The Weight Optimization Revamping Lifestyle using the Dietary Guidelines (WORLD) Study: Sustained Weight Loss Over 12 Months

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Objective: This study aimed to compare two energy-restricted, nutrient-dense diets at the upper or lower ends of the dietary fat recommendation range (lower fat [20% energy from fat] versus moderate fat [35%]) on weight loss using behavioral theory–based nutrition education.

Methods: A total of 101 premenopausal women with overweight or obesity were randomized to an energy-restricted lower-fat or moderate-fat diet for 1 year. Interventions included 28 behavioral theory–based nutrition education sessions plus weekly exercise sessions.

Results: Both treatment groups experienced weight loss (−5.0 kg for lower fat and −4.3 kg for moderate fat; $P < 0.0001$), but there was no difference in weight loss or fat intake between groups. Total and low-density lipoprotein cholesterol decreased (−3. 4 mg/dL and −3.8 mg/dL; $P < 0.05$), and high-density lipoprotein cholesterol increased (1.9 mg/dL; $P < 0.05$) in both groups at 12 months. Diet quality, assessed by the Healthy Eating Index, increased significantly at 4 months versus baseline (70.8 [0.9] vs. 77.8 [1.0]) and was maintained through 12 months. Higher Healthy Eating Index scores were associated with greater weight loss at 4 months ($r = −0.2$; $P < 0.05$).

Conclusions: In the context of a well-resourced, free-living weight-loss intervention, total fat intake did not change; however, theory-based nutrition education underpinned by food-based recommendations resulted in caloric deficits, improvements in diet quality, and weight loss that was sustained for 1 year.

Study Importance

What is already known?

► The current guideline from the American Heart Association/American College of Cardiology Task Force on Practice Guidelines and The Obesity Society for management of overweight/obesity in adults does not recommend one diet for weight loss.

► The Diet Intervention Examining the Factors Interacting with Treatment Success trial further supports this, finding no significant difference in weight loss between a healthy low-fat diet compared with a healthy low-carbohydrate diet.

What does this study add?

► Theory-based nutrition education underpinned by food-based recommendations results in a caloric deficit.

► Hypocaloric higher-fat and lower-fat diets result in sustained weight loss after 12 months.

► Higher Healthy Eating Index scores are associated with greater weight loss following 4 months of higher- and lower-fat hypocaloric diets.

How might these results change the focus of clinical practice?

► This study underscores the ineffectiveness of dietary fat-based targets for weight loss.

► Irrespective of the dietary macronutrient distribution, participants reduced overall energy intake and simultaneously improved diet quality, which in combination with an exercise regimen, resulted in weight loss, improved body composition, and reduced cardiometabolic disease risk that was maintained for 12 months.

Introduction

Approximately 72% of US adults have overweight or obesity, and 40% of women aged 20 to 39 years have obesity (1). In individuals with overweight or obesity, weight loss is recommended to reduce morbidity and mortality risk; however, effective strategies for sustained long-term weight loss are urgently needed (2).

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Weight-loss strategies are often very restrictive (3-5), difficult to follow long term (6,7), and nutritionally inadequate, which is the result of marked caloric restriction or elimination of entire food groups (5,8). The current guideline from the American Heart Association/American College of Cardiology Task Force on Practice Guidelines and The Obesity Society for management of overweight or obesity in adults does not recommend one diet for weight loss (9). Discordance exists in results from controlled trials examining different weight-loss diets, including those with varying macronutrient distributions. The Diet Intervention Examining the Factors Interacting with Treatment Success trial further supports this, finding no significant difference in weight loss between a healthy low-fat diet compared with a healthy low-carbohydrate diet. Furthermore, weight loss was not different between the diets based on three genotype responsiveness patterns and insulin secretion. Thus, heterogeneity in individual success with weight-loss diets may be more strongly influenced by behavioral factors than underlying biological mechanisms or specific macronutrient distributions. Therefore, less restrictive weight-loss strategies using a food-based approach and focusing on dietary composition, or diet quality, may more effectively promote long-term sustained weight loss.

The aim of the current randomized parallel trial (Weight Optimization: Revamping Lifestyle using the Dietary Guidelines [WORLD]) was to evaluate the effects of a lower-fat diet (LF; 20% energy from fat) compared with a moderate-fat diet (MF; 35%), consistent with the *2005 Dietary Guidelines for Americans* (DGA), in the context of a 12-month behavioral weight-loss intervention underpinned by behavior change theory. It was hypothesized that diets at the upper and lower ends of dietary fat recommendations would be equally effective for weight loss and improving cardiometabolic risk factors while achieving comparable nutritional adequacy.

Methods

Participants and experimental design

Study methods have been previously described (10). Briefly, premenopausal women with overweight or obesity and elevated low-density lipoprotein (LDL) cholesterol were recruited from March 2006 through June 2007. Individuals were ineligible if they had elevated triglycerides, used lipid-lowering medications, experienced recent weight loss, or had a history/diagnosis of comorbid conditions (Supporting Information Table S1). Interested and eligible women were screened at the General Clinical Research Center.

Participants were randomized (www.randomization.com) to follow either a LF diet (20% kilocalories from fat) or a MF diet (35% kilocalories from fat) consistent with the 2005 DGA for weight management in a parallel-arm design (Figure 1). The two phases of the study were a weight-loss phase (phase 1) and a weight-maintenance phase (phase 2). During phase 1 (months 1-4), participants consumed a hypocaloric diet. During phase 2 (months 5-12), participants transitioned to weight maintenance and they were instructed to consume a eucaloric diet.

The Institutional Review Board at the Pennsylvania State University approved the experimental protocol, and all participants provided written informed consent. This study was registered at www.clinicaltrials. gov (NCT00847574).

Intervention

Both nutrition and exercise interventions were part of the weight-loss and maintenance program tested in this study. A detailed description of the nutrition education provided to participants in this study can be found in Lohse et al. (10), and an outline is included in the online Supporting
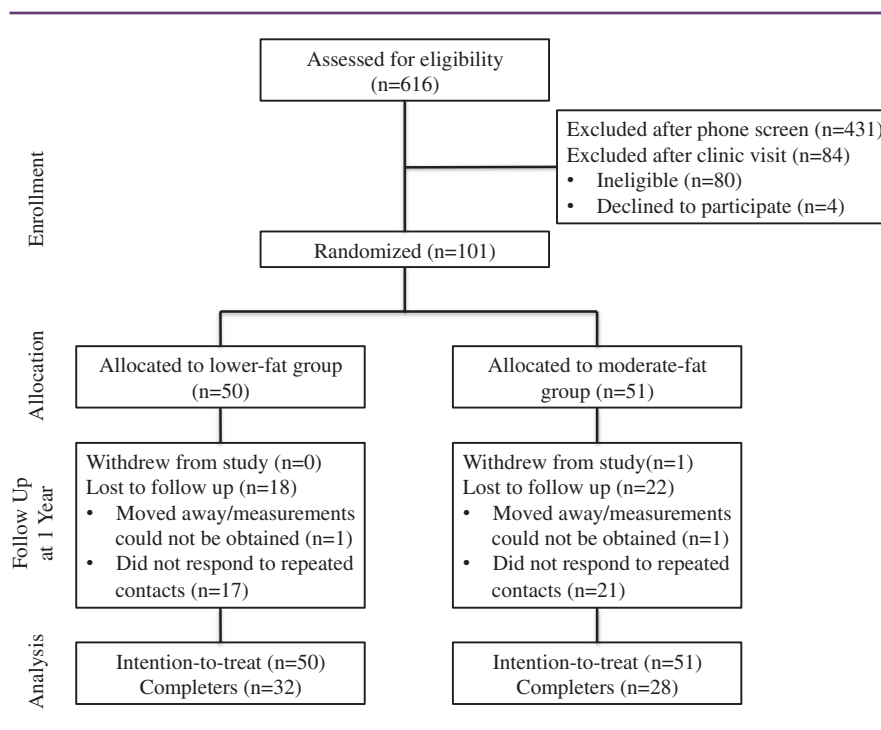

