Effectiveness of home exercise on pain and disability from osteoarthritis of the knee: a randomised controlled trial

Sheila C O’Reilly, Ken R Muir, Michael Doherty

Abstract
Objective—To assess the effect of a home based exercise programme, designed to improve quadriceps strength, on knee pain and disability.

Methods—191 men and women with knee pain aged 40–80 were recruited from the community and randomised to exercise (n=113) or no intervention (n=78). The exercise group performed strengthening exercises daily for six months. The primary outcome measure was change in knee pain (Western Ontario McMaster Osteoarthritis index (WOMAC)). Secondary measures included visual analogue scales (VAS) for pain on stairs and walking and WOMAC physical function scores.

Results—WOMAC pain score reduced by 22.5% in the exercise group and by 6.2% in the control group (between group difference p<0.05, unpaired t test). VAS scores for pain also reduced in the exercise group compared with the control group (p<0.05). Physical function scores reduced by 17.4% in the exercise group and were unchanged in controls (p<0.05).

Conclusion—A simple programme of home quadriceps exercises can significantly improve self reported knee pain and function.

Knee osteoarthritis (OA) is common and contributes greatly to morbidity in the community.1 Treatment is generally aimed at reducing pain and maintaining function. There is increasing interest in the role of various forms of exercise therapy in OA.2 Exercises designed to strengthen the quadriceps muscles are often advocated yet evidence for their effectiveness is lacking. Many of the studies to date are limited by small numbers and lack of controls.4 In addition they have generally used sophisticated and expensive apparatus, which limits their application to a community setting. As hospital based, such studies have focused on preventing exercise. Subjects who agreed to participate were randomised to exercise or control groups: already performing quadriceps exercises, clinical inflammatory arthropathy, pain referred from back or hip, serious injury within six months, previous knee replacement, unable to complete study because of imminent move or hospitalisation, no pain on WOMAC pain score, medical condition preventing exercise. Subjects who agreed to participate were randomised to exercise or to no intervention in a 3:2 ratio. Block randomisation was performed using random number tables and sealed envelopes. Four groups of randomisation were made: men aged 40–59, men aged 60–79, women aged 40–59, women aged 60–79. Subjects were asked to avoid starting new analgesics during the study period.

Assessments
Assessments were performed at baseline and at six months (second assessment). Pain was assessed by the following measures:
1 Self reported total WOMAC pain score5 (0–20, with higher scores indicating more pain)—primary outcome variable
2 Self reported visual analogue score (VAS) for pain—walking on the flat (0–100 mm)
3 Self reported VAS for pain while ascending/descending stairs (0–100 mm)
The following secondary outcome measures were included:

1. Self-reported WOMAC physical function score (0–68, with higher scores indicating more disability).
2. Isometric quadriceps strength measured by a single observer using a modified Tornvall chair.
3. Quadriceps activation, measured by a single observer using twitch superimposition.
4. Self-reported health status using the Anglicised version of the SF-36 health status questionnaire (0–100 for each dimension with higher scores indicating “better health”).
5. Self-reported anxiety and depression, using the Hospital Anxiety and Depression scale (scored 0–21, with higher scores indicating tendency to anxiety and depression).
6. Weight (kg) measured by a single observer.
7. Self-reported analgesic usage per day

The initial assessment was carried out before randomisation into the study. It was not possible for the observer to be blinded to intervention group at the second assessment. In addition to the above assessments, subjects were asked to state at the end of the study whether their knees were; much better, slightly better, the same, slightly worse or much worse. All subjects had radiograph of the knees (AP weight bearing and skyline) obtained after the first assessment. These were graded for maximum osteophyte grade in either compartment (patellofemoral or tibiofemoral) using a standard atlas. All assessments, with the exception of radiographs, were carried out at the local surgeries. Written consent was obtained for the initial assessment. After randomisation, consent was obtained for the intervention (exercise group only) and second assessment (both groups).

INTERVENTION

General advice
A simple verbal explanation concerning knee pain and knee OA was given to all study subjects before randomisation. In addition all subjects were advised on the importance of losing weight or not becoming overweight, wearing training shoes/air filled soles and maintaining fitness by walking or swimming.

Exercise group
A graded exercise programme was devised. Five exercises were included:
1. Isometric quadriceps contraction in full extension held for five seconds (subject sits on floor with back supported and legs extended, with rolled up towel under one knee and contracts quadriceps by pushing into the floor against towel).
2. Isotonic quadriceps contraction held in mid flexion for five seconds (subject sits in a chair, lifts lower leg to partially extended position and holds).
3. Isometric hamstring contraction (subject lies on front or side and bends knee bringing foot towards body).
4. Isotonic quadriceps contraction with resistance band held for five seconds (as for exercise 2).
5. Dynamic stepping exercise (walking up and down one step/stair).

