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

UK BEAM Trial Team

Abstract

Objective To assess the cost effectiveness of adding spinal manipulation, exercise classes, or manipulation followed by exercise (“combined treatment”) to “best care” in general practice for patients consulting with low back pain.

Design Stochastic cost utility analysis alongside pragmatic randomised trial with factorial design.

Setting 181 general practices and 63 community settings for physical treatments around 14 centres across the United Kingdom.

Participants 1287 (96%) of 1334 trial participants.

Main outcome measures Healthcare costs, quality adjusted life years (QALYs), and cost per QALY over 12 months.

Results Over one year, mean treatment costs relative to “best care” were £195 (\$360; €279; 95% credibility interval £85 to £308) for manipulation, £140 (£3 to £278) for exercise, and £125 (£21 to £228) for combined treatment. All three active treatments increased participants’ average QALYs compared with best care alone. Each extra QALY that combined treatment yielded relative to best care cost £3800; in economic terms it had an “incremental cost effectiveness ratio” of £3800. Manipulation alone had a ratio of £8700 relative to combined treatment. If the NHS was prepared to pay at least £10 000 for each extra QALY (lower than previous recommendations in the United Kingdom), manipulation alone would probably be the best strategy. If manipulation was not available, exercise would have an incremental cost effectiveness ratio of £8300 relative to best care.

Conclusions Spinal manipulation is a cost effective addition to “best care” for back pain in general practice. Manipulation alone probably gives better value for money than manipulation followed by exercise.

Introduction

An economic evaluation found that physiotherapy led exercise classes for back pain were less expensive and more effective than general practice care alone.¹ In contrast, a Finnish study found that patients randomised to exercise had higher costs and poorer outcomes.² A Swedish study found no differences in costs or outcomes between physiotherapy and chiropractic manipulation,³ whereas a UK trial comparing private chiropractic and NHS outpatient treatment found that reductions in time off work more than offset the net health service cost incurred by chiropractic treatment.⁴ To reduce the uncertainty surrounding the cost effectiveness of these physical treatments for back pain, we report the economic evaluation of the UK BEAM trial.⁵

Methods

Interventions

“Best care” in general practice (the “comparator” treatment)—We trained practice teams in “active management” and provided *The Back Book* for patients.



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Exercise programme—This comprised an initial assessment and up to nine classes in community settings over 12 weeks.

Spinal manipulation package—The UK chiropractic, osteopathic, and physiotherapy professions agreed to use a package of techniques developed by a multidisciplinary group, during eight sessions over 12 weeks.

Combined treatment—Participants received six weeks of manipulation followed by six weeks of exercise. Treatments were otherwise those given to the manipulation only or exercise only groups.

Study design

We randomised participants between these four interventions. We also randomised participants receiving manipulation between private and NHS premises. As we did not find statistically significant differences in outcome between manipulation in NHS and private premises, this paper analyses the simpler two by two factorial trial.

Data collection

Participants completed questionnaires, including the EQ-5D health status instrument,^{6,7} at baseline, three months, and 12 months. Over the same period they recorded use of health care—including hospital stays, visits to secondary and primary care, and physical therapists, both private and within the NHS—whether related to back pain or not. Physical therapists completed record forms, including the number of treatments they delivered.

Unit costs

We conducted an economic analysis from the perspective of health care. Follow up was between August 1999 and April 2002. We used unit costs in pounds sterling at 2000-1 prices. We costed NHS care from national averages for England.^{8,9} We costed private care by using information from a major insurance provider.¹⁰

Health outcomes

The EQ-5D measures health on five three point scales. We estimated how many quality adjusted life years (QALYs) participants had experienced over their year in the UK BEAM trial by calculating “areas under (health utility) curves”¹¹ (see bmj.com).

Cost utility analysis

We estimated the mean costs of, and mean QALYs gained by, each of four distinct treatments. Firstly, we ranked treatments by mean cost, starting from the least costly. Secondly, we calculated incremental cost effectiveness ratios for all treatments by dividing incremental costs by incremental QALYs. Finally, we excluded from the comparison “dominated” treatments and treatments subject to “extended dominance,”¹² and we recalculated ratios if necessary. See bmj.com for details.

