

Physical Therapy Treatment Effectiveness for Osteoarthritis of the Knee: A Randomized Comparison of Supervised Clinical Exercise and Manual Therapy Procedures Versus a Home Exercise Program

Background and Purpose. Manual therapy and exercise have not previously been compared with a home exercise program for patients with osteoarthritis (OA) of the knee. The purpose of this study was to compare outcomes between a home-based physical therapy program and a clinically based physical therapy program. **Subjects.** One hundred thirty-four subjects with OA of the knee were randomly assigned to a clinic treatment group (n=66; 61% female, 39% male; mean age [\pm SD]=64 \pm 10 years) or a home exercise group (n=68, 71% female, 29% male; mean age [\pm SD]=62 \pm 9 years). **Methods.** Subjects in the clinic treatment group received supervised exercise, individualized manual therapy, and a home exercise program over a 4-week period. Subjects in the home exercise group received the same home exercise program initially, reinforced at a clinic visit 2 weeks later. Measured outcomes were the distance walked in 6 minutes and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). **Results.** Both groups showed clinically and statistically significant improvements in 6-minute walk distances and WOMAC scores at 4 weeks; improvements were still evident in both groups at 8 weeks. By 4 weeks, WOMAC scores had improved by 52% in the clinic treatment group and by 26% in the home exercise group. Average 6-minute walk distances had improved about 10% in both groups. At 1 year, both groups were substantially and about equally improved over baseline measurements. Subjects in the clinic treatment group were less likely to be taking medications for their arthritis and were more satisfied with the overall outcome of their rehabilitative treatment compared with subjects in the home exercise group. **Discussion and Conclusion.** Although both groups improved by 1 month, subjects in the clinic treatment group achieved about twice as much improvement in WOMAC scores than subjects who performed similar unsupervised exercises at home. Equivalent maintenance of improvements at 1 year was presumably due to both groups continuing the identical home exercise program. The results indicate that a home exercise program for patients with OA of the knee provides important benefit. Adding a small number of additional clinical visits for the application of manual therapy and supervised exercise adds greater symptomatic relief. [Deyle GD, Allison SC, Matekel RL, et al. Physical therapy treatment effectiveness for osteoarthritis of the knee: a randomized comparison of supervised clinical exercise and manual therapy procedures versus a home exercise program. *Phys Ther.* 2005;85:1301-1317.]

Key Words: *Exercise, Knee Osteoarthritis, Manual therapy, Physical therapy.*

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osteoarthritis (OA) is the most common joint disease causing disability, affecting more than 7 million people in the United States.¹ More disability and clinical symptoms result from OA of the knee than from any other joint.^{2,3} Osteoarthritis of the knee is reported to be a major health problem worldwide.^{4,5}

The etiology of knee OA is not entirely clear, but its incidence increases with age and in women.^{6,7} Obesity is a risk factor for the development and progression of knee OA and the need for total joint replacement.^{6,8,9} The association between physical activity and knee OA remains controversial.¹⁰⁻¹² Underlying biomechanical factors also may predispose people to OA.^{13,14} Increased incidence of OA has been reported in both the intact and amputated limbs in people with amputations.¹⁵ Early degenerative changes predict progression of the disease.^{16,17} The disability and pain associated with knee OA correlate with a loss of quadriceps femoris muscle

strength (loss of force-generating capacity of muscle),¹⁸⁻²⁰ coronary heart disease,²¹ and depression.²²

Several interventions are available for OA. Well-designed studies show that capsaicin cream, laser treatment, and transcutaneous electrical nerve stimulation (TENS) decrease the pain associated with OA.²³⁻²⁵ Arthroscopic surgery has not been shown to have a role in the management of knee OA. Knee capsule injections of saline, tidal irrigation, and placebo surgery have all been shown to be equal to arthroscopy.²⁶⁻²⁸ Acetaminophen is widely prescribed and considered to be low risk, but recent studies^{29,30} have shown minimal benefit for reducing the pain associated with OA. Nonsteroidal anti-inflammatory drugs (NSAIDs) are frequently prescribed, but they have significant side effects.³¹⁻³³ Topical diclofenac has been found to decrease the pain of knee OA, with presumably fewer gastrointestinal side effects.³⁴ Cyclooxygenase-2-selective inhibitors (coxibs) were initially thought to be the safer alternative to nonselective

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NSAIDs, but recent concerns have included gastrointestinal, cardiovascular, renal, and hepatic side effects.³⁵⁻⁴⁰ Glucosamine supplements are widely used, with some controversy with regard to their efficacy and long-term benefits for people with knee OA.^{41,42} Ice massage improves range of motion (ROM), function, and knee strength, and cold packs decrease swelling in patients with knee OA.^{43,44} Hot packs or ultrasound are not thought to be of therapeutic value.^{43,45}

A growing body of evidence shows that exercise improves knee joint function and decreases symptoms.⁴⁶⁻⁵⁷ Furthermore, the findings of a recent study⁴⁸ suggest that physical therapy intervention including exercise may reduce the need for knee arthroplasty and intra-articular injections. However, the most effective types and combinations of exercise and dosage are unclear. The setting in which the exercises should be performed and the level of professional attention required to initiate and maintain the exercise program also should be the subject of further investigation.

Benefits have been reported with manual therapy techniques used in combination with joint mobility and strengthening exercises.^{48,58} Falconer et al⁵⁸ found improvements in motion (11%), pain (33%), and gait speed (11%) after 12 treatments of stretching, strengthening, and mobility exercises combined with manual therapy procedures performed in a physical therapy clinic over 4 to 6 weeks. A comparison group that received the same exercise and manual therapy interventions plus therapeutic doses of ultrasound demonstrated no additional improvement.

In a controlled, randomized, single-blinded study, Deyle et al⁴⁸ demonstrated that manual therapy techniques and exercises applied by physical therapists for 8 clinical visits produced a 52% improvement in self-reports of function, stiffness, and pain as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scale and a 12% improvement in 6-minute walk test scores. A placebo control group that received equal clinical attention showed no improvement in WOMAC scores or 6-minute walk test scores.

The need for cost effectiveness throughout the health care system emphasizes the importance of knowing whether patients require numerous visits to a physical therapist or whether they might receive a similar benefit from a well-designed home program. The primary purpose of this study was to determine the effectiveness of a clinically applied treatment that included exercise and manual therapy compared with an exercise program performed at home for OA of the knee. A secondary purpose was to determine whether the high levels of improvement in pain, stiffness, and functional ability

1. Knee pain and crepitus with active motion and morning stiffness ≤ 30 min and age ≥ 38 y
2. Knee pain and crepitus with active motion and morning stiffness > 30 min and bony enlargement
3. Knee pain and no crepitus and bony enlargement

Figure 1.

Clinical criteria for the diagnosis of osteoarthritis of the knee.⁵⁹ Subjects with examination findings consistent with any of the 3 categories were considered to have knee osteoarthritis. Sensitivity=89%, specificity=88%.

reported by Deyle et al⁴⁸ are reproducible in a multi-center trial with different subjects and treating therapists. Our hypothesis was that physical therapy consisting of manual therapy and supervised exercise conducted in the clinic would be more effective than an exercise program performed at home for improving function and decreasing pain and stiffness.

