# Physical Therapy Is Effective for Patients with Osteoarthritis of the Knee: a Randomized Controlled Clinical Trial

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*ABSTRACT.* ***Objective.*** To assess the effectiveness of physical therapy, given either as an individually attended treatment or in a small group format, in terms of pain, physical function, and health related quality of life for patients with osteoarthritis (OA) of the knee.

***Methods.*** After 2 baseline assessments, 126 patients were randomized into one of 3 allocation arms: individual treatments (n = 43), small group format program (n = 40), and waiting list control (n = 43). After reassessment at 8 weeks, patients allocated to waiting list control were randomized into one of the 2 active treatment arms. Assessments included both self-report measures (WOMAC, SF-36) and objective measures of physical performance (gait analysis and muscle strength).

***Results.*** Both physical therapy treatment allocations resulted in significant improvements in pain, physical function, and health related quality of life above the control group (standardized response mean 0.36 to 0.65). Improvements in the self-report measures were substantiated by significant correlated improvements in knee extensor strength and fast walking speed (rho 0.36–0.42). There were no significant differences in effectiveness between the 2 physical therapy allocations for any of the measured outcomes. Improvements gained were maintained for at least 2 months. Responsiveness to treatment was modified by loss of medial joint space width, the interaction being significant for physical function, gait, and knee extensor strength.

***Conclusion.*** Physical therapy, either as an individually delivered treatment or in a small group format, is an effective intervention for patients with knee OA. Responsiveness to this 8 week intervention was modified by loss of medial joint space width. (J Rheumatol 2001;28:156–64)

*Key Indexing Terms:*
OSTEOARTHRITIS KNEE EXERCISE GAIT STRENGTH FUNCTION

Symptomatic osteoarthritis (OA) of the knee occurs in about 6.1% of adults aged 30 and over[1], with prevalence increasing with age[2,3]. A large community based survey of noninstitutionalized elders revealed that knee OA accounted for the highest percentage of disability in walking, stair climbing, and housekeeping[4]. The aging of the population will result in exponential growth in the global burden of pain, physical disability, and dependency[5-7], which will be particularly marked in "young" countries such as USA, Canada, and Australia[8].

It is generally accepted that exercise potentially reduces knee pain and limits decline of physical function in people with knee OA[9,10]. A systematic review of randomized clinical trials examining the effectiveness of exercise for people with knee OA[11] could identify only 5 studies with "acceptable validity"[12-16]. Three further randomized clinical trials with possible acceptable validity have been published since this review[17-19]. Unfortunately, half of these 8 studies had insufficient power to establish even a medium effect[13,14,16,17]. Further, studies with high internal validity and sufficient power can suffer from limited generalizability by assessing either relatively costly programs not easily accessible even in developed countries[12,15] or assessing programs delivered by a single treating physical therapist[14,19]. It is also suggested that studies using volunteer samples would have limited applicability to the clinical situation, as it has been shown that volunteers from the community are unrepresentative of the population seeking treatment[20,21].

Symptomatic knee OA progresses with a pattern of disease related impairments such as joint pain, loss of lower limb muscle strength[22-24], gait disability[25-27], and reduced aerobic fitness[28,29]. Treatment intensity is often limited by these disease related impairments together with significant comorbidity in this aging population. An effective treatment "dosage" may therefore require lengthy, but often economically prohibitive, treatment duration. Due to the fairly predictable pattern of disease related impairments, knee OA would appear to be a condition suited to group format intervention programs. In

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theory, a small group format has the potential to allow time for sufficient individual monitoring as well as achieve a more efficient use of health care resources. The less obvious potential may lie in increased patient access and longterm adherence due to the influence of group association.

This study follows on from an uncontrolled pilot study at this center investigating the effectiveness of an 8 week small group format program for patients referred for physical therapy treatment[30]. The current study contrasts in many ways to most randomized controlled clinical trials studies evaluating exercise for people with knee OA published to date. The current pragmatic study extended generalizability by using a large number of physical therapists to provide treatment, recruited patients initially seeking treatment, assessed 2 feasible programs as routinely provided in the clinic, used widely validated self-report and objective outcome measures with established normative population data, and has assessed treatment sustainability. Furthermore this study was designed to analyze certain patient characteristics that were deemed by a group of clinicians to be plausible predictors of treatment responsiveness.

The primary hypothesis was that physical therapy (individual treatments or group format) can effect improvement in self-reported pain, physical function, and health related quality of life (HRQOL) in patients with knee OA referred for treatment. The secondary hypothesis was that the group format is more beneficial than individual treatments in terms of self-reported pain, physical function, and HRQOL for patients with knee OA. The tertiary hypotheses we tested were whether physical therapy can significantly improve objective measures of physical performance, whether certain baseline characteristics [age, body mass index (BMI), symptom duration, or medial joint space width (JSW)] can predict treatment responsiveness and if improvements could be maintained 2 months after completion of formal treatment.

