The Efficacy of Home Based Progressive Strength Training in Older Adults with Knee Osteoarthritis: A Randomized Controlled Trial

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ABSTRACT. ***Objective.*** To test the effects of a high intensity home-based progressive strength training program on the clinical signs and symptoms of osteoarthritis (OA) of the knee.

Methods. Forty-six community dwelling patients, aged 55 years or older with knee pain and radiographic evidence of knee OA, were randomized to a 4 month home based progressive strength training program or a nutrition education program (attention control). Thirty-eight patients completed the trial with an adherence of 84% to the intervention and 65% to the attention control. The primary outcome was the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index pain and physical function subscales. Secondary outcomes included clinical knee examination, muscle strength, physical performance measures, and questionnaires to measure quality of life variables.

Results. Patients in the strength training group who completed the trial had a 71% improvement in knee extension strength in the leg reported as most painful versus a 3% improvement in the control group ($p < 0.01$). In a modified intent to treat analysis, self-reported pain improved by 36% and physical function by 38% in the strength training group versus 11 and 21%, respectively, in the control group ($p = 0.01$ for between group comparison). In addition, those patients in the strength training group who completed the trial had a 43% mean reduction in pain ($p = 0.01$ vs controls), a 44% mean improvement in self-reported physical function ($p < 0.01$ vs controls), and improvements in physical performance, quality of life, and self-efficacy when compared to the control group.

Conclusion. High intensity, home based strength training can produce substantial improvements in strength, pain, physical function and quality of life in patients with knee OA. (J Rheumatol 2001;28:1655–65)

Key Indexing Terms:
OSTEOARTHRITIS MUSCLE THERAPEUTIC TRIALS

Symptomatic knee osteoarthritis (OA) (defined as pain on most days plus positive findings on a radiograph of the symptomatic knee) occurs in 11% of individuals over the age of 65[1]. Knee OA accounts for more dependency in lower extremity tasks such as walking and stair climbing than any other disease, especially in the elderly[2]. The risk of disability increases as physical function declines and can have devastating effects on quality of life in these individuals.

Knee extensor or quadricep weakness is common among individuals with knee OA and has been suggested as a risk factor for knee OA in women[3-6]. In the Bristol OA Knee Study, quadriceps weakness was found to be the greatest single predictor of lower limb functional limitation, exceeding that of knee pain[7]. It is notable that this study also found no influence of radiographic severity on level of functional ability. Strengthening exercise has been recommended by the American College of Rheumatology[8] as a treatment for knee OA on the basis of several small trials that demonstrated its efficacy[9-11]. More recently, several controlled trials of strengthening exercise (some of which were large) have reported very modest effects on pain and function (e.g., 10% more improvement than attention control group in one large recent trial)[12-15]. However, these studies have shown little, if any, strength gains.

Strengthening exercise has the potential to be beneficial for knee OA by several pathways: improving strength, improving psychological well being, and improving or

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maintaining cartilage integrity[9,11,16-21]. All 3 may interact and have an additive effect on the symptoms of osteoarthritis. No controlled exercise study has adequately tested these potential benefits of strength training when the goal is to actually increase strength. The purpose of our study is to examine the effects of a home based progressive strength training regimen on strength, pain, physical function, and psychosocial wellbeing in older adults with knee OA.

MATERIALS AND METHODS

Design. This was a community-based randomized controlled trial with all exercise training or attention provided in the home. All baseline and final testing was conducted at the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University (HNRC). Patients were blinded to the active intervention. The assessor for the secondary outcomes, aside from the clinical knee examination was an author and she was not blinded to the patient's group assignment. All eligible patients gave written informed consent, which was approved along with the study protocol by the Human Investigation Review Committee at Tufts University.

Patients. Participants were recruited from the general community by advertising through the local Arthritis Foundation chapter, the Massachusetts Department of Public Health Community Health Clinics, and requests to local rheumatologists and orthopedists for referrals. The eligibility criteria for participation in the study were 1) age 55 years or older; 2) body mass index (BMI) ($\leq$ 40 kg/m^2; 3) pain on more than half the days of the past month during at least one of the following activities (walking, going up or down stairs, standing upright, or in bed at night); and 4) radiographic evidence of knee OA, defined as the presence of osteophytes in the tibiofemoral compartment and/or the patellofemoral compartment, as assessed on standing anterior/posterior and lateral views[22]. Patients were excluded if they had a medical condition that precluded safe participation in an exercise program or was more limiting than the knee arthritis, had inflammatory arthritis or had participated in any regular exercise program in the past 6 months, defined as strength training and/or more than 20 minutes of aerobic activity twice per week. Initial screening for eligibility was done by telephone. If patients met the criteria for age, BMI, and knee pain, an appointment was scheduled at the HNRC for a physical examination performed by a rheumatologist (RR) and radiographs of both knees. At this visit, patients were accepted into or excluded from the study based on the results of the radiographs and physical examination. For those accepted into the study, baseline assessments were conducted at the HNRC at the same visit. Upon completion of the baseline tests, patients were randomized to either the strength training or attention control group. The randomization assignment was generated by the biostatistician at the HNRC and sent to the admissions office of the HNRC, concealed from the technician and physician collecting the data. During the study period, patients were instructed to continue all medications and other treatments as prescribed by their physicians, including over the counter or prescription nonsteroidal antiinflammatory drugs (NSAID). Patients were asked not to begin taking any new nutritional supplements during the study period.

The number of patients recruited was based on the number needed to detect a difference of 20% between the exercise and control group on the WOMAC pain and physical function scales with a power of 0.80 and an alpha of 0.05 (2 sided). The standard deviation of change over time in the WOMAC pain and physical function scales with the use of NSAID was used in the sample size calculations.

