NCT Number: NCT04484831
Name: A Trial to Test an Acceptance-based Therapy Program Among Adolescent Girls With Overweight/Obesity
Approved: 5/11/2021

Protocol

1. **Project Title:** Wellness Achieved Through Changing Habits (The WATCH Study)

2. **Principal Investigator:** Michelle Cardel, PhD, RD
   Co-Investigators: David Janicke, PhD; Matthew Gurka, PhD
   Study Coordinator: Darci Miller, MPH

3. **Abstract:**

The prevalence of overweight/obesity (OW/OB) in U.S. adolescents is 34.5%. The effectiveness of currently available adolescent weight loss interventions is limited because the amount of weight lost is modest and weight regain is common. Thus, there is a critical need to develop effective interventions in adolescents with OW/OB. The objective of this project is to address this need and to investigate the impact of an acceptance-based therapy (ABT) weight loss intervention in adolescents with OW/OB. ABT focuses on improving self-regulation skills and increasing tolerance of negative or uncomfortable emotions, and research demonstrates that it is a highly effective weight loss strategy in adults. Further, ABT has been successful in treating adolescents with chronic pain, high-risk behavior, anorexia, and depression. Given the success of ABT for treating other medical and behavioral issues in adolescents and the high percent of weight loss observed in adults, ABT could represent an effective weight loss intervention for adolescents. However, to date, no one has studied ABT as an adolescent weight loss tool. The overarching hypothesis of this proposal is that the ABT intervention will be feasible, acceptable, result in lower BMI z-scores and body fat percentage, healthier dietary intakes, increased physical activity, and improved blood pressure relative to an enhanced care condition.

4. **Background:**

The prevalence of OW/OB in U.S. adolescents is 34.5% and over 80% of youth with obesity become obese adults[1-3]. Of great concern is the significantly increasing prevalence of youth-onset type 2 diabetes (T2D) and OW/OB observed among lower socioeconomic status populations[4]. Prevalence of OW/OB in boys with a family income below 130% of the federal poverty level has increased from 12.5% in 1988-1994 to 21.2% in 2005-2008, while the prevalence of OW/OB in girls with a family income below 130% of the poverty level has increased from 11.9% in 1998-1994 to 19.3% in 2005-2008[5]. Average claims costs for children with obesity are nearly twice that of children who are normal weight. Further, average claims costs for children with T2D were $10,789 compared with $2,907 for obese

children and $1,640 for normal weight children per self-insured health plan data from the IBM Corporation[6]. T2D has also undergone a nearly 31% increase over the last 15 years, with rates particularly high in females and minority populations. Unmanaged adolescents with OW/OB are at high risk of developing hyperlipidemia, hypertension, and insulin resistance[7]; all of which are risk factors for T2D. Additional risk factors for youth-onset T2D and OW/OB include poor diet, irregular sleeping patterns, and little physical activity[8]. Multiple large population-based longitudinal studies clearly demonstrate that OW/OB in adolescence also predicts the development of cardiovascular disease (CVD) risk[1, 9-12]. Despite being associated with reduced life expectancy[1, 13], having obesity is associated with substantially higher lifetime medical expenditures, with aggregate obesity-related medical care costs in the U.S. reaching a staggering $150 billion in 2016[14]. *Weight loss in adolescents with OW/OB is essential for reducing the risk of T2D, CVD, and excessive medical costs.*

Leading health organizations have recommended comprehensive behavioral interventions to combat adolescent obesity. However, interventions have led to limited weight loss and weight regain is common, particularly in low-income populations. Thus, there is a *critical need* for the development of effective weight loss interventions in adolescents, particularly adolescents who are more likely to be low-income and OW/OB.

5. Specific Aims:

Aim 1: Develop an ABT intervention targeted to adolescents with OW/OB.

Aim 1a: Focus groups and writing groups will be conducted in adolescents with OW/OB and their parents to identify perceived barriers to weight loss and modifications needed to adapt the adult ABT curriculum and manuals to the adolescent population.

Aim 1b: Pretest the full 6-month adapted intervention in adolescents with OW/OB. Following each session and at the end of the intervention, participants will provide detailed verbal/written feedback to improve the adapted ABT intervention for adolescents.

Aim 2: Assess the feasibility, acceptability, and efficacy of a pilot adolescent ABT intervention for adolescents with OW/OB at post-treatment.

Aim 2a: Evaluate recruitment considerations, trial processes, feasibility, and participation.

Aim 2b: Estimate the efficacy of the adolescent ABT intervention in adolescents with OW/OB studied in aim 2a on improving body composition, decreasing caloric intake and increasing physical activity.

