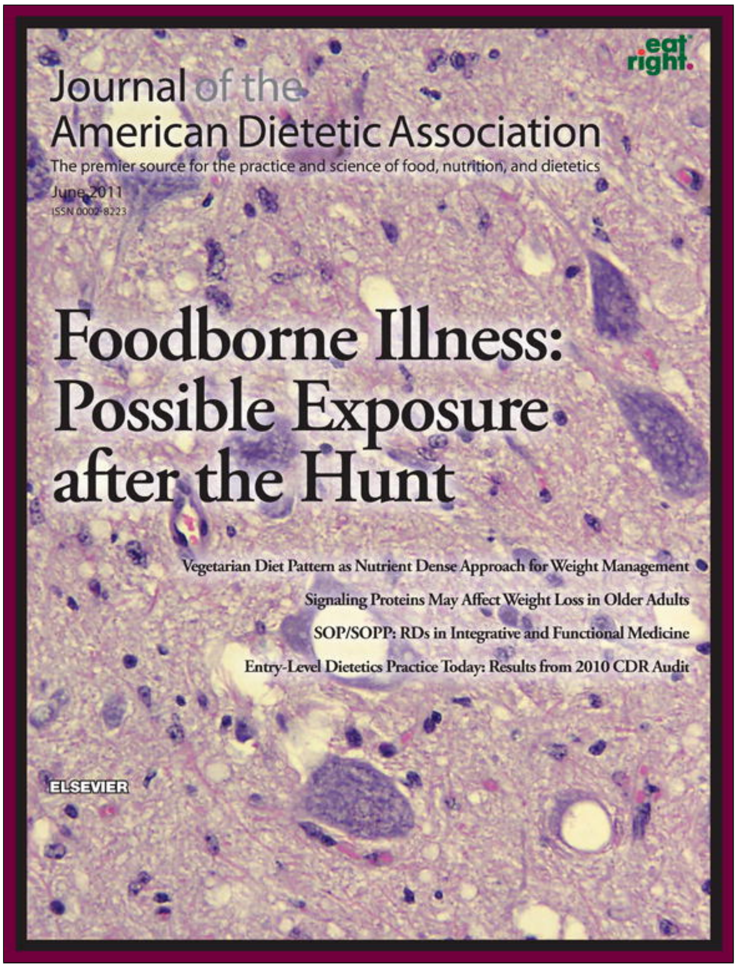
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A Structured Diet and Exercise Program Promotes Favorable Changes in Weight Loss, Body Composition, and Weight Maintenance

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ABSTRACT

Background A number of diet and exercise programs purport to help promote and maintain weight loss. However, few studies have compared the efficacy of different methods.

Objective To determine whether adherence to a meal-replacement–based diet program (MRP) with encouragement to increase physical activity is as effective as following a more structured meal-plan–based diet and supervised exercise program (SDE) in sedentary obese women.

Design Randomized comparative effectiveness trial.

Participants/setting From July 2007 to October 2008, 90 obese and apparently healthy women completed a 10-week university-based weight loss trial while 77 women from this cohort also completed a 24-week weight maintenance phase.

Intervention Participants were matched and randomized to participate in an MRP or SDE program.

Main outcome measures Weight loss, health, and fitness-related data were assessed at 0 and 10 weeks on all subjects as well as at 14, 22, and 34 weeks on participants who completed the weight maintenance phase.

Statistical analyses performed Data were analyzed by multivariate analysis of variance for repeated measures.

Results During the 10-week weight loss phase, moderate and vigorous physical activity levels were significantly higher in the SDE group with no differences observed between groups in daily energy intake. The SDE group lost more weight (-3.1 ± 3.7 vs -1.6 ± 2.5 kg; $P=0.03$); fat mass (-2.3 ± 3.5 vs -0.9 ± 1.6 kg; $P=0.02$); centimeters from the hips (-4.6 ± 7 vs -0.2 ± 6 cm; $P=0.002$) and waist (-2.9 ± 6 vs -0.6 ± 5 cm; $P=0.05$); and, experienced a greater increase in peak aerobic capacity than participants in the MRP group. During the 24-week maintenance phase, participants in the SDE group maintained greater moderate and vigorous physical activity levels, weight loss, fat loss, and saw greater improvement in maximal aerobic capacity and strength.

Conclusions In sedentary and obese women, an SDE-based program appears to be more efficacious in promoting and maintaining weight loss and improvements in markers of health and fitness compared to an MRP type program with encouragement to increase physical activity.
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Obesity has become a worldwide epidemic, with an estimated 1.2 billion people overweight and at least 300 million people considered obese (1-4). Obesity is associated with increased risk of hypertension, diabetes mellitus, dyslipidemia, and liver disease (1,4,5). It is also associated with increased morbidity, mortality, and has a significant socioeconomic effect (5-11). Whereas obesity had been thought to simply be related to an imbalance between energy intake and expenditure, more recent research has indicated that genetic, physiological, psychological, socioeconomic, cultural, and behavioral factors also play a role in the etiology of obesity in various populations (1-4,7,12). For this reason, the prevention, treatment, and management of obesity are complex and require multifaceted interventions (4,7).

A number of studies have reported that different types of diet, exercise, and/or behavioral interventions can promote weight loss. For example, studies have shown that reducing energy intake (13-15), altering macronutrient intake (16-19), increasing dietary fiber intake (20-22), use of ready-to-eat (RTE) meals as meal replacements (23-28), and increasing dietary availability of some nutrients can promote weight loss to varying degrees (17,29-33). It is also known that increasing physical activity (PA) and energy expenditure can help promote and/or maintain weight loss (25,34,35) and that the mode of exercise employed (eg, walking or resistance training) may have differential effects (36-39). In addition, a number of behavioral interventions (eg, nutrition education, counseling, provision of meal plans, use of prepared meals, monitoring of results, social support, and degree of supervision) can influence the success of weight loss and maintenance programs (7,25,40,41). However, few studies have compared one strategy to another to assess the efficacy of different diet, exercise, and/or behavioral intervention strategies on weight loss and management. Given the high costs of treating obesity and weight loss program interventions, it has become increasingly important to conduct comparative effectiveness trials on weight loss strategies and commercial programs so informed decisions can be made regarding the efficacy, safety, and value of these programs (28,42).

The purpose of this study was to determine whether adherence to an RTE meal-replacement–based diet that included additional dietary recommendations and encouraged an increase in physical activity is as effective as following a more structured diet plan and supervised exercise program. It was hypothesized that both groups would experience beneficial changes in body mass, body composition, and markers of health. However, participants following the more structured diet and supervised exercise program would experience more favorable results.

METHODS

Experimental Approach

This study was conducted as a randomized comparative effectiveness trial in a university clinical research setting from July 2007 to October 2008. Participants were matched based on age and body mass index (BMI; calculated as kg/m^2) and randomized into one of two diet and exercise interventions. Participants were tested at 0 and 10 weeks of an active weight loss phase as well as at 14, 22, and 34 weeks of a weight maintenance phase. Primary outcome measures included energy intake, physical activity, body mass, body composition, and waist and hip circumferences. Secondary outcome measures included diet quality; resting energy expenditure; markers of cardiovascular and muscular fitness; serum lipids, glucose, and insulin levels; and psychosocial assessments.