## MATERIALS AND METHODS

All patients, living in the community and referred by physicians for physical therapy treatment at a large hospital outpatient department from May 1997 until February 1999, with a diagnosis of knee pain or knee arthritis, were contacted to assess eligibility. Patients were invited to participate if they were aged 50 years and over, had knee pain on most days of the past month, and had evidence of radiographic disease[31]. Patients were excluded if they had intraarticular cortisone injections within the past 2 months, lower limb joint arthroplasty, unstable cardiac comorbidity precluding exercise at 50–60% maximum heart rate, or other comorbidity affecting gait. More than 90% of the patients considered eligible agreed to participate in the study as participation resulted in a 67% chance of evading the usual 4 to 8 week physical therapy waiting list for chronic conditions. All participants were required to sign an informed consent.

All participants were assessed 4 times, using a strictly standardized protocol: twice with an interval of one week prior to randomization (Week 00); postintervention or waiting list control period (Week 8); followup, or postintervention for controls (Week 16). The chief investigator, who was not involved in any of the treatments and remained mostly masked to treatment allocation, carried out the assessments. At baseline, demographic and radiographic data were collected. All participants were required to obtain a weight-bearing, semiflexed radiograph of their most painful knee[32-34]. The radiographs were magnification controlled using a 3/8" stainless steel ball mounted in a perspex tube taped to head of fibula. JSW was later digitally measured, a mean of 3 readings on one day providing the final measurement. Test-retest (1 month) reliability on 18 randomly selected radiographs (previous markings removed) was calculated as ICC 2,1 = 0.98 (95% confidence interval, CI, 0.94–0.99).

At each assessment, as well as collecting information concerning medications and usual physical activity level, participants were asked to complete both the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and the Medical Outcomes Study Short Form (SF-36). The WOMAC is a validated disease-specific self-report questionnaire using 100 mm visual analog scales (VAS) to assess "currently experienced" pain (5 questions) and physical disability (17 questions)[35]. The SF-36[36,37] is a validated, extensively used self-report HRQOL questionnaire measuring 8 dimensions of health status[38,39]. To increase precision and reduce the number of statistical comparisons needed, the originators of the SF-36 have developed algorithms to calculate 2 psychometrically based summary measures: the Physical Component Summary Scale Score (PCS) and the Mental Component Summary Scale Score (MCS)[40,41]. The PCS and MCS are norm-based scores so that each has a mean of 50 and a standard deviation of 10 in the general US population.

At each assessment, patients were also required to participate in a quantitative gait analysis and isometric muscle testing. The quantitative gait variables of speed, cadence, and stride length were analyzed using an 8 meter electric footswitch walkway. The system and the standardized testing protocol were the same as that for which validity and reliability had been investigated in earlier studies[42,43]. The gait variables used in this study were mean speed ($cm{\bullet}s^{-1}$), mean cadence ($steps{\cdot}min^{-1}$), and mean stride length (cm) extrapolated from 2 trials, after a familiarization trial, at a fast self-selected speed[42,43]. For the isometric muscle strength testing, patients were seated on a high metal frame chair with the thigh well supported, the foot free, and the knee passively drawn into 90˚ flexion by gravity. Bilateral isometric knee extensor and flexor muscle strength were tested in this position using an Xtran load cell (Model S1W, Applied Measurement Australia Pty. Ltd.) fixed onto the metal framework of the chair and connected to a software program sampling at 80 Hz. Both muscle groups were tested 3 times on each limb in a set sequence at each assessment, the final score being the mean peak force attained for each muscle group. One week test-retest (prerandomization assessments) measurement reliability was calculated for the knee extensors as intraclass correlation coefficient (2,1) = 0.93 (95% CI 0.90–0.95) and for the knee flexors as ICC(2,1) = 0.87 (95% CI 0.82–0.91).

After the 2 baseline assessments, the patients were randomly allocated by concealed ballot in blocks of 18, according to a random numbers table and with a clear audit trail, by hospital administrative staff. Allocations were sealed in numbered opaque envelopes prior to recruitment. The 3 allocations were as follows. (1) Individual treatments. The choice, frequency, and duration of individual treatments within an 8 week period were at the discretion of the treating physical therapist. Treatment procedures and duration were recorded and verified. (2) Group format program. The group program ran, under the supervision of a physical therapist, for 1 hour twice a week for 8 weeks and was supplemented with a home exercise program. For safety and individual supervision reasons, the group size was restricted to a maximum of 6 patients. The program content is outlined in Appendix 1 and was the same as that for which efficacy was described in a recent uncontrolled trial[30]. (3) Control. Patients allocated to remain on the waiting list were assessed before and after an 8 week nonintervention period. These patients were then randomly allocated to one of the 2 active treatments and reassessed at Week 16.

Participants were not informed that there were 2 different delivery modes of physical therapy involved in the allocation process, and individual treatments and group exercise sessions were scheduled when possible on different days of the week. Patients allocated to the waiting list were asked to continue their usual prestudy medication and physical activity regime as far as was ethically possible.