Figure 1 CONSORT diagram for a randomized, parallel-arm weight-management intervention among premenopausal women with overweight and obesity.

Information (Tables S2-S4). Briefly, the nutrition education program used the social cognitive theory (11) and a problem-based learning approach (12). Participants were instructed to follow a diet consistent with the 2005 DGA for their target calorie range (Harris-Benedict Equation (13)) at the upper or lower ends of the fat recommendations (20% or 35% calories) (14). During the first 4 months, participants were instructed to reduce intake to achieve a 500- to 1,000-calorie deficit per day with an overall weight loss goal of 10% of initial body weight. Nutrition educators led 28 1-hour sessions throughout the 12-month intervention. Sessions were held weekly for the first 4 months, bimonthly for the next 4 months, and monthly for the last 4 months of the study (Figure 2). Lessons provided information on food and behavior related to weight loss and maintenance.

The exercise component of the intervention, which was the same for both arms of the trial, consisted of daily stretching and five aerobic sessions, two supervised and three on their own, and two unsupervised strength-training sessions per week (Figure 2). The aerobic exercise sessions initially lasted 20 minutes and increased gradually to 60 to 90 minutes. The target heart rate for aerobic exercise was between 65% and 85% of the maximal heart rate obtained during the participants' initial test of maximal aerobic capacity. The strength-training routine consisted of two sets of each basic strength-training exercise, such as biceps curls, triceps extensions, lunges, and squats, two times per week on their own. The exercises were presented as part of the educational program and reviewed by trainers in the research training room.

Data collection

Anthropometric, biochemical, and other health-related data were collected at baseline and months 4, 8, and 12. The primary outcome was weight loss, and secondary outcomes included cardiometabolic risk factors (Figure 2).

Weight was measured using the same calibrated digital scale in light indoor clothing without shoes. Height was measured using a wall-mounted stadiometer. Waist circumference was measured according to the NHANES III protocol (15). After a 5-minute rest period, blood pressure was measured using a mercury sphygmomanometer (16).

Body composition was determined by dual energy x-ray absorptometry. The following three components were measured: fat mass, bone mineral content, and mineral-free lean mass for the whole body and five regions of the body (i.e., both arms, both legs, and the trunk).

Physical fitness was assessed by maximal aerobic capacity, measured by VO_2max, during a progressive exercise test on a motor-driven treadmill. Participants walked or ran until exhaustion using a modified Balke protocol (17).

Venous blood samples were drawn by antecubital venipuncture in the fasted state. Samples were stored at $-70°C$ until sample analysis. Total cholesterol and triglycerides were quantified using enzymatic assays (Olympus Diagnostica GmbH, O'Callaghan's Mills, Ireland) by Quest Diagnostics Inc. (Baltimore, Maryland). High-density lipoprotein (HDL) cholesterol was estimated according to the modified heparin-manganese precipitation procedure of Warnick and Albers (18). LDL cholesterol was calculated by the Friedewald equation (19). C-reactive protein (CRP) was measured by high-sensitivity enzyme-linked immunosorbent assay (Dade Behring, Marburg, Germany). Fasting insulin was measured by radioimmunoassay, and glucose was determined through spectrophometry, using glucose oxidase, at the Clinical Research Center Core Laboratory of the Penn State Health Milton S. Hershey Medical Center, Hershey, Pennsylvania.

Penn State's Diet Assessment Center conducted telephone-based, unannounced, random, 24-hour dietary recalls on nonconsecutive days (two weekdays, one weekend day), using the multiple-pass technique (20) at baseline, month 4, and month 12. Food portion posters (2-D Food Portion Visual; Nutrition Consulting Enterprises, Framingham, Massachusetts) were used to estimate portion sizes. The Nutrient Data System for Research software version 5.0 was used for dietary analysis (Nutrition Coordinating Center, University of Minnesota, Minneapolis, Minnesota). Three-day average intakes were calculated to estimate intake at each time point.
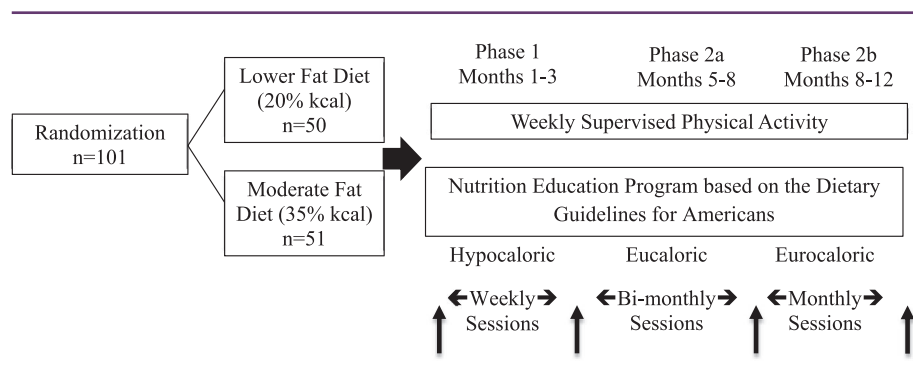

Figure 2 Timeline and outcomes for a randomized, parallel-arm weight-management intervention among premenopausal women with overweight and obesity. Premenopausal women ($n = 101$) with overweight/obesity (BMI: 25-39.9) were randomized to either a lower-fat (20% kilocalories from fat) or moderate-fat (35% kilocalories from fat) treatment group following medical, clinical, and psychosocial screening. Phase 1 was the weight-loss phase of the intervention; participants shifted into weight maintenance during phase 2 after achieving the 10% weight-loss goal. Participants attended two supervised exercise sessions weekly throughout the length of the study. One-hour education sessions were held weekly during phase 1, bimonthly sessions during phase 2a, and monthly sessions during phase 2b. Upward arrows indicate where anthropometric, biochemical, dietary, and other health-related data were collected at baseline and months 4 and 12. Biochemical and anthropometric data were also collected at month 8. Adapted from Lohse et al. (10).

