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Physical Therapy for Patellofemoral Pain

A Randomized, Double-Blinded, Placebo-Controlled Trial

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Background: Although physical therapy forms the mainstay of nonoperative management for patellofemoral pain, its efficacy has not been established.
Hypothesis: Significantly more pain relief will be achieved from a 6-week regimen of physical therapy than from placebo treatment.
Study Design: Multicenter, randomized, double-blinded, placebo-controlled trial.
Methods: Seventy-one subjects, 40 years of age or younger with patellofemoral pain of 1 month or longer, were randomly allocated to a physical therapy or placebo group. A standardized treatment program consisted of six treatment sessions, once weekly. Physical therapy included quadriceps muscle retraining, patellofemoral joint mobilization, and patellar taping, and daily home exercises. The placebo treatment consisted of sham ultrasound, light application of a nontherapeutic gel, and placebo taping.
Results: Sixty-seven participants completed the trial. The physical therapy group ($N = 33$) demonstrated significantly greater reduction in the scores for average pain, worst pain, and disability than did the placebo group ($N = 34$).
Conclusions: A six-treatment, 6-week physical therapy regimen is efficacious for alleviation of patellofemoral pain.

Patellofemoral pain occurs frequently; nine prospective cohort studies reported incidence rates of 7% in young active adults[54] and 1% to 15% in armed forces recruits.[1,2,23,27,31,40,45,46] It is a particularly regular symptom of patients seen at sports medicine practices, with the relative rates varying from 2% to 30%. Many authors cite this condition as the most common diagnosis.[3,10,13,14,25,28,36,37,42] Discrepancies in relative incidence rates most likely reflect differences in the populations treated at individual medical centers and inconsistencies in diagnosis.

Although sports medicine practitioners frequently treat patients to alleviate patellofemoral pain, the pathologic origin of this disorder is not clearly understood. It is likely that the cause of the pain is not the same for all patients. Current evidence suggests that the structures most likely to generate patellofemoral pain are the anterior synovium, infrapatellar fat pad, subchondral bone, and medial or lateral retinaculae.[6,7,15,52] Stress on any or all of these patellofemoral joint structures may lead to a conscious perception of pain.

The source of patellofemoral pain may not be correctly identifiable by clinical examination alone, making specific diagnosis difficult. In addition, more invasive and costly diagnostic procedures are not indicated for the majority of patients. For this reason, many authors use nonspecific terms to describe the signs and symptoms of this common clinical condition. "Patellofemoral pain" is one such term. Other terms, such as chondromalacia patellae, anterior knee pain, patellar malalignment, and patellofemoral ar-

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thralgia, have also been used synonymously with patellofemoral pain. Thus, in the current study, patellofemoral pain is a term used to encompass all anterior or retropatellar pain in the absence of other identifiable pathologic conditions.

Although confirmation of a specific diagnosis of patellofemoral pain is difficult because of a paucity of valid clinical tests, the clinical presentation of patellofemoral pain is characterized by a stereotypical group of signs and symptoms and is readily recognized by primary practitioners. Patellofemoral pain is associated with activities that load the patellofemoral joint, such as stair climbing, squatting, running, and kneeling. Thus, this common condition affects many aspects of daily life. In particular, it interferes with one's ability to participate in regular sport and exercise that require running or walking.

The pathogenesis of patellofemoral pain is unclear. Some authors have associated the development of patellofemoral pain with malalignment (abnormal lateral tracking) of the patella within the femoral trochlear groove,[20] leading to areas of increased stress on the patellofemoral joint.[17,41] Other authors have concluded that malalignment may not be a major factor in the cause of patellofemoral pain.[19] Measurement of patellar alignment and tracking remains problematic, and the relationship between patellar tracking and patellofemoral pain is unclear. However, despite a uniform clinical picture, it is probable that the cause is multifactorial and thus not consistent for all patients.

Nonoperative treatment is the mainstay of intervention for patellofemoral pain. Of the various nonoperative management options, physical therapy remains the most commonly used. The rationale behind the use of physical therapy for alleviation of patellofemoral pain includes restoration of patellar alignment through active or passive interventions, including quadriceps muscle-strengthening exercises, stretching, patellar taping or bracing, biofeedback, and use of corrective foot orthoses.[11] Vastus medialis oblique muscle retraining is an essential component of treatment because this muscle can provide active medial stabilization of the patella within the femoral trochlea.[34]

There are a number of approaches to the physical therapy management of patellofemoral pain. In 1986, McConnell[39] proposed a regimen that included retraining the vastus medialis oblique muscle through functional weightbearing activities. This exercise is combined with patellar taping, patellar mobilization, and stretching to improve patellar tracking, reduce pain, and enhance vastus medialis oblique muscle activation. This regimen is gaining worldwide exposure and acceptance and has yielded good-to-excellent results in case series.[18,39] Four controlled clinical trials evaluating variations of a similar program against each other provided better evidence that this regimen relieves pain and restores function.[9,16,22,32] However, the extent to which the positive results arise because of the actual treatment program or because of a placebo effect cannot be ascertained from these studies.

