Exercise and Dietary Weight Loss in Overweight and Obese Older Adults With Knee Osteoarthritis

The Arthritis, Diet, and Activity Promotion Trial

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Objective. The Arthritis, Diet, and Activity Promotion Trial (ADAPT) was a randomized, single-blind clinical trial lasting 18 months that was designed to determine whether long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, and mobility in older overweight and obese adults with knee osteoarthritis (OA).

Methods. Three hundred sixteen community-dwelling overweight and obese adults ages 60 years and older, with a body mass index of ≥ 28 kg/m^2, knee pain, radiographic evidence of knee OA, and self-reported physical disability, were randomized into healthy lifestyle (control), diet only, exercise only, and diet plus exercise groups. The primary outcome was self-reported physical function as measured with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Secondary outcomes included weight loss, 6-minute walk distance, stair-climb time, WOMAC pain and stiffness scores, and joint space width.

Results. Of the 316 randomized participants, 252 (80%) completed the study. Adherence was as follows: for healthy lifestyle, 73%; for diet only, 72%; for exercise only, 60%; and for diet plus exercise, 64%. In the diet plus exercise group, significant improvements in self-reported physical function ($P < 0.05$), 6-minute walk distance ($P < 0.05$), stair-climb time ($P < 0.05$), and knee pain ($P < 0.05$) relative to the healthy lifestyle group were observed. In the exercise group, a significant improvement in the 6-minute walk distance ($P < 0.05$) was observed. The diet-only group was not significantly different from the healthy lifestyle group for any of the functional or mobility measures. The weight-loss groups lost significantly ($P < 0.05$) more body weight (for diet, 4.9%; for diet plus exercise, 5.7%) than did the healthy lifestyle group (1.2%). Finally, changes in joint space width were not different between the groups.

Conclusion. The combination of modest weight loss plus moderate exercise provides better overall improvements in self-reported measures of function and pain and in performance measures of mobility in older overweight and obese adults with knee OA compared with either intervention alone.

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Submitted for publication January 22, 2003; accepted in revised form February 20, 2004.

Arthritis is the leading cause of physical disability among older adults, affecting more than 70 million Americans, of whom the majority are women (1–4). The joint damage and chronic pain from osteoarthritis (OA), the most common form of arthritis, lead to muscle atrophy, decreased mobility, poor balance, and, eventually, physical disability (5–8). Traditional therapies include pharmacologic, surgical, and exercise interventions. Pharmacologic therapy includes the use of antiinflammatory medications that have potentially serious long-term side effects (9,10). Recent evidence also casts doubt as to the effectiveness of arthroscopic surgery for adults with mild to moderate knee OA (11).

Consequently, the need for a safe and effective treatment for knee OA has never been more evident.

Previous clinical exercise trials have demonstrated significant, yet modest, improvements in function and pain in older adults with knee OA (12–18). There is also evidence that obesity is strongly associated with knee OA (19–27) and that weight loss may prevent the onset of this degenerative joint disease (28). Accordingly, both the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) recommend weight loss and exercise for obese patients with knee OA (29,30).

A nonrandomized trial conducted by Toda (31) demonstrated greater short-term (8-week) benefits of diet plus exercise compared with diet alone. Preliminary data from our laboratory suggest that a combined exercise and dietary weight loss approach may indeed be effective in improving clinical outcomes for older adults with OA (32). In addition, Huang and colleagues (33) reported that interventions that included diet and exercise improved weight loss, disability, and walking speed compared with pain therapy alone. Whereas these studies lend support to the efficacy of exercise and dietary weight loss in improving function in persons with knee OA, the lack of control groups, full factorial designs, short intervention periods, and small sample sizes limit the generalizability of these results. Interestingly, results from our current study suggest that the combination of diet and exercise is superior to either treatment alone in improving self-reported physical health measures of quality of life (34).

We present data from the Arthritis, Diet, and Activity Promotion Trial (ADAPT), which examined the effects of exercise and weight loss interventions, both separately and in combination, on self-reported physical function in overweight and obese older adults with knee OA. Moreover, we examined the effects of these interventions on the secondary outcome measures of weight loss, pain, mobility, and joint space narrowing.