To absorb statistical regression and subject adaptability to the assessment measures or equipment, mean data derived from the 2 prerandomization assessments were used as the baseline. Sample size estimates were based on independent T tests of self-reported pain on the 100 mm VAS of the WOMAC with a 2:1 treatment:control allocation ratio. The clinically significant difference (15 mm), as well as the standard deviation (22 mm), was based on evidence from the literature and results of a previous study[30,44]. At an overall significance level of 2 tailed p = 0.05 and allowing for a 10% loss to followup, it was calculated that 116 subjects were needed for the study to have a 90% probability of finding a treatment effect. Data were analyzed per intention-to-treat, assuming no change for subjects unavailable for followup assessment. Analyses consisted primarily of mean changes with 95% CI and standardized response means (SRM). Multiple linear regressions were used to analyze the significance of group allocation on self-report and physical performance changes scores adjusted for the associated baseline score. Correlation analysis was used to establish if changes in self-report measures were plausibly associated with changes in objective measures of physical performance (isometric muscle strength and gait). Split median stratification by age, body mass index (BMI), symptom duration, and medial JSW was used to assess possible predictors of treatment responsiveness.

## RESULTS

Radiographs were obtained of 114 of the 126 participants (90.5%). Attrition numbers during the course of the study are given in Figure 1. One hundred twenty-eight patients agreed to participate in the study. Two withdrew prior to randomization because of unrelated general poor health and minor abdominal trauma. Five patients dropped out of the 2 physical therapy treatment groups (individual and group format) at various stages due to acceptance of cortisone injection, acceptance of knee arthroplasty, family circumstances, severe asthma related symptoms, and not responding to appointments. Two waiting list control subjects were unavailable for the Week 8 assessment: not responding to appointments. After 8 weeks on the waiting list, controls were randomly allocated to one of the 2 forms of physical therapy treatment. Three wait-

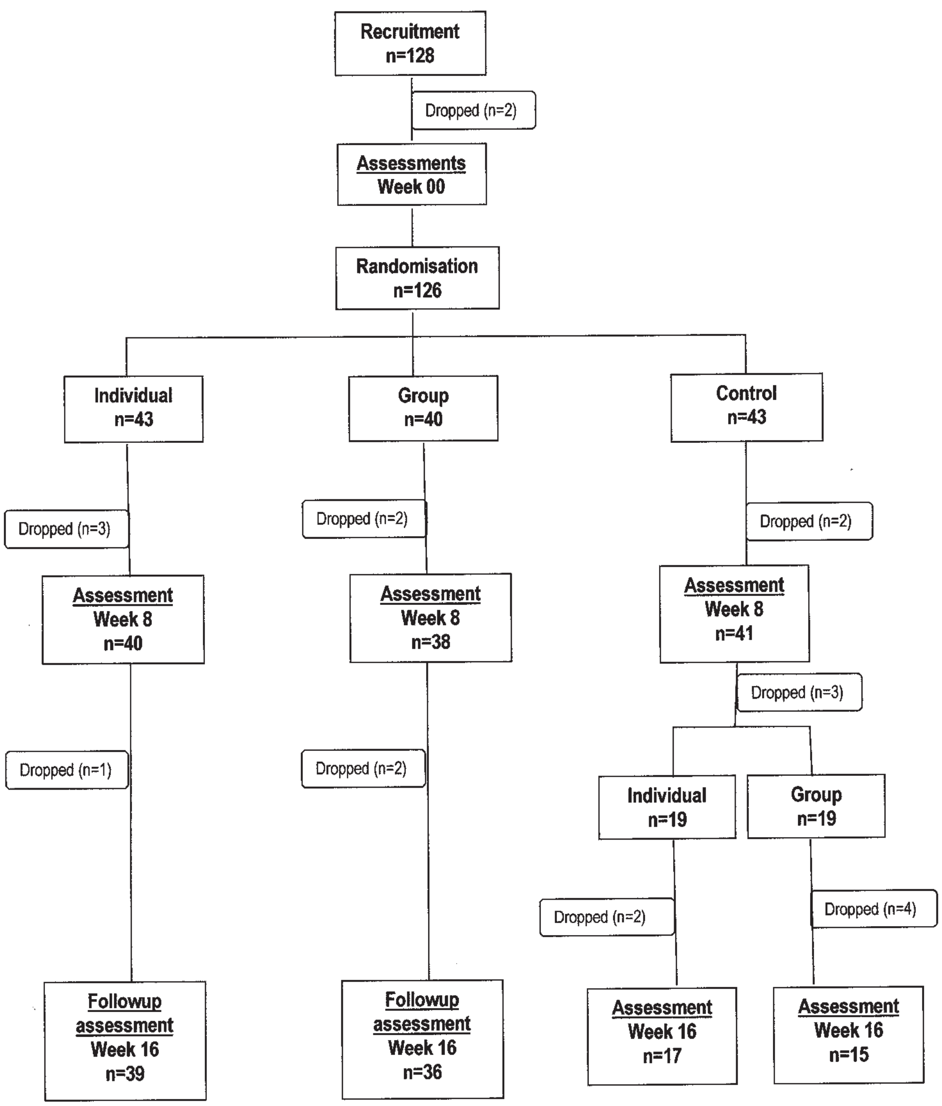


*Figure 1.* The procedure of randomization and withdrawal during the study.

ing list controls were unavailable for randomization: moving to another region, acceptance of hydrotherapy, acceptance of arthroscopy. After physical therapy (Week 16), 6 of the waiting list patients did not attend for posttreatment assessment: intraarticular cortisone injection, cardiac problems, acceptance of total knee arthroplasty, remission of severe back pain, ankle injury, and not responding to appointments.

