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# Impact of the Fit and Strong Intervention on Older Adults With Osteoarthritis

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***Purpose:*** This study assessed the impact of a low cost, multicomponent physical activity intervention for older adults with lower extremity osteoarthritis. ***Design and Methods:*** A randomized controlled trial compared the effects of a facility-based multiple-component training program followed by home-based adherence ($n = 80$) to a wait list control group ($n = 70$). Assessments were conducted at baseline and at 2 and 6 months following randomization. The training program consisted of range of motion, resistance training, aerobic walking, and education–group problem solving regarding self-efficacy for exercise and exercise adherence. All training group participants developed individualized plans for posttraining adherence. ***Results:*** Relative to the persons in the control group, individuals who participated in the exercise program experienced a statistically significant improvement in exercise efficacy, a 48.5% increase in exercise adherence, and a 13.3% increase in 6-min distance walk that were accompanied by significant decreases in lower extremity stiffness at 2 and 6 months. Program participants also experienced a significant decrease in lower extremity pain and a borderline significant improvement in efficacy to adhere to exercise over time at 6 months ($p = .052$). In contrast, persons in the control group deteriorated over time on the efficacy and adherence measures and showed no change on the other measures. No adverse health effects were encountered. ***Implications:*** These benefits indicate that this low-cost intervention may hold great promise as one of a growing number of public health intervention strategies for older adults in the United States with osteoarthritis.

*Key Words: Arthritis, Elderly, Clinical trial, Outcomes*

Osteoarthritis (OA) is the most common condition affecting older people today. It is a major cause of disability among older people and its impact is projected to increase with the aging of the U.S population from the current level of 43 million to 60 million by 2020 (Centers for Disease Control, 1999). Lower extremity OA, in particular, has been shown to be a risk factor for disability and institutionalization (Dunlop, Hughes, and Manheim, 1997; Guralnik, Ferrucci, Simonsick, Salive, & Wallace, 1995; Jette et al., 1999). OA is known to be painful and to cause limitation of mobility, as persons with OA minimize movement in order to reduce their exposure to pain. Comparisons of persons with and without OA have shown that, as a result of this reduced mobility, the condition is associated with both reduced lower extremity strength *and* reduced aerobic functioning (Minor, Hewett, Weber, Anderson, & Kay, 1989; Semble, Loeser, & Wise, 1990). Possibly because of increased pain and decreased mobility, persons with OA also experience depression and may become socially isolated (Blixen & Kippes, 1999).

Given the substantial public health significance of OA, several exercise interventions have been developed and tested among older persons with this condition over the past 20 years (Chamberlain, Care, & Harfield, 1982; Ettinger et al., 1997; Fisher, Pendergast, Gresham, & Calkins, 1991; Kovar et al., 1992; Minor et al., 1989). Three early single-group pretest–posttest studies of strengthening exercises found significant short-term treatment group improvements in knee flexor and extensor strength (Chamberlain et al., 1982; Kreindler et al., 1989;

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Fisher et al., 1991). A more rigorous controlled study by Minor and colleagues (1989) assessed the impact of aerobic walking or aquatics versus range of motion exercise alone. Findings at 3 months included significant improvements in aerobic functioning among the two aerobic treatment groups versus the control group (Minor et al., 1989). A similar trial of the impact of a supervised fitness walking and patient education intervention found significant treatment group increases on 6-min distance walk (18.4%) and physical activity (39%) at 2 months that were accompanied by a significant 27% decrease in arthritis pain at 2 months (Kovar et al., 1992).

The most rigorous study to date, by Ettinger and colleagues, used a randomized trial to compare the impact of aerobic exercise versus resistance training versus health education alone on self-reported and performance-based disability at 18 months for community-dwelling persons with knee OA. It found superior outcomes on physical functioning for both the aerobic and resistance-training interventions. Although adherence was similar for both intervention groups, slightly higher improvements were noted in the aerobic group, with improvements in performance measures averaging 10–15% vis-à-vis controls (Ettinger et al., 1997).

Although the Ettinger study found modest improvements in long-term physical functioning among community-dwelling elderly persons, it did not address the important question of whether the effects might have been stronger if the treatments had been combined, for example, whether the treatments have an additive effect if combined into a single multicomponent intervention that incorporates strength training, aerobic conditioning, *and* education for behavior change. Given the fact that findings in the literature demonstrate the presence of both strength and aerobic deficits among older adults with OA, we believed that it would be important to combine all three components in an intervention that was purposely designed to be inexpensive to conduct and simple to implement and replicate broadly.

Specifically, we designed an 8-week facility-based intervention that uses therabands and ankle cuff weights that can be purchased in any major outlet store for resistance training. Together, the resistance training and aerobic walking were hypothesized to improve lower extremity functioning, fitness, and conditioning. Each 60-min exercise component is then followed by group problem solving–discussion sessions that are designed to enhance arthritis self-care, self-efficacy for exercise, and self-efficacy for exercise adherence. The facility-based intervention is followed by a home-based component geared to reinforce long-term exercise adherence. We next tested the impact of the intervention by using a randomized trial. This article presents preliminary proximal outcome and adherence findings from this ongoing trial of the Fit and Strong Intervention at 2 and 6 months.

## Methods

This study is assessing the short- and long-term efficacy and adherence to a multicomponent exercise intervention for older persons with mild to moderate lower extremity OA. The intervention lasts 8 weeks, with each iteration accommodating approximately 15 enrollees. The intervention is repeated in successive iterations in order to achieve a final targeted sample of 200 participants. We are using a randomized block design with blocks consisting of 30 participants (15 in the treatment group and 15 in the control group). Within each block, we stratify within American College of Rheumatology (ACR) Functional Classes (I, II, or III) to achieve balance on this variable within the two study groups. The random permutation of block sizes helps to minimize manipulation of an assignment.

### *Setting*

The study is being conducted at several different senior centers and senior housing residences located on the north side of Chicago. Volunteers are community dwelling and are recruited by newsletter, announcements in the local media, and presentations to local senior groups.