6. Research Plan:

We will recruit adolescents with OW/OB for focus groups and later, writing groups, to identify key perceived barriers of weight loss and needed modifications to the adult ABT intervention in order to adapt the adult ABT curriculum and manuals for use in an adolescent ABT intervention. Once identified, potential participants (and/or their parent) will be screened for eligibility. Focus groups will be conducted among adolescent males and females separately until thematic saturation is reached. During each focus group, notes will be taken and audio/visual recording will be used. A tunneling approach will be used to ask questions with initial questions open-ended and broad to promote conversation and increasing comfort with sharing. As the discussion progresses, questions will become more focused. At the conclusion of the focus group discussions, participants in each focus group will be asked to self-report their sex, age, race/ethnicity, height/weight, socioeconomic status, subjective social standing, obesity comorbidities, and prior weight loss attempts. Writing groups will then be conducted with select participants from previous focus groups. Each writing group will be used to further assist the research team with modifying the adult ABT weight loss program for use in adolescents. There will be up to 5 writing groups conducted.

We will then pre-test the full 6-month adolescent ABT intervention with adolescents with OW/OB. Once potential participants have been identified via recruitment, eligibility for the intervention will be assessed by someone from the study team. Those who appear eligible after screening will be asked to attend clinic visit 1. Upon arrival to the study visit, written informed consent (and assent as needed) will be obtained. Eligible participants and/or their parents will be asked to sign the informed consent/assent for the adolescent ABT weight loss program, respectively, before the study is conducted. The participants and/or their parents will be provided with the contact information for the PI and the study coordinator as well as contact information for the IRB as part of the written consent process. Throughout and after the informed consent/assent process, participants will be asked if they have any questions. We will notify the participants that they may withdraw their participation at any given time. Baseline assessments for the adolescents including blood pressure, heart rate, anthropometrics (height, weight, and waist circumference), percent body fat, metabolic blood panels, urine sample, and stool sample will be assessed with the adolescents during clinic visit 1. The researcher will collect dietary intake information over a 3-day period using 24-hour dietary recalls between clinic visits 1 and 2. Recalls will include 2 weekdays and 1 weekend day. Adolescent participants will also be given an accelerometer to wear and a sleep log to use as well as instructions for use over a 7-day period. The adolescent will be instructed to return the sleep log and accelerometer at the second baseline study visit.

At clinic visit 2, an individualized feedback session with Dr. Michelle Cardel, a registered dietitian, will take place with the adolescent in the pre-test intervention. During this time, Dr. Cardel will provide personalized feedback to the adolescent based on their 3-day dietary recalls. The adolescents will be asked to complete a series of questionnaires to assess demographic information, eating behaviors, self-regulation, self-image, quality of life, social support, depression, resilience, life experiences, stress levels, and taste/sensation. These questionnaires will be completed at the beginning and at the end of the intervention.

The 6-month pre-test adolescent ABT intervention will include 90-minute sessions held weekly for 2 months, bi-weekly for 2 months, and monthly for 2 months, for a total of 15 sessions. Following each session, questions will be asked of the adolescents regarding the feasibility, process, and content of the adolescent ABT intervention. Beginning at week 2 of the intervention, weight check-ins will be conducted at each remaining session and feedback will be provided to the participants. Additionally, between sessions 14 and 15, members of the study team will contact participants to check in on their status and provide an opportunity for participants to informally discuss the program and/or ask questions the study team can address. The pre-test intervention will be completed with ~10-20 adolescents.

Adaptations to the randomized controlled trial (described below) are in response to COVID-19.

Once the ABT intervention has been modified following the pre-test, adolescent subjects will be recruited for the randomized controlled trial. Initially, this was planned to be an in-person trial, but we have adapted it to a remote intervention in response to COVID-19. Participants will complete pre-treatment and post-treatment assessments. Assessments conducted at each of these time points include surveys, weight measurements, dietary intake, and physical activity. Upon consent (and assent, as needed), participants will complete a series of questionnaires to assess demographic information, eating behaviors, self-regulation, self-image, quality of life, social support, depression, resilience, life experiences, stress levels, and taste/sensation. Dietary intake will also be assessed using 24-hour dietary recalls. Recalls will include 2 weekdays and 1 weekend day. Once participants have finished surveys and dietary recalls, they will participate in an individualized feedback session with Dr. Michelle Cardel, a registered dietitian. During this time, Dr. Cardel will provide personalized feedback to the adolescent based on their 3-day dietary recalls. Participants will then be given an accelerometer and sleep log with instructions for use during a 7-day period and will then be asked to return the sleep log and accelerometer after the 7-day period is complete. They will

also be given a wireless weight scale to obtain weight measurements throughout the trial, at which point they will be randomized to either the adapted ABT intervention or an enhanced care group using a randomized block design. The ABT intervention for adolescents will be 6 months in duration. Participants randomized to the ABT intervention group will attend 15 remote intervention visits that are each 90 minutes in length. The sessions will be weekly for the first 2 months, bi-weekly for the next 2 months, and monthly for the last 2 months. Each session will be recorded. Participants randomized to the enhanced care group will receive a total of 15 emailed handouts on elements of a healthy lifestyle over the 6-month period and will participate in a midpoint one-on-one nutrition consultation with Dr. Michelle Cardel. Handouts will be emailed at the time each of the ABT sessions occurs.

