NCT04587752

Cognitive-Behavioral Therapy for Weight-related Bullying

Document date: 6/25/2021

HRP-503B – BIOMEDICAL RESEARCH PROTOCOL
(2017-1)

Protocol Title: Cognitive-Behavioral Therapy for Teens Who Experienced Weight-related Bullying

Principal Investigator: Janet Lydecker, PhD

Version Date: Version 3 (6/17/2021)

(*If applicable*) **Clinicaltrials.gov Registration #:** NCT04587752

SECTION I: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

The aim of this study is to perform a **clinical trial** to pilot a new cognitive-behavioral treatment (CBT) for weight-related bullying testing (1) feasibility, (2) acceptability, and (3) initial efficacy. Adolescents who experienced weight-related bullying will receive this new treatment.

Hypothesis 1. CBT for weight-related bullying will be **feasible** (participants from target population recruited; intervention reliably delivered).

Hypothesis 2. CBT will be **acceptable** (retention through post-treatment; patient-reported treatment credibility and satisfaction).

Hypothesis 3. CBT will show **initial efficacy** (improvements in general health, post-traumatic stress, weight/shape concerns).

2. **Probable Duration of Project:** State the expected duration of the project, including all follow-up and data analysis activities.

Two years

3. **Background:** Describe the background information that led to the plan for this project. Provide references to support the expectation of obtaining useful scientific data.

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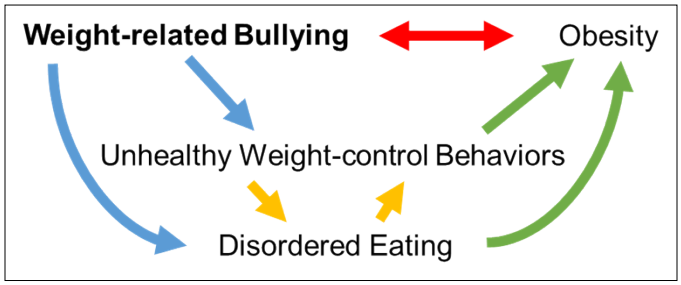
An estimated 36% of youth are bullied (1). Youth with obesity are more likely to be bullied than healthy-weight peers (2-4). Bullying is when a perpetrator with more power intentionally and repeatedly causes harm to a victim (1, 5). Bullying can be physical, verbal or relational (6) and is highly distressing (7, 8). Bullying is a significant *pediatric* public health problem: victims are more likely than non-bullied peers to have social and academic impairment (7, 9, 10), anxiety and depression (11, 12), eating disorders (13), weight gain (4), and poorer overall health (11, 14-16). Bullying is also associated with self-harm and suicide (11, 17, 18). *Childhood* bullying has long-term associations with *adult* health problems: anxiety, depression, self-harm and suicide, poorer overall health, and poorer social functioning (11, 12, 16, 19).

Approximately 41% of girls and 28% of boys who experience bullying develop post-traumatic stress disorder (PTSD) (20). The nature of bullying (that it occurs as *events*, leaves children feeling *unsafe*, and engenders emotional *distress*) fits trauma treatment criteria (21). Some experts recommend trauma treatment for bullying (22-24), although this application is untested.

Weight is the most common reason children are bullied (25). Weight-related bullying has consequences (7): binge eating (26), unhealthy weight-control behaviors (e.g., vomiting) (26), body image concerns (27), and obesity (16, 27). Bullied youth say they use binge eating and unhealthy weight-control behaviors to cope with distress (7) and avoid future victimization (28).



Taken together, obesity and bullying appear to be bi-directionally associated: children with obesity are more likely to be bullied, and bullying has serious consequences including obesogenic eating-disorder behaviors and weight gain (4). Girls appear particularly vulnerable. Girls are more likely than boys to be bullied because of weight (26), more girls have clinical levels of trauma symptoms after bullying (20), and more girls than boys have *long-term* weight gain, weight/shape concerns, binge eating, and unhealthy weight-control behaviors (27) after weight-bullying. As obesity and eating disorder prevalence are both higher among girls (29, 30), and there are immediate and long-term associations of obesity with health problems (31-36), ***girls who are bullied because of weight are particularly vulnerable****—because of their weight and bullying experiences—to health problems and impaired wellbeing.*

Treating bullying during childhood could reduce immediate and long-term health consequences. There are school-level *prevention* programs to reduce the occurrence of bullying and *policy* initiatives aimed at preventing bullying (37, 38), but **there are no established individual-level *treatments* for weight-related bullying** *despite* recommendations that they could improve children's health (20, 39) and individuals' beliefs that healthcare providers are important sources of help for youth who have been bullied (25).

Youth who are bullied because of their weight need treatment for traumatic stress *and* potentially co-occurring or developing problems with unhealthy weight-control behaviors, disordered eating, and obesity. **To address this gap in child health research, the current study will develop cognitive-behavioral therapy (CBT) for weight-related bullying.** Trauma-focused CBT (TF-CBT) will be combined with CBT for eating disorders (CBT-ED). TF-CBT helps children regulate emotions surrounding a highly-distressing stressor and enhance safety to prevent further victimization (21, 40, 41).

4. **Research Plan:** Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. **Be sure to distinguish between standard of care vs.**

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research procedures when applicable, and include any flowcharts of visits specifying their individual times and lengths. Describe the setting in which the research will take place.

Youth who are bullied because of their weight need treatment for traumatic stress *and* potentially co-occurring or developing problems with unhealthy weight-control behaviors, disordered eating, and obesity. To address this gap in child health research, the current study will develop cognitive-behavioral therapy (CBT) for weight-related bullying.

Initial Efficacy Testing. This study will combine existing evidence-based treatments for trauma (trauma-focused cognitive-behavioral therapy; TF-CBT) and eating disorders (cognitive-behavioral therapy for eating disorders; CBT-ED) into a new treatment for weight-related bullying using the Stage Model of Behavioral Therapies Research (42-44). The therapy manual, clinician training materials, and adherence/competence measures will be refined using feedback solicited from patients and clinicians at each treatment session (how helpful and relevant they found it, how much they liked it). Open-ended questions will explore preferences, feedback about material to add or remove, and perceived benefits and costs to treatment parameters.

Treatment will be piloted with N=30 teens. Research clinicians with doctoral training in psychology will administer CBT under the supervision of the PI.

