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Research Article

Kids N Fitness: A Group-based Pediatric Weight Management Curriculum Adapted for a Clinical Care Model

Manzanarez B[1], Lopez K[1], Lipton-Inga M[1], Fink C[1], Radzik M[2], Buxton R[3], Gonzalez J[1], Davis C[1] and Vidmar AP[1]*

[1]Diabetes and Obesity Program, Center for Endocrinology, Diabetes and Metabolism, Children's Hospital Los Angeles and Keck School of Medicine of USC, USA

[2]Diabetes & Obesity Program and Division of Adolescent and Young Adult Medicine, Children's Hospital Los Angeles and Keck School of Medicine of USC, USA

[3]Physical Therapy and Rehabilitation Services, Children's Hospital Los Angeles and Keck School of Medicine of USC, USA

***Corresponding author:** Alaina Vidmar, Department of Pediatrics, Center for Endocrinology, Diabetes & Obesity Program, Diabetes and Metabolism, Children's Hospital Los Angeles and Keck School of Medicine of USC, 4650 Sunset Boulevard, Mailstop #61, Los Angeles, CA 90027, USA

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Abstract

Background: The current AAP clinical practice guidelines for the management of pediatric obesity recommend a structured, comprehensive, multi-disciplinary clinical intervention. However, there is a gap in the current literature on standardized curriculums for implementation of such programs. The objective of the present study is to adapt an evidenced-based, family-centered, weekly, weight management curriculum that addresses nutritional, physical activity and behavioral topics for a clinical care model at a tertiary care children's hospital.

Methods: The curriculum was adapted for use in six individual sessions offered monthly by a multidisciplinary team, including a health educator, physician, dietitian, physical therapist and psychologist. Each provider offered specific feedback and curriculum adaptation based on their specialty. All team members completed training with scheduled treatment fidelity monitoring during implementation. To evaluate the effectiveness of the adapted curriculum, 60 adolescents, ages 14-18 years, with overweight or obesity, and at least one family member, will complete the six month intervention. The primary outcome is mean change in zBMI and %BMIp95 at six month and 18 months. Secondary outcomes include retention, satisfaction, effect on metabolic factors and activity level.

Conclusion: There is a paucity of literature on utilizing a standard curriculum in clinical weight management programs. Drawing from evidenced-based curriculum to strengthen clinical care creates an opportunity to improve existing clinical programs and potentially increase access and implementation of the current treatment recommendations for this high risk population.

Keywords: Obesity; Pediatrics; Weight Loss; Weight Management; Curriculum

Abbreviations

Body mass index (BMI); Body mass index Z-score (zBMI); Percent over the 95th percentile (%BMIp95); Alanine aminotransferase (ALT); Coefficient (coef); Confidence Interval (CI); Quality-adjusted life years (QALY)

Introduction

Pediatric obesity remains a major public health concern [1]. Recent NHANES data indicates that 18.5% of children and adolescents are obese, including 13.9% of 2- to 5-year-olds, 18.4% of 6 - to 11-year-olds, and 20.6% of 12 - to 19 year-olds [2]. In our population of lower income minority patients in Southern California, 1 in 3 adolescents have obesity or severe obesity, and of those, 30-50% go on to develop pre-diabetes or type 2 diabetes as young adults [3]. These striking findings reinforce the need to identify innovative, effective, and replicable interventions that target children and their families specifically and determine the best way to replicate these interventions across clinical practices and providers [2, 3]. The pediatric population is at high risk of poor health outcomes and therefore requires thoughtful study of the most effective treatment strategies to promote stabilization of their BMI trends [4].

The recent consensus guideline for the treatment of pediatric obesity recommends comprehensive, multi-disciplinary, family-based interventions with 26 contact hours over a 6 month period [4,5]. Interestingly, there is a paucity of literature discussing the use of a standardized, structured weight management curriculum to implement these interventions in a tertiary care setting [6]. Multiple group-based curriculums have been developed to date as intervention strategies for the management of pediatric obesity [7,8]. However, few have been adapted for individualized implementation and studied in a clinical setting. Therefore, the current study aims to investigate the adaptation of an evidence based, family-centered, group weight management curriculum to be implemented by a multi-disciplinary provider team in a clinical setting in a tertiary care center.

