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## Randomized Clinical Trial of Portion-Controlled Prepackaged Foods to Promote Weight Loss

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### Abstract

**Objective**—Providing portion-controlled prepackaged foods in a behavioral counseling intervention may promote more weight and fat loss than a standard self-selected diet. **Methods:** The primary aim was to test whether providing portion-controlled prepackaged lunch and dinner entr es within a behavioral weight loss intervention promotes greater weight loss at 12 weeks in overweight/obese adults compared to self-selected foods. Other aims were to examine effects on biological factors, fitness, and meal satisfaction. One-half of those assigned to prepackaged entr es were provided items with a higher protein level (>25% energy) as an exploratory aim.

**Results**—Participants (N=183) had a baseline weight of 95.9 (15.6) kg (mean [SD]) and BMI of 33.2 (3.5) kg/m<sup>2</sup>. Weight data at 12 weeks were available for 180 subjects. Weight loss for regular entr e, higher protein entr e and control groups was 8.6 (3.9), 7.8 (5.1), and 6.0 (4.4)%, respectively (*P*<0.05, intervention vs. control). Intervention participants lost more body fat than controls (5.7 [3.4] vs. 4.4 [3.3] kg, *P*<0.05).

**Conclusions**—A meal plan incorporating portion-controlled prepackaged entr es promotes greater weight and fat loss than a standard self-selected diet, with comparable meal satisfaction. Initial weight loss predicts long-term weight loss so these results are relevant to likelihood of longer term success.

### Keywords

Prepackaged foods; Portion control; Quality of Weight Loss; Meal satisfaction; Diet

### Introduction

Achieving and maintaining a healthy body weight is challenging for many people, as evident in the high prevalence of obesity in the U.S. today (1). The ultimate determinant of weight change is energy intake relative to expenditure, so a reduction in energy intake is the primary

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**Clinical Trial Number:** NCT02136290 on clinicaltrials.gov



## Methods

### Participants

Participants for this randomized controlled trial were recruited through word of mouth, direct marketing letters, local list serves, clinicaltrials.gov, social media, and flyers. Eligibility criteria included the following: aged 25-65 years; body mass index (BMI) 27-40 kg/m<sup>2</sup>; not pregnant or breastfeeding or planning to become pregnant in the next several months; willing to participate in any of the study diet arms over a 3-month period; no eating disorders, food allergies or intolerances; no history of bariatric surgery; willing and able to participate in clinic visits and study interactions at specified intervals and to maintain contact with the investigators for at least three months; willing to allow blood collections; and capable of performing a simple test for assessing cardiopulmonary fitness. Exclusion criteria were: inability to participate in physical activity because of comorbidity or disability (e.g., severe arthritic conditions); a history or presence of a comorbid disease for which diet modification and increased physical activity may be contraindicated or complicated; currently involved in another diet intervention study or organized weight loss program; and having a history or presence of a significant psychiatric disorder or any other condition that, in the investigator's judgment, would interfere with participation in the trial.

Participants were randomly assigned 3:3:2 to three groups: one in which the meal plan included any variety of the prepackaged entrées, one that offered only entrées with >25% energy from protein, or a meal plan based on self-selected foods (Figure 1). Randomization was stratified by age (<40 vs. ≥40 years) and BMI (27-32.9 vs. 33-40 kg/m<sup>2</sup>). The UCSD institutional review board approved the study protocol, and all participants provided written informed consent.

One hundred eighty-four subjects were randomized, and one subject was excluded post-randomization because she discovered that she had been pregnant at the time of randomization, leaving an analysis sample of 183 subjects.

### Interventions

All study participants met with a dietitian for an initial 1-2 hour personalized diet prescription and counseling session. Each was prescribed an energy-reduced diet at a deficit of 500-1500 kcal/day based on estimated energy expenditure and was encouraged to increase physical activity. Menus ranged from 1200 to 3000 kilocalories/day. All participants were provided sample meal plans and guidance for how to choose grocery and restaurant items that would achieve the meal plan to accommodate special occasions and other needs. The physical activity goal was an average of at least 60 minutes/day of purposeful exercise at a moderate level of intensity. Participants were also provided behavioral weight loss guidance and strategies via in-person, telephone or email contact on a weekly basis for three months and were provided relevant print material and resources. Behavioral strategies and approaches that were applied in this intervention included self-monitoring of weight, food intake and exercise; realistic goal-setting, using behavior-specific goals and a step-wise approach to promote self-efficacy; training and role-playing in problem-solving; relapse

prevention; strategies to increase social support; and modifying problematic thoughts and attitudes about weight, food, and physical activity.

Participants were encouraged to use Web-based and smart phone programs and applications to monitor and guide their food choices and exercise to meet their specific recommendations. Materials that were provided included recipes, guidance for eating in various restaurants, digital videos, information about exercise equipment, and sources of online education and support.

