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Efficacy and Safety of a High Protein, Low Carbohydrate Diet for Weight Loss in Severely Obese Adolescents

Nancy F. Krebs, MD, MS, **Dexiang Gao, PhD**, **Jane Gralla, PhD**, **Juliet S. Collins, MD**, and **Susan L. Johnson, PhD**

Abstract

Objective—To evaluate the efficacy and safety of a carbohydrate restricted versus a low fat diet on weight loss, metabolic markers, body composition, and cardiac function tests in severely obese adolescents.

Study design—Subjects were randomized to one of two diets: a high protein, low carbohydrate (20 g/day) diet (HPLC) or low fat (30% of calories) (LF) regimen for 13 weeks; close monitoring was maintained to evaluate safety. After the intervention, no clinical contact was made until follow-up measurements were obtained at 24 and 36 weeks from baseline. The primary outcome was change in BMI-Z-score at 13, 24, and 36 weeks.

Results—Forty-six subjects (24 HPLC, 22 in LF) initiated and 33 subjects completed the intervention; follow-up data were available on approximately half of the subjects. Significant reduction in BMI-Z-score (BMI-Z) was achieved in both groups during intervention, and was significantly greater for the HPLC group (p=0.03). Both groups maintained significant BMI-Z reduction at follow-up; changes were not significantly different between groups. Loss of lean body mass was not spared in the HPLC group. No serious adverse effects were observed related to metabolic profiles, cardiac function, or subjective complaints.

Conclusions—The HPLC diet is a safe and effective option for medically supervised weight loss in severely obese adolescents.

Keywords

Obesity; obesity treatment; body composition; hyperlipidemia; insulin resistance; satiety

Effective treatment options for childhood and adolescent obesity are limited, particularly for those who are severely obese. The recent report on treatment of childhood obesity from an Expert Committee recommended a staged approach, with greater intensity interventions for those who are severely obese and for whom traditional lifestyle changes have not been successful (1). Identification of effective treatments for severely obese children is very important for at least two reasons. First, the increased prevalence of childhood obesity has been particularly striking in the severe range, i.e., those with BMI for age above the 99th percentile

Corresponding author: Nancy F. Krebs, MD, MS, University of Colorado Denver, 12700 East 19th Ave - Box C225, Aurora, CO 80045, Phone: 303-724-3260, Fax: 303-724-3206, nancy.krebs@ucdenver.edu.
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(2,3). Secondly, the risk of significant co-morbidities increases sharply for those in this category (4).

One approach that has been used in selected treatment centers is the so called “protein sparing modified fast,” which promotes high protein and very low carbohydrate intakes (5-7). The physiologic premise of this approach is that a high protein intake may spare the breakdown of lean body mass and nitrogen loss typically associated with weight loss. The associated ketosis is also purported to enhance satiety. Although this is especially relevant to the pediatric population where growth is normally still occurring, actual sparing of lean body mass has not been well documented. Both ketogenic and non-ketogenic diets have been shown to be effective in promoting weight loss in children (8,9). Concerns remain, however, about safety, including impact on growth and lipid profiles, and the metabolic effects of low carbohydrate intake and a state of prolonged ketosis (8,10,11).

We undertook this study to investigate, in severely obese adolescents, the effects of a high protein, low carbohydrate (HPLC) diet without caloric restriction compared to a calorie-controlled, low fat (LF) diet on weight loss, body composition, and biochemical markers of lipid metabolism and insulin resistance. Safety of the HPLC diet, and the associated ketosis, was also evaluated. We hypothesized that, compared with severely obese adolescents on the LF diet, those randomized to the HPLC would have significantly greater reductions in body mass index Z-scores (BMI-Z) and weight; greater improvements in metabolic abnormalities of lipid and carbohydrate metabolism; greater loss of body fat and less loss of lean body mass; and higher subjective satiety ratings.

Methods

We employed a 12 week randomized controlled study design that compared the impact of the HPLC diet versus a LF diet in producing weight loss in severely obese adolescents. Both groups were informally prescribed an exercise program that included at least 30 minutes of daily moderately vigorous physical activity. Subjects were admitted to the Pediatric Clinical Research Center (CRC) for baseline testing and initiation of the diet, followed at 2 week intervals in the out-patient CRC clinic, and readmitted for 2 days at week 13 for final assessments. Subjects were re-contacted at 24 and 36 weeks after enrollment, and selected follow-up measurements were obtained. Between the end of the intervention period and these visits, no contact was made with the subjects to approximate a typical time limited weight loss intervention.