During each supervised training session, the type and mode of activity, duration, and heart rate were recorded. To measure exercise heart rate, a trainer counted a participant's pulse for 15 seconds at the midpoint of each exercise session and multiplied the number by four. Each activity was assigned a metabolic equivalent task (MET) score based on the method by Ainsworth et al. (21). The three most common activities in this study were brisk walking, use of the elliptical trainer, and circuit training, with MET scores of 4.3, 5.0, and 4.3, respectively (21). The scores for MET-hours per supervised session were calculated from the observed hours engaged in each activity multiplied by the assigned MET score. The MET-hours from each session were averaged across the 4 weeks prior to each time point (i.e., month 4 and month 12) to estimate average weekly MET-hours.

Statistical analysis

All statistical analyses were performed using SAS (version 9.1; SAS Institute Inc., Cary, North Carolina). The study was powered to detect a 5% weight loss over a 1-year period, assuming a withdrawal rate of 50%.

We performed an intention-to-treat analysis with imputation of missing data, for withdrawing participants, at a rate of 0.3 kg/mo of regained weight and a rate of 0.3 cm/mo of regained waist circumference after withdrawal (3,22). Intention-to-treat analyses were used for all other outcome variables with zero change from baseline imputed for missing data (23). Dietary data are presented for participants who provided recalls at each time point ($n=60$). Supervised physical activity data are presented for participants reporting to the training room during months 4 and 12.

The mixed-models procedure (PROC MIXED) was used to assess the effect of treatment diet on each outcome variable. Categorical variables were analyzed by χ^2 tests. Comparisons in activity data were analyzed by t tests. Tukey-Kramer–adjusted P values were used for post hoc testing. Change scores and percentage changes were calculated from baseline for each outcome variable.

Pearson correlation coefficients (PROC CORR) were used to assess associations between diet quality (Healthy Eating Index [HEI]) score, weight change from baseline, and the total number of sessions participants attended. The HEI-2005 was calculated using average food group intake from the three dietary recalls taken at each time point.

Results

Participant characteristics

Of the 616 women who were screened for the study, 101 (17%) were randomly assigned to follow either a LF or MF diet, and 60 (59% of those assigned) completed the study (Figure 2). Baseline characteristics, except for binge eating scale scores (as assessed by Gormally Cognitive Factors Related to Binge Eating Scale), were similar among participants assigned to the two diets and between those who completed the study and those who did not (Table 1).

Clinical parameters

Weight loss after 1 year (Table 2) was similar by randomization (LF: −5.0 kg, MF: −4.3 kg; $P<0.0001$ vs. baseline; $P>0.05$ between groups). The majority of weight loss occurred during the first 4 months (LF: −4.5 kg, MF: −3.9 kg; $P<0.0001$), with a nonsignificant loss from month 4 to month 12 (LF: −0.5 kg, MF: −0.2 kg) (Figure 3). A significant decrease in BMI (Table 2) was attained by month 4 in both treatment groups and maintained through month 12 (−1.9 and −1.5 units, respectively; time effect, $P<0.0001$).

TABLE 1 Baseline characteristics of premenopausal women in randomized, parallel weight-management intervention ($n=101$)[a]

	Randomization			
	LF dietary pattern ($n=50$)	MF dietary pattern ($n=51$)	All participants ($n=101$)	Completers ($n=60$)
Age (y)	38.8 ± 0.8	39.0 ± 0.9	38.9 ± 0.6	39.9 ± 0.8
BMI (kg/m²)				
25.0-29.9	25 (50)	27 (53)	52 (51)	31 (52)
≥30.0	25 (50)	24 (47)	49 (49)	29 (48)
Race[a]				
White	46 (92)	48 (94)	94 (93)	59 (98)
Black	0 (0)	2 (4)	2 (2)	1 (2)
Other	2 (4)	1 (2)	3 (3)	0 (0)
Education level (%)[a]				
High school	4 (8)	6 (12)	10 (10)	8 (13)
Some college	5 (10)	8 (16)	13 (13)	4 (7)
Business/technical degree	1 (2)	9 (17)	10 (10)	6 (10)
College graduate	26 (52)	16 (31)	42 (41)	25 (42)
Graduate degree	**12 (24)**	12 (24)	24 (24)	17 (28)

Baseline values after participants randomized to treatment group. Values expressed as mean ± standard error or number (percentage). No significant differences between treatments and no significant differences observed between those who completed study and those who did not.
[a]Two participants, randomized to lower-fat dietary pattern who did not complete study, did not report education level or race at baseline.
LF, lower fat; MF, moderate fat.

TABLE 2 Effects of diet treatment in randomized, parallel weight-management trial on clinical measures

Variable	Baseline	Month 4	Month 8	Month 12
Weight (kg)	82.9 ± 1.3	78.7 ± 1.3*	78.2 ± 1.3*	78.3 ± 1.4*
LF dietary pattern	84.2 ± 1.9	79.7 ± 1.9	79.2 ± 1.9	79.2 ± 1.9
MF dietary pattern	81.6 ± 1.9	77.7 ± 1.9	77.3 ± 1.9	77.5 ± 1.9
BMI (kg/m^2)	30.8 ± 0.4	29.2 ± 0.4*	29.0 ± 0.4*	29.1 ± 0.4*
LF dietary pattern	31.0 ± 0.6	29.3 ± 0.6	29.1 ± 0.6	29.1 ± 0.6
MF dietary pattern	30.6 ± 0.6	29.2 ± 0.6	29.0 ± 0.6	29.1 ± 0.6
Waist circumference (cm)	99.6 ± 1.3	95.5 ± 1.3*	95.3 ± 1.3*	97.4 ± 1.3
LF dietary pattern	99.4 ± 1.8	94.5 ± 1.8	94.9 ± 1.8	97.6 ± 1.8
MF dietary pattern	99.7 ± 1.8	96.5 ± 1.8	95.8 ± 1.8	97.1 ± 1.8
Systolic blood pressure (mm Hg)	114.8 ± 1.0	111.2 ± 1.0*	112.0 ± 1.0*	112.7 ± 1.0*
LF dietary pattern	114.4 ± 1.5	112.2 ± 1.5	111.5 ± 1.5	112.0 ± 1.5
MF dietary pattern	115.2 ± 1.4	112.1 ± 1.4	112.4 ± 1.4	113.5 ± 1.4
Diastolic blood pressure (mm Hg)	77.4 ± 0.8	75.1 ± 0.8*	75.6 ± 0.8*	76.3 ± 0.8
LF dietary pattern	76.8 ± 1.1	74.9 ± 1.2	75.6 ± 1.1	76.4 ± 1.1
MF dietary pattern	78.0 ± 1.1	75.2 ± 1.1	75.6 ± 1.1	76.2 ± 1.1
Percent lean mass	57.0 ± 0.5	59.1 ± 0.5*	-	58.9 ± 0.5*
LF dietary pattern	57.3 ± 0.7	59.5 ± 0.7	-	59.2 ± 0.7
MF dietary pattern	56.8 ± 0.7	58.7 ± 0.7	-	58.6 ± 0.7
Percent body fat	37.9 ± 0.5	36.2 ± 0.5*	-	36.1 ± 0.5*
LF dietary pattern	37.7 ± 0.7	35.9 ± 0.7	-	35.7 ± 0.7
MF dietary pattern	38.1 ± 0.7	36.4 ± 0.7	-	36.5 ± 0.7
VO$_2$max (mL/*kg/min^{-1} * min^{-1})	27.7 ± 0.8	30.4 ± 0.7*	-	31.0 ± 0.7*
LF dietary pattern	27.8 ± 1.1	30.7 ± 1.1	-	30.4 ± 1.1
MF dietary pattern	27.5 ± 1.1	30.1 ± 1.1	-	31.7 ± 1.1

