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Challenges in Improving Fitness: Results of a Community-Based, Randomized, Controlled Lifestyle Change Intervention

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ABSTRACT

***Objective*: This study tested the efficacy of an 8-week culturally targeted nutrition and physical activity intervention on body composition.**

***Methods*: A randomized, attention-controlled, two-group trial was conducted in a black-owned commercial gym with a sample of 366 predominantly healthy, obese African American women. A free 1-year membership to the study site gym was provided to participants in both groups. Data were collected at baseline, 2, 6, and 12 months.**

***Results*: Sample retention at 1 year was 71%. Between-group longitudinal analysis including only participants with complete data revealed a trend toward weight stability in the intervention group at 2 months compared with controls (+0.05 kg/m^2, $p = 0.75$; +0.32 kg/m^2, $p = 0.08$, respectively), disappearing at 12 months (+1.37 kg/m^2, $p = 0.0001$; +1.02 kg/m^2, $p = 0.001$, respectively). Within-group analysis demonstrated that intervention and control participants' fitness (1-mile run-walk) improved by 1.9 minutes ($p = 0.0001$) and 2.3 minutes ($p = 0.0001$), respectively, at 12 months. Mixed model regression analyses demonstrated a significant main effect of the intervention on fitness ($p = 0.0185$) and a marginally significant effect on body mass index (BMI) ($p = 0.057$), at 2 months, disappearing by 6 months. By 12 months, however, the controls exhibited a significant advantage in waist circumference stability compared with intervention participants (+1.1 cm, $p = 0.2763$; +2.1 cm, $p = 0.0002$, respectively).**

***Conclusions*: The intervention produced modest short-term improvements in body composition, but the economic incentive of a free 1-year gym membership provided to all participants was a more potent intervention than the education and social support intervention tested. However, longer-term fitness enhancement remains elusive and demands research and policy attention. These findings have policy implications in that employer-/insurer-subsidized gym memberships may require interventions targeting other levels of change (e.g., physical or social/environmental) to foster sustainable fitness improvements.**

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INTRODUCTION

The magnitude and associated costs of the obesity epidemic are of increasing concern as the baby boom segment of the American population ages.[1] Addressing the acceleration of this epidemic has become a national public health priority.[2,3] Although body weight increases with age for most people, African American women display a marked excess of obesity compared with women of other ethnicities and with men.[4,5] Consequently, rates are elevated in this group for a number of obesity-related health outcomes, including certain cancers.[6–9] As 20% of cancer incidence in women is attributable to obesity[4,5] and obesity increases cancer mortality, black women represent a high-risk group for such obesity-related cancers as colon cancer, breast cancer, multiple myeloma, and endometrial cancer.[10–16]

Substantial scientific attention is now directed toward eliminating ethnic disparities in health status and disease outcomes, and obesity has been highlighted as an important contributor to chronic disease disparities.[17] Public health obesity control strategies are beginning to focus on prevention of weight gain and chronic disease in populations at increased risk of obesity through promotion of physical activity and nutritious eating patterns rather than imposing aggressive caloric restriction to produce weight losses unrealistic to achieve and maintain.[18] As the importance of physical activity in preventing weight gain and in ameliorating the adverse sequelae of the less severe levels of obesity is increasingly recognized,[18–22] this approach may be particularly indicated for African American women. This population has lower physical activity levels and experiences greater barriers to physical activity participation than those of other major ethnic/gender groups.[23–25] In addition, physical activity is an independent cancer-protective factor.[26]

Progress in developing culturally salient approaches has been hampered, in part, by the lack of data from fitness-related lifestyle change interventions including meaningful numbers of African American women. Because overall physical fitness encompasses body composition, cardiorespiratory or aerobic fitness, muscular strength and endurance, and flexibility[27] and influences a range of chronic disease processes, this literature is necessarily multidisciplinary and multifaceted. However, 86% of the 231 papers included in a 2005 meta-analysis of the literature examining the effects of diet and exercise on weight loss, body composition, body fat distribution, metabolism, and aerobic fitness failed to report race/ethnicity, 11% fail to report age, 4% fail to report gender, 21% fail to report initial sample size by gender, and 69% fail to report final sample size by gender.[28] Many of the relatively few studies reporting ethnicity do not include sufficient numbers for ethnic-specific subgroup analyses.[29]

Even fewer studies specifically target ethnic minority populations. For example, a review of the literature on physical activity interventions published between 1984 and 2000 in which African American women comprised at least 35% of the sample[30] found only 18 studies, and none of them included the combination of 12 months of follow-up and a randomized, controlled design. None used an attention control group. Several additional studies with healthy volunteer samples have subsequently been published,[31,32] but high rates of attrition have remained problematic. Consistent with outcomes of studies of relatively affluent, predominantly white women,[33–36] most physical activity promotion interventions produced significant but modest changes postintervention, followed by diminution or disappearance of effects during the follow-up periods.

Weight loss trials in African American women have been no more plentiful or successful. A 2001 review identified only 13 published reports of weight loss programs in African Americans in clinical or community settings.[37] By 2005, eight relevant reports, most targeting women, had been added.[31,38] "The general impression from these very heterogeneous studies is one of modest success, i.e., weight losses of 1–4 kg over periods lasting from 2–17 months, with a variety of adaptations to increase cultural salience and appropriateness."[38] Kumanyika et al.[38] reported the findings of a recent outpatient weight management study in which 128 of 150 fully enrolled African Americans (85% female sample) provided postintervention data at 10 weeks. Mean weight loss was 1.5 kg at 10 weeks; weight was at least 5% below baseline for only 22 of the 87 presenting for the 18-month follow-up assessment (56% retention).

Partly as a consequence of this collective experience, the field of fitness-related lifestyle change promotion has increased its focus on social, economic, and physical environmental change intervention.[39] The current study is consistent with social ecological models[40,41] in its effort to intervene at multiple levels. This study, African American Women Fight Cancer with Fitness (FCF) tested the efficacy of a culturally targeted nutrition and physical activity educational and social support intervention in producing cancer-protective anthropometric, physiological, psychological, and behavioral changes in African American women. The educational component, delivered in group sessions and targeting lifestyle changes at the individual level, comprised the core of the intervention. A social support component intended to positively influence the intervention participants' social environments was included. An economic incentive, namely, a free gym membership, was provided to all participants. The feasibility of this approach had been demonstrated in a predecessor pilot study, Eating & Exercising for a Cancer-free Life (EECL).[42,43] We hypothesized that the intervention would produce favorable changes in body composition, that is, that intervention participants would lose significantly more body fat than controls after 1 year.

MATERIALS AND METHODS

Study design overview

FCF was a randomized controlled trial, with an attention control condition. Both intervention and control groups received eight weekly 2-hour sessions, including ethnically matched community role models as guest instructors. No intervention booster sessions were provided. The study site was the ethnically diverse, black-owned community health club that hosted the predecessor study.[42,43] A 1-year membership to this gym was offered as an incentive for study participation for all subjects (usable on alternate days to minimize contamination), whether assigned to the intervention or to the control condition. To minimize differential attrition resulting from disappointment because they were not selected for the intervention, control participants were permitted to extend their memberships to 1½ years by attending at least seven of the eight weekly sessions. Primary outcome measures were body mass index (BMI), bioelectrical impedance analysis (BIA), and waist/hip ratio (WHR).

