk of the program is that as participants lose weight, they may need to take less of any medications they are on or they may develop gallstones. Participants may injure themselves when engaging in physical activity. Psychological risks include reduced self-esteem in persons who fail to lose weight or regain weight or a sense of shame if not meeting program goals. Risks to privacy and/or confidentiality include the collection of identifiable information. Even though the final dataset will be stripped of identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of participants.

Alternative treatment options include commercial organizations or self-guided weight loss attempts. Potential benefits of such treatments include greater flexibility and autonomy (e.g., in self-guided programs). Risks include lower than optimal weight loss, higher cost (e.g., in commercial programs). The proposed intervention approach to be provided to subjects should be safer than that offered by commercial organizations or self-guided weight loss attempts because of our screening and monitoring. Furthermore, the proposed intervention may improve weight loss outcomes compared to the amount of weight loss achieved in commercial or self-guided programs.

Some participants undergoing study may become uncomfortable or anxious. Participants will be asked to answer questions about their mood and eating behaviors, which some patients might find distressful. Participants will also be asked to provide information regarding a number of significant health behaviors during the assessments. However, all assessment instruments have been used in past research without incidence, and participants will be informed that they can skip questions or discontinue participation at any time.

Participants will continue in their current medical treatment at time of enrollment. Medical status will be closely monitored throughout the participants' participation in the study. Concurrent psychotherapy will not be permitted during the study as this could confound data. Pharmacological management will be permitted for psychiatric co-morbidities. Any prescribed medications or dosage changes will be carefully tracked through the study.

Protection against risk. Risk to participants who follow the program's guidelines is very low. Furthermore, because the study is to be conducted near several major medical centers, resources to manage risk are readily available. Participants may easily be referred for additional medical assessment and other clinicians are available for consultation.

We expect most participants to show no change in their disordered eating symptoms during their participation in the study. If a worsening of symptoms is identified, we will follow the protocol described below to ensure the safety of participants. This protocol is based on those used in our team's current NIH funded trials for disordered

eating. If an assessor or coach identifies worsening binge eating symptoms or compensatory behaviors (e.g. self-induced vomiting, laxative use, diuretic use) or compulsive exercise behaviors (either through participant report or through self-monitoring records on the EMA app), the research coordinator will conduct a comprehensive assessment of disordered eating symptoms. If the increases in disordered eating symptoms are determined to be transient, mild, and unlikely to result in adverse health consequences, efforts will be made to keep the participant enrolled in the current study and treatment condition consistent suggestions will be made to address current symptoms.

To ensure participant confidentiality, training will be provided to all staff regarding responsibilities for maintaining and protecting participant confidentiality. Unique identifiers will be used to identify participants in the database, and all written measures and transcripts will be solely identified with a participant identifier. All data will be housed in locked files to which only the study staff will have access. The master list linking participant names and unique identifiers will be stored in a locked file cabinet in a location physically distant from the data. Laptops used for data collection will be password protected and stored in locked file cabinets when not in use. Measures across assessment points will be linked by the unique identifiers employed (which will be stored in the locked files). Participant consent forms will stipulate the research activities and intervention services they can anticipate and the protections they will receive. Study findings will make use of aggregate data only and no publication or presentation will involve any use of individual or personalized information.

14) Potential Benefits to Subjects

In comparison to the minimal risks, the health benefits expected from participation are large. The behavioral changes that are expected for participants are known to promote improved quality of life and positive health outcomes. Participants in lifestyle modification programs typically report that mood and quality of life also improve during the course of the program.

Conditions related to obesity and physical inactivity are among the leading causes of preventable death in the United States. Little is known regarding the ways in which treatments can be improved to promote greater weight loss and weight loss maintenance. The results of this study may contribute to the development of effective programs that are widely disseminable. Further, the findings from this study are likely to inform future interventions in health behavior change, including the ways in which future interventions can be best targeted to impact relevant psychological factors and produce positive intervention outcomes. The potential benefits to individuals, both to those participating in the study and those with related health risks, as well as to the

field of behavioral medicine, are numerous and valuable, outweighing the relatively minimal potential for risk.

15) Vulnerable Populations

Participants will be between the ages of 14-18. Extra precautions will be taken to ensure the safety of the adolescents. Any imminent safety risks to the child will be immediately reported to the parents or relevant authorities. All of the intervention is provided with appropriate appreciation of developmental stage. Participants and parents will be aware of the risks and benefits of participation. Should the parent or child become concerned, the study supervisor (Dr. Manasse) will work to resolve any concerns or withdraw participants from the study. These protocols are similar to those previously used in trials led by Dr. Manasse (ID #1809006646). Dr. Manasse will also work closely with a team of experts in both behavioral weight loss interventions and adolescent behavioral health while she leads the present study.

