Title Page

Comparison of a Low Carbohydrate and Low Fat Diet for Weight Maintenance in Overweight or Obese Adults Enrolled in a Clinical Weight Management Program

Contributing Authors

James D. LeCheminant

Southern Illinois University Edwardsville

Box 1126

Edwardsville, Illinois 62026

PH: 618-650-3306

jlechem@siue.edu

Cheryl A. Gibson

University of Kansas Medical Center

5026 Wescoe Pavilion

Mail Stop 1020

3901 Rainbow Boulevard

Kansas City, KS 66160

cgibson@kumc.edu

Debra K. Sullivan

University of Kansas Medical Center

4019 Delp Pavilion

Mail Stop 4013

3901 Rainbow Boulevard

Kansas City, KS 66160-7250

dsulliva@kumc.edu

Sandra Hall

University of Kansas Medical Center

004 Robinson Hall

Mail Stop 1008

3901 Rainbow Boulevard

Kansas City, KS 66160-7313

shall@kumc.edu

Rik Washburn

The University of Kansas

1301 Sunnyside Avenue

Lawrence, KS 66045

rwashburn@ku.edu

Mary C. Vernon

Private Practice

4951 W 18th Street

Lawrence, KS 66047-2090

mvernonmd@yahoo.com

Chelsea Curry

The University of Kansas

1301 Sunnyside Avenue

Lawrence, Kansas 66045

ccurry@ku.edu

Elizabeth Stewart

The University of Kansas

1301 Sunnyside Avenue

Lawrence, Kansas 66045

estewart@transformed.com

Eric C. Westman

Duke University Medical Center

2200 West Main Street, Suite B210

Durham, North Carolina 27705

Westm001@mc.duke.edu

Joseph E. Donnelly

Director, Center for Physical Activity and Weight Management

The University of Kansas

1301 Sunnyside Avenue

Lawrence, Kansas 66045

PH: 785-864-0257

Fax: 785-864-2009

Email: jdonnelly@ku.edu

Abstract

Background: Recent evidence suggests that a low carbohydrate diet may be equally or more effective for short-term weight loss than a standard low fat diet; however, less is known about how they compare for weight maintenance. Therefore, the purpose of this study was to compare body weight (BW) for participants on a low carbohydrate or low fat weight maintenance diet for 6 months following 3 months of weight loss.

Methods: Fifty-five (29 low carbohydrate diet; 26 low fat diet) overweight/obese middle-aged adults completed a 9 month weight management program that included instruction for behavior, physical activity (PA), and nutrition. For 3 months all participants consumed an identical liquid diet (2177 kJ/day) followed by 1 month of re-feeding with solid foods. For the remaining 5 months, participants followed a meal plan low in dietary carbohydrate (~20%) or dietary fat (~30%). BW and carbohydrate or fat (g) were collected at each group meeting. Energy and macronutrient intake were assessed at baseline, 3, 6, and 9 months.

Results: The low carbohydrate group increased BW from 89.2 ± 14.4 kg at 3 months to 89.3 ± 16.1 kg at 9 months (P=0.84). The low fat group decreased BW from 86.3 ± 12.0 kg at 3 months to 86.0 ± 14.0 kg at 9 months (P=0.96). BW was not different between groups during weight maintenance (P=0.87). The low carbohydrate group reported lower food energy intake, carbohydrate intake, and higher fat intake than the low fat group.

Conclusion: After a 3 month liquid diet program, a low carbohydrate and low fat diet may be equally effective for BW maintenance over 6 months.

BACKGROUND

Multiple treatment strategies are available for weight loss including energy restriction, physical activity, and/or behavioral modification. However, in general, 50% of individuals who initially lose weight will regain more than 45-75% of the weight within 12-30 months after the end of treatment and only 20% of overweight individuals losing weight are successful long-term when weight maintenance is defined as losing at least 10% of initial body weight and maintaining the loss for at least 1 year [1-4]. Thus, improved strategies to prevent weight re-gain are needed.

Recent studies have suggested that the composition of the diet may play an important role in weight management. In particular, diets lower in carbohydrate and higher in protein have shown promise for weight loss when compared to typical reduced energy and fat diets. These data indicate that a low carbohydrate diet may produce greater weight loss than a low fat diet over 6 months and may be comparable to a low fat diet over 12 months [2, 5-8].

Despite the evidence supporting a low carbohydrate diet as an effective tool for weight loss, it is unclear if this diet is effective to prevent the weight re-gain that occurs for many individuals following weight loss. There are little data in which a low carbohydrate diet has been evaluated, in comparison to the traditional low energy, low fat diet as a dietary intervention to prevent weight re-gain [9, 10]. Therefore, the purpose of this study was to compare body weight re-gain in overweight and obese adults on a low carbohydrate or a low fat diet over 6 months of weight maintenance subsequent to 3 months of weight loss**.**

METHODS

Participants

The Human Subjects Committee of University of Kansas approved this study. Participants were recruited through advertisements, fliers, and word of mouth. Participants were healthy adults, 19 to 70 years of age, previously sedentary, and overweight or obese (BMI >27 kg/m^2). Individuals were excluded if they smoked, used special diets (i.e. vegetarian), were unable to exercise (i.e. walk), were pregnant or lactating, or were in active counseling for any psychological or psychiatric condition. Prior to participation, a physician evaluated each individual to determine potential health risks relative to participation in the study. Individuals were excluded for any metabolic disease affecting energy balance (e.g. diabetes mellitus, cancer, etc.). Prior to participation individuals provided informed consent. Except for the exclusion criteria stated above, there were no restrictions for gender, race, or socioeconomic status.

