

**Study Protocol and Statistical Analysis Plan**

CNMC Pro00011128

Mindfulness in Adolescents with Obesity

1/22/2021

## Study Protocol

**Study Setting.** This study took place at a multidisciplinary, research-oriented weight management clinic located within a large children's hospital in the Mid-Atlantic during February through August of 2019. This clinic accepts patients with obesity aged 6 months to 21 years. Approximately 100 new patients are seen annually. Approximately 39% of the patients seen are Black or African Americans, 28% are Hispanic American and 20% are White Americans. 65% of the patients have Medicaid and 34% are private or commercially insured. The clinic follows the recommended standard of medical management of overweight and obesity. The clinic team conducts a comprehensive evaluation to assess dietary and activity behavior change needs of each patient and family, as well as obesity-associated comorbidities. In addition to management of comorbidities, goals for improved physical activity and dietary behaviors are set with the patient and family at each visit.

**Inclusion and exclusion.** Adolescents were eligible if they were between the ages of 12 – 17, a current patient of the affiliated obesity clinic, and had a BMI greater than 30 kg/m<sup>2</sup>. Adolescents were ineligible if they had a known genetic cause of obesity, had been diagnosed with a severe intellectual or learning disability, had been diagnosed with an autism spectrum disorder or current psychosis, or were currently in psychotherapy. These exclusion criteria were selected because they might influence the degree to which an adolescent responds to behavioral weight loss and/or their ability to actively take part in a standard mindfulness intervention.

**Recruitment.** Medical providers and other clinic staff were informed about the study and referred interested patients' parents/caregivers to the research team. Interested patients were screened for eligibility and eligible patients were consented in the presence of a parent/caregiver and scheduled to complete a baseline assessment.

**Participant assessment schedule and measures.** Participants completed a series of assessments within a private clinic room at the obesity clinic. These measures were completed at baseline and post-intervention, unless otherwise stated.

### ***Feasibility outcomes.***

*Assessing recruitment feasibility.* Recruitment feasibility was examined through research staffs' detailed tracking of recruitment processes (e.g., referrals from physicians, patients approached in the waiting room), the number of interested patients, and the number of patients eligible after the initial screening. We documented all cases of ineligibility and the reason for disqualification.

*Assessing retention feasibility.* Retention feasibility was tracked via attendance; research staff took attendance during each assessment period and intervention session. Any enrolled participants who dropped out (defined as participants who either explicitly stated that they would like to leave the program or who missed two consecutive sessions in a row without contacting the research team) were contacted by phone to inquire about their reasons for ending the program, as a method of assessing any barriers to intervention completion.

*Assessing participant satisfaction.* We assessed participants' satisfaction with the mindfulness intervention by having them complete a satisfaction survey at the end of the intervention. This survey evaluated: 1) reactions to the topics discussed and skills reviewed; 2) comfort with facilitators; 3) opinions of the materials used; and 4) overall satisfaction with the intervention at that point in time. Ten of these items were scored on a Likert-scale of 1 (strongly disagree) to 5 (strongly agree) (e.g., "Participating in this program helped me to better manage my eating habits") and eight of these items invited open-ended responses (e.g., "What were the challenges of participating in this study?"). Participants were also asked to report their favorite and least

favorite components at the end of each session. This feedback will inform potential adaptations made to the intervention prior to a larger randomized controlled trial (RCT).

### **Participant self-report measures.**

*Demographic questionnaire.* Assesses age, gender, and race/ethnicity. This measure was only completed at baseline assessment.

*Mindful Attention Awareness Scale-Adolescent (MAAS-A).* The MAAS-A is a 15-item measure of dispositional mindfulness. Participants rated how frequently they experience episodes of mindless behavior (e.g., “I find myself doing things without paying attention.”) on a scale of 1 (almost always) to 6 (almost never). This measure has established psychometric properties in diverse adolescent samples.<sup>(34-36)</sup>

*Eating Disorders Examination-Questionnaire (EDEQ).* Participants reported instances of overeating, loss of control eating, and binge eating over the last four weeks via 3 items of the EDEQ.<sup>(37)</sup> This measure was selected to examine potential changes from baseline to post-assessment in eating behaviors that are associated with emotion regulation and risk for obesity that might be influenced by mindfulness training.<sup>(22-24)</sup> The EDEQ yields reliable and valid scores.<sup>(38)</sup> Adolescent responses to the EDEQ correspond strongly with clinical interviews assessing disordered eating.<sup>(39)</sup>

*Difficulties in Emotion Regulation Scale – Short Form (DERS – SF).* The DERS-SF is an 18-item, widely used self-report measure of emotion regulation problems that has been validated in adolescent samples.<sup>(40)</sup> This measure was selected to examine potential changes from baseline to post-assessment in emotion regulation, which is theorized to be a key driver of disordered eating (e.g., binge eating, overeating) in adolescents with obesity.<sup>(41)</sup>

