

Citation:

McAuley KA, Hopkins CM, Smith KJ, McLay RT, Williams SM, Taylor RW, Mann JI. Comparison of high-fat and high-protein diets with a high-carbohydrate diet in insulin-resistant obese women. *Diabetologia*. 2005 Jan;48(1):8-16. Epub 2004 Dec 23. Erratum in: *Diabetologia*. 2005 May;48(5):1033.

PubMed ID: [15616799](#)

Study Design:

Randomized Controlled Trial

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The purpose was to compare a high-fat diet (Atkins diet) and a high-protein diet (Zone diet) for weight loss with a high-carbohydrate, high-fiber plan in obese, insulin-resistant women.

Inclusion Criteria:

- Overweight, insulin resistant females
- Normoglycemic
- BMI > 27 kg/m²
- Ages 30 -70
- Not pregnant or planning to become pregnant
- Subjects with no major medical condition(s)
- Not currently on a weight loss program or vegetarian diet
- Normal glucose tolerance
- Total cholesterol < 7 mmol/l
- Creatinine < 130 µmol/l
- Normal liver function tests

Exclusion Criteria:

- Pregnancy
- Subjects with major medical conditions
- Abnormal glucose tolerance
- Total cholesterol > 7 mmol/l
- Creatinine > 130 µmol/l
- Abnormal liver function tests

Description of Study Protocol:

Recruitment - from local advertisements in New Zealand

Design Randomized controlled trial

Blinding used - Due to the nature of the study, subjects and researchers were not blinded. However, the groups were assigned code names instead of the actual diet name to lessen cross-contamination.

Intervention

- High carbohydrate and high-fiber diet (HC)
- High-fat Atkins diet (HF)
- High-protein Zone diet (HP)

Statistical Analysis

- 3 kg weight loss between HC diet and either of the other diets was deemed clinically important.
- Random allocation was done in groups of nine. Sequential numerical assignment was done for each participant. Stratification was not performed.
- Intent to treat was used.
- Data were analyzed with mixed models. There was a random effect for each subject, with assumed underlying variance-covariance due to multiple measures for each subject. Baseline measures were included.
- Tests between the HC and HP diets and between HC and HF diets were done a priori. An overall test was also performed to compare HF and HP diets.
- Chi square distribution was used to compare the value of the test statistic.
- Logarithmic transformation was used to stabilize variance of fasting insulin, CRP, and liver enzymes.
- Overall differences were described with 95% confidence intervals.
- Diet and time interactions were studied.
- Results are presented as adjusted means.
- The STATA Statistical Software Package analyzed data.
- $p < 0.05$ was statistically significant.

Data Collection Summary:

Timing of Measurements

- The first 8 weeks of the study were a weight loss phase, although ad libitum diet was to be followed despite group allocation.
- Dietary recommendations were provided at weekly sessions. This type of supervision continued from weeks 8 to 16 with no contact with the researchers from weeks 16 to 24.
- There was no formal energy restriction during any phase.
- All subjects were encouraged to exercise 30 minutes on 5 days of the week.

Dependent Variables

- Height and weight
- Waist circumference was the midpoint between the anterior superior iliac crest and the lowest rib.
- Body mass index, **fat-free mass, fat mass**
- Blood pressure was measured after 5 minutes of rest with a random-zero sphygmomanometer.
- Oral glucose tolerance test used fasting and 2-hour measurements to determine glucose and insulin levels.
- Fasting blood samples assessed lipids and high-sensitivity C-Reactive protein (CRP) using a kit from Roche Diagnostics with an intra-assay CV of 1.5%.
- Body fat was measured with the IMP5 Bioimpedance Analyser. Subjects were fasting and had empty bladders with no alcohol intake or exercise for 24 hours before the measurement.

