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Clinically Significant Improved Fitness and Weight Loss Among Overweight Persons With Serious Mental Illness

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Abstract

Objective—The objective of this study was to evaluate the effectiveness of a fitness health mentor program (In SHAPE) in improving physical fitness and weight loss among overweight and obese adults with serious mental illness.

Methods—A randomized controlled trial was conducted with 133 persons with serious mental illness and a body mass index (BMI) >25 who were assigned either to the In SHAPE program (one year of weekly sessions with a fitness trainer plus a fitness club membership) or to one year of fitness club membership and education. Assessments were conducted at baseline and three, six, nine, and 12 months later.

Results—Participants had a mean baseline weight of 231.8±54.8 pounds and a mean BMI of 37.6±8.2. At 12-month follow-up, In SHAPE (N=67) compared with fitness club membership and education (N=66) was associated with three times greater fitness club attendance, twice as much participation in physical exercise, greater engagement in vigorous physical activity, and improvement in diet. Twice the proportion of participants (40% versus 20%) achieved clinically significant improvement in cardiorespiratory fitness (>50 m on the six-minute walk test). Weight loss and BMI did not differ between groups. Among In SHAPE participants, 49% achieved either clinically significant increased fitness or weight loss (5% or greater), and 24% achieved both clinically significant improved fitness and weight loss.

The other authors report no competing interests.

Conclusions—The In SHAPE program achieved clinically significant reduction in cardiovascular risk for almost one-half of participants at 12 months. Although the intervention showed promise in improving fitness, optimizing weight loss may require additional intensive, multicomponent dietary interventions.

Cardiovascular disease is the leading cause of the estimated 25- to 30-year reduced life expectancy for persons with serious mental illness (1,2). Lifestyle interventions aimed at increasing physical activity and healthy eating have been promoted to reduce cardiovascular risk by addressing high rates of obesity in this at-risk group. Unfortunately, this strategy has yielded disappointing results. Systematic reviews of over 24 studies evaluating community-based dietary and exercise interventions for obese persons with serious mental illness have concluded that despite findings of statistically significant weight loss, all but two interventions (3,4) have failed to achieve clinically significant mean weight loss of 5% of body weight or more (5–7). Numerous factors contribute to the lack of success of these lifestyle interventions in realizing meaningful weight loss, including metabolic burden of psychoactive medications, impact of psychiatric medications and psychiatric symptoms on motivation, difficulty affording healthy foods, and inadequate access to safe, affordable, and supported options for physical exercise.

As a complementary approach, improving cardiorespiratory fitness of obese adults in the general population contributes to significant reductions in cardiovascular risk, independent of change in body weight (8). When examining the relative contributions of improved cardiorespiratory fitness and weight loss to cardiovascular and all-cause mortality, Lee and colleagues (9) found that improved fitness is strongly associated with reduced risk, whereas weight loss is not significant after adjustment for improved fitness. Increasing the amount and intensity of physical activity is an important factor in reducing mortality (10). A systematic review of 80 cohort studies determined that a high level of activity is associated with a 65% reduction in risk of all-cause mortality (11). Behavioral interventions targeting cardiovascular fitness could reduce mortality from cardiovascular disease among persons with serious mental illness.

To date, researchers have largely focused on determining statistically significant differences in outcomes, in contrast to clinically significant changes associated with reduction in cardiovascular risk. Few studies report the proportion of participants who achieve clinically significant changes in weight, and to our knowledge, none have examined outcomes with respect to the proportion achieving clinically significant changes in fitness (7). Moreover, prior studies mostly compared active health promotion interventions to usual care in the context of poor access to affordable or accessible alternatives. This study sought to address these gaps in the knowledge base on lifestyle interventions for overweight and obese adults with serious mental illness. In a prior pilot study (12), we found promising outcomes of the In SHAPE intervention, a fitness health mentor program with combined nutrition and health education adapted for persons with serious mental illness. This report presents the primary outcomes of a 12-month randomized controlled trial (RCT) for evaluating the effectiveness of In SHAPE compared with fitness club membership and education. We hypothesized that In SHAPE contributes to greater improvements in cardiorespiratory fitness and reductions in weight and BMI compared with fitness club membership and education.