Appropriate measurement tools with known reliability and validity are needed to evaluate treatment efficacy. Among patients who have patellofemoral pain, self-reported levels of pain and disability are mostly sought through use of visual analog scales and condition-specific questionnaires such as the Functional Index Questionnaire (FIQ)[8] or the Anterior Knee Pain Scale (AKPS).[33] The reliability of these pain and disability scales has been established by a small number of studies, with most demonstrating moderate-to-good test-retest reliability. Intraclass correlation reliability coefficients range from 0.60 to 0.79 for the visual analog scale,[5,8] from 0.48 to 0.94 for the FIQ,[5,8,21,35] and 0.90 for the AKPS.[5] In addition to having acceptable reliability, a number of clinical trials indicate that a visual analog scale, FIQ, or AKPS can be used to detect a statistically significant change after treatment of patients with patellofemoral pain.[8,9,21,22,26,29,32,47,48,53] This finding indicates that the magnitude of change with treatment is greater than the measurement error associated with these scales. Further evidence for construct validity of the AKPS was provided by Kujala and colleagues,[33] who found that scores on this questionnaire differed between patient groups with and without patellofemoral pain.

The purpose of this clinical trial was to establish the efficacy of a physical therapy program for patellofemoral pain by using a battery of accepted outcome measures in a multicenter, randomized, double-blinded, placebo-controlled trial.

MATERIALS AND METHODS

Study Population

After approval was obtained from the University of Melbourne Human Research Ethics Committee, participants were recruited from health professionals, advertisements, and media in Melbourne, Australia. Those fulfilling the eligibility criteria were invited to participate in the study, and volunteers were enrolled after providing written informed consent. Participants were included if they exhibited signs and symptoms of patellofemoral pain with no evidence of any other specific pathologic condition. The diagnosis of patellofemoral pain was made on the basis of the clinical picture alone to replicate clinical practice and to increase generalizability.

The inclusion criteria were 1) anterior or retropatellar knee pain from at least two of the following: prolonged sitting, stair-climbing, squatting, running, kneeling, and hopping/jumping; 2) insidious onset of symptoms unrelated to a traumatic incident; and 3) presence of pain on palpation of the patellar facets, on step down from a 25-cm step, or during a double-legged squat.

Participants were excluded if they had signs or symptoms of meniscal or other intraarticular pathologic conditions; ligament laxity or tenderness; tenderness over the patellar tendon, iliotibial band, or pes anserinus tendons; patellar apprehension sign; Osgood-Schlatters or Sinding-Larsen-Johanssen syndromes; evidence of a knee joint effusion or hip or lumbar referred pain; or a history of patellar dislocation. Also excluded were subjects who had undergone previous surgery on the patellofemoral joint complex or who had features that could affect the implementation of the treatment (prior patellar taping experience potentially compromising participant blinding, known allergy to tape, or inability to attend all treatment sessions and assessments). Subjects with clinical factors and co-interventions that could contaminate results (symptoms less than 1 month, average pain less than 3 cm on a 10-cm visual analog scale, nonsteroidal antiinflammatory or corticosteroid medication use) were also excluded. In addition, those more than 40 years of age were ineligible, so as to reduce the possibility of degenerative joint disease as a cause of pain.

Group Assignment

Simple randomization (in blocks of four) was employed by using a computer-generated table of random numbers. One investigator (KB) kept the assignment scheme and provided the assignment to the treating physiotherapists in a series of consecutively numbered opaque envelopes. Allocation was concealed from the outcome assessor and participants at all times and from the physiotherapist until the point of treatment.

Blinding

Data entry was performed in a blinded manner from coded data collection forms. The data manager and statistician were unaware of treatment allocation. Participant blinding was attempted through the application of a realistic placebo intervention and by ensuring that participants in different groups did not attend treatment or assessment sessions concurrently. Participants were instructed not to reveal information about their treatment to the outcome assessor. At the completion of the trial, before unblinding, participants were asked to indicate to which group they thought they had been allocated.