Method

Subjects

One hundred thirty-four subjects with OA of the knee were randomly assigned to a clinic treatment group (n=66; 26 male, 40 female; mean age [\pm SD]=64 \pm 10 years) or a home exercise group (n=68; 20 male, 48 female; mean age [\pm SD] 62 \pm 9). One of the investigators used a computer random-number generator to determine group allocation. The randomization list determined the sequence of enrollment folders concealed in a locked cabinet. After a potential subject agreed to participate, a research assistant opened the cabinet to retrieve the next folder in sequence and then made allocation as indicated in the folder. All folders were identical in external appearance; each folder contained a sheet of paper indicating group assignment that could be accessed only by opening the folder. Subjects were either referred by their physicians for physical therapy or were self-referred.

Subjects who were admitted to the study were diagnosed with OA of the knee based on clinical criteria developed by Altman⁵⁹ (Fig. 1), which he found to be 89% sensitive and 88% specific. Additional inclusion criteria were eligibility for military health care and no physical impairment unrelated to the knee that would prevent the subject from safely participating in any aspect of the study. All subjects were required to have sufficient English language skills to complete the pain, stiffness, and functional assessment questionnaire. Subjects were excluded if they could not attend the required number of visits, had received a cortisone injection to the knee joint within the previous 30 days, or had a surgical procedure on either lower extremity within the past 6 months. Subjects were instructed to continue taking any medication that had been initiated 30 days or more prior to enrollment in the study.

Procedure

Informed consent was obtained after screening for inclusion and exclusion criteria. Subjects in both groups provided descriptive data for age, sex, height, weight, duration of symptoms, presence of symptoms in one or both knees, previous surgery, medications, exercise frequency, and perceived exertion levels. Sunrise and weight-bearing anteroposterior and lateral knee radiographs were obtained and examined by radiologists for a radiographic severity rating for OA of the knee,⁶⁰ with scores ranging from 0 (least severe) to 4 (most severe).

All enrollment, data collection, and clinic treatment sessions were conducted in the physical therapy clinics at 3 military hospitals: Brooke Army Medical Center in Texas, Madigan Army Medical Center in Washington, and Martin Army Community Hospital in Georgia. Radiographs were obtained in the radiology department of each military hospital. Physical therapist assistants trained to be research assistants obtained the blinded pretreatment measurements. Training of the research assistants included review of the WOMAC procedure manual⁶¹ and practice administering the WOMAC. Training for the 6-minute walk test included using a stopwatch, marking laps on a preprinted 6-minute walk test form, and measuring the distance walked in an incrementally marked long hallway under simulated test conditions.

The primary outcome measure in this study was the WOMAC.⁶¹ Secondary outcome measures were a timed 6-minute walk test, the frequency of knee injections or knee surgery, medication use, and overall satisfaction with the rehabilitative treatment. The WOMAC consists of 24 questions, each corresponding to a visual analog scale, designed to measure patients' perceptions of pain, stiffness, and dysfunction. High WOMAC scores reflect high self-perceptions (greater severity) across the 3 domains measured by the scale. The WOMAC, which was specifically designed to evaluate patients with OA of the hip or knee, has been shown to be a highly responsive, multidimensional outcome measure that yields moderately reliable and valid scores.⁶²⁻⁶⁴ The timed 6-minute walk test measures the distance a person walks in 6 minutes and has been demonstrated to yield reliable measurements of functional exercise capacity; it is frequently used in OA-related trials.^{46,65-67}

Following pretreatment measurements, subjects received a standardized clinical examination. The examination included active and passive ROM assessments, manual muscle testing, and palpation of the lumbar spine, hip, knee, and ankle. Simple functional tests (eg, squatting, step-ups) that limited or reproduced symptoms were used to obtain daily baseline measurements to help assess the effect of the manual interven-

tion. For example, if the examination revealed that a subject was limited in the ability to perform a full squat or if the subject experienced pain with that activity, squatting would be reassessed after manual techniques intended to improve knee flexion. If the symptoms associated with squatting were subsequently decreased or the range of the squatting motion improved, that technique was considered to have a positive effect and would be continued at subsequent sessions. General improvements from session to session in these quick functional tests also were considered a positive overall response to the intervention in either treatment group. A neurological examination that included muscle strength testing, muscle stretch reflex testing, and sensory testing was performed if there were complaints of weakness, radiating pain, or altered sensation in the lower extremities.

Subjects in the clinic treatment group attended 8 treatment sessions in the physical therapy clinic. Manual therapy programs were individualized based on the results of the examination. The manual therapy techniques, consisting of passive physiological and accessory movements, muscle stretching, and soft tissue mobilization, were applied by the treating physical therapist primarily to the knee and surrounding structures (Tabs. 1 and 2). Detailed descriptions of the manual therapy techniques and intervention philosophy utilized in this study are available in manual therapy textbooks.^{68,69} Similar manual treatments also were administered to the lumbar spine, hip, and ankle if these areas exhibited a limitation in either active or passive movement and were judged to contribute to the overall lower-extremity dysfunction.⁶⁸⁻⁷⁰

In addition to receiving manual therapy treatments, subjects in the clinic treatment group performed a standardized knee exercise program at each treatment session. This program consisted of active ROM exercises, muscle strengthening, muscle stretching, and riding a stationary bicycle. A physical therapist or physical therapy technician supervised these exercises. The number of strengthening exercise bouts and stationary bicycle riding time were increased or decreased by the treating physical therapist based on subject response. The exercise program was based on the best available evidence for the most efficient methods of producing the desired effects of increasing strength, flexibility, and ROM at the initiation of this study.⁷¹⁻⁷⁶ Subjects were examined for adverse signs and symptoms such as increased pain, joint effusion, and increased skin temperature over knee joints at each clinic visit. All elements of hands-on treatment and exercise were progressed only if the symptoms and signs of OA were decreasing. If any soreness lasted more than a few hours after the intervention, the regimen was decreased accordingly for that

Table 1.

Comparison of Interventions by Intervention Group

Clinical Treatment Group Interventions	Performance	Home Exercise Group Interventions	Performance
Strengthening exercise	Clinic and home	Strengthening exercise	Home
Stretching exercise		Stretching exercise	
ROM exercise		ROM exercise	
Stationary bicycle ^a		Stationary bicycle ^a	
Manual therapy	Clinic	No manual therapy	
Level of exercise supervision and instruction	1 exercise instruction session 7 supervised exercise sessions	Level of exercise supervision and instruction	2 exercise instruction sessions

^aHome stationary bicycle riding in both exercise groups was allowed if it was part of the participant's exercise program before the study. Participants in the home exercise group were not specifically instructed to ride a stationary bicycle, nor was it recorded on the exercise adherence log. ROM=range of motion.

subject. Subjects in the clinic treatment group performed the same home exercise program as the home exercise group each day that they were not treated in the physical therapy clinic.