PATIENTS AND METHODS

Design. ADAPT was a single-blind, randomized, controlled clinical trial of older overweight and obese adults with knee OA. It was designed to compare the effects of assignment to 4 distinct 18-month interventions: exercise only, dietary weight loss only, dietary weight loss plus exercise, and usual care healthy lifestyle (control). The study was conducted at the Claude D. Pepper Older Americans Independence Center of Wake Forest University, with the approval of the university's institutional review board.

Patients. The eligibility criteria for participation in the study were as follows: 1) age ≥ 60 years; 2) calculated body mass index ≥ 28 kg/m^2; 3) knee pain on most days of the month; 4) sedentary activity pattern with <20 minutes of formal exercise once weekly for the past 6 months; 5) self-reported difficulty in at least one of the following activities ascribed to knee pain: walking one-quarter of a mile (3–4 city blocks), climbing stairs, bending, stooping, kneeling (e.g., to pick up clothes), shopping, house cleaning or other self-care activities, getting in and out of bed, standing up from a chair, lifting and carrying groceries, or getting in and out of the bathtub; 6) radiographic evidence of grade I–III tibiofemoral or patellofemoral OA based on weight-bearing anteroposterior and sunrise view radiographs (35); and 7) willingness to undergo testing and intervention procedures.

Potential participants were excluded if they met any of the following criteria: 1) serious medical condition that prevented safe participation in an exercise program, including symptomatic heart or vascular disease (angina, peripheral vascular disease, congestive heart failure), severe hypertension, recent stroke, chronic obstructive pulmonary disease, severe insulin-dependent diabetes mellitus, psychiatric disease, renal disease, liver disease, active cancer other than skin cancer, and anemia; 2) a Mini-Mental State Examination score of <24; 3) inability to finish the 18-month study or unlikely to be compliant; 4) inability to walk without a cane or other assistive device; 5) participation in another research study; 6) reported alcohol consumption of >14 drinks per week; 7) ST segment depression of at least 2 mm at an exercise level of 4 METS or less, hypotension, or complex arrhythmias during a graded exercise test (36); 8) inability to complete the protocol, in the opinion of the clinical staff, because of frailty, illness, or other reasons.

Recruitment of participants from the community occurred over an 18-month period. Techniques to identify eligible participants included mass mailings to age-eligible persons within the target area, targeted mailings to employees of the university and medical center, presentations to various groups of older adults, mass media advertisement, and placement of posters (with pull-off reply cards attached) in strategic locations. Moreover, strategies were developed to enhance recruitment among racial minorities, including ads and interviews on minority-run radio stations, newspaper ads in predominantly African American publications, letters to churches attended mainly by minorities, and inserts in these church bulletins. Initial screening for major eligibility criteria was via telephone. Eligible contacts were invited to participate in a sequence of 2 face-to-face baseline visits, during which they were screened for the above-noted eligibility and exclusion criteria.

A variable-block randomization method was used to assign all eligible persons to 1 of the 4 intervention arms, stratified by race (white versus nonwhite). A list of random assignments to the 4 groups was computer-generated within each stratum, with blocks of 4, 8, and 12 chosen with equal probability. Once a subject met the eligibility criteria, a computer program displayed the next group assignment and logged it into the database. Participants were instructed to continue use of all medications and other treatments as prescribed by their personal physicians, and participants were referred to their personal physicians for all medical evaluations and care during the trial.

Interventions. *Exercise.* The 3 days/week exercise program prescribed to each participant randomized to either the exercise-only or the diet plus exercise groups consisted of an aerobic phase (15 minutes), a resistance-training phase (15 minutes), a second aerobic phase (15 minutes), and a cooldown phase (15 minutes). The first 4 months of the 18-month intervention was facility based. At any time after the first 4 months, participants who wished to exercise at home underwent a 2-month transition phase during which he or she alternated attendance between the facility and the home. Hence, some participants remained in a facility-based program, others opted for a home-based program, and some participants chose a combined facility–home-based program.

Participants were provided with an aerobic exercise prescription that included walking within a heart rate range of 50–75% of heart rate reserve. The resistance-training portion of the program consisted of 2 sets of 12 repetitions of the following exercises: leg extension, leg curl, heel raise, and step-up. Cuff weights and weighted vests were used to provide resistance. A 1–1.5-minute rest interval separated each exercise. Following 2 orientation sessions, participants began the exercise program using the lowest possible resistance. Resistance was increased after the participant performed 2 sets of 12 repetitions for 2 consecutive days.