The study was conducted in phases. During the initial phase (6 months), the model FCF intervention was refined through pretesting in a focus group setting, modified, and further pilot-tested in a sample of 15 women. In the second phase (3½ years), a study sample of 389 women from the health club catchment area (10-mile radius) was enrolled, with randomization of 197 to the intervention condition and 192 to the control condition in a two-group experimental design. The intervention and control conditions were delivered during six consecutive 3-month periods to cohorts of approximately 60 women (about one half intervention and one half control). Follow-up data were collected at 2 months (immediately postintervention), 6 months, and 12 months after initiating intervention delivery. To maximize study retention, participants in both groups were paid $50 per follow-up assessment. No payment was provided for participating in the baseline assessment in order to minimize participation that was motivated primarily by the financial incentives.

Subjects

Recruitment procedures and strategies and characteristics of the 845 women screened to generate the study sample have been described in detail elsewhere.[44] Only women who self-identified as African American were eligible. Figure 1 describes the retention statistics by condition and sampling time point (baseline, 2 months, 6 months, and 12 months). Women responding to study promotion materials were screened by telephone. Exclusion criteria included any history of invasive carcinoma, inability to walk 1 mile without assistance, current cigarette smoking, not living or working within a 10-mile radius of the intervention site, inability to commit to participating in the study or follow-up assessments for 2 years, and high level of previous use of structured weight loss programs (three or more). Research purpose, eligibility, and procedures (including randomization) were explained at this time. Those deemed eligible by screening questionnaire and willing to be randomized were given a schedule of study enrollment sessions at the study site and provided instructions on preparation for the assessment. The study was approved by the University of California Los Angeles (UCLA) Human Subjects Protection Committee.

At the study site, prospective participants provided written informed consent and were

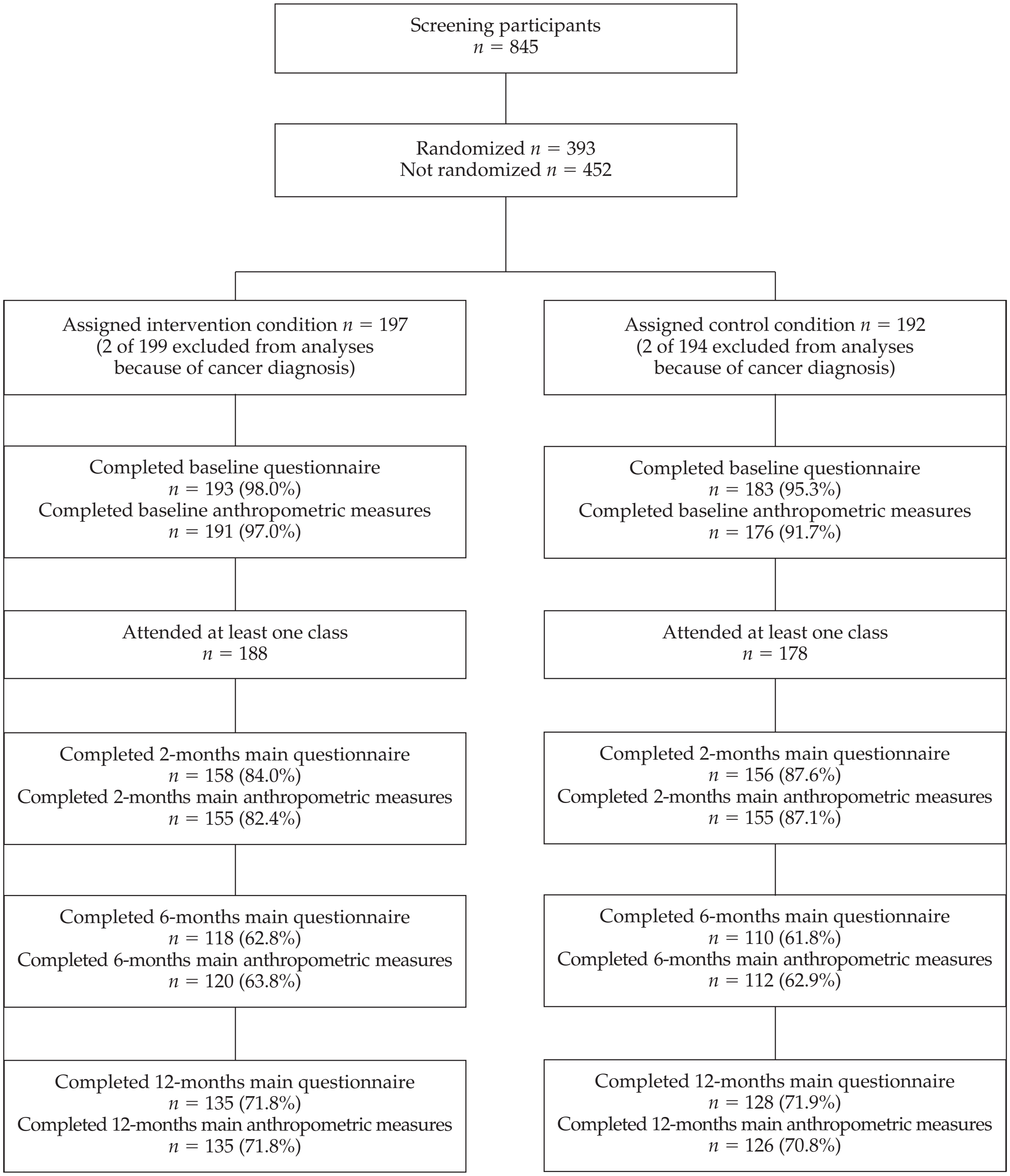

FIG. 1. Flow chart of contacts with potential study participants.

screened for conditions precluding moderate exercise, using American College of Sports Medicine guidelines.[45] They completed an extensive battery of questionnaire and anthropometric measures. This baseline assessment provided women with exposure to the demands of data collection before they fully committed to participate. Subjects were assigned consecutive enrollment numbers by the data entry staff member after the screening questionnaire data were entered for that subject. Randomization to study condition was based on the enrollment number. Each enrollment number was assigned to the control condition or experimental conditions using a random number-generating computer algorithm. The staff member assigning enrollment numbers was unaware of the previously determined experimental assignment and had no contact with study participants. Subjects were notified of their assignments by telephone and carefully instructed about meeting times and instructed to bring apparel appropriate for exercise.

Intervention and attention control conditions

Intervention group participants received eight weekly 2-hour interactive group sessions, including exercise instruction, usually facilitated by the project staff. The intervention consisted of skills training in a balanced regular exercise regimen (muscle strengthening, flexibility enhancement, and aerobic conditioning) and nutrition education promoting a low-fat, complex carbohydrate-rich diet, emphasizing the cancer-preventive benefits of increased fruit and vegetable intake. Weight loss was not a focus of the intervention. Participants in the intervention were interviewed by a dietitian about their food intake in the previous 24 hours three or four times during the intervention and given feedback on the quality and adequacy of their intake. The intervention also included instruction in lifestyle integration of a broad range of physical activities. Inexpensive incentives, for example, pedometers and exercise bands, were distributed to reinforce intervention messages. In order to provide and study the role of social support, each intervention participant was encouraged to invite one close female relative or friend to accompany her during postintervention use of health club facilities (the friend also received a free gym membership). These social contacts were not included as study subjects. Neither booster sessions nor other supportive staff contact aside from data collection was provided. Table 1 provides an overview of the intervention curriculum.

