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## Effectiveness of Manual Physical Therapy and Exercise in Osteoarthritis of the Knee

### A Randomized, Controlled Trial

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**Background:** Few investigations include both subjective and objective measurements of the effectiveness of treatments for osteoarthritis of the knee. Beneficial interventions may decrease the disability associated with osteoarthritis and the need for more invasive treatments.

**Objective:** To evaluate the effectiveness of physical therapy for osteoarthritis of the knee, applied by experienced physical therapists with formal training in manual therapy.

**Design:** Randomized, controlled clinical trial.

**Setting:** Outpatient physical therapy department of a large military medical center.

**Patients:** 83 patients with osteoarthritis of the knee who were randomly assigned to receive treatment ( $n = 42$ ; 15 men and 27 women [mean age,  $60 \pm 11$  years]) or placebo ( $n = 41$ ; 19 men and 22 women [mean age,  $62 \pm 10$  years]).

**Intervention:** The treatment group received manual therapy, applied to the knee as well as to the lumbar spine, hip, and ankle as required, and performed a standardized knee exercise program in the clinic and at home. The placebo group had subtherapeutic ultrasound to the knee at an intensity of  $0.1 \text{ W/cm}^2$  with a 10% pulsed mode. Both groups were treated at the clinic twice weekly for 4 weeks.

**Measurements:** Distance walked in 6 minutes and sum of the function, pain, and stiffness subscores of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). A tester who was blinded to group assignment made group comparisons at the initial visit (before initiation of treatment), 4 weeks, 8 weeks, and 1 year.

**Results:** Clinically and statistically significant improvements in 6-minute walk distance and WOMAC score at 4 weeks and 8 weeks were seen in the treatment group but not the placebo group. By 8 weeks, average 6-minute walk distances had improved by 13.1% and WOMAC scores had improved by 55.8% over baseline values in the treatment group ( $P < 0.05$ ). After controlling for potential confounding variables, the average distance walked in 6 minutes at 8 weeks among patients in the treatment group was 170 m (95% CI, 71 to 270 m) more than that in the placebo group and the average WOMAC scores were 599 mm higher (95% CI, 197 to 1002 mm). At 1 year, patients in the treatment

group had clinically and statistically significant gains over baseline WOMAC scores and walking distance; 20% of patients in the placebo group and 5% of patients in the treatment group had undergone knee arthroplasty.

**Conclusions:** A combination of manual physical therapy and supervised exercise yields functional benefits for patients with osteoarthritis of the knee and may delay or prevent the need for surgical intervention.

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Arthritis has been identified as the most common cause of disability in the United States (1, 2). Thirty-three percent of persons 63 to 94 years of age are affected by osteoarthritis of the knee, which often limits the ability to rise from a chair, stand comfortably, walk, and use stairs (3, 4).

Acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly used to treat osteoarthritis. Use of NSAIDs can lead to gastric complications, increased risk for hospitalization, and death (5). Other treatment options for persons with osteoarthritis of the knee include physical therapy exercise and treatment programs, cortisone injections, and joint replacement surgery.

Puett and Griffin (6) reviewed 15 controlled trials of nonmedicinal, noninvasive therapies for hip and knee osteoarthritis from 1966 through 1993 (6). The authors concluded that exercise reduces pain and improves function in patients with osteoarthritis of the knee, but the optimal exercise regimen has not been determined. Fitness walking, aerobic exercise, and strength training have all been reported to result in functional improvement in patients with osteoarthritis of the knee (6–12). Unweighted treadmill walking has not been shown to decrease pain associated with osteoarthritis of the knee (13). Other researchers (14, 15) have concluded that ex-

ercise may benefit patients with osteoarthritis but advise that long-term studies are required to determine the appropriate amounts of exercise to avoid accelerating the underlying process of arthritis.

Active and passive range-of-motion exercise is considered an important part of rehabilitation programs for patients with osteoarthritis (16–18). Physical therapists frequently use manual therapy procedures as part of comprehensive rehabilitation programs to help patients regain joint mobility and function (19).

