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

UK BEAM Trial Team


## Abstract

**Objective** To estimate the effect of adding exercise classes, spinal manipulation delivered in NHS or private premises, or manipulation followed by exercise to "best care" in general practice for patients consulting with back pain.
**Design** Pragmatic randomised trial with factorial design.
**Setting** 181 general practices in Medical Research Council General Practice Research Framework; 63 community settings around 14 centres across the United Kingdom.
**Participants** 1334 patients consulting their general practices about low back pain.
**Main outcome measures** Scores on the Roland Morris disability questionnaire at three and 12 months, adjusted for centre and baseline scores.
**Results** All groups improved over time. Exercise improved mean disability questionnaire scores at three months by 1.4 (95% confidence interval 0.6 to 2.1) more than "best care." For manipulation the additional improvement was 1.6 (0.8 to 2.3) at three months and 1.0 (0.2 to 1.8) at 12 months. For manipulation followed by exercise the additional improvement was 1.9 (1.2 to 2.6) at three months and 1.3 (0.5 to 2.1) at 12 months. No significant differences in outcome occurred between manipulation in NHS premises and in private premises. No serious adverse events occurred.
**Conclusions** Relative to "best care" in general practice, manipulation followed by exercise achieved a moderate benefit at three months and a small benefit at 12 months; spinal manipulation achieved a small to moderate benefit at three months and a small benefit at 12 months; and exercise achieved a small benefit at three months but not at 12 months.


## Introduction

The role of different physical treatments for back pain is not clear. Evidence suggests that encouraging patients to keep active is effective,[1] but evidence for the effectiveness of spinal manipulation is conflicting.[2 3] Although specific exercises seem to be ineffective,[2] weak evidence exists for general programmes that encourage physical activity.[1 4]

The main aim of this trial was to estimate, for patients consulting their general practitioner with back pain, the effectiveness of adding the following to best care in general practice[5]: a class based exercise programme ("back to fitness"),[6] a package of treatment by a spinal manipulator (chiropractor, osteopath, or physiotherapist),[7] or manipulation followed by exercise. We also aimed to test whether the manipulation package was more or less effective in manipulators' private premises than in NHS premises.

## Methods

### Protocol

*Study design*
We randomised participants between spinal manipulation delivered in NHS premises, the same in private premises, and "best care" in general practice. We also randomised them between the exercise programme and best care. Of six groups of participants, one received only best care in general practice. The other five received best care plus an intervention—exercise, manipulation in private or NHS premises, or manipulation in private or NHS premises followed by exercise. Statistically this is a three by two factorial design.[8]

We selected 14 centres, including two for the feasibility study. All centres had general practices from the Medical Research Council (MRC) General Practice Research Framework (mrc-gprf.ac.uk), with a total of at least 40 000 registered patients within travelling distance of treatment locations for manipulation and exercise; two manipulators (chiropractors, osteopaths, or physiotherapists) with private premises, willing to work in NHS premises; a physiotherapist to deliver the exercise programme; NHS premises in the community for spinal manipulation; and premises in the community for exercise classes.

Correspondence to: Martin Underwood, professor of general practice, Centre for General Practice and Primary Care, Institute of Community Health Sciences, Barts and the London, Queen Mary's School of Medicine and Dentistry, Queen Mary University of London, London E1 4NS

m.underwood@qmul.ac.uk

*BMJ* 2004;329:1377–81

*Authorship details and a list of collaborators are on bmj.com*

*This is the abridged version of an article that was posted on bmj.com on 19 November 2004: http://bmj.com/cgi/doi/10.1136/bmj.38282.669225.AE; revised 29 November 2004*

*Recruitment of participants*
Research nurses identified patients consulting with back pain and assessed potential participants' eligibility and interest by postal questionnaires. They saw interested patients on two occasions: the first was to explain the trial and assess eligibility (box); the second was to confirm eligibility, seek consent, collect baseline data, and randomise participants. To exclude patients whose back pain resolved rapidly, randomisation occurred at least four weeks after the initiating consultation.

*"Best care" in general practice— the "comparator" treatment*
The UK national acute back pain guidelines advise continuing normal activities and avoiding rest.[1] We invited clinical and support staff from participating practices to training sessions on the "active management" of back pain,[5] and provided copies of *The Back Book*,[9] a booklet for patients with back pain.

