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Pragmatic Replication Trial of Health Promotion Coaching for Obesity in Serious Mental Illness and Maintenance of Outcomes

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Abstract

Objective—Few studies targeting obesity in serious mental illness report clinically significant risk reduction, and none have been replicated within community settings or have demonstrated sustained outcomes after intervention withdrawal. This pragmatic clinical trial aims to replicate positive health outcomes demonstrated in a prior randomized effectiveness study of the In SHAPE program across urban community mental health organizations serving an ethnically diverse population.

Methods—Persons with serious mental illness and BMI>25 receiving services in three community mental health organizations were randomized to the 12-month In SHAPE program (health promotion coach and membership to a public fitness club) or to fitness club membership alone. Primary outcomes were weight and cardiorespiratory fitness (measured with the 6-Minute Walk Test) collected at baseline, 3-, 6-, 9-, 12-, and 18-months.

Results—Participants (N=210) were ethnically diverse (46% non-White) with mean baseline BMI=36.8±8.2. At 12-months In SHAPE (n=104) compared to a fitness club membership alone (n=106) contributed to greater reduction in weight and improved fitness. Primary outcomes were maintained at 18-months follow-up. Approximately half of In SHAPE participants (51% at 12-month program completion and 46% at 18-month follow-up) achieved clinically significant cardiovascular risk reduction (≥5% weight loss or >50 meter increase on the 6-Minute Walk Test).

Conclusions—Sustained weight loss and improved fitness can be achieved by community mental health organizations providing health promotion coaching and access to fitness facilities. Health promotion should be integrated into mental health services for persons with serious mental illness at risk for cardiovascular disease and early mortality.

Rates of obesity in persons with serious mental illness are nearly double those observed within the general population (1-3), contributing to reduced life expectancy largely attributable to increased burden of cardiovascular disease (4-6). Persons with serious mental illness experience numerous challenges to achieving and sustaining fitness and weight loss,

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including metabolic effects of psychoactive medications, the impact of symptoms on motivation, poor diet, difficulty affording healthy foods, physical inactivity, and inadequate access to safe, affordable, and supported options for physical exercise. Systematic reviews of health promotion interventions for persons with serious mental illness have identified at least ten randomized trials reporting statistically significant overall weight loss (7, 8), yet few studies report achieving clinically significant outcomes (9-12). None of these clinically significant trials have been replicated to determine if similar outcomes are achieved when provided by routine community mental health organizations serving ethnically diverse populations, nor if improved outcomes are sustained after the active intervention is withdrawn.

The lack of replication studies in contemporary medicine has been highlighted as a major concern in systematic reviews and in the popular press. A 2011 Wall Street Journal article called the lack of replication in research, “one of medicine’s dirty secrets”, concluding, “most results, including those in top-flight peer reviewed journals, can’t be reproduced” (13). A 2013 article in The Economist titled, “Unreliable Research: Trouble at the Lab”, summarized studies showing that only 11% to 25% of selected pivotal biomedical findings in the basic science of cancer are reproducible (14). The lack of replicated results in medical research has been attributed to a variety of causes, such as “questionable research practices” consisting of exploring multiple dependent variables or covariates and reporting only those that yield significant results (15); conducting studies with inadequate statistical power (16); and pervasive publication bias favoring novel findings over replication studies (17). Of note, within the psychological sciences, 1.6% of published findings mention the term replication, and among actual replication studies only a little over 1% are successful (18).

In a prior randomized controlled trial in a mental health center in New Hampshire we demonstrated the effectiveness of In SHAPE (19), a 12-month program consisting of individual weekly meetings in the community with a health promotion coach, a fitness club (YMCA) membership, and nutrition education adapted for persons with serious mental illness (20). We found that In SHAPE compared to an active control consisting of a fitness club membership contributed to clinically significant reduction in cardiovascular risk (either clinically significant weight loss or improved fitness) in 49% of overweight/obese adults with serious mental illness.