Study Design

This study was conducted in the context of a weight management clinic. All participants received 3 months of a weight loss diet followed by 6 months of a weight maintenance diet either low in carbohydrate or fat. A quazi-experimental design was utilized where clinic site was randomly chosen as either low carbohydrate or low fat; however, analysis was per participant. A total of six separate groups were recruited; 3 low carbohydrate and 3 low fat.

Weight Management Clinics

Weight management clinic meetings were approximately 90 min and were held weekly for the first 6 months and biweekly for the subsequent 3 months. Clinics were conducted in a group format of 15-20 individuals and each meeting began with a check-in to ensure adherence to the protocol of the study. During check-in, all participants were weighed and provided their self-reported weekly data including: # of liquid shakes consumed (weight loss period only), total g of carbohydrate or fat (weight maintenance period only), min of physical activity (PA), and number

of steps recorded by step counters. Following check-in, a 30-45 min presentation was given including instruction in behavioral lifestyle modification, exercise, or nutrition.

In order to increase accountability and protocol compliance participants were asked to provide a mid-week check-in via phone, fax, or email during the first 6 months of the study. For the mid-week check-in participants provided their weekly data (PA, steps, etc.) and presented any concerns related to the study they might have had since the previous meeting. When group meetings changed to bi-weekly, check-ins occurred during the week groups did not meet. All group meetings were lead by the same staff of registered dieticians, exercise physiologists, and behavioral therapists using an identical, standardized protocol.

The only difference between groups occurred when the meeting topic was nutrition. The participants consuming a low carbohydrate diet received information and strategies such as shopping, cooking, label reading, etc., for achieving a diet low in carbohydrate and the participants consuming low fat diet received information and strategies for eating a diet low in fat. Attendance was expected at group meetings. Prior to participation in the study, participants agreed to comply with a 75% attendance rate requirement and understood that they would be terminated from further participation in group meetings if their attendance fell below 75%.

Very Low-Energy Diet

Weight loss was facilitated using a very low-energy diet (VLED) comprised of 2177 kJ/day and utilized a milk-based product (Health Management Resources, Boston, MA) consumed primarily as a liquid shake at 5 intervals throughout the day, for 3 months. Each liquid shake included approximately 435 kJ, 13-17 g of carbohydrate, 1 g of fat, 10-14 g of protein. In addition, a vitamin and mineral supplement was taken twice daily. If participants did not lose at least 10% of their initial body weight during VLED, they were not allowed to continue with the

study. The liquid meal replacements were the only source of nutrition during VLED with the exception of non-caloric beverages that were consumed ad libitum. To ensure compliance to the VLED, participants reported their total number of liquid shakes consumed for the previous week at each group meeting.

Weight Maintenance Diet

During month 4, a progressive re-feeding schedule was utilized that decreased the number of liquid shakes and increased the number of solid foods consumed each week. This was done to limit adverse events (e.g., nausea, diarrhea, etc.) associated with the transition from the liquid to the solid food diet. Further, the low carbohydrate group was re-fed with solid foods that were low in carbohydrate, such as green leafy vegetables, broccoli florets, lean meats, and nuts and the low fat group was re-fed with low fat foods, such as fruits, vegetables, potatoes, and whole grains.

At the end of month 4, all participants were provided a gram level of carbohydrate or fat based upon their weight maintenance energy requirements. For the low carbohydrate group, the upper limit of carbohydrate grams to be consumed each day was ~20% of their total maintenance energy level and for the low fat group the upper limit of fat grams to be consumed each day was ~30% of their total maintenance energy level. Maintenance energy intakes were calculated using the Harris-Benedict equation to estimate resting energy expenditure (REE) and we used 1.4 X REE to adjust for PA levels [11].

To monitor adherence to the diet, the low carbohydrate group kept a daily tally of grams of carbohydrate and the low fat group kept a daily tally of the number of fat grams consumed, based upon the percentages previously listed, and reported their daily gram total at each weekly meeting. When participants exceeded their allotted number of daily carbohydrate or fat grams, a

member of the research staff provided dietary counseling to the particular participant. In addition, during group meetings emphasis was placed on food label reading, low carbohydrate or low fat food preparation, low carbohydrate or low fat food items and low carbohydrate or low fat food recipes, etc.

Body Weight and Regional Adiposity

Weights were obtained at the beginning of each group meeting using a digital scale (Befour, Inc., Saukville, WI) accurate to $\pm$ 0.1 kg with participants wearing normal clothing without shoes. To calculate BMI, height was measured at baseline using a stadiometer (Perspective Enterprises, Portage, MI). Body Mass Index was calculated as weight in kg divided by height in meters squared (kg/m^2). Waist circumference was measured at the narrowest portion of the abdomen and hip circumference was measured at the widest portion of the buttocks [12]. Waist and hip circumference were assessed at baseline, 3, 6, and 9 months by obtaining 2 measurements per site within 2 cm using a spring-loaded tape measure (Creative Health Products, Ann Arbor, MI).

Energy Intake

In order to determine compliance to the diet, 3-day food records were analyzed at baseline, 3, 6, and 9 months. For 3 separate days in a week, including 2 weekdays and 1 weekend day considered typical, each participant recorded all foods and beverages consumed; both type and amount. During group meetings, participants were trained to read food labels and estimate portion sizes in order for amounts to be determined. Upon collection, a trained staff member reviewed each participant's diet record and gave suggestions to better comply with the diet if needed. At each data collection period, diet records were entered into the Nutrition Data System for Research (NDSR) (version 4.05_33) by a trained staff member for nutrient composition and

energy intake analysis. After diet records were entered, a trained staff member checked for data entry errors.

