EDENTARY HABITS ACCOUNT FOR A substantial portion of deaths due to coronary heart disease,1,2 type 2 diabetes,3,4 and colon cancer.5 In 1992, the American Heart Association named physical inactivity as an independent risk factor for cardiovascular disease (CVD).6 Accumulating evidence also indicates that an active and fit way of life helps preserve functional ability and maintain independent living in older adults.7 Despite these documented benefits of exercise, fewer than one fifth of US adults engage in regular, sustained, vigorous exercise; this fraction has not increased since the mid-1980s.8

Understanding the causes of inactivity may help in developing effective programs to increase the number of those who are inactive or inadequately active to meet public health recommendations of 30 minutes or more of moderate-intensity physical activity on most, preferably all, days of the week.8,9 Barriers include lack of time, lack of social support, inclement weather, disruptions in routine, lack of access to facilities, and dislike of vigorous exercise.10 Lifestyle programs that encourage accumulating moderate-intensity physical activity through increasing behavioral skills associated with adopting and maintaining activity have been advocated

Context Even though the strong association between physical inactivity and ill health is well documented, 60% of the population is inadequately active or completely inactive. Traditional methods of prescribing exercise have not proven effective for increasing and maintaining a program of regular physical activity.

Objective To compare the 24-month intervention effects of a lifestyle physical activity program with traditional structured exercise on improving physical activity, cardiorespiratory fitness, and cardiovascular disease risk factors.

Design Randomized clinical trial conducted from August 1, 1993, through July 31, 1997.

Participants Sedentary men (n = 116) and women (n = 119) with self-reported physical activity of less than 36 and 34 kcal/kg per day, respectively.

Interventions Six months of intensive and 18 months of maintenance intervention comparing lifestyle and structured activity groups, respectively. Neither group significantly changed their weight (−0.05 [95% CI, −1.05 to 0.96 kg; P = .93]) and 0.69 [95% CI, −0.37 to 1.74 kg; P = .20])

Results Both the lifestyle and structured activity groups had significant and comparable improvements in physical activity and cardiorespiratory fitness from baseline to 24 months. Adjusted mean changes (95% confidence intervals [CIs]) were 0.84 (95% CI, 0.42-1.25 kcal/kg per day; P < .001) and 0.69 (95% CI, 0.25-1.12 kcal/kg per day; P = .002) for activity, and 0.77 (95% CI, 0.18-1.36 mL/kg per minute; P = .01) and 1.34 (95% CI, 0.72-1.96 mL/kg per minute; P < .001) for VO2peak for the lifestyle and structured activity groups, respectively. There were significant and comparable reductions in systolic blood pressure (−3.63 [95% CI, −5.54 to −1.72 mm Hg; P < .001] and −3.26 [95% CI, −5.26 to −1.25 mm Hg; P = .002]) and diastolic blood pressure (−5.38 [95% CI, −6.90 to −3.86 mm Hg; P < .001]) and 5.14 (95% CI, −6.73 to −3.54 mm Hg; P < .001) for the lifestyle and structured activity groups, respectively. Neither group significantly changed their weight (−0.05 [95% CI, −1.05 to 0.96 kg; P = .93] and 0.69 [95% CI, −0.37 to 1.74 kg; P = .20]), but each group significantly reduced their percentage of body fat (−2.39% [95% CI, −2.92% to −1.85%; P < .001]) and −1.85% [95% CI, −2.41% to −1.28%; P < .001]) in the lifestyle and structured activity groups, respectively.

Conclusions In previously sedentary healthy adults, a lifestyle physical activity intervention is as effective as a structured exercise program in improving physical activity, cardiorespiratory fitness, and blood pressure.
as an alternative to vigorous fitness center–based exercise overcome these barriers.11,12

In this article, we compare the 24-month effects of a lifestyle physical activity program designed to help participants overcome activity barriers with a traditional structured exercise program. We hypothesized that a behaviorally based lifestyle physical activity intervention, in which individuals increase moderate-intensity physical activity as part of their daily routines, would result in higher levels of physical activity and cardiorespiratory fitness at 24 months compared with baseline and that these levels of physical activity and fitness would be higher in the lifestyle group when compared with a traditional structured fitness center–based intervention. A secondary aim of this study was to compare changes in CVD risk factors from baseline to 24 months and between lifestyle and structured physical activity interventions.