Participants who were assigned to the portion-controlled prepackaged lunch and dinner frozen entrées (Lean Cuisine, Nestlé USA, Inc., Glendale, CA) were asked to select their choices from all 50 varieties, or if assigned to the higher protein group, from the 25 entrées that provided >25% of energy from protein, to be consumed 7 days/week. The meal plans specified additional servings across food groups (e.g., grains, vegetables, fruit, dairy foods, protein foods, oils), with the goal of achieving the myplate.gov nutrient composition and macronutrient distribution (45-65% energy from carbohydrate, 20-35% energy from fat, and 10-35% energy from protein) (<http://www.choosemyplate.gov/>). The average entrée provided 281 kilocalories, 6.2 grams fat (19.8% energy), 40 grams carbohydrate (56.9% energy) and 16.3 grams protein (23.2% energy). The average higher protein entrée provided 250 kilocalories, 5.6 grams fat (20% energy), 32 grams carbohydrate (51% energy) and 18.4 grams protein (29.4% energy). The two entrées (lunch and dinner) provided 20-50% of total daily energy intake.

Participants assigned to the standard self-selected diet group were provided a similar dietary prescription and specifications but without the lunch and dinner entrées, so the participant self-selected all foods for those meals from the food groups and energy intake level prescribed. Participants in this group also had individualized face-to-face follow-up and brief counseling at two weeks and one month.

All participants were reimbursed \$80 for data collection clinic visits. Participants assigned to the prepackaged entrées were provided their selected entrées free of charge on a weekly basis. The entrées were distributed from the clinic site, which allowed an assessment and reinforcement of compliance. Participants in the standard self-selected diet group were reimbursed \$225 (as cash and gift cards) as an incentive and to cover some of the cost of their self-selected foods.

## Measurements

Participants attended comprehensive data collection clinic visits at baseline and 3 months, when weight, waist circumference, height (baseline only), and blood pressure were measured; questionnaires were completed; fasting (>6 hours) blood samples were collected; and body composition measured. Body composition (fat and fat-free mass) was measured using a GE/Lunar Prodigy Dual Energy X-Ray Absorptiometer (DXA). Systolic and diastolic blood pressure was averaged from two sitting blood pressure measurements using an automated device. The 3-minute step test was used to assess aerobic fitness. This test measures heart rate during the first 30 seconds of recovery from stepping, and although less accurate than measuring maximal oxygen uptake ( $VO_{2max}$ ), the test has high reliability and

is sensitive to change (11). Brief clinic visits at 2- and 4-week follow-up visits were also conducted for additional weight measurements.

Measurements of cholesterol, triglycerides, and high-density lipoprotein cholesterol (HDL-C) were conducted with enzymatic methods using the Kodak Ektachem Analyzer system (Johnson & Johnson Clinical Diagnostics, Rochester, NY). Low-density lipoprotein cholesterol (LDL-C) values were calculated using the Friedewald equation (12). High-sensitivity CRP was assayed using the SPQ High Sensitive CRP Assay kit (DiaSorin, Inc., Stillwater, MN), a polystyrene-enhanced turbidimetric in vitro immunoassay (13). Plasma carotenoid concentrations, as a biomarker of vegetable and fruit intake, were measured by high-performance liquid chromatography (14). Accuracy and precision were monitored by the use of an in-house quality control pool and laboratory participation in the College of American Pathologists and the National Institute of Standards and Technology quality assurance programs.

Quality of life was assessed with the Short Form Health Survey (SF-36) questionnaire (15). The PANAS scale was used to assess positive and negative affect (16), along with a simple assessment of body image via a psychometric query that asks “how good do you think you look” on a scale of 1-10, as well as subjects' confidence that they “can control my eating and stick to a meal plan that will help me lose weight.” Participants also completed the three-factor Eating Inventory, a 51-item questionnaire that assesses eating attitudes and behavior across three scales: dietary restraint, disinhibition, and hunger (17). Physical activity was estimated using the Godin Leisure-Time Exercise Questionnaire, which consists of three questions that record the frequency and duration of mild, moderate, and strenuous exercise performed during leisure time in a typical week. This is a validated self-report measure of physical activity that has been widely used in previous research (18). We report weekly hours of moderate and strenuous physical activity.

### Statistical analysis

Demographic characteristics were summarized for the groups, and the study groups were compared at baseline with regard to key variables (e.g., weight, BMI, age, biochemical measures) using 2-sample tests. The main outcome measure was percent change in body weight at 12 weeks in the aggregated portion-controlled prepackaged food intervention arms vs. the control arm. Our recruitment of 184 participants was based on having >80% power to detect a mean expected difference in weight loss between the aggregated prepackaged food arms and the control group arm of 3.1% of initial weight (4.7% vs. 1.6%), based on previous studies, with a retention rate >90% as we have achieved in our prior weight loss studies within a 12-month time frame. Although we did not plan or anticipate having sufficient power to detect differences between the regular and higher protein prepackaged entrée subgroups, data from these two subgroups are presented to allow comparison of these data as an exploratory aim. Percent change from baseline weight was computed using data collected at the 2-week and 1-month weight visits and the full 3-month clinic visit. The aggregated intervention arms were compared with control subjects using t-tests. Paired t-tests within study arms compared data from subjects at baseline and 3 months.

Lipids, CRP, total carotenoids, blood pressure, physical activity, and step test heart rate were compared in the aggregated intervention arms vs. the control group using t-tests. Paired t-tests within study arms compared change data from subjects between baseline and 3 months. CRP values were log transformed to improve normality in paired t-tests, and CRP was also analyzed with a nonparametric test.