Kids N Fitness© (KNF) is an evidence-based, weight management program for children with overweight and obesity and their families [9,10]. KNF was developed at Children's Hospital Los Angeles (CHLA) in 2000 by a team of pediatric endocrinologists (MD),

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Registered Dietitian Nutritionist (RDN), social workers, Psychologists (PSY), and Physical Therapists (PT). The objectives of KNF are to: 1) reduce weight gain in youth with overweight and obesity, 2) promote healthier eating habits, more frequent exercise, and a reduction in the behaviors that encourage weight gain, and 3) provide ongoing support to help sustain healthy behaviors. The program empowers families to make healthy lifestyle changes by providing digestible, interactive nutrition education for the entire family. Each class consists of nutrition education, physical activity, and parent support sessions.

The goal-setting objectives of the present study are twofold: 1) To adapt the KNF curriculum to be implemented by a multi-disciplinary provider team in a clinical setting and 2) To evaluate how baseline demographics or clinical characteristics of treatment-seeking youth or their parents predict treatment outcomes, across BMI status metrics in this high risk population. This curriculum adaptation was created as part of a larger Randomized Controlled Trial (RCT) that is set to test the efficacy of an interactive addiction mobile health (mHealth) weight-loss intervention with personalized phone-coaching (App+Coach) compared to: 1) interactive addiction model based mHealth weight-loss intervention alone (App) or 2) multidisciplinary in-clinic weight management program (Clinic) [9].

Methods

Overview of study design

The present study will describe the development of a multi-disciplinary in-clinic weight management program that was developed as one of the intervention arms for a three-arm multi-center (n=180) RCT of a mHealth weight loss intervention plus personalized coaching (App+Coach) compared to: 1) mHealth intervention alone (App) and 2) multidisciplinary in-clinic weight management program (Clinic) [11]. The specific details of the RCT design and process have been described by Vidmar *et al* [11].

Participant recruitment and eligibility criteria

Study procedures were approved by the Children's Hospital Los Angeles (CHLA) Institutional Review Board and are in accordance with the Helsinki Declaration of 1975, as revised in 2008. The study will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement for randomized trials of no pharmacological treatments and is registered with ClinicalTrials.gov (NCT03500835). Youth interested in participating will be scheduled for a visit and informed consent will be obtained. Eligible participants will be adolescents, ages 14-18 years with BMI ≥85th percentile for age and sex with at least one family member willing to participate in the six-month intervention followed by 12-month maintenance period. Youth will be excluded if they: are currently participating in an alternative weight loss intervention; have a self- reported diagnosis of blood pressure > 99th percentile for age, gender, and height, and/or severe developmental delay in which they are unable to autonomously interact with the interventions; or are unable to read English. Participants will be recruited from: 1) four Southern California-based hospitals (CHLA, Los Angeles Biomedical Research Institute at Harbor-UCLA (LA Biomed), Mattel Children's Hospital of the University of California Los Angeles, and Cedars Sinai Medical Center) and 2) direct mailing campaign. A direct mailing campaign will be utilized to send 10,000 recruitment letters to families with adolescents' ages 14-18 years across 40 neighborhoods in Los Angeles County.

Session Design and Layout: Participants randomized to the in-clinic arm will be given an appointment to come to CHLA for a 1.5-2 hour visit once per month (+/-2 weeks) for six sessions over a six-month period. The research team consists of a physician (MD), Registered Dietitian Nutritionist (RDN), Psychologist (PSY), Physical Therapist (PT) and/or health educator (HE). Each visit will consist of five components: 1) nutrition education for the entire family, 2) physical activity for the teen, 3) a parent support session, 4) SMART (Specific, Measurable, Attainable, Relevant and Timely) goal setting, and 5) a healthy snack. Interspersed throughout the six sessions will be a facilitated discussion based on the socioecological model around barriers and strategies to health, sustained habit change and lifestyle redesign. The adaptation is designed for the RDN and/or HE to meet with the family at all six sessions and provide continuity between visits. The intention is that the MD will meet with the family twice, ideally at sessions one and six, and for the PSY to meet with the parent at sessions one and six twice and with the teen alone at session three independent of the parent once. The PT will meet with the teen on session one and provide an orientation and do an initial assessment, and make recommendations.

