ClinicalEvidence

Low back pain (acute)

Search date December 2009

Greg McIntosh and Hamilton Hall

ABSTRACT

INTRODUCTION: Low back pain affects about 70% of people in resource-rich countries at some point in their lives. Acute low back pain can be self-limiting; however, 1 year after an initial episode, as many as 33% of people still have moderate-intensity pain and 15% have severe pain. Acute low back pain has a high recurrence rate; 75% of those with a first episode have a recurrence. Although acute episodes may resolve completely, they may increase in severity and duration over time. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of oral drug treatments for acute low back pain? What are the effects of local injections for acute low back pain? What are the effects of non-drug treatments for acute low back pain? We searched: Medline, Embase, The Cochrane Library, and other important databases up to December 2009 (Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). RESULTS: We found 49 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review we present information relating to the effectiveness and safety of the following interventions: acupuncture, advice to stay active, analgesics (paracetamol, opioids), back exercises, back schools, bed rest, behavioural therapy, electromyographic biofeedback, epidural corticosteroid injections, lumbar supports, massage, multidisciplinary treatment programmes, muscle relaxants, non-steroidal anti-inflammatory drugs (NSAIDs), spinal manipulation, temperature treatments (short-wave diathermy, ultrasound, ice, heat), traction, and transcutaneous electrical nerve stimulation (TENS).

QUESTIONS

INTERVENTIONS

Key points

- Low back pain is pain, muscle tension, or stiffness, localised below the costal margin and above the inferior gluteal folds, with or without referred or radicular leg pain (sciatica), and is defined as acute when pain persists for <12 weeks.

  Low back pain affects about 70% of people in resource-rich countries at some point in their lives.

  Acute low back pain may be self-limiting, although there is a high recurrence rate with less-painful symptoms recurring in 50% to 80% of people within 1 year of the initial episode; 1 year later, as many as 33% of people still experience moderate-intensity pain and 15% experience severe pain.

- NSAIDs have been shown to effectively improve symptoms compared with placebo. However, their use is associated with gastrointestinal adverse effects.

Muscle relaxants may also reduce pain and improve overall clinical assessment, but are associated with some severe adverse effects including drowsiness, dizziness, and nausea.

The studies examining the effects of analgesics such as paracetamol or opioids were generally too small to detect any clinically important differences.

- We found no studies examining the effectiveness of epidural injections of corticosteroids in treating people with acute low back pain.
- With regard to non-drug treatments, advice to stay active (be it as a single treatment or in combination with other interventions such as back schools, a graded activity programme, or behavioural counselling) may be effective.

We don't know whether spinal manipulation improves pain or function compared with sham treatments.

We found insufficient evidence to judge the effectiveness of acupuncture, back schools, behavioural therapy, massage, multidisciplinary treatment programmes (for either acute or subacute low back pain), lumbar supports, TENS, or temperature treatments in treating people with acute low back pain.

We found no evidence examining the effectiveness of electromyographic biofeedback or traction in the treatment of acute low back pain.

Back exercises may decrease recovery time compared with no treatment, but there is considerable heterogeneity among studies with regard to the definition of back exercise. There is a large disparity among studies in the definition of generic versus specific back exercise.

Bed rest does not improve symptoms any more effectively than other treatments, but does produce a number of adverse effects including joint stiffness, muscle wasting, loss of bone mineral density, pressure sores, and venous thromboembolism.

DEFINITION

Low back pain is pain, muscle tension, or stiffness, localised below the costal margin and above the inferior gluteal folds, with or without referred or radicular leg pain (sciatica). [1] For this review, acute low back pain is defined as pain that persists for <12 weeks. Non-specific low back pain is a term some people use to indicate back pain not attributed to a recognisable pathology or symptom pattern (such as infection, tumour, osteoporosis, rheumatoid arthritis, fracture, or inflammation). [1] This review excludes acute low back pain with symptoms or signs at presentation that suggest a specific underlying pathoanatomical condition. People with solely sciatica (lumbosacral radicular syndrome), herniated discs, or both are also excluded. Unless otherwise stated, people included in this review have acute low back pain (i.e., of <12 weeks' duration). Some included RCTs further subdivided acute low back pain of <12 weeks' duration into acute (<6 weeks' duration) or subacute (6–12 weeks' duration).

