Published in final edited form as:

Transl J Am Coll Sports Med. 2020 ; 5(12): . doi:10.1249/tjx.0000000000000136.

Protocol for a randomized controlled feasibility study of a coordinated parent/child weight loss intervention: Dyad Plus

Joshua R. Dilley^a, Camelia R. Singletary^b, Jamy D. Ard^{c,d}, Steven Giles^e, Joseph A. Skelton^{d,f}, Vahé Heboyan^g, Danielle E. Jake-Schoffman^h, Gabrielle Turner-McGrievyⁱ, Matthew McGrievy^j, Edward H. Ip^k, Justin B. Moore^{b,d,l,*}

^aDepartment of Plastic Surgery, Wake forest School of Medicine, Winston-Salem, NC, USA

^bDepartment of Implementation Science, Wake Forest School of Medicine, Winston-Salem, NC, USA

^cDepartment of Internal Medicine, Wake Forest School of Medicine, Winston-Salem, NC, USA

^dDepartment of Epidemiology & Prevention, Wake Forest School of Medicine, Winston-Salem, NC, USA

^eDepartment of Communication, Wake Forest University, Winston-Salem, NC, USA

^fDepartment of Pediatrics, Wake Forest School of Medicine, Winston-Salem, NC, USA

^gDepartment of Interdisciplinary Health Sciences, Augusta University, Augusta, GA, USA

^hDepartment of Health Education & Behavior, University of Florida, Gainesville, FL, USA

ⁱDepartment of Health Promotion, Education & Behavior, University of South Carolina, Columbia, SC, USA

^jUniversity of South Carolina, Columbia, SC, USA

^kDepartment of Biostatistics & Data Science, Wake Forest School of Medicine, Winston-Salem, NC, USA

^lDepartment of Family & Community Medicine, Wake Forest School of Medicine, Winston-Salem, NC, USA

Abstract

The prevalence of in youth with overweight and obesity is a global health concern, necessitating clinical interventions to treat obesity effectively through lifestyle modification. Interventions in adolescents have demonstrated improvements in healthy eating and physical activity with only modest weight loss outcomes. Consequently, there is growing interest in developing strategies to enhance the effectiveness of clinical interventions in adolescents. Targeting the family system can be an effective approach, but existing studies have failed to examine the impact of co-enrolling both the adolescent and adult in individually tailored weight loss programs and coordinating the adolescent/adult weight loss efforts.

*Corresponding author: 525 Vine Street, Winston-Salem, NC 27101, jusmoore@wakehealth.edu.

Purpose: This paper reports on the design and conceptual framework of the Dyad Plus study, which utilizes two weight loss clinics of the Wake Forest Baptist Medical Center: Brenner Families in training (Brenner FIT®; adolescents) and By Design (adults). Dyad Plus is a coordinated program designed to facilitate self-monitoring, positive communication, joint problem solving, and social support to increase physical activity, healthy eating, and weight loss relative to Brenner FIT alone.

Methods: A total of 45 parent/adolescent dyads are randomized to one of three conditions (n = 15 for each): Brenner FIT only, Dyad (adolescent and parent both enroll simultaneously in the age appropriate program), and Dyad Plus (both parent and adolescent enroll simultaneously, but with a coordinated component for adolescent and caregiver). This study aims to develop and pilot the coordinated intervention, establish feasibility of the intervention, and determine costs associated with implementation.

Results: The results of the study are expected in winter of 2021.

Conclusion: If proven feasible and acceptable, Dyad Plus will be tested for effectiveness in a large-scale implementation-effectiveness clinical trial.

Keywords

Physical activity; obesity; adolescence; adult; family-based weight loss

1. Introduction

The prevalence of youth with overweight (BMI 85th %tile for sex/age) and obesity (BMI 95th %tile) is a global health concern (1), necessitating clinical interventions to treat obesity through lifestyle modification. The increasing prevalence of obesity is primarily due to decreasing physical activity accompanied by declines in dietary quality and increased energy intake. Clinical interventions through healthier eating and more physical activity demonstrate that improvements in these behaviors are linked to modest positive weight outcomes and improvement in cardiometabolic risk factors (2,3). Consequently, there is rising interest in developing strategies to enhance effectiveness of clinical obesity interventions in adolescents who have the highest rates of obesity (4) and dropout from treatment (5). Targeting both parents and adolescents in weight loss interventions can be an effective approach, but adherence to these programs can be sub-optimal (6). Although research suggests that parents of youth with obesity are often facing weight-related issues themselves (6,7), and that parental weight loss is a predictor of child weight loss (8), few studies have examined the effectiveness of engaging the adult caregiver and adolescent in a coordinated weight loss effort. Additionally, a growing body of literature suggests that parental weight status predicts child (9), adolescent (10), and adult weight status in offspring (11). Failure to treat the caregiver who can serve as a positive role model for the adolescent (or vice versa) represents a missed opportunity. Adult weight loss is inherently different from adolescent weight loss (12), and pursuing identical approaches with an adolescent could be harmful. As such, a large research gap exists which can be explored to make adolescent and adult obesity treatment more effective and safer. While a number of studies have included families (in supporting roles) in pediatric obesity treatment (13), no studies

have examined the impact of co-enrolling both the adolescent and adult in individually tailored weight loss programs, the feasibility of coordinating these adolescent/adult weight loss efforts, and the effectiveness of coordinated care relative to standard care.