n = 50 for lower-fat (LF) group; n = 51 for moderate-fat (MF) group. Values expressed as mean ± standard error. Data analyzed under intention-to-treat principle using MIXED procedure (SAS). No significant time-by-treatment interaction observed. Significant time effect observed for all outcomes ($P < 0.01$). No significant differences observed between treatments.
Significant differences within a row are denoted as follows:
*statistically significant change from baseline, $P \leq 0.05$.

Weight loss was inversely correlated with the total number of nutrition sessions participants attended at month 4 ($r = -0.4$, $P < 0.0001$). Thus, greater session attendance was associated with greater weight loss; every additional session attended was associated with a 0.58-kg reduction in body weight. This association was also observed at month 12 ($r = -0.4$, $P < 0.0001$); every additional session attended was associated with a 0.48-kg reduction.

Shifts in BMI classification. In a completers analysis ($n = 60$) with the treatment groups pooled, 32% of participants lost less than 5% of their initial body weight, 22% lost 5% to 9.9% of their initial body weight, 32% lost 10% to 19.9% of their initial body weight, and 14% lost more than 20% of their initial body weight. Consequently, 31 participants (52%) shifted down in BMI classification by the end of the study; 10 (17%) shifted from obesity to overweight, 20 (33%) from overweight to normal weight, and 1 (2%) from obesity to normal weight. All other participants remained in their original BMI category, and no participants gained weight throughout the study. Waist circumference (Table 2) was significantly decreased at month 4 (-4.1 cm; $P < 0.0001$ vs. baseline) and was marginally decreased at month 12 (-2.2 cm; $P = 0.06$ vs. baseline) in the pooled treatment groups. Weight loss over time and changes in BMI classification and waist circumference did not differ significantly between treatment groups.

Body composition. Percent lean mass increased and percent body fat decreased during the study (Table 2) ($P < 0.0001$ for both vs. baseline); there were no between-treatment differences. In addition, aerobic capacity, assessed by VO$_2$max, increased overall (Table 2) ($P < 0.0001$).

Improvements in weight status, body composition, and aerobic capacity from baseline were significant only in participants who provided data at month 12 ($P < 0.001$ for all vs. baseline), which is partially attributable to the conservative approach of imputing missing values for participants who did not complete the study. The change in clinical parameters did not differ between study completers assigned to the LF diet versus the MF diet (data not shown).

Cardiometabolic risk factors

No significant time-by-treatment interactions were observed for cardiometabolic risk factors. When data for all participants were pooled, total cholesterol and LDL cholesterol concentrations were significantly lower at month 12 compared with baseline values (-3.4 mg/dL and -3.8 mg/dL, respectively; $P < 0.05$), and HDL cholesterol concentration (Table 3) significantly increased over time (1.9 mg/dL; $P < 0.0001$). Triglycerides, CRP, and insulin decreased over time ($P \leq 0.05$ for trend), while blood glucose remained the same ($P = 0.22$).
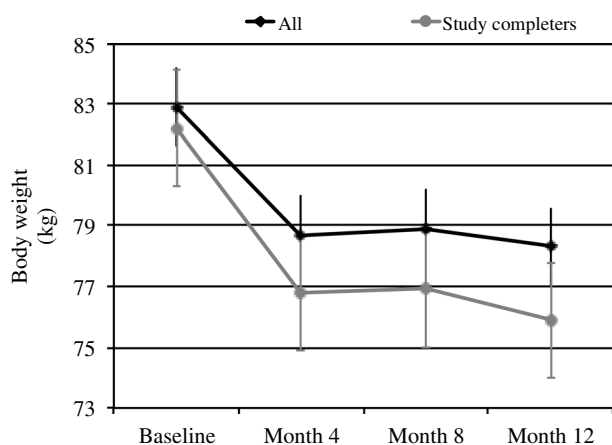
Figure 3 Effects of 1-year weight-management intervention on body weight based on all participants and completers only. Weight in kilograms (±SEM) based on intention-to-treat analyses with repeated-measures ANOVA using the MIXED procedure (SAS). Significant time effect was observed for all participants ($n = 101$) and the study completers ($n = 60$) ($P < 0.0001$). A significant time-by-group interaction was observed when comparing study completers and those participants who did not complete the study ($P < 0.0001$; data not shown).

CRP concentrations were similar for participants following both diets ($P = 0.47$) (Table 3). At months 4 and 8, CRP was significantly lower than baseline (-0.65 and -0.85 mg/L, respectively; $P < 0.05$); however, this change was not maintained through month 12 (-0.52 mg/L compared with baseline; $P = 0.44$).

There was no overall treatment effect on blood pressure (Table 2); a significant improvement in systolic blood pressure was observed over time compared with baseline (-3.6 mm Hg, -2.8 mm Hg, and -2.1 mm Hg at months 4, 8, and 12, respectively; $P < 0.001$). Diastolic blood pressure at month 12 was the same as baseline.

In a completer's analysis ($n = 60$), changes in lipid concentrations and systolic blood pressure from baseline were significantly greater ($P < 0.05$ for all) than those changes yielded by intention-to-treat analyses ($n = 101$), which reflects the imputation of missing values. The improvements in clinical and biochemical measures resulted in fewer participants who completed the study having three or more of the criteria for metabolic syndrome at month 12 (13%) than at study entry (27%). Forty-five percent of participants who completed the study met none or only one of the criteria for metabolic syndrome.

Dietary intake

All participants randomized ($n = 101$) were included in this analysis. A time-by-treatment effect for polyunsaturated fat intake was significant ($P < 0.01$) after 4 months; the LF group (6.0% [0.4%]) consumed significantly less than the MF group (7.4% [0.4%]; $P < 0.05$) (Table 4). However, this effect was not observed at month 12. No other time-by-treatment differences between groups were observed. Overall percent energy from *trans* fat was significantly different between groups (LF = 2.4% [0.1%] vs. MF = 2.8% [0.1%]; $P < 0.05$); there were no other differences between groups.

