

Commentary

The UK BEAM trial – a review and discussion

Steven Vogel^{a,*}, Joanne Dear^a, David Evans^b

^a *British School of Osteopathy, 275 Borough High Street, London, SE1 1JE, UK*

^b *School of Health and Rehabilitation, Keele University, Keele, Staffordshire, ST5 5BG, UK*

Received 29 March 2005; received in revised form 5 April 2005; accepted 6 April 2005

Abstract

In the hierarchy of evidence that influences healthcare policy, randomised controlled trials (RCTs) are considered by most to be the top individual unit of research. RCTs of treatments for simple, ‘mechanical’ low back pain have consistently shown comparative treatments to have small effect sizes. There are arguments for using both explanatory and pragmatic RCTs to evaluate this field further. The UK Back pain, Exercise And Manipulation (BEAM) trial is the largest pragmatic RCT to have investigated interventions provided by UK osteopaths.

The main aim of this review is to describe the UK BEAM trial and to help practitioners judge the external validity of the trial – the extent to which the results of the trial represent their own practices. Two main questions will be addressed: (1) Are the subjects in the trial similar to patients seen in practice? and (2) Are the interventions used in the trial similar to those used in practice? A further aim is to offer some reflections on the strengths and weaknesses of the study.

The trial compared the ‘best care’ from General Practitioners (GPs) alone, against best care from GPs plus an exercise class, against best care from GPs plus a manipulation package, against a combination of all of these interventions (best care from GPs plus a manipulation package, followed by an exercise class). The results of the study showed a small, but statistically significant additional positive effect from the manipulation package, as well as smaller positive effects from the exercise package when each was compared to best care from GPs alone. The combination of all three interventions provided a slightly increased effect, but was found to be costly. Whether the size of these positive effects is clinically meaningful remains a point of discussion. Further studies of a more explanatory nature are called for, along with a need to use usual GP care as a control arm if future evaluations are to show the potential of these interventions to contribute to the care of back pain patients.

© 2005 Elsevier Ltd. All rights reserved.

Keywords: Randomised controlled trials; Osteopathy; Manual therapy; Manipulation; Outcomes

1. Background

In the hierarchy of evidence that influences healthcare policy, randomised controlled trials (RCTs) are considered by most to be the top individual unit of research. There is a growing body of evidence from RCTs that demonstrates positive clinical effects from treatment provided by UK osteopaths for back pain.^{1–4} Although positive, the size of these clinical effects, when given as the average improvement per patient across a varied

group of back pain patients, is quite small. Yet, this treatment still appears to be cost effective.^{5,6} There is also a considerable body of evidence from other disciplines that further supports the use of certain manual therapy interventions for back pain. Despite these advances, debate still remains over how real the apparent benefits of manipulative treatment are as a treatment for back pain⁷ as no published research has shown any individual intervention to have a particularly large effect. One might therefore ask whether manipulative treatment has a worthwhile impact on pain and disability for people suffering from ‘mechanical’ back pain. Clinicians vehemently argue that the size

* Corresponding author.

E-mail address: s.vogel@bso.ac.uk (S. Vogel).

of clinical effects reported in trials of manipulative treatment for back pain does not reflect their experience of success in clinical settings.

The debate seems to polarise around two issues, which may partially explain the apparently poor results achieved to date. The first concerns the problem of identifying homogenous patient groups (where all patients have a similar problem) amongst those who suffer from ‘non-specific’ back pain. In other words, how do you select comparable people to take part in a trial so that any differences can be ascribed to the treatment intervention and not to the patients taking part? In most ‘pragmatic’ back pain trials, a gross selection of patients is made on the simple basis that patients that have serious pathology or radicular pain are not included at the outset. Therefore, patients representing the remaining entire spectrum of ‘non-specific’ back pain are included. In contrast, this does not match the strictly controlled inclusion criteria that are used in ‘explanatory’ RCTs, wherein treatment efficacy (under optimal conditions) is tested as opposed to effectiveness (under ‘usual’ conditions). This is particularly important when judging the results of these types of studies. Problems occur in pragmatic trials when the patient group being studied can be divided up into a number of subgroups. There may be a subgroup that responds well to the treatment, but any evidence of this response will be diluted by the rest of the patient population of the trial, thus leaving a smaller average effect. It also makes generalising the results and implementing them into practice difficult for practitioners who have their own classification rules and do not construe patients as having ‘non-specific’ back pain. Osteopaths and other practitioners lay claim to clinical methods that attempt to differentiate between types of ‘mechanical’ back pain, but there is little published evidence to support this claim. What we all really need is a robust system that can accurately identify subgroups from the ‘non-specific’ back pain population. Fritz et al.⁸ have recently published some promising work which may help to develop this area further. Fair and valid comparisons of different interventions could then be usefully made using a homogenous subgroup.

