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Role of Carbohydrate Modification in Weight Management among Obese Children: A Randomized Clinical Trial

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Abstract

Objective—To compare the effectiveness and safety of carbohydrate-modified diets with a standard portion-controlled diet among obese children.

Study design—Obese children (n=102) aged 7-12 years were randomly assigned to a 3-month intervention of low carbohydrate (LC), reduced glycemic load (RGL), or standard portion-controlled (PC) diet, along with weekly dietary counseling and bi-weekly group exercise. Anthropometry, dietary adherence, and clinical measures were evaluated at baseline, 3, 6 and 12 months. Analyses applied intention-to-treat longitudinal mixed models.

Results—Eighty-five children (83%) completed the 12-month assessment. Daily caloric intake decreased from baseline to all time points for all diet groups ($p < 0.0001$), although LC diet adherence was persistently lower ($p < 0.0002$). At 3 months BMI z-score was lower in all diet groups (LC: -0.27 ± 0.04 ; RGL: -0.20 ± 0.04 ; PC: -0.21 ± 0.04 ; $p < 0.0001$) and maintained at 6 months, with similar results for waist circumference (WC) and percent body fat (%BF). At 12

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months, participants in all diet groups had lower BMI z-scores than at baseline (LC: -0.21 ± 0.04 ; RGL: -0.28 ± 0.04 ; PC: -0.31 ± 0.04 ; $p < 0.0001$), and lower %BF, but no reductions in WC were maintained. All diets demonstrated some improved clinical measures.

Conclusions—Diets with modified carbohydrate intake were as effective as a PC diet for weight management in obese children. However, lower adherence to the LC diet suggests this regimen is more difficult for children to follow, particularly in the long-term.

Keywords

childhood obesity; low-carbohydrate diet; reduced glycemic load diet

The prevalence of pediatric obesity has increased more than three-fold the past four decades.¹ In addition, there has been a concurrent rise in obesity-related health complications, such as hypertension, hyperlipidemia, abnormal glucose tolerance², psychological distress, and impaired quality of life.³ These disturbing trends and associated health burden have made identifying effective weight management strategies for obese children one of the most important issues in pediatrics.

Guidelines for pediatric weight management endorsed by the American Academy of Pediatrics include increased physical activity, less sedentary time, and a nutritionally-balanced diet with an emphasis on fat and sugar restriction to limit caloric intake.⁴ However, the standard recommendations for achieving “negative energy balance” are typically associated with only modest and transient improvement in weight status, often because of poor long-term adherence.⁵

Recently, dietary interventions that modify the type or amount of carbohydrate (CHO) have shown some promise for weight management. In particular, the low carbohydrate (LC) diet limits CHO intake to no more than 60 grams/day⁶, and the reduced glycemic load (RGL) diet restricts intake of rapidly absorbed carbohydrates⁷. Diets using modified CHO intake have resulted in improved weight status in adults⁸⁻¹⁴ and adolescents¹⁵⁻¹⁸. In addition one small observational study suggested a low CHO diet may be beneficial in younger children.¹⁹ However, no randomized controlled clinical trials had investigated the acceptability, safety and effectiveness of these approaches in younger children. Therefore our objective was to conduct a randomized clinical trial to compare the safety and efficacy of LC and RGL diets to a standard dietary intervention for the management of obesity in younger children. The central hypothesis is that CHO-modified diets will have greater beneficial effects on weight status and other metabolic parameters than a standard portion-controlled diet.

METHODS

Children were recruited from referrals to a pediatric weight management program at Cincinnati Children’s Hospital Medical Center (CCHMC) who lacked health insurance coverage for the CCHMC program. Study announcements were also mailed to community pediatricians and CCHMC employees. Potential subjects were phone screened and eligibility determined at a screening visit.

