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.
compares four distinct treatments within the factorial design.

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Health outcomes

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W e costed private care by using information from a

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no difference in clinical outcome between manipulation in private and NHS premises, our main economic analysis used costs for the less expensive NHS premises. Nevertheless, we explored this assumption in a sensitivity analysis.

Health outcomes

The EQ-5D measures health on five three point scales—mobility, self care, usual activities, pain/discomfort, and anxiety-depression—thus putting participants into one of 243 (=3^5) health states. A large British sample valued these states on a "utility" scale on which being dead scores zero and perfect health scores one. 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." For example, if they reported that their utility averaged 0.5, we calculated that they had experienced half a QALY over the year in UK BEAM. To avoid bias we adjusted for differences in baseline EQ-5D scores.

Cost utility analysis

Because the accompanying clinical paper found statistically significant interactions between manipulation and exercise, it compares four distinct treatments within the factorial design. Although costs show no interaction between treatments, this paper also compares these four treatments for three reasons. Firstly, as costs vary much more than clinical outcomes, this is prudent. Secondly, those people responsible for allocating resources need to choose between these four treatments. Finally, this epitomises the Bayesian statistical approach adopted in this paper.

Unit costs

To contribute to health policy for an expensive condition, we conducted an economic analysis from the perspective of health care. Participants' follow up periods lay between August 1999 and April 2002. We therefore used unit costs in pounds sterling at 2000-1 prices to value the resources they used (table 1). We did not adjust or discount the costs, as we focused on effects over only one year. We costed NHS care from national averages for England. We costed private care by using information from a major insurance provider. As the accompanying paper found no difference in clinical outcome between manipulation in private and NHS premises, our main economic analysis used costs for the less expensive NHS premises. Nevertheless, we explored this assumption in a sensitivity analysis.

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So we estimated the mean costs of, and mean QALYs gained by, each of four distinct treatments. As most trials compare just two treatments, we adopted a more general approach. 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," and we recalculated ratios if necessary. A treatment is dominated if it generates worse health outcomes and costs more than an alternative treatment. Extended dominance occurs when a treatment is less effective and has a higher incremental cost effectiveness ratio than an alternative treatment.

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Results

Recruitment
We recruited 1334 participants from 181 practices around 14 centres across the United Kingdom. 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
The accompanying clinical paper reports that exercise achieved a small functional 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 (all statistically significant). 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 (table 2). So it cost only £125 (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
Physical interventions improved EQ-5D scores more than did best care (table 3). 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).

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 4). 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 QALY's than best care, and 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 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 ceiling was £15 000 per QALY (lower than implied by previous recommendations by the National Institute for Clinical Excellence), manipulation alone has a lower incremental cost effectiveness ratio than this; the top

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Reported mean (SD) cost (£) of health care over 12 months by treatment group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare resource</td>
<td>Best care in general practice (n=326)</td>
</tr>
<tr>
<td>Spinal manipulation within UK BEAM</td>
<td>147 (53)</td>
</tr>
<tr>
<td>Hospital inpatient stay</td>
<td>31 (112)</td>
</tr>
<tr>
<td>Private hospital admission</td>
<td>5 (85)</td>
</tr>
<tr>
<td>Outpatient attendance</td>
<td>51 (150)</td>
</tr>
<tr>
<td>Other NHS</td>
<td>44 (335)</td>
</tr>
<tr>
<td>General practice consultation</td>
<td>94 (146)</td>
</tr>
<tr>
<td>General practitioner</td>
<td>63 (129)</td>
</tr>
<tr>
<td>Practice nurse</td>
<td>7 (48)</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>102 (125)</td>
</tr>
<tr>
<td>Other</td>
<td>11 (51)</td>
</tr>
<tr>
<td>Total cost</td>
<td>346 (602)</td>
</tr>
</tbody>
</table>

* Including spinal manipulation or exercise class outside UK BEAM.

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Utilities and QALYs over 12 months by treatment group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Best care in general practice (n=326)</td>
</tr>
<tr>
<td>Mean (SD) utility from EQ-5D* at:</td>
<td>0.597 (0.233)</td>
</tr>
<tr>
<td>Baseline</td>
<td>0.626 (0.249)</td>
</tr>
<tr>
<td>Three months</td>
<td>0.629 (0.263)</td>
</tr>
<tr>
<td>One year</td>
<td>0.618 (0.232)</td>
</tr>
<tr>
<td>Mean (SD) QALYs over 12 months*</td>
<td>0.017 (−0.017 to 0.051)</td>
</tr>
</tbody>
</table>

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

QALY=quality adjusted life year.
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 (9, 16, 16, and 10 from best care, exercise alone, manipulation alone, and combined treatment respectively) whose healthcare costs exceeded £20 000. Manipulation achieves extended dominance over both exercise and combined treatment (table 5). It is thus the only alternative to best care, with an incremental cost effectiveness ratio of £3000 per additional QALY. At a ceiling of £10 000 per QALY, manipulation has a 73% chance of being best. If manipulation alone were not available, exercise would have a ratio of £4100.

The second sensitivity analysis used private costs for manipulation that took place in private premises. Combined treatment now achieves extended dominance over exercise, with an incremental cost effectiveness ratio of £6000 compared with best care (table 5). Manipulation alone then has a ratio of £8700 relative to combined treatment.

The third sensitivity analysis used private unit costs for all manipulation within the trial. The findings are analogous to those in the second scenario. Exercise is subject to extended dominance, and combined treatment has an incremental cost effectiveness ratio of £8600 compared with best care (table 5). Manipulation alone then has a ratio of £10 600 relative to combined treatment.