Sample Size

Sample size was calculated on a predetermined difference between treatment groups of 1.5-cm change in the usual pain on a 10-cm visual analog scale. This figure was based on the results of previous comparative studies and was considered to be clinically relevant. Sample size calculations, assuming a standard deviation of 2.0 cm, showed that 33 participants were required in each group to have 85% power to detect the 1.5-cm difference. This number was increased to 36 per group to allow for a possible 10% withdrawal.

Interventions

Ten experienced physiotherapists, selected to provide geographic coverage of greater Melbourne, implemented the intervention in both the physical therapy and the placebo groups. Care providers were, as in all trials of procedural interventions, unblinded. To control for the time spent with the therapist, all treatments (active and placebo) were individual sessions lasting 30 to 60 minutes, once weekly for 6 weeks. Written, standardized information about patellofemoral pain and instructions for appropriate skin care were provided.

Participants were requested to cease other knee-related therapies at least 72 hours before commencing the trial and to refrain from other treatments during the trial, except for use of paracetamol for pain relief. Cessation of co-interventions was confirmed at the time of eligibility examination. Preexisting foot orthoses were permitted, but participants could not commence using or modify orthoses during the trial. Analgesic use was registered in a daily log kept by participants.

Physical Therapy Intervention

A standardized treatment protocol was developed based on routine physical therapy practice in Australia.[38] It included patellar taping, retraining of the vastus medialis oblique muscle by using dual-channel surface EMG biofeedback (Pathway MR-20, The Prometheus Group, Dover, New Hampshire), gluteal muscle strengthening exercises, and stretching of soft tissue structures (Table 1). Physiotherapists who delivered the intervention were trained in its implementation and provided with a training manual. Participants were prescribed daily home exercises and provided with standardized home exercise sheets. Compliance with home exercises was monitored via a daily log.

Patellar taping was included to assist with pain reduction. Nonrigid, hypoallergenic tape (Fixomull, Beiersdorf Australia, North Ryde, Australia) was used to provide skin protection, and rigid zinc-oxide tape (Endura-tape, Endura-Tape Pty Ltd., Sydney, Australia) was used for taping corrections. Taping corrections were applied in a predetermined order of anterior tilt, medial tilt, glide, and fat pad unloading[38] until the participant's pain was reduced by at least 50%. Participants were taught to independently apply the taping corrections and were instructed to reapply the tape daily and wear the tape during all waking hours for the duration of the trial.

Placebo Intervention

The placebo intervention consisted of placebo taping, sham ultrasound (custom-made devices), and the light application of a nontherapeutic gel (ultrasonic gel, Parker Laboratories Inc., Fairfield, New Jersey, and Hospital Skin Care Lotion, Smith & Nephew, Clayton, Australia). Placebo tape was used in an attempt to blind participants, because many participants expect tape to be used as part of treatment for patellofemoral pain. Nonrigid hypoallergenic tape (Fixomull) was placed on the skin in a vertical direction from the center of the patella to 5 cm proximal to the patella while the participant was sitting (with the knee flexed). The alignment of the patella was not visibly altered, nor was knee motion restricted. Participants were taught to independently apply the taping corrections and were instructed to reapply the tape daily and to wear the tape during all waking hours for the duration of the trial.

TABLE 1
Elements of Physical Therapy Intervention

All treatments	
Stretches	
Mediolateral (glide & tilt) mobilization of the patella combined with deep friction massage to the lateral soft tissues[a]	3 repetitions of 60 seconds each
Hamstring muscle stretches in sitting[a]	3 repetitions of 30 seconds each
Anterior hip structures stretch. Subject in prone position, one hip externally rotated with both the hip and knee flexed[a]	
Patellar taping	
Corrective taping of the patella to correct the four components of patellar orientation: glide, lateral tilt, anterior tilt, and rotation	
Weeks 1 and 2	
Exercises	
Isometric vastus medialis oblique muscle contractions while sitting with knee at 90° of flexion[a]	
Squats to 40° of knee flexion combined with isometric gluteal muscle contractions[a]	4 sets of 10 repetitions
Isometric hip abduction against the wall while standing[a]	4 sets of 15-second hold
Weeks 3 through 6, as for weeks 1 and 2 and include:	
Step-downs[b]—slow lowering of unaffected leg with a 10-cm step[a]	3 sets of 5 repetitions or 3 sets of 10 repetitions
Isometric hip abduction while standing	4 sets of 30-second hold
Home exercise program	
Exercises from the supervised exercises in a standard program	Twice daily

[a] Exercise included in the home exercise program.
[b] Subjects were assessed at each return visit on the "step-down test." If five repetitions could be completed on the 10-cm step without pain but not on the 20-cm step, the patient progressed to the step-down exercise, three sets of five repetitions. If five repetitions could be completed on the 20-cm step without pain, the patient progressed to the step-down exercise, three sets of 10 repetitions.