After pooling treatment groups, total energy intake (-227 kcal), percent energy from saturated fat (-0.7%) and *trans* fat (-1.3%), and dietary

cholesterol (-56 mg) decreased, and percent energy from protein ($+1.5\%$) significantly increased by month 4 (Table 4). The reductions in energy, *trans* fat, and cholesterol were sustained at month 12. Pooled results from the participants with complete sets of dietary data ($n = 60$) showed total energy intake (-186 kcal) and percent energy from fat (-2.1%), saturated fat (-1.3%), and *trans* fat (-0.4%) significantly decreased and percent energy from protein ($+1.9\%$) and dietary fiber intake ($+2.5$ g/d) significantly increased by month 4 when compared with baseline ($P \leq 0.05$ for all) (Supporting Information Table S5). Only the changes in energy and fiber intake were sustained through month 12 (-157 kcal and $+2.1$g/d, respectively; $P < 0.01$ for both).

Dietary quality (HEI-2005)

All individuals randomized to the two treatment groups ($n = 101$) were included in this analysis. Overall HEI score did not differ between treatment groups. With respect to the HEI components, a significant time-by-treatment effect for sodium was observed ($P < 0.05$); however, after correcting for multiple comparisons, no differences were noted between treatments at the different time points. A significant treatment difference was observed for overall milk consumption (LF = 7.7 [0.3] vs. MF = 6.7 [0.3]). No other time-by-treatment interactions were significant, so treatment groups were pooled.

Total HEI score (70.8 [0.9] vs. 77.8 [1.0]) significantly increased by month 4 compared with baseline (Table 5). This was because of increases in the scores for the following HEI components at month 4 compared with baseline: total fruit (2.3 [0.2] vs. 3.3 [0.2]), whole fruits (2.8 [0.2] vs. 4.0 [0.2]), total vegetables (3.7 [0.1] vs. 4.2 [0.1]), whole grains (3.6 [0.2] vs. 4.2 [0.2]), meat and beans (8.1 [0.3] vs. 9.0 [0.3]), and saturated fat (5.6 [0.3] vs. 6.8 [0.3]). Scores for whole grains and total HEI were maintained at month 12. Total HEI scores and individual component scores did not differ between months 4 and 12; thus, diet quality was improved at month 4, and this was maintained through month 12.

The total HEI score was inversely correlated with the change in weight from baseline to month 4 ($r = -0.2$, $P < 0.05$). Therefore, higher HEI scores were associated with greater weight loss at month 4; every one-point increase in HEI was associated with a 0.49-kg reduction in body weight. This association was not significant at month 12. Total HEI score was also significantly correlated with the total number of nutrition education sessions participants attended ($r = 0.3$, $P < 0.01$). This shows that better attendance at the nutrition education sessions was associated with a higher HEI score; every additional session attended was associated with a 0.55 increase in HEI score.

Physical activity

Participants ($n = 81$) averaged 3.7 (0.9) MET-hours of supervised exercise per session, with an average measured heart rate of 142 (25) beats per minute, in the 4 weeks leading up to the month-4 time point. In the 4 weeks prior to the month-12 time point, participants ($n = 60$) averaged 2.6 (1.7) MET-hours per session, with an average measured heart rate of 110 (71) beats per minute. In addition to obtaining fewer MET-hours of supervised exercise and lower average heart rates ($P < 0.001$), on average, participants attended seven (out of a possible eight) supervised exercise sessions during month 4 and only four (out of a possible eight) during month 12 ($P < 0.0001$). MET-hours per session, heart rate, and attendance did not differ between treatment groups or between those who reported consuming a LF diet versus a MF diet.

TABLE 3 Effects of treatment dietary patterns over the course of parallel-arm weight-management intervention on biomarkers

Variable	Baseline	Month 4	Month 8	Month 12
Total cholesterol (mg/dL)	180.6 ± 3.9	172.5 ± 3.9[a]	176.0 ± 3.9[ab]	177.2 ± 3.9[ab]
LF dietary pattern	176.8 ± 3.9	168.7 ± 3.9[a]	172.5 ± 3.9	173.3 ± 3.9
MF dietary pattern	184.5 ± 3.9	176.4 ± 3.9[a]	179.9 ± 3.9	181.0 ± 3.9
LDL-cholesterol (mg/dL)	111.9 ± 3.9	105.7 ± 3.9[a]	107.3 ± 3.9[a]	108.1 ± 3.9[a]
LF dietary pattern	109.6 ± 3.9	103.8 ± 3.9[a]	105.4 ± 3.9	106.5 ± 3.9
MF dietary pattern	114.6 ± 3.9	107.7 ± 3.9[a]	108.9 ± 3.9[a]	109.6 ± 3.9[a]
HDL-cholesterol (mg/dL)	47.5 ± 0.8	47.1 ± 0.8	49.0 ± 0.8[ab]	49.4 ± 0.8[ab]
LF dietary pattern	46.3 ± 1.5	45.9 ± 1.5	47.5 ± 1.5	47.5 ± 1.5[b]
MF dietary pattern	48.6 ± 1.2	48.3 ± 1.2	50.2 ± 1.2[a]	51.0 ± 1.2[a,b]
Triglycerides (mg/dL)	103.7 ± 4.4	95.7 ± 4.4[a]	100.1 ± 4.4	99.2 ± 4.4
LF dietary pattern	102.8 ± 5.3	94.8 ± 5.3	98.3 ± 5.3	95.7 ± 5.3
MF dietary pattern	104.5 ± 7.1	96.6 ± 5.3	101.9 ± 5.3	101.9 ± 5.3
C-reactive protein (mg/L)	3.78 ± 0.4	3.13 ± 0.4[a]	2.93 ± 0.4[a]	3.26 ± 0.4
LF dietary pattern	3.89 ± 0.5	3.37 ± 0.5	3.42 ± 0.5	3.32 ± 0.5
MF dietary pattern	3.48 ± 0.5	2.91 ± 0.5	2.45 ± 0.5[a]	3.20 ± 0.5
Glucose (mg/dL)	88.6 ± 0.5	88.9 ± 0.5	87.8 ± 0.5	88.6 ± 0.5
LF dietary pattern	89.5 ± 0.9	90 ± 0.9	88.7 ± 0.9	89.1 ± 0.9
MF dietary pattern	87.8 ± 0.9	88.0 ± 0.9	87.1 ± 0.9	87.8 ± 0.9
Insulin (µU/mL)	13.6 ± 0.6	12.7 ± 0.6	12.7 ± 0.7	12.9 ± 0.6
LF dietary pattern	13.3 ± 0.8	12.4 ± 0.8	12.4 ± 0.8	12.9 ± 0.8
MF dietary pattern	14.0 ± 0.8	12.9 ± 0.8	13.0 ± 0.8	12.8 ± 0.8

$n = 50$ for lower-fat (LF) group; $n = 51$ for moderate-fat (MF) group. Values expressed as mean ± standard error. Data analyzed under intention-to-treat principle with repeated-measures ANOVA using MIXED procedure (SAS). Significant time effect observed for all outcomes except blood glucose ($P < 0.05$). No significant differences observed between treatments.
Significant differences within a row are denoted by:
[a]$P \leq 0.05$, compared with baseline;
[b]$P \leq 0.05$, compared with month 4.