Data suggest that weight interventions in children that involve caregivers are more successful than those not involving parents (14,15). While programs may differ in format, they generally share a family-based approach in which treatment targets multiple family members including parents (16). The involvement of parents is grounded in Family systems theory (17), which posits that youth health behaviors may be influenced by parenting style, family functioning and family interactions and emphasizes the importance of emotional support and modeling from parents (18,19). The co-enrollment of both adolescents/adults together can help strength communication, emotional support and accountability leading to better weight outcomes; these studies are now considered the gold-standard approaches to pediatric obesity (18).

Compared to pediatric obesity, the current literature lacks a strong theoretical basis for intervention components in treatment programs for adolescents with obesity. There exist key differences between pediatric and adolescent populations which may impact on the development and success of family-based interventions. For example, parent-adolescent communication is an important aspect relating to weight as poor communication has been associated with unhealthy weight practices (20). Of the interventions that identify a theoretical basis for intervention strategies, very few explicitly measure the theoretical constructs as potential mediators of program effectiveness. Social cognitive theory and self-determination theory offer constructs relevant to family-based, coordinated obesity treatment for youth and adults (21). Social cognitive theory has served as the basis of several studies targeting weight loss and its use has been associated increases in physical activity and healthy eating (22). Similarly, self-determination theory has demonstrated associated benefits with physical activity, healthy eating, and weight outcomes (23,24).

This paper describes the study design and conceptual approach of a pilot randomized controlled trial (RCT) to study the feasibility and effectiveness of co-enrolling the adolescent and adult in coordinated, individually tailored and theoretically driven weight-loss programs with a strong theoretical basis compared to standard care. Based on previous studies showing differential effects on major mediators of weight loss such as dietary intake (25) as well as physical activity (26), as well as effect modification by patient characteristics (27), the primary outcomes of the larger RCT will include detailed measures of dietary intake patterns and physical activity alongside weight status (BMI/BMI z-score). The pilot study will record the previously mentioned outcomes but will primarily focus on feasibility, acceptability, and economic cost of delivery. All data, including structured feedback from participants, will be used to optimize approaches to recruitment, refine the dyad plus curriculum, and increase retention strategies to ultimately increase the efficacy and success of future RCTs testing family-based approaches for weight management among adolescents.

2. Methods

2.1 Study Setting

The study is conducted in two weight loss clinics that are part of Wake Forest Baptist Medical Center (WFBMC). The first is Brenner Families in Training (Brenner FIT®), which is an evidence-based program that focuses on treatment of pediatric obesity from ages 2 to 18. The second is the WFBMC Weight Management Center (By Design) that provides adult patients with a range of comprehensive weight management treatment options from medical to surgical interventions. Both Brenner FIT and By Design are programs that employ best practices in the field (28,29) and consistently produce clinically meaningful weight loss.

2.2 Study Design and Randomization

The study employs a randomized, controlled design with three groups: Brenner FIT only; Dyad, where the adolescent and parent both enroll simultaneously in the age appropriate program; and Dyad Plus, where the adolescent and parent both enroll simultaneously in their respective program, but with a coordinated component. The Dyad and Dyad Plus condition includes all components of Brenner FIT (adolescents) and By Design (adults) for the participants.

Dyads are allocated by our statistician to three groups ($n = 15$ dyads each) using a fixed allocation randomization procedure and computer-based random number generating algorithm. Blocked randomization is considered to reduce the chance of between-group imbalances in number of participants, and to help protect against temporal trends. Even with blocked randomization, there is no guarantee that all baseline characteristics are equal or similar among study groups. Randomization is stratified by a child's BMI group (e.g., terciles based on our preliminary data) to protect against imbalance. Data analysis accounts for blocking and stratification as well as relevant factors such as age and sex of the dyad members.

The Brenner FIT clinic is the base of the study and recruitment source. At Brenner FIT, patients are mostly female (58%) and self-identified as white/European American (45%), black/African American (32%), Hispanic/Latino (18%) or another race (5%). Approximately half of the patient population is in their adolescent years (13–17 years). Dyads referred to Brenner FIT who are eligible for participation if the adolescent under treatment is 13–17 years old, they have a caregiver who lives in the home with a BMI > 30 , and neither member of the dyad has a contraindication for physical activity or calorie restriction.