### *Procedures*

During a phone screen, research staff assess eligibility for the study by using inclusion–exclusion criteria, explain study procedures, and set up an appointment for the baseline interview. At the baseline interview, the research staff obtain informed consent and the participant undergoes a physical exam with the study rheumatologist. The participant's name is then entered in an appropriate space in a prepared log to one of three categories on the basis of the participant's functional class, and a random number is used to assign the participant to the treatment or control group. Research staff inform participants regarding group assignment and ensure that all educational materials are provided to the physical therapists. The physical therapists lead the exercise sessions and maintain attendance and performance records for each intervention participant, and they develop individualized adherence plans with each participant before the intervention ends. Follow-up interviews regarding adherence are made quarterly by telephone, and in-person interviews are held at baseline and at 2, 6, 12, 18, and 24 months with all study participants. All procedures and consent forms used in this study were approved by the University of Illinois at Chicago Institutional Review Board.

### *Inclusion–Exclusion Criteria*

Volunteers are screened at baseline to rule out the presence of moderate to severe cognitive impairment

using the Short Portable Mental Status Questionnaire (Kahn, Goldfarb, Pollack, & Peck, 1960). They also receive a physical examination of the joints and muscles from the study rheumatologist. The physical exam determines clinical presence of OA of the hip or knee and rates degree of functional significance by using a modified version of the ACR Functional Class (American Rheumatism Association, 1982).

Clinical criteria for the presence of knee OA are knee pain plus at least three of the following six clinical findings: age $>$ 60 years, morning stiffness with a duration $<$ 30 min, crepitus on active motion, tenderness of the bony margins of the joint, bony enlargement on examination, and a lack of palpable warmth of the synovium (Altman et al., 1986). A person is classified as having hip OA if pain is present in combination with either (a) hip internal rotation $\geq$ 15°, pain present on internal rotation of the hip, morning stiffness of the hip for a time $\leq$ 60 min, and age $>$ 60 years or (b) hip internal rotation $<$ 15°, and hip flexion $\leq$ 115°. The sensitivity for this definition is 86% and specificity is 75% (Altman et al., 1991). Persons with an acutely inflamed or significantly swollen joint are advised to come back for reexamination and possible inclusion in the next iteration of the intervention. Persons who meet the inclusion criteria are invited to participate in the trial on a first-come basis. Persons with severe, limiting cardiovascular disease, active thrombophlebitis, recent pulmonary embolus, an acute systemic illness, poorly controlled diabetes, and other health conditions that might preclude exercise training are excluded.

### Sample Characteristics

We conducted these analyses on the first seven iteration groups ($N = 150$; 80 treatment and 70 control).

### The Intervention

The Fit and Strong Intervention is offered in 90-min sessions held three times per week for 8 weeks. The maximum number of participants in each iteration is 15. The sessions are led by one of two physical therapists who share responsibility for each iteration.

Because the literature indicates that older adults with OA have deficits in *both* strength and aerobic functioning, the first 60 min of the intervention include both resistance training and fitness walking. The last 30 min include an adapted version of the group discussion–educational component by Kovar and colleagues (1992) to enhance adherence efficacy. All exercises are accompanied by music. The sessions begin and end with 10-min warm-up and cool-down periods that involve neck, trunk, and extremity range of motion exercises. Static and dynamic sitting and standing balance exercises are used during these periods.

*Strengthening.*—Strengthening exercises for the lower extremities and trunk utilize a graded task-specific approach (sit to stand and postural stabilization). Building on the Fisher and Fiatarone studies, we implement resistance exercises by using a combination of cuff weights and therabands (Fisher et al., 1991; Fiatarone et al., 1994). We progressively increase resistance throughout the program by adding weight in increments of 0.5 lb (0.226 kg) to the cuff weights.

Previous literature indicates that time required to rise from a chair is significantly correlated with age and with knee flexor and extensor muscle strength (Csuka & McCarty, 1985). Because the ability to rise unassisted from a chair or the floor is critical for independent functioning in the community, strengthening exercises incorporate progressive sit-to-stand and floor-to-stand activities that target these functions. Floor-to-stand progression is achieved by progressively limiting the use of upper extremities or a chair to assist in rising from the floor.

*Fitness Walking.*—Fitness walking progresses from maximum duration at baseline to 30 min over time. Exercise intensity is 40% to 60% of maximum heart rate (13 to 15 on the Borg Scale of Perceived Exertion; Borg, 1982). The complexity of walking patterns is increased from simple circular patterns at baseline to more complicated patterns and increased speed. Balance during fitness walking is progressively challenged as tolerated by participants through the changing of the walking direction and the altering of the walking surface to include obstacles or walking outdoors. A small number of participants with knee OA experience pain while walking and instead use a bicycle ergometer on site.

*Education–Behavior Change.*—Social cognitive theory posits that self-efficacy, or individuals' confidence in their ability to achieve a desired outcome, is an important mediator for sustained behavior change (Bandura, 1986) and further posits that levels of self-efficacy vary depending on the situation that is being addressed. We believed that the key types of self-efficacy to be addressed in this intervention were self-efficacy for exercise (confidence in the ability to conduct the exercises in a safe and effective manner) and self-efficacy for exercise adherence (confidence in the ability to adhere to exercise participation over time and in the presence of barriers). The health education component also addresses self-efficacy to manage pain and other arthritis-related symptoms. To boost self-efficacy for exercise, we supplemented the educational content of Kovar and colleagues (1992) by asking participants at baseline to specify outcomes that they hope to achieve through exercise participation. We also provide systematic feedback to participants on progress made toward the achievement of these goals. In addition, to increase

self-efficacy for adherence to exercise, the trainers follow the Jensen and Lorish (1994) process model for patient–practitioner collaboration. The trainers establish a therapeutic relationship with each participant and, instead of prescribing a posttraining regimen, ask the question, ''What is the best regimen that this participant is likely to follow?'' This is followed by negotiation, including discussion of the participant's belief that the exercise will accomplish a valued goal, and iterative problem solving. In order to maximize internal locus of control, participants are asked to identify specific functions or activities that they are having trouble with, which exercise could ameliorate. Individual participant performance records are maintained and shared with participants weekly to reinforce a sense of exercise efficacy. The emphasis is on building skills and identifying strategies that will assist the participant in maintaining adherence. Thus, for example, persons with knee OA who have difficulty walking are encouraged to engage in some other less stressful form of aerobic activity such as swimming or riding a stationary bicycle. Persons who prefer exercising alone develop a home-based program, and those who prefer a group-based program are directed to ongoing classes in the community.

