

## Professional issue

# Spinal manipulation for low-back pain: a treatment package agreed by the UK chiropractic, osteopathy and physiotherapy professional associations

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**SUMMARY.** Trials of manipulative treatment have been compromised by, amongst other things, different definitions of the therapeutic procedures involved. This paper describes a spinal manipulation package agreed by the UK professional bodies that represent chiropractors, osteopaths and physiotherapists. It was devised for use in the UK Back pain Exercise And Manipulation (UK BEAM) trial—a national study of physical treatments in primary care funded by the Medical Research Council and the National Health Service Research and Development Programme. Although systematic reviews have reported some beneficial effects of spinal manipulation for low-back pain, due to the limited methodological quality of primary studies and difficulties in defining manipulation, important questions have remained unanswered. The UK BEAM trial was designed to answer some of those questions. Early in the design of the trial, it was acknowledged that the spinal manipulation treatment regimes provided by practitioners from the three professions shared more similarities than differences. Because the trial design specifically precluded comparison of the effect between the professions, it was necessary to devise a homogenous package representative of, and acceptable to, all three. The resulting package is ‘pragmatic’, in that it represents what happens to most people undergoing manipulation, and ‘explanatory’ in that it excludes discipline-specific variations and other ancillary treatments.

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## INTRODUCTION

Current guidelines for the management of low-back pain have been produced in at least 11 countries. Since the numerous national low-back pain guidelines development groups used largely the same body of scientific evidence, a consistent recommendation is that patients have early access to physical treatments and should be encouraged to return to normal activities as soon as possible (Koes et al. 2001). There is some heterogeneity, however, in the recommendations on manipulation (Koes et al. 2001). For instance, the UK, US, New Zealand, Swiss, German, Danish and Swedish guidelines recommend manipulation as an option in the initial weeks of an episode. However, the Dutch, Australian and Israeli guidelines do not recommend manipulation for acute low-back pain, and the Dutch and Danish guidelines suggest it is a useful therapeutic option for chronic back pain. The reason for the discrepancies seems to

be related to the interpretation of the evidence, and in particular, the way that chronicity is defined.

### Systematic reviews of the evidence on manipulation

There have been a number of systematic reviews of the effectiveness of manipulation for low-back pain. Koes et al. (1991) carried out a blinded review of 38 studies and concluded that, although some results were encouraging, there was a need for further trials to establish the effectiveness of manipulation. Shekelle et al. (1992) carried out a meta-analysis combining data from nine trials and concluded that manipulation could increase the rate of recovery from *acute* uncomplicated low-back pain. However, they reported there were insufficient data to provide evidence for the effectiveness of manipulation in more chronic cases. The Agency for Health Care Policy and Research (1994) report from the US, based on four meta-analyses and 12 additional randomized trials, came to the same conclusion about acute low-back pain as Shekelle et al. (1992). They also reported that the evidence to support the use of manipulation for radiculopathies or longer standing back pain was inconclusive. Thereafter, a systematic overview of reviews by Assendelft et al. (1995) was critical of the general standard of reviews; nevertheless nine of the ten best reviews, as judged by methodological criteria, reported positive effects of manipulation.

Van Tulder et al. (1996a) reported a systematic review of 11 different interventions for *acute* back pain. They concluded there is limited evidence from 16 trials for the effectiveness of manipulation when compared with a placebo, but no clear evidence that it was more effective than physiotherapy or drug therapy. In another systematic review of 14 different interventions for *chronic* back pain they identified nine trials of manipulation (van Tulder et al. 1996b). They concluded that there was strong evidence for manipulation being more effective than a placebo and moderate evidence that it was more effective than usual care in general practice, analgesics, bed rest and massage. However Koes et al. (1996), updating Koes et al. (1991b), concluded that the resulting evidence was still equivocal because of the variable quality of the trials. All the reviewers agreed on the need for further research in this field.

Although on balance there is evidence to suggest that people with back pain may derive modest benefit from spinal manipulation, there is no clear evidence from the published trials as to whether such treatment should be given early or late (Koes et al. 1991b; Shekelle et al. 1992). The only substantial pragmatic trial involving manipulation in the UK was mounted by the Medical Research Council to compare chiropractic management in its traditional private setting, with fast-tracked

(1-week availability) hospital outpatient management, for episodes of at least 1-month duration (Meade et al. 1990; 1995). It served to raise the intensity of the scientific debate about manipulation and inform the research agenda. It was also one of two trials to suggest that there might be long-term benefit from manipulation (Koes et al. 1992; Croft 1997), although its design was subsequently questioned (Assendelft et al. 1991).