INCIDENCE/ PREVALENCE

Over 70% of people in resource-rich countries will experience low back pain at some time in their lives. [2] Each year, 15% to 45% of adults suffer low back pain, and 1/20 (5%) people present to a healthcare professional with a new episode. Low back pain is most common between the ages of 35 to 55 years. [2] About 30% of European workers reported that their work caused low back pain but in a Canadian study, 67% of people not involved in workers' compensation claims could not attribute their symptoms to any specific cause or precipitating event. [3] Prevalence rates from different countries range from 13% to 44%. The longer the period of sick leave, the less likely return to work becomes. [2] [4]

AETIOLOGY/ RISK FACTORS

Symptoms, pathology, and radiological appearances are poorly correlated. An anatomical source of pain cannot be identified in about 80% of people. About 4% of people with low back pain in primary care have compression fractures and only about 1% have a tumour. [5] The prevalence of prolapsed intervertebral disc is about 1% to 3%. [2] Ankylosing spondylitis and spinal infections are less common. [5] Risk factors for the development of back pain include heavy physical work; frequent bending, twisting, or lifting; and prolonged static postures including sitting. Psychosocial risk factors include anxiety, depression, and mental stress at work. [2] [6]

PROGNOSIS

Acute low back pain may be self-limiting, although acute low back pain has a high recurrence rate with symptoms recurring in 50% to 80% of people within 1 year; [7] 1 year after the initial episode, as many as 33% of people still endure moderate-intensity pain and 15% experience severe pain.

AIMS OF INTERVENTION

Aims include: to relieve pain, to improve function, to reduce time taken to return to work, to develop coping strategies for pain, with minimal adverse effects from treatment; and to prevent the development of chronic back pain (see definition in review on low back pain [chronic]). [8] [9]

OUTCOMES

Symptom improvement: pain intensity (visual analogue or numerical rating scale); overall improvement (self-reported or observed); medication use; intervention-specific outcomes (such as coping and pain behaviour for behavioural treatment, strength and flexibility for exercise, and muscle spasm for muscle relaxants and electromyographic biofeedback). **Functional improvement:** back

pain-specific functional status (such as Roland Morris questionnaire, Oswestry questionnaire). **Return to work:** impact on employment (days of sick leave, number of people returned to work). **Adverse effects** of treatments. **Treatment effects:** some people have argued that the small effects of treatments are a consequence of the favourable natural history of non-specific low back pain. [10] The theory is that control groups have improved substantially and so there is not "room" for large treatment effects. To evaluate this argument, one review examined the baseline and follow-up scores from the acute trials in a meta-analysis. [10] The study found that the theory of no "room" for improvement does not seem consistent with the data; there is scope for treatment effects (i.e., mean between-group differences as large as 40 points that can be demonstrated in acute non-specific low back pain trials). Another argument used to explain the small treatment effects found in the non-specific low back pain literature is that most trials are conducted on samples from clinically heterogeneous populations. It is probable that specific treatments have large treatment effects on specific subgroups of patients with non-specific low back pain. [10]

METHODS

Clinical Evidence search and appraisal December 2009. The following databases were used to identify studies for this systematic review: Medline 1966 to December 2009, Embase 1980 to December 2009, and The Cochrane Database of Systematic Reviews 2009, Issue 4 (1966 to date of issue). An additional search within The Cochrane Library was carried out for the Database of Abstracts of Reviews of Effects (DARE) and the Health Technology Assessment (HTA) database. We also searched for retractions of studies included in the review. Most earlier RCTs of acute low back pain treatments were small (fewer than 50 people/intervention group), short term (mostly <6 months' follow-up), and of low overall quality. The quality of many recent RCTs is higher. In this review, we have excluded studies done solely in people with sciatica or disc herniation. We have included studies in people with acute low back pain in which the study does not describe whether people had radiation, or in which the study included people without radiation. Abstracts of the studies retrieved from the initial search were initially assessed by an information specialist. Selected studies were then sent to the contributors for additional assessment, using predetermined criteria to identify relevant studies. Study design criteria for inclusion in this review were: published systematic reviews of RCTs and RCTs in English language. RCTs had to be at least single blinded, unless blinding was impossible (e.g., physical treatments). We excluded all studies described as "open", "open label", or not blinded unless blinding was impossible. RCTs had to contain 20 or more individuals. There was no minimum length of follow-up or maximum loss to follow-up. We included systematic reviews of RCTs and RCTs where harms of an included intervention were studied applying the same study design criteria for inclusion as we did for benefits. In addition we use a regular surveillance protocol to capture harms alerts from organisations such as the FDA and the MHRA, which are added to the reviews as required. To make numerical data in our reviews more readable, we round many percentages to the nearest whole number. Readers should be aware of this approximation when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 31). The categorisation of the quality of the evidence (into high, moderate, low, or very low) reflects the quality of evidence available for our chosen outcomes in our defined populations of interest. These categorisations are not necessarily a reflection of the overall methodological quality of any individual study, because the *Clinical Evidence* population and outcome of choice may represent only a small subset of the total outcomes reported, and population included, in any individual trial. For further details of how we perform the GRADE evaluation and the scoring system we use, please see our website (www.clinicalevidence.com).

