Citation:

Wal JS, McBurney MI, Moellering N, Marth J, Dhurandhar NV. Moderate-carbohydrate low-fat versus low-carbohydrate high-fat meal replacements for weight loss. *Int J Food Sci Nutr.* 2007 Jun; 58(4): 321-329.

PubMed ID: 17566894

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare the efficacy of a low-fat, high-fiber, moderate-carbohydrate (CHO) diet, a low-CHO Atkins-type diet, and a control diet for weight loss and cardiovascular risk reduction.

Inclusion Criteria:

- Between the ages of 18 and 65 years
- Body mass index (BMI) 25kg/m^2 or more
- Less than 6.82kg weight loss in the preceding three months.

Exclusion Criteria:

- Pregnancy
- Lactation
- Intent to conceive
- Active eating disorders
- Significant cardiac disease
- Uncontrolled hypertension
- Elevated liver function tests
- High creatinine levels
- Anemia
- Diabetic retinopathy or uncontrolled diabetes
- Alcohol or substance abuse
- History of infectious disease
- Gluten sensitive enteropathy
- Aversion or allergies to breakfast cereals
- Significant systemic disease that could reasonably affect outcomes or for which calorie-restriction would be contraindicated.

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Description of Study Protocol:

Design

- For this trial, a randomized block procedure (to ensure equal gender representation across the groups) was used to assign participants to the Control, Low CHO, or Moderate CHO diet groups. Interested people were screened over the phone to determine if they met inclusion criteria, and then met with a physician and registered dietitian (RD) to further assess eligibility
- An RD instructed participants in each of the three diet groups.

Intervention

- *Control Diet:* Participants in the Control diet were instructed to follow their normal daily routines for four weeks
- *Low CHO Diet:*
  - Breakfast: An Atkins Shake, Atkins Breakfast Bar and a selection of either fruit or yogurt
  - Lunch: Atkins-consistent lunch planned by the dietitian according to each participant's preferences
  - Dinner: A 2,512kJ dinner consisting of the shake, bar, fruit and salad with fat-free dressing
- *Moderate CHO Diet:*
  - Breakfast: Special K Low-carb ready-to-eat cereal with low-fat milk
  - Lunch: Special K Low-carb ready-to-eat cereal with low-fat milk
  - Dinner: A 2,512kJ dinner consisting of fruits, salad with fat-free dressing and a low-fat, low-calorie meal planned by the dietitian according to each participant's preferences.

Statistical Analysis

- Means, standard deviations, percentages and frequencies were used to describe the sample and study constructs
- Chi-square analyses were used to examine differences in dropout according to group assignment and gender
- Analyses of variance with Tukey corrected contrasts were used to evaluate between-group differences
- The level of significance was set a $P<0.05$.

Data Collection Summary:

Timing of Measurements

Participants in all groups were required to return for visits two and four weeks after enrollment for measurement of body weight, waist and hip circumference and body composition determination.

Dependent Variables

- Height and weight were measured by study personnel
- Body mass index (BMI) was calculated using measured height and weight

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- Body composition was measured with a BODPOD, which measures body fat via air displacement
- Blood chemistries: Serum was collected and used for blood chemistry analysis by an independent laboratory.

Independent Variables

Diet group.

Description of Actual Data Sample:

Initial N

N=137 (25 males and 112 females).

Attrition (final N)

- N=125
- The 12 dropouts included 10 females and two males; dropouts did not differ significantly according to group assignment, nor according to gender.

Baseline Subject Characteristics

Variable	Control Group	Low CHO Group	Moderate CHO Group
N	44	41	40
Female/male	37/7	34/7	31/9
Age (years)	49.57±8.78	50.46±9.58	49.58±9.86
BMI (kg/m^2)	34.97±7.72	33.13±5.85	37.26±7.99
Weight (kg)	97.05±23.15	90.51±17.88	105.15±27.54
Percentage body fat	45.27±8.84	45.06±7.94	47.03±7.67
Waist (cm)	103.99±17.42	100.84±12.34	110.01±16.13
Hips (cm)	119.86±14.15	116.87±13.08	126.47±0.2

Location

United States.

Summary of Results:

Between-group Comparisons for Change in Anthropometric and Physiological Measures Between Baseline and Week Four

Variable	Control Group	Low CHO Group	Moderate CHO Group	P-Value
Weight (kg)	-0.61±1.33[a]	-2.94±2.25[b]	-2.6±2.39[b]	<0.0001
Body mass index	-0.47±1.90	-1.02±0.84	-0.94±0.85	NS

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Percent body fat	-0.47±1.50[a]	-1.22±1.21[b]	-0.76±1.13[a,b]	<0.05
Waist (cm)	0.15±1.7[a]	-4.24±2.49[b]	-4.32±2.95[b]	<0.0001
Hips (cm)	0.08±1.27[a]	-3.43±2.24[b]	-3.30±1.93[b]	<0.0001
Cholesterol (mmol per L)	0.02±0.54[a]	-0.68±0.57[b]	-0.3±0.66[c]	<0.0001
Triglycerides (mmol per L)	0.03±0.53[a]	-0.31±0.56[b]	-0.13±0.47[a,b]	<0.05
HDL (mmol per L)	0.02±0.23[a]	-0.09±0.16[b]	-0.07±0.15[a,b]	<0.05
LDL (mmol per L)	0.02±0.5[a]	-0.47±0.5[b]	-0.17±0.15[a,c]	<0.001
Very-LDL (mmol per L)	0.01±0.24[a]	-0.12±0.22[b]	-0.06±0.22[a,b]	<0.05
Glucose (mmol per L)	0.2±1.48	0.01±0.68	0.02±0.84	NS
Blood Urea Nitrogen (mmol per L)	0.10±1.67	0.21±1.37	0.52±1.41	NS
Creatinine (umol per L)	2.65±12.38	10.61±8.84	3.54±8.84	NS
Means with differing lowercase superscripts are significantly different.				

- The Low CHO and Moderate CHO groups lost significantly more weight than the Control group; however, mean weight loss did not differ between Low and Moderate CHO
- Serum cholesterol was reduced significantly in the Moderate CHO group compared to Control and Low CHO, and was significantly lower in the Low CHO compared to control
- The Low CHO group had significantly lower triglycerides, HDL and very-LDL compared with the Control group, and had significantly lower LDL compared to both the Control and Moderate CHO groups.

Author Conclusion:

- Both a Low and Moderate CHO diet produced significant weight loss, although the Low CHO diet resulted in a greater decline in percentage body fat
- The Low CHO diet produced greater improvements in cardiovascular risk profile with regards to total cholesterol, HDL, LDL, very-LDL and triglycerides compared to the Moderate CHO diet.

Reviewer Comments:

- *The authors do not report mean nutrient intakes for each of the groups and do not report the macronutrient content and proportions that subjects consumed*
- *This study had 12 subjects drop out; however, reasons for dropping out are not provided*
- *This study was four weeks in length, making it difficult to determine the long-term efficacy of using a partial meal replacement diet*
- *Analyses did not account for potential confounding factors.*

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Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes

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3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	No
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	No
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A

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6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	No
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	N/A
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	Yes

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8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	No
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**	No
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	No

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