United Kingdom back pain exercise and manipulation (UKBEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care

UK BEAM Trial Team

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
Different physical treatments for back pain were compared. The treatments were:

best care in general practice, where the authors trained practice teams in active management and provided the Back Book for patients, either alone or plus;

an exercise programme comprising an initial assessment and up to nine classes in community settings, delivered over 12 weeks;

a spinal manipulation package comprising a range of techniques developed by a multidisciplinary group, delivered during eight sessions over 12 weeks; or

combined treatment, in which patients received 6 weeks of manipulation followed by 6 weeks of exercise. Treatments were otherwise those given to the manipulation only or exercise only groups.

In the clinical paper, the authors also investigated the effects of providing the manipulation packages in National Health Service (NHS) and private settings. Hence, a total of six groups were compared in the clinical analysis, but not in the cost-utility analysis.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients consulting their general practices about lower back pain. Briefly, patients were eligible if they:

were aged between 18 and 65 years;

had a score of four or more on the Roland disability questionnaire at randomisation;

had experienced pain every day for the 28 days before randomisation, or for 21 of the 28 days before randomisation and for 21 of the 28 days before that; and

agreed to avoid physical treatments, other than trial treatments, for 3 months.

Setting
The study setting was primary care. The economic study was conducted in the UK.
Dates to which data relate
The effectiveness and resource use data related to August 1999 to April 2002. The price year was 2000/2001.

Source of effectiveness data
The effectiveness data were derived from a single study. The authors provided a brief summary of the methods and results of the clinical study in this paper. More detailed information on the clinical study was reported elsewhere (UK BEAM Trial Team 2004, see ‘Other Publications of Related Interest’ for bibliographic details).

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
To yield an 80% power of detecting significant differences at a 1% significance level, data on approximately 1,350 patients were required. A total of 1,417 patients were eligible and were willing to participate in the study, of which 83 failed randomisation eligibility criteria. Hence 1,334 were included into the study. For the cost-utility analysis, 1,286 (96%) of the 1,334 trial participants were included in the study. Three hundred and twenty-six patients were randomised to best care in general practice, 297 to best care plus exercise alone, 342 to best care plus manipulation alone, and 322 to best care plus manipulation and exercise. The authors did not provide the age and gender distribution for the sample used in the cost-utility analysis. However, they did provide the baseline characteristics of the study groups in the accompanying clinical paper.

Study design
The study was a pragmatic randomised controlled trial (RCT) with factorial design. It was carried out in 14 centres across the UK. After consenting participants had completed their baseline assessments, nurses contacted the remote randomisation service. This stratified participants by practice and allocated them by randomly permuted blocks. The participants were followed up for 12 months. The authors did not report the loss to follow-up for the study sample used in the cost-utility analysis. However, in the clinical paper, the authors reported a loss to follow-up ranging from 31% in the exercise group to 22% in the manipulation and exercise group receiving treatment in the NHS.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary health outcome used in the analysis was the EQ-5D scores at baseline, 3 months and one year after randomisation. The EQ-5D measures health on five 3-point scales. More specifically, mobility, self-care, usual activities, pain-discomfort and anxiety depression. In the accompanying clinical paper the authors reported that all groups were similar in terms of their baseline characteristics.

Effectiveness results
As the results were expressed as utilities, these are presented in the health benefits field.

The authors also stated that the accompanying clinical paper reported that exercise alone achieved a small functional benefit at 3 months, but not at one year, and that manipulation achieved a small to moderate benefit at 3 months and a small benefit at one year. Combined treatment achieved a moderate benefit at 3 months and a small benefit at one year. (All these were statistically significant). No significant differences in outcome occurred between manipulation in NHS premises and private premises.

Clinical conclusions
The authors concluded that manipulation improved back function by a small to moderate margin at 3 months and by a
small but significant margin at 12 months, also achieving sustained improvements in general physical health.

Modelling
The authors reported that as trial participants who were registered with the same general practice formed clusters within centres, and centres formed clusters within the trial, the use of standard cost-utility methods could yield misleading results. Therefore, they used Bayesian Markov Chain Monte Carlo methods to undertake a bivariate multilevel analysis.

Measure of benefits used in the economic analysis
The measure of benefits used was the quality-adjusted life-years (QALYs). QALYs were generated through participants' responses to the EQ-5D. The health states were valued by a large British sample on a utility scale on which being dead scored 0 and perfect health scored 1. The authors estimated how many QALYs participants had experienced over their year by calculating areas under the health utility curves.

Direct costs
Resource use and costs were not reported separately. The direct costs included were those to the health care system. These were the costs of the spinal manipulation package, the exercise programme, hospital inpatient stay (both in private and NHS settings), outpatient visits (both private and NHS) and general practice consultations. NHS care was costed using national averages for England, while private care was costed by using information from a major insurance provider. However, as the clinical paper found no difference in clinical outcome between manipulation in private and NHS premises, the main economic analysis used costs for the less expensive NHS premises. Nevertheless, this assumption was explored in a sensitivity analysis. Discounting was unnecessary, as all the costs were incurred during one year, and hence was not performed. The study reported the average costs. The price year was 2000/2001.