QUESTION What are the effects of oral drug treatments for acute low back pain?

OPTION MUSCLE RELAXANTS

Symptom improvement

Benzodiazepine muscle relaxants compared with placebo Benzodiazepines may be more effective than placebo at reducing pain (very low-quality evidence).

Non-benzodiazepine muscle relaxants compared with placebo Non-benzodiazepine muscle relaxants may be more effective than placebo at reducing pain and may be more effective at improving global assessment (low-quality evidence).

Muscle relaxants compared with NSAIDs We don't know whether chlormezanone plus paracetamol is more effective than mefenamic acid at increasing the proportion of people with global improvement in people with acute low back pain (very low-quality evidence).

Muscle relaxants compared with each other We don't know if any one muscle relaxant is consistently more effective than all other muscle relaxants at improving symptoms, as we found insufficient evidence (low-quality evidence).

Functional improvement
Non-benzodiazepine muscle relaxants compared with placebo We don't know whether non-benzodiazepine muscle relaxants are more effective than placebo at improving disability at 4 weeks, as we found insufficient evidence (low-quality evidence).

Note
Benzodiazepine and non-benzodiazepine muscle relaxants have been associated with an increase in adverse effects compared with placebo, particularly central nervous system effects (such as dizziness, nausea, and possibly drowsiness).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

Benzodiazepine muscle relaxants versus placebo:
We found one systematic review (search date 2002), [11] which identified one poor-quality RCT (68 people). [12] The RCT found that intramuscular diazepam followed by oral diazepam for 5 days significantly reduced pain and increased the rate of overall improvement (rating scales used to assess overall improvement not reported) compared with placebo (overall effect rated good or very good: 21/33 [64%] with diazepam *v* 6/35 [17%] with placebo; P value and pain results not reported in the review). However, treatment groups were not comparable at baseline.

Non-benzodiazepine muscle relaxants versus placebo:
We found two systematic reviews (search dates 2001 [11] and 2006 [10]) and one subsequent RCT. [13] The first review identified 9 RCTs comparing non-benzodiazepines (tizanidine, cyclobenzaprine, carisoprodol, baclofen, orphenadrine) versus placebo. [11] Meta-analysis of RCTs with adequate data found that oral non-benzodiazepines (cyclobenzaprine, tizanidine, and orphenadrine) significantly reduced pain and improved global assessment after 2 to 4 days (presence of pain: 4 RCTs, 294 people; RR 0.80, 95% CI 0.71 to 0.89; global assessment at 2–4 days, dichotomous, assessed by patient: 4 RCTs, 222 people; RR 0.49, 95% CI 0.25 to 0.95).

The second review identified 8 RCTs reporting on the analgesic effects of muscle relaxants estimated by placebo-controlled trials in people with non-specific acute low back pain. [10] This review excluded RCTs in which a contemporary treatment had been given as placebo (i.e., what might now be considered to be an active treatment, e.g., educational booklets, non-specific exercises, TENS, low-dose lidocaine injections, diphenhydramine tablets, low-force spinal manipulation and soft tissue massage, massage with placebo ointment). The review extracted data on outcomes from the first assessment after the end of therapy, as the review considered that this time point was where the largest analgesic effects would be observed. It did not include a description of individual interventions used in each RCT. The review found that muscle relaxants significantly improved pain (measured by analgesic efficacy [100-point scale]) compared with placebo (8 RCTs, 777 people; RR presented graphically; absolute numbers and figures for point estimate of RR and CI not reported; individual RCTs in analysis not reported). The review reported that the point estimate of the effects was moderate for muscle relaxants, but the confidence intervals were not narrow enough to exclude small effects, and noted that generally in all RCTs included in the review, that large effects were observed in only single trials. [10]

One RCT (192 people) included in the second review compared chiropractic adjustments, muscle relaxants, and placebo, and found no significant difference among groups in disability at 4 weeks. [14]

The subsequent RCT (562 people) was a 7-day trial that compared carisoprodol (277 people) versus placebo (285 people). [13] The RCT found that carisoprodol was significantly more effective than placebo at improving participant-rated global impression of change at 3 days (scale 0 = worsening to 4 = marked improvement: 2.24 with carisoprodol *v* 1.70 with placebo; P <0.0001) and participant-rated relief from initial backache (scale 0 = no relief to 4 = complete relief: 1.83 with carisoprodol *v* 1.12 with placebo; P <0.0001). Time until onset of moderate or marked improvement was significantly reduced with carisoprodol compared with placebo (3 days with carisoprodol *v* 6 days with placebo; P <0.0001). The RCT undertook a subgroup analysis to see if the effects were dependent on the sedative effects of carisoprodol, and there was no significant differences found between people who reported sedation (13.4% of participants) and those who did not (86.6% of participants). [13]

Muscle relaxants versus NSAIDs:
See benefits of NSAIDs, p 3 .