Baseline psychosocial measures were compared to 3-month measures within each study group using paired t-tests, and 3-month measures were compared between aggregated portion-control prepackaged intervention and standard self-selected diet groups using two-sample t-tests.

Significance was set at two-sided  $\alpha = 0.05$ . Analyses were performed using SAS version 9.4 (Cary, NC).

## Results

Participants (58% female and 42% male) were aged 25-65 years, and almost one-half were members of a minority racial/ethnic group (Table 1). Participants had mean (SD) baseline weight of 95.9 (15.6) kg and BMI of 33.2 (3.5) kg/m<sup>2</sup>. Weight data at study end were available for 180 of the 183 subjects (98.4%). Among participants assigned to the intervention, self-reported compliance with the prescribed entrées was 100% at two weeks and was diminished only minimally to approximately 80% at study end. Episodic nonadherence was attributable to interruptions due to brief illness or travel and occasional special meals.

Weight loss at 12 weeks for the regular entrée, higher protein entrée and control groups was 8.6 (3.9) (mean [SD]), 7.8 (5.1), and 6.0 (4.4)%, respectively (Table 2, Figure 2) ( $P < 0.005$ , intervention vs. control). At 3 months, a greater proportion of intervention (74%) than control (53%) participants achieved a 5% loss ( $P < 0.02$ ). Men assigned to the intervention lost a mean (SD) of 9.7 (4.4)% of their baseline weight, compared with women assigned to the intervention who lost 7.0 (4.3)% ( $P < 0.001$ ). Waist circumference decreased in all groups (Table 2). Intervention participants lost an average of 5.7 (3.4) kg of body fat (15.1% of initial body fat) compared with a loss of 4.4 (3.3) kg body fat in controls (10.7% of their initial body fat), ( $P < 0.03$  for kg fat loss and  $P < 0.01$  for % fat loss), as shown in Table 2.

Blood samples from the 3-month clinic visits were available from 169 (92.4%) of participants. Total cholesterol decreased by a mean of 6 (25) mg/dL in intervention participants ( $P < 0.01$ ), as shown in Table 3. At 3 months, cholesterol and LDL-C were higher in controls than in intervention participants ( $P = 0.04$ ). Intervention subjects decreased triglycerides at 3 months by a mean of 15 mg/dL ( $P < 0.001$ ) while controls decreased triglycerides by 11 mg/dL ( $P = 0.07$ ), as shown in Table 3.

Group differences were not observed in CRP at baseline. However, CRP in all three groups was different at 3 months ( $P < 0.03$ ), and the control group was higher at 3 months than the aggregated prepackaged food groups ( $P = 0.06$ , Wilcoxon two-sided rank sum test). Intervention subjects, but not control subjects, decreased their log transformed CRP between baseline and 3 months ( $P < 0.03$ , paired t-test). In all groups, carotenoids increased from



baseline to 3 months ( $P<0.01$ ) but did not differ across groups at study end, indicating that vegetable and fruit consumption increased similarly in prepackaged and self-selected diet study groups.

Blood pressure and recovery heart rate decreased at 3 months in all study arms ( $P<0.01$ ) (Table 3). Intervention participants had a greater decrease in step test recovery heart rate than control participants ( $P=0.03$ ). Mean hours of weekly moderate/strenuous physical activity more than doubled in each of the study arms and did not differ in intervention and control participants.

Mental quality of life improved in intervention ( $P<0.01$ ) but not in control subjects, as shown in Table 4. Meal satisfaction, as indicated by ratings of appearance and taste, did not change and was comparable in the portion-controlled prepackaged foods and standard self-selected groups (Table 4). Subjects in all study groups reported decreases in hunger and disinhibition, and increases in restraint; they also gave themselves higher ratings for “I look good” at study end (Table 4). However, at 3 months control group participants expressed less confidence that they could control eating and stick to a meal plan for weight loss ( $P=0.03$ ).

## Discussion

Findings from this study suggest that prescribing portion-controlled prepackaged foods in the context of intensive behavioral weight loss counseling promotes a greater degree of weight and fat loss than a standard self-selected diet. We observed an average weight loss of ~8% of initial weight in participants prescribed twice-daily prepackaged entrées in their meal plans, compared to a weight loss of 6% in the control group prescribed a standard self-selected diet. In association with a greater degree of weight loss, several cardiovascular disease risk factors (e.g., total cholesterol, LDL-C) also were lower in those assigned to the prepackaged foods compared to the control group at study end. Importantly, satisfaction with food and meals, which may be a critical factor that may determine long-term usefulness of this strategy, were comparable in those assigned to prepackaged entrées or a self-selected diet. The degree of weight reduction that was achieved has been shown to significantly reduce risk of diabetes and cardiovascular disease risk factors in large randomized studies (2, 19).

