# Combined chiropractic interventions for low-back pain (Review)

**Walker BF, French SD, Grant W, Green S**


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[Intervention Review]

# Combined chiropractic interventions for low-back pain

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## ABSTRACT

### Background

Chiropractors commonly use a combination of interventions to treat people with low-back pain (LBP).

### Objectives

To determine the effects of combined chiropractic interventions (that is, a combination of therapies, other than spinal manipulation alone) on pain, disability, back-related function, overall improvement, and patient satisfaction in adults with LBP, aged 18 and older.

### Search strategy

We searched: The Cochrane Back Review Group Trials Register (May 2009), CENTRAL (*The Cochrane Library* 2009, Issue 2), and MEDLINE (from January 1966), EMBASE (from January 1980), CINAHL (from January 1982), MANTIS (from Inception) and the Index to Chiropractic Literature (from Inception) to May 2009. We also screened references of identified articles and contacted chiropractic researchers.

### Selection criteria

All randomised trials comparing the use of combined chiropractic interventions (rather than spinal manipulation alone) with no treatment or other therapies.

### Data collection and analysis

At least two review authors selected studies, assessed the risk of bias, and extracted the data using standardised forms. Both descriptive synthesis and meta-analyses were performed.

### Main results

We included 12 studies involving 2887 participants with LBP. Three studies had low risk of bias. Included studies evaluated a range of chiropractic procedures in a variety of sub-populations of people with LBP.

No trials were located of combined chiropractic interventions compared to no treatment. For acute and subacute LBP, chiropractic interventions improved short- and medium-term pain (SMD -0.25 (95% CI -0.46 to -0.04) and MD -0.89 (95%CI -1.60 to -0.18)) compared to other treatments, but there was no significant difference in long-term pain (MD -0.46 (95% CI -1.18 to 0.26)). Short-

term improvement in disability was greater in the chiropractic group compared to other therapies (SMD -0.36 (95% CI -0.70 to -0.02)). However, the effect was small and all studies contributing to these results had high risk of bias. There was no difference in medium- and long-term disability. No difference was demonstrated for combined chiropractic interventions for chronic LBP and for studies that had a mixed population of LBP.

**Authors' conclusions**

Combined chiropractic interventions slightly improved pain and disability in the short-term and pain in the medium-term for acute and subacute LBP. However, there is currently no evidence that supports or refutes that these interventions provide a clinically meaningful difference for pain or disability in people with LBP when compared to other interventions. Future research is very likely to change the estimate of effect and our confidence in the results.

## PLAIN LANGUAGE SUMMARY

**Combined chiropractic interventions for low-back pain**

Low-back pain is one of the most common and costly musculoskeletal problems in modern society. About 80% of the population will experience low-back pain at some time in their lives. Many people with low-back pain seek the care of a chiropractor. For this review, chiropractic was defined as encompassing a combination of therapies such as spinal manipulation, massage, heat and cold therapies, electrotherapies, the use of mechanical devices, exercise programs, nutritional advice, orthotics, lifestyle modification and patient education. The review did not look at studies where chiropractic was defined as spinal manipulation alone as this has been reviewed elsewhere and is not necessarily reflective of actual clinical practice. Non-specific low-back pain indicates that no specific cause is detectable, such as infection, cancer, osteoporosis, rheumatoid arthritis, fracture, inflammatory process or radicular syndrome (pain, tingling or numbness spreading down the leg).Twelve randomised trials (including 2887 participants) assessing various combinations of chiropractic care for low-back pain were included in this review, but only three of these studies were considered to have a low risk of bias.

The review shows that while combined chiropractic interventions slightly improved pain and disability in the short term and pain in the medium term for acute and subacute low-back pain, there is currently no evidence to support or refute that combined chiropractic interventions provide a clinically meaningful advantage over other treatments for pain or disability in people with low-back pain. Any demonstrated differences were small and were only seen in studies with a high risk of bias. Future research is very likely to change the results and our confidence in them. Well conducted randomised trials are required that compare combined chiropractic interventions to other established therapies for low-back pain.

## BACKGROUND

Low-back pain is a very common complaint, with the lifetime prevalence reported to range from 11% to 84% (Walker 2000). In the majority of those people presenting with acute low-back pain, the cause of pain is non-specific, with serious underlying conditions being rare (Hollingworth 2002). Chronic low-back pain is a well documented, disabling condition, costly to both individuals and society (Carey 1995; Frymoyer 1991; Maniadakis 2000).

The economic burden of low-back pain is significant and a substantial burden on society (Dagenais 2008). In the United Kingdom (UK), five million individuals consult their general practitioner for back pain per year, at a cost of £140.6 million. Every year, the UK National Health Service (NHS) physiotherapy and NHS hospital costs directly related to low-back pain are £150.6 million and £512 million, respectively (Palmer 2000). Another study of healthcare costs in Britain suggested that 13% of all unemployed people reported that back pain was the reason that they were not working (Great Britain 1998). In the United States (US), in one of the largest studies of its kind (Luo 2003), investigators found that US$26 billion per year in healthcare expenses were directly attributable to treating back pain. On average, individuals with back pain incurred health care expenditures about 60% higher than individuals without back pain (Luo 2003). In Australia, the estimated direct and indirect cost of low-back pain in 2001 was AUD$9.17 billion (Walker 2003).

Chiropractic is defined by the World Federation of Chiropractic (WFC 1999) as a health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of the nervous system and general health. There is an emphasis on manual treatments, including spinal manipulation or adjustment, and this is often combined with physical therapy modalities, exercise programs, nutritional advice, orthotics, lifestyle modification and other patient education (Chapman-Smith 2000). The proposed mechanisms by which chiropractic interventions may work is a complex one with Meeker and Haldeman identifying five possible mechanisms for manipulation alone (Meeker 2002). In the case of combined chiropractic the diversity of treatments increases the number of these hypothetical mechanisms.

Chiropractic interventions are commonly sought in high income countries by people with low-back pain. In Australia, consultation with a chiropractor ranks as second behind medical practitioners when people with low-back pain seek care, with 19% seeking chiropractic care (Walker 2004). This has been a consistent finding in other high income countries. In the US, three studies spanning a ten-year period have shown that people with back pain most commonly visit medical practitioners and chiropractors (Deyo 1987; Hurwitz 1997; Shekelle 1995), and another study showed that for those with chronic back pain, chiropractic was the third most common practitioner consulted (Carey 1995). In the Canadian Province of Saskatchewan, Côté and colleagues found that 29% of persons with neck and back pain had consulted a chiropractor in the previous four weeks (Côté 2001). Among patients who attend chiropractors, between 41% and 60% present with low-back pain (Cherkin 2002; Ebrall 1993; Hartvigsen 2002; Hawk 1995; Rubinstein 2000).

The direct cost of chiropractic care in Australia in 2001 was estimated at AUD$183 million out of a total cost of AUD$1026 million (18%), representing a substantial portion of the cost of care for low-back pain (Walker 2003). In the US, from 1996 to 2005, the proportion of outpatient US healthcare expenditures spent on chiropractic care increased from 2.15% to 3.26% (Davis 2009).

Clinical trials of health care interventions can be explanatory or pragmatic (Treweek 2009; Godwin 2003). Explanatory trials seek to determine the efficacy of a specific intervention under ideal conditions, that is, whether it can have a beneficial effect. Explanatory trials have an important role to provide knowledge on the effects of precisely defined interventions applied to select groups under optimal conditions. However, it has been argued that healthcare interventions are seldom given under such circumstances and that such trials measure efficacy and not effectiveness (Treweek 2009). Pragmatic trials measure effectiveness and seek to determine the degree of benefit of the intervention in real clinical practice (Thorpe 2009). If a pragmatic trial shows an intervention to have significant beneficial effect, then there can be confidence that not only has the intervention been shown to work, but also that it works in real life (Godwin 2003). This distinction between explanatory and pragmatic trials is somewhat academic because there is wide agreement of the existence of a continuum from largely pragmatic to largely explanatory trials and the degree to which a trial is more explanatory or more pragmatic depends on a number of features of the trial (Oxman 2009). These features include the inclusion and exclusion criteria for trial participants and the nature of the intervention tested and its relevance to actual clinical practice. This review enquires about the effectiveness of combined chiropractic interventions for low-back pain as they would be implemented in practice (that is, as a combination of a number of modalities), and therefore includes primarily pragmatic trials, and takes a pragmatic approach to combining those trials. The question it seeks to answer is one that may arise from either a referring clinician, a patient seeking care or a policy maker: Is combined chiropractic care likely to help a patient with low-back pain, and if so, how does it compare to other interventions?

This review examined trials where chiropractors carried out a combination of interventions and sought to synthesise pragmatic trials that compared chiropractic interventions to other types of interventions or to no intervention. Trials of spinal manipulative therapy (SMT) delivered as a single intervention, regardless of the type of practitioner that delivered the SMT, have been examined in a previous Cochrane review (Assendelft 2004). Hence, identified trials that evaluated chiropractic SMT as a single intervention were excluded from the current effort.

Previous systematic reviews of chiropractic interventions have not been successful in conducting a meta-analysis of the effect of chiropractic interventions for low-back pain. The most recent attempt was in 1996 (Assendelft 1996), and meta-analysis was not possible due to the variety of outcome measures and follow-up timing. It was anticipated that with the inclusion of additional, more recent trials, sufficient numbers of trials would be available to permit the completion of a meta-analysis and meaningful synthesis. While other recent systematic reviews for back pain have included chiropractic interventions, these reviews have tended to concentrate only on spinal manipulation, and have not specifically investigated interventions as delivered by a chiropractor (Brønfort 2004). To reflect actual practice this review searched for and attempted to synthesise studies that investigated chiropractic interventions in their various forms and combinations.

The aim of this review was to identify and systematically review all randomised trials of combined chiropractic interventions for low-back pain (rather than trials of spinal manipulation alone) to evaluate if they are effective when compared with other therapies.

## OBJECTIVES

The objective of this review was to determine the effects of com-

bined chiropractic interventions on pain, disability, back-related function, overall improvement, and patient satisfaction in adults with low-back pain, aged 18 and older.

# METHODS

## Criteria for considering studies for this review

### Types of studies

All randomised controlled trials (RCTs) comparing combined chiropractic interventions to other therapies or to no therapy were included. Non-randomised studies, observational studies and uncontrolled studies were excluded. Trials in any language were considered for inclusion and translation obtained where needed. Published and unpublished trials, when located, were included.

### Types of participants

Trials were selected that included participants aged 18 years or over, with non-specific low-back pain. Studies were excluded that examined pathological causes of low-back pain (e.g. cancer, inflammatory arthritis), and low-back pain with radiculopathy. Low-back pain was defined as pain occurring below the lower ribs and above the gluteal folds, including the buttocks.

Duration of pain did not influence inclusion in the review, but was categorised as acute (less than six weeks), subacute (six weeks to 12 weeks) or chronic (12 weeks or more) as defined by the Cochrane Back Review Group (Furlan 2009). Results were categorised into subgroups depending on whether trial populations were acute, subacute, chronic, mixed or not defined.

### Types of interventions

An intervention was deemed as a 'chiropractic intervention' when the investigators of the trial suggested this was the case and it was delivered by a registered chiropractor. The label 'chiropractic' was found to encompass a combination of therapies such as spinal manipulative therapy (SMT) or adjustment, massage, thermotherapies, electrotherapies, the use of mechanical devices, exercise programs, nutritional advice, orthotics, lifestyle modification and patient education. The specific type of chiropractic intervention employed in the trials are outlined in the Characteristics of included studies table. Trials that were limited to chiropractic SMT as a single intervention were excluded, as these have been examined in a previous Cochrane review (Assendelft 2004). Studies were also excluded when a chiropractor delivered the intervention in both study arms, because, while these studies allow assessment of the effect of individual chiropractic interventions compared to each other, the overall effect of the combined chiropractic interventions could not be determined from this study design. Type of intervention and comparison was not an exclusion criteria but defined comparisons. We also planned to use dose (number of treatment sessions) to define comparisons, however, too few trials were available to allow this.

### Types of outcome measures

The choice of outcome measures for inclusion in this systematic review was based on those recommended by the Cochrane Back Review Group (Furlan 2009). The outcomes of interest were pain, disability, back-related function, overall improvement, patient satisfaction, and adverse effects. Results are presented for different follow-up periods. Follow-up was defined as short-term when measurement of outcome was less than one month after randomisation, medium-term follow-up was between one month and six months, and long-term follow-up was six months or more. We modified these time periods from those stated in the protocol to reflect the recently updated Cochrane Back Review Group Guidelines (Furlan 2009).

## Search methods for identification of studies

The following electronic databases were searched:

(a) The Cochrane Back Review Group Trials Register was reviewed in May 2009 (see SPECIALISED REGISTER under GROUP DETAILS)

(b) The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2009, Issue 2)

(c) MEDLINE (January 1966 to May 2009), EMBASE (January 1980 to May 2009), CINAHL (January 1982 to May 2009), MANTIS (Manual Alternative and Natural Therapy Index System) (inception to May 2009) and the Index to Chiropractic Literature (inception to May 2009).

We also screened references of identified articles and contacted chiropractic researchers to identify potential unpublished data and ongoing trials.

The search strategy was based on that recommended by the Cochrane Back Review Group (Furlan 2009). The strategy included subject headings (MeSH) and text words. These included methodological terms, disorder terms and intervention terms, and are listed in full for MEDLINE (Appendix 1) and EMBASE (Appendix 2). The remaining databases were searched with the strategy adapted appropriately and are available from the authors upon request.

## Data collection and analysis

### Selection of studies

Two review authors (SF and BW) piloted the inclusion criteria form on a sample of three abstracts. Two review authors (SF and WG) then independently applied the inclusion criteria to all of the titles and abstracts identified by the search strategy. An updated search was run in May 2009 and two review authors (SF and BW) independently screened these additional abstracts. Where the eligibility of the study was not clear from the abstract, the full text of the article was obtained and independently assessed by the two review authors. Any disagreement between the review authors was resolved by discussion and consensus, and discussion with a third review author if required.

For excluded studies that required retrieval of the full text for a decision of their eligibility, details of the reasons for exclusion are given in the Characteristics of excluded studies.

## Data extraction and management

A standard data extraction form was pilot tested on two included studies to minimise misinterpretation. BW undertook data extraction of each of the included studies using this form. A second review author (SF or SG or WG) independently assessed the risk of bias and extracted results of included studies as recommended in the updated Cochrane Handbook (Higgins 2008) and Cochrane Back Review Group Guidelines (Furlan 2009). When necessary, we approximated results from graphic representations in the reports of the included studies. If the review authors disagreed in their assessment of risk of bias or data extraction, this was resolved by discussion and consensus, followed by discussion with a third review author if necessary.

### Data Analysis

All quantitative results were entered into Review Manager 5.0 (RevMan 2008). Results for continuous variables were reported as mean difference (MD) when the outcome measures were the same, and standardized mean difference (SMD) when outcomes were measured with different instruments measuring the same construct. We used the random effects model for any statistical pooling because of the variety of chiropractic interventions in the included studies and subsequent heterogeneity. Effect estimates resulting from meta-analysis expressed as SMD were back transformed by multiplying the SMD with the standard deviation (SD) of a standard instrument used to measure the outcome (for example, centimetres (cm) on a 10 cm Visual Analogue pain scale). Standard deviation values were imputed using the average baseline SD values from both study arms of a trial that used the standard instrument of interest.

When more than two chiropractic intervention arms, or two comparison arms, were used in a study, we combined the data from the arms to create a single pair-wise comparison (Higgins 2008a, Section 7.7.3.8). We did this for the data from five included studies (Cherkin 1998; Hsieh 1992; Hsieh 2002; Brønfort 1996; Hurwitz 2002).

A descriptive analysis of the quality of the evidence for each outcome was performed using the GRADE approach, which assesses and combines the following elements across studies: study design, risk of bias, consistency of results, directness (generalisability), precision of data and reporting bias (Furlan 2009; Guyatt 2008; Higgins 2008). Quality is considered to be high when RCTs with low risk of bias provide results for the outcome, and reduces by a level for each of the factors not met, as follows:

**High quality evidence:** there are consistent findings among at least two RCTs with low risk of bias that are generalisable to the population in question. There are sufficient data, with narrow confidence intervals. There are no known or suspected reporting biases. Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality evidence:** one of the factors is not met. Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

**Low quality evidence:** two of the factors are not met. Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change it.

**Very low quality evidence:** three of the factors are not met. There is great uncertainty about the estimate.

**No evidence:** no evidence from RCTs.

## Assessment of risk of bias in included studies

Risk of bias was independently assessed by two review authors (BW and SF or SG) after retrieval of the full text of all included studies. The criteria for assessment were piloted on a sample of three studies. If the article did not contain information on any particular methodological criteria, the review authors were contacted for additional information (if possible). We classified studies into high or low risk of bias. A study with low risk of bias was one where, at a minimum, randomisation, allocation concealment and outcome assessor blinding score a "yes".

### Clinical relevance

Two review authors independently judged the clinical relevance of each included trial, using the five questions recommended by the Cochrane Back Review Group, and scored each one as a "yes (+)", "no (-)" or "don't know (?)":

1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential harms?

# RESULTS

## Description of studies

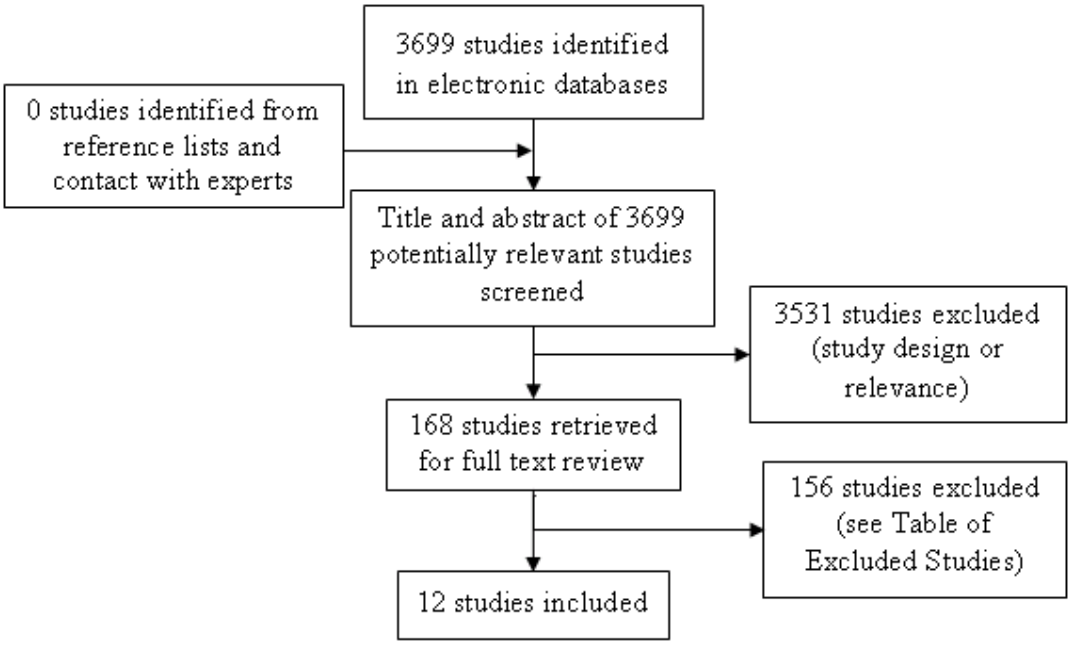
See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.