Exercise. The exercise intervention was a home based progressive strength training program. The strength training consisted of 2 functional exercises, squats and step-ups, utilizing body weight for resistance, and the following isotonic exercises utilizing ankle weights for resistance: knee extension, knee flexion, hip extension, hip abduction, and hip adduction. For the squat, patients started seated in a chair with a slight forward trunk lean. For step-ups patients stood tall with back erect and one foot on the stair. The squat exercise and step-ups were broken into 3 and 4 progressions respectively: 1) patients started the exercise with the knee at an angle greater than 90˚ by placing cushions on the chair for the squat or utilizing a step of 7-8 inches in height for the step-up. Arms were used to assist in the move if needed; 2) same modification as in 1, but arms were not used to assist in the exercise; 3) cushions were removed from the chair or a higher step was used to bring the knee angle closer to 90 degrees; 4) for the squat, the exercise was performed without sitting down between repetitions.

For the exercises utilizing the ankle weights, emphasis was on isolating the targeted muscle with proper body positioning and stabilization. Knee extension was performed seated in a chair. Knee flexion and the hip exercises were performed standing or on the floor depending on each individual's preference and ability to support their weight on one leg. If exercises were performed standing, patients were taught to keep the knee of the support leg bent slightly and for both standing and floor exercises, hips in a neutral and level position.

Patients performed 2 sets of 12 repetitions, 3 times per week for each exercise. The intensity of each exercise was based on the patient's perception of difficulty at the end of the second set using a modified 10 point Borg scale rating of perceived exertion[23], and the number of repetitions patients could complete with proper form. Patients started at a light intensity, 3-5 on the Borg scale, and remained there until they could demonstrate proper exercise form (i.e., proper body position and joint alignment at the start of and throughout the exercise). Once adequate form was achieved, they progressed to an 8, perceived as hard on the Borg scale, over the first 3-4 weeks of the study. Throughout the remainder of the study, intensity was increased when patients reported a 6 or less on the Borg scale and/or could do more than 12 repetitions. Intensity was increased by progressing through the levels for squats and step-ups and adding pellets of 1 lb each (up to 20 pounds per leg) to the ankle weights. All exercises, with the exception of the squat, were done on each side separately. The intensity of the exercise was based on the strength of the weakest leg. After the first month, when patients had achieved proper exercise form, they were taught to monitor their own progression and not rely on the trainer to increase intensity. If pain was a limiting factor, exercises were modified so that patients worked in a pain free range and at a pain free intensity.

Patients were supplied with an easy to follow instruction booklet of the exercises and 20 lb progressive ankle weights (All Pro, Jericho, New York, USA). Patients were visited at home 2 times per week for the first 3 weeks, once in Week 4, and once every 2 weeks thereafter for a total of 12 visits in 16 weeks. The exercise group kept a log for each day of training, recording the individual exercises with the respective weight lifted, repetitions, and sets.

Attention control. The attention control group served 2 purposes: to provide a placebo intervention, and to simulate the contact patients in the exercise group were receiving via the home visits. Although nutrition was not the active intervention, patients were informed we were examining the effects of both exercise and nutrition. Nutrition education was chosen because the publicity nutrition has received as a factor associated with arthritis makes it a believable treatment, and this intervention invokes a behavior change similar to exercise. The attention control group received a booklet based on eating by the food pyramid developed by Elder Source (Durham, North Carolina, USA) and scientists at Tufts University. Patients received home visits once every 2 weeks during the study period for a total of 7 home visits over 4 months. Topics covered included an introduction and overview of the program, fruits and vegetables (5 per day), grains and fiber, calcium, and fat. Goals were set at each visit (i.e., to increase fruits and vegetables from 3 to 4 servings per day) and patients were asked to keep food logs on 3 nonconsecutive days of every 2 weeks. Food logs were reviewed at each home visit and collected at the final evaluation at the HNRC.

Patient characteristics. Information on age, race, and education were obtained by questionnaire. Body weight and height were measured by standard protocol at the baseline and 4 month visits. BMI was calculated as

weight in kilograms divided by the square of height in meters. Comorbidities were assessed by self-report and medication use. Medication and supplement use were determined by having the patient bring all prescription and over the counter medications to the baseline and final visits, where they were recorded.

Knee radiographs. Anterior-posterior and lateral standing knee radiographs were obtained at the initial screening examination using the Framingham study protocol and screened by the study rheumatologist for acceptance criteria[24]. Knee radiographs were scored for descriptive purposes using the Kellgren/Lawrence (K&L) grading system for global tibiofemoral radiographic severity at the end of the study by a panel consisting of a musculoskeletal radiologist and 2 rheumatologists blinded to patient acceptance or assignment to treatment group[25]. In addition, both anterior-posterior and lateral knee radiographs were used to grade osteophytes in the medial, lateral, and patellofemoral compartments on a 0-3 Likert scale using the classification scheme for judging the severity of osteoarthritis adapted from Altman *et al*[22]. The 3 readers came to a consensus on the overall K&L grade for each knee and osteophyte grade in each compartment. The score for osteophytes in each compartment was added to give a summary score ranging from 0-30 for each knee. All scores reported are for the most severely affected knee.

All outcome measurements were made at baseline and at the end of the 4 month intervention.

Primary outcome. The primary outcome was the Western Ontario/McMaster Universities Osteoarthritis Index (WOMAC) pain and physical function subscales[26,27]. Both knees were assessed cumulatively on the questionnaire. Responses to each question were recorded on a 100 mm visual analog scale. The total of each subscale (range 0-500 mm for pain; 0-1700 mm for physical function with higher scores indicating more pain and worse physical function) was used in the analyses. The WOMAC is a self-report instrument eliminating bias by an unblinded examiner and patients were unaware which group was the active treatment group.

