

Citation:

Liao FH, Shieh MJ, Yang SC, Lin SH, Chien YW. Effectiveness of a soy-based compared with a traditional low-calorie diet on weight loss and lipid levels in overweight adults. Nutrition. 2007 Jul-Aug;23(7-8):551-6

PubMed ID: [17574819](#)

Study Design:

randomized intervention 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:

To determine the effects of a soy-based diet on weight management, body composition and blood lipid profiles in overweight subjects.

Inclusion Criteria:

- 20-60 years of age
- BMI >26 kg/m²
- No history of chronic disease (cardiovascular disease, kidney disease, diabetes)
- no pregnant or breastfeeding

Exclusion Criteria:

history of chronic illness (cardiovascular disease, renal disease, diabetes mellitus). Pregnant or breastfeeding women.

Description of Study Protocol:

Recruitment : Recruitment was by flyers and leaflets. Conducted at the Taipei Medical University. (Note: unclear how the leaflets or flyers were distributed)

Design : Randomized Intervention trial. (Traditional low calorie diet vs Soy Low calorie diet: control vs study group)

Blinding used (if applicable): Study was not blinded. Subjects received prepared meals, control group received instructions only for low calorie diet.

Intervention (if applicable):

- Study Group received prepared meals of a 1200 calorie diet with soy protein as the sole protein source; meal box provided for every lunch and dinner for 8 weeks
- Control group received instructions to maintain a traditional low calorie diet (1200 kcals) with 2/3 animal protein and 1/3 plant protein.
- Both groups received education on weight management.

Statistical Analysis: Data is presented as mean \pm SD and differences between initial and final measures were tested with a paired t-test using Student's t test. Significance was reported as a p<0.05.

Data Collection Summary:

Timing of Measurements: :

- Height, weight, blood pressure and body composition were measured weekly.
- Biochemical parameters measured at baseline and end of the intervention.

Dependent Variables (see above for how measured)

- Weight change
- Change in BMI: Height was measured by standard technique using a stadiometer.
- Change in % Body Fat: Body composition (weight ad fat percentage) were measured by electrical impedance using the InBody 3.0 Body Composition Analyzer.
- Change in waist circumference
- Serum Cholesterol
- HDL
- LDL
- Triacylglycerol
- SGOT
- GPT
- Blood pressure: measured by standard technique using a mercury sphygmomanometer.

Independent Variables

- **Soy protein diet vs traditional low calorie diet:** Diet record kept daily and analyzed using Nutritionist Pro

Control Variables:

Description of Actual Data Sample:

Initial N: 30 (6 male, 24 female)

Attrition: **N=30** Traditional low-calorie diet = 15 (3 male, 12 female); Soy group = 15 (3 male, 12 female)

Age: Soy Group (28.8 ± 9.1 years), Control Group (38.0 ± 11.1 years)

Ethnicity: Not reported (? Chinese based on recruitment and dietary practices)

Other relevant demographics: not reported

Anthropometrics:

BMI:

- Soy group: 29.6 ± 3.0 kg/m²
- Traditional group: 30.0 ± 3.9 kg/m²

Location: Taipei Medical University

Other baseline measures: Authors report no significant differences in other baseline characteristics including blood pressure, lipid profiles, and liver function tests.

Summary of Results:

Key Findings:

- Both low-calorie diets significantly reduced body weight, BMI, and body fat percentage ($P < 0.05$)
- After the intervention, the soy group had significantly lower levels of serum total cholesterol, serum LDL-C, glutamate oxaloacetate transaminase, and glutamate pyruvate transaminase than the tradition group ($P < 0.05$), whereas the traditional group had significantly decreased serum total cholesterol levels ($P < 0.05$).
- Neither group had any significant change in serum HDL-C levels.
- The HDL-C/total cholesterol ratio of the soy group was slightly higher than that of the traditional group after 8 weeks.
- Serum triacylglycerol and fasting glucose levels decreased slightly in both groups after weight reduction, but the difference between groups was not significant.

Table reports change between 2 groups during intervention trial. (mean \pm SD)

Variables	Treatment Group	Control group	Statistical Significance of Group Difference
	Measures and confidence intervals	Measures and confidence intervals	
Change in body weight	-4 ± 1.7 kg	-3.9 ± 3.3	NS
change in BMI	-1.6 ± 0.6	-1.5 ± 1.2	NS
change in body fat (%)	-2.2 ± 0.9	-1.4 ± 2.2	NS
total cholesterol mg/dl	-23.7 ± 15.7	-18 ± 18	$p < 0.05$
HDL mg/dl	-8 ± 11.7	-2 ± 4.9	NS
LDL mg/dl	-15.4 ± 7.7	-9 ± 16.5	$p < 0.05$

triacylglycerol mg/dl	-9.8 ± 35.4	-21.8 ± 46.2	NS
SGOT IU/L	-2 ± 2.4	0.7 ± 10	$p < 0.05$
SGPT IU/L	-4 ± 4	1.3 ± 4.3	$p < 0.05$
Serum glucose mg/dl	-2.9 ± 5	-7.8 ± 19.4	

Other Findings: Both diets resulted in significant reductions in body weight, BMI and percentage body fat. Total calorie intake was lower at the end of the study in the soy group.

Author Conclusion:

Weight loss diet containing high quality soy products as the main source of protein reduced body fat percentage, total serum cholesterol, and LDL levels. The results suggest that this diet might improve hyperlipidemia associated with obesity during a weight loss program.

Reviewer Comments:

This study is a small sample size in a population that most likely has a higher intake of soy protein (1/3 plant, 2/3 animal) in the traditional diet. Results include both inter and intra group comparisons. A low calorie diet resulted in changes in weight and body composition as well as lipid profiles. There were more significant reductions in total cholesterol and LDL in the soy group. Limitations include small sample size and unblinding. It is interesting to note that the energy intake at the end of the study was lower in the soy group. Was this a contributory factor to the diet effect and/or does it reflect differences in diet palatability?

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?	No
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
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?	N/A
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?		N/A
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
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?	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?	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?	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)?	N/A
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
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?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
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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