

Citation:

Rolls BJ, Roe LS, Beach AM, Kris-Etherton PM. Provision of foods differing in energy density affects long-term weight loss. *Obes Res.* 2005 Jun;13(6):1052-60.

PubMed ID: [15976148](#)

Study Design:

Randomized Controlled Trial (RCT)

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:

This one year clinical trial tested the effect on weight loss of a diet incorporating one or two servings per day of foods equal in energy but differing in energy density. The clinical trial consisted of a 6-month weight loss phase and a 6-month maintenance phase; the main outcomes were weight loss and change in diet composition at the end of 1 year.

Inclusion Criteria:

- 20 to 65 years old
- BMI of 26 to 40 kg/m²
- Participants provided written informed consent and were financially compensated for their participation. The protocol was approved by the Office of Research Protections of The Pennsylvania Stet University, and the study was conducted at the General Clinical Research Center located at the University Park campus of the university.
- Potential subjects who met the inclusion criteria were instructed in keeping a detailed record of their food and beverage intake for three nonconsecutive days.

Exclusion Criteria:

- Blood pressure >140/90 mm Hg
- Serum triglycerides >400 mg/dl
- Total cholesterol > 90th percentile for their age and sex
- Had serious medical condition that precluded participation
- Any condition limiting physical activity
- Were pregnant or lactating
- Had symptoms indicative of depression or an eating disorder
- Followed a sodium restricted diet
- Were unwilling to regularly consume soup or savory snacks

Description of Study Protocol:

Recruitment

Potential subjects were recruited by flyer and newspaper advertisement, and their eligibility for the trial was determined by a telephone interview, a physical screening session, and questionnaires that assessed symptoms of depression, symptoms of eating disorders, and ability to safely engage in physical activity.

Design: Randomized controlled trial (RCT)

Blinding used

For study completers, the 3-day diet records were coded by a dietitian who was not involved in the trial.

Intervention

- Individuals who completed a baseline 3-day diet record were assigned to an intervention group; a stratified randomized scheme was used to balance the distribution of subject sex and age across groups.
- Subjects were instructed by dietitians to follow an energy-restricted diet; in addition, subjects were randomized to one of four intervention groups.
- Subjects in three of the groups were provided a meal plan with dietary exchanges that provided 55% of energy as carbohydrate, 30% of fat, and 15% as protein; the meal plan incorporated the provided food (soup or snack food).
- These subjects were given supplies of commercially available food that was low in energy (100 kcal/serving) and fat <4 g/serving).
- During months 1 to 3, subjects participated in a weekly individual counseling session with a dietitian and completed 3-day diet records every 2 weeks; during months 4 to 6, they had a counseling session every 2 weeks and completed 3-day diet records monthly.
- During the weight maintenance phase in months 7 to 12, subjects met with a dietitian monthly and completed a total of two 3-day diet records.
- Each subject attended a maximum of 27 counseling sessions that lasted approximately 15 to 30 minutes each.
- The study foods had a similar energy content (mean 100 kcal/serving) and fat content (<4 g/serving) but different in energy density (mean 0.35 kcal/gram for soups and 4.2 kcal/gram for snacks). Thus, although the study foods had the same energy content per serving, they had very different weight, volume, and water content per serving.
- Subjects in the soup groups could select from 18 kinds of commercial soups (six of which were also available in a low-sodium version) and were given a mug that held one serving of soup (300 grams; 10.5 fl. oz.).
- Subjects in the snack group could choose from 18 varieties of commercial snacks (crackers, baked potato chips, baked tortilla chips, bagel chips, and pretzels) that were provided in packages containing a single serving (24 grams).
- In the dietary exchange system followed by the subjects, each serving of soup or snack replaced one grain exchange, so that the energy level of the assigned diet was not altered.
- Subjects in all groups were told that the purpose of the trial was to test the inclusion of different food in a weight loss diet and were not given any specific information related to energy density or other qualities of the soup and snacks.

Statistical Analysis

- Continuous outcomes were analyzed with a linear mixed model, which took into account autoregressive nature of the repeated measures.
- Intervention group, subject gender, and study week were treated as fixed effects.
- Anthropometric and physiological outcomes were analyzed for subjects who completed the study and also for all randomized subjects (testing the least-squares means from the linear mixed model).
- Food and nutrient intake data from the diet records were available only for study completers. Multivariate ANOVA was used to test macronutrient intakes as a percentage of energy intakes.
- Categorical outcomes from the questionnaires were analyzed using χ^2 test; where there was no effect of study weeks, outcomes from all available study week were analyzed together.
- Step-wise regression analyses were performed to predict weight loss based on intervention group, subject characteristics, and dietary and activity measures.
- Differences were considered significant at $p < 0.05$, except for post hoc pair-wise comparison between groups, for which modified Bonferroni adjustment was used ($p < 0.025$).

