Effectiveness and cost-effectiveness of adding a cognitive behavioral treatment to the rehabilitation of chronic low back pain

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 considered the use of cognitive behavioural therapy (CBT) in addition to usual rehabilitation care for lower back pain. The CBT element of treatment consisted of six 1.5-hour group sessions and two individual sessions of 30 minutes with a trained psychologist. Usual rehabilitation treatment consisted of a 3-week inpatient placement with daily physiotherapy, spinal massage, exercise, electrotherapeutical measures and seminars in risk factors and managing back pain.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised people with non-specific lower back pain of at least 6 months’ duration who had been assessed as suitable for inpatient rehabilitation. Patients were excluded if they had serious co-morbidities, an indication of severe spinal pathology, had been unemployed for more than 12 months, or had applied for early retirement.

Setting
The setting was inpatient care. The economic study was carried out in Germany.

Dates to which data relate
The dates to which the clinical effectiveness and resource use data referred were not reported. The price year was 2001.

Link between effectiveness and cost data
The costing was undertaken on the sample patient sample that provided the clinical effectiveness data.

Study sample
No sample size or power calculations were reported in the paper. Consecutive patients assessed by the public pension system as being suitable for rehabilitation were recruited into the trial. A total of 636 patients were assessed for inclusion in the trial, of which 119 were excluded as they did not meet the inclusion criteria and 108 refused to participate. Of the 409 patients included, 200 were allocated to the rehabilitation plus CBT group and 209 were allocated to the rehabilitation alone group.

Study design
The study was a randomised controlled trial that was conducted in two centres. Randomisation was undertaken by an external centre and was stratified by both age and the number of days off work due to back pain in the past 12 months. The paper indicated that blinding of the patients or health care staff was not plausible. Post discharge patients were followed up for 6 months. The loss to follow-up was 41.5% (21) in the rehabilitation plus CBT group and 29.7% (6) in the rehabilitation alone group. Of the 21 patients in the rehabilitation plus CBT group who dropped out before discharge, 6 withdrew for medical reasons, 2 for language reasons and 13 withdrew their consent. Of the 6 patients who dropped out of the rehabilitation alone group, 4 withdrew for medical reasons, 1 for language reasons and 1 withdrew their consent.

Analysis of effectiveness
The data analysis appears to have been undertaken on the basis of treatment completers only. The primary health outcome was the number of days off work due to sickness in the 6 months following discharge. Change in functional capacity (measured using the Hanover functional questionnaire), depression, anxiety (using the State-Trait Anxiety Inventory), and subjective pain between admission and discharge were also measured. The two patient groups had comparable characteristics at baseline but different drop-out rates.

Effectiveness results
The mean number of days off work due to sickness was 11.4 days (standard deviation, SD=28.9) in the rehabilitation plus CBT versus 16.8 days (SD=34.1) in the rehabilitation alone group, (p=0.115).

There was no statistical difference in changes between admission and discharge in functional capacity, depression, anxiety and subjective pain in the two groups.

Clinical conclusions
The authors concluded that there was no statistically significant difference in the effectiveness of inpatient rehabilitation plus CBT compared with inpatient rehabilitation alone.

Measure of benefits used in the economic analysis
The measure of health benefit used was the quality-adjusted life-years (QALYs). The health states were valued by the patient sample using the EuroQol questionnaire on admission, at discharge and after 6 months.

Direct costs
The direct costs of the health care payer and patient were identified in this study. Inpatient health care resource use was taken from routine documentation. The quantities of costs incurred by the patient and post discharge health care resource use were taken from a questionnaire completed by the patient sample. The unit costs of health care were taken from the clinical accounting system, while the unit costs for patient expenditure appear to have been taken from the questionnaire. The average costs for each category of cost were detailed in the paper. The price year was 2001.

Statistical analysis of costs
The statistical difference between costs in the two patient groups was tested using t-tests at a 5% significance level.