We added 2 questions to distinguish overall pain in the right knee and left knee separately (range 0-100 mm). At baseline, the knee reported as most painful was defined as the affected knee and the other knee was defined as the less affected knee. If the score was equal in both knees, one knee was randomly chosen as the affected knee. The definition for affected knee was used for analysis of the strength outcomes. Five percent of the 38 patients who completed the study reported equal pain in both knees.

Secondary outcomes. There were 6 secondary outcomes: clinical knee examination, strength, physical performance, quality of life, nutrition, and adherence.

Clinical knee examination. The study rheumatologist, blinded with respect to the patients' treatment assignment, assessed 5 clinical variables in the right and left knees separately: swelling, redness, tenderness on pressure, pain at rest, pain on motion, and in addition the physician and patient each provided a global score summarizing both knees. Scores for each of the above variables were recorded on a Likert scale from 0-4 corresponding to none, mild, moderate, severe or extreme, and summed together for a possible range of 0-48 for both knees.

Strength. Muscle strength was assessed by one repetition maximum (1 RM) for 3 Keiser pneumatic strength training machines (Keiser Sports Health Equipment, Fresno, CA, USA): knee extension, leg press, and knee flexion. One repetition maximum is defined as the maximum weight that can be lifted correctly for one repetition. This technique has been used extensively to monitor changes in strength with strength training interventions in the elderly[28] and patients with rheumatoid arthritis (RA)[29]. In our laboratory the reproducibility of the 1 RM is high, with a significant correlation between repeat knee extensor measurements 1 week apart (r = 0.88).

Prior to testing, as a warm up and to familiarize patients with the equipment, patients performed 15 repetitions with no resistance and 10 repetitions at 50% of their estimated 1 RM bilaterally. For the test, the weight was progressively increased with each repetition, 30 seconds rest between repetitions, until the patients failed to lift the weight through their active full range of motion minus 20°. The highest successful weight was taken as the 1 RM. Ideally, the 1 RM was obtained in 6-8 repetitions. All strength testing was done on each leg separately. The sum of the 1 RM for the right and left legs was termed total strength for each machine.

Physical performance. Chair stand time (10 times) and stair climb (ascent of 8 steps) were performed to investigate the effect strength training had on physical performance. The same chair (with arms) and set of stairs (step height 5.5 inches) were utilized for testing before and after the interventions. Patients began the chair stand seated, rose to a standing position and sat back down with their back against the back rest of the chair. The test was completed when the patient stood up for the 10th repetition. Patients who could not rise from the chair without using their arms were allowed to use the chair arms. Patients began the stair climb one foot behind the first step and completed the test when both feet were on the top landing after the 8th step. Patients who could not ascend the stairs without using the railing for support were allowed to use the railing. Both the chair stand and stair climb were performed under the same conditions before and after the intervention (i.e., if the arms of the chair or stair railing were used for the test before the intervention they were used for the test after the intervention). Patients were instructed to complete chair stand time and stair climb as quickly as possible and were timed to the nearest 0.01 second. One trial was performed for the chair stands and the best of 2 trials was used in the analysis for the stair climb. Similar tests have been used in previous exercise trials in knee OA, and have been validated in an elderly population[12,13,15,30,31].

Quality of life. The Medical Outcomes Survey Short Form (SF-36) was used to assess perceived quality of life (scores 0-100 with higher scores indicating better quality of life)[32]. The SF-36 measures 8 domains; physical functioning, role physical, bodily pain, general health, vitality, social functioning, emotional, and mental health. Self-efficacy was measured with Ewart's Scale of Self Efficacy (ESSE; 0-100 with higher scores indicating higher self-efficacy)[33]. The patient rates his/her confidence of completing different levels of 5 tasks (lifting objects from 0-120 lb; walking at 3 mph, from 1 block to 5 miles; climbing flights of stairs, from 3 steps to 8 flights; jogging at 5 mph from 1 block to 5 miles; and pushups from 1 to 40) on a scale from 0-100%, 0 corresponding to definitely cannot do and 100% to definitely can do. The responses for each scale are averaged.

Nutrition. Because vitamins C and D have been suggested to have an effect on knee OA, they were monitored at baseline and 4 months by a food frequency questionnaire[34] as well as by plasma levels. Vitamin C was measured in protein free supernatant using a colorimetric assay[35] and 25-hydroxyvitamin D was measured in plasma using a competitive protein-binding assay[36].

Adherence. The exercise and food logs patients kept, in the strength training and nutrition groups respectively, were used in conjunction with logs of home visits we kept, to track adherence to the interventions. The attention control group kept dietary logs 3 days of every 2 weeks for a total of 24 days over the 4 month intervention. Two or fewer missing logs or a total of 22 was considered 100% adherence. The total number of logs returned at the final evaluation were counted and divided by 22 for a measure of adherence. The exercise group kept exercise logs 3 days per week for a total of 48 over the 4 month intervention. Two or fewer missing days or a total of 46 was considered 100% adherence. The total number of logs returned at the final evaluation were counted and divided by 46 for a measure of adherence. If no logs were returned at the final evaluation, it was assumed they were not kept and only records of the home visits were used for adherence assessment. In this case, if exercise was done at the home visit or it was recorded that a food record was kept, patients were given credit for adherence on that day.

Analysis and interpretation. After assessing the normal distribution of the data, baseline characteristics of the attention control and exercise groups were compared using Student's t test for independent samples or Pearson's chi-square test for homogeneity of proportions, as appropriate. Continuous

variables are presented as mean ± standard deviation. Discrete variables are presented as number of patients per category.