*Interventions*
We defined "basic minimum treatment" as initial assessment plus one class for exercise and as two sessions, including assessment, for manipulation.

*Exercise programme*—We developed the exercise programme ("back to fitness"[6]) from previous trials. It comprises initial individual assessment followed by group classes incorporating cognitive behavioural principles. We trained physiotherapists to deliver this programme. Classes ran in local community facilities. Up to 10 people took part in each session. We invited participants to attend up to eight 60 minute sessions over four to eight weeks and a "refresher" class 12 weeks after randomisation.

*Spinal manipulation package*—A multidisciplinary group developed a package of techniques representative of those used by the UK chiropractic, osteopathic, and physiotherapy professions.[7] Similar numbers of qualified manipulators from each of these professions treated participants. Private manipulation took place in manipulators' own consultation rooms. NHS manipulation was with the same manipulators in NHS premises. Following initial assessment, manipulators chose from the agreed manual and non-manual treatment options. They agreed to do high velocity thrusts on most patients at least once. We invited participants to attend up to eight 20 minute sessions over 12 weeks.

**Inclusion criteria**
- Aged between 18 and 65 years
- Registered for medical care with a participating practice
- Consulted with simple low back pain—pain of musculoskeletal origin in the area bounded by the lowest palpable ribs, the gluteal folds, and the posterior axillary lines, including pain referred into the legs provided it was mainly above the knee
- Score of four or more on the Roland disability questionnaire at randomisation
- Pain every day for the 28 days before randomisation or for 21 out of the 28 days before randomisation and 21 out of the 28 days before that
- Agreed to avoid physical treatments, other than trial treatments, for three months

*Combined treatment*—We invited participants to attend eight sessions of manipulation over six weeks, eight sessions of exercise in the next six weeks, and a refresher class at 12 weeks. Other aspects of treatment were identical to those in the manipulation only or exercise only groups.

*Follow up and monitoring adverse events*
Participants completed questionnaires on general health, back pain, beliefs, and psychological wellbeing before randomisation and at one, three, and 12 months thereafter. The research team monitored serious adverse events.

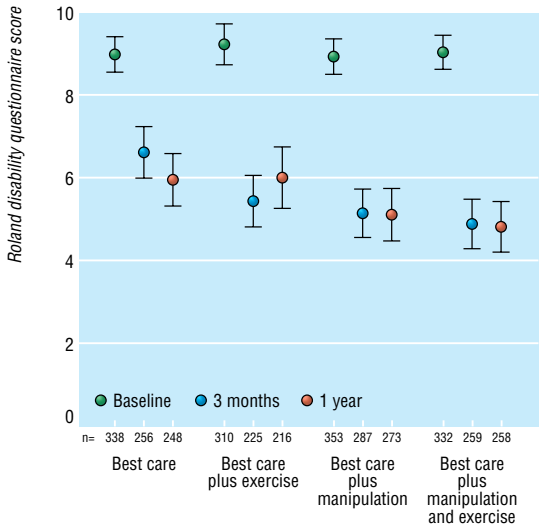
*Patient assessed outcomes*
Questionnaires included two back specific instruments—the Roland Morris disability questionnaire and the modified Von Korff scales,[10 11] two measures of belief—the back beliefs questionnaire and the fear avoidance beliefs questionnaire,[12 13] and two generic measures—the SF-36 and the EuroQol,[14 15] reported in the accompanying economic paper.[16]

*Assignment*
After participants had completed baseline assessments, they were stratified by practice and allocated between the six groups by randomly permuted blocks. Blinding of participants and professionals was neither desirable nor possible. See bmj.com for details of allocation and statistical power.

**Analysis**
We used two sided significance tests to analyse the primary outcome—Roland disability questionnaire score after three or 12 months—by intention to treat. We used analysis of covariance to adjust this score for centre and baseline score. We analysed the data in steps. Firstly, we used multilevel modelling to make allowance for the innate clustering of participants by centre, exercise class, manipulator, and practice. Secondly, we tested the effect of exercise without manipulation by comparing participants allocated to best care with those allocated to best care plus exercise. Thirdly, we tested the effect of manipulation without exercise by comparing participants allocated to best care with those allocated to best care plus manipulation. If this was significant, we tested for differences between manipulation in NHS and private premises. Finally, if either exercise or manipulation gave significant results, we tested for interactions between exercise and manipulation—that is, whether the estimated improvement in participants allocated to best care, manipulation, and exercise differed significantly from the sum of the estimated improvement due to manipulation and that due to exercise. See bmj.com for further details.