Muscle relaxants versus each other:
We found one systematic review (search date 2001), [11] which identified three RCTs. [15] [16] [17] and one subsequent RCT. [18]

The RCTs in the review found no clinically important differences in effect among muscle relaxants (cyclobenzaprine, carisoprodol, diazepam, and tizanidine), although the results were not pooled in the review. The first RCT (80 people) found that carisoprodol significantly increased overall improvement compared with diazepam, but found no significant difference in pain at 7 days (improvement rated as very good or excellent; 70% with carisoprodol *v* 45% with diazepam; pain on 100-mm visual analogue scale [VAS]: 58 mm with carisoprodol *v* 48 mm with diazepam; P values not reported in the review). [15] The second RCT (78 people) found no significant difference between carisoprodol and cyclobenzaprine in pain or overall improvement after 8 days (pain on 100-mm VAS: 30 mm with carisoprodol *v* 28 mm with cyclobenzaprine; overall improvement good or excellent: 70% with carisoprodol *v* 70% with cyclobenzaprine; P values not reported in review). [16] The third RCT (30 people with acute back pain, 20% with concomitant acute neck pain) was small and found no significant difference between diazepam and tizanidine in pain or function at 7 days (pain relief: 77.4% with tizanidine *v* 48.0% with diazepam; improvement in daily activities: 87% with tizanidine *v* 93% with diazepam; P values not reported in review). [17]

The subsequent RCT (90 people [86 assessed], acute low back pain <48 hours, with mild to severe intensity muscle contracture) compared diazepam 15 mg daily versus eperisone 150 mg daily versus eperisone 300 mg daily, given orally for 7 days. [18] The RCT found that, compared with eperisone 150 mg daily, eperisone 300 mg daily significantly improved pain at rest or palpation, muscular contracture, impaired working capacity, and hand-to-floor distance (a measure of flexion) at 7 days (all outcomes, P <0.01). It found that, compared with diazepam, eperisone 300 mg daily significantly improved muscular contracture at 3 days but not at 7 days, and significantly improved impaired working capacity (measured by limitations of activity) at 3 days and 7 days (all significant outcomes, P <0.01). [18]

Harms:

Benzodiazepine or non-benzodiazepine muscle relaxants versus placebo:
The first review found that muscle relaxants (both benzodiazepines and non-benzodiazepines) significantly increased adverse effects, particularly central nervous system effects, compared with placebo (all adverse effects: 8 RCTs, 724 people; RR 1.50, 95% CI 1.14 to 1.98; nervous system effects: 8 RCTs, 724 people; RR 2.04, 95% CI 1.23 to 3.37). [11] The most common adverse effects were drowsiness, dizziness, and nausea. The second review did not report on adverse effects. [10]

The subsequent RCT reported that treatment-emergent adverse events occurring in 3% or more of participants included: drowsiness, dizziness, and headache (drowsiness: 13.4% with carisoprodol *v* 4.6% with placebo; dizziness: 9.7% with carisoprodol *v* 3.2% with placebo; headache: 3.6% with carisoprodol *v* 1.4% with placebo; statistical analysis between groups not reported). [13] Eight (2.9%) people in the carisoprodol group and 5 (1.8%) people in the control group discontinued the study because of treatment-emergent adverse events (statistical analysis between groups not reported). The RCT reported that most adverse events were mild to moderate including those leading to discontinuation. No participant discontinued treatment with carisoprodol because of drowsiness, and no serious adverse events or clinically significant effects on laboratory values or vital signs were detected. [13]

Muscle relaxants versus NSAIDs:
See harms of NSAIDs, p 5 .

Muscle relaxants versus each other:
The subsequent RCT reported that in the diazepam group, 23 people reported adverse reactions. [18] These included somnolence (19), tachycardia with vertigo (1), epigastric pain (2), and diarrhoea (1). In the eperisone 150 mg group, it reported 5 adverse reactions which were: epigastric pain (3), somnolence (1), and headache (1). The RCT reported that there were 6 adverse reactions in the eperisone 300 mg group: somnolence (2), epigastric pain (1), vertigo (1), urinary retention (1), and anorexia (1). It did not report a statistical analysis between groups. [18]

Comment: None.