The study will be conducted remotely via Zoom. The randomized controlled trial will include intervention cohort sizes of ~7-10 adolescents with the target sample size of the study equal to 20 adolescents in each group (ABT intervention and enhanced care groups).

Data To Be Collected *(what will be collected, where it will be stored, how it will be stored)*. For those who do not pass the screening, information collected will be destroyed immediately. For those who do pass the screening, a subject ID number will be assigned. Study data will be stored using REDCap behind the firewall at the University of Florida. Only designated members of the study team will have access to the study data. The database will contain personal identifiers including name, address, phone number, email address, birth date, and race/ethnicity.

Audio/visual recordings from the focus/writing groups and ABT intervention sessions will be transcribed, as necessary. Personal information will not be identified on the transcripts and confidentiality will be strictly maintained. Study data including audio/visual recordings and paper documents will be stored in locked filing cabinets. The subject ID assigned to each participant at the beginning of interaction will be that participant's assigned ID number for all study documents.

Anthropometric and health-related data being collected at pre- and post-treatment of pre-test includes: height; weight; waist circumference; heart rate; blood pressure; percent body fat; urine sample; stool sample; metabolic blood panels; 3 24-hour dietary recalls; accelerometer data; and surveys/questionnaires. Mid-treatment data collection (in the pre-test intervention only) will be limited to anthropometrics (height, weight, waist circumference), blood pressure, heart rate, 3 24-hour dietary recalls, accelerometer data, and select questionnaires.

In the remote version of the randomized controlled trial in response to COVID-19, anthropometric and health-related data being collected at pre-treatment and post-treatment includes: height; weight; 3 24-hour dietary recalls; accelerometer data; and surveys/questionnaires.

The testing of biological samples collected for the study includes: blood, stool, and urine. Adolescents will be asked to collect stool and urine using a self-administered collection kit during or after the pre- and post-treatment visits. Self-administered collections performed at home (after the study visit) will be retrieved by the study team at no cost to participants. Blood draws will be completed by a certified phlebotomist during the clinic visits. Testing will be completed using Enzyme-Linked Immunosorbent Assay (ELISA).

Urine and stool samples may be stored for analysis in the Academic Research Building in the Department of Molecular Genetics and Microbiology, Room R1-156. Samples will be de-identified for processing and storage. Specimens in this lab are only available to authorized users. Urine and stool samples and data will only be released to the PI or PI-designated researchers with appropriate IRB approval. Blood samples may be stored in the UF Diabetes Institute as part of a bio-bank only available to authorized users. This bio-bank is the Diabetes Institute Study Bank (IRB201400703). Blood samples and data will only be released to the PI or PI-designated researchers with appropriate IRB approval.

Survey data will be collected using the following measures:; Sleep Diary; Eating Attitudes Test (EAT-26); Beck Depression Inventory II (BDI-II); Self-Efficacy Scale; Strengths and Difficulties Questionnaire (SDQ), adolescent version; Modified Adverse Childhood Experiences (ACE) questionnaire: adolescent; Modified ACE questionnaire: adult; Oral Health Status questionnaire; Connor-Davidson Resilience Scale; Acceptance and Action Questionnaire; Sociodemographics Questionnaire; MacArthur Adult Subjective Sociometric and Body Scales; and MacArthur Child Subjective Sociometric and Body Scales; Perceived Stress Scale; Kirby Questionnaire, Childhood Unpredictability Questionnaire; Mini-K Scale; Neighborhood Disorder Questionnaire; Anxiety Sensitivity Index-3 Questionnaire; Social Support and Eating Habits Survey; Pediatric Quality of Life Inventory; Three-Factor Eating Questionnaire; Youth Food Security Survey; Project EAT Questionnaire; Modified Weight Bias Internalization Scale, Youth Risk Behavior Survey, and a medication inquiry (i.e., what medications, if any, are taken by participants, name of medication, and reason for use).

Adolescent participants in the ABT pre-test and in the randomized controlled trial will wear an accelerometer for 7 days to objectively measure physical activity levels at 3 time points during

the study: pre-treatment, mid-treatment (pre-test intervention only), and post-treatment. Removal will be limited to times when the participant is sleeping, bathing, or swimming. We will assess time spent in sedentary, light, moderate, and vigorous physical activity.