*Reinforcement.*—Staff use group and individual sessions to inform participants about opportunities for maintaining exercise within the community or in the individual's home. Following the ''negotiated'' adherence model (Jensen & Lorish, 1994), staff ask all participants to develop an individualized postintervention exercise plan that incorporates strength training and aerobic activity (usually walking) a minimum of 3 days per week for a total of 30 min per day at a ''moderate'' to ''strong'' level of perceived exertion on the Borg scale (Borg, 1982). Participants are also asked to sign a postintervention exercise contract. They are given a log in which to record daily distance covered, repetitions completed, time spent exercising, and resting and exercise heart rates. This log enables participants to track their progress over time and is intended to reinforce their perceptions of adherence efficacy. All graduates are also given a copy of *The Arthritis Helpbook* (Lorig & Fries, 1995), a graduation certificate, and tapes of music used during the class at a graduation ceremony at 8 weeks.

## Control Condition

Control group participants are given a copy of *The Arthritis Helpbook* and a list of exercise programs in the community that they can access. They are also given a variety of self-care materials and handouts at each posttest. The control group is offered the opportunity to participate in the intervention at the conclusion of 24 months. No crossover has occurred between the two groups to date.

## Measures

*Screening Measures.*—The 10-item Short Portable Mental Status Questionnaire (SPMSQ; Kahn et al., 1960) is used to screen for presence of moderate to severe cognitive impairment. This instrument has demonstrated good reliability and validity, and it is short and inoffensive to respondents (Kane & Kane, 1983). Correct responses receive a score of 1 and incorrect responses receive a score of 0. Persons are considered ineligible if they answer more than 3 of 10 items incorrectly. All of the participants in this trial scored in the intact functioning range of 0–2 errors.

A physician assesses the presence of lower extremity joint OA by using a modified version of the physical examination used by Hughes, Edelman, Chang, Singer, and Schuette (1991). The lower joint extremity portion of the examination assesses nine joints or regions for pain on motion, tenderness, swelling, limitation of motion, or deformity. Type of arthritis also is identified. The physician is asked to indicate whether the participant meets the inclusion criteria previously described for the presence of OA of the hip or knee.

Persons are considered ineligible if they are under the age of 60, currently participate in an aerobic exercise program, have had uncomplicated hip or knee surgery within the previous 6 months or complicated surgery within the past year, have received steroid injections in either knee or hip within the previous 3 months, have a diagnosis of rheumatoid arthritis, or have diabetes that is not under good control.

## Outcomes

The following outcomes were assessed at baseline and at 2 and 6 months for all participants.

*Self-Efficacy for Arthritis Self-Management (Exercise, Pain, and Other Symptoms).*—We assess self-efficacy to perform self-management tasks by using the three subscales of efficacy for arthritis self-management developed by Lorig and colleagues (Lorig, Chastain, Ung, Shoor, & Holman, 1989; Lorig et al., 1996). The efficacy for exercise subscale contains three items, the pain management subscale contains five items, and the other symptoms subscale has six items. All three subscales have 10-point response formats. We calculate the score for each subscale by adding the responses and dividing by the total number of items within each subscale. Alphas for each of the three subscales for the current sample were .92 for self-efficacy for exercise, .88 for self-efficacy for pain management, and .94 for self-efficacy for management of other symptoms.

*Exercise Adherence Self-Efficacy.*—We used two scales developed by McAuley and colleagues to

measure self-efficacy for exercise adherence (McAuley et al., 1993). The "barriers" adherence efficacy scale measures self-efficacy to adhere to an exercise program in the presence of a variety of barriers. It has 13 items, which are scored by calculation of the overall mean score. The scale had $\alpha = .93$ in the current sample. The "time" exercise adherence self-efficacy measure has 6 items that ask the respondent to rate his or her level of self-efficacy to continue participating in regular exercise over a period of 6 months. Reliability analysis found $\alpha = .98$ in the current sample.

*Adherence.*—Attendance is monitored during the intervention at each session and participants are asked to maintain exercise logs during and after the facility-based program ends to track exercise activity daily. Research staff call all participants (treatment and control) every 3 months after the training ends to ask the average number of times per week that they exercised (frequency) and the number of minutes per session they exercised (duration).

King and colleagues (1997) classified adherence as successful if participants adhered to a prescribed exercise routine at least two thirds of the time. This was deemed a clinically relevant cutoff point on the basis of exercise physiology literature that showed significant improvements in functional capacity derived from regular participation in endurance exercise regimens of at least two of three 1-hr exercise sessions per week (American College of Sports Medicine, 1996; Haskell, Montoyne, & Orenstein, 1985).

*Functional Lower Extremity Muscle Strength.*—We are using the Timed-Stands Test in the method described by Guralnik and colleagues (1995) to functionally assess lower extremity muscle strength and endurance. This test measures time to complete five full stands from a sitting position. It is simple, inexpensive, rapid, and reproducible, has demonstrated a highly significant relationship with age, and has correlated well with measures of knee flexor and extensor muscle strength (Csuka & McCarty, 1985). Participants sit in a straight-back chair that is 44.5 cm high and 38 cm deep and are asked to rise with their arms folded. Participants are asked to fold their arms across their chests and to stand up from a sitting position once; if they successfully rise, they are asked to stand up and sit down five times as quickly as possible. Time to stand is measured as the nearest tenth of a second by use of a stopwatch. Raw scores are then transformed into a rate per minute in order to accurately assess change in those who were unable to perform the test at any point.

*Six-Minute Distance Walk.*—We use the 6-min walk test in the method described by Guyatt and associates (1985). The test measures functional exercise capacity reliably and correlates moderately to strongly with treadmill or bicycle ergometer tests. It is thought by some to possibly be a more relevant indicator of functional status than the high workloads associated with other exercise tests. We use a hard, smooth, surface that is free of obstructions. Participants are instructed to walk as fast and as far as possible within the 6-min period and are accompanied by research staff who have been trained in the use of a Rolatape Measure Master, which measures distance walked in feet.

*WOMAC.*—In addition to the objective measures described herein, we also used the Western Ontario and McMasters University Osteoarthritis Index (WOMAC) self-report instrument to examine lower extremity pain, stiffness, and physical function (Bellamy, 1989). The WOMAC is used in many OA outcome studies and is made up of three subscales, including a 5-item pain scale, a 2-item stiffness scale, and a 17-item physical function scale with reliabilities of .86, .71, and .96, respectively, in the current sample.

