

**Citation:**

Brunerova L, Smejkalova V, Potockova J, Andel M. A comparison of the influence of a high-fat diet enriched in monounsaturated fatty acids and conventional diet on weight loss and metabolic parameters in obese non-diabetic and Type 2 diabetic patients. *Diabet Med.* 2007 May;24(5):533-40. Epub 2007 Mar 22.

**PubMed ID:** [17381504](#)

**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 elucidate the impact of two types of individualized weight reduction diets on weight loss and on parameters of glucose and lipid metabolism.

**Inclusion Criteria:**

- Adult, obese, non-diabetic subjects or type 2 diabetics

**Exclusion Criteria:**

- Presence of pancreatic, biliary or thyroid diseases.

**Description of Study Protocol:**

**Recruitment** - recruited from Middle Bohemia, the Czech Republic, using advertisements placed in local newspapers and from the diabetic clinic.

**Design** - Randomized controlled trial which lasted 3 months.

**Blinding used (if applicable)** - none mentioned

**Intervention (if applicable)**

- Diets were individually calculated for kcal content. The menus were either prescribed or individually approved by the dietitian.
- Conventional diet: standard diabetic diet consisting of 60% carbohydrate, 10% protein, and 30% fat. The cholesterol content was < 300 mg. The fat breakdown was 10% MUFA, 10% PUFA, and 10% SFA.

- Experimental diet was a high-fat diet enriched with MUFA. The diet consisted of 45% carbohydrate, 10% protein, and 45% fat. The fat content was 22.5% MUFA, 11.25% SFA, and 11.25 % PUFA. Dietary cholesterol was < 300 mg.

### **Statistical Analysis**

- Paired Student t-test (for the comparison of initial and final data differences in each group).
- ANOVA for the comparison of the data among the groups in the test periods.

### **Data Collection Summary:**

#### **Timing of Measurements**

- The subjects visited with a dietitian every 2 weeks and a physician every month.
- The subjects were measured at baseline, and monthly during the experiment, and at the end of the third month for physical, anthropometric, and lab testing.

#### **Dependent Variables**

- Anthropometrics (weight, height, waist and hip measurements, skin fat, muscle strength, BMI)
- Metabolic parameters (total cholesterol, triglycerides, HDL, fasting blood glucose were assayed on a Konelab analyzer). LDL was calculated using the Friedewald equation. Insulin and C-peptide were analyzed using a Vitros ECI analyzer. HbA1c was assayed using a DS5 analyzer. HOMA index was calculated.

#### **Independent Variables**

- Experimental hypocaloric high-fat diet enriched with MUFA vs. a conventional diabetic diet
- Once every 2 weeks a dietitian monitored compliance with the diet by checking diet records and diet tolerance

#### **Control Variables**

### **Description of Actual Data Sample:**

**Initial N:** 27 obese, type 2 diabetics and 31 obese non-diabetic subjects, gender was not stated.

**Attrition (final N):** as above

**Age:** 45-60 years; mean age type 2 diabetics =  $54.5 \pm 3.5$  years, non-diabetics =  $53.6 \pm 3.5$  years

**Ethnicity:** not mentioned

**Other relevant demographics:** none stated

**Anthropometrics** BMI ranged from 26 to 38. No differences were found between the diabetic patients and the obese subjects in any of the metabolic parameters except for blood glucose and HbA1c.

**Location:** Czech Republic

## Summary of Results:

### Key Findings

- After 3 months, body weight, waist-hip ratio, total body fat, levels of C-peptide, triglycerides and HOMA decreased in all four groups (diabetics on MUFA diet, diabetics on control diet, obese subjects on MUFA diet, and obese subjects on the control diet,  $P < 0.001$ )
- Fasting blood glucose and HbA1c values decreased significantly ( $P < 0.01$ ) in the diabetics on MUFA diet
- HDL cholesterol increased significantly ( $P < 0.05$ ) in the diabetics on MUFA diet

### Other Findings

- All the groups were able to lower their energy intake for the duration of the study.
- Twelve percent of the participants said they wanted to eat less food because they thought they had an unbearably large amount of food to eat.
- In contrast, 40% of the subjects had to have an additional reduction of kcals by -250 kcal/day (after 4 weeks) to continue to produce weight loss.
- Most of the subjects (78%) were well satiated on the diets.

## Author Conclusion:

Individualized metabolic and conventional diets were successful in improving metabolic and anthropometric parameters in both the obese, non-diabetic and the type 2 diabetic subjects. Although the superiority of the higher fat diet did not reach statistical significance, the type 2 diabetics on the metabolic diet experienced a decline in blood glucose and HbA1c values.

## Reviewer Comments:

*Sample not well described. Authors note the following limitations:*

- *Size of study limited statistical power to detect differences between diets*
- *Study was designed as a weight reduction programme, so it was difficult to distinguish between the positive metabolic effects because of the weight loss itself from the possible positive effects of macronutrient composition*

## 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

<b>1.</b>	<b>Was the research question clearly stated?</b>	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
<b>2.</b>	<b>Was the selection of study subjects/patients free from bias?</b>	???
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?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
<b>3.</b>	<b>Were study groups comparable?</b>	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
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
<b>4.</b>	<b>Was method of handling withdrawals described?</b>	<b>Yes</b>
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?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
<b>5.</b>	<b>Was blinding used to prevent introduction of bias?</b>	<b>Yes</b>
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
<b>6.</b>	<b>Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?</b>	<b>Yes</b>
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?	N/A

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
<b>7.</b>	<b>Were outcomes clearly defined and the measurements valid and reliable?</b>	<b>Yes</b>
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?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
<b>8.</b>	<b>Was the statistical analysis appropriate for the study design and type of outcome indicators?</b>	<b>???</b>
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?	No
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)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	???
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?	Yes
<b>9.</b>	<b>Are conclusions supported by results with biases and limitations taken into consideration?</b>	<b>Yes</b>
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
<b>10.</b>	<b>Is bias due to study's funding or sponsorship unlikely?</b>	<b>Yes</b>

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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