We used Bayesian multilevel analysis.¹³ We made no assumptions about the probabilities before UK BEAM that one treatment was more effective or cost more than another.

To report the uncertainty due to sampling variation, we calculated Bayesian credibility intervals (Bayesian analogue of 95% confidence intervals) and plotted multi-treatment cost effectiveness acceptability curves.^{14,15} These curves show the posterior (after UK BEAM) probability that each strategy is better than the

other three across the range of values that decision makers may pay to achieve an additional QALY. This assumes that these people have maximum values that they are willing to pay for an additional QALY. It is this “ceiling” against which they should compare estimated incremental cost effectiveness ratios and read the probability that the corresponding treatment is “best.” This decision oriented formulation selects as “best” or “cost effective” that treatment, with an incremental cost effectiveness ratio below the ceiling, likely to be more effective than competing treatments. This is not necessarily the strategy with the lowest ratio, as that may generate fewer QALYs.¹⁴ We also plotted two-treatment cost effectiveness acceptability curves to compare best care with manipulation alone or exercise alone.

Finally, we did three sensitivity analyses to explore how dependent the results were on participants’ estimates of total costs and our estimates of unit costs. The first analysis examined the influence of cost “outliers,” very large healthcare costs reported by a few participants. The other two sensitivity analyses assessed the influence of the unit costs of manipulation: by costing the scenario in which the NHS buys all manipulation from the private sector using private manipulation costs; and by costing the scenario in which the NHS buys half its manipulation from the private sector, using private costs when trial manipulation took place in private premises and NHS costs when in NHS premises.

Results

Recruitment

We recruited 1334 participants from 181 practices around 14 centres. Of these, 1287 (96.5%) yielded enough data for inclusion in the economic analysis; 326 received best care in general practice, 297 received best care plus exercise, 342 received best care plus manipulation, and 322 received best care plus combined treatment.

Clinical outcomes

Exercise achieved a small functional benefit at three months but not at one year; manipulation achieved a small to moderate benefit at three months and a small benefit at one year; and combined treatment achieved a moderate benefit at three months and a small benefit at one year.⁵ These benefits were specific to back pain, in contrast to the general health benefits determined in this paper.

Costs

Combined treatment had the highest therapy costs but the lowest subsequent hospital costs. So it cost only £125 (\$231; €179; 95% credibility interval £21 to £228) more than best care, whereas exercise cost £140 (£3 to £278) more than best care, and manipulation cost £195 (£85 to £308) more.

Health outcomes

Relative to best care, manipulation generated a mean of 0.041 (95% credibility interval 0.016 to 0.066) QALYs per participant, combined treatment generated 0.033 (−0.001 to 0.067), and exercise generated 0.017 (−0.017 to 0.051).

Table 1 Cost utility analysis by scenario and treatment group*

Treatment group	Mean cost* (£)	Mean adjusted QALYs*†	Incremental cost effectiveness ratio to nearest £100 or comment
Manipulation and exercise both available (n=1287)			
Best care in general practice	346	0.618	
Best care plus exercise	486	0.635	Dominated by combined treatment, which costs less and gains more QALYs
Best care plus manipulation and exercise	471	0.651	£3800
Best care plus manipulation	541	0.659	£8700 relative to manipulation and exercise
Exercise not available (n=623)			
Best care in general practice	346	0.622	
Best care plus manipulation	541	0.663	£4800 relative to best care
Manipulation not available (n=668)			
Best care in general practice	346	0.610	
Best care plus exercise	486	0.627	£8300 relative to best care

QALY=quality adjusted life year.

*Markov Chain Monte Carlo estimates from bivariate multilevel model.

†Estimated by analysis of covariance with adjustment for baseline EQ-5D score and then rounded to three significant figures.