Format and Content of Treatment. Treatment will be 12 sessions (3 months, weekly telehealth sessions). Participants will be video and/or audio-recorded if they consent to this procedure. Recordings will be for the purpose of evaluating treatment fidelity, as well as part of monitoring research-clinicians in the delivery of the treatment as specified in the protocol. Drawing from TF-CBT with additional material from CBT-ED, CBT for weight-related bullying will have five stages: 1) Orienting to treatment and establishing a therapeutic foundation; 2) Coping skills training and implementation; 3) Specific behavioral strategies and their implementation; 4) Developing and processing of trauma narrative; and 5) Relapse prevention planning to maintain health behaviors.

Parents will attend sessions monthly, during which they will learn about bullying and healthy eating behaviors, identify parent and family factors that could inhibit change, and help the youth establish coping and other behavioral strategies that maximize health. Children will teach parents what they have learned to increase self-efficacy and positive communication. Other developmentally-tailored content includes using tangible therapeutic tools, setting communication strategies with parents, eliciting peer support and parent health-behavior support, and focusing on short- *and* long-term health goals.

TABLE 1. Descriptions of Sessions

Week	**CBT for Weight-Related Bullying**
1	Orient to treatment: Educate about bullying, therapy, eating/weight risk reduction; First coping skill: feeling identification; First behavioral strategy: self-monitoring (food, mood, weight)
2	Coping skills: Introduction and practice of skills (relaxation, thought stopping, cognitive coping);
3	Specific behavioral strategies: Support from family and peers; Establish regular eating pattern as self-care; Cognitive processing intro: Explanation of cognitive triangle using emotional eating
4	Create healthy, regular meals (with parent); Child teaching parent coping skills
5	Trauma (bullying) narrative: Guided creation of narrative using open-ended questions
6	
7	

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8	Identify parent and family factors that inhibit (promote) change
9	Cognitive Processing: Process bullying experience(s) by elaborating details;
10	Challenge cognitive distortions and maladaptive eating/weight thoughts
11	Prevention planning: Set long-term health goals and plans to maintain progress; Identify trauma-related triggers as opportunity to cope
12	Prepare to end treatment: Presentation of bullying narrative by child for parent; Treatment completion celebration

Assessments. Parents and adolescents will be assessed. At the beginning of treatment, adolescents will undergo a clinical assessment to confirm eligibility and to inform the course of treatment. Batteries are guided by *NIH ADOPT* workgroup recommendations (45-49). As well as established measures, acceptability (sessions attended; retention; patient/clinician ratings of content), and adherence (e.g., homework completion, clinician recordings coded for reliability and adherence), will be assessed. We will also gather clinical data on the patient's medical history prior to enrollment in the treatment.

Assessment Training: Independent outcomes assessors will receive training in diagnostic interviews from investigators following well-established protocols used in previous projects. Once interviewers are certified in the measures (MINI and EDE), they will receive ongoing supervision to ensure consistent use and prevent drift.

TABLE 2: Assessment Batteries

	Baseline	Month 1	Month 2	Post
Adolescent assessment battery				
Established interviews:				
Eating Disorder Examination interview	*			*
MINI Psychiatric Interview (MINI)	*			
Medical history	*			
• Columbia Suicide Severity Rating Scale (Columbia)	*	*	*	*
Established survey measures:				
• Children's Impact of Event Scale-13 (CRIES)	*	*	*	*
• Kirby Delay Discounting	*			*
• Questionnaire for Eating and Weight Patterns (QEWP-5)	*			*
• Eating Disorder Examination–Questionnaire (EDE-Q)	*	*	*	*
• Patient Health Questionnaire-9 (PHQ-9)	*	*	*	*
• Rosenberg Self-Esteem Scale (RSES)	*	*	*	*
• EARLY	*	*	*	*
• Perceived Stress Scale (PSS)	*			*
• Amsterdam Executive Function Inventory (AEFI)	*			*
• Sensitivity to Reward/Punishment (SRSPQ)	*			*
• Perceptions of Teasing Scale (POTS)	*	*		*
• Weight-related Victimization	*			*
• Weight Bias Internalization Scale (WBIS)	*	*		*
• Brief Resilience Scale (BRS)	*	*	*	*
• Self-compassion Scale (SCS)	*	*		*
• Self-Efficacy Questionnaire for Children (SEQ-C)	*	*		*
• CHAOS Scale	*			*
• Clinical Impairment Assessment (CIA)	*	*		*
• Palatable Eating Motives (PEMS)	*	*		*
• Medical Outcomes Study Short-Form (SF12)	*			*

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Anthropometric: BMI-z	*	*	*	*
Acceptability:				
• Treatment credibility	*			
• Ratings of session content		*	*	*
Parent assessment battery				
Established survey measures:				
• Questionnaire for Eating and Weight Patterns (QEWP-5)	*			*
• Eating Disorder Examination–Questionnaire (EDE-Q)	*	*	*	*
• Child Feeding Questionnaire (CFQ)	*	*	*	*
• Perceived Stress (PSS)	*	*	*	*
• Weight Bias Internalization Scale (WBIS)	*	*		*
• General Self-Efficacy Scale (GSES)	*	*		*
• Fat Talk Questionnaire (FTQ)	*	*		*
Anthropometric: BMI	*	*	*	*
Acceptability:				
• Treatment credibility	*			
• Ratings of session content		*	*	*

Eating Disorder Examination (EDE) interview (50) for adolescents (51), the questionnaire version *(EDE-Q)* (52), and *Questionnaire for Eating and Weight Patterns (QEWP-5)* (53, 54) will assess disordered eating thoughts and behaviors (including binge/LOC eating). The EDE/EDE-Q and QEWP show good concordance (55-57), reliability (intra-class correlation .95-.99) and validity (58, 59).

MINI International Neuropsychiatric Interview-Version 7.0 (MINI) (60) is a brief structured interview for Axis I psychiatric disorders, including PTSD and eating disorders. Validation and reliability studies have supported the MINI, including good convergence with SCID (60). The MINI requires much less time than the SCID and reduces participant burden while providing adequate psychiatric data to characterize patients and determine exclusion criteria.

Children's Impact of Event Scale-13 (CRIES) (61) assesses trauma symptoms with good reliability and validity (62, 63) and has been used in clinical trials (64).