Participants

This research protocol was reviewed and approved by the university Institutional Review Board before initiation. Participants were recruited through advertisements in local newspapers, campus flyers, radio, and Internet advertisements. Interested participants were asked to contact the laboratory for an initial telephone prescreening interview. General entrance criteria included being an apparently healthy woman between ages 18 and 55 years with a BMI between 27 and 40 and no recent participation in a diet or exercise program. Individuals who met initial entrance criteria were invited to attend a familiarization session in which the details of the study were explained, human subject consent forms were signed, and personal and medical history information obtained. Participants were not allowed to participate in this study if the subjects reported the following at baseline: a recent history of weight change (±3.2 kg or 7 lb) within 3 months; any metabolic or cardiovascular disorder, including known electrolyte abnormalities, heart disease, arrhythmias, diabetes, thyroid disease, hypogonadism, or a history of hypertension, hepatorenal, musculoskeletal, autoimmune, or neurologic disease; any prescription thyroid, hyperlipidemic, hypoglycemic, anti-hypertensive, and/or androgenic medications; a history of pregnancy or lactation within the past 12 months or intentions to become pregnant during the next 12 months; participation in a regular exercise program within the past 3 months; an unwillingness to consume study products on a regular basis after tasting the cereals and bars to be used in the study; taking any weight loss medications and/or dietary supplements that may have affected muscle mass or body weight during the 3 months before beginning the study; and, any condition that classified them as high risk for cardiovascular disease according to American College of Sports Medicine criteria (43). Information obtained during the familiarization session was reviewed by a research nurse to determine eligibility to participate in the study. Those meeting eligibility criteria were scheduled to undergo baseline assessments.

A total of 255 women responded to advertisements to participate in this study. Of these, 236 women met phone interview entrance criteria and were invited to attend familiarization sessions. A total of 196 women showed up for familiarization sessions and 167 women met entrance criteria to participate in the study after obtaining consent and evaluating medical history. Of these, 103 participants completed baseline testing and were cleared to participate in the study. Ninety women completed the 10-week weight loss phase of the study while 77 women also completed a 24-week weight maintenance portion of the study. The primary reasons participants dropped out of the study were due to time constraints, job conflicts, and relocation.

Testing Sessions

Before each testing session, participants were asked to complete a 4-day food intake log and a 7-day physical activity questionnaire. Participants were also asked to refrain from vigorous physical activity, alcohol intake, and ingestion of over the counter medications for 24 hours before testing. In addition, participants fasted for 12 hours before reporting to the laboratory. Baseline assessments included body mass and body composition; anthropometric measurements; resting energy expenditure; resting heart rate and blood pressure; fasting whole blood and serum markers; a maximal cardiopulmonary exercise test; upper and lower body muscular strength and endurance tests; and completion of physical activity, diet quality, and psychosocial questionnaires. Once baseline testing was completed, participants were matched by age (within 5-year intervals) and body mass (within 2 BMI point intervals) randomized into a meal-replacement–based program (MRP) or a more structured diet and exercise program (SDE) according to the methods described below. Intervention follow-up data were obtained after 10 weeks of active weight loss and after 4, 12, and 24 weeks of weight maintenance intervention (ie, 14, 22, and 34 weeks of the study). All testing sessions were scheduled at similar times in the morning to control for diurnal variations and conducted in an identical fashion. Participants were given small monetary or gift incentives several times throughout the study to encourage compliance with the study protocol.

Dietary Intervention

Participants were randomized into one of two popular weight loss program intervention groups that followed a three-phase weight loss and weight maintenance protocol. For 2 weeks (Phase I), participants in the MRP group followed the Special K (SK) Challenge program (44), which involved replacing two meals per day with SK RTE cereal (SK Original, Kellogg Company, Battle Creek, MI), 2/3 c skim milk, and a serving of fruit. In addition, participants were instructed to consume their third meal as usual, and eat fruits and vegetables for snacks. For weeks 2 through 10 (Phase II), participants were instructed by a registered dietitian (RD) to reduce energy intake (−500 kcal/day) by providing participants with a list of common foods, serving sizes, and approximate energy intake value and encouraged them to reduce energy intake. In addition, participants continued to eat the SK breakfast as described above (SK Original or SK Red Berry Cereals, Kellogg Company), as well as SK cereal bars (Strawberry or Chocolate flavors, Kellogg Company) and fruits and vegetables as occasional snacks. This 10-week period was intended to promote weight loss. For the following 24 weeks (Phase III), participants were instructed to consume adequate calories to maintain weight and to continue consumption of the SK breakfast and cereal bars as needed to help accomplish this goal. Participants met with an RD at each testing session and at 2-week intervals during the study to discuss diet compliance.

Participants in the SDE group followed the Curves (Curves International, Waco, TX) diet program (45), which consisted of a 1-week structured diet plan (1,200 kcal/day) during Phase I, followed by a 9-week diet plan (1,600 kcal/day) during Phase II. For the following 24 weeks (Phase III), participants were instructed to follow a 2,100 kcal/day weight maintenance plan, with intermittent dieting (1,200 kcal/day) for 2 to 3 days if a participant gained 3 lb (1.36 kg) or more of body weight. All three diet phases in the SDE group consisted of ~45% carbohydrate, ~30% protein, and ~25% fat and included whole-grain RTE cereals (Curves Whole Grain Crunch, Curves Fruit & Nut Crunch, and Curves Honey Crunch cereals; General Mills, Inc, Minneapolis, MN) for breakfast at least four times per week and snack bars (Curves Strawberry & Cream and Curves Chocolate Peanut, General Mills, Inc) as occasional snacks at least three times per week. Participants were given diet plans and menus to follow at the start of the study. Participants met with an RD at each testing session and at 2-week intervals between testing sessions to discuss how to substitute meals and exchange foods to maintain compliance with dietary goals.

Exercise Intervention

Participants in the MRP group were encouraged to increase physical activity throughout the study to increase daily energy expenditure. This was accomplished by having an exercise physiologist explain a general exercise program and provide examples of the amount of energy expended while participating in 30 minutes of common exercise and recreational activities with individuals ranging from 150 lb (68 kg) to 300 lb (126 kg) as recommended by the SK Challenge program. Participants in the SDE program participated in a supervised Curves exercise program using the computerized CurvesSmart system (Curves International, Waco, TX) equipped with software designed by MYTRAK (version 4.2.0.0, copyright 2004-2011, MYTRAK Health System, Mississauga, Ontario, Canada) 3 days/week throughout the 34-week study (a total of 102 workouts). The circuit-style workouts consisted of 14 exercises (ie, elbow flexion/extension, knee flexion/extension, shoulder press/lat pull, hip abductor/adductor, chest press/seated row, horizontal leg press, squat, abdominal crunch/back extension, chest flies, oblique, shoulder shrug/dip, hip extension, side bends, and stepping) constructed with pneumatic or hydraulic resistance that targeted opposing muscle groups in a concentric-only fashion.

Participants were informed of proper use of all equipment and performed three repetition maximums on each machine before initiation of training to estimate one-repetition maximums (1RM). Participants were instructed to complete as many repetitions in a 30-second time period using proper form and to exert enough force to elicit a green light on the system indicating the participant exceeded 70% or 1RM goal for that repetition. This system automatically readjusts 1RM strength estimates based on the amount of force produced on each machine from workout to workout to promote training progression. In a continuous and interval fashion, participants performed floor-based low-impact callisthenic type exercises (eg, high knee walking in place, leg kicks, boxing moves, and arm circles) for a 30-second time period after each resistance exercise in an effort to maintain a consistent exercise heart rate that corresponded to 60% to 80% of their maximum heart rate (43). All workouts were supervised by trained fitness instructors who assisted with proper exercise technique and maintenance of adequate exercise intensity. Participants were required to complete two complete circuits which corresponded to exercising for approximately 28 minutes followed by a standardized whole-body stretching routine. Compliance to the exercise program was set a priori at a minimum of 80% compliance (82 out of 102 exercise sessions). Participants were also encouraged to walk briskly for 30 minutes on noncircuit training days.