Physical Activity

Physical activity was considered as any planned activity of at least moderate intensity, such as brisk walking, involving major muscle groups that lasted for at least 10 min. Participants were issued pedometers (Accusplit®, San Jose, CA) and instructed in their use. Weekly totals for PA in min and steps were reported at each group meeting. Physical activity was initiated after the second clinic meeting and was progressive beginning with 15 min per day, three times/week and reached 50-60 min, 5-6 times/week at month 6. The overall goal was for participants to reach a PA level of 300 min/week at 6 months and maintain that level for the remainder of the study. The progression was intentionally slow as many of the participants were very de-conditioned.

Blood Pressure

Blood pressure was assessed at baseline, 3, 6, and 9 months. Blood measure was measured on the right arm using a mercury sphygmomanometer with participants lying in the supine position for 5 min prior to measurement [13]. A minimum of two blood pressure measurements were taken. If the first two readings differed by more than 5 mmHg, an additional reading was obtained. The lowest systolic and diastolic blood pressure values were used for analysis [14].

Adverse Events

At each clinic meeting, participants reported any adverse events experienced during the previous week. A form was provided to assess potential adverse events that included questions about nausea, fatigue, flatulence, bad breath, constipation, bloating, stomach cramps, diarrhea, hair loss, change in sleeping patterns, over the counter drugs, insomnia, irritability, body odor, etc. The form containing the list of potential adverse events also included a space to allow

participants to explain the adverse event or to describe an event not listed on the form (i.e. "other").

Statistical Analysis

This was a per protocol study; therefore, data were analyzed only for participants who completed all clinic and laboratory measures. The primary outcome was a comparison of body weight during weight maintenance (4 months to 9 months) for the two treatment conditions. The statistical software package PC-SAS (version 8.2, SAS Institute, Inc., Cary, NC) was employed for all statistical analyses. The level of significance was set at 0.05 for all statistical tests. Descriptive statistics (mean, standard deviation, etc.) were reported for all dependent measures. T-tests and repeated measures ANOVA were used to detect differences in the change in body weight over time. In addition, mixed effects models were used in order to assess if there was a significant interaction (group*time) for each dependent variable. An autoregressive [AR(1)] covariance structure was assumed for the mixed effects models. In the absence of a significant interaction term, analysis was completed for the main effects of group and time.

RESULTS

Participants

A total of 102 participants met the inclusion criteria and initiated the study. The participants were healthy adults (26 men and 76 women), middle-aged, and obese. Ninety-four percent (96/102) of participants were Caucasian, 3% (3/102) were African-American, and 3% (3/102) were Hispanic. Twenty percent (20/102) of participants reported using medications including: anti-hypertensives, diuretics, thyroid medications, or anti-depressants. At baseline, 52 participants were assigned to the low carbohydrate diet group and 50 participants were assigned

to the low fat diet group. There were no statistical differences between the low carbohydrate and low fat group at baseline for age, weight, or BMI.

Attrition and Adherence

The low carbohydrate group had 44% attrition and the low fat group had 48% attrition. A summary of reasons for participant attrition and the number of dropouts are included in Table 1. Attrition was greatest during months 4 to 6 for both groups. A total of 55 participants (29 low carbohydrate; 26 low fat) completed all testing and clinic measures at 9 months. Subsequent data will be presented only for participants who completed the entire study. There was no statistical difference at baseline for body weight between those who completed the study and those that did not (P=0.14). Characteristics of completers at baseline are presented in Table 2.

During the weight loss portion of the study, participants achieved the required number of liquid meal replacements averaging 35 ± 3 per week for the low carbohydrate group and 36 ± 4 per week for the low fat group. Throughout the duration of weight maintenance (months 4-9) participants kept track of daily carbohydrate or fat grams with the low carbohydrate group self-reporting a consumption of 78 ± 30 g of carbohydrate per day and the low fat group self-reporting 39 ± 18 g of fat per day. In addition, analysis of 3-day food records showed the low carbohydrate group consumed 91 ± 39 g of carbohydrate per day averaging ~25% of total kJ from carbohydrate and the low fat group consumed 48 ± 20 g of fat per day averaging ~26% of total kJ from fat.

Pre Study Diet

Prior to participation (baseline), energy intake was higher in the low fat group compared with the low carbohydrate group (9419 ± 2428 kJ vs. 7761 ± 1980 kJ; P=0.01). At baseline the low carbohydrate group was significantly higher for g of carbohydrate, fat, and alcohol (P<0.05);

however, the percentage of total kJ from carbohydrate, protein, and fat were not significantly different between groups (Table 3).

Weight Loss Period

During the weight loss period (months 1-3) both groups lost significant amounts of body weight on the liquid diet. The low carbohydrate group decreased body weight by 20.4 ± 6.2 kg (19%) and the low fat group 19.1 ± 5.4 kg (18%); the difference between groups was not statistically significant. Likewise, BMI, waist circumference, and blood pressure decreased significantly for both groups but differences between groups were not significant.

Weight Maintenance Period

Differences in body weight between the two groups were not significant across the 6 months of weight maintenance (P=0.87). Adjusting for medication use and body weight at the beginning of weight maintenance did not influence the outcome. Figure 1 shows body weight at 2 week intervals across the 6 months of weight maintenance. At the beginning of weight maintenance the low carbohydrate group had a body weight of 89.2 ± 14.4 kg that increased to 89.3 ± 16.1 kg at 9 months (P=0.84) and the low fat group had a body weight of 86.3 ± 12.0 kg at 3 months that decreased to 86.0 ± 14.0 kg at 9 months (P=0.96). In the low carbohydrate group, 55% (16/29) of participants decreased their body weight during weight maintenance and 50% (13/26) of participants in the low fat group decreased their body weight during weight maintenance (Figures 2 & 3).