The home exercise group received detailed verbal and hands-on instruction in a home-based program of the same exercises as the clinical treatment group. Similar to the subjects who received clinical treatment, subjects in the home exercise group were instructed that pain should be avoided in all exercises except in the case that pain or stiffness decreased with each repetition. Each subject received a detailed supporting handout containing instructions and photographs of the exercises. A home program adherence log was maintained by each subject. Subjects in the home exercise group were allowed to ride a stationary bicycle if they stated that riding a bicycle was currently part of their exercise routine or if they could not walk for safety reasons. Riding of the stationary bicycle was not recorded on the exercise adherence log for the home exercise group. The details of the manual therapy and exercise interventions for both groups are shown in Tables 1 through 5.

A follow-up examination was performed for the home exercise group 2 weeks after the initial visit. Examiners checked for adverse signs and symptoms such as increased pain, joint effusion, and increased skin temperature over knee joints. The exercise log was reviewed, the subjects were again supervised performing the home-based program, and observed performance deficiencies were corrected. Exercises were progressed only if the symptoms and signs of OA were stable or decreasing.

Neither group of subjects was aware of the intervention that the other group was receiving. Subjects in both groups were instructed to take a daily walk at a comfortable pace and gradually progressed distance. After 4 weeks, subjects from both groups returned to the clinic

for another blinded assessment of WOMAC scores and 6-minute walk test measurements. Subjects in both groups were instructed to refrain from their home exercises and their daily walk on the day of the second assessment. Assessments were performed at the same time of day as the pretest to help control for daily cycles in pain and stiffness.

During the second 4-week period, subjects in both groups continued their daily home exercise program. At 8 weeks, both groups of subjects returned for a third assessment of WOMAC scores and 6-minute walk test measurements. At 1 year, subjects were contacted and queried about knee injections, knee surgeries, medication use, and overall satisfaction with outcomes of their rehabilitative treatment. WOMAC scores and 6-minute walk test measurements were obtained at 1 year for those subjects who were able to return to the clinic for measurement.

The sample size was determined a priori by a statistical power calculation based on anticipated group differences in WOMAC scores at 4 weeks. For this calculation, the standard deviation was estimated to be 400 mm, the minimal clinically important difference between groups was defined as 200 mm (about 20% of anticipated average baseline score), and statistical power was 80% with approximately 64 subjects per group.

Data Analysis

Data from the initial measurement session were analyzed to determine whether significant group differences existed using independent *t*, Mann-Whitney *U*, and chi-square tests for ratio, ordinal, and categorical variables, respectively. All data analyses were performed with SPSS for Windows (version 10.1).^{*} Descriptive data

^{*} SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.

Table 2.
Common Knee Impairments Addressed by Manual Therapy

Impairment	Manual Intervention	Typical Delivery
Loss of knee extension	Manual mobilization through range of motion (ROM) and knee extension at end range Knee extension Knee extension with valgus or abduction Knee extension with varus or adduction	Mobilization grades III and IV to III++ and IV++ 2–6 bouts of 30 s per manual technique Clinical observation: this manual intervention may provide near-immediate decrease of symptoms and may be approached with relatively more vigor than knee flexion
Loss of knee flexion	Manual mobilization through ROM and knee flexion at end range Knee flexion Knee flexion plus medial (internal) rotation	Mobilization grades of III- and IV- to III+ and IV+ 2–6 bouts of 30 s per manual technique Clinical observation: pain with end-range knee flexion may be due to degenerative meniscal tears; end-range techniques should be utilized with caution
Loss of patellar glides	Manual mobilization of the patella in 5°–10° of knee flexion Medial Lateral Caudal Cephalad	Mobilization grades of IV to IV++ 2–6 bouts of 30 s per manual technique Clinical observation: some patients may be intolerant of even slight compressive forces over the patella; therapist hand placement is important
Muscle tightness	Manual stretches at end length of the muscle Quadriceps femoris Hamstrings Gastrocnemius Adductors Iliopsoas Tensor fasciae latae and the iliotibial band	Sustained manual stretches of 12–30 s duration repeated 1–3 times per muscle Clinical observation: the lumbar spine should be manually stabilized and protected during all extremity stretches, particularly hip flexor stretches; many of these patients also will have arthritic changes in the spine, and symptoms can be increased without care in positioning
Soft tissue tightness	Soft tissue mobilization Suprapatellar and peripatellar regions Medial and lateral joint capsule Popliteal fossa	Circular fingertip and palm pressure mobilization at the depth of the capsule or retinaculum for 1–3 bouts of 30 s per area Clinical observation: the soft tissue work in the popliteal fossa seems to work best when performed slowly with occasional sustained positions of 10–12 s, this technique works well when combined with the manual mobilizations into knee extension

analysis and tests for the assumptions of normality and homogeneity of variance were followed by a 2×3 mixed-model multivariate analysis of variance (MANOVA) with an alpha level of .05 for the subset of 120 study participants who provided all data at baseline, 4 weeks, and 8 weeks. The independent variables for the MANOVA were group (with 2 levels) and time (with 3 levels). The 2 dependent variables were WOMAC scores and 6-minute walk test distances. Subsequent 2×3 univariate analyses of variance (ANOVAs) for each dependent variable were performed with a Bonferroni-corrected alpha level of .025. *Post hoc* analyses of significant group \times time interaction effects were performed with the Tukey multiple-comparison procedure.

In order to investigate the potential for confounding variables, a separate multiple regression model was created for each outcome variable. In each model, 13

possible predictors among baseline variables were included in a forced-entry analysis: treatment group assignment, age, height, weight, sex, duration of symptoms, self-rating of physical activity level, days per week of aerobic activity, bilaterality of symptoms, use of medications, severity of radiographic findings, and initial scores for the WOMAC and the 6-minute walk test. The WOMAC scores and 6-minute walk test measurements obtained at the 4-week follow-up were entered as dependent variables for the regression analyses. An intention-to-treat analysis was conducted by carrying the last obtained measurements forward for those subjects who did not complete all aspects of the study.

Results

Of the 134 subjects initially enrolled in the study (Fig. 2), 60 subjects in the clinic treatment group and 60 subjects in the home exercise group completed all treatment and

Table 3.