OPTION NSAIDS

Symptom improvement
Compared with placebo NSAIDs may be more effective than placebo at improving pain in people with acute low back pain (very low-quality evidence).

Compared with each other We don't know if any one NSAID is consistently more effective than all other NSAIDs at improving symptoms in people with acute low back pain (low-quality evidence).

Compared with paracetamol (acetaminophen) We don't know whether NSAIDs and paracetamol (acetaminophen) differ in effectiveness at improving pain or global improvement in people with acute low back pain as we found insufficient evidence (very low-quality evidence).

Compared with muscle relaxants We don't know whether mefenamic acid is more effective than chlormezanone plus paracetamol at increasing the proportion of people with global improvement in people with acute low back pain (very low-quality evidence).

Compared with non-drug treatments (physiotherapy or spinal manipulation) We don't know whether diflunisal, physiotherapy, and spinal manipulation differ in effectiveness at improving pain at 4 and 12 days in people with acute low back pain (low-quality evidence).

Compared with NSAIDs plus adjuvant treatment We don't know whether naproxen is more effective than naproxen plus cyclobenzaprine at improving pain in people with acute low back pain (low-quality evidence).

Compared with heat wrap Ibuprofen may be less effective than heat wraps at improving pain at 1 and 4 days (low-quality evidence).

Functional improvement
Compared with each other We don't know if dexketoprofen is more effective than diclofenac at improving disability in people with acute low back pain as we found insufficient evidence (low-quality evidence).

Compared with heat wrap Ibuprofen may be less effective than heat wraps at improving disability at 4 days (low-quality evidence).

Compared with specific back exercises We don't know whether NSAIDs are more effective than McKenzie treatment at 3 months at improving short-term disability as we found insufficient evidence (low-quality evidence).

Note
NSAIDs have been associated with an increase in gastrointestinal and other adverse effects compared with placebo.

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found two systematic reviews (search dates 2007 [19] and 2006 [10]), one additional RCT, [20] and one subsequent RCT. [21]

The first review included RCTs in people with acute, chronic, and mixed back pain, and also RCTs in people with no sciatica, all participants with sciatica, mixed populations, and RCTs in which the presence or absence of sciatica was not specified. [19] We have reported RCTs exclusively undertaken in acute back pain that included a homogeneous population of people without sciatica.

NSAIDs versus placebo:
We found two systematic reviews (search dates 2007 [19] and 2006 [10]).

The first review included three RCTs (724 people) in people with acute low back pain without sciatica and pooled results. [19] The RCTs included piroxicam, ibuprofen, and tenoxicam (see comment below). The review found that NSAIDs significantly improved pain compared with placebo (pain measured on 100-mm visual analogue scale; change from baseline: 3 RCTs, 577 people; mean difference –7.69, 95% CI –12.08 to –3.30; P = 0.00059). Two of the included RCTs were described as being of high methodological quality, while the third was described as being of low quality. One included RCT reported data on the need for additional analgesic use; analgesics were not permitted in one included RCT. [19]

The second review identified three RCTs evaluating the analgesic effects of NSAIDs estimated by placebo-controlled trials in people with non-specific low back pain. [10] In this review, RCTs using a placebo consisting of what might now be considered to be an active treatment were excluded (see benefits of muscle relaxants, p 3). The review extracted data on outcomes from the first assessment after the end of therapy, because the review considered that this time point was where the largest analgesic effects would be observed. It did not include a description of individual interventions used in each RCT. The review included two RCTs included in the analysis in the first review, and one further RCT that may have included people with sciatica. The review found that NSAIDs significantly improved pain (measured by analgesic efficacy [100-point scale]) compared with placebo (3 RCTs, 427 people; RR presented graphically; absolute numbers and figures for point estimate of RR and CI not reported; individual RCTs in analysis not reported). The review reported that the point estimate of the effects for NSAIDs was small, and noted that generally in all RCTs included in the review, large effects were observed in only single trials. [10]

NSAIDs versus each other:
We found one systematic review (search date 2007, 6 RCTs, 1353 people), [19] one additional RCT, [20] and one subsequent RCT. [21]

Overall, the review found 21 RCTs comparing different NSAIDs versus each other, of which 15 RCTs found no significant difference between groups. [19] However, some of these RCTs included either a proportion of people, or all the study population, with sciatica. We have therefore reported the 6 included RCTs that compared different traditional NSAIDs in people with acute low back pain without sciatica. The review did not pool data. In the review, 4 high-quality RCTs and two low-quality RCTs compared different types of traditional NSAIDs versus each other. The review reported that none of the high-quality RCTs evaluating NSAIDs found any significant differences between groups (further statistical analysis not reported). [19]

