THE ROLE OF PARENTS IN ADOLESCENT OBESITY TREATMENT: RANDOMIZED CONTROL TRIAL OF TEENS+

NCT03851796

OCTOBER 13, 2025

STUDY PROTOCOL

We propose to conduct a 2x5 repeated-measures, randomized clinical trial to test study aims and hypotheses. We will randomly assign families to either: Parents as Coaches (PAC) or Parent Weight Loss (PWL). All adolescents will participate in the 4-month TEENS+ protocol. The proposed intervention is modeled after our pilot and designed to test its efficacy in a fully powered trial over 1-year follow-up. Assessments will be conducted at 0, 2, 4, 8 and 12 months (m). The primary dependent variable of interest is ΔBMI at 12m ($\Delta BMI_{4\text{-}12m}$), representing adolescent weight loss maintenance. Eight waves of adolescent/parent dyads will be stratified by sex and race and randomized to TEENS+PAC or TEENS+PWL. We will recruit 210 families (105 randomly assigned to each condition) using established strategies, and employ a block randomization scheme, stratified for adolescent sex and race, to ensure equal group allocation on these variables. Participants who consent/assent, meet eligibility criteria and complete baseline assessments will be eligible for randomization and assigned to either TEENS+PAC or TEENS+PWL. To reduce contamination, adolescents will be in groups according to their parents' assignment. Participants will be informed of their intervention assignment at the first group meeting.

TEENS+ Adolescent Intervention. TEENS+ was informed by the integration of theory and previous research.[1-3] After baseline, families will be randomized to TEENS+PAC or TEENS+PWL. All adolescents participate in TEENS+. Adolescent groups are single-sex, to facilitate interaction at this critical developmental stage, led by 2 trained, supervised lifestyle coaches (psychology doctoral trainee paired with a registered dietitian), *masked to study hypotheses*. Over 16 weeks, adolescents meet weekly for 1-hour groups. Content in TEENS+PAC and TEENS+PWL is identical; however, in PAC, adolescents alternate weekly between concurrent, separate group visits and conjoint (parent and child) group nutrition education visits. In PWL, all core adolescent groups occur separately from their parents. TEENS+ considers the adolescent developmental tasks of individuation and autonomy development, and includes strategies to navigate peer influences, while also eliciting adolescent-driven reasons for change. TEENS+ recognizes that responsibility for eating choices shifts from parents to adolescents, yet acknowledges that parent influence remains strong (e.g., ~50% of adolescents eat ≥5 meals/week with their family).[4] As such, autonomy is emphasized, and adolescents are also encouraged to consider what they need from significant others (including parents) for successful goal attainment (e.g., asking parents to keep certain foods in/out of the home; transportation to the YMCA).

Manualized sessions follow a behavior therapy approach, including guided goal-setting, self-monitoring, identifying barriers and solutions, contingency management, stimulus control, dealing with setbacks, maintenance and relapse prevention. Weight is assessed weekly by the coaches, with MI-consistent, autonomy-supportive feedback provided. Weekly food and physical activity (PA) logs are maintained and reviewed by coaches, with personalized, written feedback provided. A point system (1 raffle ticket/point) is implemented to reinforce attendance and log completion, consistent with behavior theory. Raffles are drawn on a variable reinforcement schedule. Group incentives (e.g., water bottles) are provided monthly. In these ways, TEENS+ facilitates group cohesion and reinforces adherence and attendance, increasing engagement. Families also attend a cooking class and receive YMCA memberships. In the maintenance phase (4-12m), monthly, arm-specific newsletters are mailed to participants to reinforce content and maintain engagement with the trial.

Adolescents have 4 motivational interviewing (MI)-based, 30-min individual visits. In month 1, adolescents meet with their behavior coach for a values exploration exercise to explore the consistency of TEENS+ with adolescents' goals and values, to increase internal motivation for change and treatment engagement. In months 2 and 3, adolescents meet with their dietitian for personalized nutrition education. The final behavior visit (month 4) includes development of a personalized relapse prevention and maintenance plan, linking weight loss maintenance to adolescents' goals and values. These visits also serve to monitor emergence of psychopathology.

