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Rationale and design of a pilot study to evaluate the acceptability and effectiveness of a revised protein sparing modified fast (rPSMF) for severe obesity in a pediatric tertiary care weight management clinic

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ABSTRACT

Aggressive dietary interventions may provide an accessible treatment option for children and adolescents with severe obesity who are not successful with traditional lifestyle behavioral interventions or do not want or qualify for weight loss surgery. One such intensive dietary option is the protein sparing modified fast (PSMF). The PSMF involves minimal carbohydrate intake to induce ketosis, while maintaining adequate or high protein intake to minimize catabolism. The PSMF, under medical supervision, can be an effective and safe intervention for children and adolescents, yet the PSMF diet is not regularly used in the treatment of pediatric severe obesity. This paper describes the rationale and design for a pilot study to evaluate the acceptability and effectiveness of a revised PSMF (rPSMF) implemented as a weight loss treatment option for children and adolescents with severe obesity in a pediatric tertiary care weight management clinic. The primary aim of the study is to evaluate the acceptability of the rPSMF as assessed by adherence, satisfaction with the intervention, and participation rate using quantitative and qualitative methods. The secondary aim is to investigate the effectiveness of the rPSMF on improving a) anthropometric measures (weight, body mass index [BMI], BMI z-score); b) metabolic measures (lipid profile, glycosylated hemoglobin, liver function tests); and c) quality of life. Results of this study will provide guidance for the standardization of a pediatric rPSMF protocol in a clinic setting, delineate which factors improve or hinder adherence and weight loss and provide preliminary data for a multicenter randomized controlled trial.
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1. Introduction

Approximately six percent of children and adolescents 2–19 years old in the United States have severe obesity, defined as a Body Mass Index (BMI) greater than or equal to 120% of the 95th percentile for their age and sex, or a BMI of 35 or greater [1]. The risk for co-morbidities such as cardio-metabolic diseases and nonalcoholic fatty liver disease are significantly greater among children and adolescents with severe obesity compared to their peers with obesity [2,3]. Furthermore, children with severe obesity are at greater risk of becoming adults with obesity [4]. Unfortunately, traditional lifestyle behavioral interventions for children with severe obesity rarely achieve significant or sustainable weight loss, regardless of the intensity or length of the programs [5–8].

Given the prevalence of obesity and ineffectiveness of conventional lifestyle behavioral interventions, national organizations [2,9] like the American Heart Association [3] have called for innovative interventions to treat pediatric severe obesity. Currently, weight loss surgery is the most effective intervention for children with severe obesity [3]. However, surgery may not be appropriate for all children with severe obesity. For example, a child might be too young, have significant and untreated psychological symptoms or the adolescent and family may

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not desire surgery as a treatment option. There has been a push to increase the use of medications treating obesity, but there are limited studies on the effectiveness of these medications in children and adolescents [10–12]. To date, only Orlistat has been approved by the Food and Drug Administration (FDA) for pediatric population.

Aggressive dietary interventions may provide an accessible treatment option for children and adolescents with severe obesity who have not been successful with traditional lifestyle behavioral interventions or do not want or qualify for weight loss surgery. Additionally, there are occasions where children and adolescents may require rapid weight loss such as the presence of a serious complication (e.g., idiopathic intracranial hypertension, obstructive sleep apnea, fatty liver disease) or prior to undergoing bariatric surgery. One such intensive dietary option is the protein sparing modified fast (PSMF), a very low carbohydrate diet, which has been used in adult populations with severe obesity and/or significant obesity-related comorbidities such as type 2 diabetes [13]. Three decades ago, the PSMF, when delivered under medical supervision, was shown to be an effective and safe intervention for adolescents with severe obesity [14]. More recently, low carbohydrate approaches have shown promising weight loss results, including a case series using a slightly more liberalized version of the PSMF diet in inpatient and outpatient settings [15,16]. Despite this promising evidence, the PSMF diet is not a treatment option regularly offered in pediatric tertiary care weight management clinics [14,15,17–20]. The purpose of this paper is to describe the rationale and design of a pilot study to evaluate the acceptability and effectiveness of a revised protein sparing modified fast (rPSMF) implemented as a weight loss treatment option for children and adolescents with severe obesity.