The alternative to the explanatory trial is the pragmatic trial. Anecdotally, pragmatic trials seem to be favoured by clinicians as they allow for practitioners’ own treatment decisions. Inherent in their design is the presumption that the participating practitioners ‘know best’ when treating the patient, or at least treats to a standard consistent with their normal ability. Pragmatic trials assess effectiveness as opposed to efficacy and tend to test outcomes in the context of usual practice as opposed to the more contrived context of strongly controlled explanatory trials. Trials of this nature have particular use for informing decisions about the value of delivered healthcare services, and tend to

mirror real services where possible. They are commonly used by healthcare purchasers when deciding which treatments are worthy of funding. This is why pragmatic trials often assess cost-effectiveness as well as patient outcomes.

The nature of osteopathic, chiropractic, and physiotherapy interventions in trials causes much discussion. Clinicians and academics have concerns that interventions are not similar to anything they might do in real life or are delivered by practitioners without specific experience or requisite training. These concerns arise partly from fears that individualised assessment and treatment, often cherished by clinicians, will be undervalued or constrained in a tightly standardised ‘protocol’ of treatment used in an explanatory trial. A pragmatic trial allows more freedom for the clinicians to act as they normally would, thus partly addressing this concern. The flipside of this is that the intervention is less tightly controlled than would be the case in an explanatory trial, and it will be less clear as to which components of a treatment were responsible for any improvements, if they are shown.

The second issue concerns what is being measured. There seems to be a high level of patient satisfaction with osteopathic treatment even in the absence of changes in clinical outcome.⁹ In a chiropractic cohort, Breen and Breen¹⁰ showed that only a small amount of the variation in global improvement can be explained by the commonly used measures of pain and disability. Whilst we can anticipate factors such as satisfaction and perceived competence will have an effect, we need to explore other potential outcomes as important factors in the patients experience of treatment. This has led to calls for a return to further exploration of such issues as patients’ beliefs and expectations about their pain and treatment.¹¹ Such exploration could provide insight into what future trials should be measuring.

The UK Back pain, Exercise And Manipulation (BEAM) trial is the largest pragmatic RCT to have investigated the effect of interventions provided by UK osteopaths. It is the main focus of this commentary, and is an example of a large pragmatic trial. After much anticipation, the trial has recently been published in the *Br Med J*.^{4,6} The main results of the trial have been reported in two papers; one that focuses on the clinical effectiveness of the interventions on patient outcomes⁴ and the other that reports the cost-effectiveness by way of an economic analysis.⁶ Previously published work provides background to the trial: the protocol methodology,¹² training the GPs and their staff to provide ‘best care’,¹³ the manipulation package¹⁴ and the exercise class intervention.¹⁵ This review aims to describe the trial in some detail to help osteopaths judge how the results of the trial may represent their own practices (its external validity) and to identify some of the issues to consider when evaluating the strengths of the trial.