The study protocol was approved by the Colorado Multiple Institutional Review Board (COMIRB) and the Pediatric CRC. All participants provided assent and their parents or guardians gave informed consent. A local Data Safety Monitoring Board established through the CRC reviewed study data and progress at quarterly intervals.

Severely overweight adolescents between the ages of 12 and 18 were recruited through referral to a weight management clinic at The Children's Hospital, through word of mouth, and through advertisements in local newspapers. Inclusion criteria included primary obesity and a body weight estimated to be ≥ 175% of ideal body weight. Ideal body weight was defined as weight at the 50th percentile for a subject's height age (age at which height is 50th percentile) or weight at 50th percentile BMI for age. Exclusion criteria included current diagnosis of Type II Diabetes Mellitus; gall bladder, liver or renal disorders; known eating disorders; severe hypercholesterolemia (total cholesterol >300 mg/dl); endocrine disorders such as hypothyroidism or polycystic ovary syndrome; pregnancy; genetic disorder, such as Prader-Willi syndrome; mental retardation; severe depression; or use of any chronic medication that

could impact appetite. Patients with poor family support that might have potentially precluded compliance with the study requirements were also excluded.

Subjects on the HPLC diet were instructed by the CRC bionutritionists to aim for a sustained very low carbohydrate intake (≤ 20 g/day) and for a concomitant high lean protein intake, which was estimated to provide 2.0-2.5 g protein/kg ideal body weight per day. Fat and energy intakes were not restricted; the only monitored restriction was carbohydrate intake. Subjects were instructed on appropriate food choices for the diet, and each subject was provided a diet education booklet, including a "food pyramid" tailored to the HPLC. Daily multivitamin-mineral and calcium supplements (500 mg/day elemental calcium) were recommended, as was a non-caloric fluid intake of ≥ 48 oz/day.

The low fat diet control group was instructed on a diet with a daily energy intake goal of 70% of resting energy expenditure estimated from the Harris-Benedict equation (12), and with less than or equal to 30% of calories from fat. The subjects received a diet education booklet, based on the USDA Food Guide Pyramid. Multivitamin-mineral supplement and fluid recommendations similar to those for the HPLC group were also provided.

Both groups were encouraged to have at least 30 minutes/day of vigorous physical activity. Handouts were provided with ideas to encourage physical activity and an activity log was maintained. Quantitative data on physical activity were not collected.

Height and weight measurements were obtained with a wall mounted stadiometer and a 500 lb capacity scale, respectively. Measurements and age were entered into *Epi Info*, (Epi Info Version 3.5.1, Centers for Disease Control and Prevention, Atlanta, GA, 2008), through which BMI percentiles and Z-scores for age and sex were calculated.

Three-day diet records were scheduled at random times throughout the intervention period for a given subject. The number of days of records actually obtained varied among subjects, ranging from a minimum of 3 and up to 14 days, with an average of 8.1 days. Nutrient analyses were calculated by CRC bionutritionists using the Nutrient Data Systems for Research (NDS-R, V4.05, Minneapolis, MN: University of Minnesota).

At the time of the completion of diet records, subjects also recorded subjective feelings of hunger and fullness nine times throughout the day: before and after meals, and between meals. A 10 cm visual analog scale, with 0 being "not at all hungry" and 10 being "extremely hungry," was used to rate hunger and satiety (13).

Body composition measurements were obtained at baseline and at the 13 week in-patient visit by dual energy X-ray absorptiometry (DEXA; Lunar DPX-IQ, Madison, Wisconsin) on those subjects less than or equal to 136 kg, the machine's maximum capacity. All DEXA studies were performed by the Radiology department at The Children's Hospital.

Biochemical tests included fasting lipid profile, 2-hr oral glucose tolerance test, and β-hydroxybutyrate, which were analyzed through the CRC core laboratories. The homeostasis model assessment of insulin resistance (HOMA-IR) (14) was calculated by dividing the product of the fasting insulin level (mU/mL) and glucose level (in mg/dL) by 402. The cut-off of 3.16 recommended for adolescents (15) was applied to interpretation of the HOMA-IR data.