2. Methods

2.1. Study design and aims

This pilot study will employ a prospective cohort study design. Thirty children, 11-19 years-old, with severe obesity, who have been prescribed the rPSMF as part of their treatment in a tertiary care pediatric weight management clinic (PWMC), will be recruited along with their attending parent to participate in the study. The primary aim of the study is to evaluate the acceptability of a revised (i.e., liberalized) PSMF (henceforth referred to as rPSMF) diet in a tertiary care PWMC as assessed by adherence, satisfaction with the intervention, and participation rates. The secondary aim is to investigate the effectiveness of the rPSMF on improving a) anthropometric measures (weight, Body Mass Index (BMI), BMI z-score); b) metabolic measures (lipid profile, glycosylated hemoglobin (Hgb A1c), liver function tests); and c) quality of life [21]. A schematic representation of the intervention and study protocol is shown in Fig. 1. The study is approved by the Institutional Review Board of Nationwide Children's Hospital.

2.2. Screening and recruitment

Participants will be recruited from a tertiary care PWMC staffed by a multidisciplinary team of healthcare providers (pediatricians, nurse practitioners, dietitians, physical therapists, psychologists). During routine clinic visits, the attending medical provider (pediatrician/nurse practitioner) will be responsible for identifying children and adolescents, for whom the rPSMF may be appropriate based on their weight status and/or presence of obesity-related comorbidities. If the child/adolescent and parent/caregiver meet the major inclusion criteria (see Table 1) for the rPSMF, the medical provider will discuss the rPSMF in addition to other treatment options available through the clinic (e.g., behavioral lifestyle intervention, low glycemic load diet, bariatric surgery). If the child/adolescent and parent/caregiver are interested in the rPSMF, participation in the study will be discussed. Children/adolescents and parents/caregivers may choose the rPSMF treatment option, but choose not to participate in the study; but a child/adolescent cannot participate in the study if the rPSMF is not their treatment option.

2.2.1. Inclusion and exclusion criteria

Given the limited use of the PSMF diet in pediatric weight management, the inclusion criteria are conservative, with more stringent criteria in younger children (see Table 1). There are three major inclusion criteria: (1) presence of severe obesity categorized as Class 2 (defined as a BMI ≥ 120% of the 95th age and gender-specific percentile, or a BMI ≥35) or Class 3 obesity (defined as a BMI ≥ 140% of the 95th age and sex-specific percentile, or a BMI ≥40), (2) pubertal Tanner stage of 3 or above, and (3) the presence of obesity-related comorbidities. Younger participants (11–13 years) will be required to have at least one complication related to obesity that is categorized as severe (Table 1). Since the diet involves restriction of a major macronutrient (carbohydrates) and the potential for nutritional deficiencies exists, Tanner staging will be used as a proxy to assess expectation for linear growth. Minor inclusion criteria (see Table 1) will be evaluated by the multidisciplinary clinic team, along with the attending parent/caregiver, over a 6–8 week ramp-up period [22]. Determination on whether to move forward on the rPSMF will be finalized at the end of the 6–8 week ramp-up period. For example, if the parent/caregiver indicates that the family cannot afford or commit to buying the recommended foods or if the participant still has significant food selectivity with limited vegetable intake by the end of the ramp-up period, the team will not recommend proceeding with the rPSMF diet. The team will also assess the parent-child relationship, including their ability to work together and follow through on the rPSMF goals. Additionally, children and adolescent's psychological and behavioral symptoms will also be considered, given the need to follow strict guidelines for adherence with the rPSMF.

Exclusion criteria include a history or presence of arrhythmia, impaired renal function defined as creatinine > 0.9 mg/dL or Glomerular Filtration Rate (GFR) < 90 mL/min/1.73 m^2, elevated baseline uric acid, a positive pregnancy test and lack of insurance coverage for medical or nutritional services. Prior to initiating the rPSMF diet, children/adolescents will complete all screening and baseline labs and demonstrate proficiency with the goals set during the 6–8 week ramp-up period.