Independent Variables

- High-fat Atkins diet (HF) had no restrictions except carbohydrate. During the first 2 of the 8 weeks, subjects were told to consume less than 20 grams of carbohydrate/day. Starting with week 3, carbohydrates were increased 5 grams/day each week to a maximum of 50 grams daily being consumed by week 8. During the following 8 weeks in the supervised phase, each subject increased carbohydrate intake by 5 grams/day until reaching maximum carbohydrate intake at which weight was not gained. The unsupervised follow-up encouraged adequate carbohydrate to prevent weight gain.

- High-protein Zone diet (HP) included 40% low glycemic carbohydrates, 30% protein, and 30% fat (mostly monounsaturated). Subjects ate 5 times per day with no more than 5 hours between meals. Subjects were instructed on serving sizes and the portion of each food to select. Additional foods were limited to one serving daily. The supervised phase allowed subjects to have slightly larger food portions to maintain weight. Subjects were to consume enough food to prevent weight gain during the follow-up phase.
- High carbohydrate and high-fiber diet (HC) included at least 6 servings of grains (whole grains preferred), at least 3 vegetable servings and 2 fruit servings (emphasizing soluble fiber), at least 2 low-fat dairy foods, and at least 1 serving of lean meat/meat substitutes. Subjects were encouraged to decrease intake of fat, salt, and sugar and were given guidance on portion control. During the supervised and unsupervised phases, subjects were to consume slightly larger evening meals to maintain weight.

Control Variables

Description of Actual Data Sample:

Initial N: 251 females

Attrition (final N): 84 (high carbohydrate diet $n = 32$, high-protein diet $n = 30$, high-fat diet $n = 31$)

Age: 30 to 70 years (high carbohydrate diet mean age of 45 ± 7.5 years, high-protein diet mean age of 47 ± 7.9 years, high-fat diet mean age of 45 ± 7.4 years)

Ethnicity: European descent

Other relevant demographics:

Anthropometrics Authors note that groups were different at baseline, no details provided

Location: New Zealand

Summary of Results:

Key Findings

- There were no differences in reported energy intake in the 3 groups during all 6 months.
- The subjects in the high-fat group met the week 8 carbohydrate goal. The other diet groups did not meet protein or carbohydrate targets, since the calories from total fat were higher than intended.
- The HF diet was lower in carbohydrate than the HC diet (-94 grams, 95% CI - 112 to -75) and fiber (-8 grams, 95% CI -10 to -6). Total fat was higher (+40 grams, 95% CI 29 - 52), as was saturated fat (+17 grams, 95% CI 12-22).
- The protein intake for the group was 20 grams higher than the HC group (95% CI 11 - 30). Fiber intake was similar for these two diet groups.
- Reduced fasting triglycerides and insulin were noted for all 3 diets.
- Modest reduction of systolic and diastolic blood pressure occurred.
- HF and HP diet groups lost significantly more weight than the HC control group. **The HF group had higher initial weight loss.**
- LDL in the HF group was significantly higher than in the HP group, despite similar weight changes.

Variables	Diet	Baseline	24 Weeks
Weight	HC	98.8±15.1	93.3±14.5
	HP	93.2±14.5	86.3±14.2
	HF	96.0±10.8	88.9±10.6
BMI	HC	36.6±5.6	34.9±5.6
	HP	34.5±5.3	31.5±5.1
	HF	36.0±3.9	33.1±3.7

Waist circumference	HC	109.1±11.6	102.2±11.8
	HP	108.0±11.5	99.2±10.9
	HF	108.9±9.9	99.1±9.2

Author Conclusion:

In conclusion, the high-fat Atkins diet is a successful short-term approach for weight loss, however, LDL levels should be monitored, and those who show a significant increase should be advised to discontinue the diet. The potential deleterious effects of the diet in the long-term remain a concern. In the context of this study the HP Zone Diet appears to be the most appropriate overall approach to reducing the risk of cardiovascular disease and type 2 diabetes.

Reviewer Comments:

Groups were different at baseline but these were adjusted for in the statistical analysis.

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?	???
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
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?	Yes
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?	Yes

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 intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
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?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
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?	Yes
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?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
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)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	???
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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