The primary outcome and clinical knee examination were analyzed by modified intent to treat. The modified intent to treat group was defined as all patients who completed the study in addition to those who had dropped out and who had some followup data collected. If a patient dropped out of the study, every attempt was made to obtain a followup WOMAC and clinical knee examination at the time of drop out. Secondary outcomes, aside from the clinical knee examination described above, were analyzed with patients who completed the 4 month trial and both baseline and final testing. Significance in the outcomes was a comparison between groups of the final measurement by analysis of covariance adjusted for the baseline values of the outcome variable. Pearson correlation coefficients were used to quantify associations between the change in outcome variables of interest. A 2 sided p value less than or equal to 0.05 was considered to indicate statistical significance. Mean percentage change was calculated for some of the variables. Calculations of mean percentage change were done from the percentage change calculated for each individual. Analyses were carried out using Systat/PC 7.0.

RESULTS

Patients. Fifty-six potential patients were brought into the HNRC for further screening; of these 46 (82%) were eligible after screening and randomized to the strength training or attention control group. The major reasons for ineligibility included not fulfilling the criteria for knee pain, absence of radiographic evidence of knee osteoarthritis, or participating in an exercise program within the 6 months prior to the phone screen.

There were no significant differences between groups in the baseline characteristics of the 46 patients randomized in the study (summarized in Table 1) or in the 38 patients who completed the study. Figure 1 presents a flow diagram of the patients participating in the study. Eight patients (17%) withdrew prior to completing the 4 month intervention. There were no differences in the baseline characteristics of the 8 patients who withdrew when compared to the patients who completed the trial. A minimum of one followup WOMAC was obtained from 6 of these patients. Two of the 6 patients were able to return to the HNRC for a clinical knee examination. Therefore, a modified intention to treat analysis was performed on 44 patients for the WOMAC (the primary outcome) and 40 patients for the clinical knee examination. Analysis on all other secondary outcomes was performed on the 38 patients who completed the 4 month trial.

There were no changes in body weight over the 4 month intervention in either group, 0.05 kg (95% CI, -0.54 to 0.64 kg) and 0.22 kg (95% CI, -0.56 to 1.0 kg) in the exercise and attention control group, respectively. Mean adherence for the exercise group was 84 ± 27%, with a range of 24-100%, and 65 ± 32% in the attention control group, with a range of 27-100%. There were no adverse events due to the exercise protocol.

Strength. Changes in total strength (the sum of the right and left leg 1 RM) and affected knee strength are presented for knee extension, knee flexion, and leg press (see Table 2). The number of patients completing baseline and final evaluations for knee flexion was less than 19 because some patients were unable to complete the test due to fatigue or leg cramps. The greatest gains in strength over the 4 month intervention were observed in affected knee extension, 71% (95% CI, 3 to 139 %) in the exercise group versus 3% (95% CI, -12 to 19%) in the attention control group, (p = 0.001). Affected knee flexion strength improved in the exercise

Table 1. Baseline characteristics of study patients assigned to exercise and control intervention*.

	Attention Control	Exercise
Gender		
Male	4	6
Female	19	17
Age, yrs	68 ± 6	69 ± 6
BMI, kg/m^2	32 ± 5	31 ± 4
K and L** radiographic score, median	3	3
Bilateral OA, ng with K and L ≥ 2 on both knees	12	11
Osteophyte score, 0–30 for both knees combined	8.0 ± 5.8	8.2 ± 5.9
Clinical knee exam score, 0–48 for both knees	10 ± 5	9 ± 4
WOMAC pain†, 0–500 mm	204 ± 93	205 ± 87
WOMAC physical function, 0–1700 mm	774 ± 318	725 ± 291
Knee extension strength, kg	30.9 ± 15.5	30.9 ± 22.2
Knee flexion strength, kg	34.7 ± 15.6	34.2 ± 18.8
Self efficacy score‡, 0–500	168 ± 101	152 ± 72
Receiving NSAID prior to study, n	9	9
Self-reported chronic diseases		
CHD	1	2
Hypertension	10	12
Diabetes	3	2

*Values are mean ± SD unless otherwise noted. **K and L: Kellgren and Lawrence. †Higher scores on the WOMAC indicate increased pain and decreased physical function. ‡Higher scores indicate greater self-efficacy.