2.3 Informed Consent

All eligible dyads being treated at Brenner FIT or By Design clinics are asked to participate in the study. Informed consent is sought from each adolescent's guardian for participation in the interventions and data collection activities. Family members and youth are encouraged to ask any questions they have regarding the procedures. There is no coercion to participate or prejudice against those who choose not to take part in the study. We submitted an application to the Wake Forest Baptist Medical Center Institutional Review Board for approval of study procedures and the informed consent protocol. For adolescents, written informed consent

from at least one parent/guardian and voluntary written assent is obtained prior to participation in the study. No data collection takes place prior to IRB approval or informed parental/adolescent consent/assent.

2.4.1 Condition One: Brenner FIT only (standard care)—Brenner FIT is an interdisciplinary, family-based pediatric weight management clinic informed by the Familial Approach to Treatment of Childhood Obesity (30–34). Patients are between the ages of 2–18 years old and referred by a physician for obesity or overweight with a weight-related comorbidity. Treatment teams are composed of a pediatrician, counselor, dietitian, and a physical activity specialist, with others (e.g., social workers, physical therapists) as needed. The entire family is encouraged to attend all aspects of the program, although only one attending caregiver is required. Treatment is guided by an established protocol as is recommended with tertiary care stage 3–4 weight management programs (35). In Brenner FIT, a database ensures treatment progresses within the protocol. After referral, families attend an orientation at which they are scheduled for an introductory 90-minute group session that focuses on parents' role in the intervention; these usually occur within 2–4 weeks of orientation. The family then attends a 2-hour intake session, where they are seen by the physician, family counselor (LCSW), and activity specialist. After the initial intake sessions, monthly 1-hour long visits with the dietitian, counselor and physical activity specialist are held for 6 months, in which the adolescent and caregiver see the pediatrician. During the 6 months of the intervention, the adolescent and caregiver attend 4 group classes, choosing from topics such as meal planning, physical activity, and parenting. Specialized visits with the physical activity specialist or dietitian are scheduled as pertinent issues arise. Clinic visits with the pediatrician include individualized goal setting (for behaviors family/clinician have agreed to address), healthy eating and physical activity education, and behavioral counseling to implement changes at home. Motivational interviewing, modified by Brenner FIT for use with families (36), is central to the intervention. Family counselors are trained in cognitive behavioral therapy and parenting support and employ these approaches to assist families in developing healthy habits. Self-monitoring is part of the intervention as Brenner FIT uses hand-written diet and physical activity logs completed by parents and children. Brenner FIT successfully enrolls a diverse array of families into studies, including those who identify as African American and Latino.

Participants randomized to Brenner FIT receive no additional components except for a Fitbit™ activity tracker. Six additional nutrition and exercise sessions are offered to standardize the number of contact hours across the conditions.

2.4.2 Condition Two: Dyad (combination of the two standard care programs)—The Dyad condition is simply co-enrollment in the Brenner FIT for the adolescent and By Design for their caregiver. No coordination is made between the two programs for the participants, but each participant is engaged by the staff from the program in which they're enrolled.

Adult participants in the By Design condition will be prescribed the *Essentials* lifestyle intervention which includes tailored dietary and physical activity goals designed to achieve 1–2lbs/week for weight loss, provided by a multidisciplinary team of medical providers,

dietitians, behaviorists, and exercise specialists. A daily calorie reduction of 500 kcal/day is prescribed based on estimates of total energy expenditure obtained from a measured resting metabolic rate prior to enrollment. The minimum calorie prescription is 1200 kcal/day. A dietitian provides each participant with a detailed program manual that describes the prescribed diet. The dietitian utilizes standard behavioral techniques to promote lifestyle behavior changes that enable participants to implement and maintain behaviors necessary to adhere to the dietary prescription. Participants also receive a standard exercise program designed to promote exercise energy expenditure of approximately 600 kcal/week. The exercise prescription includes resistance training for 2 days per week and aerobic training for 3 days per week, to meet a 600 kcal/week expenditure goal.

Behaviorists meet with participants to provide individual and group-based counseling to learn the skills necessary to adopt the prescribed diet and exercise plans. Group sessions are delivered consecutively over 6 months (20 total; 1.5 hours each), followed by 6 months of bi-monthly sessions, then 12 months of monthly sessions. During the initial 6-months (intensive behavior change and weight loss phase), intervention sessions are designed to be participant-centered and interactive and include guided physical activity or food demonstration. Participants have individual visits to review treatment goals and overall progress at weeks 0, 12, and 24. Group sessions include behavioral strategies known to support weight loss and lifestyle behavior change including goal setting, problem solving, and self-monitoring. Key targets in the second year of the intervention include reinforcement messages, self-monitoring, relapse prevention, social support, and problem solving.