Outcome Measurements

A set of self-administered outcome tools was selected on the basis of the reliability and validity of the tool, its use in previous trials, and its relevance to patellofemoral pain. Primary outcome measures were 1) worst and usual pain in the previous week measured with a 10-cm visual analog scale, 2) FIQ, 3) AKPS, and 4) participant perceived response to treatment. The latter was measured with a five-point scale that was later dichotomized in two different manners: First, marked worsening, moderate worsening, or the same (1) versus moderate improvement or marked improvement (2); second, marked worsening, moderate worsening, the same or moderate improvement (1) versus marked improvement (2).

Secondary outcome measures included generic health-related quality of life assessed with the SF-36 questionnaire,[50] the amount of activity that the participant performed during the previous week,[43] and a functional measurement of the number of step-ups, step-downs, and squats that the participant could perform before pain onset or increase. The participants were asked to describe adverse effects of treatment through open probe questioning and elicited responses. All analgesic use was recorded, and compliance for treatment session attendance (both groups) and home exercises (physical therapy treatment group only) was sought.

A blinded examiner (KC or SC) performed all outcome assessments at baseline and at the conclusion of the trial. Participants in the placebo group were offered physical therapy treatment immediately after the final assessment, thus preventing the collection of long-term follow-up data from this group. Three-month follow-up assessments were performed on the physical therapy group participants to observe the maintenance of treatment effects. During the course of the trial, participants were withdrawn if they fell into one of the following categories: 1) violation of entry criteria, 2) serious concurrent illness, 3) adverse reaction preventing treatment, or 4) at the participant's request.

Statistical Analysis

All data were analyzed with the Statistical Package for the Social Sciences (Norusis/SPSS, Inc., Chicago, Illinois). Comparison of treatment groups at baseline with respect to demographic and possible prognostic factors was performed with use of appropriate nonparametric tests. Main comparative analyses were performed by using an intention-to-treat analysis of the difference between baseline and final scores with 95% confidence intervals and Mann-Whitney U tests or independent *t*-tests. Relative risk analyses were used to compare improvement and marked improvement between the physical therapy and placebo groups based on the dichotomized results of the perceived ratings of change. Effect sizes were calculated for all measures with an effect size of 0.2 considered small, 0.5 medium, and 0.8 large. Spearman's rank-order correlation coefficient was used to assess the effect of baseline participant characteristics on treatment outcome.

RESULTS

Between August 1998 and March 2000, 188 participants were referred to the trial, and 73 participants (39%) fulfilled the eligibility criteria. Two of the 73 recruited participants withdrew before randomization, leaving 71 participants to be randomized into the two groups (Fig. 1). Their characteristics are summarized in Table 2.

Four participants dropped out of the study, of these, three were lost to follow-up and one could not attend treatment or assessment sessions. Visual inspection of baseline data for these participants revealed no difference from the data of the 67 participants who completed the trial. Participants in the physical therapy group reported that they completed the exercises an average of 86% of the required days. Thirty-one of 33 participants (97%) in the physical therapy group and 27 of 34 participants (79%) in the placebo group attended all six of the treatment sessions.

Assessment of baseline comparability showed no significant differences between participants in the physical therapy and placebo groups for any demographic characteristics (Table 2). Baseline pain and disability, as assessed by study outcome measures, did not differ between patients in the physical therapy and placebo groups (Table 3). After the 6-week intervention, the physical therapy treatment group demonstrated significantly greater improvement than did the placebo group in three of the four primary outcomes (Table 3). Greater improvements were noted in worst pain and usual pain in the preceding week and in the AKPS (95% confidence interval does not cross zero). Effect sizes for these three outcomes were large. There was no significant difference in the change in the FIQ between the two treatment groups, and there was a moderate effect size. By using the dichotomized perceived response to treatment, the relative risk of improvement for participants in the physical therapy treatment group was 1.41 (95% CI, 1.07 to 1.84) times that of participants in the placebo treatment group. The relative risk of reporting a marked improvement for those in the physical therapy group was 3.39 (95% CI, 1.69 to 6.80) times that of the participants in the placebo group.