Subjects assigned to the control condition received eight weekly, 2-hour interactive group sessions on current African American women's health topics without the external social support component. These sessions were facilitated by project staff not involved in intervention delivery. The majority of sessions explored ethnic disparities in cancer incidence and outcomes. Emphasis was placed on barriers to and facilitators of tobacco control and screening behaviors for breast, cervical, uterine, colorectal, prostate, and skin cancer among African Americans. Two noncancer topics, menopause and depression, were also included. These topics were selected by vote of participants during the first session. Guest role models for the control group were recruited among cancer survivor support groups and a black women physicians' organization. The series of nationally distributed breast, cervical, and prostate cancer prevention videos developed in the UCLA Division of Cancer Prevention and Control Research were featured in the control condition sessions.[46,47]

Measures

As earlier noted, primary outcome measures were BMI, BIA, and WHR. The secondary outcome measure was cardiorespiratory or aerobic fitness as measured by the 1-mile run-walk. A number of self-reported mediating variables were included as indicators of behavioral change. Of these, only physical activity and TV viewing (as a proxy for sedentary behavior) are included here, as increasing physical activity was the main focus of the intervention.

Measures were collected at baseline and at 2 months (immediately postintervention), 6 months, and 12 months. The assessment staff was independent of the intervention staff and blind to the experimental assignment of each participant. Follow-up assessments were conducted by individual appointment in the same commercial gym in which the group sessions were held. Because of the high prevalence of undetected and uncontrolled hypertension among African Americans, blood pressure was measured at baseline, and participants with readings above 140 mm Hg systolic or 90 mm Hg diastolic were referred to their primary care providers. (All were insured.) At least two staff members were usually present: one to collect the height, weight, BIA, and blood pressure measurements and the other to monitor the women's performance on the treadmill. While waiting for the treadmill, the women completed an 11-page questionnaire.

Anthropometry. Anthropometric measures were always performed before the women did their 1 mile run-walk on the treadmill. Weight was ob-

TABLE 1. OVERVIEW OF INTERVENTION CURRICULUM

Session 1	
Lecture/discussion:	Introduction to nutrition and exercise fundamentals for fitness; bonding through goal sharing (e.g., bring an item of clothing from your lightest and most active days). Explanation of the concept of cancer risk. Introduction of simple self-monitoring techniques, such as tying a string around the waist to provide constant feedback on progress and provision of step counters. Completion of Block food frequency questionnaire.
Exercise:	Warmup and stretching.
Session 2	
Lecture/discussion:	Overview of diet-physical activity synergy; influence of both on cancer, e.g., exercise and colon cancer, WHR and breast cancer (especially exercise decreasing WHR; alcohol and smoking increasing WHR). Masking of initial fat losses by increases in denser muscle mass—need for participant attention to size decrease rather than weight loss in the short run.
Exercise:	Add aerobic activity.
Session 3	
Lecture/discussion:	Counting fat grams and reading labels; benefits of substitution of legume/whole grain combinations and soy-based foods for meats to achieve dietary fat reduction and, possibly, decrease reproductive cancer risk. Monitoring the frequency/duration/intensity of physical activity.
Exercise:	Add muscle strengthening (calisthenics).
Session 4	
Lecture/discussion:	Shopping the low-fat, high-carbohydrate way at reasonable cost (video supermarket tour).
Exercise:	Add muscle strengthening (machines).
Session 5	
Lecture/discussion:	Cooking low-fat, high-carbohydrate meals; meal timing and size to minimize body fat storage (benefits of consuming heavier foods earlier in the day and nibbling/grazing).
Exercise:	Add muscle strengthening (free weights).
Session 6	
Lecture/discussion:	Eating low-fat, high-carbohydrate meals while dining out.
Exercise:	Full workout (stretching, aerobic activity, muscle strengthening).
Session 7	
Lecture/discussion:	Establishing consumption habits that prevent overeating, e.g., slower and more frequent eating, no serving dishes on the table, clearing the table after eating, storing leftovers quickly, maintaining good hydration. Adjusting and revitalizing a personalized workout program.
Exercise:	Full workout (stretching, aerobic activity, muscle strengthening).
Session 8	
Lecture/discussion:	Distinguishing boredom, stress, and negative emotional states from hunger; avoiding the dieting cycle of excess and guilt. Lifestyle integration of physical activity.
Exercise:	Full workout (stretching, aerobic activity, muscle strengthening).

tained without shoes and with the women dressed in conventional gym clothes, using a medical balance beam scale (Detecto, Cardinal Scale Mfg. Co., Webb City, MO) calibrated periodically by a professional calibration service. Height was measured via use of a stadiometer attached to the scale. Circumference measures were taken after partial disrobing, in a private area of the women's locker room, with a plastic, medical-quality tape measure. Waist circumference was taken at a point approximately 2 inches above the umbilicus, where the torso circumference is at a minimum. Hip circumference was measured around the buttocks at the point of largest circumference. Three measurements were performed, and the results were averaged. BMI was calculated as kg/m^2.

BIA. A portable, Valhalla 1990B computerized bioelectrical impedance analyzer (Valhalla Scientific, San Diego, CA) was used.[48] Prior to exposure to the electrical current, women were asked to lie on a flat surface, arms and legs abducted, without shoes, for 5 minutes. They were asked to refrain from daily exercise and fast for at least 4 hours before the BIA testing. They were also encouraged to be well hydrated and to avoid consumption of diuretics shortly before the assessment. Two measures were taken, and the results were averaged. The equations by Segal et al.[49] were used to calculate percent body weight as fat.

Fitness. The minimal time required to complete a distance of 1 mile on a Quinton (Quinton Instrument Co., Bothell, WA) treadmill is accepted as an indirect estimate of maximum oxygen consumption appropriate for field studies.[45] Assessment staff encouraged participants to complete the mile as quickly as possible but not to exert themselves to the point of breathlessness. For all participants, the treadmill position was flat, not elevated; participants were permitted to vary only the speed of the treadmill.

Physical activity. A four-item scale was used at all four data collection time points.[50] Leisure time physical activity level was operationalized as: No physical activity (scored as 1); Only light physical activity/weekly; Vigorous physical activity at least 20 minutes once or twice weekly; Vigorous physical activity at least 20 minutes three or more times weekly (scored as 4).

Sedentary behavior. Hours of television watched on the prior Saturday was used as a proxy for sedentary behavior.

Data analysis

Because there is no ideal single field measure of body fat loss and redistribution, the study was powered at 80% to detect, at the 95% confidence level (CI), changes in three separate and complementary primary outcome measures, BMI, BIA, and WHR, with Bonferroni correction for multiple outcomes. The nominal alpha per test is, therefore, 0.017. We used effect size estimates from somewhat similar studies in the literature for these three primary outcome measures and found that the outcome measure, BMI, required the largest sample size to detect the hypothesized intervention effect at 1 year; that is, 144 subjects are required per group. The other two primary outcomes, BIA and WHR, required only 125 and 60 subjects per group, respectively. Consequently, a preliminary total sample size of 288 was chosen to provide sufficient statistical power to detect as small an intervention effect as 1.2 kg/m^2 in the BMI outcome measure. This sample size is conservative because with repeated measures analyses, we reduce the between-group error terms and, thereby, produce more powerful tests of the hypotheses. The final total sample size of 360 allowed for 20% study attrition over the 1-year observation period.

