# 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**

Bonnie J. Brehm

Thursday, September 3, 2020 1:47 PM

#### Introduction

This study investigated the affect the ketogenic diet had on a series of health markers (blood pressure, weight loss, blood sugar, and much more

## Conclusions

- The ketogenic diet likely has greater satiety than a low fat diet.
- The ketogenic diet leads to greater weight and fat loss than a low fat diet.
- The ketogenic diet decreased lean mass more than a low fat diet.
- The ketogenic diet does not negatively affect blood pressure, blood sugar, insulin, leptin, cholesterol, or triglycerides over 6 months, with weight loss.

#### Amendments

The ketogenic diet group maintained ketosis only for the first 3 months of their diet intervention, not the full 6 months.

## Study Design & Additional Information

This study was designed using only women who were overweight (but weight stable defined as not gaining or losing more than 10% of their bodyweight in the last 6 months), but largely healthy. 20 participants were put into a low fat group with the expressed instructions to limit kcalorie intake to below maintenance (~ 450 kcalorie deficit). 22 participants finished the study as the ketogenic diet (low carbohydrate) group that was not expressly instructed to reduce energy consumption. Participants worked with two dietitians over the first 3 month period and participants met with counselors over the weeks going over their nutrition tracking for the week. The final 3 months the participants were not given weekly check ins (making the study last a total of 6 months).

0013-7227/03/815.00/0 Printed in U.S.A.

The Journal of Clinical Endocrinology & Metabolism 88(4):1617-1042 Copyright © 20103 by The Endocrine Society doi: 10.1210/js.2002-021480

## 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**

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Untested alternative weight loss diets, such as very low carbohydrate diets, have unsubstantiated efficacy and the po-tential to adversely affect cardiovascular risk factors. There-fore, we designed a randomized, controlled trial to determine he effects of a very low carbohydrate diet on body composi-ized to 6 months of either in *nd* libitum very low carbohydrate diet or a calorie-restricted diet with 30% of the calories as fat. Anthropometric and metabolic measures were assessed at baseline, 3 months, and 6 months. Fifty-three healthy, obese female volunteers (mean body mass index, 35.6  $\pm$  0.3 kg/m<sup>3</sup>) both diets reduced calorie consumption by comparable amounts at 3 and 6 months. The very low carbohydrate diet

group lost more weight ( $8.5 \pm 1.0$  rs.  $3.9 \pm 1.0$  kg; P < 0.001) and more body fat ( $4.8 \pm 0.67$  rs.  $2.0 \pm 0.75$  kg; P < 0.01) than the low fat diet group. Mean levels of blood pressure, lipids, fasting glucose, and insulin were within normal ranges in both groups at baseline. Although all of these parameters improved over the course of the study, there were no differences ob-body and groups at baseline. Although all of these parameters improved interval of the study, there were no differences ob-body drate groups at 3 months (P = 0.001). Based on these data, a very low carbohydrate diet is more effective than a low fat diet for short-term weight loss and, over 6 months, is not as-sociated with deleterious effects on important cardiovascular risk factors in healthy women. (*J Clin Endocrinol Metab* 88: 1617–1623, 2003)

wk) (9-16), the clinical benefits of ketogenic diets are

wk) (9–16), the clinical benefits of ketogenic diets are unproven. Because low carbohydrate diets derive large proportions of calories from protein and fat, there has been considerable concern for their potentially detrimental impact on cardio-vascular risk (17). Increased consumption of fat, particularly saturated fat, has been linked to increased plasma concen-trations of lipids (18), insulin resistance, glucose intolerance (19, 20), and obesity (21, 22). Therefore, it is possible that many Americans could actually suffer adverse health effects by using very low carbohydrate diets in an attempt to lose weight. To evaluate the effects of a very low carbohydrate diet on weight loss and cardiovascular risk factors, we ran-domized 53 healthy obses women to 6 months of a very low carbohydrate the guidelines currently recommended by the American Heart Association and other expert panels (23).