Cost utility analysis

When manipulation and exercise are both available, combined treatment generates 0.033 more QALYs than does best care at an additional cost of £125, yielding an incremental cost effectiveness ratio of £3800 (table 1). This achievement dominates that of exercise alone, which costs more and achieves less over 12 months. Manipulation alone, however, can generate 0.008 more QALYs than combined treatment for an extra £70, yielding a ratio of £8700 relative to combined treatment. If exercise is not available, however, manipulation generates 0.041 more QALYs than best care, yielding an incremental cost effectiveness ratio of £4800. If manipulation is not available, exercise generates 0.017 more QALYs than best care, yielding a ratio of £8300.

The cost effectiveness acceptability curves in the top panel of the figure show the probability that each of the four treatments is better than the other three when all are available. If the ceiling was only £2000 per QALY, the top panel shows a 74% probability that best care would be the best strategy. If the ceiling was £5000 per QALY, combined treatment has a lower incremental cost effectiveness ratio than this; the top panel of the figure shows a 46% chance that it would be best. If the ceil-

ing was £15 000 per QALY (lower than implied by previous recommendations by the National Institute for Clinical Excellence¹⁶), manipulation alone has a lower incremental cost effectiveness ratio than this; the top panel shows a 50% probability that it would be best. The cost effectiveness acceptability curve in the middle panel of the figure shows the probability that manipulation is better than best care when exercise is not available; and vice versa for the curve in the bottom panel.

Sensitivity analyses

To assess the robustness of these results to the presence of “outliers,” we excluded the 51 participants whose healthcare costs exceeded £2000. Manipulation achieves extended dominance over both exercise and combined treatment (table 2). The second sensitivity analysis used private costs for manipulation that took place in private premises, and the third sensitivity analysis used private unit costs for all manipulation within the trial (table 2).

Discussion

Principal findings

This economic evaluation supports and extends the findings of the clinical evaluation of the UK BEAM

Table 2 Sensitivity analyses by treatment group*

Treatment group	Mean cost* (£)	Mean adjusted QALYs*†	Incremental cost effectiveness ratio to nearest £100 or comment
Excluding participants with health care costing more than £2000 over 12 months (n=1266)			
Best care in general practice	277	0.621	
Best care plus exercise	322	0.632	Subject to extended dominance by manipulation
Best care plus manipulation and exercise	403	0.647	Subject to extended dominance by manipulation
Best care plus manipulation	411	0.665	£3000 relative to best care
NHS provides manipulation for only 50% of patients (n=1287)			
Best care in general practice	346	0.616	
Best care plus exercise	486	0.628	Subject to extended dominance by manipulation and exercise
Best care plus manipulation and exercise	537	0.645	£6600 relative to best care
Best care plus manipulation	624	0.655	£8700 relative to manipulation and exercise
Manipulation provided only in private premises (n=1287)			
Best care in general practice	346	0.616	
Best care plus exercise	486	0.628	Subject to extended dominance by manipulation and exercise
Best care plus manipulation and exercise	595	0.645	£8600 relative to best care
Best care plus manipulation	701	0.655	£10 600 relative to manipulation and exercise

QALY=quality adjusted life year.

*Markov Chain Monte Carlo estimates from bivariate hierarchical multilevel model.