*Independent Variables.*—The primary independent variable is group membership, which was coded 1 for the treatment group and 0 for the control group.

*Demographic Variables.*—The demographic variables include age, race, gender, income, type of health insurance coverage, and maximum level of education obtained.

## Analyses

The design involves one between-group factor (experimental vs. control) and one within-subject factor (time). Our analyses use only one covariate, which is baseline disease severity as measured by ACR Functional Class. By using arthritis severity as a covariate in the analyses, we can determine the effect of the treatment separate from the impact of severity. We treat time nonlinearly by including indicator variables for the 2- and 6-month measurement points, treating baseline as the reference category. We can write a simple linear model for the data:

$$\begin{aligned} Y_{it} = {} & b_0 + b_1\text{Time}_2 + b_2\text{Time}_6 + b_3\text{Group} \\ & + b_4\text{Time}_2 \times \text{Group} + b_5\text{Time}_6 \times \text{Group} \\ & + b_6\text{Severity}, \end{aligned}$$

where the interaction terms, $\text{Time}_2 \times \text{Group}$ and $\text{Time}_6 \times \text{Group}$, test whether the two groups change differently over time; that is, they test whether the time

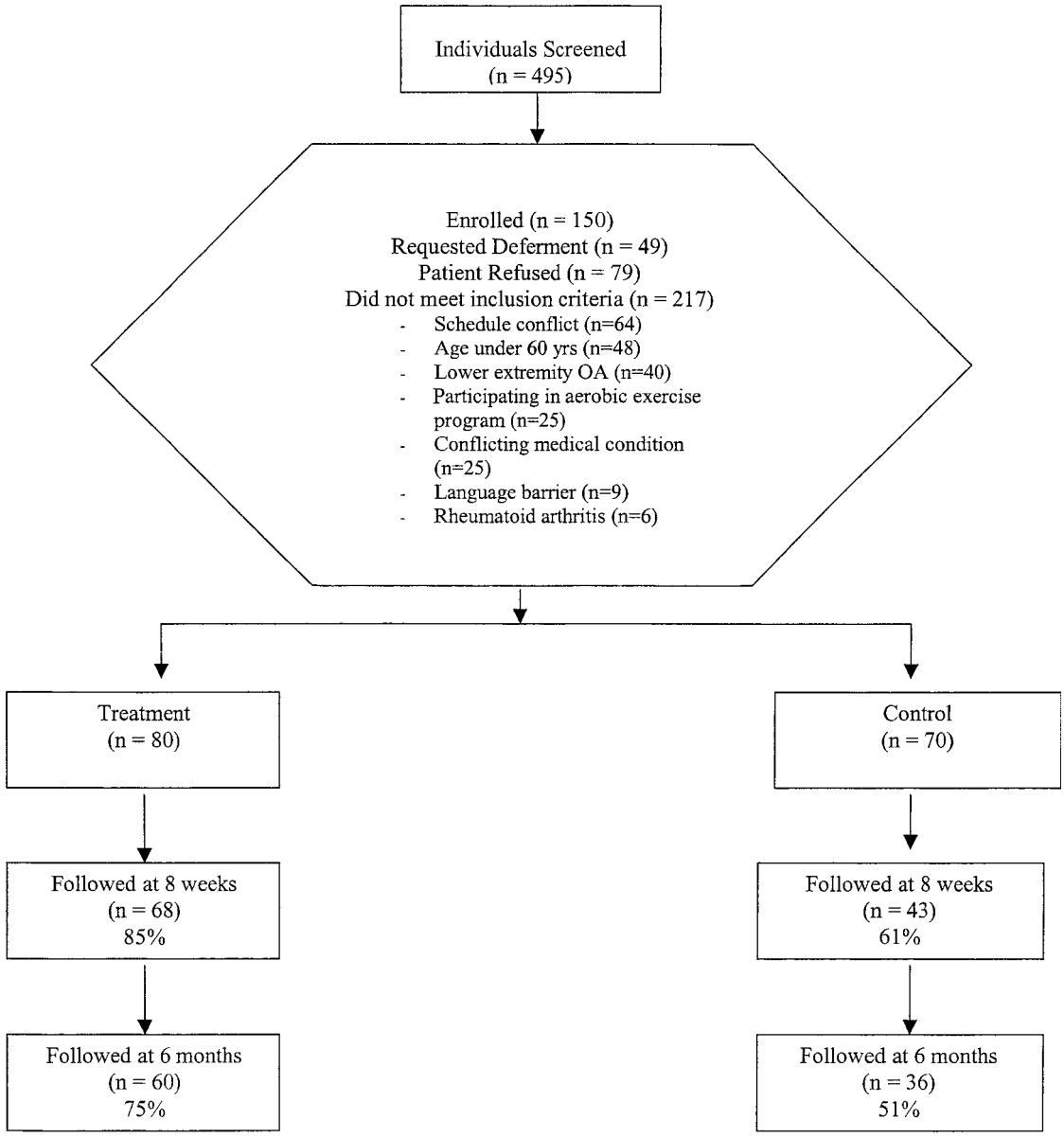


Figure 1. Flow diagram: Iterations 1–7 (OA = osteoarthritis).

trend differs by group. Because we have repeated measures data, we cannot assume independence of observations. In addition, because we have different numbers of respondents by group over time, we needed to use a more complex approach than a simple repeated measures analysis based on an analysis of variance (ANOVA). We, therefore, analyzed the data by using generalized estimating equation (GEE) methodology (Liang & Zeger, 1986). GEE methodology provides consistent estimators of regression coefficients and their corresponding variances under mild assumptions about time dependence. We assumed an exchangeable correlation structure in the analysis; however, GEE estimates of standard errors are robust to violations of that assumption. The $Time_2 \times Group$ interaction tests whether the treatment and control groups differ at two months, whereas the $Time_6 \times Group$ interaction tests whether the groups differ at 6 months relative to their baseline scores.

## Results

Enrollment in this study began in 1997 and is still ongoing. The data presented in this paper pertain to the first 150 persons enrolled in the study between the study start date and the completion of 6-month outcomes data on Iteration Groups 1–7. As data in the flow diagram (Figure 1) demonstrate, 495 individuals were screened for eligibility over this period. Of this group, 150 (30.3%) met the criteria and were enrolled in the study, 217 (43.8%) were ineligible (Figure 1), 79 (16%) were eligible but refused to participate, and 49 (9.9%) were eligible but requested to defer enrollment to a later date.