For participants in the home-based program, weights were exchanged at the participant's request or after a determination was made during face-to-face or telephone contact to increase the weights. Telephone contacts were made every other week during the first 2 months of home-based exercise, every third week during the following 2 months, and monthly thereafter. Exercise and attendance logs were used to gather data and monitor progress. Exercise adherence was defined as the number of exercise sessions completed divided by the total number of prescribed sessions. All medical questions regarding the safety of exercise were referred to the participant's personal physician.

Dietary weight loss. The goal of the dietary intervention was to produce and maintain an average weight loss of 5% during the 18-month intervention period. The weight loss goal was based on results of the Trial of Nonpharmacologic Interventions in the Elderly (37), in which obese, hypertensive, older adults were able to maintain a 5.4% decrease in body weight over 2.5 years.

The dietary intervention was based on principles from the group dynamics literature (38) and social cognitive theory (39) and was divided into 3 phases: intensive (months 1–4), transition (months 5–6), and maintenance (months 7–18). The major emphasis of the intensive phase was to heighten awareness of the importance of and need for changing eating habits in order to lower calorie intake. Behavior change was facilitated using self-regulatory skills. These skills included self-monitoring, goal setting, cognitive restructuring, problem solving, and environmental management. One introductory individual session was followed by 16 weekly sessions (3 group sessions and 1 individual session each month). Each group session included problem solving, the review of a specific topic, and tasting of several well-balanced, low-fat, nutritious foods prepared with widely available ingredients. The individual sessions were used to review individual progress, solve problems, answer questions, and set goals. Body weight was mea-

sured weekly in both the diet-only and diet plus exercise groups and was recorded to the nearest 0.05 kg.

The transition phase included sessions every other week for 8 weeks (3 group sessions and 1 individual session). The goals for this phase included assisting participants who had not reached their weight loss goals in establishing new goals, and maintaining and preventing relapse in those participants who had reached their weight loss goals. The maintenance phase included monthly meetings and phone contacts, alternated every 2 weeks. Additionally, newsletters that provided pertinent nutritional information and notice of upcoming meetings were mailed at regular intervals. The goals of the maintenance phase included assisting participants who had reached their weight loss goals to maintain this weight loss, and providing counseling for participants who had a difficult time losing weight and adhering to the intervention. Adherence to the intervention was based on attendance at scheduled sessions and completion of the monthly assessment of weight.

Dietary weight loss plus exercise. The dietary weight loss plus exercise intervention used both the exercise and dietary weight loss programs described above. Contacts for the 2 interventions were done consecutively on the same day and at the same location.

Healthy lifestyle. The healthy lifestyle control group served as a usual-care comparison group with the 3 intervention groups and was designed to provide attention, social interaction, and health education. The group met monthly for 1 hour for the first 3 months. A health educator, who scheduled videotaped presentations and physician talks on topics concerning OA, obesity, and exercise, organized the healthy lifestyle program. Patients were advised to follow the ACR and EULAR recommendations for weight loss and exercise as treatments for OA (29,30). Question-and-answer sessions followed each presentation. Monthly phone contact was maintained during months 4–6, followed by contact every other month during months 7–18. During phone contact, information on pain, medication use, illnesses, and hospitalization was obtained.

Measurements and procedures. Data collection visits occurred at baseline and at 6 and 18 months postrandomization. All staff involved in data collection were blinded to the treatment assignment of the participants.

Primary outcome measure. The primary outcome measure was self-reported physical function as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (40,41). More specifically, the WOMAC uses 17 questions concerning the degree of difficulty performing activities of daily living (e.g., descending stairs) to assess a person's physical function. In the LK version of the WOMAC, the participant is asked to indicate on a scale from 0 (none) to 4 (extreme) the degree of difficulty he/she has experienced in the past 48 hours due to knee OA. The individual scores for the 17 items were added to generate a summary score that could range from 0 to 68, with higher scores indicating poorer function. This instrument, which also includes questions regarding pain and stiffness that were used as secondary outcomes, has been validated and is recommended by the Osteoarthritis Research Society as the measure of choice when assessing health status in older adults with knee OA (40).

Secondary outcome measures. *Weight.* Each subject's weight (without shoes) was measured at baseline and at the

6-month and 18-month followup visits, using the same calibrated scale. Measurement at each session was scheduled for the same time of day.

Measures of mobility. Two performance-based tasks, with high test–retest reliability (>0.85) for patients with knee OA, were used as measures of mobility (42). These included the distance walked in 6 minutes and a timed stair-climbing task.

