Comparison of the Atkins, Ornish, Weight Watchers, and Zone Diets for Weight Loss and Heart Disease Risk Reduction

A Randomized Trial

Michael L. Dansinger, MD
Joi Augustin Gleason, MS, RD
John L. Griffith, PhD
Harry P. Selker, MD, MSPH
Ernst J. Schaefer, MD

Context The scarcity of data addressing the health effects of popular diets is an important public health concern, especially since patients and physicians are interested in using popular diets as individualized eating strategies for disease prevention.

Objective To assess adherence rates and the effectiveness of 4 popular diets (Atkins, Zone, Weight Watchers, and Ornish) for weight loss and cardiac risk factor reduction.

Design, Setting, and Participants A single-center randomized trial at an academic medical center in Boston, Mass, of overweight or obese (body mass index: mean, 35; range, 27-42) adults aged 22 to 72 years with known hypertension, dyslipidemia, or fasting hyperglycemia. Participants were enrolled starting July 18, 2000, and randomized to 4 popular diet groups until January 24, 2002.

Intervention A total of 160 participants were randomly assigned to either Atkins (carbohydrate restriction, n=40), Zone (macronutrient balance, n=40), Weight Watchers (calorie restriction, n=40), or Ornish (fat restriction, n=40) diet groups. After 2 months of maximum effort, participants selected their own levels of dietary adherence.

Main Outcome Measures One-year changes in baseline weight and cardiac risk factors, and self-selected dietary adherence rates per self-report.

Results Assuming no change from baseline for participants who discontinued the study, mean (SD) weight loss at 1 year was 2.1 (4.8) kg for Atkins (21 [53%] of 40 participants completed, $P=.009$), 3.2 (6.0) kg for Zone (26 [65%] of 40 completed, $P=.002$), 3.0 (4.9) kg for Weight Watchers (26 [65%] of 40 completed, $P<.001$), and 3.3 (7.3) kg for Ornish (20 [50%] of 40 completed, $P=.007$). Greater effects were observed in study completers. Each diet significantly reduced the low-density lipoprotein/high-density lipoprotein (HDL) cholesterol ratio by approximately 10% (all $P<.05$), with no significant effects on blood pressure or glucose at 1 year. Amount of weight loss was associated with self-reported dietary adherence level ($r=0.60$; $P<.001$) but not with diet type ($r=0.07$; $P=.40$). For each diet, decreasing levels of total/HDL cholesterol, C-reactive protein, and insulin were significantly associated with weight loss (mean $r=0.36$, 0.37, and 0.39, respectively) with no significant difference between diets ($P=.48$, $P=.57$, $P=.31$, respectively).

Conclusions Each popular diet modestly reduced body weight and several cardiac risk factors at 1 year. Overall dietary adherence rates were low, although increased adherence was associated with greater weight loss and cardiac risk factor reductions for each diet group.

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POPULAR DIETS HAVE BECOME INcreasingly prevalent and controversial.[1] More than 1000 diet books are now available,[2] with many popular ones departing substantially from mainstream medical advice.[3] Cover stories for major news magazines, televised debates, and cautionary statements by prominent medical authorities[4,5] have fueled public interest and concern regarding the effectiveness and safety of such diets.[6-8]

Although some popular diets are based on long-standing medical advice and recommend restriction of portion sizes and calories (eg, Weight Watchers),[9] a broad spectrum of alternatives has evolved. Some plans minimize carbohydrate intake without fat restriction (eg, Atkins diet),[10] many modulate macronutrient balance and glycemic load (eg, Zone diet),[11] and others restrict fat (eg, Ornish diet).[12] Given the growing obesity epidemic,[13] many patients and clinicians are interested in using popular diets as individualized eating strategies for disease prevention.[14] Unfortunately, data regarding the relative benefits, risks, effectiveness, and

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Author Affiliations: Division of Endocrinology, Diabetes, and Metabolism (Drs Dansinger and Schaefer), and Institute for Clinical Research and Health Policy Studies (Drs Griffith and Selker), Tufts-New England Medical Center; and Lipid Metabolism Laboratory, Jean Mayer US Department of Agriculture Human Nutrition Research Center on Aging, Tufts University (Dr Schaefer and Ms Gleason), Boston, Mass.
Corresponding Author: Michael L. Dansinger, MD, Atherosclerosis Research Laboratory, Tufts-New England Medical Center, Box 216, Boston Dispensary 342, 750 Washington St, Boston, MA 02111 (mdansinger@tufts-nemc.org).

sustainability of popular diets have been limited.[15-25]

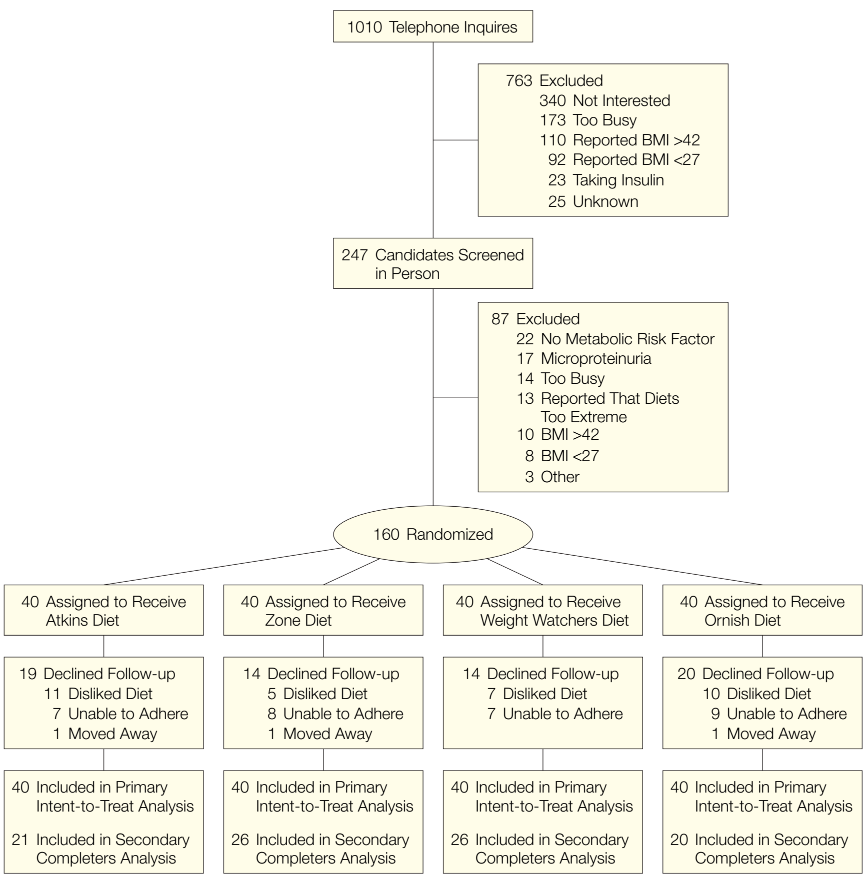
We conducted a 1-year randomized trial of the dietary component of the Atkins, Zone, Weight Watchers, and Ornish plans, aiming to determine their realistic clinical effectiveness and sustainability for weight loss and cardiac risk factor reduction. Of note, this study only evaluated the dietary components and did not include other specific components that may be unique to each individual dietary program.