Studies undertaken for safety and potential adverse effects included serum electrolytes, blood urea nitrogen, creatinine, serum calcium, phosphorus, and magnesium; liver function tests (alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, gamma-glutamyl transpeptidase; and urine pregnancy test (β-HGG) for the female subjects. All surveillance laboratory tests were performed by the clinical laboratory at The Children's Hospital. At

baseline, 6, and 13 weeks, an electrocardiogram (ECG) and a 24-hr Holter monitor were obtained and reviewed within 24 hr by a pediatric cardiologist at The Children's Hospital. Abdominal ultrasounds, performed by the Radiology department at The Children's Hospital, were obtained at baseline and 13 weeks.

A two-tailed, two-sample t-test with 0.05 Type I error was used to calculate sample size. Power calculations were based on an assumption that there would be a decrease of 6 kg in weight with the HPLC diet, and 1 kg with the LF diet. These assumptions were based upon the findings reported by Willi et al (5,6). With an expected standard deviation of 4.5 kg, a sample size of 14 would provide 80% power to detect a 5 kg difference in weight loss between the groups. It was planned to randomize 50 subjects to allow for an expected drop-out rate of 40% by the end of the follow-up period.

Study data were entered into a secure, password protected Access (Microsoft Office, 2003) database constructed by the CRC bioinformatics core. Statistical analyses included two-sample t-tests to assess differences between the two dietary groups in baseline characteristics, 13 weeks, and the changes from 13 weeks to baseline, and average daily dietary intakes for continuous variables. Due to approximately half the subjects not completing the study, for a variety of reasons, the assumption of data missing at random could not be made. T-tests were therefore used to analyze the data rather than repeated measures or a mixed model approach. A chi-square test or Fisher exact test, if necessary, was used to determine differences between the two groups in categorical variables. For the variables total cholesterol (TC), triglycerides, and fasting insulin, the p-values were based on the logarithmic scale of the original values.

Results

A total of 51 subjects were consented and randomized for the study. The majority of the subjects were Caucasian (26, 56%); 10 (22 %) were African American; 6 (13%) were Hispanic; and 4 (9%) were Asian. Five subjects (3 HPLC and 2 LF) dropped out before or during the initial in-patient stay; baseline data from these subjects were not included since they did not initiate the intervention. An additional 13 subjects (6 from HPLC, and 7 from LF groups) dropped out during the course of the 13 week intervention due to non-compliance with the demands of the study. A total of 24 subjects completed baseline studies and initiation of the HPLC diet, and 22 subjects likewise initiated the LF diet. Eighteen HPLC and 15 LF (75% and 68%, respectively) subjects completed the 13 week intervention. For the 24 and 36 week follow-up measurements, 13 (54%) and 11 (46%), respectively, were available from HPLC group, and 14 (64%) and 11 (50%), respectively, were available from LF group. We were unable to detect any significant differences in subject characteristics between those who dropped out and those who completed the study.

As shown in Table I, the subjects did not differ between groups in their weight and metabolic characteristics at baseline; mean and median BMI were above 35 for both groups. Dietary data were available during the intervention period for 83 and 86% of the HPLC and LF subjects, respectively (Table II). The data indicated imperfect compliance with the prescribed carbohydrate restriction, but the mean carbohydrate intake of the HPLC group was less than 40 g/day, an intake likely to maintain ketosis. The 13 week serum β-hydroxybutyrate concentrations support this: 2.28 ± 0.34 versus 1.0 ± 0.12, for the HPLC and LF groups, respectively ($p = 0.002$). The other macronutrient intakes reflected the anticipated differences in the two diet regimens, with the protein and fat intakes significantly higher in the HPLC group. Of note, the mean fat intake of the LF group was near the target of 30% or less of energy from fat.