Pain. The WOMAC (40) was used to assess a participant's level of pain. The rating scale for pain items is identical to the WOMAC physical function scale, ranging from 0 (none) to 4 (extreme). The pain subscale consists of 5 items, and total scores can range from 0 to 20, with higher scores indicating greater dysfunction.

Knee radiographs. Bilateral anteroposterior weight-bearing knee radiographs were used to assess the presence of tibiofemoral arthritis, and bilateral sunrise views were used to assess the presence of patellofemoral arthritis. Both radiographs were obtained at baseline and at 18 months. The weight-bearing radiographs were obtained with the subject's knees flexed at a 15° angle. The x-ray beam was centered on the joint space. Foot maps were used at baseline and followup to assure similar positioning for the 2 radiographs. The focus-to-film distance was held constant throughout the study.

A single physician blinded to the treatment group read the radiographs. Severity of tibiofemoral OA was measured using the Kellgren/Lawrence grading scale (35). The minimum joint space width of the medial and lateral compartments was measured using a 0.1-mm graduated magnifying lens to assess disease progression (43,44). Patellofemoral disease was graded as present or absent based on the presence of osteophytes or joint space narrowing.

Demographics. Age, race, education, and income data were acquired by self-report. Information that was obtained concerning comorbid conditions was based on the subject's medical history, medication use, and a physical examination.

Statistical analysis. The primary objective of the trial was to compare the effects of diet and exercise interventions on self-reported physical function. The trial was designed to randomize 300 subjects to achieve 254 evaluable subjects at the end of 18 months. A total sample size of 254 subjects was projected to provide a power of 90% to detect a 25% difference in the WOMAC scale for physical function between pairwise comparisons of the intervention and control groups. Primary analyses were conducted by intent-to-treat, with participants analyzed according to their initial assignments. All tests of hypotheses and reported P values are 2-sided.

Analysis of variance and the chi-square test were used to test for differences in baseline characteristics by treatment group. The effects of diet and/or exercise programs on disability, physical function, pain, and measures of mobility assessed at 6 and 18 months postrandomization were determined by two-way repeated-measures analysis of covariance (ANCOVA). Analyses were conducted using SAS Proc Mixed software version 8.2 (SAS Institute, Cary, NC), which analyzes all available followup information. This procedure does not assume that missing data are missing completely at random. This method for repeated-measures ANCOVA adjusts the means at each time point for potential biases resulting from missing observations being dependent on values of the outcome at other time points or baseline values of the covariates.
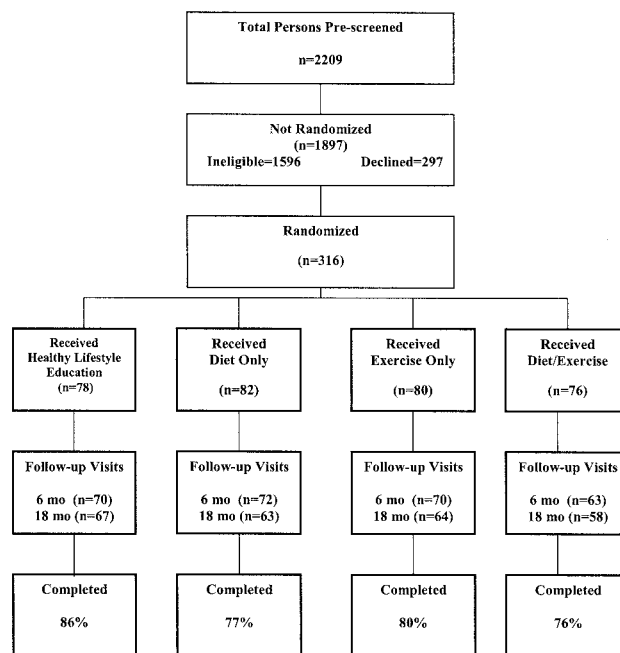
ADAPT Participant Progress

Figure 1. Progress of participants through the Arthritis, Diet, and Activity Promotion Trial (ADAPT).

Estimates of intervention effects were obtained at each followup observation. Tests of time of followup by intervention effects were conducted to test for consistency of effects over the followup period. Group-by-time interactions were not significant, and average intervention effects over the followup period were estimated and tested for significance. Analyses of group differences were adjusted for the prerandomization levels of the baseline value of the outcome being analyzed and sex. Reported within-group changes (i.e., 18-month value − baseline value) are presented as supplemental information.