ASSESSMENTS

Physical Activity

Physical activity patterns were quantified by assessing responses to the 7-day version of the International Physical Activity Questionnaire (IPAQ) (46-48) obtained at each testing session. This assessment tool evaluates the frequency and intensity of job-related physical activity; transportation physical activity; housework, house maintenance, and caring for family-related activities; and, recreation, sport, and leisure-time physical activity based on established metabolic equivalent (MET) levels for common activities. The IPAQ defines light physical activity as walking level intensities (3.3 METs), moderate physical activity as activities at a 4.0 MET level, and vigorous physical activity as activities at an 8.0 MET level. The IPAQ has been reported to provide a valid indicator of general changes in physical activity patterns (46-48).

Diet Assessment

Participants recorded all food and fluid intake for 4 days before each testing session. This included 3 weekdays and 1 weekend day. Dietary inventories were reviewed by an RD and subsequently analyzed for average energy and macronutrient intake using the ESHA Food Processor Nutritional Analysis software (version 8.6, 2006, ESHA Research Inc, Salem, OR). Diet quality was assessed by having the participants complete a self-reported 10-point Likert style inventory that assessed appetite, hunger, diet satisfaction, feeling of fullness, energy levels, and quality of the diet on a 0- (no agreement) to 10- (highest agreement) point scale.

Anthropometrics and Body Composition

Height and body mass were determined according to standard procedures using a Healthometer (Telstar LLC, Bridgeview, IL) self-calibrating digital scale with an accuracy of ± 0.02 kg. Waist circumference was measured using a Gulick tape measure using standard criteria (43). Intracellular, extracellular, and total body water was assessed using a Xitron 4200 Bioelectrical Impedance Analyzer (Xitron Technologies, Inc, San Diego, CA) to monitor hydration status among testing sessions. Bone density and body composition (excluding cranium) was assessed using a Hologic Discovery W (Hologic Inc, Waltham, MA) dual-energy x-ray absorptiometer equipped with APEX Software (APEX Corporation Software, Pittsburgh, PA). Mean coefficients of variation for bone mineral content and bone mineral density measurements performed on the spine phantom ranged between 0.41% and 0.55%. Test–retest reliability studies performed on male athletes with this dual energy x-ray absorptiometer machine have previously yielded mean coefficients of variation for total bone mineral content and total fat free/soft tissue mass of 0.31% to 0.45% with a mean intraclass correlation of 0.985 (49).

Resting Energy Expenditure

Resting energy expenditure assessments were made using a ParvoMedics TrueMax 2400 Metabolic Measurement System (ParvoMedics, Inc, Sandy, UT). This test was conducted in fasted state with the participants lying in the supine position on an exam table. A clear, hard plastic hood and soft, clear plastic drape was placed over the participants' neck and head to determine resting oxygen uptake and energy expenditure. All participants remained motionless without falling asleep for approximately 20 minutes. Data were recorded after the first 10 minutes of resting during a 5-minute period of time in which criterion variables (eg, oxygen uptake) changed <5% (50). Test–retest measurements on 14 participants from a study previously reported (17) revealed that test–retest correlations (*r*) of collected oxygen uptake ranged from 0.315 to 0.901 (mean 0.638) and coefficient of variation ranged from 8.2% to 12.0% (mean 9.9%) with a mean intraclass coefficient of 0.942; $P<0.001$.

Exercise Capacity

Resting heart rate was measured via palpation of the radial artery and resting blood pressure was determined using a mercury sphygomometer (American Diagnostic Corporation, Model AD-720, Hauppuage, NY) according to previously accepted procedures (43). Maximal graded cardiopulmonary exercise tests were performed using the Bruce treadmill protocol (51). Standard test termination criteria were monitored to assess maximal volitional fatigue (43). A Quinton 710 electrocardiograph (Quinton Inc, Bothell, WA) was used to assess heart function using a standard 12-lead arrangement (43). Expired gases were collected using a ParvoMedics TrueMax 2400 Metabolic Measurement System (ParvoMedics Inc, Sandy, UT). Calibration of gas and flow sensors was completed every morning before testing and was found to be within 3% of the previous calibration point.

Participants had their 1RM determined using an isotonic Olympic bench press (Nebula Fitness, Versailles, OH) and standard hip sled/leg press (Nebula Fitness) to determine changes in maximal strength. Muscular endurance was assessed by having participants perform as many repetitions as possible with 80% of their predetermined 1RM on the bench press and leg press using standard lifting techniques and testing criteria (52). Test-to-test reliability of performing these strength tests in our lab on resistance-trained participants have yielded low mean coefficients of variation and high reliability for the bench press (1.9%, intraclass $r=0.94$) and hip sled/leg press (0.7%, intraclass $r=0.91$).

Blood Collection and Analysis Procedures

Fasted whole blood and serum samples were collected using standard phlebotomy techniques. Whole blood samples were analyzed for complete blood counts with platelet differentials using an Abbott Cell Dyn 3500 (Abbott Laboratories, Abbott Park, IL) automated hematology analyzer. Serum samples were analyzed for a complete metabolic panel using a calibrated Dade Behring Dimension RXL (Siemans AG, Munich, Germany) automated clinical chemistry analyzer. Coefficient of variation for the tests using this analyzer was similar to previously published data for these tests (range 1.0% to 9.6 %) (53).

Due to relocation of the lab after completing data collection that resulted in some lost samples, serum fasting insulin levels were only obtained on a subset of 62 subjects completing the 10-week active weight loss phase of the study and 45 subjects completing the weight maintenance phase of the study at 0, 10, and 34 weeks. Fasting insulin was assayed in duplicate using a commercially available enzyme-linked immunoabsorbent assay kit (No. 80-INSHU-E10, ALPCO Diagnostics, Salem, NH) using a BioTek ELX-808 Utlramicroplate Reader (BioTek Instruments Inc, Winooski, VT) at an optical density of 450 nm against a known standard curve using standard enzyme-linked immunoabsorbent assay procedures with BioTek Gen5 Analysis Software (BioTek Instruments Inc, Winooski, VT). Intra-assay coefficient of variation ranged from 2.9% to 6.2%, whereas interassay coefficient of variation ranged from 5.4% to 8.6%. The homeostasis model assessment (HOMA) for estimating insulin sensitivity was calculated as the product of fasting glucose times fasting insulin expressed in conventional units divided by 405 (54).

Psychosocial Assessments

Participants completed the SF-36 Health-Related Quality of life (QOL) inventory (55) at each test session before performing exercise tests. The SF-36 QOL inventory assesses a number of physical and mental components, including physical functioning (ie, ability to perform most vigorous physical activities without limitation to health), role physical (ie, ability to work and perform daily activities), bodily pain (ie, limitations due to pain), general health (ie, assessment of personal health), vitality (ie, feelings of having energy), social functioning (ie, ability to perform normal social activities), role emotion (ie, problems with work or other daily activities), and mental health (state of feelings of peacefulness, happiness, and calm). This instrument has been shown to be a valid indicator of psychosocial dimensions that may be influenced by general improvements in health and/or weight loss.

STATISTICAL METHODS

Baseline demographic data were analyzed by one-way analysis of variance (ANOVA). Data were normally distributed and did not require any transformation before statistical analysis. Only participants completing the 10-week weight loss phase and 24-week weight maintenance phase were included in the analyses. Missing data, if any, were replaced using the last observed value method. Related variables were grouped together and analyzed by multivariate ANOVA with repeated measures (PASW Statistics, version 18.0.2, 2010, SPSS Inc, Chicago, IL). Noncorrelated variables were analyzed by repeated measures ANOVA. Delta values were calculated and analyzed on select variables by ANOVA for repeated measures to assess changes from baseline values. Data were considered statistically significant when the probability of type I error was 0.05 or less. In some instances, quadratic interaction *P* levels are reported indicating that nonlinear but significant differences were observed between groups over time. Tukey's least significant difference post hoc analyses were performed when a significant time or group×time interaction was observed to determine where significance was obtained. Power analysis of previous studies using a similar design and subject population indicated that a sample size of 30 subjects per group yielded high power (>0.8) for delta values of 0.75 to 1.25 for weight and fat loss.