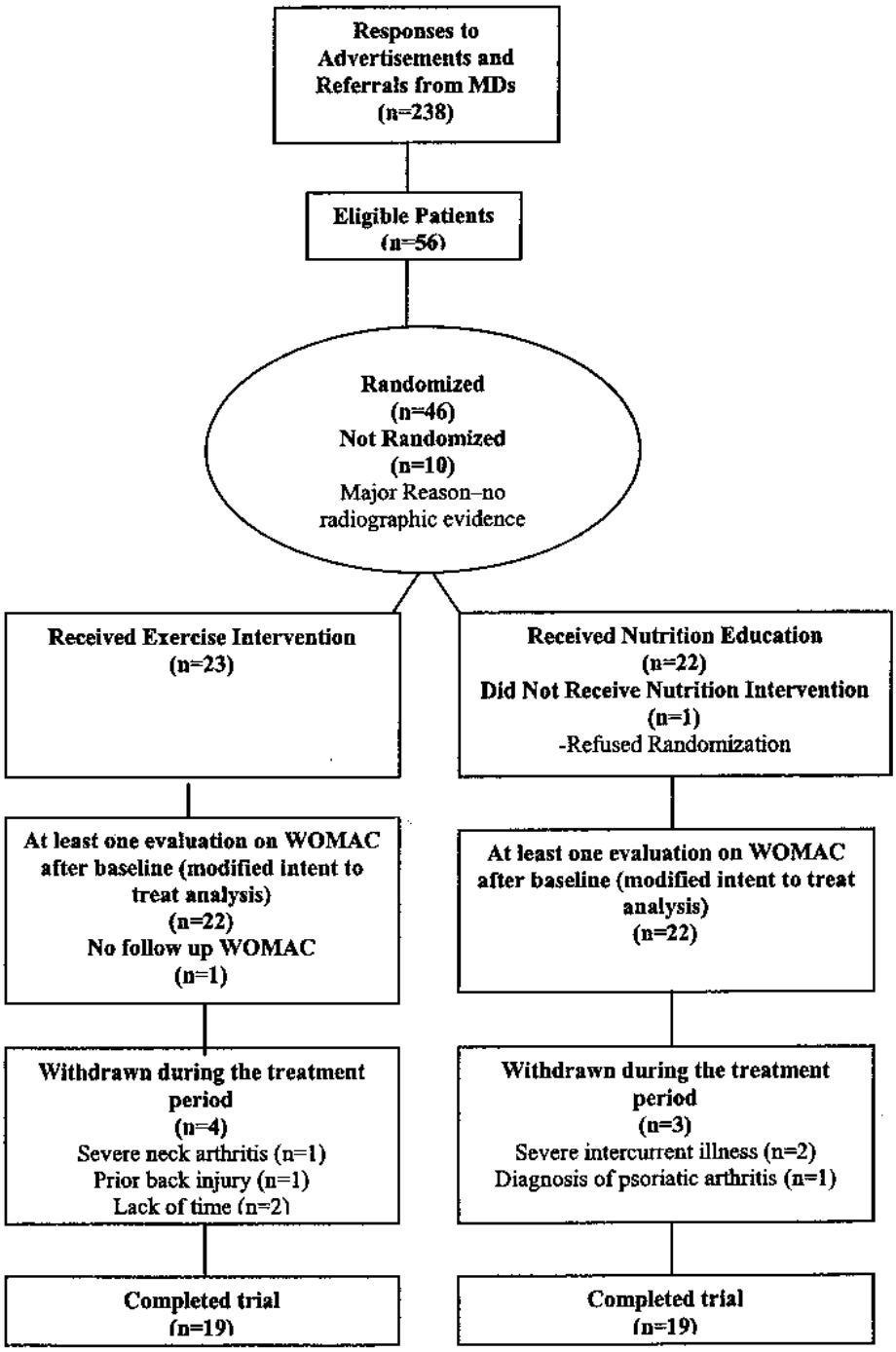

Figure 1. Flow diagram of patients participating in our trial.

group by 32% (95% CI, 15 to 49%), while the attention control group became weaker, (-12%, 95% CI, -27 to 2 %, p = 0.001). Total knee extension and flexion strength also improved significantly, but the smaller improvement in total knee extension and flexion strength indicates that most of the strength improvement came in the affected leg.

The mean starting weight lifted in the ankle weights for the knee extension exercise was 4.5 lbs/leg and the mean weight lifted at 4 months was 12.1 lbs/leg, an average increase of 7.6 lbs/leg in 4 months.

Primary outcome. In the modified intent to treat analysis, the exercise group experienced a 36% decrease in knee pain as measured by the WOMAC pain scale (see Table 3) (95% CI, -19 to -50%), compared to an 11% decrease in the attention control group (95% CI, 9 to -32%), (p = 0.01 for between group comparison). There was a trend toward

Table 2. Strength measurements*†. Values are presented as mean [95% CI].

	Attention Control Group			Exercise Group			
	Baseline (n)	Final	Change	Baseline (n)	Final	Change	p value for Δ between groups
Total knee extension, kg	33.8 [26.1, 41.6] (n = 19)	34.8 [27.6, 42.1]	1.0 [–1.4, 3.4]	32.5 [21.3, 43.7] (n = 19)	40.6 [27.1, 54.2]	8.2 [12.1, 4.2]	0.002
Affected knee extension, kg	16.1 [12.6, 19.7] (n = 19)	15.5 [13.6, 19.0]	–0.6 [–2.3, 1.0]	13.6 [8.7, 18.6] (n = 19)	19.6 [12.7, 26.4]	5.9 [9.3, 2.5]	0.001
Total knee flexion, kg	38.1 [29.8, 46.4] (n = 16)	34.8 [26.1, 39.6]	–3.3 [0.3, –6.3]	36.9 [27.4, 46.3] (n = 18)	43.3 [32.3, 54.3]	6.4 [3.1, 9.8]	≤ 0.001
Affected knee flexion, kg	15.6 [12.2, 19.0] (n = 17)	13.1 [10.2, 16.1]	–2.5 [–5.4, 0.5]	14.4 [9.9, 19.0] (n = 18)	18.5 [13.0, 23.9]	4.1 [2.1, 6.1]	0.001
Total leg press, kg	89.2 [75.2, 103.2] (n = 12)	91.2 [79.3, 103.1]	2.0 [–3.2, 7.2]	94.0 [70.0, 118.1] (n = 16)	101.8 [78.2, 125.4]	7.8 [13.0, 2.6]	0.089
Affected leg press, kg	43.2 [34.9, 51.4] (n = 13)	45.4 [37.9, 52.9]	2.2 [–1.5, 6.0]	45.2 [32.4, 57.9] (n = 16)	48.0 [36.4, 59.6]	2.8 [–0.5, 6.2]	0.696

*Significance is comparison between groups of final measurement by analysis of covariance adjusted for baseline values of the outcome variable. Number of patients at baseline is the same for final. The number of patients for knee flexion is less than 19 because some were unable to perform the movement due to leg cramps or fatigue, and for leg press due to faulty equipment and in one case hip pain from coexisting hip OA.

†Strength changes were determined by one repetition maximum (1 RM) for knee extension, knee flexion, and leg press on each leg individually. Affected is the 1 RM for the leg reported as most painful on visual analog scale at baseline. Total is the sum of the 1 RM for the right and left legs.

Table 3. Changes in WOMAC scores in strength training and control groups by modified intent to treat (results for completers in parentheses)*. Data are presented as mean [95% CI].

