Effectiveness and cost-effectiveness of three types of physiotherapy used to reduce chronic low back pain disability: a pragmatic randomized trial with economic evaluation

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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
The study examined three treatments for low back pain. These were usual outpatient physiotherapy, spinal stabilisation classes, and physiotherapist-led pain management classes. Usual outpatient physiotherapy involved individual advice, exercises and joint manipulation or mobilisations (individual physiotherapy). Spinal stabilisation training consisted of very specific exercises of deeper trunk muscles. Physiotherapist-led general exercise involved brief education in small groups. A detailed description of each of these strategies was given.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised adult patients with low back pain of more than 12 weeks' duration, with or without leg symptoms or neurologic signs. People were excluded if they had undergone prior spinal surgery or had received physiotherapy in the last 6 months, or had rheumatological diseases.

Setting
The setting was an outpatients department. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered from January 2002 to June 2005. The costs were evaluated using 2003/04 prices.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
Power calculations were performed in the preliminary phase of the study. These showed that an overall sample of 240 participants was required to identify a clinically significant improvement in the primary end point (power of 90% and alpha of 0.05) when considering 25% attrition. The patients were recruited from referrals by a specialist or primary care practitioner to hospital physiotherapy departments. Of the initial group of 1,790 patients referred, 1,011 were interviewed. However, only 212 were finally randomised. There were 71 patients (59% women) in the individual physiotherapy group, 72 (71% women) in the spinal stabilisation group, and 69 (62% women) in the pain management group. The mean age was 45 (+/- 12) years in the individual physiotherapy group, 44 (+/- 13) years in the spinal
stabilisation group, and 44 (+/- 12) years in the pain management group. Reasons for refusal to participate (323 patients) and for non-eligibility (476 patients) were reported.

**Study design**
This was a prospective, pragmatic randomised, assessor-blinded trial that was carried out in two inner-city London public hospitals. Randomisation was based on a computer-generated sequence. Masking was performed only for assessors, since masking the participants or the clinicians was not feasible and not desirable. The length of follow-up was 18 months. At the end of the follow-up period, there were 59 patients in the individual physiotherapy group, 54 in the spinal stabilisation group, and 47 in the pain management group. Patients remaining in the trial were significantly older, more likely to be female, and less disabled than those who left the study. Socioeconomic factors were also different.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on both an intention to treat basis and for treatment completers only. The primary outcome measure was the Roland Disability Questionnaire, a disease-specific questionnaire ranging from 0 (no limitation) to 24 (maximum limitation). The secondary end points were:

- pain assessment on a visual analogue scale (VAS),
- health-related quality of life measured using the EQ-5D (EuroQol) questionnaire,
- work participation (days not working because of back pain in the last 6 months),
- patient satisfaction, and
- adverse events.

At baseline, the study groups were similar in terms of their clinical and demographic characteristics. Statistical analyses were carried out to assess the potential impact of baseline factors on the estimated end points. Missing values were imputed using the last known value carried out.

**Effectiveness results**
The Roland disability score improved in all treatment groups, but the difference between the groups did not reach statistical significance. For example, the mean Roland disability score improved from 11.1 (baseline) to 6.9 (18 months) with usual outpatient physiotherapy, from 12.8 to 6.8 with spinal stabilisation, and from 11.5 to 6.5 in the pain management group. (p=0.46).

Similar results were achieved with the other clinical end points. In particular, the EQ-5D mean scores improved from 0.57 to 0.67 in the usual outpatient physiotherapy group, from 0.48 to 0.63 in the spinal stabilisation group, and from 0.54 to 0.68 in the pain management group.

No serious adverse events were reported. Satisfaction was good and comparable in all groups.

**Clinical conclusions**
The effectiveness analysis showed that the three treatments were similarly effective.

**Measure of benefits used in the economic analysis**
The summary benefit measure used was the expected number of quality-adjusted life-years (QALYs). These were estimated using the health-related quality of life estimates derived directly from the clinical trial. The QALYs were discounted at an annual rate of 3.5%.
Direct costs
The analysis of the costs was performed from the viewpoint of the NHS. It included the costs physiotherapy, health care visits (general practitioners, consultants and others), medications and investigations. The unit costs and the quantities of resources used were presented separately for most items. Resource use was estimated using data derived from the sample of trial participants with complete economic data (53 in the individual physiotherapy group, 53 in the spinal stabilisation group, and 44 in the pain management group). The costs were derived from the Personal Social Services Research Unit Database, NHS Reference Costs and the British National Formulary. Discounting was considered relevant, although only 18-month costs were evaluated, and an annual rate of 3.5% was applied. The costs were expressed using 2003/04 prices.