#### Subjects and Methods

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Subjects Subjects Fifty-three obese females were recruited by advertisement and ran-domized to the 2 diets based on a prior estimate that 20-25 subjects/ group wouldbe sufficient to demonstrate 25% difference in weight loss and a 30% difference in low density lipoprotein (LDI) cholesterel levels between the 2 segments. Inclusion conteris were age takest 18 yr, mod-between the 2 segments. Inclusion conteris were age takest 18 yr, mod-preceding 6 months (no weight loss or gain >10% of their body weight). Exclusion criteria were the presence of ancifovascular disease, untreated hypertension, diabetes, hypothyroidism, substance abuse, pregancy, or lactation. All subjects gave informed corsent for the study, which was approved by the University of Cincinnati and Cincinnati Children's Hoopital Medical Center institutional review bords.

THE INCIDENCE OF obesity in the United States has risen continuously over the last several decades, and the associated medical and economic costs to society are substantial (1-3). Despite considerable desire on the part of obese individuals to lose weight (4) and the clear health benefits of doing so (5), there are currently no proven, ef-fective approaches for meaningful and long-term weight loss for most overweight individuals (2). Dietary strategies sup-orted by the majority of physicians and dietitians, which emphasize restriction of fat intake, are associated with only modest weight loss and poor long-term compliance (6, 7). emphasize restriction in an intake, are associated with only modest weight loss and poor long-term compliance (6, 7). Given these difficulties and the popular demand for effective weight loss methods, it is not surprising that a number of diet plans have been developed outside the medical and nutri-tional mainstream that are marketed directly to the public as

tional mainstream that are marketed directly to the public as weight loss strategies. The very low carbohydrate, high protein diet, promoted extensively by Atkins and others, is one of the most popular of the alternative weight loss approaches (8). The central rationale of this diet is that severe restriction of dietary car-bohydrate (<10% of daily caloric intake), with its resulting ketosis, promotes lipid oxidation, satiety, and increased en-ergy expenditure, factors that should promote negative en-ergy balance and weight loss (8). However, these purported responses to very low carbohydrate feeding have not been established. Furthermore, as studies that severely restrict carbohydrate intake have all been of short duration (*i.e.* <6

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Abbreviations: DEXA, Dual energy x-ray absorptiometry; HDL, high usity lipoprotein; LDL, low density lipoprotein.

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1. Very low carbohydrate diets increase ketosis (ketone production), increased fat oxidation ("burning"), satiety, and increased energy use

Researchers recruited enough participants (all women) to have 20 to 25 people in each group. The two groups were a "high carb, low fat" group and "very low carbohydrate, high fat diet (ketogenic style)" group. Participants were overweight, but had not lost or gained more than 10% of their bodyweight in the last 6 months, making them "weight stable" and had to be in generally good health with no health abnormalities.

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## Assessments

Assessmenta Subject assessments were conducted at the General Clinical Research Center of Cincinnati Children's Hospital Medical Center by trained research nurses. Subjects were accremed by medical history and mes-surements of height, weight, bloed pressure, and fasting glucose, and each was given an electrocardingsrum. Bloed pressure measurements subject seated quietly. Individuals moeting the criteria for study par-ticipation were enrolled in the study by the research assistant or the principal investigator. Subjects gave a sample of fasting bloed and had body fat messing by data deregy x-ray absorptionetry (DEXA) using a total body scanner (#S00A, Hologic, Inc., San Francisco, CA), DEXA General Clinical Research Center by trained technicians. Each of these measures was repeated after 3 and 6 months of diet.

#### Study diets

Study diets The primary objective of the study was to compare the effects of a wey composition and cardiovascular risk factors. Therefore, after each block of subjects was assessed, the principal investigator used a random num-ber table to randomly assign those subjects to one of two diets. One proup of dieters was instructed to follow and lithium diet with a dimensional state of the study of the study of the study of the principal state of the study of the direct study of the study of the study of the study of the direct study of the study of uniform of the study of the study of the study of the study of direct study of the and addressed of completions of the study of the and addressed of completions of the study of the study of the and addressed of completions of the study of the study of the and addressed of completions of the study of the study of the study and addressed of completions of the study of the study of the study of the and addressed of completions the study of the study of the study of the and addressed begins the study of the study of the study of the study of the and addressed begins the study of the study of the study of the study at a study of the study of the study of the study of the study at a study and study of the study of the study of the study at a study of the study at a study and study and study of the study of the study of the study at a study and subjects from read of the study of the study at a study of the study of t

#### Analyses

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Determination of total cholesterol, LDL cholesterol, high density li-poprotein (HDL), cholesterol, glucose, insulin, leptin, j-hydroxybu-trate, and trigbycridis in fasting paisma were made using conventional methods (25-27). The results of DEXA and biochemical analyses were made by personnel blinded to the group assignment of the subjects.