Patient Exercise Program: Strengthening Exercises

Exercise	Performance	Repetitions
Statis quad sets in knee extension	Perform daily Patient is positioned fully supine or supine supported on elbows with the knee in full extension Patient contracts the quadriceps femoris muscle and pushes the knee down while maintaining the foot in full dorsiflexion	Hold each contraction for 6 s with a 10-s rest between repetitions Repeat 10×
Standing terminal knee extension	Perform 3× per week Patient stands with a resistive band or a cuff from a weighted pulley mechanism behind a slightly flexed knee Patient contracts the gluteal and quadriceps femoris muscles to fully straighten the hip and knee	Hold each contraction for 3 s Repeat 10× Increase resistance as tolerated
Closed-chain progression, ordered from least to most challenging	Patient performs one of the following activities 3× per week Patient should progress to the most challenging activity that he or she can successfully complete with minimal or no pain	
Seated leg presses	Patient is seated holding a resistive band in both hands Patient places his or her foot against the band, then straightens the knee by pushing the foot down and forward by contracting the gluteal and quadriceps femoris muscles	Hold each contraction 3 s with knee as straight as possible Slowly return to starting position and repeat for a 30 s bout. Progress to bands of increasing resistance and additional bouts
Partial squats weight-lesened with arm support as needed	Patient stands with arm support as needed Patient performs a partial squat, keeping the knees centered over the feet Return to standing by contracting the quadriceps femoris and gluteal muscles	Hold each contraction 3 s with hips and knees as straight as possible Repeat for 30 s Progress to full body weight without support and additional bouts
Step-ups	Patient stands in front of a low step Patient places foot of involved leg on step and brings body over foot to stand on the step Use as little push-off assistance from the contralateral foot as possible Step down with the contralateral foot	Slowly repeat for 30 s Progress to increased height of the step and additional bouts Alternate legs if both knees are involved

testing at 0, 4, and 8 weeks. In the clinic treatment group, 1 subject withdrew due to unrelated medical reasons, 2 subjects were disqualified after receiving knee injections, 1 subject changed medications during the study, and 1 subject failed to return for unknown reasons. The 6-minute walk test measurement for the 8-week testing session was unavailable for 1 additional subject in the clinic treatment group. In the home exercise group, 3 subjects moved from the area, 1 subject changed medications during the study, 1 subject withdrew to receive shoulder surgery, 1 subject was disqualified after receiving cortisone injections to the knee, and 2 subjects failed to return for unknown reasons. No subjects were discontinued due to lack of adherence to the treatment regimen. All 120 subjects who completed the study attended all clinical appointments and reported for testing at 0, 4, and 8 weeks. The other 14 subjects reflect an overall dropout rate of 11%: 9% in the clinic treatment group and 12% in the home exercise group.

Baseline characteristics for completers and non-completers in each group are given in Table 6. Table 7 contains mean scores with 95% confidence intervals (CIs) for the dependent variables measured at 0, 4, and 8 weeks for the completer subjects. Medication use by subjects in each group of completers is presented in Table 8.

For subjects who completed all aspects of the study, the randomization procedure resulted in reasonably homogenous groups at the outset of the study (Tab. 6). The 14 subjects who failed to return for the 4-week or 8-week measurement session appeared to differ from the subjects who completed the study, as measured by several variables. However, the statistical tests revealed significant differences only for the initial WOMAC scores, which were about 22% worse ($P=.03$) for the subjects who did not complete the study, and for radiographic severity scores ($P=.002$) (median=2 for the subjects who completed the study and median=3 for the subjects who

Table 4.

Patient Exercise Program: Stretching Exercises

Exercise	Performance	Repetitions
Standing calf stretch	<p>Perform daily</p> <p>Patient stands with the heel of the foot on the ground behind the patient; the toes point straight ahead</p> <p>The patient leans forward until a moderate pull is perceived in the calf musculature</p> <p>The patient may use his or her arms for support against a wall or furniture as needed</p>	<p>Hold for 30 s and repeat 3×</p>
Supine hamstring muscle stretch	<p>Perform daily</p> <p>Patient is positioned supine with the contralateral lower extremity maintained as straight as possible</p> <p>The ipsilateral hip is flexed to 90°</p> <p>The knee is straightened and the proximal lower leg supported with the hands until a moderate pull is perceived in the posterior thigh and calf</p> <p>The ipsilateral ankle should be dorsiflexed</p>	<p>Hold for 30 s and repeat 3×</p> <p>Clinical observation: if radicular symptoms are produced, decrease or eliminate the ankle dorsiflexion or the intensity of the stretch</p>
Prone quadriceps femoris muscle stretch	<p>Perform daily</p> <p>Patient is positioned prone with both hips and knees extended</p> <p>A strap is placed around the ipsilateral ankle and brought posteriorly and superiorly over the ipsilateral shoulder</p> <p>The patient grasps the strap in the ipsilateral hand and bends the knee by straightening his or her elbow and pulling on the strap</p> <p>The knee is progressively flexed until a gentle stretch is perceived in the anterior thigh</p>	<p>Hold for 30 s and repeat 3×</p> <p>Clinical observation: hamstring muscle cramping may occur if the patient attempts to actively bend the knee; to reduce this possibility, always use the strap to passively flex the knee</p> <p>Maintain a gentle stretch and comfortable position for the lumbar spine</p> <p>Hard stretching will frequently create lumbar symptoms in this population</p>

Table 5.

Patient Exercise Program: Range of Motion Exercises

Exercise	Performance	Repetitions
Knee in mid-flexion to full-extension	<p>Performed once daily</p> <p>Patient is positioned supine or supine supported on elbows</p> <p>Knee is brought to 45° of flexion with the ipsilateral foot sliding on the surface that the patient is lying on</p> <p>The knee is then fully extended with a strong quadriceps femoris muscle contraction against any limitation to full knee extension</p>	<p>Two 30-s bouts with 3-s hold at end range</p> <p>Clinical observation: these exercises work best if performed on a smooth surface such as a hardwood or linoleum floor or if a sliding board is used</p>
Knee in mid-flexion to full-flexion	<p>Performed once daily</p> <p>Patient is positioned supine or supine supported on elbows</p> <p>Knee is brought to full flexion with assistance of the upper extremities or a strap</p> <p>A gentle challenge to end-range flexion is sustained</p>	<p>Two 30-s bouts with 3-s hold at end range</p> <p>Clinical observation: pain with end-range knee flexion may be due to degenerative meniscal tears</p> <p>Over-pressure to end range should be applied with caution</p>
Stationery bicycle	<p>Performed once daily</p> <p>Knees should be at nearly full extension at bottom of pedal stroke</p>	<p>5 min, increase time as tolerated</p> <p>Clinical observation: some patients are intolerant of the stationary bicycle, and clinical judgment is required to continue the activity</p>