2. Aims of the UK BEAM trial

The BEAM trial aimed to answer questions as to whether there were additional benefits to best care from GPs from three separate intervention combinations: best care from GPs plus an exercise class¹⁵; best care from GPs plus a manipulation package¹⁴; and a combination of all of these interventions (best care from GPs plus a manipulation package, followed by exercise class). They further aimed to address an unresolved issue from a previous trial of chiropractic and physiotherapy¹⁶ which suggested that the location of treatment (private vs UK National Health secondary care setting) influenced the outcome for patients.¹⁷

3. Design

The focus of the trial was on whether the interventions work in ‘real’ settings and what they may mean to patients rather than answering questions about how and why the interventions might work. Therefore this trial was sited up in primary care. Patients were identified by asking GPs and their staff in addition to searching computerised records of those attending for back pain. Rapidly resolving back pain was excluded by randomising patients only 4 weeks after initial assessment for suitability for the trial.

Patients were randomised into one of six groups and allocated to the following arms of the trial:

- ‘Best care’ in general practice only
- ‘Best care’ in general practice plus manipulation in private practice
- ‘Best care’ in general practice plus manipulation in NHS setting
- ‘Best care’ in general practice plus manipulation in private practice followed by exercise
- ‘Best care’ in general practice plus manipulation in NHS setting followed by exercise
- ‘Best care’ in general practice plus exercise

4. Manipulation intervention

Three members of the UK BEAM Working Party representing chiropractic, osteopathy and physiotherapy developed a treatment ‘package’ that defined, in advance of the trial, the range of techniques permitted, the timing of delivery, and the accompanying advice.¹⁴ The package was informed by a previously described model for osteopathic management of back pain.¹⁸ The development process involved consultation with professional associations, opinion leaders and information circulated for comment in professional newsletters. The

final agreed package of care comprised an initial session lasting 30–50 min, which included an ‘assessment’ (case history, examination and tests as deemed appropriate by the treating practitioner), ‘explanation’ (description of proposed treatment rather than a profession-specific diagnosis) and ‘treatment’ (the administration of one or more elements of the treatment package). Subsequent sessions, lasting about 20 min, focused on administration of elements of the treatment package (see Table 1). Practitioners had discretion to deliver up to eight treatment sessions over a period of 12 weeks (or over a period of 6 weeks in the group that received both manipulation and the exercise classes), as they judged clinically suitable.

It is worth highlighting that this was a pragmatic study designed to test a consensus-agreed package of manipulative treatment, not an explanatory study seeking to assess the effect of one particular form of manipulation. As such, clinicians administering the manipulation treatment in the trial were able to treat their back pain patients using only elements from the package, but were free to use any of those elements as they thought appropriate. There was a minimum target usage of high velocity–low amplitude thrust (HVT) manipulation, which was to be used in at least 75% of all patients randomised to the manipulation package, at least once during their treatment. The validity of this package with respect to it representing usual osteopathic treatment for low back pain remains unknown. Examination of the elements included within the manipulation package, together with the profile of patients in the trial, will enable practitioners to make a judgement as to whether the UK BEAM results are likely to represent their own clinical effectiveness.

5. ‘Best care’ GP intervention

The ‘best care’ GP intervention followed UK evidence-based guidelines for primary care.¹⁹ It promoted an active approach to recovery from back pain. Normal activities were recommended along with the avoidance of rest as a treatment. ‘The back book’,²⁰ an evidence-based information booklet designed for patients to deliver a message consistent with the RCGP guidelines, was also given out. GPs and their support staff were given special training in these approaches prior to the start of the trial.¹³

6. Exercise intervention

The ‘back to fitness’ exercise programme was developed from previous trials and consisted of an individual assessment followed by circuit type group exercise classes. The style of delivery included cognitive