Table 1. Changes in nutritional intake and physical activity patterns after 10 weeks of dieting and/or training in the meal-replacement (MRP) supervised diet and exercise program (SDE) groups[a]

Variable	Group	Week 0	Week 10	*P* value
		←—— mean±standard deviation ——→		
Energy intake (kcal/d)	MRP	1,689±473	1,404±399[b]	G[d]=0.73
	SDE	1,702±466	1,339±331[b]	T[e]=0.001
				I[f]=0.52
Carbohydrate intake (g/d)	MRP	205±54	170±53[b]	G=0.80
	SDE	198±64	171±47	T=0.001
				I=0.51
Protein intake (g/d)	MRP	66±21	66±17	G=0.05
	SDE	71±23	77±27[c]	T=0.31
				I=0.05
Fat intake (g/d)	MRP	66±27	52±21[b]	G=0.50
	SDE	71±26	41±14[b]	T=0.001
				I=0.02
Light PA[g] (min/wk)	MRP	170±310	180±299	G=0.13
	SDE	124±180	101±137	T=0.83
				I=0.60
Moderate PA (min/wk)	MRP	88±248	160±242	G=0.80
	SDE	64±88	199±175[b]	T=0.001
				I=0.26
Vigorous PA (min/wk)	MRP	2±10	17±52	G=0.001
	SDE	9±37	92±101[bc]	T=0.001
				I=0.001
Light PA (sessions/wk)	MRP	2.8±3.0	3.1±3.5	G=0.13
	SDE	2.2±2.2	2.2±2.7	T=0.74
				I=0.70
Moderate PA (sessions/wk)	MRP	1.1±1.7	2.6±3.1[b]	G=0.001
	SDE	1.6±2.1	4.9±3.9[bc]	T=0.001
				I=0.04
Vigorous PA (sessions/wk)	MRP	0.1±0.3	0.5±1.4	G=0.001
	SDE	0.2±1.1	2.9±3.1[bc]	T=0.001
				I=0.001
Light PA (min/session)	MRP	52±70	47±60	G=0.22
	SDE	44±48	41±53	T=0.10
				I=0.82
Moderate PA (min/session)	MRP	25±49	42±54[b]	G=0.52
	SDE	24±39	33±28	T=0.01
				I=0.40
Vigorous PA (min/session)	MRP	1.4±6	5.8±16	G=0.005
	SDE	4.3±19	17.7±16[bc]	T=0.001
				I=0.03

[a]Complete food intake records were obtained on 37 participants in the MRP group and 38 participants in the SDE group (n=75) and analyzed using ESHA Food Processor Nutritional Analysis Software (version 8.6, 2006, ESHA Research Inc, Salem, OR). Physical activity (PA) data were analyzed on all participants completing the 10-wk weight loss phase of the study group (n=90).
[b]$P<0.05$ difference from baseline.
[c]$P<0.05$ difference between MRP and SDE groups.
[d]G=group alpha level.
[e]T=time alpha level.
[f]I=group×time interaction alpha level.
[g]PA=physical activity.

RESULTS

Weight Loss Phase

Ninety apparently healthy but sedentary and obese women (age 41.4±11 years, height 163±7 cm; weight 89±13 kg; BMI 33.5±4.5, 44.3±4 % fat, 22.1±4 mL/kg/min peak oxygen uptake, 6.3±1.2 peak METs) completed the 10-week weight loss phase of the study (n=45 in each group). No significant differences were observed between groups in baseline age, height, weight, BMI, or percent body fat. Table 1 presents changes in energy intake and physical activity patterns. Complete food records were obtained on 75 of the 90 participants completing the weight loss phase of the study. Energy and fat intake decreased significantly over time with no significant dif-

Table 2. Changes in body composition, resting energy expenditure, and fitness related data observed after 10 weeks of dieting and/or training in the meal-replacement program (MRP) and supervised diet and exercise program (SDE) groups[a]

Variable	Group	Week 0	Week 10	*P* value
		←—— *mean±standard deviation*	——→	
Weight (kg)	MRP	89.3±14	87.6±14[b]	G[d]=0.76
	SDE	89.2±12	86.1±11[bc]	T[e]=0.001
				I[f]=0.03
Fat mass (kg)	MRP	37.3±8	36.4±8[b]	G=0.47
	SDE	36.8±8	34.5±7[bc]	T=0.001
				I=0.02
Lean tissue mass (kg)	MRP	43.8±7	43.2±6[b]	G=0.82
	SDE	44.2±6	43.3±6[b]	T=0.002
				I=0.60
Body fat (%)	MRP	44.8±4	44.5±4	G=0.24
	SDE	44.1±4	43.1±5[bc]	T=0.005
				I=0.10
Body mass index	MRP	34.1±5	33.5±5[b]	G=0.19
	SDE	33.1±4	32.0±4[bc]	T=0.001
				I=0.03
Waist (cm)	MRP	97.0±11	96.4±10	G=0.007
	SDE	92.7±10	89.8±9[bc]	T=0.004
				I=0.05
Hip (cm)	MRP	118.0±9	117.9±10	G=0.23
	SDE	118.1±10	113.4±11[bc]	T=0.001
				I=0.002
Resting energy expenditure (kcal/d)	MRP	1,683±276	1,517±233[b]	G=0.93
	SDE	1,682±264	1,532±215[b]	T=0.001
				I=0.75
Peak oxygen uptake (mL/kg/min)	MRP	22.6±4	22.1±5	G=0.59
	SDE	21.9±4	23.7±5[bc]	T=0.06
				I=0.001
Bench press 1 repetition maximum (kg)	MRP	31.3±8	32.7±8[b]	G=0.64
	SDE	29.9±8[c]	32.6±8[b]	T=0.001
				I=0.17
Leg press 1 repetition maximum (kg)	MRP	182±58	194±59[b]	G=0.36
	SDE	166±52[c]	187±63[bc]	T=0.001
				I=0.10

[a]Data are from on 45 participants in the MRP group and 45 participants in the SDE group (n=90) who completed the 10-wk weight loss portion of the study.
[b]$P<0.05$ difference from baseline.
[c]$P<0.05$ difference between MRP and SDE groups.
[d]G=group alpha level.
[e]T=time alpha level.
[f]I=group×time interaction alpha level.

ferences observed between groups. Protein intake was significantly higher in the SDE group. Assessment of diet quality inventories revealed that participants in the SDE group reported a trend toward perceptions of more energy ($P=0.07$) compared to subjects in the MRP group. However, no significant interactions were observed between groups in appetite ($P=0.56$), hunger ($P=0.84$), fullness ($P=0.89$), diet satisfaction ($P=0.58$), or diet quality ($P=0.12$). Analysis of physical activity patterns revealed that the amount of time engaged in vigorous physical activity and number of sessions per week of moderate and vigorous physical activity was greater in the SDE group compared to the MRP group.

Table 2 shows body composition, resting energy expenditure, and fitness related data observed after 10 weeks of dieting and/or training. No significant time or group×time effects were observed in intracellular water, extracellular water, or total body water. Both groups lost weight and fat mass. However, the SDE group lost significantly more weight (−3.1±3.7 vs −1.6±2.5 kg; $P=0.03$), fat mass (−2.3±3.5 vs −0.9±1.6 kg; $P=0.02$), and centimeters from the hips (−4.6±7 vs −0.2±6 cm; $P=0.002$), and waist (−2.9±6 vs −0.6±5 cm; $P=0.05$) than participants in the MRP group. REE levels significantly decreased by 153±236 kcal/day ($P=0.001$) in both groups with no significant differences observed between groups. Participants in the SDE group experienced a significantly greater increase in peak aerobic capacity ($P=0.001$) and tended to increase leg press 1RM strength to a greater degree ($P=0.10$). Changes in upper and lower body lifting volume were similar between groups.

