

Citation:

Hannum SM, Carson LA, Evand Em, Petr EL, Wharton CM, Bui L, Erdman JW. Use of packaged entrees as part of a weight-loss diet in overweight men: an 8-week reandomized clinical trial. Diabetes Obes Metab 2006 (2):146-156.

PubMed ID: [16448518](#)

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 assess the efficacy of a weight-loss diet by using packaged portion-controlled entrees versus a self-selected diet based on the United States Department of Agriculture Food Guide Pyramid (FGP).

Inclusion Criteria:

Male

BMI 26-42 kg/m²

24-60 years of age

Access to a microwave oven during the day

Willingness to consume foods from all food groups

Exclusion Criteria:

Use of drugs for cholesterol-lowering

Hypertension

Weight loss

Use of any drugs that affect weight tor alter body composition

Use of herbal supplements

Strict vegetarian

Smoking

Diabetes

Severe hypertension defined as systolic BP >159 and/or diastolic FB>99 mmHg

Other chronic disease states

Description of Study Protocol:

Recruitment: Participants were recruited from the Champagin-Urbana, Illinois area by means of a mailed flyer and screening website.

Design: Participants were randomized into 2 groups. Group P was instructed to consume a diet based on the USDA's Food Guide Pyramid (FGP) that included three servings from the meat and meat alternatives group, two servings of non-fat dairy foods, three servings of fruit, four servings of vegetables, seven servings of grains, and eight cups of water per day. Group E was instructed to consume two Uncle Ben's bowls daily, one at lunch and one at dinner, plus additional foods (one serving of meat and meat alternates, two cups of non-fat milk or yogurt, 2 1/2 cups of salad vegetables three servings of fruit, four servings of whole grains, and 8 cups of water per day. Those in Group E were able to choose from 24 varieties of Uncle Ben's bowls that were divided into two categories.

Both diets had approximately the same calorie level (1700 calories) and the same macronutrient composition (55% carbohydrate, 25% protein, and 20% fat).

Participants were interviewed individually by a registered dietitian and information was collected by means of health history and physical activity questionnaires. The dietitian explained how to complete the food intake and activity records.

At baseline, each participant submitted a 3 day food record and 2-day activity record. Starting weight, height, waist and hip circumference, BP and body composition were measured. Fasting blood samples (drawn two consecutive days and averaged) for baseline levels of lipids, insulin, and basic metabolic panel measurements.

Participants were monitored once weekly for the duration of the 8-week study at a group meeting with a dietitian. Each group met separately with the dietitian. Compliance scores were calculated based on attendance at weekly meetings, completion of written records, and dietary adherence as reported by the participants. Three day food records were submitted every 2 weeks during the intervention that included 2 week days and 1 weekend day. Food records were analyzed for diet composition.

Weights were obtained weekly at breakfast meetings. Other anthropometric and body composition measures and blood tests were completed at individual appointments at baseline and at the end of 8 weeks. Blood pressure was measured bi weekly at breakfast meetings.

Participants were advised not to change their activity level during the 8-week intervention.

Compliance scores were calculated based on attendance, completion of written records, and dietary adherence as reported by participants.

Blinding used: Participants were blinded to the protocol of the other study group and each group met separately to receive diet instruction. Investigators were not blinded while taking weights and

dietary intake records, but were blinded when taking other anthropometric and body composition measures and blood serum analysis.

Intervention: A diet that contained two Uncle Ben's rice bowls per day in addition to one serving of meat and meat alternatives, two cups of non-fat milk or yogurt, 2 1/2 cups of salad vegetables, three servings of fruit, four servings of whole grains, and eight cups of water per day.

Statistical Analysis: An intention-to-treat analysis was performed on the primary outcome using data from all randomized participants, in order to determine the efficacy and acceptability of the weight loss regimen. Effectiveness of randomization was determined by using student's *t*-test. Significant differences in treatment compliance and dietary adherence were determined by means of a student's *t* test. Significant differences in changes in outcomes of interest between the two intervention groups were determined by means of repeated measures ANOVA.

Data Collection Summary:

Timing of Measurements: The study was 8 weeks long. Measurements were obtained at baseline and at the end of 8 weeks.

Dependent Variables:

- Weight loss as measured by wearing street clothes without shoes or heavy outwear on a balance beam scale.
- Changes in body composition as measured by dual energy x-ray absorptiometry
- Changes in waist and hip circumference (method of measurement not specified)
- Changes in blood pressure as measured using a standard sphygmomanometer
- Changes in serum insulin, blood lipids, direct LDL-cholesterol, and CRP as measured by Laboratory Corporation of America

Independent Variables:

- Two portion-controlled entrees of Uncle Ben's rice bowls daily, plus recommended servings from the Food Guide Pyramid to total 1700 calories/day, as measured by food diaries and nutritional analysis using Nutritionist Pro Version 1.2

Control Variables

- 1700 calorie-diet based on servings of various food groups from the Food Guide Pyramid, as measured by food diaries and nutritional analysis using Nutritionist Pro Version 1.2.