Table 1
Manipulation package¹⁴

The manual elements	The non-manual elements	Excluded procedures
<i>Soft tissue techniques</i> : cross-fibre stretch, longitudinal stretch, direct pressure, deep friction; neural mobilisation.	<i>Exercises</i> : passive flexion and extension, active side-bending, active trunk rotation, passive or active hip joint stretching, abdominal or lumbar strengthening and neural mobilisation.	High-velocity thrusts to the neck (cervical manipulation with a rotary component) taking the neck beyond its normal physiological range, because there is a very small chance of serious adverse effects.
<i>Articulatory techniques</i> (mobilisations): low through high-amplitude passive movements of lumbar spine and sacroiliac joints (and necessarily hips); flexion, extension, rotation, side-bending, manual traction; oscillation.	Advice (in line with the RCGP guidelines and <i>The back book</i> (Roland et al. ²⁰))	Printed educational material, so as to avoid possible contradiction with the active management approach.
<i>Thrust techniques</i> ('manipulations'): high or low velocity; low amplitude; direct or leverage; directed at central lumbar, zygapophysial or sacroiliac joints; unilateral or bilateral; at one or more locations.	<i>In respect of activity</i> : advocate continuance of leisure activities, work activities and performance of daily tasks (and do not prescribe bed rest or work absence); analgesics are allowed but not encouraged. <i>In respect of psychosocial issues</i> : give generally positive messages and advocate benefits of activity (with avoidance of emotive language and concepts).	Modalities: acupuncture, bed rest, biofeedback, electrotherapy and ultrasound. Appliances: lumbar corsets, belts and strapping. X-rays: practitioners were asked to refer the participant back to the general (family) practitioner if an X-ray was considered essential.

behavioural principles, thus attempting to address issues such as fear of movement and activity whilst exercising. Physiotherapists with some experience received extra training to deliver the package and ran sessions in local community facilities. Groups included up to 10 patients and up to eight 60-min sessions over 4–8 weeks were suggested for patients. One refresher class was offered to patients 12 weeks post-randomisation.

7. Manipulation package and exercise class intervention

Subjects were offered eight appointments with a clinician offering the manipulation package followed by eight exercise sessions over another 6 weeks. As with the exercise alone package a refresher class was offered to patients at 12 weeks.

8. Who were the patients?

Patients were selected if they were between 18 and 65 years, had 'simple mechanical back pain' (low back, gluteal region and pain mainly above the knees).¹⁸ The Roland-Morris Disability Questionnaire (RMDQ) was used in the trial. Subjects had to score greater than 4 points from a maximum of 24 to be included. Furthermore, they also had to have been in pain on a daily basis for 28 consecutive days, or for 42 out of the 56 days prior to randomisation. Patients were excluded for the usual reasons for a trial of this type, including if their pain was predominantly below the knee.

All subjects were drawn from 181 general practices participating in the trial. Initially, 11,929 potential participants were identified. After various screenings, non response to invitations to participate, and GP review for appropriateness, the final number in the trial at randomisation was 1334. The final allocation led to groups of over 300 in the four arms of the trial (the manipulation arm and the manipulation plus exercise arm were further divided into private vs NHS settings).

9. Measurements

Assessments were made at baseline, 3 months and at 1 year. Pain related disability, pain 'troublesomeness', change in back pain over the last 4 weeks, 'back beliefs', fear avoidance beliefs and general health were measured. These measures are generally regarded as the most appropriate for a range of relevant variables in back pain. The questionnaires used were:

- The Roland Disability Questionnaire (RDQ)
- Modified Von Korff Scale (disability, pain, troublesomeness, change in back pain over last 4 weeks)
- Back Beliefs Questionnaire (BBQ)
- Fear Avoidance Beliefs Questionnaire (physical scale) (FABQ)
- SF-36 (physical and mental components)

Monitoring for serious adverse events took place throughout the study period. These were defined as

events related to and within a week of treatment that led to hospital admission or death. There was no attempt to record minor adverse events such as increased post-treatment pain.

10. What happened?

The baseline characteristics of the groups appear comparable and suggest that the randomisation process succeeded in producing similar groups in each arm of the trial. No serious adverse events occurred during the study period.

For disability, patients in all arms of the trial improved. The mean improvement was 3.3 points on the RDQ at 3 months and 3.5 at 1 year. Putting this in context the range of this questionnaire is 0–24 and the mean score was 9 at baseline. There were small differences in the results for the main outcome (disability) between the interventions. For detailed results the full original paper should be consulted. The summary below selects and describes some of the results that reached statistical significance. Confidence intervals are reported in the paper and should be consulted to understand the range of likely effect sizes.

