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Long-Term Impact of Fit and Strong! on Older Adults With Osteoarthritis

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Purpose: We present final outcomes from the multiple-component Fit and Strong! intervention for older adults with lower extremity osteoarthritis. ***Design and Methods:*** A randomized controlled trial compared the effects of this exercise and behavior-change program followed by home-based reinforcement (n = 115) with a wait list control (n = 100) at 2, 6, and 12 months. Fit and Strong! combined flexibility, aerobic walking, and resistance training with education and group problem solving to enhance self-efficacy for exercise and maintenance of physical activity. All participants developed individualized plans for long-term maintenance. ***Results:*** Relative to controls, treatment participants experienced statistically significant improvements in self-efficacy for exercise (p = .001), minutes of exercise per week (p = .000), and lower extremity stiffness (p = .018) at 2 months. These benefits were maintained at 6 months and were accompanied by increased self-efficacy for adherence to exercise over time (p = .001), reduced pain (p = .040), and a marginally significant increase in self-efficacy for arthritis pain management (p = .052). Despite a substantially smaller sample size at 12 months, significant treatment-group effects were maintained on self-efficacy for exercise (p = .006) and minutes of exercise per week (p = .001), accompanied by marginally significant reductions in lower extremity stiffness (p = .056) and pain (p = .066). No adverse health effects were seen. Effect sizes for self-efficacy for exercise and for maintenance of physical activity were 0.798 and 0.713, and 0.905 and 0.669, respectively, in the treatment group at 6 and 12 months. ***Implications:*** This consistent pattern of benefits indicates that this low-cost intervention is efficacious for older adults with lower extremity osteoarthritis.

Key Words: Arthritis, Exercise, Outcomes, Physical activity, Self-efficacy

Osteoarthritis 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 a current level of 43 million affected adults to 60 million by 2020 (Centers for Disease Control and Prevention, 1999). Lower extremity osteoarthritis, in particular, is a known risk factor for disability (Guralnik, Ferrucci, Simonsick, Salive, & Wallace, 1995; Jette, Branch, & Berlin, 1990), and lower extremity joint impairment that is due to osteoarthritis has been demonstrated to be a major mechanism through which disability develops (Dunlop, Hughes, & Manheim, 1997). Osteoarthritis is painful and causes limitation of mobility, as individuals with osteoarthritis, particularly in their large lower extremity weight-bearing joints, minimize movement in order to reduce their exposure to pain. Comparisons of age-matched peers with and without osteoarthritis have shown that the condition is associated with both reduced lower extremity strength and reduced aerobic functioning (Minor, Hewett, Weber, Anderson, & Kay, 1989; Semble, Loeser, & Wise, 1990). The latter finding indicates that reduced physical activity associated with lower extremity osteoarthritis may negatively affect cardiovascular capacity.

Over the past 20 years, several exercise interventions have been developed and tested among older adults with osteoarthritis. Three early single-group pretest–post-test studies of strengthening exercises found significant short-term treatment-group

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improvements in knee flexor and extensor strength (Chamberlain, Care, & Harfield, 1982; Fisher, Pendergast, Gresham, & Calkins, 1991; Kreindler, Lewis, Rush, & Schaefer, 1989). A more rigorous controlled study by Minor and colleagues (1989) assessed the impact of aerobic walking or aquatics versus range-of-motion exercise alone among individuals with osteoarthritis and rheumatoid arthritis. Findings at 3 months included significant improvements in aerobic functioning among both aerobic treatment groups versus the control group (Minor et al.).

Between 1992 and 2003, findings were published from several trials both here and abroad that tested the impact of exercise on individuals with lower extremity osteoarthritis. Kovar and colleagues (1992) tested supervised fitness walking combined with patient education and found significant increases on 6-minute distance walk (18.4%) and physical activity (39%) that were accompanied by a significant 27% decrease in arthritis pain at 2 months. These improvements were not sustained at 12 months (Sullivan, Allegrante, Peterson, Kovar, & Mackenzie, 1998).

Ettinger and colleagues (1997) compared the impact of aerobic exercise versus resistance training versus health education alone on self-reported and performance-based disability at 18 months for individuals with knee osteoarthritis. They found superior outcomes on physical functioning for both the aerobic exercise and resistance-training groups. Although maintenance of physical activity was similar in both of these intervention groups, slightly higher improvements were noted in the aerobic group, with improvements in performance measures averaging 10% to 15% versus controls.

A Dutch study by van Baar and colleagues (2001) tested prescribed strength exercise as well as exercises provided by a physiotherapist that were intended to improve mobility, coordination, and locomotion. The 12-week exercise treatment was associated with an 11.5% decrease in pain at 24 weeks that was not sustained at 36 weeks.

A Turkish study by Evcik and Sonel (2002 tested home-based resistance training versus regular walking 3 times per week versus a no-treatment control group. At 3 months, lower extremity pain and disability scores were significantly lower in both treatment groups than in the control group, but quality of life improved significantly in the walking group only.

Finally, a British study by Thomas and colleagues (2002) tested home-based resistance training and range of motion versus monthly telephone contact (socialization) versus exercise plus monthly telephone socialization versus no intervention. Findings at 24 months included significant reductions in knee pain, stiffness, and functional disability in the pooled exercise groups (difference, $M = -0.82$). The reduction in pain was greater among those who adhered closely to the exercise plan.

Although both the Ettinger study and the Thomas study found improvements in long-term physical functioning among older adults with lower extremity osteoarthritis, they did not address the important question of whether the effects might have been stronger if the treatments had been combined; for example, they did not address whether the treatments have an additive effect if they are combined into a single multicomponent intervention that incorporates range of motion, aerobic conditioning, strength training, *and* education for behavior change. Because the literature has documented both strength and aerobic deficits in older adults with osteoarthritis compared with age-matched controls, we believed that the next step in the development of an intervention would be the development and testing of such a multicomponent intervention. We also believed that it was important to develop an intervention that was low cost and easy to replicate broadly.

Thus, we developed Fit and Strong!, an 8-week facility-based intervention that uses elastic exercise bands and ankle cuff weights that can be purchased in any major outlet store for resistance training. The strength training was combined with aerobic walking and education and group problem-solving sessions designed to foster self-efficacy for exercise, maintenance of physical activity, and commitment to lifestyle change. Fit and Strong! meets for 90 minutes, 3 times a week, for 8 weeks. Progressively advanced flexibility, aerobic walking, and resistance exercises are conducted in the first hour, followed by 30 minutes of group problem-solving discussions. The facility-based intervention is followed by a home-based component geared to reinforce long-term exercise maintenance. We tested the impact of Fit and Strong! by using a randomized trial.