Table 3 presents fasting blood lipid, glucose, and insu-

Table 3. Fasting blood lipid, glucose, and insulin values obtained at 0 and 10 weeks of dieting and/or training for the meal-replacement program (MRP) and supervised diet and exercise program (SDE) groups[a]

Variable	Group	Week 0	Week 10	*P* value
		⟵ *mean± standard deviation* ⟶		
Total cholesterol (mg/dL)[b]	MRP	194±33	194±29	G[c]=0.34
	SDE	197±32	203±41	T[d]=0.29
				I[e]=0.27
Low-density lipoprotein cholesterol (mg/dL)[b]	MRP	125±29	123±27	G=0.84
	SDE	124±29	127±37	T=0.73
				I=0.44
High-density lipoprotein cholesterol (mg/dL)[b]	MRP	50±13	47±10[f]	G=0.03
	SDE	54±13	53±11[g]	T=0.004
				I=0.51
Triglycerides (mg/dL)[h]	MRP	137±62	138±61	G=0.17
	SDE	117±60	124±72	T=0.51
				I=0.52
Glucose (mg/dL)[i]	MRP	99±11	106±9[f]	G=0.63
	SDE	100±13	107±14[f]	T=0.001
				I=0.98
Insulin (μIU/mL)[j]	MRP	13.8±13	15.8±20	G=0.87
	SDE	15.5±19	15.2±17	T=0.76
				I=0.69
Glucose/insulin ratio	MRP	13.5±10	12.8±10	G=0.63
	SDE	12.9±9	15.6±12	T=0.36
				I=0.15
Homeostatic model assessment	MRP	3.4±3.2	4.2±5.4	G=0.75
	SDE	3.9±5.0	4.2±5.2	T=0.51
				I=0.76

[a]Lipid and glucose data were obtained on 45 participants in the MRP group and 45 participants in the SDE group (n=90) completing the 10-wk weight loss program. Insulin levels were analyzed at 0 and 10 wks from 28 participants in the MRP group and 34 participants in the SDE group (n=62).
[b]To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.6. Cholesterol of 194 mg/dL=5.04 mmol/L.
[c]G=group alpha level.
[d]T=time alpha level.
[e]I=group×time interaction alpha level.
[f]*P*<0.05 difference from baseline.
[g]*P*<0.05 difference between MRP and SDE groups.
[h]To convert mg/dL triglyceride to mmol/L, multiply mg/dL by 0.0113. To convert mmol/L triglyceride to mg/dL, multiply mmol/L by 88.6. Triglyceride of 137 mg/dL=1.55 mmol/L.
[i]To convert mg/dL gluocose to mmol/L, multiply mg/dL by 0.0555. To convert mmol/L glucose to mg/dL, multiply mmol/L by 18.0. Glucose of 99 mg/dL=5.5 mmol/L.
[j]To convert μIU/mL insulin to pmol/L, multiply μIU/mL by 6.945. To convert pmol/L insulin to μIU/mL, multiply pmol/L by 0.144. Insulin of 13.8 μIU/mL=95.8 pmol/L.

lin levels observed at zero and 10 weeks of training. Training and diet had no effects on total cholesterol, low-density lipoprotein cholesterol, triglycerides, insulin, glucose to insulin ratio, or insulin sensitivity estimated using the HOMA method. Fasting glucose levels increased by 7 mg/dL in both groups after 10 weeks. High-density lipoprotein cholesterol levels were significantly higher in the SDE group than the MRP group. In terms of psychosocial measures, significant time effects were seen in physical function (P=0.02), vitality (P=0.01), and mental health (P=0.001) with no differences observed between groups. Ten weeks of training and dieting had no significant effects on role physical, bodily pain, general health, social functioning, or role emotion.

Weight Maintenance Phase

Seventy-seven women (age 42.6±10 years; height 163±6 cm; weight 89±14 kg, BMI 33.5±5, 44.1±4 % fat, 22.0±4 mL/kg/min peak oxygen uptake, 6.3±1.2 peak METs) completed the 10-week weight loss and 24-week weight maintenance phases. Subject demographics were similar among the women completing the weight loss phase (n=90) and the weight loss and weight maintenance phases (n=77). One-way ANOVA revealed no significant differences between groups in baseline measures. Table 4 presents nutritional intake and physical activity pattern data. Complete food records were obtained on 59 of the 77 participants completing the weight loss and weight maintenance phases of the study. Dieting significantly decreased total energy intake (P=0.001) and fat intake (P=0.001) in both groups over time. However, no significant interactions were observed between groups in total energy intake (P=0.17), carbohydrate intake (P=0.45), or fat intake (P=0.42). Mean protein intake was about 13 g/day (16%) higher in the SDE group (P=0.008) and tended to differ between groups (P=0.07). Analysis of diet satisfaction inventories revealed that participants in the SDE group reported significantly more energy (P=0.05).

Table 4. Changes in nutritional intake and physical activity (PA) patterns observed at 0, 10, 14, 22, and 34 weeks of dieting and/or training for the meal-replacement program (MRP) and supervised diet and exercise program (SDE) groups[a]

		Week					
Variable	**Group**	**0**	**10**	**14**	**22**	**34**	***P* value**
		←— *mean± standard deviation* —→					
Energy intake (kcal/d)	MRP	1,719±472	1,447±424[b]	1,312±398[b]	1,242±368[b]	1,367±390[b]	G[c]=0.85
	SDE	1,627±492	1,308±318[b]	1,376±363[b]	1,316±335[b]	1,388±353[b]	T[d]=0.001
							I[e]=0.17
Carbohydrate intake (g/d)	MRP	205±55	177±56	171±52[b]	167±62[b]	181±64	G=0.55
	SDE	187±66	167±45	172±57	165±51	176±61	T=0.08
							I=0.45
Protein intake (g/d)	MRP	67±22	67±18	59±15	55±17[b]	61±18	G=0.008
	SDE	70±23	79±28[f]	77±29[f]	72±23[f]	76±28[f]	T=0.30
							I=0.07
Fat intake (g/d)	MRP	68±28	53±23[b]	45±22[b]	40±18[b]	46±19[b]	G=0.54
	SDE	68±29	41±13[b]	45±11[b]	43±12[b]	45±13[b]	T=0.001
							I=0.42
Light PA (min/wk)	MRP	161±323	151±260	335±567[b]	205±307	225±471	G=0.002
	SDE	125±178	94±138	80±136[f]	70±142[f]	71±135[f]	T=0.73
							I=0.04
Moderate PA (min/wk)	MRP	93±270	179±266	182±187	177±207	116±227	G=0.04
	SDE	58±86	214±173[b]	264±203[b]	310±330[bf]	262±212[bf]	T=0.001
							I=0.004
Vigorous PA (min/wk)	MRP	3±12	20±58	25±66	25±80	37±123	G=0.004
	SDE	10±38	95±100[bf]	130±275[bf]	115±238[bf]	72±123[b]	T=0.008
							I_q=0.02
Light PA (sessions/wk)	MRP	2.6±2.7	2.6±3.1	3.0±3.3	2.2±2.7	2.6±3.6	G=0.09
	SDE	2.2±2.1	1.8±2.4	1.6±2.4	1.3±2.2	2.2±3.0	T=0.64
							I_q=0.15
Moderate PA (sessions/wk)	MRP	1.1±1.4	2.7±3.3[b]	4.0±3.7[b]	3.6±3.59[b]	2.7±3.8[b]	G=0.001
	SDE	1.4±1.8	5.4±3.8[bf]	6.2±4.6[bf]	6.6±4.1[bf]	6.2±4.5[bf]	T=0.001
							I=0.007
Vigorous PA (sessions/wk)	MRP	0.1±0.4	0.6±1.6	0.3±0.8	0.5±1.7	1.1±2.2[b]	G=0.004
	SDE	0.3±1.1	3.0±3.1[bf]	2.3±2.9[bf]	2.1±2.8[bf]	1.7±2.7[bf]	T=0.004
							I_q=0.001
Light PA (min/session)	MRP	49±71	40±53	80±150[bf]	47±60	55±108[f]	G=0.003
	SDE	45±50	29±37	24±37	20±32	19±26	T=0.48
							I=0.04
Moderate PA (min/session)	MRP	29±54	48±58[b]	39±37	32±41	20±26	G=0.64
	SDE	24±40	35±28	38±25	42±29[b]	43±42[bf]	T=0.65
							I=0.003
Vigorous PA (min/session)	MRP	1.8±7	5.6±15	17.7±56[b]	13.6±53	8.5±19	G=0.11
	SDE	4.9±20	18.2±16	23.4±35[b]	27.2±56[b]	17.9±34	T=0.03
							I=0.59