Compared to results from two previous 8-week studies of prescribing prepackaged entrées (9, 10), we observed somewhat greater weight loss in both intervention and standard self-selected diet groups, likely attributable to the intensive behavioral weight loss counseling (which was not provided in those previous trials) as well as increased length of the intervention. Testing the effect of portion-controlled prepackaged foods within a comprehensive behavioral weight loss counseling intervention allows isolation of the specific effects of food provision. When examining outcomes of commercial weight loss programs that involve both behavioral counseling and the provision of portion-controlled prepackaged foods (20-22), it is difficult to disentangle the effects of providing prepackaged food from other aspects of the intervention. Also, the multifaceted intervention used in the present study increases the likelihood of sustained behavior change, because factors important for long-term weight control, such as exercise and social support, were addressed

in addition to incorporating a portion control strategy. At study end, intervention group participants expressed more confidence that they could control eating and stick to a meal plan for weight loss, compared to those who were not prescribed the prepackaged entrées. Self-efficacy, an individual's confidence in his or her ability to carry out the behavior, is associated with better adoption of behavior change (23).

Incorporating food provision and structured meal plans into a behavioral weight loss intervention has been suggested to facilitate weight loss by reducing the complexity of planning and preparing reduced-energy food and meals (8). This strategy also affects the portion size effect as an approach to modifying energy intake. Possible mechanisms to explain the effect of portions on food consumption have recently been reviewed (24). These mechanisms include the response to the unit size (e.g., the observed tendency to eat whole units of food), providing a reference point that affects judgments about how much is appropriate to consume, and possibly, alterations in the meal microstructure (bite size, rate and frequency) (4, 24).

This was a relatively short-term study, but initial weight loss has been consistently found to predict long-term weight loss (5, 25, 26). Thus, these results are relevant to longer term success. In addition to improved mental QOL, participants who were prescribed prepackaged entrées reported meal and food satisfaction that was comparable to those eating self-selected foods. These findings suggest that monotony is not inevitable with portion-controlled prepackaged foods and may be avoided with sufficient varieties of entrées, supporting long-term acceptability and usefulness of this strategy.

There are both strengths and limitations of this study. One strength is the nearly equal distribution of women and men in the study, and the large proportion of participants from minority racial/ethnic groups, which supports the applicability of the results to the general population. The low rate of drop-out, a recognized problem in the interpretation of results of many diet and weight loss studies, minimizes ambiguity in drawing inferences from this study.

An important limitation is the lack of detailed dietary intake data. Participants were encouraged to self-monitor dietary intake through tools and technology of their choice, but standardized dietary recalls or records were not conducted or analyzed. The sample was a free-living population, so variability in adherence is likely. Self-reported dietary data have well-recognized limitations in accuracy, which is characterized as substantial underreporting and misreporting especially among overweight and obese individuals. An implication of this limitation is that the relationship between adherence and response is not known. All study groups reported a substantial increase in physical activity, but more weight loss was observed in those assigned to prepackaged foods, suggesting better adherence with reduced energy intake in those participants. The behavioral intervention and prepackaged foods were provided without cost to the participants, as was also the case in Look AHEAD and in other weight loss and diet intervention studies (19-22, 26), which also may affect generalizability.

In conclusion, a meal plan incorporating portion-controlled prepackaged entrées promotes greater weight and fat loss than a standard self-selected diet in the context of an intensive



behavioral weight loss counseling intervention in overweight and obese adults, with comparable meal satisfaction. Initial weight loss predicts long-term weight loss so these results are relevant to likelihood of longer term success.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

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## References

1. Flegal KM, Carroll MD, Kit BA, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. *JAMA*. 2012; 307(5):491–497. [PubMed: 22253363]
2. Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ, Jordan HS, Kendall KA, Lux LJ, Mentor-Marcel R, Morgan LC, Trisolini MG, Wnek J, Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, DeMets D, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK, Smith SC Jr, Tomaselli GF. American College of Cardiology/American Heart Association Task Force on Practice G, Obesity S. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation*. 2014; 129(25 Suppl 2):S102–38. [PubMed: 24222017]
3. Piernas C, Popkin BM. Increased portion sizes from energy-dense foods affect total energy intake at eating occasions in US children and adolescents: patterns and trends by age group and sociodemographic characteristics, 1977-2006. *Am J Clin Nutr*. 2011; 94(5):1324–32. [PubMed: 21918222]
4. Rolls BJ. What is the role of portion control in weight management? *Int J Obes (Lond)*. 2014; 38(1):S1–8.
5. Casazza K, Fontaine KR, Astrup A, Birch LL, Brown AW, Bohan Brown MM, Durant N, Dutton G, Foster EM, Heymsfield SB, McIver K, Mehta T, Menachemi N, Newby PK, Pate R, Rolls BJ, Sen B, Smith DL Jr, Thomas DM, Allison DB. Myths, presumptions, and facts about obesity. *N Engl J Med*. 2013; 368(5):446–54. [PubMed: 23363498]
6. Berkowitz RI, Wadden TA, Gehrman CA, Bishop-Gilyard CT, Moore RH, Womble LG, Cronquist JL, Trumpikas NL, Levitt Katz LE, Xanthopoulos MS. Meal replacements in the treatment of