2.2.2. Consent

The consent/assent documents will be provided at the initial clinic visit when the decision has been made by the medical provider and family to consider the rPSMF diet. The family will be encouraged to read the consent/assent documents and to call the research assistant with any questions. To participate in the pilot study, the parent/caregiver must have primary physical and legal custody of the child and be fluent in English because the study materials are only available in English. All participants and their parent/caregiver will complete a written informed consent and assent to participate in the study following completion of the ramp-up period. Once enrolled, the participant will continue in the study regardless of their adherence to the rPSMF, unless they voluntarily request to withdraw from the study. Thus, the results of the study will reflect a pragmatic and comprehensive assessment of the acceptability and effectiveness of the rPSMF in a tertiary care PWMC.

2.3. rPSMF: description and delivery of intervention

First introduced by Blackburn and Bistrian in 1970s, the PSMF is a subset of the very-low-calorie diet (VLCD), providing much more protein than a typical VLCD [23,24]. The PSMF combines features from a VLCD and a very-low-carbohydrate ketogenic diet [13]. In the absence of carbohydrates, the liver oxidizes fatty acids and produces ketones as a by-product. Although the mechanism is not fully understood, ketones have been shown to suppress appetite [25]. This is opposed to the increased hunger resulting from changes in appetite-regulating hormones

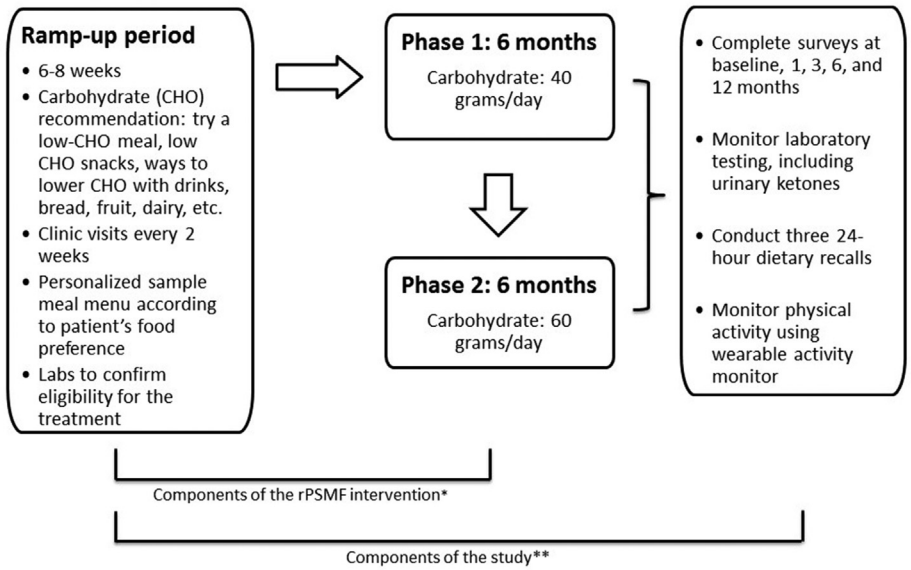

Fig. 1. Schematic representation of the rPSMF intervention and study protocol.
*: rPSMF intervention will be implemented per the clinic protocol.
**: The study is designed to investigate components of the rPSMF protocol, implementation and outcomes.

Table 1
Eligibility criteria for the rPSMF diet.

	Major Criteria	
	11-13 Age Group	14 + Age Group
Co-morbidity	Must have severe co-morbidity: Obstructive Sleep Apnea, Diabetes (type II), Fatty Liver, SCFE, Blount Disease, Pseudotumor Cerebri	Must have 1 severe co-morbidity ***OR*** 1 co-morbidity with sustained weight gain
Tanner Stage	Tanner Stage III,IV,V	Tanner Stage III,IV,V
BMI	Class 2 or 3[a]	Class 2 or 3[a]
	Minor Criteria for both age groups[b]	
Rapid Weight Gain [22]	• A weight increase of more than 5% prior to initiating the ramp-up period • Increase in BMI z-score of 0.5 standard deviation or more at any point during the treatment to account for age- and sex- appropriate growth	
Imminent Harm	• Determined by severity of co-morbidity as determined by sub-specialty service	
Adequate Social/ Psychological Capacity[c]	• Access to resources • Presence of a supportive caregiver • Without ODD or other psychological condition likely to impede success • Without significant feeding aversion	