Dietary intakes of the adolescents will be assessed using 3 24-hour dietary recalls (2 weekdays and 1 weekend day) during the study: pre-treatment, mid-treatment (pre-test intervention only), and post-treatment. Outcome variables to be analyzed include total energy intakes, macronutrient intakes, and micronutrient intakes. A sleep log will be used during the study: pre-treatment, mid-treatment (pre-test intervention only), and post-treatment.

Inclusion/Exclusion Criteria. We will limit our recruitment to adolescents ages 14-19 and OW/OB equal to or greater than the 85th percentile for sex and age as determined by CDC growth charts. Adolescents will be excluded if they have active cancer or cancer requiring treatment in the past 2 years, active or chronic infections (e.g., HIV or TB), active kidney disease, lung disease, known pregnancy or plans to become pregnant in the next 2 years, plans to move out of the area in the next year, a diagnosis of CVD or diabetes, autism, any intellectual disability (e.g., down syndrome), any condition prohibiting physical activity, an eating disorder or substance abuse disorder, having recently begun a course of or changed the dosage of any medications known to affect appetite or body composition, weight loss ≥5% in the previous 6 months, or if they do not follow the study plan.

How Participants Will Be Recruited. Eligible participants will be identified at outpatient clinics such as Children's Medical Services, the Consent2Share program through IDR, and HealthStreet. Social media recruitment will also be conducted via the CTSI Recruitment Center. Based on study interest, the study team will notify potentially eligible persons about the research study and elicit feedback regarding their interest in participation. Once interest has been assessed and confirmed, the research team will reach out to these potential participants regarding the specific program requirements and will move forward with conduct of the screening and baseline visits to determine qualification to participate.

Randomization. Adolescent participants in the randomized controlled trial, stratified by sex, will be randomized by block randomization using random block sizes of four and eight for the ABT intervention portion of this project. Only the biostatistician on the project (Dr. Matthew Gurka) will have access to the file of random assignments, created before the study. Cards will be created with the study ID numbers and the corresponding assignments and will be placed into sealed envelopes, which will be kept in a locked drawer. As successive patients are recruited and assigned their study ID, the envelope with the next chronological number

will be opened for assignment to one of the two groups. Randomization will occur after participants have completed all pre-treatment assessments and the personalized nutrition consultation.

Blinding. Due to the nature of the intervention, it will not be possible to blind the instructor administering the intervention or participants. In all other aspects of the trial, we will employ blinding. Data managers, statisticians, and investigators drawing conclusions will be fully blinded. We will follow the rule that statistical analyses are conducted with the arms coded as 'intervention A' and 'intervention B'. The investigators will write two abstracts while blinding is intact; one assuming the ABT (experimental arm) is 'intervention A' and the enhanced care arm is 'intervention B', and one assuming the opposite. After this, the code will be broken by the data manager.

Data Analysis Plan. Qualitative outcomes data will be collected after each focus group to develop thematic saturation for adaptation of the adult ABT protocol for the OW/OB adolescent population.

Primary and secondary outcome data will be collected at 3 time points for the ABT pre-test (baseline, mid-treatment, and post-treatment).

Primary and secondary outcome data will be collected at 2 time points for both the in-person ABT intervention and self-guided, at-home ABT intervention groups: baseline and post-treatment. We will begin with comparing descriptive statistics for baseline data between the two adolescent groups, followed by data from post-treatment. All data will be inspected for errors and inconsistencies across time points. For the feasibility and acceptability aim (Aim 2a), outcomes will be defined primarily by rates: recruitment, retention, and satisfaction will be calculated and compared between the groups. These rates will aid determination of overall feasibility of this intervention for a larger trial and will inform modifications to improve recruitment/retention of participants. While we will not be adequately powered to demonstrate efficacy, we will use analytic techniques similar to what would be done for a larger trial that did have sufficient statistical power (using an intention to treat approach). For the outcomes of change in BMI z-score and percent body fat (and other continuous measures), linear mixed models will be used to estimate and compare mean changes in BMI z-score between the groups, adjusting for baseline BMI z-score. Given the small sample size, the Kenward-Roger approximation for the denominator degrees of freedom will be utilized to ensure valid inference[15]. Model selection of the covariance structure is minimized; and we will model directly the variance of the outcome at post-intervention. As this is a pilot study, SDs of these

changes and estimates of the correlations will be important to allow for planning of a larger trial. Effect sizes will be reported to demonstrate potential efficacy of the intervention but will not be used in future power analyses[16]. In addition, we will examine interactions between group x time and other covariates such as sex and race/ethnicity to get preliminary data on whether these demographic characteristics modify the effect of the intervention. The mixed model framework allows for outcomes to be missing at random. It is probable that this assumption will not be met and the observed dropout will be non-ignorable. While not possible to test, we will examine closely the nature of the missingness, compare retention rates between groups, and examine for possible participant characteristics that may be associated with retention to aid in planning a future trial. Models that accommodate non-ignorable missingness will be fit and used as a sensitivity analysis to compare with the framework described above, which will aid in the elucidation of the missing data mechanism for planning purposes. For secondary outcomes that may not be normally distributed or continuous, generalized linear mixed models across the 2 time points (baseline, post-treatment) will be utilized, with the appropriate distribution and link function specified.