Methods

An RCT compared the 12-month In SHAPE fitness mentor program with a control condition involving fitness club membership and education. In SHAPE is a health promotion intervention consisting of a free fitness club membership and a health mentor. The mentor has basic certification as a fitness trainer and has received training for providing instruction on principles of healthy eating and nutrition and for tailoring individual wellness plans to the needs of persons with serious mental illness. Before enrollment, participants were required to obtain medical clearance by their primary care provider. After conducting comprehensive lifestyle and fitness evaluations, the health mentors developed personalized fitness plans using shared goal setting. Thereafter, they met with participants once a week for 45–60 minutes at a local fitness club (YMCA) and provided fitness coaching, support, and reinforcement of physical activity. The nutrition component focused on healthy eating as opposed to caloric restriction and involved discussions at each session, individual meetings with a registered dietitian, and group cooking classes or grocery store tours (or both), depending on participant goals and preferences.

The fitness club membership and education comparison condition also consisted of a free membership to the same local fitness club and included introduction to the exercise equipment and educational materials on the health benefits of exercise and healthy diet. This RCT did not use a usual care control group because usual care does not afford year-round safe and accessible opportunities for physical activity and therefore would not have represented a fair comparison with the In SHAPE program. In addition, we were primarily interested in evaluating the effectiveness of health mentors separate from access to a fitness club. Participants in both arms continued to receive their usual mental health services. Blinded outcome assessments were conducted at baseline and three, six, nine, and 12 months later.

Inclusion criteria were age 21 or older; diagnosis of major depression, bipolar disorder, schizoaffective disorder, or schizophrenia, (based on the Structured Clinical Interview for DSM–IV); serious mental illness, defined by an axis I disorder and persistent impairment in multiple areas of functioning (such as work, school, and self-care) (13); body mass index (BMI) >25; and ability and willingness to provide informed consent for participation. Participants must also have been on stable pharmacological treatment, defined as receiving the same psychiatric medications over the prior two months. Exclusion criteria were residing in a nursing home or other institution, primary diagnosis of dementia or significant cognitive impairment as determined by a Mini-Mental Status Exam (14) score <24, terminal illness expected to cause death within one year, or current diagnosis of substance dependence (based on the substance abuse module of the Structured Clinical Interview for DSM–IV).

Health mentors

In SHAPE was delivered by four health mentors in a community mental health center in New Hampshire. They received basic psychoeducation on the primary symptoms of schizophrenia, schizoaffective disorder, bipolar disorder, and major depression before working with study participants. They also received three-day training in the In SHAPE program and instruction in motivational interviewing to support consumers in adopting

lifestyle changes, setting goals and objectives, and tracking eating and physical activity behaviors. Mentors then received two-day training in healthy eating from a community nutrition educator and three-day training in nutrition education from a doctoral candidate in nutrition science. Throughout the study, mentors participated in two required 60-minute supervision calls each week—a call with the program director of In SHAPE, an experienced certified fitness trainer, and a call with a study coinvestigator (SIP), a clinical psychologist with expertise in behavior change and motivational interviewing. All cases were reviewed during these supervision calls.

Primary outcomes

Cardiorespiratory fitness—Our primary measure of cardiorespiratory fitness was the six-minute walk test (6MWT) (15), which measures the distance an individual can walk in six minutes. For obese adults, the 6MWT is a reliable and valid measure of cardiovascular fitness with favorable test-retest and discriminant validity (16,17) and has been used with adults with a variety of chronic health conditions (18–27). A change in distance of 50 m or more is associated with clinically significant improvement in general medical conditions such as cardiovascular disease (28,29).

Weight and BMI—Weight was measured as the change in body weight over time. BMI was calculated by the formula weight (kg)/height (m^2), and the measure provides a reliable indicator of body fatness for most people (30).