BMI was used because it is associated with minimal measurement error and is used extensively as a change indicator but is relatively insensitive to body composition changes, particularly in the studies of exercise adoption that include resistance training. BIA and WHR were chosen because they are more sensitive indicators of fitness-related lifestyle change, assessing different aspects of body composition, that is, body fat percentage and body fat distribution, respectively. Both are subject to greater measurement error in women as a result of variation in subject hydration and menstrual cycle timing. At the time of study conceptualization, however, a National Institutes of Health (NIH) consensus panel report had just been released, concluding that BIA is a reliable method for estimating percent body fat in healthy adults.[51] WHR, in particular, was selected because increasing exercise is known to disproportionately decrease central adiposity.[51]

Prior to proceeding with analyses, we conducted distributional checks to identify outliers. When outliers were identified, we first verified to ascertain whether clerical error was involved, referring back to the raw data. Outliers were discarded only if they had impossible values. To explore longitudinal trends as a first pass prior to modeling, we used paired *t* tests on the subsample of participants with data at all four assessment points to conduct a time trend analysis of the significance of changes from baseline.

We used mixed effects models to analyze the data because the repeated measurements over time on each subject are correlated and allow regression coefficients to vary across subjects.[52] Thus, some parameters in our regression model are fixed, and some are random. Age and educational attainment were chosen as covariates because these characteristics are known to substantively influence intervention effects.[28] We used mixed effects model linear regression,[53] with age and educational attainment as fixed effects, and intercept, time as a random effect. Although we treated these covariates as fixed effects, participant-specific effects were modeled by treating them as random. Models were estimated using a maximum likelihood procedure that takes missing data into account. No substantial differences emerged in the several resulting models for the random effects covariance matrix. We chose for the analyses presented below the simplest covariance structure that permitted use of variable follow-up periods. For the fixed effects, no intercept was estimated in order to facilitate interpretation.

Once the final model was obtained, hypotheses were tested through contrasts. Each contrast was estimated at time points 0, 2, 6, and 12 months. Estimated contrasts focused on differences between the intervention and control groups and within-group changes over time. Data were analyzed using the Statistical Analysis System, version 8.2 and using STATA, version 7.0.

RESULTS

Sample composition

Following the practice of other community-based lifestyle intervention trials, only those participating in at least one class session were included in the analyses ($n = 366$).[54] Of 192 women tentatively randomized to the control condition, 14 (7.3%) failed to attend a single class; of 197 women tentatively randomized to the intervention condition, 9 (4.6%) failed to attend a single class. This difference was not statistically significant; that is, there was no differential attrition between groups prior to full study enrollment. Comparisons of baseline data on these 23 women revealed no significant differences between them and the 366 participants.

The early and unanticipated success of the recruitment strategies in generating prospective participants outstripped the capacity of the scheduled classes to enroll them.[45] Some participants, therefore, had to wait more than 2 months (3–7 months) before enrolling in classes and receiving their free gym membership. In some instances, lack of an immediate match between the participant's availability and the availability of a class for her experimental condition delayed enrollment. This may have explained some of the 23 aforementioned prospective participants' loss of interest or unavailability to participate by the time their assigned class was set to begin. The time elapsed between baseline measurement and attendance at the first class varied among respondents, but this variability was unrelated to

TABLE 2. DESCRIPTIVE STATISTICS FOR FULLY ENROLLED STUDY PARTICIPANTS AT BASELINE[a]

	Control condition					*Intervention condition*				
Variable	n	*Minimum*	*Maximum*	*Mean*	*SD*	n	*Minimum*	*Maximum*	*Mean*	*SD*
Age at baseline (years)	165	23	77	46.52	10.10	183	21	73	44.56	10.82
Household income[b]	169	1	6	3.02	1.31	184	1	6	3.09	1.39
How many years of education have you had? (20 years maximum)[c]	173	10	20	14.98	2.16	186	12	20	15.06	2.24
Total time to cover 1 mile at baseline (min)	169	8.72	38.67	20.23	3.82	178	9.27	31.50	20.21	3.93
Height (m)	178	1.50	1.91	1.66	0.07	188	1.47	1.93	1.66	0.07
BMI (kg/m^2)	175	17.58	48.43	30.81	6.51	187	19.26	50.48	29.72	6.36
Weight (kg)	175	40.86	148.91	85.09	19.26	187	51.30	149.82	82.07	18.78
Maximum lifetime weight (kg)	172	45.85	167.07	87.07	20.86	183	52.21	148.00	85.57	19.13
Average waist circumference (cm)	174	58.33	132.33	91.96	14.57	185	63.33	137.33	89.21	15.67
Average hip circumference (cm)	173	77.67	149.00	112.75	12.54	185	85.00	159.67	111.36	12.66
Average WHR	173	0.65	1.13	0.81	0.08	185	0.63	1.11	0.80	0.08
Body fat percent by bio-electrical impedance	163	22.80	51.69	38.04	8.46	177	19.91	52.79	36.25	8.77
Average systolic blood pressure (mm Hg)	173	94	170	124.10	15.10	182	90	180	121.76	17.65
Average diastolic blood pressure (mm Hg)	173	40.5	100	73.95	9.40	181	38.5	102	73.90	10.79
Physical activity level[d]	173	1	4	2.56	0.967	185	1	4	2.57	0.965
TV watching (hours)	170	0	15	2.90	2.59	186	0	10	2.65	2.09

[a] *n* varies due to random missing data.
[b] Household income included the following categories: (1) <\$20,000, (2) \$20K–\$39K, (3) \$40K–\$59K, (4) \$60K–\$79K, (5) \$80K–\$99K, (6) ≥\$100K.
[c] Educational attainment: 12 = high school, 16 = B.A., 18 = M.A., 19 = J.D., 20 = Ph.D. or M.D.
[d] Physical activity level self-reported on 4-item scale: 1 = no PA, 2 = only light PA weekly, 3 = vigorous PA ≥ 20 minutes 1–2 times/week, 4 = vigorous PA ≥ 20 minutes 3 or more times/week.

experimental assignment. For simplicity of presentation of these analyses, we have not shown data corrected for the varying latency between baseline assessment and enrollment date, although women who began classes within 2 months of baseline data collection exhibited greater weight losses and lesser weight gains.

Contacting participants and completing the assessments often required repeated attempts and rescheduling of a number of missed appointments. As indicated in the Data analysis section, and fairly typical of intervention studies with large samples and long follow-up periods, not all assessments were completed on all subjects, and there was considerable variability in the intervals between the repeated measures.

Of the resulting study sample, 188 were assigned to the intervention condition and 178 to the control condition. The proportion of classes attended was associated with experimental condition (control mean = 87% of classes, intervention = 80% of classes; $t(364) = 3.33$; $p < 0.001$). More than 70% of study participants were retained in the study at 12 months follow-up.

Baseline characteristics of the study participants are shown in Table 2. On average, the women were in their mid-40s, had completed 3 years of college, earned moderate incomes, and were, on average, obese. Comparing the baseline characteristics of the participants randomly assigned to the experimental condition with those in the control condition showed that they had a marginally lower percentage of body fat (mean = 36.3 and 38.0, respectively; $t(338) = 1.91$; $p = 0.057$) that did not quite reach statistical significance. Other variables did not differ significantly between the two experimental groups, including medication usage prevalence (27%–32%) and chronic disease diagnoses.

Bivariate analysis: Time trend assessment

Time trend analyses of the primary and secondary outcome measures and physical activity mediating variable of the 139–166 participants (37%–46% of the sample) on whom we obtained data at all four assessments are presented in Table 3.