Participants in both treatment groups showed a similar response for blood pressure and anthropometrics during the weight maintenance period. At the beginning of weight maintenance, systolic and diastolic blood pressure were not significantly different between groups although systolic blood pressure was slightly higher in the low carbohydrate group (122 vs. 116 mmHg;

P=0.08). Over the duration of weight maintenance the low carbohydrate group showed a decrease in systolic blood pressure from 122 ± 11 to 120 ± 10 mmHg and diastolic blood pressure from 75 ± 7 to 73 ± 10 mmHg. The low fat group decreased systolic blood pressure from 116 ± 13 to 111 ± 13 mmHg and diastolic blood pressure from 73 ± 8 to 70 ± 9 mmHg. There were no significant differences in blood pressure between or within groups across the duration of weight maintenance. Likewise, waist circumference and BMI were not statistically different between or within groups at any time period (Table 4).

Comparison of dietary intake data during weight maintenance showed that the low carbohydrate group consumed significantly more g of protein, fat, and percentage of total kJ from protein, and fat compared to the low fat group. The low fat group consumed a significantly greater number of total kJ, g of carbohydrate, fiber, and alcohol and a greater percentage of kJ from carbohydrate and alcohol compared to the low carbohydrate group. After adjusting for baseline values, the values during weight maintenance for kJ and protein intake were no longer significantly different between groups.

Physical Activity

There was a non-significant group*time interaction for min of physical activity during weight maintenance. Physical activity for the low carbohydrate group averaged 268 ± 17 min/week and for the low fat group was 265 ± 23 min/week during weight maintenance. Likewise, there was no significant group*time interaction for pedometer steps during weight maintenance. The low carbohydrate group averaged approximately 63,000 ± 3200 steps per week and the low fat group 68,000 ± 3500 steps per week during weight maintenance.

Adverse Events

Adverse events occurred in both groups during weight maintenance. The most commonly reported adverse events in the low carbohydrate group during weight maintenance included headache, constipation, flatus, hair loss, change in sleeping patterns, and stomach cramps. The most commonly reported adverse events in the low fat group during weight maintenance included headache, nausea, fatigue, and diarrhea.

Unexpected adverse events reported in the low carbohydrate diet included dizziness (N=2), leg cramps (N=2), a missed menstrual period (N=1), dandruff (N=1), decreased sex drive (N=1), and a 100 mg/dL increase in total cholesterol in 1 participant. Unexpected adverse events reported in low fat diet included change in taste (N=1) and dizziness (N=1).

DISCUSSION

Weight Loss Period

It is well documented that a VLED is effective to produce significant weight loss [15-17]. A VLED is motivating for many individuals due to the rapid weight loss experienced by a large proportion of individuals who use this diet. The low carbohydrate group had ~19% decrease in initial body weight and the low fat group had ~18% decrease in initial body weight on VLED.

Weight Maintenance Period

Attrition was similar for both groups. The primary reason for attrition during weight maintenance for both groups was lack of attendance. Participants would not always provide reasons for their unwillingness to continue attendance or they intentionally discontinued correspondence and were removed from the study because they dropped below the required attendance level (75%). As a result, in some cases we do not know the actual reasons for those classified as dropping out due to lack of attendance. Other studies have also reported high rates

of attrition up to 38% for low carbohydrate groups and 46% for low fat groups [6-8]. In a recent meta-analysis of 5 low carbohydrate vs. low fat trials reported by Nordmann et al, attrition rates were 30% and 43% for a low carbohydrate and low fat diet, respectively, after 6 months and 38% and 46%, respectively, after 12 months [18].

Prevention of weight re-gain is difficult for many individuals [19-21]. The main finding of this investigation was that subsequent to substantial weight loss on a VLED a low carbohydrate diet and a low fat diet were similar for weight maintenance over 6 months. For the low carbohydrate group, body weight remained approximately 19% below baseline body weight and the low fat group remained approximately 18% below baseline body weight.

However, not all participants responded uniformly to either intervention. Fifty-five percent and 50% for the low carbohydrate and low fat groups, respectively, continued to decrease their body weight during weight maintenance while the remainder re-gained a portion of their body weight. Differences between weight gainers and losers within the low carbohydrate and low fat groups were not statistically significant for energy intake or carbohydrate and fat gram intake. However, one statistically significant difference in dietary intake between the low carbohydrate weight gainers and losers is noteworthy. The low carbohydrate weight losers consumed an average of 15 g of protein/day more than the low carbohydrate weight gainers (P=0.02). This is consistent with other human and rodent studies [10, 22]. For instance, Westerterp-Plantenga et al reported that additional protein intake (18% vs. 15%) resulted in less weight re-gain after 4 weeks of weight loss on a VLED [10, 22]. Thus, we cannot rule out the possibility that the increased protein intake for the low carbohydrate group weight losers was an important factor for their continued decrease in body weight. In addition, increasing the ratio of protein to carbohydrate, as reported by Layman et al, may have also contributed to the increased weight

loss for the low carbohydrate participants [23]. As this study was not set up to address these mechanisms, further studies are warranted.

Physical activity is an important component of successful weight maintenance [24, 25]. In addition, interventions that promote lifestyle changes along with PA have shown better weight maintenance than interventions that do not have these components [24]. However, for most individuals, weight increases across time [24]. Physical activity was an important component for participants of the present study and compliance to the study protocol for PA was good and was similar for both groups. In this study both groups were prescribed an identical amount of PA and there was little variation between groups. As a result, any difference in body weight change between groups during weight maintenance is not likely due to differences in PA.