Kirby Delay Discounting (65) will measure reward-based decision making by comparing relative values of immediate and delayed rewards; this is related to adult weight loss (46, 66) and youth binge eating (67). The Kirby yields stable scores at 5-weeks (r=.71) and 1-year (r=.63) (65).

EARLY is a 2-item questionnaire about self-weighing frequency and scale access (47, 68, 69).

Amsterdam Executive Function Inventory (AEFI) is a brief questionnaire assessing executive functioning ability, such as attention, self-control, and self-monitoring. The construct validity and reliability are considered adequate (70).

Sensitivity to Punishment/Sensitivity to Reward Questionnaire (SPSRQ) (71) assesses reinforcement sensitivity, has been validated with people with eating disorders, and has a reliability of .75-.83.

*Self-Compassion Scale (SCS) (72)*is a widely used measure of self-compassion and is reliable (α=.77-.78)

Perceptions of Teasing Scale (POTS) (73) is an assessment of whether an individual has been teased and how

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teasing affected them. Reliability for the subscales ranges .66-.90.

Brief Resilience Scale (BRS) (74) is a 6-item measure of resilience with good reliability (α=.80-.91).

Weight Bias Internalization Scale-Modified (WBIS) (75) is an 11-item measure of weight-based self-stigma for children and adults across the weight spectrum. It is reliable (α=.90), has strong construct validity, and relates to eating pathology, body image, and self-esteem.

Weight-related Victimization is an unpublished measure developed by the UConn Rudd Center (which specializes in weight-related discrimination and stigma). These items examine different negative experiences related to weight for school-aged youth. It also examines how the weight-related victimization affects the child.

Self-Efficacy Questionnaire for Children (SEQ-C) (76) is a 21 item measure of children's self-efficacy in social, academic, and emotional areas; only the social and emotional subscales will be included, which have good reliability (α= .85 to .88).

CHAOS Scale (77) measures environmental processes within familial households, including perceive chaos, hubbub, and order. CHAOS has a reliable total score (α=.79) and a 12-month test-retest stability (r=.74).

General Self-Efficacy Scale (GSES) (78) is a 10-item measure of self-efficacy beliefs, such as coping with adversity, for adults. The measure has adequate reliability (α=.76 to .90)

Fat Talk Questionnaire (FTQ) (79) is a measure of negative discussions about weight that the parent engages in; there are three subscales including fat talk about themselves (self), their child (child) or people with obesity (obesity). The measure has excellent reliability (α=.93).

Medical Outcomes Study Short-Form (SF12) (80) is a widely-used measure of general health with well-established reliability and validity for physical- and mental-health quality of life (81, 82).

Patient Health Questionnaire-9 (PHQ-9) is a widely-used, brief measure of depression (83) developed with 6000 adults, validated with 2291 adolescents, showing good sensitivity and specificity (84).

Rosenberg Self-Esteem Scale (RSES) is used extensively and is a reliable (α=.88) measure of global self-esteem (85, 86) and has been used in work with adolescents and research on childhood obesity (87).

Child Feeding Questionnaire (CFQ) (88) will assess parent feeding practices (Restriction, Pressure to Eat, Monitoring) and attitudes (Perceived Responsibility, Concerns about Child Weight). The CFQ is reliable (α=.65-.91) and valid for work with diverse parents (89) seeking weight loss treatment for their children (90).

Perceived Stress Scale (PSS) (91) is a widely used measure that examines how individuals perceive their lives as unpredictable, uncontrollable, and overloaded. The PSS has a reliable total score (α=.83), 6-week temporal stability (r=.81) and validity associated with health behaviors including eating (92). It has also been validated in an adolescent sample (93, 94), with adequate convergent validity for stressful life events and internal consistency (α=.79).

Clinical Impairment Assessment (CIA) (95, 96) is used to assess clinical psychosocial impairment related to eating disorder pathology. It has good construct and criterion validity, and strong internal consistency (α=.93),

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including with adolescent females (97-99).

Palatable Eating Motives (PEM; Coping subscale) (100) is a measure of motives for eating highly palatable and tasty foods. Only the coping subscale will be used, which measures eating palatable foods to cope with emotions and feelings. Internal consistency is strong (α=.91), and the coping subscale has incremental validity.

Columbia Suicide Severity Rating Scale (Columbia) (101) is a semi-structured assessment intended for administration by clinicians or study staff during scheduled study visits. It explores suicidal ideation and intensity, as well as behaviors and lethality. This measure will alert clinicians to safety concerns. See section on minimizing risks for the plan to manage any suicidality.

Anthropometric measures: Height will be reported to the nearest 0.25 inch using a stadiometer. Weight will be reported to the nearest 0.1 pound using a digital scale. Height/weight data will calculate BMI (49). Adolescent BMI data will use CDC growth charts (age/sex-normed) to calculate BMI percentile, BMI z-score, and expected change in BMI (102).

Ratings of Session Content. Patients and parents will be asked open-ended questions about the treatment (examples listed below). Patients and parents will also rate session content on likert scales.

- What did you not like about this treatment?
- What would you change?
- What was helpful about this treatment?
- What would you make sure to keep in the treatment?
- What were challenges in this program that were difficult to overcome?
- What advice would you give to someone starting treatment? To a clinician?

5. Genetic Testing N/A ☒

6. **Subject Population:** Provide a detailed description of the types of human subjects who will be recruited into this study.

Teens who experienced weight-related bullying will be recruited using flyers in the community, primary care and other medical offices, schools, and on relevant websites. Appropriate referrals will be provided to youth who are not eligible for this treatment study.

7. **Subject classification:** Check off all classifications of subjects that will be specifically recruited for enrollment in the research project. Will subjects who may require additional safeguards or other considerations be enrolled in the study? If so, identify the population of subjects requiring special safeguards and provide a justification for their involvement.

☒Children	☐ Healthy	☐Fetal material, placenta, or dead fetus
☐Non-English Speaking	☐ Prisoners	☐Economically disadvantaged persons
☐Decisionally Impaired	☐ Employees	☐Pregnant women and/or fetuses
☐Yale Students	☒ Females of childbearing potential	

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential subjects?

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Yes ☐ No ☒

8. **Inclusion/Exclusion Criteria:** What are the criteria used to determine subject inclusion or exclusion?

