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Use of packaged entrees as part of a weight-loss diet in overweight men: an 8-week randomized clinical trial

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Aim: This study assessed the efficacy of a weight-loss diet by using packaged portion-controlled entrees vs. a self-selected diet based on the United States Department of Agriculture Food Guide Pyramid (FGP).

Methods: Sixty healthy overweight men (body mass index (BMI) 26–42 kg/m^2; aged 24–60 years) were randomized into two groups for an 8-week intervention. Group E consumed two portion-controlled entrees daily, plus recommended servings from the FGP. Group P consumed a self-selected diet consisting of a recommended number of servings from the FGP. Diets were designed to be isocaloric (1700 kcal) and identical in macronutrient composition (55% carbohydrate, 25% protein and 20% fat). Participants were instructed to make no changes in physical activity levels. Each group was blinded to the protocol of the other group, and received separate diet instructions, but no behavioural or diet counselling. Outcomes included weight, BMI, body composition by dual energy X-ray absorptiometry, waist and hip circumference, blood pressure (BP), fasting blood lipids, glucose, insulin and C-reactive protein.

Results: Fifty-one men completed the study. The portion-control group E (n = 25) experienced greater decreases in weight (−7.4 ± 3.1 vs. −5.1 ± 4.0 kg), BMI (−2.4 ± 1.0 vs. −1.6 ± 1.3 kg/m^2), fat mass (−3.6 ± 1.8 vs. −2.5 ± 1.8 kg), waist circumference (−6.6 ± 3.3 vs. −4.3 ± 2.9 cm) and diastolic BP (−6.0 ± 7.2 vs. + 0.2 ± 10.1 mmHg) than group P (n = 26) ($p < 0.05$). Consumption of a packaged entree diet resulted in greater losses of weight and fat mass, and reduced BP.

Conclusions: 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 fat mass in overweight men.

Keywords: cardiovascular disease risk, portion control, weight loss

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Introduction

The rapidly increasing incidence of overweight, and the associated chronic diseases, has become a major public health concern [2,3]. According to the NHANES, incidence of overweight in the US increased from 55.9 in the 1988–1994 survey to 64.5% in the published data from 1999 to 2000 [4].

Well-controlled dietary interventions can be effective for both weight loss and reduction of cardiovascular disease (CVD) risk in overweight people, as showed in a recent 3-week hospital study [5]. In addition, a series of multicentre clinical trials studied the efficacy of dietary treatment on people having one or more risk factors for CVD. For 10 weeks, people consumed nutritionally equivalent meal plans that were either prepared or self-selected [6,7]. The group consuming the prepared meals experienced greater reductions in weight, plasma lipids and lipoproteins, blood pressure (BP), glucose and

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glycosylated haemoglobin. The results were further confirmed in a series of 1-year studies repeating the same intervention at the same centres [7,8]. The researchers attributed this result to the fact that the prepared meal group did not have to deal with several obstacles faced by the self-selecting group, such as the time commitment required for food planning and preparation, and the need to understand portion sizes.

Investigations by Jeffery *et al.* into weight-loss success from a behavioural point of view have determined that providing prepared meals leads to greater success and improved diet quality [9]. Further studies by the same researchers have looked into which aspects of providing food are crucial for weight-loss success. They concluded that providing menus and providing food both led to a significantly greater weight loss than providing monetary incentives or standard behavioural therapy [10,11]. In other words, providing meals and/or meal plans leads to greater weight-loss success, not because the food is provided free, but because the people know exactly what to eat [9–11].

Previous work in our laboratory determined that portion control was an important factor in diet effectiveness in overweight, free-living women, using virtually the same protocol as in this current research, but with a lower kilocalorie level [12]. The diets prescribed for the two study groups were isocaloric (1365 kcal) and had the same macronutrient profile (55% carbohydrate, 25% protein and 20% fat), but one group consumed two portion-controlled packaged entrees per day as more than half of their energy intake, whereas the other group self-selected all of their foods based on the USDA Food Guide Pyramid (FGP) [1]. Losses of weight (5.6 ± 2.2 vs. 3.6 ± 2.5 kg) and body fat (3.6 ± 1.8 vs. 2.3 ± 1.4 kg) were significantly greater in the packaged entree group [12]. That study concluded that accurate portion control is an important factor in weight-loss success in women and that the use of packaged portion-controlled entrees is an effective method of achieving this. The current study was undertaken in order to confirm our hypothesis that this same approach would be effective in men.