Weight outcomes included both the change in BMI-Z over time and the absolute weight loss over time. The mean BMI-Z for the subjects in the HPLC group was significantly lower at 13 weeks (Table I), and the decrease was significantly greater than that for the LF group (p=0.03, Figure). Both groups maintained significant reductions in BMI-Z at the follow-up time points: -0.21±0.07 (p=0.01) and -0.14±0.04 (p=0.01) for HPLC (n=13) and LF (n=14), respectively at 24 weeks; and -0.22±0.09 (p=0.04) and -0.15±0.04 (p=0.002), for HPLC (n=11) and LF (n=11), respectively, at 36 weeks (Figure). Thirty percent of the subjects lost at least 10% of their baseline weight, and 24% lost between 5 and 10% of baseline weight; neither of these weight loss categories differed by group. By the 24 week follow-up point, the HPLC group weight loss compared with baseline (-6.31 kg) was still significant (p = 0.01), whereas that of the LF group (-1.41 kg) was no longer significantly different from baseline. At the 36 week follow-up point, although both groups' weight was lower than baseline, the difference was not significant for either group or between groups.

Body composition data from DEXA measurements at 13 weeks are shown in Table I. No significant differences between groups were present at either study initiation or completion of the intervention. Comparison of the mean loss in fat mass over the intervention yielded significant results for both groups, and there was a trend for greater fat loss in the HPLC group (p=0.08, data not shown). Contrary to the hypothesis, however, the HPLC group had a marginally significant mean loss of lean body mass (p = 0.05), whereas the LF group did not demonstrate a significant change; the difference between the 2 groups was also marginally significant (p=0.05). No significant changes in mean bone mineral density occurred over the intervention period.

The mean biochemical data did not differ significantly between the groups at 13 weeks (Table I); both groups, however, experienced improvements in several biomarkers. Both groups had significant reductions in TC and LDL cholesterol levels; modest HDL cholesterol reductions were significant for LF but not for the HPLC group. None of these cholesterol changes were significantly different between the groups. In contrast, the mean reduction in triglycerides was approximately 3-fold greater and strongly significant in the HPLC group (p = 0.0003), whereas there was only a marginal reduction for the LF group (p =0.10); comparison of the change in triglycerides between groups was also significant (p = 0.03).

Fasting glucose and two-hour glucose levels were not significantly different between groups after the intervention, nor was there a significant change for either group. The mean reduction in two-hour insulin concentration at 13 weeks was significant in the HPLC group (p=0.03) but showed only a trend for the LF group (p=0.07). The proportions of HOMA-IR scores >3.16 in both groups were reduced to approximately one-third of subjects at 13 weeks compared with greater than 50% of subjects at study initiation. No significant group differences were observed in HOMA-IR (Table I).

No differences between groups were observed in pre- or post-meal hunger, fullness or nausea. For example, pre-meal hunger was 5.4 ± 0.5 and 6.1 ± 0.4 for the HPLC and LF groups, respectively (p= 0.26). Similarly, post-meal “fullness” did not differ between groups: 7.1 ± 0.3 and 7.4 ± 0.3 for HPLC and LF groups, respectively (p=0.50). No significant correlations were found between energy, protein, fat or carbohydrate intakes and either the hunger or fullness scores.

With respect to the safety monitoring, linear growth did not differ between groups over the intervention period or at the 36 week follow-up visits. For the HPLC and LF groups, the mean increases in height at 13 weeks were 1.4 ± 0.4 cm and 1.2 ± 0.3 cm, respectively (p=0.71); at 36 weeks the means from baseline were 3.0 ± 0.9 cm and 2.6 ± 0.8 cm, respectively (p=0.72). Likewise, no adverse effects were observed for any of the biochemical indices, including

complete blood count, serum chemistries, liver function tests, blood urea nitrogen and creatinine. Readings of the EKG and Holter monitor data were also within normal limits and not different between the groups at baseline or at the 13 week follow-up. Two subjects, both in HPLC group, were noted to have "sludge" or gallstones on abdominal ultrasound at baseline; one subject in LF group had "sludge" noted at 13 week. Although several subjects (6 HPLC and 4 LF) were noted to have fatty liver on baseline ultrasound, no adverse changes were identified on ultrasound at the end of the intervention for either group. Reports of side effects were recorded at all follow-up visits during the intervention period. Subjective complaints of adverse effects were infrequent overall. Complaints of headache were registered by 9 subjects in the HPLC group, compared with 2 in the LF group ($p=0.04$); a total of 12 complaints of headache were recorded during the 13 week period. Non-specific side effects that were recorded but not different between groups included: low energy, muscle pain, abdominal pain, depression, nausea, dizziness, frequency of urination, dysuria, thirst, bad breath, dry mouth, insomnia, and loss of appetite.

