Physiotherapy, Including Quadriceps Exercises and Patellar Taping, for Knee Osteoarthritis with Predominant Patello-Femoral Joint Involvement: Randomized Controlled Trial

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ABSTRACT. ***Objective.*** To design and carry out a randomized controlled trial of a complex, physical therapy based intervention for patello-femoral joint (PFJ) osteoarthritis (OA) of the knee, examining medium to longterm outcomes.

Methods. The participants, who had knee pain and predominant PFJ OA, were recruited from a large population based study. The study design was a controlled trial using prerandomization and a blind observer, comparing the intervention package with standard nonphysiotherapy treatment. The physiotherapy intervention was delivered in local community health centers and clinics and comprised education, quadriceps and functional exercises, and patellar taping delivered by a single physiotherapist in nine 30-minute sessions over 10 weeks, with advice to continue thereafter. The outcome measures were pain in the worse knee by 100 mm visual analog scale score, the disability domain of the Western Ontario and McMaster University OA index (WOMAC), and quadriceps muscle strength by maximum voluntary contraction.

Results. Eighty-seven patients were recruited to the study, 43 were randomized to the treatment arm. At 5 months post-baseline (10 weeks post-treatment) the treatment group had a small decrease in pain and a significant increase in quadriceps strength of the index knee. After one year there were no significant differences in any outcome measure, most of which had returned towards pretreatment levels.

Conclusion. The treatment package produced small improvements in knee pain scores and quadriceps muscle strength 10 weeks after the end of the treatment period. There was no difference between the 2 groups at 12 months. (J Rheumatol 2003;30:1311–7)

Key Indexing Terms:
KNEE OSTEOARTHRITIS EXERCISE PHYSIOTHERAPY
RANDOMIZED CONTROLLED TRIAL PATELLO-FEMORAL JOINT

To practice evidence based medicine we need good evidence. The randomized controlled trial (RCT) is the accepted gold standard to determine whether an intervention is effective. Knee pain is one of the most common presenting complaints in family practice, and the most common cause of knee pain in older people is osteoarthritis (OA)[1]. OA of the knee is an example of a condition that is frequently treated by physical therapy with or without drugs. Current guidelines on the management of knee OA suggest that interventions such as physical therapy and quadriceps exercises should be used as first-line therapy[2,3]. However, considering the prevalence of the problem and the potential costs of this approach to the community, the evidence base to support these guidelines has been limited. The European League Against Rheumatism (EULAR) recommendations for the management of knee OA also propose exercise as a first-line therapy for knee OA[4]. However, this recommendation was based on only 4 controlled trials and there are still only a small number of good quality published trials examining the effectiveness of a variety of different exercise therapies for knee OA[5-14]. Many other reported studies have been flawed by lack of randomization, control group, or blinded assessment, and most have only short-term followup. Two systematic reviews report the results for these trials as well as providing descriptions of the interventions, assessment of methodological quality, and standardized effect sizes[15,16].

The heterogeneity of knee pain and knee OA causes further problems. The evidence base comes mostly from patients recruited from secondary care rather than the

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community, and concentrates on tibiofemoral joint (TFJ) OA. However, people with knee pain in the community are likely to differ from those who access secondary care. In addition, it has been shown that patello-femoral joint (PFJ) OA is as common as TFJ OA in the population at large[17], and this form of OA may respond to specific forms of treatment, such as patellar taping, that do not affect TFJ OA[18]. As the quadriceps mechanism works through the PFJ, it is also possible that physical therapy aimed at strengthening the quadriceps muscles may have different effects on people with dominant TFJ or PFJ OA.

We have designed and carried out a RCT of a commonly used physiotherapy package (patellar taping, functional exercises, education, quadriceps strengthening exercises, postural advice, and education) for PFJ OA[17] that attempts to avoid the methodological problems inherent in most trials of physiotherapy, while providing longterm followup data.