We included 12 studies that involved 2887 participants with low-back pain.

### Selection of studies for inclusion

Figure 1 describes the process from searching to study inclusion. We identified a total of 3699 non-duplicate potentially relevant citations from electronic databases (the Cochrane Back Review Group (CBRG) Trials Register, CENTRAL, MEDLINE, EMBASE, CINAHL, MANTIS and the Index to Chiropractic Literature). After two review authors (SF and WG or BW) independently screened the titles and abstracts of these studies, we excluded 3531 records and obtained 168 studies for full text review. Twelve of these studies met our inclusion criteria and their details are described in the Characteristics of included studies table. Studies initially appearing to meet the eligibility criteria but which we subsequently excluded are reported in the Characteristics of excluded studies table along with our first reason for exclusion. One ongoing study was identified from a published trial protocol (Maiers 2007); this study is described in the Characteristics of ongoing studies table.

**Figure 1. Flow chart of study inclusion**




Of the twelve included studies, eight had one comparison group (two-arm study), two studies had two comparison groups (three-arm study), and two studies had three comparison groups (four-arm study). Four studies entered participants with acute or subacute low-back pain, seven studies entered participants with mixed pain duration, and one study entered participants with chronic low-back pain.

### Characteristics of study setting

Four studies were conducted in the USA, two in the UK and one in Denmark. Five studies did not report the country in which the

study was conducted. Three studies were conducted in hospital settings, one in a health maintenance organisation care facility, one in a teaching chiropractic clinic and two in private chiropractic clinics. In the remainder of the studies, the setting was not reported.

### Characteristics of interventions evaluated

The included studies employed a range of chiropractic and comparator treatments and are outlined in Table 1. Based on our inclusion criteria for types of interventions, none of the included studies evaluated SMT alone. Of the 12 studies included, 10 studies used SMT as part of their chiropractic intervention. The two studies that did not employ SMT as part of their chiropractic intervention evaluated flexion distraction technique as their primary chiropractic intervention (Gudavalli 2006; Hawk 2005). Only two of the 12 included studies used the same chiropractic intervention (Beyerman 2006; Hsieh 1992), SMT plus heat packs. Only four studies reported the level of experience of the chiropractors involved in therapy provision.

**Table 1. Interventions employed in included studies**

| Study ID | Chiropractic intervention | Comparison 1 | Comparison 2 | Comparison 3 |
|---|---|---|---|---|
| **Comparison 01: Chiropractic vs Other therapies (acute and subacute low-back pain)** | | | | |
| Cherkin 1998 | 1. SMT<br>2. Cold<br>3. Massage<br>4. Exercise | 1. Physical Therapy ( McKenzie approach)<br>2. McKenzie booklet<br>3. Lumbar support cushion | Educational booklet | N/A |
| Cramer 1993 | 1. SMT<br>2. Electrical muscle stimulation<br>3. Cold | 1. Detuned ultrasound<br>2. Cold<br>3. Massage | N/A | N/A |
| Hsieh 1992 | 1. SMT<br>2. Heat | 1. Massage<br>2. Heat | Lumbosacral corset | Transcutaneous muscular stimulation |
| Hsieh 2002 | 1. SMT<br>2. Massage<br>3. Education | 1. SMT<br>2. Education | 1. Massage<br>2. Heat<br>3. Education | 1. Back school<br>2. Exercise<br>3. Education |
| **Comparison 02: Chiropractic vs Other therapies (chronic low-back pain)** | | | | |
| Bronfort 1996 | 1. SMT<br>2. Strengthening exercises | 1. NSAIDs<br>2. Strengthening exercises | 1. SMT<br>2. Stretching exercises | N/A |
| Gudavalli 2004-05 | 1. Flexion-distraction<br>2. Ultrasound<br>3. Cold | 1. Exercise<br>2. Ultrasound<br>3. Cold | N/A | N/A |
| Wilkey 2008 | Chiropractic treatment at the discretion of treating practitioner (including SMT, flexion distraction, drop technique, massage, dry needling, exercise) | Pain clinic treatment at the discretion of the treating consultant (including pharmaceutical therapy, facet joint injection, soft-tissue injection, transcutaneous electrical | N/A | N/A |

**Table 1. Interventions employed in included studies** (*Continued*)

| | | | | |
|---|---|---|---|---|
| | | nerve stimulation) | | |
| **Comparison 03: Chiropractic vs Other therapies (mixed duration low-back pain)** | | | | |
| Beyerman 2006 | 1. Flexion/ distraction<br>2. SMT<br>3. Heat | Heat | N/A | N/A |
| Bronfort 1989 | 1. SMT<br>2. Education | 1. Analgesics<br>2. Local analgesics/injections<br>3. Bed rest<br>4. Physiotherapy (ultrasound, diathermy and ergonomic advice)<br>5. Education | N/A | N/A |
| Hawk 2005 | 1. Flexion-distraction<br>2. Massage | 1. Sham (hand-held instrument)<br>2. Massage (light) | N/A | N/A |
| Hurwitz 2002 | 1. SMT<br>2. Exercise<br>3. Education | Chiropractic plus Physical Modalities<br>1. SMT<br>2. Exercise<br>3. Education<br>4. Physical Modalities ( heat, cold, ultrasound, electrical muscle stimulation (EMS)) | Medical care<br>1. Medication at discretion of practitioner (including analgesics, muscle relaxants or anti-inflammatory agents<br>2. Exercise<br>3. Education | Medical care plus Physical Therapy<br>1. Medication at discretion of practitioner (including analgesics, muscle relaxants or anti-inflammatory agents<br>2. Exercise<br>3. Education<br>4. Physical Therapy at discretion of practitioner ( including heat, cold, ultrasound, EMS, massage, joint mobilisation, traction, supervised exercise) |
| Meade 1990 | Chiropractic treatment at the discretion of treating practitioner (including SMT, mobilisation, traction, corset and exercises) | Physiotherapy treatment at the discretion of treating practitioner (including mobilisation, traction, corset and exercises) | N/A | N/A |

Studies have been grouped by comparison.
Abbreviations: SMT: broad range of therapies were named as "Spinal Manipulative Therapy (SMT)" by authors of the included studies, including high velocity, short-amplitude specific thrusting manipulation, drop techniques and mobilisation; N/A: not applicable

## Risk of bias in included studies

See Figure 2 for the risk of bias assessment for each included study. Only three of the included studies (3/12) had low risk of bias (Brønfort 1996; Gudavalli 2006; Hawk 2005). All 12 studies were described as randomised but the method of random sequence generation was clear in only four studies and allocation concealment was adequate in only six studies. Blinding of study participants was reported in one study, of providers in none of the studies and of outcome assessors in seven studies. Blinding of participants and providers in studies of manual therapy is problematic, as participants often know which therapy is being delivered, and providers obviously know what they are delivering. In some studies, authors reported blinding of outcome assessment, but this was not feasible for the primary outcomes as they were self-reported measures of pain, disability and improvement.

**Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

## Effects of interventions

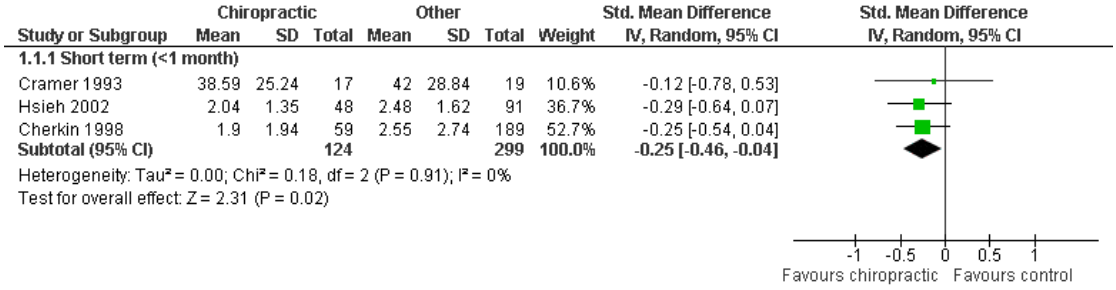
### Comparison 01: Chiropractic versus other therapies (acute and subacute low-back pain)

For the comparison of chiropractic versus other therapies for acute and subacute low-back pain, data were only available for pain and disability.

#### Pain

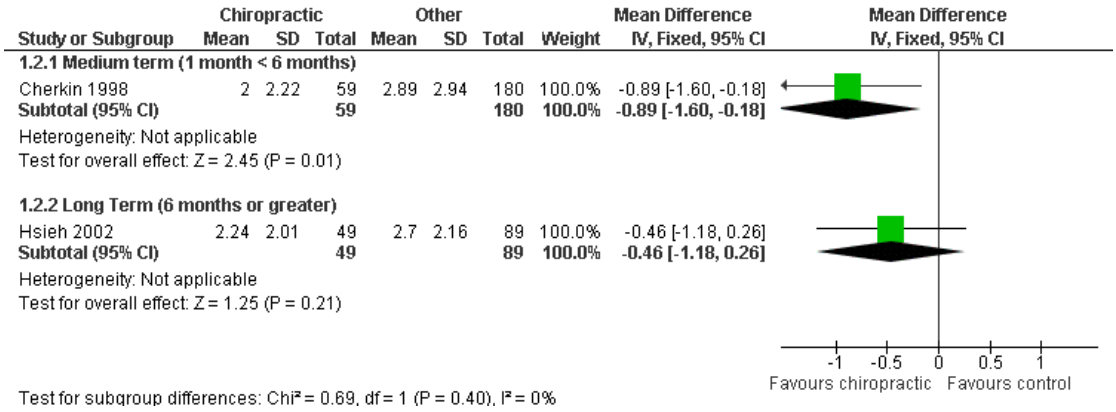
Three included studies (all high risk of bias) measured pain at short-term follow-up (Cherkin 1998; Cramer 1993; Hsieh 2002). For these studies, the chiropractic intervention included lumbosacral spine adjustments/manipulation plus one or more of the following: drop-table adjustments, massage, ice packs, and exercises. The comparator interventions included myofascial therapy, Back School, McKenzie therapy, an instructional booklet, ultrasound, cold pack and massage. Across the three studies, 124 participants received chiropractic interventions and 299 received the other therapies. Both chiropractic and comparator groups improved from baseline, however short-term pain relief was greater for the chiropractic groups when compared to other therapies (combined SMD -0.25 (95% confidence interval (CI) -0.46 to -0.04)) (Figure 3). When this SMD is back transformed into units on the 10 cm VAS, the treatment effect was equivalent to a decrease of 0.48 cm (95% CI 0.08 to 0.87), which is not considered a clinically significant difference.

**Figure 3. Forest plot of comparison: 1 Chiropractic vs Other (acute and subacute LBP), outcome: 1.1 Pain.**




For medium-term follow-up of pain, there was one study with a high risk of bias (Cherkin 1998). Chiropractic interventions included lumbosacral spine adjustments/manipulation plus one or more of the following: drop-table adjustments, massage, ice packs, and exercises. The comparative therapies included ice packs, gentle massage, exercises and McKenzie therapy. Fifty-nine participants received chiropractic interventions and 180 received other therapies. Medium-term pain relief was greater for the chiropractic group when compared to other therapies combined, with MD -0.89 (95%CI -1.60 to -0.18) (Figure 4), but this is not considered a clinically significant difference.

**Figure 4. Forest plot of comparison: 1 Chiropractic vs Other (acute and subacute LBP), outcome: 1.2 Pain medium-term and Long Term.**

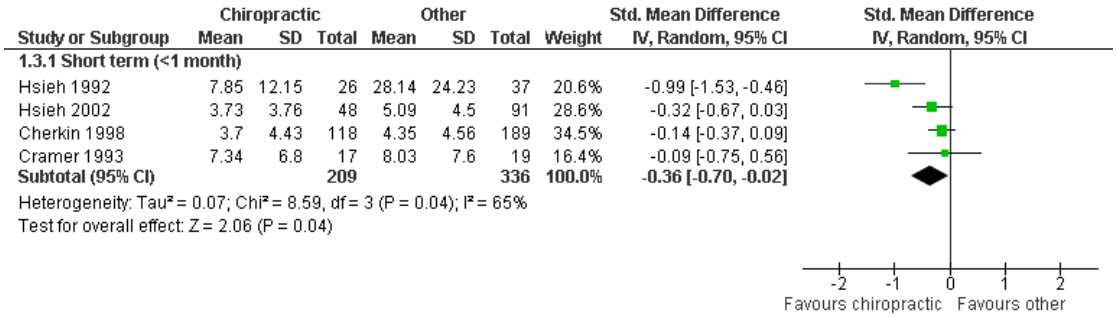



Only one study with high risk of bias reported long-term follow-up for pain (Hsieh 2002). Chiropractic interventions included spinal manipulation and massage and the comparative therapies were a Back School program or myofascial therapy. There were 49 participants in the chiropractic group and 89 in the comparative therapies. There was no significant difference between these groups for long-term pain relief, MD -0.46 (95% CI -1.18 to 0.26) (Figure 4).

### Disability

There were four included studies, all with high risk of bias (Cherkin 1998; Cramer 1993; Hsieh 1992; Hsieh 2002), that measured short-term follow-up of disability. The chiropractic interventions included lumbosacral spine adjustments/manipulation plus one or more of the following: drop-table adjustments, massage, hot packs, ice packs, and exercises. The comparator therapies included myofascial therapy, Back School, McKenzie therapy, an instructional booklet, ultrasound, cold pack, corset, transcutaneous muscle stimulation, and massage. There were 209 participants who received chiropractic and 336 who received the other therapies. Short-term improvement in disability was greater in the chiropractic group compared to other therapies (combined SMD -0.36 (95% CI -0.70 to -0.02)) (Figure 5). When this SMD was back transformed into units on the Roland Morris Disablity Questionnaire, the treatment effect was equivalent to a decrease of 1.94 points on a 24-point scale (95% CI 0.11 to 3.78).

**Figure 5. Forest plot of comparison: 1 Chiropractic vs Other (acute and subacute LBP), outcome: 1.2 Disability.**



For medium-term follow-up of disability, there was one study with a high risk of bias (Cherkin 1998). Chiropractic interventions included lumbosacral spine adjustments, drop-table adjustments, massage, ice packs, and exercises. The comparative therapies included Back School, McKenzie therapy, and an instructional booklet. One hundred and eighteen participants received chiropractic and 180 received the other therapies. Medium-term improvement in disability was greater in the chiropractic group compared to other therapies (combined MD -1.07 (95% CI -2.11 to -0.03)). One study with high risk of bias reported long-term follow-up of disability (Hsieh 2002). The chiropractic interventions included lumbosacral spine manipulation plus massage. The comparator therapies included a Back School program and myofascial therapy. Forty-eight participants received chiropractic and 89 received the other therapies. There was no significant difference between the study groups for long-term disability MD -0.75 (95% CI -2.07 to 0.57).

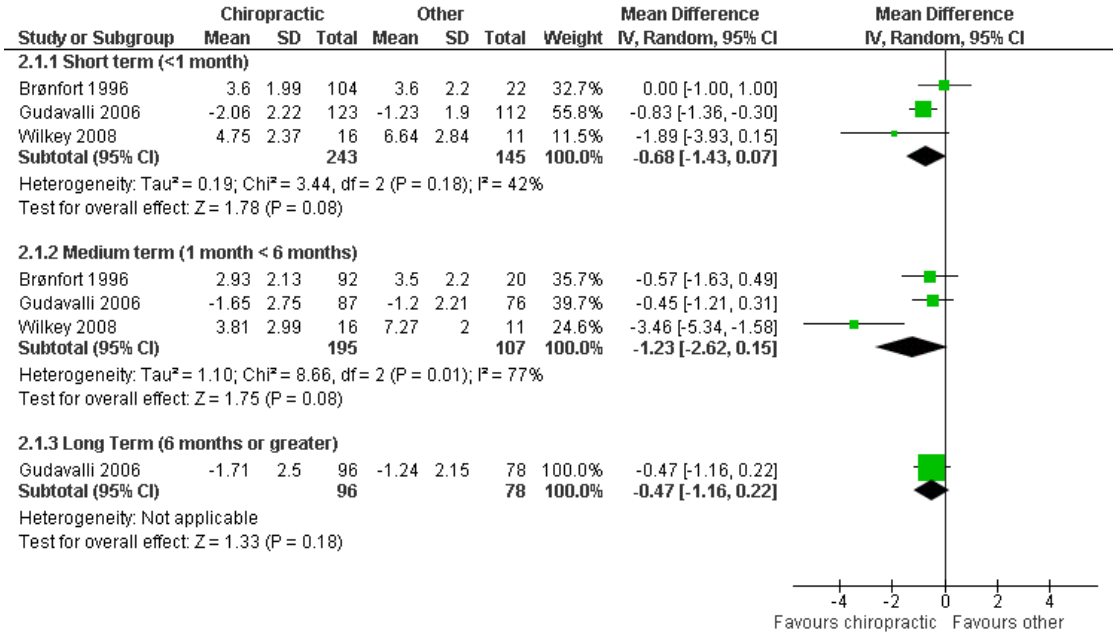
## Comparison 02: Chiropractic versus other therapies (chronic low-back pain)

For the comparison of chiropractic versus other therapies for chronic low-back pain, data were available for the outcomes of pain, disability and general health status.

