


# The Protein-Sparing Modified Fast Diet: An Effective and Safe Approach to Induce Rapid Weight Loss in Severely Obese Adolescents

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## Abstract

**Objectives:** The protein-sparing modified fast (PSMF) is a rigorous way of rapidly losing a large amount of weight. Although adult studies have shown the PSMF to be effective, data in adolescents are lacking. The aim of this study was to determine the efficacy and safety of the PSMF in severely obese adolescents. **Methods:** 12 subjects who were evaluated in the Obesity Management Program at the Cleveland Clinic from 2011 to 2014 were included. The subjects were initiated on the PSMF after failing other conventional methods of weight loss. Once the goal weight was achieved, subjects were transitioned to the refeeding phase for weight maintenance. **Results:** Follow-up was scheduled at 3-month (11 patients) and 6-month (6 patients) intervals. At the 6-month follow-up visit, the average weight loss was 11.19 kg (95% confidence interval = -5.4, -27.8, P = .028), with average of 9.8% from baseline. Fifty percent of subjects had >5% weight loss and 20% had >10% weight loss. Four patients were lost to the follow-up (40%). An improvement was noted in total cholesterol and high-density lipoprotein. Due to a small sample size these results were not statistically significant. Side effects reported by subjects were mild dehydration due to nausea (2 patients), decreased energy (1 patient), and transient labile mood (1 patient). No life-threatening side effects were reported. **Conclusion:** Our results show that the PSMF diet can be used as an effective and safe method in the outpatient setting for rapid weight loss in adolescents with severe obesity.

## Keywords

protein-sparing modified fast, weight loss, safety, severely obese adolescents

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## Introduction

The epidemic of childhood and adolescent obesity remains on the rise. According to the Centers for Disease Control and Prevention, over the past 30 years childhood obesity in adolescents has quadrupled.<sup>1</sup> Obese adolescents suffer from both immediate and long-term adverse effects on their health including increased risk of cardiovascular disease, prediabetes, stroke, hypertension, and cancer. Weight loss can play a pivotal role in preventing morbidity and mortality related to obesity.

Morbidly obese people who have tried unsuccessfully to lose weight by other means can lose weight rapidly by following the protein-sparing modified fast (PSMF), which is a form of controlled starvation that provides a rigorous way of rapidly losing a large amount of body weight.<sup>1–6</sup>

The PSMF has been studied extensively in the adult population and has proven to be a safe method for rapid

weight loss.<sup>2–4</sup> It is a form of very low calorie diet that was first introduced in 1970s but over the years has undergone several modifications. Several studies have shown that in adults with moderate or more severe obesity, PSMF provided a safe opportunity to lose a large fraction of their excess weight and maintain long-term weight reduction.<sup>2–4</sup> In one study over a 6-week period, 15 obese patients were found to have lost 31.8 lb (14.4 kg) of body fat on average, while maintaining lean body mass.<sup>7</sup> Although adult studies have shown the PSMF to be an effective method for weight loss, data in adolescents are lacking. The aim

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**Table 1.** The Protein-Sparing Modified Fast Program at Cleveland Clinic.**At baseline and ongoing**

Baseline assessment (history, physical examination, electrocardiography) by physician or nurse practitioner and dietitian, with continued follow-up  
 Dietitian visits every 2 weeks for first month and monthly thereafter physician or nurse practitioner visits every 6 to 8 weeks  
 Laboratory tests at baseline, every 2 weeks for first month, and monthly thereafter  
 Comprehensive metabolic panel—uric acid  
 Behavior modification  
 Exercise

**Intensive phase (up to 6 months) per day**

1.5 g protein/kg ideal body weight (typically a total of 12-17 oz in the form of lean meat, poultry, fish, seafood, eggs, low-fat cheese, tofu)  
 <20 g carbohydrate (2 servings of low-starch vegetables, unlimited lettuce salad)  
 Trace carbohydrates from other foods and shakes  
 Restriction of fats not found in protein sources (no butter, margarine, oils, nuts, seeds, or dips; protein sources should contain <3 g fat per ounce)  
 Required supplements—multivitamin/mineral tablet; potassium 16-20 mEq; calcium 1000-1200 mg; magnesium 400-500 mg; sodium 1500-2000 mg  
 At least 64 oz of fluid

**Refeeding phase (6-8 weeks)**

Slowly reintroduce complex carbohydrates and fats; reduce protein  
 Month 1: up to 45 g carbohydrate  
 Month 2: up to 90 g carbohydrate  
 Low-glycemic, high-fiber cereals, fruits, vegetables  
 Low-fat foods  
 Daily protein reduced by 1-2 oz each month  
 Stop potassium and magnesium supplements after week 2

of this study is to determine the efficacy and safety of the PSMF in severely obese adolescents presenting to our outpatient obesity management program after 6 months of the PSMF.