Subjects were children age 7 to 12 years, with fasting blood glucose ≥ 100 milligrams/deciliter (mg/dl) and a body mass index (BMI) z-score of 1.60-2.65. This BMI-z score range was chosen because extremely obese children are more likely to have genetic and metabolic abnormalities not present in the general population. Other requirements included no developmental or physical disabilities, the ability to function independently in group exercise sessions, and parent/guardian commitment to attending study sessions. Exclusion

criteria were: medical conditions such as cardiac, pulmonary, thyroid, renal, or liver disease, hyperlipidemia, diabetes, or significant mental illness. The physiological and psychological effects of modified carbohydrate diets in youth are not known. Therefore subjects with the aforementioned medical conditions were excluded to avoid the potential exacerbation of these other health concerns. In addition, subjects taking medications that could alter bone density, lipid or glucose metabolism or appetite (e.g. stimulants, atypical antipsychotics) were also excluded.

Written informed consent was obtained from each child's parent/guardian and assent from each child. The study protocol was approved by the CCHMC Institutional Review Board.

Children were stratified by pubertal development (4 categories) and BMI z-score (2 categories: ≤ 2.1 SD or > 2.1 SD). Within these eight strata, randomly-permuted block sizes were used to generate the randomized allocation sequence. Subjects were randomly assigned to one of 3 diet groups: low carbohydrate (LC, n=35), reduced glycemic load (RGL, n=36), or portion-controlled (PC, n=31) and informed of their diet assignment at the initial intervention visit. Neither subjects nor study staff were blinded to diet assignment.

Study Diets

Subjects in the LC diet group were instructed to limit CHO intake and to measure ketones daily with Keto-Diastix[®] reagent strips (Bayer Corporation) and log the results. Subjects were instructed to follow a two-week induction phase with ≤ 20 grams of CHO per day⁶, and unrestricted intake of high protein foods (e.g. meat, poultry, fish and eggs) and added fats. After induction, CHO intake was increased by 5 to 10 grams/week, up to a maximum of 60 grams/day, with no limit on energy intake or high protein foods. If not ketotic, the diet was reviewed and strategies were identified to improve adherence.

Subjects in the RGL diet group were instructed to limit intake of high glycemic index (GI) foods (e.g. white bread, concentrated sugars).²⁰ A "stoplight approach"²¹ was modified to classify foods according to GI values (red foods: high GI ≥ 70 ; yellow foods: medium GI of 56-69; and green foods: low GI ≤ 55).²² 'Green' foods were unrestricted (e.g. fruit, non-starchy vegetables, 100% whole grains, and unbreaded meat, poultry, and fish). Yellow foods were to be consumed less frequently (pizza, macaroni and cheese, corn, dried fruits). High GI or 'red' foods (e.g. sugary drinks, refined baked goods, candy, white bread, and white potatoes) were restricted to ≤ 7 servings/week and ≤ 2 servings/day. There were no specific restrictions on energy or fat intake.

Subjects in the PC diet group were instructed to consume age-appropriate, portion-controlled amounts of grains, vegetables, fruits, lean proteins, and skim/low fat dairy products. Calories were distributed as 55-60% CHO, 10-15% protein and 30% fat. Calorie-defined meal plans were developed to establish a 500-calorie deficit relative to each subject's expected energy requirement (based on sex, age, and height), and then decreased by 10% to account for sedentary lifestyle.²³ This initial calorie target was re-evaluated during frequent follow-up visits and adjusted based on rate of weight loss that complied with recommended guidelines.²⁴

All diet groups were advised to take a daily vitamin/mineral supplement and consume adequate fluids, with a goal of 48 ounces (1.42 liters)/day, preferably water.

Study Design

3-month Intervention—This randomized clinical trial began with 12 weekly parent-child sessions, alternating between 30-minute individual counseling and 90-minute group exercise/education sessions. Body weight was measured weekly. Individual sessions led by

registered dietitians, included nutrition education on treatment group-specific dietary guidelines, incorporating family-based interactive menu planning. The dietitians also provided counseling on behavioral strategies (e.g. contracted goals, self-monitoring). To promote adherence, parent/guardians provided age-appropriate incentives when weekly contracted goals were met.

Bi-weekly, diet specific group sessions incorporated 1 hour of exercise for subjects (i.e. active “play”, resistance training, and aerobic activities) led by an exercise specialist, and 30 minutes of parent-child diet education. Subjects were encouraged to be physically active for 30 minutes/day on most days of the week.