In this report, we present the results of a pragmatic clinical trial (21) of In SHAPE conducted to determine if the primary outcomes of weight loss and improved fitness are replicated when the intervention is delivered by health promotion coaches employed by routine mental health provider organizations serving an ethnically diverse population of overweight/obese adults with serious mental illness. We also evaluate secondary outcomes of BMI, waist circumference, physical activity, diet, blood pressure, and serum lipids. Finally, we evaluate whether our primary outcomes of weight loss and improved fitness persist following withdrawal of the active intervention. We hypothesized that the In SHAPE program (health promotion coaching and a fitness club membership) contributes to greater reduction in weight and improvements in cardiorespiratory fitness when compared to a fitness club membership alone, and that these improvements will be maintained at 18-month follow-up.

Methods

Participants

Inclusion criteria were: age 21 or older; serious mental illness defined by an axis I diagnosis of major depression, bipolar disorder, schizoaffective disorder, or schizophrenia, (based on the Structured Clinical Interview for *DSM–IV*); and persistent impairment in multiple areas of functioning (e.g., work, school, self-care) (22); body mass index (BMI) greater than 25; and provision of informed consent for participation. Participants were on stable pharmacological treatment defined as receiving the same psychiatric medications over the prior 2 months. Exclusion criteria were: residing in a nursing home or other institution; primary diagnosis of dementia or significant cognitive impairment defined as a Mini Mental Status Exam (23) score<24; inability to walk one city block; pregnant or planning to become pregnant within the next 18 months; inability to speak English; terminal illness with mortality expected within 1 year; or current diagnosis of an active substance dependence disorder (based on the substance abuse module of the Structured Clinical Interview for *DSM–IV*). The sample size was chosen to obtain 80% power for comparisons of the repeated time points at the two-sided 0.05 significance level, while assuming up to 20 percent attrition from baseline to 12 months. Pilot findings on waist circumference and fitness were used to anticipate effect size in these calculations (20).

Study Procedures

Recruitment occurred between 2007 and 2011 from three non-profit community mental health providers in the Boston area: Vinfen, Massachusetts Mental Health Center, and Bay Cove Human Services. Randomization between In SHAPE and the comparison group was stratified by age (21 to 44 versus 45 and older) and mental health diagnosis (mood disorder versus schizophrenia spectrum disorder). Each combination of stratification categories had its own randomization schedule that was blocked on every fourth assignment to assure balance between treatment arms. Randomization was conducted sequentially across all sites (not within sites).

Committees for the Protection of Human Subjects at Dartmouth College and the Department of Mental Health in Massachusetts approved the study procedures. Informed consent was obtained from all participants. Participants were paid for completing assessments, but not for attending In SHAPE sessions. Blinded assessments were conducted at baseline, 3-, 6-, 9-, 12-, and 18-month follow-up for weight, BMI, waist circumference, and physical activity, and at baseline, 6-, 12-, and 18-month follow-up for fitness, diet, blood pressure, and serum lipids.

Intervention Group

In SHAPE is a health promotion intervention consisting of a fitness club membership and a health promotion coach with basic certification as a fitness trainer, instruction on healthy eating and nutrition, and training in tailoring individual wellness plans to the needs of persons with serious mental illness (19, 20). Prior to enrollment, participants obtain medical clearance from their primary care provider. After conducting lifestyle and fitness evaluations, the health promotion coach develops personalized fitness plans for each

participant using shared goal setting. Thereafter, they meet with participants individually each week for 45–60 minutes at a local fitness club (YMCA) and provide fitness coaching, support, and reinforcement for physical activity. The nutrition component consists of individualized instruction during each meeting emphasizing healthy eating.

In SHAPE was delivered by four health promotion coaches who were either mental health case managers with basic certification in fitness training or certified fitness trainers interested in working with individuals with disabilities. All coaches also completed a one-week In SHAPE training consisting of instruction in motivational interviewing, fitness goal setting, healthy nutrition, strategies for health behavior change, and tracking eating and physical activity behaviors. To ensure fidelity to the In SHAPE intervention, the health promotion coaches participated in two 60-minute supervision calls each week with an experienced certified fitness trainer, a clinical psychologist with expertise in behavior change and motivational interviewing, and a dietitian.

Control Group

The comparison condition consisted of a fitness club membership to the same local fitness clubs (YMCAs) with an introduction in safe use of the exercise equipment.

Primary Outcome Measures

Weight—Weight (lbs.) was measured as the change in body weight over time.