- adolescent obesity: a randomized controlled trial. *Obesity (Silver Spring)*. 2011; 19(6):1193–9. [PubMed: 21151016]
7. Metz JA, Stern JS, Kris-Etherton P, Reusser ME, Morris CD, Hatton DC, Oparil S, Haynes RB, Resnick LM, Pi-Sunyer FX, Clark S, Chester L, McMahon M, Snyder GW, McCarron DA. A randomized trial of improved weight loss with a prepared meal plan in overweight and obese patients: impact on cardiovascular risk reduction. *Arch Intern Med*. 2000; 160(14):2150–8. [PubMed: 10904458]
  8. Wing RR, Jeffery RW. Food provision as a strategy to promote weight loss. *Obes Res*. 2001; 9(4): 271S–5S. [PubMed: 11707553]
  9. Hannum SM, Carson L, Evans EM, Canene KA, Petr EL, Bui L, Erdman JW Jr. Use of portion-controlled entrees enhances weight loss in women. *Obes Res*. 2004; 12(3):538–46. [PubMed: 15044672]
  10. Hannum SM, Carson LA, Evans EM, Petr EL, Wharton CM, Bui L, Erdman JW Jr. Use of packaged entrees as part of a weight-loss diet in overweight men: an 8-week randomized clinical trial. *Diabetes, Obesity & Metabolism*. 2006; 8(2):146–55.
  11. McArdle, W., Katch, F., Katch, V. *Exercise Physiology: Energy, Nutrition, and Human Performance* 6th ed Ardl. EPM. , editor. Lippincott Williams & Wilkins; 2006.
  12. Friedewald WT, Levy RI, Fredrickson DS. Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. *Clin Chem*. 1972; 18(6):499–502. Epub 1972/06/01. [PubMed: 4337382]
  13. Roberts WL, Moulton L, Law TC, Farrow G, Cooper-Anderson M, Savory J, Rifai N. Evaluation of nine automated high-sensitivity C-reactive protein methods: implications for clinical and epidemiological applications. Part 2. *Clin Chem*. 2001; 47(3):418–25. [PubMed: 11238291]
  14. Gamboa-Pinto AJ, Rock CL, Ferruzzi MG, Schowinsky AB, Schwartz SJ. Cervical tissue and plasma concentrations of alpha-carotene and beta-carotene in women are correlated. *J Nutr*. 1998; 128(11):1933–6. [PubMed: 9808645]
  15. Brazier JE, Harper R, Jones NM, O’Cathain A, Thomas KJ, Usherwood T, Westlake L. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ*. 1992; 305(6846):160–4. Epub 1992/07/18. [PubMed: 1285753]
  16. Thompson ER. Development and validation of an internationally reliable short-form of the Positive and Negative Affect Schedule (PANAS). *Journal of Cross-Cultural Psychology*. 2007; 38(2):227–42.
  17. Hays NP, Roberts SB. Aspects of eating behaviors “disinhibition” and “restraint” are related to weight gain and BMI in women. *Obesity (Silver Spring)*. 2008; 16(1):52–8. Epub 2008/01/29. [PubMed: 18223612]
  18. Milne HM, Wallman KE, Gordon S, Courneya KS. Effects of a combined aerobic and resistance exercise program in breast cancer survivors: a randomized controlled trial. *Breast Cancer Res Treat*. 2008; 108(2):279–88. [PubMed: 17530428]
  19. Pi-Sunyer X, Blackburn G, Brancati FL, Bray GA, Bright R, Clark JM, Curtis JM, Espeland MA, Foreyt JP, Graves K, Haffner SM, Harrison B, Hill JO, Horton ES, Jakicic J, Jeffery RW, Johnson KC, Kahn S, Kelley DE, Kitabchi AE, Knowler WC, Lewis CE, Maschak-Carey BJ, Montgomery B, Nathan DM, Patricio J, Peters A, Redmon JB, Reeves RS, Ryan DH, Safford M, Van Dorsten B, Wadden TA, Wagenknecht L, Wesche-Thobaben J, Wing RR, Yanovski SZ. Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes: one-year results of the Look AHEAD trial. *Diabetes Care*. 2007; 30(6):1374–83. Epub 2007/03/17. [PubMed: 17363746]
  20. Foster GD, Wadden TA, Lagrotte CA, Vander Veur SS, Hesson LA, Homko CJ, Maschak-Carey BJ, Barbor NR, Bailer B, Diewald L, Komaroff E, Herring SJ, Vetter ML. A randomized comparison of a commercially available portion-controlled weight-loss intervention with a diabetes self-management education program. *Nutr Diabetes*. 2013; 3:e63. [PubMed: 23507967]
  21. Rock CL, Flatt SW, Sherwood NE, Karanja N, Pakiz B, Thomson CA. Effect of a free prepared meal and incentivized weight loss program on weight loss and weight loss maintenance in obese and overweight women: a randomized controlled trial. *JAMA*. 2010; 304(16):1803–10. [PubMed: 20935338]