Each dietitian educated a comparable number of subjects from each diet group. Individual nutrition counseling sessions were audio-taped and reviewed by a behavioral psychologist to provide on-going feedback regarding consistency of behavioral intervention delivery.

Follow-up period—After the intervention, subjects had no further contact with the study team except for scheduled assessments. Subjects were instructed to continue their assigned diets and behavioral strategies if they were still overweight (BMI ≥ 85th percentile) or to follow a weight maintenance plan with the same CHO composition as their assigned diet if they were at a healthy weight (BMI < 85th percentile).

Assessment Visits

Assessments were conducted at baseline, and at 3, 6 and 12 months post-intervention. Trained research staff using standardized protocols obtained: height using a wall-mounted stadiometer (Ayrton 226, Stadiometer.com, Snoqualmie, WA); body weight using a digital scale (Model 5002 Stand-on Scale, Scale Tronix, Inc. White Plains, NY); and waist circumference (WC) using a fiberglass tape measure with calibrated tension device (Gulick M-22C Creative Health Products, Plymouth, MI). Percent body fat (%BF) was determined by dual energy X-ray absorptiometry scan (Choplogix whole-body scanner 4500, Waltham, Massachusetts). Blood was drawn after a 12-hour fast to measure fasting insulin, glucose, total cholesterol, triglycerides (TG), low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol. Blood pressure (BP) was obtained by auscultation with the subject in a seated position using an appropriate size cuff. Food records were kept over 3 consecutive days (two weekdays and one weekend day) during the week prior to the assessment visit. Food records were analyzed using the Nutrition Data System (Windows Version 4.04; Minnesota, 2001).

Statistical Analysis

The primary anthropometric outcomes were BMI z-score, WC, and %BF. BMI z-score was calculated using the Centers for Disease Control 2000 growth charts²⁵ and the SAS macro designed for this purpose²⁶. The energy-adjusted glycemic load (GL; units= g/1000kcal) for each time point was calculated as follows: $\sum GI_f \times CHO (g)_f \times 1000 \text{ kcal} / 100 \times 3\text{-day caloric intake (kcal)}$, where ‘f’ is equal to all foods consumed over a 3-day period.^{18, 20} Dietary adherence was evaluated using dichotomous criteria at the 3-, 6- and 12-month time points: LC group: CHO intake ≤ 60 grams/day; RGL group: glycemic load reduced from baseline; PC group: kilocalories (kcal) per day ≤ subject-specific assigned caloric intake. To assess safety, the incidence of elevated BP (systolic or diastolic BP > 95thile for age and sex),²⁸ hyperlipidemia (LDL cholesterol >140 mg/dl or TG >150 mg/dl)²⁹ and elevated fasting glucose (> 110 mg/dl)^{30, 31} were determined.

Analyses were conducted using Statistical Analysis Software (SAS) v.9.2 (SAS Institute, Cary, NC). Demographic descriptions of participants at baseline were compared across diet

groups using ANOVA or χ^2 or Fisher Exact tests, as appropriate. Individuals with data at all visits (completers) were compared with non-completers to assess differential drop-out.

The primary outcomes (dietary intake and anthropometry) were analyzed for all randomized participants using longitudinal repeated measures analysis. The primary analyses tested for differences among diets at each time point ($n=3$ comparisons at each of 4 time points=12), as well as differences from baseline within each diet ($n=3$ comparisons with baseline for each of 3 diets=9). Thus, for the primary analyses, a Bonferroni-adjusted $p = 0.0024$ ($= 0.05/21$ total comparisons) was considered statistically significant. The same statistical methods were used for analyzing secondary outcomes (clinical metabolic parameters), including concurrent BMI z-score as a covariate, with $p = 0.05$ considered significant. The decision to include BMI z-score as a covariate in the secondary analysis was motivated by our desire to examine the effects of diets on clinical metabolic parameters, independent of expected changes due to improvement in weight status.