METHODS

Participants

We recruited study candidates from the Greater Boston area using newspaper advertisements and television publicity (local news coverage). Of 1010 telephone inquiries, 247 individuals agreed to be screened in person and 160 individuals were enrolled at an academic medical center in Boston, Mass, from July 18, 2000, through January 24, 2002 (FIGURE 1). We included adults of any age who were overweight or obese with body mass index (calculated as weight in kilograms divided by the square of height in meters) between 27 and 42, and having at least 1 of the following metabolic cardiac risk factors: fasting glucose of at least 110 mg/dL (≥6.1 mmol/L), total cholesterol of at least 200 mg/dL (≥5.2 mmol/L), low-density lipoprotein (LDL) cholesterol of at least 130 mg/dL (≥3.4 mmol/L), high-density lipoprotein (HDL) cholesterol of 40 mg/dL or less (≤1.0 mmol/L), triglycerides of at least 150 mg/dL (≥1.7 mmol/L), systolic blood pressure of at least 145 mm Hg, diastolic blood pressure of at least 90 mm Hg, or current use of oral medication to treat hypertension, diabetes mellitus, or dyslipidemia. Exclusion criteria included unstable chronic illness, insulin therapy, urinary microalbumin of more than 2 times normal, serum creatinine of at least 1.4 mg/dL (≥123.8 µmol/L), clinically significant abnormalities of liver or thyroid test results, weight loss medication, or pregnancy. Participants did not receive any monetary compensation. All participants provided written informed consent, and the local institutional review board approved the protocol. Our recruitment strategy was designed to meet race and sex criteria consistent with federal guidelines.[26]

Figure 1. Study Flow Diagram of Participants



BMI indicates body mass index, calculated as weight in kilograms divided by the square of height in meters.

Randomization and Intervention

We administered dietary advice to small groups rather than individually. Because not all individuals were available to meet for diet group classes at the same time of day, we allowed participants to select 1 of 4 class times based on personal preference. Once each of the 4 class rosters contained approximately 10 participants, 1 of the 4 diets was assigned to each group according to a computer-generated randomized Latin-square sequence. This method was used to ensure that each diet was administered to each of the class times only once, therefore minimizing potential confounding between class time and diet type. Study personnel were blinded to dietary assignments (revealed by the study statistician) until after each class roster was finalized, to avoid the potential for biased recruiting according to diet type. A new set of diet classes was administered every 3 to 4 months for 4 cycles.

A single team composed of a dietitian and physician (M.L.D., J.A.G.) administered diet-specific advice to each group, meeting for 1 hour on 4 occasions during the first 2 months of the study. At the first meeting, the team revealed the diet assignment and provided the corresponding rationale, written materials, and official diet cookbook.[12,27-29] Subsequent meetings aimed to maximize adherence by reinforcing positive dietary changes and addressing barriers to adherence.

The Atkins diet group aimed for less than 20 g of carbohydrate daily, with a gradual increase toward 50 g daily. The Zone group aimed for a 40-30-30 balance of percentage calories from carbohydrate, fat, and protein, respectively. The Weight Watchers group aimed to keep total daily "points" in a range determined by current weight. Each "point" was roughly 50 calories, and most participants aimed for 24 to 32 points daily. Lists provided by the Weight Watchers Corporation determined point values of common foods. The Ornish group aimed for a vegetarian diet containing 10% of calories from fat.

In an effort to isolate the effects of the dietary component of each plan, we standardized recommendations pertaining to supplements, exercise, and external support. We encouraged all participants to take a nonprescription multivitamin daily, obtain at least 60 minutes of exercise weekly, and avoid commercial support services. To approximate the realistic long-term sustainability of each diet, we asked participants to follow their dietary assignment to the best of their ability until their 2-month assessment, after which time we encouraged them to follow their assigned diet according to their own self-determined interest level.

Dietary Adherence

We used 2 techniques to measure dietary adherence. We asked participants to complete 3-day food records at baseline, 1, 2, 6, and 12 months.[30] Using a computerized diet analysis program (Nutritionist Five, version 2.3, First DataBank Inc, San Bruno, Calif), we calculated the average daily macronutrient and micronutrient intakes, and used a 10-point score to reflect the degree to which each group achieved the specified dietary target vs baseline intake. We also telephoned participants monthly and asked them to rate the dietary adherence level during the previous 30 days using a similar 10-point scale, ranging from perfect score (10) to baseline (1). Using these scales facilitated comparisons between the 2 dietary adherence methods. We also asked participants to report medication changes, hospitalizations, and adverse effects during the monthly telephone calls.

Outcome Measures

We assessed outcome measures at baseline, 2, 6, and 12 months. Participants were blinded to timing of assessments until 2 weeks before each visit, and baseline measurements occurred within 2 weeks before dietary intervention. Study nurses and laboratory personnel who as-

Table 1. Baseline Characteristics of Study Participants

Characteristics	Atkins Diet (n = 40)	Zone Diet (n = 40)	Weight Watchers Diet (n = 40)	Ornish Diet (n = 40)	All Diets (N = 160)	*P* Value
Demographics						
Age, mean (SD), y	47 (12)	51 (9)	49 (10)	49 (12)	49 (11)	.41
Women, No. (%)	21 (53)	20 (50)	23 (58)	17 (43)	81 (51)	.61
White race, No. (%)	32 (80)	26 (65)	30 (75)	32 (80)	120 (75)	.37
Risk factors, No. (%)						
Smoker*	3 (8)	5 (13)	1 (3)	4 (10)	13 (8)	.41
Hyperglycemia†	16 (40)	8 (20)	8 (20)	12 (30)	44 (28)	.14
Exercise‡	8 (20)	14 (35)	12 (30)	5 (13)	39 (24)	.09
Weight factors, mean (SD)						
BMI	35 (3.5)	34 (4.5)	35 (3.8)	35 (3.9)	35 (3.9)	.60
Body weight, kg	100 (14)	99 (18)	97 (14)	103 (15)	100 (15)	.43
Waist size, cm	109 (11)	108 (13)	108 (11)	111 (13)	109 (12)	.63
Blood pressure, mean (SD), mm Hg						
Systolic	129 (17)	130 (16)	133 (17)	133 (17)	131 (17)	.50
Diastolic	77 (9)	77 (10)	74 (11)	76 (9)	76 (10)	.50
Glucose, mean (SD), mg/dL	127 (62)	116 (48)	116 (53)	121 (55)	120 (54)	.78
Insulin, mean (SD), μIU/mL	22 (16)	31 (37)	20 (10)	30 (18)	26 (23)	.06
Cholesterol, mean (SD), mg/dL						
Total	214 (31)	222 (46)	221 (46)	214 (34)	218 (40)	.72
LDL	136 (31)	138 (45)	142 (39)	136 (37)	138 (38)	.89
HDL	48 (16)	48 (13)	47 (2.3)	45 (2.0)	47 (1.1)	.72
Total/HDL ratio	4.9 (1.7)	5.1 (1.5)	5.1 (2.1)	5.1 (1.5)	5.1 (1.7)	.96
LDL/HDL ratio	3.2 (1.5)	3.1 (0.9)	3.3 (1.7)	3.2 (1.1)	3.2 (1.3)	.91
Triglycerides	152 (98)	194 (123)	154 (87)	174 (130)	169 (111)	.29
C-reactive protein, mean (SD), mg/L	4.4 (3.8)	3.7 (3.4)	3.7 (2.9)	4.4 (3.5)	4.1 (3.4)	.65

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); HDL, high-density lipoprotein; LDL, low-density lipoprotein.
SI conversions: To convert glucose to mmol/L, multiply by 0.0555; HDL, LDL, and total cholesterol to mmol/L, multiply by 0.0259; insulin to pmol/L, multiply by 6.945; and triglycerides to mmol/L, multiply by 0.0113.
*Defined as smoking more than 1 cigarette per week.
†Defined as a fasting blood glucose of at least 110 mg/dL (5.55 mmol/L).
‡Defined as weekly exercise greater than mild, according to participant report.