Baseline demographic and disease data on study participants are shown in Table 1. Participants had a mean age of 74 years; a majority were female, White, had annual incomes under $20,000, had at least a high school education, and had Class 2 ACR functional class scores. Approximately 60% of the total sample also reported the presence of cardiovascular disease; 10% reported diabetes, and 5% reported asthma, emphysema, and cancer. All participants received scores in the "intact functioning" range on the SPMSQ (0–2 errors), indicating a lack of cognitive impairment. No significant differences were noted by group on any of the demographic measures.

Baseline values of the study outcome measures are shown in Table 2. The treatment group had significantly higher scores at baseline versus the control group with respect to the Lorig Self-Efficacy and McAuley Adherence Efficacy Scales as well as the timed sit–stands rate per minute. However, no significant differences were seen by group at baseline with respect to the WOMAC, the 6-min distance walk, or the total minutes of exercise per week, with both groups exercising for roughly 90–110 min per week at baseline. We expect that the differences seen represent chance deviations from equality. However, our statistical methods evaluate experimental effects relative to expected variances in group means over time, assuming no experimental effect; that is, the statistical tests do not require or assume that group means are equal at baseline.

**Table 1. Baseline Demographic and Disease Characteristics by Group, Iterations 1–7**

| Characteristic | Treatment Group ($n = 80$) % or $M$ | Control Group ($n = 70$) % or $M$ | $p$ Value |
|---|---|---|---|
| Age | 73.5 (*SD* 6.75) | 73.7 (*SD* 6.32) | .82 |
| Gender | 81.0 | 87.1 | .33 |
| Education | | | .26 |
| <High school | 9.0 | 10.0 | |
| High school | 25.6 | 22.9 | |
| >High school | 65.4 | 67.1 | |
| Income | | | .80 |
| <$20,000 | 30.1 | 38.2 | |
| Race | | | .44 |
| White–Caucasian | 84.6 | 78.6 | |
| African American | 12.8 | 12.9 | |
| Hispanic | 1.3 | 4.3 | |
| Asian–Pacific Islander | 1.3 | | |
| Other | | | |
| ACR class | | | .90 |
| I | 23.0 | 21.0 | |
| II | 66.2 | 66.1 | |
| III | 10.8 | 12.9 | |
| Comorbid conditions | | | |
| Cardiovascular disease | 58.5 | 61.0 | .81 |
| Asthma | 5.1 | 6.3 | .78 |
| Emphysema | 5.1 | 3.1 | .56 |
| Diabetes | 11.4 | 10.9 | .91 |
| Cancer | 6.4 | 4.8 | .67 |

*Note*: ACR = American College of Rheumatology.

### *Attendance*

Treatment group participants attended a mean of 18.9 ($SD = 4.3$) sessions out of the 24 possible sessions. Seventy percent of treatment group participants attended at least 75% of the sessions.

### *Attrition*

Two-month posttests were obtained for 85% of the treatment group participants and 61% of the control group participants. Six-month posttests were obtained for 75% of treatment group participants and 51% of control group participants (see Figure 1). Logistic regression analyses were conducted to determine if differential attrition occurred between baseline and 2 and 6 months. These analyses demonstrated no significant differences between responders and nonresponders on any of the outcome measures. The analysis also indicated that there are no statistically significant differences between responders and nonresponders in terms of demographic characteristics or level of arthritis severity.

### *Two- and Six-Month Outcomes*

Table 2 shows mean outcome scores by time for the treatment and control groups. Table 3 shows the results of the GEE analyses, which included baseline and 2- and 6-month measures of the outcomes. In each analysis, the $\text{Time}_2 \times \text{Group}$ and $\text{Time}_6 \times \text{Group}$ tests whether the experimental group shows greater change relative to baseline than the control group at 2 and 6 months. Our GEE analyses automatically included the baseline measures as well as the 2-month and 6-month measures of the outcomes, under the assumption that measures from an earlier time point are correlated with subsequent measures of the same outcome. Thus, in a sense, the analyses control for baseline status on these measures. All tests are based on one-tailed tests, assuming Time × Group coefficients greater than zero with ACR functional class as a covariate.

*Lorig Self-Efficacy Scales.*—A significant difference ($p < .05$) was seen favoring the treatment vs. the control group at 2 and 6 months on the Lorig Self-Efficacy for Exercise Scale (Figure 2). Treatment group scores increased at 2 months and remained slightly higher than baseline levels at 6 months. In contrast, control group scores declined steadily between both time periods. No differences were seen by group at either time period on the Lorig Self-Efficacy for Arthritis Pain Management or Symptom

Table 2. Mean Outcome Scores Over Time by Treatment Group

| Measure | Treatment Group | | | Control Group | | |
|---|---|---|---|---|---|---|
| | Baseline ($n = 80$) | 2 Months ($n = 68$) | 6 Months ($n = 60$) | Baseline ($n = 70$) | 2 Months ($n = 43$) | 6 Months ($n = 36$) |
| Lorig Self-Efficacy Scale | | | | | | |
| Exercise | 7.8 | 8.2 | 7.9 | 6.9 | 6.6 | 5.9 |
| | (2.6) | (2.4) | (2.5) | (3.9) | (4.3) | (2.8) |
| Arthritis pain management* | 74.3 | 74.7 | 73.5 | 65.4 | 66.1 | 60.2 |
| | (21.5) | (20.6) | (22.6) | (22.2) | (19.9) | (23.1) |
| Symptom management* | 78.6 | 78.7 | 75.5 | 72.2 | 71.2 | 67.9 |
| | (18.5) | (20.6) | (22.4) | (19.8) | (21.6) | (22.1) |
| McAuley Self-Efficacy Scale | | | | | | |
| Barriers adherence* | 73.5 | 59.1 | 59.7 | 65.5 | 54.3 | 50.5 |
| | (22.9) | (28.2) | (24.1) | (22.6) | (24.3) | (19.6) |
| Time adherence | 82.8 | 79.2 | 73.1 | 78.2 | 67.6 | 53.1 |
| | (21.0) | (24.9) | (32.3) | (19.3) | (32.9) | (35.8) |
| Adherence | | | | | | |
| Minutes spent exercising* | 100.3 | 168.9 | 148.8 | 92.1 | 98.0 | 72.9 |
| | (112.6) | (112.4) | (146.1) | (92.9) | (101.9) | (96.2) |
| Performance measures | | | | | | |
| Timed sit–stand | 21.5* | 25.1 | 24.9 | 16.6* | 20.3 | 18.0 |
| | (8.6) | (9.7) | (11.5) | (8.8) | (8.6) | (8.4) |
| 6-min walk | 1157.0 | 1311 | 1310.2 | 1075.6 | 1108.5 | 1095.4 |
| | (395.8) | (3839) | (437.2) | (343.8) | (347.5) | (354.9) |
| WOMAC | | | | | | |
| Pain | 5.9 | 4.9 | 5.1 | 6.5 | 6.2 | 6.7 |
| | (3.9) | (3.4) | (3.7) | (3.9) | (4.3) | (3.9) |
| Stiffness | 3.2 | 2.7 | 2.8 | 2.9 | 3.2 | 3.2 |
| | (1.8) | (1.3) | (1.5) | (1.7) | (1.8) | (1.7) |
| Physical function | 21.1 | 17.3 | 18.3 | 25.0 | 22.3 | 24.1 |
| | (11.9) | (12.6) | (12.6) | (13.9) | (12.8) | (14.6) |

