Individual active treatment combined with group exercise for acute and subacute low back 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
The study compared two fast-access interventions for managing simple low back pain.

In one intervention, patients were provided with a back advice booklet (The Back Book) and received one session of advice, carrying on with their standard care as instructed by their general practitioners.

In the other intervention, patients were provided with the back advice booklet and received one session of advice. The patients were also assessed by a musculoskeletal physician or senior physiotherapist and received a back treatment programme. Treatment depended on the results of the assessment and consisted of manipulation in cases of joint dysfunction and restriction, joint and soft tissue mobilisation, and steroid injection including caudal epidural injection (in cases of segmental paravertebral or facet joint tenderness, or cases with positive sciatic stretch test). Patients with lumbar flexion and/or extension followed specific exercises according to the McKenzie technique, carrying out 10 repetitions three or four times daily. All patients received exercise classes for 1 or 2 weeks. Group exercises were provided in 1-hour sessions, three times a week in a gym. These consisted of a programme of nine stations including aerobic exercise and exercises addressing proprioception, spinal stability, strengthening of quadriceps, glutei, abdominal and various spinal muscles.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with a new episode (onset in the previous year) of low back pain and who were off work or on light duties. Patients with red flags and possible serious pathology were excluded from the study, as were those with continuous pain, paraesthesia or numbness below the knee. Other criteria for exclusion were chronic back conditions, Cauda Equina Syndrome/Widespread neurological disorder, recent spinal surgery and other diseases likely to affect the back.

Setting
The setting was secondary care (district general hospital) with a rehabilitation gym. The economic study was carried out in the UK.

Dates to which data relate
The dates to which effectiveness evidence related were not reported. The costs of productivity losses were derived from sources published between 1994 and 1999. The dates for health service costs and the price year were not reported.
Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
It seems that the costing has been carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The sample size was not determined in the planning phase of the study. The Kaplan-Meier technique was used retrospectively to assess whether differences in rate of return to work between the two groups were statistically significant at the 5% level. Occupational health physicians and local general practitioners tried to select patients who met the inclusion and exclusion criteria, and an appointment with eligible patients was programmed. Initially, 119 patients were selected as eligible to participate in the study. Eight patients were excluded before randomisation because they did not show up for the appointment (2), failed to meet the inclusion and exclusion criteria by the time of the appointment (4), or would not be available to attend exercise classes (2). Therefore, 111 patients were randomised to the two groups, 56 to group 1 (Back Book, advice and normal route of care) and 55 to group 2 (Back Book, advice and back programme).

Study design
The analysis was based on single-centre, randomised controlled trial. Randomisation was performed using a computer programme (Sampsize v.2.0, 1997), with patients being given a sealed envelope containing the randomised group number. It would appear that none of the participants were blinded to the intervention. Patients were followed up at 1 and 2 months (total duration of follow-up, 2 months). At 1 month, 10 (17.8%) patients were lost to follow-up in group 1. One of these patients had moved, while no reasons were provided for the rest of the patients lost to follow-up. Five (9%) patients were lost to follow-up in group 2, but no justification was provided. At 2 months, of the 46 patients in group 1, nine were on light duties and therefore not off work and were excluded from analysis. Seven of the 50 patients in group 2 were excluded for the same reason.

Analysis of effectiveness
It was not reported whether the analysis was conducted on an intention to treat basis or for treatment completers only. The health outcomes assessed were:

- pain scores measured using the Short Form McGill Pain Questionnaire,
- general health status measured using the SF-12 Health Survey, and
- days to return to work.

Patients were administered the questionnaires at their initial appointment (baseline) and at the 1- and 2-month follow-up. The questionnaires were administered by post. It was not reported whether the two groups were comparable in terms of their baseline characteristics.

Effectiveness results
In terms of pain level and severity, in both groups a greater reduction in pain scores occurred during the first month rather than the second month.

The authors conducted an analysis of covariance (ANCOVA) to assess whether differences between the two groups were statistically significant. The analysis took baseline values as a covariate.

At 1 month, the mean pain scores for three elements of the Short Form McGill Pain Questionnaire were as follows.
Visual Analogue Scale (VAS) score: 34.92 in group 1 and 23.64 in group 2; the difference was statistically significant, (p=0.047).

Present pain intensity: 1.75 in group 1 and 1.13 in group 2; the difference was statistically significant, (p=0.039).

Sensory: 6.85 in group 1 and 4.32 in group 2; the difference was statistically significant, (p=0.021).

