Cost effectiveness of a two-year home exercise program for the treatment of knee pain

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Non-medical interventions for knee osteoarthritis (OA) were examined. These were exercise therapy, monthly telephone contact, and a combination of exercise therapy and telephone contact.

The exercise programme comprised quadriceps strengthening and aerobic exercise taught in a graded programme. Resistance exercises were taught using rubber exercise bands. A research nurse taught the programme in the participants' homes. The initial training phase consisted of 4 visits lasting approximately 30 minutes in the first 2 months, with follow-up visits scheduled every 6 months thereafter. The participants were encouraged to perform the programme daily, taking 20 to 30 minutes to do so.

Monthly telephone contact was used to monitor symptoms and to offer simple advice on the management of knee pain. This intervention aimed to control for the psychosocial contact of the exercise programme. The calls typically lasted 2 minutes (8 minutes for the first call), although the time spent on the administration of calls was considerably more (more than 4 times).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients reporting current knee pain. The exclusion criteria were total knee replacement, lower limb amputation, cardiac pacemaker, unable to give informed consent, or no current knee pain.

Setting
The setting was primary and secondary care. The economic study was carried out in the UK.

Dates to which data relate
The clinical evidence and resource use data were derived from a study published in 2002. The price year was 1996.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.
Study sample
The patients were identified from a postal questionnaire of 9,296 people aged at least 45 years who were registered at two general practices in Nottingham. Of these, 3,261 did not respond and 4,103 were knee pain negative. Of the 1,932 who were knee pain positive, 295 refused to participate, 327 were excluded, and 464 were unable to be contacted. A further 60 patients were excluded or refused to participate. Thus, a group of 786 patients was included in the final study sample and allocated to the different groups. The mean age of the participants was 62 years, and 64% were women. There were 235 patients in the exercise plus telephone group, 235 in the exercise group, 160 in the telephone group, and 156 in the placebo or no intervention group. It was not stated whether any power calculations were carried out in the primary study.

Study design
This was a prospective, randomised clinical trial that was carried out at two general practices in Nottingham. The participants were randomised using a computer-generated list with a block size of 10, and stratified by age and gender. To limit the number of dropouts in the trial, participants allocated to the no-intervention control group and the combined exercise and telephone group were further randomised to receive or not receive a placebo health food tablet. However, given that no differences were found between the groups receiving or not receiving the placebo health food tablet, all analyses were presented according to the original design. The length of follow-up was 2 years. Data were not available for 27 patients (9 in the exercise plus telephone group, 9 in the exercise group, 6 in the telephone group and 3 in the placebo group) who were then excluded from the primary analysis. However, the authors stated that these patients were comparable, in terms of their age and gender, to those whose follow-up data were available.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary effectiveness measure was a clinically significant improvement in knee pain (≥50%) at 24 months, measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The authors stated that the study groups were comparable at baseline.

Effectiveness results
Both the exercise and no-exercise groups had reduced WOMAC pain scores at 2 years. This improvement was significantly greater in the exercise groups than in the no-exercise groups (mean change compared with no exercise -0.74, 95% confidence interval, CI: -1.22 - -0.25; p=0.003).

Similar improvements were not observed for the telephone groups compared with the no-telephone groups (mean change compared with no telephone -0.19, 95% CI: -0.67 - 0.29; p=0.44), and no interaction between exercise and telephone was seen, (p=0.72).

One hundred and twenty (27%) participants allocated to receive exercise therapy showed an improvement of at least 50% in knee pain compared with 62 (20%) participants allocated to the non-exercise groups, (p=0.1).

Ninety-one (24%) participants allocated to the telephone group showed an improvement of at least 50% in knee pain compared with 91 (24%) participants allocated to no telephone, (p=0.87).

Clinical conclusions
The effectiveness analysis showed that the mean improvements in knee pain were significantly better in the exercise group than in the no-exercise group, while no significant differences were found between the telephone and no-telephone groups.