Health behavior outcomes

Physical activity—Physical activity was measured with the short-form International Physical Activity Questionnaire (IPAQ) (31). Summary scores were calculated for vigorous activities obtaining an estimate of weekly metabolic equivalent expenditure (MET) minutes of vigorous physical activity. The reliability and validity of the IPAQ as a measure of physical activity for persons with serious mental illness are comparable with those in the general population, with correlation coefficients of .68 for test-retest reliability and .37 for criterion validity (31). Health mentors also collected self-report data on total minutes exercised per week. Frequency of fitness club visits was tracked with a sign-in log at the YMCA.

Dietary behavior—Readiness to engage in nutrition behaviors was assessed with the Weight Loss Behavior–Stage of Change Scale (WLB-SOC) (32), a self-report measure focused on dietary behaviors and physical activity that reflects the five stages of readiness from the transtheoretical model (33), including precontemplation, contemplation, preparation, action, and maintenance. Higher scores indicate greater engagement. In addition to separately analyzing scores for portion control, intake of dietary fat, and intake of fruits and vegetables, we calculated an overall dietary readiness score consisting of the mean for the three subscales, where scores of ≥4 represented a composite categorical determination of engagement in dietary change.

Study procedures

Recruitment occurred between April 2007 and November 2008 at a community mental health center in Concord, New Hampshire. Committees for the Protection of Human Subjects at Dartmouth College and the New Hampshire Bureau of Behavioral Health approved all study procedures. Informed consent was obtained from all participants. After baseline assessments, 133 participants were randomly assigned to In SHAPE (N=67) and to fitness club membership and education (N=66) conditions. [A CONSORT diagram provides details in an online data supplement to this article.] Participants were paid $35 for completing the Structured Clinical Interview for DSM–IV, $35 for completing baseline, nine-, and 12-month assessments, and $20 for completing three- and six-month assessments. Participants were not paid for attending In SHAPE sessions. Assessors were blind to treatment group.

Statistical analyses

Using two-tailed t tests and chi square tests, we compared both groups for demographic characteristics, psychiatric history, and outcome measures at baseline. Treatment effects were evaluated by intent-to-treat analyses of both study groups, regardless of exposure to treatment, with total scores or subscale scores for outcome measures as the dependent measures. Because there were no significant between-group differences at baseline and there were only four follow-up assessments, rather than fitting parametric curves with random effects, we included baseline as a covariate and fitted baseline-adjusted mean response profile models (34)—also referred to as covariance pattern models (35)—selecting appropriate covariance structures and handling missing data with maximum likelihood estimation (36). Because outcomes were statistically adjusted for baseline levels, treatment effects were evaluated by group main effects (differences in group mean response profiles). Two-tailed statistical tests were conducted, and differences were considered significant based on $p \leq .05$. Between-group effect sizes at endpoint were computed with Cohen's d.

Results

Participants assigned to In SHAPE did not differ significantly from those assigned to fitness club membership and education on demographic, diagnostic, or baseline measures (Table 1). Equivalent 12-month follow-up retention and attrition (78%; N=52 in each group) emerged for both groups [see CONSORT diagram online].

Results of intent-to-treat analyses at the three-, six-, nine-, and 12-month follow-ups are listed in Table 2. Significant differences in our primary outcome of cardiorespiratory fitness were found for In SHAPE compared with fitness club membership and education based on the 6MWT. At the 12-month follow-up, In SHAPE was associated with an overall mean increase of 97.3 feet, in contrast to a decrease of 20.0 feet in the comparison group, for a between-group difference of 117.3 feet (35.8 m). No differences in mean weight change or BMI were observed between groups. From baseline to 12-month follow-up, there were no significant mean differences in weight or BMI in either group. Figure 1 shows the proportion of participants achieving clinically significant changes in fitness, and Figure 2 highlights those achieving clinically significant changes in weight loss. Over twice as many In SHAPE

compared with control group participants realized clinically significant improvements in cardiorespiratory fitness, defined as >50-m gain on the 6MWT at three-and 12-month follow-ups. Similar proportions of In SHAPE and comparison groups achieved clinically significant weight loss of ≥5% body weight (30% and 33%, respectively) at the 12-month follow-up. Weight changes were not associated with baseline antipsychotic type or psychiatric medication's propensity to cause weight gain.