RESULTS

Retention and adherence. The total number of persons prescreened via telephone during an 18-month recruitment period was 2,209 (Figure 1). Of these, 72% (1,596 of 2,209) were ineligible, and 13% (297 of 2,209) declined to participate, leaving 316 persons who were randomized to 1 of the 4 treatment groups. The characteristics of the randomized cohort are shown in Table 1.

Of the 316 randomized participants, 252 (80%) completed the study (returned for the final data-collection visit). The study participants who did not complete the study were not significantly different from those who remained in terms of age, sex, race, number of

Table 1. Demographic and clinical characteristics of the study participants*

Characteristic	Healthy lifestyle (n = 78)	Diet only (n = 82)	Exercise only (n = 80)	Diet plus exercise (n = 76)
Age, mean ± SEM years	69 ± 0.1	68 ± 0.7	69 ± 0.8	69 ± 0.8
% female	68	72	74	74
% nonwhite	21	28	25	22
Weight, mean ± SEM kg	96 ± 0.2	95 ± 0.2	92 ± 0.2	92 ± 0.2
Height, mean ± SEM meters	1.67 ± 0.01	1.66 ± 0.01	1.64 ± 0.01	1.64 ± 0.01
BMI, mean ± SEM kg/m^2	34.2 ± 0.6	34.5 ± 0.6	34.2 ± 0.6	34.0 ± 0.7
Annual household income, %				
<$15,000	19	19	17	19
$15,000–$35,000	30	33	32	36
$35,000–$50,000	15	24	31	20
>$50,000	36	24	21	24
Education, %				
<12 years	4	3	1	0
12 years	11	8	9	11
>12 years	85	90	90	89
Comorbid illnesses, %				
Obesity (BMI ≥30 kg/m^2)	76	81	84	70
Arthritis in other joints	58	58	55	53
Hypertension	46	51	54	44
Coronary heart disease	28	23	34	26
Diabetes	9	6	11	12
Kellgren/Lawrence score	2.21 ± 0.09	2.31 ± 0.75	2.19 ± 0.81	2.31 ± 0.88
WOMAC function (range 0–68)	26.0 ± 1.3	23.3 ± 1.3	24.0 ± 1.3	23.6 ± 1.4

* Nonwhite = Hispanic or non-Caucasian; BMI = body mass index; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

comorbidities, initial radiographic score, knee pain, or physical function. Two deaths that occurred during the course of the study were unrelated to the interventions. Retention of participants was not significantly different between the 4 groups (for healthy lifestyle, 86%; for diet only, 77%; for exercise only, 80%; for diet plus exercise, 76%) (Figure 1).

In the healthy lifestyle group, adherence was 77% for the first 3 months (defined as attendance at the 3 healthy lifestyle classes) and 73% for months 4–18 (defined as the percentage of followup calls that were successfully completed). For those participants completing the diet and/or exercise interventions, adherence was as follows: for diet only, 72% (defined as attendance at nutrition classes); for exercise only, 60% (defined as the number of exercise sessions completed divided by the number of sessions scheduled); and for diet plus exercise, 64% (defined as the average of the 2 intervention requirements). There was no significant difference in adherence between the 3 diet and/or exercise intervention groups. One serious adverse event related to participation in the trial occurred when a participant tripped while exercising and sustained a laceration to his head.

After the first 4 months of facility-based exercise, 64% of the subjects in the 2 exercise groups chose to remain in the facility-based program, 24% opted for the home-based program, and 12% of the subjects chose a
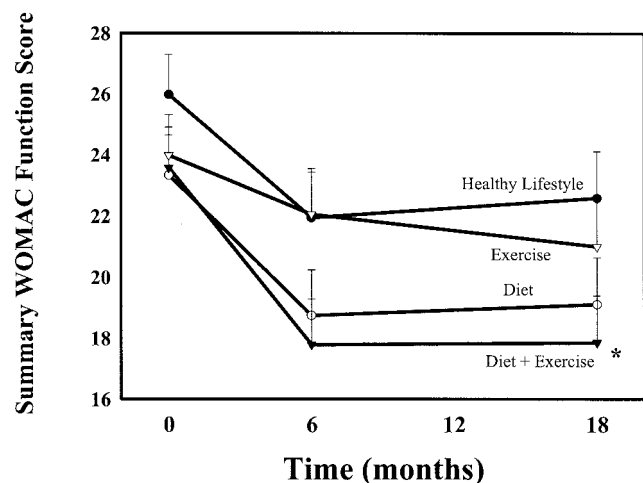

Figure 2. Mean ± SEM unadjusted Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) physical function summary scores across the 18-month intervention period. * = $P < 0.05$, diet plus exercise group versus healthy lifestyle group.