10.1. Exercise intervention

There was a small positive difference between ‘best care’ and exercise for the RDQ (1.4 on this disability questionnaire) at 3 months, but no difference at 12 months. The Von Korff disability and pain scores also improved at 3 months and 12 months. The SF-36 physical score and Fear Avoidance Beliefs Questionnaire (FABQ) also measured an improvement but only at 3-month post-intervention. The SF-36 mental component did not differ from the ‘best care’ arm.

10.2. Manipulation package

There were no differences between the groups treated in NHS settings and private practice. Manipulation produced slightly larger effects than the exercise package, with the RDQ disability score being 1.6 at 3 months and 1.0 at 1 year. There were also improvements in other scores at both 3 months and 12 months: mean Von Korff pain score, Back Beliefs Questionnaire score and SF-36 physical subscale. The SF-36 mental component score was better at 3 months, but not at 12 months and the Von Korff disability scale was better at 12 months, but not at 3 months. Mean fear avoidance beliefs (FABQ) were unchanged by the manipulation alone package.

10.3. Manipulation package and exercise class intervention

There were also significant benefits in this group compared with the ‘best care’ GP package. Roland disability score was 1.9 at 3 months and 1.3 at 1 year. The Von Korff disability and pain scores, back beliefs, fear avoidance beliefs and SF-36 physical component scores were better at 3 months and 1 year. The SF-36 mental component score was only better at 3 months. Back beliefs (BBQ) and fear avoidance (FABQ) were the only outcomes to achieve significant findings beyond those receiving only the ‘manipulation package’.

11. Design problems

One of the limitations of this study was the early decision not to have a true control arm for the trial. What would have been most insightful for all concerned was ‘usual care’ rather than ‘best care’ from GPs. Whether this was due to difficulties of participant recruitment or for some other reason, the use of ‘best care’ as the control arm makes it difficult to assess the comparative in situ effectiveness in the real world. ‘Best care’ is not likely to be representative of current usual GP care.

12. The manipulation package – was it all it’s cracked up to be?

The package represents the approaches most commonly used by the professions of osteopathy, physiotherapy and chiropractic in the UK. It does not give provision for the ‘cranial’ approach used exclusively by some osteopaths, and will therefore offer no insight for those practitioners. Furthermore, there is little detail as to what elements of the manipulation package were delivered, and by whom. Specifically, it is not clear how often HVT or other specific manipulative interventions were used, and as such we have little information to judge either the quantity or quality of the treatment. This may be reasonable as comparative data do not currently exist for osteopathy, and are only emerging in physiotherapy and chiropractic. There were no explicit criteria for the precise application of HVT manipulation within the package. Although cervical HVT was not permitted by the BEAM package, the precise anatomical location to be targeted with HVT manipulation was left entirely at the discretion of the treating practitioner. This meant that there was no control over whether HVT was to be specifically targeted at the symptomatic region, or over the quantity and frequency of HVT delivered to each patient and this was true for any of the specific techniques used. Indeed, the research literature

currently provides little guidance on these important issues. Consequently, the inherent presumption that the participating practitioners ‘know best’ or will at least do what they normally do may be a key factor in explaining the modest effect of the manipulation package. This may give good reason to pursue a tighter explanatory trial where treatment is more strongly controlled. This would provide an opportunity to unpick the elements of the manipulation package to see if it could be further optimised. This would not be without cost however. Cherished values such as the proposed unique nature of osteopathic assessment and intervention would be temporarily lost, but the gain maybe a clearer understanding of when and what osteopathic and other manual therapy interventions work. After all, the results show that the manipulation package used in the UK BEAM trial did not produce a large effect.

What is unclear is the extent of variability in how the manipulation package was delivered by the various practitioners. Ernst²¹ has called for the subgroups to be analysed by profession. Getting the trial up and running was a complex and extremely expensive feat; it is unlikely that subgroup analyses by profession will be performed because any comparisons between the professions would be statistically underpowered. Furthermore, because participants were allocated to therapists nearest their home, in a non-randomised manner, such a comparison was specifically precluded when the professions agreed to the treatment package. The trial was designed as a pragmatic trial and as such probably does its job in representing the average treatment given by the professions involved. This is, of course, with the exception of the GPs who were specially trained to give the best approach they possibly could, based on current available evidence.