The additional RCT (194 people) found no significant difference in pain or global assessment between acemetacin and diclofenac (absolute numbers and P value not reported). [20]

The subsequent RCT (323 people, acute low back pain, 1 week or less) compared intramuscular dexketoprofen versus diclofenac. [21] The RCT measured pain on a 100-mm visual analogue scale. The RCT found no significant difference between groups in pain intensity (sum of analogue pain intensity difference [SAPID] score at 6 hours after the first dose administration: 111.8 mm/hour with dexketoprofen *v* 112.7 mm/hour with diclofenac; adjusted ratio of means 0.993, lower 95% CI 0.79, upper 95% CI not reported). The RCT reported that there was no significant difference between groups in disability (median change in Roland Disability Questionnaire score –6 points for both groups; P = 0.69). [21]

NSAIDs versus paracetamol (acetaminophen):
We found one systematic review (search date 2007, 3 RCTs). [19] The three included low-quality RCTs compared some type of NSAID versus paracetamol (acetaminophen). None of the RCTs found a significant difference between groups in outcomes (pain intensity [various scales]: first RCT, 219 people; ibuprofen *v* paracetamol, SMD –0.09, 95% CI –0.35 to +0.18; second RCT, 30 people; phenylbutazone *v* paracetamol, SMD –0.58, 95% CI –1.31 to +0.16; proportion of people experiencing global improvement: third RCT, 48 people; ibuprofen *v* paracetamol; RR 1.23, 95% CI 0.77 to 1.96). There was no reporting of allocation concealment in any of the RCTs, randomisation was according to participant's military identification numbers in one RCT, and two RCTs were undertaken solely in male military participants. [19]

NSAIDs versus muscle relaxants:
We found one systematic review (search date 2007, 1 RCT, 122 people). [19] The RCT found no significant difference between mefenamic acid plus placebo and chlormezanone plus paracetamol plus placebo in the proportion of people with global improvement (80 people; RR 1.05, 95% CI 0.86 to 1.29). The randomisation procedure was not described and allocation concealment was unclear. [19]

NSAIDs versus non-drug treatments (physiotherapy or spinal manipulation):
We found one systematic review (search date 2007, 1 RCT, 112 people). [19] The included RCT found no significant difference between NSAIDs (36 people) and physiotherapy (34 people) or spinal manipulation (38 people) in pain after 4 and 12 days (mean change in pain intensity on 4-point scale; 4 days: –0.9 with diflunisal *v* –0.9 with physiotherapy *v* –1.1 with spinal manipulation, McKenzie therapy, or both; 12 days: –1.7 with diflunisal *v* –1.6 with physiotherapy *v* –1.7 with spinal manipulation, McKenzie therapy, or both; reported as no significant difference; P value not reported). [19] However, the study lacked power because of the small groups.

NSAIDs versus NSAIDs plus adjuvant treatment:
We found one systematic review (search date 2007, 1 RCT). [19] The review reported that the low-quality RCT (40 people) indicated that the combination of an NSAID with a muscle relaxant was better than the NSAID alone, although there were no statistically significant differences between groups (days to resolution of pain: 12.5 days with naproxen *v* 8.5 days with naproxen plus cyclobenzaprine; days to sit without pain: 7 days with naproxen *v* 5 days with naproxen plus cyclobenzaprine; further statistical analysis and P value not reported). [19]

NSAIDs versus heat wrap:
See benefits of temperature treatments, p 19 .

NSAIDs versus back exercises:
See benefits of back exercises, p 22 .

Harms: NSAIDs may cause gastrointestinal and other complications (see review on NSAIDs).

The first review reported that an earlier meta-analysis of controlled epidemiological studies concluded that ibuprofen was associated with the lowest relative risk of serious gastrointestinal complications, but this was mainly attributable to the relatively low doses prescribed (see NSAIDs versus placebo below). [19]

The review reported that for all RCTs included in the review, adverse effects were frequently reported; they included: abdominal pain, diarrhoea, oedema, dry mouth, rash, dizziness, headache, and tiredness. The review reported that according to the authors of the RCTs, most adverse effects were considered mild to moderately severe, but the sample sizes were relatively small, and therefore no clear conclusion could be drawn from these studies regarding the risks for gastrointestinal and other adverse effects of NSAIDs. [19]

NSAIDs versus placebo:
One systematic review of harms of NSAIDs found no significant difference in adverse effects between NSAIDs as a class and placebo (pooled OR for adverse effects *v* placebo 1.30, 95% CI 0.91 to 1.80). [22] The review reported that ibuprofen and diclofenac had the lowest gastrointestinal complication rate, mainly because of the low doses used in practice.