Participants and Methods

Participants

Participants were recruited from the Champaign-Urbana, Illinois area by means of a mailed flyer and a screening website. Participant inclusion criteria were as follows: male; body mass index (BMI) of 26–42 kg/m^2; 24–60 years of age; access to a microwave oven during the day; and willingness to consume foods from all food groups. Men were excluded from the study for any of the following: use of drugs for cholesterol-lowering, hypertension or weight loss; use of any other drugs that affect weight or alter body composition; use of herbal supplements; strict vegetarian diet; smoking; diabetes; severe hypertension defined as systolic $BP > 159$ and/or diastolic $BP > 99$ mmHg; or other chronic disease states. The study protocol was approved by the Institutional Review Board of the University of Illinois before participant recruitment.

Protocol

Sixty men were recruited and interviewed individually by a registered dietician. At the interview, information was collected by means of health history and physical activity questionnaires. In addition, measurements of height, weight and BP were taken. The dietician explained how to complete the baseline food and physical activity records. Participants were instructed to keep the same physical activity level throughout the 8 weeks of the study, because there was no exercise component in the intervention. Using a stratified randomization based on BMI, age and activity level, the participants were divided into the two study groups. For the randomization, activity level was based on the results of the activity questionnaire administered in the interview.

Intervention

Details of the diet and study protocols were explained in separate orientation sessions for the two groups. Group P was instructed to consume a diet based on the FGP, consisting of the following: three servings from the meat and alternatives group, two servings of non-fat dairy foods, three servings of fruit, four servings of vegetables, seven servings from the grain group and eight cups of water per day. Group E was instructed to consume the following: two Uncle Ben's® bowls (Masterfoods USA, Vernon, CA, USA) per day (one at lunch and one at dinner), plus one serving from a meat and alternatives list, two cups of non-fat milk or yogurt, 2½ cups of salad vegetables, three servings of fruit, four servings of whole grains and eight cups of water per day. The frozen entrees were provided free of charge to Group E. In addition, both groups were given the same optional choices from fats and oils, desserts and alcohol. All serving sizes were as defined by the FGP. Both diets were prescribed to have the same approximate calorie level (1700 kcal) and the same macronutrient composition (55% carbohydrate, 25% protein and 20% fat). Each group was blinded with regard to the protocol for the other group until the conclusion of the study.

The composition of the Uncle Ben's® bowls varies somewhat, so they were divided into two categories (orange and blue) as showed in table 1. Group E participants were allowed to choose from all 24 varieties, but were required to consume one from each category every day in order to achieve a more equal diet composition. A wide range of cuisine styles is represented in the bowls, including American, Chinese, Mexican, Thai and Italian. The entrees are all combination foods, including starch (rice or pasta), various vegetables and meat (chicken, beef, turkey or shrimp). The average daily intake provided by two entrees was 733.4 kcal, 113.4 g of carbohydrate, 43.4 g of protein and 12.5 g of fat, with the remainder of the daily intake coming from the additional foods mentioned above. Therefore, the frozen entrees provided 43% of the prescribed daily calorie intake.

At baseline, each participant submitted a 3-day food record and a 2-day activity record representing his usual food intake and physical activity level. Starting weight, height, waist and hip circumference, BP and body composition by dual energy X-ray absorptiometry (DXA) were measured. Fasting blood samples were drawn on two consecutive days, analysed and averaged for baseline levels of lipids, insulin and basic metabolic panel measures.