Indirect Costs
Productivity costs were included in the analysis, as the aim of the study was to assess the impact on the number of days work lost due to sickness of adding CBT to inpatient rehabilitation. Quantity data were taken from the national insurance records of the study sample for the 6 months following discharge. The source for the cost of a day off work was age- and gender-adjusted wage rates plus insurance contributions. A breakdown of the average number of days off sick and their average cost was provided. The price year was 2001.
Currency
Euros (EUR).

Sensitivity analysis
Sensitivity analyses were undertaken to assess the impact of different methods of valuing important cost components. Bootstrapping techniques were also used to assess uncertainty around the incremental cost-utility ratio. Further, multiple imputation methods were used to assess the impact of missing data.

Estimated benefits used in the economic analysis
In the 6 months following discharge, the mean QALYs were 0.401 in the rehabilitation plus CBT group and 0.399 in the rehabilitation alone group, (p=0.870).

Cost results
The total mean cost was EUR 8,849.3 (SD=5,820.6) in the rehabilitation plus CBT group and EUR 10,519.9 (SD=8,073.6) in the rehabilitation alone group, (p=0.054).

Synthesis of costs and benefits
Adding CBT to inpatient rehabilitation resulted in an increased benefit at a reduced cost. It was therefore the dominant strategy, with a saving of EUR 126,731 per QALY.

The bootstrapping methods indicated that adding CBT to inpatient rehabilitation would dominate inpatient rehabilitation alone in 61% of repetitions.

The sensitivity analysis showed that using a cost friction rather than a human capital approach had the largest impact on the cost estimates.

Authors' conclusions
The addition of cognitive behavioural therapy (CBT) to standard inpatient rehabilitation treatment for lower back pain may reduce the number of days off work sick and, therefore, reduce costs from a societal perspective.

CRD COMMENTARY - Selection of comparators
The authors provided a clear justification for comparing inpatient rehabilitation plus CBT with inpatient rehabilitation alone. It was chosen as it represented usual practice in their setting. You should consider how this compares to usual practice in your own setting before applying the results of this study.

Validity of estimate of measure of effectiveness
The effectiveness data were taken from a randomised controlled trial. The method of randomisation, length of study, and loss to follow-up were reported in the paper. The overall methods employed in the trial suggest that the internal validity is likely to be reasonable. However, the nature of the interventions meant that blinding of the patients and health care staff was not plausible, and this potentially impacts on the internal validity of the study. The two patient groups were shown to be comparable at baseline, although they did suffer different drop-out patterns. Multiple imputation methods were used to account for missing data. The results of this analysis were presented. No power calculations were reported, so it was not clear whether the trial had sufficient power to detect any difference in effectiveness between the two treatments.

Validity of estimate of measure of benefit
The summary measure of health benefit (QALYs) was taken directly from data collected in the randomised controlled
trial. The health states were valued by the patients included in the trial using established methods. The use of QALYs allows the full health benefits of the intervention to be captured. It also means that the results of this study can be compared with other interventions to treat lower back pain and interventions across the health care system.

Validity of estimate of costs
The study was conducted from a societal perspective. All categories of cost appear to have been included. Differences between the cost categories were tested using appropriate statistical tests. The authors used bootstrapping methods to assess uncertainty in the cost data and effectiveness estimates and resultant incremental cost-utility ratio. Although a complete breakdown of resource use and unit costs was not provided, mean costs by category were. The date of the resource use data was not reported but a clear price year was, which will facilitate future reflation exercises. The costs were not discounted as they were incurred during less than one year.

Other issues
The authors do not appear to have presented their results selectively and their conclusion acknowledged the uncertainty around their findings. The authors compared their results with other similar studies and discussed reasons for the differences in their findings. The authors did not consider how their findings could be generalised to other settings or identify which variables are likely to vary across settings.

Implications of the study
The authors suggest further research into which elements of CBT are effective, by systematically varying elements of the treatment.

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Other publications of related interest
Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.

Indexing Status
Subject indexing assigned by NLM

MeSH
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