

Citation:

Tanumihardjo SA, Valentine AR, Zhang Z, Whigham LD, Lai HJ, Atkinson RL. Strategies to increase vegetable or reduce energy and fat intake to induce weight loss in adults. *Exp Biol Med* (Maywood). 2009 May; 234(5): 542-552.

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Study Design:

Randomized 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 if advising high vegetable and moderate fruit consumption would result in weight reduction in obese individuals.

Inclusion Criteria:

- 19 to 50 years of age
- Body mass index (BMI) between 30 and 40kg/m²
- Willing to visit the study kitchen twice per week during the first 16 weeks of the study for food pick-up and group lessons.

Exclusion Criteria:

- Participation in aerobic exercise more than 90 minutes per week
- Consumption of five or more servings of vegetables and fruits per day
- History of insulin treatment
- History of drug or alcohol abuse
- Participation in other research studies that could confound results
- Plans to move away from the study area within 12 months of the study start
- Pregnancy or lactation
- Serious medical or psychiatric illness
- Unwillingness or inability to discontinue use of supplements containing carotenoids
- Use of drugs that might affect weight loss
- Weight change of more than 3% of body weight during the three months prior to recruitment
- Participation in study by another household member.

Description of Study Protocol:

Recruitment

Subjects were recruited from the greater Madison, Wisconsin area using posted flyers and newspaper Web site advertisements seeking obese volunteers for a weight-loss study.

Design

Randomized trial (high vegetable group vs. reduction group).

Dietary Intake/Dietary Assessment Methodology

Subjects completed three-day diet records at baseline, three, 12 and 18 months.

Blinding Used

Researchers and consultants who analyzed blood samples were unaware of treatment assignments.

Intervention

- High vegetable group: Subjects were educated about counting vegetable and fruit intake using the Food Guide Pyramid, based on the *Dietary Guidelines for Americans, Fifth Edition* and had a daily goal of consuming eight servings of vegetables and two to three servings of fruits. They were also asked not to consume potato chips, fried vegetables or fruit and vegetable juices to meet their goal.
- Reduction group: Subjects were supposed to reduce caloric intake by 500kcal from the estimated kcal for weight maintenance each day and consume less than 25% energy from fat
- Food was provided to subjects during the first four months of the study. Food packaging and meal choices were similar between groups, but the high vegetable group received seven to eight servings of vegetables per day compared to 3.5 to four for the reduction group.
- The trial was comprised of four phases:
 - Phase I (week one to three): Subjects were advised to transition from their usual eating habits to their assigned dietary strategy. Subjects attended morning educational sessions two times per week and food was provided five times per week during the weekdays.
 - Phase II (week four to 12): Subjects were asked to meet their dietary goals, educational sessions continued two days per week and food was provided five days per week
 - Phase III (month four): Subjects were to transition to following their assigned diet independently. Food was provided two days per week and group lessons were not offered (but individual consultations were available upon request).
 - Phase IV (months five to 18): Subjects were asked to follow their assigned diet independently, but could still request individual consultations. Support calls by telephone were provided with decreasing frequency (from weekly to monthly) from months five to 12.

Statistical Analysis

- Primary outcomes (change in weight, fat mass, fat-free mass and absolute BMI), secondary outcomes (fasting serum lipid profile, insulin, glucose, hematocrit and C-reactive protein) and Baecke Physical Activity Scores were examined for main effects of treatment, time and treatment-by-time using PROC MIXED to account for repeated measures. Age at baseline and age of overweight onset were included as fixed effects in all models. Baseline BMI and gender were included as a fixed effects as appropriate.

- Changes within treatment groups were examined using PROC MIXED or adjusted T-tests controlling for age at baseline, age of overweight onset and baseline BMI (as appropriate)
- Between-group differences in primary outcomes from baseline to three months only were examined using adjusted T-tests (primary outcomes) or Student's T-tests (secondary outcomes).

Data Collection Summary:

Timing of Measurements

- Primary outcomes (change in weight, fat mass, fat-free mass and absolute BMI) were measured at baseline, three, 12 and 18 months
- Secondary outcomes (fasting serum lipid profile, insulin, glucose, hematocrit and C-reactive protein) were measured at baseline, three and 12 months.

