

Citation:

Ortega RM, Rodríguez-Rodríguez E, Aparicio A, Marín-Arias LI, López-Sobaler AM. Responses to two weight-loss programs based on approximating the diet to the ideal: Differences associated with increased cereal or vegetable consumption. *Int J Vitam Nutr Res*. 2006 Nov; 76(6): 367-376.

PubMed ID: [17607956](#)

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:

To analyze the anthropometric changes induced by two weight control programs, based on approximating the diet to the theoretical ideal (increasing the consumption of foods with the largest differences between the recommended and observed intakes: Cereals and vegetables, for which a minimum of six and three servings per day are recommended, respectively).

Inclusion Criteria:

- Female sex
- Age 20 to 35 years
- Body mass index (BMI) 24 to 35kg/m²
- Not having quit smoking in the previous two months
- No disease or medical condition that might interfere with the results: Diabetes, hyperthyroidism, metabolic disease, hypertriglyceridemia, lactose or gluten intolerance (celiac disease) and food allergies
- Not currently involved in a weight loss program
- Not to have lost more than 4.5kg in the two months prior to the study
- Not to have lost or gained more than 3kg between the first interview and the start of the study
- To have a regular menstrual cycle
- To consume no more than two alcoholic drinks per day
- To be neither pregnant or lactating (or plan to become pregnant while on study)
- Residing in Madrid, Spain
- Per the requirements of the Ethics Committee of the Faculty of Pharmacy, all subjects gave their written, witnessed consent to be included.

Exclusion Criteria:

- Male sex
- Age less than 20 or more than 35 years
- BMI less than 24 or more than 35kg/m²
- Anyone having quit smoking in the previous two months

- Anyone having a disease or medical condition that might interfere with the results: Diabetes, hyperthyroidism, metabolic disease, hypertriglyceridemia, lactose or gluten intolerance (celiac disease) and food allergies
- Anyone currently involved in a weight loss program
- Anyone having lost more than 4.5kg in the two months prior to the study
- Anyone having lost or gained more than 3kg between the first interview and the start of the study
- Anyone having an irregular menstrual cycle
- Anyone consuming more than two alcoholic drinks per day
- Anyone who is pregnant or lactating (or plan to become pregnant while on study)
- Anyone residing outside of Madrid, Spain.

Description of Study Protocol:

Recruitment

- Participants were recruited through a public offer to take part in a study on "the assessment of nutritional status and improvement of weight control"
- The study was publicized using posters, radio announcements and publications directed towards young, female university students
- Most participants were university students; the others were females who worked at the university of had heard of the study through recruitment advertisements.

Design

- Randomized control trial
- Subjects were randomly assigned to one of two dietary intervention groups using an Excel random number generator function.

Dietary Intake/Dietary Assessment Methodology

- A "food and drink record" was used to register all food and drink intake both at home and away from the home for three consecutive days, including a Sunday
- Subjects were instructed to record the weights consumed if possible, and household measurements (spoonfuls, cups, etc.), if not. The aim was to have as true a record as possible.

Blinding Used

The assessors were blind to the hypotheses of the study but not to the conditions of the subjects. Each subject was blind to the condition of all other subjects and also to the hypotheses.

Intervention

- Subjects were randomly assigned to one of two dietary intervention groups:
 - DIET C: With this diet, the weight control measures were based on restricting the consumption of energy-rich foods and increasing the proportional consumption of cereals, especially breakfast cereals
 - DIET V: With this diet, the weight control measures were based on restricting the consumption of energy-rich foods and increasing the proportional consumption of greens and vegetables
- Justification of DIET C: This food group is under-represented in the Spanish diet (normal consumption is approximately two servings per day compared to a recommended minimum of six servings per day). Breakfast and cereal bars were selected for the intervention since, apart from carbohydrate, they also provide fiber, vitamins and minerals. The breakfast cereal chosen was Special K (Kellogg, Espana), because of it's particularly high mineral and vitamin content per unit weight. However, subjects were also advised to eat other cereals and bread, rice, pasta, etc.
- Justification of DIET V: This diet is justified by the notable difference in the recommended (three

servings per day) vs. observed consumption (one to 1.5 servings per day) of these foods.

Statistical Analysis

- Means and standard deviation (SD) were calculated for all variables
- ANOVA and the Newman-Keuls test were used to determine the changes in an individual subject's weight and other variables over time
- Student's T-test was used to compare DIET C to DIET V (with homogeneous distributions)
- Mann-Whitney was used to compare DIET C to DIET V when distributions were not homogeneous
- Linear correlation coefficients between dietary and anthropometric data were calculated using the Pearson test
- At the conclusion of the study, associations of weight loss with the change in cereal consumption, as well as with changes in energy intake and macronutrient intake, were assessed by using multiple regression analysis.
- All calculations were made using RSIGMA BABEL Software (Horus Hardward, Madrid)
- Significance was set at $P < 0.05$

Data Collection Summary:

Timing of Measurements

Data were collected from all subjects during the pre-intervention state (seven to 10 days between screening visit and baseline visit), and again at two and six weeks.