	Attention Control			Exercise			
	Baseline (n)	Final	Change	Baseline (n)	Final	Change	p value for Δ between groups
WOMAC pain, 0–500 mm	209 [168, 250] (194 [154, 235])	189 [141, 238] (178 [123, 232])	–20 [–51, 12] (–17 [–51, 17])	207 [168, 247] (210 [171, 249])	128 [86, 169] (119 [75, 163])	–79 [–119, –41] (–91 [–134, –48])	0.013 (0.010)
WOMAC physical function, 0–1700 mm	783 [640, 926] (727 [583, 871])	664 [482, 847] (622 [418, 825])	–119 [–223, –15] (–105 [–199, –12])	734 [603, 864] (761 [628, 895])	462 [301, 623] (434 [266, 603])	–272 [–415, –128] (–327 [–473, –181])	0.070 (0.012)

*Higher scores correspond to worse pain and function. Significance is comparison between groups of final measurement by analysis of covariance adjusted for baseline values of the outcome variable. The modified intent to treat group included all patients who completed the study in addition to those who dropped out but on whom we were able to obtain some followup data. The completers are those patients who completed the 4 month intervention and baseline and followup testing. n = 22 per group for modified intent to treat and n = 19 per group for completers.

greater improvement in physical function with exercise (38% [95% CI, 19 to 56%]) compared to the attention control group (21% [6 to 36%]), (p = 0.07).

Among study completers (Table 3) pain decreased in the exercise group by 43% (95% CI, -27 to -59%) versus decreasing by 12% (95% CI, 11 to -35%) in the attention control group (p = 0.01), and physical function improved by 44% (95% CI, 27 to 62%) versus 23% (95% CI, 7 to 39%) in the attention control group (p = 0.01).

Improvements in affected knee extension strength for the exercise group were correlated with improvements in WOMAC physical function, r = -0.336 (Figure 2).

Clinical knee examination. The clinical knee examination also improved in the exercise group versus the attention control group [37% (95% CI, 27 to 62%) vs 17% (95% CI, -7.2 to 40%), respectively, p = 0.049] in the modified intent to treat analysis. In an analysis of patients who completed the study, scores on the clinical examination improved by a similar magnitude.

Physical performance. The exercise group had a greater decrease in the time to ascend 8 stairs and complete 10 chair stands (a decrease of 4.79 and 1.03 seconds, respectively) than the attention control group (a decrease of 2.29 and 0.18 seconds, respectively, p = 0.03-0.04).

Quality of life and psychological variables. Many of the scales in the SF-36 deteriorated in the control group while improving in the exercise group (Table 4). Out of the 8 scales in the SF-36, 4 significantly improved with the exercise intervention compared to the control intervention: physical function, role physical, social, and mental health (p =

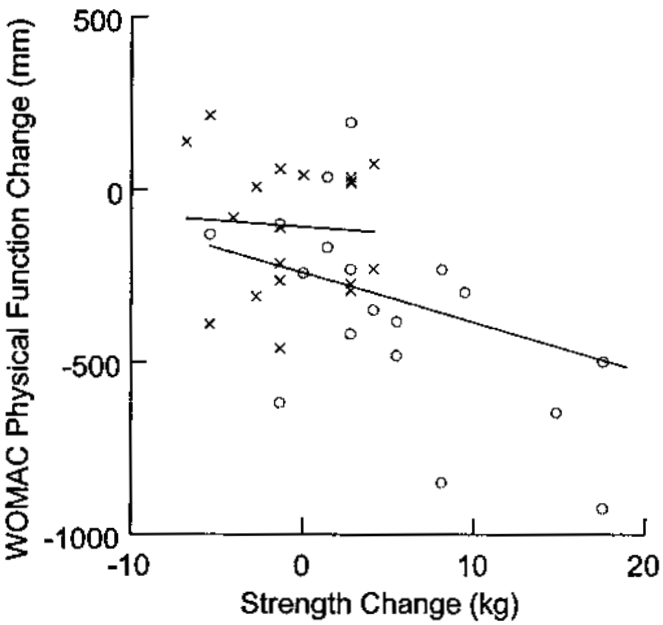

Figure 2. The correlation between the absolute difference in affected knee extension strength (kg) (larger values represent increased strength) and self-reported physical function (mm) measured by the WOMAC (negative values represent improvement in WOMAC score) (x:controls, r = –0.064; o: strength training, r = –0.336).

0.0001-0.01). Out of the 5 scales for self-efficacy, walking improved by 8% (95% CI, -2 to 19%) in the exercise group and decreased by 7% (95% CI, -15 to 1%) in the control group (p = 0.046). For the whole group, improvements in walking self-efficacy were associated with increases in affected knee extension strength, r = 0.383.

Nutrition. There were no differences in changes in the daily intake or plasma levels of vitamins C and D between the 2 groups over the 4 month intervention.

DISCUSSION

Our trial demonstrates that a 4 month home-based progressive strength training program significantly decreases pain and improves self-reported physical function by approximately 30% more than improvements observed in the control group. These changes are accompanied by improvements in a clinical knee examination, physical performance measures, quality of life, and self-efficacy. Improvements in strength may have accounted for the benefits achieved in physical function and self-efficacy. There is evidence to suggest that the determinants of physical function and pain differ in a number of important respects[7,37-39]. Quadriceps weakness and self-efficacy are strong independent predictors of physical function (disability)[7,40].

Four controlled studies have examined the effects of strengthening exercise on knee OA; strength improvements were minimal or non-existent in all these studies[12-15]. All of these studies reported minimal impact on physical function; improvements in pain were more varied. Two uncontrolled studies conducted in the laboratory by Fisher, *et al* (1994 and 1997) showed greater improvements in strength and self reported physical function[16,41]. Figure 3 illustrates the comparison of strength gains and physical function gains from studies in which data were comparable. Although in our study strength was an important outcome that seems to be lacking in previous exercise trials, differences between the studies such as severity of OA, measurement of muscle

Table 4. Quality of life outcomes (SF-36) (completers)*. Values are presented as mean [95% CI].