### Pain

Two studies with low risk of bias and one with high risk of bias reported short-term follow-up of pain (Brønfort 1996; Gudavalli 2006; Wilkey 2008). The chiropractic interventions included SMT plus strengthening exercises or SMT plus stretching exercises, or flexion distraction therapy plus or minus cold or ultrasound, or Diversified SMT, flexion/distraction, drop techniques, trigger point therapy, stretching, dry needling, massage, home exercises, postural advice, and advice on activities of daily living. The comparator therapies included active truck exercises, non-steroidal anti-inflammatory medication and stretching exercises. Two hundred and forty-three participants received chiropractic and 145 received the other therapies. There was no significant difference in short-term pain relief between the groups with a combined SMD of -0.68 (95% CI -1.43 to 0.07) (Figure 6).

**Figure 6. Forest plot of comparison: 2 Chiropractic vs Other (Chronic LBP), outcome: 2.1 Pain.**




These same three studies reported medium-term follow-up for pain (Brønfort 1996; Gudavalli 2006; Wilkey 2008). There were 195 participants who received chiropractic and 107 participants who received the other therapies. Medium-term pain relief was not significantly different between the groups with a combined SMD of -1.23 (95% CI -2.62 to 0.15) (Figure 6).

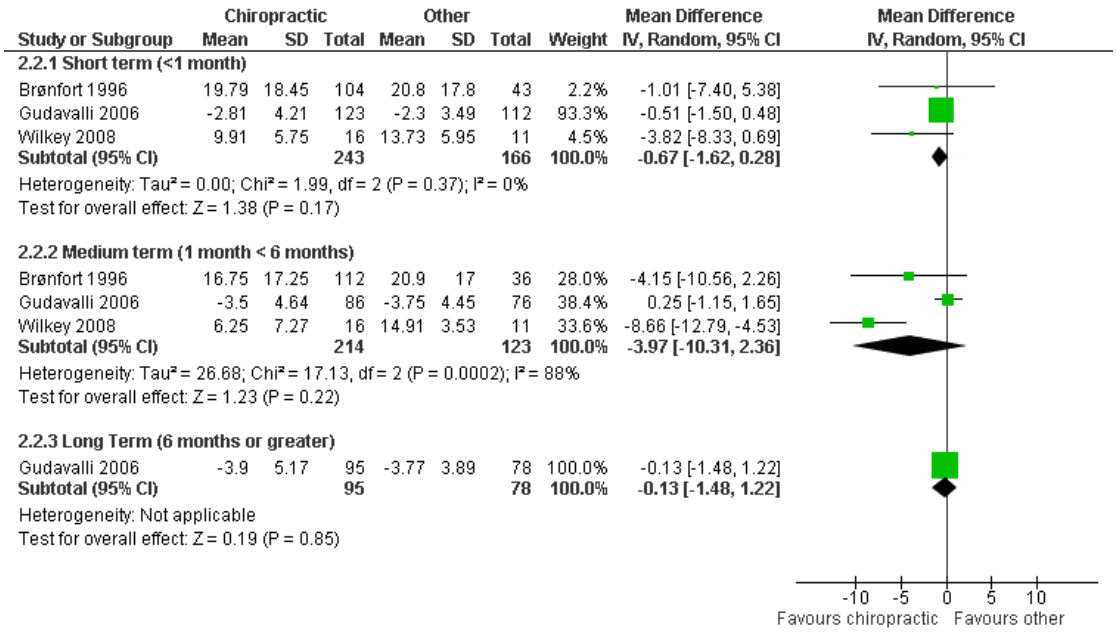
Only one study with low risk of bias reported long-term follow-up

of pain (Gudavalli 2006). The chiropractic interventions included flexion distraction therapy, plus or minus cold or ultrasound. The comparator therapy was active trunk exercises. Ninety-six participants received chiropractic and 78 received the comparator therapy. There was no significant difference in long-term pain relief between the groups with an SMD of -0.47 (95% CI -1.16 to 0.22) (Figure 6).

### Disability

Two studies with low risk of bias and one with high risk of bias reported short-term follow-up of disability (Brønfort 1996; Gudavalli 2006; Wilkey 2008). The chiropractic interventions included SMT plus strengthening exercises or stretching exercises or flexion distraction therapy plus or minus cold or ultrasound, or diversified SMT, flexion/distraction, drop techniques, trigger point therapy, stretching, dry needling, massage, home exercises, postural advice, and advice on activities of daily living. The comparator therapies included active truck exercises, non-steroidal anti-inflammatory medication and stretching exercises. There were 243 participants who received chiropractic and 166 who received the other therapies. There was no significant difference in short-term follow-up of disability between the groups with a MD of -0.67 (95% CI -1.62 to 0.28) (Figure 7).

**Figure 7. Forest plot of comparison: 2 Chiropractic vs Other (Chronic LBP), outcome: 2.2 Disability.**




The same three studies reported medium-term follow-up of disability (Brønfort 1996; Gudavalli 2006; Wilkey 2008). There were 214 participants who received chiropractic and 123 who received other therapies. Medium-term disability was not significantly different between the groups with a MD of -3.97 (95% CI -10.31 to 2.36) (Figure 7).

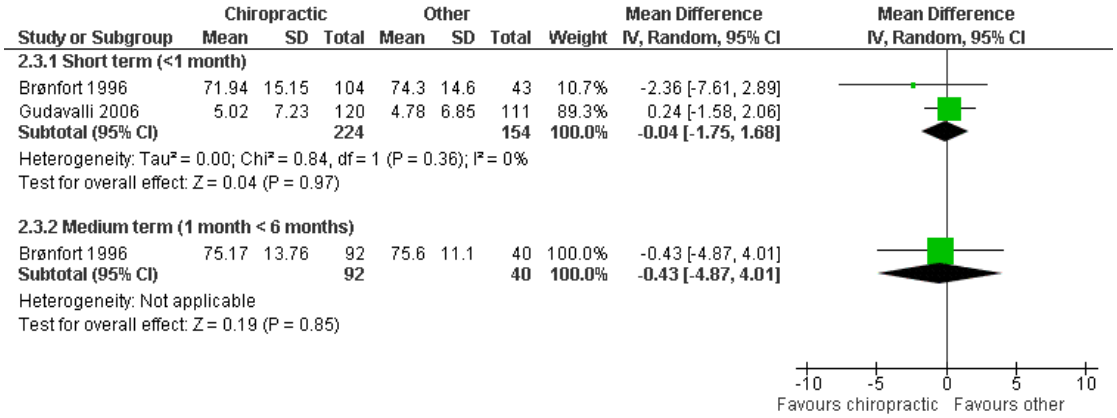
Only one study with low risk of bias reported long-term follow-up of disability (Gudavalli 2006). Chiropractic interventions included flexion distraction therapy plus or minus cold or ultrasound. The comparator therapy was an active trunk exercise protocol. Ninety-five participants received chiropractic and 78 received other therapies. There was no significant difference in long-term disability between the groups with a MD of -0.13 (95% CI -1.48 to 1.22) (Figure 7).

### General health status

Two studies with low risk of bias reported general health status at short-term follow-up (Brønfort 1996; Gudavalli 2006). The chiropractic intervention included spinal manipulation plus strengthening exercises or spinal manipulation plus stretching exercises or flexion distraction therapy plus or minus cold or ultrasound. The

comparator therapies included one or more of: active trunk exercise protocol, non-steroidal anti-inflammatory medication and stretching exercises. There were 224 participants who received chiropractic and 154 who received other therapies. There was no significant difference for short-term follow-up of general health status between the groups with a MD of -0.04 (95% CI -1.75 to 1.68) (Figure 8).

**Figure 8. Forest plot of comparison: 2 Chiropractic vs Other (Chronic LBP), outcome: 2.5 General health status.**




Only one study with low risk of bias reported medium-term follow-up of general health status (Brønfort 1996). Chiropractic interventions consisted of SMT and strengthening exercises or SMT and stretching exercises. The comparator therapies consisted of non-steroidal anti-inflammatory medication and stretching exercises. Ninety-two participants received chiropractic and 40 received other therapies. There was no significant difference between the groups with a MD of -0.43 (95% CI -4.87 to 4.01) (Figure 8).

There were no studies that measured general health status in the long-term.

## Comparison 03: Chiropractic versus other therapies (mixed duration low-back pain)

Five studies included participants with a mixed duration of low-back pain and compared chiropractic interventions to other interventions (Beyerman 2006; Hurwitz 2002; Hawk 2005; Meade 1990; Brønfort 1989). From these studies, data were available for the outcomes of pain, average pain in the past week, disability, participant satisfaction, pain relief, pain free status, further pain episodes, daily pain, further disability and rate of improvement.

### Pain

No studies were found that measured pain in the short and long term. One study with high risk of bias reported medium-term follow-up of pain (Beyerman 2006). The chiropractic interventions included SMT and moist heat pack. The comparison therapy was moist hot pack alone. One hundred and twenty-four participants received combined chiropractic interventions and 93 received moist hot pack. The combined chiropractic interventions relieved pain in medium-term follow-up more than the moist hot packs with a MD of -1.44 (95% CI -2.02 to -0.86).

One study with high risk of bias reported "average pain" experienced in the past week at short-, medium- and long-term follow-up (Hurwitz 2002). The chiropractic interventions were SMT or another spinal-adjusting technique (for example, mobilisation), instruction in strengthening and flexibility exercises, and instruction in proper back care, or chiropractic care as described above plus one or more of the following at the discretion of the chiropractor: heat or cold therapy, ultrasound, and electrical muscle stimulation (EMS). There were two comparator therapies including (1) one or more of the following at the discretion of the medical provider: instruction in proper back care and strengthening and

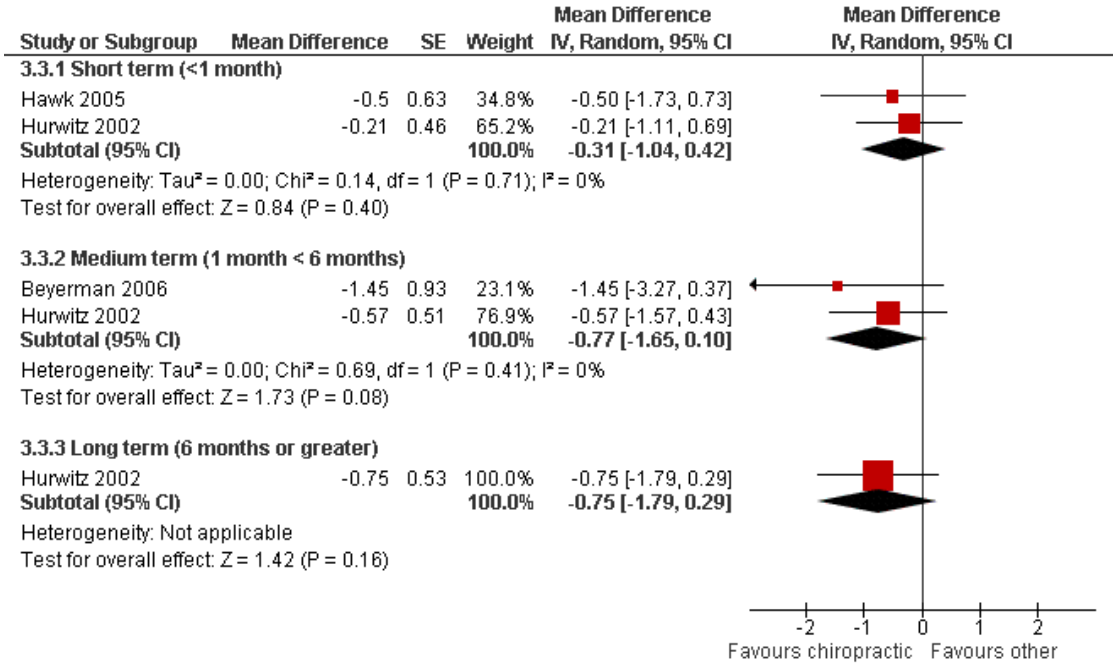
flexibility exercises; prescriptions for analgesics, muscle relaxants, anti-inflammatory agents, and other medications used to reduce or eliminate pain or discomfort; and recommendations regarding bed rest, weight loss, and physical activities; (2) medical care as described above, instruction in proper back care from the physical therapist, plus one or more of the following at the discretion of the physical therapist: heat therapy, cold therapy, ultrasound, EMS, soft-tissue and joint mobilisation, traction, supervised therapeutic exercises, and strengthening and flexibility exercises. At the long-term follow-up, there were 326 participants who received chiropractic and 329 who received the other therapies. The number of participants at the short and medium-term follow-up periods was not reported. There was no significant difference between the chiropractic interventions and the comparator therapies in the short-term (MD of 0.00 (95% CI -0.37 to 0.37)), medium-term (MD of -0.22 (95% CI -0.65 to 0.21)) or long-term follow-up (MD of -0.22 (95% CI -0.69 to 0.25)).

One study with high risk of bias also reported the outcome of "pain partially or completely relieved" at medium-term follow-up (Meade 1990). The chiropractic intervention group reported significantly more partial or complete pain relief than the comparator group with a Risk Ratio (RR) of 1.12 (95% CI 1.04 to 1.21). There were no significant differences between the chiropractic or physiotherapy groups for long-term follow-up of the participants being "pain free for several months" (RR of 1.08 (95% CI 0.90 to 1.29)), whether participants had experienced "further equally severe episode" (RR of 0.97 (95% CI 0.65 to 1.44)), or whether they were "experiencing pain daily" (OR of 0.83 (95% CI 0.64 to 1.08)).

#### Disability

Two studies, one with low risk of bias and one with high risk of bias, reported disability at short-term follow-up (Hawk 2005; Hurwitz 2002). The chiropractic interventions and comparator therapies for the Hurwitz 2002 study are described above. In the Hawk 2005 study, the chiropractic interventions consisted of flexion distraction technique and trigger point therapy and the comparator therapies included sham manipulation and effleurage massage. The Hurwitz 2002 paper does not quote the exact number of participants in each group at the short-term follow-up (also no response to our inquiries) but together with the Hawk participants, we estimate that 380 participants received chiropractic interventions and 381 participants received the other therapies. There was no significant difference between the chiropractic interventions and the comparator interventions for disability in the short-term with a MD of -0.31 (95% CI -1.04 to 0.42) (Figure 9).

**Figure 9. Forest plot of comparison: 3 Chiropractic vs Other (Mixed), outcome: 3.4 Disability.**



Two studies with high risk of bias reported medium-term follow-up for disability (Beyerman 2006; Hurwitz 2002). We estimate that 450 participants received chiropractic and 422 received the other therapies.There was no significant difference between the chiropractic and comparator therapies for medium-term disability with a MD of -0.77 (95% CI -1.65 to 0.10) (Figure 9).

Only one study with high risk of bias reported long-term follow-up of disability (Hurwitz 2002). There was no significant difference for disability between the chiropractic and comparative therapies with a MD of -0.75 (95%CI -1.79 to 0.29) (Figure 9).

One study with high risk of bias reported on "Oswestry score as high or higher than before treatment", measured at medium-term and long-term follow-up (Meade 1990). The chiropractic intervention group scored better than the physiotherapy group in the medium-term (RR of 0.63 (95% CI 0.46 to 0.86)), and long-term follow-up (RR of 0.70 (95% CI 0.52 to 0.94)).

### Other outcomes

One study with high risk of bias reported participants being "satisfied or very satisfied" with their care (Meade 1990). There were 329 participants who received chiropractic interventions and 329 who received the physiotherapy intervention. There was no short-term or long-term follow-up reported. For medium-term follow-up, those who received the chiropractic intervention were significantly more satisfied with their care than those who received physiotherapy (RR of 1.12 (95% CI 1.05 to 1.19)).

One study with high risk of bias reported on "rate of improvement" at the short-, medium- and long-term follow-ups (Brønfort 1989). In this study, there were 10 participants in the chiropractic group and nine in the control group. The chiropractic intervention was SMT plus advice on prevention of future episodes and the comparator group consisted of analgesics, bed rest, ultrasound, ergonomic advice and prevention advice. There was no significant difference in rate of improvement in the short-term (RR 1.05 (95% CI 0.57 to 1.94)), medium-term (RR 1.05 (95% CI 0.57 to 1.94)), or long-term (RR 1.20 (95% CI 0.69 to 2.09)).

## Comparison 4: Chiropractic versus no treatment

No RCTs were located that compared combined chiropractic interventions to no treatment.

## Adverse effects

Adverse effects were reported in only two of the included studies ( Hawk 2005; Hsieh 2002). From these two studies, 16 out of a total of 106 participants who received the chiropractic interventions reported minor, transient, exacerbations of symptoms. None of the included studies reported any serious adverse effects in participants that received the chiropractic interventions. However, relatively small and short-term RCTs included in this review are not the best study design for detecting adverse events, and longer term large observational studies are needed to provide a valid evaluation of adverse effects, particularly those that are uncommon or rare.

## Clinical Relevance

Table 2 shows the clinical relevance assessment for each included study. Overall, the effect sizes for the included studies were small and did not provide a clinically significant difference for the chiropractic interventions.

**Table 2. Clinical Relevance**

| Study | Patients | Interventions | Relevant Outcomes | Size of effect | Benefits and harms |
|---|---|---|---|---|---|
| **Comparison 01: Chiropractic vs Other therapies (acute and subacute low-back pain)** | | | | | |
| Cherkin 1998 | + | + | + | ? | + |
| Cramer 1993 | - | ? | ? | ? | - |
| Hsieh 1992 | + | + | - | ? | ? |
| Hsieh 2002 | + | + | + | - | ? |
| **Comparison 02: Chiropractic vs Other therapies (chronic low-back pain)** | | | | | |
| Bronfort 1996 | + | + | + | ? | + |
| Gudavalli 2005 | + | + | - | ? | ? |

**Table 2. Clinical Relevance** (*Continued*)

| | | | | | |
|---|---|---|---|---|---|
| Wilkey 2008 | + | ? | - | + | ? |
| **Comparison 03: Chiropractic vs Other therapies (mixed duration low-back pain)** | | | | | |
| Beyerman 2006 | - | + | - | ? | ? |
| Bronfort 1989 | - | ? | - | - | ? |
| Hawk 2005 | + | + | - | - | - |
| Hurwitz 2002 | + | - | + | ? | - |
| Meade 1990 | + | + | + | + | ? |

Studies have been grouped by comparison.