Analyses of secondary outcome measures demonstrated that significantly more step-ups (P = 0.01), step-downs (P = 0.03), and squats (P = 0.04) could be performed before pain onset or increase by participants in the phys-

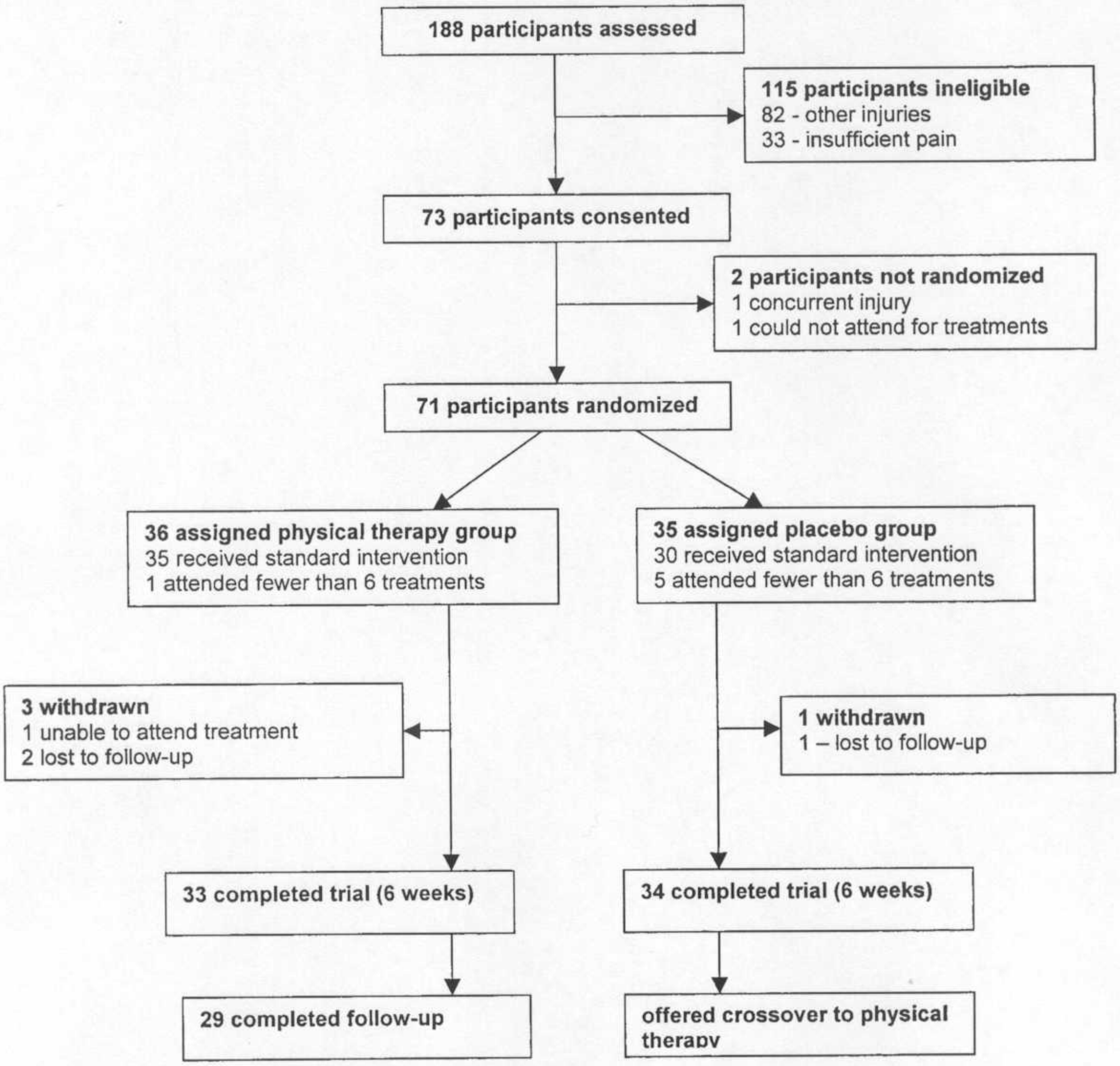

Figure 1. Flow chart describing the progression of participants through the trial.