All participants were monitored once per week at a breakfast meeting with the dieticians. The two study groups attended on different days, but were offered the same foods. Breakfast foods included fruits and juices, whole grain breads and fortified cereals, skim milk and yogurt, and coffee and tea. During these visits, weights of participants were measured and compliance was assessed. In order to avoid investigator bias throughout the study, both groups were given straightforward instructions and information, but no individual behavioural and diet counselling. The weekly contacts also served to promote commitment to the study and a feeling of camaraderie among the participants. In addition, Group E was provided with frozen entrees for the week.

Table 1 Macronutrient composition of frozen entrees*

Blue bowl list				
Bowl name	**kcal**	**Fat (g)**	**Protein (g)**	**CHO (g)**
Chicken fried rice	400	6	21	67
Garlic chicken bowties	380	7	23	55
Homestyle chili with beans	360	7	26	48
Honey dijon chicken	400	3.5	19	73
Beef steak stir fry	370	9	21	52
Spicy peanut chicken	400	11	22	53
Chicken fajita	380	6	23	58
Teriyaki chicken	380	3.5	20	66
Three cheese ravioli	380	7	21	61
Tomato sausage rotini	420	8	27	67
Group average	387	6.8	22.3	60
Orange bowl list				
Bowl name				
Beef fajita	340	5	20	54
Cajun style chicken and sausage	350	7	19	56
Chicken and vegetables	360	4.5	21	56
Spicy beef and broccoli	370	4.5	21	62
Sweet and sour chicken	270	7	16	41
Szechuan chicken	360	4	23	58
Turkey, wild rice and cranberries	360	4	21	61
Chicken fettuccine alfredo	350	7	27	47
Four cheese lasagna with meat sauce	330	7	24	41
Garden vegetable lasagna	320	7	19	44
Parmesan shrimp penne	370	7	26	52
Honey ginger chicken	350	5	21	57
Spicy Thai style chicken	370	7	20	57
Santa Fe chicken	350	3.5	18	61
Group average	346.4	5.7	21.1	53.4

*Participants in the frozen entree group (E) were instructed to consume one bowl from the orange list and one from the blue list each day, in addition to one serving of meat or alternative, two servings of non-fat dairy products, three servings of fruit, two and a half servings of salad vegetables, four servings of whole grains and eight cups of water daily.

Compliance

Compliance scores were calculated based on attendance (percentage of all time points), completion of written records (percentage of all required records) and dietary adherence, as reported by the participants. Our calculation of dietary compliance was based on answers to specific questions asked at every weekly meeting: 'Did you consume everything on your diet plan? If not, describe. Did you consume anything that is not on your diet plan? If so, describe. Was the plan easy/hard to follow?' The researchers engaged the participants in conversation and noted any comments on how they felt, and their opinions about the diet. The researchers were careful to remain non-judgemental regardless of the responses, and were able to develop a close rapport with the participants by means of the weekly visits. Subjective comments were noted, but not analysed statistically.

Answers to the direct questions regarding inclusion or exclusion of dietary items were used in order to calculate a dietary adherence score. A percentage value was calculated based on how the intake differed from the prescribed diet. For example, everyone was required to consume two servings of dairy products per day. If a participant skipped one serving during the week, that was 7% less than the prescribed amount for that food group. The score for all the food groups provided a total exclusion score for that week. Inclusion of an item not on the plan was calculated by giving the added food a weighted value, based on estimated kilocalorie. The approximate percentage it added to the week's calorie intake could then be calculated. Total percentage scores for dietary exclusions and inclusions were compiled for each week, and deviations from 100% compliance were deducted.

Diet Analysis

Three-day food records were submitted at baseline and every 2 weeks during the intervention. Each record included the intake from 2 week days and 1 weekend day. The baseline record represented the participant's usual intake before the study. The other four records represented his typical intake while following the study protocol. All food records were analysed for diet composition by using Nutritionist Pro Version 1.2 (First Data Bank, 2002, San Bruno, CA, USA), supplemented with additional information on the product content of the Uncle Ben's® bowls provided by Masterfoods USA. The four records submitted during the study were averaged in order to determine usual dietary intake throughout the 8-week intervention.