Similarly, to those randomized to Brenner FIT, participants enrolled in Dyad receive a Fitbit™ activity tracker. As mentioned above, six additional nutrition and exercise sessions are offered to standardize the number of contact hours across the conditions.

2.4.3 Condition Three: Dyad Plus—Dyad Plus includes all components of the standard Brenner FIT program (adolescents) and By Design (adults) with three additional components: (1) dyad group sessions, (2) one-on-one parent/adolescent communication sessions, and (3) joint goal setting/tracking. This innovative approach seeks to employ components of motivation and communication theories to encourage self-monitoring, positive communication, and problem solving. In addition, the approach uses social support to increase healthy physical activity and eating behaviors to improve the effectiveness of the weight loss programs beyond that observed in matched controls (see Figure 1).

The exact mixture of the sessions depends on the needs of the family, but the dyads are participating in six, one-hour sessions in addition to those required by their weight loss program. Joint goal setting and tracking is enabled by a commercially available device (a Fitbit™ activity tracker) and a custom, mobile enabled website. Each caregiver and adolescent receive an activity tracker and access to the website designed for self-monitoring of dietary and activity habits and “social accountability,” which allows caregivers and the Brenner FIT team to monitor and encourage. Furthermore, an evaluation of the home food and activity environments is conducted to inform tailored feedback to families.

2.5 Primary Outcomes/Measures

2.5.1 Physical Activity—Physical activity is collected using ActiGraphtm accelerometers. The accelerometers are set to collect data in a raw format and analyzed by converting the data into 1-second epochs to account for the intermittent and sporadic nature of youth physical activity. Monitors are dispersed at baseline (prior to randomization) and at 6 months (following the intervention phase) for a seven-day data collection period. These monitors are affixed to a strap and worn on the subject's non-dominant wrist. This is a protocol being employed in NHANES (37), which has already been successfully used in studies of physical activity. We distill the cut points in a manner consistent with the emerging research in the area and work previously completed that allows for comparability with waist-based estimates. Participants are instructed to wear the monitor continuously over the next 7 days except during bathing and water-based activities consistent with the best practices in community-based data collection.

2.5.2 Diet—To assess diet in each participant, the National Cancer Institute's automated, self-administered 24-hour dietary recall, the Automated Self-Administered 24-hour (ASA 24®) dietary assessment tool (38) is used on three, non-consecutive days (including one weekend day). Results of the ASA 24® are reported in kilocalories. The ASA 24® is available on both computers and mobile devices. All participants complete one ASA 24® at their baseline orientation and 6-month follow-up visits to encourage compliance while simultaneously allowing youth and caregivers to ask questions and gain comfort using the system. The project coordinator contacts participants when they should complete the second/third dietary recall and offers to conduct the recall over the phone if the youth need assistance. The ASA 24® has been demonstrated to perform equally well as a self-administered or interviewer administered questionnaire (39). A series of follow-up reminder messages and/or phone calls are made by the coordinator to encourage completion for the second/third of the two recalls if not completed within 24 hours following the first contact after the clinic visit.

2.5.3 Socio-demographic Variables and Weight Status—Caregiver reported age, sex, race, and ethnicity are collected at the initial visit. Weight status is quantified through body mass index (BMI) derived from measurement of height and weight ($BMI = (kg/m^2)$) without shoes in normal clothing at the intake visit. Both height (accurate to 0.1 cm) and weight (accurate to 0.5 kg) is recorded twice by a female research assistant and values are averaged to produce the final value using a digital scale and stadiometer respectively.

2.5.4 Psychological variables: Family and individual constructs will be assessed to identify potential mediators or moderators of observed effects of the intervention. Brenner FIT uses Family Systems Theory as a guiding model to addressing child and parent behaviors and presently uses several scales to assess families participating in Brenner FIT. Specifically, Brenner FIT families complete the Family Assessment Device General Functioning (capturing family function) and communication subscales, perceived stress, self-efficacy for physical activity, behavioral self-regulation, and health behaviors of the family).

In addition, the team administers scales to capture Social Cognitive Theory and Self-Determination Theory constructs targeted by the intervention that are not captured as part of the intake process. These include outcome expectations, autonomy, autonomy support, and relatedness (40). All psychosocial data are collected at baseline (prior to randomization), 3 months, and 6 months.

2.5.5 Economic Costs of Delivery: The costs associated with implementing the three conditions are collected over the duration of the program. These costs allow calculation of the full economic cost of delivering each condition, which includes both direct and indirect as well as opportunity costs. Examples include supplies and materials utilization (e.g., printing of materials for participants), training costs (e.g., hourly wages for employees), costs associated with actual delivery of the coordinated sessions, and opportunity costs (e.g., volunteer time, donated materials). Economic costs of implementing these three conditions are compared to identify the most cost-efficient condition. Costs related to the evaluation of these strategies/conditions are excluded to capture the true economic cost of replicating the strategies across other clinics.