## Materials and Methods

We conducted a retrospective chart review of all subjects started on a PSMF who were seen in our multidisciplinary weight-management program at Cleveland Clinic Children's hospital.

Eligibility criteria included adolescents older than 12 years of age who reached puberty (Tanner stage V) with a body mass index (BMI) of at least 27 kg/m<sup>2</sup> and had failed conventional low-calorie dietary approaches to weight loss. They were then offered the PSMF option.

The primary outcome was weight loss achieved at the end of 6 months. Secondary outcomes included improvement in dyslipidemia (low-density lipoprotein, high-density lipoprotein, and non-high-density lipoprotein cholesterol, and triglyceride levels), glycemic control, and blood pressure. The outcome of the PSMF was examined utilizing anthropometric data, laboratory values, dietary compliance, and screening for side effects at

enrolment and at 3-month intervals throughout the course of the study.

Quantitative data (eg, demographic and all other dichotomous data) were analyzed using descriptive statistics and frequency analysis and Wilcoxon Signed Rank tests for data using SPSS.

### PSMF Description

The PSMF requires a multidisciplinary approach and it incorporates medical, nutritional, and behavioral components. It consists of elimination of all carbohydrates and added fats in the diet, which in turn induces ketosis. Intake of food high in proteins ensures that the body does not go into a catabolic state (Table 1). Both ketosis and increase protein intake are known to aid in appetite suppression.<sup>8</sup> Nutrition is obtained from lean meat, poultry, and seafood, hence the term *modified fast*. On average this diet provides around 800 cal/day utilizing 1.2 to 1.5 g protein/kg/day. The diet is not nutritionally complete. To make up for deficiencies, patients also take additional supplements.<sup>5</sup>

Patients enrolled in our PSMF diet program were scheduled to meet the registered dietitians every other week in first month and then monthly thereafter. They

**Table 2.** Baseline Characteristics and Descriptive Statistics.

	N	Range	Minimum	Maximum	Mean	Standard Deviation
Baseline characteristics						
Age	12	5	13	18	16.17	1.337
Baseline weight	12	82.40	75.60	158.00	115.0667	27.52091
Baseline BMI	12	34.80	28.01	62.81	41.7475	9.79409
Descriptive statistics						
Age	6	3	15	18	16.67	1.033
Baseline weight	6	62.40	81.50	143.90	111.5667	26.87026
Baseline BMI	6	18.01	31.90	49.91	39.1617	6.71095

Abbreviation: BMI, body mass index.

**Table 3.** Weight Loss for 11 Patients at 3-Month Follow-up.

	No. of Patients	Mean Weight Loss (%)	SD	95% CI	Mean Weight Loss (kg)	SD	P Value	95% CI
3 months	11	7.4%	6.7	-6.0, 20.8	8.2	6.9	.010	-5.6, 22.0

Abbreviations: SD, standard deviation; CI, confidence interval.

were provided with extensive resources including an extensive list of protein choices, recipes, grocery shopping lists, and dining out options. Concurrently, behavioral modification techniques were also extensively taught on these visits to allow the subjects to learn adopting and maintaining a healthier lifestyle. Patients also had scheduled visits with physicians every 6 to 8 weeks for close monitoring of vital signs, laboratory values, and side effects. Patients were also equipped with keto-stix, stool softeners, and supplements including potassium, calcium, multivitamins, magnesium, and sodium. All patients were strictly instructed to consume a minimum of 64 ounces of fluids daily (sugarless) to help eliminate ketones and prevent renal injury. During this fast subjects are at risk for electrolyte abnormalities, and accordingly our patients were closely monitored using a renal function panel, magnesium, and phosphorus levels. The laboratory values are typically obtained every other week during the first month and then subsequently monthly. When goal weight was achieved, the next phase of this program involves a slow, reintroduction of carbohydrates and fats (Refeeding Phase) over a period of 6 to 8 weeks. Food items included in the refeeding phase includes complex carbohydrates, foods rich in fiber including fruits and vegetables, as well as fats.