**METHODS**

**Study Participants and Design**

The study protocol for this trial (known as Project Active13) was conducted from August 1, 1993, through July 31, 1997, and approved annually by the Cooper Institute Institutional Review Board, Dallas, Tex. Each participant gave written informed consent prior to testing and again prior to randomization. The sample size was calculated to detect a 3-mL/kg per minute or 2-kcal/kg per day difference between treatment groups at the end of 24 months, and was based on a 24-month intervention of home-based structured exercise in sedentary adults13 that produced a 10% increase in peak oxygen consumption (VO2peak) or approximately 3 mL/kg per minute. An energy expenditure of 2 kcal/kg per day is 150 kcal/d for a 75-kg person or about 1000 kcal/wk (≈16 km of brisk walking for 1 week), and is the amount of exercise recommended in *Physical Activity and Health: A Report of the Surgeon General.*8 It is estimated that this amount of increased physical activity would be adequate to move sedentary, low-fit individuals from the highest risk category into the moderately active, moderately fit category.8 In addition to these effect sizes, we also anticipated a 15% annual dropout rate, yielding 90% power at a .05 level of significance. Based on these parameters, the recruitment goal was determined to be 210 participants.

Study participants were 235 healthy sedentary men (n = 116) and women (n = 119) aged 35 to 60 years who lived or worked within a 16-km (10-mile) radius of our center. They were randomized to either a lifestyle physical activity program or a structured exercise program (Figure 1). Participants were recruited in 3 cohorts, randomized at 6-month intervals. Exclusion criteria were (1) self-reported history of myocardial infarction, stroke, type 1 diabetes mellitus, osteoporosis, and osteoarthritis (if it limited mobility); (2) weight more than 140% of ideal body weight; (3) plans to move from the local area during the study period; (4) 3 or more drinks of alcohol daily; (5) exercising at least 3 days a week for 20 minutes or more or having an estimated total energy expenditure exceeding 36 kcal/kg per day (men) or 34 kcal/kg per day (women)15; (6) blood pressure of 160/100 mm Hg or more; (7) use of medication (such as β-blockers) that could impair exercise performance; and (8) for women, plans to become pregnant in the next 2 years.

**Clinical Measurements**

Following telephone screening, eligible participants were invited to an orientation session to obtain written informed consent and determine baseline physical activity using the 7-Day Physical Activity Recall (PAR).13 The PAR estimates total energy expenditure by asking participants to recall the amount of time spent in sleep and in moderate, hard, and very hard activities during the previous 7 days and multiplying time in each category by an established MET value (1 MET is the metabolic equivalent at rest; moderate-intensity activities are 3-6 times greater, or 3-6 METs). Reliability and validity of the PAR have been established and have been summarized by Pereira and colleagues.13 One experienced interviewer conducted 95% of all PAR measurements. We also determined the convergent validity of the PAR with concurrent temporally matched data from the Tritrac R-3D (Hemokinetics Inc, Madison, Wis) activity monitor in a subset of participants (n = 33) at 24 months. Correlations between estimated total energy expenditure from the PAR and the

![Figure 1. Participant Flow](image-url)
proposes that individuals differ in their motivational readiness for change. They may be (1) not intending to change, (2) intending to change, (3) making small changes, (4) meeting a behavior change criterion (eg, meeting public health recommendations of accumulating ≥30 minutes of moderate-intensity activity on most days of the week), or (5) sustaining the change over time. Fundamental to the model are 10 cognitive and behavioral strategies to help people progress from lower to higher levels of motivational readiness. These 10 skills include 5 cognitive strategies aimed at changing ways of thinking and 5 behavioral strategies aimed at increasing specific behaviors. This model was used in both groups, and its implementation is described more completely elsewhere.13,26

**Intervention Procedures.** Participants in both groups received 6 months of intensive intervention and 18 months of maintenance intervention. The physical activity goal for both groups at 6 months was to increase energy expenditure by 3 kcal/kg per day and increase fitness (VO2peak) by 5 mL/kg per minute, then to maintain an increase in physical activity of 2 kcal/kg per day and 3 mL/kg per minute at the end of 24 months.