We evaluated the effectiveness of manual physical therapy for osteoarthritis of the knee, as applied by physical therapists with formal training in such an approach (20). Our hypothesis was that physical therapy consisting of manual therapy to the knee, hip, ankle, and lumbar spine combined with range-of-motion, strengthening, and cardiovascular exercises would be more effective than placebo for improving function, decreasing pain and stiffness, and increasing the distance walked in 6 minutes.

## Methods

### Patients

Eighty-three patients with osteoarthritis of the knee were randomly assigned to receive treatment ( $n = 42$ ; 15 men and 27 women [mean age,  $60 \pm 11$  years]) or placebo ( $n = 41$ ; 19 men and 22 women [mean age,  $62 \pm 10$  years]). All patients were referred by physicians to physical therapy for osteoarthritis of the knee. Physicians at the various clinics in the medical center who normally see patients with osteoarthritis of the knee were informed of the study so that appropriate referrals could be made. If the patients met our inclusion criteria, they were offered the opportunity to participate. The main inclusion criterion was a diagnosis of osteoarthritis of the knee based on fulfillment of one of the following clinical criteria developed by Altman and colleagues (21): 1) knee pain, age 38 years or younger, and bony enlargement; 2) knee pain, age 39 years or older, morning stiffness for more than 30 minutes, and bony enlargement; 3) knee pain, crepitus on active motion, morning stiffness for more than 30 minutes, and bony enlargement; or 4) knee pain, crepitus on active motion, morning stiffness for more than 30 minutes, and age 38 years or older. Altman and colleagues found this criteria to be 89% sensitive and 88% specific (21–23).

Patients were required to be eligible for military health care, have had no surgical procedure on either lower extremity in the past 6 months, and have no physical impairment unrelated to the knee that would prevent safe participation in a timed 6-minute walk test or any other aspect of the study. Patients had to have sufficient English-language

skills to comprehend all explanations and to complete the assessment tools. They were also required to live within a 1-hour drive of the physical therapy clinic. Patients who could not attend the required number of visits or had received a cortisone injection to the knee joint within the previous 30 days were not enrolled. Patients were instructed to keep taking any current medications and not to start taking new medications for osteoarthritis during the clinical treatment and 8-week follow-up. Therapy with any osteoarthritis medication must have been initiated at least 30 days before participation in the study.

The study was approved by the institutional review board of Brooke Army Medical Center, Fort Sam Houston, Texas. All patients completed an informed consent form and were advised of the risks of the study, including increased symptoms, injuries from falls, and cardiovascular events. No external funding was received for this study.

### Procedure

Patients who met the inclusion criteria were randomly assigned to one of two groups. Blank folders were numbered from 1 to 100 and were given concealed codes for the group of assignment, determined by a random-number generator. When a patient was eligible and gave consent to participate, the treating therapist drew the next folder from the file, which determined the group of assignment.

The treatment group received a combination of manual physical therapy and supervised exercise. The placebo group received ultrasound at a subtherapeutic intensity. Neither group was aware of the treatment that the other group was receiving. Demographic data collected for each patient included age, sex, occupation, height, weight, duration of symptoms, presence of symptoms in one or both knees, previous knee surgery, medications, and present activity level. Knee radiographs were obtained and read by a radiologist who assigned a radiographic severity rating for osteoarthritis (24).

Dependent variables measured in this study were the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score (25) and distance covered during a timed 6-minute walk test. The WOMAC Osteoarthritis Index consists of 24 questions, each corresponding to a visual analogue scale. This test has been shown to be a reliable, valid, and responsive multidimensional outcome measure for evaluation of patients with osteoarthritis of the hip or knee (26). The timed 6-minute walk test measures the distance a patient walks in 6 minutes and has been demonstrated to be a reliable measurement of functional exercise capacity (27). All measurements of dependent variables were obtained by a trained research assistant who was blinded to group assignment.

After research assistants obtained pretreatment values for the dependent variables, patients returned to the treating physical therapist for thorough standardized clinical examination of the knee, hip, ankle, and lumbar spine. Treatment was initiated according to group assignment. The treatment group received manual physical therapy as indicated by the results of the examination. The manual therapy treatment techniques, consisting of passive physiologic and accessory joint movements, muscle stretching, and soft-tissue mobilization, were applied primarily to the knee. The same treatments were also administered to the lumbar spine, hip, or ankle if these areas showed limitation in active or passive movement, were symptomatic, or were contributing to overall lower limb dysfunction (28–31). A minimal pain level was not exceeded in any treatment.