The Fisher's Exact test was used to determine differences in study retention and dietary adherence between diet groups, with Bonferroni-adjusted p -value $= 0.006$ ($= 0.05/9$ comparisons) significant. Attendance at group exercise sessions and incidence of categorical risk factors were compared using Fisher's Exact test, with critical p -values $= 0.02$ ($= 0.05/3$ comparisons) and $= 0.05$ considered significant, respectively.

Results

Subject recruitment occurred in six cycles from February 2005 through May 2007. Of the 440 families contacted by phone, 116 (26%) completed the initial medical screening. Of these children, 102 (89%) met inclusion criteria and completed the baseline assessment (Figure 1; available at www.jpeds.com). Fourteen were excluded due to age ($n=1$); dyslipidemia ($n=9$); thyroid disease ($n=1$); and inability to complete study procedures ($n=3$).

Subjects in the three diet groups at baseline had comparable demographic, anthropometric, dietary and clinical parameters (Table I). However it should be noted mean fasting insulin levels at baseline were elevated and met criteria for insulin resistance (above normal range at CCHMC clinical lab: pre-pubertal $<2-13 \mu\text{U/ml}$; pubertal $<2-17 \mu\text{U/ml}$) for all diet groups (LC: 25.8 ± 15.3 ; RGL: 25.1 ± 15.3 ; PC: 31.4 ± 21.1).

Subjects with complete data at all time points ($n=80$; 78%) were more likely to be white ($p=0.04$), but otherwise did not differ from those with partial data ($n=22$). Retention of subjects for follow-up assessments was 82% at the 12-month follow-up and did not differ significantly among the 3 diet groups at any time point (RGL - 3-month: 92%; 6-month: 89%; 12-month: 89%; PC - 3-month: 94%; 6-month: 87%; 12-month: 90%; LC - 3-month: 69%; 6-month: 69%; 12-month: 69%).

Effects of Diet on Anthropometric Measures and Dietary Intake

After 3 months of intervention, BMI z-score decreased in all three diet groups (all $p < 0.0001$; Figure 2), and remained significantly reduced from baseline through 12 months for all 3 groups (all comparisons with baseline, $p < 0.0001$). Percent BF also declined significantly from baseline to 3 months (all $p < 0.0002$), and remained lower than baseline at 6 (all $p < 0.0001$) and 12 months (all $p < 0.002$) in all groups. For all three groups, WC was significantly lower than baseline at 3 months (all $p < 0.0001$) and 6 months (all $p < 0.0001$), but none of the groups maintained this reduction at 1 year (all $p > 0.08$). No significant differences in BMI z-score, WC or %BF (all $p > 0.04$) were detected between diet groups at any time point.

Daily caloric intake decreased in all diet groups by 3 months ($p < 0.0002$) and remained significantly below baseline at 12 months for all groups (all $p \leq 0.0001$). At 3 months, the RGL group consumed significantly more kcal/day than the PC group (Figure 3, A; $p=0.0002$), but these differences disappeared by the 6- and 12-month time points.

Despite similar overall energy intake, subjects consumed diets with distinct macronutrient composition (Figure 3, C, E and F). At 3 months, the LC group had the highest proportional fat (50.3%) and protein (25.1%) intake, and the lowest proportional carbohydrate intake (27.0%), effects that were maintained throughout the trial. The LC group also had the lowest glycemic load (32.0 g/1000 kcal) at 3 months ($p < 0.0001$ vs. RGL and PC), but did not differ from the RGL group by 12 months. The PC group had higher carbohydrate (50.3%) and lower fat intake (31.8%) than the RGL group (Figure 3, B and F; both $p \leq 0.002$) at 3 months, and had the highest glycemic load of any group at all time points (Figure 3, D; all $p \leq 0.0024$).

Attendance and Dietary Adherence

Attendance at the twelve weekly intervention sessions ($n=1079$ visits scheduled) was significantly lower in the LC group (76%) than the RGL (87%) or PC (87%) groups (both $p < 0.0001$). Dietary adherence was consistently high in the RGL group ($> 75\%$), and adherence was significantly lower in the LC group than the other two groups at all visits (Figure 2, D; all $p \leq 0.004$). In the LC group, only 16% of subjects tested positive for urinary ketones at any point (only 8% [6/76] of all tests done), and carbohydrate intake exceeded the goal of 60 grams/day at all time points (3-months: 85.3 ± 11.8 gm; 6-months: 108.2 ± 11.6 gm; 12-months: 122.6 ± 11.4 gm).