Randomization: Randomization will be at the level of the youth utilizing block randomization to ensure the groups are balanced in terms of number of subjects and the distribution of potential confounding variables. Youth (n=180) will be randomly assigned to one of the intervention arms. Investigators and study staff will be blinded to block size.

Intervention Components

Table 1 outlines the components of the multi-disciplinary curriculum.

Kids N Fitness© (KNF): KNF is an evidence-based, family-centered, weight management program for children and adolescents with overweight and obesity [9,10]. KNF was originally designed as a twelve-week clinical group program offered at CHLA for children ages of 8 - 16 years and their parents. Post-intervention feedback from parents in the initial implementation period revealed that the length of the program and distance to the hospital created challenges for many families already facing significant day-to-day stresses to consistently attend all sessions. The curriculum was then revised to be implemented in six weekly 90 minute sessions. The core components of the KNF curriculum are founded on the socioecological model and cognitive theory and include: 1) family-centered nutrition education, 2) acquiring exposure and practice with different types of physical activity, 3) utilizing goal setting and self-monitoring techniques to create sustained healthy behavior change and 4) fostering family support.

The traditional group based model utilized nutrition based education components includes the following topics: understanding food groups, preparing healthy meals, determining appropriate portion sizes, reading food labels, mindful eating, and the development of refined shopping skills to identify healthy food options. Daily physical activity is also promoted throughout the

Traditional KNF	
Participants	Children ages 8-16 with overweight/obesity At least one parent or legal guardian Able to participate in a group setting
Instructors	Health Educator (HE) and/or Registered Dietitian (RD), and volunteers
Length	Six weekly 90-minute sessions
Setting	Group classes Hospital, schools, summer camps, churches
Physical Activity	Group-based games, nutrition embedded messages in games, family games
Materials	Student binder with handouts, incentives
Supplies	Food models, posters, fresh snack Gym bag: balls, jump ropes, games, music speaker
Staff Training	Two-day training

Clinical Care Model	
Participants	Adolescents ages 14-18 with overweight or obesity At least one adult family member Both willing to participate
Instructors	Physician (MD), RD, HE, Physical Therapist (PT), and Psychologist (PSY)
Length	Six monthly 90-minute sessions
Setting	One-on-one visits In clinic
Physical Activity	Circuit training, weights, sport drill exercises, parent and teen workouts
Materials	Student binder with handouts, incentives
Supplies	Food models, instructor visual binder, packaged snack Weights, jump rope, yoga mat, balls
Provider Training	Two-day training, and on-going support

Curriculum Topics	
Session 1	Nutrition & the Food Groups
Session 2	Portions & Label Reading
Session 3	Natural & Processed Foods
Session 4	Sugar & Label Reading
Session 5	Healthy Shopping/Market Tour
Session 6	Celebrations & Eating Out

KIDS N FITNESS

Curriculum Adaptations

**Same curriculum topics*

Adaptations:

1. Individual-based versus class-based setting
2. Deliver as a clinical care model
3. 6-month versus 6-week session format
4. Activities and discussion addressing the socio-ecological factors of obesity
5. Addition of individual session with PT and PSY
6. Monthly self-efficacy survey

Table 1: KNF Adaptations.

program. The physical activity sessions include strength training, stretching, and core training. The youth are introduced to a variety of fun, engaging, play based activities that can be done at home without need for expensive equipment or parental supervision. The families create SMART goals around eating and physical activity. The development of habit change is implemented through discussion of internal and external motivation and the creation of improved rapport between parents and youth. Skill based trainings and goal setting are techniques utilized to promote sustained habit change.

Parents participate in facilitated discussions to share and learn strategies to support their children in making healthy changes, overcome personal and environmental barriers, and role model healthy behavior. The curriculum has served as a framework used to develop multiple innovative programs designed to help a diverse range of youth and families in multiple settings. These include adaptations for pre-school aged children, children with developmental delays (such as autism), high school students, for a faith-based environment, and for summer camp platforms.