## Results

**Participant flow and follow up**
We recruited 1334 participants from 181 general practices around 14 centres; these were broadly typical of UK practices in size and deprivation. The feasibility study recruited 164 participants between March 1998 and April 1999.[8] The main trial recruited 1170 participants between August 1999 and April 2001. At three




Mean Roland disability questionnaire scores (with 95% confidence intervals) over 12 months by group: "best care" in general practice, best care plus exercise alone, best care plus manipulation alone, and best care plus manipulation and exercise

months, 1029 (77%) returned questionnaires; at 12 months, 995 (75%) returned questionnaires. Responders were much more likely than non-responders to be female, above average age, and educated beyond age 16 and to have had severe back pain at randomisation. These trends were consistent across randomised groups.

**Baseline data**

The mean (SD) age of participants at randomisation was 43 (11) years; 56% were female, and 9% were not working because of poor health. More than half had had pain for more than 90 days. Mean (SD) Roland disability score at randomisation was 9.0. The six randomised groups had similar characteristics.

**Process**

The message about active management reached most participants: when asked at randomisation, 1160 (87%) recalled seeing *The Back Book*. Of 686 participants allocated to manipulation, 633 (92%) received "basic minimum treatment." Of 643 participants allocated to exercise, 408 (63%) received basic minimum treatment.

**Analysis**

Roland disability questionnaire scores improved by a mean (SD) of 3.3 (4.5) points at three months and 3.5 (4.7) points at 12 months (figure).

*Exercise programme*

Exercise produced statistically significant improvements in mean Roland disability score at three months only (difference = 1.4; 95% confidence interval 0.6 to 2.1), in mean Von Korff disability and pain scores and back beliefs score at both three and 12 months, and in mean SF-36 physical score and fear avoidance beliefs physical score at three months only. Mean SF-36 mental score did not differ.

*Manipulation package*

Manipulation produced statistically significant improvements in Roland disability scores at three months (1.6; 0.8 to 2.3) and at one year (1.0; 0.2 to 1.8); in mean Von Korff pain score, back beliefs score, and SF-36 physical score at both three and 12 months; in mean Von Korff disability score at 12 months only; and in mean SF-36 mental score at three months only. Mean fear avoidance beliefs physical score did not differ.

We found no significant differences between the outcome of manipulation delivered in NHS or private premises. The adjusted difference in disability scores was 0.2 (−0.6 to 0.9) in favour of private premises at three months and 0.1 (−0.7 to 0.9) in favour of NHS premises at 12 months.

*Manipulation followed by exercise*

Manipulation followed by exercise produced significant improvements in Roland disability scores at three months (1.9; 1.2 to 2.6) and at one year (1.3; 0.5 to 2.1); in mean Von Korff disability and pain scores and back beliefs, fear avoidance beliefs, and SF-36 physical scores at both three and 12 months; but in mean SF-36 mental score only at three months (table). Three of these 13 significant improvements were significantly greater than the corresponding improvements from manipulation without exercise—in fear avoidance beliefs scores at three and 12 months and back beliefs scores at 12 months.

## Discussion

**Principal findings**

At three months, participants randomised to the "back to fitness" programme reported significant improvements in the primary functional outcome measure and several secondary outcomes—disability and pain, back beliefs, fear avoidance, and general physical health. Their mean improvement in disability score was equal to 35% of the population standard deviation—a "standardised difference" of 0.35. At 12 months, they maintained their reductions in disability and pain in full, and their improved beliefs about back pain in part, but not their other improvements, notably in Roland disability scores.

At three and 12 months, participants randomised to the spinal manipulation package reported significant improvements in Roland disability scores and several secondary outcomes—pain, back beliefs, and general physical health. Their disability scores improved by a standardised difference of 0.39 at three months and 0.25 at 12 months. They also reported improved mental health at three months, and improved disability at 12 months. These benefits did not differ between NHS and private premises.