Participants randomized to the structured exercise group received a traditional exercise prescription (exercise intensity of 50%-85% of maximal aerobic power for 20-60 minutes).27 Individual supervised sessions were offered 5 days per week for 6 months at a state-of-the-art fitness center. We asked participants to initially attend at least 3 supervised sessions per week and to gradually increase to 5 days per week. Initial levels and progression of exercise dosage followed American College of Sports Medicine recommendations.27 Group leaders helped participants learn to set realistic physical activity goals, monitored their physical activity, and provided verbal reinforcement. Following 3 weeks of initial instruction and supervised exercise, structured exercise group participants chose the aerobic activities they most enjoyed and individualized their programs among all activities available at the center. Participants who failed to attend at least 1 session per week were contacted and encouraged to return to a regular schedule of exercise. During the 18-month follow-up intervention, the group met quarterly for group activities. They also received a monthly activities calendar and a quarterly newsletter on the benefits of activity and research findings related to physical activity.

Participants randomized to the lifestyle group were advised to accumulate at least 30 minutes of moderate-intensity physical activity on most, preferably all, days of the week, in a way uniquely adapted to each person’s lifestyle. They were encouraged to progress toward this goal in a manner best suited for their level of motivational readiness for change. In the format of small groups that met for an hour 1 night a week for the first 16 weeks, then biweekly until week 24, participants learned cognitive and behavioral strategies found to be related to physical activity behavior. Meetings were held in a small classroom setting and participants in this group were not provided free membership to the fitness center facilities. Group facilitators worked weekly with participants using a problem-solving approach to discuss cognitive and behavioral strategies and techniques to help them initiate, adopt, and maintain a physical activity program. Participants were assessed on Stages of Change each month and were given an intervention manual tailored for their level of readiness.23 We gave weekly home assignments aimed at enhancing behavioral skills and problem solving. During the 18-month follow-up, meetings decreased at 6-month intervals to monthly, then bimonthly, and finally tri-monthly. Group meetings consisted of a variety of activities that included a mall walk, orienteering, volleyball, and a life-size board game designed to reinforce cognitive and behavioral skills. Participants also received a monthly activities calendar and a quarterly newsletter.

**Data Analysis**
Statistical comparisons between intervention groups were made using all available data (Figure 1), with participants...
INTerventions to Increase Physical Activity and Fitness

grouped as originally randomized, regardless of the degree of intervention compliance or types of activities actually performed. We did not impute values for any missing data for participants who did not complete some clinical and laboratory measurements. At 6 and 24 months, we used analysis of covariance28 to assess changes after baseline in physical activity, cardiorespiratory fitness, blood pressure, lipoprotein levels, and body composition. The change in each clinical outcome measure was compared between interventions with adjustment for the baseline measure and for age, sex, body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters), cohort, and ethnicity. The latter covariates were selected a priori. Summary changes are reported as adjusted least squares means,29 standardizing changes are reported as adjusted least squares means,29 as already performed. We did not impute values for those few who were cigarette smokers.

RESULTS

Baseline Characteristics and Measurement Adherence

Selected baseline characteristics for the 235 participants included in the efficacy population are shown in Table 1. The mean (SD) age of study participants was 46.0 (6.6) years. All were sedentary and most were moderately overweight. The group had normal blood pressure levels and lipoprotein profiles and few were cigarette smokers.

We randomized 122 participants into the lifestyle exercise program and 115 into the structured exercise program in 3 separate recruitment cohorts at 6-month intervals. Each cohort was randomized in a 1-week period prior to the start of the intervention. During the first month of the intervention period, 1 man in the lifestyle group and 1 woman in the structured exercise group were dropped from the study because of clinical manifestation of heart disease that made their participation unsafe. These adverse events did not occur during exercise. At 6 months, 109 lifestyle group and 103 structured exercise group participants completed the examination in full or in part, and 100 and 90 participants, respectively, completed the 24-month examination in full or in part. Differences between interventions in completion rates were not significant (Figure 1).