Dependent Variables

- Primary outcomes (change in weight, fat mass, fat-free mass and absolute BMI)
- Secondary outcomes (fasting serum lipid profile, insulin, glucose, hematocrit and C-reactive protein).

Independent Variables

High vegetable group or reduction group.

Control Variables

- Age at baseline
- Age of overweight onset
- Baseline BMI
- Gender.

Description of Actual Data Sample:

- *Initial N*: 60 (22 females and eight males in each group)
- *Attrition (final N)*:
 - Three months: 56
 - 12 months: 45
 - 18 months: 32
- *Age*: Mean age \pm SD of 30.7 \pm 6.6 years for the high vegetable group and 36.4 \pm 9.4 years for the reduction group
- *Ethnicity*: 78.3% white, 8.3% black, 5% Hispanic, 3.3% Asian, 5% not reported
- *Other relevant demographics*: 51.7% were married
- *Anthropometrics*: Groups differed in age, so analyses controlled for age
- *Location*: Wisconsin, US.

Summary of Results:

Key Findings

- At three months, there was a difference between treatment groups in change in weight,

change in fat mass and BMI ($P \leq 0.0011$)

- In the high vegetable group, weight and fat mass were lower than baseline at three months ($P=0.0087$ and $P=0.0002$, respectively), while fat-free mass increased from baseline at three months ($P=0.0075$). Body mass index was lower than baseline at only three months ($P=0.014$)
- The reduction group decreased weight at three ($P < 0.0001$), 12 ($P=0.0001$) and 18 ($P=0.019$) months. Fat mass was lower than baseline at three ($P < 0.0001$) and 12 ($P=0.0032$) months and fat-free mass did not differ from baseline at any follow-up ($P \geq 0.058$). Mean BMI was lower than baseline at all three follow-ups ($p \leq 0.045$).

Mean Body Mass Index (Standard Deviation) Over Time of Obese Subjects Following Two Dietary Strategies for Weight Loss

	High Vegetable Diet	Reduction Diet	Effect	P-value
Baseline	33.7 (3.8)	33.3 (3.5)	treatment-by-time	0.67
Three months	33.3 (3.9) ^{a,b}	31.7 (3.4) ^{a,c}	treatment	0.019
12 months	33.3 (4.2)	31.3 (4.3) ^{a,c}	time	0.41
18 months	33.2 (4.1)	31.7 (4.6) ^{a,c}		

^a Values significantly ($P \leq 0.05$) different from baseline (adjusted T-tests controlling for age at baseline and age of onset of overweight).

^b Change from baseline significantly different between groups (adjusted T-tests, controlling for age at baseline and age of onset of overweight).

^c Values within a group that differed significantly from baseline as evidenced by a mixed effects model with repeated measures showing a significant effect of time.

Other Findings

- Within the high vegetable group (comparing three-month data to baseline), total blood cholesterol, LDL and cholesterol:HDL decreased ($P=0.0001$, $P < 0.0001$ and $P=0.0040$, respectively)
- Within the reduction group, there was a decrease from baseline at three months for hematocrit, triacylglycerols ($P=0.0030$), total cholesterol ($P=0.0001$), LDL ($P=0.0008$), VLDL ($P=0.0031$) and cholesterol:HDL ($P=0.0061$)
- Daily energy consumed did not differ between the groups long-term, but the reduction group consumed fewer kcals per day than the high vegetable group at three months ($P=0.033$). The reduction group also increased their physical activity relative to baseline and the high vegetable group did not.
- At three months, only 39.1% of the high vegetable group consumed seven or more servings of vegetables a day.

Author Conclusion:

The increased vegetable and moderate amounts of fruit diet was not as effective for weight loss as the more traditional energy and fat restriction diet after three months of an intensive food and education intervention or for weight loss maintenance long-term.

Reviewer Comments:

- *Study strengths:*
 - *Food was provided during the first four months to improve compliance*
 - *Follow-up was long-term (18 months) and outcomes were also assessed after subjects transitioned to independently attempting to meet diet goals*
 - *Compliance was measured with diet records*
- *Study limitations:*
 - *Not all subject returned diet records, and the returned records may not have reflected the entire group's intake*
 - *Only 14 of 30 completed the high vegetable intervention through 18 months of follow-up, and 18 of 30 completed the intervention in the calorie reduction group*
 - *The eight servings of vegetables per day was not achieved by most subjects in the high vegetable group over the long-term.*

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