2.6 Secondary Outcomes

2.6.1 Fasting Serum biomarkers—Cardiometabolic markers are collected at baseline and 6 months to examine for any changes. The markers collected include fasting glucose, fasting insulin level, hemoglobin A1c, aspartate aminotransferase level, alanine aminotransferase level, and total cholesterol. These markers can identify physiological changes related to obesity such as fatty liver disease, diabetes and hyperlipidemia which have large, long-term health implications.

2.7 Exploratory Outcomes

2.7.1 Feasibility—Feasibility is assessed consistent with the recommendations of Leon and colleagues (41). Specifically, screening, recruitment, randomization, retention, adherence, fidelity, and the assessment process are all examined. The number of patients screened per month, the number enrolled per month, the proportion that are eligible who enroll, and the intervention participation remain enrolled in the study by condition is tracked. Retention (completion of at least 75% of monthly sessions through 6 months) is tracked for each intervention condition. Adherence to the intervention protocol by the participants is measured using a computer-aided tracking system. Finally, the time needed for assessments and gathering feedback on participant burden is monitored.

2.7.2 Acceptability.—Acceptability is assessed both qualitatively and quantitatively with open-ended questions at post-test, tracking of attendance at required sessions, and compliance with self-monitoring. A brief survey is utilized for caregivers and youth to gain insight into their perception of the Dyad plus components following completion of the 6-month assessments (i.e., completion of the study). Surveys include the System Usability Scale (42) to inquire about the usability of the tracking apps, Fitbit tracking device, and session format and content.

2.8 Analysis Plan

Intervention groups are compared on baseline characteristics including psychosocial, behavioral, and anthropometric measures using statistical procedures determined by type of measure and distribution (e.g., nominal, ordinal, ranked, discrete, and continuous). Outlying values are checked for plausibility and thorough logical and statistical checks. Measures with skewed distributions are considered for statistical transformation and robust estimation.

Procedures for preventing and monitoring missing data are implemented whenever possible, and patterns of observed data are taken into account in selection of analysis methods. For methods with unverifiable assumptions, sensitivity analyses are conducted. Analysis covariates (e.g., parent/adolescent age, sex, baseline pre/diabetes status) are selected a priori. Statistical significance will be denoted by two tailed p values < 0.05 and 95% confidence intervals (CIs)

2.8.1 Aim 1: Develop a coordinated intervention for adolescents and adults with obesity co-enrolled in Brenner FIT and By Design Weight loss clinics.—

No formal hypothesis testing is conducted in aim 1; however, perceptions are collected, including on the four novel components: (1) dyad group sessions, (2) one-on-one parent/adolescent communication sessions, (3) joint goal setting/tracking, and (4) home environment assessment. We anticipate reaching high perceived acceptability and a corresponding increase in the likelihood of a smooth transition to the pilot trial.

2.8.2 Aim 2: Pilot the coordinated intervention in adolescent/caregiver dyads to establish the feasibility of the intervention in terms of accrual, retention, and adherence.—The goal of aim 2 is to test the hypothesis that retention will be at least 75% in each intervention group. Within-group retention in the pilot trial is calculated as the percentage of dyads within the intervention group completing at least 75% of monthly sessions through six months. For inclusion in this definition, one measure is selected a priori among each category of outcome (psychosocial, behavioral, and anthropometric). An intention-to-treat analysis is followed. Two-tailed 95% Wilson CIs for unknown proportions are calculated for retention in each group.

2.8.3 Aim 3: Establish the costs associated with the implementation of Dyad Plus relative to delivering By Design and Brenner FIT without the coordination component—Economic costs of delivery (i.e., resource use) associated with implementing the three conditions are collected over the duration of the program. These costs allow calculation of the full economic cost of delivering each condition, which includes both direct and indirect as well as opportunity costs. Examples of these include supplies and materials utilization (e.g., printing of materials for participants), training costs (e.g., hourly wages for employees), costs associated with actual delivery of the *mHealth* components, and opportunity costs (e.g., volunteer time, donated materials). Net costs associated with delivering the strategies are calculated by subtracting the costs for Brenner FIT from the costs of the two additional conditions. Costs related to the evaluation of these strategies/conditions are excluded to capture the true economic cost of replicating the strategies across other clinics. One way to express cost is cost per adolescent enrolled. The more money

caregivers pay for enrollment, the lower the likelihood of participation, especially when patients are from lower socioeconomic categories. For the proposed study, there is no additional costs for participants beyond those associated with the standard Brenner FIT program (e.g., co-pays).