Summary of 6-Month Results

Results after 6 months of intervention are reported in full elsewhere.26,30 Briefly, both groups significantly increased physical activity and cardiorespiratory fitness. The structured exercise group increased their cardiorespiratory fitness significantly more than the lifestyle group, but at 6 months, the groups had comparable increases in physical activity. Both groups had similar significant improvements from baseline to 6 months for ratio of total cholesterol level to high-density lipoprotein cholesterol (HDL-C) level, systemic and diastolic blood pressure, and percentage of body fat.

Major Findings at 24 Months

Primary Outcomes—Physical Activity and Cardiorespiratory Fitness. Table 2 shows changes from baseline to 24 months as least squares adjusted means, adjusted for between-intervention differences in the covariates. Both lifestyle and structured exercise groups significantly increased total energy expenditure from baseline to 24 months (P < .001 and P = .002, respectively). Components of the physical activity measure show that lifestyle-group participants increased their moderate-intensity physical activities nearly 3 times more than structured exercise group participants (P < .001 and P = .18, respectively). The structured exercise group had a more than 2-fold increase in their vigorous activities (hard and very hard) compared with the lifestyle group (P = .008 and P < .001, respectively). However, these measures were not significantly different between the 2 groups (P = .63 for moderate and P = .08 for vigorous).

Table 1. Selected Baseline Characteristics by Intervention Group*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Lifestyle (n = 121)</th>
<th>Structured Exercise (n = 114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>45.9 (6.8)</td>
<td>46.2 (6.5)</td>
</tr>
<tr>
<td>Women, %</td>
<td>50.0</td>
<td>50.9</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>83.0 (16.2)</td>
<td>82.6 (16.0)</td>
</tr>
<tr>
<td>Height, cm</td>
<td>170.6 (8.6)</td>
<td>171.1 (10.0)</td>
</tr>
<tr>
<td>Body fat, %</td>
<td>31.5 (7.9)</td>
<td>30.9 (7.2)</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>28.4 (4.1)</td>
<td>28.0 (3.8)</td>
</tr>
<tr>
<td>Energy expenditure, kcal/kg per day</td>
<td>33.1 (1.5)</td>
<td>33.0 (1.0)</td>
</tr>
<tr>
<td>VO₂peak, mL/kg per minute</td>
<td>26.8 (6.3)</td>
<td>26.5 (6.2)</td>
</tr>
<tr>
<td>Treadmill time, min</td>
<td>8.0 (1.7)</td>
<td>8.0 (1.6)</td>
</tr>
<tr>
<td>Maximal heart rate, beats/min</td>
<td>179.4 (11.4)</td>
<td>178.3 (11.8)</td>
</tr>
<tr>
<td>Resting heart rate, beats/min</td>
<td>73.6 (8.3)</td>
<td>73.4 (8.2)</td>
</tr>
<tr>
<td>Total cholesterol level, mmol/L [mg/dL]</td>
<td>5.5 (1.1)</td>
<td>212.7 (40.8)</td>
</tr>
<tr>
<td>HDL-C level, mmol/L [mg/dL]</td>
<td>1.3 (0.4)</td>
<td>48.7 (14.7)</td>
</tr>
<tr>
<td>LDL-C level, mmol/L [mg/dL]</td>
<td>3.4 (1.0)</td>
<td>136.8 (38.4)</td>
</tr>
<tr>
<td>Ratio of total cholesterol to HDL-C</td>
<td>4.7 (1.7)</td>
<td>4.9 (1.9)</td>
</tr>
<tr>
<td>Triglycerides level, mmol/L [mg/dL]</td>
<td>1.8 (1.1)</td>
<td>1.9 (1.2)</td>
</tr>
<tr>
<td>Resting systolic blood pressure, mm Hg</td>
<td>124.0 (12.1)</td>
<td>126.3 (12.2)</td>
</tr>
<tr>
<td>Resting diastolic blood pressure, mm Hg</td>
<td>86.5 (8.7)</td>
<td>87.7 (7.4)</td>
</tr>
<tr>
<td>Smokers, %</td>
<td>8.3</td>
<td>7.9</td>
</tr>
</tbody>
</table>