*Notes*: WOMAC = Western Ontario and McMasters University Osteoarthritis Index.
Standard deviations are given in parentheses.
*Significant difference at baseline ($p < .05$).

Management Scales. Efficacy for arthritis pain management increased slightly from baseline levels at 2 months in both groups, and it was maintained in the treatment group but declined in the control group by 6 months.

*McAuley Barriers and Time Exercise Adherence Efficacy.*—No significant differences were seen by group on the McAuley scale that assessed confidence in ability to continue exercising despite the existence of a variety of barriers at 2 or 6 months relative to the baseline scores. No differences were seen at 2 months between the treatment and control groups on the second McAuley scale, which measures confidence to adhere to exercise over varying periods of time in the future; however, differences bordering on significance ($p = .052$) favoring the treatment group were seen at 6 months.

*Adherence.*—Significant differences ($p = .006$) were seen favoring the treatment group versus the control group at both 2 and 6 months on number of minutes of exercise per week. Control group mean minutes of exercise per week increased from 92.1 at baseline to 98 min at 2 months; however, this rate dropped to 72.9 at 6 months. In contrast, the comparable values for the treatment group were 100.2 at baseline, 168.9 at 2 months, and 148.8 at 6 months, yielding an increase of 48.5% over baseline scores at 6 months. Although minutes of exercise per week declined slightly among the treatment group between 2 and 6 months, their level of participation continued to be above the goal of 30 min three times per week.

*Timed Stand.*—No significant differences were seen by group at either 2 or 6 months in rate of timed stands per minute. The range of values for both treatment and control group members for the rate of timed stands per minute was very large, 0–50.0 at baseline for treatment and 0–33.7 for control group members, indicating that a larger sample size might be necessary to detect a difference on this outcome. A post hoc within-group analysis revealed a significant increase within the treatment group on this outcome, compared with no difference with the control group.

**Table 3. GEE Outcome Analyses**

| Measure | Group | 2 Months | 6 Months | ACR Class | $Time_2 \times Group$ | $Time_6 \times Group$ |
|---|---|---|---|---|---|---|
| Lorig Self-Efficacy Scale | | | | | | |
| Exercise | | | | | | |
| Coefficient | 0.410 | −0.603 | −1.189 | −0.697 | 1.057 | 1.316 |
| *z* Score | 0.97 | −1.65 | −2.68 | −2.51 | 2.15 | 2.36 |
| *p* Value | .166 | .049 | .004 | .006 | .016* | .009* |
| Arthritis pain management* | | | | | | |
| Coefficient | 6.542 | −0.310 | −5.501 | −10.265 | 0.688 | 5.326 |
| *z* Score | 1.8 | −0.11 | −1.77 | −4.41 | 0.18 | 1.23 |
| *p* Value | .036 | .456 | .038 | .000 | .43 | .11 |
| Symptom management* | | | | | | |
| Coefficient | 4.902 | −1.853 | −3.148 | −11.100 | 2.045 | 1.414 |
| *z* Score | 1.56 | −0.56 | −1.09 | −4.87 | 0.52 | 0.38 |
| *p* Value | .060 | .288 | .138 | .000 | .301 | .351 |
| McAuley Self-Efficacy Scale | | | | | | |
| Barriers efficacy | | | | | | |
| Coefficient | 7.802 | −10.522 | −12.641 | −6.052 | −2.780 | −2.0175 |
| *z* Score | 1.8 | −2.31 | −3.35 | −2.24 | −0.47 | −0.4 |
| *p* Value | .036 | .010 | .001 | .013 | .318 | .344 |
| Adherence efficacy | | | | | | |
| Coefficient | 4.702 | −8.280 | −23.287 | −5.703 | 2.712 | 12.077 |
| *z* Score | 1.23 | −1.92 | −3.67 | −1.82 | 0.51 | 1.63 |
| *p* Value | .109 | .028 | .000 | .34 | .304 | .051 |
| Adherence | | | | | | |
| Adherence (log of min/week) | | | | | | |
| Coefficient | −.1443 | .026 | −.240 | −.283 | .602 | .791 |
| *z* Score | −.074 | 0.20 | −1.25 | −2.16 | 3.08 | 3.17 |
| *p* Value | .228 | .419 | .101 | .015 | .001* | .001* |
| Performance measures | | | | | | |
| Timed sit–stand rate/min | | | | | | |
| Coefficient | 4.557 | 2.912 | 1.543 | −3.981 | −.309 | 1.592 |
| *z* Score | 3.19 | 1.67 | 1.55 | −2.77 | −0.16 | 1.06 |
| *p* Value | .001 | .048 | .061 | .003 | .436 | .145 |
| 6-min distance walk (ft) | | | | | | |
| Coefficient | 47.167 | 19.147 | 34.270 | −222.159 | 126.740 | 115.190 |
| *z* Score | 0.76 | 0.42 | 0.78 | −4.30 | 2.48 | 2.10 |
| *p* Value | .224 | .336 | .218 | .000 | .007* | .018* |
| WOMAC | | | | | | |
| Pain | | | | | | |
| Coefficient | −2.172 | −.137 | .495 | 2.541 | −.789 | −1.439 |
| *z* Score | 0.35 | −0.28 | 0.90 | 6.31 | 1.23 | −2.06 |
| *p* Value | .724 | .779 | .370 | .000 | .220 | .019* |
| Stiffness | | | | | | |
| Coefficient | .424 | .436 | .197 | .540 | −.904 | −.639 |
| *z* Score | 1.49 | 1.98 | 0.75 | 2.71 | −2.88 | −1.92 |
| *p* Value | .137 | .048 | .456 | .007 | .002* | .028* |
| Physical function | | | | | | |
| Coefficient | −2.874 | −1.744 | −.844 | 9.120 | −2.211 | −2.025 |
| *z* Score | −1.43 | −1.22 | −0.47 | 6.32 | −1.16 | −0.90 |
| *p* Value | .152 | .221 | .637 | .000 | .246 | .366 |