Body Composition Measures

Participants were weighed wearing street clothes, without shoes or heavy outerwear, on a balance beam scale (physician's scale no. D439; Detecto, Webb City, MO, USA). The weekly weight measures taken at the breakfast meetings could not be blinded to group. Because the two groups met on separate days, and the bowls were distributed to the entree group at this time, personnel could not be blinded to which group was in attendance.

All other anthropometric and body composition measures were completed at individually scheduled appointments by personnel blinded to groups. Heights were determined by using a stadiometer. Whole body composition was assessed by means of DXA (Hologic 4500A; Hologic, Bedford, MA, USA). The following anthropometrics were taken in triplicate by the same investigator by using a retractable measuring tape (Gulick II; Country Technology, Gays Mills, WI, USA): waist, hip, arm and thigh circumferences.

BP Measures

BP values were taken biweekly at the breakfast meetings, thus these measures were not blinded to group. Using a standard sphygmomanometer (model nos. 79 and 682; Prestige Medical, Northridge, CA, USA), two BP measures were taken after 5 min of seated rest. The average of the two readings was calculated for use in the statistical analysis.

Blood Serum Measures

In order to eliminate differences because of normal day-to-day fluctuations, fasting blood samples were drawn on 2 consecutive days under identical conditions, and results were averaged. All serum analyses were performed by Laboratory Corporation of America (Elmhurst, IL, USA), and the analysts were blinded to participant groups. Blood samples were collected after a 12-h fast in serum separator tubes, allowed to clot at room temperature for 15–30 min and centrifuged for 10 min. Serum samples were refrigerated within 60 min of venipuncture, and remained refrigerated during transfer to the laboratory by courier. The fresh serum was analysed for the following: basic metabolic panel, insulin, lipid panel, direct measure of LDL-cholesterol and C-reactive protein (CRP).

Activity Records

Physical activity levels were assessed by 2-day activity diary, based on a modification of the method of Bouchard *et al.* [13]. Records from baseline and endpoint were compared as an indicator of consistency throughout the study.

Statistical Analysis and Power Calculation

Using SPSS version 12.0 (Chicago, IL, USA), statistical analysis was performed. An intention-to-treat analysis was performed on the primary outcome, weight change, using data from all randomized participants, in order to determine both efficacy and acceptability of this weight-loss regimen. The primary statistical evaluation was a per-protocol analysis by using data from participants who completed all primary and secondary outcome measures and had a compliance score of at least 70% in all areas. Effectiveness of randomization was determined by using student's *t*-test. Significant differences in treatment compliance and dietary adherence were determined by means of 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. Significance for all tests was determined as $\alpha < 0.05$.

The primary dependent variable in this study was body weight change. All other evaluated data were secondary outcomes of interest. It was anticipated that with an estimated effect size of 0.70 (difference between groups in weight loss of 2.0 ± 2.9 kg), based on the work by Metz *et al.* [6] and McCarron *et al.* [7], an α (significance) level of 0.05 (one-tailed test) and a power of 80%, a sample size of 24 participants per group would be required to find statistical differences in weight loss between the entree group (Group E) and self-selected FGP diet group (Group P) should it exist. With an estimated retention rate of 80%, it was planned to recruit 60 people into the study.

Results

Sixty men were recruited into the study and were randomized into Groups P and E, as described above. At enrolment, there were no differences between the groups with regard to BMI, age and activity score (table 2). Four men voluntarily withdrew from the study: two for lack of time (one from each group); one for a loss of interest (Group E); and one for religious reasons (Group E). Five others were dropped for circumstances that conflicted with the protocol: one had to begin taking a drug on the exclusion list (Group P); one had to be out of the country for an extended time (Group E); two decided to train and compete in athletic contests (Group P); and one admitted non-adherence to the diet protocol (Group E). Consequently, 51 participants (85%) completed the study and were included in the final analyses (25 in Group E; 26 in Group P). Ethnicity of the finishing cohort was as follows: 41 White, two African American and eight from other racial/ethnic groups. Participants in Group E (n = 25) consisted of 19 Whites and 6 minorities, whereas Group P (n = 26) consisted of 22 Whites and four minorities.