## DISCUSSION

Combined chiropractic interventions (rather than SMT alone) provide short- and medium-term relief for pain and disability for individuals with acute and subacute low-back pain when compared to other treatments, but the effect sizes are small and although statistically significant, they are not clinically relevant. Also, the studies that demonstrated this effect were assessed as having a high risk of bias. There was no evidence of a significant difference between chiropractic and other treatments for any outcomes for individuals with chronic or mixed duration low-back pain. This review found no studies that would allow us to conclude about the effects of combined chiropractic interventions compared to the natural history of acute and subacute low-back pain.

There was no significant difference in reduction of pain or disability at long-term follow-up for chiropractic compared to other interventions. Improvement at long-term follow-up after a finite amount of therapy may be optimistic in trials of this nature given the 25% recurrence rate of low-back pain within a year of an episode (Stanton 2008).

Clinical significance for the 10 cm VAS is considered to be a 1.4 cm change (Kelly 2001), for the Oswestry Disability Index, a 10% change (Ostelo 2005) and for the Roland Morris Disability Questionnaire, a change of two to three points on a 24-point scale (Bombardier 2001). The results for the included studies did not provide a clinically significant difference for the chiropractic interventions.

The Cochrane Back Review Group (Furlan 2009) recommends that systematic reviews of low-back pain should be concerned with important patient-centred outcomes, such as: symptoms (for example, pain), overall improvement or satisfaction with treatment, back-specific functional status (for example, Roland Morris Disability Questionnaire (RMDQ), Oswestry Disability Index (ODI)), well-being (for example, quality of life measured with the SF-36, SF-12, EuroQuol), and disability (for example, ability to perform activities of daily living, return-to-work status, work absenteeism). The included studies in this review looked at a variety of outcomes but the most commonly measured were pain (VAS or NRS) and disability (RMDQ or ODI). Other outcomes of importance were used infrequently in the trials and were often measured with different instruments. For example, general health was measured in two trials (Brønfort 1996; Gudavalli 2006) using two different measurement instruments. No study measured return-to-work rates or specific activities of daily living. Future trials for chiropractic interventions should include these important outcome measures.

The dose of the chiropractic interventions employed in the included studies may not have been sufficient to make a difference until after the short-term follow-up outcomes were recorded. However, dose-response has not been studied extensively for chiropractic interventions for low-back pain. In a dose-response trial for chronic low-back pain, Haas et al (Haas 2004) found that there was a positive, clinically important effect of the number of chiropractic treatments for chronic low-back pain on pain intensity and disability at four weeks. Relief was substantial for patients receiving care three to four times per week for three weeks. How-

ever, given the small amount of research, it is difficult to draw a conclusion. It is also possible that there is no dose-response effect with chiropractic care for low-back pain, and this is indicated by some favourable spinal manipulation trials that have only a few treatments (Assendelft 2004).

We have synthesised studies of heterogeneous chiropractic therapy approaches and compared them to a heterogeneous group of comparator treatments. This approach has advantages and disadvantages. An advantage is that the therapies in both chiropractic and comparator groups more closely replicate what is delivered in a clinical situation. A disadvantage is that we cannot be sure whether one or all components of any package is having an effect. On balance, we believe there is a place for both approaches, that is, systematic reviews of both pragmatic (mixed therapies that replicate practice) and explanatory or fastidious trials (trials that test only one single intervention modality), as each approach addresses a different type of question.

In some of the studies included in this review, the comparison treatments were very similar to the chiropractic interventions employed, limiting the opportunity for the comparison of different interventions. Meta-analysis was possible for many of the comparisons but not possible for others, mainly due to the small number of included studies. The global chiropractic treatment approach adopted for this review includes various potential confounding factors such as the type of intervention chosen by the chiropractors, the number of treatment sessions, experience of the chiropractors, and the heterogeneity of participants.

Only three of the 12 included studies were rated as low risk of bias. Future trials of chiropractic interventions need to be carefully planned and reported. Although we planned to undertake sensitivity analyses based on risk of bias, we were unable to do this due to the small number of trials available for each comparison. Also, there was an insufficient number of included trials to attempt any meaningful sub-group analysis. This review would benefit from subgroup analysis allowing interpretation of effects of different kinds of chiropractic interventions as the subgroups, with an overall synthesis of results to address the primary objective of the review. However, we were not able to achieve this due to the small number of included studies and the diversity of interventions. This approach will be employed for updates if further trials are identified.

This review looked at pragmatic studies, where chiropractic treatment was diverse in approach and did not include explanatory or fastidious studies of chiropractic where only SMT was used. These fastidious studies have been included in a previous Cochrane review of SMT for low-back pain that concluded that SMT was not superior to other effective treatments, but was more effective than placebo (Assendelft 2004). Sub-group analysis determined that the profession of the manipulator did not alter this result. It may be useful to combine the chiropractic pragmatic trials in this review with the fastidious trials of SMT for low-back pain where the therapist was a chiropractor. This may give a more overarching answer to the question of the effectiveness of chiropractic interventions for low-back pain compared to other therapies.

Trials included in our review and more broadly those of previous reviews examining different therapies for low-back pain (Van Tulder 2000; Assendelft 2004), have examined these therapies when directed at a symptom (non-specific low-back pain), and not a diagnosis. Previous systematic reviews (Van Tulder 2000; Assendelft 2004) have described the benefit of a broad range of physical and pharmacological interventions over natural history or placebo therapies, but have conceded that effect sizes are small, with little difference in outcomes observed when alternative therapies are compared. This apparent lack of effect may be due, at least in part, to the tendency to treat non-specific low-back pain as a homogenous condition, rather than a heterogeneous collection of as yet undefined but differing conditions, some of which might respond and others that do not respond to a particular therapy (Hancock 2009). Research to identify diagnostic subsets within non-specific low-back pain may be worthy and if successful, individual therapies such as chiropractic may be better directed.

## AUTHORS' CONCLUSIONS

### Implications for practice

This review has shown that while combined chiropractic interventions slightly improved pain and disability in the short-term and pain in the medium-term for acute and subacute low-back pain, current evidence neither supports nor refutes that these interventions provide a clinically meaningful difference for pain or disability in people with low-back pain when compared to other interventions.

Any demonstrated differences in effects are small and not clinically relevant compared to other treatments and any benefits do not appear to be long lasting. No study has been undertaken of combined chiropractic interventions compared to no treatment, hence no conclusion about this can be drawn. Most of the included studies were at high risk of bias and there is a need for more high quality trials in this area.

### Implications for research

Due to the challenges in comparing this type of intervention to a placebo (inability to blind patient and practitioner), and unless novel placebos are developed, further research should compare chiropractic interventions to other effective interventions for low-back pain to determine the effect of chiropractic interventions compared to these established therapies. Aspects that need to be addressed in future studies include: examining the relative effects of different frequencies of visits to chiropractors; research to identify diagnostic subsets within non-specific low-back pain that may

more favourably respond to chiropractic interventions so that chiropractic may be better directed; the use of appropriate outcome measures including pain, disability, overall improvement, satisfaction with treatment and return-to-work; and cost-effectiveness studies comparing chiropractic interventions with other therapies.

## ACKNOWLEDGEMENTS

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Konstantinou K, Foster N, Rushton A, Baxter D, Wright C, Breen A. Flexion mobilizations with movement techniques: The immediate effects on range of movement and pain in subjects with low back pain. *Journal of Manipulative & Physiological Therapeutics* 2007;**30**(3):178–85.

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* *Indicates the major publication for the study*

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies *[ordered by study ID]*

**Beyerman 2006**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: USA<br>Number recruited: 252<br>Number randomised: 252 |
| Participants | Population: Experiencing lower back pain at the time of the study and DJD confirmed on x-ray<br>Settings: It appears that this study occurred at Winchester Hospital, MA, USA, but not clearly described.<br>Mean Age: Not described<br>Work status: Not described<br>Pain duration: Not described |
| Interventions | Chiropractic: A moist hot pack was applied for 15 minutes at each visit. Flexion/distraction technique and spinal manipulation was provided at each visit.<br>Comparison: A moist hot pack was applied for 15 minutes at each visit.<br>Country of training: Not described<br>Years in practice: Not described |
| Outcomes | Outcome measures at baseline and then follow-up measurement after: Visit 5, 10, 15 and 20 (no actual times given). Using:<br>1. Lumbar Ranges Motion with J-Tech Dual Digital Inclinometer.<br>2. Oswestry low-back Pain Questionnaire<br>3. Visual analogue pain scale (0-100 mm) |
| Notes | |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | "Randomly assigned" was the only information given |
| Allocation concealment? | Unclear | Not reported |
| Blinding?<br>All outcomes - patients? | No | "Given the nature of the study, neither the participants nor the researchers were blind to the assignment." |
| Blinding?<br>All outcomes - providers? | No | "Given the nature of the study, neither the participants nor the researchers were blind to the assignment." |

**Beyerman 2006** (*Continued*)

| | | |
|---|---|---|
| Blinding?<br>All outcomes - outcome assessors? | No | "Given the nature of the study, neither the participants nor the researchers were blind to the assignment." |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | Unclear | 35 subjects withdrew but without explanation. There were 19 and 16 drop-outs from the "Chiropractic" group and "hot pack group" respectively. |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | No | Thirty five drop-outs before completion of the trial but no explanation of why. Intention-to-treat analysis not described or mentioned. |
| Free of selective reporting? | Unclear | Outcomes described and measured over "5 measurement intervals" but not described when this was. The five intervals were baseline and then at visit 5, 10, 15, and 20. No time of outcome measurement given. |
| Free of other bias? | Unclear | Unsure about size of the effect until we see proper analysis carried out; i.e. what are the actual differences between the groups at each of the follow-ups, and what time periods were actually followed up? |
| Similarity of baseline characteristics? | Yes | "It is noted that the treatment and moist heat groups were equivalent in terms of pain levels and inclinometer values before treatment and moist heat procedures" |
| Co-interventions avoided or similar? | Unclear | Not reported |
| Compliance acceptable in all groups? | Unclear | Not reported |
| Timing of the outcome assessment similar in all groups? | Unclear | Not adequately reported |

**Brønfort 1989**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: Denmark<br>Number recruited: 19<br>Number randomised: 19 |
| Participants | Population: Experiencing LBP of various duration with or without radiation to one or both extremities<br>Settings: Patients were recruited from medical practices in Lolland Falster, Denmark |

**Brønfort 1989** (*Continued*)

| | |
|---|---|
| | Mean Age: Not reported (range 18 to 70 years)<br>Work status: Not reported (They did measure percentages of the population presently unable to work or previously unable to work due to LBP, but not all patients fell into these two categories)<br>Pain duration: Less than 4 weeks or greater than 8 weeks. |
| Interventions | Chiropractic: Low amplitude, high velocity manipulative procedure aimed at dysfunctional articulations involving all areas of the spine and pelvis. No specific chiropractic technique was adhered to. Patient education on how to minimize LBP episodes given. Average of 7 visits.<br>Comparison: received analgesics, local analgesics/injections, bed rest and/or physiotherapy (ultrasound, diathermy and ergonomic advice). Also given patient education on how to minimize LBP episodes. Average of 7 visits.<br>Country of training: Unknown<br>Years in practice: "many years" |
| Outcomes | Outcome measures at baseline* and then follow-up measurement after 1, 3, and 6 months (not immediately after intervention):<br>1. Patient reported improvement<br>2. Number of days with symptoms<br>3. Number of days with bed rest<br>4. Inability to work<br>5. Use of medication |
| Notes | *None of the measurements (gender, previous LBP episodes, onset, duration, other) taken at baseline were subjected to statistical analysis other than percentages. |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | Unclear | Not stated, just "randomly allocated" |
| Allocation concealment? | Unclear | Not stated |
| Blinding?<br>All outcomes - patients? | No | Not stated, but assumed that patients knew what they were receiving; that is, medicine or physical treatment |
| Blinding?<br>All outcomes - providers? | No | Not possible |
| Blinding?<br>All outcomes - outcome assessors? | Yes | There was blinding of assessors at 1 month and thereafter outcomes measures were self-administered. |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | Unclear | Not reported |

**Brønfort 1989** (*Continued*)

| | | |
|---|---|---|
| Incomplete outcome data addressed? All outcomes - ITT analysis? | No | Two drop-outs without explanation and no intention-to-treat analysis. |
| Free of selective reporting? | No | Methods included use of MMPI but results not reported |
| Free of other bias? | Unclear | No statistical analysis other than percentages. |
| Similarity of baseline characteristics? | Yes | The groups were "somewhat similar" except for gender. |
| Co-interventions avoided or similar? | Yes | Both groups received patient education |
| Compliance acceptable in all groups? | Unclear | Not reported |
| Timing of the outcome assessment similar in all groups? | Yes | After 1, 3 and 6 months. |

**Brønfort 1996**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: Not reported<br>Number recruited: 617<br>Number randomised: 174 |
| Participants | Population: Patients with nonspecific LBP for at least 6 weeks with or without radiating pain to one or both legs at level of knee<br>Settings: Not reported<br>Mean Age: Not reported (range 20 to 60 years old)<br>Work status: 77.1% full work status<br>Pain duration: At least 6 weeks |
| Interventions | Group 1: Spinal manipulation therapy (SMT): high velocity, low amplitude manual spinal thrusting technique with contact over the vertebral osseous process, muscle or ligament and thrust over vertebral or sacroiliac joints PLUS Strengthening exercises.<br>Group 2: NSAID: patients in this group were given 500 mg Naproxen sodium each morning and evening for 5 weeks; PLUS trunk and leg extensions and abdominal strengthening<br>Group 3. SMT PLUS Stretching exercises.<br>People in groups 1 and 2 received 20 supervised sessions: 10 sessions lasting 10 to15 minutes for 5 weeks, then 10 sessions of exercise alone (1 hour duration) and for 6 weeks.<br>Country of training: Not reported<br>Years in practice: Chiropractors had 5 to 25 years of experience. |
| Outcomes | Outcome measures at baseline:<br>1. Pain radiation to leg %<br>2. Analgesic use in past week % |

**Brønfort 1996** (*Continued*)

| | |
|---|---|
| | 3. Depression score (CES-D, 0-60 scale)<br>4. LBP score (0-10)<br>5. Global general health (COOP charts 0-100)<br>6. Roland Morris 0-100 validated<br>7. MMPI<br>8. Waddell's score<br>Outcome measured at 3, 5, and 11 weeks follow-up<br>1. LBP: ordinal 11-box scale (validity similar to VAS),<br>2. Disability: Roland-Morris index (validated)<br>3. General health status: COOP charts (validated |
| Notes | |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Yes | "The allocation process was verified by an independent professional agent" |
| Allocation concealment? | Yes | Opaque envelopes |
| Blinding?<br>All outcomes - patients? | No | Patients were aware of therapy |
| Blinding?<br>All outcomes - providers? | No | Providers were aware of therapy |
| Blinding?<br>All outcomes - outcome assessors? | Yes | Outcome assessors blinded |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | Yes | 42 lost after 11 weeks and 48 lost after 1 year. Reasons given for drop-outs. |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | Yes | Common reasons and statistical analysis of drop outs provided with ITT analysis. |
| Free of selective reporting? | Unclear | Primary outcome measures were done via patient-rated questionnaires. Trunk performance and range of motion data were collected by clinicians. |
| Free of other bias? | Yes | No other detected |
| Similarity of baseline characteristics? | Yes | Variable table provided |
| Co-interventions avoided or similar? | Yes | All participants asked to record co-interventions |

**Brønfort 1996** (*Continued*)

| | | |
|---|---|---|
| Compliance acceptable in all groups? | Yes | 85% compliance |
| Timing of the outcome assessment similar in all groups? | Yes | Three, five and eleven weeks then 1 year. |

**Cherkin 1998**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: Not reported<br>Number recruited: 714<br>Number randomised: 323 |
| Participants | Population: Patients seen by their primary care physician for LBP who still had pain seven days after their visit (no definition of LBP provided)<br>Settings: Not reported<br>Mean Age: Not reported (range 20 to 64 years old)<br>Work status: Most (average of 88.5%) participants were either self-employed or employed elsewhere (85%, 91%, 89%, 89% for each group)<br>Pain duration: At least 7 days; the study reports "most" had pain less than 6 weeks ( average 77.5%) |
| Interventions | Chiropractic: Short-lever high velocity thrust. All participants underwent manipulation to lumbar or lumbosacral regions or both. 54% received sacral or sacroiliac manipulation, 27% thoracic manipulation, 12% cervical manipulation, 6% hip, pelvis or ischium manipulation, 64% received manipulation of more than one region of spine. 20% received ice packs, 49% received localized massage, 41% performed exercises in the office and 58% performed exercises at home. The number of sessions was 9.<br>Comparison 1: Physical Therapy: The McKenzie approach was used to teach patients exercises that would allow them to "centralize" pain. This group was also given an educational book entitled *Treat Your Own Back.* Patients in this group reported using lumbar rolls (71%), and recommended sitting posture (83%). The number of sessions was 9.<br>Comparison 2: Booklet group: patients received an educational booklet that has been shown in a previous study to have little effect on improved outcomes.<br>Country of training: Not reported<br>Years in practice: Chiropractors had 6 to 14 years experience. Physical therapists had 14 years experience. |
| Outcomes | Outcome measures at baseline:<br>1. "Bothersomeness" of back pain, leg pain and numbness/tingling during preceding 24 hours: 11-point scale (validity similar to similar scale).<br>2. Disability: Roland Disablity Scale (validated).<br>3. Subject characteristics (validation not mentioned).<br>4. Two subscales of the SF36: General health perceptions score and the Mental health score. Not validated.<br>5. Narcotic use. Not validated.<br>Outcomes measured at 1, 4, and 12 weeks follow up:<br>1. "Bothersomeness" of pain: 11-point scale (validity similar to similar scale). |

**Cherkin 1998** (*Continued*)

| | |
|---|---|
| | 2. Disability: Roland Disability Scale (validated). |
| Notes | |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | "Randomly assigned' was only text reported. |
| Allocation concealment? | Yes | Use of "sealed, opaque envelopes" |
| Blinding?<br>All outcomes - patients? | No | Assigned to McKenzie therapy, manipulation or a booklet. |
| Blinding?<br>All outcomes - providers? | No | Providers knew the therapy they were administering |
| Blinding?<br>All outcomes - outcome assessors? | Yes | Outcome assessors were unaware of therapy assignment |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | No | Not reported |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | Yes | "Data were analyzed according to intention-to-treat" |
| Free of selective reporting? | Unclear | Contact author did not respond to email on this question |
| Free of other bias? | Yes | None found |
| Similarity of baseline characteristics? | Yes | Table provided of key baseline variables |
| Co-interventions avoided or similar? | Yes | Reported for the 3 groups |
| Compliance acceptable in all groups? | Yes | Number of visits for chiropractic or physical therapy were discretionary with a maximum of 9. |
| Timing of the outcome assessment similar in all groups? | Yes | 1, 4 and 12 weeks |