The treatment group also performed a closely supervised standardized knee exercise program at each of the eight treatment sessions. This program consisted of active range-of-motion exercises for the knee, muscle strengthening exercises for the hip and knee, muscle stretching for the lower limbs, and riding a stationary bike. All of the activities were mutually reinforcing, with repeated gentle challenges to the end ranges of movement. An outline of the exercise program is shown in the **Appendix Figure**. The physical therapist increased the number of strengthening exercise bouts and the stationary bike riding time on the basis of patient tolerance. The current literature provides efficient methods to produce the desired effects of increasing strength, flexibility, and range of motion (32–35). At each session, the physical therapist examined the patient for adverse signs and symptoms, such as increased pain, joint effusion, and increased skin temperature over knee joints. These signs and symptoms of osteoarthritis had to be stable or decreasing before manual therapy or exercise was progressed. Patients exercised in a painless or minimally painful manner. If any post-treatment or exercise soreness lasted more than a few hours, the regimen was decreased accordingly for that patient.

The placebo group received treatment by the physical therapist that consisted of subtherapeutic ultrasound for 10 minutes at an intensity of 0.1 W/cm<sup>2</sup> and 10% pulsed mode (lowest setting and greatest cycle interruption) to the area of knee symptoms. The placebo group received the same subjective and hands-on objective reevaluation before and after each session as the treatment group. The amount of time directly spent with the treating therapist was approximately 30 minutes for both groups. The treatment group required an additional 30 to 45 minutes to perform their exercises in the clinic. Both groups were treated twice weekly for 4 weeks, for a total of eight clinic treatments.

Patients in the treatment group also performed the same exercises at home, except for the closed-chain strengthening exercises, on the days on which they were not treated in the physical therapy clinic. They also walked at home each day at a comfortable pace and distance. The treating physical therapist instructed each patient in the performance of the exercises and provided a detailed handout containing instructions and photographs of the exercises. Each patient maintained a home exercise program compliance log for all exercises. Compliance was assessed by inspection of home exercise logs, interviews with patients at testing times, and reviewing treatment attendance records. The home exercise treatment logs reflected a high degree of compliance with the home exercise sessions. It is possible that the logs were completed in the absence of performing the exercises; however, the general knowledge of the exercise program seemed consistent with regular performance of the home exercises. After completing the eight treatment sessions, patients were instructed to continue the home exercises and add the closed-chain strengthening exercises (**Appendix Figure**). Patients in the placebo group were instructed to continue their normal daily activities.

Therapists and patients had no further contact after completion of the eight sessions. A post-treatment retest was scheduled by the testers at least 2 days after the last clinic treatment and at the same time of day as the pretreatment test to allow full strength recovery and account for daily fluctuations in pain and stiffness.

Both groups of patients returned for additional tests at 1 year. At the 1-year follow-up visit, the number of patients in each group who required knee surgery was recorded. Orthopedic surgeons who were unaware of group assignment or the details of the study made the decisions for surgery. Patients in both groups who had not received injections in the knee or a surgical intervention again completed the WOMAC and 6-minute walk test.

### Statistical Analysis

Independent *t*-tests, Mann–Whitney U tests, and chi-square tests were used to analyze ratio, ordinal, and categorical variables, respectively, from the initial measurement session to detect significant differences between groups. All data analysis was performed by using SPSS for Windows, version 7.5 (SPSS, Inc., Chicago, Illinois). Descriptive data analysis and tests for the assumptions of normality and homogeneity of variance were followed by a 2 × 3 mixed-model multivariate analysis of variance with an  $\alpha$  level of 0.05. The independent variables for the multivariate analysis of variance were group (two levels) and time (three levels). The two depen-