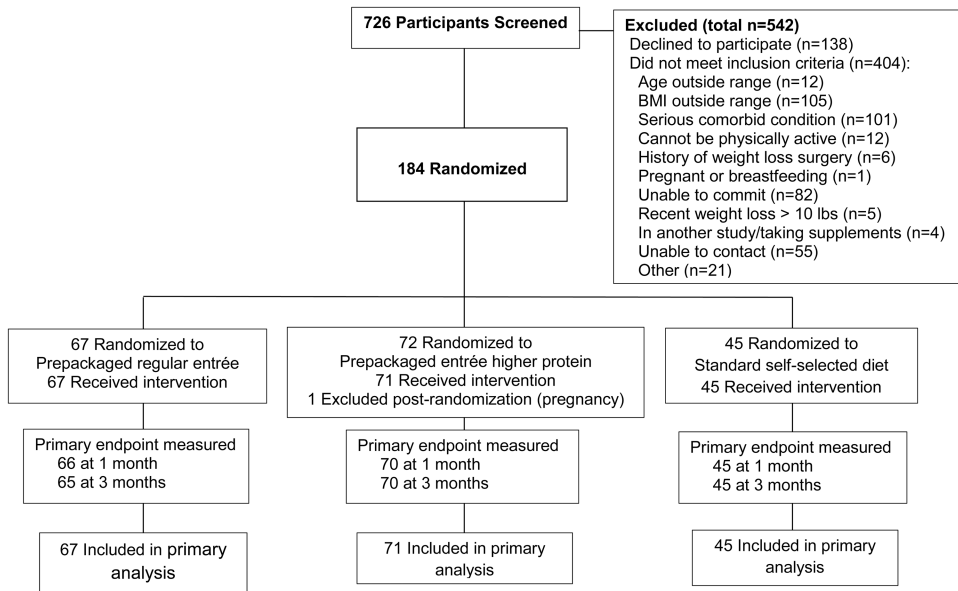
22. Rock CL, Flatt SW, Pakiz B, Taylor KS, Leone AF, Brelje K, Heath DD, Quintana EL, Sherwood NE. Weight loss, glycemic control, and cardiovascular disease risk factors in response to differential diet composition in a weight loss program in type 2 diabetes: a randomized controlled trial. *Diabetes Care*. 2014; 37(6):1573–80. [PubMed: 24760261]
23. Wingo BC, Desmond RA, Brantley P, Appel L, Svetkey L, Stevens VJ, Ard JD. Self-efficacy as a predictor of weight change and behavior change in the PREMIER trial. *Journal of Nutrition Education and Behavior*. 2013; 45(4):314–21. [PubMed: 23433966]
24. English L, Lasschuijt M, Keller KL. Mechanisms of the portion size effect. What is known and where do we go from here? *Appetite*. 2015; 88:39–49. [PubMed: 25447010]
25. Astrup A, Rossner S. Lessons from obesity management programmes: greater initial weight loss improves long-term maintenance. *Obes Rev*. 2000; 1(1):17–9. [PubMed: 12119640]
26. Unick JL, Neiberg RH, Hogan PE, Cheskin LJ, Dutton GR, Jeffery R, Nelson JA, Pi-Sunyer X, West DS, Wing RR, Look ARG. Weight change in the first 2 months of a lifestyle intervention predicts weight changes 8 years later. *Obesity (Silver Spring)*. 2015; 23(7):1353–6. [PubMed: 26110890]

### Study Importance Questions

What is already known about this subject?

What does this study add?

- Providing liquid meal replacements or prepackaged foods is one portion control strategy that may promote more weight and fat loss than standard dietary and behavioral counseling. A comparison of prescribing commercially-available prepackaged foods to standard diet counseling in the context of behavioral weight loss counseling has not been previously conducted or reported.
- Testing the effect of portion-controlled prepackaged foods within a comprehensive behavioral weight loss counseling intervention allows isolation of the specific effects of the food provision, which is not possible when examining outcomes in commercial weight loss programs that involve both behavioral counseling and the provision of portion-controlled prepackaged foods.
- Findings from this study suggest that prescribing portion-controlled prepackaged foods in the context of intensive behavioral weight loss counseling promotes a greater degree of weight and fat loss compared to a standard self-selected diet, and improves cardiovascular disease risk markers, with comparable meal satisfaction.



**Figure 1.**

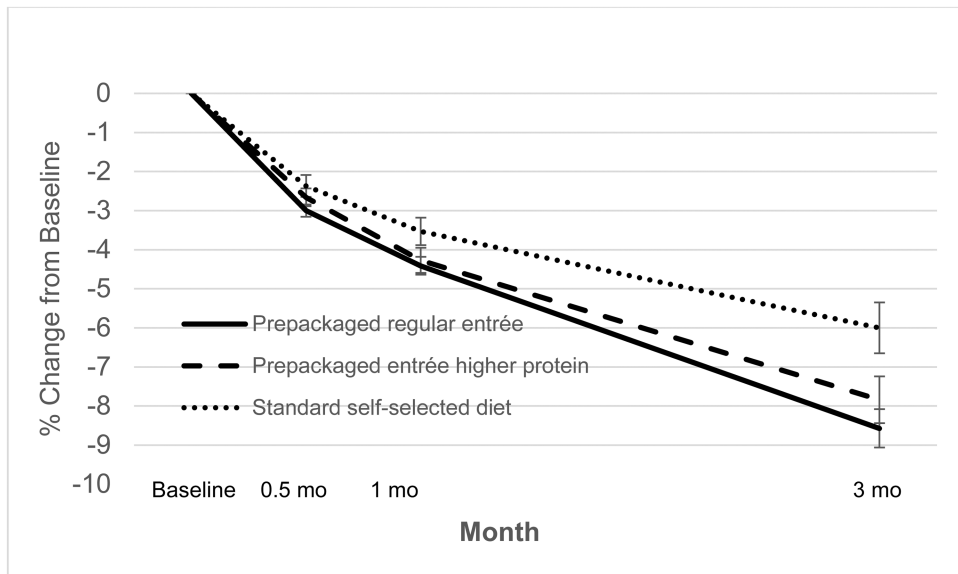


Figure 2.