**Cramer 1993**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: Not reported<br>Number recruited: Not reported<br>Number randomised: 36 |
| Participants | Population: Patients were included if they had back pain of less than 2 weeks duration, an Oswestry score of greater than or equal to 8, a VAS score of greater than or equal to 33 mm, no litigation of worker's compensation and not pregnant.<br>Settings: Outpatient clinic<br>Mean Age: Not reported (range 18 to 56 years)<br>Work status: Not reported<br>Pain duration: Less than 2 weeks |
| Interventions | Chiropractic: Clinicians assigned to the treatment group gave whatever treatment they saw fit to the patients as long as it included a side-lying manipulation to the affected area of the lumbar spine. Most frequently patients received electrical muscle stimulation, cold pack in addition to the manipulation. 3 to 5 sessions delivered over 10 days<br>Comparison: Ultrasound to low-back followed by cold pack for 10 to 15 minutes and 15 to 30 seconds of very gentle soft tissue massage.<br>Country of training: Not reported<br>Years in practice: Not reported |
| Outcomes | Outcome measures at baseline and then immediately after the 10 day intervention:<br>1. Pain: VAS (validation not mentioned)<br>2. Function: Oswestry (validation not mentioned)<br>3. Electrodiagnostics procedures: isometric strength of lumbar extensions and flexions (validation not mentioned), maximum voluntary strength tests (validation not mentioned), maximum flexion and extension measurements (validation not mentioned), bilateral nerve conduction velocity and F wave latencies (validation not mentioned), evaluation of H reflex (validation not mentioned), |
| Notes | |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | Not reported |
| Allocation concealment? | Unclear | Not reported |
| Blinding?<br>All outcomes - patients? | Unclear | Not reported |
| Blinding?<br>All outcomes - providers? | No | Not possible. Providers knew what they were administering |
| Blinding?<br>All outcomes - outcome assessors? | Unclear | Self reported VAS and Oswestry. Blinding not reported |

**Cramer 1993** (*Continued*)

| | | |
|---|---|---|
| Incomplete outcome data addressed? All outcomes - drop-outs? | Unclear | Not reported |
| Incomplete outcome data addressed? All outcomes - ITT analysis? | No | Not reported |
| Free of selective reporting? | Unclear | Insufficient information provided |
| Free of other bias? | Unclear | Not reported |
| Similarity of baseline characteristics? | Unclear | Not reported |
| Co-interventions avoided or similar? | Unclear | Not reported |
| Compliance acceptable in all groups? | Unclear | Not reported |
| Timing of the outcome assessment similar in all groups? | Unclear | Not reported |

**Gudavalli 2006**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: USA<br>Number recruited: 312<br>Number randomised: 235 |
| Participants | Population: Participants were over 18 years, with a primary complaint of low-back pain for more than 3 months with no contra-indication to manual therapy. Chronic low-back pain was defined as back pain from L1 to S1 joint and palpatory tenderness over one or more lumbar zygapophyseal joints<br>Settings: Consecutive new patients with chronic low-back pain were recruited from two chiropractic clinics and two orthopaedic clinics in Chicago, USA<br>Mean Age: 42.22 (SE1.03) and 40.88 (SE1.21) in the flexion-distraction group and active trunk exercise protocol group respectively.<br>Work status: 34% and 29% participants were employed in a manual labour job, 54% and 56% in a non-manual labour job, and 12% and 15% were unemployed or retired. (FD $1^{st}$, ATEP $2^{nd}$ listed)<br>Pain duration: Duration of greater than 3 months |
| Interventions | Chiropractic: Series of flexion-distraction procedures performed on a specially constructed table with a moveable headpiece, a stationary thoraco-lumbar piece, and a moveable lower extremity piece. With the subject lying prone, the clinician places one hand over the lumbar region at the level of interest and uses the other hand to flex, laterally flex, and/or rotate the lower extremity section of the table. Technique repeated three times at each week, all clinically affected levels. Also ultrasound and ice.<br>Comparison: Active trunk exercise protocol (ATEP) was administered by licensed physical therapists and consisted of flexion or extension exercises, weight training, flexibility |

| | |
|---|---|
| | exercises, and cardiovascular exercises depending on patient symptoms. Biomechanically the ATEP did not concentrate on a specific joint level but sought to impact the lumbar spine as a whole. Also ultrasound and ice.<br>Study participants in both groups were seen 2 to 4 times a week, at the discretion of the treatment provider, for 4 weeks.<br>Country of training: Not reported (but study occurred in USA)<br>Years in practice: Not reported |
| Outcomes | Outcome measures at baseline, immediately after the 4-week treatment period, and at 1-year follow-up:<br>1. 100 mm VAS for perceived pain<br>2. Roland-Morris Questionnaire to measure function<br>3. SF-36 to measure health status<br>Outcome measures only at end of 4 weeks treatment:<br>1. Levels of satisfaction (would they recommended to others?) (validity not reported)<br>Outcome measures only at 1-year follow-up:<br>1. Health care utilisation (weekly phone interview with access to services; validity not reported)<br>2. low-back biomechanics (method not reported) |
| Notes | 100 mm VAS for perceived pain transformed to 10 to allow meta-analysis with other pain scales |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | Yes | Participants were randomised using random number tables |
| Allocation concealment? | Yes | Sequentially numbered manila envelopes held each successive randomised treatment group allocation |
| Blinding?<br>All outcomes - patients? | Unclear | No description of attempts to blind to purpose of study |
| Blinding?<br>All outcomes - providers? | No | Providers administer the therapy so were not blinded but were blinded to outcome |
| Blinding?<br>All outcomes - outcome assessors? | Yes | Outcome assessors were blinded, and the primary measures were self-administered questionnaires that were not completed in the presence of the attending clinician at any time. |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | Yes | Although some participants were lost to follow-up, data were retrieved from 78% (96/123) subjects in the FD group and 70% ( |

**Gudavalli 2006** (*Continued*)

| | | |
|---|---|---|
| | | 78/112) of subjects in the ATEP group after 12 months. |
| Incomplete outcome data addressed? All outcomes - ITT analysis? | Yes | "Analysis ... used an intention-to-treat approach." |
| Free of selective reporting? | Unclear | Insufficient information provided |
| Free of other bias? | Unclear | Not reported |
| Similarity of baseline characteristics? | Yes | Table of key variables provided showing similarity |
| Co-interventions avoided or similar? | Unclear | Not reported |
| Compliance acceptable in all groups? | Yes | 83.8% of patients completed treatment |
| Timing of the outcome assessment similar in all groups? | Yes | Primary outcomes at baseline, 5 weeks and 1 year |

**Hawk 2005**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: USA<br>Number recruited: 111<br>Number randomised: 111 |
| Participants | Population: Participants were 18 years of age and over with subacute (onset 4 to 12 weeks prior to contact) or chronic (onset more than 12 weeks prior to contact) low-back pain<br>Settings: Not reported<br>Mean Age: Age across the treatment and control groups were similar, with the mean age 51 (SD 14.2) and 53 (SD 14.2) years respectively.<br>Work status: Not reported<br>Pain duration: 4 median years (0.1 to 45 range) for active group and 7 median years ( 0.1 to 50 range) for the control group. |
| Interventions | Chiropractic: In the active group patients received FDT and trigger point therapy. In FDT, the clinician moves the patient's spine in small increments while manually directing inferior-to-superior force against the vertebrae, assisted by movable table sections and manual posterior-to-anterior stabilising pressure. Trigger point therapy involved manual ischaemic compression to muscles with localised regions of painful contracted tissue. Eight treatments were delivered over 3 weeks.<br>Comparison: Patients received sham manipulation and effleurage. Sham manipulation was performed with a hand-held instrument.<br>Country of training: Likely USA as study conducted in USA<br>Years in practice: Not reported |

**Hawk 2005** (*Continued*)

| | |
|---|---|
| Outcomes | Outcome measures at baseline and immediately after 3 weeks treatment:<br>1. Pain Disability Index, as a mean change, a patient self-report instrument with demonstrated reliability and validity<br>2. Roland Morris Back Pain Questionnaire<br>3. VAS for Pain<br>4. Beck Depression Inventory<br>5. Medical Outcomes Study 36-item Short-Form Health Survey<br>6. Patient expectation of improvement was indicated on a 100 mm VAS scale at baseline and prior to treatment at visit 4 |
| Notes | |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | Yes | Determined using adaptive computer generated randomization |
| Allocation concealment? | Yes | Central random assignment was undertaken |
| Blinding?<br>All outcomes - patients? | Yes | Success of blinding assessed: 66% accurately guessed group, greater proportion in the control group |
| Blinding?<br>All outcomes - providers? | No | The 'treating clinicians' were not blinded 'primary clinician' was blind: therefore main patient interaction blinded and only person performing technique (sole role) unblinded. |
| Blinding?<br>All outcomes - outcome assessors? | Yes | The 'primary clinician' was blinded. Outcomes were assessed by patient-completed questionnaire. |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | Yes | drop-out rate was described and acceptable |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | Yes | "All analyses were conducted on an intention-to-treat basis." |
| Free of selective reporting? | Unclear | Insufficient information provided |
| Free of other bias? | Yes | None found |
| Similarity of baseline characteristics? | Yes | Duration of low-back pain was different between groups (median 7 years in compari- |

**Hawk 2005** (*Continued*)

| | | |
|---|---|---|
| | | son group versus 4 years in the chiropractic group) |
| Co-interventions avoided or similar? | Unclear | Not reported |
| Compliance acceptable in all groups? | Unclear | Not reported |
| Timing of the outcome assessment similar in all groups? | Yes | At 3 weeks |

**Hsieh 1992**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: Not reported<br>Number recruited: 85<br>Number randomised: 85 |
| Participants | Population: Aged 18 to 55 yrs, LBP >3 weeks <6 months, general good health<br>Settings: Whittier health centre<br>Mean Age: 33.91 ( 9.81) yrs, range 18 to 54 years<br>Work status: Not reported<br>Pain duration: Not reported |
| Interventions | Chiropractic intervention: SMT; hot pack for 10 mins; 3 times per week for 3 wks<br>Comparison 1: Massage. 3 massage therapists "interns". 3 times per week for 3 wks. Hot pack for 10mins, then gentle stroking massage to whole back area w/out any deep soft tissue manipulation<br>Comparison 2: Freeman lumbosacral corset. Initial fitting then weekly follow-up for 3 weeks Patients told to wear for 8 hrs per day. Chiropractor gave instruction<br>Comparison 3: Transcutaneous muscular stimulation. Myocare PLUS (3M) unit. Initial instruction then weekly follow-up for 3 wks. Patients told to wear for 8 hrs per day. Chiropractor gave instruction<br>Country of training: Not reported<br>Years in practice: Between 1 and 17 yrs |
| Outcomes | Outcome measures at baseline (only Oswestry and Roland Morris results reported at Visit 1 and Visit 3. It is not clear if Visit 1 is baseline or immediately after treatment):<br>1. VAS*<br>2. Borg scale*<br>3. Confidence scale*<br>4. Schober test*<br>5. SLR*<br>6. Trunk extension strength*<br>7. Sorensen back endurance*<br>8. Oswestry<br>9. Roland Morris |
| Notes | *These measures were not reported in publication. |

**Hsieh 1992** (*Continued*)

| *Risk of bias* | | |
|---|---|---|
| **Item** | **Authors' judgement** | **Description** |
| Adequate sequence generation? | Unclear | "predetermined randomization table" is only description provided |
| Allocation concealment? | Unclear | Not reported |
| Blinding?<br>All outcomes - patients? | No | Not possible |
| Blinding?<br>All outcomes - providers? | No | Not possible |
| Blinding?<br>All outcomes - outcome assessors? | Yes | Says assessment was blinded but no detail provided. |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | No | 85 patients randomized but only data for 63 were analysed with no details provided |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | Unclear | Not reported |
| Free of selective reporting? | Unclear | Insufficient information provided |
| Free of other bias? | Unclear | Insufficient information provided |
| Similarity of baseline characteristics? | Unclear | Baseline measures not reported |
| Co-interventions avoided or similar? | Unclear | Not reported |
| Compliance acceptable in all groups? | Unclear | Not reported |
| Timing of the outcome assessment similar in all groups? | Unclear | Not clear |

**Hsieh 2002**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: Not reported<br>Number recruited: 206<br>Number randomised: 200 |
| Participants | Population: Age of 18 years of age or older, LBP duration of more than 3 weeks and less than 6 months for the current episode or a pain-free period of at least 2 months in the preceding 8 months for recurrent LBP |

**Hsieh 2002** (*Continued*)

| | |
|---|---|
| | Settings: Not reported<br>Mean Age: 48.4 13.7 for the joint manipulation plus myofascial therapy group; 47.9 13.7 for the Back School group; 47.4 14.0 for the joint manipulation group; and 49.0 14.8 for the myofascial therapy group.<br>Work status: 8% for the joint manipulation plus myofascial therapy group, 11% of the Back School group, 4% of the joint manipulation group, and 16% of the myofascial therapy group worked with vibration equipment.<br>Pain duration: 11.5 7.2 weeks for the joint manipulation plus myofascial therapy group; 10.7 6.6 weeks for the Back School group; 11.8 7.2 weeks for the joint manipulation group; and 11.8 6.8 weeks for the myofascial therapy group. |
| Interventions | Chiropractic: The patients received both SMT and myofascial therapy treatments. SMT included joint manipulation (the 'Diversified' technique) and drop table techniques. Myofascial therapy treatments included intermittent Fluori-Methane sprays and stretches, Ischaemic compressions using a massage finger, stripping massage and hot packs for 10 minutes at the completion of therapy. Treatment frequency was three times a week for three weeks.<br>Comparison 1: Back School Program once per week for a total of three weeks. Participants watched three videos about spine anatomy, common causes of LBP, and body mechanics for daily activities. Subsequently, the participants received individual instructions and supervised practice of their home program by experienced licensed physical therapists at UCIMC and trained experienced licensed chiropractors at LACC.<br>Comparison 2: SMT (see description above)<br>Comparison 3: Myofascial therapy (see description above)<br>Country of training: Not reported<br>Years in practice: 5-year minimum of clinical experience |
| Outcomes | Outcome measures at baseline and then follow-up measurement after 3 weeks and 6 months:<br>1. VAS<br>2. Roland-Morris<br>3. MOS<br>4. Short form of the Minnesota Multiphasic Personality Inventory:<br>5. Confidence score<br>6. Satisfaction score<br>7. Palpation for active trigger points<br>8. Palpation for tenderness |
| Notes | |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | "Randomized" is only description provided |
| Allocation concealment? | Unclear | Not reported |

**Hsieh 2002** (*Continued*)

| | | |
|---|---|---|
| Blinding?<br>All outcomes - patients? | No | Not possible with this design |
| Blinding?<br>All outcomes - providers? | No | Not possible with this design |
| Blinding?<br>All outcomes - outcome assessors? | Yes | "... assessor-blinded clinical trial" |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | Yes | drop-out rate recorded |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | Yes | All statistical analyses were based on an intent-to-treat methodology |
| Free of selective reporting? | Unclear | Insufficient information provided |
| Free of other bias? | Yes | None significant found |
| Similarity of baseline characteristics? | Yes | Age, sex, pain and therapy preference provided. No major differences. |
| Co-interventions avoided or similar? | Yes | Recorded and similar |
| Compliance acceptable in all groups? | Yes | Overall satisfactory with the Back school group least compliant |
| Timing of the outcome assessment similar in all groups? | Yes | Satisfactory at 3 weeks and 6 months. Not other follow up. |

**Hurwitz 2002**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: Not reported<br>Number recruited: 1469<br>Number randomised: 681 |
| Participants | Population: Patients were required to be health maintenance organisation members with the medical group chosen as their health care provider, sought medical care from a health provider on staff at one of the three study sites during the enrolment period, presented with a complaint of low-back pain, had not received treatment for low-back pain within the previous month, and were at least 18 years old.<br>Settings: People presenting at three study (HMO) ambulatory care facilities<br>Mean Age: Not reported. Participants were required to be over 18 years of age. 10% were under 30 years, 20% in 30 to 39 years, 20% in 40 to 49 years, 20% in 50 to 59 years, 15% in 60 to 69 years, 20% in 70 plus years. Very little difference between treatment groups.<br>Work status: Almost 60% are employed full time. 8% employed part time. 25% are |

| | |
|---|---|
| | retired. Little difference across treatment groups.<br>Pain duration: 47% of participants had been in pain for longer than 1 year, 26% had been in pain for less than 3 weeks, 17% had been in pain for 3 weeks to 3 months, and 12% had been in pain for 3 months to 1 year. Differences ranged by 8% across treatment groups. |
| Interventions | Chiropractic 1: Patients assigned to *chiropractic care only* received spinal manipulation or another spinal-adjusting technique, instruction in strengthening and flexibility exercises, instruction in proper back care. At 6 months average back pain-related visits were 5.3 in the chiropractic only group. Chiropractors spent an average of 15 minutes with patients at each visit.<br>Chiropractic 2: Patients assigned to the *chiropractic care with physical modalities* received care as described in 'chiropractic care only', as well as one or more of the following at the discretion of the chiropractor: heat or cold therapy, ultrasound and EMS. At 6 months average back pain-related visits were 5.7 in the chiropractic plus physical modalities group. Chiropractors spent an average of 15 minutes with patients at each visit<br>Comparison 1: Patients assigned to the *medical care only* group received one or more of the following at the discretion of the primary care provider: instruction in proper back care and strengthening and flexibility exercise, prescriptions for pain killers, muscle relaxants, anti-inflammatory agents, other medications to reduce or eliminate pain or discomfort, and recommendations regarding bed rest, weight loss and physical activities. At 6 months average back pain-related visits were 2.9 in the medical care only group. Medical providers spent an average of 15 minutes with patients at each visit.<br>Comparison 2: Patients assigned to the *medical care with physical therapy* received medical care as described in 'medical care only', plus one or more of the following at the discretion of the physical therapist: heat therapy, cold therapy, ultrasound, electrical muscle stimulation, soft tissue and joint mobilisation, traction, supervised therapeutic exercise, strengthening and flexibility exercises. At 6 months average back pain-related visits were 5.4 in the medical care plus physical modalities group. Physical therapy providers averaged 31 minutes per patient visit.<br>85% patients in the chiropractic groups received high velocity spinal manipulation. The physical modalities most often given to patients were heat therapy alone (28%), heat and EMS (25%), heat, EMS and ultrasound (23 %), and heat therapy and ultrasound (15%). 4% patients in the modalities group were not treated with any modalities and 13 % patients in the chiropractic-only group received modalities. The most common intervention in the physical therapy group were heat or cold therapy (71%), supervised physical exercise (59.5%), ultrasound (45%), EMS(33.6%), and mobilisation (20%). Prescription pain medications (58.5%), muscle relaxants (48.5%) and non prescription pain medications (30%) were the most frequent interventions in the medical groups.<br>Country of training: Not reported<br>Years in practice: Not reported |
| Outcomes | Outcome measures at baseline and then follow-up measurement after 2 weeks*, 6 weeks, 6 months, and 18 months:<br>1. Disability resulting from low-back pain using the 24-item Roland-Morris adaptation of the Sickness Impact Profile (validated)<br>2. Numerical ratings of pain intensity (validated)<br>3. Pain History<br>4. Psychological distress and well-being assessed by the Medical Outcomes Study |

| | |
|---|---|
| | 36-Item Short-Form Health Survey (validated)<br>5. Sociodemographic data |
| Notes | *At 2 weeks: low-back pain severity, improvement, and related disability, cut-down days and bed days attributed to low-back pain, and use of over-the-counter and prescription medication for low-back pain using questionnaires. Functional status was measured by Roland-Morris Low-Back Disability Questionnaires. Pain status was measured by repeat numerical rating scales and scales of global improvement. Health care use data were extracted from the organisations computerised health care systems. Telephone interview to determine patients' low-back pain visits.<br>Combined baseline SD values from control and intervention groups in this study were used to back transform treatment effects expressed as SMD into treatments effects on a 10 cm VAS and on the 24 point scale of the Roland Morris Disability Questionnaire. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Yes | "Study statistician ran computer program to generate randomised assignments in blocks of 12, stratified by site." |
| Allocation concealment? | Yes | "Each treatment assignment was placed in a numbered security envelope. A separate series of sequentially numbered sealed envelopes was provided for each of the three sites." |
| Blinding?<br>All outcomes - patients? | No | Not explicitly stated but patients would have known whether they were visiting a chiropractor or medical practitioner |
| Blinding?<br>All outcomes - providers? | No | Not explicitly stated but practitioners would have known what treatment was being supplied |
| Blinding?<br>All outcomes - outcome assessors? | Unclear | Not reported |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | Yes | "Completers were 99.7% in the first 6 weeks and 95.7% in the first 6 months" |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | Yes | Intention-to-treat analyses were performed throughout |
| Free of selective reporting? | Unclear | Insufficient information provided |