#### Statistics

Statistics Baseline characteristics were compared between the two groups us-ing tests. To assess the effects of the diets, two-way repeated measures ANOVA, with time as the repeated factor, was performed using the software package SAS (version SZ, SAS Institute, Inc., Cary, NC). The level of significance was set at 0.05 for testing the main effects of det and before the software package software software and the software package software software software and the software software before the software software software software and the Beoefficient differences. If the interaction was significant, the Bonferroet adjustment was used to keep the overware significance at 0.05. Differences between groups are indicated only when there is a signif-

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icant interaction between diet and time. Body weight, biochemical pa-rameters, and DEXA measurements were analyzed for the 42 subjects who completed the study (iz. those for whom follow-up data were available). Body weight was also analyzed for the entire randomized cohort. In this intention to treat analysis, the initial weights for the subjects who withdress from the study were used as their follow-up weights al 3 and 6 months (iz. an assumption of 04 go everyph10es). Data are presented as the mean and st unless designated otherwise.

#### Results

Subjects

Subjects Subjects were recruited through advertisements from May 2000 through January 2001. Fifty-three obese females (13 African-Americans and 40 Caucasians) were enrolled in the study. Volunteers were enrolled in 3 successive groups of 14, 20, and 19 subjects at 3- to 4-month intervals. Forty-two of the 53 subject (7%)6 completed the 6-month study, with 4 drop-outs from the very low carbohydrate diet group and 7 drop-outs from the low fat diet group (Fig. 1). The majority of subjects discontinuing the study cited difficulty maintaining the scheduled visits as the primary reason, and follow-up measurements were obtained for only 1 of the these women. One subject from each diet group dropped out due to dislike for their assigned diet. Age and anthropometric character-istics of those subjects completing the study are included in Table 1. Table 1

#### Nutrient intake

Subjects randomized to the low fat (n = 20) and the very low carbohydrate (n = 22) diet groups consumed similar amounts of calories at the initiation of the diets (1707  $\pm$  104 and 1608  $\pm$  123 kcal respectively) with similar distribution of macronutrients (Fig. 2). Based on the results of the weekly food records, subjects compiled with their assigned diets. Although subjects on the carbohydrate-restricted diet were



3. Participants of the study split into two groups: 1. very low carbohydrate (high fat) ketogenic diet that they were allowed to consume "at will" (meaning, they were not prompted to necessarily try to count calories or how much they were consuming), and 2. a calorie restricted, low fat diet. Participants were randomly assigned to avoid bias. Participants worked with two dietitians over the first 3 month period and participants met with counselors over the weeks going over therin tritto tracking for the week. The final 3 months the participants were not given weekly check ins (making the study last a total of 6 months).

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not specifically asked to limit caloric intake as were those on the low fail die, both groups reported a decrease in caloric intake of approximately 450 calories compared with baseline. Although caloric intakes in the two groups were similar, the proportions of carbohydrate, protein, and fat consumed dif-fered dramatically. At 3 months, caloric intake in the very low carbohydrate diet group was distributed as 15% carbo-hydrate. 2% protein, and 5% fat. In contrast, the low fat diet group had daily calories distributed as 54% carbohydrate, 18% protein, and 28% fat. At 3 months, the very low carbo-hydrate diet group consumed significantly less carbohy-drate, vitamin C, and fiber and significantly more protein, total fat, saturated fat, monumsaturated fat, polyunsatu-rated fat, and cholesterol than the low fat diet group (P < 0.01for all comparisons). At 6 months, the two groups still dif-fered significantly for most of these measures (Table 2).