**Discussion**
**Principal findings**
This economic evaluation supports and extends the findings of the clinical evaluation of the UK BEAM trial reported in the accompanying paper. 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**
Although two of our three sensitivity analyses—those that used larger unit costs in whole or in part—changed these critical thresholds a little, they did not alter the essentials of these conclusions. The other sensitivity analysis, which 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. Indeed, 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. The detailed clinical outcomes reported in the accompanying paper reinforce these findings by showing that the improvements in health status reported here reflect statistically significant improvements in function, pain, disability, physical and mental aspects of quality of life, and beliefs about back pain.

**Unanswered questions**
Funding constraints prevented us from following up participants for more than 12 months. Given that they continued to show
Table 5 Sensitivity analyses by treatment group*

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Mean cost* (£)</th>
<th>Mean adjusted QALYs†</th>
<th>Incremental cost effectiveness ratio to nearest £100 or comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excluding participants with health care costing more than £2000 over 12 months (n=1266)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best care in general practice</td>
<td>277</td>
<td>0.621</td>
<td></td>
</tr>
<tr>
<td>Best care plus exercise</td>
<td>322</td>
<td>0.632</td>
<td>Subject to extended dominance by manipulation</td>
</tr>
<tr>
<td>Best care plus manipulation and exercise</td>
<td>403</td>
<td>0.647</td>
<td>Subject to extended dominance by manipulation</td>
</tr>
<tr>
<td>Best care plus manipulation</td>
<td>411</td>
<td>0.665</td>
<td>£3000 relative to best care</td>
</tr>
<tr>
<td>NHS provides manipulation for only 50% of patients (n=1287)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best care in general practice</td>
<td>346</td>
<td>0.618</td>
<td></td>
</tr>
<tr>
<td>Best care plus exercise</td>
<td>486</td>
<td>0.628</td>
<td>Subject to extended dominance by manipulation and exercise</td>
</tr>
<tr>
<td>Best care plus manipulation and exercise</td>
<td>537</td>
<td>0.645</td>
<td>£6600 relative to best care</td>
</tr>
<tr>
<td>Best care plus manipulation</td>
<td>624</td>
<td>0.655</td>
<td>£8700 relative to manipulation and exercise</td>
</tr>
<tr>
<td>Manipulation provided only in private premises (n=1287)</td>
<td></td>
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<td>595</td>
<td>0.645</td>
<td>£6600 relative to best care</td>
</tr>
<tr>
<td>Best care plus manipulation</td>
<td>701</td>
<td>0.655</td>
<td>£10 600 relative to manipulation and exercise</td>
</tr>
</tbody>
</table>
| QALY=quality adjusted life year.
†Estimated by analysis of covariance with adjustment for baseline EQ-5D score and then rounded to three significant figures.

benefits of treatment at 12 months, the cost effectiveness of both manipulation and combined treatment may be better than we have reported.

Commissioning decisions should depend on local circumstances, notably the availability of spinal manipulation and exercise physiotherapists. Although combined therapy is an attractive option, this 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. In the United Kingdom there are 2100 registered osteopaths, 3900 registered osteopaths, and about 5000 manipulative physiotherapists (Ann Thomson, Chair of British Association of Chartered Physiotherapists in Manipulation, on behalf of the Chartered Society of Physiotherapy, personal communication, 2003). According to the unit costs we used in our analysis, they 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 in the United Kingdom to meet potential demand, and it will take several years to produce additional manipulators. Indeed, if this needs new training programmes, 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.

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

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.

Contributors: See accompanying clinical paper.

Funding: Medical Research Council (research costs); NHS in England, Northern Ireland, Scotland, and Wales (excess treatment and support costs).

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.

8 Underwood M, O'Meara S, Harvey E, UK BEAM Trial Team. The acceptability to primary care staff of a multidisciplinary training package on acute back pain guidelines. *Fam Pract* 2002;19:511-5.
doi 10.1136/bmj.38282.607859.AE
Correspondence to: Andrea Manca, research fellow, Centre for Health Economics, University of York, York YO10 5DD am126@york.ac.uk

**Amendment**

This is Version 2 of the paper. In this version, the text relating to the figure has been amended to state that the curve in the middle panel 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 [these were incorrectly given the other way round in the previous version].
Design: Randomised controlled trial of progressive exercise programme compared with usual primary care management. Patients’ preferences for type of management were elicited independently of randomisation. Participants: 187 patients aged 18-60 years with mechanical low back pain of 4 weeks to 6 months’ duration. Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences. Top article: Moffett 1999 Randomised CT, title: Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences, author: J. K. Moffett and D. Torgerson and S. Bell-Syer and D. Jackson and H. Llewlyn-Phillips and A. Farrin and J. Barber, journal: BMJ, year: 1999, volume: 319, pages: 279-283. Low back pain has major health and social implications. Although there have been many randomised controlled trials of manipulation and exercise for the management of low back pain, the role of these two treatments in its routine management remains unclear. A previous trial comparing private chiropractic treatment with National Health Service (NHS) outpatient treatment, which found a benefit from chiropractic treatment, has been criticised because it did not take treatment location into account. There are data to suggest that general exercise programmes may have beneficial effects on low back pain. UK BEAM Trial Team United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care. BMJ. 2004; 329: 1377. A randomised clinical trial of subgrouping and targeted treatment for low back pain compared with best current care. The STarT Back Trial Study Protocol. BMC Musculoskeletal Disorders.