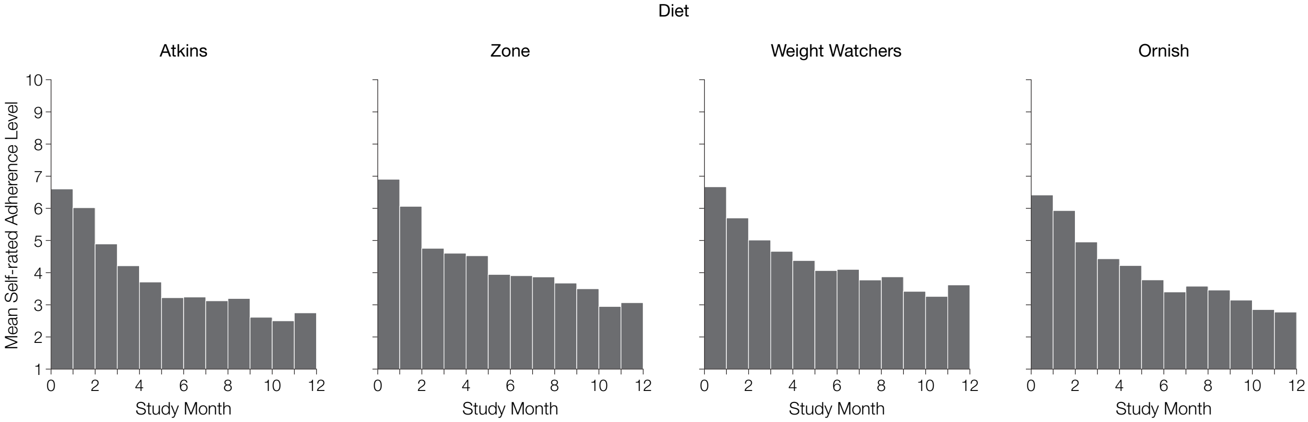
sessed outcomes were blinded to participants' dietary assignment. We measured body weight using a single calibrated scale (Detecto, Webb City, Mo) of the participants with them wearing light clothing and no shoes. We measured waist size as the mean of 2 readings at the umbilicus of the participant using a spring-calibrated tape measure and blood pressure was measured as the mean of 1 reading in each arm of the participant while he/she was sitting, using an automated instrument with digital readout (Dinamap, Criticon Inc, Tampa, Fla). We ob-

Table 2. Dietary Macronutrient Intake According to 3-Day Diet Records in an Analysis in Which Missing Data Were Replaced by Baseline or Subsequent Values*

	Diet Group, Median (Interquartile Range)				
Variable	Atkins (n = 40)	Zone (n = 40)	Weight Watchers (n = 40)	Ornish (n = 40)	*P* Value for Linear Trend
Calories/d					
Baseline	1898 (1556-2544)	2059 (1610-2252)	2056 (1755-2400)	1947 (1652-2255)	.71
1 mo	1705 (1292-2180)†	1417 (1200-1831)†	1477 (1152-1819)†	1393 (1139-1945)†	.17
2 mo	1736 (1481-2145)‡	1434 (1234-1920)†	1615 (1352-1947)†	1439 (1124-2089)†	.22
6 mo	1846 (1307-2384)‡	1886 (1262-2093)‡	1755 (1521-1992)†	1711 (1315-2139)†	.56
12 mo	1886 (1509-2290)‡	1757 (1373-2059)†	1832 (1614-2130)†	1819 (1315-2139)‡	.73
Carbohydrates, g/d					
Baseline	239 (186-283)	239 (186-267)	242 (190-260)	236 (183-273)	.70
1 mo	68 (39-209)†	159 (124-199)†	174 (145-239)†	229 (187-271)	.01
2 mo	137 (54-223)†	157 (129-217)†	191 (143-245)†	230 (171-272)	.01
6 mo	190 (90-239)†	198 (151-239)†	202 (158-248)†	237 (168-271)	.01
12 mo	190 (127-239)†	173 (133-239)†	208 (164-263)‡	218 (178-258)	.01
Total fat, g/d					
Baseline	78.0 (53.5-100.0)	81.1 (57.0-101.0)	82.1 (59.0-108.8)	75.5 (64.0-94.8)	.99
1 mo	95.5 (69.5-118.5)†	53.5 (42.3-70.0)†	43.5 (37.3-60.5)†	26.5 (13.3-74.3)†	.01
2 mo	89.5 (73.3-115.8)‡	54.5 (39.3-73.3)†	54.5 (39.3-72.3)†	27.5 (18.0-69.3)†	.01
6 mo	80.5 (52.3-105.8)	66.0 (39.3-92.8)	58.0 (45.0-85.8)†	54.5 (22.3-80.5)†	.01
12 mo	80.5 (50.5-106.8)	71.5 (46.0-85.5)	64.0 (45.3-92.3)‡	64.0 (29.8-81.1)†	.03
Saturated fat, g/d					
Baseline	26.0 (17.3-37.0)	28.6 (20.0-32.8)	27.0 (19.0-38.8)	25.5 (21.3-33.8)	.52
1 mo	31.0 (22.3-44.5)†	15.5 (12.0-23.8)†	15.5 (10.5-19.8)†	7.5 (2.0-23.8)†	.01
2 mo	34.5 (22.3-42.8)†	16.5 (13.0-25.8)†	17.5 (13.3-26.3)†	9.5 (4.0-22.5)†	.01
6 mo	25.5 (18.8-37.3)	18.0 (13.0-28.6)‡	20.5 (15.0-26.5)†	18.5 (5.3-29.7)†	.01
12 mo	27.3 (21.0-39.8)	24.0 (14.3-32.0)	20.5 (15.3-35.3)†	20.5 (7.0-29.7)†	.03
Protein, g/d					
Baseline	86.0 (66.5-115.3)	90.4 (67.3-98.3)	90.2 (75.0-109.3)	87.0 (74.0-103.3)	.41
1 mo	109.0 (73.3-132.8)†	89.7 (74.3-107.3)	72.0 (59.3-85.5)†	66.0 (47.0-90.3)†	.01
2 mo	93.5 (69.3-128.0)	90.4 (65.3-112.5)	80.5 (66.3-101.8)	70.0 (49.8-93.1)†	.01
6 mo	82.0 (64.3-113.0)	90.4 (71.8-110.3)	80.0 (64.5-110.8)	74.0 (55.3-99.3)‡	.13
12 mo	86.0 (65.3-116.5)	90.4 (63.0-111.8)	82.5 (60.0-105.8)†	76.5 (60.0-94.0)‡	.10
Cholesterol, mg/d					
Baseline	287 (196-351)	326 (210-356)	331 (196-401)	326 (233-436)	.12
1 mo	501 (308-686)†	198 (154-317)‡	184 (134-237)†	82 (18-324)†	.01
2 mo	347 (241-615)‡	243 (151-326)‡	217 (168-309)†	112 (21-281)†	.01
6 mo	324 (222-446)	225 (139-326)	245 (165-363)†	218 (56-412)†	.01
12 mo	321 (238-449)	293 (166-335)	219 (142-365)†	280 (124-388)†	.03
Fiber, g/d					
Baseline	16.0 (12.3-20.8)	17.4 (14.0-21.0)	15.0 (12.3-20.0)	14.0 (11.0-16.8)	.02
1 mo	8.5 (5.3-15.8)†	18.0 (12.3-24.8)	15.0 (12.0-19.8)	20.5 (14.0-29.5)†	.01
2 mo	12.5 (6.3-17.8)†	18.5 (15.0-24.8)	16.0 (12.0-20.8)	19.0 (13.3-27.5)†	.01
6 mo	13.0 (7.3-19.0)†	17.4 (13.0-23.0)	14.0 (12.0-18.8)	14.5 (12.0-21.0)	.39
12 mo	15.0 (10.5-19.0)	17.0 (11.3-19.0)	14.5 (12.0-20.0)	15.0 (12.0-20.8)‡	.61