MATERIALS AND METHODS

Ascertainment of patients. Patients were recruited from a large community cohort study (SASH)[19] that was set up to estimate future health care requirements for a large district. We selected participants with both chronic knee pain and radiographic evidence of predominant PFJ involvement, without advanced TFJ changes and without hip disease.

Participants from the original SASH cohort who reported chronic knee or hip pain to a postal questionnaire were invited to attend for radiographs, including anteroposterior (AP), lateral, and skyline views of the knee joint, and AP views of the pelvis. These radiographs were read by 2 observers who graded them for knee and hip OA using the Kellegren and Lawrence (K&L) system[20], and for the presence or absence of PFJ osteophytes[21]. Those identified with both chronic knee pain and PFJ osteophytes in the absence of advanced radiographic changes of hip or TFJ OA (Grade 3 K&L score and above) were subsequently contacted by letter and telephone and invited to take part in this nested study. At that point those who were no longer in pain, had previously received patellar taping, or were currently receiving treatment from a physiotherapist for knee problems were excluded. Patients were also excluded if they had previous major knee surgery, fractures involving the knee joint or rheumatoid arthritis.

At the baseline visit all patients had a half-hour discussion with the physiotherapist concerning diagnosis, prognosis, footwear, weight reduction, and activity. General exercise was encouraged but no specific quadriceps exercises were advised.

Randomization, consent, and ethics. A modification of Zelen's method was used with a 2 stage consent procedure[22]. In the first stage, study entry, all patients were asked to provide consent for a one-year observational study examining the relationship between pain, disability, and muscle strength in knee OA. In the second stage, randomization into treatment and control groups was organized by computer generated random numbers in blocks of 6. After the initial baseline visit, sequentially numbered opaque sealed envelopes containing the allocation were opened by the treating physiotherapist. Those patients randomized to the treatment group were contacted by telephone and invited to take part in a trial of supervised physiotherapy. If they agreed, they were asked to provide a second consent. No attempt was made to influence any other treatment received by either group. Patients in the control group were not informed of their allocation or that they were in a trial. Patients were assessed individually at all followup visits to limit casual contact between treatment and control groups. Five local research ethics committees approved the study design.

Intervention. All treatments were carried out by a single physiotherapist. Patients who were randomized to the active treatment group underwent a second assessment by the physiotherapist lasting roughly 1 hour, followed by 9 sessions over a 10 week period lasting half an hour each and carried out in community settings such as local health centers and clinics. An initial assessment included observations of patellar alignment, gait, and postural abnormalities. The intervention was a package of physiotherapy-delivered treatments for patients with knee OA that were in common use in the local area at the time of the study. The subsequent 9 treatment sessions consisted of patellar taping, 7 exercises, posture correction, and footwear advice.

Physiotherapy. The exercises included: (1) vastus medialis oblique (VMO)[23] muscle contractions in sitting position (squeezing a rolled-up towel between the knees); (2) exercise 1 with gluteal muscle contractions at the same time; (3) controlled sitting to standing squeezing a rolled-up towel between the knees to encourage contraction of the VMO muscle; (4) controlled small knee bends squeezing a rolled-up towel; (5) controlled stepping up and down steps emphasizing contraction of the VMO muscle and correct posture; (6) 10 maximal isometric quadriceps contractions in mid-range (roughly 70°) using a resistive rubber band; and (7) controlled balancing on one leg for as long as possible. All exercises were tailored to the patient's ability to perform them without pain, e.g., they started the exercise sitting at a height they could stand up from without experiencing pain. Exercises were progressively modified by doing lower knee bends, standing up from lower chairs, and stepping up and down from higher steps.

All exercises were to be pain-free and performed 10 times each, 5 times a day, except for exercise 6, which was to be performed once each day.

All patients started their exercise regime using an electromyographic biofeedback machine to help them recognize and monitor VMO contractions.