Effects of Diets on Cardiovascular Risk Factors

All diet groups had significant improvements in some clinical measures which were sustained at 12 months, even adjusting for concurrent BMI z-score (Table II). However, the profile of improved outcomes differed by diet group and across time. By the 12-month follow-up, the LC group demonstrated improvements in TG and HDL cholesterol; the PC group had improved fasting glucose, insulin and HDL cholesterol; and the RGL group exhibited improved fasting insulin and LDL cholesterol.

The only significant differences in these metabolic parameters *between* diet groups were insulin which at 3 months was significantly lower in the LC group than the RGL and PC groups (LC vs. PC, $p=0.04$; LC vs. RGL, $p=0.03$); and systolic and diastolic BP at 6 months, when the PC and RGL groups experienced transient increases in mean BP (diastolic BP: LC vs. PC, $p=0.01$; systolic BP: LC vs. PC, $p=0.009$ and PC vs. RGL, $p=0.02$).

During the study, 3.6% (3/84) of individuals with no prior cardiovascular risk developed elevated BP, 12.2% (9/74) high TG, 3.5% (3/86) high LDL cholesterol, and 3.5% (3/86) high fasting glucose; however, the incidence of these adverse metabolic outcomes did not differ by diet group, with no pattern of occurrence.

DISCUSSION

In this randomized trial comparing diets with modified CHO content with a clinically standard portion-controlled diet (effectively an energy-reduced, low-fat diet), the central finding was that all 3 diets were efficacious in improving BMI z-score for up to 9 months post-intervention. These findings are consistent with other diet comparisons in obese adolescents¹⁶ and adults.^{9, 12, 13, 32, 33} However, the results of our study do not support the hypothesis that CHO-modified diets would be more effective in improving weight status than a standard portion-controlled diet among obese children. Subjects in all 3 diet groups

showed significant improvements in adiposity measures (BMI z-score, %BF and WC) during the initial 3-month intervention with relatively intensive intervention and contact with study dietitians. At 12-months, improvements in BMI z-score and %BF were maintained in all 3 diet groups; however, none of the groups sustained improvement in WC. These results are similar to clinical trials of the LC and low-fat diets in a 12-week study of adolescents¹⁶ and a 12-month study of adults,¹² reporting comparable improvements in weight status. However, other clinical trials found the LC diet to be superior to a low-fat diet with both adolescents¹⁵ and adults.^{8-11, 13,14} In addition, controlled studies of the RGL diet with obese children and adolescents showed a greater decrease in BMI^{17, 18} and body fat mass¹⁸ than those assigned to low-fat diet regimens. Factors behind these discrepant results are not clear at this time.

It is noteworthy that subjects in all diet groups were successful in maintaining a reduced caloric intake and altered dietary composition even in the final 9 months without intervention contact. These findings raise the possibility that intensive guidance with the initial clinical application of weight management diets could lead to long-term success in children.

Each of the diets led to improvement in some of the clinical measures, but there was variability among the results. The LC group had significant improvement in HDL cholesterol and triglycerides, and the PC and RGL diets seemed to have a relatively greater effect on lowering fasting insulin and glucose. Other clinical trials of the LC and low-fat diets also reported improvements in metabolic parameters.^{8-11, 15, 16} It is not clear the degree to which the diet's macronutrient composition in our study contributed to these variable outcomes because they are undoubtedly also affected by other factors. Moreover the clinical implications of these findings are not clear given the relatively normal baseline values. Nonetheless, none of the diets had systematic adverse effects on incidence of cardiovascular risk factors, and were in this regard safe.