Therefore, despite previous trials of manipulation therapy for back pain, there remained major uncertainties about the role of treatments in clinical practice in the UK. One serious problem in interpreting the evidence is that reports often do not make it clear exactly what manipulative procedures have been given to patients, over what period of time, and whether other elements of care (such as advice on activity and exercise) were included. Furthermore, there are substantial problems in mounting such trials: people with back pain usually do not have a clear diagnostic label; doctors, practitioners and manipulators use different clinical paradigms; it is not generally possible to identify homogeneous groups of sufferers; and indications for specific physical treatments are difficult to define. For these and other reasons, many of the previous trials have been subject to methodological problems (Koes et al. 1995).

### Manipulation in the UK

Spinal manipulation has been practised for many years by a variety of practitioners. In the mid-1990s, two of the main professional groups in the UK—chiropractic and osteopathy—were formally recognized by Acts of Parliament that established systems of regulation analogous to those of the General Medical Council. Also in the UK, the similarities between chiropractors and osteopaths are probably much greater than their differences; in particular a broadly common type of manipulation underlies both treatment approaches. It was therefore agreed that it would be unnecessary (and almost certainly impossible in view of the large sample size that would be needed) to compare the effectiveness of the two approaches in the current state of knowledge.

UK general practitioners commonly refer patients with back pain to physiotherapists working in the National Health Service. The majority of those physiotherapists practicing hands-on therapy in the UK use passive mobilization techniques (Foster et al. 1999). McKenzie exercises, which can include manipulation for a small proportion of sufferers, are often advocated, but there are only a few fully trained McKenzie physiotherapists in the UK. A minority of physiotherapists attend post-registration courses and

specialise in manual therapy, including high-velocity thrusts, often referred to in the profession as 'Grade Vs'. The range of techniques used by these specialist physiotherapists are probably similar in many respects to those used by chiropractors and osteopaths, although the use of high-velocity thrust techniques is considerably less frequent.

Traditionally, the three professions have seen themselves (and each other) as quite separate entities with little common ground philosophically. However, despite differences in the extent of use of certain manipulative techniques and exercise, there is anecdotal evidence that some measure of commonality exists in terms of the management approach to back pain. Indeed, it seems possible that within-profession differences may be greater than typical between-profession differences.

The term manipulation covers a bewildering array of manual techniques and terminologies that can confuse other health professionals (Breen et al. 2000). However, these can be broken down into three general areas: techniques directed primarily at soft tissue structures (muscle, ligament, fascia, etc.); techniques that are intended to articulate joints through physiological ranges of movement; and techniques that involve application of a high-velocity, low-amplitude thrust with the intention of creating cavitation of a synovial joint. The precise manner in which each technique will be delivered does vary between professions, but the greatest source of variance is probably the perceived needs of the patient. Individual practitioners also develop specific preferences and skills according to their own experience. In addition to manual techniques, practitioners will make variable use of exercises and advice; the between-profession variation here again may be substantial. A further source of variation within-profession is the number of treatment sessions; most practitioners will deliver a number of treatments to a back pain patient over a period of weeks rather than rely on a single procedure.

Any attempt to mount a trial of manipulative treatment needs to take account of the above sources of variation when defining the nature and content of the 'manipulation' under test. Whilst it would be possible to control the variance by testing the value of, say, a single manual technique applied by practitioners from a single discipline, this tells us little about the way manipulation is used in practice. Conversely, simply testing the uncontrolled use of manipulation will lose any semblance of the homogeneity needed to draw valid and useful conclusions from the result of a trial. Thus, what is required is a package that defines in advance the range of techniques permitted, the timing of delivery, and the accompanying advice. One such approach is described below.

### **The UK BEAM trial**

The spinal manipulation approach for low-back pain is currently being evaluated in a national, multi-centre trial in 14 UK centres. The UK Back pain Exercise And Manipulation (UK BEAM) trial is funded by the Medical Research Council and the National Health Service (NHS) Research and Development Programme (UK BEAM 2002). In this trial, all eligible patients who had simple mechanical low-back pain for at least 4 weeks were randomized between the spinal manipulation package and GP management. Those randomized to spinal manipulation were also randomized between NHS premises and manipulators' own private premises (the same practitioner delivered treatments in both settings in each area). Each participant (patient) recruited was also randomized between the *Back to Fitness* progressive exercise package (Klaber Moffett & Frost 2000) and GP management. Therefore, some participants received both the spinal manipulation and exercise treatments. In addition, all members of GP surgery staff were invited to training in the 'active management' of back pain (that is, advice to avoid bed rest and return to normal activities as soon as possible) (Underwood et al. 2002) and encouraged to give participants copies of *The Back Book* (Roland et al. 1996).