#### Weight and body composition

Body weight and body fat in the low fat and very low carbohydrate groups were similar at baseline (Table 1). After the initiation of the diets, both groups had a decrease in body

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weight that was more rapid in the earlier weeks of obser-vation and became less pronounced as the study progressed (Fig. 3). The women in the very low carbohydrate group lost an average of  $7.6 \pm 0.7$  kg after 3 months and 8.5  $\pm 1.0$  kg after 6 months of diet. Women following the low fat diet lost  $4.2 \pm 0.8$  and  $3.9 \pm 1.0$  kg at 3 and 6 months, nespectively. The amount of weight lost was significantly greater in the very low carbohydrate group compared with the low fat group, whether analyzed as intention to treat with all randomized subjects in the analysis (P < 0.001 at 3 and 6 months) or with only the subjects who competed the trial (Fig. 3. P < 0.001only the subjects who completed the trial (Fig. 3; P < 0.001at 3 and 6 months).

at 5 and 6 months). Body composition data for the two groups of women are shown in Table 3. Both fat mass and fat-free mass decreased significantly (P < 0.001) in the two groups over the course of the trial. However, similar to body weight, fat mass and lean body mass decreased significantly more in the very low carbohydrate group compared with the low fat group at both 3 and 6 months (P < 0.01). The reduced fat mass comprised D = 60% of the weight lost in both groups. There were no changes in bone mineral content over the course of the study.



## Table 1

This table shows the baseline characteristics of the two groups - so, this is before the study started.

#### **Primary Results**

cant differences between the two groups. were no sig

Take Away: We will be able to compare the groups against each other, because they are similar enough at the beginning of the study.

#### Figure 2

This figure shows the kcalorie consumption, per day, at the beginning of the study (baseline), then again at 3 months and at the end (6 months); it also shows the proportion of each macronutrient (Lines c archodyrdrates, White = protein, Blacks = fait). Low Card Group = Ketogenic Diet without instructed kcalorie restriction; Low Fat Group = Instructed kcalorie restriction diet, high carbohydrate.

Primary Results ts led to a significant decrease in kcalorie consumption. - Both die

Take Away. The Ketogenic diet (Low Carb Group) may have an innate satiety effect leading to lower kcalorie consumption without having to be mindful of kcalorie intake.

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TABLE 2. Mean nutrient intake of women before and after 3 and 6 months of dieting

	Baseline	3 months	6 months	Recommended intake <sup>a</sup>	
Very low carbohydrate diet grou	p(n = 22)				
Carbohydrate (g)	188.92	$41.13^{\circ}$	96.98°	$\geq$ 55% total keal	
Protein (g)	63.32	$78.15^{\circ}$	74.13 <sup>c</sup>	10-15% total keal	
Total fat (g)	65.79	$71.32^{c}$	65.45°	≤30% total kcal	
Saturated fat (%)	12.4	$20.7^{\circ}$	17.4 <sup>b</sup>	≤10% total kcal	
Monounsaturated fat (%)	10.1	20.6°	15.8°	10% total kcal	
Polyunsaturated fat (%)	6.2	9.0°	8.2	10% total kcal	
Cholesterol (mg)	215.25	460.87°	285.44 <sup>6</sup>	<300	
Vitamin C (mg)	70.28	35.65	58.46	75	
Folate (µg)	155.14	139.65	195.89	400	
Calcium (mg)	590.81	444.20	739.01	1000	
Fiber (g)	12.03	$5.27^{\circ}$	8.40°	20-35	
Low fat diet group $(n = 20)$					
Carbohydrate (g)	200.06	169.40	162.88	$\geq$ 55% total kcal	
Protein (g)	66.06	55.93	54.74	10–15% total keal	
Total fat (g)	71.60	39.77	43.13	≤30% total kcal	
Saturated fat (%)	12.3	9.9	11.1	$\leq 10\%$ total kcal	
Monounsaturated fat (%)	10.1	9.0	7.3	10% total kcal	
Polyunsaturated fat (%)	5.8	4.5	3.7	10% total kcal	
Cholesterol (mg)	273.51	169.00	182.21	<300	
Vitamin C (mg)	76.92	94.18	53.14	75	
Folate (µg)	170.95	221.72	193.90	400	
Calcium (mg)	607.25	567.19	662.62	1000	
Fiber (g)	12.48	13.31	12.35	20-35	