Patellar taping, postural, footwear, and weight reduction advice. Initially all patients were asked to perform an activity that produced their pain (e.g., getting out of a chair), medial patellar taping was applied[18], and an immediate assessment was made by repeating the same activity and asking the patient if their pain had changed. If there was less than a 50% improvement, the tape was adjusted to obtain optimal pain reduction. If there was no improvement in pain, the tape was not used. At subsequent sessions patients were taught how to apply the tape and how to prevent skin problems developing. They were told to wear the tape only if it was effective in reducing their pain. Posture correction emphasized the correct alignment of the lower limb in standing and during activity. Footwear advice concentrated on wearing shoes that provided shock absorption and supported the medial arches. Weight reduction was advised for overweight patients. All patients were given an information sheet and encouraged to continue with the exercises after the formal period of supervised therapy.

Outcome measures. The predefined primary outcome measures were overall pain in the most painful knee during the previous month measured on 100 mm visual analog scale (VAS), and self-reported disability assessed by questionnaire using the Western Ontario and McMaster University OA index (WOMAC) function sub-score (Likert scale)[24], range 0–68. Secondary outcome measures included the assessment of quadriceps strength by maximum voluntary contraction (MVC), measured using a standard technique[25]. The patient sat with arms crossed in front of the chest and with hip and knee joints flexed to 90°. An adjustable seat belt was fastened across the hips to prevent the tendency of the hip joint to extend when the quadriceps contracted. The maximum reproducible extension force that could be sustained for 0.5 s [MVC force, measured in Newtons (N)] was recorded at ankle level with a precalibrated high precision 1 kN load cell, amplified via a high-gain strain gauge amplifier interfaced to a computer. The output from the strain gauge amplifier was also displayed on a digital voltmeter, which the patients could observe during their efforts in order to obtain immediate feedback. The external lever arm from the tibiofemoral joint space to the center of the lateral malleolus was measured to ensure identical positioning of the ankle strap on subsequent occasions and to enable calculation of the extensor moment of force generated at the knee joint in Newton meters (Nm). Depending on fatigue and tolerance of the test, 3 to 5 attempts at generating an MVC (with 1 min rest in between) were usually required to ensure that values were reproducible, with varia-

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tion < 10% where possible, and the peak value obtained was used in the analysis.

Assessments were made in both treatment and control groups immediately prior to treatment and at 5 and 12 months from baseline. The first post-treatment assessment was about 10 weeks after treatment had finished.

Statistical analysis. Data were analyzed on an intention-to-treat basis with the last observation carried forward when data were unavailable. Results are presented as means with standard deviations. Between-group differences at each followup time point were compared using analysis of covariance (ANCOVA), with baseline measures as covariates to account for any random baseline variability between the groups. Reported p values, effect sizes, and 95% confidence intervals (CI) for between-group differences were derived from the ANCOVA.

We estimated that a sample of 50 patients per group would be required to measure a difference of 30% between the groups in terms of VAS pain, with a power of 90% and an alpha of 0.05.

RESULTS

Identification of suitable patients from the SASH cohort. The baseline population of the SASH study comprised 26,046 individuals; 88.2% replied to the initial screening questionnaire, 1519 attended for a detailed interview and for hip and knee radiographs, and 348 of these had the pattern of radiographic changes described above. Only 178 of these had reported knee pain rather than hip pain at the time of the initial SASH consultation and were also available for contact for this treatment trial.

Invitation to participate and exclusions. The patient pathway summarizing the further recruitment process is shown in Figure 1. We contacted 178 patients by letter; 24 did not reply, 24 declined to participate, and 46 were excluded for reasons listed in Table 1. We recruited 84 patients from the SASH cohort and 3 patients from rheumatology clinics, of whom 43 were assigned to the treatment arm and 44 to the control group.

The baseline demographics are shown in Table 2. Baseline levels of pain, disability, and quadriceps strength were similar to those found in other cohorts of people with knee OA[12].