Cardiorespiratory Fitness—The 6-Minute Walk Test (6-MWT) (24) measures the distance an individual can walk in six minutes. In obese adults, the 6-MWT is a reliable and valid measure of fitness with favorable test-retest and discriminant validity (25, 26), and has been used in adults with a variety of chronic health conditions (27-36). An increase in distance of >50 meters is associated with clinically significant reduction in risk for cardiovascular disease (37, 38).

Secondary Outcome Measures

Body Mass Index (BMI)—BMI was calculated by the formula: Weight (kg)/Height(m)^2. BMI provides a reliable indicator of body fatness for most people (39).

Physical Activity—Physical activity was measured using the short-form International Physical Activity Questionnaire (IPAQ) (40). Summary scores were calculated for vigorous activities obtaining an estimate of weekly metabolic equivalent expenditure (MET) minutes of vigorous physical activity. The IPAQ is reliable and valid for use among persons with serious mental illness (40). Health promotion coaches also collected self-report data on total exercise time per week. Frequency of fitness club visits was tracked using electronic records of membership card swipes at the YMCA.

Diet—Readiness to change eating behaviors was assessed using a scale adapted from the Stages of Change Modified Motivational Interviewing instrument (41) focused on dietary behaviors. Higher scores indicate greater readiness. We calculated an overall dietary behavior score consisting of the mean for the items related to portion control, consumption

of fat, and intake of fruits and vegetables. Dietary intake was assessed using the Brief Block Food Frequency Questionnaire (FFQ) (42). The FFQ yields estimates of daily consumption of calories and servings of fruits and vegetables with comparable validity to other measures of diet, and is sensitive to dietary intake over time (43).

Blood Pressure—Blood pressure was measured before (resting heart rate) and after completing the 6-MWT.

Serum Lipids—Lipids were measured using the CardioChek PA Analyzer, a portable testing system that produces reliable values for total cholesterol, LDL, HDL, and triglycerides using a multi-panel test strip and a single drop of blood acquired with a finger prick (44).

Statistical Analysis

Both groups were compared for demographic characteristics, psychiatric history, and outcome measures at baseline using two-tailed t-tests and chi-square tests. Primary outcomes were changes in weight and fitness from randomization to 12-months, and maintenance of outcomes from 12- to 18-months. Treatment effects were evaluated by intent-to-treat analyses, with total values for outcome measures as the dependent measures. To test our main hypotheses, we conducted analyses in two steps. In the first step, we examined group difference in outcome change for treatment period (baseline to 12 month). Rather than fitting parametric curves with random effects, we included baseline as a covariate and fit baseline-adjusted mean response profile models (45), also referred to as covariance pattern models (46). Within-subject correlation over time was modeled by selecting unstructured covariance structures and missing data were accommodated with maximum likelihood estimation (47). The model was also adjusted for by including diagnosis and the interaction of group and diagnosis. Given the outcomes were adjusted for baseline levels, treatment effects were evaluated by group main effects (i.e., differences in group mean response profiles during the treatment period). In the second step, we fitted models with group, time (12 to 18 months), and group-by-time interaction effect. We tested whether or not the results at treatment period sustained at 18-month follow-up by looking at the effect of group-by-time interaction term. Generalized estimating equations (GEE) were used to compare the percentages of participants in the two groups who met clinically significant weight loss and fitness criteria at 12-months and 18-months. We computed Pearson's correlation coefficients (r) to examine relationships between number of fitness trainer visits and weight loss and fitness.

Results

A total of 210 eligible participants were randomized to the 12-month In SHAPE program (N=104) or to fitness club membership (N=106) (see Consort Diagram in online Supplement). As shown in Table 1, study participants mean age was 43.9±11.2 years, mean BMI was 36.8±8.2 kg/m^2, half (51%) were female, and 46% were non-White (see online Supplement for additional baseline characteristics). In SHAPE participants did not differ significantly from those assigned to the fitness club membership comparison group on

demographic, diagnostic, use of psychiatric medications with high weight gain propensity, elevated lipid and cholesterol levels, or other baseline measures. Comparable 12-month and 18-month follow-up retention rates were observed across both groups (84% at 12-months and 77% at 18-months in In SHAPE; 77% at 12-months and 78% at 18-months in the comparison group).