Inclusion Criteria: To be included, adolescents must:

1. Be in the age range ≥11 years old and ≤17 years old;
2. Report experiencing weight-related bullying OR report BMI percentile >85th and any kind of bullying
3. Report current distress about bullying
4. Be otherwise-healthy youth (i.e., no uncontrolled or serious medical conditions);
5. Read, comprehend, and write English at a sufficient level to complete study-related materials;
6. Provide a signed and dated written assent prior to study participation;
7. Provide a signed and dated written consent from one parent prior to study participant; and
8. Be available for participation in the study for 3 months.

Exclusion Criteria: Prospective participants will be excluded if the adolescent:

1. Has a medical or psychiatric condition that would require hospitalization or intensive care (e.g., severe anorexia, neurological disorder, psychotic disorders, suicidality);
2. Has uncontrolled medical condition(s) (e.g., uncontrolled diabetes or hypertension);
3. Is pregnant or breastfeeding;
4. Is taking medication(s) or participating in concurrent treatment(s) that focus on trauma-related stress;
5. Began taking hormonal contraceptives less than 3 months prior;
6. Has a developmental or cognitive disorder (e.g., autism spectrum disorder);
7. Has avoidant/restrictive food intake disorder; or
8. Is participating in another clinical research study.

9. How will **eligibility** be determined, and by whom? Write here

Participants will be interviewed during an initial intake by a study clinician. The structured Mini International Neuropsychiatric Interview (MINI) will be used to assess psychiatric disorders and psychopathology. The MINI along with the Eating Disorder Examination will also determine whether participants have any co-existing psychiatric conditions that require referrals, hospitalization or more intensive/different treatment. Data from the CRIES will be used to determine whether the adolescent is experiencing distress related to bullying (responding “sometimes” or “often” to items about the trauma), in conjunction with clinical assessment.

Final determination of eligibility will be from the PI. Monitoring will occur at treatment visits and referrals will be provided if warranted. If a study participant experiences any psychiatric symptoms or distress (e.g., depressive symptoms or suicidality) at any stage of study participation he/she will receive short-term treatment and support from the PI and study treatment team (which includes psychologists) and will be connected with a local emergency department (e.g., the Crisis Intervention Unit at Yale-New Haven Hospital) and their pediatrician or a therapist for ongoing care.

10. **Risks:** Describe the reasonably foreseeable risks, including risks to subject privacy, discomforts, or inconveniences associated with subjects participating in the research.

The primary risks of the behavioral interventions, assessment procedures, and unknown treatment efficacy.

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TF-CBT is an established treatment for trauma-related concerns, and CBT-ED am established treatment for disordered eating. TF-CBT is widely used in youth, and CBT-ED is widely used in research and clinical settings, for both youth and adults. The only foreseeable risks include some discomfort or embarrassment when discussing bullying, eating patterns, weight, or body image concerns.

Previous controlled clinical trials conducted by the PI and study team with similar interventions with adult and adolescent participants have not reported problems. Any troublesome effects would be readily identifiable by the experienced study clinicians during repeated evaluations. Thus, the risks of the CBT intervention are judged to be minimal.

Research assessments are noninvasive and should add no substantial risk. The major disadvantages are the time taken to complete them and potential for a breach of confidentiality. Completion of the assessment interviews and surveys may cause some mild anxiety or embarrassment to some participants. Past experiences of the PI and study team indicate that the measures are acceptable to participants. Careful efforts aimed at maintaining confidentiality will be made (as described below).

There is a chance that participants' mood or eating concerns may fail to improve or may worsen during the study. Participants will be provided with short-term treatment and support from the PI and clinical team (which includes psychologists) and/or the participant will be withdrawn from the study if their clinical condition deteriorates to a significant degree. Any participant who is withdrawn will be provided with appropriate referrals.

11. Minimizing Risks: Describe the manner in which the above-mentioned risks will be minimized.

The study clinicians will be carefully trained and supervised by the PI. All study clinicians and study staff will have IRB and ethics training; because of their educational experience and training (e.g., in psychology), they can reasonably be expected to identify potential problems and to take appropriate action as medically indicated.

Changes in suicidal thoughts will be assessed at each assessment visit using a structured interview (the Columbia) and as-needed according to clinicians' judgment. The PI will be continuously available to the study clinicians to discuss any problems and to implement any needed interventions or offer appropriate referrals. The detailed assessments repeated during the course of treatment will allow for additional and ample opportunity to identify difficulties. In the event that a participant experiences undue distress, the team will provide referrals.

Because treatment will be delivered via telehealth and may include participants who are not local, we will talk with the parent and child at the first appointment about what we will do if the teen reports thoughts of suicide. This will include telling the parent (either the parent in the study or another trusted adult caregiver) or recommending that the teen go to the emergency department, or telling the police that there is an emergency if the parent cannot be contacted. We will also identify the local emergency department and contact information for the teen's pediatrician and therapist (if applicable) so that all the information is in one place. We will also work with the teen to come up with a more detailed plan if passive or active suicidality is reported (e.g., pleasurable distracting activities, trusted friends and family, reasons for living, active coping skills).

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Potential participants will be informed of alternative treatments, and if indicated or requested, appropriate referrals will be provided. Potential participants will also be informed that they may drop out of the study at any time.

To ensure confidentiality, all research records will be kept either electronically, or in locked files in the Department of Psychiatry at Yale School of Medicine. All research personnel will be trained and supervised around confidentiality issues. The training will include formal Yale IRB modules with testing certification as well as HIPAA guidelines to follow around confidentiality. All participants will be assigned a study number. Subsequently, participants will be identified only by that number and an encoded version of their initials. A list of numbers and the corresponding names will be maintained by the PI and stored on a secure server and in a locked research file. Any information published as a result of the study will be such that it will not permit identification of any participant. All information collected will remain confidential except when we are legally required to disclose such information by law. These circumstances include knowledge of abuse of a child or elderly person, threats of harm to self or others, and plans to harm to property.

Data will be stored as described for 7 years after the final data are collected. Research records may be audited by a regulatory agency within the federal government. Organizations that have a responsibility for protecting human subjects, including the Yale IRB (Human Investigation Committee), may have access to the research records.