Body weight and composition. Within-group longitudinal analysis revealed a trend toward weight stability in the intervention group at 2 months compared with controls (+0.05 kg/m^2, $p = 0.75$; +0.32 kg/m^2, $p = 0.08$, respectively), with both groups significantly heavier at 12 months (+1.37 kg/m^2, $p = 0.0001$; +1.02 kg/m^2, $p = 0.001$, re-

Table 3. Time Trend Analysis for Participants with Data at All Assessment Points

Measure[a]	*Experimental conditions*	*Sample size*	*Baseline*	*2 months*	p[c]	*6 months*	p	*12 months*	p
BMI	C	75	30.05	30.37	0.08	30.34	0.22	31.07	0.001
	I	91	29.11	29.16	0.76	29.51	0.03	30.48	<0.0001
Weight	C	79	82.66	82.94	0.36	82.68	0.93	83.29	0.28
	I	92	81.47	81.21	0.38	81.49	0.95	83.38	0.0002
BIA	C	76	34.49	34.72	0.60	34.08	0.44	34.91	0.40
	I	88	33.70	33.84	0.82	33.70	0.99	34.05	0.49
Waist	C	78	90.79	91.02	0.90	91.05	0.86	91.36	0.70
	I	91	87.68	88.11	0.42	88.24	0.32	90.35	<0.0001
WHR	C	78	0.81	0.82	0.58	0.81	0.76	0.81	0.77
	I	91	0.78	0.80	0.05	0.79	0.21	0.80	0.02
Fitness	C	61	19.82	17.32	<0.0001	17.33	<0.0001	17.52	<0.0001
	I	72	19.89	17.34	<0.0001	17.72	<0.0001	18.01	<0.0001
PA	C	75	2.67	2.84	0.06	2.83	0.18	2.72	0.59
	I	92	2.79	3.25	<0.0001	3.02	0.04	2.86	0.63
TV	C	72	2.85	2.56	0.21	2.56	0.31	2.36	0.10
	I	92	2.54	2.52	0.92	2.26	0.21	2.40	0.55

[a]BMI, body mass index (kg/m^2); Weight, body weight (kg); BIA, bioelectrical impedance assessment (% body fat); Waist, waist circumference (cm); WHR, waist/hip ratio; Fitness, 1 mile run-walk (min); PA, self-reported physical activity (Likert scale); TV, duration of television watching on the prior Saturday (hours).

[b]C, control; I, intervention.

[c]*p* values are associated with paired *t* tests, comparing change from baseline to 2 months, baseline to 6 months, and baseline to 12 months, respectively.

spectively) (Table 3). Baseline BMI was a significant predictor of weight gain, indicating that the women who gained the most weight were those whose BMI was greatest at baseline ($p < 0.0001$). The only other differential impact on BMI change by weight status observed over time was among nonobese control participants. Their increase in BMI was significantly less at 12 months than that of their obese counterparts (0.46 kg/m^2 vs. 1.32 kg/m^2, respectively; $t = -2.0419$; $p = 0.045$) but still a significant increase from baseline ($t = 2.1832$; $p = 0.025$). Nonobese and obese intervention participants' BMI increases at 12 months were not significantly different (0.85 kg/m^2 vs. 1.04 kg/m^2, respectively; $t = 0.621$; $p = 0.529$).

Weight change patterns were similar. On average, 57% of intervention participants lost weight (>5 lbs) or maintained their weight (+5 lbs) at 2 months compared with 43% of controls ($p = 0.05$). By 12 months, 42% of intervention women and 36% of controls had lost or maintained their weight ($p = 0.08$) (Fig. 2).

With regard to waist circumference, however, the control group exhibited consistently minimal increases in contrast to larger increases experienced by the intervention group. The widening differences between groups culminated in a significant increase in central adiposity for the intervention group at 12 months, with no significant increase in the control group (+2.67 cm, $p = 0.0001$; +0.57 cm, $p = 0.70$, respectively). WHR similarly reflected this experimental contrast.

Estimates of body fat percentage did not change significantly with time in either experimental condition.

Cardiorespiratory fitness. Within-group longitudinal analysis demonstrated that intervention and control participants' fitness levels (1 mile run-walk times) improved by 1.9 minutes ($p = 0.0001$) and 2.3 minutes ($p = 0.0001$), respectively, at 12 months. The postintervention decay, however, was significantly less marked in the control group than in the intervention group at 6 months (t_{diff} (512) = 3.13, $p = 0.002$); the difference between conditions disappeared by 12 months (t_{diff} (696) = −1.66, $p = 0.10$).

Physical activity and sedentary behavior. Physical activity levels increased significantly from baseline only among intervention participants ($p < 0.0001$ and $p = 0.04$ at 2 months and 6 months, respectively).

Control participants demonstrated a trend toward decreasing TV viewing that approached significance at nearly $^1/_2$ hour by 12 months ($p = 0.10$) compared with intervention participants' 8 1/2-minute decrease ($p = 0.55$).

Multivariate analyses: Linear mixed effects modeling

Body weight and composition. Consistent with the time trend analysis, there was a marginally significant main effect of the intervention on BMI at 2 months (+0.033 kg/m^2 vs. +0.093 kg/m^2; $p = 0.057$), which disappeared by 6 months and remained nonsignificant at 12 months. Similarly, both intervention and control groups were significantly heavier than baseline at 12 months (+1.20 kg/m^2, $p = 0.0000$; +1.02 kg/m^2, $p = 0.0000$, respectively) (Figs. 2 and 3).

Multivariate analyses confirmed the stability of central adiposity in the control group at 12 months (+1.1 cm, $p = 0.2763$) compared with a significant increase in waist circumference among intervention participants by 12 months (+2.1 cm, $p = 0.0002$). There was no experimental effect on body fat percentage either between or within groups.

Cardiorespiratory fitness. There was a significant main effect of the intervention on fitness at 2 months ($p = 0.0185$), disappearing by 6 months and remaining nonsignificant at 12 months. Both intervention and control groups significantly decreased their 1 mile run-walk times at 2, 6, and 12 months compared with baseline (−2.81 minutes, −2.34 minutes, −1.97 minutes, $p = 0.0000$, for the baseline–12-month comparison; −1.64 minutes, −2.21 minutes, −2.20 minutes, $p = 0.0000$, for the baseline–12-month comparison, respectively). However, the control group displayed steady improvements between baseline and 6 months, with no erosion at 12 months, whereas the intervention group achieved its maximal improvement postintervention, decaying thereafter (Fig. 4).