MI[5] is integrated into both group[6] and individual sessions, based on findings from *MI Values*,[3,7] in which 2 MI sessions enhanced TEENS treatment engagement, retention, and diet, compared with a control group. Dr. Bean will use methods previously described[8,9] to train coaches and maintain fidelity to MI. Specific MI strategies include: normalize ambivalence, highlight autonomy, elicit adolescents' personal reasons for change (and normalize that these might differ from those of their parents and other participants), and relate weight loss to participant-stated values and goals.[5] Coaches empathize with difficulties involved in making behavior changes, while building adolescent self-efficacy. Last, information is presented collaboratively, to avoid the "expert role," reduce discord and enhance engagement.[5]

The TEENS+ dietary intervention was designed to result in a caloric deficit via adding low calorie, nutrient-dense foods ("Go Foods")[10] while remaining within a prescribed calorie limit. Within the context of the Traffic Light Diet with a calorie goal, Epstein et al. found that targeting an *increase in healthy foods* vs. *a reduction in unhealthy foods* was associated with greater BMI reduction (among younger, primarily white children).[11] Importantly, interventions targeting an increase in fruits and vegetables in the absence of a calorie goal *did not* result in a reduction of fat and sugar.[12] Consequently, individual calorie (1200-1400 for girls and 1500-1800 for boys) and Go Food goals are provided and adjusted as needed throughout treatment. Calorie goals were determined based on our pilot baseline data, which suggested that these prescriptions will result in ≥500kcal/ day deficit, to result in a 1-2lb/week weight loss. Go Food goals are individualized based on baseline food records, and increased as previous goals are met. Standardized lessons provide education about energy balance, calories, macronutrients, and high-risk eating behaviors associated with obesity, coupled with evidence-based behavioral strategies to help adolescents implement changes. In these ways, participants add healthy foods (and must reduce unhealthy foods to remain within calorie goals) while losing weight.

The TEENS+ PA intervention includes identifying strategies to achieve ≥1hr/day of moderate PA[13] (tracked in logs); PA can occur at the HLC, YMCA, or other location, with a focus on free/low-cost, realistic strategies to promote sustainable PA. Adolescents are required to exercise ≥1x/week at the HLC gym (30min of resistance training; 30min of cardiorespiratory exercise). During HLC exercise sessions, participants wear heart rate monitors (E600 Polar Electro, Inc.) and are encouraged to maintain a heart rate >150 beats/min during the aerobic portion. TEENS+ includes setting goals and learning strategies to achieve ≥1 hour/day of moderate PA.[13] Adolescents are provided a progression that gradually increases the frequency and duration of PA, with a prescribed weekly duration of vigorous PA. We successfully implemented this protocol in the TEENS+ pilot.

Parent Interventions. Parents will participate in their assigned, *distinct* intervention (PAC/PWL), matched on contact, led by trained, supervised lifestyle coaches (psychology doctoral trainee and registered dietitian), with different leaders from the adolescent treatments to minimize potential contamination.