Data Sharing. We will be sending de-identified data to collaborators from FSU for analyses.

7. Possible Discomforts and Risks:

There are no known risks associated with any of the proposed study activities. Possible risks are described as follows:

Confidentiality: There is a slight risk that information could be revealed inappropriately or accidentally. Depending upon the nature of the information, such a release could upset or embarrass participants.

Stress: Individuals may experience feelings of stress or anxiety while taking part in the study. Participants will be informed that “feelings of stress or anxiety” are a risk in participation.

Pain: A blood draw is a standard medical procedure used to obtain blood for medical testing and will be completed by a certified phlebotomist, but this brief portion of the study may induce some pain and/or a bruise.

Precautions will be taken to minimize participant risk including: 1) participants will be told they can discontinue participation at any time or decline to answer any specific questions; 2) unique participant IDs will be utilized on all study documents; and 3) data will be kept confidential, stored on secure servers, identifiers will be destroyed when possible, and data access will be

limited to the study team. Individual information will not be released to anyone outside this project and will only be assessed by those actively working with the study team. If a participant indicates that he/she is going to hurt his/herself or someone else at any time throughout the study, a member of the study team will call '911' and the participant will be asked not to leave their home until first responders arrive. Additionally, we utilize the BDI-II as a screening tool for this study to identify suicidality. Answers to any question regarding suicidality are reviewed by study staff prior to the participant being randomized into either of the arms of the study. Should any participant indicate anything other than that they are non-suicidal, our team will refer the individual to the Crisis Hot Line and consult with co-investigator, Dr. David Janicke, a licensed psychologist.

8. Possible Benefits:

There are minimal risks associated with this project and the benefits outweigh the risks. There may be immediate and direct benefits to some of the individuals who participate in this study. Through conduct of this research, we will be able to adapt and assess the effects of an ABT weight loss intervention in adolescents ages 14-19. This will assist in the development of future weight loss interventions for adolescents. Of direct benefit to the participants, some may be likely to lose weight and improve their cardiometabolic health profile.

9. Conflict of Interest:

There are no conflicts of interest to disclose.

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Aim 1b: Pretest the full 6-month adapted intervention in adolescents with OW/OB. Following each session and at the end of the intervention, participants will provide detailed verbal/written feedback to improve the adapted ABT intervention for adolescents.

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Aim 2a: Evaluate recruitment considerations, trial processes, feasibility, and participation.

Aim 2b: Estimate the efficacy of the adolescent ABT intervention in adolescents with OW/OB studied in aim 2a on improving body composition, decreasing caloric intake and increasing physical activity.

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We will then pre-test the full 6-month adolescent ABT intervention with adolescents with OW/OB. Once potential participants have been identified via recruitment, eligibility for the intervention will be assessed by someone from the study team. Those who appear eligible after screening will be asked to attend clinic visit 1. Upon arrival to the study visit, written informed consent (and assent as needed) will be obtained. Eligible participants and/or their parents will be asked to sign the informed consent/assent for the adolescent ABT weight loss program, respectively, before the study is conducted. The participants and/or their parents will be provided with the contact information for the PI and the study coordinator as well as contact information for the IRB as part of the written consent process. Throughout and after the informed consent/assent process, participants will be asked if they have any questions. We will notify the participants that they may withdraw their participation at any given time. Baseline assessments for the adolescents including blood pressure, heart rate, anthropometrics (height, weight, and waist circumference), percent body fat, metabolic blood panels, urine sample, and stool sample will be assessed with the adolescents during clinic visit 1. The researcher will collect dietary intake information over a 3-day period using 24-hour dietary recalls between clinic visits 1 and 2. Recalls will include 2 weekdays and 1 weekend day. Adolescent participants will also be given an accelerometer to wear and a sleep log to use as well as instructions for use over a 7-day period. The adolescent will be instructed to return the sleep log and accelerometer at the second baseline study visit.

At clinic visit 2, an individualized feedback session with Dr. Michelle Cardel, a registered dietitian, will take place with the adolescent in the pre-test intervention. During this time, Dr. Cardel will provide personalized feedback to the adolescent based on their 3-day dietary recalls. The adolescents will be asked to complete a series of questionnaires to assess demographic information, eating behaviors, self-regulation, self-image, quality of life, social support, depression, resilience, life experiences, stress levels, and taste/sensation. These questionnaires will be completed at the beginning and at the end of the intervention.