Results of intent-to-treat analyses at 3-, 6-, 9-, and 12-months for primary and secondary outcomes are shown in Table 2. In SHAPE, compared to fitness club membership, was associated with greater reduction in weight and increased fitness (distance on 6-MWT). For secondary outcomes, In SHAPE participants achieved greater reductions in BMI and waist circumference, and more minutes of physical activity. Secondary diet, blood pressure and serum lipid outcomes are provided in Table 3. There were greater self-reported improvements in eating behaviors, but no between group differences in total calorie consumption, calories from fat or sweets, and consumption of fruits and vegetables. No between group differences were found for blood pressure or lipid outcomes for the total sample, nor for the subgroup with abnormal lipid values at baseline (not shown in table). No differences in outcomes where found with respect to age, gender, psychiatric diagnosis, or use of high vs. low weight gain propensity psychiatric medications.

In addition to observed differences between groups, both In SHAPE and the fitness club membership groups were associated with decreased weight, BMI, and percent weight loss, and increased physical activity over time. For the total sample (regardless of assignment), there were decreases in total calorie consumption, calories from fat or sweets, and consumption of fruits and vegetables. The subgroup of participants across both groups with abnormal baseline lipid values showed significant reductions at 12-months for triglycerides ($F=5.88$; $df=1, 64$; $p=0.018$) and at 18-months for HDL ($F=3.93$; $df=1, 101$; $p=0.050$) and LDL ($F=10.55$; $df=1, 18$; $p=0.004$).

Primary weight and fitness outcomes and secondary outcomes were maintained from 12- to 18-month follow-up as indicated by no group-by-time interactions, with the exception of decreases in readiness to change eating behaviors and increases in systolic blood pressure among In SHAPE participants relative to the comparison group (see online Supplement for 12-18 month outcomes). At 12-months, over half (51%) of In SHAPE participants achieved clinically significant reduction in overall cardiovascular risk (either ≥5% weight loss or increase of >50m on the 6-MWT) compared to fitness club membership (38%). Similar rates were found at 18-month follow-up: 46% of In SHAPE participants compared to 37% of participants receiving a fitness club membership.

Frequency of visits to the gym was associated with weight loss at 12-months across both groups ($r=0.284$; $p<0.01$). In SHAPE compared to fitness club membership was associated with over two and one-half times the mean number of gym visits (28.5 ± 36.9 vs. 10.7 ± 2.4; $t=-4.1$; $p<0.0001$). In SHAPE participants attended a mean of 21.3 ± 12.6 sessions with their health promotion coach (median=22.5 sessions), of a possible 50 sessions. Attendance at sessions with the health promotion coach was correlated with weight loss ($r=0.342$; $p=0.002$) but not improvement in fitness ($r=0.050$; $p=0.670$).

At 12-months the gym membership was discontinued for both groups and regularly scheduled sessions with the health promotion coach ended for In SHAPE participants. A transitional support option to facilitate transitioning to community-based fitness activities was provided to In SHAPE participants at the end of the active 12-month intervention upon request. Approximately half of In SHAPE participants (46%, n=44) had at least one additional contact in the first month after the end of the intervention (most consisting of a brief office visit, phone call, or going for a walk with the coach). By 18-month follow-up (6 months following the 12-month intervention) fewer than 16% (N=15) of participants were in contact with their health promotion coach. No differences were observed between In SHAPE participants who elected to have transitional support and those who did not with respect to primary and secondary outcomes at 12-month and 18-month follow-up.

Discussion

In SHAPE compared to a fitness club membership alone is associated with greater weight loss and improved fitness at 12-months, as well as sustained outcomes at 18-month follow-up. This study replicated our prior finding that approximately half of individuals receiving In SHAPE (49% in the first randomized trial and 51% in the current study) achieve reduced cardiovascular risk defined as either clinically significant weight loss (≥5%) or clinically significant improved fitness (>50 meter increase on the 6-MWT).

We applied a pragmatic randomized clinical trial design (21) to determine whether the effectiveness demonstrated in our prior trial (19) would be replicated when delivering the In SHAPE program using health promotion coaches working at multiple urban community mental health organizations serving an ethnically and diagnostically diverse population. Our first randomized study was conducted with an ethnically homogeneous population (92% white) in a single mental health center in New Hampshire with access to a fitness club within the same block, and was intensively supervised by our research team located in offices less than one mile away (19). In contrast, this second study achieved similar effectiveness with remote supervision by our staff in a different state, involving ethnically diverse participants (46% non-White), in an urban setting (Boston, Massachusetts) involving three different mental health organizations, and using multiple YMCA fitness clubs dispersed across the city. Results from this pragmatic trial confirm that comparable outcomes for the In SHAPE program can be achieved among individuals receiving services in community mental health organizations across diverse “real-world” settings.