Some participants were on prescription medications during the study. However, medication use was stable and did not change and statistical adjustment for medication use did not significantly influence body weight outcomes. As a result, we do not believe that medication use was a confounding factor. Further, the results are likely to generalize well to the overweight or obese adult population, who are typically taking 1 or more medications for co-morbid diseases such as blood pressure, depression, and lipids [26].

Energy Intake

Participants were required to report carbohydrate or fat gram intake at each group meeting to assure compliance with the specific dietary protocol and to keep detailed food records at baseline, 3, 6, and 9 months in order to examine the role of energy and macronutrient intake on potential body weight regain. To date, we are unaware of a standardized definition of a low carbohydrate diet. However, Bilsborough and Crowe have suggested that a low carbohydrate diet is one containing <100 g of carbohydrate/day or approximately 30% or less of total kJ from

carbohydrate [27]. In the present study, the low carbohydrate group averaged 91 g of carbohydrate per day accounting for 25% of their total daily energy intake. Thus, the present study is consistent with the definition of low carbohydrate diet as suggested by Bilsborough and Crowe [27]. For the low fat group, the energy consumption and fat intake of <30% of total kJ from fat was similar to those levels seen in other studies comparing a low carbohydrate and low fat diet [7-9].

Under reporting of energy intake is a common phenomenon recognized by many researchers and clinicians. Weber et al. analyzed two large data bases for under-reporting and found that lean women under-reported energy intake by 23% to 30%, and obese women under-reported energy intake by ~39% when compared to total energy expenditure measured by doubly labeled water [28]. Despite the similar energy intake and macronutrient content of the diet in the present study to other comparison studies, it is probable that both groups significantly under-reported energy intake as their averages were lower than what is physiologically plausible for adults of their size to maintain their weight.

Adverse Events

There were more total adverse events in the low carbohydrate group than in the low fat group. However, it should be noted that when adverse events were considered excluding the re-feeding period (month 4) the total number of adverse events reported were essentially the same for both groups. It is possible that the transition from a liquid VLED to solid food is more difficult when consuming a low carbohydrate diet or that our method of re-feeding can be improved to smooth this transition. Commonly reported adverse events for the low carbohydrate group were consistent with other studies, specifically, constipation, and diarrhea [8, 29]. One participant in the low carbohydrate group had an unexplainable increase in total cholesterol after 3 months on

the low carbohydrate diet (total cholesterol increased from 136 to 306 mg/dL). This participant was advised to seek medical attention immediately. After consultation with a physician, a lipid lowering medication was prescribed and this participant's cholesterol levels immediately returned to normal.

Limitations

We recognize that there are several limitations with this study. (1) The diet and PA data were self-reported. There are known biases and limitations with self-reported data, such as under-reporting energy intake [28]. Nevertheless, diet records are commonly used and acceptable research instruments. There were considerably more women than men participants and so results were not reported by gender. (2) We chose to use a quazi-experimental design rather than to randomize individual participants to a particular group. This was done because the popularity of the Atkins diet was at its height during our data collection. We felt that if participants assigned to different dietary protocols were in the same group or location there would be increased likelihood of data contamination by participants choosing to follow the dietary protocol of their choice rather than their assignment. We note there were no significant differences between groups at baseline for anthropometric characteristics and doubt any appreciable bias was present. (3) The data collected for adverse events may be biased due to the assessment method. Adverse event data was collected from participants by administering a single sided page that listed specific adverse events seen in other low carbohydrate and low fat studies. We may have inadvertently prompted the participants to consider a specific adverse event they would not necessarily have reported had it not been listed.

Since this was a study analyzing results only for compliant participants, non-compliant participants including participants that did not attend at least 75% of meetings, and those without

complete laboratory data were terminated from the investigation and analysis. We recognize that this was not an effectiveness study and that application of the results to the general population will require a larger, randomized, controlled trial.

Conclusions

This study addressed a significant gap in the current low carbohydrate literature by comparing body weight in participants on either a low carbohydrate diet or low fat diet during a 6 month weight maintenance period following weight loss. The primary finding of this study was that a low carbohydrate and low fat diet, combined with a behaviorally based weight management program, are effective and comparable for body weight maintenance over 6 months.

List of Abbreviations

BW=Body Weight (Abstract Only)

PA=Physical Activity

g=grams

min=minutes

kJ=kilojoules

kg=kilograms

BMI=body mass index

VLED=very low-energy diet

REE=resting energy expenditure

cm=centimeters

Competing Interests

Dr. Mary C. Vernon receives honoraria as a consultant for Mrs. Veronica Atkins, Chairperson of the Board of Directors for the Robert C. Atkins Foundation. The Atkins Foundation provided partial support for this project. The remaining authors declare that they have no competing interests.

Authors Contributions

JD conceived the study design with input from JL, RW, DS, CG, SH, MV, and EW. JL, CC, and ES coordinated and executed all aspects of the study with input from RW, DS, CG, and SH. MV provided medical oversight of all subjects. Data were analyzed by JL with support by SH. The manuscript was prepared by JL and JD, and all authors contributed to the editing of the final manuscript.

Acknowledgements

The following research has been supported, in part, by Health Management Resources and the Atkins Foundation.