Preliminary findings on the efficacy of Fit and Strong!, based on the first consecutively enrolled 150 participants at 2 and 6 months, have already been published (Hughes et al., 2004). Those findings included significant improvements in self-efficacy for exercise and a 48.5% increase in minutes of exercise per week that were accompanied by significant decreases in lower extremity stiffness at 2 and 6 months among treatment-group participants (Hughes et al.) Treatment-group participants ($n = 80$) also experienced a significant decrease in lower extremity pain and a borderline significant improvement in self-efficacy to adhere to exercise over time ($p = .052$). In contrast, individuals in the no-treatment control group ($n = 70$) deteriorated over time on the measures of efficacy and minutes of exercise per week and showed no change on the other measures. No adverse health effects were encountered. Although these preliminary findings were positive, it was important to report the final findings with the full study sample, which was tracked over a longer period of time. Thus, in this article we present the final findings

from the trial based on 215 participants at 2, 6, and 12 months.

Methods

In this study we assessed the short- and long-term efficacy of and adherence to a multicomponent exercise intervention for older adults with mild to moderate lower extremity osteoarthritis. The Fit and Strong! intervention lasts 8 weeks and each iteration accommodates approximately 15 enrollees. We repeated the intervention in successive iterations in order to achieve a final targeted sample of 215 participants. We used a randomized block design with blocks consisting of 30 participants (15 treatment and 15 control). Within each block, we stratified within American College of Rheumatology (ACR) functional classes (I, II, or III) (American Rheumatism Association, 1982) to achieve balance on this variable within the two study groups.

Setting

We conducted the study at senior centers and senior housing residences on the north side of Chicago. Participants were community-dwelling older adults who were recruited by newsletter, announcements in the local media, and presentations to local senior groups.

Procedures

We used a phone screen to assess participants' study eligibility, explain study procedures, and schedule a baseline interview. At the baseline in-person interview, research staff obtained informed consent, the participant underwent a physical exam with a rheumatologist, and the baseline interview was completed. At that point, we randomized the participant to either the treatment or the control group. We entered the participant's name in an appropriate space in a prepared log to one of three categories based on functional class, and we used a random number to assign the participant to the treatment or control group. Research staff informed participants regarding group assignment and ensured that all educational materials were provided to the class instructors. Physical therapists trained in geriatrics led the exercise sessions, maintained attendance and performance records for each intervention participant, and developed individualized maintenance plans with each participant before the intervention ended. Follow-up interviews regarding maintenance were made quarterly by telephone; in-person interviews were conducted at baseline and at 2, 6, and 12 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

We screened volunteers at baseline to rule out the presence of moderate to severe cognitive impairment by using the Short Portable Mental Status Questionnaire (Kahn, Goldfarb, Pollack, & Peck, 1960). The study rheumatologist also performed a physical examination of their joints and muscles. In the physical examination, the rheumatologist determined the clinical presence of osteoarthritis of the hip or knee and rated the degree of functional significance by using a modified version of the ACR functional classes (American Rheumatism Association, 1982).

Clinical criteria for the presence of knee osteoarthritis were knee pain plus at least three of the following six clinical findings: age > 60 years, morning stiffness that lasts < 30 minutes, 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). We classified a person as having hip osteoarthritis if pain was 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 ≤ 60 minutes, 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). We advised individuals with an acutely inflamed or significantly swollen joint to come back for reexamination and possible inclusion in the next iteration of the intervention. We invited those who met the inclusion criteria to participate in the trial on a first-come basis. We excluded individuals 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.

Sample Characteristics

We conducted these analyses on 215 study participants (treatment = 115, control = 100), using data that we collected at baseline and at 2, 6, and 12 months.

The Intervention

We offered Fit and Strong! in 90-minute sessions held three times per week for 8 weeks. The maximum number of participants in each iteration was 15. We addressed treatment fidelity in several ways over the duration of the study. First, we had all sessions led by one of three physical therapists who shared responsibility for each iteration. Second, we developed instructor and participant manuals during the first iteration of the program and used the same manuals for the duration of the study. Third, the physical therapists maintained detailed notes on

each class that they shared with each other and with the research team to assess and monitor treatment fidelity during each iteration. Fourth, the principal investigator and research assistants attended several classes throughout each 8-week iteration to assess treatment fidelity. These class visits revealed a substantial degree of consistency across classes and instructors. Finally, the research team met with the instructors at the end of each iteration to "debrief" and continuously solve problems with respect to improving the exercise routines or other issues such as space or equipment needs.

Because the literature indicates that older adults with osteoarthritis have deficits in both aerobic functioning and strength, the first 60 minutes of the 90-minute intervention addressed flexibility exercises, coupled with fitness walking, and resistance training. The last 30 minutes included an adapted version of the Kovar and colleagues (1992) group discussion–educational component to enhance self-efficacy for adherence. All exercises were accompanied by music. The sessions began and ended with 10-minute warm-up and cool-down periods that involved neck, trunk, and extremity range-of-motion exercises. Static and dynamic sitting and standing balance exercises were used during these periods.

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

Strengthening.—Strengthening exercises for the lower extremities and trunk utilized a graded task-specific approach (sit to stand and postural stabilization). Building on the studies of Fiatarone and associates (1994) and Fisher and colleagues (1991), we implemented resistance exercises that used a combination of cuff weights and elastic exercise bands. We progressively increased the resistance throughout the program by adding weight in increments of 0.5 lb (0.22 kg) to the cuff weights.

Because the ability to rise unassisted from a chair or the floor is critical for independent functioning in the community, the strengthening exercises incorporated progressive sit-to-stand and floor-to-stand activities that targeted these functions. We achieved floor-to-stand progression by progressively limiting the use of upper extremities or a chair to assist in rising from the floor.