Exercises were started in the above order and increased to a maximum of 20 repetitions on each leg. Exercises were performed at home on a daily basis, having been taught by a nurse metrologist. In addition to the initial visit, subjects were visited on three further occasions (at two weeks, six weeks, and three months) by the metrologist.

Control group
Subjects in the control group did not receive specific intervention and were not visited between assessments.

COMPLIANCE
Subjects were asked to complete a diary documenting the number of exercises performed each day. Compliance was graded into four categories based on the number of exercises performed over the study period.
Table 2  Mean change (with 95% confidence intervals) in global WOMAC pain scores, visual analogue scores for pain on walking and stairs and global WOMAC physical function scores; with corresponding between group differences and 95% confidence intervals (*p between group difference, unpaired t test)

<table>
<thead>
<tr>
<th></th>
<th>Exercise group</th>
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<th>Control group</th>
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<tbody>
<tr>
<td></td>
<td>Mean change</td>
<td>95% CI</td>
<td>% change</td>
<td>Mean change</td>
<td>95% CI</td>
</tr>
<tr>
<td>Global pain score</td>
<td>−1.45</td>
<td>−2.04, −0.86</td>
<td>−22.5</td>
<td>0.42</td>
<td>−1.09, 0.25</td>
</tr>
<tr>
<td>VAS walking</td>
<td>−0.64</td>
<td>−1.09, −0.21</td>
<td>−20.9</td>
<td>0.43</td>
<td>−3.88, 4.74</td>
</tr>
<tr>
<td>VAS stairs</td>
<td>−0.08</td>
<td>−1.53, −2.84</td>
<td>−18.6</td>
<td>1.34</td>
<td>−3.50, 6.00</td>
</tr>
<tr>
<td>Physical function score</td>
<td>−3.55</td>
<td>−5.34, −1.75</td>
<td>−17.4</td>
<td>−0.01</td>
<td>−1.75, 1.72</td>
</tr>
</tbody>
</table>

STATISTICAL ANALYSIS

Data were analysed on an intention to treat basis, irrespective of the degree of compliance with the exercise programme. Differences from baseline were calculated for all primary and secondary outcome variables. Mean differences and 95% confidence intervals (CI) were calculated for all outcome measures. Between group differences were compared using unpaired t tests. Statistical testing for secondary outcome measures was restricted to function and muscle strength. All analyses were performed using SPSS for Windows 6.0 (SPSS Inc).

Results

SUBJECTS

The response rate to the postal survey was 81.9% with 28.7% of subjects reporting knee pain. Four hundred and seventy four of these subjects were telephoned, of whom 131 were pain free at the time of the telephone contact and 43 were unwilling to participate. Of the 300 subjects with knee pain who attended the baseline assessment, 191 subjects were recruited into the intervention study, of which 113 were randomised to the exercise group and 78 to the control group (fig 1). Of the 109 subjects not recruited, 35 were unwilling to participate and 74 were excluded (already performing quadriceps exercises n=24, clinical inflammatory arthropathy n=12, pain referred from back or hip n=12, serious injury in last six months n=7, previous knee replacement n=5, unable to complete study because of imminent move or hospitalisation n=5, pain free (WOMAC score=0) at first assessment n=4, medical condition preventing exercise n=5. One hundred and eighty subjects (94.2%) attended for reassessment; 108 exercisers and 72 controls. The proportion of men and women in each group was similar (exercise group 64.8% women, control group 68.1% women). Table 1 shows other baseline characteristics. Mean values were similar for all data with the exception of activation where standard deviations were wide. Radiographs were obtained on 161 subjects (89.4%) who completed the study. Frequency of subjects with ≥ grade 1 osteophyte (in either knee in any compartment) was high in both groups (75.3% in exercise group, 78.1% in control group). Osteophyte (≥ grade 1) was more common in the patellofemoral compartment (73.9% of subjects) than in the tibiofemoral compartment (52.8% of subjects). Grade 2 osteophyte or above was less common, occurring in 66 subjects (40.9%). Analgesic usage was similar in the two groups. Values were obtained for all outcome variables for each subject and hence the results presented relate to the 108 subjects in the exercise group and 72 subjects in the control groups.

PAIN

Table 2 shows the differences in WOMAC pain scores. Pain scores were reduced by 22.5% in the exercise group and by 6.2% in the control group. The between group difference was statistically significant (p<0.05). VAS assessments for pain (walking on the flat and negotiating stairs) showed a similar trend (table 2).

PHYSICAL FUNCTION

Table 2 shows the results for physical function. WOMAC score was reduced by 17.4% in the exercise group and was unchanged in the control group; the between group difference being statistically significant (p<0.05).

QUADRICEPS STRENGTH AND ACTIVATION

Table 3 shows the differences for right and left isometric quadriceps voluntary strength. Gains in strength were demonstrated in the exercise group with reductions in the control group. Corresponding figures for quadriceps activation were more variable (table 3), but suggested small increases in the exercise group.