Data Collection Summary:

Timing of Measurements

- Body weight was measured at each counseling session
- Blood pressure was measured monthly using a standard method.
- Fasting (12-h) blood specimens were collected at baseline and at 3, 6, and 12 months
- Dietary intake measured at baseline and 1, 3, 6, 9 and 12 months.
- Physical activity assessed at each counseling visit

Dependent Variables

- Weight measured with the subject wearing light clothing without shoes, using a scale that was regularly calibrated.
- Blood pressure was measured using a standard method.
- Fasting (12-h) blood specimens analyzed for measurements of serum lipids and lipoproteins, performed at the Lipid Laboratory (Mary Imogene Basset Research Institute, Cooperstown, NY), which participates in the Center for Disease Control Lipid Standardization Program.
- Change in diet composition

Independent Variables

- Intervention group (either one or two servings of low energy-dense soup, two servings of high energy-dense snack foods, or no special food)
- Food records were analyzed for nutrients and food group servings using U.S. Department of Agriculture food comparison data supplemented with data from commercial sources.
- Food energy density (kilocalories per gram) were calculated as the ratio between food energy and food weight, both excluding beverages; soup was calculated as a food in this calculation.
- Eating occasions were categorized either as main meals (breakfast, lunch, or dinner) or as between-meal snacks, based on the time of day and type and amount of food eaten.
- Subjects in the soup and snack intervention groups were asked to complete daily records for their study food intake and were told that it was preferable to consume their servings of

provided foods just before their lunch and dinner meals.

- The Diet Satisfaction Questionnaire assessed subjects' satisfaction with their food plan using seven-point scales
- The Eating Inventory measured dietary restraint (the tendency to consciously restrict food intake to control body weight), distribution (the loss of control over eating in response to emotional or social cues) and hunger (tendency to subjective feelings of hunger)
- The Food Preference questionnaire assessed preference for the taste of low-and high-fat versions of common foods.
- Leisure –Time Exercise Questionnaire was used to assess physical activity during the past week

Control Variables

Description of Actual Data Sample:

Initial N: 200 overweight and obese women and men (154 women and 46 men), 50 in each group.

Attrition (final N): At the end of 12 months, 147 subjects remained in the trial (74%); these subjects were referred to as study completers. The most frequent reasons for withdrawal were inability to attend counseling sessions, and difficulty in complying with the requirements of the diet or the record-keeping. 37 subjects in the Two Snack group, 39 subjects in the One Soup group, 34 subjects in the Two Soups group, and 37 subjects in the Comparison group.

Age: 20 - 65 years old, see Results

Ethnicity: Not specified

Other relevant demographics:

Anthropometrics

There were no differences among intervention groups in baseline demographic, physiological, or psychological characteristics, but there were some differences in dietary intakes. At baseline, the two soup group reported a greater mean daily intake of fruits and vegetables than the other three groups ($P = 0.024$) and also a greater sodium intake ($P = 0.028$).

Location: University Park, Pennsylvania

Summary of Results:

Table 1. Baseline characteristics (mean \pm SE) of the 200 randomized subjects

Characteristics	Intervention group			
	Two snacks (n=50)	One soup (n=50)	Two soups (n=50)	Comparison (n=50)
Age(years)	44.5 \pm 1.2	45.1 \pm 1.2	43.8 \pm 1.2	45.2 \pm 1.2
Height(cm)	168.4 \pm 1.1	167.4 \pm 1.4	169.5 \pm 1.3	167.8 \pm 1.1

Body weight(kg)	89.2±1.9	86.5±1.9	88.4±1.8	88.1±1.7
BMI(kg/gm ²)	31.4±0.4	30.9±0.5	30.8±0.5	31.3±0.4
Activity score*	272±29	367±42	400±40	356±44
Energy expenditure(kcal/d)¶	2073±39	2049±44	2046±35	2052±36
Energy intake(kcal/d)§	1978±82	2209±82	2191±113	2056±94
Energy goal for weight loss(kcal/d)	1323±39	1299±34	1296±35	1302±36

*From the Leisure-time Exercise Questionnaire (19)

¶ Estimated from sex, age, and activity level (15)

§ From 3 days of diet records for study completers only (n=147).

Table 2. Mean (±SE) weight loss and reported dietary intakes for 147 study completers at major time-points