To our knowledge, this is the first replication study confirming the effectiveness of a health coaching intervention in achieving clinically significant reductions in cardiovascular risk for overweight and obese persons with serious mental illness, and the first study to demonstrate persistent reduction in cardiovascular risk after the active intervention is withdrawn. Half (51%) of In SHAPE participants achieved clinically significant reduction in cardiovascular risk at 12-month completion of the intervention and a similar reduction in risk persisted 6 months later (46% at 18-month follow-up). Participants also continued to demonstrate improved health behaviors, including engaging in three times the amount of exercise at 18-months compared to baseline. We found overall improvement in eating behaviors, though we did not find between group differences with respect to calorie intake (consumption of

specific foods and categories of foods). This may reflect the focus of the health promotion coach emphasizing consuming healthier foods, in contrast to focusing on portion control. Almost half of In SHAPE participants made use of optional transitional support to independent health promotion activities in the first month following intervention completion, but only a small subgroup (16%) continued to seek transitional support at 18-months, and no differential benefit was observed for those receiving (versus not receiving) transitional support.

By comparing In SHAPE to an active comparison condition (a fitness club membership), it was possible to test the specific contribution of the health promotion coach. The health promotion coach was associated with over two and one-half times the mean amount of fitness club attendance, which in turn was associated with greater weight loss and improved fitness. Our finding of no difference in lipid reduction between groups (despite overall improvements in HDL and LDL at 18-months for the total sample of at-risk participants) may reflect the benefits of either intervention in risk reduction. Alternatively, improved overall lipid values may be due to factors external to our study, though we did not find any change in prescribing practices of antipsychotics or lipid lowering agents during the period of follow-up assessments.

We replicated findings from our prior trial (19), and also replicated the finding of clinically significant reduction in cardiovascular risk demonstrated in two other randomized trials of lifestyle interventions of a similar duration, sample size, and design, including the ACHIEVE (11) and STRIDE trials (12). The ACHIEVE trial evaluated the effectiveness of an intensive 18-month group intervention within psychiatric rehabilitation day treatment programs. ACHIEVE consisted of two to three weekly intensive group exercise sessions, a weekly group weight management session, and provided two meals each day for participants emphasizing healthy food offerings. ACHIEVE was associated with clinically significant weight loss for 32.5% of participants at 12-months and 37.8% at 18-months (11).

The STRIDE trial also evaluated a group-based weight loss intervention, but in contrast to ACHIEVE (which was provided as a component of a day treatment program), participants traveled to stand-alone group sessions focused on dietary changes in weekly two-hour sessions, complemented by moderate physical activity (primarily consisting of walking). STRIDE resulted in clinically significant weight reduction for 40% of participants at 6 months and 47% of participants at 12 months (12).

In contrast to ACHIEVE and STRIDE, In SHAPE focused on improving overall physical fitness through individually tailored coached exercise in local YMCAs, coupled with individual coaching on healthy food choices. Results from these three studies confirm the effectiveness of lifestyle interventions for overweight and obese persons with serious mental illness in achieving clinically significant reduction in cardiovascular risk either through group or individual coaching, and for different degrees of intensity of dietary and exercise programming. It is likely that maximum benefit might be achieved through a multi-pronged approach combining intensive dietary modification and supported exercise, along with encouraging switching to low-weight gain propensity psychiatric medications (51, 52). In

addition, the effectiveness of lifestyle interventions might be enhanced with pharmacological agents associated with weight loss such as metformin (53).

Several limitations warrant consideration when interpreting our results. First, we did not evaluate the effectiveness of In SHAPE or fitness club membership compared to usual care. However, this allowed us to specifically evaluate the impact of the health promotion coach on weight loss and improvement in fitness. Second, the diagnostically and ethnically heterogeneous nature of the study sample has the strength of broad clinical application, but our sample size did not allow for evaluation of potential differences in outcomes that might be associated with psychiatric diagnosis or racial/ethnic subgroups. Finally, although we demonstrated persistence of outcomes six months following the end of the intervention, a longer follow-up period may be necessary to assess long-term cardiovascular risk reduction and to determine if the intervention is associated with reduced health care service use and costs.