Education–Behavior Change.—Social cognitive theory posits that self-efficacy, or individuals' confidence in their ability to achieve a personally meaningful outcome, is an important mediator for sustained behavior change (Bandura, 1986), and it 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 ability to conduct the exercises in a safe and effective manner) and self-efficacy for exercise adherence (confidence in ability to maintain exercise participation over time and in the presence of barriers). The health education component also addressed 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 hoped to achieve through exercise participation. We also provided 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 followed the Jensen and Lorish (1994) process model for patient–practitioner collaboration. The trainers established a therapeutic relationship with each participant and, instead of prescribing a post-training regimen, asked what regimen this participant was most likely to follow, followed by negotiation, including discussion of the participant's belief that the exercise would accomplish a valued goal, and iterative problem solving. In order to maximize internal locus of control, we asked participants to identify specific functions or activities with which they had trouble, which exercise could ameliorate. Trainers maintained individual participant performance records and shared them with participants weekly to reinforce a sense of exercise self-efficacy. We emphasized building skills and identifying strategies that would assist participants to maintain physical activity over time. Thus, for example, individuals with knee osteoarthritis who had difficulty walking were encouraged to engage in a less stressful form of aerobic activity such as swimming or cycling. We encouraged individuals who preferred exercising alone to develop a home-based program, and we directed those who preferred a group-based program to ongoing classes in the community.

Reinforcement.—We used group and individual sessions to inform participants about opportunities to maintain exercise within the community or in an individual's home. Following the "negotiated" adherence model (Jensen & Lorish, 1994), we asked all participants to develop individualized postintervention exercise plans that incorporated flexibility,

aerobic activity (usually walking), and strength training a minimum of 3 days per week for a total of 30 minutes per day at a ''moderate'' to ''strong'' level of perceived exertion. We also asked participants to sign individualized postintervention exercise contracts. We gave participants a log in which to record daily distance covered, repetitions completed, time spent exercising, and resting and exercise heart rates. This log enabled participants to track their progress over time and was intended to reinforce their perceptions of adherence self-efficacy. We also gave all graduates 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. We encouraged participants to incorporate physical activity into their lifestyles in order to maintain home-based physical activity programs from that point forward. Research staff tracked the maintenance of activity at quarterly intervals for a period of 10 months, either by telephone or at scheduled in-person interviews.

Control Condition

We gave control-group participants a copy of *The Arthritis Helpbook* and a list of exercise programs in the community that they could access. We also gave them a variety of self-care materials and handouts at each post-test. We offered the control group the opportunity to participate in the intervention at the conclusion of 24 months. No crossover occurred between the two groups.

Measures

Screening Measures

We used the 10-item Short Portable Mental Status Questionnaire (Kahn et al., 1960) to screen for the presence of moderate to severe cognitive impairment. Correct responses receive a score of 1 and incorrect responses receive a score of 0. We considered individuals to be ineligible if they answered more than 3 of 10 items incorrectly. All of the participants in this trial scored in the intact functioning range of 0–2 errors.

We assessed the presence of lower extremity joint osteoarthritis 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 assessed nine joint or regions for pain on motion, tenderness, swelling, limitation of motion, or deformity. Type of arthritis also was identified. We asked the physician to indicate whether the person met the inclusion criteria previously described for the presence of osteoarthritis of the hip or knee.

We considered individuals to be ineligible if they were under the age of 60 years, currently participated in an aerobic exercise program, had undergone uncomplicated hip or knee surgery within the previous 6 months or complicated surgery within the past year, had received steroid injections in either knee or hip within the previous 3 months, had a diagnosis of rheumatoid arthritis, or had diabetes that was not under good control.

Outcomes

We assessed the following outcomes at baseline and at 2, 6, and 12 months for all participants.

Self-Efficacy for Arthritis Self-Management (Exercise, Pain, and Other Symptoms)

We assessed 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 calculated 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 $\alpha = 0.89$ for self-efficacy for exercise, $\alpha = 0.88$ for self-efficacy for pain management, and $\alpha = 0.94$ for self-efficacy for management of other symptoms.

Exercise Adherence Self-Efficacy

We used two scales developed by McAuley, Lox, and Duncan (1993) to measure self-efficacy for exercise adherence. 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 with a 0–100 response scale and is scored by calculating an overall mean score. The scale had an alpha of $\alpha = 0.94$ in the current sample. The ''Time'' Exercise Adherence scale has 6 items that ask respondents to rate their level of self-efficacy to continue participating in regular exercise over a period of 6 months. Through the use of a reliability analysis, we found an alpha of $\alpha = 0.95$ in the current sample.

Adherence to Fit and Strong!

We monitored attendance at each session and asked participants to maintain exercise logs during the facility-based program to track exercise activity daily.

Maintenance of Physical Activity

We used a 6-item measure that included type of exercise (e.g., walking, swimming, biking), duration,

and frequency to calculate total minutes of exercise per week for each participant in both treatment and control groups. Research staff called all participants (treatment and control) at 9 months after Fit and Strong! ended to ask the average number of times per week that they exercised (frequency) and the number of minutes per session they exercised (duration). We obtained the same information in person at the 6- and 12-month interviews.

Functional Lower Extremity Muscle Strength

We used 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. 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. They are then 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. Using a stopwatch, we measured time to stand as the nearest 10th of a second. We then transformed raw scores into a rate per minute in order to accurately assess change in those who were unable to perform the test at any point.

Functional Exercise Capacity

We used the 6-minute walk test in the method described by Guyatt and colleagues (1985) to measure functional exercise capacity. We used a hard, smooth surface, free of obstructions. Participants were instructed to walk as fast and as far as possible within a 6-minute period and were accompanied by research staff members who had been trained in the use of a Rolatape Measure Master, which measures distance walked in feet.

Western Ontario and McMasters University Osteoarthritis Index

In addition to the objective measures already described, 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 osteoarthritis 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 0.85, 0.80, and 0.95, respectively, in the current sample.

Geri-AIMS Pain

The Geri-AIMS Pain Scale, a four-item measure developed and tested by Hughes and colleagues (1991), assessed arthritis-specific pain. Items asked respondents to rate their usual level of arthritis pain, frequency of severe arthritis-related pain, duration of morning stiffness from waking, and frequency of pain in two or more joints at the same time during the past month. Reliability analysis indicated an alpha of $\alpha = 0.83$ for the current sample.

Independent Variables

The primary independent variable was group membership, which we coded as 1 for the treatment group and as 0 for the control group.

Demographic variables included age, race, gender, income, type of health insurance coverage, and maximum level of education obtained.