NSAIDs versus each other:
The review reported that there was no clear difference in the reported number or severity of adverse effects between the different types of NSAIDs. [19] Only one low-quality RCT reported statistically significant differences in adverse effects.

The additional RCT found that a similar proportion of people reported adverse effects in the acemetacin and diclofenac groups (30/94 [32%] with acemetacin *v* 39/100 [39%] with diclofenac; significance not assessed; P value not reported). [20] No other information on adverse effects was reported. One RCT included in the review found that similar proportions of people reported adverse effects in the diclofenac and ibuprofen groups (13% with diclofenac *v* 12% with ibuprofen; absolute numbers not reported; significance not assessed; P value not reported). [19]

The subsequent RCT reported that dexketoprofen was well tolerated, with a reported incidence of adverse events similar to that of diclofenac (percentage of participants with adverse effect: 27% with dexketoprofen *v* 31% with diclofenac; P = 0.43). [21] No serious adverse events were reported in either treatment group. Six people withdrew from the study as a result of adverse effects (dexketoprofen, 4 people: liver pain, hot flushes and headache, vomiting and stomach ache; diclofenac, 2 people: dyspepsia and nausea; statistical analysis between groups not reported). With regard to intensity, the RCT reported that adverse effects were mild or moderate in the majority of cases. Headache, pain at the site of injection, nausea, and abdominal pain were the most common adverse effects in both treatment groups. [21]

COX-2 NSAIDS: The review noted that debates on the increased risk for cardiovascular events associated with the use of selective COX-2 inhibitors are important, and the increased risks of COX-2 NSAIDs (when compared with placebo) had been demonstrated in large RCTs. [19] These findings had resulted in the removal of some COX-2 inhibitors from the market. The review noted that the current question is whether the increased risk pertains to all selective COX-2 inhibitors and traditional NSAIDs too. It concluded that more data are needed from large epidemiological studies to answer this question and that such studies must consider the dose, frequency, and duration of NSAID intake. It reported that in many people with acute low back pain, the intake is of short duration and might not reach the level associated with increased cardiovascular risks. [19]

NSAIDs versus paracetamol (acetaminophen):
The review reported that NSAIDs were associated with significantly more adverse effects compared with paracetamol (proportion of people with adverse effects: 3 RCTs [2 RCTs may have included people with sciatica], 309 people; RR 1.76, 95% CI 1.12 to 2.76; P = 0.014). [19]

NSAIDs versus muscle relaxants:
The RCT found no significant difference between groups in the proportion of people with adverse effects (80 people; RR 0.59, 95% CI 0.30 to 1.18). [19]

NSAIDs versus non-drug treatments (physiotherapy or spinal manipulation):
The review gave no information on adverse effects for this comparison. [19]

NSAIDs versus NSAIDs plus adjuvant treatment:
The review reported that adverse effects were more frequent in the combination groups (4 people with naproxen *v* 12 people with naproxen plus cyclobenzaprine; further details not reported; statistical analysis between groups not reported). [19]

NSAIDs versus heat wrap:
See harms of temperature treatments, p 19 .

NSAIDs versus back exercises:
See harms of back exercises, p 22 .

Comment: Originally, COX-2 inhibitors, such as valdecoxib, were associated with fewer gastrointestinal adverse effects in osteoarthritic and rheumatoid arthritis studies; [23] however, they have been associated with serious cardiovascular adverse effects. Valdecoxib has been removed from the market in some countries because of concerns about its potential association with increased risk of MI and stroke. [24] Piroxicam is no longer recommended for the treatment of short-term painful and inflammatory conditions. Although piroxicam can still be used for the symptomatic relief of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, it is not recommended as a first-line treatment for these conditions. Treatment should be used in the lowest dose (no more than 20 mg/day) and for the shortest duration possible. Piroxicam could be associated with a higher risk of gastrointestinal adverse effects and serious skin reactions compared with other non-selective NSAIDs.

OPTION ANALGESICS (PARACETAMOL, OPIOIDS)

Symptom improvement
Compared with NSAIDs We don't know whether paracetamol (acetaminophen) and NSAIDs differ in effectiveness at improving pain or global improvement in people with acute low back pain as we found insufficient evidence (very low-quality evidence).

Compared with non-drug treatments We don't know whether paracetamol or analgesics (not specified) are more effective than electroacupuncture or ultrasound treatment at relieving pain as we found insufficient evidence (very low-quality evidence).