To increase generalizability, 24 physical therapists were involved in the individual treatments and 4 different physical therapists supervised the group format program. Individual treatments consisted almost universally of at least 20 minutes of muscle strengthening exercise or manual techniques aimed at increasing range of motion and 5–10 minutes of an electrophysical agent such as heat, ultrasound, laser, or interferential therapy. The mean number of half-hour individual treatments attended was 7 (range 2–4). About 90% of the patients allocated to the group format program attended at least 12 of the 16 sessions.

The WOMAC scores were reverse scored (100 = no pain or difficulty, 0 = extreme pain or difficulty), so that for all outcome measures higher scores are better scores.

*Primary hypothesis*. The initial 3 allocation groups were comparable at baseline 1 (Week 00, Figure 1) for age, sex, BMI, symptom duration, medial JSW, and self-report measures (Table 1). The primary hypothesis, that physical therapy (individual treatments or group format) can effect improvements in pain, physical function, and HRQOL, is substantiated by the results of this study. Patients originally allocated to physical therapy had significantly decreased pain and physical dysfunction (WOMAC) as well as improved HRQOL (SF-36) at Week 8 (Table 2). In contrast, patients allocated to remain on the waiting list had no significant changes in any of these measures at Week 8. To avoid a Type I error at the overall significance level of $2P < 0.05$, the required significance level for each of the 4 outcomes was adjusted to $p < 0.01$. Only the generic SF-36 PCS failed to achieve statistical significance for the effect of treatment above control (Table 2). The effects of treatment above control, as assessed by the SRM, would be rated as medium for pain, physical function, and the SF-36 MCS, and small for the SF-36 PCS.

*Table 1*. Baseline 1 characteristics, individual treatments, group format, and control (Week 00).

| | Individual, n = 43, mean (SD) | Group, n = 40, mean (SD) | Control, n = 43, mean (SD) |
|---|---|---|---|
| Age, yrs | 68.5 (8.7) | 65.3 (7.1) | 66.1 (10.3) |
| Sex, % female | 74 | 78 | 67 |
| BMI | 30.0 (4.6) | 29.9 (5.9) | 28.3 (4.5) |
| Symptoms 1,2–5, > 5 yrs | 5, 18, 20 | 6, 18, 16 | 5, 21, 17 |
| Medial JSW, mm | 2.0 (1.4) | 2.2 (1.3) | 2.0 (1.4) |
| Lateral JSW, mm | 4.9 (1.8) | 5.0 (2.1) | 4.9 (1.7) |
| WOMAC pain, 100–0 | 59.5 (20.0) | 61.4 (18.9) | 65.8 (19.4) |
| WOMAC function, 100–0 | 58.5 (18.8) | 63.1 (21.0) | 60.0 (20.5) |
| SF-36 PCS, mean = 50 | 31.4 (6.6) | 34.3 (9.1) | 34.8 (8.2) |
| SF-36 MCS, mean = 50 | 42.7 (7.2) | 44.5 (7.8) | 42.9 (7.0) |
| Knee extensors, N | 167.9 (72.9) | 171.0 (63.4) | 173.3 (67.1) |
| Knee flexors, N | 89.5 (38.2) | 99.8 (35.6) | 100.1 (40.9) |
| Fast speed, $cm \cdot s^{-1}$ | 121.5 (28.5) | 135.7 (23.1) | 127.8 (24.1) |
| Fast cadence, $steps \cdot min^{-1}$ | 117.6 (14.3) | 122.2 (13.6) | 117.6 (10.3) |
| Fast stride length, cm | 123.2 (21.1) | 133.2 (17.8) | 130.3 (22.2) |

N: newtons, BMI: body mass index, JSW: joint space width, PCS: physical component score, MCS: mental component score.

*Secondary hypothesis*. After the waiting list controls were randomized to one of the 2 forms of physical therapy treatment delivery (Figure 1), the total individual treatment group (n = 62) was comparable with the total group format group (n = 59) (Table 3). The secondary hypothesis, that the group format program is more beneficial than individual treatments, could not be substantiated by our results (Table 4). Both forms of physical therapy achieved significant improvements. For pain and physical function (WOMAC), the immediate effects of treatment (SRM) would be rated as medium for the group format program and small for the individual treatments. For HRQOL (SF-36), the immediate effects of treatment would be

*Table 2*. Treatment outcomes, treatment (individual and group) vs control (Week 8–Week 00).