Physical activity and sedentary behavior. There was a significant main effect of the intervention on physical activity at 2 months ($p = 0.0148$), remaining marginally significant at 12 months ($p = 0.058$). No significant differences in TV viewing were observed either within or between groups, although the trend toward a reduction in the con-

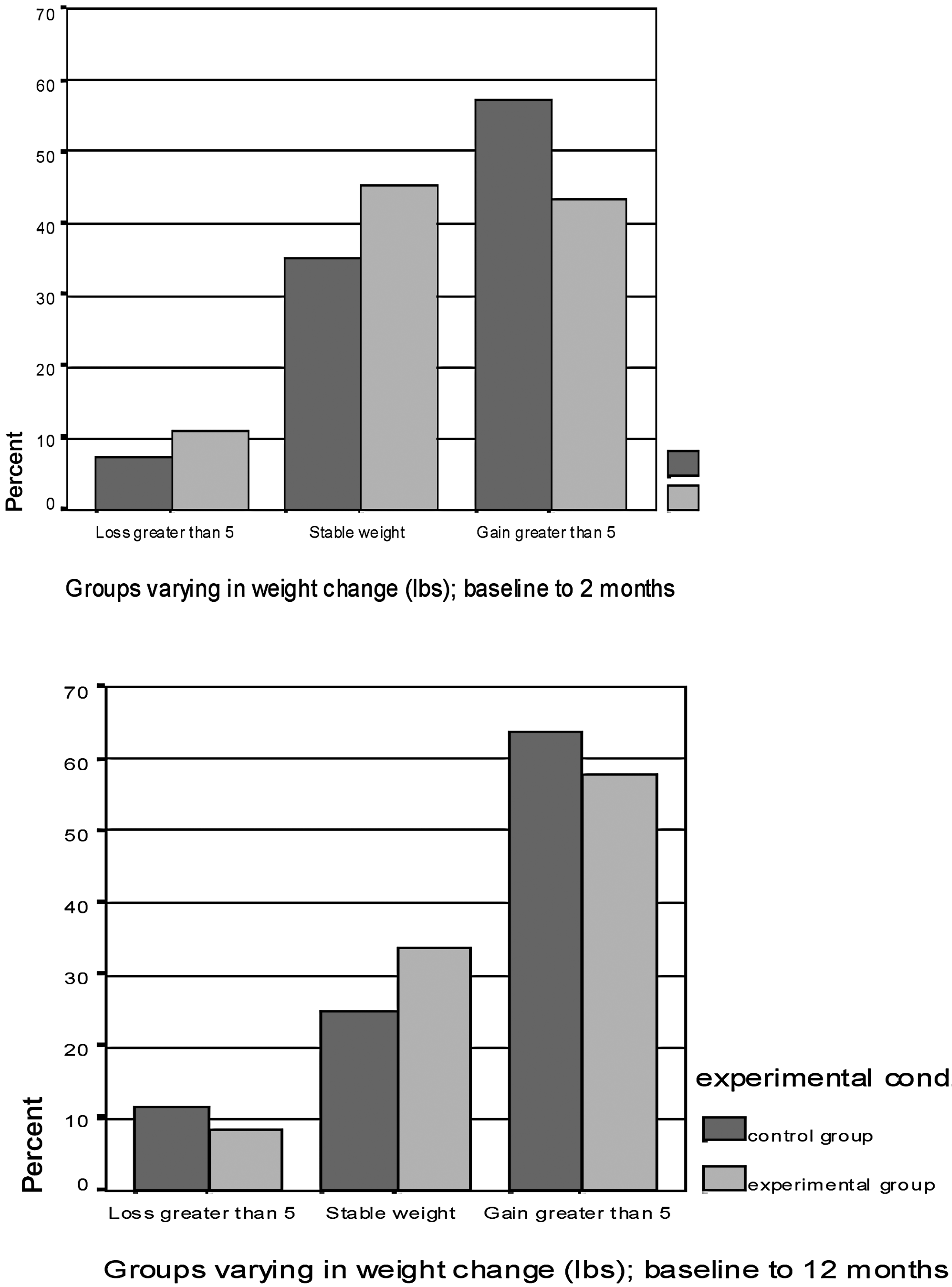

FIG. 2. Comparing weight change for the intervention and control conditions at 2 and 12 months follow-up.

trol group's TV time, previously identified in the time trend analysis, was apparent (−0.13 hour, $p = 0.697$; −0.45 hour, $p = 0.125$, respectively) (Fig. 5).

DISCUSSION

The results of this study mirror those of fitness-related lifestyle change interventions engaging

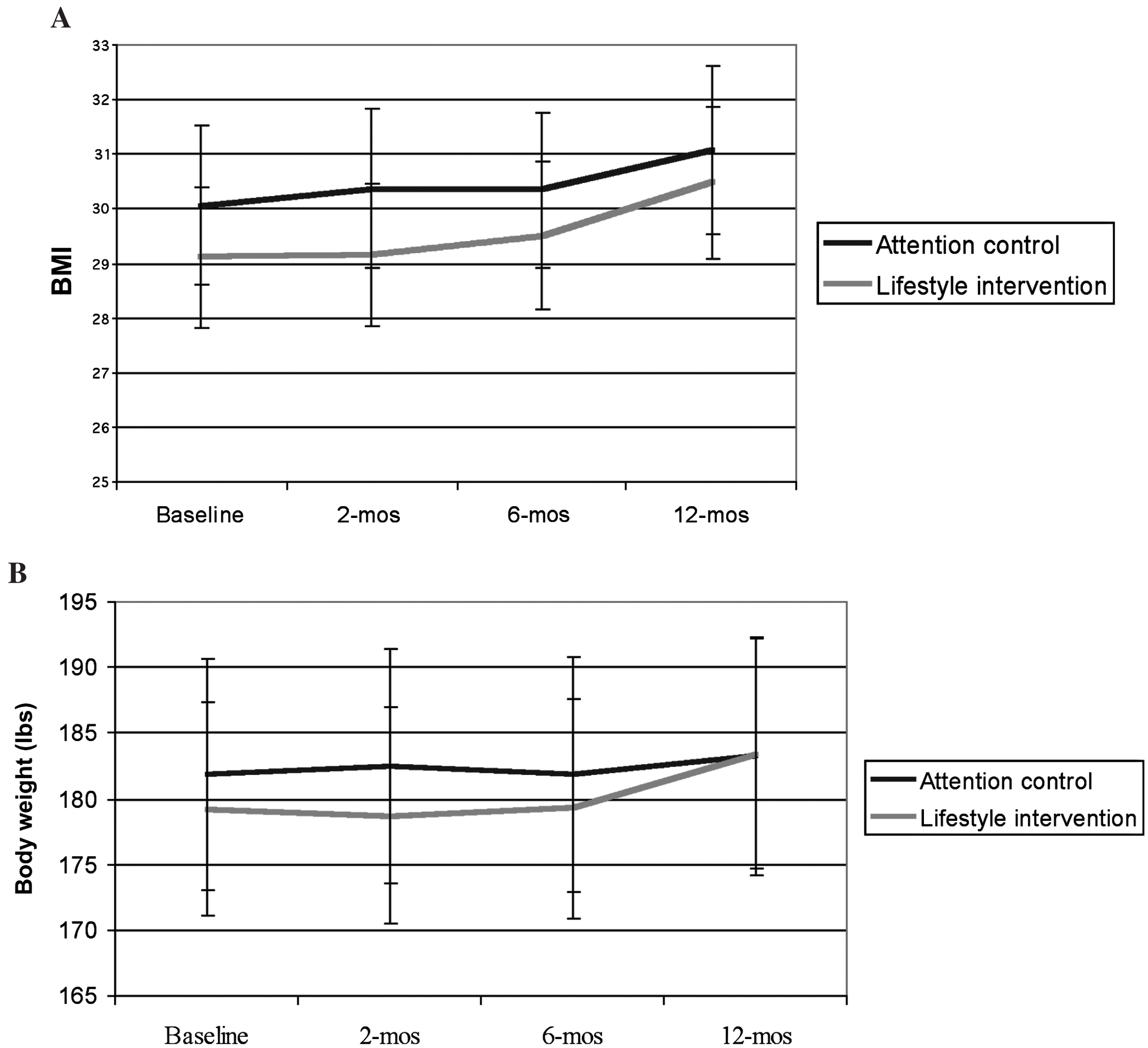

FIG. 3. (**A**) Mean BMI over four assessments, by condition. Total n = 171 (92 intervention and 79 control) for those respondents having no missing values for all weight assessments. Pattern is similar to that tested in the mixed effects regression but includes fewer repsondents because only those respondents with no missing values for all weight assessments were included. (**B**) Mean weight over four assessments, by condition. Total n = 171 (92 intervention and 79 control) for those respondents having no missing values for all weight assessments. Pattern is similar to that tested in the mixed effects regression but includes fewer respondents because only those respondents with no missing values for all weight assessments were included.

