Home based exercise programme for knee pain and knee osteoarthritis: randomised controlled trial

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Abstract

Objectives To determine whether a home based exercise programme can improve outcomes in patients with knee pain.
Design Pragmatic, factorial randomised controlled trial of two years' duration.
Setting Two general practices in Nottingham.
Participants 786 men and women aged ≥45 years with self reported knee pain.
Interventions Participants were randomised to four groups to receive exercise therapy, monthly telephone contact, exercise therapy plus telephone contact, or no intervention. Patients in the no intervention and combined exercise and telephone groups were randomised to receive or not receive a placebo health food tablet.
Main outcome measures Primary outcome was self reported score for knee pain on the Western Ontario and McMaster universities (WOMAC) osteoarthritis index at two years. Secondary outcomes included knee specific physical function and stiffness (scored on WOMAC index), general physical function (scored on SF-36 questionnaire), psychological outlook (scored on hospital anxiety and depression scale), and isometric muscle strength.
Results 600 (76.3%) participants completed the study. At 24 months, highly significant reductions in knee pain were apparent for the pooled exercise groups compared with the non-exercise groups (mean difference −0.82, 95% confidence interval −1.3 to −0.3). Similar improvements were observed at 6, 12, and 18 months. Regular telephone contact alone did not reduce pain. The reduction in pain was greater the closer patients adhered to the exercise plan.
Conclusions A simple home based exercise programme can significantly reduce knee pain. The lack of improvement in patients who received only telephone contact suggests that improvements are not just due to psychosocial effects because of contact with the therapist.

Introduction

Knee osteoarthritis contributes greatly to disability in the general population, particularly in the elderly.[1 2] Pain is the principal feature of knee osteoarthritis, but it is well recognised that severity of pain equates poorly with radiographic and structural change.[3 4] Drug treatments aimed at relieving pain are often limited by side effects. Physiotherapy is often recommended, although until recently relatively few studies confirmed its efficacy. Most successful physiotherapy approaches incorporate exercises to strengthen quadriceps. Many of these programmes, however, have employed intensive supervision and sophisticated equipment.[5 6] Since knee osteoarthritis is a considerable public health issue, a less expensive community based approach would be desirable. Previous studies have focused on radiographically defined knee osteoarthritis rather than knee pain.[7 8] In the early stages of disease, when exercise intervention may be most appropriate, however, radiographs may be normal. We have shown previously that a simple six month exercise programme can reduce knee pain.[9] This study assessed relatively short term outcomes, however, and it did not control for social contact from the therapist, which may itself have a positive effect on pain reporting.[10]

We aimed to assess whether a home based exercise programme lasting two years could reduce knee pain and improve physical function in people with knee pain. We also aimed to determine the relative contribution of contact with a therapist in explaining these health outcomes.

Methods

Participants

A postal survey was sent to 9296 patients aged 45 and over registered at two general practices in Nottingham. Patients were defined as having knee pain if they responded "yes" to both of the following questions: "Have you ever had pain in or around the knee on most days for at least a month?" and "If so, have you experienced any pain during the last year?"[11] Participants with knee pain were invited to an initial assessment. The following exclusion criteria were applied: total knee replacement, lower limb amputation, permanent cardiac pacemaker, unable to give informed consent, and no knee pain within the last week.

The protocol was approved by local hospital research ethics committees, and all participants provided written informed consent.

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Interventions

The two year exercise programme was simple to use and applicable for all age groups. It was designed to maintain and improve the strength of muscles acting around the knee, the range of motion at the knee joint, and locomotor function. The programme was self paced but became progressively more challenging. Graded elastic bands were used to increase the resistance against which the muscles worked. The programme was taught in the participants' homes by a trained researcher. The initial training phase consisted of four visits lasting approximately 30 minutes in the first two months, with follow up visits scheduled at six monthly intervals. Participants were encouraged to perform the programme with both legs for 20-30 minutes a day. They were instructed to increase the number of repetitions up to a maximum of 20 per leg. Adherence was assessed by means of self completed diaries, which were collected every six months.