In SHAPE was significantly associated with achieving both clinically significant improved fitness and weight loss. At the 12-month follow-up, 49% (N=22 of 45) of In SHAPE participants experienced reduced cardiovascular risk by achieving either clinically significant improved fitness or weight loss and 24% (N=11 of 45) had both an increase on the 6MWT of at least 50 m and a 5% or greater reduction in body weight (χ^2=10.42, df=1, p=.003). In contrast, 41% (N=19 of 46) of the comparison group participants reduced their risk by either measure, but only 9% (N=4 of 46) achieved both (χ^2=1.04, df=1, p=.42)—nearly a threefold difference compared with In SHAPE.

Over the 12-month duration of the program, 40% (N=27) of In SHAPE participants attended a minimum of half of their weekly visits to the YMCA, compared with only 11% (N=7) of participants in the fitness club membership and education group (χ^2=15.41, df=1, p<.001). At the 12-month follow-up, In SHAPE contributed to more than three times greater attendance at the YMCA and more than twice as much moderate to vigorous exercise (192 versus 95 minutes per week). In SHAPE was also associated with significantly greater total MET minutes of vigorous activity. Significant differences emerged between In SHAPE and the comparison group with respect to three dietary behavior subscales of the WLB-SOC scale, including reduced consumption of dietary fat, better portion control, and increased intake of fruits and vegetables.

Discussion

The In SHAPE health mentor program, compared with fitness club membership and education, was associated with greater fitness club attendance, more participation in physical exercise, increased vigorous physical activity, and greater improvement in dietary habits. There were no differences in mean weight and BMI among In SHAPE participants from baseline to 12-month follow-up or when compared with fitness club membership and education participants, as hypothesized. However, compared with participants in the control group, over twice as many In SHAPE participants achieved clinically significant improvements in cardiorespiratory fitness. Of note, this improvement was obtained early in the intervention, at three months (46% versus 20%), and was maintained as of the 12-month follow-up (40% versus 20%). In SHAPE participants exceeded the threshold for engaging in the ≥150 minutes or more of moderate to vigorous physical activity each week that has been associated with an 86% reduction in risk of all-cause mortality (11). These findings suggest that a mentoring approach can be effective in rapidly reducing cardiovascular mortality risk for overweight and obese individuals with serious mental illness by significantly improving fitness.

Prior studies indicate that persons with serious mental illness have low levels of confidence in their ability to participate in exercise, especially during symptomatic periods (37,38), and that providers can be a source of motivation in overcoming obstacles to health behavior change (37,39). Our results demonstrate that a health mentor intervention may help to overcome the motivational challenges and low self-efficacy often experienced by persons with serious mental illness. In SHAPE was associated with greater improvement in participants' motivational "readiness" to change dietary practices, a critical and necessary step toward adopting and maintaining healthy dietary behaviors (40).

The absence of statistically significant changes in weight and BMI among In SHAPE participants compared with fitness club membership and education differs from some prior RCTs that have reported significant (although not clinically significant) mean differences in weight loss between intervention and control groups (41–50). In addition, many weight management interventions focus on reducing caloric intake and monitoring intake with daily food diaries (51,52), whereas In SHAPE health mentors provided advice on healthy eating and improving nutrition but did not focus on reducing calories. Our results confirm that physical activity alone is of limited benefit in inducing weight loss (53). However, it is noteworthy that almost one-third of participants in both study groups achieved clinically significant weight loss (5% or more of body weight), illustrating the common finding of heterogeneous outcomes for lifestyle interventions for obesity.