Discussion

We report a large randomized intervention trial in severely obese adolescents, which compared the efficacy and safety of a high protein, low carbohydrate diet versus a low fat hypocaloric diet for weight loss. As has been seen in one other study in adolescents (5) and several studies in adults (16-20) we found a significantly greater short term decrease in BMI-Z and in weight loss with the HPLC diet. This study in adolescents included 6 month follow-up measurements for the two dietary interventions. We found persistence of significant reductions in BMI-Z for both groups at both 3 and 6 months after the end of the intervention, despite no intervening contact with study personnel. We compared changes in body composition associated with the two treatments, and did not observe a "sparing" of lean tissue loss in the HPLC group. Importantly, with prospective comprehensive monitoring, we also found no differences in adverse effects between the two arms.

The significantly greater decline in BMI-Z HPLC group during the intervention occurred despite similar reported energy intakes for the two diet groups. Limitations of dietary data notwithstanding, our findings are similar to those of several other investigations in which ad lib energy intakes with carbohydrate restriction to approximately 10% of energy were associated with greater weight loss despite similar or higher mean energy intakes (5,21,22). These and other observations have led to the suggestion that there is a "metabolic advantage" of carbohydrate restricted diets (16,23-25). Despite generally consistent findings of greater short-term weight loss with carbohydrate restricted diets (5,16-19), mechanisms to account for such a phenomenon have not been demonstrated, and this thus remains an area of controversy (10,26). One of the proposed "mechanisms" of the greater weight loss associated with low carbohydrate diets is that it results in greater satiety, even anorexia, and thus is associated with lower caloric intake (27). Our subjective hunger and satiety scores on the visual analog scales did not support this premise, but without measurements of putative biologic markers related to appetite and satiety, such as ghrelin, leptin, or cholecystokinin, more definitive conclusions are not possible.

The persistence of significant absolute weight loss at 24 weeks in our HPLC group but the convergence to non-significance by 36 weeks for both groups, is similar to observations in studies in adults in which long term support has not been implemented (18). Data from studies in both adults (10) and children (28) indicate better long-term maintenance of weight loss with continued support, especially for those who are severely obese (10), consistent with the concept of obesity as a chronic condition (26,29).

The measures of body composition indicated that the HPLC group lost significantly more fat than the LF group. Along with their greater absolute weight loss, however, they also lost significantly more lean body mass than the LF group, despite a significantly and substantially greater dietary protein intake. The literature is conflicting with respect to body composition changes in children on a so-called “protein sparing modified fast.” Studies that have relied on skinfold measurements have reported preservation of lean body mass with a high protein, very low calorie diet (30-32). In contrast to our protocol, several of these interventions had a structured exercise component, which may have affected the impact of weight loss on lean body mass (31,32). Studies in adults have reported an additive effect of exercise and protein in the preservation of lean body mass during weight loss (21,33). Our data suggest that HPLC diet alone cannot be accurately termed a “protein sparing” regimen. The absence of significant changes in bone mineral density over the intervention for either group is reassuring. An increase in urinary calcium excretion and a small decrease in bone mineral content were reported during 8 weeks of a carbohydrate restricted diet in adolescents, but these changes were reversed with liberalization of carbohydrates. The absence of a comparison control group and the very small sample size limits the generalizability of those findings (6).

Despite significantly different fat intakes, and without specific directions for types of fat choices, both groups had significant improvements (reductions) from baseline in total and LDL-cholesterol, suggesting that weight loss rather than macronutrient distribution may be the predominant beneficial factor. For the two lipid components most strongly associated with insulin resistance and metabolic syndrome, triglycerides and HDL-cholesterol, the profile after the intervention was more favorable in the HPLC group, with a significantly greater reduction in triglycerides, and non-significant decline in HDL-C. Although this study was not powered on changes in metabolic biomarkers, the findings are consistent with several reports showing significant beneficial effects of an HPLC type diet in adults and adolescents with metabolic syndrome or type 2 diabetes (16,17,34,35), and provide reassurance that the high fat intake of the HPLC diet is not associated with adverse metabolic profiles after a short-term intervention.