*BMI indicates body mass index (defined as weight in kilograms divided by the square of height in meters); VO₂peak, peak oxygen consumption; HDL-C, high-density lipoprotein cholesterol; and LDL-C, low-density lipoprotein cholesterol. Values are mean (SD) unless otherwise noted.
Both groups increased their cardiorespiratory fitness from baseline to 24 months (P = .002 for lifestyle and P < .001 for structured exercise), with no significant difference between groups (P = .22). The distribution of cardiorespiratory fitness changes (not shown) indicates that 21% of lifestyle group and 30% of structured exercise group participants increased their cardiorespiratory fitness by 10% or more from baseline.

In addition, we compared these results with the last-observation-carried-forward (LOCF) method by replacing missing values with 6-month or baseline measures if we did not have 24-month measures. We did not find that the LOCF method changed the nominal significance of the results in any way. For example, by not imputing values for VO_{2peak} and energy expenditure, the mean adjusted changes, respectively, were 0.77 mL/kg per minute and 0.84 kcal/kg per day for the lifestyle group, and 1.34 mL/kg per minute and 0.69 kcal/kg per day for the structured exercise group. Using the LOCF method, the results for VO_{2peak} and energy expenditure, respectively, were 0.77 mL/kg per minute and 0.83 kcal/kg per day for the lifestyle group and 1.72 mL/kg per minute and 0.77 kcal/kg per day for the structured exercise group. For the lifestyle group, the results were nearly identical while for the structured exercise group, these results were somewhat higher because their results were higher at 6 months. A second LOCF analysis in which only baseline data were used to impute missing 24-month results also showed little change from the original analysis.

**Maintenance of Physical Activity and Cardiorespiratory Fitness From 6 to 24 Months.** We evaluated maintenance of physical activity and cardiorespiratory fitness from baseline to 6 months and 24 months (Figure 2). Both groups had similar increases in physical activity at 6 months and similar decreases from 6 to 24 months (0.7 kcal/kg per day [P = .005] and 0.8 kcal/kg per day [P = .02] for lifestyle and structured exercise groups, respectively). These decreases were not significantly different (P = .83).

Maintenance of physical activity also could be defined as the percentage of individuals meeting or exceeding public health recommendations for physical activity, defined in Physical Activity and Health: A Report of the Surgeon General as increasing physical activity by 150 kcal/d. Examination of the distribution of physical activity changes (not shown) indicates that in each group, 20% met or exceeded the public health recommendations.

Figure 2 (bottom) shows increases in both groups for cardiorespiratory fitness from baseline to 6 months. Fitness (VO_{2peak}) increased 1.58 mL/kg per minute (P < .001) in the lifestyle group and 3.64 mL/kg per minute (P < .001) in the structured exercise group. There was a significant between-group difference at 6 months (P < .001). From 6 to 24