Recently it has been suggested that strategies to individualize diet interventions to match patients' metabolic profiles could have increased efficacy.^{34, 35} For example, a carbohydrate-modifying diet may be advantageous in subjects with elevated triglycerides, and a low-fat diet may be more effective in individuals with high LDL cholesterol.³⁶ Our trial provides limited support for these hypotheses, as we detected differential effects on specific metabolic profiles (e.g., lipids vs. insulin resistance) by dietary intervention. More trials matching dietary approaches with children's specific risk factors are greatly needed.

The LC diet led to notable long-term improvements in both anthropometric and clinical metabolic profiles, despite several indications that it was a less acceptable diet to participants. The LC diet was the only group to which individuals refused randomization, and randomized participants had significantly lower dietary adherence compared with the RGL and PC groups. A question raised by the study's findings is whether adherence to a less stringent version of the LC diet is more realistic, sustainable, and yet still effective for improving BMI z-score and other obesity-related clinical measures. The study results showed strict adherence to the LC diet was extremely difficult to achieve with children, (i.e., very few Keto-Diastix[®] results were positive for ketones in the urine). However, the reported mean carbohydrate intake in the LC group was still significantly less than in the RGL and PC groups at all time points, and resulted in significant improvements in BMI z-score and some clinical measures after one year. Although not statistically significant, this study also suggests that the LC group's longer-term results may be associated with adherence. For example, a trend toward rebound in %BF and BMI z-score occurred when dietary adherence dropped to near zero in this group. Larger scale studies would be required to assess this relationship.

By contrast, the sustained high adherence to the RGL diet coupled with anthropometric and clinical improvements may make it the most promising intervention for the long-term weight management of children. Alternatively, prescribing one of the 3 diets based on the patient's preferences for the initial intervention and then transitioning to the RGL diet for longer-term maintenance may also be an effective strategy. A prior retrospective study showed elevated fasting insulin in obese youth is a risk factor for being unsuccessful with weight management (i.e. increased BMI z-score) when participating in an obesity intervention that included a RGL diet.³⁷ However our study does not reflect this finding. The conflicting results may be explained in part by the difference in study design as well as the level of engagement and motivation of our study population as evidenced by a high retention rate.

In this randomized clinical trial with obese children, we tested the long-term efficacy and safety of 3 diet interventions using similar evidence-based behavioral strategies. The intervention was delivered in a consistent manner with strong family-based behavioral components across the 3 diet groups with quality control procedures to ensure treatment fidelity. The strong retention rate (77% of subjects) increased the validity of reported findings, and gave the study adequate power despite enrollment levels less than the initial target of 50 subjects per group. We note that the PC group included a lower proportion of boys than the other groups; although this was not statistically significant, we may have lacked power to detect true differences. However, we believe this would have a minimal impact on the conclusions of this study, given subjects were stratified according to sexual maturity and extent of overweight.

It is unknown whether the reported improvements would be sustained beyond one year or whether one diet would be more effective than the others in the longer term. Because the study was implemented in a research context and the most severely obese children were excluded, the ability to generalize the findings to a clinical population of obese children is unknown. Lastly, the reliance on self-report of dietary intake is a limitation that is encountered by most diet trials. Underreporting of dietary intake for obese adults is well documented. Thus it seems likely that this phenomenon would have occurred with equal magnitude among the 3 diet groups.

We conclude that the three diets that differed in macronutrient content and glycemic load resulted in similar and significant improvement in BMI z-score and related health measures in children. Though strict adherence to the LC diet was more difficult to achieve in children, all diets were effective in improving some adiposity and clinical outcomes. These findings suggest that practitioners may offer any of these dietary approaches for achieving a healthier weight with obese children.

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Abbreviations

BMI	body mass index
CHO	carbohydrate
LC	low carbohydrate
RGL	reduced glycemic load

PC	portion controlled
WC	waist circumference
%BF	percent body fat
BP	blood pressure
LDL	low-density lipoprotein
HDL	high-density lipoprotein
TG	triglycerides
SAS	Statistical Analysis Software
CCHMC	Cincinnati Children's Hospital Medical Center
GI	glycemic index
SD	standard deviation
LS	least squares
SE	standard error
kcal	kilocalories
gm	grams
mg	milligrams
dl	deciliter

Figure 1.
Flow Diagram of Participants through the Trial

Figure 2.