13. The exercise intervention – does it fit with osteopathic practice?

The ‘back to fitness’ programme is a standardised, group based activity combining strengthening, stretching and aerobic progressive type exercise.¹⁵ This type of group based, multimodal, progressive exercise intervention is currently successfully being used as part of a wider multidisciplinary rehabilitation programme in community and hospital settings with cardiac patients.²² The advantage of this type of intervention is the level of flexibility afforded to the exercise practitioner in terms of the patients’ personal progression. Furthermore, the group dynamics of working in this type of social milieu and the leadership style exhibited by the instructor (rewarding positive behaviours) has benefits for the patients.²³ The question is how applicable is this to the current clinical practice situation? It is useful to know that exercise in this format is to some extent helpful, but

how does this help the practicing osteopath? There is a tangible exercise message communicated by the results of the trial in that general exercise is beneficial, but to apply this into a structured programme in osteopathic practice might be a challenge. Osteopathic practices lack facilities for group exercise and osteopathic education has traditionally focussed on hands on, one to one skills, rather than group remedial exercise. It is unclear how osteopaths currently integrate exercise advice and general health promotion into daily practice. It may be that delivering exercise based intervention will become a more integrated clinical skill for osteopaths in the future. Perhaps of more interest to osteopaths, might be to see whether habitual levels of exercise (day to day activity outside of the exercise class) increased, be it as a function of physiological/psychological impact (feeling fitter, increased feelings of self efficacy) of the exercise or the general exercise message. This might suggest that the exercise message is being applied outside of the treatment/clinical situation, which is essentially the road to prolonged lifestyle and behavioural change and perhaps something, which an osteopath could readily promote. Habitual levels of activity could have been gauged in the other groups also, to evaluate whether *The back book* and its message of activity had any impact.

Sixty three percent ($n = 408$) of the exercise group received basic minimum treatment (assessment and one exercise class). Further investigation as to the reasons for a patient’s decision not to continue exercising might provide some useful indication for future practice and the potential for the use of exercise. Despite intention to treat analyses, the disparate rates of loss to follow up may have influenced the final results in this arm of the trial. The characteristics of those who did complete the exercise intervention may have influenced how well or how badly they did. We do not know whether they were more or less likely to respond to this treatment and therefore the results may inflate or deflate the size of effect.

14. Size of effect

The largest changes in disability (as measured by the RDQ) in this trial were all under 2 points when compared with the ‘best care’ arm of the trial. This has to be considered a small change. The clinical significance of such a small change will no doubt be scrutinized by purchasers. Nevertheless this is a statistically significant difference, which represents a real difference between arms in the trial that is very unlikely to be due to chance alone.

With specific focus on the effects of the manipulation package, which showed average changes per patient on the RDQ disability score of 1.6 at 3 months and 1.0 at 1 year. If we consider the issue of subgroups in this

context and the likelihood that not all back pain patients are likely to benefit from manipulative treatment, we may view these results in a manner that may be more meaningful and perhaps more representative of clinicians' experiences of patients that respond particularly well to manipulative treatment. If we make the conservative, hypothetical assumption that only half of the patients randomised to receive the manipulation package were ever likely to improve from the treatment, then we can ascribe the measured improvements to this subgroup of patients only. This will effectively produce an average effect size per patient that actually improved from the manipulation package of twice the magnitude reported in the trial for the entire group (i.e. changes in the RMQ disability score of 3.2 at 3 months and 2.0 at 1 year), which are much more impressive, and more in line with previous estimates of a required 'minimal clinically important difference'.²⁴ This of course is only a hypothetical example to illustrate the concept, but future work from the UK BEAM Trial Team is expected to explore this area further.

15. Summary

For purchasers, the trial does provide some robust information as to the effect of buying manipulative therapy as typically delivered by the three professional groups. As such, the results represent a valid assessment of the clinical and cost-effectiveness of this type of approach.