Statistical analysis of costs
The costs were reported as means with their respective SDs.

Indirect Costs
The indirect costs were not included.

Currency
UK pounds sterling (€).

Sensitivity analysis
To report the uncertainty due to sampling variation, the authors calculated Bayesian credibility intervals. The authors did three sensitivity analyses to explore how dependent the results were on participants' estimates of total costs and their estimates of unit costs. In the first analysis, the authors excluded cost "outliers" (i.e. those participants whose costs exceeded 2,000) in case their chance allocation between groups had distorted the results. The other two sensitivity analyses assessed the influence of the unit costs of manipulation.

Estimated benefits used in the economic analysis
The estimated QALYs gained over one year were:

for best care in general practice, 0.618 (+/- 0.232);

for best care plus exercise alone, 0.635 (+/- 0.245);

for best care plus manipulation alone, 0.659 (+/- 0.241); and
for best care plus manipulation and exercise, 0.651 (+/- 0.237).

Cost results
The cost per patient with each treatment strategy was:

with best care in general practice, 346;

with best care plus exercise alone, 486;

with best care plus manipulation alone, 471; and

with best care plus manipulation and exercise, 541.

Synthesis of costs and benefits
The costs and benefits were combined using an incremental cost-utility ratio (i.e. the extra cost required per QALY gained). Best care plus exercise was found to be dominated by best care in general practice (i.e. it cost more, and fewer QALYs were gained than with best care in general practice). When manipulation and exercise were both available, combined treatment together with best care yielded an incremental cost-utility ratio of 3,800 relative to best care. Manipulation combined with best care yielded an incremental cost-utility ratio of 8,700 compared with combined treatment (i.e. manipulation plus exercise plus best care).

The results from the sensitivity analysis showed that if the ceiling was only 2,000 per QALY, there would be a 74% probability that best care would be the best strategy. If the ceiling was 15,000 per QALY, manipulation in combination with best care would have a 50% probability of being the best strategy.

When outliers were excluded from analysis, manipulation achieved extended dominance over both combined treatment and exercise treatment, and an incremental cost-utility ratio of 3,000 per QALY, with a 73% chance of being best.

The second sensitivity analysis used private costs for manipulation that took place in private premises. Combined treatment now achieved extended dominance over exercise, with an incremental cost-utility ratio of 6,600 compared with best care. Manipulation alone had a ratio of 8,700 relative to combined treatment.

When private costs were used for all manipulations within the trial, the results were very similar to those from the second sensitivity analysis.

Authors' conclusions
Spinal manipulation was a cost-effective addition to best care for back pain in general practice. Manipulation alone probably gave better value for money than manipulation followed by exercise.

CRD COMMENTARY - Selection of comparators
A justification was given for using best care in general practice as the comparator. It represented current practice in the authors' settings. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The study was based on a pragmatic RCT with factorial design. This was appropriate for the study question, as well-conducted RCTs are generally considered the 'gold' standard when comparing health interventions. The study sample appears to have been representative of the study population, and in the accompanying clinical paper it was shown that the patient groups were comparable. In the present paper, the authors failed to mention why resource and cost information was not collected for 4% of the trial participants. This omission, however, is unlikely to have affected the results, owing to the large number of patients and the proportion being so small. It would have also been desirable if the authors had reported a few more details of the clinical paper in the economic analysis. However, the study is likely to
have been internally valid because of, amongst other things, the large number of patients involved, the method of randomisation used, and the basis of the analysis being intention to treat.

**Validity of estimate of measure of benefit**
The estimation of benefits was obtained from the clinical study. However, it was unclear what the multilevel analysis model involved. The authors reported that it was used, but did not report any more details.

**Validity of estimate of costs**
All the categories of cost relevant to the perspective adopted were included. In addition, all unit costs within those categories appear to have been considered in the analysis. Although the costs and the quantities were not reported separately, the authors reported all unit costs, and all costs were broken down by resource category, which will enhance the generalisability of the authors' results. The unit costs were derived from national averages for NHS costs, while a major insurance provider provided private care costs. Appropriate sensitivity analyses of the costs were undertaken. Discounting was unnecessary, as all costs were incurred during one year, and hence was not performed. The price year was reported, which will ease any possible inflation exercises.

**Other issues**
The authors made appropriate comparisons with other economic evaluations undertaken in the UK, Sweden and Finland. These studies all had conflicting results. The issue of generalisability to other settings was addressed in the sensitivity analysis. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors reported as a limitation to their study the fact that they were unable to follow the patients for more than one year. Given that these patients were continuing to show benefits of treatment at 12 months, the cost-effectiveness of both manipulation and combined treatment could have been better than was reported in the paper.

**Implications of the study**
The authors reported that since physiotherapists and osteopaths could achieve higher incomes in private practice than in the NHS, it would be difficult to make manipulative or combined treatment generally available in the NHS. However, they also reported that, as the results of the sensitivity analysis showed, purchasing manipulation from the private sector to provide treatment within the NHS would still represent good value for money if decision-makers were willing to pay 10,000 per additional QALY.

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**Other publications of related interest**


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