The 6-month pre-test adolescent ABT intervention will include 90-minute sessions held weekly for 2 months, bi-weekly for 2 months, and monthly for 2 months, for a total of 15 sessions. Following each session, questions will be asked of the adolescents regarding the feasibility, process, and content of the adolescent ABT intervention. Beginning at week 2 of the intervention, weight check-ins will be conducted at each remaining session and feedback will be provided to the participants. Additionally, between sessions 14 and 15, members of the study team will contact participants to check in on their status and provide an opportunity for participants to informally discuss the program and/or ask questions the study team can address. The pre-test intervention will be completed with ~10-20 adolescents.

Adaptations to the randomized controlled trial (described below) are in response to COVID-19.

Once the ABT intervention has been modified following the pre-test, adolescent subjects will be recruited for the randomized controlled trial. Initially, this was planned to be an in-person trial, but we have adapted it to a remote intervention in response to COVID-19. Participants will complete pre-treatment and post-treatment assessments. Assessments conducted at each of these time points include surveys, weight measurements, dietary intake, and physical activity. Upon consent (and assent, as needed), participants will complete a series of questionnaires to assess demographic information, eating behaviors, self-regulation, self-image, quality of life, social support, depression, resilience, life experiences, stress levels, and taste/sensation. Dietary intake will also be assessed using 24-hour dietary recalls. Recalls will include 2 weekdays and 1 weekend day. Once participants have finished surveys and dietary recalls, they will participate in an individualized feedback session with Dr. Michelle Cardel, a registered dietitian. During this time, Dr. Cardel will provide personalized feedback to the adolescent based on their 3-day dietary recalls. Participants will then be given an accelerometer and sleep log with instructions for use during a 7-day period and will then be asked to return the sleep log and accelerometer after the 7-day period is complete. They will

also be given a wireless weight scale to obtain weight measurements throughout the trial, at which point they will be randomized to either the adapted ABT intervention or an enhanced care group using a randomized block design. The ABT intervention for adolescents will be 6 months in duration. Participants randomized to the ABT intervention group will attend 15 remote intervention visits that are each 90 minutes in length. The sessions will be weekly for the first 2 months, bi-weekly for the next 2 months, and monthly for the last 2 months. Each session will be recorded. Participants randomized to the enhanced care group will receive a total of 15 emailed handouts on elements of a healthy lifestyle over the 6-month period and will participate in a midpoint one-on-one nutrition consultation with Dr. Michelle Cardel. Handouts will be emailed at the time each of the ABT sessions occurs.

The study will be conducted remotely via Zoom. The randomized controlled trial will include intervention cohort sizes of ~7-10 adolescents with the target sample size of the study equal to 20 adolescents in each group (ABT intervention and enhanced care groups).

Data To Be Collected *(what will be collected, where it will be stored, how it will be stored)*. For those who do not pass the screening, information collected will be destroyed immediately. For those who do pass the screening, a subject ID number will be assigned. Study data will be stored using REDCap behind the firewall at the University of Florida. Only designated members of the study team will have access to the study data. The database will contain personal identifiers including name, address, phone number, email address, birth date, and race/ethnicity.

Audio/visual recordings from the focus/writing groups and ABT intervention sessions will be transcribed, as necessary. Personal information will not be identified on the transcripts and confidentiality will be strictly maintained. Study data including audio/visual recordings and paper documents will be stored in locked filing cabinets. The subject ID assigned to each participant at the beginning of interaction will be that participant's assigned ID number for all study documents.

Anthropometric and health-related data being collected at pre- and post-treatment of pre-test includes: height; weight; waist circumference; heart rate; blood pressure; percent body fat; urine sample; stool sample; metabolic blood panels; 3 24-hour dietary recalls; accelerometer data; and surveys/questionnaires. Mid-treatment data collection (in the pre-test intervention only) will be limited to anthropometrics (height, weight, waist circumference), blood pressure, heart rate, 3 24-hour dietary recalls, accelerometer data, and select questionnaires.

In the remote version of the randomized controlled trial in response to COVID-19, anthropometric and health-related data being collected at pre-treatment and post-treatment includes: height; weight; 3 24-hour dietary recalls; accelerometer data; and surveys/questionnaires.

The testing of biological samples collected for the study includes: blood, stool, and urine. Adolescents will be asked to collect stool and urine using a self-administered collection kit during or after the pre- and post-treatment visits. Self-administered collections performed at home (after the study visit) will be retrieved by the study team at no cost to participants. Blood draws will be completed by a certified phlebotomist during the clinic visits. Testing will be completed using Enzyme-Linked Immunosorbent Assay (ELISA).