2.8.4 Trial sample size and precision of estimates—Given a sample size $n=15$ (each group), we anticipate a range of possible precision for our retention probability estimates (confidence intervals) as follows: a true probability of 0.6 yields a median (and approximate mean) 95% CI length of 0.44 (approximate first and third quartile lengths ± 0.01); for 0.9, this is 0.29 ± 0.06 . The observed CIs provide a plausible range for the true retention in our population and trial conditions. If the CIs exclude values <0.75 , we declare acceptable retention to plan a large-scale trial of Dyad Plus; regardless, these estimates (CIs) are weighed heavily, and together with many other components of the trial experience, to determine overall acceptability and feasibility, and help assist with design aspects of any future trial.

2.8.5 Secondary Analyses—Longitudinal data analysis is conducted, including for estimation of weight loss. Though not primary outcomes of the pilot trial, these intervention effects (Dyad Plus vs. Dyad, and Dyad Plus vs. Brenner FIT) and the variability estimates, together with additional estimates from the pilot trial, will be important for design of a future trial. This includes estimates of accrual, ineligibility by reason, retention, completeness of data, and adherence to interventions.

3. Discussion

Despite a large body of literature on adult and pediatric weight loss, including family-based treatment, studies have been less successful in creating or implementing effective strategies for weight loss in adolescents. There are very few studies that target adolescents with a comprehensive behavior intervention as outlined in this current study. While the concept of coordinated intervention has been explored, the results produced by the few studies to attempt a coordinated treatment plan have been promising in some cases and paradoxical in others. This will be the first study to develop a coordinated adolescent/caregiver weight loss intervention grounded in communication, family systems and motivational theory.

The current study substantially departs from previous studies by creating a joint weight loss program with a co-monitoring component between caregiver/adolescent that is backed by a strong theoretical foundation. Furthermore, the study focuses on the safety of the adolescent patient by not involving them in programs designed for adults that focus on restrictive behaviors that are potentially harmful. The outcomes from this study can help provide evidence regarding the feasibility, acceptability, and effectiveness of a coordinated model relative to standard care and lead to a larger trial studying weight loss outcome data.

4. Conclusion

In this paper, we describe the design and conceptual approach of a coordinated care model between adolescent and caregivers with overweight or obesity and assess the feasibility,

acceptability, and effectiveness of the coordinated model relative to standard care of enrolling solely the adolescent in treatment. The proposed project has considerable translational potential, as adult and pediatric obesity treatment programs co-exist in most academic medical centers. The proposed research will inform a proposal to test the effectiveness of a coordinated versus an uncoordinated approach and will allow us to examine 6-month adherence and weight loss outcome data to inform sample size calculations and generate estimates of variability for a larger trial.

Sources of Support/Funding

Research reported in this publication was supported by the National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH) under award number R21HD101036. The project described was supported by the National Center for Advancing Translational Sciences (NCATS), NIH, through Grant Award Number UL1TR001420. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the American College of Sports Medicine. This study is registered in [Clinicaltrials.gov](https://clinicaltrials.gov) as [NCT04036331](https://clinicaltrials.gov/ct2/show/study/NCT04036331).

Bibliography

1. Ogden CL, Carroll MD, Lawman HG, Fryar CD, Kruszon-Moran D, Kit BK, et al. Trends in Obesity Prevalence Among Children and Adolescents in the United States, 1988–1994 Through 2013–2014. *JAMA* [Internet]. 2016;315(21):2292–9. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27272581>
2. Kalarchian MA, Levine MD, Arslanian SA, Ewing LJ, Houck PR, Cheng Y, et al. Family-based treatment of severe pediatric obesity: Randomized, controlled trial. *Pediatrics* [Internet]. 2009 10 [cited 2020 Feb 11];124(4):1060–8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19786444>
3. Knop C, Singer V, Uysal Y, Schaefer A, Wolters B, Reinehr T. Extremely obese children respond better than extremely obese adolescents to lifestyle interventions. *Pediatr Obes* [Internet]. 2015 2 1 [cited 2020 Feb 11];10(1):7–14. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24347523>
4. Kumar S, Kelly AS. Review of Childhood Obesity: From Epidemiology, Etiology, and Comorbidities to Clinical Assessment and Treatment. Vol. 92, Mayo Clinic Proceedings. Elsevier Ltd; 2017. p. 251–65.
5. Savoye M, Shaw M, Dziura J, Tamborlane WV, Rose P, Guandalini C, et al. Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial. *JAMA* [Internet]. 2007 6 27 [cited 2020 Feb 11];297(24):2697–704. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/17595270>
6. Epstein LH, Paluch RA, Roemmich JN, Beecher MD. Family-Based Obesity Treatment, Then and Now: Twenty-Five Years of Pediatric Obesity Treatment. *Heal Psychol*. 2007 7;26(4):381–91.
7. Bahreynian M, Qorbani M, Khaniabadi BM, Motlagh ME, Safari O, Asayesh H, et al. Association between obesity and parental weight status in children and adolescents. *JCRPE J Clin Res Pediatr Endocrinol*. 2017;9(2):111–7. [PubMed: 28008863]
8. Wrotniak BH, Epstein LH, Paluch RA, Roemmich JN. Parent Weight Change as a Predictor of Child Weight Change in Family-Based Behavioral Obesity Treatment. *Arch Pediatr Adolesc Med* [Internet]. 2004;158(4):342–7. Available from: <http://archpedi.jamanetwork.com/data/journals/peds/11999/poa30237.pdf>
9. Keane E, Layte R, Harrington J, Kearney PM, Perry IJ. Measured parental weight status and familial socio-economic status correlates with childhood overweight and obesity at age 9. *PLoS One*. 2012 8 17;7(8).
10. Notara V, Magriplis E, Prapas C, Antonogeorgos G, Rojas-Gil AP, Kornilaki EN, et al. Parental weight status and early adolescence body weight in association with socioeconomic factors. *J Educ Health Promot*. 2019;8:77. [PubMed: 31143794]