*Notes*: GEE = generalized estimating equation; ACR = American College of Rheumatology; WOMAC = Western Ontario and McMasters University Osteoarthritis Index.
*One-tailed tests.

*Six-Minute Distance Walk.*—Significant differences were seen favoring the treatment group at 2 ($p = .007$) and 6 months ($p = .018$; Figure 3). Mean treatment group scores increased from 1,157 ft (350.6 m) at baseline to 1,311 ft (397.2 m) at 2 months and remained at 1,310 ft (396.9 m) at 6 months, whereas the control group mean increased from 1,075 ft (325.8 m) at baseline to 1,108 ft (335.8 m) at 2 months but reverted to 1,095 ft (331.8 m) at 6 months. Overall, treatment group scores increased by 13.3% between baseline and 6 months.

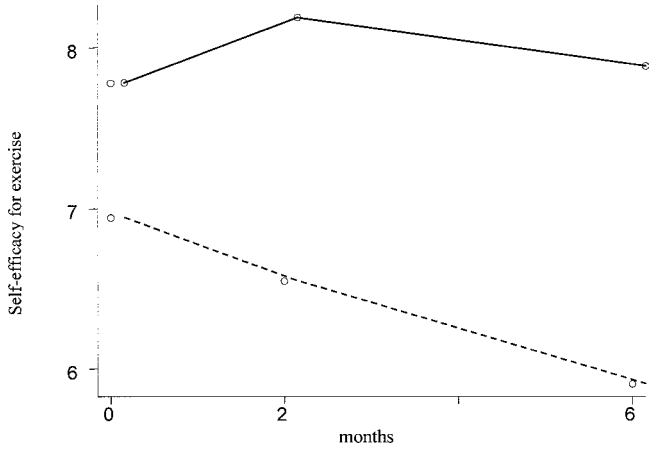


Figure 2. Lorig Self-Efficacy for Exercise Scale. Treatment group (solid line); control group (dashed line).

*WOMAC.*—Significant differences favoring the treatment group were seen on two of the three WOMAC scales. The treatment group improved significantly vis-à-vis controls with respect to pain scores ($p = .019$) at 6 months. Stiffness scores decreased significantly in the treatment group by the 2-month observation ($p = .002$) and continued to be significant at 6 months ($p = .028$; Figure 4). However, no differences were seen between the two groups on the physical function scale at either 2 or 6 months. Both groups' physical function scores improved between baseline and 2 months, with the treatment group experiencing more improvement. This improvement over baseline was maintained in the treatment group at 6 months, whereas the control group mean reverted to close to baseline status. If the latter trends in both groups continue, it is possible that significant differences will be seen on this measure at subsequent measurement points.

## Discussion

Lower extremity impairment is a known risk factor for future disability and is highly prevalent among persons with OA. Given the substantial increases that are expected in the number of older persons with OA over the next 20 years, the need to develop and test interventions that can improve lower extremity functioning is imperative. Older adults with OA are known to have both compromised lower extremity strength and aerobic capacity compared with persons of the same age without OA. Thus, it is important that interventions address both of these limitations. Finally, because the benefits of strength and aerobic exercise can be maintained only among persons who adhere to exercise routines over time, it is essential that interventions include educational components that help motivate older adults with OA to embrace and adhere to exercise behaviors over time. Because of the urgency of this public health problem, we believed it was important to publish the early findings of a multicomponent intervention that addressed all of these issues simultaneously.

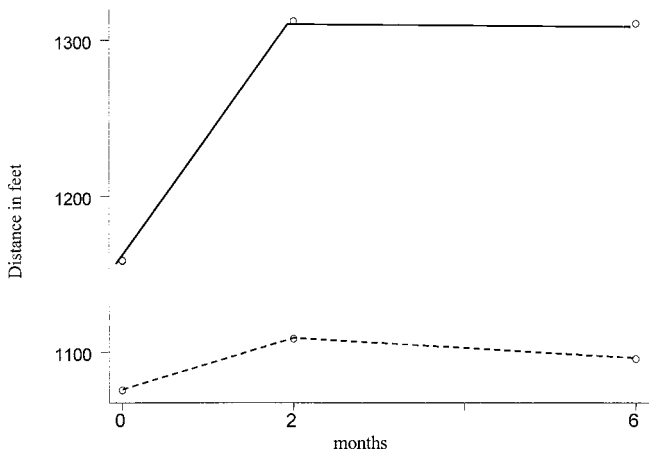


Figure 3. Six-minute walk. Treatment group (solid line); control group (dashed line).

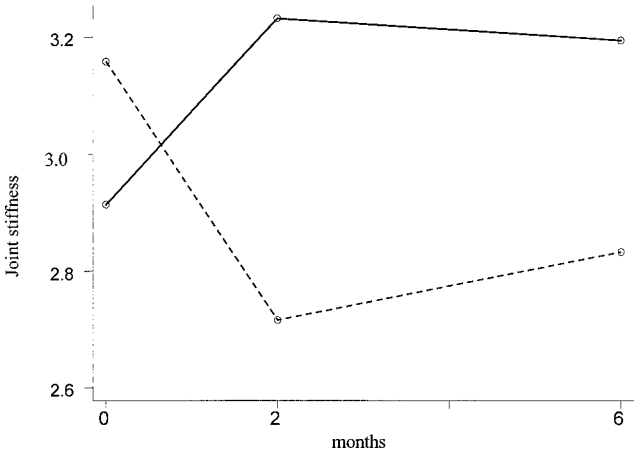


Figure 4. Western Ontario and McMasters University Osteoarthritis Index (WOMAC) Stiffness Scale. Treatment group (solid line); control group (dashed line).