ODD: oppositional defiant disorder.
[a] Class II obesity: a BMI ≥ 120% of the 95th percentile, or a BMI ≥35, whichever is lower; Class III obesity: a BMI ≥ 140% of the 95th percentile, or a BMI ≥40, whichever is lower.
[b] These criteria will be finalized during the 6–8 week ramp-up period.
[c] Relative or absolute contraindication dependent on clinical decision by the team following assessment.

reported with weight loss resulting from balanced-macronutrient diets [26,27]. In addition, the use of fatty acids as an energy source promotes catabolism of adipose tissue. Unlike with traditional VLCDs, individuals following a PSMF maintain normal levels of protein intake (i.e., protein is "spared") to protect against losses in lean body mass [18,28,29]. Weight loss can be as much as 1–3 kg per week in the intensive phase [23]. Other benefits include decreased blood glucose level and improved insulin resistance [30–32].

The rPSMF used for this pilot study has been revised to allow for higher amounts of daily calorie intake (1200–1800 kcal) when compared to the typical PSMF (less than 800 kcal) [33]. The rPSMF will be implemented over 12 months in three phases (see Table 2). Phase 1 is the most restrictive, allowing up to 40 g of carbohydrate per day for a total of six months. During Phase 2, daily carbohydrate intake will be increased to 60 g per day with the introduction of limited amounts of fruits and low-fat dairy into the diet. Finally, in Phase 3, the carbohydrate intake will be increased to a set-point of approximately 100 g per day. Daily fluid intake of 2–3 L will be encouraged throughout all three phases. To avoid nutritional deficiencies, daily multivitamin and calcium/vitamin D supplements will be prescribed throughout the intervention.

2.3.1. Intervention protocol and implementation

The rPSMF will be implemented within the framework of usual care in a tertiary PWMC. To improve the likelihood of adherence, children/adolescents and their parent/caregiver will undergo a pre-screening process during a 6–8 week ramp-up phase. This phase includes a 60-min visit every two weeks (or more frequently if desired by the participant or provider) where the physician and registered dietitian review the diet, expectations of the rPSMF protocol (including potential rate of weight loss and frequency of visits), and possible complications (e.g., cold intolerance, dizziness, constipation). Other team members (psychologist, physical therapist or social worker) will meet with the children and adolescents, as needed, during the ramp-up period. The registered dietitian will assess food preferences to guide meal planning, provide nutrition education on food groups, meal preparation, cooking, nutritional deficiencies, and outline nutritional expectations. The child/adolescent and their parent/caregiver will be expected to try components of the rPSMF to improve their self-efficacy with following the rPSMF, work on targeted problem solving and plan for potential contingencies such as eating out, peer and family member support or disapproval, and adjustments to food choices within the family. For example, an initial goal may be to try rPSMF acceptable snacks or a single meal per day, create appropriate grocery lists, or increase the variety of vegetables eaten.

The medical provider will obtain lab results to evaluate for contraindications for the rPSMF and to test for the presence of urinary ketones, provide education on the rPSMF and treatment protocol,

Table 2
Description of components of the rPSMF.

	Phase 1	Phase 2	Phase 3
Duration	6 months	6 months	From 12 months onward
Energy (kcal/day)	1200–1600	1200–1600	1400–1800
Carbohydrates	40 g/day	60 g/day	Gradually increase to 100 g/day
Protein	1.5–2 g/kg ideal body weight[a]	1.5–2 g/kg ideal body weight[a]	1.5–2 g/kg ideal body weight[a]
Fat	[b]Unrestricted	[b]Unrestricted	30–35% of caloric intake
Supplements	Multivitamin and calcium	Multivitamin and calcium	Multivitamin and calcium
Fluid	70-100 fl. Oz/day	70-100 fl. Oz/day	64 fl. Oz/day

[a] Ideal body weight: For women: 100 lb for the first 5 ft + 5 lb for each additional inch; For men: 106 lb for the first 5 ft + 6 lb for each additional inch.
[b] Unrestricted means no specific amount of fat is recommended, however, we recommend heart healthy food choices.

Table 3
Laboratory tests monitored throughout the study.