**Hurwitz 2002** (*Continued*)

| | | |
|---|---|---|
| Free of other bias? | No | No sample size calculation. Interventions and treatment settings described well enough |
| Similarity of baseline characteristics? | Yes | Relatively small differences between treatment groups in the baseline distributions of sociodemographic and health status variables. Minor differences with respect to low-back pain severity and related disability, but these differences are clinically insignificant. |
| Co-interventions avoided or similar? | No | Approximately 20% patients in the chiropractic group received concurrent medical care, and 7% of patients in the medical group received concurrent chiropractic care in the first 6 months. |
| Compliance acceptable in all groups? | No | Approximately 33% patients randomly assigned to medical care with physical therapy had no physical therapy visits |
| Timing of the outcome assessment similar in all groups? | Yes | At two weeks, 6 weeks, 6 months and 18 months |

**Meade 1990**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: Not reported<br>Number recruited: Not clearly reported<br>Number randomised: 741 |
| Participants | Population: Participants aged 18 to 65 with LBP and no contraindication to SMT<br>Settings: Hospital and chiropractic clinics<br>Mean Age: Not reported (range 18 to 65 yrs)<br>Work status: Not reported<br>Pain duration: 226 (59%) of the chiropractic group and 214 (60%) of the physiotherapy group had a current episode of LBP for > 1 month duration |
| Interventions | Chiropractic: Treatment at the discretion of treating practitioner including SMT, mobilisation, traction, corset and exercises. Maximum of 10 sessions delivered (mean = 9.1)<br>Comparison: Physiotherapy treatment at the discretion of treating practitioner. Maximum of 10 sessions delivered (mean = 6.3)<br>Country of training: Not reported<br>Years in practice: Not reported |

**Meade 1990** (*Continued*)

| | |
|---|---|
| Outcomes | Outcome measures at baseline and then follow-up measurement after 6 weeks, 6 months, and 1, 2, and 3 years:<br>1. Oswestry - results presented as mean score physio minus mean score for chiropractic group. Validated.<br>2. Satisfaction<br>3. Partial or complete relief<br>4. Using drugs (analgesics or NSAIDs)<br>5. Pain free |
| Notes | |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | "patients were randomly allocated to treatment..." was only information provided |
| Allocation concealment? | Unclear | Not reported |
| Blinding?<br>All outcomes - patients? | No | Patients would have known whether they were visiting a chiropractor or physiotherapist |
| Blinding?<br>All outcomes - providers? | No | Chiropractors or physiotherapists would have known what treatment was being supplied |
| Blinding?<br>All outcomes - outcome assessors? | Unclear | Not reported |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | No | Approximately 18% dropped out by six weeks follow-up, and 35% by one year. The drop-out rate was described but the non completers were not accounted for. |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | Yes | "Analysed with intention-to-treat analysis" |
| Free of selective reporting? | Unclear | Insufficient information provided |
| Free of other bias? | Yes | No other significant bias found |
| Similarity of baseline characteristics? | Yes | Table provided showing similar key characteristics |
| Co-interventions avoided or similar? | Unclear | Not reported |

**Meade 1990** (*Continued*)

| | | |
|---|---|---|
| Compliance acceptable in all groups? | Yes | Treatment at the discretion of provider. 608 of 741 finished the course of therapy |
| Timing of the outcome assessment similar in all groups? | Yes | Weekly appraisal |

**Wilkey 2008**

| | |
|---|---|
| Methods | Study design: RCT<br>Country: UK<br>Number recruited: 48<br>Number randomised: 30 |
| Participants | LBP for at least 12/52 with or without radiation to the legs. Aged 18 to 65. All from NHS referrals to the Pain Clinic at Royal Oldham Hospital. Pain duration: PC group: range: 0.5 to 10 years, Chiro group:range 0.5 to 20 years. PC group mean: 4.04 yrs, Chiro 7.34 years |
| Interventions | Chosen from this list: Diversified MT, flexion/distraction, drop techniques; trigger point therapy, stretching, dry needling, massage, home exercises, postural advice, ADL advice. Frequency at the discretion of the chiropractor. But chiropractic group got mean of 11.3 sessions by chiropractor.<br>Control: Pain clinic group saw 2 anaesthetists. On average 1.9 times and they received medication and/or injections into soft tissues or facet joints. |
| Outcomes | NRS 11points, X2. 1 for current pain and 1 for average pain over past 2, 4, 6, 8 weeks<br>Roland Morris Disability Q, Validated: 2, 4, 6, 8 weeks<br>11 point satisfaction Q (validation not stated) at 8 weeks<br>Medication diary for PC group (validation not mentioned). |
| Notes | Neurologic disease, neurological deficit from herniated IV disc, spinal stenosis, acute fracture, history of CA, gross anatomical abnormality. Also high comorbidity resulting in significant disability |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | Unclear | "were randomized into the treatment or control group" was only information given. Personal correspondence with Dr. P. McCarthy (co-author) revealed the following: "*...equal numbers of envelopes were created for each group. These were initially mixed together and then shuffled into each other and boxed. As patients became available the nurse registering the patients would select an enve-* |

| | | |
|---|---|---|
| | | *lope from the box and hand it to the patient. We did not use a random number list to generate the order as this could have also been abused (either by disturbing the order of the envelopes or moving patients into particular groups). Using this method led to a greater degree of uncertainty regarding the group allocated."* |
| Allocation concealment? | Yes | Envelopes used but not reported whether opaque. Personal correspondence from Dr. McCarthy confirmed "*...it was not possible to see through the envelopes and determine the group without opening them*" |
| Blinding?<br>All outcomes - patients? | No | Patients knew which therapy they were receiving |
| Blinding?<br>All outcomes - providers? | No | Providers knew what therapy they were giving |
| Blinding?<br>All outcomes - outcome assessors? | No | Self rated assessments and blinding of assessors not reported |
| Incomplete outcome data addressed?<br>All outcomes - drop-outs? | Yes | Only 1 participant in pain clinic group and 2 in chiropractic group dropped out. |
| Incomplete outcome data addressed?<br>All outcomes - ITT analysis? | No | Not reported |
| Free of selective reporting? | No | Medication diary mentioned in methods but not reported in results |
| Free of other bias? | Yes | No other significant bias found |
| Similarity of baseline characteristics? | No | Some imbalance in age and duration of pain but unclear whether these are important prognostic indicators. |
| Co-interventions avoided or similar? | Unclear | Medication diary mentioned in methods but not in results |
| Compliance acceptable in all groups? | Unclear | Not reported |
| Timing of the outcome assessment similar in all groups? | Yes | 2, 4, 6 and 8 weeks |

## Characteristics of excluded studies *[ordered by study ID]*

| | |
|---|---|
| Bialosky 2008 | Physical therapists provided the intervention |
| Breen 1998 | Post-hoc analysis of Meade study |
| Davis 2005 | Non-randomised |
| Dutro 1986 | Not randomised |
| Eisenberg 2007 | Unable to isolate effects of chiropractic therapy from other therapies delivered |
| Gemmell 1995 | A chiropractor delivered the intervention in both study arms |
| Gemmell 1998 | A chiropractor delivered the intervention in both study arms |
| Giles 1999 | Chiropractic therapy was spinal manipulative therapy as a single intervention |
| Godfrey 1984 | Treatment delivered by chiropractor or medical practitioner and unable to isolate effects of chiropractic therapy from other therapies delivered |
| Haaker 1997 | Therapists delivering treatment not chiropractors |
| Haas 2004 | A chiropractor delivered the intervention in both study arms |
| Hadler 1990 | Therapy was spinal manipulative therapy as a single intervention |
| Hawk 1999 | Cross-over study |
| Herzog 1991 | Therapy was spinal manipulative therapy as a single intervention |
| Hoiriis 1999 | A chiropractor delivered the intervention in both study arms |
| Hoiriis 2004 | SMT only |
| Konstantinou 2007 | Therapists were not chiropractors |
| Lalanne 2009 | SMT only. Fastidious design |
| Muller 2005 | Follow-up for Giles 1999 and chiropractic therapy was spinal manipulative therapy as a single intervention |
| Palmieri 2002 | Not randomised, chiropractic intervention in both study arms |
| Rupert 2005 | Controlled before-after study |
| Santilli 2006 | Therapy was spinal manipulative therapy only and included patients with sciatica |
| Shearer 2005 | A chiropractor delivered the intervention in both study arms |

(*Continued*)

| | |
|---|---|
| Skagren 1997-98a | Unable to isolate effects on low-back pain versus neck pain |
| Snyder 2007 | Controlled before-after study |
| UK BEAM | Unable to isolate effects of chiropractic therapy from other therapies delivered |
| Williams 1989 | Cross-over study |
| Zhang 2008 | A chiropractor delivered the intervention in both study arms |

## Characteristics of studies awaiting assessment *[ordered by study ID]*

**Atkinson 2001**

| | |
|---|---|
| Methods | Study design: RCT |
| Participants | 60 patients with LBP |
| Interventions | 1. "Action Potential" therapy; 2. Placebo |
| Outcomes | Not reported |
| Notes | Conference proceedings and unable to contact author for more information |

**Wiegand 2003**

| | |
|---|---|
| Methods | Not reported |
| Participants | 57 years and older with chronic LBP |
| Interventions | Logan Basic Methods |
| Outcomes | Not reported |
| Notes | Conference proceedings and unable to contact author for more information |

## Characteristics of ongoing studies *[ordered by study ID]*

**Maiers 2007**

| | |
|---|---|
| Trial name or title | Chiropractic and exercise for seniors with low-back pain or neck pain: the design of two randomized clinical trials |
| Methods | Study design: RCT |
| Participants | 240 people > 65 years of age with subacute and chronic LBP (minimum 6 weeks duration) |
| Interventions | 1. Chiropractic manual treatment plus home exercise<br>2. Home exercise program<br>3. Supervised rehabilitative exercise plus home exercise |
| Outcomes | Pain, disability, general health status, overall improvement, satisfaction, medication use, spinal biomechanical measures, health care costs. |
| Starting date | 2003 |
| Contact information | Gert Bronfort, email: gbronfort@nwhealth.edu |
| Notes | |

## DATA AND ANALYSES

### Comparison 1. Chiropractic vs Other (acute and sub-acute LBP)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Pain Short term | 3 | | Std. Mean Difference (IV, Random, 95% CI) | Subtotals only |
| 1.1 Short term (<1 month) | 3 | 423 | Std. Mean Difference (IV, Random, 95% CI) | -0.25 [-0.46, -0.04] |
| 2 Pain Medium term and Long Term | 2 | | Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
| 2.1 Medium term (1 month < 6 months) | 1 | 239 | Mean Difference (IV, Fixed, 95% CI) | -0.89 [-1.60, -0.18] |
| 2.2 Long Term (6 months or greater) | 1 | 138 | Mean Difference (IV, Fixed, 95% CI) | -0.46 [-1.18, 0.26] |
| 3 Disability Short term | 4 | | Std. Mean Difference (IV, Random, 95% CI) | Subtotals only |
| 3.1 Short term (<1 month) | 4 | 545 | Std. Mean Difference (IV, Random, 95% CI) | -0.36 [-0.70, -0.02] |
| 4 Disability Medium term and Long term | 2 | | Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
| 4.1 Medium term (1 month < 6 months) | 1 | 298 | Mean Difference (IV, Fixed, 95% CI) | -1.07 [-2.11, -0.03] |
| 4.2 Long Term (6 months or greater) | 1 | 137 | Mean Difference (IV, Fixed, 95% CI) | -0.75 [-2.07, 0.57] |

### Comparison 2. Chiropractic vs Other (Chronic LBP)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Pain | 3 | | Mean Difference (IV, Random, 95% CI) | Subtotals only |
| 1.1 Short term (<1 month) | 3 | 388 | Mean Difference (IV, Random, 95% CI) | -0.68 [-1.43, 0.07] |
| 1.2 Medium term (1 month < 6 months) | 3 | 302 | Mean Difference (IV, Random, 95% CI) | -1.23 [-2.62, 0.15] |
| 1.3 Long Term (6 months or greater) | 1 | 174 | Mean Difference (IV, Random, 95% CI) | -0.47 [-1.16, 0.22] |
| 2 Disability | 3 | | Mean Difference (IV, Random, 95% CI) | Subtotals only |
| 2.1 Short term (<1 month) | 3 | 409 | Mean Difference (IV, Random, 95% CI) | -0.67 [-1.62, 0.28] |
| 2.2 Medium term (1 month < 6 months) | 3 | 337 | Mean Difference (IV, Random, 95% CI) | -3.97 [-10.31, 2.36] |
| 2.3 Long Term (6 months or greater) | 1 | 173 | Mean Difference (IV, Random, 95% CI) | -0.13 [-1.48, 1.22] |
| 3 General health status | 2 | | Mean Difference (IV, Random, 95% CI) | Subtotals only |
| 3.1 Short term (<1 month) | 2 | 378 | Mean Difference (IV, Random, 95% CI) | -0.04 [-1.75, 1.68] |
| 3.2 Medium term (1 month < 6 months) | 1 | 132 | Mean Difference (IV, Random, 95% CI) | -0.43 [-4.87, 4.01] |

## Comparison 3. Chiropractic vs Other (Mixed)

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Pain | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 1.1 Medium term (1 month < 6 months) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2 Pain (average) | 1 | | Mean Difference (Fixed, 95% CI) | Totals not selected |
| 2.1 Short term (<1 month) | 1 | | Mean Difference (Fixed, 95% CI) | Not estimable |
| 2.2 Medium term (1 month < 6 months) | 1 | | Mean Difference (Fixed, 95% CI) | Not estimable |
| 2.3 Long term (6 months or greater) | 1 | | Mean Difference (Fixed, 95% CI) | Not estimable |
| 3 Disability | 3 | | Mean Difference (Random, 95% CI) | Subtotals only |
| 3.1 Short term (<1 month) | 2 | | Mean Difference (Random, 95% CI) | -0.31 [-1.04, 0.42] |
| 3.2 Medium term (1 month < 6 months) | 2 | | Mean Difference (Random, 95% CI) | -0.77 [-1.65, 0.10] |
| 3.3 Long term (6 months or greater) | 1 | | Mean Difference (Random, 95% CI) | -0.75 [-1.79, 0.29] |
| 4 Number of back pain related visits needed | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 4.1 Medium term (1 month < 6 months) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 4.2 Long Term (6 months or greater) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5 Satisfaction | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 5.1 Medium term (1month <6 months) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6 Pain partially or completely relieved | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 6.1 Medium term (1 month < 6 months) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 7 Pain free for several months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 7.1 Long term (6 months or greater) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 8 Further equally severe episode | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 8.1 Long term (6 months or greater) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 9 Experiencing pain daily | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 9.1 Long term (6 months or greater) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 10 Oswestry as high or higher than before treatment | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 10.1 Medium (1 month < 6 months) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 10.2 Long term ( >6 months) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 11 Rate of improvement | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 11.1 Short term (<1 month) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

| | | | |
|---|---|---|---|
| 11.2 Medium term (1 month < 6 months) | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 11.3 Long Term (6 months or greater) | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

**Analysis 1.1. Comparison 1 Chiropractic vs Other (acute and sub-acute LBP), Outcome 1 Pain Short term.**

Review: Combined chiropractic interventions for low-back pain

Comparison: 1 Chiropractic vs Other (acute and sub-acute LBP)

Outcome: 1 Pain Short term

| Study or subgroup | Chiropractic N | Mean(SD) | Other N | Mean(SD) | Std. Mean Difference IV,Random,95% CI | Weight | Std. Mean Difference IV,Random,95% CI |
|---|---|---|---|---|---|---|---|
| 1 Short term (<1 month) | | | | | | | |
| Cramer 1993 | 17 | 38.59 (25.24) | 19 | 42 (28.84) | | 10.6 % | -0.12 [ -0.78, 0.53 ] |
| Hsieh 2002 | 48 | 2.04 (1.35) | 91 | 2.48 (1.62) | | 36.7 % | -0.29 [ -0.64, 0.07 ] |
| Cherkin 1998 | 59 | 1.9 (1.94) | 189 | 2.55 (2.74) | | 52.7 % | -0.25 [ -0.54, 0.04 ] |

### Analysis 1.2. Comparison 1 Chiropractic vs Other (acute and sub-acute LBP), Outcome 2 Pain Medium term and Long Term.