The Fit and Strong Intervention that we developed for community-dwelling older adults with lower extremity OA attempted to meet the aforementioned needs by developing an intervention that combined lower extremity strength and aerobic walking with health education for exercise, disease management, and exercise adherence efficacy. We intentionally used readily available, inexpensive materials to design an intervention that could be reproduced at minimal cost for large numbers of participants. The intention of the intervention was to train participants to exercise independently after the formal training ended. Preliminary findings at 6 months from this 24-month randomized trial demonstrate multiple beneficial outcomes of the intervention. Persons in the treatment group had significantly better outcomes than persons in the control group with respect to exercise efficacy, exercise adherence, lower extremity stiffness (WOMAC), and 6-min distance walk at 2 and 6 months. A significant improvement in lower extremity pain was also seen

in the treatment group at 6 months that was accompanied by a borderline significant improvement in self-efficacy to adhere to exercise over time.

Mean number of minutes participating in exercise over 6 months increased in the treatment group by 48.5% while declining in the control group by 20.8% over the same time period. As a result, the adherence rate at 6 months in the treatment group was twice that in the control group (148.8 vs. 72.9, respectively). This increase in adherence is particularly meaningful in view of the fact that individuals developed their own exercise regimens for the 4-month period following the completion of the 2-month training.

It is important to compare our outcomes with those reported in the single-component trials referenced earlier, but it is difficult to make exact comparisons because different outcome measures and time frames were used across studies. One outcome that was measured consistently across several studies was the 6-min distance walk. We observed a significant 13.3% increase in this outcome in the treatment group at 2 months that was maintained at 6 months. This finding compares reasonably well with an 18.4% increase reported by Kovar and colleagues (Kovar et al., 1992) at 2 months that was not maintained at 12 months (Sullivan, Allegrante, Peterson, Kovar, & MacKenzie, 1998) and to an 11.7% difference between the aerobic training and health education control group reported by Ettinger and colleagues (1997) at 18 months.

It is interesting to note that self-reported joint stiffness declined significantly in the treatment group at 2 months and was sustained at 6 months, whereas scores on the WOMAC pain scale did not decrease significantly until 6 months. This temporal difference may indicate that a decrease in stiffness is a necessary precondition for a diminution of pain, a finding that would be worth exploring in future research.

No significant differences were seen between groups in self-efficacy for disease management or arthritis pain, possibly because the majority of the discussion sessions were devoted to issues regarding exercising safely with OA and overcoming barriers to exercise adherence. Despite this latter emphasis, actual scores on self-efficacy to overcome barriers to adherence declined in both groups. A possible explanation for this finding is that participants might have initially overestimated their ability to deal with the barriers, and over time grew to view the barriers with more respect. We also did not find treatment effects on the WOMAC functional status scale or the timed-stand test. We originally hypothesized that functional status was a distal outcome in contrast to more proximal outcomes of exercise efficacy and pain. Thus, it will be important to continue to monitor this outcome at the outstanding 12-, 18-, and 24-month posttests. The lack of a treatment effect on the timed-stand test may reflect the substantial amount of variance on this measure in both groups at baseline and may indicate that a larger sample is needed to test this adequately. This interpretation is bolstered by the fact that within-group analyses found that treatment group scores increased significantly over baseline whereas control group scores did not.

This study has some limitations. First, although our multicomponent intervention is based on evidence regarding deficits in older adults with OA and is theoretically driven, it is impossible to conclude from this design whether all three components of the intervention are necessary to attain the reported results. However, previous trials of individual components have indicated that aerobic walking and aquatics achieve similar results (Minor et al., 1989) and that strength training and aerobic training achieve similar results (Ettinger et al., 1997). Thus, we believed the compelling research question and the question with the greatest public health significance concerned the impact of a multicomponent intervention that combined strength and aerobic training with education for sustained behavior change, and we did not have the resources to conduct a study with four cells that compared the combined components with each of their individual parts. Second, attrition from posttest measurement was higher among control group participants. However, logistic regression analyses found no significant differences between responders and nonresponders on any of the outcome, demographic, or arthritis severity measures. Third, it is not possible to blind participants in an exercise trial as to their treatment status. Thus, some of the self-reported outcomes may reflect respondent bias. However, a robust treatment effect was also seen on the 6-min distance walk, which is a timed performance measure. Thus, we do not believe these limitations seriously affect the validity of the results.

Several exercise approaches can be used to increase fitness among older adults. Of these, we selected fitness walking because it has demonstrated efficacy in previous randomized trials with younger participants with OA (Kovar et al., 1992; Minor et al., 1989), and we believed it would be relatively easy for older persons to adhere to over time. Fitness walking requires almost no equipment except a pair of well-fitting shoes and can be performed in a variety of settings that can be adapted to the circumstances of each participant. The strength training component relied on ankle cuff weights that are available at any major outlet store and low-cost therabands that are commonly used in exercise programs for seniors.

In addition to instruction in the use of equipment that is low cost and easily obtainable, participants also need mechanisms to provide positive reinforcement of exercise behavior after the formal exercise training ends (Duncan & McAuley 1993). Although earlier studies (Ettinger et al., 1997; Jette et al., 1999) included telephone calls and home visits in efforts to boost exercise and exercise adherence efficacy,

neither trial directly assessed the impact of reinforcement on efficacy outcomes. Thus, we believe that this is one of a few if not the first arthritis exercise trial among older adults to demonstrate the benefits of an intervention on these important intermediate outcomes. Actual exercise minutes per week at 6 months in this trial were twice as high in the treatment group (148.8) than in the control group (72.9), probably reflecting these benefits in self-efficacy that were achieved by 8 weeks of discussion sessions, the development of negotiated exercise adherence plans and contracts, the use of exercise logs, and quarterly telephone calls.

In summary, preliminary findings from this 24-month trial suggest that this low cost, multiple-component intervention with older adults with lower extremity OA can increase self-efficacy for exercise and substantially increase exercise adherence while modestly decreasing participants' lower extremity pain and stiffness and increasing their functional status as measured by the 6-min distance walk. It is important that no adverse health outcomes were observed in the treatment group, indicating that the intervention is safe to replicate with this target group. Future work will examine whether these benefits continue to be maintained at 12, 18, and 24 months.

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