A comparison of 2-day activity records from baseline and 8 weeks showed that both groups followed our instruction to maintain the same level of activity throughout the study. The changes from baseline in activity levels were 1.3 ± 10.8 vs. 1.7 ± 11.5%, for Group E vs. Group P, respectively, neither of which was significant ($p < 0.05$).

Total compliance of the 51 participants completing the study has been showed in table 3. There were no statistically significant differences between the groups in compliance scores.

Actual food intakes of the participants were self-reported by means of five 3-day food records. A macronutrient comparison of the baseline food record to the average of the four intervention records has been showed in table 4. Group E reported a significantly lower intake of fat, and a significantly lower percentage of energy as fat, than Group P. In addition, Group E reported consumption of a significantly higher percentage of energy as carbohydrate than Group P. Protein intakes were not different between the groups.

During the 8-week intervention, both groups lost a significant ($p < 0.05$) amount of weight, as showed in table 5. The entree Group E achieved a significantly greater weight loss than the pyramid Group p (−7.4 ± 3.1 vs. −5.1 ± 4.0 kg, $p < 0.05$). This represents a loss of 7.6% body weight for Group E, compared to a 5.2% loss for Group P. Figure 1 illustrates weight changes at all time points, and shows that the difference between the groups became significant at 7 weeks. Although not statistically significant, the intention-to-treat analysis involving all randomized people (n = 60) produced similar results, indicating that Group E lost more weight than Group P on an absolute (−6.1 ± 4.0 vs. −4.5 ± 4.1 kg, p = 0.11) and relative (−6.3 ± 4.0 vs. −4.5 ± 4.1%, p = 0.08)

Table 2 Characteristics of participants at enrolment (n = 60)

Stratification outcome	Pyramid group P (n=30); mean ± s.d.	Entree group E (n=30); mean ± s.d.
BMI (kg/m^2)	31.4 ± 3.2	31.3 ± 3.1
Age (years)	38.1 ± 10.2	38.0 ± 9.9
Activity score	1.9 ± 0.8	1.9 ± 0.7

Table 3 Compliance of participants completing the study (n = 51)

Compliance outcome	Pyramid group P (n=26); mean ± s.d.	Entree group E (n=25); mean ± s.d.
Weekly attendance (%)	98.6 ± 2.9	99.1 ± 2.4
Completion of written records (%)	97.8 ± 5.4	98.1 ± 4.3
Adherence to diet protocol (%)	91.2 ± 5.0	92.9 ± 4.0

Table 4 Reported dietary intakes: energy and macronutrients

	Pyramid group P (n=26); mean ± s.d.			Entree group E (n=25); mean ± s.d.		
	At baseline	During intervention	Change	At baseline	During intervention	Change
Energy intake (kcal)	2439.0 ± 650.5	1715.8 ± 339.8	−723.2 ± 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	54.4 ± 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 difference between groups in intervention intakes and in change from baseline; $p < 0.05$.

basis. Notably, as detailed above, there were no differences in attrition because of the type of weight-loss protocol as reflected by similar drop-out rates in Group E (n = 5), compared to Group P (n = 4). These results suggest that this portion-controlled weight-loss regimen using pre-packaged entrees is both effective and acceptable on a short-term basis for this population.

The average reduction in BMI was significantly greater for Group E than for Group P (−2.4 ± 1.0 vs. −1.6 ± 1.3 kg/m^2, $p < 0.05$). Body composition testing by means of DXA determined that Group E also achieved a significantly greater reduction in body fat mass than Group P (−3.6 ± 1.8 vs. −2.5 ± 1.8 kg, $p < 0.05$). Losses of lean body mass were not significantly different between the groups. With regard to regional fat loss, there was a trend towards greater loss of trunk fat mass in the entree group, but the change did not achieve significance ($p = 0.06$). Decreases in waist circumference, measured at the umbilicus, were significantly greater in the entree group (−6.6 ± 3.3 vs. −4.3 ± 2.9 cm, $p < 0.05$). A trend was seen towards a greater decrease in hip circumference in Group E (−4.6 ± 3.7 vs. −3.0 ± 2.0 cm), but it did not reach significance ($p = 0.06$). No significant differences between the groups were observed in the other anthropometric measurements.