Review: Combined chiropractic interventions for low-back pain

Comparison: 1 Chiropractic vs Other (acute and sub-acute LBP)

Outcome: 2 Pain Medium term and Long Term

| Study or subgroup | Chiropractic N | Mean(SD) | Other N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Weight | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| 1 Medium term (1 month < 6 months) | | | | | | | |
| Cherkin 1998 | 59 | 2 (2.22) | 180 | 2.89 (2.94) | | 100.0 % | -0.89 [ -1.60, -0.18 ] |
| **Subtotal (95% CI)** | **59** | | **180** | | | **100.0 %** | **-0.89 [ -1.60, -0.18 ]** |
| Heterogeneity: not applicable | | | | | | | |
| Test for overall effect: Z = 2.45 (P = 0.014) | | | | | | | |
| 2 Long Term (6 months or greater) | | | | | | | |
| Hsieh 2002 | 49 | 2.24 (2.01) | 89 | 2.7 (2.16) | | 100.0 % | -0.46 [ -1.18, 0.26 ] |
| **Subtotal (95% CI)** | **49** | | **89** | | | **100.0 %** | **-0.46 [ -1.18, 0.26 ]** |
| Heterogeneity: not applicable | | | | | | | |
| Test for overall effect: Z = 1.25 (P = 0.21) | | | | | | | |
| Test for subgroup differences: $Chi^2$ = 0.69, df = 1 (P = 0.40), $I^2$ =0.0% | | | | | | | |

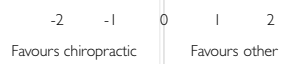

### Analysis 1.3. Comparison 1 Chiropractic vs Other (acute and sub-acute LBP), Outcome 3 Disability Short term.

Review: Combined chiropractic interventions for low-back pain

Comparison: 1 Chiropractic vs Other (acute and sub-acute LBP)

Outcome: 3 Disability Short term

| Study or subgroup | Chiropractic N | Mean(SD) | Other N | Mean(SD) | Std. Mean Difference IV,Random,95% CI | Weight | Std. Mean Difference IV,Random,95% CI |
|---|---|---|---|---|---|---|---|
| 1 Short term (<1 month) | | | | | | | |
| Hsieh 1992 | 26 | 7.85 (12.15) | 37 | 28.14 (24.23) | | 20.6 % | -0.99 [ -1.53, -0.46 ] |
| Hsieh 2002 | 48 | 3.73 (3.76) | 91 | 5.09 (4.5) | | 28.6 % | -0.32 [ -0.67, 0.03 ] |
| Cherkin 1998 | 118 | 3.7 (4.43) | 189 | 4.35 (4.56) | | 34.5 % | -0.14 [ -0.37, 0.09 ] |
| Cramer 1993 | 17 | 7.34 (6.8) | 19 | 8.03 (7.6) | | 16.4 % | -0.09 [ -0.75, 0.56 ] |

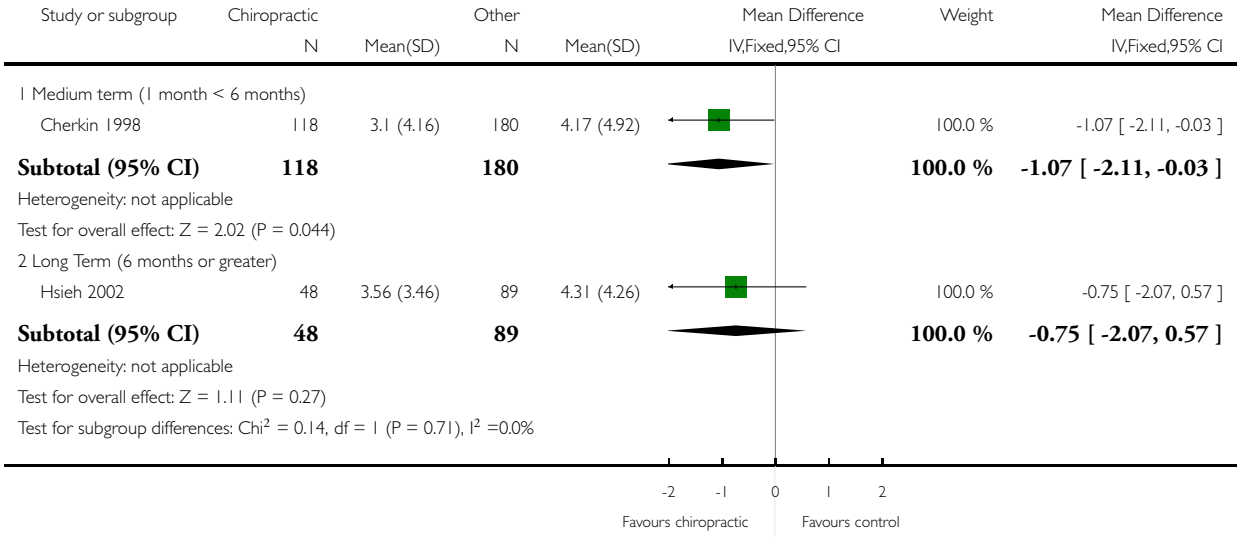


### Analysis 1.4. Comparison 1 Chiropractic vs Other (acute and sub-acute LBP), Outcome 4 Disability Medium term and Long term.

Review: Combined chiropractic interventions for low-back pain

Comparison: 1 Chiropractic vs Other (acute and sub-acute LBP)

Outcome: 4 Disability Medium term and Long term



### Analysis 2.1. Comparison 2 Chiropractic vs Other (Chronic LBP), Outcome 1 Pain.

Review: Combined chiropractic interventions for low-back pain

Comparison: 2 Chiropractic vs Other (Chronic LBP)

Outcome: 1 Pain

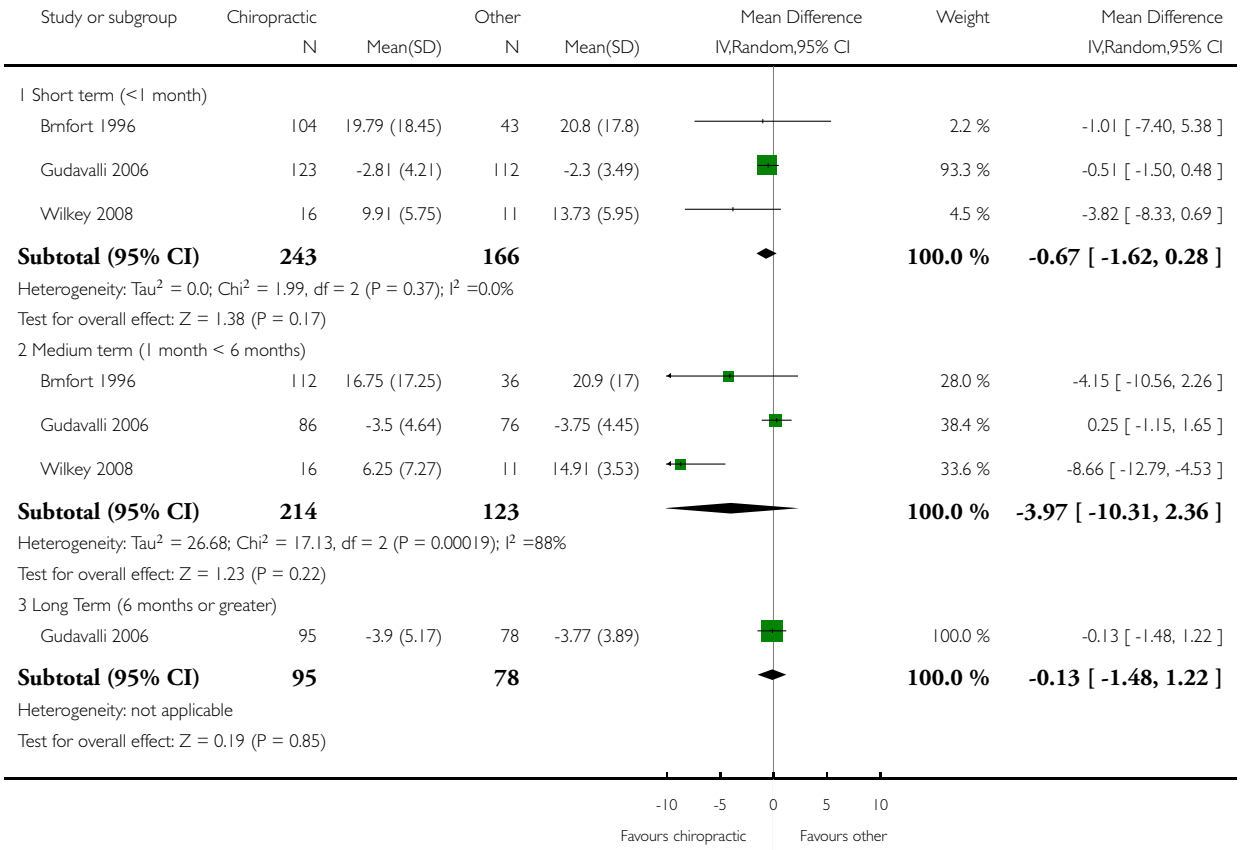
| Study or subgroup | Chiropractic N | Mean(SD) | Other N | Mean(SD) | Mean Difference IV,Random,95% CI | Weight | Mean Difference IV,Random,95% CI |
|---|---|---|---|---|---|---|---|
| 1 Short term (<1 month) | | | | | | | |
| Bmfort 1996 | 104 | 3.6 (1.99) | 22 | 3.6 (2.2) | | 32.7 % | 0.0 [ -1.00, 1.00 ] |
| Gudavalli 2006 | 123 | -2.06 (2.22) | 112 | -1.23 (1.9) | | 55.8 % | -0.83 [ -1.36, -0.30 ] |
| Wilkey 2008 | 16 | 4.75 (2.37) | 11 | 6.64 (2.84) | | 11.5 % | -1.89 [ -3.93, 0.15 ] |
| **Subtotal (95% CI)** | **243** | | **145** | | | **100.0 %** | **-0.68 [ -1.43, 0.07 ]** |
| Heterogeneity: $Tau^2 = 0.19$; $Chi^2 = 3.44$, df = 2 (P = 0.18); $I^2 = 42\%$ | | | | | | | |
| Test for overall effect: Z = 1.78 (P = 0.076) | | | | | | | |
| 2 Medium term (1 month < 6 months) | | | | | | | |
| Bmfort 1996 | 92 | 2.93 (2.13) | 20 | 3.5 (2.2) | | 35.7 % | -0.57 [ -1.63, 0.49 ] |
| Gudavalli 2006 | 87 | -1.65 (2.75) | 76 | -1.2 (2.21) | | 39.7 % | -0.45 [ -1.21, 0.31 ] |
| Wilkey 2008 | 16 | 3.81 (2.99) | 11 | 7.27 (2) | | 24.6 % | -3.46 [ -5.34, -1.58 ] |
| **Subtotal (95% CI)** | **195** | | **107** | | | **100.0 %** | **-1.23 [ -2.62, 0.15 ]** |
| Heterogeneity: $Tau^2 = 1.10$; $Chi^2 = 8.66$, df = 2 (P = 0.01); $I^2 = 77\%$ | | | | | | | |
| Test for overall effect: Z = 1.75 (P = 0.081) | | | | | | | |
| 3 Long Term (6 months or greater) | | | | | | | |
| Gudavalli 2006 | 96 | -1.71 (2.5) | 78 | -1.24 (2.15) | | 100.0 % | -0.47 [ -1.16, 0.22 ] |
| **Subtotal (95% CI)** | **96** | | **78** | | | **100.0 %** | **-0.47 [ -1.16, 0.22 ]** |
| Heterogeneity: not applicable | | | | | | | |
| Test for overall effect: Z = 1.33 (P = 0.18) | | | | | | | |

### Analysis 2.2. Comparison 2 Chiropractic vs Other (Chronic LBP), Outcome 2 Disability.

Review: Combined chiropractic interventions for low-back pain

Comparison: 2 Chiropractic vs Other (Chronic LBP)

Outcome: 2 Disability

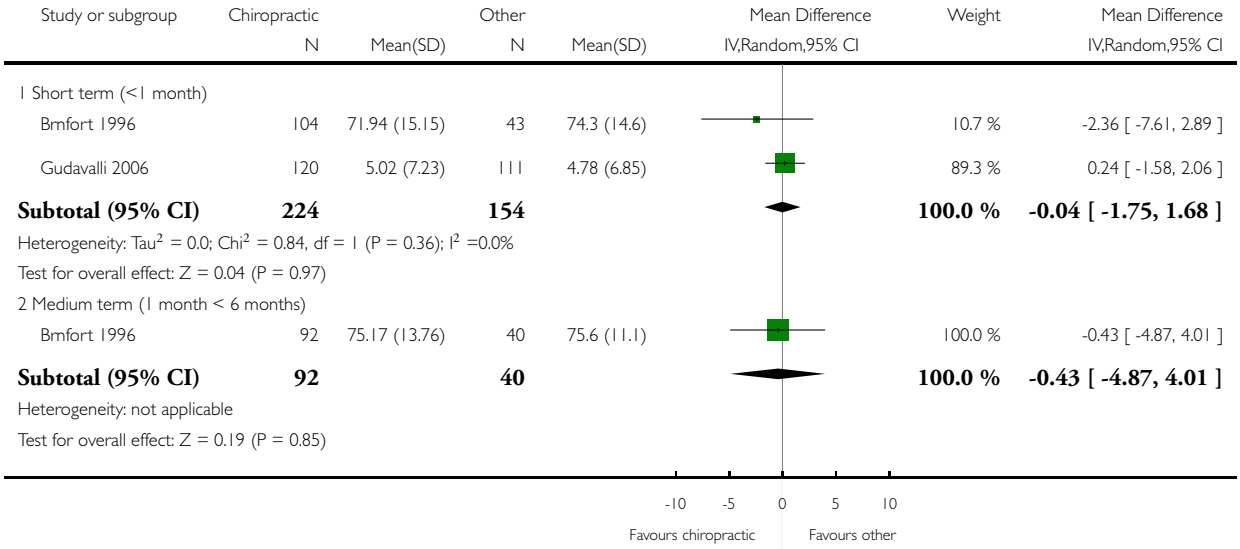


### Analysis 2.3. Comparison 2 Chiropractic vs Other (Chronic LBP), Outcome 3 General health status.

Review: Combined chiropractic interventions for low-back pain

Comparison: 2 Chiropractic vs Other (Chronic LBP)

Outcome: 3 General health status

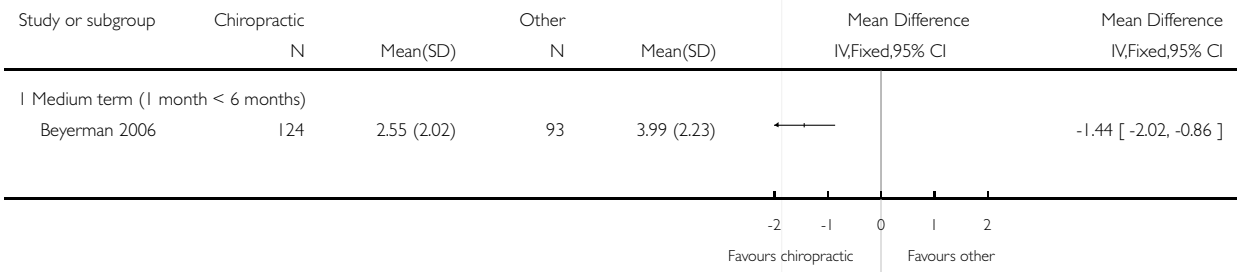



### Analysis 3.1. Comparison 3 Chiropractic vs Other (Mixed), Outcome 1 Pain.

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 1 Pain

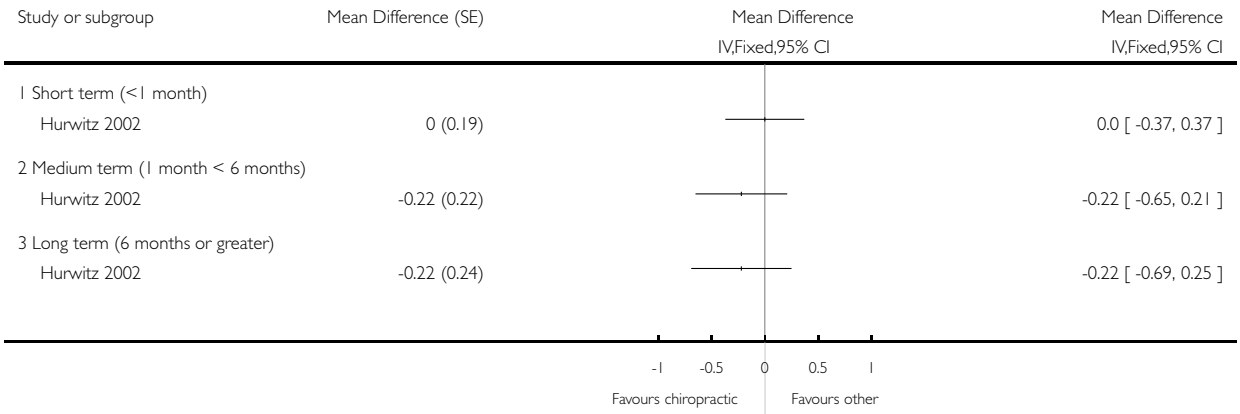


### Analysis 3.2. Comparison 3 Chiropractic vs Other (Mixed), Outcome 2 Pain (average).

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 2 Pain (average)