Despite these limitations, this study confirms that In SHAPE is associated with weight loss and improved fitness when offered by routine community-based provider organizations serving ethnically diverse participants with serious mental illness. However, numerous barriers exist to broad dissemination of health promotion as a component of community mental health services. Providing health promotion coaches and access to exercise facilities and affordable healthy food will require significant changes in the way that we finance and prioritize community mental health services.

Current efforts to increase the life expectancy for persons with serious mental illness are focused on improving the quality and delivery of primary health care by integrating “health homes” within mental health care (54). These initiatives address inadequate access and poor quality health care experienced by persons with mental illness (55). However, only 10-15% of preventable mortality is estimated to be due to health care (56), in contrast to health behaviors that are estimated to account for the majority (57%) of a population’s health status and 40% of early deaths (57). By also providing health promotion as a core service, it may be possible to further reduce early morality while improving both the psychological and physical wellness of “the whole person” (58).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline demographic and clinical characteristics of participants in the In SHAPE and Fitness Club Membership groups[a]

	Total Sample (N=210)		Fitness Club Membership and Education (N=106)		In SHAPE (N=104)	
Characteristic	**N**	**%**	**N**	**%**	**N**	**%**
Age (M±SD)	43.9±11.2		43.5±11.6		44.3±10.9	
Weight in lbs (M±SD)	235.4±54.1		238.9±57.9		231.8±50.1	
Body Mass Index (M±SD)	36.8±8.2		37.5±8.8		36.2±7.5	
Gender						
Male	103	49	48	45	55	53
Female	107	51	58	55	49	47
Ethnicity						
White	113	54	57	54	56	54
Black	71	34	38	36	33	32
American Indian/Alaska Native	4	2	2	2	2	2
Asian	7	3	3	3	4	4
Native Hawaiian/Pacific Islander	5	2	2	2	3	3
More than one race	10	5	4	3	6	5
Latino						
Yes	35	17	15	14	20	20
No	174	83	91	86	83	80
Diagnosis						
Schizophrenia	49	23	24	23	25	24
Schizoaffective	68	32	34	32	34	33
Bipolar	60	29	34	32	26	25
Major Depression	33	16	14	13	19	18
Marital Status						
Never Married	153	73	70	66	83	80
Currently Married	10	5	7	7	3	3
Previously married	47	22	29	27	18	17
Education						
Less than high school	42	20	21	20	21	20
High school graduate	168	80	85	80	83	80
Residential						
Living independently	124	59	60	57	64	61
Supervised/supported housing	85	41	45	43	40	39

[a]Means were compared by t tests, and proportions were compared by chi square tests.

Table 2

Primary weight and fitness outcomes and secondary outcomes between In SHAPE and fitness club membership groups

Outcome	Group	Baseline		3-Month		6-Month		9-Month		12-Month		Group Main Effect (3-12 Months)[a]		
		M	SD	M	SD	M	SD	df	F	M	SD	df	F	*p*
Primary Outcomes														
Weight (lbs.)	**In SHAPE**	231.8	50.1	228.1	48.9	224.6	49.3	227.6	50.0	226.5	48.8	1, 185	4.9	.029
	FCME	238.9	57.9	240.4	60.2	239.2	61.0	236.4	580.1	239.6	61.9			
Cardiorespiratory Fitness 6 MWT Distance (feet)	**In SHAPE**	1356.8	292.7	-	-	1382.2	291.0	-	-	1385.3	275.4	1, 170	4.4	.037
	FCME	1311.4	287.4	-	-	1308.3	307.2	-	-	1247.3	319.4			
Secondary Outcomes														
BMI	**In SHAPE**	36.2	7.6	35.8	7.3	34.9	7.3	35.4	7.3	35.0	7.1	1, 184	4.6	.034
	FCME	37.5	8.8	37.7	9.1	37.7	9.4	37.6	9.9	37.4	9.6			
Waist Circumference (inches)	**In SHAPE**	46.0	6.7	45.1	6.6	43.9	6.4	44.1	6.9	44.3	6.6	1, 190	5.37	.022
	FCME	47.5	7.2	47.2	7.4	46.7	7.7	46.4	7.9	46.1	7.6			
Exercise Minutes	**In SHAPE**	41.2	76.4	142.4	158.3	137.0	199.3	141.3	209.2	99.8	135.0	1, 183	6.8	.01
	FCME	79.1	236.3	125.1	190.9	117.0	176.3	91.2	158.4	148.9	224.3			
IPAQ Total Vigorous Score (Log of MET min)	**In SHAPE**	172.7	783.6	533.8	1331.8	529.8	1027.4	732.0	1537.1	379.8	890.8	1, 190	7.6	.006
	FCME	238.5	1256.2	458.3	885.3	238.2	624.1	236.4	580.1	433.7	1080.1			