Telephone contact consisted of monthly calls all made by the same researcher. The principal aim of the calls was to monitor symptoms and to offer simple advice on the management of knee pain. This intervention provided a control for the psychosocial contact inherent in delivery of the exercise programme. For those participants who received telephone contact and exercise therapy, discussion of the exercise programme was discouraged and specific problems were referred back to the therapist responsible for teaching the programme. Calls typically lasted about two minutes.

Participants in the control group (no intervention) received no contact between assessment visits.

Outcome measures

The primary outcome measure was self reported knee pain at two years. This was measured using the knee specific questionnaire of the Western Ontario and McMaster universities (WOMAC) osteoarthritis index. This has three domains: pain, stiffness, and physical function.[12] The pain domain produces a score of 0-20, with higher scores indicating more pain.

Secondary measures consisted of change in knee specific stiffness (0-8) and disability (0-68) (WOMAC), general physical function (anglicised SF-36),[13] psychological score (hospital anxiety and depression scale),[14] and isometric quadriceps muscle strength (measured with a modified Tornvall chair in participants from one practice).[15] Economic data were also collected and will be reported separately.

Radiographic osteoarthritis was defined by the presence of definite osteophyte in either compartment of at least one knee, as determined with a standard atlas.[16]

Randomisation and blinding

Participants were randomised with a factorial design based around the two main factors for evaluation—exercise and contact with a therapist. They were allocated to one of four groups: exercise therapy, monthly telephone contact, exercise therapy plus telephone contact, or no intervention. As this was a long term study, we were concerned that some patients in the no intervention control group would lack motivation to remain in the study. As a result, participants allocated to the no intervention and combined exercise and telephone groups were further randomised to receive or not receive a placebo tablet (dolomite) twice a week. Dolomite is a health food product containing calcium and magnesium and is normally taken at a dose of three tablets per day. Even at its full dose, no benefit in arthritis has been proved.

Randomisation was achieved by means of computer generated lists in permuted blocks of 10, stratified by sex and age. As participants were enrolled in the study, the study administrator added them to the list in sequential order. More participants were randomised to the groups involving exercise to allow for a predicted high dropout rate in these groups. Participants were assessed every six months for two years. The assessor was blinded to the intervention group and was the same for each assessment.

Statistical analysis

We aimed to recruit 800 participants—the number calculated to detect a 20% change in the primary outcome measure with greater than 90% power at the 5% significance level. Analysis was performed on an intention to treat basis, with data carried forward from the last available assessment unless values were missing at the first assessment.

All analyses were performed with SPSS version 9.0.0. We used a factorial analysis of variance model to assess changes in self reported knee pain at two years and number needed to treat to assess the clinical significance of these findings.[17 18] A clinically significant improvement was defined as a reduction in pain $\geqslant$50%. As number needed to treat is known to be highly sensitive to baseline values, the odds ratio is also presented.

Results

In total, 786 participants were recruited between January 1996 and January 1997. Follow up was completed in January 1999. Recruitment and progress through the study are summarised in the figure. Characteristics and baseline measures are shown in table 1; no statistically significant differences were seen between the groups.

Overall, 600 (76.3%) participants completed the study and returned for final assessment at 24 months (figure). A further 83 (10.6%) participants who withdrew from the interventions completed a postal questionnaire at 24 months. These participants were more likely to be aged over 75, have higher baseline pain scores, and be randomised to one of the groups involving exercise.