Table 2. Six-minute walk distance at baseline, 6 months, and 18 months and absolute change from baseline*

| | 6-minute walk distance, meters | | | |
Study group	Baseline	6 months	18 months	Change from baseline at 18 months (95% confidence interval)
Healthy lifestyle	434.61 ± 10.96	428.56 ± 12.88	429.89 ± 12.77	−4.72 (−29.75, 20.31)
Diet only	425.98 ± 10.89	433.68 ± 11.94	435.63 ± 12.88	9.65 (−15.79, 35.09)
Exercise only	424.15 ± 11.42	465.04 ± 12.13	472.73 ± 13.12†	48.58 (22.87, 74.29)
Diet plus exercise	416.15 ± 11.34	482.37 ± 12.65	477.76 ± 13.12†	61.61 (35.90, 87.32)

* Values are the mean ± SEM.
† $P < 0.05$ versus healthy lifestyle.

combined facility–home-based program. There were no significant group-by-time interaction effects for any of the primary or secondary outcome measures; therefore, average intervention effects over the followup period (6 and 18 months) were estimated and tested for significance.

Primary outcome. The primary outcome of ADAPT was self-reported physical function using the WOMAC. An ANCOVA, using baseline function and sex as covariates, revealed that subjects in the diet plus exercise group significantly improved their physical function ($P < 0.05$) relative to the healthy lifestyle control group during the 18-month intervention (Figure 2). There were no significant differences between the exercise-only or diet-only groups and the healthy lifestyle group.

The within-group change in WOMAC physical function during the 18-month intervention revealed significant improvements of 24% and 18% in the diet plus exercise group (mean 5.73; 95% confidence interval [95% CI] 2.63, 8.83) and the diet-only group (mean 4.23; 95% CI 1.27, 7.19). Nonsignificant improvements of 12% and 13% were noted in the exercise-only group (mean 3.07; 95% CI 1.91, 6.13) and the healthy lifestyle group (mean 3.40; 95% CI 0.48, 6.32).

Secondary outcomes. *Weight loss.* Both weight loss intervention groups (diet only, diet plus exercise) lost significantly ($P < 0.05$) more weight relative to the healthy lifestyle group. Subjects in the diet-only group lost an average of 4.9% of their body weight (mean 4.61 kg; 95% CI 0.38, 8.84) during the 18-month intervention, whereas those in the diet plus exercise group lost 5.7% of their body weight (mean 5.20 kg; 95% CI 0.85, 9.55). Individuals in the exercise-only group lost 3.7% of their body weight (mean 3.46 kg; 95% CI −0.77, 7.69) while those in the healthy lifestyle group lost 1.2% of their body weight (mean 1.10 kg; 95% CI −3.00, 5.20).

Mobility measures. There was a significant difference in the 6-minute walk distance ($P < 0.05$) and the stair-climb time ($P < 0.05$) between the diet plus exercise and the healthy lifestyle groups during the 18-month intervention period (Tables 2 and 3). In the exercise-only group, the 6-minute walk distance significantly improved ($P < 0.05$) relative to that of the healthy lifestyle group. Improvements in the 2 mobility measures for the diet-only group, however, were not significantly different from those occurring in the healthy lifestyle group.

Pain. The diet plus exercise group made significant improvements in self-reported pain ($P \leq 0.05$)

Table 3. Stair-climb time at baseline, 6 months, and 18 months and absolute change from baseline*

| | Stair-climb time, seconds | | | |
Study group	Baseline	6 months	18 months	Change from baseline at 18 months (95% confidence interval)
Healthy lifestyle	9.59 ± 0.64	9.97 ± 0.75	9.37 ± 0.76	−0.22 (−1.71, 1.27)
Diet only	9.74 ± 0.65	9.88 ± 0.70	8.43 ± 0.78	−1.31 (−2.84, 0.22)
Exercise only	10.52 ± 0.66	8.87 ± 0.73	8.89 ± 0.78	−1.63 (−3.16, −0.10)
Diet plus exercise	10.99 ± 0.67	8.83 ± 0.78	8.45 ± 0.81†	−2.54 (−4.13, −0.95)

* Values are the mean ± SEM.
† $P < 0.05$ versus healthy lifestyle.