| | Treatment (n = 83), mean change (95% CI) | Control (n = 43), mean change (95% CI) | p* (Treatment vs Control) | SRM (Treatment over Control) |
|---|---|---|---|---|
| WOMAC pain, 100–0 | 10.6 (6.3, 15.0) | –1.5 (–5.5, 2.4) | < 0.01 | 0.65 |
| WOMAC function, 100–0 | 7.7 (4.2, 11.2) | –0.1 (–3.9, 3.7) | < 0.01 | 0.49 |
| SF-36 PCS, mean = 50 | 3.6 (1.9, 5.3) | 0.5 (–1.5, 2.3) | 0.05 | 0.36 |
| SF-36 MCS, mean = 50 | 2.0 (0.8, 3.3) | –0.7 (–1.8, 0.5) | < 0.01 | 0.51 |
| Knee extensors, N | 10.8 (4.3, 17.3) | –2.4 (–9.2, 4.5) | 0.01 | 0.46 |
| Knee flexors, N | 8.4 (4.0, 12.7) | –0.6 (–5.5, 5.2) | 0.02 | 0.46 |
| Fast speed, $cm \cdot s^{-1}$ | 7.1 (4.7, 9.4) | 0.4 (–1.3, 2.1) | < 0.01 | 0.58 |
| Fast cadence, $steps \cdot min^{-1}$ | 1.9 (0.7, 3.2) | 0.3 (–0.6, 1.3) | 0.05 | 0.26 |
| Fast stride length, cm | 4.7 (3.0, 6.3) | 0.4 (–1.3, 2.0) | < 0.01 | 0.55 |

*Significance adjusted for baseline differences in the variable. SRM: standardized response mean, N: newtons.

*Table 3*. Baseline 2 characteristics, individual treatments and group format, Week 00 (active treatment) and Week 8 (former controls).

| | Individual, n = 62, mean (SD) | Group, n = 59, mean (SD) |
|---|---|---|
| Age, yrs | 66.7 (10.1) | 66.8 (7.5) |
| Sex, % female | 75 | 71 |
| Height, cm | 162.8 (8.6) | 163.0 (8.5) |
| BMI | 29.7 (4.6) | 29.0 (5.6) |
| Symptoms 1,2–5, > 5 yrs | 9, 27, 27 | 7, 27, 23 |
| Medial JSW, mm | 2.0 (1.4) | 2.1 (1.3) |
| Lalteral JSW, mm | 5.1 (1.7) | 4.7 (2.0) |
| WOMAC pain, 100–0 | 60.7 (21.3) | 62.7 (18.4) |
| WOMAC function, 100–0 | 58.7 (21.1) | 62.1 (19.7) |
| SF-36 PCS, mean = 50 | 33.2 (8.8) | 34.3 (9.1) |
| SF-36 MCS, mean = 50 | 43.1 (8.0) | 43.5 (7.3) |
| Knee extensors, N | 173.7 (75.2) | 168.5 (67.1) |
| Knee flexors, N | 97.0 (42.1) | 96.9 (39.1) |
| Fast speed, $cm \cdot s^{-1}$ | 125.4 (28.1) | 133.3 (22.7) |
| Fast cadence, $steps \cdot min^{-1}$ | 118.1 (12.5) | 121.1 (12.8) |
| Fast stride length, cm | 126.8 (22.6) | 132.4 (20.6) |

N: newtons.

*Table 4*. Treatment outcomes, individual treatment vs group format, Week 8–Week 00 (active treatment); Week 16–Week 8 (former controls).

| | Individual, mean change (95% CI), SRM | Group, mean change (95% CI), SRM |
|---|---|---|
| WOMAC pain, 100–0 | 7.7 (3.0, 12.4)<br>0.42 | 11.4 (6.7, 16.0)<br>0.65 |
| WOMAC function, 100–0 | 6.6 (2.7, 10.5)<br>0.42 | 8.5 (4.5, 12.5)<br>0.55 |
| SF-36 PCS, mean 50 | 2.7 (0.9, 4.5)<br>0.38 | 2.3 (0.6, 4.1)<br>0.34 |
| SF-36 MCS, mean 50 | 1.6 (0.2, 2.9)<br>0.28 | 2.1 (0.8, 3.4)<br>0.41 |
| Knee extensors, N | 6.5 (0.8, 13.0)<br>0.25 | 5.9 (0.3, 11.6)<br>0.27 |
| Knee flexors, N | 6.5 (1.9, 11.0)<br>0.36 | 7.1 (2.4, 11.8)<br>0.39 |
| Fast speed, $cm \cdot s^{-1}$ | 1.6 (0.5, 6.7)<br>0.30 | 6.3 (3.7, 8.9)<br>0.63 |
| Fast cadence, $steps \cdot min^{-1}$ | 1.1 (–0.4, 2.6)<br>0.19 | 2.2 (0.8, 3.7)<br>0.40 |
| Fast stride length, cm | 2.3 (–0.1, 4.7)<br>0.24 | 3.6 (1.8, 5.5)<br>0.51 |

SRM: standardized response mean, N: newtons.

rated as small for both forms of physical therapy. Further, increased levels of physical activity and decreased medication use after treatment were similar in both groups. There were no statistically significant differences between the effects of the 2 modes of physical therapy treatment.