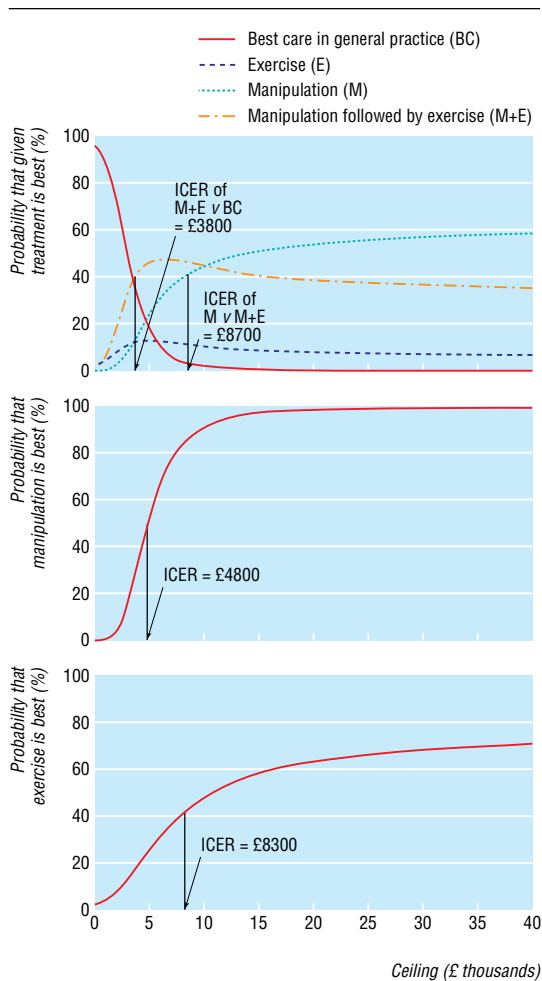
†Estimated by analysis of covariance with adjustment for baseline EQ-5D score and then rounded to three significant figures.

trial reported in the accompanying paper.⁵ If decision makers value additional quality adjusted life years (QALYs) at much less than £3800, “best care” in general practice is probably the best strategy. If their valuation lies between £3800 and £8700, spinal manipulation followed by exercise classes (“combined treatment”) is likely to be the best treatment. If their valuation is well above £8700, manipulation alone is probably the best treatment.

Strengths and weaknesses of the study

The sensitivity analysis that removed 51 “outliers” from the UK BEAM dataset, was more favourable to manipulation than was the primary analysis. Under this scenario manipulation cost only £3000 per QALY relative to best care in general practice.

We believe that this is the first study of physical therapy for low back pain to show convincingly that both manipulation alone and manipulation followed by exercise provide cost effective additions to care in general practice. As we trained practice teams in the best care of back pain, we may have underestimated the benefit of physical therapy when compared with “usual care” in general practice.



Cost effectiveness acceptability curves. Top: manipulation and exercise available; middle: exercise not available; bottom: manipulation not available. ICER=incremental cost effectiveness ratio

What is already known on this topic

Back pain is a major economic problem

Little evidence exists for the effectiveness and cost effectiveness of two commonly used treatments—exercise classes and spinal manipulation

What this study adds

Spinal manipulation, exercise classes, and manipulation followed by exercise all increased participants’ quality of life over 12 months by more than did “best care” in general practice

Adding spinal manipulation to best care in general practice is effective and cost effective for patients in the United Kingdom

If the NHS can afford at least £10 000 for each quality adjusted life year yielded by physical treatments, manipulation alone probably gives better value for money than manipulation followed by exercise

Unanswered questions

Funding constraints prevented us from following up participants for more than 12 months. Combined therapy depends on an ample supply of both trained manipulators prepared to work for the NHS and exercise physiotherapists with access to suitable premises. As back pain is a common problem, making manipulation generally available will require many therapists. Therapists can achieve higher incomes in private practice than in the NHS. In the short term it may be difficult to make manipulative or combined treatment generally available within the NHS.

Whereas physiotherapists can rapidly train to deliver the exercise package, insufficient trained manipulators are available to meet potential demand, and it may be decades before the NHS can implement these findings. Fortunately, using private costs for manipulation had little effect on the choice of best treatment. 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.

Meaning of the study

Adding spinal manipulation to best care in general practice is effective and cost effective for patients with back pain in the United Kingdom. If the NHS can afford more than £10 000 for an extra QALY, manipulation alone probably gives better value for money than manipulation followed by exercise. These conclusions hold even if the NHS has to buy spinal manipulation from the private sector.

We thank all participants—patients, primary care staff, and collaborators listed in the accompanying clinical paper—for their contributions. We thank Mark Sculpher and Daphne Russell for advice on analysis. Members of the UK BEAM Trial Team: Ian Russell, Martin Underwood, Stephen Brealey, Kim Burton, Simon Coulton, Amanda Farrin, Andrew Garratt, Emma Harvey, Louise Letley, Andrea Manca, Jeannett Martin, Jennifer Klaber Moffett, Veronica Morton, David Torgerson, Madge Vickers, Ken Whyte, Melanie Williams. The trial ISRCTN is 32683578.