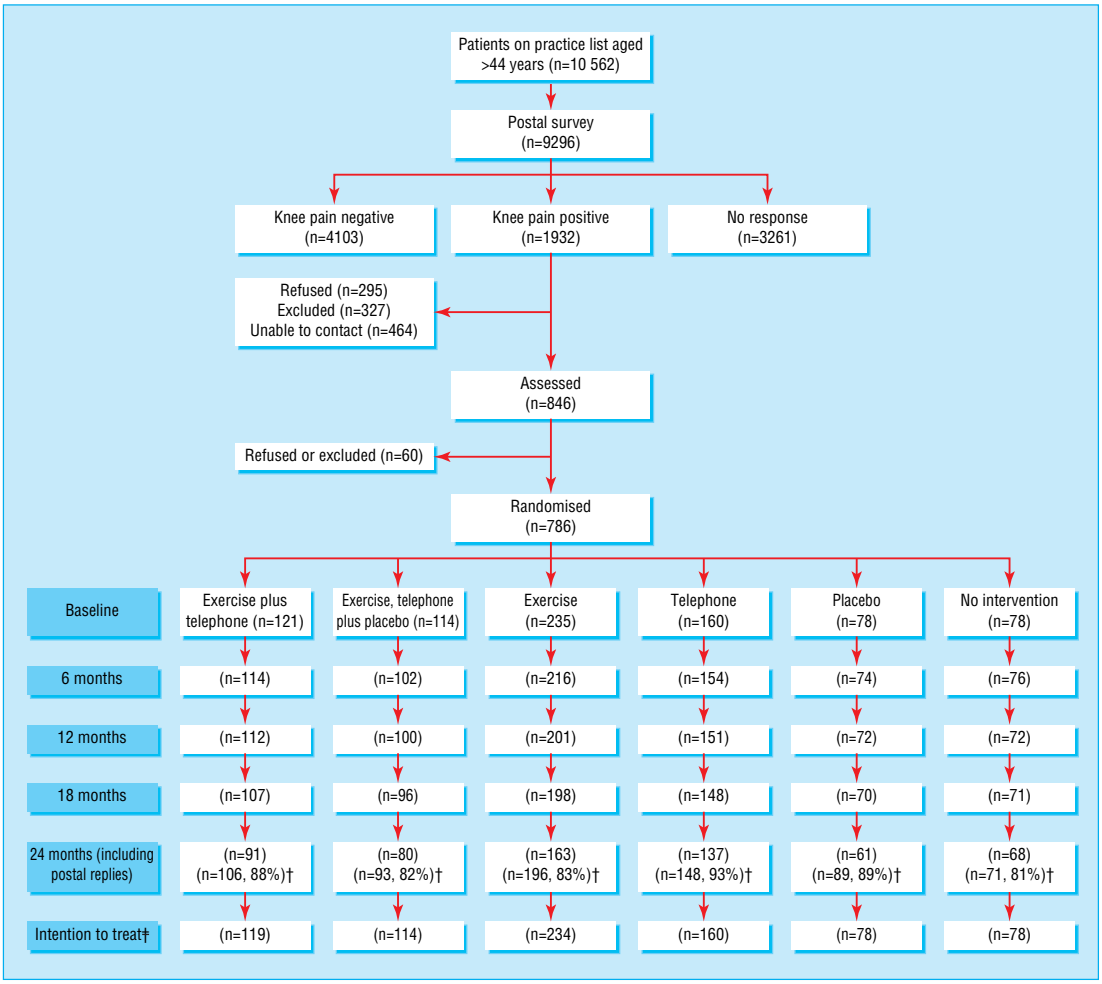
Factorial analysis

No significant differences were found between the groups that did and did not receive the placebo intervention (no intervention *v* placebo, P=0.66; exercise plus telephone *v* exercise, telephone, and placebo, P=0.94). These subgroups were therefore merged, and the analysis performed on the original four groups. The validity of this decision was tested with a sensitivity analysis.

Primary outcome

At 24 months, the exercise groups differed significantly from the non-exercise groups (table 2). Similar improvements were not observed for the telephone groups compared with the non-telephone groups or

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Progress of participants through the trial. †Includes participants who dropped out but still returned the final questionnaire. ‡Data were missing for three participants at baseline; they were not included in the intention to treat analysis at 24 months

for the interaction of the exercise and telephone groups.

Sensitivity analysis excluding those patients who received the placebo tablet did not change our conclusions. Mean differences were −1.12 (95% confidence interval −1.71 to −0.54) for exercise versus non-exercise and −0.44 (−1.02 to 0.13) for telephone versus non-telephone.

On the basis of a the comparison of the exercise group with the non-exercise group, the number needed to treat to achieve a >50% improvement in knee pain in 13.0 (6 to 20). This equates to an odds ratio of 1.5.