Exercises were encouraged throughout the program to help establish a healthy lifestyle.

## Results

A total of 12 subjects were included in the analysis. The average age was  $16.7 \pm 2$  years, 85% of the subjects

were females, 90% of the subjects were Caucasian, and 10% were Hispanic (Table 2). Subjects had a baseline mean weight of 115 kg (95% confidence interval [CL] = 87.5, 142.5). Sequential data were available for 11 patients that were followed up at 3 months and 6 patients at 6 months. Remaining patients did not return for follow-up owing to moving away, transportation difficulty, or refusal to participate further.

At 3 months from initiation of the PSMF, 11 patients (1 lost to follow-up) had an average weight loss of 8.2 kg (95% CI = -5.6, 22.0;  $P = .010$ ) from baseline visit (Table 3). The mean percentage of weight loss from the initial visit was 7.4% (95% CI = -6.0%, 20.8%). A total of 7 subjects had >5% weight loss, out of those 4 patients had >10% weight loss. Only one patient gained weight (5.5 kg).

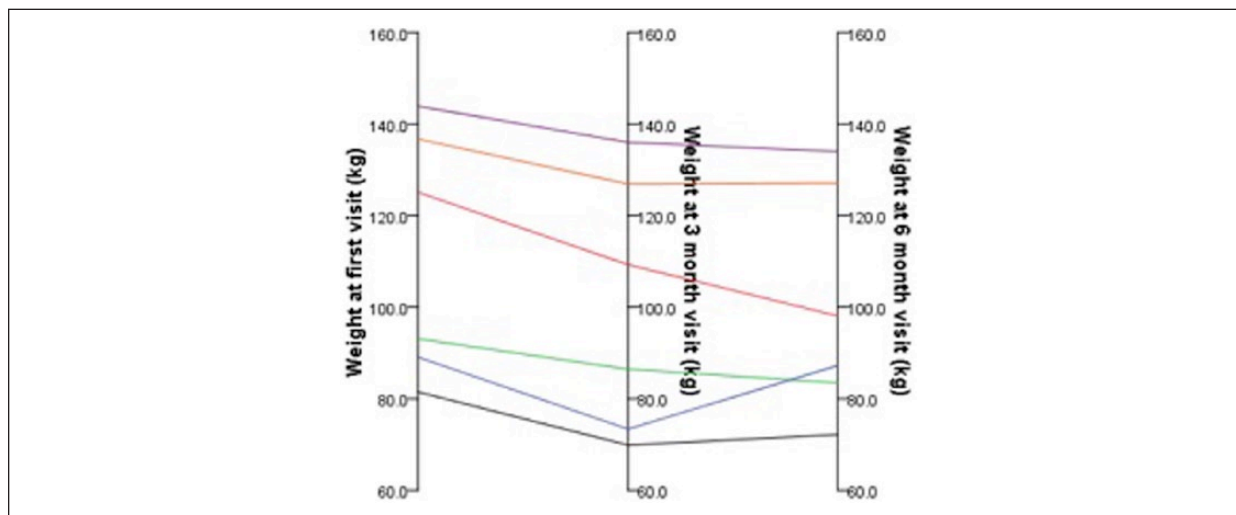
When evaluating the 6 subjects who followed up throughout the study, we observed a mean weight loss of 11.23 kg (95% CI = 3.6, 18.8) at the 3-month follow up visit, which is 10.6% (95% CI = 1.0, 20.2) from baseline. Subsequently at the 6-month follow-up visit the mean weight loss was 11.19 kg (95% CI = -5.4, 27.8), which is 9.8% (95% CI = -3.0, 22.6) from baseline (Table 4).

When looking at the weight loss trend, all 6 patients continued to lose weight at the 3-month follow-up visit. At the 6-month interval only 1 out of the 6 subjects gained more than their baseline weight due to noncompliance during the refeeding phase (Figure 1). In terms of BMI there was a mean decrease of 4.1 at the 6-month interval (Figure 2). Side effects reported by subjects were mild dehydration due to nausea (2 patients), decreased

**Table 4.** Weight Loss for 6 Patients at 6-Month Interval.

	No. of Patients	Average Weight Loss (%)	SD	95% CI	Mean Weight Loss (kg)	SD	P Value	95% CI
3 months	6	10.6%	4.8	1.0, 20.2	11.23	3.8	.028	3.6, 18.8
6 months	6	9.8%	6.4	-3.0, 22.6	11.19	8.3	.028	-5.4, 27.8

Abbreviations: SD, standard deviation; CI, confidence interval.