Since its launch, KNF has evolved to become a robust intervention reaching a wide range of families and communities in a variety of organizational and community settings. To date, KNF has been delivered to over 3000 participant families. KNF has been evaluated for efficacy, measuring outcomes such as adiposity and metabolic indicators, program length, knowledge and behavior change, self-efficacy, retention, cost-effectiveness, and instructor impact [12] [13]. It has been well received by healthcare and public health professionals and advocates as it has proven to significantly improve nutrition knowledge (e.g. label reading and principles of MyPlate), eating behavior (e.g. eating breakfast daily, decreasing amount of sugar-sweetened beverages and fast foods, increasing consumption of fruits and vegetables) increase physical activity, reduce zBMI scores, body fat percentage and fat mass in children who participate [8].

Curriculum Adaptations for Implementation in a Clinical Setting: As there is a lack of standardized, multi-disciplinary weight management curriculum's, the KNF curriculum was modified to be implemented by multiple providers in a clinical model. Adaptations were required so that the curriculum was appropriate for: 1) a clinical setting, 2) a multi-disciplinary team of providers (MD, RDN, HE, PT and PSY), 3) individualized administration, and 4) adolescents. A side-by-side comparison of KNF adaptations can be found in Table 1. The modified curriculum was taught to the participating providers by KNF master trainers. The master trainers implemented the intervention across multiple different settings and were able to teach the intervention implementation.

Modifications for the one-on-one clinical setting: The first adaptation was to modify the KNF curriculum to be administered in a traditional clinic setting. This was accomplished by breaking down the curriculum into six, monthly sessions to be implemented by a team of providers. The curriculum topics were divided by session and assigned to the provider with the most expertise in that area (See Table 2 for an example of the time spent by each provider per session). Providers were instructed to share with the greater team if / when an individual's issues (positive or negative) came up during their time with the participant to ensure continuity of care and minimize unnecessary repetition while maximizing desired reinforcement. The adapted intervention model is administered *via* monthly visits with one or more providers (averaging 100 minutes at the initial visit and 80 minutes per follow up visitor approximately eight contact hours per participant per six month intervention period, Table 2).

A team of multi-disciplinary providers were identified and trained to administer the curriculum in a clinical setting. The providers participated in 2 days, 3-hour training sessions over the course of two months. This intensive training session was followed by role playing of each of the six sessions performed by the KNF master trainers. The training included didactic lectures, role playing, modeling and observation. Session checklists were created to be utilized by each provider as they implemented the intervention. Fidelity instruments were created to be used by the KNF master trainers as they observed each provider implementing the intervention. Ten percent of the sessions will be observed for treatment fidelity and to identify any

Clinical KNF - Draft

STUDY SUBJECTS: T-teen, P-parent, F-family STAFF: HE- health educator, RD – registered dietitian, MD – medical doctor, PSY – psychologist

CLINIC VISIT	NUTRITION (FAMILY)	PHYSICAL ACTIVITY (TEEN Only)	PARENTING (PARENT Only)	TIME BREAKDOWN	STAFF	TOOLKIT	SNACK	GOAL
Session 1 *Nutrition and the Food Groups*	1 F: [HE/RD] **Introduction to KNF Program:** goals, overview, different expertise of the team. Setting realistic expectations. 1a. **What is health? & barriers to health activity** *(global, not personal yet- from TNF)* 1b. **Nutrition overview:** -Introduction to My Plate & food groups -Eat a rainbow -Healthy My Plate -Go, Slow, Woah foods -Importance of breakfast and not skipping meals 3 F. [MD] **MD consult:** - Checkup/ discussion of labs and individual health issues. Put into perspective the other risks of obesity 4 F. [HE&PSY] **Wrap Up**: Snack, introduction to logbooks, and goals	2 T: [HE] **Activity assessment:** - Current level - Likes/dislikes - MI for interest in trying a new activity 2a. **Physical activity:** - Stretching - Brisk walk - Stairs - Hand weights 2b.**PA reinforcing nutrition theme:** - Red-light/Green-light race - beat time 2c. **PA goal setting:** - Creating a smart goal around activity	2 P: [PSY] **Build parent rapport:** - Setting realistic expectations for program - parent views of challenges: for child, for the parent, for the family - parent/child roles - how to be supportive *(create worksheet to document for team)*	*Session 1: 1hr 50min* **Family** 1F. 10 min 1a. 10 min 1b. 25 min **Teen** 2T. 30 min **Parent** 2P. 30 min **Family/MD** 3. 20 min F **Wrap Up** 4F. 15 min _____ *110 mins* *10 min flex time*	1F: RD &/or HE 2T: HE 2P: PSY 3F: MD 4F: HE &PSY	- KNF athletic bag - KNF student workbook	Apple oatmeal	**Dietary-related goal:** -Eat breakfast every day -Individualized SMART nutrition goal **Physical activity-related goal:** -Individualized SMART PA goal **Home Activity Reflection:** - Challenge teens to think about their personal barriers to health