### Table 2. 24-Month Adjusted Mean Changes in Clinical Measures

<table>
<thead>
<tr>
<th>Measures</th>
<th>Lifestyle Group</th>
<th>Structured Exercise Group</th>
<th>Between-Group Difference, P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy expenditure, kcal/kg per day</td>
<td>0.84 (0.42 to 1.25)†</td>
<td>0.69 (0.25 to 1.12)</td>
<td>0.63</td>
</tr>
<tr>
<td>Moderate activity</td>
<td>0.93 (0.47 to 1.46)</td>
<td>0.33 (−0.15 to 0.82)</td>
<td>0.08</td>
</tr>
<tr>
<td>Vigorous activity§</td>
<td>0.40 (0.11 to 0.70)</td>
<td>0.80 (0.49 to 1.111)</td>
<td>0.07</td>
</tr>
<tr>
<td>Sitting, h/wk</td>
<td>−1.18 (−4.98 to 2.62)</td>
<td>−6.85 (−10.80 to −2.91)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Walking, min/d</td>
<td>13.07 (−0.77 to 26.92)</td>
<td>26.75 (12.37 to 41.13)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Stair climbing, flights/d</td>
<td>2.56 (0.91 to 4.21)</td>
<td>2.29 (0.57 to 4.00)</td>
<td>.009</td>
</tr>
<tr>
<td>Treadmill time, min</td>
<td>0.23 (0.09 to 0.38)</td>
<td>0.37 (0.21 to 0.52)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>VO_{2peak}, mL/kg per minute</td>
<td>0.77 (0.18 to 1.36)</td>
<td>1.34 (0.72 to 1.96)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Submaximal heart rate, beats/min</td>
<td>−2.62 (−4.72 to −0.53)</td>
<td>−4.88 (−7.03 to −2.74)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Body fat, %</td>
<td>−2.39 (−2.92 to −1.85)</td>
<td>−1.85 (−2.41 to −1.28)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>−0.05 (−1.05 to 0.96)</td>
<td>0.69 (−0.37 to 1.74)</td>
<td>.20</td>
</tr>
<tr>
<td>Total cholesterol level, mmol/L [mg/dL]</td>
<td>−0.11 (−0.23 to 0.01)</td>
<td>−0.13 (−0.25 to −0.01)</td>
<td>.03</td>
</tr>
<tr>
<td>HDL-C level, mmol/L [mg/dL]</td>
<td>−0.03 (−0.07 to 0.02)</td>
<td>−0.05 (−0.10 to −0.01)</td>
<td>.02</td>
</tr>
<tr>
<td>LDL-C level, mmol/L [mg/dL]</td>
<td>−0.04 (−0.16 to 0.97)</td>
<td>−0.12 (−0.24 to −0.01)</td>
<td>.04</td>
</tr>
<tr>
<td>Ratio of total cholesterol to HDL-C</td>
<td>0.06 (−0.13 to 0.25)</td>
<td>0.20 (0.00 to 0.39)</td>
<td>.05</td>
</tr>
<tr>
<td>Triglycerides level, mmol/L [mg/dL]</td>
<td>−0.11 (−0.23 to 0.02)</td>
<td>0.07 (−0.05 to 0.20)</td>
<td>.25</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td>−3.63 (−5.54 to −1.72)</td>
<td>−3.26 (−5.26 to −1.25)</td>
<td>.002</td>
</tr>
<tr>
<td>Diastolic blood pressure, mm Hg</td>
<td>−5.38 (−6.90 to −3.86)</td>
<td>−5.14 (−6.73 to −3.54)</td>
<td>.001</td>
</tr>
</tbody>
</table>

*CI indicates confidence interval; VO_{2peak}, peak oxygen consumption; HDL-C, high-density lipoprotein cholesterol; and LDL-C, low-density lipoprotein cholesterol.
†Least squares means were adjusted for baseline measure, age, sex, body mass index (defined as weight in kilograms divided by the square of height in meters), cohort, and ethnicity.
‡Data are based on comparison of adjusted means for treatment groups.
§Vigorous activity is the total of hard and very hard components from the 7-Day Physical Activity Recall.

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They maintained activity 40% to 60% of the time, and 32% of lifestyle and 40% of structured exercise participants said they maintained their activity 0% to 30% of the time. Because there was no significant difference between the 2 groups in maintenance of activity, data were combined to examine the dose-response relationship between maintenance and primary and secondary outcomes. Regression analyses indicated that for all outcomes, those who responded that they were active 70% or more of the time had at least twice as much improvement compared with those who did not (P < .01).

For example, the increase in total activity was 1.29 kcal/kg per day for those who maintained 70% or more compared with 0.28 kcal/kg per day for those in the lowest 30%. Similarly, for physiological outcomes, weight was decreased by 0.88 kg for those who maintained 70% or more compared with an increase of 2.48 kg for those who maintained 30% or less. Systolic and diastolic blood pressure and total cholesterol level showed greater improvements for those who maintained 70% or more (−5.31 mm Hg, −9.12 mm Hg, and −0.43 mmol/L [−16.7 mg/dL], respectively, compared with −2.6 mm Hg, −5.18 mm Hg, and −0.22 mmol/L [−8.37 mg/dL] for those who maintained ≥30%).