*Tertiary hypotheses.* This study also revealed that: (1) Both forms of physical therapy treatment resulted in significantly increased isometric muscle strength, gait speed, and stride length above controls (Table 2). After inclusion of the waiting list controls into one of the 2 forms of physical therapy, the group format program appeared to result in consistently superior gains in these measures of physical performance (Table 4); however, the difference between the 2 active treatments did not reach statistical significance. (2) Changes in self-reported pain were correlated with changes in isometric extensor strength (rho = 0.42) and fast walking speed (rho = 0.36). Changes in self-reported physical function were similarly correlated with changes in isometric extensor strength (rho = 0.38) and fast walking speed (rho = 0.38). All reported associations were significant at the $p < 0.01$ level. (3) A median-split stratification according to medial JSW revealed a consistent trend in treatment effectiveness between the stratified groups (Table 5). That the group with greater loss of medial JSW had higher baseline extensor strength and comparable gait variables is attributed to the significantly greater proportion of men in this group (39% vs 16%). Subjects in the group with a medial JSW < 1.9 mm (mean 0.9 mm, range 0.2–1.8) improved markedly less than subjects with a medial JSW > 1.9 mm (mean 3.2 mm, range 1.9–6.7). Indeed the group with more severe loss of medial JSW consistently showed small effect sizes, with significant treatment effect only in self-reported pain. The group with less severe loss of medial JSW showed moderate to large effect sizes with significant treatment effect for all the measured outcomes. The statistical sig-

*Table 5*. Outcomes stratified by medial joint space width, individual treatments or group format.

| | Baseline, mean (SD) | Change, mean (95% CI) | SRM |
|---|---|---|---|
| Medial JSW < 1.9 mm, n = 57 | | | |
| WOMAC pain, 100–0 | 62.4 (20.3) | 5.6 (0.6, 10.6) | 0.30 |
| WOMAC function, 100–0 | 59.9 (19.3) | 2.6 (–1.6, 6.8) | 0.17 |
| SF-36 PCS, mean = 50 | 33.6 (9.3) | 1.4 (–0.5, 3.3) | 0.20 |
| SF-36 MCS, mean = 50 | 44.0 (7.6) | 1.3 (–0.0, 2.6) | 0.27 |
| Knee extensors, N | 185.1 (76.2) | 4.0 (–2.5, 10.5) | 0.16 |
| Knee flexors, N | 98.9 (40.8) | 4.9 (–0.0, 9.8) | 0.26 |
| Fast velocity, $cm \cdot s^{-1}$ | 127.7 (25.2) | 1.5 (–1.0, 4.0) | 0.16 |
| Fast stride length, cm | 129.3 (22.0) | 1.1 (–0.9, 3.1) | 0.14 |
| Medial JSW > 1.9 mm, n = 57 | | | |
| WOMAC pain, 100–0 | 61.2 (20.3) | 11.0 (6.3, 15.5) | 0.63 |
| WOMAC function, 100–0 | 62.1 (22.6) | 9.1 (5.7, 12.5) | 0.72 |
| SF-36 PCS, mean = 50 | 33.2 (9.8) | 4.5 (2.5, 6.5) | 0.59 |
| SF-36 MCS. mean = 50 | 42.4 (9.8) | 2.8 (1.4, 4.3) | 0.51 |
| Knee extensors, N | 153.0 (60.3) | 11.7 (5.9, 17.5) | 0.53 |
| Knee flexors, N | 91.0 (38.1) | 10.3 (5.7, 14.9) | 0.59 |
| Fast velocity, $cm \cdot s^{-1}$ | 130.1 (26.4) | 8.9 (6.0, 11.3) | 0.82 |
| Fast stride length, cm | 128.1 (21.7) | 5.2 (3.1, 7.3) | 0.67 |

JSW: joint space width; SRM: standardized response mean.

*Table 6*. Two month followup data, individual treatments and group format.

| n = 83 | Week 8, mean (SD) | Week 16, mean (SD) |
|---|---|---|
| WOMAC pain, 100–0 | 71.1 (18.8) | 70.7 (21.3) |
| WOMAC function, 100–0 | 68.2 (21.0) | 68.7 (21.9) |
| SF-36 PCS, mean = 50 | 36.4 (8.8) | 36.8 (9.4) |
| SF-36 MCS, mean = 50 | 45.5 (7.5) | 44.9 (7.8) |
| Knee extensors, N | 178.2 (74.5) | 179.6 (76.0) |
| Knee flexors, N | 102.1 (38.1) | 104.1 (40.1) |
| Fast speed, $cm \cdot s^{-1}$ | 135.1 (27.4) | 135.0 (27.9) |
| Fast stride length, cm | 132.4 (19.2) | 132.3 (19.9) |

nificance levels of the interactions were: WOMAC physical function ($p = 0.04$), SF-36 PCS ($p < 0.01$), fast gait speed ($p < 0.01$), fast stride length ($p = 0.02$), and isometric knee extensor strength ($p = 0.05$). (4) In contrast, a median-split stratification on age, BMI, and reported symptom duration (log transformed to attain normal distribution) did not reveal trends in treatment effectiveness. (5) Followup data collected at Week 16 (Figure 1) showed that improvements gained in both self-report questionnaires and objective measures of physical performance did not deteriorate over this period (Table 6).