12. Data and Safety Monitoring Plan: Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HIC will make the final determination of the risk to subjects.)

a. What is the investigator's assessment of the overall risk level for subjects participating in this study? Minimal risk

b. If children are involved, what is the investigator's assessment of the overall risk level for the children participating in this study? Minimal risk

c. Include an appropriate Data and Safety Monitoring Plan. Examples of DSMPs are available here http://your.yale.edu/policies-procedures/forms/420-fr-01-data-and-safety-monitoring-plans-templates for (i) Minimal risk or (ii) Greater than minimal risk

d. For multi-site studies for which the Yale PI serves as the lead investigator: n/a

The treatment interventions and assessment protocols are well-established and pose primarily low risks to participants. The DSMP for the proposed pilot focuses on close monitoring by the PI in conjunction with an independent Safety Monitor. Excessive adverse events and/or any serious events (should they occur) will be reported promptly to the Yale School of Medicine IRB (Human Investigation Committee). Other (less serious) adverse events will be reported to the IRB periodically during regular reporting periods.

Monitoring for the safety of participants and the integrity and quality of data will be the responsibility of the PI, independent safety monitor, the study team, and the Yale IRB (Human Investigation Committee).

The PI will be responsible for monitoring the safety of participants and the integrity and quality of data for the proposed pilot RCT, executing the DSMP, and complying with reporting requirements to the Yale IRB.

Qualifications and responsibilities of the Safety Monitor.

The Safety Monitor for this trial will be Mahnoosh (Mona) Sharifi, MD, MPH. Dr. Sharifi is an Assistant Professor of Pediatrics in the section of General Pediatrics at Yale, and practices as a general pediatrician at the Yale Pediatric Primary Care Center. Dr. Sharifi is an experienced pediatrician with substantial clinical

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research and clinical expertise with adolescents and families, including those with obesity. Dr. Sharifi is not involved in the study design or clinical intervention or related to any chain of command. As Safety Monitor, Dr. Sharifi will review the reports sent by the PI and will determine whether there is any corrective action, trigger of an ad hoc review, or stopping rule violation that should be communicated to the study PI, the IRB at the Yale School of Medicine.

Risk Assessment

This is a behavioral (NON-medication) clinical trial that does not involve multiple sites, treatment blinding, or high-risk interventions. Although the clinical trial does include vulnerable individuals (adolescents 11-17 years old), the risks associated with the proposed treatment, including the cognitive-behavioral treatment and assessment protocols, are judged to pose minimal risks to participants. Therefore, we provide the following plan for monitoring the safety of participants and the integrity and quality of data:

Measurement and Reporting of Data Integrity and Quality

The PI is responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews. During the review process, the PI will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment.

The PI will provide a summary of the DSMP report to the Yale IRB on a yearly basis. The DSMP reports will include Subject accrual, Treatment completion rates, Interim analyses, and Adverse and serious adverse events. These reports will be discussed with the mentoring team during regular meetings and sent to the Safety Monitor for review. The frequency of data review is summarized in the following table:

	Data Type	Frequency of Review by PI	Frequency of Review by PI and Safety Monitor
1	Subject accrual	Monthly	Annually
2	Treatment completion rates (retention/attrition)	Quarterly	Annually
3	Interim analyses	Twice Yearly	Annually
4	Adverse and serious adverse event rates	As needed	Annually
5	Checklist for Safety Monitor	NA	Annually

The PI, the Institutional Review Board (IRB) and/or the Safety Monitor have the authority to stop or suspend the study or require modifications.

Subject Accrual

Subject accrual reviews will help to assure that subjects are being enrolled (accrued) at a rate necessary to meet the recruitment goals in general and with regard to racial/ethnic diversity. Subject accrual rates will be discussed with the PI monthly and annual accrual rates will be reported by the PI to the Safety Monitor to determine if any corrective action is needed to meet the recruitment goals.

Treatment Completion Rates

Retention, attrition and completion rates will be carefully tracked and reviewed. This will be done quarterly to highlight any possible concerns and will be reviewed formally with the PI and Safety Monitor annually. Differential dropout across treatments and/or higher than expected dropout will be reviewed to determine whether any problems are present and what, if any, corrective action needs to be taken. “Trigger points” for corrective action, as described below, include: 35% (“low alert”), 40% (“mid alert”), 45% (“high alert”), and

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50% ("extreme alert"). With early alerts to problems, action would be taken to avoid higher level alerts; if a higher-level alert should arise, more drastic actions would be taken.

It is possible that baseline differences between the treatment conditions, excessive attrition, and/or missing data will limit the value of the data analysis, and hence knowledge to be gained from this study. For these reasons, interim analyses will be conducted twice yearly. Baseline differences, if present, will be considered in relation to potential effects on the power to detect differences in the primary outcomes. If these effects were to develop and be sizeable, alterations to the randomization schedule would be considered. Such effects would be evaluated and discussed by the PI and mentors, and plans would be communicated to the Yale IRB. To address excessive attrition and missing data, the following actions would be taken at the "trigger point" for each level of alert:

1) Low-level alert (35%): Review of potential problems by PI and review of procedures for supervision of study clinicians.
2) Mid-level alert (40%): Meeting between PI and senior study team members to discuss approaches to minimize further dropouts.
3) High-level alert (45%): Meeting between PI, safety monitor, and senior study team members to determine further alterations to study protocol to complete the study with no further losses.
4) Extreme-level alert (50%): In the unlikely event that a 50% dropout rate occurs prior to the mid-study time point, the PI and senior study team members would convene to discuss the usefulness of continuing the study.

It is possible that other situations could occur that might warrant stopping the trial. Any concerns would be discussed with appropriate parties (PI, Mentors, Safety Monitor, Yale IRB).

Measurement and Reporting of Adverse Events

Data on adverse events will be collected on an ongoing basis. Adverse events data will be monitored by the PI and reviewed with the Safety Monitor throughout the pilot RCT (see Table above).

This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such problems occur, Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related) or UPIRSOs that may require a temporary or permanent interruption of study activities will be reported immediately (if possible), followed by a written report within 5 calendar days of the PI becoming aware of the event to the IRB. The PI will apprise study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project through regular study meetings, and via email as they are reviewed by the PI.

Attribution of Adverse Events:

Adverse events will be monitored for each subject participating in the study and attributed to the study procedures by the PI according to the following categories:

a) Definite: Adverse event is clearly related to the study treatment or assessment procedure.
b) Probable: Adverse event is likely related to the study treatment or assessment procedure.
c) Possible: Adverse event may be related to the study treatment or assessment procedure.
d) Unlikely: Adverse event is likely not to be related to the study treatment or assessment procedure.
e) Unrelated: Adverse event is clearly not related to the study treatment or assessment procedure.