*For Atkins group, the actual numbers of records available were 39 at baseline, 22 at 1 month, 22 at 2 months, 15 at 6 months, and 17 at 12 months; for Zone group, 30 at baseline, 24 at 1 month, 18 at 2 months, 22 at 6 months, and 25 at 12 months; for Weight Watchers group, 39 at baseline, 26 at 1 month, 31 at 2 months, 28 at 6 months, and 24 at 12 months; for Ornish group, 39 at baseline, 22 at 1 month, 24 at 2 months, 15 at 6 months, and 17 at 12 months.
†Wilcoxon rank sum test, $P \leq .05$ for difference from baseline within the group.
‡Wilcoxon rank sum test, $P \leq .01$ for difference from baseline within the group.

Figure 2. Mean Self-reported Dietary Adherence Scores of All 4 Diet Groups, According to Study Month



Possible range of self-rated adherence level was from 1 (none) to 10 (perfect). Baseline values were carried forward in cases of missing data. Range of standard deviation for all 4 diet groups was from 1.9 to 3.5.

tained blood samples after an overnight fast for measurement of serum total cholesterol, HDL cholesterol, triglycerides, glucose, insulin, high-sensitivity C-reactive protein, and creatinine levels by standard methods.[31] We used the Friedewald formula[32] to calculate LDL cholesterol. We also obtained urine samples from 24-hour collections for measurement of total protein, nitrogen, and creatinine levels. We documented changes in exercise category (vigorous, moderate, mild, or minimal) according to self-report.

Statistical Analysis

The primary end point was mean absolute change from baseline weight at 1 year. Using *t* tests and a 2-sided type I error of 5%, we estimated that 40 participants in each group would be necessary to achieve 80% power to detect a weight change of 2% from baseline or 3% between diets.

Analysis of variance was used to assess differences in baseline variables between diet groups, and independent *t* tests were used to compare baseline variables between study participants who discontinued the study with those participants who remained. Absolute changes for each outcome variable at 2, 6, and 12 months were normally distributed for weight loss and cardiac risk variables but not for dietary variables. To assess the null hypothesis of no change from baseline, we used 1-sample *t* test for normally distributed variables and Wilcoxon rank sum test for skewed variables. Missing data were replaced with baseline data for a primary intent-to-treat analysis or excluded for a secondary completers analysis. To compare the adherence data obtained from diet records and self-reports, we used Pearson correlation coefficient in a single analysis that paired the 2 mean scores for each diet across 5 time points. We used linear regression to assess the relationship between changes in weight, dietary adherence variables, and cardiac risk factors, and to assess the independent effects of potentially confounding variables, including baseline characteristics, and changes in exercise and medication use. We used SPSS version 10.1 (SPSS Inc, Chicago, Ill) for all statisticall analyses. All *P* values were 2-sided; $P \leq .05$ was considered statistically significant.

RESULTS

Participant Characteristics

The 40 participants in each of the 4 diet groups were well matched in terms of baseline characteristics (TABLE 1). Age, race, sex, body mass index, and metabolic characteristics generally matched those of the overweight population in the United States.[13] Baseline characteristics did not differ significantly between diet groups and regression models adjusting for these (eg, hyperglycemia, baseline insulin levels) or other potentially confounding variables such as time of diet class demonstrated no confounding effects.

Of the 160 participants, the mean (SD) age was 49 (11) years (range, 22-72 years) and 81 were women (n=21 in Atkins, n=20 in Zone, n=23 in Weight Watchers, n=17 in Ornish groups; $P=.90$ for sex difference between diets). Compared with men, women had significantly lower mean baseline weight (93 vs 106 kg), waist size (103 vs 114 cm), diastolic blood pressure (74 vs 78 mm Hg), and triglyceride levels (150 vs 188 mg/dL [1.7 vs 2.1 mmol/L]) (all $P<.05$), and higher mean levels of C-reactive protein (4.8 vs 3.3 mg/L) and HDL cholesterol (52 vs 41 mg/dL [1.35 vs 1.06 mmol/L]). Women were also more likely to be nonwhite (38% vs 11%).

Attrition and Adverse Effects

The number of participants who did not complete the study at months 2, 6, and 12 were 34 (21%), 61 (38%), and 67 (42%), respectively. At 1 year, there was a nonsignificant trend ($P=.08$) toward a difference in discontinuation rates between the more extreme diets (48% for Atkins and 50% for Ornish) and moderate diets (35% for Zone and 35% for Weight Watchers). Twenty-seven of 61 participants who discontinued before 6 months were evaluated at 2 months

Table 3. Changes in Weight and Cardiac Risk Factors in an Analysis in Which Baseline Values Were Carried Forward in the Case of Missing Data*