Analyses

The design involved one between-group factor, experimental versus control, and one within-subject factor (time). In addition to the group and time variables, our analyses used one covariate, arthritis functional class, in order to control for baseline disease severity. We treated time nonlinearly by including indicator variables for the 2-, 6-, and 12-month measurement points, treating baseline as the reference category. A simple linear model for the data can be written as

$$\begin{aligned} Y_{it} = {} & b_0 + b_1\text{Time}_2 + b_2\text{Time}_6 + b_3\text{Time}_{12} + b_4\text{Group} \\ & + b_5\text{Group} \times \text{Time}_2 + b_6\text{Group} \times \text{Time}_6 \\ & + b_7\text{Group} \times \text{Time}_{12} + b_8\text{Severity} + u_i + e_{it} \end{aligned}$$

where the interaction terms, Group $\times$ Time$_2$, Group $\times$ Time$_6$, and Group $\times$ Time$_{12}$, test whether the two groups changed differently over time (i.e., whether the time trend differs by group). There are two error terms. The first, u_i, indicates a normally distributed zero mean person-specific error that accounts for all unmeasured between-person differences. It is the source of the ''random intercept'' or the adjustment to the overall intercept, b_0, associated with each participant. The second error term, e_{it}, varies by person and time and also is assumed to be normally distributed with mean 0.

Because we had repeated measures data, we could not assume independence of observations. Furthermore, because we had different numbers of respondents by group over time, we needed to use a more complex approach than a simple univariate repeated measures analysis based on an analysis of variance. Therefore, we analyzed the data by using a random intercept hierarchical model in which participants were assumed to have a common within-group time trajectory but intercepts were allowed to randomly vary from person to person under the assumption that participant-specific intercepts consisted of a

common intercept plus a random draw from a normal distribution with a mean of zero and variance estimated from the data (Willett & Singer, 1991). Unlike generalized estimating equation models, which make very strong assumptions regarding missing data in longitudinal studies, the random effect approach assumes that the data are missing at random; that is, that the missing data are independent of true outcomes, conditional on covariates. The $Time_2 \times$ Group interaction tests whether the treatment and control groups differed at 2 months, the $Time_6 \times$ Group interaction tests whether the groups differed at 6 months, and the $Time_{12} \times$ Group interaction tests whether the groups differed at 12 months relative to their baseline scores.

In addition, we computed effect sizes for each of the outcome measures at all three time points. At each time point, we computed the difference between the treatment and control groups, and then we computed the pooled standard deviation for the two groups for each time point. We computed the effect sizes as the difference between the two groups at a particular time, divided by the pooled standard deviation.

Results

Enrollment in this study began in 1997 and ended in September 2002. The data presented in this article pertain to 215 participants enrolled at baseline. As data in the flow diagram (Figure 1) demonstrate, 704 individuals were screened for eligibility over this period. Of this group, 215 (30.5%) met the criteria and were enrolled in the study, 365 (51.8%) were ineligible, 84 (11.9%) were eligible but refused to participate, and 40 (5.7%) 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 73.3 years; the majority of participants were female, were White, had annual incomes less than $30,000, had at least a high school education, and had Class 2 ACR functional class scores. Approximately 55% of the total sample also reported presence of hypertension, 42% of the total sample reported presence of cardiovascular disease, 13% reported diabetes, and 5% reported asthma, emphysema, or cancer. All participants received scores in the ''intact functioning'' range on the Short Portable Mental Status Questionnaire (0–2 errors), indicating a lack of cognitive impairment. We noted no significant differences by group on any of the demographic or disease measures.

Baseline values of the study outcome measures are shown in Table 2. The treatment group had significantly higher scores at baseline on the Pain Management subscale and for symptom management as well as the timed sit–stands rate per minute. However, we saw no significant differences by group at baseline with respect to the WOMAC, the 6-minute distance walk, or total minutes of exercise per week, with both groups exercising for roughly 120–135 minutes per week at baseline. We expect that these baseline differences represent chance deviations from equality that are caused by the randomization process. Our statistical methods evaluate experimental effects relative to such chance differences at baseline by assuming no experimental effect; that is, given randomization, the statistical tests do not require or assume that group means are exactly equal at baseline.

Adherence to Fit and Strong!

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

Attrition

We obtained 2-month post-tests on 72% of treatment-group participants and 55% of controls. We obtained 6-month post-tests on 64% of treatment-group participants and 44% of controls (see Figure 1). At 12 months, 50% of treatment-group participants and 32% of control-group participants completed post-tests. Reasons for attrition over the 12 months are shown in Table 3 by group. Research staff members were unable to contact 28 treatment-group participants and 43 control-group participants to schedule post-test interviews after a minimum of 10 attempts. Eight treatment-group and 11 control-group participants refused to participate in additional post-test interviews, and 5 treatment-group and 6 control-group participants refused to participate because of illness. An additional 3 participants in each of the two groups moved out of state and did not want to participate in telephone interviews or to complete a mailed survey. Two treatment-group and 3 control-group participants could not participate in post-test interviews because they had caregiving responsibilities. Finally, research staff members were unable to contact 1 treatment-group and 2 control-group participants as a result of disconnected telephone numbers.

We conducted analyses to determine if differential attrition occurred over time by group. These analyses demonstrated no significant differences between responders and nonresponders on any of the outcome measures. The analyses also found no statistically significant differences between responders and nonresponders in terms of demographic characteristics or level of arthritis severity. In both groups, participants who attrited from post-test measurement had slightly worse scores on the study outcome measures at baseline.