At 2 months, the relative benefit in group 2 was statistically significant for VAS only, 30.87 in group 1 versus 18.41 in group 2, (p=0.023).

It was reported that emotional scores (fourth element of Short Form McGill Pain Questionnaire) did not differ between the two groups during the study. In terms of the Physical and Mental Component Summary Scores of the SF-12, there was an improvement in both groups over time with group 2 demonstrating somewhat better results.

Using the Kaplan-Meier technique and a log-rank test, it was demonstrated that the number of days to return to work was 20 in group 1 and 13 in group 2. This difference was statistically significant, (p=0.0343).

**Clinical conclusions**
The authors concluded that receiving one session of individualised physical treatment or injection and a simple back programme achieved a quicker return to work. However, differences in measures of pain and health status were not statistically significant between the two groups.

**Measure of benefits used in the economic analysis**
The authors did not derive a summary measure of benefit in the economic analysis. In effect, a cost-consequences analysis was conducted.

**Direct costs**
The health service costs included in the analysis were for the initial assessment, treatment and exercise classes. All costs included professional salaries, administration, material and overhead costs. The costs and the quantities were not described separately. The sources of the costs were not reported, whereas the quantities of resources used were derived directly from the study. Since the costs were incurred during a short time, discounting was not relevant. The price year was not reported.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
To account for the cost of being off work, the authors included average weekly and daily wages. The costs and the quantities were described separately. The costs were derived from official published sources but no adjustments for inflation were reported. Days off work were derived directly from the study. Since the costs were incurred during a short time, discounting was not relevant. The price year was not reported.

**Currency**
UK pounds sterling (£). US dollar and Euros were also used, but conversion rates were not reported.

**Sensitivity analysis**
The authors conducted one- and two-way sensitivity analyses by varying the average daily wage (using minimum and maximum estimates derived from published sources) and the number of patients attending the programme (capacity).
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total, health care weekly costs per patient were 134.79 in group 1 and 857.92 in group 2.

When productivity losses due to days off work were incorporated into the analysis, the authors conducted an incremental analysis and reported cost-savings only in group 2. Depending on the average daily wage, the cost-savings for group 2 ranged from 336.77 (at an average daily wage of 48.11) to 620.97 (at an average daily wage of 88.71).

The sensitivity analysis demonstrated that if the programme capacity was halved in group 2, the cost per patient would be 85.79 and the cost-savings would only be 250.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
Cost-savings produced by the active back programme, arising from earlier return to work, did not exceed its health care costs.

CRD COMMENTARY - Selection of comparators
The authors justified their selection of the comparators with reference to the Clinical Standards Advisory Group. You should decide if this represents a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial, which was appropriate given the study question. The study sample was representative of the study population and, although s statistical analysis was not carried out, the patient groups appear to have been comparable in terms of their baseline characteristics. The method of randomisation, duration of the study and loss to follow-up were all reported, suggesting that the internal validity of the study is likely to be good. In addition, the analysis was handled credibly: an appropriate statistical analysis was undertaken to take potential biases and confounding factors into consideration.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit in the economic analysis. In effect, a cost-consequences analysis was performed.

Validity of estimate of costs
As the perspective of the economic analysis was not reported reported, it is not possible to know if all the relevant cost categories were included in the analysis. The costs and the quantities were not reported separately, thus making it difficult to reproduce the study in other settings. The quantities of resources used were derived from the single study, but no statistical analysis was undertaken. The sources of the direct health care costs were not reported, and no sensitivity analysis was conducted to assess the robustness of the estimates used. The price year was not reported, thus hindering any future reflation exercises.

Other issues
The authors compared their study findings with those from published studies, reporting that any differences were due to their inclusion criteria which were applied to the study population. The issue of generalisability of the results to other
settings was not directly addressed. The authors do not appear to have presented their results selectively, although they did not always report results from the statistical tests performed. The study enrolled patients with a new episode of low back pain and this was reflected in the authors' conclusions.

The authors reported a number of limitations to their study. First, in some professions (e.g. nurses), patients absent from work were replaced by agency or "bank" staff, thus incurring extra costs which were not taken into account in the analysis. The analysis did not account for reduced use of certain health services in group 2 compared with group 1, and data on the amount of drugs administered were not available. The authors acknowledged that the inclusion of a "no treatment" group would have allowed for the active value of the treatment to be estimated. In addition, since the follow-up period was short, the analysis did not take the reoccurrence rate of low back pain into consideration.

**Implications of the study**
The authors did not make explicit recommendations for changes in policy or practice or the need for further research. However, their discussion highlighted areas where more robust information is needed.

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