Sex Differences in Primary Outcomes. Although this study was not powered to examine the effect of sex on outcomes, we did observe some within-sex differences between lifestyle and structured exercise participants in 24-month changes in physical activity and fitness. However, these differences were variable and none were statistically significant. But there were significant within-treatment differences between men and women in 24-month changes in fitness, with greater increases in men than women in each treatment group (P < .001). The corresponding sex differences in changes in total and vigorous activity were consistent in direction across treatments, with greater increases in men than women, but these differences were not significant (P = .59 for total activity and P = .11 for vigorous activity).

Secondary Outcomes—CVD Risk Factors. Table 2 shows adjusted mean changes in CVD risk factors. Changes in systolic and diastolic blood pressure were significantly different from baseline to 24 months for both intervention groups. In examining the changes in systolic and diastolic blood pressure from 6 to 24 months, diastolic blood pressure but not systolic blood pressure continued to improve. The mean (SE) decrease in diastolic blood pressure from 6 to 24 months was −3.16 (0.82) mm Hg (P < .001) for the lifestyle group and −2.66 (0.86) mm Hg (P = .002) for the structured exercise group.

None of the lipid or lipoprotein measures changed from baseline to 24 months in the lifestyle group, but total cholesterol, low-density lipoprotein cholesterol (LDL-C), and HDL-C measures decreased significantly for the structured exercise group, and the ratio of total cholesterol to HDL-C increased significantly in this group. From 6 to 24 months, none of the lipid measures significantly changed for either intervention group, except that the ratio of total cholesterol to HDL-C increased significantly in both groups (P = .03 for lifestyle and P < .001 for structured exercise).

Body weight was unchanged from baseline to 24 months, but percentage of body fat decreased significantly in both intervention groups (P < .001) (Table 2). Participants in the lifestyle group had no significant change in weight (mean [SE], 0.41 [0.46] kg; P = .37) from 6 to 24 months, but percentage of body fat decreased (−1.13% [0.29%]; P = .001) significantly. The structured exercise group increased their weight (2.10 [0.49] kg; P < .001) from 6 to 24 months with no change in percentage of body fat (−0.07% [0.31%]; P = .82). These 6- to 24-month changes in weight and percentage of body fat differed significantly (P = .01) between the 2 intervention groups.

COMMENT

The principal finding from this study is that both the lifestyle and the structured interventions produced significant and comparable beneficial changes in physical activity, cardiorespiratory fitness, blood pressure, and percentage of body fat at 24 months.
INTERVENTIONS TO INCREASE PHYSICAL ACTIVITY AND FITNESS

months compared with baseline measures. This supports the hypothesis that a behaviorally based lifestyle physical activity intervention can significantly increase physical activity and fitness by 24 months. The novel finding is that this approach is as effective in producing beneficial changes in physical activity, cardiopulmonary fitness, blood pressure, and body composition as the traditional structured approach. For sedentary persons whose barriers to physical activity may include lack of time, dislike of vigorous exercise, or lack of access to facilities, this is good news. It means that health care professionals who are counseling their patients about physical activity can provide options beyond traditional fitness center–based recommendations.

There were no significant differences between lifestyle and structured exercise groups in changes for any of the primary or secondary outcome measures from baseline to 24 months. This finding is contrary to our hypotheses that the lifestyle group would do significantly better at 24 months while the structured exercise group would return to baseline levels 24 months later. At 6 months, the structured exercise group had increased their fitness nearly 2 times more than the lifestyle group, but by 24 months the 2 groups were nearly equivalent on every measure. In the 18-month follow-up period, there was a greater decline in fitness and a greater increase in weight in the structured exercise group, whereas the lifestyle group significantly decreased percentage of body fat by 6 to 24 months. Although both groups declined in physical activity and cardiopulmonary fitness, there was a greater decline in the structured exercise group, which suggests this group was not able to maintain its physical activity routines as effectively as the lifestyle group. Nevertheless, the structured exercise group did better than expected, perhaps because of delivering an enhanced structured intervention that included goal setting, self-monitoring, and reinforcement for reaching goals in addition to skills related to increasing physical fitness. Additional analyses from this study indicate that the lifestyle group was significantly more cost-effective, with total costs of about one third to one fourth of the structured exercise group (Mary A. Sevick, ScD; A.L.D.; Melba S. Morrow, MA; B.H.M.; John Chen, MD, PhD; S.N.B.; unpublished data, 1998).