Plan for Grading Adverse Events:

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The following scale will be used to grade the severity of adverse events (should they occur) during the study:

a) Mild adverse event
b) Moderate adverse event
c) Severe adverse event

Plan for Determining Seriousness of Adverse Events:

In addition to grading adverse events, the PI will determine whether the adverse event meets the criteria for a Serious Adverse Event (SAE). An adverse event will be considered serious if it results in any of the following outcomes:

a) Death;
b) A life-threatening experience that results in in-patient hospitalization;
c) A persistent or significant disability or incapacity;
d) A congenital anomaly or birth defect; or
e) Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Plan for reporting events to the Yale IRB that are unexpected AND related AND involve risk of harm to subjects or others:

The PI will report to the IRB any incident, experience or outcome that meets ALL 3 of the following criteria:

1) Is unexpected (in terms of nature, specificity, severity, or frequency) given (a) the research procedures described in the protocol-related documents, such as the IRB-approved protocol and informed consent document and (b) the characteristics of the subject population being studied; and
2) Is related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3) Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, legal, or social harm) than was previously known or recognized.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) may be medical or non-medical in nature, and include – but are not limited to – serious, unexpected, and related adverse events.

All related events involving risk but not meeting the prompt reporting requirements described above will be reported to the IRB in summary form at the time of continuing review. If appropriate, such summary may be a simple brief statement that events have occurred at the expected frequency and level of severity as previously documented.

Plan for reporting adverse events to the PI, Safety Monitor, and study team:

For the current study, the following individuals, funding, and/or regulatory agencies will be notified:

- PI
- All Co-Investigators listed on the protocol; and
- Yale IRB

The PI will review all adverse events upon completion of every study subject. The PI will evaluate the frequency and severity of adverse events and determine if modifications to the protocol or consent form are required.

Procedures for providing follow up care:

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Study participant safety will be monitored by the study team and reported to the PI at all clinical and assessment visits and referrals will be provided if warranted and/or requested. If a study participant experiences any psychiatric symptoms or distress (e.g., depressive symptoms or suicidality) at any stage of study participation he/she will receive short-term treatment and support from the study treatment team (which includes psychologists) and will be connected to a local emergency department (e.g., the Crisis Intervention Unit at Yale-New Haven Hospital) and her pediatrician or therapist for ongoing care.

Other Potential Issues Relating to Stopping Rules for the Study Include:

1) New Information: It is unlikely that any new information would become available during this trial that would necessitate stopping the trial. If new data become available, these will be evaluated.
2) Limits of Assumptions: It is possible that baseline differences between the treatment conditions, excessive attrition, and/or missing data could limit the value of data analysis. Baseline differences across treatment groups, if present, will be evaluated twice yearly and considered in relation to potential effects on the power to detect differences in the primary outcomes. If these effects were to develop and be sizeable, alterations to the randomization schedule would be considered.

Limits of Rules: There are other situations that could occur that might warrant stopping the trial and/or including a section on the safety report entitled "Other situations that have occurred since the last safety report that warrant discussion" to allow for communication of concerns.

13. Statistical Considerations: Describe the statistical analyses that support the study design.

Continuous variables will be examined for normality using probability plots and Kolmogorov-Smirnov tests. If normality is not satisfied and transformations do not achieve acceptable normality, nonparametric strategies will be considered. Analyses will be intent-to-treat. Outcomes will be tested at the α=0.05 threshold.

As this is a pilot study, results are anticipated to yield significant impact by providing effect sizes that will allow outcome variables to be selected and sample size to be calculated for a fully-powered randomized controlled trial that includes a control group. Descriptive statistics will characterize putative outcome variables (Aim 1: general health, trauma symptoms, weight/shape concerns) and variability, including confidence intervals. Exploratory analyses will identify potential outcome, predictor, and moderator variables to be tested in an adequately-powered RCT comparing CBT for weight-related bullying with a control group in preventing disordered eating and weight gain.

Variables and Analyses for Primary Aims. (1) Establish feasibility: descriptive statistics will quantify total/last sessions attended, and clinician adherence (ratings of recorded sessions). (2) Acceptability: descriptive statistics will quantify treatment ratings (clinician/patient). (3) Test initial efficacy at post relative to baseline on clinical outcomes: descriptive statistics (means and variability, including confidence intervals) will characterize change and paired t-tests will test changes from baseline to post in (a) improvements in general health (SF12), (b) reductions in traumatic symptoms (CRIES) and (c) reductions in weight/shape concerns (EDEQ). Repeated-measures growth mixture models (103) will explore response over time for these three variables (SF12, CRIES, EDEQ). This approach allows for different numbers of observations per participant, uses all available data on each participant, accounts for clustered data observations (e.g., parent-child), and is unaffected by data missing at random. Because we cannot *a priori* predict the shape of the response over time, we will first treat time as categorical and then test for polynomial trends. Attendance will be examined for informative dropout patterns.

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Variables and Analyses for Secondary Aims: **Explore** whether clinical features improve with treatment: descriptive statistics (means and variability, including confidence intervals) will characterize change and paired t-tests will test changes from baseline to post in (1) eating disorder behaviors (episode frequency), (2) depression (PHQ), (3) weight (BMI-z). As with primary aims, repeated-measures growth mixture models will explore response over time for these variables.

Power Analysis and Justification of Sample Size for Pilot Study. Power estimates for the pilot RCT were based on change in weight concerns during CBT-ED for adolescents (104). Assuming a two-sided test at α=0.05 threshold, we have 80% power to detect clinically-meaningful within-subject effects (d=0.64) with a sample size of 23. With a sample size of 30, we have 80% power to detect clinically-meaningful effects if there is 20% dropout. Thus, we have a reasonable chance of finding statistically significant change, even in this pilot study.

SECTION II: RESEARCH INVOLVING DRUGS, BIOLOGICS, RADIOTRACERS, PLACEBOS AND DEVICES

If this section (or one of its parts, A or B) is not applicable, check off N/A and delete the rest of the section.

A. RADIOTRACERS ☒N/A

B. DRUGS/BIOLOGICS ☒N/A

B. DEVICES ☒N/A

SECTION III: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. **Targeted Enrollment: Give the number of subjects:**
   a. Targeted for enrollment at Yale for this protocol: **30**
   b. If this is a multi-site study, give the total number of subjects targeted across all sites: n/a

2. **Indicate recruitment methods below.** Attach copies of any recruitment materials that will be used.