This study had a number of strengths, including the random assignment to treatment group, although blinding was not possible. The assessments were conducted by the CRC personnel, who were not directly involved in subject recruitment or administration of the study intervention. Similarly, the cardiac monitoring (ECG and Holter monitors) and radiologic tests (ultrasounds and DEXA) were performed and read by individuals completely unaware of participants' intervention assignments. The prospective monitoring of a broad range of potential subjective and objective adverse effects has not previously been reported for the HPLC diet. We also acknowledge limitations in our study, including especially the drop out rates which, although similar to those reported for other similar studies, may have influenced the outcomes. In particular, from baseline to 13 weeks, slightly more subjects dropped from the LF group, but by the 36 week follow-up point, both groups had lost about 50% of subjects. The exclusion of potential subjects whose family support systems were unlikely to be sufficient to meet the demands of a research study also is a limitation with possible implications for generalizability.

In summary, we found that the HPLC diet resulted in significantly greater reduction in BMI-Z (and trend for greater weight loss) compared with the LF diet over the 13 week intervention, and was found to be without serious adverse effects. Markers of cardiovascular risk and insulin resistance improved in both groups, with the HPLC having a more potent beneficial effect on markers of insulin resistance. We thus conclude that a high protein, carbohydrate restricted diet should be considered a safe and effective option for medically supervised treatment of severe obesity in adolescents. The fact that the BMI-Z for both groups was still significantly lower at 6 months follow-up compared with baseline, with no intervening contact, argues for on-going, perhaps less intensive, support to achieve further benefit. With the unprecedented prevalence of severe obesity and its co-morbidities in the pediatric population, the important

question is not whether one diet is better than the other, but rather which of several potential strategies is most likely to be effective for a given individual.

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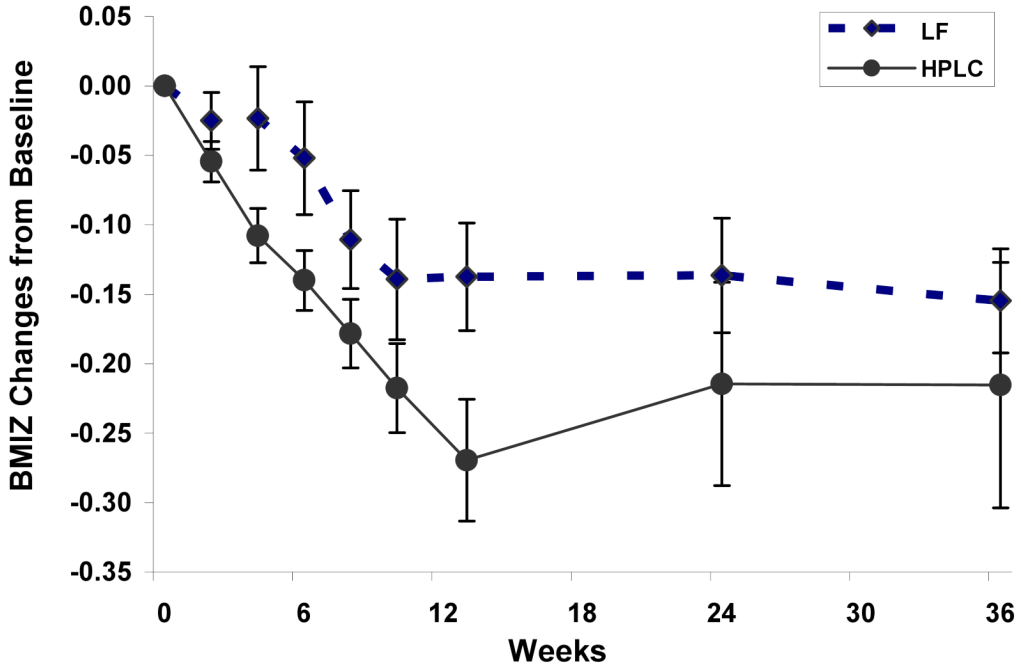
List of Abbreviations

BMI-Z	Body Mass Index Z-Score for age and sex
CRC	Clinical Research Center
COMIRB	Colorado Multiple Institutional Review Board
DEXA	Dual energy X-ray absorptiometry
ECG	Electrocardiogram
HOMA-IR	Homeostasis model assessment of insulin resistance
HPLC	High protein, low carbohydrate
LF	Low fat
TC	Total cholesterol



	2 wk	4 wk	6 wk	8 wk	10 wk	13 wk	24 wk	36 wk
LF	-	-	-	*	*	*	*	*
HPLC	*	*	*	*	*	*	*	*
Between groups	-	*	-	-	-	*	-	-

* Significant change with $p \leq 0.05$.