Table 2: KNF Clinical Care Model: Visit Breakdown.

additional areas of training required by the providers.

Thirdly, the curriculum was adapted to be administered to individual participants rather than a group model. Group-based discussion topics from the education sessions were extracted and tailored for an individualized approach using motivational interviewing techniques. One of the key components of the original curriculum in a group setting was the adult and child peer interaction which organically provided support and motivation and shared strategies for behavior change. In order to ensure some level of peer familial and/or community support in the clinical model, discussion aiming to identify or form the youth's support structure was incorporated.

The final adaptation was adjustment of the education modules and activities to better target the adolescent population. To accomplish this task, the team utilized didactic topics and activities that are designed to engage adolescents and target cognitive behavior change, habit formation, executive function and health autonomy. Similar to the facilitated discussions and sample scenarios that make up the parent sessions, the clinical adaptation includes opportunities for teens to discuss health, barriers, setbacks and successes and create action plans to promote sustained habit change at every session.

Measurements

The measurements and outcomes of this trial are described in detail in Vidmar *et al*. Below is a brief description pertinent to the present report. Assessments will occur at months 0, 6, 12, and 18 and include a combination of data collection by telephone and in-person visits (Table 2). Telephone-based assessments are designed to reduce participant burden and maximize data collection. All data will be collected and stored in REDCap, a secure web application for managing online databases.

Primary outcomes:

Participant's weight change: Height and weight will be assessed at in-person visits with the on-site clinical research coordinator (CRC) at baseline, 3, 6 (intervention completion), 12 and 18 months (weight maintenance measures) for all participants. Height will be measured using a Quick Medical stadiometer, accurate to 0.1 cm (Quick Medical, Issaquah, WA). Weight will be measured on a self-calibrating Mobile Stand Digital Scale, accurate to 0.1 kg. Participants will wear minimal clothing during the height and weight measurements. BMI will be calculated as kilograms per meter squared and zBMI and percent over the 95th percentile (%BMIp95) will be determined utilizing the CDC growth charts.

Secondary outcome:

Adherence and retention: We will use strategies to increase retention, including: incentives for participation and adherence; frequent contacts with participants to maintain engagement and foster open communication; email and text reminders about face-to-face visits; and recording contact information of relatives or friends to be able to reach participants. The number of sessions attended by each participant and any required rescheduling of sessions will be collected throughout the study period. Additionally, the number of reminder phone calls and emails received by each participant will be collected and reviewed at completion of the study.

Change in metabolic parameters: The following laboratory samples will be obtained after an 8-h overnight fast at baseline, 6 and 18 months: plasma glucose (FPG), lipid profile, Alanine aminotransferase (ALT), Aspartate aminotransferase (AST) and

Table 3: Clinic Curriculum Education Topics.

Topic	Nutrition Session	Physical Activity Session	Parent Session	Healthy Snack	Monthly Goal
Nutrition and the Food Groups	• Food groups • Traffic light Guide •Importance of breakfast	• Warm-up and stretches • Exercise circuit intro	• Setting realistic expectations for program • Risks of obesity	• Dried apple slices	• Eat breakfast every day
Portions and Label Reading	• Portion sizes • Label reading • Mindfulness	• Exercise circuit	• Address behavior change barriers • Physical activity recommendations • Keeping to portions • Managing overeating	• Protein bar	• Walk as much as possible, aiming for 10,000 steps a day
Natural and Processed Foods	• Real and processed foods • Read ingredients list • Choosing healthier snacks • Fiber	• Weights	• Types of fat and cholesterol • Healthier cooking methods • Healthier food alternatives	• Packaged snack size hummus and baby carrots	• Eat five fruits and vegetables everyday
Sugar and Label Reading	• Natural and added sugar • Identify sugar and quantity in food label	• Sports drills	• Setting limits in relation to food • Giving appropriate rewards	• Natural fruit bar	• Drink water instead of sugary beverages • Limit juice to 6oz of 100-percent juice a day
Healthy Shopping and Market Tour	• Grocery shopping tips • Practice label reading	• Teen and parent physical activity	• Parents exercise with their teens	• String cheese or individually packaged trail mix	• Limit screen time to less than two hours a day • Try to be more physically active
Celebrations and Eating Out	• Balancing eating healthy during celebrations and eating out	• Exercise circuit	• Healthy cooking Maintaining healthy habits • Managing relapse	• Individual air-popped popcorn bag	• Continue monitoring