☒ Flyers	☒ Internet/web postings	☐ Radio
☐ Posters	☐ Mass email solicitation	☒ Telephone
☐ Letter	☒ Departmental/Center website	☐ Television
☐ Medical record review*	☐ Departmental/Center research boards	☐ Newspaper
☐ Departmental/Center newsletters	☒ Web-based clinical trial registries	☒ Clinicaltrails.gov
☒ YCCI Recruitment database	☒ Social Media (Twitter/Facebook):	
☒ Other: EPIC direct-to-patient ☒ Other: messages to provider EPIC inbox		

* **Requests for medical records should be made through JDAT as described at**
http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx

3. **Recruitment Procedures:**

a. Describe how potential subjects will be identified.

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Participants will be recruited using widespread media advertising, internet and printed materials throughout the community. The study will also be posted on the website for clinical trials at Yale and on websites run by the Yale Program for Obesity, Weight, and Eating Research (including Yale Teen POWER).

b. Describe how potential subjects are contacted.

Pre-screening. Interested parents/adolescents will be screened briefly to determine whether the teen is likely to be eligible to participate in the study. If they seem potentially eligible and interested in the study, parents and their children will be scheduled for an initial assessment visit.

Initial Assessment. After initial contact, study clinicians will meet with potential participants to discuss the study, the treatments, the assessments, and the informed consent procedures and forms.

EPIC Direct to Patient MyChart confidential messaging will be utilized for recruitment of subjects meeting specific parameters (youth meeting age and gender criteria, using other exclusion criteria to refine sample to those likely eligible). The following template will be utilized:

> Title of study, Phase or type of study: Cognitive-Behavioral Therapy for Teens Who Experienced Weight-related Bullying
>
> Principal Investigator: Janet Lydecker, Ph.D.
>
> Study Contact: Janet Lydecker, Ph.D. Phone # 203-785-7210
>
> Description:
> Teens 11 to 17 years old who have experienced weight-based bullying (being teased or bullied because of weight) may be eligible to participate in a free and confidential treatment study that may help with coping. Talk therapy is provided (no medications). Participants will receive up to $80 compensation. To learn more or see if you are eligible to participate, please call the Yale Program for Obesity, Weight, and Eating Research at: (203) 785-7210 or visit http://power.yale.edu
>
> Please indicate how often you would like to receive new names of potential participants ☐ daily ☒ weekly

EPIC Inbox Messages will be utilized to send information to providers about referring subjects to the treatment study. Providers will receive the inbox message if they meet specific parameters (seeing patients under age 18). The following template will be utilized:

> Title of study, Phase or type of study: Cognitive-Behavioral Therapy for Teens Who Experienced Weight-related Bullying
>
> Principal Investigator: Janet Lydecker, Ph.D.
>
> Study Contact: Janet Lydecker, Ph.D. Phone # 203-785-7210
>
> Description:

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We are recruiting adolescents who have experienced weight-based bullying for a trauma-focused treatment. Bullying is a risk factor for future eating disorders and weight gain.

About the treatment:

- The study treats distress related to weight-based bullying by improving coping
- There is no cost to the patient, and no cost to their insurance
- All teens receive a behavioral trauma treatment
- Treatment lasts 3

Who to refer:

- Adolescents between 11-17 years old
- Teens who report being bullied (we will assess bullying and emotional distress)

To refer a patient who may be eligible:

- The **teen or parent** can call: (203) 785-7210 or email: teenpower@yale.edu
- The **teen or parent** can request information: http://m.yale.edu/teenpower
- Direct**-to-provider**: email Dr Lydecker at janet.lydecker@yale.edu

c. Who is recruiting potential subjects?

PI and study staff will be recruiting potential participants.

4. **Assessment of Current Health Provider Relationship for HIPAA Consideration:** Does the Investigator or any member of the research team have a direct existing clinical relationship with any potential subject?

☐Yes, all subjects
☐Yes, some of the subjects
☒No

If yes, describe the nature of this relationship.

5. **Request for waiver of HIPAA authorization:** (When requesting a waiver of HIPAA Authorization for either the entire study, or for recruitment purposes only. Note: if you are collecting PHI as part of a phone or email screen, you must request a HIPAA waiver for recruitment purposes.)

Choose one:

☐ For entire study
☒ **For recruitment/screening purposes only**
☐ For inclusion of non-English speaking subject if short form is being used and there is no translated HIPAA research authorization form available on the University's HIPAA website at hipaa.yale.edu.

i. Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data:
ii. If requesting a waiver of **signed** authorization, describe why it would be impracticable to obtain the subject's signed authorization for use/disclosure of this data:

Potential participants will initially call us in response to advertisements, at which time, if they seem eligible, we will schedule them for an initial assessment and collect contact information. If potential participants elect

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to participate, they would then provide informed consent including HIPAA authorization as described at their initial appointment.

The investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the "accounting for disclosures log", by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer.

6. Process of Consent/Assent: Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure subjects' independent decision-making.

After initial screening and preliminary determination of eligibility, study clinicians will meet with potential participants for an initial intake appointment. At the intake, study clinicians will discuss the study and all procedures, treatments, and risks and obtain written informed consent from one parent and assent from the adolescent. All prospective participants will be free to decide whether or not to participate and enrolled participants are free to withdraw from the study at any time. Alternative treatments will be discussed and referrals offered if requested. Written informed consent from parents, and assent from adolescents, will be obtained after they have the opportunity to discuss and address all questions with a study clinician and/or the PI. If a child turns 18 while in the study, we will have them sign an adult consent form. As talk therapy is minimal risk, and the treatment condition is likely to provide some direct benefit to the adolescent, only one parent signature will be obtained. As this is a telehealth treatment, electronic signatures will be collected.

7. Evaluation of Subject(s) Capacity to Provide Informed Consent/Assent: Indicate how the personnel obtaining consent will assess the potential subject's ability and capacity to consent to the research being proposed.

With all participants, we will describe the study verbally during the consent process and allow participants to ask any questions they might have. To ensure understanding, we will use open-ended questions with all participants to ask that they paraphrase the nature of the research and what they are being asked to do as part of the study, and also summarize the potential risks and benefits of the study.