[a]Complete nutritional intake records were obtained on 31 participants in the MRP group and 28 participants in the SDE group (n=59) and analyzed using ESHA Food Processor Nutritional Analysis Software (version 8.6, 2006, ESHA Research Inc, Salem, OR). PA questionnaires were obtained on 40 participants in the MRP group and 33 participants in the SDE group (n=73) completing the 34-wk study.

[b]$P<0.05$ difference from baseline.

[c]G=group alpha level.

[d]T=time alpha level.

[e]I=group×time interaction alpha level; q=quadritic alpha level.

[f]$P<0.05$ difference between MRP and SDE groups.

Table 5. Changes in body composition, anthropometric measurements, and resting energy expenditure data obtained at 0, 10, 14, 22, and 34 weeks for the meal-replacement program (MRP) and supervised diet and exercise program (SDE) groups[a]

Variable	Group	Week 0	Week 10	Week 14	Week 22	Week 34	*P* value
		←mean±standard deviation→					
Body mass (kg)	MRP	89.1±15	87.5±14[b]	87.3±14[b]	86.8±14[b]	86.9±14[b]	G[d]=0.45
	SDE	88.1±12	84.8±12[bc]	84.2±12[bc]	84.1±12[bc]	85.0±13[bc]	T[e]=0.001
							I_q^f=0.001
Fat mass (kg)	MRP	37.6±8	36.6±8[b]	36.5±8[b]	36.2±8[b]	36.1±9[b]	G=0.17
	SDE	36.2±8	33.8±8[bc]	33.6±7[bc]	33.3±8[bc]	33.6±8[bc]	T=0.001
							I_q=0.01
Lean tissue mass (kg)	MRP	43.3±7	42.9±6	42.0±7	42.6±6	43.2±7	G=0.96
	SDE	43.7±5	42.9±6	42.3±5	42.4±6	43.0±6	T=0.19
							I[g]=0.53
Body fat (%)	MRP	45.2±4	44.7±4	45.3±4	44.6±4	44.2±5[b]	G=0.05
	SDE	43.9±5[c]	42.7±5[bc]	42.8±5[bc]	42.5±5[bc]	42.5±5[bc]	T=0.005
							I=0.10
Body mass index	MRP	34.0±5	33.4±5[b]	33.3±5[b]	33.1±5[b]	33.1±5[b]	G=0.20
	SDE	33.1±5	31.9±4[bc]	31.6±4[bc]	31.6±5[bc]	32.0±5[bc]	T=0.001
							I_q=0.001
Waist (cm)	MRP	97±11	96±10[b]	95±10[b]	93±10[b]	94±10[b]	G=0.05
	SDE	93±11[c]	90±10[bc]	90±10[bc]	90±9[bc]	91±10[bc]	T=0.001
							I=0.07
Hip (cm)	MRP	118±10	118±11	117±11[b]	115±11[b]	116±10[b]	G=0.37
	SDE	118±11	114±10[bc]	113±10[bc]	114±10[bc]	116±10[b]	T=0.007
							I_q=0.001
Resting energy expenditure (kcal/d)	MRP	1,672±282	1,507±221[b]	1,549±248[b]	1,515±228[b]	1,499±244[b]	G=0.93
	SDE	1,684±248	1,538±227[b]	1,522±267[b]	1,481±238[b]	1,496±215[b]	T=0.001
							I=0.39

[a]Data are on 40 participants in the MRP group and 37 participants in the SDE group (n=77) completing the 10-wk weight loss and 24-wk weight maintenance program.
[b]*P*<0.05 difference from baseline.
[c]*P*<0.05 difference between MRP and SDE groups.
[d]G=group alpha level.
[e]T=time alpha level.
[f]I_q=quadratic alpha level.
[g]I=group×time interaction alpha level.

However, no significant interactions were observed between groups in appetite (P=0.29), hunger (P=0.34), fullness (P=0.58), diet satisfaction (P=0.57), or diet quality (P=0.97). Significant interactions were observed in the number of sessions per week, amount of time per week engaged in moderate and vigorous physical activity, and minutes per session of light and moderate physical activity. Participants in the SDE group averaged 127±40 minutes/week less of light physical activity (P=0.002) while averaging 72±33 minutes/week more of moderate physical activity (P=0.04) and 62±21 minutes/week more of vigorous physical activity (P=0.004) throughout the study compared to participants in the MRP group.

Table 5 presents body composition, anthropometric, and REE data for participants who completed the 34-week weight loss and weight maintenance portions of the study. No significant time or group×time effects were observed in intracellular water, extracellular water, or total body water. After 10, 14, 22, and 34 weeks of dieting and training, respectively, participants in the SDE group lost significantly more weight (SDE −3.3±4.0, −4.0±4.6, −4.1±5.3, −3.1±6.0; MRP −1.6±2.6, −1.8±3.1, −2.3±4.5, −2.2±6.3 kg, P=0.001); fat mass (SDE −2.4±3.7, −2.7±3.2, −2.9±4.1, −2.6±3.6; MRP −1.0±1.6, −1.1±2.6, −1.4±3.7, −1.5±4.8 kg, P=0.01); and centimeters from the hips (SDE −3.8±6, −4.5±6, −3.9±6, −1.9±5; MRP −0.2±6, −0.9±6, −2.6±7, −1.6±7 cm, P=0.001) than those in the MRP group. BMI was also decreased to a greater degree in the SDE group. Mean REE significantly decreased in both groups over time (−180±222 kcal/day). However, no significant differences (P=0.39) were observed between groups in REE values throughout the study.

Table 6 presents general health and exercise capacity data for the MRP and SDE groups. No significant interactions were observed between groups in resting heart rate or diastolic blood pressure although there was some evidence that systolic blood pressure was differentially affected between groups. Participants in the SDE group observed significantly greater improvements in peak aerobic capacity (P=0.001) as well as upper (P=0.006) and lower body (P=0.02) 1RM strength. No significant differences were observed between groups in upper or lower extremity muscular endurance.