**Table 1**  
**Participant demographic characteristics**

	Prepackaged Regular Entrée (n = 67)	Prepackaged Entrée Higher Protein (n = 71)	Standard Self-Selected Diet (n = 45)	Total Sample (N = 183)
<b>Sex, %</b>				
<b>Female</b>	56.7	54.9	64.4	57.9
<b>Male</b>	43.3	45.1	35.6	42.1
<b>Age, years</b>				
<b>Mean (SEM)</b>	46.9 (1.2)	46.4 (1.3)	46.5 (1.5)	46.6 (0.8)
<b>Ethnicity, %</b>				
<b>Non-Hispanic white</b>	53.7	53.5	48.9	52.5
<b>Hispanic</b>	19.4	21.1	26.7	21.9
<b>African American</b>	10.5	5.6	17.8	10.3
<b>Asian American</b>	9.0	9.9	0	7.1
<b>Mixed/other</b>	7.4	9.9	6.7	8.2
<b>Education, years</b>				
<b>Mean (SEM)</b>	15.4 (0.3)	16.3 (0.3)	16.1 (0.4)	15.9 (0.2)

SEM = standard error of mean.

**Table 2**  
**Anthropometric measurements**

Mean (SEM)	Prepackaged Regular Entrée (n = 67)	Prepackaged Entrée Higher Protein (n = 71)	Standard Self-Selected Diet (n = 45)
<b>Weight, kg</b>			
Baseline	96.0 (1.7)	95.8 (2.1)	95.9 (2.3)
Month 3	87.7 (1.6)*	87.9 (1.9)*	90.1 (2.2)*
<b>BMI, kg/m<sup>2</sup></b>			
Baseline	33.3 (0.4)	32.8 (0.4)	33.5 (0.6)
Month 3	30.6 (0.4)*	30.2 (0.4)*	31.6 (0.6)*
<b>% Weight change<sup>†</sup></b>			
2 Weeks	-3.0 (0.2)*	-2.7 (0.2)*	-2.4 (0.3)*
Month 1	-4.4 (0.2)*	-4.3 (0.3)*	-3.5 (0.3)*
Month 3	-8.6 (0.5)*	-7.8 (0.6)*	-6.0 (0.7)***
<b>Waist, cm</b>			
Baseline	111.9 (1.2)	109.6 (1.2)	112.0 (1.5)
Month 3	102.1 (1.2)*	100.8 (1.2)*	104.6 (1.5)*
<b>Fat mass, kg</b>			
Baseline	39.9 (1.0)	38.3 (0.9)	40.4 (1.3)
Month 3	33.6 (1.1)*	32.9 (1.1)*	36.2 (1.2)* <sup>‡</sup>
<b>% of fat mass lost</b>	15.8 (1.0)	14.4 (1.2)	10.7 (1.2)*

SEM = standard error of mean; BMI = body mass index.

<sup>†</sup>Weight change compared with baseline weight.

\* Change within group compared with baseline,  $P < .001$  paired t-test.

\*\*  $P < 0.01$ , intervention compared with standard self-selected diet, t-test.

<sup>‡</sup>  $P < 0.05$ , intervention compared with standard self-selected diet, t-test.

**Table 3**  
**Biochemical, physiologic, physical activity and fitness measurements<sup>1</sup>**

	Prepackaged Regular Entrée	Prepackaged Entrée Higher Protein	Standard Self-Selected Diet
<b>Baseline</b>			
Total cholesterol, mg/dL	181 (4)	171 (4)	189 (5) *
HDL cholesterol, mg/dL	50 (2)	49 (1)	53 (2)
LDL cholesterol, mg/dL	105 (4)	97 (3)	114 (5) *
Triglycerides, mg/dL	127 (7)	120 (8)	111 (7)
CRP, mcg/mL	3.97 (0.44)	3.05 (0.34)	4.21 (0.62)
CRP, median (IQR)	2.85 (1.19-5.69)	1.93 (0.92-4.40)	2.38 (1.10-5.75)
Total carotenoids, umol/L	1.44 (0.07)	1.68 (0.10)	1.73 (0.11)
Systolic BP, mmHg	126 (2)	125 (2)	127 (3)
Diastolic BP, mmHg	84 (1)	84 (1)	84 (2)
Physical activity, hrs/wk	2.5 (0.3)	2.7 (0.3)	2.2 (0.3)
Step Test HR	55 (1)	54 (1)	53 (1)
<b>Month 3</b>			
Total cholesterol, mg/dL	169 (5) **	169 (4)	186 (5) *
HDL cholesterol, mg/dL	50 (2)	51 (2)	54 (2)
LDL cholesterol, mg/dL	96 (4) **	97 (4)	112 (5) *
Triglycerides, mg/dL	113 (58) **	102 (54) **	103 (39)
CRP, mcg/mL †	3.48 (0.47) **	2.60 (0.35) **	4.57 (0.71)
CRP, median (IQR)	2.14 (0.95-5.07)	1.82 (0.85-3.48)	3.25 (0.88-7.40)
Total carotenoids, umol/L	1.76 (0.09) **	1.85 (0.09) **	1.96 (0.14) **
Systolic BP, mmHg	116 (1) **	118 (2) **	121 (3) **
Diastolic BP, mmHg	75 (1) **	78 (1) **	78 (2) **
Physical activity, hrs/wk	5.5 (0.4) **	6.1 (0.5) **	4.7 (0.5) **
Step Test HR	47 (1) **	47 (1) **	49 (1) **

CRP = C-reactive protein; BP = blood pressure; HR = heart rate; IQR = interquartile range.