Urine and stool samples may be stored for analysis in the Academic Research Building in the Department of Molecular Genetics and Microbiology, Room R1-156. Samples will be de-identified for processing and storage. Specimens in this lab are only available to authorized users. Urine and stool samples and data will only be released to the PI or PI-designated researchers with appropriate IRB approval. Blood samples may be stored in the UF Diabetes Institute as part of a bio-bank only available to authorized users. This bio-bank is the Diabetes Institute Study Bank (IRB201400703). Blood samples and data will only be released to the PI or PI-designated researchers with appropriate IRB approval.

Survey data will be collected using the following measures:; Sleep Diary; Eating Attitudes Test (EAT-26); Beck Depression Inventory II (BDI-II); Self-Efficacy Scale; Strengths and Difficulties Questionnaire (SDQ), adolescent version; Modified Adverse Childhood Experiences (ACE) questionnaire: adolescent; Modified ACE questionnaire: adult; Oral Health Status questionnaire; Connor-Davidson Resilience Scale; Acceptance and Action Questionnaire; Sociodemographics Questionnaire; MacArthur Adult Subjective Sociometric and Body Scales; and MacArthur Child Subjective Sociometric and Body Scales; Perceived Stress Scale; Kirby Questionnaire, Childhood Unpredictability Questionnaire; Mini-K Scale; Neighborhood Disorder Questionnaire; Anxiety Sensitivity Index-3 Questionnaire; Social Support and Eating Habits Survey; Pediatric Quality of Life Inventory; Three-Factor Eating Questionnaire; Youth Food Security Survey; Project EAT Questionnaire; Modified Weight Bias Internalization Scale, Youth Risk Behavior Survey, and a medication inquiry (i.e., what medications, if any, are taken by participants, name of medication, and reason for use).

Adolescent participants in the ABT pre-test and in the randomized controlled trial will wear an accelerometer for 7 days to objectively measure physical activity levels at 3 time points during

the study: pre-treatment, mid-treatment (pre-test intervention only), and post-treatment. Removal will be limited to times when the participant is sleeping, bathing, or swimming. We will assess time spent in sedentary, light, moderate, and vigorous physical activity.

Dietary intakes of the adolescents will be assessed using 3 24-hour dietary recalls (2 weekdays and 1 weekend day) during the study: pre-treatment, mid-treatment (pre-test intervention only), and post-treatment. Outcome variables to be analyzed include total energy intakes, macronutrient intakes, and micronutrient intakes. A sleep log will be used during the study: pre-treatment, mid-treatment (pre-test intervention only), and post-treatment.

Inclusion/Exclusion Criteria. We will limit our recruitment to adolescents ages 14-19 and OW/OB equal to or greater than the 85th percentile for sex and age as determined by CDC growth charts. Adolescents will be excluded if they have active cancer or cancer requiring treatment in the past 2 years, active or chronic infections (e.g., HIV or TB), active kidney disease, lung disease, known pregnancy or plans to become pregnant in the next 2 years, plans to move out of the area in the next year, a diagnosis of CVD or diabetes, autism, any intellectual disability (e.g., down syndrome), any condition prohibiting physical activity, an eating disorder or substance abuse disorder, having recently begun a course of or changed the dosage of any medications known to affect appetite or body composition, weight loss ≥5% in the previous 6 months, or if they do not follow the study plan.

How Participants Will Be Recruited. Eligible participants will be identified at outpatient clinics such as Children's Medical Services, the Consent2Share program through IDR, and HealthStreet. Social media recruitment will also be conducted via the CTSI Recruitment Center. Based on study interest, the study team will notify potentially eligible persons about the research study and elicit feedback regarding their interest in participation. Once interest has been assessed and confirmed, the research team will reach out to these potential participants regarding the specific program requirements and will move forward with conduct of the screening and baseline visits to determine qualification to participate.

Randomization. Adolescent participants in the randomized controlled trial, stratified by sex, will be randomized by block randomization using random block sizes of four and eight for the ABT intervention portion of this project. Only the biostatistician on the project (Dr. Matthew Gurka) will have access to the file of random assignments, created before the study. Cards will be created with the study ID numbers and the corresponding assignments and will be placed into sealed envelopes, which will be kept in a locked drawer. As successive patients are recruited and assigned their study ID, the envelope with the next chronological number

will be opened for assignment to one of the two groups. Randomization will occur after participants have completed all pre-treatment assessments and the personalized nutrition consultation.

Blinding. Due to the nature of the intervention, it will not be possible to blind the instructor administering the intervention or participants. In all other aspects of the trial, we will employ blinding. Data managers, statisticians, and investigators drawing conclusions will be fully blinded. We will follow the rule that statistical analyses are conducted with the arms coded as 'intervention A' and 'intervention B'. The investigators will write two abstracts while blinding is intact; one assuming the ABT (experimental arm) is 'intervention A' and the enhanced care arm is 'intervention B', and one assuming the opposite. After this, the code will be broken by the data manager.