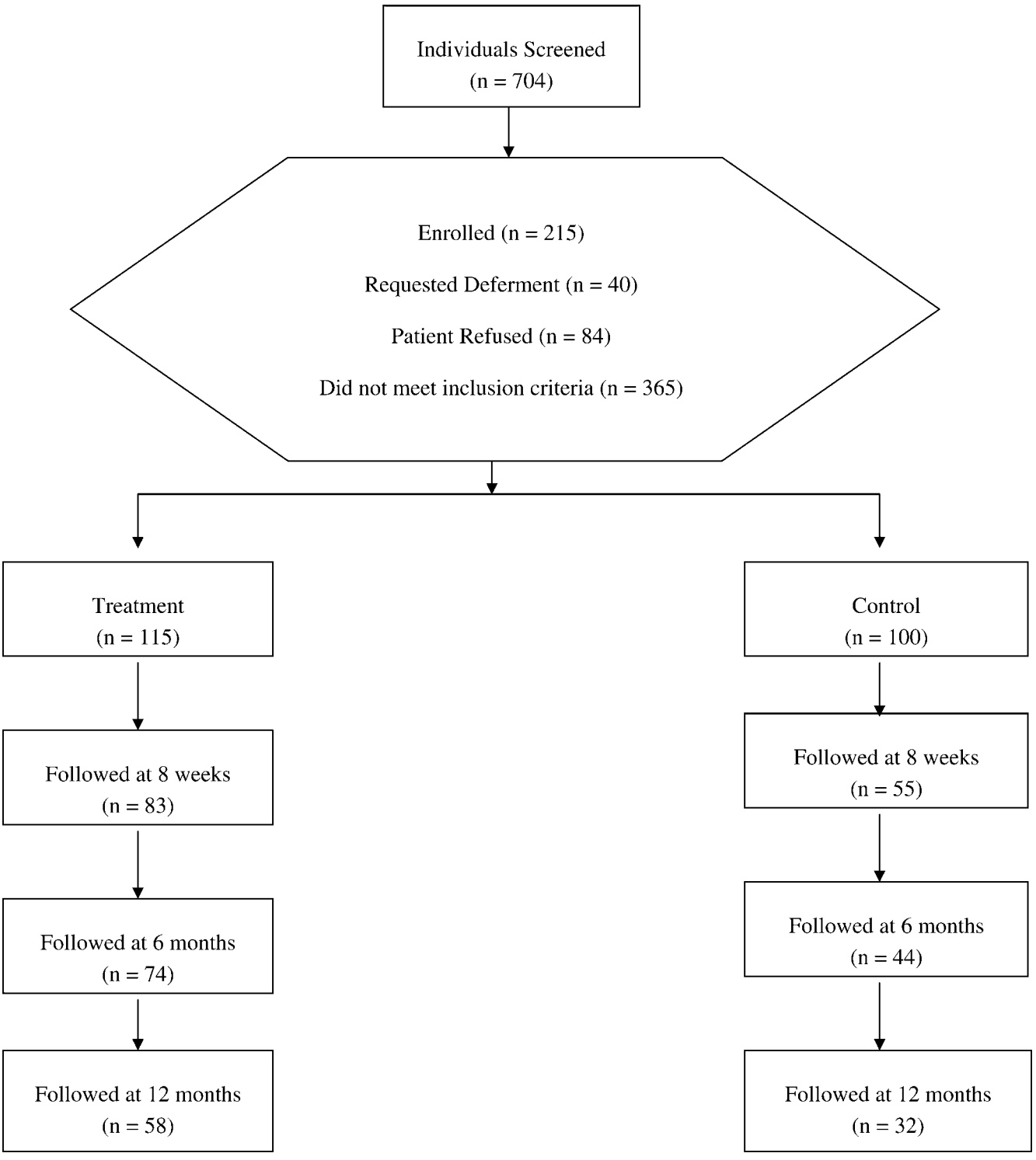

Figure 1. Flow diagram.

Outcomes at 2, 6, and 12 Months

Table 2 shows mean outcome scores by time for the treatment and control groups. Table 4 shows the results of the statistical analyses, which included baseline and 2-, 6-, and 12-month outcome measures. In each analysis, the $Time_2 \times Group$, $Time_6 \times Group$, and $Time_{12} \times Group$ tests whether the experimental group shows greater change relative to baseline than the control group at 2, 6, and 12 months. All tests are based on one-tailed tests, assuming Group × Time coefficients greater than zero with arthritis severity, as measured by ARA functional class, as a covariate. Table 5 shows the

Table 1. Baseline Demographic Characteristics by Group

Characteristics	Treatment Group % or *M*	Control Group % or *M*	*p*
Age (years)	73.3	73.4	.868
Female	80.6	85.9	.319
Education			.383
<High school	12.1	8.8	
High school	21.5	18.5	
>High school	66.4	72.7	
Income ($)			.847
<20,000	32.4	33.7	
Race			.125
White–Caucasian	69.4	75.0	
African American	27.8	16.3	
Hispanic	1.9	3.3	
Asian–Pacific Islander	0.9	3.3	
Other	0	2.2	
ARA class			.991
I	22.6	22.2	
II	64.5	64.2	
III	12.9	13.6	
Comorbid conditions			
Hypertension	51.4	58.3	.270
Cardiovascular disease	46.7	42.3	.551
Asthma	6.1	7.0	.788
Emphysema	3.5	5.0	.734
Diabetes	14.6	12.8	.722
Cancer	6.1	2.0	.185

Notes: Treatment group and control group are $n = 115$ and $n = 110$, respectively; ARA = American Rheumatism Association.

effect sizes calculated for each of the outcomes at each time point.

Lorig Self-Efficacy Scales

We saw a significant difference ($p < .01$) favoring the treatment versus the control group at 2, 6, and 12 months on the Lorig Exercise Efficacy Scale (Figure 2). Treatment-group scores increased at 2 months and remained slightly higher than baseline levels at 6 months and 12 months. In contrast, control-group scores declined steadily across all three time periods. We found effect sizes of 0.783 at 2 months, 0.798 at 6 months, and 0.905 at 12 months for this scale. We found a borderline significant difference between treatment- and control-group participants for the Lorig Pain Management subscale at 6 months ($p = .052$), but we saw no differences by group at 2 or 12 months. We saw no differences by group at any time period on the Lorig Symptom Management scales.

McAuley Barriers and Time Exercise Adherence Efficacy

We saw no significant differences by group on the McAuley "Barriers" Adherence Efficacy scale, which

Table 2. Mean Scores Over Time by Treatment Group

	Treatment Group				Control Group			
	Baseline	2 mo	6 mo	12 mo	Baseline	2 mo	6 mo	12 mo
Self-Efficacy								
Exercise (1–10)	7.5 (2.67)	8.26 (2.22)	7.96 (2.43)	7.69 (2.58)	6.91 (2.63)	6.31 (2.85)	5.91 (2.77)	5.44 (2.34)
Pain mgt. (10–100)[a]	72.89 (20.53)	75.37 (20.10)	73.86 (23.22)	74.52 (19.56)	64.40 (22.44)	65.70 (18.69)	59.26 (21.29)	64.00 (20.27)
Other symptom mgt. (10–100)[a]	76.77 (18.64)	79.63 (20.06)	76.56 (21.89)	77.39 (19.32)	70.00 (20.63)	71.91 (20.55)	66.98 (20.99)	72.6 (18.06)
Barriers adherence (0–100)	71.58 (23.17)	59.01 (27.69)	61.85 (23.19)	62.51 (21.85)	65.79 (22.99)	55.14 (23.99)	49.06 (19.64)	53.46 (18.80)
Time adherence (0–100)	80.24 (22.49)	79.17 (24.91)	74.75 (30.11)	78.51 (25.57)	78.17 (20.55)	68.09 (31.81)	50.21 (35.31)	58.65 (31.74)
Exercise maintenance								
Minutes spent exercising	135.27 (145.11)	248.89 (150.45)	214.46 (174.11)	210.52 (153.18)	122.55 (128.05)	126.67 (128.66)	104.66 (117.33)	115.65 (122.67)
Performance measures								
6-minute walk	1133.14 (400.91)	1273.27 (390.30)	1250.12 (464.25)	1281.53 (502.93)	1048.79 (379.88)	1150.62 (507.70)	1129.40 (564.74)	1106.29 (484.10)
Timed sit–stand[a]	18.79 (10.26)	24.47 (9.62)	23.19 (12.45)	21.91 (12.27)	15.21 (8.94)	19.27 (8.37)	17.84 (8.55)	18.18 (10.30)
WOMAC								
Pain (0–20)	6.32 (3.84)	4.89 (3.53)	5.04 (3.75)	5.39 (3.72)	7.04 (3.84)	6.45 (4.01)	6.84 (3.87)	5.31 (4.42)
Stiffness (0–8)	3.27 (1.80)	2.70 (1.35)	2.72 (1.45)	2.57 (1.57)	3.16 (1.77)	3.19 (1.72)	3.25 (1.60)	2.94 (1.95)
Physical function (0–68)	22.68 (11.75)	17.45 (12.25)	17.74 (12.19)	17.81 (11.15)	27.11 (14.24)	22.57 (12.21)	24.46 (13.65)	20.15 (14.71)
Geri-AIMS								
Pain (0–10)	4.58 (0.94)	4.67 (0.85)	4.68 (1.00)	4.77 (0.82)	4.64 (0.95)	4.65 (0.86)	4.41 (1.23)	4.61 (0.91)