11. Magarey AM, Daniels LA, Boulton TJ, Cockington RA. Predicting obesity in early adulthood from childhood and parental obesity. *Int J Obes* [Internet]. 2003 4 1 [cited 2020 Feb 11];27(4):505–13. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12664084>
12. Hoey H. Management of obesity in children differs from that of adults. In: *Proceedings of the Nutrition Society* [Internet]. Cambridge University Press; 2014 [cited 2020 Feb 11]. p. 519–25. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25115345>
13. Trier C, Dahl M, Stjernholm T, Nielsen TRH, Bøjsøe C, Fonvig CE, et al. Effects of a family-based childhood obesity treatment program on parental weight status. *PLoS One*. 2016 8 1;11(8).
14. Berge JM, Everts JC. Family-based interventions targeting childhood obesity: A meta-analysis. *Child Obes*. 2011 4;7(2):110–21. [PubMed: 26182126]
15. Kitmann KM, Dalton WT, Stanley CM, Beech BM, Reeves TP, Buscemi J, et al. Lifestyle interventions for youth who are overweight: a meta-analytic review. *Health Psychol*. 2010;29(1):91–101. [PubMed: 20063940]
16. Kitmann KM, Beech BM. Family-based interventions for pediatric obesity: Methodological and conceptual challenges from family psychology. *J Fam Psychol* [Internet]. 2006 6 [cited 2020 Apr 20];20(2):175–89. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/16756393>
17. Kitman-Ulrich H, Wilson DK, St. George SM, Lawman H, Segal M, Fairchild A. The integration of a family systems approach for understanding youth obesity, physical activity, and dietary programs. *Clin Child Fam Psychol Rev*. 2010;13(3):231–53. [PubMed: 20689989]
18. Skelton JA, Buehler C, Irby MB, Grzywacz JG. Where are family theories in family-based obesity treatment: Conceptualizing the study of families in pediatric weight management [Internet]. Vol. 36, *International Journal of Obesity*. 2012 [cited 2020 Apr 20]. p. 891–900. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22531090> [PubMed: 22531090]
19. Kitman-Ulrich H, Wilson DK, St. George SM, Lawman H, Segal M, Fairchild A. The integration of a family systems approach for understanding youth obesity, physical activity, and dietary programs. *Clin Child Fam Psychol Rev* [Internet]. 2010 9 [cited 2020 Apr 20];13(3):231–53. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20689989>
20. Vander Wal JS. The relationship between body mass index and unhealthy weight control behaviors among adolescents: The role of family and peer social support. *Econ Hum Biol*. 2012 12;10(4):395–404. [PubMed: 22609397]
21. Patrick H, Williams GC. Self-determination theory: Its application to health behavior and complementarity with motivational interviewing. Vol. 9, *International Journal of Behavioral Nutrition and Physical Activity*. BioMed Central; 2012. p. 18.
22. Bagherniya M, Taghipour A, Sharma M, Sahebkar A, Contento IR, Keshavarz SA, et al. Obesity intervention programs among adolescents using social cognitive theory: A systematic literature review. Vol. 33, *Health Education Research*. Oxford University Press; 2018. p. 26–39. [PubMed: 29293954]
23. Teixeira PJ, Silva MN, Mata J, Palmeira AL, Markland D. Motivation, self-determination, and long-term weight control [Internet]. Vol. 9, *International Journal of Behavioral Nutrition and Physical Activity*. 2012 [cited 2020 Feb 11]. p. 22. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22385818>
24. Silva MN, Vieira PN, Coutinho SR, Minderico CS, Matos MG, Sardinha LB, et al. Using self-determination theory to promote physical activity and weight control: a randomized controlled trial in women. *J Behav Med* [Internet]. 2010 4 [cited 2020 Feb 11];33(2):110–22. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20012179>
25. Jiang JX, Xia XL, Greiner T, Lian GL, Rosenqvist U. A two year family based behaviour treatment for obese children. *Arch Dis Child*. 2005 12;90(12):1235–8. [PubMed: 16188958]
26. Gutin B, Barbeau P, Owens S, Lemmon CR, Bauman M, Allison J, et al. Effects of exercise intensity on cardiovascular fitness, total body composition, and visceral adiposity of obese adolescents. *Am J Clin Nutr*. 2002;75(5):818–26. [PubMed: 11976154]
27. Watts AW, Loth KA, Peterson C, Boutelle KN, Neumark-Sztainer D. Characteristics of a Favorable Weight Status Change from Adolescence to Young Adulthood. *J Adolesc Heal*. 2016 4 1;58(4):403–9.