TABLE 2
Baseline Participant Characteristics of the Physical Therapy and Placebo Treatment Groups

Variable	Physical therapy treatment group (N = 36)				Placebo treatment group (N = 35)				P value
	Mean	(SD)	Median	(range)	Mean	(SD)	Median	(range)	
Age (years)	29	(8)	31	(14–40)	26	(8)	24	(12–38)	0.06
Height (meters)	1.70	(0.09)	1.71	(1.53–1.95)	1.70	(0.07)	1.69	(1.55–1.89)	0.92
Weight (kg)	68.6	(13.7)	65	(42–102)	72.3	(13.3)	72	(41–108)	0.25
Body mass index (kg/m^2)	23.5	(3.8)	22.9	(18–32)	24.8	(3.7)	24.7	(16–31)	0.08
Physical activity[a] (kcal/day)	44	(12)	40	(32–85)	44	(9)	42	(33–70)	0.53
Exercise in past week[b]	4	(4)	4	(0–13)	3	(3)	3	(0–10)	0.35
Total duration of knee pain (months)	39	(43)	24	(1–144)	31	(32)	18	(1–120)	0.70
Current symptoms (months)	9	(9)	6	(1–36)	5	(3)	4	(1–12)	0.74
Functional limitation[c]			3	(2–4)			3	(2–4)	0.49
Sex	23 female, 13 male				23 female, 12 male				0.87[d]
Leg dominance	31 right, 5 left				33 right, 2 left				0.25[d]
Side of most pain	19 right, 17 left				21 right, 14 left				0.38[d]

[a] Amount of physical activity in previous week, physical activity questionnaire.
[b] Total number of exercise sessions (including competition) in the preceding week.
[c] Five-point scales: 1, no limitation; 2, annoying; 3, some limitation; 4, most limitation; 5, disabled.
[d] Chi-square test.

TABLE 3
Results of Intention-To-Treat Analysis of Primary Outcomes

Variable (max score)	Physical therapy group (mean [SD])		Placebo group (mean [SD])		Difference in mean change scores (95% CI)	Effect size
	Baseline (N = 36)	Final (N = 33)	Baseline (N = 35)	Final (N = 34)		
Worst pain[a]	7.0 (1.5)	3.0 (2.0)	7.0 (1.5)	5.0 (2.5)	2.0 (1.0; 3.5)[b]	0.80
Usual pain[a]	4.5 (1.0)	1.0 (1.5)	4.5 (1.0)	2.5 (2.0)	1.5 (0.5; 2.5)[b]	0.75
FIQ[c]	9 (2)	13 (3)	9 (2)	11 (3)	−1 (−3; 0)	0.33
AKPS[d]	68 (7)	86 (9)	69 (9)	78 (12)	−10 (−14; −5)[b]	0.91

[a] Measured on 10-cm visual analog scale in the previous week; 0, no pain; 10, maximum pain.
[b] $P < 0.05$.
[c] Functional index questionnaire; 0, maximum disability; 16, no disability.
[d] Anterior knee pain scale; 0, maximum disability; 100, no disability.

ical therapy group than by those in the placebo group (Fig. 2). There were no differences for changes in the health-related quality of life ($P > 0.05$) or the amount of physical activity ($P > 0.05$) performed in the previous week between the two groups.

Age was the only demographic variable that significantly correlated with the improvements in the primary outcome measures, with better outcome seen in the younger participants ($r = 0.44$ to 0.47). There were equal numbers of younger participants in the two groups. There were no significant correlations between global rating of change and the other demographic variables (height, weight, body mass index, physical activity level, total duration of symptoms, and duration of current symptoms). The worst pain on a 10-cm visual analog scale at baseline was significantly correlated with improvement in worst pain ($r = -0.63$) and in the FIQ ($r = 0.39$). Similarly, usual pain on a 10-cm visual analog scale at baseline correlated with changes in usual pain ($r = -0.63$), and more disability correlated with greater improvements in the FIQ ($r = -0.38$) and AKP ($r = -0.38$). Participants with greater initial pain and disability reported more improvement. Although significant, these variables were not highly correlated.

No serious adverse effects of treatment were described, although minor skin irritations from the tape were noted. The mean number of days during which the participants did not tape because of skin irritation was 1.4 (SD, 4.2) days. Three other adverse reactions were minor and did not affect the implementation of the interventions. Four participants in each group (eight in total) required some analgesic use of paracetamol during the trial.

Of the 64 participants who were available for questioning regarding the success of masking, 52 participants (81%) responded that they were in the physical therapy group or could not decide to which group they had been assigned. In the physical therapy group, 25 (76%) thought they were in the physical therapy group, 3 (9%) thought they were in the placebo treatment group, and 5 (15%) could not decide. In the placebo group, 11 (35%) thought they were receiving physical therapy, 9 (29%) thought they had been randomized to the placebo group, and 11 (35%) were unsure.