Anthropometric Outcomes and Dietary Adherence by Diet Group. Least square means $\pm$ SE presented from repeated measures mixed models for A, BMI Z-score, B, waist circumference and C, % body fat. Significant differences ($p < 0.0024$) within each diet group versus baseline: ^a LC; ^b RGL; ^c PC. D, Percent of participants within each diet group adhering to dietary recommendations. Significant differences ($p < 0.0024$) from baseline (^a, ^b, and ^c designations as in 2A-2C) and pairwise differences among diet groups indicated as follows: ^d LC vs. RGL; ^e LC vs. PC using Fisher Exact Test.

Figure 3.

Dietary Intake by Diet Group. Least square means $\pm$ SE presented from repeated measures mixed models for A, total caloric intake, B, carbohydrate (g/day), C, carbohydrate (% of kcal), D, glycemic load, E, protein and F, fat. Significant differences ($p \leq 0.0024$) between diet groups indicated as follows: ^d LC vs. RGL; ^e LC vs. PC; ^f RGL vs. PC.

Table 1**Baseline Characteristics of Randomized Participants**

	Total	Diet Assignment†		
		LC	RGL	PC
	N= 102	n=35	n=36	n=31
Demographics				
Age, years	9.8 ± 1.5	9.9 ± 1.6	9.8 ± 1.7	9.7 ± 1.3
Sex (% male)	43 (42.2)	16 (45.7)	19 (52.8)	8 (25.8)
Race, (% white)	79 (77.5)	26 (74.3)	31 (86.1)	22 (71.0)
Puberty stage (% pre-pubertal)	44 (43.1)	16 (45.7)	15 (41.7)	13 (41.9)
Anthropometrics				
BMI, kg/m ²	29.4 ± 4.0	29.9 ± 4.4	29.2 ± 3.8	29.1 ± 3.8
BMI Z-score, SD units	2.3 ± 0.2	2.3 ± 0.3	2.3 ± 0.2	2.3 ± 0.3
Waist circumference, cm	98.7 ± 11.5	99.9 ± 12.0	98.6 ± 12.2	97.5 ± 10.1
Body fat, %	40.7 ± 3.7	41.3 ± 3.3	41.1 ± 3.4	39.6 ± 4.4
Lean body mass, kg	37.7 ± 8.7	38.8 ± 8.6	36.0 ± 8.1	38.4 ± 9.4
Dietary Intake				
Energy Intake, kcal	1920 ± 530	1950 ± 490	1920 ± 510	1900 ± 610
Carbohydrate, g/day	243 ± 72	242 ± 62	251 ± 77	234 ± 75
Carbohydrate, % of kcal	50.6 ± 6.8	50.1 ± 7.2	51.9 ± 6.3	49.6 ± 6.9
Protein, g/day	70.9 ± 22.0	77.6 ± 24.0	67.6 ± 16.3	68.4 ± 24.9
Protein, % of kcal	14.9 ± 2.9	16.1 ± 3.3	14.5 ± 2.8	14.3 ± 2.4
Fat, g/day	76.5 ± 26.9	76.1 ± 27.4	74.3 ± 23.4	79.4 ± 30.5
Fat, % of kcal	35.6 ± 5.7	34.7 ± 5.5	34.8 ± 5.3	37.3 ± 6.0
Glycemic load, g/1000 kcal	74.7 ± 11.7	73.2 ± 11.4	76.5 ± 11.2	74.0 ± 12.6
Clinical Measures				
Insulin, µU/ml	26.8 ± 17.2	25.8 ± 15.3	25.1 ± 15.3	31.4 ± 21.1
Glucose, mg/dL	95.3 ± 6.7	94.7 ± 6.0	95.3 ± 7.0	96.1 ± 7.2
Total cholesterol, mg/dL	161 ± 27	165 ± 24	159 ± 28	160 ± 31
Triglycerides, mg/dL	99.3 ± 39.6	102 ± 41	91.6 ± 38.0	105 ± 40
LDL-cholesterol, mg/dL	93.7 ± 23.7	96.9 ± 22.6	92.3 ± 23.4	92.0 ± 25.7
HDL-cholesterol, mg/dL	47.6 ± 9.9	47.2 ± 9.3	48.3 ± 8.9	47.4 ± 11.7
Systolic BP, mmHg	101 ± 10	101 ± 7.1	99.4 ± 9.7	103 ± 13
Diastolic BP, mmHg	59.7 ± 8.3	61.2 ± 8.0	58.3 ± 6.8	59.8 ± 9.9