a. Parents as Coaches (PAC): PAC focuses on parent skills training to support their adolescents' weight management. It includes combined nutrition education sessions with adolescents as well as independent parent skills training group sessions, delivered while adolescents are in their own BWL groups. In these ways, PAC capitalizes on adolescent autonomy and independence, while acknowledging the need for parent support and involvement. Parents are taught authoritative parenting (providing structure with warmth), and how to apply this to weight management (e.g., setting limits around food kept in the house). PAC teaches positive reinforcement principles to promote behavior change, the importance of role modeling, and communication about eating and weight. Throughout, developmentally appropriate strategies to promote adolescent behavior change are emphasized. For example, most adolescents need some assistance (at least initially) to self-monitor caloric intake accurately. Parents are taught to collaborate with their adolescent to determine optimal strategies for assisting with this task (highlighting its consistency with adolescents' goals). This approach reduces adolescent resistance and increases autonomy, while also enhancing skill development. As skills are demonstrated, parents provide positive reinforcement, and re-negotiate the level of assistance needed. In PAC, parents' own weight management is not specifically addressed and parent weight is not monitored. However, PAC emphasizes parents' roles as important models of health behaviors, the value of healthy eating and exercise for the entire family (regardless of weight), and the importance of setting up the home environment to facilitate their adolescents' successful goal attainment. PAC also emphasizes the critical need for all caregivers to use consistent feeding strategies and teaches parents how be assertive in communicating these concerns. PAC teaches parents to be agents of change for the family and to promote consistent feeding and eating behaviors for all family members, including siblings and other caregivers.

Parents set specific goals each week, related to achieving PAC treatment targets, which focus efforts on areas within their control to impact adolescent behavior. Specifically, parents maintain a daily log to self-monitor: the number of meals planned and prepared at home for their adolescent; whether they reviewed their adolescents' logs; responsibility for adolescent logging (parent/child/combined); and provision of Go Food and PA opportunities for their adolescent. Progress on goals is reviewed weekly, facilitating group brainstorming of strategies to overcome barriers and positively reinforce successes. Behavior coaches also deliver personalized coaching in brief individual check-ins before group, and examine the relation between parental behaviors and their adolescents' behaviors and weight change, guiding adjustments as needed to assist in goal attainment. Parent coaches also observe TEENS+ sessions, to facilitate integration of content between the adolescent and parent treatments. In these ways, coaches guide parents to focus on empirically-supported strategies within their control to foster healthy behavior changes in adolescents.

b. Parent Weight Loss (PWL): In PWL (developed based on Dr. LaRose's NIH trials),[14-17] parents participate in a 16-week adult BWL program, concurrent, yet independent from their adolescents. Monthly activities

(common across both arms) foster shared engagement in BWL strategies between parents and adolescents (i.e., cooking class, YMCA orientation, recipe makeover, and final celebration). Consistent with adult BWL, the goal is to produce parent weight losses of 5-7% during the 4m program. Participants receive daily calorie and fat gram goals based on initial weight, designed to yield 1-2lb/wk weight loss, with education about energy balance, diet quality, and calories in macronutrients provided. They are instructed to self-monitor weight, dietary intake and PA within the context of a self-regulation framework that teaches them to use this information to evaluate their behavior and make adjustments as needed to assist in goal attainment. Parents are trained in core evidence-based behavioral strategies[18] (e.g., goal-setting, problem solving, stimulus control) to help them meet their own diet and PA goals. The adapted BWL program also includes specific content focused on navigating financial, environmental, social and emotional barriers to weight management, and implementation planning is conducted weekly in group to develop personalized plans for goal attainment. Further, MI is integrated into PWL, consistent with Dr. LaRose's previous weight loss trials.[19] Weight is measured weekly in a brief individual check-in prior to group, and feedback is provided in an MI-consistent manner. Parents also receive weekly personalized feedback from their coaches on their food diaries.

Participants are encouraged to consume a heart healthy diet (low in saturated/trans-fats and rich in fruits/ vegetables/whole grains). Nutrition education in PWL is consistent with that taught to adolescents with key distinctions: 1) more emphasis on reducing saturated fat as a strategy to meet calorie goals; 2) more focus on energy density; and 3) parents do not receive Go Food goals. However, to maximize use of shared strategies, PWL emphasizes consuming Go Foods within the context of diet quality and energy density, to assist in increasing satiety and adherence to calorie goals. Participants are instructed to gradually increase PA until achieving ≥250 min/wk of moderate intensity PA. The importance of both structured PA and lifestyle activity is stressed. Typical barriers to PA are discussed, and suggestions for exercise that incorporate activities of daily living are presented. Note that PWL does not focus on how to support adolescents' weight loss directly (although emphasizes that concurrent engagement in these behaviors should be helpful for their adolescent).