At three and 12 months, participants randomised to combined treatment reported significant improvements in all reported outcomes except general mental health, which was significant only at three months. Their Roland disability scores improved by a standardised difference of 0.47 at three months and 0.32 at 12 months. However only two outcomes—back beliefs and fear avoidance—achieved significant improvements over manipulation alone. Although combined treatment offers little more than manipulation alone, firm recommendations depend on detailed economic analysis (reported in accompanying paper).[16]

Changes in outcome attributable to manipulation followed by exercise.† Values are mean (SE) scores unless stated otherwise

| Outcome measure (description) | At three months: Best care (max n=256/338: 76%) | At three months: Best care plus manipulation plus exercise (max n=258/333: 77%) | At three months: Net benefit from manipulation plus exercise (95% CI) | At 12 months: Best care (max n=248/338: 73%) | At 12 months: Best care plus manipulation plus exercise (max n=257/333: 77%) | At 12 months: Net benefit from manipulation plus exercise (95% CI) |
|---|---|---|---|---|---|---|
| Roland disability questionnaire (0-24, 0=best) | 6.71 (0.28) (n=256) | 4.84 (0.28) (n=258) | 1.87*** (1.15 to 2.60) | 6.02 (0.30) (n=248) | 4.72 (0.29) (n=257) | 1.30** (0.54 to 2.07) |
| Modified Von Korff scale: | | | | | | |
| Disability (0-100, 0=best) | 34.56 (1.50) (n=239) | 29.05 (1.49) (n=246) | 5.51** (1.75 to 9.28) | 34.80 (1.60) (n=235) | 28.09 (1.59) (n=246) | 6.71** (2.62 to 10.80) |
| Pain (0-100, 0=best) | 48.96 (1.60) (n=239) | 40.76 (1.59) (n=246) | 8.21*** (4.20 to 12.21) | 46.39 (1.66) (n=235) | 39.68 (1.65) (n=245) | 6.71** (2.47 to 10.95) |
| Back beliefs questionnaire (9-45, 45=best) | 27.97 (0.42) (n=239) | 31.25 (0.42) (n=245) | 3.28*** (2.23 to 4.33) | 27.61 (0.44) (n=233) | 30.56 (0.43) (n=244) | 2.96*** (1.84 to 4.07) |
| Fear avoidance beliefs questionnaire—physical scale (0-24, 0=best) | 13.08 (0.40) (n=236) | 10.68 (0.39) (n=245) | 2.40*** (1.41 to 3.39) | 12.81 (0.45) (n=208) | 11.58 (0.48) (n=204) | 1.24* (0.07 to 2.41) |
| SF-36 (mean=50, SD=10, 100=best): | | | | | | |
| Physical component score | 43.91 (0.48) (n=227) | 46.46 (0.48) (n=231) | 2.55*** (1.34 to 3.75) | 42.58 (0.62) (n=221) | 45.11 (0.64) (n=221) | 2.53** (0.96 to 4.09) |
| Mental component score | 46.59 (0.58) (n=227) | 48.89 (0.59) (n=231) | 2.30** (0.82 to 3.78) | 46.71 (0.73) (n=221) | 48.01 (0.75) (n=221) | 1.30 (−0.55 to 3.14) |

*Significant at 5% level; **significant at 1% level; ***significant at 0.1% level.
†Estimated by analysis of covariance adjusting for centre and baseline score. Because correlation coefficients within clusters (centres, exercise classes, manipulators, and practices) are small, this analysis generates estimates very similar to the corresponding, but more complex, multilevel model.

### Strengths and weaknesses of the study

The patients of the participating general practices were broadly typical of the United Kingdom. As we randomly allocated manipulators delivering therapy between their own and NHS premises, the absence of any difference in outcome answers some of the criticisms of the previous MRC trial of chiropractors.[17 18]

We used "best care" in general practice as the "comparator" treatment, which may have limited the size of our positive findings. That only 63% of participants allocated to the exercise programme received "basic minimum treatment" may have reduced its effectiveness. We cannot be sure whether limiting the treatments available to manipulators reduced or enhanced their effectiveness.

### What is already known on this topic

The role of different physical treatments for back pain is not clear

Evidence for the effectiveness of spinal manipulation is conflicting; one trial reported that treatment by private chiropractors was superior to routine outpatient treatment in the NHS but did not consider the effect of treatment location

Weak evidence exists for general programmes that encourage physical activity as a treatment for back pain

### What this study adds

The spinal manipulation package improves back function by a small to moderate margin at three months and by a smaller but still statistically significant margin at one year, irrespective of location

The exercise programme improves back function by a small but significant margin at three months but not at one year

Manipulation followed by exercise improves back function by a moderate margin at three months and by a smaller but still significant margin at one year

### Meaning of the study

The Roland disability questionnaire comprises 24 items designed to measure functional disability due to back pain, including walking, bending, sitting, lying down, sleeping, dressing, self care, and other daily activities.[10] Each item contributes one point to the total score. We found that exercise enabled participants to perform an average of 1.4 additional personal functions at three months, manipulation generated 1.6 additional personal functions at three months and 1.0 at 12 months, and combined treatment generated 1.9 additional personal functions at three months and 1.3 at 12 months.