* Data presented are n (%) or mean ± SD

Table 2
Clinical Metabolic Characteristics by Diet Group and Visit

	LC	RGL	PC
Fasting Glucose (mg/dl)			
Baseline	93.9 ± 1.1	94.5 ± 1.1	95.5 ± 1.2
3 months	92.1 ± 1.0	93.9 ± 1.2	93.6 ± 1.0
6 months	93.5 ± 1.2	93.4 ± 1.0	94.9 ± 1.0
12 months	94.2 ± 1.2	92.5 ± 1.0	93.1 ± 1.1 *
Fasting Insulin (μU/l)			
Baseline	22.9 ± 2.4	23.7 ± 2.5	30.2 ± 3.6
3 months	16.9 ± 1.5 ***	22.0 ± 1.8	22.8 ± 2.5 **
6 months	19.8 ± 1.5	21.1 ± 1.6 **	23.9 ± 2.2 **
12 months	22.7 ± 2.3	20.7 ± 1.7 *	22.8 ± 2.2 **
Total cholesterol (mg/dl)			
Baseline	162 ± 4	158 ± 5	159 ± 5
3 months	157 ± 5	153 ± 4	155 ± 5
6 months	160 ± 5	157 ± 4	155 ± 5
12 months	161 ± 5	153 ± 4	160 ± 6
Triglycerides (mg/dl)			
Baseline	100 ± 7	87 ± 6	102 ± 7
3 months	69 ± 6 ***	81 ± 7	88 ± 8
6 months	76 ± 7 **	77 ± 6 *	82 ± 6 ***
12 months	83 ± 7 *	82 ± 6	89 ± 7
HDL cholesterol (mg/dl)			
Baseline	47.6 ± 1.4	49.8 ± 1.4	48.2 ± 2.1
3 months	50.9 ± 1.5 **	49.2 ± 1.5	48.2 ± 2.1
6 months	51.6 ± 1.7 **	48.3 ± 1.4	49.0 ± 1.7
12 months	52.7 ± 1.8 ***	50.3 ± 1.5	51.7 ± 2.1 ***
LDL cholesterol (mg/dl)			
Baseline	95.0 ± 3.9	91.1 ± 4.0	90.8 ± 4.6
3 months	92.7 ± 4.4	87.5 ± 3.4	89.3 ± 4.5
6 months	93.4 ± 4.3	92.8 ± 4.0	90.0 ± 4.2
12 months	91.7 ± 4.6	86.1 ± 3.5 *	89.9 ± 4.7
Systolic BP (mmHg)			
Baseline	99.9 ± 1.3	98.3 ± 1.7	102.0 ± 2.3
3 months	98.6 ± 1.6	100.0 ± 1.7	99.7 ± 1.7
6 months	98.2 ± 1.6	99.0 ± 1.5	104.0 ± 1.7
12 months	101.0 ± 1.8	100.0 ± 1.7	99.8 ± 1.7
Diastolic BP (mmHg)			
Baseline	60.8 ± 1.4	57.9 ± 1.1	59.3 ± 1.8

	LC	RGL	PC
3 months	59.3 ± 1.6	61.6 ± 1.9	60.7 ± 1.8
6 months	59.2 ± 1.5	62.4 ± 1.8 *	64.8 ± 1.6 *
12 months	62.5 ± 2.2	60.3 ± 1.5	59.4 ± 1.7

LC = Low Carbohydrate; RGL = Reduced Glycemic Load; PC = Portion Control. LS means ± SE presented from longitudinal models, adjusting for concurrent BMI Z-score.

*
p 0.05 vs. baseline

**
p 0.01 vs. baseline

p 0.001 vs. baseline