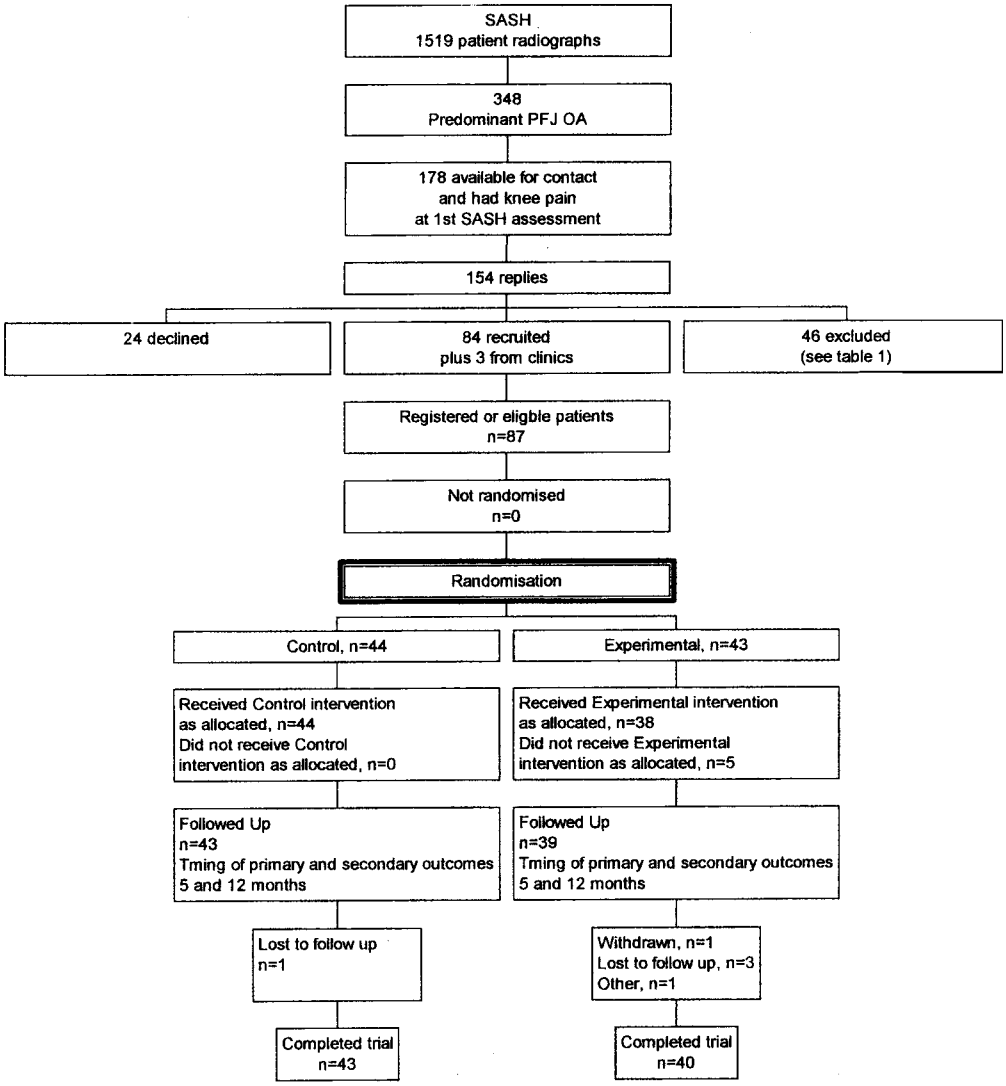

Figure 1. Patient recruitment.

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The randomization procedures did not result in any dropouts, although 5 patients in the treatment group did not subsequently receive the full intervention as allocated and one person in the control group was also lost to followup. By the end of the study 8 people had inadvertently revealed their allocation status during the trial, all of whom were in the treatment group. At the end of the study, but before unblinding, the assessor attempted to guess the allocation of the remaining 79 patients. The guesses were only correct in 43 cases (i.e., no better than chance), indicating that allocation concealment had been successful for the majority.