## DISCUSSION

The main results of this randomized clinical study are that physical therapy, for this sample of referred patients with mostly chronic symptomatic and definite radiographic OA knee, had a moderate effect on pain and physical function and a small effect on health related quality of life. These results are in broad agreement with randomized controlled trials of acceptable validity and power[11]. There were, however, important differences with previous studies relating to the population sampled.

Most methodologically sound studies reporting on exercise for people with knee OA have used community volunteers or patients with more recent and less severe symptomatic disease[12,15,18]. In our sample, 44% reported symptom duration of greater than 5 years, 76% had bilateral symptomatic knee OA, and 71% reported a minimum one comorbidity for which they were daily taking prescription medication. Not unexpectedly, the study sample had SF-36 scores (Table 1) well below both stratified United States (65 years and over) and Australian (65–74 years) population norms[45,46]. The Australian National Health Survey of 1995 found a PCS score of 42.8 and a MCS score of 51.3 in persons aged 65–74 years (n = 1658). Using the derived Australian factor score coefficients, the current sample of patients with knee OA gave a PCS score of 32.0 and a MCS score of 42.9, indicating that both physical and mental HRQOL are affected in these older patients with knee OA seeking treatment.

The second hypothesis, that the group format program would be more clinically effective than individual treatments, could not be substantiated. However, data collected during this study indicated that the group format program was less human-resource intensive than the individual treatments. For the individual treatments, 7.02 half-hour treatments extrapolates conservatively (missed appointments were not included) to 3.5 hours of 1:1 treatment time. For the group format program, 16 hours with 6 patients per group extrapolates to 2.7 hours of 1:1 treatment time. Furthermore, the equipment costs of each delivery mode would be comparable. The group format used 3 stationary bicycles, 3 simple heart rate monitors (Polar Pacer, Polar Electro Oy), some weights, an exercise machine allowing both eccentric and concentric lower limb strengthening, a set of stairs, and a stepper machine (Appendix 1). Physical therapists providing individual treatments at times used various electro-physical agents to supplement exercise: laser (6 patients), interferential (12 patients), ultrasound (18 patients), and local heat treatment (10 patients).

In retrospect, this study was not sufficiently powered to establish statistical significance for the smaller differences in clinical effect realistically anticipated between 2 active treatments compared with the difference between an active treatment and a waiting list control group. For example, at an overall significance level of $p = 0.05$, it is calculated that roughly 500 subjects would be needed for the study to have 80% probability of establishing a 5 point difference in the WOMAC scores as statistically significant. However, if the secondary hypothesis is viewed purely as a pragmatic trial to aid clinical decisions[47], then the study would appear to show that the small group format program is sufficiently effective to provide a cost-effective alternative to the usual individual treatments for knee OA.

Some interesting results emerged from the tertiary hypotheses of this study. While the self-reported improvements were substantiated by improvements in objective measures of physical performance, there were only small absolute changes in the measures of physical performance despite no evidence of a possible ceiling effect. Fast gait speed reached by women in this sample was only 124 $cm \cdot s^{-1}$ (167 $cm \cdot s^{-1}$ for age matched controls) and by men only 136 $cm \cdot s^{-1}$ (177 $cm \cdot s^{-1}$ for age matched controls)[42]. The patients also demonstrated muscle strength substantially below matched normative data for both lower limbs[48,49]. In fact, baseline interquartile range (IQR) for knee extensor strength in the current study was 34–46% for the weaker limb (46–75% for the stronger limb) of reported normative values. Similarly, but in contrast to a recent population based study[23], the patients in this study also showed markedly decreased knee flexor strength compared to normative controls. Baseline IQR for knee flexor strength was only 32–60% for the weaker limb (41–73% for the stronger limb)[48,49]. However, most of the patients in this study had moderate to severe radiological and symptomatic disease, suggesting that loss of knee flexor strength is a late disease related impairment associated with disuse atrophy. The nonlinear relationship between muscle strength and physical function, or "why small changes in physiological capacity may produce relatively large effects on performance in frail adults," has been described in large population based samples of older adults[50,51]. Two randomized controlled studies evaluating exercise for people with knee OA have also shown only small absolute and relative changes in isometric knee muscle strength compared with changes in measures of physical function[12,18]. Our sample of referred patients had moderate to severe loss of medial JSW, 54% having a medial JSW < 2 mm. A previous study found a strong correlation between reduced medial JSW and increased varus-valgus laxity at the semiflexed knee joint[52]. The current finding of small absolute changes in isometric muscle strength would support the hypothesis that "strengthening may have a smaller impact in lax knees"[53]. Further, about 73% of this sample were women and it is claimed that "older women gain only about half as much strength as older men under the same exercise protocol"[54]. It seems clear that particularly patients with moderate–severe loss of medial JSW, relatively poor muscle strength, and unable to perform high intensity training due to age and/or comorbidity may have potential to benefit from lengthier treatments than the 8 weeks assessed by our study.