Time	Laboratory tests
Baseline[a]	Lipid Profile, LFTs, FBS, Hgb A1C, BUN, Cr, vitamin profile (Vitamin B1, B6, and B12, Vitamin D 25-OH, Folate), iron studies, uric acid, TSH, urinalysis for ketones[b]
1 Month	LFTs, calcium, lipid profile, Hgb A1C
3 Months	LFTs, lipid profile, Hgb A1C
6 Months	LFTs, calcium, lipid profile, FBS, Hgb A1C, vitamin profile.
12 Months	LFTs, calcium, lipid profile, FBS, Hgb A1C, vitamin profile

LFTs: Liver Function Tests; FBS: Fasting Blood Sugar; Hgb A1C: Hemoglobin A1C; BUN: Blood urea nitrogen; Cr: Serum creatinine; TSH: Thyroid stimulating hormone.
[a] If lipid, FBS, Hgb A1c, BUN, Cr have been collected within 3 months of the initiation of rPSMF, these tests will not be repeated at baseline.
[b] In addition to the lab-based urinalysis, home urinalysis using Ketostix was recommended daily for the first month.

counsel parents/caregivers to strengthen parenting skills to support their child, help build self-efficacy within the family and problem solve any challenges with the family and team. Laboratory tests will be conducted during the ramp-up period (if not completed within the prior 3 months), at 1 month, 3 months, 6 months, 9 months (only if clinically indicated), and 12 months (see Table 3). The baseline study visit will occur following completion of the 6–8 week ramp-up phase.

During the intervention, the child/adolescent and their parent/caregiver will see the multidisciplinary team (medical provider, dietitian, and physical therapist) at each visit. The psychologist and/or social worker will meet the child and family as needed. The family and dietitian will develop meal plans for breakfast, lunch, dinner, and two snacks based on their food preferences. Recipes will be provided and a shopping list will be developed to match the meal plans. Table 4 provides an example of a 24-h meal plan.

2.3.2. Monitoring safety of the rPSMF

Given that ketosis is expected with marked limitation of carbohydrates, selected laboratory tests (electrolytes, uric acid, folate, iron studies, vitamins B1 (cyanocobalamin), B6 (pyridoxine), B12 (thiamine), 25-OH Vitamin D, and urinary ketones) will be used to monitor the safety and adverse effects of the diet. A laboratory-based urinalysis test to check for ketones will be obtained at baseline, two weeks, and one month on the rPSMF diet. The first two weeks of the rPSMF can be challenging for the families with maintaining appropriate carbohydrate restriction and adequate hydration. Participants will be taught how to conduct daily ketone testing on their urine at home for the first month to check for ketosis. Given the level of carbohydrate restriction, anticipated ketone level is “mild” or “moderate”. If “large” ketones are present, increased hydration is recommended. If “large” ketones are present for three consecutive days despite adequate hydration, the dietitian will adjust the diet temporarily by adding a small portion of fruit, yogurt or milk for 24–48 h. The expectation is that there will be no ketones on subsequent urinary ketone testing. The diet will then be reintroduced at 40 g of carbohydrates a day.

2.4. Adjunct intervention: physical activity

Each child or adolescent will receive an activity monitor (Fitbit Charge) at their baseline study visit to encourage physical activity (Fig. 1). After one week of monitoring daily step count, the physical therapist will decide on the participant's initial step goal. Step goals will be set in increments of 2500 steps, ranging from 2500 to 12,500, based on the overall clinical assessment and the participant's baseline step count. The step goals will be set and increased at increments of 2500 steps if a participant meets their step goals for 5 consecutive days. For example, if the participant's average daily step count is 2600 at baseline, the physical therapist would assign an initial goal of 5000 steps. If the participant achieves 5000 steps or greater for 5 consecutive days, the goal will be increased to 7500 steps. The participant's average daily step count will be reviewed by the physical therapist at each clinic visit. A 3-min step test will also be performed at baseline, 3, 6, and 12 months to measure improvement in aerobic fitness. Participants will be instructed to step forward onto an 8-inch step as many times as possible within 3 min. Total number of steps achieved and pre-and post-test heart rate will be recorded.

Table 4
An example of a 24-hr 40 g carbohydrate rPSMF meal plan.