16) Multi-Site Research

Does not apply

17) Community-Based Participatory Research

Does not apply

18) Sharing of Results with Subjects

Participants will have access to their own personal survey and interview results upon request; however, researchers will not share data with each participant as part of study protocol. If participant requests their data, they will be provided with a password protected Excel file with their own responses. A password will be sent in a separate email to ensure protection of data.

19) Setting

Participants will be recruited from across the United States. Study activities (including data analysis and storage) will occur in the Center for Weight, Eating, and Lifestyle Sciences (WELL Center) clinical offices located at 3201 Chestnut St., Stratton Hall, on the University City Campus or remotely via HIPAA-compliant Zoom software. The intervention and all assessments will occur remotely via HIPAA-compliant Zoom software.

Resources Available:

Research and support staff. All co-investigators and graduate students will be able to dedicate 10 hours a week to the project. Access to ample support staff (general administration, ordering of equipment and supplies, etc.) will be readily available due to several other studies being conducted in the lab.

Center for Weight, Eating, and Lifestyle Sciences (WELL Center). Dr. Manasse, the PI of the current project, is an expert in the area of the treatment for eating

disorders and weight loss. The lab has several NIH-funded research grants related to eating behavior and weight loss.

Department of Psychology. The Department of Psychology is actively engaged in research initiatives to advance the science and practice of psychology. The faculty is highly collaborative, frequently cooperating on research projects, co-mentoring doctoral students, and providing consultation to one another as needed.

Laboratory Space. Clinical resources are available in the Department of Psychology, including individual faculty offices and treatment rooms for therapy sessions and assessments. Additionally, a reception and waiting area are available for participants.

Computing Facilities. At present, all personnel have desktop computers with broadband Internet connections and necessary word processing and statistical software. The system is protected by firewalls and password protection for security of sensitive data.

Independent Evaluator Training, Supervision, and Integrity. Outcome assessments will be conducted by independent evaluators (IEs). IEs will be highly trained and closely supervised clinical psychology doctoral students. IEs will be trained until they reach 100% agreement on eating disorder symptomatology and acceptable reliability (> .80) on EDE scoring. Assessments will be audio-recorded for review. The identity of participants will not be discussed in order to prevent the possibility of this information influencing feedback and rating decisions. If reliability falls < .80, retraining procedures will be implemented. If this is insufficient, the IE will be replaced. Five randomly selected tapes will be reviewed to compute reliability statistics for diagnoses and ratings.

20) Prior Approvals

Does not apply

21) Recruitment Methods

Recruitment will begin in January 2021 and continue until recruitment goals are met. Participants will be recruited through advertisements via flyering throughout the greater Philadelphia area, Bucks, Montgomery, and Chester counties in Pennsylvania and Camden and Gloucester counties in New Jersey. The WELL Center website will also include information about the study (see web recruitment text). Participants will also be recruited through existing clinical networks by informing them about the study via flyering and through community announcements. As such, we will mail the study recruitment flyers (including study summary, target population, opportunity for free intervention and a link to Drexel WELL Center website) to the local health care networks that provide eating disorder and weight loss services to alert them of the study. Detailed contact information (email address and link to Drexel WELL Center website) will be provided in the flyer so providers at clinical and local healthcare networks can choose to refer potential participants to the study. Additionally, we will be sending the study listing (Drexel WELL Center

website link) for the study to society listservs (e.g., the Society for Behavioral Medicine) that contain providers who may choose to refer potential participants to the study. The study will recruit participants until a sufficient number of participants has been obtained.

These recruitment strategies have been successfully utilized by Dr. Manasse for other adolescent clinical trials. Participants will be able to contact us through phone, e-mail, and by completing a confidential online pre-screen questionnaire. Additionally, ongoing weight loss studies in our laboratory will serve as a recruitment source for binge eating participants; in particular, those excluded from other weight loss trials due to binge eating will be referred to the current study. Additionally, we will use audio ads on radio stations, Spotify, and podcasts; news ads in the Metro paper and other news sources; and ads on social media as additional recruitment sources.

Participants will be screened by phone for preliminary eligibility and interest. At two subsequent clinic visits, eligibility will be verified, informed consent obtained, and baseline assessment completed. This process will allow participants to determine whether the assessment burden and demands of the program are acceptable; this is expected to reduce attrition. Participants' participation in other weight control programs during the maintenance phase will be statistically controlled but will also be actively discouraged by emphasizing the clinical and research rationale for this requirement.

Adolescent participants will be reimbursed for their time with $20 for pre-intervention assessment, $20 for the mid-intervention assessment, $50 for the post-intervention assessment, $50 for the first follow-up assessment, and $75 for the second follow up assessment.