*Youth Quality of Life Instrument – Short Form (YQOL-SF).* The 15-item YQOL-SF measures generic quality of life in youth with and without chronic conditions, ages 11-18 years. It has established psychometric properties in adolescent samples.<sup>(42, 43)</sup>

### **Executive function measure.**

*Go/No-Go Task.* The Go/No-Go Task examines inhibitory control via a computerized program. This measure was selected to examine potential changes from baseline to post-assessment in impulse control, which is associated with binge eating<sup>(25)</sup> and obesity,<sup>(44)</sup> to provide evidence of the cognitive mechanisms through which MBIs might improve eating behaviors. Participants are instructed to press a button (or “Go”) when a certain image is shown on the screen (i.e., an image of food). They are instructed not to respond (or “No-Go”) when another image is shown on the screen (i.e., an image of a toy).<sup>(45)</sup> The entire task is approximately 15 minutes and each image is shown on the screen for approximately 500 milliseconds. Poor impulse control is evident by more failures to inhibit responses in the No-Go condition (e.g., a false alarm). Omission occurs when a participant fails to respond to a Go stimuli. Reaction time is the processing speed for correct Go trials. This task demonstrates reasonable reliability and validity in adolescent samples.<sup>(46, 47)</sup>

### **Anthropometric and CVD biomarker measures.**

*Anthropometrics.* Height and weight was assessed in order to calculate BMI. Height was measured to the nearest 1/8 inch using a wall-mounted stadiometer. Weight was measured in indoor clothing, without shoes, to the nearest .1 lb using a calibrated digital scale.

*Blood pressure measurement.* Blood pressure was measured using an automatic upper arm cuff while the participant was seated. Participants were instructed to sit quietly, with both feet uncrossed on the floor, and their arm in a still position, to increase accuracy of each measurement.

**Intervention.** The mindfulness intervention consisted of 6 weekly sessions, blending material from the evidence-based Learning to BREATHE<sup>(48)</sup> and Mindfulness-Based Eating Awareness Training<sup>(19)</sup> manualized interventions. Participants met individually with a therapist for each 60-minute session. Sessions focused on: experiential mindfulness exercises, such as mindful eating, loving kindness practices, breath awareness, and mindful movement; hunger and satiety awareness; improving responses to emotions; practicing acceptance and being non-judgmental; and tolerating negative feelings and sensations, including those related to hunger and cravings. Participants were assigned brief homework exercises (approximately 10 minutes) daily in between appointments. Sessions were offered via telemedicine to improve attendance.

**Adverse Events and Criteria for Discontinuation.** Expected risks to participants in this study were generally mild. There was the unlikely but possible risk that participants could experience negative emotions during the practice of mindfulness. Participants were informed about this risk during the consent process and encouraged to inform a member of the research team if they had a strong negative reaction. Mindfulness facilitators were trained to provide adaptations to the mindfulness exercises in order to reduce the intensity of these experiences and ground the participant in the present moment. If an individual continued to experience intense negative emotions that interfered with their ability to participate in the program despite these adaptations, they would have been withdrawn from the study and provided with appropriate referrals. The investigators and research staff met regularly to discuss participants' reactions to the assessments and intervention and any study withdrawals. No adverse events were reported.

**Facilitators and Training.** The mindfulness components of the intervention were facilitated by two interventionists with established mindfulness practices, including one graduate-level clinical psychology student and one first-year medical student. Each facilitator received extensive supervision from the first and second authors (both licensed clinical psychologists) via weekly meetings. Participants met with the same facilitator throughout the course of the intervention. The usual care components were facilitated by medical providers within the obesity clinic.

**Adequacy of Sample Size.** Our study's primary aim was to examine feasibility and refine aspects of the research approach; therefore, a formal sample size calculation was not warranted.<sup>(49)</sup> Given budgetary and logistical constraints, our aim was to recruit 15 adolescents over a six-month period through a single clinic site, which is sufficient to provide useful information about the feasibility of the protocol.<sup>(50)</sup>

### **Statistical Analysis Plan**

IBM SPSS Statistics version 24 was used to complete all quantitative data analyses. Frequencies were used to examine feasibility, including recruitment and eligibility rates, rates of attendance at each session and assessment appointment, and satisfaction with the intervention. Paired *t* tests were conducted to examine pre-post differences in the health outcomes of interest and Cohen's *d* effect sizes and confidence intervals were calculated to examine the effect size of any changes in BMI, mindfulness, emotion regulation, eating behaviors, quality of life, impulsivity, and blood pressure.<sup>(51, 52)</sup> For participants who did not complete post-assessment (*n* = 3), we used a last observation carried forward imputation.