Meal/Snack	Foods Consumed	Grams of Carbs
Breakfast	3 slices of turkey bacon with 2 scrambled eggs and sprinkle of low-fat cheese, and water (or sugar-free drink alternative)	0
Lunch	½ can chicken (in water) with 2T of lite mayo, 2 hard-boiled eggs, 2 lettuce leafs, light string cheese, sugar-free gelatin snack, and water (or sugar-free drink alternative)	4
Snack	6oz low-fat low carbohydrate yogurt[a] with 1/2c fresh strawberries	10
Dinner	Lemon chicken with ½ c Green beans with side salad (1 cup romaine lettuce, 3 cherry tomatoes, 1/2c cucumber slices, 2 baby carrots) and 2T light ranch dressing with water (or sugar-free drink alternative)	21
Snack	pre-portioned high protein snack package[b]	3
Totals:		38

[a] Low-fat, low carbohydrate yogurt has 4 g carbohydrates, 9 g of protein, and 60 calories.
[b] Pre-portioned high protein snack package contains a meat, nut, and cheese and has 3–5 g of carbohydrates, 12–13 g of protein, and 180–200 calories.

2.5. Data collection and analysis plan

2.5.1. Acceptability of the rPSMF

To assess acceptability, we hypothesize that a) more than 50% of participants will demonstrate adherence to the rPSMF at all measurement time points; b) participants and parents will report high satisfaction with the intervention; and c) participants will attend at least 75% of their scheduled clinic visits. In addition, close and open-ended questions on participants' and parents' perspectives of: 1) self-efficacy with the rPSMF diet (choosing low carbohydrate foods, locating the carbohydrate content on food labels, following meal plans provided by dietitians, checking urine for ketones); 2) satisfaction with the rPSMF and weight change; and 3) difficulty with the rPSMF diet will be included on the surveys. Adherence to the dietary intervention will be measured via lab-based urinalysis studies for ketones (at week 2) and an in-home urinalysis for ketones using Ketostix during the first month. The presence of ketones indicates that carbohydrate intake levels are adequately low. Three unannounced 24-h dietary recalls using the validated multiple pass approach at 1, 4, and 7 months will be conducted by a trained research assistant via telephone [34]. The United States Department of Agriculture (USDA) 5-step Automated Multiple Pass Method (AMPM) will be used due to its improved the validity of the 24-h recalls. In addition, the validity of conducting 24-h recalls by phone is comparable to doing recalls in person [35]. Caloric, protein, and carbohydrate intake will be assessed using the Nutrition Data System for Research software version 2016, developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN. Adherence to physical activity recommendations will be assessed using a Fitbit pedometer/accelerometer.

Participation rate will be calculated as number of visits attended divided by number of clinic visits expected multiplied 100%, at 3, 6, and 12 months. Intervention completion is defined as attending 75% of the scheduled clinic visits. Participants who discontinue clinic visits or use of the rPSMF but are still enrolled in the study will be contacted to complete study surveys. Finally, medical providers and registered dietitians involved in delivering the rPSMF in the clinic will be invited to participate in a one-time focus group to explore their perceptions about: 1) the level of provider confidence in implementing the rPSMF diet; 2) factors that influence the clinical decision to introduce the rPSMF to potential participants; 3) factors that influence adherence or non-adherence to the rPSMF; and 4) opportunities to improve the protocol and delivery of the rPSMF in a tertiary care PWMC.