Table 4. Self-reported pain at baseline, 6 months, and 18 months and absolute change from baseline*

	WOMAC pain score			
Study group	Baseline	6 months	18 months	Change from baseline at 18 months (95% confidence interval)
Healthy lifestyle	7.25 ± 0.39	6.19 ± 0.46	6.02 ± 0.45	−1.23 (−2.11, −0.35)
Diet only	6.58 ± 0.40	5.10 ± 0.43	5.51 ± 0.45	−1.07 (−1.95, −0.19)
Exercise only	6.64 ± 0.39	6.22 ± 0.45	6.24 ± 0.47	−0.40 (−1.32, 0.52)
Diet plus exercise	7.27 ± 0.41	5.47 ± 0.47	5.07 ± 0.47†	−2.20 (−3.12, −1.28)

* Values are the mean ± SEM scores (range 0–20, with higher scores indicating greater dysfunction).
WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.
† $P = 0.05$ versus healthy lifestyle.

relative to the healthy lifestyle group (Table 4). Pain decreased 30.3% in the diet plus exercise group during the 18-month intervention. Although there were no other significant between-group differences, pain tended to improve in all 4 groups.

Radiographic progression. Changes in medial and lateral joint space width were not significantly different between the groups (Table 5). In general, medial joint space width narrowed more compared with the lateral joint space width.

DISCUSSION

Results of previous short-term studies suggest that the combination of dietary weight loss plus exercise is effective in improving self-reported physical function and mobility in osteoarthritic patients compared with exercise only (32), diet only (31), and pain therapy (ultrasound and transcutaneous electric stimulation) (33). Our statistical analysis indicated that all of the intervention groups and the healthy lifestyle (control) group tended to have improved function; however, it was when diet was combined with exercise that subjects realized the greatest and statistically significant benefit in function. Interestingly, the 3 intervention groups improved within the first 6 months, and then *maintained*

these improvements for an additional 12 months. This was especially noteworthy among patients in the diet plus exercise group, who maintained a 24% improvement. Only the healthy lifestyle group experienced regression of function toward baseline values. Therefore, we suggest that the combination of diet plus exercise produces consistently better and clinically relevant improvements in self-reported physical function compared with either diet or exercise alone.

The effects of long-term exercise programs (aerobic or resistance) on self-reported physical function indicate significant, yet modest, beneficial effects (1–11%) with a gradual return toward baseline values (12,13,15). The improvement observed in our exercise-only group (13% improvement) compared favorably with that observed in previous studies (12,13,15), yet there was no significant difference relative to the healthy lifestyle control group. The surprising 13% improvement in the control group combined with the high functional level of the entire cohort (see Table 1) made attaining significant gains more difficult.

The decision to use an attention control versus a no-treatment control group in clinical trials research usually creates considerable debate among investigators. Equating the amount of contact time between interven-

Table 5. Lateral and medial joint space width at baseline and 18 months and absolute change from baseline*

Joint space width	Healthy lifestyle	Diet only	Exercise only	Diet plus exercise
Lateral				
Baseline	4.73 ± 0.16	4.62 ± 0.16	4.54 ± 0.20	4.85 ± 0.18
18 months	4.58 ± 0.20	4.56 ± 0.17	4.48 ± 0.18	4.63 ± 0.19
Change (95% CI)	−0.15 (−0.54, 0.24)	−0.06 (−0.39, 0.27)	−0.06 (−0.41, 0.29)	−0.22 (−0.59, 0.15)
Medial				
Baseline	3.18 ± 0.21	3.18 ± 0.18	3.37 ± 0.19	3.23 ± 0.23
18 months	2.93 ± 0.20	2.98 ± 0.17	3.18 ± 0.21	2.93 ± 0.21
Change (95% CI)	−0.25 (−0.64, 0.14)	−0.20 (−0.53, 0.13)	−0.19 (−0.60, 0.22)	−0.30 (−0.71, 0.11)

* Values are the mean ± SEM mm. 95% CI = 95% confidence interval.

tion and attention control groups is difficult and costly. Recently, we observed declines over a 30-month period of 10% and 6% in lower extremity strength and balance, respectively, in older adults with knee OA (45). These data suggest that in the absence of any intervention, a decline in physical ability and physical performance is likely in this older, osteoarthritic population. The improvements in our control group suggest that the healthy lifestyle intervention was effective in slowing the decline in function commonly seen in no-treatment control groups.