Exercise was consistently better at reducing pain at 6, 12, and 18 months than no exercise (table 2). A significant interaction was observed between exercise and telephone contact at 6 months (P=0.001). This effect was not observed at any of the other time points. As exercise was associated with an improvement in the telephone and non-telephone groups, we decided to present results of the main effect rather than the simple main effects (table 2). Our interpretation is that this interaction occurred by chance.

Table 1 Characteristics of treatment groups

Characteristic	Exercise and telephone	Exercise, telephone, and dolomite	Exercise	Telephone	Dolomite	No intervention
No of participants	121	114	235	160	78	78
Mean (SD) age	62.6 (9.36)	62.5 (8.86)	61.5 (9.58)	61.5 (9.02)	61.9 (9.84)	61.9 (9.39)
Mean (SD) body mass index	27.58 (3.93)	28.19 (4.76)	28.02 (4.18)	28.24 (4.93)	27.87 (5.53)	28.14 (4.81)
Mean (SD) WOMAC pain score	6.96 (3.54)	7.82 (3.61)	6.93 (3.55)	7.43 (3.48)	7.49 (3.63)	7.04 (3.67)
Mean (SD) strength of left quadriceps	204.61 (133.22) (n=74)	207.62 (109.96) (n=64)	218.16 (117.96) (n=141)	221.24 (127.14) (n=94)	213.46 (117.99) (n=45)	205.31 (99.96) (n=49)
Sex ratio (male:female)	39:61	38:62	36:64	34:66	35:65	35:65
No (%) with bilateral pain	89 (74)	79 (69)	161 (69)	102 (64)	50 (64)	48 (62)
No (%) with radiograph showing definite osteophyte present	61/112 (54)	42/100 (42)	87/206 (42)	78/139 (56)	29/71 (41)	33/72 (46)

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Table 2 Change in WOMAC pain scores at 6, 12, 18 and 24 months† and knee related physical function and stiffness at 24 months

Outcome	No of participants	Baseline	Mean difference at 24 months†	95% confidence interval for mean difference	df	F	P	Effect size
Primary								
Knee pain at 24 months*:								
Exercise	467	7.15	−0.82	−1.3 to −0.3	1 and 779	11.14	0.001	0.25
Non-exercise	316	7.35						
Telephone	393	7.10	−0.16	−0.6 to 0.3	1 and 779	0.45	0.50	0.05
Non-telephone	390	7.40						
Knee pain at 6 months:								
Exercise	467	7.15	−0.61	−1.0 to −0.2	1 and 779	8.64	0.003	0.21
Non-exercise	316	7.35						
Knee pain at 12 months:								
Exercise	467	7.15	−0.61	−1.0 to −0.2	1 and 779	7.80	0.005	0.20
Non-exercise	316	7.35						
Knee pain at 18 months:								
Exercise	467	7.15	−0.69	−1.1 to −0.2	1 and 779	9.10	0.003	0.22
Non-exercise	316	7.35						
Secondary								
Physical function:								
Exercise	466	23.15	−2.57	−4.1 to −1.1	1 and 778	11.44	0.001	0.25
Non-exercise	316	22.97						
Stiffness:								
Exercise	470	3.42	−0.29	−0.5 to −0.1	1 and 782	6.44	0.01	0.18
Non-exercise	316	3.46						

*Interaction of exercise and telephone (P=0.54).
†Negative values for mean differences reflect improvements in knee symptoms compared with baseline.

Secondary outcomes

At two years, 226 (48.1%) of those allocated to receive exercise therapy completed the programme. The most common reasons for failing to adhere to the programme were related to health problems (back and hip pain) and lack of time. Fifty two (11%) of those exercising reported side effects, but these were generally minor (for example, the exercise band was painful around their ankle). Self reported adherence to the exercise programme was crudely graded as high (n=128), medium (n=32), or low (n=307). The impact of exercise adherence on self reported pain at 24 months suggested a dose-response effect, with effect sizes of 0.42, 0.34, and 0.16 for the three grades of adherence, respectively.

