Active exercise, education, and cognitive behavioral therapy for persistent disabling low back pain: a randomized controlled trial


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.

CRD summary
This study investigated the costs and clinical benefits of an intervention for the treatment of persistent lower back pain, which was exercise and education, using cognitive behavioural therapy, compared with standard general practitioner care plus educational materials. The authors concluded that their intervention was likely to be cost-effective compared with usual care as it produced similar effects at lower costs. The methods and findings were not transparently reported, which makes it difficult to assess the validity of the authors’ conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
The aim was to examine the cost-effectiveness of a community-based, group, exercise and education intervention for patients with persistent lower back pain (LBP), using cognitive behavioural therapy (CBT).

Interventions
This study examined the cost-effectiveness of an intervention for the treatment of LBP, which comprised exercise and education using CBT, compared with standard general practitioner (GP) care plus educational material. The intervention was delivered in group sessions by physiotherapists specifically trained in CBT. The population was patients aged 18 to 65 years old, who consulted their GP with persistent disabling LBP and who did not have any ‘red flag’ symptoms, which were reported in full. Persistent disabling LBP was defined as 20mm pain or more on a visual analogue scale (VAS) and five points or more on the Roland and Morris Disability Questionnaire (RMDQ).

Location/setting
UK/primary care.

Methods
Analytical approach:
This evaluation was based on data collected from a single clinical trial which lasted 15-months. The time horizon of the economic evaluation was 12 months. The authors did not state the study perspective.

Effectiveness data:
The clinical data came from a randomised controlled trial, in nine GP practices in East Cheshire. The patients were followed up at 3, 9 and 15 months. The primary clinical outcomes were the reductions in pain and disability scores, which were collected by means of postal questionnaires, at the follow-up times. Pain was measured using a VAS while disability was measured using the RMDQ. Only those who completed treatment were included in the base-case. Additional analyses were undertaken to assess the impact on the outcomes of a priori patient preferences for treatment. Both groups of patients had similar demographic and clinical characteristics at baseline and the analyses were adjusted for baseline pain, disability, age, gender, LBP history, and psychological distress.

Monetary benefit and utility valuations:
The utilities were measured on all participants using the European Quality of life (EQ-5D) questionnaire at baseline, and follow ups at 3, 9 and 15 months. These scores, like the effectiveness outcomes, were collected by means of postal questionnaires at follow up times.
Measure of benefit:
The summary measure of benefit was quality-adjusted life-years (QALYs). These were adjusted to cover a 12-month period, as opposed to the 15-month trial period.

Cost data:
The direct costs included health care utilisation data, aids and equipment purchased by the individual, and the costs of delivering the intervention. The health care utilisation, aids and equipment were measured by participant surveys at the follow up times. These were valued identically to these items in a large back pain trial (UK Beam Trial Team. 2004, see ‘Other Publications of Related Interest’ below for bibliographic data). The private care costs were valued from a major insurance provider (see ‘Other URL’ below for the link). No details were provided on the intervention resources or costs. All data were reported in 2004 UK pounds sterling (£) and US dollars ($), after inflationary adjustments at an exchange rate of £1.00 equals $1.73. The average costs were calculated and adjusted to cover a 12-month period instead of the 15-month trial period.

Analysis of uncertainty:
Bootstrap methods were used to estimate the mean differences, in terms of QALYs and costs, between the trial arms. These estimates were then used to generate a cost-effectiveness acceptability curve, which illustrated the uncertainty in the results at various levels of willingness to pay.

Results
The intervention group showed a substantial reduction in pain, from 44.9mm at baseline to 27.9mm at 15 months, on the VAS compared with the usual care group, which reduced from 51.6mm at baseline to 36.4mm at 15 months. However this difference was not statistically significant at -3.63 (95% confidence interval, CI: -8.48 to 1.23). A similar pattern was found for disability scores.

In the patient preference analysis, participants allocated to the intervention group showed important clinical reductions in pain and disability compared with the control group at 9 and 15 months.

The mean difference in cost was reported to be £27 (95% CI: -159 to 213) or $47.

The mean incremental cost-effectiveness ratio was £5,000 per QALY or $8,650 per QALY. The cost-effectiveness acceptability curve showed that there was a 90% probability that the intervention would be cost-effective at £30,000 per QALY or $51,900 per QALY.

Authors’ conclusions
The authors concluded that, although the intervention had minimal, non-significant clinical effectiveness, the intervention was delivered at a relatively low cost and was cost-effective.

CRD commentary
Interventions:
Although there was no explicit justification for the authors’ choice of comparator, it seemed to represent the usual practice of treating LBP in the authors’ primary care setting.

Effectiveness/benefits:
The analysis was based on a randomised controlled trial which is considered the ‘gold standard’ in preserving internal validity. The patient groups were similar in both their demographic and clinical characteristics at baseline. The method of randomisation, reasons for participation and non-participation, and numbers of participants lost to follow-up were clearly reported. In addition, the authors further tested patient preferences for treatment type and their influence on the intervention effectiveness. Also, the intervention delivery was analysed to monitor treatment fidelity. The study was adequately powered and appropriate statistical analyses were undertaken. Adjustments were made for potential confounders, which was necessary because patients, who were lost to follow-up may have differed in their characteristics compared with those who completed the trial. The utility data was elicited directly from patients in the trial, over the 15-month period.
Costs:
The authors did not state the study perspective and it was therefore unclear whether all the relevant costs were included. Also, no information was given on the type and quantities of resources used. The resource use data was collected directly from patients at each follow-up point and no further details were reported. Also neither the total costs nor the unit costs were presented. Overall, the level of reporting about the costs was limited.

Analysis and results:
The QALY results for the two trial arms were not reported and nor were the incremental differences. Further the methods used for the sensitivity analyses were not reported. The authors did identify and discuss the possible limitations of their study, which included the intervention compliance, the mild LBP at baseline, which potentially created unrealistic expectations of finding clinically relevant effects, and the training levels of the physiotherapists. A more comprehensive approach to reporting the details of the economic evaluation methods and inputs would have been better.

Concluding remarks:
The costing methods and the cost and effectiveness results were not fully reported or transparent. In light of this, it is difficult to confirm the authors’ conclusions.

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