Acknowledging that an individual health club membership and personal trainer can be costly, we calculated the cost of providing the In SHAPE program, consisting of a health mentor employed by the mental health center and a discounted, bulk-rate fitness club membership. The per-person annual cost of In SHAPE ranges from $1,450 (rural) to $1,692 (urban). To put this into perspective, based on an estimate of the additional annual health care costs for diabetes in schizophrenia in 2012-adjusted dollars ($3,015) (54), the five-year cost as a chronic condition amounts to $15,075. The health care savings achieved over five years by preventing diabetes for approximately 10% of In SHAPE participants (9.7%–11.2%) would offset the costs of providing In SHAPE as a 12-month intervention. A subsequent study is under way that will include a formal analysis of the costs of the In SHAPE program and potential savings in health care expenditures.

Limitations of this study warrant caution when interpreting the results. First, the study design did not evaluate the effectiveness of In SHAPE or fitness club membership and education compared with usual care. However, the conditions we used allowed us to evaluate the impact of the mentor on engagement in vigorous exercise and improvement in cardio-respiratory fitness. Second, the diagnostically heterogeneous nature of the study sample has the strength of broad clinical application but did not allow evaluation of potential differences in response that might be associated with psychiatric diagnosis. Third, this study was conducted at a single site in New Hampshire, which creates the possibility that site-specific factors may have influenced the results. However, the use of several health mentors reduced the potential that the findings are attributable to the characteristics or skills of a single health mentor. Fourth, although the study sample represented overweight and obese adults with serious mental illness, participants were predominantly female (62%) and white (92%).

Hence, the results do not necessarily generalize to an ethnically diverse or more gender-balanced sample.

Conclusions

The results of this study suggest that integrated provision of a fitness program that includes a health mentor as a component of community mental health services is feasible and associated with clinically significant reduction in cardiovascular risk. Although In SHAPE did not contribute to greater mean weight loss or reduction in BMI when compared with fitness club membership and education, the program was associated with positive health behavior change, including increased physical exercise and vigorous activity and progression in revising dietary habits. In contrast to prior reports, a unique strength of this study is our evaluation of clinically significant weight loss and fitness outcomes, in addition to mean differences. Almost half (49%) of In SHAPE participants at 12 months achieved clinically significant improvement in either cardiorespiratory fitness or weight loss, and 24% achieved both. Finally, despite these encouraging results, the rest of the In SHAPE participants did not achieve clinically significant risk reduction at the one-year follow-up. It is likely that individually tailored health promotion interventions will be needed to optimize outcomes. Future large-scale studies or pooled analyses across multiple investigations should be considered to identify individual predictors of treatment response.

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Disclosures

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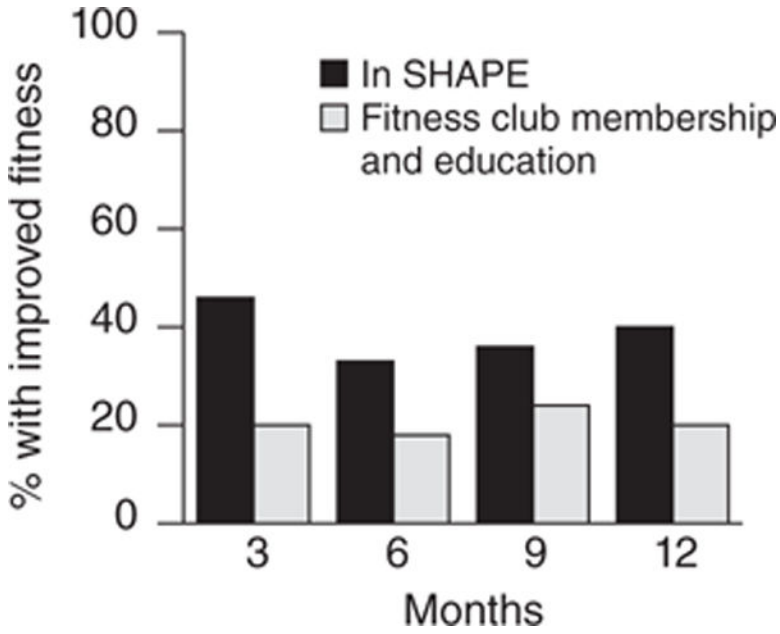

Figure 1. Proportion of participants achieving clinically significant improved fitness in In SHAPE versus fitness club membership and education[a]

[a]Improvement was defined as >50-m increase on the six-minute walk test, at 3-, 6-, 9-, and 12-month follow-ups.