### **THE UK BEAM SPINAL MANIPULATION PACKAGE**

The UK BEAM spinal manipulation package was developed by three members of the UK BEAM Working Party, representing chiropractic, osteopathy and physiotherapy. The starting point was consultation (correspondence and face-to-face meeting) with a group of representatives appointed by the British Chiropractic Association (BCA), the Chartered Society of Physiotherapy (CSP) and the General Council and Register of Osteopaths (GCRO). (Negotiations with the CSP were delegated to the special interest group—the British Association of Chartered Physiotherapists in Manipulation (BACPIM).) The combined group strongly recommended that the manipulation arm of the trial not be based on the intervention's use in isolation, but on a package of care that reflected the holistic nature of their approaches. The UK BEAM Working Party developed such a package, based on a previously described model for osteopathic management of low-back pain (McClune et al. 1997). This model was refined, using an iterative process, to take account of the needs and practices of the three professions, and to place it in the context of the research project. The revised draft was re-submitted to representatives of each professional body, and circulated to opinion leaders and

officials among the three professions. In addition, the trial design and the package were offered to professional newsletters and conferences. Whilst direct contact between the research team was limited to two appointed representatives from each profession, they in turn discussed the matter openly with various colleagues. Following detailed feedback and appropriate further refinement, a package of care emerged that was acceptable to all concerned. It defines a common core of manipulative practice that omits some lesser-used modalities, yet permits enough flexibility in both assessment and treatment to be representative of all three professions. It is 'pragmatic' in that it represents what happens to most people undergoing manipulation, and 'explanatory' in excluding confounding variations (Schwartz & Lellouch 1967).

The assumption underlying the package was that participants would have 'simple mechanical back-ache', with or without referred leg pain (Royal College of General Practitioners 1999). Practitioners were free to exclude from manipulative treatment any participant who was found at their assessment to be unsuitable for manipulation. As all participants had previously been pre-screened for inclusion, the number of participants excluded at this point was low.

### **Trial procedures**

Fourteen trial centres were established across the UK (two feasibility study sites and 12 main trial sites). For reasons of homogeneity, and to accommodate the then imminent legislation concerning osteopathy and chiropractic, manipulators were invited to participate from the membership lists of the BCA, the GCRO and BACPIM. In general, in each centre there were two main manipulators, each with a back-up from the same profession to cover any absences. (In some larger centres, extra main and back-up manipulators were recruited.) As far as possible, representatives were recruited from the three professions to provide a balance of professions across the UK. On occasions, this ideal was modified to reflect the local availability of practitioners. In the end, there were 12 main osteopaths, seven main chiropractors and nine main physiotherapists (each with one or more back-up).

Although the elements of the package were familiar to practitioners, the package was described in full prior to the trial and a detailed manual was provided. In addition, practitioners attended familiarization sessions in which the principles of the trial and the manipulation package were presented and discussed. Practitioners were asked to commit themselves to the 'active' philosophy of the trial. To avoid participants receiving different information from different professionals, practitioners were also asked to confine

explanation to the proposed treatment, and to avoid offering specific diagnoses and commenting on other health professions.

When a participant was randomized to their care, the practitioner was notified by letter and asked to make the initial appointment. The notification letters would instruct practitioners to carry out the treatments in either their own premises, or in NHS premises hired on their behalf (usually a room in a local general (family) practice, equipped with a suitable treatment table). Further treatments were scheduled according to the practitioner's usual practice.

Practitioners were asked to complete a simple treatment record for each session with each participant. At the end of treatment, they completed a discharge form, giving the reason for the end of treatment (e.g. participant recovery, end of maximum number of sessions). Practitioners were asked to notify the trial team immediately of any potential adverse events following treatment.

On average, each manipulator in the trial received about 30 participants randomized to his or her care during the 12-month recruitment period. Half were allocated to private premises and the other half to NHS premises.

### **Spinal manipulation package**

For individual participants, the package comprised a series of scheduled sessions with the same practitioner. The first session, lasting 30–50 min, included an 'assessment' (case history and appropriate clinical examinations and tests), 'explanation' (description of the proposed treatment, but not a discipline-specific diagnosis) and 'treatment' (the administration of one or more elements from the treatment package). Subsequent sessions, lasting about 20 min, focussed on the administration of elements from the treatment package.

At the discretion of the practitioner, a maximum of eight sessions could be spread over the intervention period of 12 weeks (or 6 weeks in the case of participants randomized to receive both manipulation and exercise). For example, it was permissible to schedule four sessions over the first 2 weeks and two sessions over the next 2 weeks, keeping two sessions in reserve for the remaining 8 weeks.