	Attention Control Group (n = 19)			Exercise Group (n = 19)			
	Baseline	Final	Change	Baseline	Final	Change	p value for Δ between groups
Physical function	56.6 [45.6, 67.6]	60.8 [47.6, 74.0]	4.2 [–1.3, 9.7]	46.8 [37.4, 56.3]	63.4 [50.5, 76.3]	16.6 [8.4, 24.7]	0.010
Role physical function	64.5 [45.1, 83.9]	52.6 [33.4, 71.9]	–11.8 [–28.1, 4.4]	42.1 [22.4, 61.8]	75.0 [57.5, 92.5]	33.0 [10.2, 55.6]	0.009
Social	81.6 [70.5, 92.7]	75.7 [63.7, 87.6]	–5.9 [–16.2, 4.4]	78.3 [64.8, 78.3]	90.8 [79.5, 100.0]	12.5 [1.3, 23.7]	0.012
Mental	80.4 [72.5, 88.3]	77.3 [70.2, 84.3]	–3.2 [–9.0, 2.9]	80.4 [69.9, 91.0]	88.6 [82.6, 94.6]	8.2 [2.1, 14.3]	≤ 0.001
Bodily pain	59.5 [51.5, 67.6]	56.3 [46.6, 66.0]	-3.2 [–10.0, 3.7]	48.0 [38.6, 57.3]	59.6 [48.7, 70.6]	11.7 [1.6, 21.8]	0.060
Vitality	55.5 [45.4, 65.7]	55.3 [45.2, 65.3]	–0.3 [–7.0, 6.5]	56.8 [44.1, 69.6]	60.8 [49.7, 72.0]	4.0 [–2.1, 10.0]	0.264
General health	69.4 [61.0, 77.8]	70.8 [62.0, 79.6]	1.4 [–2.9, 5.8]	74.7 [64.8, 84.6]	77.5 [66.7, 88.4]	2.8 [–3.2, 8.8]	0.617
Emotional	77.2 [58.6, 95.8]	73.7 [54.7, 92.7]	–3.5 [–26.2, 19.2]	73.7 [53.2, 94.1]	77.2 [58.6, 95.8]	3.5 [–10.6, 17.6]	0.636

*Medical outcomes survey short form 36 (SF-36). Scores range from 0–100, with higher scores reflecting better quality of life. Significance is comparison between groups of final measurement by analysis of covariance adjusted for baseline values of the outcome variable.

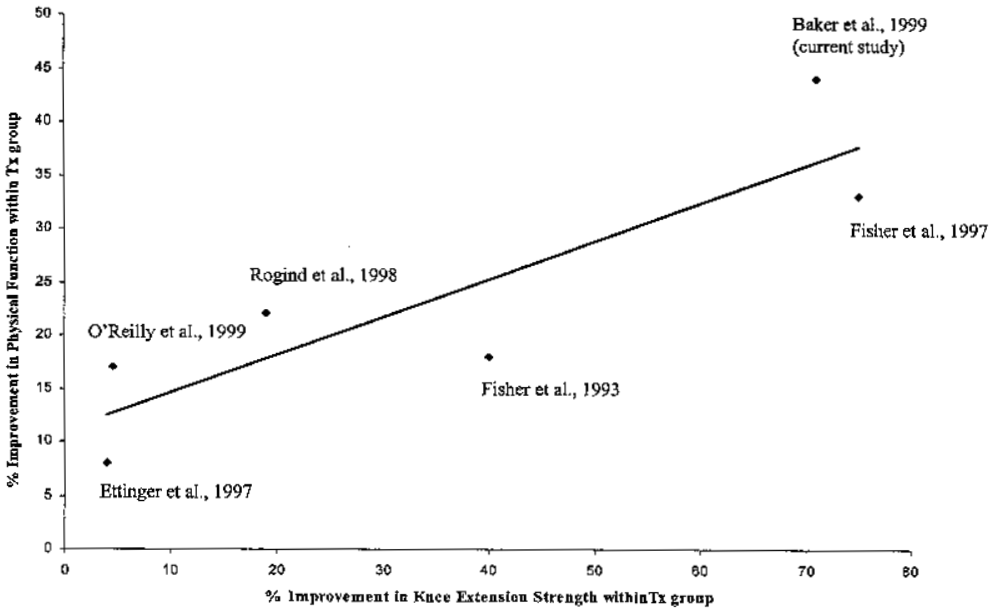

Figure 3. Association between change in strength and change in physical function in published studies of exercise in knee OA, including the present study. Physical function is self-report. r = 0.877, p= 0.02.

strength and length of the study may have prevented others from observing strength changes. It is important for these issues to be explored further in future studies.

A recent trial in knee OA involving 8 weeks of manual physical therapy and knee exercises reported a 56% improvement in the overall WOMAC score including pain, stiffness, and physical function subscales[42]. No strength measurements were taken, so it was not included in Figure 3, and due to the multifaceted intervention, it is difficult to determine whether increased strength played a role in the improvements observed.

Because of concern about injury to the arthritic joint, it is likely that a conservative approach to strength training has been taken in previous studies that may have mitigated strength improvements. Greater improvements in strength, in turn, are due to more intense training regimens, such as the one used in our study. We have previously shown that older frail individuals, including those with musculoskeletal complaints and RA, can safely participate in high intensity strength training while safely and effectively improving strength[28,29]. This study shows, for the first time, that patients with knee OA can also safely participate in high intensity strength training carried out in the home. Other home programs have not been as effective in improving strength and function[14,43].