**Table 1. Baseline Characteristics of Study Patients\***

Variable	Patients Who Completed the Study		Patients Who Did Not Complete the Study	
	Treatment Group (n = 33)	Placebo Group (n = 36)	Treatment Group (n = 9)	Placebo Group (n = 5)
Mean age, y	59.6 ± 10.1	62.4 ± 9.7	62.0 ± 12.9	59.0 ± 14.7
Mean body mass index, kg/m <sup>2</sup>	31.1 ± 6.7	30.4 ± 5.0	31.4 ± 7.1	26.1 ± 5.2
Mean duration of symptoms, mo	81.7 ± 88.2	57.2 ± 96.1	36.2 ± 31.8	21.0 ± 30.0
Mean WOMAC score, mm	1046.7 ± 455.0	1093.5 ± 497.1	1347.3 ± 418.4	1418.0 ± 463.4
Mean distance walked in 6 minutes, m	431.2 ± 120.2	402.9 ± 104.5	355.6 ± 130.8	373.3 ± 147.7
Sex, %				
Men	36	50	33	20
Women	64	50	67	80
Bilateral symptoms, %	33	36	67	20
Medication use, %	83	81	78	80
Days of vigorous physical activity per week				
0	18	40	50	40
<3	36	43	25	20
≥3	46	17	25	40
Severity of radiographic findings†‡				
0	9	9	25	0
1	31	18	13	50
2	22	38	25	50
3	31	29	38	0
4	6	6	0	0

\* Values following the plus/minus sign are the SD. WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

† Some sets of values may not total 100% because of rounding.

‡ Based on reference 29.

dent variables were WOMAC scores and 6-minute walk distances. Subsequent post hoc 2 × 3 univariate analysis of variance was performed for each dependent variable, with a Bonferroni corrected  $\alpha$  level of 0.025. For univariate analysis of variance, the degrees of freedom were conservatively adjusted to compensate for potential violations of the homogeneity-of-covariance assumption. Post hoc analyses of significant group × time interaction effects were performed by using the Tukey multiple comparison procedure to examine pairwise comparisons of mean scores between groups and across the three data collection times. Analyses of 6-minute walk distances and WOMAC scores were conducted on the subset of 69 study patients for whom those data were available at baseline, 4 weeks, and 8 weeks. Paired *t*-tests were used to compare average scores at 8 weeks and 1 year for the 55 study patients who provided data at those times. An intention-to-treat chi-square analysis was used to determine group differences in the number of surgical interventions at 1 year among all patients who were entered into the study.

To investigate potential confounding variables,

separate multiple regression models were created for each of the two dependent variables. In each regression model, 15 possible predictors 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 WOMAC scores, 6-minute walk distances, knee flexion, and extension range-of-motion scores. Values from the initial testing session were used for all 15 predictors. The WOMAC scores and 6-minute walk distances measured at week 8 were entered as dependent variables.

## Results

Of the 83 patients initially enrolled in the study, 33 in the treatment group and 36 in the placebo group completed all treatment and testing at baseline, 4 weeks, and 8 weeks. Fourteen patients (17%; 9 in the treatment group [21%] and 5 in the placebo group [12%]) dropped out of the study. In the treatment group, 4 patients withdrew because of

**Table 2. The WOMAC Scores and Distance Walked in 6 Minutes at Baseline and at 4 and 8 Weeks\***

Test	Baseline	Week 4	Week 8
Mean WOMAC score (95% CI), mm			
Treatment group	1046.7 (891.4–1202.0)	505.2 (438.0–572.4)	462.4 (312.9–611.9)
Placebo group	1093.5 (931.1–1255.9)	921.2 (730.8–1112.1)	934.3 (720.8–1147.8)
Mean distance walked in 6 minutes (95% CI), m			
Treatment group	431.0 (390.0–472.0)	484.0 (442.7–525.3)	487.4 (447.6–527.2)
Placebo group	402.9 (368.8–437.0)	402.1 (359.9–444.3)	409.7 (366.0–453.4)

\* Includes only patients who completed testing at 8 weeks (33 in the treatment group and 36 in the placebo group). WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

unrelated medical reasons, 1 sustained a knee injury in an altercation, 2 had transportation difficulties, 1 was caring for a terminally ill husband and declined to return, and 1 withdrew for unknown reasons. In the placebo group, 1 patient developed cardiac problems, 1 acquired plantar fasciitis, 1 was disqualified after receiving a cortisone injection to the knee, and 2 had transportation difficulties. No patients were excluded because of lack of compliance with or intolerance to either treatment regimen. The 69 patients who completed the study attended all clinical appointments and reported for testing at baseline, 4 weeks, and 8 weeks.