For most people, healthy aging is accompanied by a gradual loss of muscle strength[48,49], kinesthetic acuity[55], and biological quality of the cartilage, resulting in decreased ability of the joint to safely absorb the repetitive impulse loading associated with walking. Peak loading rate increases with increasing walking speed, accounting for the finding that gait at a fast self-selected speed has higher discriminative validity than gait at a normal self-selected speed for people with lower limb disability[42]. The knee extensors function to attenuate peak loading rate at heel strike[56]. Indeed, this study showed that changes in knee extensor strength were more highly associated with reduced knee pain and improved physical function compared with changes in knee flexor strength. It is suggested that limiting appropriate neuromuscular compensatory responses by reducing nociceptive stimuli during weight-bearing activities with regular analgesia is not an optimal strategy in early disease[57]. It is of concern, therefore, that roughly 50% of rheumatologists referred patients with knee OA for physical therapy "sometimes," "rarely," or "never"[58]. This reported poor referral to physical therapy compared with the prescription of pharmacologic agents may be due to uncertainty concerning the effectiveness provided by physical therapy services or to economic constraints of either the health-care funder or the patient. We have tried to address both these concerns.

This study provides initial evidence that radiographic disease severity will modify physical therapy treatment responsiveness. Radiographic severity was measured by medial JSW with the knee in a semiflexed weight-bearing position, as this position provides a better indicator of cartilage thickness compared with the fully extended position[59]. Furthermore, large cross sectional community studies have shown that the presence of radiographic knee OA is significantly associated with the presence or absence of knee pain[5,60]. If symptoms are present, however, our results suggest that radiographic disease severity does not have a linear association with symptom severity (Table 5). Self-reported pain, physical function, and HRQOL were comparable between the groups stratified by medial JSW. It may be that these results are confounded by differences between the stratified groups in patello-femoral joint involvement, or radiographic or symptomatic disease severity of the contralateral knee but many studies have clearly shown the significant influence of psychological distress and social and behavioral variables on self-report measures[7,61,62]. It has been suggested that people with chronic disease simply adapt their expectations, lifestyle, and environment over time. Our study does, however, strongly suggest that medial JSW has important relevance for short term treatment responsiveness, substantiating the general recommendation that physical therapy is particularly indicated in relatively early disease.

This study deals with tertiary prevention or attempting to limit disability in established symptomatic disease. The intensity of physical treatment possible in older people with marked chronic joint disease is often limited, suggesting lengthy treatment duration may be needed to reach an adequate treatment dosage. Due to future health care resource constraints in many countries, financial support for lengthy treatments may only be feasible with a more cost-effective strategy than provided by the current usual individual physical therapy treatment mode. A more clinically effective strategy may be secondary prevention or screening persons for early disease and providing an easily accessible and effective intervention. It is hypothesized that people with early disease will be better able to tolerate an intensive program aimed at controlling damaging impulse loading of the knee joint compared with patients with late disease. A longitudinal study is needed to establish the effectiveness of this secondary prevention strategy.

This randomized controlled clinical study confirms the effectiveness of physical therapy for patients with knee OA seeking treatment in terms of self-reported pain, physical function, and HRQOL. Improvements revealed by self-report questionnaires were significantly associated with improvements in objective measures of physical performance, and treatment effectiveness was still apparent 2 months after formal treatment stopped. The sample size was insufficient to show a statistically significant difference in clinical effectiveness between individual treatments and a small group-format program. Treatment effectiveness was not modified by age, sex, BMI, or symptom duration, but patients with a severe loss of medial JSW were less responsive to this relatively short intervention.

**Appendix.** Group Format Program.

Gymnasium: 8 weeks, attendance twice weekly for about 1 h. Group sizes were limited to 6 and were supervised by a physical therapist. The initial visit consisted of an education session outlining the benefits of exercise for people with arthritis and the importance of appropriate footwear and weight control. In the gymnasium, subjects were requested to perform all exercises bilaterally, start the session with stretches and then proceed with the remaining exercises in random order. Subjects were advised to adjust the weights used so that the exercises were performed with some effort but with a minimum of pain during the session. Subjects were to note any adverse reactions to exercise and seek advice from the supervising physical therapist.

| Exercise | Repetition/(weight range) |
|---|---|
| Stretches: quadriceps, hamstrings, gastrocnemius | 3 × 30 s hold each muscle group |
| Stationary bicycle | 20 min/50–60% maximum heart rate |
| Non-weight-bearing quadriceps muscle strengthening: inner range with weight attached to ankle | 20–40/(0–6 lbs) |
| Weight-bearing quadriceps muscle strengthening: Tunturi 401 Variable Resistance Climber | 100 steps/(0 setting) |
| Non-weight-bearing concentric/eccentric quadriceps and knee flexors: full range with Isolator bench (Chattanooga Corp.) | 20–40/(10–30 lbs) each muscle group |
| Weight-bearing eccentric quadriceps: Controlled stepdown from 10–15 cm step. Patella taping applied by physical therapist if required to reduce pain. | 20–40 |

Home program: 3 days per week: Stretches as per group exercise sessions followed by 20 min of continuous outdoor walking or indoor stationary bicycle.

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