Although both groups maintained BP within normal limits throughout the entire study (table 6), Group E achieved significant reductions in systolic and diastolic BP over time, whereas that of Group P remained unchanged. The difference between groups in change from baseline was significant for diastolic BP (−6.0 ± 7.2 vs. +0.2 ± 10.1 mmHg, $p < 0.05$), Groups E and P, respectively.

As illustrated in table 7, both study groups experienced significant decreases in serum triglycerides, total cholesterol and LDL-cholesterol over the 8-week treatment

Table 5 Weight and body composition changes

	Pyramid group P (n = 26); mean ± s.d.			Entree group E (n = 25); mean ± s.d.		
	Baseline	Eight weeks	Change	Baseline	Eight weeks	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*
Body mass index (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; $p < 0.05$.

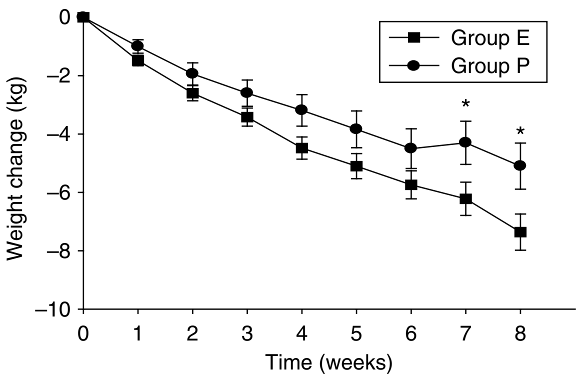

Fig. 1 Weight changes at all time points. *Significant difference between groups at same time point; $p < 0.05$.

period, but there were no differences between the groups. Regarding HDL-cholesterol, the average value for entree Group E was unchanged, whereas that of pyramid Group P increased slightly (-1.0 ± 5.1 vs. $+2.8 \pm 4.5$ mg/dl, $p < 0.05$), resulting in a significantly different value in change from baseline between the groups. Both groups experienced reductions in fasting insulin levels over time, but the changes were not statistically different between the groups. There were no changes in fasting glucose or CRP over time, and no differences between the groups in these parameters.

Discussion

The results of this study support the conclusion 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. Using the lowest number of recommended servings in each category of the FGP, as performed by Group P, does provide the basis for a healthful weight-loss diet. However, a substantial effort is required to choose, prepare, measure and consume foods in the correct portion sizes. Although both groups were prescribed diets containing 1700 kcal, and the same macronutrient profile, the men consuming the portion-controlled entrees were better able to achieve reductions in weight and body fat mass.

The results of this research are similar to those of our previous weight-loss study in women [12], in that decreases of weight, BMI, fat mass and waist circumference were all significantly greater in the group consuming the packaged entrees. However, the women's study also found a significantly greater reduction in total cholesterol, which was not seen in the men. Although the study protocols were essentially the same, the men's study diet was higher in calories (1700 vs. 1365 kcal). As a result, the two frozen entrees comprised only 43.1% of total prescribed calories in the men's study diet, compared to 53.7% of calories in the women's. This would account for a more powerful portion-control effect in the women's study. Another difference in results between the two studies was that the entree group in the men's study achieved a significantly greater reduction in diastolic BP than the FGP group, which was not seen in the women. However, it is worth noting that at all time points, the BP values of the women were lower than the lowest levels achieved by the men, so BP was not a health issue for the women. Both total cholesterol and BP are secondary outcomes that are directly correlated with weight loss, and could be expected to decrease in those who have high starting values.