Twenty-nine of the 33 participants (88%) allocated to the physical therapy group were followed up 3 months after completion of the trial to observe the maintenance of treatment effects and any later adverse effects. Participants continued to improve, and the results of their worst

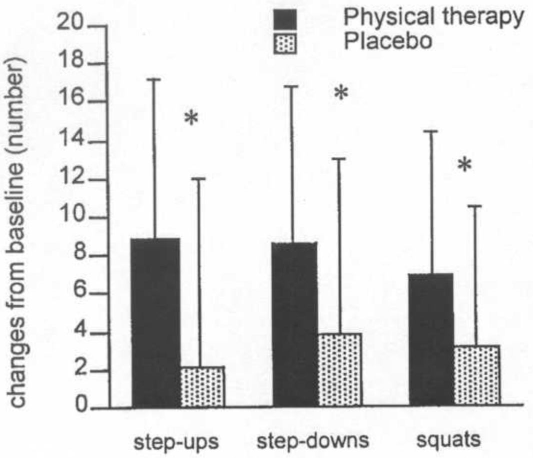

Figure 2. Difference in functional activities between baseline and follow-up for each group. The asterisks indicate $P < 0.05$.

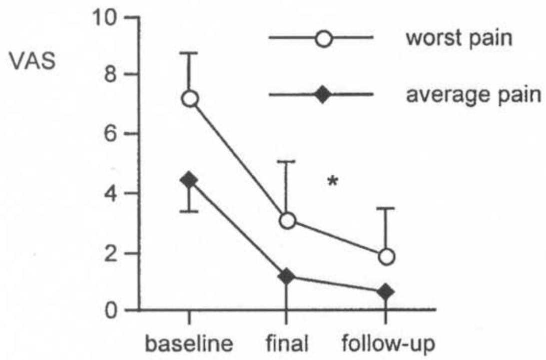

Figure 3. Follow-up of worst pain and average pain among patients in the physical therapy group. The asterisk indicates $P < 0.05$. VAS, visual analog scale score.

and average pain are presented in Figure 3. Four participants continued to have physical therapy treatment, 9 continued to tape, and 13 were continuing their exercises.

DISCUSSION

Despite the widespread use of physical therapy treatment for patellofemoral pain, there is no systematic review or randomized controlled trial to support the use of this intervention. This trial demonstrated that treatment of patellofemoral pain with a 6-week physical therapy program was efficacious. Participants were treated individually with standardized programs. Beneficial effects significantly greater than that of the placebo regimen were found for pain, disability, impairment, and perceived response to treatment. The magnitude of the effect was large for pain and for most disability scales. In addition, beneficial results were observed for three of the secondary outcome measures, number of step-ups, step-downs, and squats performed before pain onset or increase, with moderate effect sizes. These results support the use of this program of physical therapy for reducing short-term pain and disability for patients with patellofemoral pain.

Limitation of physical activity levels and reductions in health-related quality of life may be reasons for patients to visit a sports medicine practitioner. The failure to find differences between the physical therapy and placebo treatment groups in these secondary measures may indicate that physical therapy has no effect on health-related quality of life or physical activity levels. Conversely, it may be that these generic outcome measures are not sufficiently responsive to change in a group of patients with patellofemoral pain. In addition, the sample size was calculated to determine the effect of treatment on pain and, therefore, may have been underpowered to detect differences in these secondary measures.

Because there is no standard measure with which to assess the outcome of trials for patellofemoral pain, a number of outcome measures were selected. Additionally, the threshold effect size for minimal clinical importance in patellofemoral pain has not been determined for these measures. For osteoarthritis, an effect size of 0.5 has been described as the threshold[49] and a change of 0.5 cm on a 10-cm visual analog scale is described as the minimal clinically important difference.[4] According to these criteria, the beneficial effects in this trial were clinically relevant.