Notes: For the treatment group, the baseline and 2, 6, and 12 months is $n = 115$, 83, 74, and 58, respectively; for the control group, the baseline and 2, 6, and 12 months is $n = 110$, 55, 44, and 32, respectively. WOMAC = Western Ontario and McMasters University Osteoarthritis Index.
[a]There is a significant difference at baseline.

assessed confidence in ability to continue exercising in the face of barriers at 2, 6, or 12 months relative to the baseline scores. We also saw no differences at 2 months between treatment and control groups on the McAuley "Time" Exercise Adherence scale, which measures confidence to adhere to exercise over time in the future. However, we did see significant differences ($p < .01$) favoring the treatment group at 6 and 12 months on the Self-Efficacy for Adherence Over Time measure. We found effect sizes of 0.398 at 2 months, 0.760 at 6 months, and 0.705 at 12 months for this measure.

Maintenance of Physical Activity

We saw significant differences ($p < .01$) favoring the treatment group versus the control group at 2, 6, and 12 months on number of minutes of exercise per week. The mean minutes of exercise for the control group per week increased from 122.55 at baseline to 126.67 minutes at 2 months; however, this rate dropped to 104.66 at 6 months and 115.65 at 12 months. In contrast, the comparable values for the treatment group were 135.27 at baseline, 248.89 at 2 months (83.9% increase), 214.46 at 6 months (58.5% increase), and 210.52 at 12 months (55.6% increase). Although minutes of exercise per week declined slightly among the treatment group between 2 and 12 months, their levels of participation continued to be above the goal of 30 minutes 3 times per week. We found effect sizes of 0.860 at 2 months, 0.713 at 6 months, and 0.669 at 12 months for minutes of exercise per week.

Timed Stand

We saw no significant differences by group at 2, 6, or 12 months in rate of timed stands per minute. The range of values for both treatment- and control-group members on this measure was very large, that is, 0–50.0 ($SD = 10.26$) at baseline for treatment-group and 0–33.7 ($SD = 8.94$) for control-group members, indicating that a larger sample size might be necessary to detect a difference on this outcome. We found effect sizes of 0.569 at 2 months, 0.483 at 6 months, and 0.324 at 12 months for this test.

The 6-Minute Distance Walk

We saw no significant differences by group at 2, 6, or 12 months on 6-minute distance walk scores. Control-group means for the 6-minute distance walk increased from 1,048.79 at baseline to 1,150.62 minutes at 2 months; however, this rate dropped to 1,129.40 at 6 months and 1,106.29 at 12 months. In contrast, the comparable values for the treatment group were 1,133.14 at baseline, 1,273.27 at 2 months, 1,250.12 at 6 months, and 1,281.53 at 12 months (Figure 3).

Table 3. Reasons for Attrition by Group

Reason	Treatment Group	Control Group
Nonresponders at 12 months	57	68
Unable to contact	38	43
Refused interview	8	11
Illness	5	6
Moved out of state	3	3
Caregiving responsibilities	2	3
Disconnected phone	1	2

Western Ontario and McMasters University Osteoarthritis Index

We saw significant differences favoring the treatment group on two of the three WOMAC scales. The treatment group improved significantly vis-à-vis controls with respect to pain scores ($p = .040$) at 6 months, but we found no difference at 2 and 12 months. We found effect sizes of –0.418 at 2 months, –0.474 at 6 months, and 0.20 at 12 months for the WOMAC Pain scale. Stiffness scores decreased significantly in the treatment group at 2 months ($p = .018$), continued to be significant at 6 months ($p = .032$), and were borderline significant at 12 months ($p = .056$; see Figure 4). We found effect sizes of –0.325 at 2 months, –0.351 at 6 months, and –0.214 at 12 months for the Stiffness scale. In contrast to the pain and stiffness findings, we saw no differences between the two groups on the Physical Function scale at 2, 6, or 12 months. Both groups' physical function scores improved between baseline and 2 months, and this improvement over baseline was maintained in both groups at 6 and 12 months.

Geri-AIMS Pain Scale

We saw significant differences favoring the treatment group at 6 months ($p = .039$), with borderline significance at 12 months ($p = .066$). We found effect sizes of 0.023 at 2 months, 0.246 at 6 months, and 0.187 at 12 months on this scale.