Description of Actual Data Sample:

Initial N: 60 male participants, 30 in each of two groups.

Attrition (final N): 51 participants completed the study. Nine dropped out of the study for various reasons. Final n for group P was 26. Final n for group E was 25.

Age: 24-60

Ethnicity:The finishing cohort was 41 white, two African American, and eight from other ethnic groups.

Other relevant demographics: No information on SES or education level of participants was provided.

Anthropometrics: Groups were similar at baseline, with Group P having a BMI of 31.4±3.2 and Group E having a BMI of 31.3 ±3.1. Waist circumference of group P was 105.5±8.1 and group E was 105.6±10.0 at baseline. Hip circumference of group P was 100.7±7.1 at baseline and group E was 101.6±9 at baseline.

Location:Champaign-Urbana Illinois area.

Summary of Results:

Key Findings:

- During the 8-week intervention, both groups lost a significant amount of weight, but group E achieved a significantly greater weight loss than Group P (-7.4±3.1 versus -5.1 ±4.0 kg), or 7.6 percent loss of body weight for Group E versus 5.3% loss for Group P.
- The average reduction in BMI was significantly greater for Group E than Group P (-2.4±1.0 versus -1.6 ±1.3 kg/m²).

Weight and body composition changes

	Group P Baseline	Group P Eight weeks	Group P Change	Group E Baseline	Group E Eight weeks	Group E Change
Body weight (kg)	98.0±12.7	92.9±12.3	-5.1±4.0	96.8±11.3	89.5±10.5	-7.4±3.1*
BMI (kg/m ²)	31.2±3.4	29.6±3.3	-1.6± 1.3	31.0±3.2	28.7±3.0	-2.4±1.0*
Body Fatness (%)	26.3±3.6	24.8±4.4	-1.5±1.4	26.8±5.8	24.7±5.8	-2.1±1.2
Fat mass (kg)	25.8±5.6	23.3±6.1	-2.5±1.8	26.3±8.0	22.7±7.4	-3.6±1.8*
Lean mass (kg)	71.7±9.3	70.1±8.7	-1.7±2.1	70.2±5.7	67.5±5.9	-2.7±2.2
Trunk fat mass (kg)	14.0±3.5	12.3±3.6	-1.8±1.3	14.0±4.1	11.5±3.7	-2.5±1.3
Waist circumference (cm)	105.5±8.1	101.1±8.5	-4.3±2.9	105.6±10.0	99.0±10.2	-6.6±3.3*
Hip circumference (cm)	100.7±7.1	97.8±7.1	-3.0± 2.0	101.6±9.0	97.0±7.9	-4.6±3.7

*Significant difference in change from baseline between groups, p<0.05

Reported dietary intake: energy and macronutrients

	Group P Baseline	Group P During Intervention	Group P Change	Group E Baseline	Group E During Intervention	Group E Change
Energy intake (kcal)	2439.0±650.5	1715.8±339.8	-732.2±660.9	2406.2±716.1	1651.8±231.9	-754.3±679.6
Carbohydrate (g)	302.3±114.4	232.1±45.7	-70.2±112.2	298.3±94.3	260.5±39.8	-37.8±96.6
Carbohydrate (%)	48.7±8.0	54.5±6.2	+5.7±7.2	49.5±8.1	63.1±5.3	+13.7±7.3*
Protein (g)	99.8±20.3	83.8±13.9	-16.1±22.4	102.9±36.5	83.2±13.0	-19.8±39.0

Protein (%)	17.2±4.9	19.9±3.3	+2.7±4.3	17.5±3.9	20.2±1.6	+2.7±4.5
Fat (g)	93.3±28.6	53.6±18.9	-39.8±25.6	91.1±38.6	32.4±11.8	-58.6±33.0*
Fat (%)	34.4±7.1	27.5±5.9	-6.9±6.2	33.5±7.5	17.6±5.1	-16.0±7.8*

*Significant differences between groups in intervention intakes and in changes from baseline:
p<0.05

Other Findings

- Group E achieved significant reductions in systolic and diastolic blood pressure over time, while Group P remained unchanged, however both groups maintained blood pressure WNL during the study period.
- Both study groups exhibited significant decreases in serum triglycerides, total cholesterol and LDL-cholesterol over the 8-week treatment period.
- There were no differences in fasting glucose or CRP over time.

Author Conclusion:

The authors conclude that the results of this study support their hypothesis that the use of packaged entrees as part of a weight-loss diet is an effective means of achieving portion control and enhancing losses of weight and body fat.

Reviewer Comments:

Health and demographic information about the study population was not provided.

Participants in Group E were provided with a wide variety of entrees to choose from. Participants in Group P had to self-select and prepare their own foods, estimate their portion sizes, and report them. Errors in portion preparation or reporting of portion sizes could have skewed the results of this study.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

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|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| 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?	No
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?	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?	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)?	Yes
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?	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?	No

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