Figure.
Mean changes (± SEM) in BMI-Z for subjects who provided measurements at time progressive time points.

TABLE I

Characteristics of subjects at baseline and 13 weeks (mean ± SEM)

	HPLC (n=24 at baseline and n=18 at 13 weeks)*	LF (n=22 at baseline and n=15 at 13 weeks)*	p-value
Age	14.2 ± 0.4	13.7 ± 0.3	0.16
Sex	13 F, 11 M	12 F, 10 M	0.98
Weight (kg) at baseline	109.3 ± 4.7	107.1 ± 6.1	0.47
Median (range)	105.2 kg (72.2 – 158.8 kg)	95.4 (78 - 206.8 kg)	
Weight (kg) at 13 weeks	96.1 ±4.9	99.8 ± 7.8	0.68
BMI at baseline	38.0 ± 1.2	40.1 ± 1.8	0.70
Median (range)	36.7 (30.8-57.3)	37.1 (31.8-68.3)	
BMI at 13 weeks	33.9 ± 1.4	36.9 ± 2.4	0.26
BMI-Z at baseline	2.48 ± 0.06	2.51 ± 0.05	0.67
BMI-Z at 13 weeks	2.1 ±0.1	2.4 ± 0.1	0.04
Body Composition			
Lean mass (kg) at baseline	47.08 ± 1.69 (n=21)	44.09 ± 1.9 (n=19)	0.24
Lean mass (kg) at 13 weeks	45.84 ± 2.1 (n=16)	45.34 ± 2.1	0.87
Bone mineral density (g/cm^2) at baseline	1.22 ± 0.02 (n=21)	1.21 ± 0.02	0.82
Bone mineral density (g/cm^2) at 13 weeks	1.22 ± 0.02 (n=17)	1.22 ± 0.03	0.93
Lipid profile			
TC (mg/dL) (< 200 mg/dL) † at baseline	166.8 ± 7.7	161.3 ± 6.9	0.62‡
TC (mg/dL) at 13 weeks	154.1 ± 8.6	144.7 ± 7.0	0.46‡
LDL-cholesterol (mg/dL) (< 100 mg/dL) † at baseline	103.5 ± 6.8	97.4 ± 5.6	0.49
LDL-cholesterol (mg/dL) at 13 weeks	96.8 ± 7.6	85.5 ± 5.6	0.24
HDL-cholesterol (mg/dL) (38 - 68 mg/dL) † at baseline	39.2 ± 1.3	42.6 ± 2.3	0.20
HDL-cholesterol (mg/dL) at 13 weeks	38.4 ± 2.2	39.1 ± 2.5	0.83
Triglycerides (mg/dL) (35-134 mg/dL) † at baseline	125.8 ± 9.7	107.0 ± 12.7	0.08‡
Triglycerides (mg/dL) at 13 weeks	80.3 ± 6.5 (n=18)	96.5 ± 13.8	0.36‡
Insulin Resistance			
HOMA at baseline	4.3 ± 0.6	4.9 ± 0.7	0.54
HOMA at 13 weeks	2.8 ± 0.4	3.3 ± 0.4	0.34

*Number of subjects, unless indicated otherwise by number in parentheses in cells;

†Laboratory normal range for variable

‡P-value is based on the log scale of the original unit

Table II

Mean (± SEM) daily dietary intakes during the intervention, weeks 1-13

	HPLC (15)*	LF (13)*	p-value
Energy (kcal)	1285±80	1465 ± 90	0.15
Protein (g)	99.5± 6.0	75.5 ± 5.5	0.006
% of Energy	32 ± 1.0	21 ± 1.0	
Carbohydrate (g)	32 ± 4.5	188 ± 14.2	<.0001
% of Energy	11 ± 1.1	51 ± 2.0	
Fat (g)	84 ± 5.9	49 ± 4.0	<.0001
% of Energy	57 ± 1.2	29 ± 1.6	

*Number of subjects