Discussion

Currently, 37% of adults with arthritis are estimated to be inactive, which is a risk factor for multiple adverse outcomes including other chronic diseases, morbidity, and mortality (Shih, Hootman, Kruger, & Helmick, 2006). We designed Fit and Strong! to address the important public health challenge posed by the growing number of older adults with osteoarthritis who can be expected to become disabled over time because of the presence of osteoarthritis in their lower extremity, weight-bearing joints. We designed the program to address documented strength and aerobic deficits in this target population and to be inexpensive and simple to replicate broadly. Fit and Strong! is the only

Table 4. Random Effects Outcome Analyses

Item	Group	2 mo	6 mo	12 mo	ARA Class	$Time_2$	$Time_6$	$Time_{12}$
Self-Efficacy								
Exercise								
Coefficient	0.617	−0.586	−0.879	−1.359	−1.059	1.291	1.158	1.357
z score	1.75	−1.84	−2.54	−3.18	−4.37	3.14	2.63	2.54
p value	.040	.033	.006	.001	.000	.001	.005	.006
Arthritis pain mgt.								
Coefficient	8.752	0.139	−5.322	−2.310	−9.136	1.489	5.550	1.770
z score	3.09	0.06	−1.98	−0.77	−4.63	0.47	1.63	0.47
p value	.001	.478	.024	.221	.000	.319	.052	.320
Symptom mgt.								
Coefficient	6.997	0.451	−2.831	2.110	−9.321	1.429	2.237	−3.278
z score	2.58	0.20	−1.14	0.76	−4.88	0.49	0.74	−0.94
p value	.005	.421	.127	.223	.000	.313	.230	.173
Barriers efficacy								
Coefficient	6.822	−9.553	−14.116	−11.250	−5.894	−3.541	2.517	−0.534
z score	1.97	−2.92	−3.87	−2.82	−2.63	−0.83	0.55	−0.11
p value	.024	.002	.000	.003	.005	.204	.293	.458
Adherence efficacy								
Coefficient	3.360	−8.541	−24.372	−18.439	−7.859	6.803	17.148	13.640
z score	0.88	−2.27	−5.79	−4.02	−3.24	1.39	3.23	2.35
p value	.190	.012	.000	.000	.001	.083	.001	.010
Exercise maintenance								
Maintenance								
Coefficient	−0.101	−0.105	−0.157	−0.281	−0.317	0.781	0.728	0.780
z score	−0.67	−0.68	−0.90	−1.53	−3.40	4.01	3.37	3.42
p value	.253	.247	.185	.064	.001	.000	.001	.001
Performance measures								
Timed sit–stand								
Coefficient	3.549	3.189	2.824	2.283	−5.255	0.363	0.936	0.208
z score	2.63	2.88	2.32	1.60	−5.35	0.26	0.61	0.12
p value	.004	.002	.010	.056	.000	.399	.271	.453
6-min distance walk								
Coefficient	94.448	80.360	96.577	48.076	−294.503	23.864	6.027	76.673
z score	1.72	1.72	1.85	0.78	−7.41	0.40	0.09	1.02
p value	.043	.043	.032	.219	.000	.344	.463	.155
WOMAC								
Pain								
Coefficient	−0.790	−0.442	−0.060	−1.089	2.460	−0.618	−1.047	0.406
z score	−1.63	−1.04	−0.13	−2.08	7.44	−1.11	−1.76	0.61
p value	.051	.149	.449	.019	.000	.133	.040	.271
Stiffness								
Coefficient	0.101	0.089	−0.004	−0.101	0.651	−0.561	−0.527	−0.510
z score	0.45	0.43	−0.02	−0.39	4.16	−2.09	−1.85	−1.59
p value	.327	.333	.492	.347	.000	.018	.032	.056
Physical function								
Coefficient	−4.524	−3.526	−2.970	−3.618	8.364	−0.651	−1.022	0.020
z score	−2.74	−2.87	−2.19	−2.29	7.02	−0.41	−0.60	0.01
p value	.003	.003	.014	.011	.000	.342	.275	.496
Geri-AIMS								
Pain								
Coefficient	−0.066	−0.153	−0.255	−0.123	−0.045	0.125	0.347	0.330
z score	−0.50	−0.11	−1.66	−0.72	−0.55	0.68	1.76	1.51
p value	.307	.457	.048	.237	.292	.249	.039	.066

Notes: Exercise maintenance is the log of total minutes per week; timed sit–stand is the rate per minute; 6-minute distance walk is the log of feet walked. WOMAC = Western Ontario and McMasters University Osteoarthritis Index; ARA = American Rheumatism Association.

Table 5. Effect Size (*d*)

Item	2 mo	6 mo	12 mo
Self-Efficacy			
Exercise	0.783	0.798	0.905
Pain management	0.495	0.650	0.530
Other symptom management	0.381	0.445	0.254
Barriers adherence	0.147	0.585	0.437
Time adherence	0.398	0.760	0.705
Exercise maintenance			
Minutes spent exercising	0.860	0.713	0.669
Performance measures			
6-minute walk	0.278	0.238	0.354
Timed sit–stand	0.569	0.483	0.324
WOMAC			
Pain	−0.418	−0.474	0.020
Stiffness	−0.325	−0.351	−0.214
Physical function	−0.419	−0.525	−0.184
Geri-AIMS			
Pain	0.023	0.246	0.187

Notes: WOMAC = Western Ontario and McMasters University Osteoarthritis Index.

program of which we are aware that combines instruction in multiple components of physical activity with education and group problem solving for maintenance of lifestyle change.

Findings at 2 and 6 months from the final, larger sample tested in this randomized trial agree substantially with those described in our preliminary 2- and 6-month study. Both analyses found significant effects of Fit and Strong! at 2 and 6 months on self-efficacy for exercise and maintenance of physical activity that were accompanied by significantly decreased lower extremity stiffness. In both analyses, participants at 6 months also experienced a significant reduction in pain. Whereas the earlier analyses found a marginally significant improvement in self-efficacy to adhere to exercise over time, the final analyses with a larger sample found a significant difference on this outcome. Finally, the new 12-month analyses, although based on a reduced number of participants, found continued benefits of the program on self-efficacy for exercise, self-efficacy to continue to adhere to exercise over time, maintenance of physical activity, and borderline significant reductions in lower extremity stiffness and pain.

Figure 3: 6-Minute Distance Walk

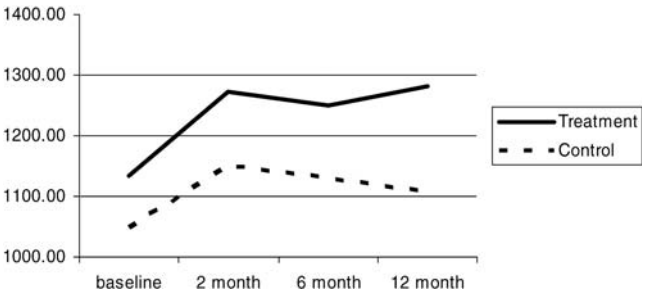

Figure 3. 6-Minute Distance Walk.

Although significant between-group differences were not seen in performance measures, the substantial amount of variance seen on these measures in this sample suggests that a larger sample size is required to demonstrate a treatment effect on these outcomes.