### **The elements**

The package comprised two groups of 'elements'—manual and non-manual. Each main element listed below is followed by a subgroup of 'techniques', some of which are discipline-specific. The practitioner was confined to using only the techniques listed, but had free choice of which to use when. All patients were

expected to receive the first two manual elements and verbal advice at each treatment session, and most were expected to receive a high-velocity thrust procedure at least once during the overall treatment period. The frequency of use of each element depended on the practitioners' assessment of the participants' needs. (The target for the use of thrust techniques was 75% of all participants randomized to spinal manipulation, at some stage during their treatment. It was expected that the use of exercises would be a minor part of the package.) Use of special treatment tables, for example chiropractic or swing-leaf, was permitted.

The manual elements were:

- *Soft tissue techniques*: cross-fibre stretch, longitudinal stretch, direct pressure, deep friction; neural mobilization.
- *Articulatory techniques* (mobilizations): low-through high-amplitude passive movements of lumbar spine and sacroiliac joints (and necessarily hips); flexion, extension, rotation, side-bending, manual traction; oscillation.
- *Thrust techniques* ('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.

The non-manual elements were:

- *Exercises*: passive flexion and extension, active side bending, active trunk rotation, passive or active hip joint stretching, abdominal or lumbar strengthening and neural mobilization.
- *Advice* (in line with the RCGP guidelines and *The Back Book* (Roland et al. 1996)—see Table 1).
  - (i) *In respect of activity*: 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.
  - (ii) *In respect of psychosocial issues*: give generally positive messages and advocate benefits of activity (with avoidance of emotive language and concepts).

Excluded procedures were:

- High-velocity thrusts to the neck (cervical manipulation with a rotary component) taking the neck beyond its normal physiological range, because there would be a very small chance of serious adverse effects (Assendelft et al. 1996).
- Printed educational material, so as to avoid possible contradiction with the active management approach.

**Table 1.** Key patient advice points (taken from the Royal College of General Practitioners 1996 'Clinical guidelines for the management of acute low-back pain')\*

*Simple backache*

Give positive messages

- There's nothing to worry about. Backache is very common
- No sign of any damage or disease. Full recovery in days or weeks—but may vary
- No permanent weakness. Recurrence possible—but does not mean re-injury
- Activity is helpful—too much rest is not. Hurting does not mean harm

*Nerve root pain*

Give guarded positive messages

- No cause for alarm. No sign of disease
- Conservative treatment should suffice—but may take a month or two
- Full recovery expected—but recurrence possible

*Possible serious spinal pathology*

Avoid negative messages

- Some tests are needed to make the diagnosis
- Often these tests are negative
- The specialist will advise on the best treatment
- Rest or activity avoidance until appointment to see specialist

\**Patient Booklet*: The above messages can be enhanced by an educational booklet given at consultation. *The Back Book* is an evidence-based booklet developed for use with these guidelines.

- *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.

### Examples of how the package could be used

As examples of how use of the package was envisaged, the following three general categories of participant were considered appropriate: acute, sub-chronic and chronic. Table 2 indicates the choice of elements that might typically be used: it was not prescriptive.

### CONCLUSION

The UK BEAM spinal manipulation package was developed for the treatment of simple mechanical low-back pain and was accepted by the three professions who perform this treatment in the UK. It defines a common core of manipulative practice while permitting enough flexibility in both assessment and treatment to be representative of all three professions. It is the outcome of a successful, strenuous attempt to overcome inter-disciplinary barriers in order to enable the value of 'manipulation', as typically practised in the UK, to be tested scientifically. In practice, the UK BEAM trial team encountered minimal problems in recruiting representatives from the three professions to deliver spinal

**Table 2.** Examples of how the manipulation package could be used

Low-back pain type	Soft tissue	Articularity	Thrust	Exercises/activities	Advice
Acute	Paraspinal cross-fibre, inhibition	Small amplitude	Short leverage or direct	Encourage walking; neural mobilization	Limit aggravating factors; encourage work/sport as soon as possible; reduce fear of future
Subchronic	Cross-fibre, stretching, friction	Larger amplitude	Normal leverage or direct	Spinal exercises; encourage general exercise/activity; neural mobilization	Early uptake of sport or work; ergonomic advice; promote positive attitudes
Chronic	Stretching	Larger amplitude	Normal leverage or direct	Spinal exercises; encourage daily walking and exercise; neural mobilization	Progressive uptake of sport; reduce fear-avoidance; promote positive attitudes

manipulation treatments to trial participants, and received few reports of problems using the package. The package is offered as a template for use in the context of further pragmatic trials in the UK or elsewhere. Full trial results are expected towards the end of 2002.

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