<sup>b</sup> Denotes values different from the low fat diet group,  $P \simeq 0.05$ <sup>c</sup> Denotes values different from the low fat diet group,  $P \simeq 0.01$ 



Fig. 3. Mean body weight of women randomized to very low carbo-hydrate and low fat diets over the course of the 6-month trial. The first time point (wk 1) represents the subject's body weights immediately before randomization. Follow-up for the 2 groups included 17–20 subjects in the low fat group and 10–92 subjects in the very low carbohydrate group. For subject amissing a follow-up visit, their last reserved weight is included in the calculation of the group mean, ", Value different from very low carbohydrate diet group (i.e. signif-ient interaction of time and diet, P < 0.001.

Cardiovascular risk factors

EKG. There were no electrocardiographic abnormalities in any of the subjects during the study.

any or the subject burning the study. Bload pressure. The blood pressures in the two groups were within the normal range at the outset of the study and re-mained so throughout the study (Table 4). Significant dif-ferences in blood pressure were not found between the groups during the study.

Plasma lipids. Mean plasma concentrations of total choles-terol, triglycerides, LDL cholesterol, and HDL cholesterol were normal in each of the two groups before starting the diets. A significant interaction ( $l^p < 0.05$ ) was found for plasma triglycerides, but this was probably due to a differ-ence between the groups at baseline. Differences in plasma lipids between the groups at baseline. Differences in plasma lipids between the lipids of the start time effects ( $l^p <$ 0.01) for all of the plasma lipids indicated that the subjects improved their lipids profiles during the course of the study, with significant decreases in total cholesterol, LDL choles-terol, and triglycerides at 5 months and significant increases in HDL cholesterol at 6 months (Table 4).

in HDL cholesterol at 6 months (Table 4). Fasting hormones and substrates. Fasting glucose and insulin did not differ between the two groups at the 3- or 6-month assessments. However, significant time effects for glucose and insulin levels decreased significantly in the women on the distribution of the second significantly in the women on differences in leptin levels between the two groups (Table 5). Yet a significant time effect (P < 0.0001) indicate that the glucose and insulin levels decreased significantly in both groups of sub-science of the second the second significantly in both groups of sub-gicst at 3 months (Table 5). A significant difference between the groups was detected for plasma β-hydroxybutyrate, with this ketone increasing significantly more in the very low carbohydrate group at 3 months (P = 0.0005) Table 5). Weekly testing of urinary ketones was positive in the ma-pirity of subjects on the very low carbohydrate diet and negative in those on the low fat diet.

#### Discussion

The results of this study demonstrate that a very low carbohydrate diet, taken without a specified restriction of

Table 2

The researchers are showing the information from the food logs from baseline, 3 months into their respective diets (low carb/ketogenic and high carb/kcalorie restricted), and 6 months (end of the study).

#### Primary Results:

Primary Results: - Ketogenic diet has low carbohydrate intake and high fat intake. - Low Fat diet has high carbohydrate and low fat intake. - Ketogenic diet consumed more saturated and unsaturated fats than the low fat diet. - Cholesterol consumption was higher with the ketogenic diet. - Ketogenic diet consumed more protein.

Ketogenic diet consumed less fiber.

Take Away: There are many differences in key nutrient consumption between the two diets, making further results difficult to interpret.

## Figure 3

rchers are showing the change in bodyweight between the two diets.

Primary Results
- Both diet groups experienced weight loss.
- The ketogenic diet experienced more weight loss from week 12 onward.

Take Away: While both groups lead to weight loss, the ketogenic diet leads to greater weight loss over a 6 month period

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caloric intake, is effective for weight loss over a 6-month period in healthy, obese women. Compared with the low fat group, who followed a diet conforming to currently recom-mended distributions of macronutrient calories, the very low carbohydrate group lost significantly more weight, a finding that was apparent both when the women completing the diet were considered alone and when the data were analyzed using intent to treat principles. In addition, despite eating a high percentage of calories as fat and having relatively high intakes of saturated fat and cholesterol, the women in the very low carbohydrate group maintained normal levels of blood pressure, plasma lipids, glucose, and insulin. These data suggest that the deleterious effects of diets containing a high percentage of fat on body weight and cardiac risk factors are mitigated by restriction of caloric intake and as-cualed weight loss.