Contributors: See bmj.com

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Competing interests: LL, JM, MU, MV, and KW have received salaries from the MRC. MU has received fees for speaking from Menarini Pharmaceuticals, the manufacturers of dexketoprofen and ketoprofen, and Pfizer, the manufacturers of celecoxib and valdecoxib. The other 12 authors have nothing to declare.

Ethical approval: The Northern and Yorkshire multicentre research ethics committee and 41 local research ethics committees approved the trial protocol.

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Corrections and clarifications

Inappropriate use of randomised trials to evaluate complex phenomena: case study of vaginal breech delivery

In the final stage of production of this Education and Debate article by Andrew Kotaska, human error conspired with an electronic glitch to produce two correspondence addresses—only one of which was correct (30 October, pp 1039-42). As well as publishing Kotaska's email address, we wrongly inserted the email address for the corresponding author (P Garner) of the preceding article (although that email address also appeared in the correct place, attached to Garner's article).

Newly diagnosed hypothyroidism

We failed to spot a spelling mistake and an outdated drug name in this "10-minute consultation" article by H U Rehman and T A Bajwa (27 November, p 1271). It should be carpal (not carpel) tunnel syndrome, and the recommended international non-proprietary name (rINN) of the treatment for hypothyroidism is levothyroxine (not thyroxine, which is the former British approved name, BAN).

A memorable teacher

Serendipity

In retrospect, my belief in serendipity began in the summer of 1951. I was between my first and second years as a clinical medical student at the Welsh National School of Medicine when I was attracted to a medical secretary working in the MRC unit at nearby Llandough Hospital.

She told me that the unit was looking for two medical students who, for a modest stipend, would assist in an MRC survey of coal miners' chest diseases in one of the South Wales mining valleys. Apart from the attractions of the secretary, no stipend was too modest for me at that time, and I applied. Having been interviewed by Archie Cochrane, who was running the survey, I was the third choice of the four who applied. One of the first two dropped out, so I was in.

During that long distant summer, I cannot recall having been given any important duties beyond arranging x ray envelopes in alphabetical order. But I do remember many hours in the company of Archie Cochrane. It was a small team, and we spent long hours classifying chest x rays and poring over the data, which were well beyond my comprehension. We also spent time in his Jaguar car, of which he was quite proud, visiting individual miners in their homes who for many diverse and interesting reasons did not wish to be x rayed. Considerable energy was expended in ensuring that the survey should be 100%.

Once or twice he had a migraine, which meant a longer session the next day. To me, he was kind and quizzical. I doubt that I ever gave him any of the answers he wanted, but he tried hard to make me think.

Subsequent distractions of examinations and surgical training meant that I knew little of him again until I became a consultant in Cardiff in 1966 and was able to meet him on more equal terms. By this time he had become an international figure on healthcare policy, which was later crystallised in his 1972 classic monograph *Effectiveness and Efficiency: Random Reflections on Health Services*. To my mind, this remains the definitive work on the functioning of the NHS and, at only 92 pages, should be compulsory reading for all clinicians and managers who work in it.

I cannot now remember much about the medical secretary, but I remain most grateful to her for telling me about that holiday job in 1951. Because of it, I came to know a really remarkable man and, to a certain extent, to understand what made him tick. He died in 1988. I feel sure that all the current talk of "integrated medicine" must be making him turn in his grave.

David Crosby *retired surgeon, University Hospital of Wales, Cardiff*

We welcome articles up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake*, or any other piece conveying instruction, pathos, or humour. Please submit the article on <http://submit.bmj.com> Permission is needed from the patient or a relative if an identifiable patient is referred to. We also welcome contributions for "Endpieces," consisting of quotations of up to 80 words (but most are considerably shorter) from any source, ancient or modern, which have appealed to the reader.