Hemoglobin A1c (HbA1c). FPG, total cholesterol, HDL cholesterol, and TG will be measured *via* Vitros 960 colorimetric assay, and LDL cholesterol will be calculated. Fasting insulin level will be obtained and the homeostatic model assessment of insulin resistance will be calculated. Hemoglobin A1c will be measured using a DCA 2000 (Bayer Corporation, Elkhart, IN).

Psychosocial Questionnaires: The following questionnaires will be collected at 0, 3, 6, 12 and 18 months. 1) Quality of life is assessed through the validated Short-Form 12 (SF-12), which provides measures of health-related quality of life for physical and mental health. 2) Leisure-time physical activity is assessed with the Physical Activity Questionnaire, which includes items about daily walking, stair climbing, and participation in recreational activities. 3) Health care utilization will be collected *via* self- reported responses including hospitalizations, ER/physician office visits, prescription drugs, etc) [11].

Cost analysis: An extensive cost analysis will be completed as part of the larger RCT design to determine the net impact on direct healthcare costs and to numerically estimate future (longer-term) healthcare costs, both direct and indirect [11]. The net-health benefits will be measured in Quality Of Life Years (QALY), during the study period and future QALY health benefits will be estimated *via* computational models. Those results will be used to calculate Incremental Cost-Effectiveness Ratios (ICERs) for all three intervention arms, to inform both reimbursement decisions by healthcare payers, and system-level policy decisions.

Covariates:

Demographics and medical history: At baseline, we will assess participant demographics, completed by the family member, including family member's age, family member and child's race/ethnicity, household composition, socioeconomic status (education, income), as well as family and child medical history. In addition, each family member will report on the frequency of health encounters for each youth over the past 12 months and assess the frequency in which the youth and family member eat outside the home. These variables will be entered as covariates in the analysis [11].

Family member's weight: One family member's weight and height will be measured at baseline and 18 months using a Quick Medical stadiometer, accurate to 0.1 cm (Quick Medical, Issaquah, WA). Weight will be measured on a self-calibrating Mobile Stand Digital Scale, accurate to 0.1 kg. BMI will be calculated as kilograms per meter squared ($BMI=kg/m^2$) [11].

Analytic plan and power analysis

See Vidmar et al for the full power analysis and statistical plan [11]. In brief, the power analysis is prepared for comparing mean change in zBMI and %BMIp95 from baseline to post-intervention (6 months) and from baseline to one year post-intervention (18 months) between the two intervention arms described by Vidmar et al, AppCoach and Clinic (the curriculum described in the present paper) [11]. Sample size calculations were informed by Cochrane review of life style interventions in obese adolescents reported difference in zBMI of 0.15-0.25 as clinically important change in zBMI [14,15]. With 180 participants assuming 20% dropout rate, a sample size of 60 per intervention group will achieve the desired study power of 80% to detect an effect size of 0.567 corresponds to the mean difference of pre and post change at least 0.20 SD with the common standard deviation of 0.353 between two intervention groups. These calculations utilize an estimate of standard deviation of change based on the conservative correlation of 0.50 between pre and post measurement within each group (nQuery + nTerim 4.0).