Baseline characteristics of patients who completed the study and those who did not are given in **Table 1**. **Table 2** shows mean values with 95% CIs for the dependent variables measured at baseline, 4 weeks, and 8 weeks. Medication use is shown in **Table 3**.

For patients who completed all aspects of the study, application of the randomization scheme resulted in reasonably homogenous groups at the outset (**Table 1**). The 14 patients who did not return for the 4-week or 8-week visit seemed to differ substantially from those who completed the study, as measured by several variables. However, independent *t*-tests, Mann–Whitney U tests, and chi-square tests revealed statistical significance only for the initial WOMAC scores, which were about 30% worse in patients who did not complete the study (**Table 1**).

The assumptions of normality and homogeneity of variance were met for both of the dependent variables. For the 69 patients for whom data were available at baseline and at 4 and 8 weeks, multivariate analysis of variance revealed a group  $\times$  time interaction effect ( $P = 0.001$ ), suggesting that changes in average scores over time depended on treatment group assignment. Subsequent univariate analysis of variance also demonstrated group  $\times$  time interaction effects for 6-minute walk distances ( $P = 0.001$ ) and WOMAC scores ( $P < 0.001$ ). The nonparallel plots of the WOMAC average scores (**Figure 1**) and the average distances walked (**Figure 2**) reflect the differential effect over time of treatment and placebo administration on these outcome variables.

Post hoc pairwise comparisons of mean WOMAC scores and 6-minute walk distances revealed that the patients from both groups who completed the study were homogeneous at initial testing ( $P > 0.05$ ). However, the average 6-minute walk distance was 82 m better in the treatment group than in the placebo group at 4 weeks and was 78 m better at 8 weeks ( $P < 0.05$ ) (**Table 2**). Average WOMAC scores were 416 mm better in the treatment group than in the placebo group at 4 weeks and were 472 mm better at 8 weeks ( $P < 0.05$ ) (**Table 2**). These

**Table 3. Medication Use in the Treatment and Placebo Groups\***

Medication	Patients Who Completed the Study	
	Treatment Group (n = 33)	Placebo Group (n = 36)
	n (%)	
Acetaminophen	1 (3)	6 (18)
Aspirin	4 (12)	0 (0)
Diclofenac sodium	1 (3)	0 (0)
Flurbiprofen	1 (3)	0 (0)
Ibuprofen	4 (12)	7 (21)
Nabumetone	6 (18)	2 (6)
Naproxen	5 (15)	2 (6)
Naproxen sodium	0 (0)	1 (3)
Piroxicam	0 (0)	2 (6)
Prednisone	1 (3)	0 (0)
Salicylate	1 (3)	3 (9)

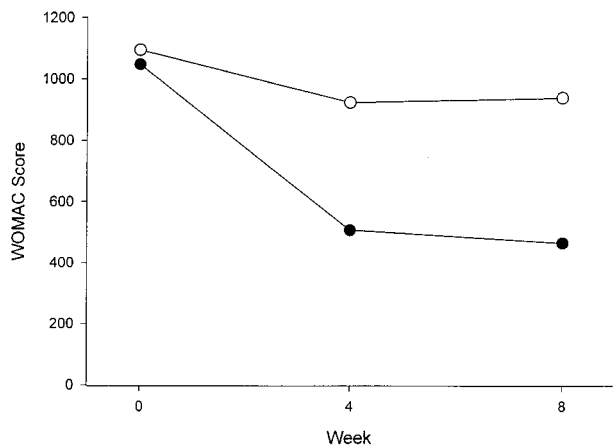
\* Use of medication was documented but not controlled in this study. Other co-interventions, such as cortisone injections or surgical procedures, were grounds for removal from the study.

between-group differences were based on analysis of the raw scores before controlling for potential confounding variables with multiple regression analysis.