Over the course of the 8-week study, men in both groups achieved reductions in total cholesterol, LDL-cholesterol and triglycerides, all of which are considered risk factors for CVD. The changes from baseline were not significantly different between the groups. There was no change over time in HDL-cholesterol for the entree Group E. However, there was a slight increase in HDL levels in the pyramid Group P. This difference is difficult to explain, but may relate to the higher-fat intake in Group P. In any case, men in both study groups maintained HDL levels in the recommended range (over 35 mg/dl), while improving their total cholesterol levels from slightly high to the recommended range (100–199 mg/dl).

Another biomarker for atherosclerosis risk is CRP, an indicator of inflammation, which is involved in the atherosclerotic process [14]. Research has demonstrated that CRP levels are correlated with obesity, and decrease

Table 6 Blood pressure (BP) changes

	Pyramid group P (n = 26); mean ± s.d.			**Entree group E (n = 25); mean ± s.d.**		
	Baseline	**Eight weeks**	**Change**	**Baseline**	**Eight weeks**	**Change**
Systolic BP (mmHg)	126.4 ± 10.7	124.4 ± 11.1	−2.0 ± 10.4	129.5 ± 8.2	123.7 ± 10.2	−5.8 ± 12.0
Diastolic BP (mmHg)	80.9 ± 8.9	81.1 ± 9.7	+0.2 ± 10.1	88.8 ± 7.2	82.8 ± 8.0	−6.0 ± 7.2*

*Significant difference in change from baseline between groups; $p < 0.05$.

Table 7 Serum markers of CVD risk

	Pyramid group P (n = 26); mean ± s.d.			Entree group E (n = 25); mean ± s.d.		
	Baseline	**Eight weeks**	**Change**	**Baseline**	**Eight weeks**	**Change**
Total cholesterol (mg/dl)	208.0 ± 32.6	177.2 ± 27.9	−30.8 ± 27.9	212.3 ± 39.3	170.1 ± 38.2	−42.1 ± 27.2
HDL-cholesterol (mg/dl)	37.2 ± 8.1	40.0 ± 7.8	+2.8 ± 4.5	38.0 ± 10.4	37.0 ± 8.8	−1.0 ± 5.1*
LDL-cholesterol direct (mg/dl)	132.3 ± 27.6	112.9 ± 25.0	−19.4 ± 23.4	129.4 ± 41.1	104.1 ± 35.5	−25.3 ± 24.9
Triglycerides (mg/dl)	181.9 ± 80.6	118.0 ± 39.6	−63.8 ± 76.7	231.7 ± 188.9	152.6 ± 76.8	−79.1 ± 153.8
C-reactive protein, cardiac (mg/l)	2.5 ± 2.5	2.9 ± 4.7	+0.4 ± 2.9	2.9 ± 2.1	2.7 ± 3.6	−0.2 ± 4.3
Fasting insulin (μU/ml)	11.0 ± 8.2	7.4 ± 3.3	−3.7 ± 5.9	10.1 ± 5.2	8.1 ± 4.4	−2.0 ± 4.2
Fasting glucose (mg/dl)	94.0 ± 11.8	91.8 ± 7.1	−2.2 ± 7.7	89.4 ± 6.9	90.2 ± 7.3	+0.8 ± 7.2

*Significant difference in change from baseline between groups; $p < 0.05$.

with weight loss [15]. However, other studies have concluded that elevated CRP levels are related to insulin resistance, independent of obesity [16]. In the current research, no changes in CRP were detected. Our study population consisted of healthy, overweight men who had low baseline serum CRP concentrations, so it is not surprising that no changes were seen. In addition, our participants maintained normal fasting levels of serum insulin and glucose from baseline throughout the study. As with all biomarkers for risk, one would hope to see changes only if the initial values were outside of the normal range.

Waist circumference and BMI correlate directly with CVD risk [17,18]. Group E had significantly greater reductions in both of these parameters than Group P. In this way, the entree group further enhanced their reduction in CVD risk.