### Unanswered questions

Are these small to moderate clinical benefits worth the cost of therapy? The large cost of back pain means that small differences in clinical outcomes may have large economic effects. We report the costs and benefits in quality of life of manipulation, exercise, and combined treatment in the accompanying economic paper.[16]

We thank all participants—patients, primary care staff, and the collaborators listed on bmj.com—for their contributions. 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

Funding: Medical Research Council (research costs); National Health Service in England, Northern Ireland, Scotland, and Wales (excess treatment and service support costs). The MRC established a trial steering committee to advise the grant holders and trial team on trial design; the collection, analysis, interpretation; and writing up of data; and publication policy.

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.

1 Waddell G, Feder G, McIntosh G, Lewis M, Hutchinson A. *Low back pain evidence review*. London: Royal College of General Practitioners, 1999.
2 Van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain: a systematic review of randomized controlled trials of the most common interventions. *Spine* 1997;22:2128-56.
3 Assendelft WJ, Morton SC, Yu EI, Suttorp MJ, Shekelle PG. Spinal manipulative therapy for low back pain: a meta-analysis of effectiveness relative to other therapies. *Ann Intern Med* 2003;138:871-81.
4 Van Tulder M, Malmivaara A, Esmail R, Koes B. Exercise therapy for low back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine* 2000;25:2784-96.
5 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.
6 Klaber Moffett J, Frost H, UK BEAM Trial Team. Back to fitness programme: the manual for physiotherapists to set up the classes. *Physiotherapy* 2000;85:295-305.
7 Harvey E, Burton AK, Moffett JK, Breen A, UK BEAM Trial Team. Spinal manipulation for low back pain: a treatment package agreed by the UK chiropractic, osteopathy and physiotherapy professional associations. *Man Ther* 2003;8:46-51.
8 UK BEAM Trial Team. UK back pain exercise and manipulation (UK BEAM) trial—national randomised trial of physical treatments for back pain in primary care: objectives, design and intervention. *BMC Health Serv Res* 2003;3:16.
9 Roland M, Waddell G, Klaber Moffett J, Burton AK, Main CJ, Cantrell T. *The back book*. Norwich: Stationery Office, 1996.
10 Roland M, Morris R. A study of the natural history of back pain. I: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8:141-4.
11 Underwood MR, Barnett AG, Vickers MR. Evaluation of two time-specific back pain outcome measures. *Spine* 1999;24:1104-12.
12 Symonds TL, Burton AK, Tillotson KM, Main CJ. Do attitudes and beliefs influence work loss due to low back trouble? *Occup Med* 1996;46:25-32.
13 Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993;52:157-68.
14 Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I: conceptual framework and item selection. *Med Care* 1992;30:473-83.
15 The EuroQol Group. EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199-208.
16 UK BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care. *BMJ* 2004;329:1381-5.
17 Meade TW, Dyer S, Browne W, Townsend J, Frank AO. Low back pain of mechanical origin: randomised comparison of chiropractic and hospital outpatient treatment. *BMJ* 1990;300:1431-7.
18 Assendelft WJ, Bouter LM, Kessels AG. Effectiveness of chiropractic and physiotherapy in the treatment of low back pain: a critical discussion of the British randomized clinical trial. *J Manipulative Physiol Ther* 1991;14:281-6.


*(Accepted 13 October 2004)*

doi 10.1136/bmj.38282.669225.AE

# 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.

Correspondence to:
Andrea Manca, research fellow, Centre for Health Economics, University of York, York YO10 5DD

am126@york.ac.uk

Full authorship details are given in the accompanying paper on page 1380

*BMJ* 2004;329:1381–5

ELPS *This is the abridged version of an article that was posted on bmj.com on 19 November 2004: http://bmj.com/cgi/doi/10.1136/bmj.38282.607859.AE; revised 29 November 2004*