predominantly white women: significant but modest changes immediately postintervention, decaying with time thereafter. Research subjects under both conditions derived anthropometric and physiological benefits from their participation, especially during the active intervention phase. Participants in the intervention condition experienced a broader spectrum of early favorable changes in overall fitness (including body composition) than did participants in the control condition. However, longer-term improvements favored the control participants. Their fitness levels gradually improved over time and stabilized, whereas those of intervention participants declined from their postintervention peak at 2 months. Controls also succeeded in defying aging-related (and, perhaps, secular) trends of increasing central adiposity with time, whereas intervention participants succumbed to those trends with significant increases in waist circum-

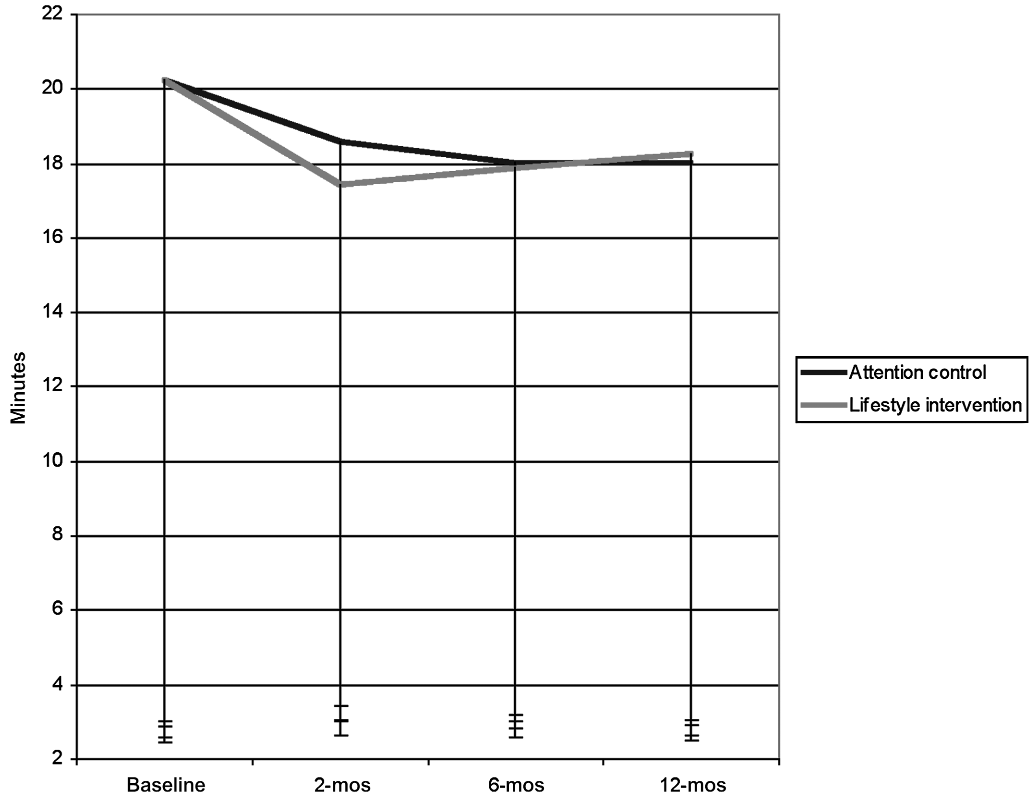

FIG. 4. Fitness: 1-mile run-walk times, by experimental condition.

ference after a year. Although many, if not most, of the participants may have had weight loss as an intended goal of participation, weight loss was not the focus of the intervention, nor was it featured in the marketing and promotion used to recruit participants.[44] Rather, the overall health, and specifically cancer-protective, benefits of increasing physical activity and fitness and of a nutritious diet were emphasized.

In contrast to most lifestyle change studies, a substantive economic environmental intervention was offered to participants in both conditions, namely, the incentive of a free gym membership. Although this incentive was selected to prevent the overall and differential attrition attendant to most lifestyle change interventions in ethnic minority populations and to create a level playing field in terms of access to exercise facilities, it was likely a more sustainable intervention in the long term than the educational and social support experimental condition.

In addition, the similarities of this attention control condition to the intervention condition (presentation of ethnic-specific data, fostering rapport and social support between participants through group delivery in cohorts, interactive educational approach using multimedia ethnically targeted materials, inclusion of ethnically matched guest, and staff role models) likely constituted a more substantive social environmental intervention than the social support intervention component in the experimental contrast (free membership for female friend or family member).

Thus, the control group's study benefits were more sustained than those of the intervention group, although they took longer to achieve in the absence of the content-specific intervention. It is possible that the initiative involved in having to figure it out for themselves produced more individually tailored and relevant change strategies that were more sustainable. The minor differences between conditions may also be attributable to dietary influences, but that discussion is beyond the scope of this paper. It is likely that a second experimental contrast with secular trends in this population (null control) would have permitted demonstration of a more substantial experimental effect of the intervention package (educational, social, and economic) on overall fitness, particularly central adiposity and

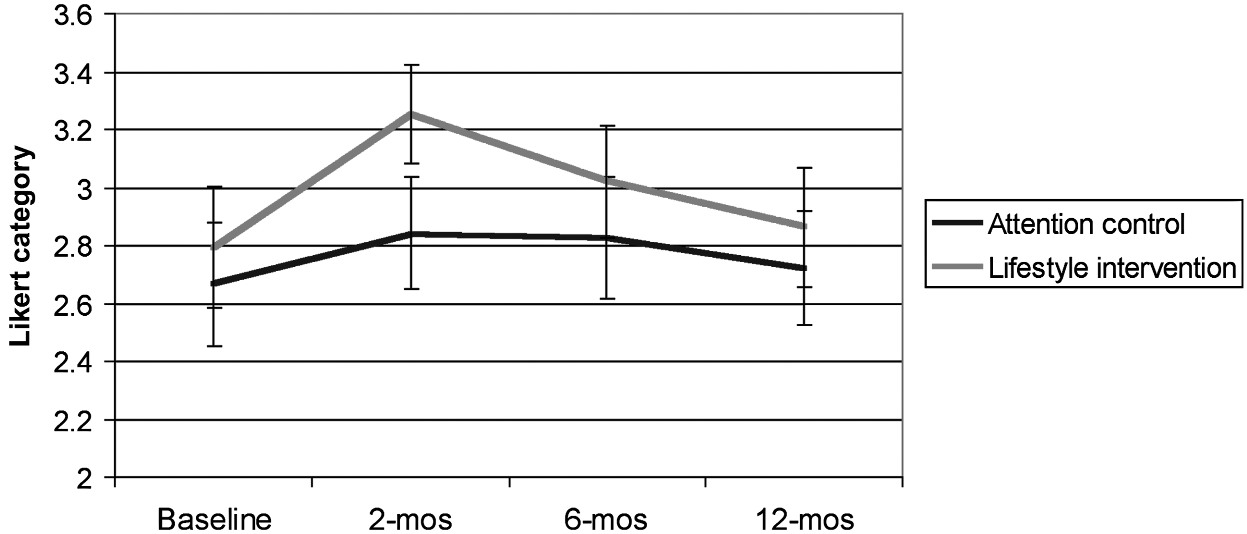

FIG. 5. Self-reported physical activity level, by experimental condition.

cardiorespiratory fitness. An attention control condition that did not include a gym membership incentive would likely also have enhanced the experimental contrast, if attrition could have been prevented by other means.