According to the food records, both groups consumed very similar diets at baseline, with approximately 2400 kcal, 49% as carbohydrate, 17% as protein and 34% as fat. Both groups of participants significantly decreased their average daily energy intakes during the intervention ($p < 0.01$). The reduction was −754.3 ± 679.6 kcal for Group E, and −723.2 ± 660.9 kcal for Group P. There were no differences between the groups in reported energy intake throughout the study. However, entree Group E reduced their daily intake of fat significantly more than pyramid Group P (−58.6 ± 33.0 vs. −39.8 ± 25.6 g, $p < 0.05$). Group E, in addition, decreased the percentage of energy consumed as fat significantly more than Group P (−16.0 ± 7.8 vs.−6.9 ± 6.2%, $p < 0.05$). By contrast, Group E increased the percentage of energy as carbohydrate significantly more than Group P (+13.7 ± 7.3 vs. +5.7 ± 7.2%, $p < 0.05$). There were no differences in protein consumption, or in percentage of calories as protein, between the groups or over time. The differences in fat and carbohydrate percentages consumed by the two groups reflect the low-fat content of the prepared entrees.

In view of the ongoing debate on the efficacy of high-protein, moderate-fat diets, vs. high-carbohydrate, low-fat diets, it is interesting to see how successfully our participants were able to lose weight following a balanced low-calorie diet that includes all food groups. Popular high-protein diet plans, such as Atkins [19] and the Zone [20], warn of the obesigenic effects of carbohydrates, but our study does not support this concept. This study does support the concept that total energy intake is important for weight loss.

Nutritionally balanced, low-energy diets sometimes make use of liquid meal replacements. These types of weight-loss diets have been showed to be effective [21–23], and are easy to use. They do provide excellent portion control, but can become monotonous over time. In addition, the liquid formulas do not contain some important components found in real foods, such as non-traditional nutrients and phytochemicals, that may provide health benefits. Using varied packaged entrees, one can avoid the potential downsides of the liquid formulas, and still achieve accurate portion control. Research by Raynor *et al.* has showed that food group variety affects weight control. Increased variety of fats, oils and sweets promotes weight gain, whereas increased variety of low-fat foods promotes weight loss [24]. In this study, the variety of low-fat entrees may have been an additional benefit.

One limitation of our study is the short-term of the intervention. We know that a permanent lifestyle change is required if a permanent weight loss is to be maintained. In this 8-week study, we hoped to break old habits, and provide training in consumption of reasonable portion sizes. We would not expect participants to continue using portion-controlled entrees every day, but we would expect them to learn that using such entrees from time-to-time is a convenient alternative to restaurant eating that will not cause them to regain weight.

In a free-living, whole-diet study, it is difficult to determine actual food intakes with confidence, which represents another limitation of this research. The accuracy of food records is often questioned because of difficulty estimating portion size and a tendency towards underreporting, especially in overweight persons [25–27]. However, keeping food records helps people to be aware of what they are eating, so it is still a useful tool for research [28]. Food records, in addition, serve to provide the researchers an overall picture of the macronutrients being consumed by the participants. The food records and the direct questions asked of the participants regarding intakes both showed that the participants believed that they were complying well. Both groups reported similar reductions in energy intake, and similar total calories. Although both groups were prescribed diets with the same macronutrient profiles, the food records showed that the entree group consumed a lower percentage of fat and a higher percentage of carbohydrate. The value of these data is limited by the usual inaccuracies of self-reported diets, but the difference in macronutrient composition is logical, given the low-fat content of the entrees.

With the busy lifestyles that are typical today, many people do not want to invest time in preparing and cooking meals at home. Those who choose to eat in restaurants on a regular basis are exposed to overly generous portion sizes, and are vulnerable to weight gain. Researchers have demonstrated that people will usually consume the amount of food that is served to them [29]. For a person who is trying to lose weight, using portion-controlled frozen entrees is a reasonable alternative to restaurant eating.

Conclusion

Accurate portion control has been showed to be a key factor in weight loss. Use of packaged frozen entrees as part of a nutritionally balanced, low-calorie diet is an effective way to achieve portion control and to enhance weight-loss success in overweight men.

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