Discussion

The WORLD study is the first 12-month randomized, parallel trial evaluating the effects of a behavioral weight-loss and weight-management program emphasizing the food-based recommendations of the 2005 DGA and physical activity. The primary study finding is individuals had difficulty adhering to macronutrient-based recommendations for weight loss but reduced caloric intake and improved diet quality regardless of macronutrient distribution, which resulted in sustained weight loss. Body weight, body composition, risk factors for cardiometabolic diseases, and diet were improved to a similar extent across treatment groups after 1 year. Thus, our results demonstrate sustained weight loss can be achieved with a comprehensive behavioral intervention that is based on a reduced-energy healthy eating pattern delivered using a theory-based nutrition education program that teaches food-based recommendations together with increased physical activity.

Our findings demonstrate that a comprehensive lifestyle intervention utilizing a theory-based nutrition education program in addition to physical activity induces weight loss that is sustained for up to 12 months. The majority of participants (68%) lost at least 5% of their initial body weight, with 14% losing and maintaining 20% of their initial body weight. Given that weight maintenance is rare and that modest weight loss is associated with significant reductions in risk for developing diabetes (24), experiencing a cardiovascular event (25,26), and mortality (26), this finding is very significant and supports the DGA for overall health and disease reduction. However, participants in both treatment groups were unable to achieve the target goals for dietary fat. Consistent with the Women's Health Initiative (27), attaining a LF diet was difficult; only one participant in the LF group approached the target level for dietary fat (i.e., consumed 21% kilocalories from fat). Our findings are also similar to Sacks et al. (3), who reported reduced-calorie diets resulted in clinically meaningful weight loss regardless of which macronutrients they emphasized. During the intervention, dietary fat for most participants (57%), regardless of treatment group, matched reported intake of fat at baseline despite a rigorously implemented intervention. These results are consistent with previous findings indicating that people have difficulty changing the macronutrient profile of their habitual diets (3). However, individuals are able to alter the type and amount of foods consumed such that they do, in fact, lose weight and consume a diet that approaches current recommendations. Thus, the results suggest that within the context of an intensive weight-loss intervention, recommendations to improve diet quality may be more effectively implemented compared with macronutrient-focused recommendations. Our findings are consistent with recent studies that have reported improvements in diet quality as part of a weight-loss intervention (28,29). Furthermore, this study together with the previous results we reported (10) suggests a need for additional study of behavioral interventions and Eating Competence (EC) in the context of weight-loss interventions.

Lohse et al. (10) reported EC, a state of being positive, comfortable, and flexible with eating as well as getting enough to eat of enjoyable and nourishing food (30), significantly improved in WORLD participants,

TABLE 4 Macronutrient distributions over time for pooled treatment groups and between treatment groups ($n = 101$)

Variable	Baseline	Month 4	Month 12
Energy (kcal)	1,614.0 ± 35.7	1,387.0 ± 44.8*	1,411.5 ± 39.3*
LF dietary pattern	1,594.5 ± 50.7	1,386.5 ± 53.1	1,354.4 ± 61.1
MF dietary pattern	1,633.5 ± 50.3	1,387.5 ± 57.8	1,468.6 ± 65.7
Carbohydrates (% energy)	50.8 ± 0.7	52.5 ± 0.8	52.6 ± 0.9
LF dietary pattern	50.7 ± 1.0	52.2 ± 1.0	51.8 ± 1.2
MF dietary pattern	50.9 ± 1.0	52.8 ± 1.1	53.4 ± 1.3
Protein (% energy)	17.8 ± 0.3	19.3 ± 0.4*	18.4 ± 0.4
LF dietary pattern	18.1 ± 0.5	20.2 ± 0.6	18.3 ± 0.5
MF dietary pattern	17.6 ± 0.5	18.4 ± 0.6	18.4 ± 0.5
Total fat (% energy)	32.0 ± 0.6	30.1 ± 0.7	31.1 ± 0.8
LF dietary pattern	31.4 ± 0.9	29.3 ± 1.1	31.6 ± 1.0
MF dietary pattern	32.6 ± 0.9	30.8 ± 1.1	30.6 ± 1.0
SFA (% energy)	10.7 ± 0.2	10.0 ± 0.3*	9.6 ± 0.4
LF dietary pattern	10.4 ± 0.4	9.9 ± 0.5	10.2 ± 0.4
MF dietary pattern	11.0 ± 0.4	9.2 ± 0.5	9.8 ± 0.5
MUFA (% energy)	11.9 ± 0.3	11.3 ± 0.3	11.5 ± 0.4
LF dietary pattern	11.5 ± 0.4	10.9 ± 0.5	11.3 ± 0.4
MF dietary pattern	12.2 ± 0.4	11.6 ± 0.5	11.7 ± 0.4
PUFA (% energy)	6.8 ± 0.2	6.7 ± 0.2	7.1 ± 0.3
LF dietary pattern	6.9 ± 0.3	6.0 ± 0.4[a#]	7.4 ± 0.3[b]
MF dietary pattern	6.8 ± 0.3	7.4 ± 0.4[#]	6.7 ± 0.3
TFA (% energy)	3.4 ± 0.1	2.1 ± 0.2*	2.3 ± 0.2*
LF dietary pattern	3.0 ± 0.2	2.0 ± 0.2	2.2 ± 0.3
MF dietary pattern	3.8 ± 0.2	2.3 ± 0.2	2.4 ± 0.3
Fiber (g/d)	17.0 ± 0.6	18.4 ± 0.6	18.1 ± 0.7
LF dietary pattern	16.8 ± 0.8	17.7 ± 0.8	17.3 ± 1.0
MF dietary pattern	17.3 ± 0.8	19.0 ± 0.9	18.8 ± 1.1
Cholesterol (mg/d)	213.0 ± 9.5	157.0 ± 10.6*	172.1 ± 12.5*
LF dietary pattern	224.9 ± 13.5	165.2 ± 14.3	162.0 ± 16.9
MF dietary pattern	201.2 ± 13.3	148.7 ± 15.6	182.2 ± 18.3

Values expressed as mean ± standard error. All outcomes analyzed using MIXED procedure (SAS). Significant time-by-group interaction observed for PUFA ($P = 0.04$); lower-fat (LF) dietary pattern consuming significantly less PUFA at month 4 compared with moderate-fat (MF) dietary pattern. Significant time effect observed for total energy, percent of energy from protein, SFA and TFA, and cholesterol ($P < 0.05$). Significant group effect observed for TFA ($P < 0.05$).
Significant differences within a row are denoted as follows:
*$P < 0.05$ compared with baseline;
#$P < 0.05$ between treatment groups at the same time points; different letters indicate significant differences between time points ($P < 0.05$).
SFA, saturated fatty acids; MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids; TFA, *trans* fatty acids.

and those in the lowest tertile of EC had the highest weight, BMI, and waist circumference at 12 months. Data from the present study showed attendance at the education sessions was correlated with weight loss and diet quality measured by HEI. Participants who attended more group sessions had higher HEI scores and lost more weight. This highlights the importance of implementing weight-loss interventions underpinned by behavior change theory with regular interventionist contact.