8. Non-English Speaking Subjects: Explain provisions in place to ensure comprehension for research involving non-English speaking subjects. If enrollment of these subjects is anticipated, translated copies of all consent materials must be submitted for approval prior to use.

n/a

As a limited alternative to the above requirement, will you use the short form* for consenting process if you unexpectedly encounter a non-English speaking individual interested in study participation and the translation of the long form is not possible prior to intended enrollment? YES ☐ NO ☒

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9. Consent Waiver: In certain circumstances, the HIC may grant a waiver of signed consent, or a full waiver of consent, depending on the study. If you will request either a waiver of consent, or a waiver of signed consent for this study, complete the appropriate section below.

☐Not Requesting any consent waivers

☒Requesting a waiver of signed consent:

☒ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ Entire Study (Note that an information sheet may be required.)

For a waiver of signed consent, address the following:

- Would the signed consent form be the only record linking the subject and the research? YES ☒ NO ☐
- Does a breach of confidentiality constitute the principal risk to subjects? YES ☒ NO ☐

OR

- Does the research pose greater than minimal risk? YES ☐ NO☒
- Does the research include any activities that would require signed consent in a non-research context? YES ☐ NO ☒

☐ Requesting a waiver of consent:

☐ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ Entire Study

SECTION IV: PROTECTION OF RESEARCH SUBJECTS

Confidentiality & Security of Data:

1. What protected health information (medical information along with the HIPAA identifiers) about subjects will be collected and used for the research?

Height, weight, medical and psychosocial history will be collected and used for research.

HIPAA identifiers to be collected:

☒ Names

☒ All geographic subdivisions smaller than a State, including: street address, city, county, precinct, zip codes and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly-available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

☒ Telephone numbers

☒ E-mail addresses

☒ All elements of dates for dates related to an individual, including: birth date

2. How will the research data be collected, recorded and stored?

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Data will be collected via interview by trained clinicians and data will be collected via surveys using Qualtrics. Data will be recorded using the Zoom application for telehealth (or other platforms approved by Yale School of Medicine) for those participants who consent to audio and/or video recording. Data will be stored on the secure Yale server and/or in locked file cabinets.

3. How will the digital data be stored?

☐CD ☐DVD ☐Flash Drive ☐Portable Hard Drive ☒Secured Server ☐Laptop Computer ☐Desktop Computer ☐Other

4. What methods and procedures will be used to safeguard the confidentiality and security of the identifiable study data and the storage media indicated above during and after the subject's participation in the study?

To ensure confidentiality, all research records will be kept on Yale secure servers and in locked files in the Department of Psychiatry at Yale School of Medicine. All research personnel will be trained and supervised around confidentiality issues. The training will include formal NIH or Yale IRB modules with testing certification as well as HIPAA guidelines to follow around confidentiality. The PI and all essential research personnel will have access to the data. All essential personnel will be included as research staff on the HIC protocol submitted for approval.

All participants will be assigned a study number. Subsequently, participants will be identified only by that number and an encoded version of their initials (e.g., John Smith [adolescent] = JSMI-A). A list of numbers and the corresponding names will be maintained by the PI and stored on a Yale secure serve and/or in a locked research file. Any information published as a result of the study will be such that it will not permit identification of any participant.

Individually identifiable health information will be protected in accordance with the Health Insurance Portability and Accountability Act of 1996. All information collected will remain confidential except when we are legally required to disclose such information by law. These circumstances include knowledge of abuse of a child or elderly person, threats of harm to self or others, and plans to harm to property. Research records may be audited by a regulatory agency within the federal government. Organizations that have a responsibility for protecting human subjects, including the Yale IRB (Human Investigation Committee), may have access to the research records.

All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu

5. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured.

Data will be stored in locked cabinets for 7 years after the final data are collected. At the end of the study, participants will only be identified by their study code.

6. If appropriate, has a Certificate of Confidentiality been obtained?

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Yes

SECTION V: POTENTIAL BENEFITS

Potential Benefits: Identify any benefits that may be reasonably expected to result from the research, either to the subject(s) or to society at large. (Payment of subjects is not considered a benefit in this context of the risk benefit assessment.)

The study may have no direct benefit to the participant. The treatment is known to be helpful to youth with distress associated with other forms of trauma, but we do not know if it will be help adolescents who have experienced weight-related bullying. We anticipate that some of the knowledge from this study will be used to improve treatments for adolescents and to increase our understanding of treatments for weight-related bullying.

SECTION VI: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. **Alternatives:** What other alternatives are available to the study subjects outside of the research?

Alternatives include community referrals for weight loss counseling, cognitive behavioral therapy and interpersonal psychotherapy for eating disorders. These treatments do not generally address bullying.

2. **Payments for Participation (Economic Considerations):** Describe any payments that will be made to subjects, the amount and schedule of payments, and the conditions for receiving this compensation.

Parents and children will be paid for completing assessments (Mo.1=$20/each; Mo.2=$20/each; Post=$40/child, $20/parent).

3. **Costs for Participation (Economic Considerations):** Clearly describe the subject's costs associated with participation in the research, and the interventions or procedures of the study that will be provided at no cost to subjects.

The treatment will be provided at no cost to the participants.

4. **In Case of Injury:** This section is required for any research involving more than minimal risk, and for minimal risk research that presents the potential for physical harm (e.g., research involving blood draws).

This treatment is considered to be minimal risk and does not involve the potential for physical harm. Referrals will be provided if indicated.

IMPORTANT REMINDERS

Will this study have a billable service? **Yes** ☐ **No**☒

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Are there any procedures involved in this protocol that will be performed at YNHH or one of its affiliated entities?
Yes ☐ No ☒

IMPORTANT REMINDER ABOUT RESEARCH AT YNHH

Please note that if this protocol includes Yale-New Haven Hospital patients, including patients at the HRU, the Principal Investigator and any co-investigators who are physicians or mid-level practitioners (includes PAs, APRNs, psychologists and speech pathologists) who may have direct patient contact with patients on YNHH premises must have medical staff appointment and appropriate clinical privileges at YNHH. If you are uncertain whether the study personnel meet the criteria, please telephone the Physician Services Department at 203-688-2615. By submitting this protocol as a PI, you attest that you and any co-investigator who may have patient contact has a medical staff appointment and appropriate clinical privileges at YNHH.

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