Scores for stiffness and physical function on the WOMAC index both showed significant improvements for the exercise groups compared with the non-exercise groups (table 2). Isometric muscle strength was higher in the exercise groups than in the non-exercise groups (mean difference 18.4 N (95% confidence interval 7.0 to 29.8); P=0.002), but general physical function (indicated by score on the SF-36), anxiety, and depression at 24 months were not significantly altered by any of the study interventions (data not shown).

Discussion

This study shows that simple home based exercise therapy over two years can produce small but significant reductions in knee pain. Improvements in pain were achieved by six months and sustained throughout the study period; this suggests that follow up at six monthly intervals may be enough to ensure adherence to exercise programmes. Compared with the non-exercise groups, groups that performed exercise had an average reduction in knee pain of 12%. This effect was incremental to benefits resulting from normal care and is of some clinical relevance. In addition to improvements in pain, the exercise programme also produced significant improvements in knee stiffness and physical function.

The exercise programme was generally well tolerated, although adherence was moderate. The introduction of telephone support contributed little to observed reductions in knee pain. It is reasonable to attribute the beneficial effects primarily to the exercise intervention rather than to secondary effects because of improved psychosocial contact.

Comparison with other studies

That this was a pragmatic study is important when comparing it with other studies. In addition to using an intention to treat analysis, we used a practical intervention that involved limited input from health professionals, a long period of follow up, and entry criteria based upon knee pain rather than radiographic status. We anticipated that these factors would improve the generalisability of our study findings, but that effect sizes would be smaller than those reported by other exploratory trials. For example, a large study comparing exercise therapy with education reported effect sizes of 0.3-0.6 for pain and function.[7] It was based in primary care, it involved contact with a physiotherapist one to three times per week, and outcomes were assessed after 12 weeks. Follow up data show that these improvements were not sustained at nine months.[19]

A more comparable 18 month study compared aerobic exercise and resistance exercise with an education programme.[20] This study reported 12% and 8% reductions in pain and effect sizes of 0.5 and 0.3 in the aerobic and resistance exercise groups, respectively. Again this involved an element of supervised therapy, and patients were included on the basis of both radio-

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What is already known on this topic

Physiotherapy is often prescribed for the treatment of knee pain

Previous trials have usually been short and used intensive supervision and sophisticated equipment

The impact of psychological factors in reducing pain is unclear

What this study adds

Home based programmes involving exercise for up to 30 minutes a day significantly reduce self reported knee pain

Social support alone does not improve health outcomes

Reductions in pain are greater for patients the closer they adhere to exercise programmes

graphic evidence of osteoarthritis and difficulty with activities of daily living, in addition to self reported knee pain.

Limitations

Despite a highly significant difference between the exercise and non-exercise groups, some patients may consider the effect (a reduction in pain of 12%) to be too small to be worth the effort of half an hour of daily exercise for two years. Future work should focus on establishing which patients are likely to benefit most from an intervention of this kind.

Adherence to treatment may be higher in a trial setting than in routine clinical practice. Nevertheless, participants for this study were approached directly in the community rather than through general practices. Patients who contact their general practitioner may be more inclined to adhere to a treatment programme.

More importantly, patients with pain referred from sites such as the back or hips may have been included in this study on the basis of self reported knee pain. Such individuals are unlikely to benefit from the study interventions. Nevertheless, 740 (94.5%) of the participants had signs suggesting pain originating in the knee (localised pain and tenderness or pain on movement, or both) rather than referred pain (diffuse pain involving the thighs with no pain on knee movement).

Conclusion

Simple home based exercise programmes can produce significant reductions in knee pain over two years. Such programmes are ideally suited for primary care.

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Contributors: All authors were involved in the design of the study and final approval of the article. KT was involved in the acquisition, analysis, and interpretation of the data and drafted the article. KM, MD, AJ, and JB interpreted the data and revised the article. SO'R interpreted the data and drafted and revised the article. P Miller provided advice on the economic evaluation of study interventions. B Palmer, A Sutton, and S Armstrong provided statistical advice. E Ware and L Naylor conducted assessment interviews. L Naylor and M Smith helped to deliver the exercise programme. A Follows conducted all telephone support conversations, helped with study recruitment, and maintained the study database. MD will act as guarantor.

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