Dependent Variables

- Physical activity: This information was used to calculate subjects' energy expenditure. It indicated the length of time spent sleeping, eating, playing sports, etc., during work days and weekends. An activity coefficient was established for each study subject
- Anthropometric information, including:
 - BMI: $\text{Weight (kg)}/\text{height(m}^2\text{)}$
 - Waist-to-hip ratio: $\text{Waist circumference (cm)}/\text{hip circumference (cm)}$
 - Percentage body fat (BF) calculated from the body density using the equation:
 $\%BF = (495/\text{density}) - 450$
 - Fat mass (kg) = $\text{Percentage BF} \times \text{weight(kg)}/100$
 - Fat-free mass (FFM) = $\text{weight} - \text{fat mass}$
 - FFM (Percentage) = $(\text{FFM} \times 100) / \text{weight}$
 - Weight lost by subjects was recorded at two and six weeks
- Health Variables: Information was collected on any disease problems, on consumption of medication and supplements and manufactured dietary foods
- Dietetic Study: Collected through a three-day food and drink record. This information was used to observe energy intake (total intake and discrepancy (intake and expenditure in kJ and percentage) and macronutrient (proteins, lipids, carbohydrates, fiber, alcohol) intakes.

Independent Variables

- DIET C: With this diet, the weight control measures were based on restricting the consumption of energy-rich foods and increasing the proportional consumption of cereals, especially breakfast cereals
- DIET V: With this diet, the weight control measures were based on restricting the consumption of energy-rich foods and increasing the proportional consumption of greens and vegetables.

Description of Actual Data Sample:

- *Initial N:*

- 67 (100% female) began the study
- 193 women were screened, 114 were excluded in the initial phase (52 had a BMI lower than 24kg/m²; 29 were older than 35 years; eight were younger than 20 years; three had a BMI higher than 35; and 22 had hormonal problems, were taking medication, planning to become pregnant, lactating or lived outside of Madrid)
- *Attrition (final N)*: 57 women completed the study
- *Age*: 20 to 35 years (mean ±SD: 27.8±4.7)
- *Ethnicity*: Spanish (all participants resided in Madrid, Spain)
- *Other relevant demographics*: Most participants were university students; the others were females who worked at the university or had heard of the study through recruitment advertisements
- *Anthropometrics*: Groups did not differ on important measures at baseline
- *Location*: Madrid, Spain.

Summary of Results:

The Healthy Eating Index (HEI) improved with both diets. The Healthy Eating Index is a measure of diet quality that assesses conformance to dietary guidance.

- The HEI improved from a mean of 56.4±12.3 (for both groups) in the pre-intervention phase to a mean of 84.8±8.0 at two weeks and 85.3±9.0 at six weeks
- Improvements were made with both diets, but significantly more so with diet C
- At both two weeks and six weeks the intakes of greens and vegetables, fruits, fats (total and saturated) and cholesterol, had become closer to those recommended
- The adequacy of cereal intake only improved with diet C
- Dietary variety improved with diet V
- In both groups, the percentage of subjects with “poor” or “needing improvement” diets was reduced while the percentage of subjects with “good” diets increased.

Table 1. Reductions in Body Weight, BMI, and the Amount of Body Fat (kg) Were also Achieved with Both Diets (X±SD)

	Pre-intervention Data		Results at Two Weeks		Results at Six Weeks	
	Diet V	Diet C	Diet V	Diet C	Diet V	Diet C
Weight (kg)	72.15±7.22	76.80±10.57	71.13 ^{a**} ±7.24	75.24 ^{a**} ±10.54	70.1 ^{b**c**} ±7.3	74.0 ^{b**c**} ±10.9
BMI (kg/m²)	27.59±2.54	28.32±3.37	27.20 ^{a**} ±2.56	27.77 ^{a**} ±3.42	36.8 ^{b**c**} ±2.6	27.3 ^{b**c**} ±3.6
Fat (%)	37.2±2.7	38.0±2.4	37.0±2.6	36.5 ^{a**} ±3.0	35.2 ^{b**c**} ±2.9	34.6 ^{b**c**} ±3.7
Fat-free Mass (%)	62.8±2.7	62.0±2.4	63.0±2.6	63.5 ^{a**} ±3.0	64.8 ^{b**c**} ±2.9	65.4 ^{b**c**} ±3.7
Fat (kg)	26.9±3.9	29.4±5.4	26.4 ^{a**} ±3.7	27.7 ^{a**} ± 5.6	24.8 ^{b**c**} ±4.0	25.9 ^{b**c**} ±6.1
Fat-free Mass (kg)	45.2±4.2	47.5±5.5	44.8 ^{a**} ±4.4	47.7±5.5	45.4 ^{c*} ±4.2	48.1±5.5

* P<0.05.

** P<0.01.

*** P<0.001.

^a Difference between pre-intervention and two-week data.

^b Difference between pre-intervention and six-week data.

^c Difference between two-week and six-week data using the repeated measure ANOVA and Newman Keuls tests.

Table 2. Weight Loss Since Start of Study

	Pre-intervention Data		Results at Two Weeks		Results at Six Weeks	
	Diet V	Diet C	Diet V	Diet C	Diet V	Diet C
Weight loss since start (kg)			1.02±5.5	1.56 ^{d**} ±0.93	2.0 ^{c**} ±1.3	2.8 ^{c**d*} ±1.4

* P<0.05.

** P<0.01.

^c Difference between two-week and six-week data using the repeated measure ANOVA and Newman Keuls tests.

^d Difference between diets C and V (unpaired T-test or Mann-Whitney test).

Other Findings

- Weight loss was 2.8±1.4kg and 2.0±1.3kg at six weeks (P<0.05) with diet C and V, respectively. This was statistically significant
- Weight loss was 1.56±0.93kg and 1.02±0.55kg at two weeks with diet C and V, respectively.

Author Conclusion:

Approximating the diet to the theoretical ideal by increasing the consumption of vegetables or cereals may be of use in weight control. In terms of weight loss and the improvement of the diet quality (energy profile and HEI), diet C was significantly more effective than diet V.

Reviewer Comments:

Study was financed by Kellogg España and cereal of interest was Kellogg's Special K.

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?	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?	???
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?	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?	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)?	N/A
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?	???
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	???