References

1. Kramer FM, Jeffery RW, Forster JL, Snell MK: **Long-term follow-up of behavioral treatment for obesity: patterns of weight regain among men and women**. *Int J Obes* 1989, **13**:123-136.
2. Safer DJ: **Diet, behavior modification, and exercise: a review of obesity treatments from a long-term perspective**. *South Med J* 1991, **84**:1470-1474.
3. Kruger J, Blanck HM, Gillespie C: **Dietary and physical activity behaviors among adults successful at weight loss maintenance**. *Int J Behav Nutr Phys Act* 2006, **3**:17.
4. Lantz H, Peltonen M, Agren L, Torgerson JS: **A dietary and behavioural programme for the treatment of obesity. A 4-year clinical trial and a long-term posttreatment follow-up**. *J Intern Med* 2003, **254**:272-279.
5. Brehm BJ, Seeley RJ, Daniels SR, D'Alessio DA: **A randomized trial comparing a very low carbohydrate diet and a calorie-restricted low fat diet on body weight and cardiovascular risk factors in healthy women**. *J Clin Endocrinol Metab* 2003, **88**:1617-1623.
6. Foster GD, Wyatt HR, Hill JO, McGuckin BG, Brill C, Mohammed BS, Szapary PO, Rader DJ, Edman JS, Klein S: **A randomized trial of a low-carbohydrate diet for obesity**. *N Engl J Med* 2003, **348**:2082-2090.
7. Samaha FF, Iqbal N, Seshadri P, Chicano KL, Daily DA, McGrory J, Williams T, Williams M, Gracely EJ, Stern L: **A low-carbohydrate as compared with a low-fat diet in severe obesity**. *N Engl J Med* 2003, **348**:2074-2081.
8. Yancy WS, Jr., Olsen MK, Guyton JR, Bakst RP, Westman EC: **A low-carbohydrate, ketogenic diet versus a low-fat diet to treat obesity and hyperlipidemia: a randomized, controlled trial**. *Ann Intern Med* 2004, **140**:769-777.
9. Stern L, Iqbal N, Seshadri P, Chicano KL, Daily DA, McGrory J, Williams M, Gracely EJ, Samaha FF: **The effects of low-carbohydrate versus conventional weight loss diets in severely obese adults: one-year follow-up of a randomized trial**. *Ann Intern Med* 2004, **140**:778-785.
10. Westerterp-Plantenga MS, Lejeune MP, Nijs I, van Ooijen M, Kovacs EM: **High protein intake sustains weight maintenance after body weight loss in humans**. *Int J Obes Relat Metab Disord* 2004, **28**:57-64.
11. Lin PH, Proschan MA, Bray GA, Fernandez CP, Hoben K, Most-Windhauser M, Karanja N, Obarzanek E: **Estimation of energy requirements in a controlled feeding trial**. *Am J Clin Nutr* 2003, **77**:639-645.
12. Lohman TG: **Research progress in validation of laboratory methods of assessing body composition**. *Med Sci Sports Exerc* 1984, **16**:596-605.
13. Schuna AA: **1988 report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure: a commentary**. *Clin Pharm* 1988, **7**:837-841.
14. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, Jr., Jones DW, Materson BJ, Oparil S, Wright JT, Jr. *et al*: **The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report**. *Jama* 2003, **289**:2560-2572.
15. Mustajoki P, Pekkarinen T: **Very low energy diets in the treatment of obesity**. *Obes Rev* 2001, **2**:61-72.

16. Prasad N: **Very-low-calorie diets. Safe treatment for moderate and morbid obesity**. *Postgrad Med* 1990, **88**:179-182, 187-178, 190.
17. Wadden TA: **Treatment of obesity by moderate and severe caloric restriction. Results of clinical research trials**. *Ann Intern Med* 1993, **119**:688-693.
18. Nordmann AJ, Nordmann A, Briel M, Keller U, Yancy WS, Jr., Brehm BJ, Bucher HC: **Effects of low-carbohydrate vs low-fat diets on weight loss and cardiovascular risk factors: a meta-analysis of randomized controlled trials**. *Arch Intern Med* 2006, **166**:285-293.
19. Brownell KD, Kramer FM: **Behavioral management of obesity**. *Med Clin North Am* 1989, **73**:185-201.
20. Foreyt JP, Goodrick GK: **Evidence for success of behavior modification in weight loss and control**. *Ann Intern Med* 1993, **119**:698-701.
21. van Dale D, Saris WH, ten Hoor F: **Weight maintenance and resting metabolic rate 18-40 months after a diet/exercise treatment**. *Int J Obes* 1990, **14**:347-359.
22. Kennedy AR, Pissios P, Otu HH, Xue B, Asakura K, Furukawa N, Marino FE, Liu FF, Kahn BB, Libermann TA *et al*: **A High Fat, Ketogenic Diet, Induces a Unique Metabolic State in Mice**. *Am J Physiol Endocrinol Metab* 2007.
23. Layman DK, Boileau RA, Erickson DJ, Painter JE, Shiue H, Sather C, Christou DD: **A reduced ratio of dietary carbohydrate to protein improves body composition and blood lipid profiles during weight loss in adult women**. *J Nutr* 2003, **133**:411-417.
24. McGuire MT, Wing RR, Klem ML, Lang W, Hill JO: **What predicts weight regain in a group of successful weight losers?** *J Consult Clin Psychol* 1999, **67**:177-185.
25. Shick SM, Wing RR, Klem ML, McGuire MT, Hill JO, Seagle H: **Persons successful at long-term weight loss and maintenance continue to consume a low-energy, low-fat diet**. *J Am Diet Assoc* 1998, **98**:408-413.
26. Potteiger CE, Paragi PR, Inverso NA, Still C, Reed MJ, Strodel W, 3rd, Rogers M, Petrick A: **Bariatric surgery: shedding the monetary weight of prescription costs in the managed care arena**. *Obes Surg* 2004, **14**:725-730.
27. Bilsborough SA, Crowe TC: **Low-carbohydrate diets: what are the potential short- and long-term health implications?** *Asia Pac J Clin Nutr* 2003, **12**:396-404.
28. Weber JL, Reid PM, Greaves KA, DeLany JP, Stanford VA, Going SB, Howell WH, Houtkooper LB: **Validity of self-reported energy intake in lean and obese young women, using two nutrient databases, compared with total energy expenditure assessed by doubly labeled water**. *Eur J Clin Nutr* 2001, **55**:940-950.
29. Westman EC, Yancy WS, Edman JS, Tomlin KF, Perkins CE: **Effect of 6-month adherence to a very low carbohydrate diet program**. *Am J Med* 2002, **113**:30-36.