We calculated effect sizes for these final findings. The effect sizes for self-efficacy for exercise and maintenance of physical activity were large according to Cohen's (1977) effect size conventions at 0.783, 0.798, and 0.905 for exercise efficacy at 2, 6, and 12 months and 0.860, 0.713, and 0.669 for maintenance of physical activity (minutes spent exercising) at the same time points. Although self-efficacy for adherence to exercise over time was not significant at 2 months, significant effect sizes of 0.760 and 0.705 were found at 6 and 12 months. This latter finding would appear to indicate that self-efficacy for exercise adherence over time is reinforced by continued maintenance of physical activity. In other words, as participants actually adhered to exercise over extended periods of time, their perceived efficacy to achieve this objective increased. This finding in somewhat unusual in that it indicates that cognition is reinforced by the behavior rather than the reverse.

More modest but consistent effect sizes were seen on the WOMAC and Geri-AIMS pain measures,

Figure 2: Self-Efficacy for Exercise

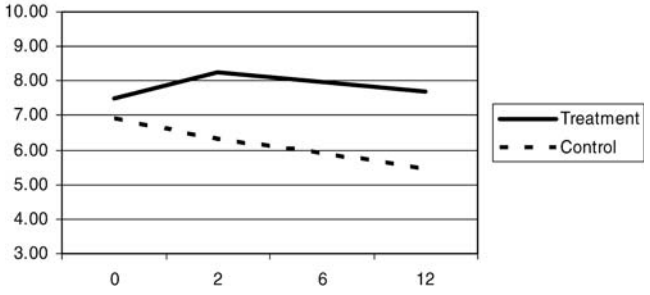

Figure 2. Self-Efficacy for Exercise.

Figure 4: WOMAC Stiffness Subscale

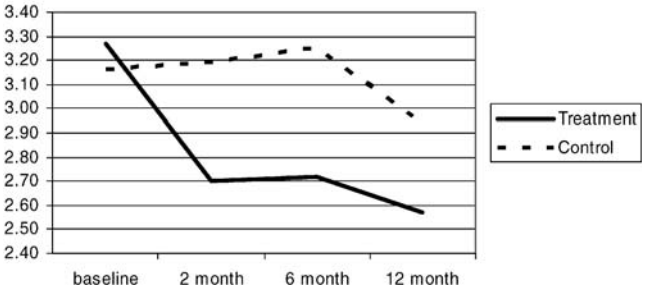

Figure 4. WOMAC Stiffness Subscale.

with effect sizes of –0.418 and –0.474, at 2 and 6 months on the WOMAC measure and 0.246 and 0.187 at 6 and 12 months on the Geri-AIMS measure. The effect sizes for decrease in WOMAC stiffness were similar at –0.325, –0.351, and –0.214 at 2, 6, and 12 months, respectively. The fact that an impact on stiffness was reported 4 months before an impact on pain was reported may indicate that joints have to be loosened up before significant reductions in pain are experienced.

We did not find significant differences on the WOMAC functional status measure; however, the effect sizes seen on this measure were in the right direction and increased from –0.419 at 2 months to –0.525 at 6 months, with a slight decrement but still in the right direction at 12 months and an effect size of –0.184. Compared with treatment-group members, members of the control group for the most part remained the same or deteriorated on the same outcomes tested. It is important to note that no adverse events were experienced among treatment-group participants.

This study has some limitations. The multicomponent Fit and Strong! intervention is based on evidence concerning deficits in older adults with osteoarthritis and is theoretically driven. However, it is impossible to conclude from this trial whether all three components (flexibility, aerobic walking, and strength training) are necessary to attain the reported results. Second, attrition from post-test measurement was high in both groups but higher among control-group than treatment-group participants. Retention rates of participants in this study at 12 months were 50.4% for treatment-group participants versus 32% for controls. These rates are low in comparison with other retention rates reported in the literature, which range from 61% (Sullivan et al., 1998) to 90.9% (van Baar et al., 2001) for treatment-group participants and from 51% (Sullivan et al.) to 92% (Thomas et al., 2002) for control-group participants. In both groups, nonresponders tended to have lower baseline scores than those who remained. However, attrition analyses of treatment and control groups found no significant differences between responders and nonresponders on any of the outcome measures. Thus, attrition does not appear to impact the validity of the findings.

Third, participants were not blinded regarding their treatment status. It is not possible in an exercise study to blind the instructor to the participants, nor is it possible to blind the exercise participants to the fact that they are receiving a treatment. In this comparatively small study, it also was not possible to blind the research staff regarding group assignment because many of the staff also helped to set up the class, assisted the physician to conduct the physical examinations, and other activities. Thus, some of the self-reported measures may reflect respondent bias. However, substantial group differences were shown on the Timed-Stands test and the 6-minute distance walk, which are timed objective performance measures. Thus, we do not believe that these limitations seriously affect the validity of the results.

It is important to compare our findings with those of others but difficult to do so because the same measures were not used in many cases across studies. With respect to the persistence of benefits over time, our findings compare favorably with those previously reported by Kovar and colleagues (1992) and by van Baar and colleagues (2001). Both of those studies found short-term benefits of exercise for older adults with lower extremity osteoarthritis that did not persist over the longer term (Sullivan et al., 1998). In contrast, benefits observed in our sample were somewhat attenuated at 12 months, compared with the findings of Ettinger and colleagues (1997) and Thomas and associates (2002), both of whom found benefits of exercise on pain and physical function at 24 months. However, it is important to note that both studies enrolled substantially larger samples at baseline; they used samples of 439 and 786, respectively, compared with our baseline sample of 215. Although many of our findings trended in the same direction, we believe that the sample was too small to demonstrate an impact on several outcomes such as the timed-stand and walk-rate measures that exhibited substantial variability in our study population. A follow-up study that is currently testing Fit and Strong! with a sample of 600 participants at five senior centers in Chicago may shed some light on this issue.

In an effort to do no harm to participants, Fit and Strong! was developed by master's-trained physical therapists who had a substantial amount of experience working with older adults. Because we are interested in making the program as inexpensive and simple to offer as possible, we have since trained certified exercise instructors and have conducted 3 iterations of Fit and Strong! at 5 sites (15 classes) with these exercise leaders to date with no untoward results.

To summarize, we believe that Fit and Strong! is an efficacious program that can promote safe and sustained involvement in flexibility, strength training, and aerobic walking for older adults with lower extremity osteoarthritis. We believe that the intervention efficiently targets older adults who are at substantial risk of developing disability and significantly reduces their arthritis pain and stiffness, necessary precursors of functional independence. We look forward to its broad adoption among individuals who can benefit from it.

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