Table 6. Changes in general health and fitness obtained at 0, 10, 14, 22, and 34 weeks of dieting and/or training for the meal-replacement program (MRP) and supervised diet and exercise program (SDE) groups[a]

Variable	Group	Week 0	Week 10	Week 14	Week 22	Week 34	*P* value
		←——— *mean±standard deviation* ———→					
Resting heart rate (bpm)	MRP	73±11	70±11	68±10	66±10	68±11	G[b]=0.13
	SDE	69±9	66±9	66±9	67±11	65±9	T[c]=0.001
							I[d]=0.28
Resting systolic blood pressure (mm Hg)	MRP	121±12	117±15	120±14	120±15	120±13	G=0.59
	SDE	122±14	124±19[f]	120±15	122±22	117±14[e]	T=0.16
							I=0.07
Resting diastolic blood pressure (mm Hg)	MRP	78±11	77±10	76±8	76±7	74±8	G=0.67
	SDE	77±11	78±11	74±10	74±12	76±9	T=0.01
							I=0.57
Peak oxygen uptake (mL/kg/min)	MRP	22.5±4	22.0±4	22.1±5	21.9±4	22.0±5	G=0.30
	SDE	21.8±4	23.8±5[ef]	23.7±6[ef]	23.4±5[ef]	23.1±5[ef]	T=0.65
							I_q^g=0.001
Bench press 1 repetition maximum (kg)	MRP	30.9±7	32.3±8	32.3±8	31.5±8	31.4±7	G=0.45
	SDE	30.4±9	33.1±8[e]	33.6±9[e]	34.0±8[ef]	33.8±8[ef]	T=0.005
							I=0.006
Leg press 1 repetition maximum (kg)	MRP	181±56	192±55	193±54[e]	198±54[e]	195±56[e]	G=0.89
	SDE	168±53[f]	185±64[e]	190±65[e]	204±75[e]	199±65[e]	T=0.001
							I=0.02

[a]Data are on 40 participants in the MRP group and 37 participants in the SDE group (n=77) completing the 10-wk weight loss and 24-wk weight maintenance program.
[b]G=group alpha level.
[c]T=time alpha level.
[d]I=group×time interaction alpha level.
[e]$P<0.05$ difference from baseline.
[f]$P<0.05$ difference between MRP and SDE groups.
[g]$_q$=quadratic alpha level.

Table 7 shows fasting blood lipid levels, glucose, and insulin-related variables. No significant interactions were observed between groups in total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, blood glucose, insulin, the glucose to insulin ratio, or HOMA. However, as seen in the weight loss phase of the study, fasting glucose levels were slightly increased by 5 and 8 mg/dL in the MRP and SDR groups, respectively, after 10 weeks of weight loss. These values remained elevated in the MRP group throughout the maintenance phase, whereas values returned toward baseline in the SDE group. The glucose/insulin ratio and HOMA values were not affected over time though. Triglyceride levels in the MRP group were significantly higher than the SDE group. All hematological values analyzed were within normal clinical ranges. No significant differences were observed among groups on measures of physical function, role physical, bodily pain, general health, vitality, social function, role emotion, or mental health between groups. However, physical function (P=0.06) and vitality (P=0.09) levels tended to increase to a greater degree in the SDE group.

DISCUSSION

One of the challenges in promoting weight loss and preventing weight regain is the difficulty in adhering to diet, exercise, and/or behavioral interventions over time. Although individuals can typically follow a strict diet or exercise program in the short term, research has shown that it is difficult to maintain weight loss unless the diet and/or exercise intervention can be incorporated into the individual's lifestyle. Consequently, there has been interest in identifying dietary, exercise, and/or behavioral interventions that are easy to implement and incorporate into lifestyle behaviors (41,56). One recommended approach has been to use RTE meals, cereals, and/or bars as a way to replace meals to help reduce total daily energy intake and promote weight loss (23,24,26-28,57,58).

Several studies have reported that replacing meals with portion-controlled RTE foods is an effective way to promote weight loss. For example, Mattes and colleagues (23) reported that use of RTE cereals resulted in an approximately 600 kcal/day reduction in energy intake which promoted a 1.4 to 1.8 kg (3 to 4 lb) reduction in weight during a 6-week intervention compared to controls who had no dietary intervention. Wal and associates (24) found that use of a cereals and nutrition bars as meal replacements during a 4-week weight loss program promoted significantly greater weight loss (about 2.3 to 2.7 kg or 5 to 6 lb) than participants in a control group following their normal dietary practices. Similarly, Konig and associates (58) found that subjects who replaced two meals per day with a low-energy ready-to-drink supple-

Table 7. Fasting blood lipid, glucose, and insulin values obtained at 0, 10, 14, 22, and 34 weeks of dieting and/or training for the meal-replacement program (MRP) and supervised diet and exercise program (SDE) groups[a]

Variable	Group	Week 0	Week 10	Week 14	Week 22	Week 34	*P* value
		←——— *mean±standard deviation* ———→					
Total cholesterol (mg/dL)[b]	MRP	191±33	192±31	196±35	197±34	192±29	G[c]=0.22
	SDE	201±32	208±40	203±32	202±33	196±33	T[d]=0.67
							I[e]=0.11
Low-density lipoprotein cholesterol (mg/dL)[b]	MRP	121±29	120±29	121±28	121±28	114±24[f]	G=0.34
	SDE	126±28	130±37[g]	128±33[g]	124±31	118±31[f]	T=0.004
							I=0.48
High-density liproptein cholesterol (mg/dL)[b]	MRP	51±14	48±11[f]	48±11	49±12	52±12	G=0.08
	SDE	55±14[g]	53±11[g]	54±11[g]	54±12[g]	55±13[g]	T=0.30
							I=0.27
Triglycerides (mg/dL)[h]	MRP	133±65	138±64	147±98	149±90	141±77	G=0.05
	SDE	117±56	122±65	114±49[g]	102±45[g]	119±59[g]	T=0.65
							I=0.12
Glucose (mg/dL)[i]	MRP	99±12	104±13[f]	106±12[f]	106±13[f]	103±15[f]	G=0.40
	SDE	97±13	105±12[f]	104±13[f]	101±11[fg]	100±13	T=0.04
							I=0.16
Insulin (μIU/mL)[j]	MRP	11.9±12	15.3±21	—	—	16.2±14	G=0.91
	SDE	15.5±19	13.2±13	—	—	13.7±11	T=0.63
							I=0.24
Glucose/insulin ratio	MRP	14.5±9	13.3±9	—	—	11.1±8	G=0.80
	SDE	11.9±8	15.5±12	—	—	13.3±10	T=0.49
							I=0.10
H homeostatic model assessment	MRP	3.0±2.8	4.1±5.9	—	—	4.4±4.1	G=0.84
	SDE	3.9±5.0	3.5±3.5	—	—	3.6±2.9	T=0.46
							I=0.22

[a]Lipid and glucose data were obtained on 40 participants in the MRP group and 37 participants in the SDE group (n=77) completing the 10-wk weight loss and 24-wk weight maintenance program. Insulin levels were analyzed at 0, 10, and 34 wk from from 23 participants in the MRP group and 22 participants in the SDE group (n=45).
[b]To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.6. Cholesterol of 194 mg/dL=5.04 mmol/L.
[c]G=group alpha level.
[d]T=time alpha level.
[e]I=group×time interaction alpha level.
[f]$P<0.05$ difference from baseline.
[g]$P<0.05$ difference between MRP and SDE groups.
[h]To convert mg/dL triglyceride to mmol/L, multiply mg/dL by 0.0113. To convert mmol/L triglyceride to mg/dL, multiply mmol/L by 88.6. Triglyceride of 137 mg/dL=1.55 mmol/L.
[i]To convert mg/dL gluocose to mmol/L, multiply mg/dL by 0.0555. To convert mmol/L glucose to mg/dL, multiply mmol/L by 18.0. Glucose of 99 mg/dL=5.5 mmol/L.
[j]To convert μIU/mL insulin to pmol/L, multiply μIU/mL by 6.945. To convert pmol/L insulin to μIU/mL, multiply pmol/L by 0.144. Insulin of 13.8 μIU/mL=95.8 pmol/L.

ment for 6 weeks lost more weight than individuals who were counseled to follow a fat-restricted diet. Cheskin and colleagues (59) reported that individuals who followed a diet that used portion-controlled meal replacements for 34 weeks observed greater weight loss (3.7 kg) and less weight regain after 1 year of maintenance than individuals following a standard, self-selected, food-based diet. In another study, Wadden and colleagues (25) reported that consumption of meal replacements during a weight loss program lasting 1 year was one of the primary factors that correlated with weight loss success in a large cohort of men and women with type 2 diabetes. Finally, Rock and colleagues (28) recently reported that provision of free prepared meals and incentives promoted greater weight loss and maintenance (6.2 to 7.4 kg) after 2 years compared to usual care (2 kg). In addition, participants monitored via telephone counseling observed similar results to those involved in a one-on-one center-based counseling.