Few studies present strength data on the individual legs. In our study, the greatest gains in strength were observed in the affected leg; in the exercise group, these gains were correlated with improvements in physical function. This relationship is strong even with the presence of an outlier that weakens the relationship. The outlier was also diagnosed with severe hip OA and had difficulty distinguishing between hip and knee pain. The patient could perform only knee extension and flexion (non-weight bearing) without pain. Strength improved, but not self-reported pain and physical function. The data from the other patients are consistent in that those who gained the most strength in the affected extensors also improved the most in function.

At baseline, extensor strength in the affected knee was on average 27% less than strength in the less affected knee, while at the final measurement in the exercise group, it was only 10% weaker. The training protocol was designed so that the intensity of each exercise was determined by the weaker leg. This is probably why changes in strength in the affected knee were so much greater than the less affected knee, as the former was trained at a higher relative intensity because it started out appreciably weaker. The muscles trained in the squat exercise, which is done simultaneously with both legs, are specific to the muscles used for the leg press. Strength of the more affected leg did not significantly improve in the leg press, but there was a trend toward improvement in total leg press strength. This suggests that when exercises were done with both legs simultaneously, the weaker leg was not worked to its potential.

Improvement in muscle strength cannot completely explain the decrease in pain we observed. Studies have reported that inherent psychosocial traits may put individuals more at risk for knee pain. Psychosocial interventions have had a larger impact on pain than physical function[44-47]. Other studies without improvements in strength reported larger improvements in pain versus physical function[12,14]. In addition, Van Baar, *et al* showed that muscle strength was

not an independent predictor of pain[39], but the small strength gains reported with the intervention may have limited the authors' ability to detect the effects of strength training. Exercise can improve many psychosocial variables such as depression, mood disturbance, emotional health, and self-efficacy[21,33,48–50].

Adherence to exercise is often a matter of concern, yet was high in our study. In a disease like OA, where outcomes such as pain and disability have the potential to have a significant impact on a person's quality of life, an exercise program with large effects on pain and disability may result in positive feedback that, in turn, improves adherence. In fact, in a home based study by Fisher, *et al*, it was reported that patients (7/19, 37%) dropped out because they felt the exercise was ineffective in improving their arthritis[51].

Mechanism of strength training. It is not known why strength training improves symptoms in knee OA. A number of explanations for its effect could be put forward. Further, training may work differently in different individuals. Neurological abnormalities, impaired knee joint proprioception, and quadricep reflex inhibition have been reported in individuals with knee OA[52,53]. A recent study showed an improvement in proprioception and muscle inhibition with strength training[30]. A stronger muscle may absorb more of the force that otherwise would be transferred across the joint. This may be especially important in walking, where stronger knee extensors slow the deceleration phase before heel strike and decrease impulse loading[54]. However, because muscle contraction is responsible for a large portion of the force across the joint, and may increase with a stronger muscle, it is unlikely that it is an absolute decrease in force across the joint that is responsible. In fact, joint loading is required to maintain the integrity of the cartilage[18-20]. Weak and unbalanced muscles may overload specific compartments of the knee joint and damage cartilage, which is what occurs with injury. A strength training program that increases muscle strength in a balanced and symmetrical way, and focuses on primary weaknesses, may more evenly distribute force across the joint.

Limitations and strengths. There are several limitations to the present study that are important to address in future research. First, our sample size was small. Second, the time period of the intervention was short (4 months), therefore longterm adherence and longterm efficacy were not addressed. A longterm study that cycles periods of higher with lower intensity training would be a compromise to avoid overtraining or injury and achieve gains similar to those observed in our study. Finally, with the exception of the clinical knee examination, secondary outcomes were completed by the same individual who conducted the strength training and nutrition education interventions. Therefore, blinding to group assignment was not possible for these secondary outcomes. The testing protocols have been standardized in our laboratory to minimize bias.

It may be argued that the difference in the number of home visits between the exercise and control group may have affected the results. However, it was only the first 3 weeks of the study that the exercise group received additional visits, for the remaining 9 weeks of the study contact between the 2 groups was similar. It may also be argued that patients in the exercise group became desensitized to the strengthening equipment and the testing process therefore confounding the strength results. However, the exercises used in the home training program were conducted with free weights and the testing protocol was carried out on machines that varied from the types of exercises conducted at home. Both groups were exposed to the same strength testing equipment only at pre and post testing.

There are also characteristics of the design of this study that strengthen its results. Nutrition as the control group provided several advantages over other types of control groups. Other interventions, such as education, provide attention control but do not control for the behavioral modifications that occur in the treatment group. The nutrition group was treated as an intervention group, and just as the goal in the exercise group was to change exercise behavior, the goal in the nutrition group was to change eating behaviors. In the lay literature, there has been some suggestion that nutrition may affect the signs and symptoms of arthritis. Therefore, nutrition is a believable treatment. However, the lack of scientific evidence that nutrition is beneficial for arthritis symptoms (especially in a short time period), the short study period, and the non-specific nature of the nutrition intervention make it unlikely to have an effect on arthritis symptoms beyond the attention effect. The study was carried out in the home with the exercise group conducting a majority of the exercise sessions on their own. This enhances the feasibility of the intervention in clinical practice. However, future studies should be conducted to determine if similar results may be obtained with fewer home visits.

This study demonstrates that a home-based progressive strength training program substantially improves muscle strength, physical function, and pain in individuals with knee OA. The improvements in some of the quality of life and self-efficacy scales are of interest and should be explored in future larger studies. The larger effect on physical function we observed compared to other strength training studies is probably due to the greater improvements in dynamic muscle strength in this study. This is an important finding that deserves further investigation since few treatments are available that have a formidable impact on physical function in knee OA.

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