The physical therapy treatment was designed to improve patellar tracking through a number of components. Potential dysfunction in motor control was addressed though retraining of the vasti muscles in general and the vastus medialis oblique muscle in particular by using surface EMG biofeedback during treatment sessions. Previous case series have demonstrated that surface EMG biofeedback can enhance vastus medialis oblique muscle activation compared with the vastus lateralis muscle among patients who have patellofemoral pain[51] and improve patellofemoral joint alignment in healthy participants.[24] These case series provide preliminary evidence to support the use of surface EMG biofeedback in treatment to alleviate patellofemoral pain. The exercises were selected to incorporate the motor control retraining into functional activities by using a standardized progression. Other techniques were also employed to assist in improving patellar tracking. Patellar taping was included for all participants to improve patellar alignment, to reduce pain, to stimulate vastus medialis oblique muscle activation, and to provide feedback to the neural control centers.[12]

The cause of patellofemoral pain is currently thought to be multifactorial. One hypothesized contributing factor is altered alignment or tracking of the patella. However, patellar tracking was not assessed in this trial because there are no reliable clinical measures. Therefore, although the intervention in this trial was efficacious for the alleviation of patellofemoral pain, it is not known whether altered patellar alignment or tracking was initially present in the patients in the physical therapy group or whether the intervention affected patellar tracking.

The results of this trial may be applied to a population with a clinical diagnosis of insidious onset patellofemoral pain. The predominance of women and the age range (12 to 40 years of age) of participants in this trial reflect the characteristics of the population that is likely to experience patellofemoral pain. The duration of this program concurs with that of routine clinical practice and that of previous trials.[16,22,53] The physical therapy treatment regimen in this trial was standardized but still maintained many features of routine clinical practice. The lack of individual protocols was balanced by the use of a reproducible program. It is possible that a greater effect could have been achieved if a physical therapy program had been tailored to account for individual variation.

The inclusion of multiple components in the physical therapy intervention reflects standard clinical practice. However, evaluation of this complex treatment regimen does not enable conclusions to be drawn on the relative benefits of the various components. Future studies could focus on the effects of individual treatment constituents on patellofemoral pain, especially when identification of clinical classifications is improved. Classification will enable the practitioner and researcher to identify subsets of patients with patellofemoral pain who have specific deficits (such as motor control or bony malalignment). Then more specific treatments can be designed and evaluated for these subsets of patients.

The results of this trial cannot be compared with those of other studies because a placebo-controlled trial has not been previously performed. The four controlled clinical trials that investigated variations of similar physical therapy interventions for patellofemoral pain have been recently reviewed.[11] These trials essentially compared one physical therapy intervention with another, and none fulfilled all of the requirements for a randomized controlled trial.[9,16,22,32] Inconsistencies in the results of these trials may reflect disparity in the rigorous nature of the trial methods.

The significant but weak correlation that we found between age and response to treatment concurs with the findings of Kannus and Niittymaki.[30] This suggests that age, in the range measured, is unlikely to play a major role in determining the outcome of treatment. In addition, the results of this trial suggest that other participant characteristics do not reliably predict treatment outcome.[30] Although baseline pain and disability as potential predictors of outcome have not been evaluated in previous studies, the weak correlation that we found contributes minimally to the understanding of treatment response.

This study did not include a controlled follow-up period, and, therefore, no conclusions can be drawn about the long-term benefits of physical therapy. It was perceived that a short intervention period (6 weeks) with the guarantee to those in the placebo group of immediate crossover to the physical therapy treatment would enhance participant recruitment and prevent undue attrition from the placebo group. Because of the short intervention and observation periods, one cannot infer that the positive effects of physical therapy seen at 6 weeks will lead to prolonged improvements. The results of the uncontrolled follow-up of patients in the physical therapy group suggest that the beneficial effects will be maintained, with no adverse effects developing over time. However, because there was no placebo group to compare with, it is possible that the beneficial effect represents spontaneous improvement unrelated to the treatment. Further controlled studies with longer observation periods are required to establish whether physical therapy interventions result in long-term improvement of symptoms.

There are several other methodologic issues that warrant consideration. Blinding was not completely successful; 9% of the physical therapy group and 27% of the placebo group responded that they thought they had been assigned to the placebo group. Furthermore, in a physical therapy trial it is impossible to blind the treating therapists, which can account for overestimation of an effect by up to 17%.[44] However, the effect size for most of the outcome measures was large, and these potential biases are unlikely to have affected the conclusions. Four participants (three in the physical therapy and one in the placebo) were lost to follow-up, but analyses of best case (participants received the best score) and worst case (participants received the worst scores) did not alter the results.

In conclusion, this randomized, double-blinded, placebo-controlled trial provided evidence to support the use of a physical therapy regimen in the short-term management of patellofemoral pain. Further studies could focus on the long-term benefits of physical therapy for this condition and the relative effectiveness of this treatment regimen compared with alternative approaches.

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