Weight loss and improvements in body composition resulted in comparable beneficial changes in total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides at month 12 versus baseline in both groups. However, no between-group differences in blood lipids were observed; this is not surprising because diet composition did not differ across treatment groups. However, HDL cholesterol concentration was higher at month 12 compared with baseline in the MF group but not the LF group. Because nutrient intakes did not differ between treatment

groups, one explanation for the difference in HDL cholesterol concentration is that the majority of participants actually consumed a MF diet, which likely accounted for this change. Another possible explanation may be that the treatment groups differed in exercise level; however, aerobic capacity over the course of the study was similar between treatment groups, so this is unlikely.

Strengths of our study include a focus on a less restrictive approach than many weight-loss diets (31), which has shown benefits of a weight-loss dietary pattern that is more similar to participants' usual dietary intake. In addition, an education program based on social cognitive theory and delivered with a problem-based learning approach that encouraged active participation in the learning process was implemented. Moreover, our retention rate was comparable to other long-term interventions (32) and powered to account for this attrition (regarding weight loss and lipid changes). Limitations of this study included the lack of separation between

TABLE 5 Healthy Eating Index (HEI) over time for pooled and between treatment groups at baseline, month 4, and month 12 (*n* = 101)

HEI Component	Baseline	Month 4	Month 12
Total fruit (maximum score 5)	2.3 ± 0.2	3.3 ± 0.2*	2.8 ± 0.2
LF dietary pattern	2.3 ± 0.2	3.5 ± 0.2	2.7 ± 0.2
MF dietary pattern	2.2 ± 0.2	3.1 ± 0.3	2.9 ± 0.4
Whole fruits (maximum score 5)	2.8 ± 0.2	4.0 ± 0.2*	3.4 ± 0.3
LF dietary pattern	2.8 ± 0.3	4.1 ± 0.3	3.4 ± 0.3
MF dietary pattern	2.8 ± 0.2	3.9 ± 0.3	3.4 ± 0.4
Vegetables total (maximum score 5)	3.7 ± 0.1	4.2 ± 0.1*	4.0 ± 0.2
LF dietary pattern	3.7 ± 0.2	4.3 ± 0.2	4.1 ± 0.2
MF dietary pattern	3.7 ± 0.2	4.0 ± 0.2	3.9 ± 0.3
Dark green/orange vegetables and legumes (maximum score 5)	2.9 ± 0.2	3.3 ± 0.2	3.6 ± 0.3
LF dietary pattern	3.0 ± 0.3	3.3 ± 0.3	3.3 ± 0.3
MF dietary pattern	2.9 ± 0.3	3.2 ± 0.3	3.8 ± 0.5
Grains total (maximum score 5)	4.8 ± 0.04	4.9 ± 0.04	4.9 ± 0.1
LF dietary pattern	4.9 ± 0.1	4.8 ± 0.1	5.0 ± 0.1
MF dietary pattern	4.8 ± 0.1	4.9 ± 0.1	4.9 ± 0.1
Whole grains (maximum score 5)	3.6 ± 0.2	4.2 ± 0.2*	4.1 ± 0.2*
LF dietary pattern	3.5 ± 0.2	4.0 ± 0.2	4.0 ± 0.2
MF dietary pattern	3.5 ± 0.2	4.4 ± 0.2	4.2 ± 0.3
Milk (maximum score 10)	7.2 ± 0.3	7.5 ± 0.3	6.9 ± 0.3
LF dietary pattern	7.4 ± 0.4	7.9 ± 0.4	7.7 ± 0.4
MF dietary pattern	7.0 ± 0.4	7.1 ± 0.4	6.0 ± 0.5
Meat and beans (maximum score 10)	8.1 ± 0.3	9.0 ± 0.3*	8.5 ± 0.4
LF dietary pattern	8.0 ± 0.4	9.0 ± 0.4	8.7 ± 0.4
MF dietary pattern	8.2 ± 0.3	9.1 ± 0.4	8.3 ± 0.6
Oils (maximum score 10)	7.9 ± 0.2	8.5 ± 0.3	8.4 ± 0.3
LF dietary pattern	7.9 ± 0.3	7.8 ± 0.4	8.4 ± 0.4
MF dietary pattern	7.9 ± 0.3	9.2 ± 0.4	8.3 ± 0.6
SFA (maximum score 10)	5.6 ± 0.3	6.8 ± 0.3*	6.6 ± 0.4
LF dietary pattern	5.9 ± 0.4	6.5 ± 0.4	6.0 ± 0.4
MF dietary pattern	5.4 ± 0.4	7.1 ± 0.5	7.2 ± 0.7
Sodium (maximum score 10)	2.9 ± 0.2	2.9 ± 0.3	3.1 ± 0.4
LF dietary pattern	3.1 ± 0.3	3.0 ± 0.4	2.1 ± 0.4
MF dietary pattern	2.8 ± 0.3	2.9 ± 0.4	4.0 ± 0.6
SoFAAS (maximum score 20)	19.0 ± 0.3	19.2 ± 0.3	19.6 ± 0.4
LF dietary pattern	18.8 ± 0.4	19.3 ± 0.4	19.5 ± 0.4
MF dietary pattern	19.1 ± 0.4	19.1 ± 0.4	19.7 ± 0.6
Total (maximum score 100)	70.8 ± 0.9	77.8 ± 1.0*	75.7 ± 1.3*
LF dietary pattern	71.4 ± 1.3	77.7 ± 1.4	75.0 ± 1.3
MF dietary pattern	70.2 ± 1.3	77.9 ± 1.5	76.5 ± 2.1

Values expressed as mean ± standard error. All outcomes analyzed using MIXED procedure (SAS). Significant time-by-group interaction observed for sodium (*P* = 0.03), but no differences after correcting for multiple comparisons. Significant time effect observed for total fruits, whole fruits, total vegetables, whole grains, SFA, meat and beans, and total HEI score (*P* < 0.05). Significant treatment effect observed for milk (*P* < 0.05); lower-fat (LF) dietary pattern had better score for milk compared with moderate-fat (MF) dietary pattern.
Significant differences within a row are denoted as follows:
*P < 0.05 compared with baseline.
SFA, saturated fatty acids; SoFAAS, solid fats, alcoholic beverages, and added sugars.

the treatment groups regarding fat and carbohydrate intake and participant recruitment via self-selection. Thus, we were not able to evaluate our primary hypothesis, which was that weight-loss diets at the upper and lower limit of the acceptable macronutrient distribution range for fat intake would be equally effective for weight loss. Rather, the study provided a test of the effectiveness of macronutrient targets in the context of free-living premenopausal women enrolled in a comprehensive behavioral weight-loss intervention. Participants unexpectedly had higher HEI scores

at baseline relative to the national average in 2005 to 2006 (33), which could affect weight-loss efficacy, but participants still showed significant improvements in HEI. Although this study was conducted in 2006 to 2007 and the 2005 DGA was the basis of the dietary recommendation, these findings support the most up-to-date recommendations (9,34-36).