	Diet Group, Mean Change (SD)				
Variable	Atkins (n = 40)	Zone (n = 40)	Weight Watchers (n = 40)	Ornish (n = 40)	*P* Value for Trend Across Diets
Weight, kg					
2 mo	−3.6 (3.3)†	−3.8 (3.6)†	−3.5 (3.8)†	−3.6 (3.4)†	.89
6 mo	−3.2 (4.9)†	−3.4 (5.7)†	−3.5 (5.6)†	−3.6 (6.7)†	.76
12 mo	−2.1 (4.8)†	−3.2 (6.0)†	−3.0 (4.9)†	−3.3 (7.3)†	.40
BMI					
2 mo	−1.3 (1.1)†	−1.3 (1.2)†	−1.2 (1.3)†	−1.2 (1.1)†	.83
6 mo	−1.1 (1.7)†	−0.9 (2.4)‡	−1.2 (2.0)†	−1.2 (2.3)†	.65
12 mo	−0.7 (1.6)†	−1.1 (2.0)†	−1.1 (1.7)†	−1.4 (2.5)‡	.36
Waist circumference, cm					
2 mo	−3.3 (3.1)†	−3.0 (3.5)†	−3.5 (4.2)†	−2.7 (3.2)†	.37
6 mo	−3.2 (4.9)†	−2.9 (5.2)†	−3.5 (5.9)†	−2.5 (5.3)†	.69
12 mo	−2.5 (4.5)†	−2.9 (5.3)†	−3.3 (5.4)†	−2.2 (5.5)‡	.89
Total cholesterol, mg/dL					
2 mo	−1.8 (24)	−18.4 (25)†	−14.8 (26)†	−19.0 (28)†	.01
6 mo	−0.9 (18)	−6.2 (19)‡	−8.1 (21)‡	−11.4 (26)†	.03
12 mo	−4.3 (23)	−10.1 (35)	−8.2 (24)‡	−10.8 (21)†	.35
LDL cholesterol, mg/dL					
2 mo	1.3 (18)	−9.7 (27)‡	−12.1 (25)†	−16.5 (25)†	.001
6 mo	−2.7 (14)	−6.7 (22)	−7.0 (24)	−10.5 (22)†	.10
12 mo	−7.1 (24)	−11.8 (34)‡	−9.3 (27)‡	−12.6 (19)†	.46
HDL cholesterol, mg/dL					
2 mo	3.2 (6.2)†	1.8 (7.6)	−0.2 (11.8)	−3.6 (7.3)†	.001
6 mo	3.8 (6.4)†	3.6 (10.5)‡	2.4 (9.0)	−1.5 (7.0)	.005
12 mo	3.4 (7.1)†	3.3 (10.3)‡	3.4 (9.9)‡	−0.5 (6.5)	.06
Total/HDL cholesterol ratio					
2 mo	−0.36 (0.66)†	−0.66 (1.06)†	−0.49 (1.86)	−0.18 (1.01)	.40
6 mo	−0.38 (0.68)†	−0.46 (0.93)†	−0.60 (1.57)‡	−0.25 (1.07)	.75
12 mo	−0.39 (0.69)†	−0.52 (1.04)†	−0.70 (1.67)‡	−0.30 (0.96)	.89
LDL/HDL cholesterol ratio					
2 mo	−0.18 (0.57)‡	−0.33 (0.79)†	−0.42 (1.55)	−0.21 (0.67)	.81
6 mo	−0.30 (0.55)†	−0.30 (0.74)†	−0.47 (1.37)‡	−0.22 (0.70)	.90
12 mo	−0.39 (0.81)†	−0.40 (0.81)†	−0.55 (1.39)‡	−0.31 (0.68)†	.92
Triglycerides, mg/dL					
2 mo	−32.3 (66)†	−54.1 (105)†	−9.2 (39)	−0.4 (77)	.01
6 mo	−10.6 (40)	−14.8 (57)	−1.5 (55)	−2.3 (71)	.35
12 mo	−1.2 (84)	2.5 (147)	−12.7 (61)	5.6 (36)	.93
Systolic BP, mm Hg					
2 mo	−4.2 (13)‡	−4.1 (14)	−4.8 (13)‡	−1.3 (8.8)	.19
6 mo	−3.7 (10)‡	−3.9 (14)	−4.8 (14)‡	−0.6 (8.7)	.32
12 mo	0.2 (12)	1.4 (15)	−2.7 (13)	0.5 (7.7)	.71
Diastolic BP, mm Hg					
2 mo	−4.2 (8.3)†	−4.8 (7.6)†	−3.1 (7.4)‡	−2.5 (7.1)‡	.19
6 mo	−4.0 (6.5)†	−4.0 (9.1)†	−1.8 (6.9)	−0.3 (6.2)	.01
12 mo	−1.4 (7.5)	−1.2 (9.5)	−1.7 (6.4)	0.2 (4.6)	.40
Glucose, mg/dL					
2 mo	−9.8 (30)‡	−9.0 (29)	−5.5 (24)	−3.1 (23)	.21
6 mo	−7.8 (26)	−8.2 (33)	−3.8 (22)	−5.1 (25)	.50
12 mo	1.4 (30)	−4.2 (18)	−4.7 (19)	−4.1 (30)	.34

(continued)

(mean weight loss, 2.6 kg) and 10 of 67 participants who discontinued before 12 months were evaluated at 6 months (mean weight loss, 1.3 kg). Individuals who discontinued the study had less formal education ($P = .001$) and lower baseline diastolic blood pressure (74 vs 78 mm Hg, $P = .02$) than those who completed. The most common reasons cited for discontinuation of the study were that the assigned diet was too hard to follow or not yielding enough weight loss. We were unable to identify any diet-related adverse event or serious adverse effects during the study. We found no evidence of clinically significant renal impairment in any of the diet groups.

Dietary Intake and Adherence

Dietary intake according to an intent-to-treat analysis of 3-day diet records is shown in TABLE 2. At baseline, 147 (92%) of the participants submitted food records. Mean total energy intake was 2059 calories daily, with 46.4%, 34.5%, and 17.6% of calories derived, respectively, from carbohydrate, fat, and protein. There were no significant caloric or macronutrient differences between diet groups at baseline. For each group, dietary adherence as assessed by diet records decreased progressively with time, although the specifically targeted dietary parameters for each diet were significantly different from baseline (all $P < .01$) at each time point, according to both the primary and secondary analyses. At 1 year, the mean caloric reductions from baseline were 138 for Atkins, 251 for Zone, 244 for Weight Watchers, and 192 for Ornish groups (all $P < .05$, $P = .70$ between diets).

Group mean adherence scores according to diet records and self-assessment were highly associated for the duration of the study (Pearson $r = 0.90$; $P < .001$). As with diet records, adherence according to self-report gradually decreased over time, and to a similar extent in each diet group (FIGURE 2). Nevertheless, approximately 25% of participants in each diet group sustained a mean adherence level of at least 6 of 10, which appeared to delineate a clinically meaningful adherence level.

Weight Loss

According to the primary intent-to-treat analysis (TABLE 3) and the secondary analysis that excluded missing data (TABLE 4), all 4 diets resulted in modest statistically significant weight loss at 1 year, with no statistically significant differences between diets ($P=.40$). In each diet group, approximately 25% of the initial participants sustained a 1-year weight loss of more than 5% of initial body weight and approximately 10% of participants lost more than 10% of body weight. Weight reductions were highly associated with waist size reductions for all diets (Pearson $r=0.86$ at 1 year; $P<.001$), with no significant difference between diets. In women, mean (SD) body weight decreased by 2.4 (5.1) kg (2.5% change from baseline) and waist size by 2.3 (4.5) cm, whereas in men body weight decreased by 3.3 (6.4) kg (3.1% change from baseline) and waist size by 3.1 (5.8) cm at 1 year ($P=.30$ for sex differences).

In contrast with the absent association between diet type and weight loss ($r=0.07$; $P=.40$), we observed a strong curvilinear association between self-reported dietary adherence and weight loss ($r=0.60$; $P<.001$) that was almost identical for each diet (FIGURE 3). Participants in the top tertile of adherence lost 7% of body weight on average.