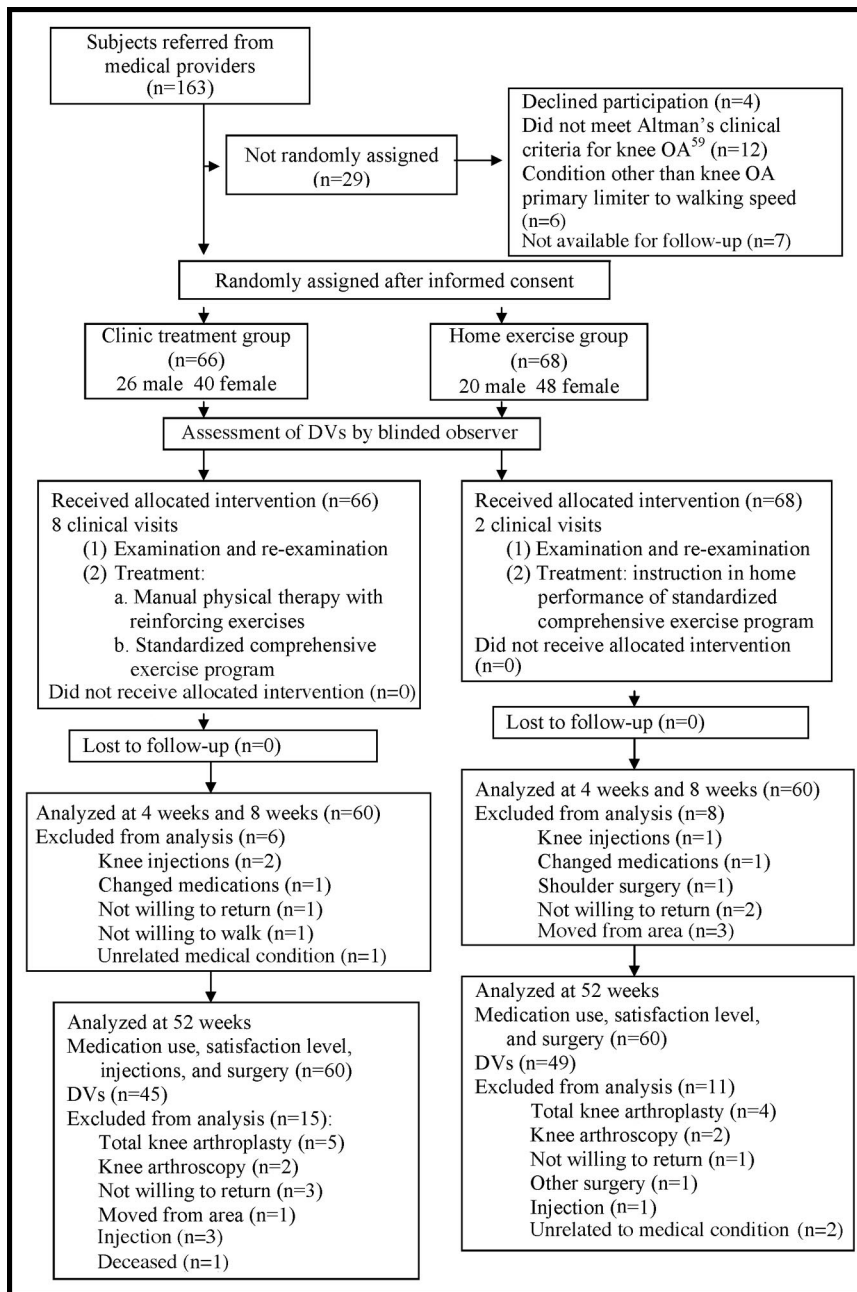


Figure 2. Flow chart describing the progress of subjects through the trial. OA=osteoarthritis, DV=subjects for whom the dependent variables were measured.

did not complete the study) (Tab. 6). Durations of symptoms appeared to be longer but were not significantly different for the subjects who did not complete the study ($P=.43$). This apparent difference in mean duration was attributable primarily to one subject who reported symptoms lasting 564 months. Upon removing the outlier, mean duration of symptoms for the subjects who completed the study was 74 months versus 71 months for the subjects who did not complete the study ($P=.91$).

The assumptions of normality and homogeneity of variance were met for both WOMAC scores and 6-minute walk test measurements. For the 120 subjects who provided data at 0, 4, and 8 weeks, the MANOVA revealed a group \times time interaction effect ($P=.001$), suggesting that changes in average scores over time depended on treatment group assignment. Subsequent univariate ANOVAs also demonstrated a group \times time interaction effect for the WOMAC scores ($P=.001$) but not for the 6-minute walk test distances ($P=.199$). The nonparallel plots of the average WOMAC scores (Fig. 3) reflect the differential effect over time of the clinic treatment and home exercise treatment on this outcome variable. In contrast, the relatively parallel plots of the average distances walked reflect the lack of an interaction effect for this variable (Fig. 4). For both the WOMAC scores and the 6-minute walk test measurements, there was a statistically significant ($P<.001$) main effect for time, reflecting an improvement from average initial values to those recorded at 4 weeks.

Post hoc pair-wise comparisons of mean scores revealed that the 2 groups of subjects who completed the study were homogenous at the time of initial testing for WOMAC scores and 6-minute walk test distances ($P>.05$). Compared with initial 6-minute walk test distances, both groups improved, on average, about 40 m (about 10%) at 4 weeks (95% CI=30–48 m) and did not change substantially between 4 and 8 weeks (Tab. 7). Both groups also improved in average WOMAC scores between baseline and 4 weeks, but the clinic treatment group improved about twice as much as the home exercise group. The average 4-week WOMAC score improved 52% (535 mm, 95% CI=426–644 mm) for the clinic treatment group and 26% (270 mm, 95% CI=193–346 mm) for the home exercise group. Neither group changed significantly in average WOMAC scores between 4 weeks and 8 weeks. Average WOMAC scores for the clinic treatment group were 263 mm better (95% CI=93–432 mm) than those for the home exercise group at 4 weeks and 217 mm better (95% CI=34–400 mm) at 8 weeks (Tab. 7). The multiple regression

Table 6.
Baseline Characteristics: Descriptive Statistics and Group Comparisons

Variable	Clinic Treatment Group Completers (n=60)	Home Exercise Group Completers (n=60)	Clinic Treatment Group Noncompleters (n=6)	Home Exercise Group Noncompleters (n=8)
	$\bar{X} \pm SD$	$\bar{X} \pm SD$	$\bar{X} \pm SD$	$\bar{X} \pm SD$
Age (y)	64.0±9.9	62.2±9.2	62.2±8.6	63.8±8.7
Body mass index	25.3±5.1	27.1±5.8	28.0±4.1	28.0±7.6
Duration of symptoms (mo)	78.3±92.7	69.8±79.7	159.4±233.5	78.1±80.0
WOMAC ^a score	1,038.2±451.4	1,035.8±493.3	1,389.0±347.7	1,277.1±407.8
Distance walked, 6 min (m)	431.0±107.6	408.1±122.8	399.2±18.2	427.1±79.1
Sex				
Male	38%	27%	50%	50%
Female	62%	73%	50%	50%
Bilateral symptoms	37%	45%	67%	57%
Use medication	60%	70%	100%	83%
Days/week of vigorous physical activity				
0	54%	38%	67%	29%
1-2	12%	13%	17%	14%
≥3	34%	48%	17%	57%
Severity of radiographic findings ⁶⁰				
0	3%	3%	0%	0%
1	24%	31%	0%	0%
2	41%	31%	17%	43%
3	19%	28%	33%	29%
4	12%	7%	50%	29%

^a WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index.