In the placebo group, changes across time for average scores for either of the dependent variables were not statistically significant. In the treatment group, the average distance walked in 6 minutes improved by 12.3% at 4 weeks ( $P < 0.05$ ) and by 13.1% at 8 weeks ( $P < 0.05$ ); the average distance walked by the placebo group did not meaningfully change ( $P > 0.05$ ) (**Figure 2**). At 4 weeks, average WOMAC scores were 51.8% lower in the treatment group ( $P < 0.05$ ) and 15.8% lower in the placebo group ( $P > 0.05$ ). At 8 weeks, the reduction in WOMAC scores from baseline was 55.8% in the treatment group ( $P < 0.05$ ) and 14.6% in the placebo group ( $P$  value not significant) (**Figure 1**). Therefore, only the treatment group experienced improvements in both outcome measures after 4 weeks of clinical treatment with exercise and manual physical therapy and maintained these improvements over the 4 weeks after clinical treatment.

All 83 patients were contacted 1 year after enrollment into the study. By 1 year, patients in the placebo group had more knee surgeries than patients in the treatment group ( $P = 0.039$ ). Twenty percent of the 41 patients in the placebo group had undergone a total knee arthroplasty compared with only 5% of the 42 patients in the treatment group. Fifteen percent of patients in the placebo group and 5% of patients in the treatment group had received steroid injections to the knees. Patients who had had a total knee replacement or an injection into the knee were not retested. One additional patient in the treatment group was eliminated from testing at 1 year because of a bony mass in the hip.

The remaining 29 patients in the treatment group repeated the 6-minute walk test and WOMAC eval-



**Figure 1. Average WOMAC scores at baseline, 4 weeks, and 8 weeks.** Lower scores indicate perceived improvement in pain, stiffness, and function. Black circles represent the treatment group; white circles represent the placebo group. Among patients who completed the study, those in the treatment group had a greater average improvement in WOMAC scores compared with placebo recipients by week 8 ( $P < 0.001$ ). WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

uation to determine whether the improvements seen at 8 weeks were still evident 1 year after the intervention. In the treatment group, the average change in distance walked from 8 weeks to 1 year was a negligible  $-7.8$  m (95% CI,  $-30.2$  to  $14.5$  m) and the average increase in WOMAC scores was  $169.0$  mm (CI,  $28.2$  to  $309.9$  mm). However, compared with scores collected at baseline, average WOMAC scores in the treatment group were still reduced at 1 year by  $371.9$  mm (CI,  $211.5$  to  $532.3$  mm).

Twenty-two patients in the placebo group were available for testing at 1 year; 8 patients had had surgery and 6 had had injections. In placebo recipients, no meaningful change was seen from 8 weeks to 1 year for the average distance walked ( $-22.1$  m [CI,  $-51.9$  to  $7.7$  m]) or average WOMAC score ( $69.2$  mm [CI,  $-113.6$  to  $251.9$  mm]).

Among patients who completed the study, average WOMAC scores and average 6-minute walk times were clinically and statistically significantly better in the treatment group than in the placebo group at 8 weeks, after controlling for potential confounding variables with multiple regression analysis. On average, 8-week WOMAC scores were  $599$  mm (CI,  $197$  to  $1002$  mm) better in the treatment group than in the placebo group and the average distance walked in 6 minutes was  $170$  m (CI,  $71$  to  $270$  m) more.

## Discussion

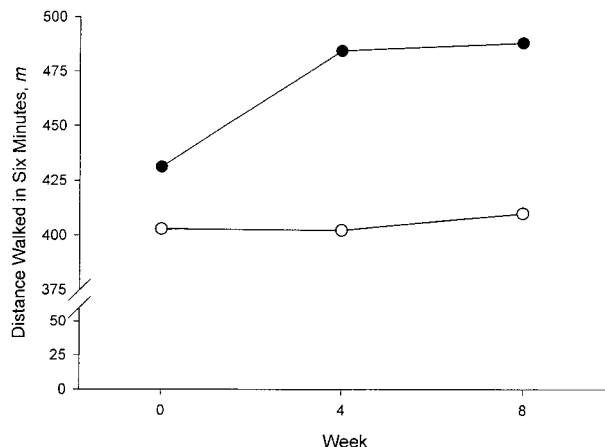
Patients with osteoarthritis of the knee who were treated with manual physical therapy and exercise experienced clinically and statistically significant improvements in self-perceptions of pain, stiffness, and functional ability and the distance walked in 6 min-

utes. The beneficial effects of treatment persisted at 4 weeks and 1 year after the conclusion of clinical treatment.