HEALTH STATUS

Table 4 shows the results for SF-36 health status dimensions. A trend towards improvements

Table 3  Mean change (with 95% confidence intervals) in voluntary quadriceps strength and quadriceps activation; with corresponding between group differences and 95% confidence intervals (*p between group difference, unpaired t test)

<table>
<thead>
<tr>
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<th>Control group</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Mean change</td>
<td>95% CI</td>
<td>% change</td>
<td>Mean change</td>
<td>95% CI</td>
</tr>
<tr>
<td>Right quadriceps</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quads strength (kgF)</td>
<td>1.09</td>
<td>−0.21, 2.40</td>
<td>4.7</td>
<td>−1.13</td>
<td>−2.54, 0.25</td>
</tr>
<tr>
<td>Activation (%)</td>
<td>4.50</td>
<td>0.00, 9.00</td>
<td>5.7</td>
<td>2.32</td>
<td>−3.99, 8.62</td>
</tr>
<tr>
<td>Left quadriceps</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quads strength (kgF)</td>
<td>0.88</td>
<td>−0.37, 2.12</td>
<td>4.0</td>
<td>−1.63</td>
<td>−3.15, −0.10</td>
</tr>
<tr>
<td>Activation (%)</td>
<td>4.96</td>
<td>0.71, 9.21</td>
<td>6.4</td>
<td>−5.90</td>
<td>−12.07, 0.27</td>
</tr>
</tbody>
</table>
Table 4  Mean change (with 95% confidence intervals) in SF-36 health status dimensions

<table>
<thead>
<tr>
<th>Exercise group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean change</strong></td>
<td><strong>% change</strong></td>
</tr>
<tr>
<td>Physical function</td>
<td>2.68</td>
</tr>
<tr>
<td>Mental health</td>
<td>-0.21</td>
</tr>
<tr>
<td>Energy</td>
<td>2.47</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>9.7</td>
</tr>
<tr>
<td>Health perception</td>
<td>1.93</td>
</tr>
<tr>
<td>Role limitation physical</td>
<td>3.19</td>
</tr>
<tr>
<td>Role limitation emotional</td>
<td>1.85</td>
</tr>
<tr>
<td>Social functioning</td>
<td>1.89</td>
</tr>
</tbody>
</table>

The possibility that improvements in pain and disability may, at least in part, relate to factors other than muscle strength, must be considered. With the exception of muscle strength, outcome measures were self assessed and may therefore, as with all exercise studies, be influenced by lack of subject blinding. It was also impossible for the assessor to be blinded to treatment group in this study. While, as mentioned, this could have influenced assessment of muscle strength, it is unlikely to have had a major effort on the other more important outcome measures. Reduction in levels of anxiety and depression were apparent in the
exercise group. It is not clear whether this was a primary or secondary effect. Contact with a therapist may have had an effect on psychological outlook. Positive effects on pain and disability in OA have previously been reported with telephone contact.²³ Alternatively, self perceived reduction in pain and disability may lead to improved mental health. Such an effect has been demonstrated previously following aerobic exercise.²⁴

Reductions in weight are also apparent in the exercise group. Two small studies have demonstrated a positive effect on symptoms after weight reduction.²⁵ ²⁶ It is possible, however, that this represents a secondary effect because of improvements in physical activity. Analgesic usage is unlikely to account for improvements in pain. Baseline assessments were similar in the groups, and analgesic requirements tended to reduce in the exercise group.

The trend towards greater improvements in pain and function in the subjects most compliant with the exercise programme adds support for strength gain being the key factor. The improvement in WOMAC pain score in the least compliant group is, however, somewhat contradictory. It is possible that these subjects stopped exercising because of clinical improvement. While numbers are small, there is some evidence for this, with 35% of this group reporting improvement, compared with none in the next most compliant group.

Distinguishing between clinical and statistical significance is important in any clinical trial. Levels for statistical significance reached in the current study are borderline. This may in part relate to “placebo effect”, as pain scores were reduced in the control group, an effect that is well recognised in osteoarthritis trials. As baseline measures were similar between groups it would have been possible to analyse within group differences. This would, however, have required additional comparisons with the inherent risk of type I errors. An alternative and perhaps more important influence in terms of statistical outcome is the dispersion of outcome values. Deviations and hence confidence intervals were wide in comparison with previously reported figures in hospital referred populations. As power calculation were based on a slightly lower standard deviation than measured, a power of 80% has not been achieved. Nevertheless for several reasons the result can be regarded as clinically significant. Subjects were highly heterogeneous in terms of age, muscle strength, severity of pain, and radiological change. Overall the population had less pain than in previous studies. In addition this was a simple low cost package of exercise with minimal supervision. A mean reduction in pain of 22% may, in this context, be considered to have clinical importance.

This study has focused on knee pain rather than structural change. Although most subjects did have evidence of osteophytosis, these results may not be generalisable to a population with severe radiographic OA. As pain is the most common reason for seeking medical intervention, however, these results are highly pertinent to the primary care setting.

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