Statistical analysis of costs
Statistical analyses were carried out to test the statistical significance of cost-differences. Arithmetic mean and standard one-way analysis of variance test-based confidence intervals (CIs) were calculated.

Indirect Costs
The productivity costs were not considered.

Currency
UK pounds sterling (€).

Sensitivity analysis
A sensitivity analysis was carried out to assess the impact of including or excluding imputed missing values and cost outliers. A bootstrapping approach was also used to generate cost-effectiveness acceptability curves.

Estimated benefits used in the economic analysis
The total QALYs over 18 months were 0.99 (+/- 0.27) in the individual physiotherapy group, 0.90 (+/- 0.37) in the spinal stabilisation group, and 1.00 (+/- 0.28) in the pain management group.

Cost results
Over the 18-month period, the total costs per patient were 474 (+/- 840) in the individual physiotherapy group, 379 (+/- 1,040) in the spinal stabilisation group, and 165 (+/- 202) in the pain management group.

Synthesis of costs and benefits
Incremental cost-utility ratios were calculated in order to combine the costs and benefits of the alternative strategies. Overall, pain management was the dominant strategy, as it was less expensive and marginally more effective than the other two interventions. In comparison with spinal stabilisation, individual physiotherapy had an incremental cost per QALY gained of 1,055.

The cost-effectiveness acceptability curves showed that, at a willingness-to-pay threshold of 30,000 per QALY, the probability that treatments were cost-effective was 65% for pain management, 35% for usual physiotherapy, and negligible for spinal stabilisation.

The sensitivity analysis revealed that the inclusion or exclusion of missing values or cost outliers did not alter the conclusions of the analysis.

Authors' conclusions
All three interventions for low back pain improved quality of life, time off work, and health service utilisation.
However, from the perspective of the National Health Service (NHS), pain management is likely to be the most cost-effective strategy because of a marginally greater effectiveness and lower health care costs.

CRD COMMENTARY - Selection of comparators
The selection of the comparators appears to have been appropriate in that all available treatments for low back pain were considered. A strategy of no intervention was not included because it was considered unethical. All strategies were accurately described. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data came from a clinical trial, which was appropriate to the study question. The randomisation and masking approaches were successful, as the authors demonstrated. These aspects represent strengths of the study. However, the authors noted that inadvertent masking occurred occasionally at the 6-month assessments. A statistical justification for the size of the sample was provided. The baseline comparability of the study groups was further strengthened by the use of statistical analyses taking the potential impact of confounding factors into account. Moreover, the analysis was carried out according to the principles of both intention to treat and treatment completers only. These issues tend to enhance the internal validity of the study. However, the high proportions of patients refusing to participate or who were not eligible, and their differences from those who participated, limits the representativeness of the study sample.

Validity of estimate of measure of benefit
The benefit measure (QALYs) was derived directly from the clinical trial. The use of QALYs was appropriate given the impact of the disease on quality of life, which represents the key component of QALYs. Clearly the interventions had no effect on survival. Discounting was performed, as recommended by UK guidelines.

Validity of estimate of costs
The cost analysis included all categories of costs relevant to the perspective of the study. The authors stated that the potential inclusion of indirect costs would have presumably favoured the pain management strategy. Typical NHS sources were used to derive the costs, which were extensively reported. A breakdown of the cost items was given, and this will assist in replicating the analysis in other settings. The impact of including or excluding patients consuming a large amount of resources was tested in the sensitivity analysis. Statistical analyses of the costs were performed. The prices used to derive the costs were reported, thus facilitating reflation exercises in other time periods.

Other issues
The authors reported the results from other studies, some of which drew different conclusions, presumably due to differences in the pain management programme and in the patient population. The authors stated that an important strength of the study was the generalisability of the study results, which was ensured by the fact that the interventions could be easily replicated in other settings. The study referred to patients with low back pain and this was reflected in the authors’ conclusions.

Implications of the study
The study results suggest that a pain management programme is likely to represent the most cost-effective treatment for patients with low back pain. The authors recommend that pain management programmes should be offered routinely as first-line interventions.

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