sociated weight loss. The subjects recruited for this study were healthy adult women who were moderately obese by current standards. As such they were representative of many American women who embark on weight loss efforts each year using the al-ternative dietary plans currently marketed in this country. Although compliance with the diets was assessed primarily Autoogn compliance with uses was assessed primating by dietary records, these data are supported by more objec-tive measures. For example, the average 3-month weight loss in the low fat diet group (~4 kg) is what would be expected for individuals decreasing their daily caloric consumption by in the low fat diet group (-4 kg) is what would be expected for individuals decreasing their daily caloric consumption by about 400 kcal (28), approximately the restriction these women reported making. In addition, there was a significant correlation between reported changes in caloric intake and weight loss (r = 0.41, P < 0.001). Finally, the presence of measurable ketonemia and ketonurai an the very low car-bohydrate group is consistent with severe carbohydrate re-striction and was not seen in the low fait dieters. Thus, we believe that the outcomes of this study can be attributed primarily to differences in the prescribed diets of the two groups and are applicable to the large number of obese, but obterwise healthy. American women exploring very low car-bohydrate diets. One conclusion of previous reports on low carbohydrate diurse is that accompanies severe calori cristicion or was due to decreased body water, presumably accompanying depletion of stored glycogen (29, 30). However, these studies and in fact, we noted the most rapid weight loss in both groups over the first w or 2 of their use, and in fact, we noted the low fat diet group lost 1.6 kg in the first 2 wk, representing 38% of their mean weight loss in the first 2 wk, representing 30% of their mean weight loss to the study. The very low carbo-

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hydrate group lost 3.0 kg during the first 2 wk, or 39% of their mean 3-month weight loss. We analyzed body composition at 3 and 6 months of dieting, well after the expected period of diuresis. Our analysis of body composition showed that the weight lost in the very low carbohydrate diet group consisted of a similar percentage of at mass as in the low fat diet group. Thus, we think it is very unlikely that differences in weight between the two groups at 3 and 6 months are a result of disproportionate changes in body water in the very low carbohydrate dietgroup low carbohydrate dietgroup low carbohydrate dietgroup is not clear. Based on dietary records, the reduction in daily caloric intake was similar in the two groups. For the greater

caloric intake was similar in the two groups. For the greater weight loss in the very low carbohydrate group to be strictly a result of decreased caloric consumption, they would have had to consume approximately 300 fewer calories/d over the first 3 months relative to the low fat diet group (28). Although the inaccuracy of dietary records for obese individuals is well documented (31, 32), it seems unlikely that a systematic discrepancy of this magnitude occurred between groups of subjects who were comparably overweight. Therefore, it is difficult to explain the differences in weight loss between the two groups primarily as a function of differing caloric intake. Despite instructions to maintain baseline levels of activity, it is possible that the women in the very low carbohydrate diet group exercised more than those in the low fat diet group.

is possible that the women in the very low carbohydrate diet group exercised more than those in the low fat diet group. Additionally, it is possible that consuming a very low car-bohydrate diet increases resting or postprandial energy ex-penditure. The possibility that differences in the macrou-trient composition of the diet alter energy expenditure is an interesting question that bears further investigation. Another unexplained, but important, observation was the spontaneous restriction of food intake in the very low car-bohydrate diet group to a level equal to that of the control subjects who were following a prescribed restriction of cal-ories. This raises the possibility that the very low carbohy-drate diet may have been more satiating. Previous studies have suggested that, calorie for calorie, protein is more sa-tiating than either carbohydrate or fat (33, 4), and it may be that the higher consumption of protein in the very low carbohydrate group played a role in limiting food intake. Another explanation for restricted food intake in the very low carbohydrate group a hattry adherence per se may have forced caloric restriction due to practical factors. Although it has been proposed that ketary adherence per se may have forced caloric restriction due to practical factors. Although the observed real that were to also is developing from severe car-bohydrate intake contributes to a decrease in appetite (8), this does not seem likely based on our data. Although the women