Assessments.

Assessments of anthropometrics, dietary intake, PA, parenting and home environment variables will be completed by trained, masked assessors at 0, 2, 4, 8, and 12m, with the primary endpoint at 12m follow-up. Measures for parents and adolescents include the following: anthropometrics (after a 12 hour fast), dietary intake, physical activity, parenting style, eating disorders and depression, parent/child conflict, weight control strategies (physical activity, dietary behaviors, and self-monitoring), Parents will also complete measures assessing demographics, child feeding behaviors, the home food and home exercise environments, self-efficacy to support their child's healthy weight management, and readiness to change. Adolescents will also complete measures assessing perceived autonomy support from their parents, family social support for eating and exercise, and perceptions of parent's dieting behaviors. Parents and adolescents will complete exit surveys at the end of treatment (4 month). Attendance and adherence to program components will be monitored, and interventionists will maintain fidelity checklists after each session. Formal fidelity monitoring will also be conducted.

Statistical Analysis Plan

Analyses will be conducted with SAS v9.4 and Mplus. Descriptive statistics will be generated for outcome variables and potential covariates according to PAC/PWL. Non-normally distributed variables will be transformed and between-group baseline differences for outcomes and covariates will be assessed. All study hypotheses will be tested using Intent-To-Treat (ITT) methods,[20] with multiple imputation incorporating auxiliary variables used to handle missing data, and all primary analyses will be performed using imputed data sets. We will also conduct additional, less conservative complete-case analyses and we will compare these results to the ITT analyses.

For **Aim 1**, the primary outcome is between-group (PAC vs. PWL) differences in adolescent $\Delta BMI_{4\text{-}12m}$. Both within- and between-group effects of treatment on $\Delta BMI_{4\text{-}12m}$ will be compared via linear mixed model analyses. This model will also be used for **Secondary Aim** analyses, to examine within- and between-group changes in adolescent energy intake (kcal/d); energy expenditure (kcal/d); and PA (min/wk) from 4-12m. For **Aim 2**, both within- and between-group effects of treatment on parental variables, home food and exercise environment, and adolescent perceived autonomy support from 0-4m will be compared via linear mixed model analyses. Multivariate linear regressions will examine the impact of 0-4m changes in these variables on adolescent weight loss maintenance ($\Delta BMI_{4\text{-}12m}$). We will then evaluate whether the treatment effects for weight loss maintenance are mediated by *authoritative parenting* using Structural Equation Modeling (SEM). Model fit will be compared using chi-square analyses. To evaluate whether BE/LOC moderates the effects of treatment on authoritative parenting and/or authoritative parenting on weight loss maintenance, we will apply a moderated mediation model[21] by adapting the SEM model above using a multiplicative regression approach. In the **Exploratory Aim**, we will evaluate the effect of concordance of parent and adolescent variables on adolescent weight loss maintenance using linear mixed models. Concordance will be defined by the possible response pairs or using difference scores for categorical and continuous variables, respectively.

Power analyses were conducted using SD and effect sizes from the pilot for between-group (PAC/PWL) $\Delta BMI_{4\text{-}7m}$, projected to 12m (the primary endpoint of this trial; $\Delta BMI_{4\text{-}12m}$). We assumed a constant rate of weight change and increased SD. A proposed sample size of 210 (105 dyads per arm) will have >80% power (2-sided, alpha=.05) to detect significant *between-group* differences in adolescent $\Delta BMI_{4\text{-}12m}$, with SD≤2.9, which corresponds to a small to moderate effect size (Cohen's *d*=.39). The 12m projections, with SD≤1.7, and N=210 provide 80% power to test BE/LOC as a moderator. This sample size also provides 80% power to evaluate authoritative parenting as a mediator in a partially mediated model. We used effect sizes to power this trial given lack of agreed-upon clinically significant thresholds for adolescent BMI change.