The effects of the study may have been understated because our unanticipated recruitment success meant that a substantial portion of the sample had their baseline data collected 3–7 months before beginning classes. As noted earlier, those whose data were collected within 2 months of their attendance at the first class lost more/gained less weight, suggesting that the longer delays were associated with more weight gain, and, thus, their true preintervention baseline weights were higher than the ones recorded for them. Because participants with longer delays were essentially evenly divided between intervention and control groups, this probably did not influence the magnitude of the experimental effect but may have affected the magnitude of changes in body composition from baseline for both groups. This is one explanation for why the increase in cardiorespiratory fitness in both groups from baseline to 12 months was not paralleled by significant decreases in BMI, body fat percentage, or waist circumference from baseline. Alternatively, the stabilization of waist circumference in the control group and increased cardiorespiratory fitness in both groups may reflect the influence of moderate increases in physical activity, without marked changes in energy balance.

The inclusion of strength or resistance training as a key component of the intervention sessions is consistent with our likely outcome of exercise-induced gains in muscle mass at the expense of body fat, with no substantial weight change. Given the study incentive of the free gym membership and the novelty of weight training for many women at that time, participants in both conditions may have preferentially engaged in resistance activity vs. the more monotonous and perhaps demanding aerobic activity. (One other consideration was that the treadmills, which most women seemed to prefer to exercise cycles, elliptical cross-trainers, and stair climbers/aerobic steppers, were more continually occupied and, therefore, less accessible during peak attendance periods at this gym.) The improvement in fitness in both groups over the 12-month period in the face of weight gain could reflect higher levels of resistance training than aerobic activity. Unfortunately, electronically gathered utilization data from the health club for study participants was not available. Thus, we lost the opportunity to ascertain, for example, if increased gym attendance during the course of the year was more closely correlated with body composition changes than cardiorespiratory fitness changes (taking into account physical activity changes).

This study has additional limitations. Although there is merit in attempting to determine if there was a differential benefit of the intervention condition or a benefit of both conditions (commensurate with the effect on fitness) in ameliorating central adiposity, measurement error may have impeded our ability to detect significant changes. Evaluation staff found it difficult to consistently identify the smallest and largest circumferences on the trunks of the mostly overweight/obese women. It is also likely that some women lost fat in both the waist and hip areas, retaining the same WHR, which would explain the significant finding for waist circumference but not for WHR. In summary, it was prudent to use multiple measures to assess the influence of the intervention on body composition, but it is not surprising that study effects on these parameters were modest.

Other limitations or constraints should be noted as well. The physical activity and inactivity measures were crude. Instruments more sensitive to intervention change now have demonstrated reliability and precision. However, the methodology of physical activity assessment at the time of study inception in 1996 was in some flux as a result of the recently released changes in physical activity recommendations by the Centers for Disease Control and Prevention (CDC)/American College of Sports Medicine (ACSM)[29] and subsequently by the U.S. Department of Health and Human Services (DHHS), and sedentary behavior assessment was even less developed. These suboptimal measures and our failure to capture gym use constrain our disentangling the influences of resistance vs. aerobic exercise, or increased physical activity vs. decreased sedentary behavior, on our outcomes. Part of the experimental intervention was to have featured cooking demonstrations and samplings of healthy, tasty, and culturally compatible foods in the juice bar and kitchen. The gym proprietors effectively dismantled the kitchen, unfortunately, by the time of intervention initiation. This rendered the nutrition education component of the intervention relatively weak, without the opportunities for experiential learning (e.g., skills modeling, development, and rehearsal) of the exercise component and decreasing the likelihood of favorable changes in body composition. In addition, our 6-month retention was lower than at the 12-month assessment because of a bureaucratic error in the university accounting department that delayed mailing of the $50 incentive payment. (We addressed this by supplying the checks on-site immediately on completion of the 12-month assessment.)

Unfortunately, these latter issues underscore the many challenges of working in ethnic minority communities.[29] The very collaborations, such as the public-private partnership with a small minority-owned business established here, that facilitate seamless recruitment, intervention delivery, and study retention are fraught with unanticipated challenges threatening the integrity of the study. Gains in external validity often compromise internal validity. In fact, the gym closed for business within 1 month of our completing the 12-month assessments on our last study cohort of 60 women. The tenure of small, minority-owned businesses is not long in large, high cost-of-living urban areas. The gym's viability for the entire, nearly 8-year duration of the EECL and Fitness Funatics[29] (predecessor) and FCF studies was fortuitous because there was no comparable health club (marketed and promoted through media, decor, and staff training to women; diverse with regard to ethnicity and age; black-owned; located centrally to the city's black communities, given the substantial ethnic segregation of even affluent blacks compared with Latinos and Asian Americans) in Los Angeles at that time.

The findings of this study underscore the need for multilevel social ecological intervention, i.e., organizational practice and legislative policy changes targeting the physical and sociocultural environments, as well as educational and economic ones targeting the individual, particularly in underserved populations with many barriers to active leisure participation.[55] These findings also have health policy implications in that a commonly identified obesity control policy is employer-subsidized or medical care insurer-subsidized health club memberships. FCF data suggest that among highly motivated women (i.e., our middle-income study volunteers), a free membership can produce only very modest sustainable changes in overall fitness and physical activity at best. The likelihood, then, that lower-cost memberships alone will produce sustainable change in the much less motivated and affluent individuals comprising the general population is remote. This parallels evidence from the worksite fitness intervention literature that on-site fitness facilities and physical activity programs are used primarily by leaner, already less sedentary men.[56,57]

Perhaps another substantive achievement of this project was to demonstrate that a large sample of a heretofore difficult to reach population, namely, healthy (at least, asymptomatic), adult African American women could be successfully recruited to an ambitious 8-week lifestyle change program[44] and followed for 12 months with an acceptable 70%–72% retention rate. Future investigations of the potential health impact of lifestyle change programs targeted to healthy African American women can build on these findings to further illuminate the factors governing effective recruitment and retention and the major influences on fitness-related lifestyle change in this understudied population. However, our obesogenic, or obesity-producing, postmodern environment undermines any progress that might be achieved through individual level interventions (those aimed primarily at inducing changes in the individual) without the corresponding institution of structural or systemic changes in that individual's social, physical, or economic environments. Practical strategies for ameliorating the obesogenic features of today's environment must be a focus of research and policy attention, particularly in underserved communities.

CONCLUSIONS

This multilevel, culturally targeted lifestyle change intervention succeeded in recruiting a large sample of 366 predominantly overweight, middle-income African American women and retaining them through 1 year of follow-up assessment at a level sufficient to lend reasonable confidence to the results. The intervention produced significant, modest, but mostly short-lived improvements in overall fitness. The experimental contrast did not permit a test of the apparently more potent intervention component, the economic incentive of a free gym membership, which was offered to all study participants. However, this incentive was likely a key ingredient in the success of the recruitment, intervention delivery, and retention of this high-risk, underserved, and understudied population.

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