Outcome measures. The primary outcomes are shown in Table 3 and Figure 2. At 5 months from baseline, there was a 16% decrease in knee pain in the treated group, from 51 mm to 42.8 mm compared with a 7.5% decrease in the control group, from 53.4 mm to 50.5 mm. Comparisons for knee pain at either followup time point did not show statistically significant differences between the groups and the estimated treatment effect size is small at 0.2 of a standard deviation (at 5 months: –6.4 mm, 95% CI 15.3 to 2.4, p = 0.16; at 12 months: –4.9 mm, 95% CI 13.6 to 3.8, p = 0.27). There were no significant between-group differences in disability at any time. There was a significant increase in quadriceps strength in index knees in the treatment group compared to the control group at 5 months (+11.7 Nm; 95% CI 4.5 to 19.0, p = 0.002). At 12 months the difference was no longer significant and quadriceps strength was returning towards pretreatment levels (+7.8 Nm; 95% CI 0.9 to 16.6, p = 0.08).

There were no major side effects associated with the treatment, but 7 patients in the physiotherapy group experienced mild and short-lived skin reactions associated with prolonged use of the zinc oxide patellar tape.

Table 1. Reasons for exclusion.

n	Reason for Exclusion
24	No longer had knee pain at time of contact
3	Had recently seen physiotherapists for their knees
3	Previously treated by patellar taping, 2 currently using the technique
3	Previous knee surgery (2 meniscectomy, 1 patellar realignment)
3	Rheumatoid arthritis
3	Too disabled or ill too attend
2	Previous fractures involving the knee
1	Unable to take time off work
2	Expressed interest but replied too late to take part in the recruitment phase
2	Could not be contacted again although replied positively to first letter

DISCUSSION

Knee pain and disability associated with PFJ OA is very common, and is largely treated in primary rather than secondary care. Physiotherapy, which can include patella taping and VMO exercises, is a recommended treatment for knee OA, but there is limited RCT based evidence to support the recommendation. We believe that this is largely because of the difficulty in applying RCT methodologies developed for drug therapies to complex physical therapy programs.

There are important differences between our study and others, which have been adopted to avoid these methodological difficulties and to enable generalization of the results to this very common group of patients. These differences relate to the target population and the randomization and allocation procedures.

Patients for this study were recruited from the community and not from hospital based practice. We recognize that while results from hospital based cohorts may not be generalizable, our approach does run other risks. This community-derived group may not be representative of those patients who usually receive physiotherapy care. They were not seeking healthcare and many may not have previously sought help for their problems; the perceived severity of symptoms probably influences compliance with exercise regimes.

Although the approach has not been widely adopted, we also believe it is important to differentiate between the 2 major forms of knee compartment involvement. The 2 compartments are anatomically and functionally distinct and PFJ involvement by OA is more prevalent than TFJ involvement, particularly in women with knee pain[17].

The other major difference between our study and others

Table 2. Baseline data for demographics and main outcome measures.

Variable	Treatment Group Mean	Treatment Group SD	Control Group Mean	Control Group SD	95% CI
Age, yrs	66.8	9.5	66.7	11.2	–4.3, 4.5
Height, m	1.63	0.1	1.61	0.1	0.0, 0.1
Weight, kg	80.5	15.4	78	15.9	–4.2, 9.2
Body mass index, kg/m^2	30.2	5.2	30	6.2	–2.2, 2.6
VAS index knee, mm (0–100)	51.0	29.3	53.4	25.9	–14.0, 9.3
WOMAC function score (0–64)	27.4	12.2	27.8	10.1	–5.1, 4.3
MVC index knee, Nm	75	37.1	84.8	48.4	–27.9, 8.4

MVC: maximum voluntary contraction.