TABLE 3. Means (and SD) of body composition measures of women before and after 3 and 6 months of dieting = 22) Low fat diet group (n = 20) 6 months Baseline 3 -----<sup>3</sup> Very low earbohydrate diet group (n = 22) Baseline 6 mon 3 months 
 namemory
 nametrix
 6 months
 Baseline
 3 months
 6 months

 3.270.10 (4.787.7)
 33.036.27 (4.766.9)
 32.554.07 (5.170.5)
 37.872.179 (2.661.8)
 35.396.5 (6.460.4)
 35.853.3 (4.125.2)

 2.782.8 (321.2)
 2.799.2 (313.7)
 2.775.7 (312.7)
 2.819.7 (284.7)
 2.827.7 (288.2)
 2.792.8 (296.7)
 Body fat (g) Bone mineral content (g) Lean body m  $nss \ (g) \quad 50,385.9 \ (5,999.9) \quad 47,565.3^{\circ} \ (5,922.0) \quad 48,418.0^{\circ} \ (5,871.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \quad 51,026.8 \ (5,010.4) \quad 50,181.3 \ (5,124.9) \quad 50,295.9 \ (5,197.5) \ (5,197.5) \quad 50,295.9 \ (5,197.5) \ (5,197.5$ <sup>a</sup> Denotes value different from the low fat group (i.e., significant interaction of time and diet), P < 0.01.

### Table 3

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This tables shows the change from baseline (pre-study), 3 months, to 6 months in body fat, bone mineral content, and lean body mass (like muscle and bone). Statistics only compare between the groups, not baseline vs 6 months.

Primary Results - Body fat decreased more for the ketogenic group. - Bone mineral density was maintained. - Lean mass decreased more for the ketogenic diet.

Take Away: The ketogenic diet leads to greater fat loss, but may also have greater lean mass loss.

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### Table 4

The researchers are showing the blood values of both diet groups at baseline, 3 months, and after 6 months - only comparing against group vs group.

#### **Primary Results**

Blood pressure is unaffected by either diet.
 Cholesterol is unaffected by either diet.
 LDL, HDL cholesterol and triglycerides are unaffected by either diet.

Take Away: Neither diet affects blood pressure, cholesterol, or triglycerides negatively or positively.

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TABLE 5. Means (and SE) of substrate and hormone concentrations of women before and after 3 and 6 months of dieting

	Very low c	Very low carbohydrate diet group $(n = 22)$			Low fat diet group $(n = 20)$		
	Baseline	3 months	6 months	Baseline	3 months	6 months	
flucose (mg/dl)	99.1 (2.6)	93.8 (2.7)	90.1 (2.1)	91.1 (2.1)	90.5 (2.5)	87.5 (2.0)	
nsulin (µU/ml)	16.9(1.8)	11.6(1.2)	14.4 (1.4)	23.9(2.34)	18.1(2.5)	18.4(2.1)	
eptin (ng/ml)	25.43 (1.49)	16.23(1.09)	21.68 (1.49)	30.08 (1.88)	25.35 (1.82)	29.40 (2.58)	
-hydroxybutyrate (mg/dl)	1.04(0.31)	4.30° (1.10)	1.52(0.51)	1.01 (0.40)	1.17(0.27)	1.14(0.44)	

<sup>a</sup> Denotes value different from the low fat group (*i.e.*, significant interaction of time and diet), *P* < 0.01.</li>
 <sup>b</sup> Nenotes value different from the low fat group (*i.e.*, significant interaction of time and diet), *P* < 0.01.</li>
 <sup>c</sup> Neiner March (*i.e.*) (*i.e* 

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### Table 5

This table shows the blood values looking at blood sugar, ketones (B-hydroxybutyrate), and two key hormones (leptin and insulin).

## Primary Results:

Blood glucose (sugar), insulin, and leptin were no different between both groups across time.
 B-hydroxybutyrate (ketone) is elevated (compared to other diet group) in the ketogenic diet, but only for the 3 month

Take Away; This implies something pretty damning, because while the ketogenic diet group was in ketosis for the first 3 months, they were not in the final 3 months - meaning they were only in a strict "ketogenic" state for half the time of the study. Still, all other parameters were not different between groups.