References

1. Macdonald RS, Bell CMJ. An open controlled assessment of osteopathic manipulation in non specific low back pain. *Spine* 1990; **5**:364–70.
2. Burton AK, Tillotson KM, Cleary J. Single blind randomised controlled trial of chemonucleolysis and manipulation in the treatment of symptomatic lumbar disc herniation. *Eur Spine J* 2000; **9**:202–7.
3. Williams NH, Wilkinson C, Russell I, Edwards RT, Hibbs R, Linck P, et al. Randomized osteopathic manipulation study (ROMANS): pragmatic trial for spinal pain in primary care. *Fam Pract* 2003; **20**:662–9.
4. 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. *Br Med J* 2004; **329**.
5. Williams N, Edwards R, Linck P, Muntz R, Hibbs R, Wilkinson C, et al. Cost utility analysis of osteopathy in primary care: results from a pragmatic randomized controlled trial. *Fam Pract* 2004; **21**:643–50 [epub: 05 Nov 2004].
6. 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. *Br Med J* 2004; **329**.
7. Assendelft WJ, Morton SC, Yu EI, Suttrop 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.
8. Fritz J, Whitman J, Flynn T, Wainner R, Childs J. Factors related to the inability of individuals with low back pain to improve with a spinal manipulation. *Phys Ther* 2004; **84**:173–90.
9. Pincus T, Vogel S, Savage R, Newman S. Patients' satisfaction with osteopathic and GP management of low back pain in the same surgery. *Complement Ther Med* 2000; **8**:180–6.
10. Breen A, Breen R. Back pain and satisfaction with chiropractic treatment: what role does the physical outcome play? *Clin J Pain* 2003; **19**:263–8.
11. Foster N, Pincus T, Underwood M, Vogel S, Breen A, Harding G. Treatment and the process of care in musculoskeletal conditions. A multidisciplinary perspective and integration. *Orthop Clin North Am* 2003; **34**:239–44.
12. 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.
13. Underwood M, O'Meara S, Harvey E, UKBEAM Trial Team. The acceptability to primary care staff of a multidisciplinary training package on acute back pain guidelines. *Fam Pract* 2002; **19**:511–5.
14. 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 associations. *Man Ther* 2003; **8**:46–51.
15. Klaber Moffett J, Frost H, UK BEAM Trial Team. Back to Fitness programme: the manual for physiotherapists to set up the programme. *Physiotherapy* 2000; **86**:295–305.
16. Meade TW, Dyer S, Browne W, Townsend J, Frank AO. Low back pain of mechanical origin: randomised comparison of chiropractic and hospital outpatient treatment. *Br Med J* 1990; **300**:1431–7.
17. 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 Manip Physiol Ther* 1991; **14**:281–6.
18. McClune T, Clarke R, Walker C, Burton K. Osteopathic management of mechanical low back pain. In: Giles LGF, Singer KP, editors. *The clinical anatomy and management of back pain series, volume 1: clinical anatomy and management of low back pain*. Oxford: Butterworth-Heinemann; 1997. p. 358–68.
19. RCGP. *Clinical guidelines for the management of acute low back pain*. London: Royal College of General Practitioners; 1996.
20. Roland M, Waddell G, Klaber Moffett J, Burton K, Main C, Cantrell E. *The back book*. London: The Stationery Office; 1996.
21. Ernst E. Comments on the UK BEAM trial rapid response. <http://bmj.bmjournals.com/cgi/eletters/329/7479/1377> [accessed 29.03.05].
22. Giannuzzi P, Saner H, Bjornstad H, Fioretti P, Merdes M, Cohen-Solal A, et al. Secondary prevention through cardiac rehabilitation. Position paper of the working group on cardiac rehabilitation and exercise physiology of the European Society of Cardiology. *Eur Heart J* 2003; **24**:1273–8.
23. Fox LD, Rejeski WJ, Gauvin L. Effects of leadership style & group dynamics on enjoyment of physical activity. *Am J Health Promot* 2000; **14**:277–83.
24. Bombardier C, Hayden J, Beaton DE. Minimal clinically important difference. Low back pain: outcome measures. *J Rheumatol* 2001; **28**:431–8.