	Baseline:					6 months				12 Months			
	All groups (n=147)	Two snacks (n=37)	One soup (n=39)	Two soups (n=34)	Comparison (n=37)	Two snacks (n=37)	One soup (n=39)	Two soups (n=34)	Comparison (n=37)	Two snacks (n=37)	One soup (n=39)	Two soups (n=34)	Comparison (n=37)
Weight loss													
Weight loss(kg)	NA*	6.1±0.7 a	7.9±0.9 ab	7.6±0.8 ab	9.0±1.1 b	4.8±0.7 a	6.1±1.1 ab	7.2±0.9b	8.1±1.1b				
Percentage weight loss (% initial weight)	NA	7.0±0.8 a	9.1±0.9 ab	8.4±0.9 ab	10.2±1.2 b	5.5±0.8 a	6.9±1.2 ab	7.9±1.0b	9.2±1.2b				
Dietary intakes													
Soup intake (servings/d)	0.10±.02	0.25±.06 a	1.09±0.09 b	1.72±0.09 c	0.40±0.07 a	0.11±.04 a	0.90±0.09 b	1.33±0.12c	0.10-0.04a				
Snack food intake (servings/d)	0.16±0.03	1.93±0.06 a	0.20±0.06 b	0.13±0.04 b	0.20±0.05 b	1.90±0.15 a	0.26±0.07 b	0.18±0.06b	0.13±0.05b				
Total energy(kcal/d)	2110±47	1430±45	1557±82	1390±57	1538±90	1441±26	1496±42	1443±32	1496±0.42				
Food weight(g/d)	1013±25	830±33 a	1214±65 b	1226±47 b	1001±44 c	859±30 a	1125±55 b	1244±67b	955±41a				
Dietary energy density (kcal/g)¶	1.86±0.03	1.61±0.05 a	1.23±0.05 b	1.03±0.04 c	1.40±0.05 d	1.73±0.06 a	1.32±0.06b	1.23±0.06b	1.54±0.05c				
Fruit and vegetable group (servings/d)	5.8±0.2¶	4.7±0.3 a	6.1±0.5 b	6.4±0.3 b	5.8±0.3 ab	5.2±0.3 a	5.9±0.5 ab	6.8±0.4b	6.0±0.05ab				
Grain and cereal group(servings/d)	7.5±0.2	6.5±0.3 a	6.1±0.5 a	4.8±0.3 b	5.8±0.4 ab	6.7±0.3	5.8±0.5	6.2±0.5	5.8±0.4				

At a given time-point, means with different superscript letters are significantly different (modified Bonferroni comparison, $p < 0.025$).

*NA, not applicable

¶ Energy density of food only, excluding beverages.

§ Fruit and vegetable intake differed by group at baseline; subjects in the two soups groups had a greater intake than the other group ($p = 0.024$).

Other Findings

- All four groups showed significant weight loss at 6 months that was well maintained at 12 months.
- The magnitude of the weight loss, however, differed by group ($P = 0.006$).
- At 1 year, weight loss in the comparison (8.1 ± 1.1 kg) and two-soup (7.2 ± 0.9 kg) groups were significantly greater than that in the two-snack group (4.8 ± 0.7 kg); weight loss in the one-soup group (6.1 ± 1.1 kg) did not differ significantly from other groups.
- Weight loss was significantly correlated with the decrease in dietary energy density from baseline at 1 and 2 months ($P = 0.0001$) but not at 6 and 12 months.

Author Conclusion:

- The hypothesis, that changes in daily energy intake were caused by differences in satiety

attributable to the dietary modifications, remained feasible. The variations in reported food energy density and food weight that resulted from changing only two servings of food per day were striking: at 6 months, food energy density was 1.6 kcal/d in the two snack group and 1.0 kcal/d in the 2 soup group.

- This randomized trial of modification of an energy restricted diet resulted in substantial weight loss in all intervention groups after 6 months, which was well maintained for a further 6 months and resulted in improvements in blood pressure and blood lipids.
- The magnitude of the weight loss, however, varied among groups.
- The main evaluation of the trial demonstrated that consuming two servings of soup daily led to greater weight loss than consuming the same amount of energy as two servings of a dry snack food daily.
- After 1 year, weight loss in the two groups was 50% greater than in the snack group (7.2 vs. 4.8 kg). thus, substituting a type of food that was low in energy density for one that was high energy density increased the magnitude of the weight loss.
- These results extend the findings of single-meal experiments showing that consuming a food low in energy density increases satiety and decreases energy intake compared with consuming a food high in energy density.
- The responses to the Diet Satisfaction questionnaire provided evidence that satiety played a role in the differential weight loss among groups; a greater percentage of subjects in the soup group reported feeling very full and not hungry during the intervention. The regression analysis showed that the decrease in food energy density was the most significant predictor of weight loss at 1 and 2 months, when subjects were the most motivated and compliant and achieved most of the weight loss.
- Weight loss in the trial was predicted by scores from the EATING Inventory. The decrease in the disinhibition score and increase in dietary restraint score predicted the amount of weight loss at 6 and 12 months.
- The diet followed by the subjects in the comparison group was a standard one used for treating obesity. Because subjects in the comparison group were not required a special food and record this intake each day, it is possible that they were able to concentrate on the dietary advice with fewer distractions.
- These findings provide support for regular consumption of food low in energy density, such as soup, as a strategy for weight management.

Reviewer Comments:

High dropout rate of 26%, unclear if withdrawals from groups were similar. Differences in dietary intake between groups at baseline. Authors note the following limitations:

- *The authors noted that although they expected differences in satiety to affect compliance with the diet, they were unable to demonstrate differences in reported energy intake that would account for differences in weight loss among the groups.*
- *The most likely reason for this finding is that the diet records were insufficiently precise to measure the differences in daily energy intake that were involved (<120 kcal/d).*

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?	No
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?	No
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?	???
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?	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?	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)?	N/A
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?	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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