Table 7.
Group Comparisons: Means and 95% Confidence Intervals (CIs) for the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the 6-Minute Walk Test at 0, 4, and 8 Weeks^a

	Initial		Week 4		Week 8	
	\bar{X}	95% CI	\bar{X}	95% CI	\bar{X}	95% CI
WOMAC (mm)						
Clinic treatment group	1,038.2	921.6-1,154.8	503.5	399.6-607.4	513.4	392.7-634.2
Home exercise group	1,035.8	908.3-1,163.2	766.2	632.7-899.7	730.2	584.7-875.8
6-minute walk test (m)						
Clinic treatment group	431.0	403.2-458.8	473.1	444.6-501.7	483.6	453.6-513.6
Home exercise group	408.1	376.4-439.8	444.3	413.5-475.1	441.4	407.5-475.3

^a Includes only subjects who completed testing at 8 weeks. Clinic treatment group: n=60; home exercise group: n=60.

analysis revealed no meaningful influence of the potential confounding variables on the outcome scores. WOMAC subscale analyses also were conducted for those subjects who adhered to protocols through week 8. Results were consistent and similar to the results of the total WOMAC score analysis, with significant group × time interaction effects ($P \leq .004$) for each of the pain, stiffness, and function subscales (Fig. 5).

The results of the intention-to-treat analysis conducted for all 134 subjects enrolled in the study yielded results

that did not differ substantially from the results of the analysis for the 120 subjects who completed the study. In the intention-to-treat analysis, both groups improved about 9% in average 6-minute walk test distances at 4 weeks; average 4-week WOMAC scores were improved 45% for the clinic treatment group and 24% for the home exercise group.

All 120 subjects who completed testing through 8 weeks were contacted 1 year after enrollment into the study. By 1 year, 5 subjects (8%) in the clinic treatment group and

Table 8.Medication Use^a in the Clinic Treatment Group and Home Exercise Group

Medication	Clinic Treatment Group Completers (n=60)		Home Exercise Group Completers (n=60)	
	No. of Subjects Taking Medication	% of Subjects Taking Medication	No. of Subjects Taking Medication	% of Subjects Taking Medication
Acetaminophen	9	15%	11	18%
Aspirin	4	7%	2	3%
Celecoxib ^b	2	3%	0	0%
Codeine phosphate	1	2%	0	0%
Flurbiprofen ^c	0	0%	1	2%
Ibuprofen	9	15%	12	20%
Nabumetone ^d	1	2%	1	2%
Naproxen	10	17%	8	13%
Piroxicam ^c	0	0%	6	10%
Salicylate	2	3%	1	2%
Sulindac ^e	2	3%	0	0%

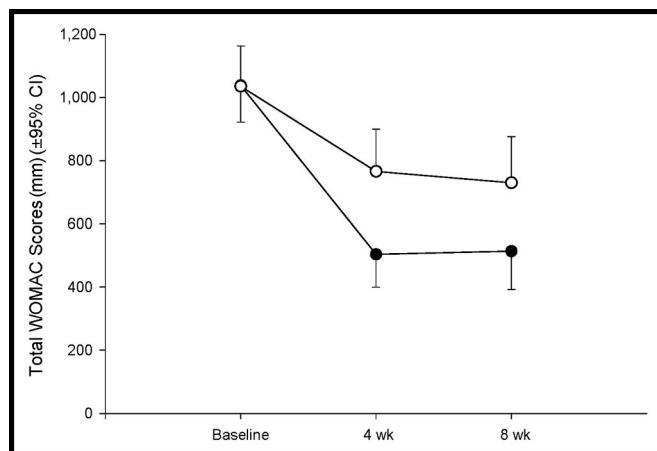
^a Use of medication was documented but not controlled in this study. Invasive cointerventions such as cortisone injections or surgical procedures were grounds for removal from the study.

^b G.D. Searle & Co, Div of Pfizer, 235 E 42nd St, New York, NY 10017-5755.

^c Mylan Pharmaceuticals Inc, 781 Chestnut Ridge Rd, PO Box 4310, Morgantown, WV 26504-4310.

^d GlaxoSmithKline, Five Moore Dr, Research Triangle Park, NC 27709.

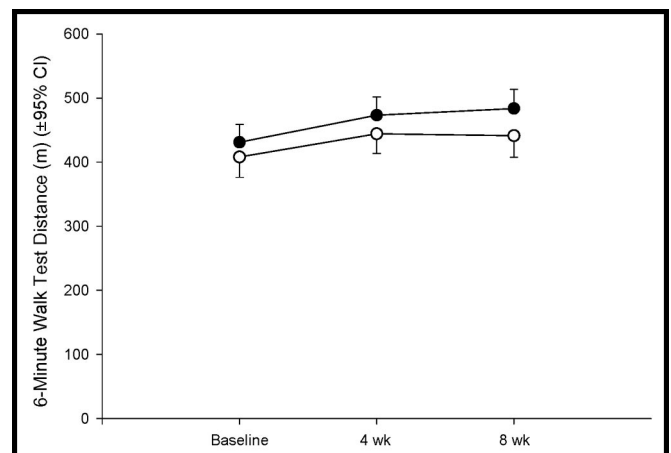
^e LKT Laboratories Inc, 2233 University Ave W, St Paul, MN 55114-1629.

**Figure 3.**

Average Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores at initial visit, 4 weeks, and 8 weeks. Lower scores indicate perceived improvement in pain, stiffness, and function. Closed circles represent the clinic treatment group; open circles represent the home exercise group. Among subjects who completed the study, those in the clinic treatment group had a greater average improvement in WOMAC scores over the 8-week period ($P < .001$) than those in the home exercise group. CI=confidence interval.

4 subjects (7%) in the home exercise group had received a total knee arthroplasty. Two subjects (3%) in the clinical treatment group and 2 subjects (3%) in the home exercise group had knee arthroscopy. Two subjects (3%) in the clinic treatment group and 1 subject (2%) in the home exercise group received steroid injections.

Among the 120 subjects who completed testing through 8 weeks, 45 subjects in the clinic treatment group and 49 subjects in the home exercise group were available for

**Figure 4.**

Average distance walked in 6 minutes at initial visit, 4 weeks, and 8 weeks. Closed circles represent the clinic treatment group; open circles represent the home exercise group. On average, subjects in both groups improved over the 8-week period ($P < .001$). CI=confidence interval.

testing at 1 year to determine whether the improvements in 6-minute walk test distances and the WOMAC scores at 8 weeks were still evident 1 year after the intervention. At the 1-year follow-up, average improvements in WOMAC scores and 6-minute walk test distances were still significantly improved. Compared with baseline scores, average 1-year WOMAC scores were 32% better in the clinic treatment group and 28% better in the home program group. However, after 11 months of identical home program regimens, both groups were equally improved over baseline WOMAC measurements.