**Figure 1.** Trend in weight loss for 6 patients who were followed at 3- and 6-month intervals.

energy (1 patient), and transient labile mood (1 patient). No life-threatening side effects were reported.

## Discussion

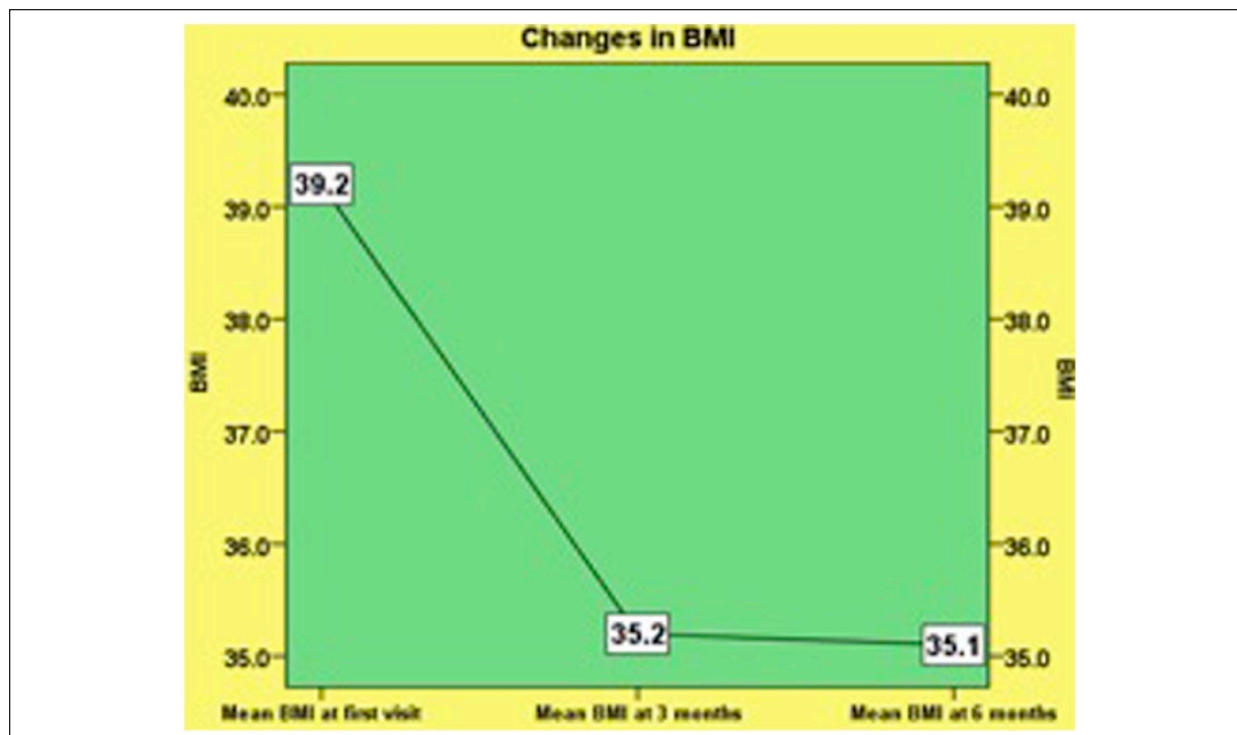
Rapid rise in obesity and obesity-related comorbidities over the last decade have increased interest in more alternative approaches to weight loss, which offer rapid results compared to more conventional methods particularly in severely obese individuals. PSMF diet is one such example of a very low calorie diet that ensures a substantial decrease in weight with one adult study reporting up to 1 to 3 kg decrease in weight/week in its intensive phase<sup>9,10</sup> with additional benefits including lack of hunger, improved energy, and improved blood glucose and blood pressure.<sup>11</sup> Several adult studies have also now established a good safety profile of this diet but the data persistently lack for adolescent age group.