The increase in disability and dependence in performing daily activities observed in older adults with OA is accelerated by mobility impairment (46). Although short-term exercise programs have demonstrated between 4% and 18% improvements in mobility in patients with knee OA (16–18), the effects of long-term exercise programs indicate more modest improvements (1–2%), with a return toward baseline values (15). Our physical performance (6-minute walk distance, stair-climb time) data indicate that exercise can result in clinically relevant (16% overall improvement) and statistically significant long-term gains in mobility, effectively slowing the increase in mobility impairment that is common in an older, osteoarthritic population (45,46).

Radiographic progression of disease, as measured by joint space narrowing, was similar among the 4 study groups. The relatively short duration (18 months) of the intervention and the number of subjects per group (~80) probably prevented the detection of meaningful differences in radiographic disease progression.

Often, older adults with knee OA are reluctant to exercise for fear of exacerbating their knee pain. In the diet plus exercise group, walking velocity significantly increased, suggesting an increase in the load placed on the lower extremity joints, yet knee pain significantly *decreased* (by 30%). For the exercise-only group, the improvement in walking velocity did not have an adverse effect on knee pain, which improved 6% from baseline. These data are consistent with results of 2 previous studies of older adults with knee OA who were enrolled in exercise or diet plus exercise programs (15,32). Interestingly, diet produced a 16% improvement in knee pain; however, it was diet in combination with exercise that had the greatest and only significant effect on pain (see Table 4). From a clinical perspective, these results suggest that physicians can prescribe either diet or exercise for their overweight and obese patients with mild to moderate knee OA without the likelihood of worsening their symptoms. Furthermore, patients are most likely to realize the greatest improvements in pain

when they combine diet with exercise. We acknowledge, however, that this assertion is based on mean values, and that there will be individuals whose symptoms may worsen with exercise.

The diet plus exercise and diet-only groups lost significantly more weight (5.7% and 4.9%, respectively) than did the control group. This weight loss is consistent with that observed in previous long-term weight loss studies (37,47,48). Williams and Foulsham (49) reported that the degree of weight loss was related to clinical improvement. While this held true for our self-reported measures, subjects in the exercise group, who experienced only a 3.7% weight loss, generally performed better on mobility measures than did the diet-only group. Change in muscle mass, which was not measured, may have contributed to the differences in mobility between the groups.

Relative to our prior experience with a combined facility- and home-based exercise clinical trial (15), overall adherence was lower in ADAPT but was similar to that observed in the facility-based group in another large-scale community-based exercise trial (50). These data underscore the difficulty in maintaining standard exercise and dietary weight loss programs in previously sedentary, overweight adults with mobility disability, and emphasizes the need for studies that focus on strategies that improve adherence to long-term exercise and dietary therapy programs.

Improvement in the diet and exercise groups was dependent on the type of outcome measure. More specifically, the diet-only group performed better than the exercise-only group on self-reported measures (although neither group was statistically different from the healthy lifestyle group), while the reverse was true for mobility measures. It appears logical, then, that combining the 2 interventions would lead to the diet plus exercise group's consistently superior results on both self-reported and mobility measures. Further research is needed to determine whether there is a significant dose response to both exercise and weight loss on measures of physical function and mobility.

For many years, physicians have recommended that overweight patients with knee OA exercise and lose weight, and this approach has been recommended in the ACR guidelines for the management of knee OA (29). However, our study is the first large, randomized, controlled clinical trial to demonstrate the relative and combined contributions of exercise and weight loss on function, pain, and mobility in patients with knee OA. This study indicates that combining modest weight loss with moderate exercise provides the best overall im-

provements in self-reported measures of function and pain and performance measures of mobility. These data also show that long-term weight loss through calorie restriction can be achieved in this population. Without the addition of exercise, however, dietary weight loss alone does not result in significant improvements in mobility (an important determinant of disability) or self-reported function and pain. Considering the side effects that often limit the use of OA drug therapy (9) and the possible ineffectiveness of surgical intervention in cases of mild to moderate knee OA (11), our results give strong support to the combination of exercise and weight loss as a cornerstone for the treatment of overweight and obese patients with knee OA.

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