Measure of benefits used in the economic analysis
The summary benefit measure used was the proportion of patients achieving at least a 50% improvement in knee pain. This was derived directly from the effectiveness analysis.
Direct costs
The cost analysis was performed from the perspective of the NHS and the patient. The costs of the interventions, medical costs (secondary and primary care costs) and personal costs (costs incurred by the patient in accessing health services) were included. In particular, intervention costs included start-up and ongoing costs for both exercise and telephone, while long-term costs included the general practitioner (GP), GP-prescribed drugs and secondary care costs. A detailed breakdown of the cost items was provided. The unit costs were presented separately from the quantities of resources used. The costs were estimated using the Personal Social Services Research Unit, the local hospital finance department, and the British National Formulary. The resource use data were derived from the sample of patients included in the effectiveness study, after excluding 27 patients for whom data were not available. Two patients incurred very high medical costs, thus the economic results were presented both with and without these patients. The costs that were incurred in the second year were discounted at a rate of 5%. The price year was 1996.

Statistical analysis of costs
A non-parametric bootstrapping approach was used because of the skewed distribution of the cost estimates. Two thousand re-sampled estimates were calculated. Statistical tests were also performed to test the statistical significance of differences in the costs.

Indirect Costs
The indirect costs were not considered in the economic analysis.

Currency
UK pounds sterling ().
Synthesis of costs and benefits

An incremental cost-effectiveness ratio (i.e. the incremental cost per clinically significant improvement) was calculated to combine the costs and benefits of the interventions examined in the study.

The incremental cost per a clinically significant improvement with exercise in comparison with no exercise was 2,570. Cost-effectiveness acceptability curves showed that if decision-makers were prepared to pay 8,000 for each patient showing at least a 50% improvement in knee pain, the probability that the exercise intervention would be cost-effective was very high. However, if health providers were only willing to pay less than 500, it was almost certain that it would not be cost-effective.

The sensitivity analysis showed that the cost-effectiveness ratio would have fallen to 2,090 when incorporating physiotherapy assistant costs and to 814 if the analysis was restricted only to patients who presented to their GP. Even better cost-effectiveness ratios were achieved in the sub-groups of non-obese patients and those with no radiographic evidence of OA.

Authors' conclusions

Exercise therapy provided significant health benefits for individuals with knee pain, but the cost of delivering the exercise programme was not offset by any reduction in medical resource use. Thus, the cost-effectiveness of the intervention depends on the decision-makers' willingness to pay.

CRD COMMENTARY - Selection of comparators

The rationale for the choice of the comparators was clear. The interventions examined in the study were described. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness

The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The trial had been published already, but extensive details on the methods of sample selection and randomisation were given. The numbers of patients refusing to participate or excluded from the study sample were reported, although the authors did not report the reasons for such refusals. The internal validity of the study was further ensured by the baseline comparability of the study groups and the use of intention to treat analysis. The length of follow-up was appropriate. The study sample appears to have been representative of the patient population. It was not stated whether power calculations were carried out to justify the size of the sample.

Validity of estimate of measure of benefit

The summary benefit measure was specific to the disease considered in the study. It is not comparable with the benefits of other health care interventions.

Validity of estimate of costs

The analysis of the costs was consistent with the perspective adopted in the study. The authors noted that the inclusion of indirect costs would have been interesting. The unit costs and quantities of resources used were reported extensively, which would help replication of the study in other settings. Discounting was relevant for some costs incurred in the second year. The source of the data was reported. Statistical analyses were performed to deal with the skewed distribution of the costs. Further, a sensitivity analysis was carried out on a key cost estimate. The price year was reported, which aids reflation exercises in other time periods.

Other issues

The authors reported the results of some US studies (that reported small savings associated with exercise therapy) and some UK studies (which showed little or no benefits associated with exercise therapy). Several sub-group analyses were performed, which enhanced the applicability of the study results. However, the issue of the generalisability of the study...
results to other settings was not explicitly addressed and limited sensitivity analyses were performed. This reduces the external validity of the analysis. The study referred to patients with knee pain and this was reflected in the authors' conclusions.

**Implications of the study**
The study results showed some sub-groups of patients who may benefit from the exercise programme at a cost affordable to the NHS. Future studies should be carried out to better identify such patients.

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None stated.

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**Other publications of related interest**


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