Cardiac Risk Factors

According to the primary intent-to-treat analysis (Table 3), all diets achieved modest, although statistically significant, improvements in several cardiac risk factors at 1 year. All diets reduced mean LDL cholesterol levels at 1 year, although this did not reach statistical significance in the case of the Atkins group ($P=.07$). All diets significantly increased mean HDL cholesterol levels, except in the Ornish diet group ($P=.60$). The LDL/HDL ratio decreased approximately 10% in each diet group (all $P<.05$). No diet program significantly altered triglycerides, blood pressure, or fasting glucose at 1 year. The lower carbohydrate diets (Atkins and Zone) were more likely to reduce triglycerides, diastolic blood pressure, and insulin in the short term, although the Atkins diet failed to significantly reduce mean fasting insulin levels at 1 year ($P=.26$). All the diets reduced 1-year C-reactive protein levels by approximately 15% to 20%, al-

Table 3. Changes in Weight and Cardiac Risk Factors in an Analysis in Which Baseline Values Were Carried Forward in the Case of Missing Data* (cont)

	Diet Group, Mean Change (SD)				
Variable	Atkins (n = 40)	Zone (n = 40)	Weight Watchers (n = 40)	Ornish (n = 40)	*P* Value for Trend Across Diets
Insulin, μIU/mL					
2 mo	−5.1 (13)†	−7.1 (12)†	−1.8 (6.0)	−1.7 (12)	.06
6 mo	−2.3 (11)	−1.9 (16)	−2.5 (7.1)	−0.4 (18)	.60
12 mo	−1.2 (6.7)	−5.4 (14)†	−2.6 (6.1)†	−3.0 (6.3)‡	.70
C-reactive protein, mg/L					
2 mo	−0.33 (1.6)	−0.22 (1.9)	−0.04 (1.2)	−0.61 (2.6)	.61
6 mo	−0.71 (2.0)‡	−0.42 (1.9)	−0.50 (1.5)‡	−0.70 (2.8)	.97
12 mo	−0.70 (2.1)‡	−0.58 (2.1)	−0.58 (1.3)†	−0.88 (2.4)‡	.70

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
SI conversions: To convert glucose to mmol/L, multiply by 0.0555; HDL, LDL, and total cholesterol to mmol/L, multiply by 0.0259; insulin to pmol/L, multiply by 6.945; and triglycerides to mmol/L, multiply by 0.0113.
*For Atkins group, the actual numbers of records available were 31 at 2 months, 22 at 6 months, and 21 at 12 months; for Zone group, 33 at 2 months, 26 at 6 months, and 26 at 12 months; for Weight Watchers group, 33 at 2 months, 30 at 6 months, and 26 at 12 months; for Ornish group, 29 at 2 months, 21 at 6 months, and 20 at 12 months.
†$P<.01$ for difference from baseline within the group.
‡$P<.05$ for difference from baseline within the group.

Table 4. Changes in Weight and Cardiac Risk Factors in an Analysis in Which Missing Values Were Excluded*

	Diet Group, Mean Change (SD)			
Variable	Atkins (n = 40)	Zone (n = 40)	Weight Watchers (n = 40)	Ornish (n = 40)
Weight, kg				
2 mo	−4.7 (2.9)†	−4.6 (3.4)†	−4.2 (3.8)†	−5.0 (3.0)†
6 mo	−5.8 (5.3)†	−5.2 (6.4)†	−4.7 (6.1)†	−6.7 (8.0)†
12 mo	−3.9 (6.0)†	−4.9 (6.9)†	−4.6 (5.4)†	−6.6 (9.3)†
BMI				
2 mo	−1.6 (1.0)†	−1.6 (1.2)†	−1.5 (1.3)†	−1.7 (1.0)†
6 mo	−2.0 (1.9)†	−1.7 (2.2)†	−1.7 (2.1)†	−2.4 (2.7)†
12 mo	−1.4 (2.1)†	−1.6 (2.3)†	−1.7 (1.9)†	−2.3 (3.2)†
Waist circumference, cm				
2 mo	−4.3 (2.9)†	−3.6 (3.5)†	−4.2 (4.3)†	−3.7 (3.2)†
6 mo	−5.9 (5.3)†	−4.4 (6.0)†	−4.7 (6.4)†	−4.8 (6.5)†
12 mo	−4.7 (5.4)†	−4.5 (6.0)†	−5.0 (6.0)†	−4.3 (7.2)‡
Total cholesterol, mg/dL				
2 mo	−2.3 (27)	−22.3 (26)†	−17.9 (29)†	−26.2 (30)†
6 mo	−1.6 (24)	−9.6 (23)‡	−10.8 (24)‡	−21.6 (33)†
12 mo	−8.1 (31)	−15.6 (43)	−12.6 (28)‡	−21.5 (26)†
LDL cholesterol, mg/dL				
2 mo	1.6 (20)	−11.7 (29)‡	−14.7 (27)†	−22.7 (27)†
6 mo	−4.9 (18)	−10.3 (26)	−9.4 (27)	−20.0 (28)†
12 mo	−13.5 (32)	−18.1 (41)‡	−14.2 (32)‡	−25.2 (20)†
HDL cholesterol, mg/dL				
2 mo	4.2 (6.7)†	2.2 (8.4)	−0.3 (13.0)	−4.9 (8.2)†
6 mo	7.0 (7.4)†	5.5 (12.7)‡	3.2 (10.3)	−2.8 (9.6)
12 mo	6.4 (8.8)†	5.1 (12.5)‡	5.2 (12.0)‡	−1.1 (9.3)
Total/HDL cholesterol ratio				
2 mo	−0.47 (0.71)†	−0.80 (1.12)†	−0.60 (2.03)	−0.24 (1.19)
6 mo	−0.70 (0.80)†	−0.71 (1.08)†	−0.80 (1.79)‡	−0.48 (1.46)
12 mo	−0.75 (0.81)†	−0.79 (1.21)†	−1.07 (1.98)‡	−0.59 (1.30)
LDL/HDL cholesterol ratio				
2 mo	−0.23 (0.63)‡	−0.40 (0.86)‡	−0.50 (1.70)	−0.29 (0.77)
6 mo	−0.55 (0.66)†	−0.49 (0.85)‡	−0.63 (1.56)‡	−0.41 (0.93)
12 mo	−0.73 (1.01)†	−0.61 (0.94)†	−0.85 (1.65)‡	−0.62 (0.87)†

(continued)

Table 4. Changes in Weight and Cardiac Risk Factors in an Analysis in Which Missing Values Were Excluded* (cont)