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Table 3. Main outcome measures.

Outcome Measure	Time Point, mo	Treatment, mean (SD)	Control, mean (SD)	Adjusted Difference Between Means*	95% CI*	p*
VAS pain index knee, mm	0	51.0 (29.3)	53.4 (25.9)	–2.3	–14.0, 9.3	
	5	42.8 (25.1)	50.5 (25.6)	–6.4	–15.3, 2.4	0.16
	12	48.1 (25.7)	54.1 (22.5)	–4.9	–13.6, 3.8	0.27
Womac function, scale 0–68	0	27.4 (12.2)	27.8 (10.1)	–0.4	–5.1, 4.3	
	5	26.5 (13.2)	27.5 (10.7)	–0.6	–3.7, 2.4	0.68
	12	29.7 (11.2)	28.3 (11.3)	1.7	–1.8, 5.2	0.34
MVC index knee, Nm	0	75.0 (37.1)	84.8 (48.4)	–9.8	–27.9, 8.4	
	5	82.9 (37.2)	79.4 (42.6)	11.7	4.5, 19.0	0.002
	12	73.0 (37.4)	73.2 (44.3)	7.8	–0.9, 16.6	0.08

* Difference between means; confidence intervals and p values are derived from ANCOVA.

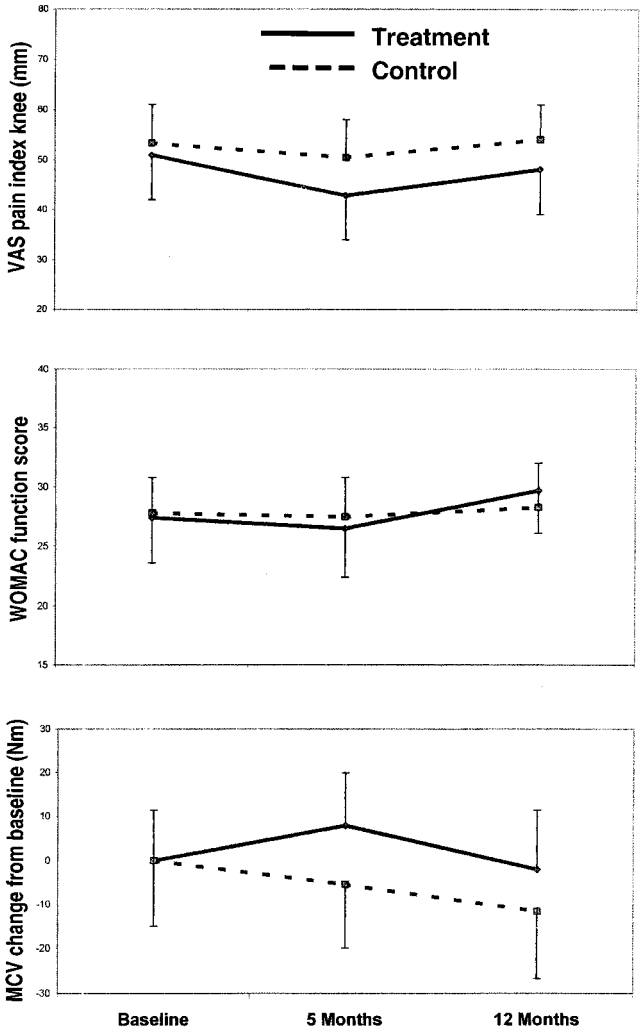

Figure 2. Results of main trial outcome measures (mean and 95% CI); pain in the index knee (100 mm VAS), WOMAC function score (range 0–68), and change in quadriceps maximum voluntary contraction from baseline (Nm).

was the randomization and allocation procedure. Conventional randomization to an untreated group in RCT of physical therapy may risk the control group either withdrawing from the study or modifying their behavior in unpredictable ways, either by doing their own exercises or seeking therapy elsewhere. To reduce this risk we used a blind observer and a modification of Zelen's procedure so that the control group was unaware of their participation in the trial. Zelen's design is controversial and has been criticized by some as unethical, particularly in the context of drug trials[26], but others have proposed this design as a potential solution to trial recruitment difficulties[27]. No patients withdrew from this trial as a result of the randomization and allocation procedures and the design was effective in terms of maintaining the blinding of the assessor, who was unable to distinguish between those allocated to the control or treatment groups.