Our lifestyle physical activity approach differs from other lifestyle interventions previously published31-33 because we focused on a single risk factor (ie, physical inactivity) vs multiple risk factors (eg, high-fat diet, high sodium, and physical inactivity). Although we did not intervene on diet behavior, we did measure diet with 3-day diet records in our sample. Preliminary analyses indicate that participants did not significantly change their dietary behavior as a result of either lifestyle or structured exercise interventions. At baseline, 6 months, and 24 months, both groups had comparable values on all dietary variables. We believe the changes or lack of changes in some CVD risk factors are consistent with this finding. For example, the changes in blood pressure are consistent with recommending moderate-intensity exercise for lower blood pressure.34 Furthermore, to achieve changes in lipids or weight, most studies indicate that changing dietary behavior as well as performing vigorous exercise yields the most improvement35,36; thus, it is not surprising that our participants did not significantly experience changes in lipid levels or decrease weight. It is of practical importance that our participants lost body fat and that the lifestyle group did not gain weight during the 24-month period because some studies show weight gain in sedentary controls over even shorter periods.37 Changes in physical activity, cardiopulmonary fitness, and CVD risk factors were well maintained during the follow-up period from 6 to 24 months, unlike the results recently reported by Wing et al.33 Our results are comparable to those reported by King et al.14 in which individuals assigned to a home-based exercise program significantly increased activity and fitness levels and remained significantly higher at 24 months compared with baseline.

Even though the mean increases over 24 months in physical activity and cardiopulmonary fitness were statistically significant, some may not consider them to be practically significant. We believe it is important to examine these changes within a public health context. The increases may seem small, but in examining the distributions of change in physical activity, one fifth of initially sedentary participants were achieving or exceeding public health recommendations for physical activity at the end of 24 months. Furthermore, at the end of 24 months, at least one fourth of participants had maintained an increase in cardiopulmonary fitness of 10% or more. A previous study of change in fitness among men demonstrates that a 2-MET increase in maximal treadmill performance was associated with a 30% reduction in mortality.38 Accordingly, we estimate that the 10% increase in treadmill performance in this study might result in a 15% reduction in mortality. If this intervention were widely disseminated in an efficacious manner, it could have far-reaching positive effects on the public’s health. Further studies are needed to examine whether lifestyle approaches can be efficacious in other settings, populations.

This study has several potential limitations. The study protocol did not include a “no treatment” control group. This control condition was not incorporated into the original design because physical inactivity increases the risk for several chronic diseases and decreases longevity.7,9-11 We considered it unethical to incorporate a treatment condition that did not encourage and promote physical activity over a 2-year period. Instead, we chose a study design similar to other clinical trials, in which a novel treatment (ie, lifestyle) is compared with a usual treatment (ie, structured). As to the generalizability of these results, our study participants were highly educated. However, we did not find differences across educational levels on any of the primary or secondary outcome variables.

This is, to our knowledge, the first demonstration that a lifestyle approach to increasing physical activity in previously sedentary healthy adults is as effective over 24 months as more traditional structured exercise approaches. Our results show that sedentary but otherwise healthy individuals can make significant improvements in physical activity, cardiopulmonary fitness, and CVD...
risk factors without having to go to a fitness center and perform high-intensity workouts. It is likely that many clinicians could promote the recent public health recommendations of 30 minutes of moderate-intensity physical activity on most days of the week and be assured that patients who adhere will achieve positive health benefits. Counseling patients to fit moderate-intensity activity into daily life may have significant health benefits and could aid public health efforts to reduce the prevalence of sedentary lifestyles.

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