[a]Means shown in table consist of raw (unadjusted) means. Main effect calculated for 3-12 months adjusted for baseline value as a covariate.

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Table 3

Secondary dietary behavior, blood pressure, and serum lipid outcomes between In SHAPE and fitness club membership groups

Outcome	Group	Baseline		6-Month		12-Month		Group Main Effect (6-12 Months)[a]		
		M	SD	M	SD	M	SD	df	F	p
Secondary Dietary Behavior Outcomes										
Readiness to Change Dietary Behaviors	**In SHAPE**	3.3	0.6	3.6	0.6	3.7	0.7	1, 191	4.9	.028
	FCME	3.3	0.6	3.5	0.6	3.4	0.6			
Total calories[b]	**In SHAPE**	2226	1246	1836	980	1893	907	1, 168	.098	.755
	FCME	2085	1176	1799	965	1787	967			
% calories fat[b]	**In SHAPE**	39.4	7.4	36.7	8.2	37.9	7.6	1, 159	.169	.681
	FCME	36.3	7.4	36.9	8.1	36.8	7.9			
% calories sweets[b]	**In SHAPE**	12.4	11.5	8.8	9.2	9.7	10.8	1, 160	.246	.621
	FCME	11.7	10.3	9.7	8.5	9.7	10.0			
Fruit servings/day[b]	**In SHAPE**	1.1	0.9	1.2	0.9	1.3	0.9	1, 169	.000	.986
	FCME	1.1	1.0	1.2	1.0	1.3	1.0			
Veg. servings/day[b]	**In SHAPE**	3.1	2.8	3.0	2.6	3.6	2.8	1, 156	.007	.932
	FCME	3.3	2.5	3.2	2.2	3.3	3.4			
Secondary Blood Pressure and Lipid Outcomes										
Systolic Blood Pressure	**In SHAPE**	128.4	20.4	129.0	17.5	130.6	17.3	1, 180	.404	.526
	FCME	132.0	17.7	135.6	18.7	130.3	18.2			
Diastolic Blood Pressure	**In SHAPE**	79.7	12.7	80.9	11.3	80.0	12.2	1, 180	3.09	.080
	FCME	84.1	10.9	84.1	13.6	84.4	11.4			
Total Cholesterol	**In SHAPE**	170.6	44.0	174.4	45.3	166.3	42.8	1, 157	.047	.828
	FCME	179.0	48.7	178.4	44.0	172.9	42.7			
HDL	**In SHAPE**	42.9	15.7	46.3	16.7	49.2	17.2	1, 116	.508	.477
	FCME	44.6	16.0	47.7	17.7	48.4	17.2			

Outcome	Group	Baseline		6-Month		12-Month		Group Main Effect (6-12 Months)[a]		
		M	SD	M	SD	M	SD	df	F	p
LDL	**In SHAPE**	96.8	37.6	99.1	37.7	89.8	34.9	1, 136	.173	.678
	FCME	104.9	35.8	104.7	36.2	96.8	34.8			
Triglycerides	**In SHAPE**	166.1	112.0	139.1	83.0	156.1	108.0	1, 173	.151	.698
	FCME	161.9	113.8	149.6	90.2	158.3	103.9			

[a] Means shown in table consist of raw (unadjusted) means. Main effect calculated for 6-12 months adjusted for baseline value as a covariate.

[b] Block Food Frequency Questionnaire