Variable	Diet Group, Mean Change (SD)			
	Atkins (n = 40)	Zone (n = 40)	Weight Watchers (n = 40)	Ornish (n = 40)
Triglycerides, mg/dL				
2 mo	−42 (72)†	−66 (112)†	−11 (43)	−1 (90)
6 mo	−19 (53)	−23 (70)	−2 (64)	−4 (99)
12 mo	−2 (117)	4 (183)	−20 (75)	11 (53)
Systolic BP, mm Hg				
2 mo	−5.4 (15)‡	−4.9 (15)	−5.9 (14)‡	−1.8 (10)
6 mo	−6.7 (12)†	−6.1 (17)	−6.4 (16)‡	−1.2 (12)
12 mo	0.3 (17)	2.1 (18)	−4.1 (16)	0.9 (11)
Diastolic BP, mm Hg				
2 mo	−5.5 (9.0)†	−5.8 (8.0)†	−3.7 (8.0)‡	−3.4 (8.1)‡
6 mo	−7.3 (7.4)†	−6.2 (10.8)†	−2.4 (7.9)	−0.5 (8.6)
12 mo	−2.6 (10.3)	−1.8 (11.8)	−2.6 (7.8)	0.4 (6.6)
Glucose, mg/dL				
2 mo	−12.7 (34)‡	−10.8 (31)	−6.6 (26)	−4.2 (27)
6 mo	−14.1 (34)	−12.6 (40)	−5.0 (25)	−9.6 (34)
12 mo	2.5 (42)	−6.4 (22)	−7.1 (23)	−8.2 (43)
Insulin, μIU/mL				
2 mo	−6.5 (15)‡	−8.6 (13)†	−2.2 (7)	−2.3 (15)
6 mo	−4.1 (15)	−3.0 (20)	−3.4 (8)‡	−0.7 (25)
12 mo	−2.3 (9)	−8.5 (17)‡	−4.1 (7)†	−5.9 (8)‡
C-reactive protein, mg/L				
2 mo	−0.42 (1.8)	−0.27 (2.1)	−0.05 (1.3)	−0.84 (3.0)
6 mo	−1.29 (2.6)‡	−0.65 (2.3)	−0.67 (1.7)‡	−1.33 (3.8)
12 mo	−1.33 (2.8)‡	−0.88 (2.6)	−0.88 (1.6)†	−1.76 (3.1)‡

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
SI conversions: To convert glucose to mmol/L, multiply by 0.0555; HDL, LDL, and total cholesterol to mmol/L, multiply by 0.0259; insulin to pmol/L, multiply by 6.945; and triglycerides to mmol/L, multiply by 0.0113.
*For Atkins group, the actual numbers of records available were 31 at 2 months, 22 at 6 months, and 21 at 12 months; for Zone group, 33 at 2 months, 26 at 6 months, and 26 at 12 months; for Weight Watchers group, 33 at 2 months, 30 at 6 months, and 26 at 12 months; for Ornish group, 29 at 2 months, 21 at 6 months, and 20 at 12 months.
†$P<.01$ for difference from baseline within the group.
‡$P<.05$ for difference from baseline within the group.

though the reduction did not reach statistical significance in the case of the Zone diet ($P=.09$). The secondary analysis, which excluded missing data (Table 4), demonstrated larger but otherwise similar changes overall.

The amount of weight loss predicted the amount of improvement in several cardiac risk factors (FIGURE 4). For each diet, weight loss was significantly associated with changes in total/HDL cholesterol ratio ($r=-0.36$), C-reactive protein ($r=-0.37$), and insulin levels ($r=-0.39$), regardless of diet type ($P=.48$, $P=.57$, $P=.31$, respectively, for difference between diets). No diet significantly worsened any cardiac risk factor in association with weight loss or dietary adherence at 1 year.

Exercise and Medication Use

Exercise levels, according to participant report (vigorous, moderate, mild, minimal), were modestly increased from baseline throughout the trial (all $P<.05$), and to a similar extent for each diet group ($P=.70$ between diets). At 1 year, the numbers of participants with increased and decreased exercise levels from baseline were 11 and 2 for Atkins, 10 and 7 for Zone, 14 and 3 for Weight Watchers, and 8 and 3 for Ornish groups, respectively. The amount of weight loss was associated with changes in exercise level ($r=0.27$; $P=.001$), with no significant differences between diets ($P=.70$). After accounting for dietary adherence, there was no significant association between change in exercise and change in body weight or any cardiac risk factor at 1 year.

The number of prescription medications (mean, 2.4) did not significantly change in the 126 participants who remained in the study for at least 2 months. The net change in total number of prescription medications for the Atkins, Zone, Weight Watchers, and Ornish groups was +7, −4, −7, and +5, respectively ($P=.16$ for difference between diets). Adjusting for changes in baseline medication use did not materially affect the study outcomes. For example, 4 to 7 participants in each group were initially taking cholesterol-lowering medication, which was discontinued by 1 individual in the Zone group and initiated during the study by primary care physicians for 1 each in the Atkins and Weight Watchers groups and for 3 in the Zone group. When individuals who initiated cholesterol-lowering medication were excluded from the intent-to-treat analysis, the reductions in LDL/HDL cholesterol ratios observed with each diet remained statistically significant, and associations between weight loss and lipid changes were unchanged or slightly stronger.

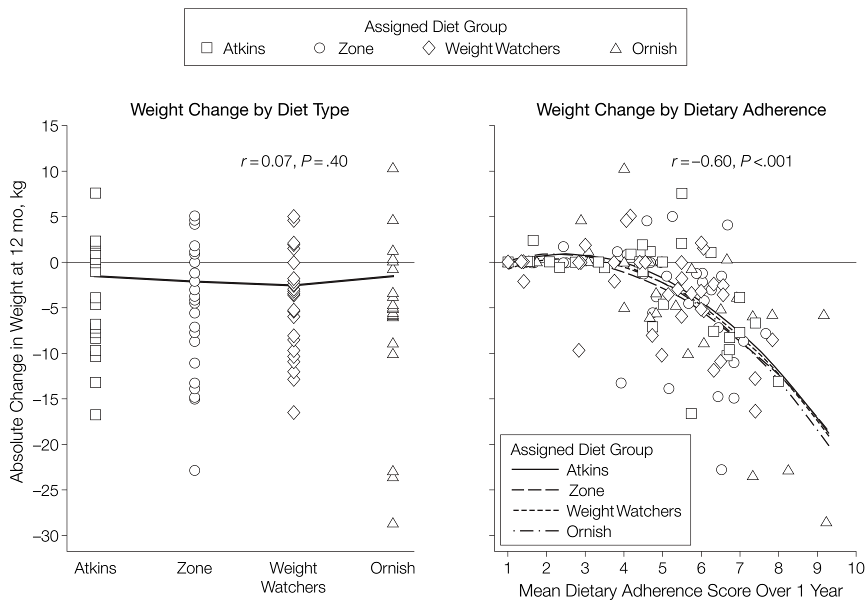
COMMENT

In our randomized trial, we found that a variety of popular diets can reduce weight and several cardiac risk factors under realistic clinical conditions, but only for the minority of individuals who can sustain a high dietary adherence level. Despite a substantial percentage of participants who could sustain meaningful adherence levels, no single diet produced satisfactory adherence rates and the progressively decreasing mean adherence scores were practically identical among the 4 diets. The higher discontinuation rates for the Atkins and Ornish diet groups suggest many individuals found these diets to be too extreme. To optimally manage a national epidemic of excess body weight[33] and associated cardiac risk factors, practical techniques to increase dietary adherence rates are urgently needed.