Adolescent participants will also receive up to $100 for completion of EMA surveys during each period of EMA (i.e., pre- and post-treatment). $1.75 will be deducted for every missed EMA survey, and participants will receive $25 for having completed 85% of all surveys in a given EMA period.

Parent participants will receive up to $75 for completion of EMA surveys during each period of EMA (i.e., pre- and post-treatment). $1.70 will be deducted for every missed EMA survey, and participants will receive $15 for having completed 85% of all surveys in a given EMA period.

Subjects will receive complementary intervention. Payments will be made in cash if assessments are conducted in person or via gift cards if assessments are done remotely, and payment will be given to the participant immediately upon completion of each assessment (e.g., they will receive payment for their baseline assessment when they finish the baseline). If a participant is determined ineligible after the baseline assessment, they will receive $10 for partially completing the baseline assessment.

22) Number of Subjects

The current study is seeking to recruit 80 subjects to enroll in the study. We plan to screen 200 subjects over the phone and conduct 120 baseline assessments.

23) Confidentiality

Subject confidentiality will be protected by storing all data in locked filing cabinets in a limited access, locked room. Electronically collected data (e.g. audio recordings, electronic surveys, databases) will be stored on a research lab computer within an encrypted password protected directory (using Sophos SafeGuard Enterprise) maintained and implemented by Drexel University. No subject identifiable information will be put into the database and no names or identifying information will be associated or published with any reports. Access to subject data will be limited to project staff, on an as-needed basis and as determined by the PI. Only if required by law will subjects' identifiable data be disclosed to persons or organizations not directly involved in the research. With the exception of release of information required by law, no subject identifiable information will be released without the subject's explicit permission.

24) Provisions to Protect the Privacy Interests of Subjects

This study is designed in order to maximize the privacy interest of participants. Data will be collected from participants continuously throughout the study by both in-person assessment (e.g. baseline period) and through continuous contextual assessment methods (e.g. ecological momentary assessment). This is to ensure ease of data collection, but also to ensure privacy interest of participants in limiting researcher interaction. Survey responses will remain anonymous and all data will be de-identified with unique subject identifiers. Identifiable information will only be used for payment and will be kept separate from all data.

All questions are worded as to minimize stress and anxiety for participants. Researcher contact information will be provided and participants will be encouraged to contact the study team and/or the Human Research Protection Office if they have any questions regarding the research process.

25) Compensation for Research-Related Injury

Does not apply.

26) Economic Burden to Subjects

Subjects may incur increased data usage from their smartphones for filling out the EMA surveys on their phones, and depending upon subjects' phone payment plans, this may result in an increased phone bill. We have used similar surveys in previous trials and have received no complaints of increased phone bills, so we estimate this possibility to be of low likelihood.

27) Consent Process

Informed Consent and Assent will take place in a private office at the Department of Psychology at Drexel University or via HIPAA-compliant Zoom software and will be

conducted by a research coordinator or graduate student who can answer questions about the study. The researcher will explain the consent/assent form in detail to the potential participant and their parent. Consent will be obtained from either a parent or legal guardian; only one parent/guardian needs to be present and consent to allow their child in the study. The potential participant and his/her parent/guardian will be given the opportunity to ask questions. The staff member will then assess the potential participant's understanding of the risks and benefits of participation by asking: 1) What is the purpose of this study? 2) What will be done? 3) What risks and discomforts may occur from participating in this study? 4) What benefits may be gained from participating in this study? This process may take anywhere from 5 to 15 minutes depending on the participant.

Consent and assent will be obtained at the same time that they will be informed. The consent forms will include information on the funding for the current project, which comes from the National Institutes of Health. Additionally, consent will be obtained to recontact participants after they have completed their participation in the study, if they would like to be considered for other WELL Center studies.

28) Process to Document Consent in Writing

If a baseline assessment is conducted in person, consent will be obtained in writing. After a participant and his/her parent/legal guardian reads the consent form, they will be asked if they have any questions regarding the research and a member of the research team will be present to read through the consent and answer questions. They will then be asked to sign the consent and initial each page as they review it. Researchers will sign the document as well. They will be given a copy of the consent form and will be encouraged to contact the PI at any time if they have any questions or concerns.

If a baseline assessment is conducted remotely, the consent process will occur over HIPAA-compliant Zoom software. The consent process will largely be identical to the in-person consent process, with one minor exception. Participants and their legal guardians/parents will provide assent and consent, respectively, by selecting a box on a secure form on the Drexel REDCap server; this process will occur in place of the signing process that would occur in person. Everything else about the remote consent and assent processes will be identical to how these processes will be conducted in person.