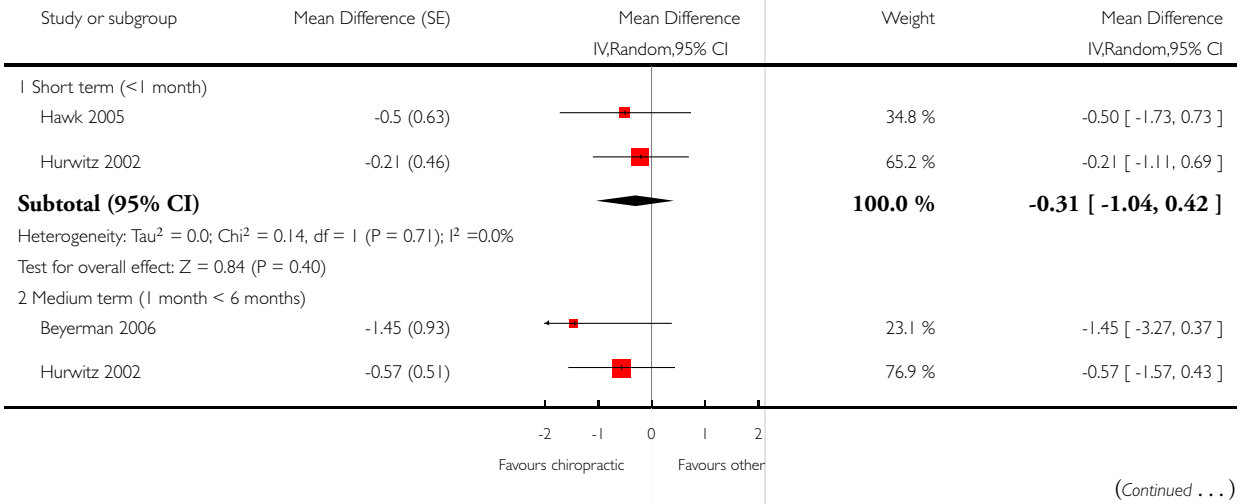



### Analysis 3.3. Comparison 3 Chiropractic vs Other (Mixed), Outcome 3 Disability.

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 3 Disability

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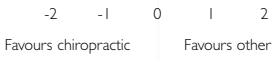
(. . . *Continued*)

| Study or subgroup | Mean Difference (SE) | Mean Difference IV,Random,95% CI | Weight | Mean Difference IV,Random,95% CI |
|---|---|---|---|---|
| **Subtotal (95% CI)** | | | **100.0 %** | **-0.77 [ -1.65, 0.10 ]** |
| Heterogeneity: Tau² = 0.0; Chi² = 0.69, df = 1 (P = 0.41); I² =0.0% | | | | |
| Test for overall effect: Z = 1.73 (P = 0.084) | | | | |
| 3 Long term (6 months or greater) | | | | |
| Hurwitz 2002 | -0.75 (0.53) | | 100.0 % | -0.75 [ -1.79, 0.29 ] |
| **Subtotal (95% CI)** | | | **100.0 %** | **-0.75 [ -1.79, 0.29 ]** |
| Heterogeneity: not applicable | | | | |
| Test for overall effect: Z = 1.42 (P = 0.16) | | | | |




**Analysis 3.4. Comparison 3 Chiropractic vs Other (Mixed), Outcome 4 Number of back pain related visits needed.**

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 4 Number of back pain related visits needed

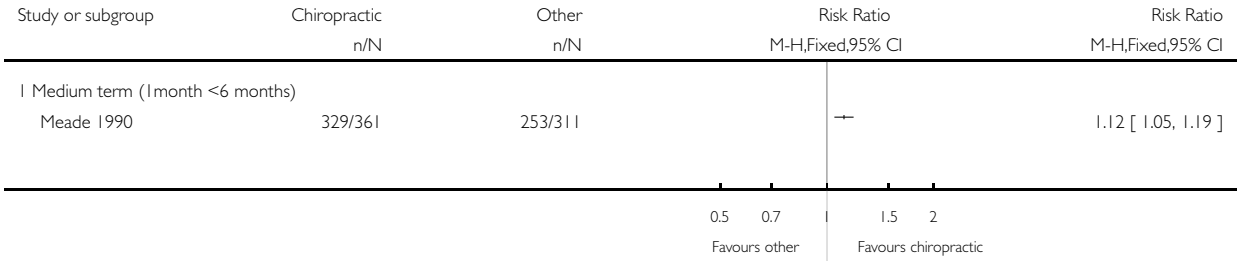
| Study or subgroup | Chiropractic N | Mean(SD) | Other N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Medium term (1 month < 6 months) | | | | | | |
| Hurwitz 2002 | 326 | 3.45 (1.62) | 329 | 2.72 (2.3) | | 0.73 [ 0.43, 1.03 ] |
| 2 Long Term (6 months or greater) | | | | | | |
| Hurwitz 2002 | 326 | 5.5 (3.56) | 329 | 4.17 (4.2) | | 1.33 [ 0.73, 1.93 ] |

### Analysis 3.5. Comparison 3 Chiropractic vs Other (Mixed), Outcome 5 Satisfaction.

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 5 Satisfaction

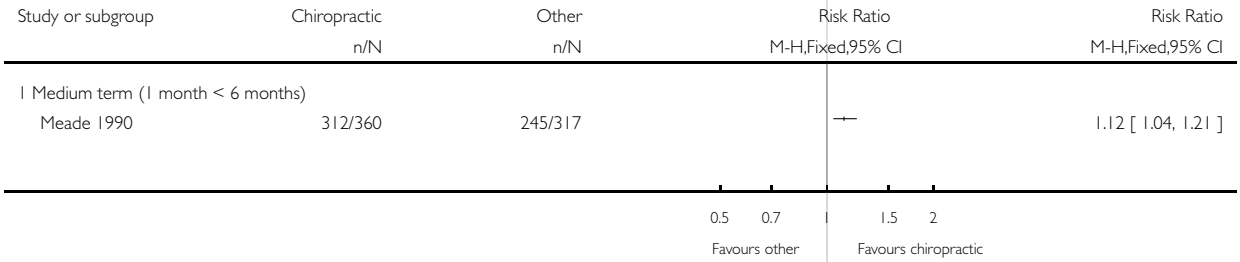



### Analysis 3.6. Comparison 3 Chiropractic vs Other (Mixed), Outcome 6 Pain partially or completely relieved.

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 6 Pain partially or completely relieved

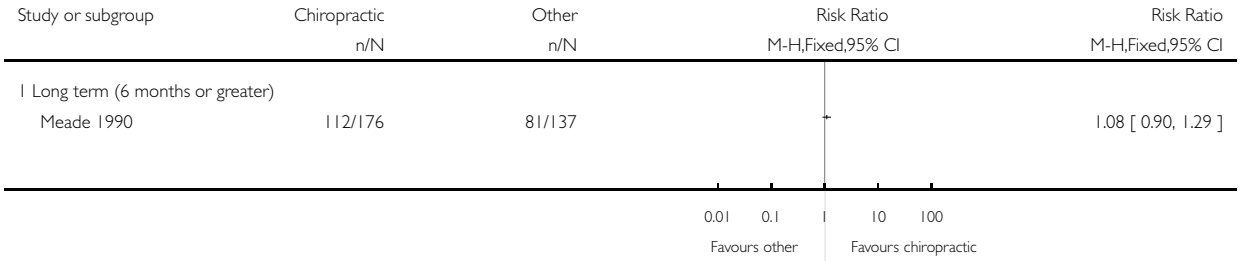


### Analysis 3.7. Comparison 3 Chiropractic vs Other (Mixed), Outcome 7 Pain free for several months.

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 7 Pain free for several months

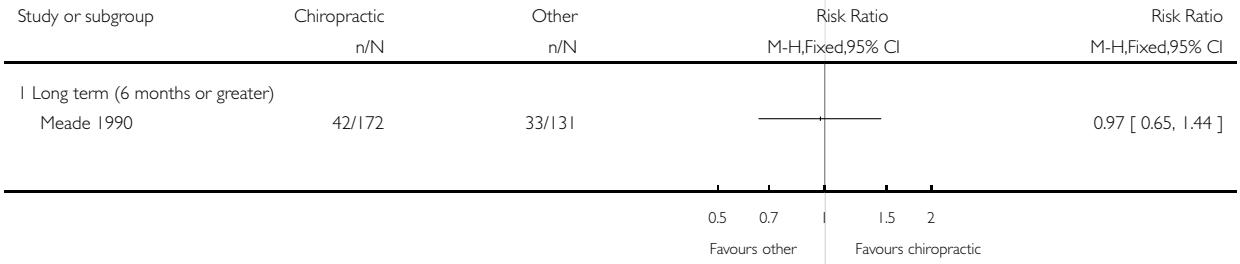



### Analysis 3.8. Comparison 3 Chiropractic vs Other (Mixed), Outcome 8 Further equally severe episode.

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 8 Further equally severe episode



### Analysis 3.9. Comparison 3 Chiropractic vs Other (Mixed), Outcome 9 Experiencing pain daily.

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

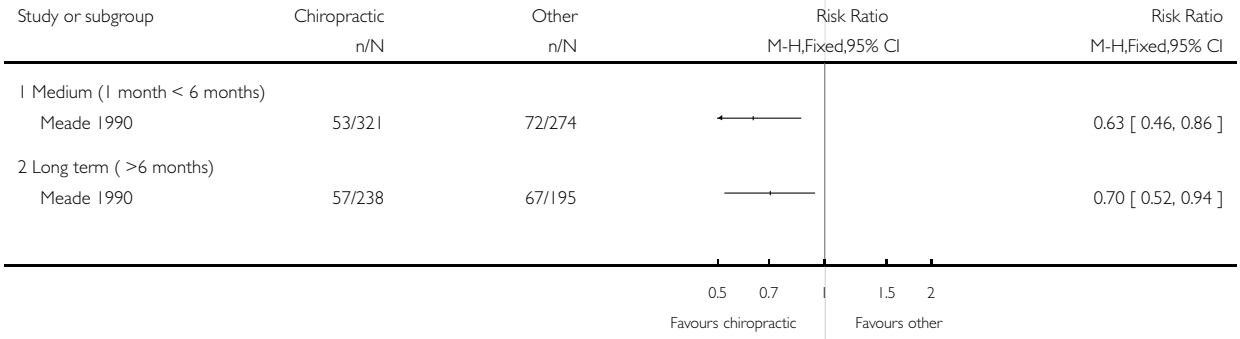
Outcome: 9 Experiencing pain daily


### Analysis 3.10. Comparison 3 Chiropractic vs Other (Mixed), Outcome 10 Oswestry as high or higher than before treatment.

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 10 Oswestry as high or higher than before treatment

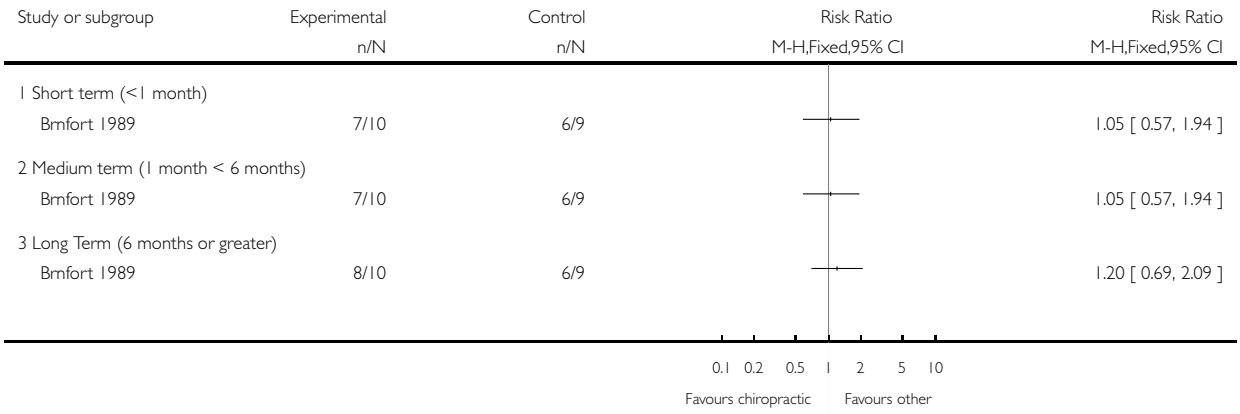


**Analysis 3.11. Comparison 3 Chiropractic vs Other (Mixed), Outcome 11 Rate of improvement.**

Review: Combined chiropractic interventions for low-back pain

Comparison: 3 Chiropractic vs Other (Mixed)

Outcome: 11 Rate of improvement




# APPENDICES

## Appendix 1. MEDLINE search strategy

1. randomized controlled trial.pt.
2. controlled clinical trial.pt
3. Randomized Controlled Trials/
4. Random Allocation/
5. Double-Blind Method/
6. Single-Blind Method/
7. or/1-6
8. Animal/ not Human/
9. 7 not 8
10. clinical trial.pt.
11. exp Clinical Trials/
12. (clin$ adj25 trial$).tw.
13. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
14. Placebos/
15. placebo$.tw.
16. random$.tw.
17. Research Design/
18. (latin adj square).tw.
19. or/10-18
20. 19 not 18
21. 20 not 9
22. Comparative Study/

23. exp Evaluation Studies/
24. Follow-Up Studies/
25. Prospective Studies/
26. (control$ or prospective$ or Volunteer$).tw.
27. Cross-Over Studies/
28. or/22-27
29. 28 not 8
30. 29 not (9 or 21)
31. 9 or 21 or 30
32. low back pain/
33. low back pain.tw.
34. backache.tw.
35. lumbago.tw.
36. or/32-35
37. 31 and 36
38. Chiropractic/
39. Manipulation, Chiropractic/
40. chiropract$.tw.
41. (activator or adjustment or atlas orthogonality or BEST or biophysics or flexion distraction or diversified or gonstead or hio or kinesiology or logan or manipulation or network spinal analysis or neural organi?ation or neuro emotional or pierce stillwagon or sot or sacro occipital or thompson or toftness or toggle or torque release or upper cervical specific or vax-d).tw.
42. Or/38-41
43. 42 and 37

## Appendix 2. EMBASE search strategy

1 clinical article
2 clinical study
3 clinical trial
4 controlled study
5 randomized controlled trial
6 major clinical study
7 double blind procedure
8 multicenter study
9 single blind procedure
10 phase 3 clinical study
11 phase 4 clinical study
12 crossover procedure
13 placebo
14 or/1-13
15 allocat$.ti,ab.
16 assign$.ti,ab.
17 blind$.ti,ab.
18 (clinic$ adj25 (study or trial)).ti,ab.
19 compar$.ti,ab.
20 control$.ti,ab.
21 cross?over.ti,ab.
22 factorial$.ti,ab.
23 follow?up.ti,ab.
24 placebo$.ti,ab.
25 prospectiv$.ti,ab.
26 random$.ti,ab.

27 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
28 trial.ti,ab.
29 (versus or vs).ti,ab.
30 or/15-29
31 14 or 30
32 human
33 nonhuman
34 animal
35 animal experiment
36 33 or 34 or 35
37 32 not 36
38 31 not 36
39 31 not 37
40 38 not 39
41 dorsalgia.ti,ab.
42 exp Back pain
43 backache.ti,ab.
44 (lumbar adj pain).ti,ab.
45 coccyx.ti,ab.
46 coccydynia.ti,ab.
47 sciatica.ti,ab.
48 sciatica
49 spondylosis.ti,ab.
50 lumbago.ti,ab.
51 or/41-50
52 manipulative medicine
53 chiropract$.tw.
54 (activator or adjustment or atlas orthogonality or BEST or biophysics or flexion distraction or diversified or gonstead or hio or kinesiology or logan or manipulation or network spinal analysis or neural organ?ation or neuro emotional or pierce stillwagon or sot or sacro occipital or thompson or toftness or toggle or torque release or upper cervical specific or vax-d).tw.
55 or/52-54
56 51 and 55

## Appendix 3. Operational definitions for risk of bias criteria

*1. Was the method of randomization adequate?*
A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with two groups), rolling a dice (for studies with two or more groups), drawing of balls of different colours, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelops, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments
Examples of inadequate methods are: alternation, birth date, social insurance/security number, date in which they are invited to participate in the study, and hospital registration number
*2. Was the treatment allocation concealed?*
Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
*Was knowledge of the allocated interventions adequately prevented during the study?*
*3. Was the outcome assessor blinded to the intervention?*
Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or:

- **for patient-reported outcomes** in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes"

- **for outcome criteria assessed during scheduled visit and that supposes a contact between** workers **and outcome assessors** (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination
- **for outcome criteria that do not suppose a contact with** workers (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome
- **for outcome criteria that are clinical or therapeutic events** that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "caregivers" is scored "yes"
- **for outcome criteria that are assessed from data of the medical forms**: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data

*4. Was the patient blinded to the intervention?*
This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.
5. *Was the care provider blinded to the intervention?*
This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful
*Were incomplete outcome data adequately addressed?*
*6. Was the drop-out rate described and acceptable?*
The number of workers who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a 'yes' is scored. (N.B. these percentages are arbitrary, not supported by literature).
*7. Were all randomized* workers *analysed in the group to which they were allocated?*
All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.
*8. Are reports of the study free of suggestion of selective outcome reporting?*
In order to receive a 'yes', the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.
*Other sources of potential bias?*
*9. Were the groups similar at baseline regarding the most important prognostic indicators?*
In order to receive a "yes", groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).
*10. Were co-interventions avoided or similar?*
This item should be scored "yes" if there were no co-interventions or they were similar between the index and control groups.
*11. Was the compliance acceptable in all groups?*
The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (for ex: surgery), this item is irrelevant.
*12. Was the timing of the outcome assessment similar in all groups?*
Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.

## HISTORY

Protocol first published: Issue 3, 2005

Review first published: Issue 4, 2010

## CONTRIBUTIONS OF AUTHORS

Bruce Walker: database searching, screening trials for inclusion, risk of bias assessment, data extraction, editing and contributing to the writing of the review, formulating drafts of the review.

Simon French: database searching, screening trials for inclusion, risk of bias assessment, data extraction, editing and contributing to the writing of the review, formulating drafts of the review.

William Grant: screening trials for inclusion, risk of bias assessment, data extraction, editing and contributing to the writing of the review.

Sally Green: data extraction, analysis and interpretation of the results, editing and contributing to the writing of the review.

## DECLARATIONS OF INTEREST

BW is an academic chiropractor and has previously practised as a chiropractor from which he derived an income.

SF has previously practised as a chiropractor from which he derived an income.

WDG and SG - no known conflicts

## SOURCES OF SUPPORT


### Internal sources

- Australasian Cochrane Centre, Monash Institute of Health Services Research, Monash University, Australia.
- School of Chiropractic and Sports Science, Murdoch University, Western Australia, Australia.

Travel and time for Dr. Walker

### External sources

- No sources of support supplied