Protocol Changes		
DATE	CHANGE	REASON
June 2018	Modified adolescent baseline calorie goal ranges. Throughout the intervention, baseline female calorie range goals ranged from 1200-1400 to 1700-1900. Baseline male calorie range goals ranged from 1400-1600 to 2400-2600.	Enhanced specificity based on starting height and sex.
March 2020	1. Intervention sessions transitioned from in-person to virtual (Zoom) due to COVID-19. 2. Exercise program transitioned from in-person to pre-recorded exercise workout videos provided on a private YouTube channel for participants accessible from study website. Heart rate monitors were no longer worn. 3. Transitioned to remote assessments due to restrictions. Calibrated scales and stadiometers were left on participants' porches with video instructions on obtaining height and weight measurements. Recalls were conducted over Zoom. 4. Cooking classes transitioned to virtual. Participants were provided a gift card and ingredient list to purchase supplies needed prior to classes led by chefs.	COVID-19 restrictions and mandates
August 2020	Resumed in-person assessments but continued to offer remote assessments. Remote assessments transitioned to being conducted by assessor in the participant home (or designated location) as an option to accommodate families' comfort level.	Virginia now in Phase 3 of re-opening. In-person interactions permitted with proper protections in place.
September 2020	Exercise program transitioned to live group workouts via Zoom. Group exercise sessions occurred on respective group nights (Mon-Thurs) and on Saturday mornings which were treatment arm specific. Pre-recorded exercise videos still available on private YouTube channel accessible from study website.	To increase participant engagement and attempt to mimic in-person style workout approach.
February 2021	Virtual group exercise sessions transitioned to being offered two nights per week-- one night for each treatment group. Four virtual one-on-one personal training sessions were offered to each participant to use throughout the 16-week intervention. Pre-recorded exercise videos still available on private YouTube channel accessible from study website.	Group exercise engagement and attendance was low. One-on-ones were added increase interest and engagement.
October 2023	1. Exercise program included the option of in-person personal training sessions (4) in addition to the previously offered Zoom sessions (4 sessions max in either format). Group exercise session format remained the same. Cooking class was offered in-person and virtually.	Participants eager for in-person interactions. COVID-19 concerns no longer as relevant.

Assessment Measure Changes		
DATE	CHANGE	REASON
January 2020	1. Changed Food Security (FS) questionnaire from the 6-item version to the 18-item version. 2. Added the Perceived Stress Scale (PSS) questionnaires to both parent and adolescent assessments.	1. Full measure provides a more comprehensive level of food security. 2. Stress was an important variable to examine given its relation to obesity and within the current context of the COVID-19 pandemic
July 2020	1. Adolescent questionnaires were modified to ask about the participating parent, only, in the following questionnaires at assessments: a. Family Experiences Related to Food (FERFQ) b. Perceived Parental Autonomy Support Scale (P-PASS) 2. The Conflict Behavior Questionnaire (CBQ) questionnaire was removed from both parent and adolescent assessments. 3. The FERFQ was modified to only include questions regarding modeling of dieting behaviors	Reduce participant burden considering additional demands on families' lives in the context of the COVID-19 pandemic; removed variables not directly associated with study aims.
January 2021	1. Removed Parent Readiness to Change (PRC) questionnaire from parent assessments. 2. Removed Parent Efficacy for Child Healthy Weight Behavior (PECHWB) questionnaire from parent assessments.	Reduce participant burden and measures not required for testing conceptual model.
January 2021	The Conflict Behavior Questionnaire (CBQ) questionnaire was added back for both parent and adolescent assessments. Adolescents were only asked about the participating parent.	Perceptions of parent/adolescent conflict was an important variable to continue to examine.
June 2022	Added the Standardized Screening Tool for Health questionnaire at all assessment time points	Expanded assessment as part of ancillary project and given greater burden of social determinants of health in context of pandemic.

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