2.5.2. Anthropometric, laboratory and quality of life outcomes

We hypothesize that participants will demonstrate a statistically significant decrease in BMI z-score at 6 months on the rPSMF. We will also examine changes in: a) weight, BMI, and percent of the 95th age and sex-specific BMI percentile; b) metabolic measures (lipid profile, glycosylated hemoglobin (Hgb A1c), and liver function tests) at 1, 6 and 12 months; and c) pediatric quality of life at 1, 6, and 12 months [21]. Participant weight will be measured to the nearest 0.1 kg using a digital platform scale and height will be measured to the nearest 0.1 cm using a laser wall stadiometer at each visit. These measurements will be used to calculate BMI, age and sex-specific BMI percentile, and BMI z-score [36,37]. BMI may not be a reliable measure of adiposity in certain populations, e.g., very muscular individuals; however it is reproducible and easy to obtain especially in a clinical setting. Parent-reported height and weight at baseline will be used to calculate parental BMI, categorized into normal/healthy weight (BMI 18.5 to 24.9), overweight (BMI 25 to 29.9), Class 1 obesity (BMI 30.0 to 34.9), Class 2 obesity (35.0–39.9), or Class 3 obesity (BMI ≥ 40). To assess changes in cardiometabolic outcomes, markers of diabetic risk (blood glucose, glycosylated hemoglobin (Hgb A1c), non-alcoholic fatty liver disease (alanine transaminase), and dyslipidemia (total cholesterol, triglycerides, low density lipoprotein and high density lipoprotein) will be evaluated at baseline, 6, and 12 months. Change in laboratory values, including studies obtained to monitor the safety of the rPSMF as part of the clinical care, will be tracked across the study. Participants and caregivers/parents will complete questions adapted from the National Health and Nutrition Examination Survey [38] on family sociodemographic factors (e.g., age, race, ethnicity, family composition, income, maternal education) and family history of cardio-metabolic disorders (i.e., hypertension, type 2 diabetes), and questions on food insecurity via the USDA Household Food Security Scale [39]. Quality of life will be assessed using the validated Pediatric Quality of Life (PedsQL) questionnaire for both child and parent [21]. The PedsQL, which has four subscales that assess physical, social, emotional and school-related quality of life, is a standard evaluation tool used as part of their clinical care.

2.5.3. Analytic plan

Data from the surveys will be analyzed using descriptive statistics (mean, median, standard deviation, frequencies) and general linear models if appropriate. Paired t-tests or the appropriate non-parametric equivalent will be used to compare baseline anthropometric, laboratory, and quality of life measures to each of the follow-up time points. We will also examine the proportion of participants who shift from severe obesity to moderate obesity following the intervention. Power estimations were not calculated as this is a pilot study. Effect size estimates obtained from the study will be used to determine sample size requirements for a subsequent randomized controlled trial.

A constant comparative approach will be used for analysis of the open-ended survey questions and focus group. The focus group transcript will be imported into a single NVivo® database. Two independent raters will thematically code the focus group transcription using the software. Inter-coder reliability will be assessed. Differences in coding will be discussed and resolved by the research team, through the use of verification strategies such as triangulation. Data will be analyzed for patterns and themes to discover the categories that are most salient.

3. Discussion

This pilot study will evaluate the acceptability and effectiveness of a specialized low carbohydrate diet implemented in a tertiary care PWMC as a treatment option for children and adolescents with severe obesity and related comorbidities. The rPSMF offers more structure than typical dietary recommendations by dictating food choices and exactly how many grams of carbohydrate a patient is allotted each day. This may minimize the need for food-related decision making, which is a benefit for families that prefer more structured dietary guidance. The rPSMF also offers an intermediate option for patients and families that desire more intensive non-surgical treatment options or can be used in preparation for bariatric surgery when significant pre-operative weight loss is needed [16].

We expect this pilot study will contribute to the gap in research on specialized diets for children and adolescents with severe obesity and who are seeking structured weight management programs. More importantly, the study is structured more as a pragmatic trial as the rPSMF is provided as part of clinical care in the PWMC. Thus the results of the pilot will most likely mirror what is to be expected in real-life scenarios rather than in a randomized controlled trial. Findings from studies with adult participants suggest that when an energy deficit is achieved, there is equivalence in effectiveness with different dietary approaches for treating obesity regardless of whether fat or carbohydrates are restricted [40–42]. However, there may be a subset of children and adolescents with severe obesity for whom the rPSMF diet would be the better option than fat restricted diet.

This study will provide preliminary data for a multicenter randomized controlled trial, which will help us to better delineate who is likely to benefit from the rPSMF diet and what factors can improve or hinder adherence and weight loss. Furthermore, the qualitative aspects of the study will be invaluable in understanding the adolescent,

caregiver and healthcare providers' perspectives on implementing the diet. Collectively, the results will guide additional changes and standardization for the rPSMF protocol and implementation within pediatric weight management clinics.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2019.100388.

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