<sup>1</sup>Values (excepting rows for CRP median [IQR]) are mean (SEM).

\* Self-selected diet group higher than intervention group,  $P < 0.05$ , t-test.

\*\* Change within group compared with baseline,  $P < 0.05$ , paired t-test.

† The standard self-selected diet group was higher at 3 months than the combined intervention groups, although not significantly,  $P = 0.06$  Wilcoxon two-sided rank sum test.

**Table 4**  
**Psychosocial measurements<sup>1</sup>**

	Prepackaged Regular Entrée	Prepackaged Entrée Higher Protein	Standard Self-Selected Diet
<b>Baseline</b>			
Physical QOL	84.8 (1.5)	85.6 (1.4)	87.8 (1.8)
Mental QOL	82.4 (1.6)	82.6 (1.6)	81.9 (2.2)
<b>Meal Satisfaction</b>			
Appearance	3.9 (0.1)	4.0 (0.1)	4.1 (0.1)
Taste	4.0 (0.1)	4.1 (0.1)	4.2 (0.1)
Disinhibition	6.9 (0.4)	7.3 (0.4)	8.0 (0.5)
Hunger	4.6 (0.4)	5.0 (0.4)	5.0 (0.6)
Restraint	9.8 (0.6)	9.7 (0.5)	9.3 (0.7)
<b>PANAS</b>			
Negative Affect Today	6.1 (0.2)	6.0 (0.2)	6.6 (0.4)
Positive Affect Today	17.7 (0.5)	17.7 (0.5)	18.7 (0.6)
Negative Affect Days	6.5 (0.2)	6.5 (0.3)	6.9 (0.4)
Positive Affect Days	17.2 (0.5)	17.8 (0.5)	18.0 (0.6)
Negative Affect Weeks	6.7 (0.2)	6.8 (0.3)	7.4 (0.4)
Positive Affect Weeks	17.2 (0.5)	17.7 (0.5)	17.8 (0.6)
I look good	5.2 (0.2)	4.9 (0.3)	5.4 (0.2)
Confident I can lose	8.6 (0.2)	8.7 (0.2)	9.1 (0.2)
<b>Month 1</b>			
<b>Meal Satisfaction</b>			
Appearance	4.0 (0.1)	4.1 (0.1)	4.2 (0.1)
Taste	4.0 (0.1)	4.1 (0.1)	4.3 (0.1)
Disinhibition	5.7 (0.4) *	5.9 (0.3) *	5.9 (0.7)
Hunger	3.5 (0.4)	3.9 (0.3) *	3.6 (0.5)
Restraint	15.5 (0.5) *	15.1 (0.5) *	14.8 (0.8)
<b>Month 3</b>			
Physical QOL	86.9 (1.7)	87.5 (1.3)	88.7 (1.8)
Mental QOL	87.9 (1.5) *	86.3 (1.5)	82.1 (2.8)
<b>Meal Satisfaction</b>			
Appearance	4.1 (0.1)	4.0 (0.1)	4.2 (0.1)
Taste	4.1 (0.1)	4.0 (0.1)	4.2 (0.1)
Disinhibition	4.6 (0.3) *	5.0 (0.3) *	5.6 (0.6) *
Hunger	3.1 (0.3) *	3.1 (0.3) *	3.1 (0.5) *
Restraint	16.1 (0.4) *	16.3 (0.5) *	15.3 (0.6) *
<b>PANAS</b>			
Negative Affect Today	5.7 (0.2)	6.1 (0.2)	6.5 (0.3)
Positive Affect Today	19.7 (0.5) *	19.3 (0.5) *	19.0 (0.5)

	Prepackaged Regular Entrée	Prepackaged Entrée Higher Protein	Standard Self-Selected Diet
<b>Negative Affect Days</b>	6.3 (0.3)	6.6 (0.3)	6.9 (0.4)
<b>Positive Affect Days</b>	19.9 (0.5)*	19.5 (0.5)*	18.8 (0.5)
<b>Negative Affect Weeks</b>	6.2 (0.2)	6.8 (0.3)	6.7 (0.4)
<b>Positive Affect Weeks</b>	19.9 (0.5)*	19.6 (0.5)*	19.1 (0.5)
<b>I look good</b>	7.0 (0.3)*	7.0 (0.2)*	6.7 (0.3)*
<b>Confident I can lose</b>	9.0 (0.2)	8.7 (0.2)	7.9 (0.4)**

QOL = quality of life; PANAS = Positive and Negative Affect Schedule.

<sup>1</sup>Values shown are mean (SEM).

\*  $P < 0.01$  compared with baseline, paired t-test.

\*\*  $P = 0.03$  between intervention and control groups, t-test.

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