The observed improvements are most likely attributable to the physical therapy intervention. Given the design of the study (which included random assignment to study groups, relatively homogenous groups at the outset, and testers who were blinded to group assignment) and given the lack of improvement in the placebo group, it is unlikely that the desirable outcomes were caused by the passage of time or by tester bias. It is also unlikely that other causes unrelated to the intervention were responsible for the observed improvements, given the results of the regression analyses with simultaneous consideration of 14 potential confounding variables. Although regression models that include fewer than 10 patients per predictor may not be reliable, the results of our regression analysis confirm the usual protections provided in a randomized, controlled clinical trial to guard against confounding influences.

The dropout rate was higher in the treatment group (21%) than in the placebo group (12%). If the treatment itself had led to negative outcomes, causing the patients to withdraw, this differential dropout rate might significantly affect the interpretation of our results. However, the reasons given for withdrawal were unrelated to treatment. Previously reported dropout rates in similar trials of exercise for osteoarthritis of the knee are 9.8% (10), 15% (9), 17% (11), 20% (8), 25% (36), 26% (7), and 52% (37).

Patients with higher initial WOMAC scores may be less likely to complete a regimen of physical therapy. However, because initial WOMAC scores were substantially higher in patients from both the treatment and the placebo groups who did not complete the study than in those who completed the



**Figure 2. Average distance walked in 6 minutes at baseline, 4 weeks, and 8 weeks.** Black circles represent the treatment group; white circles represent the placebo group. Among patients who completed the study, those in the treatment group had a greater average improvement in distance walked compared with placebo recipients by week 8 ( $P = 0.001$ ).

study, we do not believe that aspects of the therapeutic regimen were responsible for the failure to complete all visits during the treatment phase. Our primary findings were based on analyses of data from patients who completed the study; our results therefore pertain only to patients who comply with the therapeutic regimen and attend treatment sessions.

At 1 year, improved performance in the 6-minute walk test was maintained in the treatment group, indicating that the objective gains in functional performance persisted in the absence of supervised exercise and treatment. Despite the deterioration in the WOMAC scores in this group from 8 weeks to 1 year ( $P = 0.02$ ), scores at 1 year remained better than those obtained at baseline ( $P < 0.001$ ).

The benefits of treatment were achieved in eight clinic visits. Most previous studies have demonstrated the benefits of exercise in 36 to 48 clinical visits (7–10, 36). One study required 24 telephone contacts and 4 home visits in addition to 36 clinical visits (11).

Previous reports of average improvement with exercise have ranged from 8% to 27% decreases in pain and 10% to 39% improvements in function (10, 11). The total improvement in WOMAC score in our study averaged 56%; average subscale improvements were 60% for pain, 54% for stiffness, and 54% for functional ability. Most important, these changes can be compared with those in control patients who experienced no meaningful change. Changes of 20% to 25% are generally considered to be clinically important (38).

The greater overall improvement compared with results of previous studies may be due to the manually applied treatment, which allowed the therapist to focus treatment on the specific structures that produced pain and limited function for each patient. The comprehensive exercise program may also have addressed more of the impairments found in patients with osteoarthritis of the knee. The design of our study precludes determination of which aspect of the treatment program produced the changes in performance. The effects of the manual therapy procedures cannot be separated from either the clinical or home exercise programs. However, a recent randomized clinical trial found that a combination of manual therapy and clinical exercise provided greater improvements in strength, pain, and function than did clinical exercise alone for impingement syndrome of the shoulder, another chronic inflammatory joint condition (39).

The exercise program was simple, but it adequately addressed the lower limb physical findings that are common in patients with osteoarthritis of the knee. To prevent increasing inflammation, pain, and boredom with the program, patients did not perform multiple exercises with the same therapeutic effect or exercise more than once each day.

Ytterberg (18) stressed the importance of targeting the clinical treatment and appropriately dosing the exercise to improve joint motion, muscular strength, and cardiovascular fitness for patients with osteoarthritis of the knee.