In our study, RTE cereals and bars were used in the MRP group as a primary means of promoting weight loss and maintenance. Participants were also instructed on how to reduce energy intake and increase physical activity as well has had access to Internet support to encourage adherence and weight loss. Results revealed that this approach was effective in reducing energy intake by approximately 300 to 450 kcal/day throughout the study. In addition, the MRP diet intervention was as effective in reducing total daily energy and fat intake as providing a structured diet and meal plan. The reduction in energy intake contributed to a 1.6 kg (3.5 lb) loss in body weight and a 1.0 kg (2.2 lb) loss in fat mass during the 10-week active weight loss phase. During the 24-week weight maintenance phase, participants in the MRP group continued to lose weight with a peak weight loss of 2.3 kg (5 lb) and 1.5 kg (3.3 lb) loss in fat mass. This amounted to a 2.4% decrease in body mass during the course of the study. These findings support prior reports that an MRP-based diet intervention can reduce energy intake and promote and/or maintain weight loss (23,24,26,27,58,59).

One of the major differences observed between diet, exercise, and behavioral intervention approaches investigated in this study was in physical activity patterns. Although provision of exercise recommendations and encouragement to increase physical activity resulted in an increase in light physical activity levels in the MRP group, participants in the SDE group engaged in more than an hour per week more of moderate and vigorous physical activity throughout the study. The increase in physical activity levels observed appears to be the primary reason that participants in the SDE group experienced nearly twice the amount of weight loss (3.1 vs 1.6 kg [6.8 vs 3.5 lb]) and fat mass loss (2.2 vs 1.0 kg [4.8 vs 2.2 lb]) during the 10-week active weight loss phase. This diet and exercise strategy was also effective in helping participants continue to lose up to 4.1 kg (9.0 lb) of weight and 2.9 kg (6.4 lb) of fat during the weight maintenance phase of the study. Although this amount of weight loss seems modest, participants in the SDE group lost up to 4.5% of their body weight during the course of the study. These findings suggest that adherence to a meal-plan–based diet and supervised exercise program is more effective in promoting and maintaining weight loss and increases in physical activity than a meal replacement diet approach that provides education and encouragement about increasing physical activity.

Our findings support prior reports indicating that engagement in regular physical activity is a major contributor to success of promoting and maintaining weight loss (13,25,60). For example, Wadden and colleagues (60) reported that participants who lost weight and maintained a regular exercise program in the months preceding a 1-year follow-up assessment were able to maintain weight loss more effectively than those who did not engage in regular exercise. Miller and colleagues (13) found that individuals involved in a self-selected exercise and diet program who regularly participated in exercise observed greater weight loss compared to more sedentary counterparts. In addition, Wadden and colleagues (25) found that greater self-reported physical activity was the strongest predictor of success in following a weight loss program.

Results also indicate that participants in the SDE group experienced greater gains in markers of fitness, health, and markers of QOL compared to those in the MPR group. In this regard, participants in the SDE experienced a greater reduction in BMI following the 10-week active weight loss period and were able to maintain a lower BMI throughout the weight maintenance phase. In addition, subjects in the SDE group experienced a 6% to 9% increase in peak aerobic capacity during the study compared to 2% reduction in the MRP group. Participants in the SDE group also experienced significantly greater gains in upper body maximal strength (9% to 12% vs 1% to 4%) and lower body maximal strength (12% to 22% vs 6% to 9%). Moreover, fasting triglyceride levels decreased by as much as 12% in the SDE group while increasing up to 12% in the MRP group. There was also evidence that participants in the SDE group experienced greater energy levels while physical function and vitality scores tended to be improved to a greater degree in the SDE group. Interestingly, both groups experienced a modest increase in fasting glucose levels throughout the course of the study with no differences observed among groups. The etiology of these changes is unclear but could be related to changes in diet and/or normal variation in assays. Nevertheless, no differences were observed in the fasting insulin, the glucose to insulin ratio, or HOMA, suggesting there was no apparent negative metabolic influence of the observed changes.

Because participants in the SDE group engaged in a greater amount of moderate and vigorous activity as well as performed resistance-training exercise, these findings were expected. Interestingly though, the type of circuit resistance-training used in our study did not preserve fat free mass, maintain REE, or influence insulin levels as has been previously reported (61-64). Nevertheless, present results support previous findings that participating in a supervised exercise program can improve markers of health and fitness (17,36,63,64). In addition, that participation in a supervised exercise program can promote greater gains in fitness than being educated about exercise training and encouraged to increase levels of physical activity.

Although both programs were beneficial in promoting and maintaining weight loss in our study, there are several limitations in conducting weight loss clinical trials that should be discussed when interpreting results. First, participants who volunteer to participate in weight loss trials are typically more motivated to adhere to a weight loss program than the general population because they want to lose weight and receive the benefits of participating in a free program. The programs studied may not be as effective in populations who are not as motivated to lose weight. Second, both of the programs studied would have costs associated for individuals to participate (ie, to purchase food and/or pay members fees) and, therefore, may be limited to populations that can afford to participate in these types of programs. Third, incentives were used to promote participant compliance to the study protocol. This helped achieve an 87% and 75% compliance rate for the 10-week weight loss and 24-week weight maintenance portions of the study, respectively. Although these are reasonable compliance rates for a long-term weight loss trials that involve multiple testing sessions and adherence to an exercise program (SDE group) in sedentary and obese individuals, results may not be generalizable to populations that do not receive these types of incentives. On the other hand, some participants may be more motivated to adhere to a weight loss program when they are paying for the costs to participate. Fourth, results observed are limited to the population studied (ie, sedentary and obese women) and may not be applicable to other populations. Finally, results are limited to the inherent difficulties in conducting clinical trials of this nature; compliance to diet and/or exercise protocols; and accuracy in data collection and analysis.

CONCLUSIONS

Results from our study indicate that within the limitations of the study both diet and exercise strategies were effective in promoting and maintaining a modest, yet significant, amount of weight loss in apparently healthy but obese sedentary women. The MRP program that involved replacing meals with RTE cereals and cereal bars along with additional diet and exercise recommendations resulted in a decrease in total energy intake, an increase in the amount of light physical activity, and a modest amount of weight loss. This strategy was also effective in maintaining weight loss during a 6-month maintenance period. However, adherence to a more structured meal-plan–based diet and supervised exercise program was found to be more efficacious in promoting and maintaining weight loss, favorable changes in body composition, and markers of health and fitness in sedentary obese women compared to adherence to an MRP-based program with encouragement to increase physical activity. The more favorable outcomes appear to be due to an increase in the amount of moderate and vigorous physical activity the participants engaged in throughout the duration of the study in the SDE group.

There are several important practical findings from this study that exercise and nutrition practitioners should consider. First, an MRP-based diet and a structured meal-plan–based diet can both help women reduce energy intake and promote a modest amount of weight loss. In addition, both dietary strategies can help individuals maintain weight loss. Second, simply replacing normal meals with relatively inexpensive lower-energy RTE foods and/or bars is a cost-effective way to help manage energy intake. Finally, nutrition practitioners working with clients who want to lose weight should encourage them to participate in a supervised exercise program. Although this may be more expensive than encouraging clients to start walking or an exercise program on their own, results from our study indicate that individuals engaged in a supervised exercise program while dieting experience better results. As has been recently recommended (28,42), additional research is needed to compare the efficacy of various diet and exercise interventions so that health, nutrition, and exercise practitioners can provide appropriate guidance about effective strategies to help individuals meet their weight loss and maintenance goals.

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