Figures

Figure 1. Body weight across weight maintenance for low carbohydrate and low fat groups.

Figure 2. Individual participant responses in body weight for the low carbohydrate group during weight maintenance

Figure 3. Individual participant responses in body weight for the low fat group during weight maintenance

.

Tables

Table 1. Reasons for withdrawal from the study at each 3 month interval for the low carbohydrate and low fat groups.

	Base to 3 months	3 to 6 months	6 to 9 months	Total
Lack of Attendance	0/0	2/6	7/1	**9/7**
Disliked the Dietary Protocol During Maintenance	NA	3/0	1/1	**4/1**
Unable to Comply with a Liquid VLED During Weight Loss	4/3	NA	NA	**4/3**
Injury	0/0	2/0	0/0	**2/0**
Disliked Record Keeping or Other Components of the Program	0/0	1/4	0/2	**1/6**
Monetary Conflict	0/0	1/0	0/1	**1/1**
Pregnant	0/0	1/0	0/0	**1/0**
Work Conflicts	0/0	1/2	0/1	**1/3**
Family Conflict	0/0	0/0	0/2	**0/2**
Moved from Area	0/0	0/1	0/0	**0/1**
Total Dropouts	4/3	11/13	8/8	**23/24**

Low carbohydrate/low fat

655

Table 2. Baseline characteristics of completers by group.

660

	LC	LF	*P*
N	29	26	
Weight (kg)	109.6 ± 17.3	105.5 ± 15.9	0.36
BMI (kg/m^2)	39.1 ± 5.0	37.6 ± 4.9	0.27
Waist (cm)	110.5 ± 12.7	106.6 ± 9.6	0.21
Age (y)	47.9 ± 10.1	45.7 ± 10.6	0.28

Mean ± SD. LC=Low carbohydrate group. LF=Low fat group.

665

670

675

680

Table 3. Macronutrient intake at baseline and during weight maintenance for the low carbohydrate and low fat groups.

	Baseline		Maintenance	
	LC	LF	LC	LF
Energy Intake (kJ)	7761 ± 1980	9439 ± 2428†	5923 ± 1754*	6911 ± 1967*‡J
Carbs (g)	192.90 ± 51.88	229.76 ± 79.62†	90.94 ± 38.98*	221.47 ± 67.46‡
Protein (g)	85.12 ± 28.05	90.24 ± 22.34	93.34 ± 30.46	84.00 ± 22.70‡J
Fat (g)	83.2 ± 29.0	102.53 ± 31.75†	76.43 ± 30.70	47.58 ± 20.48*‡
Alcohol (g)	2.93 ± 5.61	10.71 ± 14.80†	2.46 ± 6.03	8.45 ± 16.07‡
Dietary Fiber (g)	16.02 ± 5.29	15.17 ± 5.48	13.59 ± 5.94	25.33 ± 9.95*‡

Mean ± SD. LC=low carbohydrate group. LF=low fat group.

†Indicates a significant difference between groups at baseline.

*Indicates a within group difference between baseline and maintenance.

‡Indicates a between group difference.

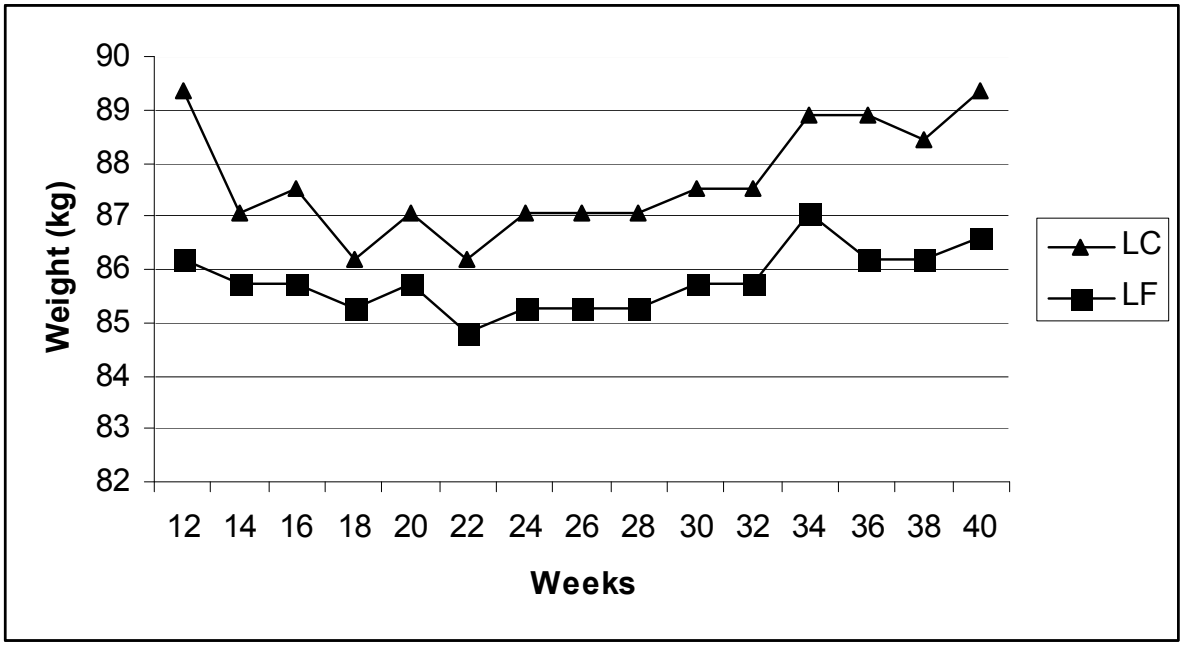
J No statistical difference between groups during weight maintenance after control of baseline values.