Patients frequently reported 20% to 40% relief of symptoms after only two to three clinical treatments of manual therapy and exercise. This rapid reduction of symptoms implies that the structures responsible for at least part of the pain are not the most fixed or unchangeable aspects of the pathology of osteoarthritis. Periarticular connective and muscular tissue could be implicated as symptom sources. Perhaps the repeated challenge to the end range of movement, as occurs with closed-chain strengthening exercises, manually applied passive movement, and active range-of-movement exercises, provides a strong stimulus to connective tissue, resulting in pain relief. Of note, unweighting the knee joint during walking has not been demonstrated to relieve pain in patients with osteoarthritis of the knee (13). It seems logical that if the articular surfaces or subchondral bone were the primary pain generators, walking under decreased loads would decrease pain.

The effects of the physical therapy intervention beyond 1 year are unknown. Continued relief over a longer period may depend in part on patient compliance with the home exercise program. Longer-term follow-up may answer some of these questions. Many patients with osteoarthritis typically receive very little physical therapy before undergoing total joint replacement. Because short-term physical therapy can decrease pain and stiffness and increase functional capacity in patients with osteoarthritis of the knee, it represents a cost-effective way to improve patient function.

Physical therapy may also delay or defer the need for total joint replacement. We observed fewer knee replacement surgeries in the treatment group ( $P = 0.039$ ). As military health system beneficiaries, all patients had equal access to orthopedic surgery. The surgeons were aware that a study was under way to examine the effectiveness of a physical therapy intervention, but they were unaware of patients' group assignments. The surgeons were also unaware that the number of patients receiving surgery in the two groups would be compared. Patients were asked at 1 year if they were seeking knee surgery; no patient who had not undergone surgery was seeking it.

We conclude that a combination of manual physical therapy and supervised exercise is more effective than no treatment in improving walking distance and decreasing pain, dysfunction, and stiffness in patients with osteoarthritis of the knee. Such treatment may defer or decrease the need for surgical intervention.

### Stretching Exercises

Exercise	Measures
1. Standing calf stretch.	Three repetitions with 30-sec hold.
2. Supine hamstring stretch.	Three repetitions with 30-sec hold.
3. Prone quadriceps stretch.	Three repetitions with 30-sec hold.

### Range-of-Motion Exercises

Exercise	Measures
1. In long sitting position, knee mid-flexion to end-range extension.	Two 30-sec bouts with 3-sec hold at end range.
2. In long sitting position, knee mid-flexion to end-range flexion.	Two 30-sec bouts with 3-sec hold at end range.
3. Stationary bike.	Five min. Increase time as tolerated.

### Strengthening Exercises

Exercise	Measures*
1. Static quad sets in knee extension.	One set of 10 repetitions with 6-sec hold. 10-sec rest between repetitions.
2. Closed-chain progression†:	
A. Standing terminal knee extension.	One 30-sec bout. Increase resistance as tolerated.
B. Seated leg press.	One 30-sec bout. Increase resistance as tolerated.
C. Dips weight-lesened.	One 30-sec bout. 1 sec during concentric phase and 2 sec during eccentric phase. Progress from 2 legs to 1 leg as tolerated.
D. Step-ups.	One 30-sec bout. Increase step height as tolerated.

**Appendix Figure. Patient exercise program.** \*The number of exercise bouts were increased according to the patient's tolerance. †Patients performed closed-chain exercises B, C, or D depending on which one they could perform pain-free.

## Glossary

The definitions of the following manual physical therapy terms are based on those used in references 29 and 40.

**Accessory movements:** All movements at articular surfaces that cannot be performed actively in the absence of resistance; also known as *joint play* or *glide*.

**Closed-chain exercise:** Exercises that are performed with the distal segment fixed, allowing motion to occur at the proximal segments.

**Impairment:** A temporary or permanent loss or abnormality of physiologic or anatomic structure.

**Manual therapy:** A clinical approach involving skilled, specific hands-on techniques, including but not limited to mobilization, that are used by the physical therapist to diagnose and treat soft tissues and joint structures for the purpose of modulating pain; increasing range of motion; reducing or eliminating soft tissue inflammation; inducing relaxation; improving repair, extensibility, or stability of contractile and noncontractile tissue; facilitating movement; and improving function.

**Mobilization:** Skilled passive movement applied a joint or the related soft tissues at varying speeds and intensities.

**Physiological movement:** Movements that can be performed actively under voluntary muscle control.

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