Conclusion

The WORLD study demonstrated that weight loss can be achieved and maintained for up to 12 months with a comprehensive lifestyle intervention utilizing theory-based nutrition education consistent with the food-based 2005 DGA and physical activity. Irrespective of the dietary macronutrient distribution, participants reduced overall energy intake and simultaneously improved diet quality, which in combination with an exercise regimen, resulted in weight loss, improved body composition, and reduced cardiometabolic disease risk that was maintained for 12 months.**O**

Acknowledgments

References

1. Centers for Disease Control and Prevention. Obesity and overweight. https://www.cdc.gov/nchs/fastats/obesity-overweight.htm. Updated June 13, 2016. Accessed September 25, 2017.
2. Flodgren G, Gonçalves-Bradley DC, Summerbell CD. Interventions to change the behaviour of health professionals and the organisation of care to promote weight reduction in children and adults with overweight or obesity. *Cochrane Database Syst Rev* 2017;11:CD000984. doi:10.1002/14651858.CD000984.pub3
3. Sacks FM, Bray GA, Carey VJ, et al. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. *N Engl J Med* 2009;360:859-873.
4. Gardner CD, Trepanowski JF, Del Gobbo LC, et al. Effect of low-fat vs low-carbohydrate diet on 12-month weight loss in overweight adults and the association with genotype pattern or insulin secretion: the DIETFITS randomized clinical trial. *JAMA* 2018;319:667-679.
5. Harris L, Hamilton S, Azevedo LB, et al. Intermittent fasting interventions for treatment of overweight and obesity in adults: a systematic review and meta-analysis. *JBI Database Syst Rev Implement Rep* 2018;16:507-547.
6. Dansinger ML, Gleason JA, Griffith JL, Selker HP, Schaefer EJ. Comparison of the Atkins, Ornish, Weight Watchers, and Zone diets for weight loss and heart disease risk reduction. *JAMA* 2005;293:43-53.
7. Lin Ms H-H, Tsai Phd P-S, Fang Ms S-C, Liu J-F. Effect of kiwifruit consumption on sleep quality in adults with sleep problems. *Asia Pac J Clin Nutr* 2011;20:169-174.
8. Matarese LE, Pories WJ. Adult weight loss diets: metabolic effects and outcomes. *Nutr Clin Pract* 2014;29:759-767.
9. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults. *Circulation* 2014;129:S102-S138.
10. Lohse B, Krall JS, Psota T, Kris-Etherton P. Impact of a weight management intervention on eating competence: importance of measurement interval in protocol design. *Am J Health Promot* 2018;32:718-728.
11. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory*. Englewood Cliffs, NJ: Prentice Hall; 1986.
12. Barrows HS. A taxonomy of problem-based learning methods. *Med Educ* 1986;20:481-486.
13. Harris JA, Benedict FG. A biometric study of human basal metabolism. *Proc Natl Acad Sci U S A* 1918;4:370-373.
14. National Academy of Science. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)*. Washington, DC: National Academies Press; 2005.
15. U.S. Department of Health and Human Services. *NHANES III Anthropometric Procedure Videos*. Washington, DC: U.S. Government Printing Office; 1996.
16. Chobanian AV, Bakris GL, Black HR, et al. The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA* 2003;289:2560-2572.
17. Balke B. *A Simple Field Test for the Assessment of Physical Fitness*. Oklahoma City: Civil Aeromedical Research Institute; 1963.
18. Warnick GR, Albers JJ. A comprehensive evaluation of the heparin-manganese precipitation procedure for estimating high density lipoprotein cholesterol. *J Lipid Res* 1978;19:65-76.
19. 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;18:499-502.
20. Jonnalagadda SS, Mitchell DC, Smiciklas-Wright H, et al. Accuracy of energy intake data estimated by a multiple-pass, 24-hour dietary recall technique. *J Am Diet Assoc* 2000;100:303-308; quiz 309-11.
21. Ainsworth BE, Haskell WL, Herrmann SD, et al. 2011 Compendium of Physical Activities: a second update of codes and MET values. *Med Sci Sports Exerc* 2011;43:1575-1581.
22. Wadden TA, Berkowitz RI, Sarwer DB, Prus-Wisniewski R, Steinberg C. Benefits of lifestyle modification in the pharmacologic treatment of obesity: a randomized trial. *Arch Intern Med* 2001;161:218-227.
23. Allison P. *Missing Data*. Thousand Oaks, CA: SAGE Publications, Inc.; 2002.
24. Wilding JPH. The importance of weight management in type 2 diabetes mellitus. *Int J Clin Pract* 2014;68:682-691.
25. Seimon RV, Espinoza D, Ivers L, et al. Changes in body weight and blood pressure: paradoxical outcome events in overweight and obese subjects with cardiovascular disease. *Int J Obes* 2014;38:1165-1171.
26. Clifton PM, Keogh JB. Effects of different weight loss approaches on CVD risk. *Curr Atheroscler Rep* 2018;20:27. doi:10.1007/s11883-018-0728-8
27. Howard BV, Manson JE, Stefanick ML, et al. Low-fat dietary pattern and weight change over 7 years: The Women's Health Initiative Dietary Modification Trial. *JAMA* 2006;295:39-49.
28. Christifano DN, Fazzino TL, Sullivan DK, Befort CA. Diet quality of breast cancer survivors after a six-month weight management intervention: improvements and association with weight loss. *Nutr Cancer* 2016;68:1301-1308.
29. Ptomey LT, Steger FL, Lee J, et al. Changes in energy intake and diet quality during an 18-month weight-management randomized controlled trial in adults with intellectual and developmental disabilities. *J Acad Nutr Diet* 2018;118:1087-1096.
30. Satter E. Eating competence: definition and evidence for the Satter Eating Competence model. *J Nutr Educ Behav* 2007;39:S142-S153.
31. Gudzune KA, Doshi RS, Mehta AK, et al. Efficacy of commercial weight-loss programs: an updated systematic review. *Ann Intern Med* 2015;162:501-512.
32. Moroshko I, Brennan L, O'Brien P. Predictors of dropout in weight loss interventions: a systematic review of the literature. *Obes Rev* 2011;12:912-934.
33. US Department of Agriculture Food and Nutrition Service. HEI scores for Americans. https://www.fns.usda.gov/hei-scores-americans. Accessed February 15, 2020.
34. Eckel RH, Jakicic JM, Jamy C-C, et al. 2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation* 2014;129(25 Suppl 2):S76-S99.
35. Raynor HA, Champagne CM. Position of the Academy of Nutrition and Dietetics: interventions for the treatment of overweight and obesity in adults. *J Acad Nutr Diet* 2016;116:129-147.
36. Evert AB, Dennison M, Gardner CD, et al. Nutrition therapy for adults with diabetes or prediabetes: a consensus report. *Diabetes Care* 2019;42:731-754.