However, there are other important differences between this trial and the true clinical setting that may limit the degree to which these results can be generalized. In practice, patients would be treated by different physiotherapists whereas we used only one. In addition, physiotherapists tailor treatments to individual patients rather than adhering closely to a prescription and are likely to treat patients for fewer sessions.

Our study found only small and transient changes in pain and quadriceps strength over the longer term and it could be debated whether these treatment effects are of clinical significance. It can be difficult to make direct comparisons between our results and other studies examining response to physical therapies in knee OA because of the different methodologies used. However, these findings are in general agreement with the effect sizes for pain reported in a recent large community study of home-based exercise therapy[28], and others have found a similar reduction in treatment effect at 9 months from baseline in a more intensive program[29].

Recruitment fell a little short of targets based on power calculations derived from published studies available at the time the study was designed. However, *post hoc* power calculations suggest that about 250 patients would be

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required in each group to avoid type 2 errors with a treatment effect of this size, so the small shortfall from target that we experienced is unlikely to be of critical importance. Future research should take these effect sizes into account during study design.

There was a large variation in response: some treated patients responded particularly well, in contrast to the overall modest effect size, compared to published trials of drug therapy for knee OA[30].

Results of other longitudinal exercise therapy studies suggest that there may have been a greater response in the immediate post-treatment period during which we did not collect data[5,6,13,14,18]. We suggest that all future studies should look at a longer time period as well as immediately post-treatment.

We have taken into consideration the radiographic severity of different knee compartments and recruited a group with predominant PFJ OA. This approach has not been widely used and makes comparisons difficult. It seems likely that participants in other trials had more TFJ OA. It is worth considering whether TFJ OA actually responds better to this type of treatment package than OA. This may initially seem contrary to theories about muscular control of patellar movement. However, perhaps severe involvement of the PFJ limits the response to taping and exercise therapy from which patients with more isolated TFJ involvement can benefit. It is also possible that different specific exercises or taping methods might be more effective.

It is worth commenting that patello-femoral pain can also occur in younger patients who do not have radiographic evidence of OA. It is interesting that one study of such patients has reported that adding patellar taping to quadriceps exercise therapy did not improve outcomes[31].

A major aspect of most exercise interventions is the advice given to continue with exercises after the formal treatment period. Very little is known about adherence to exercise therapy, but as most outcome measures returned to pretreatment levels after 12 months, this suggests that most of those in the intervention group may not have continued with the exercise regime. This aspect of the intervention was explored by qualitative methods[32]. It is also worth commenting that comparison of the qualitative and quantitative data on a subgroup of these patients showed marked discrepancy between the 2 forms of assessment in a significant number of patients[33], suggesting that using quantitative data alone may not reflect the full benefit of such treatment package.

We measured the longterm benefits of a physiotherapy-delivered package including quadriceps exercises, patellar taping, and educational advice on pain and quadriceps strength for community patients with predominant PFJ OA by means of a RCT. The measured benefits were of small magnitude and were transient. The crucial question is whether these small changes justify using physical therapy to treat the large numbers of patients with this problem in the community. It seems that repeated treatment sessions over long time periods may be required to maintain longterm benefits and this aspect deserves scrutiny. Larger studies will be needed to determine whether these observed changes are more than just chance occurrences and whether a greater treatment response would be seen in the short term, and consensus is needed on the degree of change considered clinically meaningful or worthwhile.

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