Table 4. Body weight, BMI, and waist circumference for the low carbohydrate and low fat groups during weight maintenance.

	3-Months		6-Months		9-Months	
	LC	LF	LC	LF	LC	LF
N	29	26	29	26	29	26
Body Weight (kg)	89.2 ± 14.4	86.3 ± 11.9	87.1 ± 15.0	85.3 ± 13.2	89.3 ± 16.1	86.0 ± 14.0
BMI (kg/m^2)	31.8 ± 4.5	30.9 ± 4.2	31.1 ± 4.8	30.5 ± 4.5	31.9 ± 5.3	30.8 ± 5.2
Waist (cm)	95.9 ± 10.7	91.4 ± 8.7	94.9 ± 14.5	91.4 ± 10.3	96.3 ± 12.7	93.4 ± 10.5

Mean ± SD. LC=low carbohydrate group. LF=low fat group. No significant interactions, no differences at 3 months, or within/between groups differences across the duration of the study ($P>0.05$).

Figure 1. Body weight across weight maintenance for low carbohydrate and low fat groups.



LC=low carbohydrate group. LF=low fat group. No significant group*time interaction or within group differences (P>0.05).

Figure 2. Individual Participant Responses in Body Weight for the Low Carbohydrate Group during Weight Maintenance

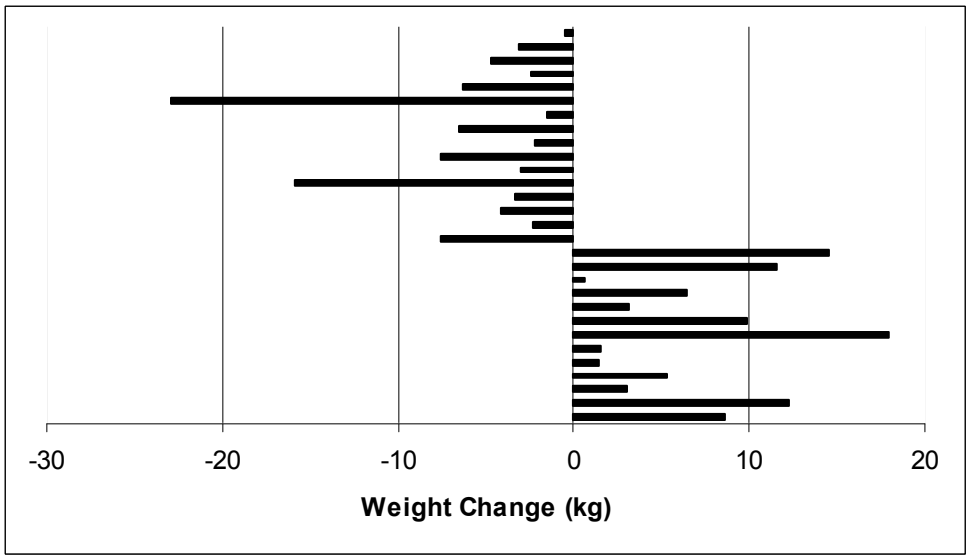


Figure 3. Individual participant responses in body weight for the low fat group during weight maintenance

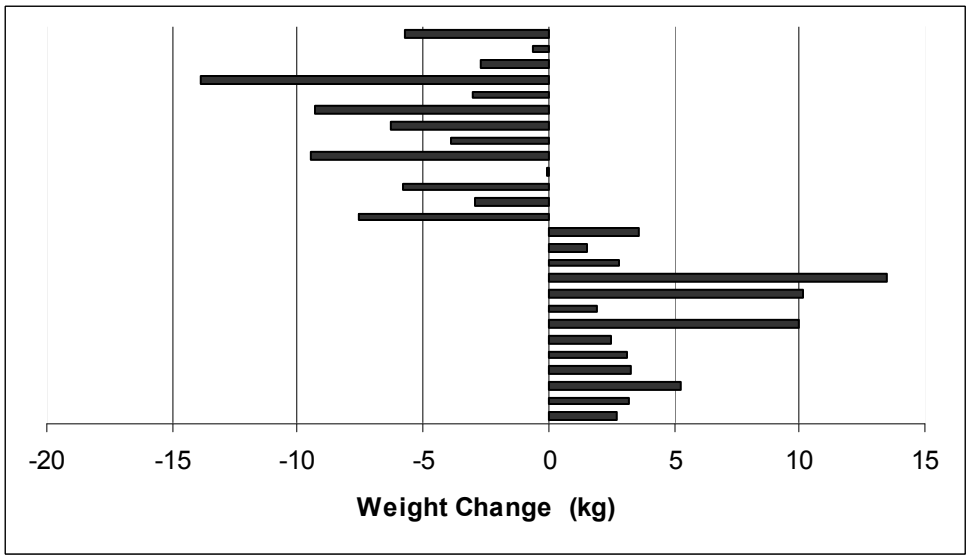


Figure 3