Subjects contacted at 1 year responded to a 5-point Likert-type question asking how satisfied they were with

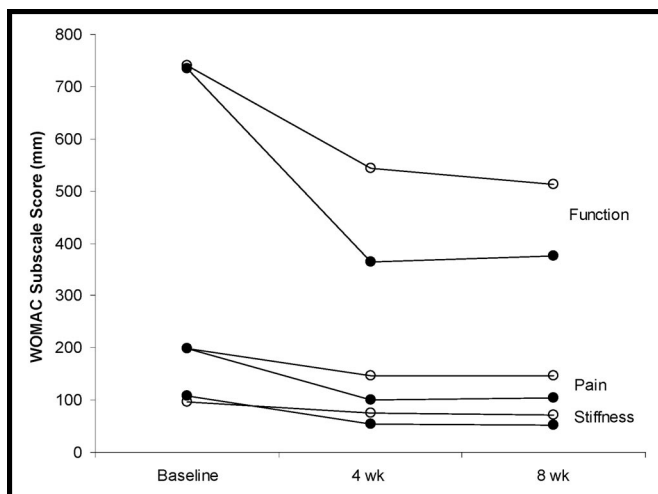


Figure 5. Average Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) subscale scores at initial visit, 4 weeks, and 8 weeks. Lower scores indicate perceived improvements in pain, stiffness, and function. Closed circles represent the clinic treatment group; open circles represent the home exercise group. The upper pair of plots represent mean scores for the function subscale, the middle pair of plots represent mean scores for the pain subscale, and the lower pair of plots represent mean scores for the stiffness subscale. Among subjects who completed the study, those in the clinic treatment group had greater average improvements, with all 3 WOMAC subscale scores over the 8-week period ($P \leq .004$) than those in the home exercise group.

the overall result of their rehabilitative treatment. Potential responses were: “not at all satisfied,” “a little satisfied,” “a fair amount satisfied,” “much satisfied,” and “very much satisfied.” Subjects in the clinic treatment group indicated a greater level of satisfaction ($P = .018$) than those in the home exercise group. Fifty-two percent of those in the clinic treatment group said they were “very much satisfied” with their outcomes compared with only 25% in the home exercise group. Sixteen percent of those in the home exercise group stated they were “a little satisfied” or “not at all satisfied” compared with only 5% in the clinic treatment group.

Subjects contacted at 1 year also were asked whether they were taking any medications for their OA. Sixty-eight percent of the subjects in the home exercise group were taking medications compared with 48% in the clinic treatment group ($P = .03$).

Discussion

Both treatment groups obtained successful outcomes, as measured by significant reductions in WOMAC scores and improvement in 6-minute walk test distances over a 4-week period. The reductions in WOMAC scores in both groups exceeded the 20% to 25% levels suggested as minimally meaningful by Barr et al.⁷⁷ The post-treatment WOMAC scores in the group who received biweekly treatments in the physical therapy clinic were markedly better than the WOMAC scores seen in the

home exercise group. Improvements and between-group differences seen at 4 weeks were still measurable at 8 weeks. The benefits of a 4-week intervention were not lost for either group during an intervening month with no treatment other than continued home exercises. Subjects in the clinic treatment group appeared to be more satisfied with the overall outcome of their rehabilitative treatment than subjects in the home exercise group. These results suggest that clinical intervention consisting of manual therapy and supervised exercise was more effective than a home exercise program for increasing function and decreasing pain and stiffness over an 8-week period.

The difference between groups is likely attributable to the additional effects of the clinical intervention consisting of manual therapy, stationary bicycling, and supervision of the exercises that the other group was performing unsupervised at home. Deyle et al⁴⁸ demonstrated no significant change in WOMAC scores or 6-minute walk test measurements in patients with knee OA who received a clinically applied placebo treatment.

The clinical intervention was more expensive than the home intervention. Per-visit reimbursement for the clinical physical therapy interventions would range from \$83 for Medicare to \$129 for commercial reimbursement rate. Therefore, the cost for 2 to 3 visits to initiate and maintain the home program is minimal. The difference for 8 clinical visits in the clinic treatment group versus 2 clinical visits in the home program group would range from \$498 to \$774. These additional costs are comparable to the costs of other interventions such as the cost of a series of viscosupplementation injections, and they are less than one tenth of the cost of a total knee replacement.⁷⁸ The question then becomes whether twice the level of improvement in the WOMAC score over a period from 8 weeks to less than 1 year merits the additional cost.

The results observed in the clinic treatment group in this study are nearly identical to those previously reported in an earlier study for the same intervention.⁴⁸ In both studies, subjects in the clinic treatment groups improved an average of about 50% in WOMAC scores and about 10% in 6-minute walk test distances over the 4-week period of active treatment (Fig. 6). The reproducibility of these observed treatment effects is apparent from nearly identical improvements for the clinical treatment groups in these 2 studies that enrolled completely distinct sets of subjects and used distinct sets of treaters and measurers.

The reproduction of these findings is important to the management of patients with OA of the knee. The level of functional improvement with this clinical treatment

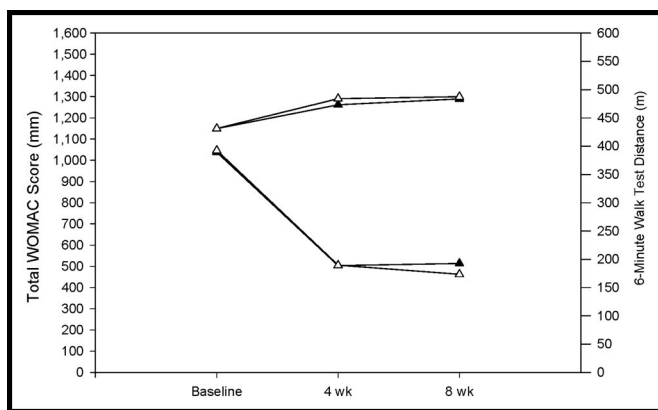


Figure 6. Average distances walked and average Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores at initial visit, 4 weeks, and 8 weeks from 2 separate groups of subjects who received identical manual therapy plus supervised exercise treatments from 2 studies with similar research designs. The upper set of plots represents average 6-minute walk test distances scaled on the right axis; the lower set of plots indicates average WOMAC scores, scaled on the left axis. Closed triangles represent the subjects from the current study ($n=60$); open triangles represent subjects from the 2000 study by Deyle et al⁴⁸ ($n=33$). Both sets of plots combine to demonstrate the reproducibility of these results.

program of manual therapy and supervised exercise is greater than has been reported for other conservative treatments^{24,53,54} and has been compared with improvements seen after total knee arthroplasty.⁷⁹

The benefit from the comprehensive clinically instructed home exercise program in the current study is consistent with the highest levels of benefit from exercise reported in the previously cited studies. This benefit accrued to patients in the current study with only 2 clinic visits, whereas previously reported home regimens required a range of 1 to 12 (mean of 4) clinical visits for instruction and reinforcement to yield similar or lesser benefits.^{46,47,49,51,55,56,80,81} The success of the home program may be attributable to any or all of the features designed into the program: careful instruction, minimal exercise performance time, an adherence log, a high-quality exercise folder, and a comprehensive set of exercises addressing muscle tightness, limitations in joint movement, muscle weakness, and general fitness. Although the exercises of the subjects in the clinic treatment group were observed and corrected as necessary, subjects in the home exercise group exercised without the supposed benefits of frequent supervision; they received one-to-one supervision only initially and at the 2-week follow-up visit.