Statistical Analysis

The main analyses focus on comparing BMI status change of youth between baseline, the end of the intervention (6 months) and one year follow up (18 months). Linear association of each

intervention arm with BMI status changes will be estimated and adjusted for demographic information and other measured covariates by performing mixed regression models. In addition to evaluating potential mediators, we will also investigate for moderator effect of race by presenting aforementioned statistics by race and evaluating interaction effect between groups and race in the models. Missing data will be addressed using multiple imputation and/or full information maximum likelihood estimation. Final results will be determined to be statistically significant when the accompanying statistical test yields a two-tailed probability of 0.05 or less [11].

Discussion

This study describes the adaptation of a group-based, standardized curriculum for a multi-disciplinary clinical intervention for pediatric weight management. The current guideline for stage 3 treatment of pediatric obesity recommend comprehensive, multi-disciplinary weight management interventions administered over 26 contact hours in 6 months. However many clinical interventions are unable to implement programs that achieve the recommended amount of contact hour due to the significant cost and labor burden involved. Although many programs have implemented these types of interventions clinically, there remains a paucity of information regarding the foundational curriculum components, training requirements and strategies utilized for successful and sustainable implementation. While a standardized curriculum may not necessarily decrease the total cost of implementation, it could improve efficacy, reproducibility and sustainment in the clinical setting. To our knowledge, this is the first description of a standardized multi-disciplinary curriculum created for implementation in a clinical setting for the management of pediatric obesity. This study will contribute to the development and dissemination of effective clinical curriculums for use in adolescents with obesity and will provide important information about the long term impact of this type of in-clinic intervention on long term weight control and habit change in this population.

Furthermore, this study aims to evaluate and explain how such curriculums are developed and teams are trained to ensure treatment fidelity across providers in a clinical setting. The implementation and training process will allow for creation of a manual of procedures to support the expansion of this type of program to other clinical settings and institutions. Additionally, by utilizing expertise from multiple different and complimentary provider groups in the development of the curriculum, future implementations can have the recommended multi-disciplinary components and expertise but be implemented by the available personnel in any given clinical setting, such as a health educator or promotora.

Equally important to the above mentioned is that a cost analysis component will provide the data required to understanding exactly the monetary requirements needed to implement such an intervention in a clinical setting and provide information regarding the cost saving potentials of standardized in-clinic models for pediatric weight management that can be used in negotiations with payers. The investigation of both the structured curriculum and its implementation costs will allow for such a method to be implemented in other institutions to provide a resource to care for this patient population more broadly.

There are a number of potential challenges that must be considered and discussed. First, we recognize that the in-clinic curriculum provides less contact hours than the current clinical practice guidelines recommend (26 hours/6 month intervention) [6]. However, on review of the clinical practices in the area, we determined that the average contact hours administered across the 4 centers in the study was 8-12 contact hours/6 month intervention period. Therefore the curriculum reflects what is actually being administered in real life clinical practice in this area and thus is an accurate metric of what payers are being asked to reimburse for this patient population in this location [9]. Second, because this is the first RCT to assess the implementation of this curriculum we considered making the inclusion criteria more stringent to increase homogeneity of our sample. However, the researchers felt that as this is a pragmatic study design, all youth should be encouraged to participate regardless of any underlying medical complexity or chronic illness, as the targeted behaviors are relevant and beneficial for all youth with obesity. Finally, the study design lacks an age-matched randomized, routine care group who are not receiving any organized care for weight management. Unfortunately, this sample is difficult to identify longitudinally in a prospective manner and ethically as these patients are seeking care it is inappropriate to randomize them to a no-treatment control given the increased risk of morbidity that could ensure from the underlying condition itself without treatment. Moreover, in current literature of pediatric obesity interventions and the natural trajectory for youth with obesity, it is well described that weight velocity of youth not receiving any intervention continues to increase and therefore historical comparison is adequate [5].

Conclusions

Although in-clinic behavioral interventions for pediatric weight management are the gold standard of care for this high risk population there is a paucity of literature on utilizing a standard curriculum to ensure consistent, effective implementation of such programs. Therefore this study will allow for further investigation and exploration into how a standardized curriculum can strengthen clinical care and create an educational tool to improve existing clinical programs.

Contributors' Statements

All authors conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Clinical Trial Registration

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Conflict of Interest

The additional authors have no financial relationships or conflict

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Contributors' Statements

Ms. Manzanarez, Lopez, Lipton-Inga, Fink and Gonzalez along with Drs. Radzik, Vidmar and Buxton conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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