28. Barlow SE. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics* [Internet]. 2007;120 Suppl(Suppl 4):S164–192. Available from: http://pediatrics.aappublications.org/cgi/content/abstract/120/Supplement_4/S164
29. Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: A report of the American College of cardiology/American Heart Association task force on practice guidelines and the obesity society. Vol. 129, *Circulation*. Lippincott Williams and Wilkins; 2014.
30. Skelton JA, Irby MB, Beech BM. Bridging the Gap between Family-Based Treatment and Family-Based Research in Childhood Obesity. *Child Obes* [Internet]. 2011/08/01. 2016;7(4):323–6. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25019510>
31. Golan M, Weizman A. Familial approach to the treatment of childhood obesity: Conceptual model. *J Nutr Educ Behav*. 2002/05/29. 2001;33(2):102–7.
32. Brown CL, Irby MB, Houle TT, Skelton JA. Family-based obesity treatment in children with disabilities. *Acad Pediatr* [Internet]. 2015/03/10. 2015;15(2):197–203. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25748977>
33. Irby MB, Boles KA, Jordan C, Skelton JA. TeleFIT: Adapting a multidisciplinary, tertiary-care pediatric obesity clinic to rural populations. *Telemed e-Health* [Internet]. 2012/02/24. 2012;18(3):247–9. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22356527>
34. Guzman A, Irby MB, Pulgar C, Skelton JA. Adapting a tertiary-care pediatric weight management clinic to better reach Spanish-speaking families. *J Immigr Minor Heal* [Internet]. 2011/09/13. 2012 Jun 11 [cited 2019 Mar 7];14(3):512–5. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21909984>
35. Spear BA, Barlow SE, Ervin C, Ludwig DS, Saelens BE, Schetzina KE, et al. Recommendations for treatment of child and adolescent overweight and obesity. [Internet]. Vol. 120 Suppl, *Pediatrics*. 2007. p. S254–88. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/18055654> [PubMed: 18055654]
36. Irby M, Kaplan S, Garner-Edwards D, Kolbash S, Skelton JA. Motivational Interviewing in a Family-Based Pediatric Obesity Program: A Case Study. *Fam Syst Heal* [Internet]. 2010/10/14. 2010;28(3):236–46. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/20939628>
37. Troiano RP, McClain JJ, Brychta RJ, Chen KY. Evolution of accelerometer methods for physical activity research. *Br J Sports Med*. 2014;48(13):1019–23. [PubMed: 24782483]
38. Subar AF, Kirkpatrick SI, Mittl B, Zimmerman TP, Thompson FE, Bingley C, et al. The Automated Self-Administered 24-Hour Dietary Recall (ASA24): A Resource for Researchers, Clinicians, and Educators from the National Cancer Institute. *J Acad Nutr Diet* [Internet]. 2012 8 [cited 2020 Feb 11];112(8):1134–7. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22704899>
39. Thompson FE, Dixit-Joshi S, Potischman N, Dodd KW, Kirkpatrick SI, Kushi LH, et al. Comparison of Interviewer-Administered and Automated Self-Administered 24-Hour Dietary Recalls in 3 Diverse Integrated Health Systems. *Am J Epidemiol*. 2015 6 15;181(12):970–8. [PubMed: 25964261]
40. Johnston MM, Finney SJ. Measuring basic needs satisfaction: Evaluating previous research and conducting new psychometric evaluations of the Basic Needs Satisfaction in General Scale. *Contemp Educ Psychol*. 2010 10;35(4):280–96.
41. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res* [Internet]. 2011 5 [cited 2019 Jan 10];45(5):626–9. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21035130>
42. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. *Int J Hum Comput Interact* [Internet]. 2008;24(6):574–94. Available from: <http://www.tandfonline.com/doi/abs/10.1080/10447310802205776>

Modified from Jake-Schoffman, 2016

Figure 1:
Dyad Plus Conceptual Model