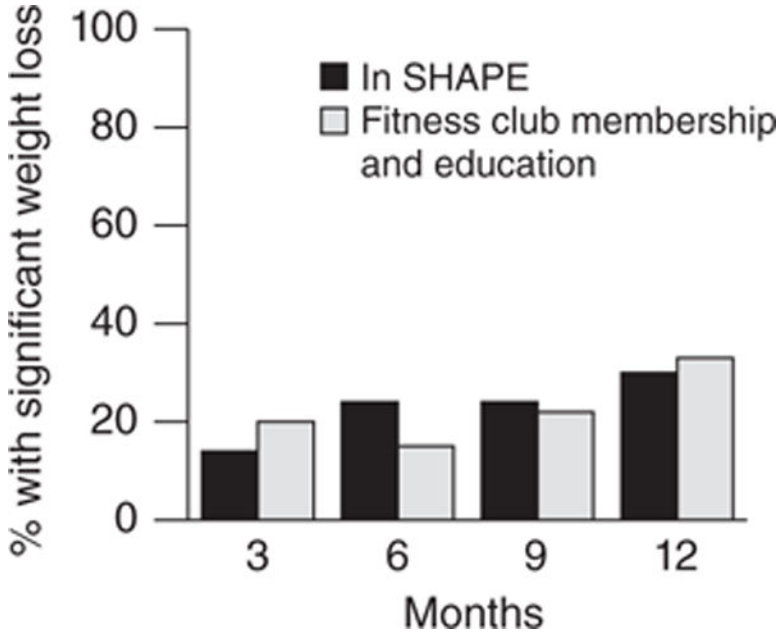

Figure 2. Proportion of participants achieving clinically significant weight loss in In SHAPE versus fitness club membership and education[a]

[a]Improvement was defined as >5% decrease in weight (in pounds) at 3-, 6-, 9-, and 12-month follow-ups.

Table 1

Characteristics of participants in the In SHAPE and fitness club membership and education groups[a]

	Total sample (N=133)		Fitness club membership and education (N=66)		In SHAPE (N=67)	
Characteristic	**N**	**%**	**N**	**%**	**N**	**%**
Age (M±SD)	43.8±11.5		44.4±10.6		43.1±12.4	
Weight (M ±SD lbs)	231.8±54.8		236.3±54.4		227.3±55.3	
Body mass index (M±SD)[b]	37.6±8.2		38.3±8.5		36.8±7.8	
Waist circumference in inches (M±SD)	46.8±7.5		47.6±7.9		46.0±7.0	
Gender						
Male	51	38	23	35	28	42
Female	82	62	43	65	39	58
Race						
White	122	92	60	91	62	93
Nonwhite	11	8	6	9	5	8
Latino						
Yes	5	4	1	2	4	6
No	128	96	65	99	63	94
Marital status						
Married	77	58	45	68	32	48
Never married	56	42	21	32	35	52
Education						
Less than high school	9	7	2	3	7	10
High school graduate	124	93	64	97	60	90
Residential						
Living independently	105	79	51	77	54	81
Supervised or supported housing	28	21	15	23	13	19
Diagnosis						
Schizophrenia	24	18	9	14	15	22
Schizoaffective	17	13	12	18	5	8
Bipolar	46	35	22	33	24	36
Major depression	45	34	22	33	23	34

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	Total sample (N=133)		Fitness club membership and education (N=66)		In SHAPE (N=67)	
Characteristic	**N**	**%**	**N**	**%**	**N**	**%**
Other	1	1	1	2	0	—

[a] No significant between-group differences were found.

[b] Body mass index is the weight in kilograms divided by the square of the height in meters, with >25 indicating overweight or obese.