Data Analysis Plan. Qualitative outcomes data will be collected after each focus group to develop thematic saturation for adaptation of the adult ABT protocol for the OW/OB adolescent population.

Primary and secondary outcome data will be collected at 3 time points for the ABT pre-test (baseline, mid-treatment, and post-treatment).

Primary and secondary outcome data will be collected at 2 time points for both the in-person ABT intervention and self-guided, at-home ABT intervention groups: baseline and post-treatment. We will begin with comparing descriptive statistics for baseline data between the two adolescent groups, followed by data from post-treatment. All data will be inspected for errors and inconsistencies across time points. For the feasibility and acceptability aim (Aim 2a), outcomes will be defined primarily by rates: recruitment, retention, and satisfaction will be calculated and compared between the groups. These rates will aid determination of overall feasibility of this intervention for a larger trial and will inform modifications to improve recruitment/retention of participants. While we will not be adequately powered to demonstrate efficacy, we will use analytic techniques similar to what would be done for a larger trial that did have sufficient statistical power (using an intention to treat approach). For the outcomes of change in BMI z-score and percent body fat (and other continuous measures), linear mixed models will be used to estimate and compare mean changes in BMI z-score between the groups, adjusting for baseline BMI z-score. Given the small sample size, the Kenward-Roger approximation for the denominator degrees of freedom will be utilized to ensure valid inference[15]. Model selection of the covariance structure is minimized; and we will model directly the variance of the outcome at post-intervention. As this is a pilot study, SDs of these

changes and estimates of the correlations will be important to allow for planning of a larger trial. Effect sizes will be reported to demonstrate potential efficacy of the intervention but will not be used in future power analyses[16]. In addition, we will examine interactions between group x time and other covariates such as sex and race/ethnicity to get preliminary data on whether these demographic characteristics modify the effect of the intervention. The mixed model framework allows for outcomes to be missing at random. It is probable that this assumption will not be met and the observed dropout will be non-ignorable. While not possible to test, we will examine closely the nature of the missingness, compare retention rates between groups, and examine for possible participant characteristics that may be associated with retention to aid in planning a future trial. Models that accommodate non-ignorable missingness will be fit and used as a sensitivity analysis to compare with the framework described above, which will aid in the elucidation of the missing data mechanism for planning purposes. For secondary outcomes that may not be normally distributed or continuous, generalized linear mixed models across the 2 time points (baseline, post-treatment) will be utilized, with the appropriate distribution and link function specified.

Data Sharing. We will be sending de-identified data to collaborators from FSU for analyses.

7. Possible Discomforts and Risks:

There are no known risks associated with any of the proposed study activities. Possible risks are described as follows:

Confidentiality: There is a slight risk that information could be revealed inappropriately or accidentally. Depending upon the nature of the information, such a release could upset or embarrass participants.

Stress: Individuals may experience feelings of stress or anxiety while taking part in the study. Participants will be informed that “feelings of stress or anxiety” are a risk in participation.

Pain: A blood draw is a standard medical procedure used to obtain blood for medical testing and will be completed by a certified phlebotomist, but this brief portion of the study may induce some pain and/or a bruise.

Precautions will be taken to minimize participant risk including: 1) participants will be told they can discontinue participation at any time or decline to answer any specific questions; 2) unique participant IDs will be utilized on all study documents; and 3) data will be kept confidential, stored on secure servers, identifiers will be destroyed when possible, and data access will be

limited to the study team. Individual information will not be released to anyone outside this project and will only be assessed by those actively working with the study team. If a participant indicates that he/she is going to hurt his/herself or someone else at any time throughout the study, a member of the study team will call '911' and the participant will be asked not to leave their home until first responders arrive. Additionally, we utilize the BDI-II as a screening tool for this study to identify suicidality. Answers to any question regarding suicidality are reviewed by study staff prior to the participant being randomized into either of the arms of the study. Should any participant indicate anything other than that they are non-suicidal, our team will refer the individual to the Crisis Hot Line and consult with co-investigator, Dr. David Janicke, a licensed psychologist.

8. Possible Benefits:

There are minimal risks associated with this project and the benefits outweigh the risks. There may be immediate and direct benefits to some of the individuals who participate in this study. Through conduct of this research, we will be able to adapt and assess the effects of an ABT weight loss intervention in adolescents ages 14-19. This will assist in the development of future weight loss interventions for adolescents. Of direct benefit to the participants, some may be likely to lose weight and improve their cardiometabolic health profile.

9. Conflict of Interest:

There are no conflicts of interest to disclose.

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