The major finding of this study was that the PSMF appears to be an effective method of producing weight loss in adolescents and maintenance over a 6-month period in a medically supervised clinic-based intervention. Looking at the trend of weight loss in our study, it appears that even though all the patients had weight loss from the baseline visit, 3/6 patients started regaining the

weight after 3 months (Figure 1). Only one patient gained 5.5 kg, most likely secondary to poor compliance since the patient was lost to follow-up after 3 months.

In adults, studies evaluating the PSMF had similar results. In one of the first PSMF studies done by Palgi et al,<sup>12</sup> evaluating 668 patients with an average baseline weight of 98 kg, the mean weight loss was 21 kg after the intensive phase and 19 kg by the end of the refeeding phase. In a more recent study, Li et al<sup>13</sup> found near-identical weight change between diabetes mellitus versus non-diabetes mellitus patients, where the mean total weight loss for all patients was  $12.0 \pm 5.6$  kg at 3 months and  $15.6 \pm 8.4$  kg at 6 months. Adult studies also reported significant downward trend in serum triglycerides, total cholesterol, low-density lipoprotein cholesterol and an upward trends in high-density lipoprotein cholesterol levels from baseline to 6 months.<sup>9,12-14</sup> Our study showed a similar trend for serum lipids. However, none of the differences were statistically significant by Wilcoxon test, possibly because the available sample size was very small for all these variables.

Koeck et al<sup>6</sup> evaluated the PSMF in 3 adolescents with extreme obesity ( $BMI > 60 \text{ kg/m}^2$ ) prior to bariatric surgery. As a result Patient 1 lost 16 kg, Patient 2 lost 33 kg, and Patient 3 lost 57 kg through the preoperative



**Figure 2.** The graph represent an overall downward trend in BMI. It was noted that between the 3-month follow-up visit and the 6-month follow-up visit the BMI for all 6 subjects increased but not back to baseline prior to the start of the PSMF.

inpatient weight management program. These subjects were then able to undergo surgery without complications and this maximized the weight loss benefits with regard to surgical and anesthetic safety and aided in minimizing weight gain. However, the study was conducted in the inpatient setting only, which adds significant cost and inconveniences to participants, whereas our present investigation was conducted in a real-world outpatient setting—the patient’s home, giving more flexibility and a chance for maintaining long-term weight reduction.

There were no significant side effects in our study population when compared to prior studies. In addition, we incorporated a strict behavioral modification component along with a rigorous exercise regimen. Family support and participation was strongly encouraged and was instrumental in the success of these studies.

## Summary

Our results show that the PSMF diet can be used as an effective and safe method in outpatient settings for rapid weight loss in adolescents with severe obesity who have failed more conventional methods or appear frustrated due to slow rate of outcomes. While the initial weight loss was significant with few side effects, further continuation of weight loss and long-term compliance rate need to be determined. The limitations of our study

include small sample size, patients lost to follow-up, and lack of a control group. In order to validate the results of our study we need a larger study population. In addition, it will be important to assess long-term weight maintenance in obese adolescents who effectively lose weight in this multidisciplinary program. Additional factors including total cost of the dietary plans, convenience of office visits, and perception toward frequent blood work that could affect patient compliance should be assessed.

## Study Highlights

### What Is Current Knowledge

- Adult studies have shown that, in adults with moderate or more severe obesity, PSMF provided a safe opportunity to lose a large fraction of their excess weight and maintain long-term weight reduction.
- The efficacy and safety of PSMF in severely obese adolescents is unknown.

### What Is New Here

- PSMF diet can be used as an effective and safe method in outpatient settings for rapid weight loss in adolescents with severe obesity.

## Author Contributions

MB: Contributed to acquisition, analysis, or interpretation; drafted the manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

VS: Contributed to acquisition, analysis, or interpretation; critically revised the manuscript.

TH: Contributed to acquisition, analysis, or interpretation; critically revised the manuscript.

SL: Contributed to conception and design; contributed to acquisition, analysis, or interpretation; critically revised the manuscript.

NB: Contributed to acquisition, analysis, or interpretation; drafted the manuscript.

SM: Contributed to acquisition, analysis, or interpretation; drafted the manuscript; critically revised the manuscript.

NA: Contributed to conception and design; contributed to acquisition, analysis, or interpretation; critically revised the manuscript; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

## Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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