Table 2

Health behavior, fitness, and weight-loss outcomes between In SHAPE and fitness club membership and education (FCME) groups

	Baseline		3 months		6 months		9 months		12 months		Group main effect at 3–12 months[a]			
Outcome	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**	**ES[b]**	**df**	**F**	**p**
Physical activity														
YMCA days attended														
In SHAPE			11.0	8.9	9.8	10.2	7.1	9.4	4.4	6.6	.51	1, 131	18.3	<.001
FCME			4.1	5.4	2.9	5.6	2.0	5.6	1.4	5.1				
Mean exercise minutes														
In SHAPE	102.2	186.3	177.1	248.0	179.6	294.4	140.8	178.1	191.5	355.3	.28	1, 137	11.6	.001
FCME	84.3	150.6	137.3	259.1	90.3	167.5	97.7	157.8	94.7	162.8				
IPAQ total vigorous activity score (log of MET min)[c]														
In SHAPE	112.0	396.6	464.6	640.1	994.5	2,341.2	694.8	2,013.4	393.7	1,048.8	.48	1, 143	12.0	.001
FCME	128.8	353.4	167.0	595.7	53.9	175.3	255.0	667.8	484.3	1,992.6				
Weight loss behavior stage of change[d]														
Dietary fat														
In SHAPE	2.7	1.4	3.4	1.4	3.2	1.2	3.4	1.5	3.5	1.5	.69	1, 129	13.0	<.001
FCME	2.9	1.4	3.2	1.5	3.0	1.6	2.8	1.6	2.9	1.7				
Portion size														
In SHAPE	2.5	1.1	2.9	1.2	3.0	1.2	3.2	1.2	3.1	1.5	.15	1, 128	4.0	.047
FCME	2.6	1.2	3.2	1.2	2.4	1.2	2.5	1.4	3.0	1.5				
Consumption of fruits and vegetables														
In SHAPE	2.8	1.2	3.3	1.2	3.2	1.1	3.3	1.5	3.1	1.4	.17	1, 136	3.7	.055
FCME	2.8	1.4	2.8	1.4	2.8	1.5	2.9	1.4	2.9	1.6				
Fitness and weight-loss outcomes														
Cardiorespiratory fitness 6MWT distance (feet)[e]														
In SHAPE	1,426.2	390.1	1,545.4	333.4	1,561.4	322.6	1,546.9	353.8	1,523.5	361.3	.37	1, 101	5.6	.020
FCME	1,443.8	323.9	1,466.6	353.0	1,462.4	373.9	1,525.6	351.9	1,423.8	371.8				
Weight (lbs)														
In SHAPE	227.3	55.3	225.5	60.0	231.8	62.3	225.6	57.7	228.7	63.9	.00	1, 120	.03	.858
FCME	236.3	54.4	231.9	46.7	231.9	46.6	225.0	45.5	227.9	60.0				

Outcome	Baseline		3 months		6 months		9 months		12 months		Group main effect at 3–12 months[a]			
	M	SD	M	SD	M	SD	M	SD	M	SD	ES[b]	df	F	p
BMI[f]														
In SHAPE	36.8	7.8	36.6	8.4	37.1	8.3	36.5	7.6	36.8	8.4	−.02	1, 119	.004	.951
FCME	38.3	8.5	37.7	7.2	37.5	7.4	36.5	7.5	37.1	8.8				

[a] Means shown above consist of raw (unadjusted) means, and the main effect calculated for 3–12 months was adjusted for baseline value as a covariate.

[b] Effect size calculated for endpoint effect size (not overall group effect)

[c] IPAQ, International Physical Activity Questionnaire; MET, metabolic equivalent expenditure. Possible IPAQ total vigorous activity scores in this study were continuous and ranged from 0 to 11,520 weekly MET minutes, with higher scores indicating greater weekly participation in vigorous physical activity.

[d] Possible scores range from 1 to 5, with higher scores reflecting a higher stage of readiness (1, precontemplation; 2, contemplation; 3, preparation; 4, action; 5, maintenance).

[e] The six-minute walk test is a measure of the distance in feet that an individual can walk in six minutes.

[f] Body mass index is the weight in kilograms divided by the square of the height in meters, with >25 indicating overweight or obese.