One way to improve dietary adherence rates in clinical practice may be to use a broad spectrum of diet options, to better match individual patient food preferences, lifestyles, and cardiovascular risk profiles. Participants in our study were not allowed to choose their dietary assignment; however, we suspect adherence rates and clinical improvements would have been better if participants had been able to freely select from the 4 diet options. Our findings challenge the concept that 1 type of diet is best for everybody and that alternative diets can be disregarded. Likewise, our findings do not support the notion that very low carbohydrate diets are better than standard diets, despite recent evidence to the contrary.[17,22,23,25]

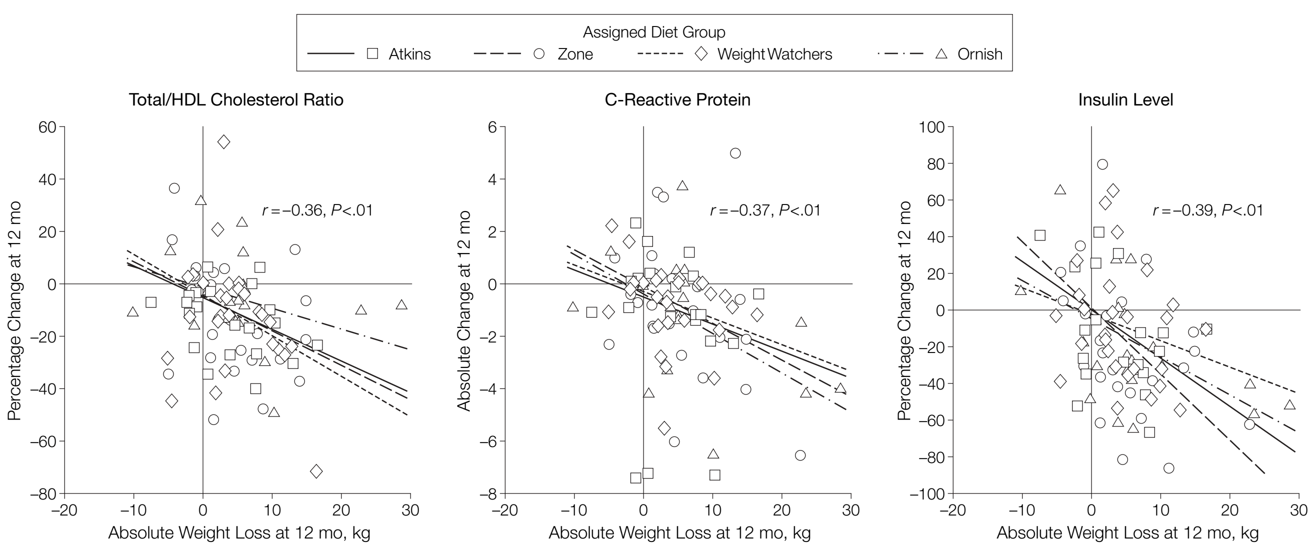
Our results support a growing body of research suggesting that carbohydrate restriction and saturated fat restriction have different effects on cardiovascular risk profiles. Low carbohydrate diets consistently increase HDL cholesterol,[17,20] and low–saturated fat diets consistently decrease LDL cholesterol levels.[34] Low carbohydrate diets have typically been more effective for short-term reduction of serum triglycerides, glucose, and/or insulin.[17,19,22,23,35,36] These findings may suggest to some clinicians that the degree to which a patient exhibits features of the metabolic syndrome might guide the degree of carbohydrate restriction to recommend. In the long run, however, sustained adherence to a diet rather than diet type was

Figure 3. One-Year Changes in Body Weight as a Function of Diet Group and Dietary Adherence Level for All Study Participants



Baseline values were carried forward in cases of missing data. The curve in the weight change by diet type plot indicates the Lowess regression function, a locally weighted, least-squares method using 3 iterations to fit the data. The curves in the weight change by dietary adherence plot indicate the quadratic regression functions for each diet group.

Figure 4. One-Year Changes in Total/High-Density Lipoprotein Cholesterol Ratio, C-Reactive Protein, and Insulin as a Function of Weight Loss for All Study Participants



Baseline values were carried forward in cases of missing data. HDL indicates high-density lipoprotein. The curves in all 3 plots indicate the linear regression functions for each diet group. For difference between diet groups, P = .48 for total/HDL cholesterol ratio; P = .57 for C-reactive protein; and P = .31 for insulin level.

the key predictor of weight loss and cardiac risk factor reduction in our study.

The clinical significance of diet-induced changes in HDL cholesterol is unclear. High-carbohydrate/low-fat diets typically reduce or fail to increase HDL cholesterol levels, but insufficient data exist to determine whether this is harmful or benign in terms of cardiac events or atherosclerosis progression.[34,37,38] Similarly, the increase in HDL cholesterol associated with low-carbohydrate/high-fat diets is of unclear benefit due to a lack of relevant dietary intervention trials. Increased saturated fat intake may potentially contribute to HDL cholesterol increases in the case of the Atkins diet, although we observed no such association between changes in HDL cholesterol and saturated fat in our study. The reduction in LDL/HDL cholesterol ratio observed for each diet is suggestive but not conclusive of net beneficial effects on lipid profiles. Clearly, the cardiovascular and other health effects of dietary alternatives require additional study.

By design, our study provided a limited amount of support beyond the initial 2 months to estimate the real-world effectiveness and sustainability of the diets when a long-term support system was lacking. A benefit of this approach was the enhanced ability to demonstrate a dose-response relationship between dietary adherence levels, weight loss, and clinical benefits. A drawback is that this approach is poorly suited to determine the effects of each diet in highly adherent individuals. Research studies and clinical programs that aim to maximize adherence to dietary and other lifestyle recommendations are known to obtain greater clinical benefits.[39,40]

Our study has several limitations. Our study was designed to identify the clinical strengths and weaknesses of each diet under identical conditions but was not necessarily designed to identify a "best diet." If one diet produces more weight loss or cardiac risk reduction than the other diets do, a much larger sample size would probably be required to detect such differences under similar conditions. Our study had a relatively high rate of attrition, which confounds the interpretation of the results because the magnitude of the results depends on the accuracy of an unverifiable assumption. The assumption that participants who discontinued the study were unchanged from baseline is reasonable but imprecise.[41] Nevertheless, we believe our general findings are reasonably valid based on 3 observations: participants who discontinued were reasonably similar to the other participants from a demographic and clinical perspective, the participants who discontinued had evidence of weight loss rather than weight gain before discontinuing, and we obtained meaningful (albeit modest) results despite a rather conservative approach to handling the missing data. Our study was limited in its ability to exclude long-term safety risks or occasional dangerous adverse effects resulting from the diets, even though we found no short-term safety risks in our study. Finally, the measurements of dietary intake and adherence relied on self-reporting and are therefore subjective.

In conclusion, poor sustainability and adherence rates resulted in modest weight loss and cardiac risk factor reductions for each diet group as a whole. Cardiac risk factor reductions were associated with weight loss regardless of diet type, underscoring the concept that adherence level rather than diet type was the key determinant of clinical benefits. Cardiovascular outcomes studies would be appropriate to further investigate the potential health effects of these diets. More research is also needed to identify practical techniques to increase dietary adherence, including techniques to match individuals with the diets best suited to their food preferences, lifestyle, and medical conditions.

Author Contributions: Dr Dansinger had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Dansinger, Griffith, Selker, Schaefer.
Acquisition of data: Dansinger, Gleason, Schaefer.
Analysis and interpretation of data: Dansinger, Gleason, Selker, Schaefer.
Drafting of the manuscript: Dansinger, Griffith, Schaefer.
Critical revision of the manuscript for important intellectual content: Dansinger, Gleason, Griffith, Selker, Schaefer.
Statistical analysis: Dansinger, Griffith.
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I touch the future. I teach.
—Christa McAuliffe (1948-1986)