The WOMAC scores at the 1-year follow-up measurement were still improved over baseline measurements, although group differences on this scale that were evident at 4 weeks and 8 weeks were not observed at 1 year. The reduction of the treatment effect after 1 year

in the clinical treatment group to the level of the home exercise group is presumably due to withdrawing the clinical sessions consisting of manual therapy, stationary bicycling, and supervised exercise. Both groups continued the common home exercise program and maintained an equal level of improvement.

Typically, when manual therapy and reinforcing exercises are utilized in a clinical setting, periodic follow-up appointments help maintain the effects of the intervention. It will be important to determine the optimal frequency of follow-up treatment sessions required to maintain the higher level of improvement realized from clinical treatment in this study. The practice of establishing periodic recheck appointments or allowing the patient to contact the physical therapist when relief from manual treatment and reinforcing exercise diminishes appears appropriate on the basis of the results of this study. The 8 clinical visits also might be spread more evenly over a longer period in order to sustain the effects of manual therapy. Some subjects derived benefit after only 2 to 4 interventions; for these subjects, the remaining clinical sessions could have been distributed over a longer period of time. Some authors^{82,83} have advocated the use of periodic physical therapy treatment for chronic conditions and have compared this strategy with the use of other therapeutic approaches, including use of medications for chronic conditions.

The treatment effects associated with other common interventions for knee OA also are known to diminish over time and may be additionally associated with significant side effects. Viscosupplementation is a widely used and recommended knee OA therapy.⁸⁴ Individual studies that have demonstrated benefit for hyaluronic acid also revealed a return to near-baseline levels after 3 to 6 months.^{85–88} Intra-articular hyaluronate injections have been associated with calcium pyrophosphate dehydrate arthritis and inflammatory flares of other types.^{89,90} Intra-articular steroids have been associated with increased risk for septic arthritis.⁹¹ Single intra-articular injections of steroids for knee OA have been demonstrated to be equivalent to placebo. Multiple injections have produced pain relief indistinguishable from a placebo at 4 to 6 weeks.⁸⁶

It would be important to know whether the subjects who received the interventions in this study were better prepared for total joint replacement surgery or had lower postoperative complication rates. In general, referring physicians and other clinicians need to know whether short-term physical therapy interventions for chronic conditions such as OA of the knee can influence eventual utilization of more invasive treatments such as injections and joint arthroplasties. More attention needs to be placed on studying the effects of combinations of

therapies such as glucosamine use, viscosupplementation, and physical therapy. More work also is needed to further define the relative benefits of home programs and intensive clinical intervention in physical therapy.

Both groups in the current study improved their walking distance to about the same extent, presumably because of the identical instructions regarding a daily walking program. This finding is consistent with results from a previous study⁴⁸ in which placebo group patients received no instructions for a walking program and did not improve their walking distances.

The combination of manual therapy and exercise has been shown to reduce the need for total knee replacement and steroid injections, with a number needed to treat of 7 when compared with placebo intervention.^{48,78} In the current study, there was not a difference in the surgical rates between the 2 effective interventions. This finding may be due, in part, to the fact that both groups performed the same home exercise program and the additional benefit of the clinical intervention was allowed to regress over time. It would be interesting to determine whether additional sessions would further reduce the need for total joint replacement and other invasive procedures.

Alternatively, it may be possible for patients or their spouses to administer simple manual therapy techniques to perpetuate the effects of clinical intervention. However, patients with knee OA may be elderly and have involvement in other joints, which may make it difficult for self-treatment or even treatment administered by a spouse. Future studies, we believe, should address whether patients with OA of the knee might be categorized into specific subgroups with preferentially greater probabilities of responding to specific interventions.

Two potential threats to internal validity in the current study warrant consideration. It is possible that both groups improved for reasons unrelated to our intervention. The clinical treatment group may have improved more dramatically simply because of the increased intensity of the relationship with the physical therapists. We consider this explanation unlikely for 2 reasons. First, both groups comprised patients with chronic OA; the average duration of symptoms was more than 5 years. It is unlikely in these groups that spontaneous improvements of 35% to 50% would be observed over a 1-month period. Second, the current study builds on the results of an earlier study⁴⁸ with a placebo group. In that study, no changes in the WOMAC scale or in 6-minute walk test distances were observed in the placebo group from initiation of treatment through the 1-year follow-up. The placebo group in the earlier study had the same intensity of physical therapist interaction as the clinical interven-

tion group in this study and yet failed to demonstrate any change over time.

Results of this study should be reasonably generalizable to patients with knee OA of either sex with similar ages and OA severity levels. There is a common perception that studies of patients in military health care facilities may suffer from limited external validity because of cultural differences and unique factors related to subject adherence to treatment regimens. We do not think it is likely that the high level of benefit demonstrated for either treatment group was due to any factors related to military service. Foremost, 63% of the subjects in this study were family members who had never served in the military. Only one subject was on active duty during the study. The mean body mass index (BMI) for the former military subjects (BMI=30.6, 95% CI=29.0–32.1) was not significantly different from that of subjects who had never served in the military (BMI=32.5, 95% CI=30.9–34.0); the subjects in both groups were equivalently obese. The mean level of physical activity also was equivalent for those subjects who had served in the military and for those subjects who had not served in the military. The average number of days per week of vigorous physical activity at the time of study enrollment also was equivalent for those subjects with prior military service (average days per week=2.13, 95% CI=1.45–2.80) versus those subjects without prior military service (average days per week=2.00, 95% CI=1.48–2.52). Finally, most of the subjects who had served in the military had been retired for periods of time longer than the duration of their military service.

One rationale for the manual therapy approach to OA is that the reduced pain and stiffness associated with the manual therapy intervention allows patients to participate more successfully in the exercise program and activities of daily living. Knee OA symptoms may result from restricted mobility and adhesions due to recurrent inflammations of both intra-articular and periarticular tissues. Movement restrictions due to changes within these tissues also may alter the biomechanical forces on articular surfaces to create additional symptoms. The manual therapy passive movement techniques were applied to increase excursion in both intra-articular and periarticular tissues when restricted mobility was judged to be related to the reproduction of symptoms or functional limitation.

Conclusion

A clinical physical therapy program of manual therapy to the lower quarter combined with supervised exercise applied by skilled physical therapists was compared with a home exercise program for improving function and decreasing stiffness and pain in subjects with OA of the knee. The comprehensive clinical treatment program

resulted in large improvements, reproducing the results previously reported for the same therapeutic regimen. After 1 month of treatment, the average improvement in pain, stiffness, and function seen in the clinic treatment group was twice the magnitude of the improvement observed in the home exercise group.

One year after withdrawing the clinical intervention and further patient contact, this difference between groups was no longer evident. Both groups remained substantially improved over baseline measurements. Subjects in the clinic treatment group appeared less likely to be taking medications for their arthritis and were more satisfied with the overall outcome of their rehabilitative treatment at 1 year compared with subjects in the home exercise group.

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