Analgesics alone compared with combination analgesics Paracetamol plus tramadol may be no more effective at 10 days than tramadol alone at reducing pain intensity, but may cause fewer adverse effects (very low-quality evidence).

Compared with heat wrap Paracetamol (acetaminophen) may be less effective at 1 and 4 days at improving pain (low-quality evidence).

Functional improvement
Compared with heat wrap Paracetamol (acetaminophen) may be less effective at improving disability at 4 days (low-quality evidence).

Note
We found no direct information about whether analgesics (paracetamol, opioids) are better than no active treatment in people with acute low back pain. FDA has issued a drug safety alert on the risk of rare but serious skin reactions with paracetamol (acetaminophen).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

Analgesics versus placebo:
We found two reviews (search dates 1995 [25] and 1997 [19]), which identified no RCTs.

Paracetamol (acetaminophen) versus NSAIDs:
See benefits of NSAIDs, p 5 .

Analgesics versus non-drug treatments:
We found one systematic review (search date 1995), which identified one RCT (40 people) that found that electroacupuncture significantly reduced pain after 6 weeks compared with paracetamol (change in pain scores from baseline [on a 100-point visual analogue scale]: from 54.4 to 13.7 with paracetamol *v* from 52.7 to 3.3 with electroacupuncture; reported as significant; P value not reported). [25] The review identified a second RCT (73 people), which found that ultrasound treatment significantly increased the proportion of people who were pain free after 4 weeks compared with analgesics (unspecified) (41% with ultrasound *v* 7% with analgesics; reported as significant; P value not reported). [25]

Combination analgesics versus analgesic alone:
We found one RCT (119 people with moderate-intensity low back pain [40 mm or more on a 100-mm visual analogue scale] for 10–42 days before enrolment), which compared 10 days' treatment with paracetamol 325 mg plus tramadol 37.5 mg versus tramadol 50 mg alone. [26] The RCT found no significant difference between groups in change in pain intensity after 10 days' treatment

(measured on a 100-mm visual analogue scale: from 67.5 mm to 27.9 mm with combination *v* from 65.3 mm to 24.8 mm with tramadol alone; P = 0.455).

Analgesic versus heat wrap:
See benefits of temperature treatments, p 19 .

Harms:

See review on paracetamol (acetaminophen) poisoning. RCTs have found adverse effects (constipation and drowsiness) with analgesics in about 50% of people. One earlier systematic review (search date 1995) found that combinations of paracetamol plus weak opioids increased the risk of adverse effects compared with paracetamol alone (15 single-dose studies; OR 1.1, 95% CI 0.8 to 1.5; 3 multiple-dose studies; OR 2.5, 95% CI 1.5 to 4.2).

Analgesics versus placebo:
The reviews identified no RCTs. [25] [19]

Paracetamol (acetaminophen) versus NSAIDs:
See harms of NSAIDs, p 5 .

Analgesics versus non-drug treatments:
The review gave no information on adverse effects for this comparison. [25]

Combination analgesics versus analgesic alone:
The RCT found that a significantly smaller proportion of people receiving combination treatment reported adverse effects compared with those receiving tramadol alone (30/59 [51%] with paracetamol plus tramadol *v* 44/60 [73%] with tramadol alone; P = 0.019). [26] The most common adverse effects reported were nausea, dizziness/vertigo, and sleepiness. The RCT found that the incidences of nausea and dizziness/vertigo were significantly lower in the combination group compared with the tramadol-alone group (nausea: 8/59 [14%] with combination *v* 21/60 [35%] with tramadol alone; P = 0.012; dizziness/vertigo: 3/59 [5%] with combination *v* 15/60 [25%] with tramadol alone; P = 0.006). However, there was no significant difference between groups in incidence of sleepiness (7/59 [12%] with combination *v* 15/60 [25%] with tramadol alone; P = 0.198).

Analgesic versus heat wrap:
See harms of temperature treatments, p 19 .
Drug safety alert:
August 2013, paracetamol (acetaminophen) The Food and Drug Administration (FDA) issued a safety alert on the risk of rare but serious skin reactions with paracetamol (acetaminophen). These skin reactions, known as Stevens–Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalised exanthematous pustulosis (AGEP), can be fatal.(www.fda.gov/)

Comment:

None.

QUESTION What are the effects of local injections for acute low back pain?

OPTION EPIDURAL CORTICOSTEROID INJECTIONS

We found no clinically important results from RCTs about the effects of epidural corticosteroid injections in people with acute low back pain. Epidural corticosteroid injections have been associated with serious adverse effects.

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found one systematic review (search date 1998), which identified no RCTs on the effects of epidural corticosteroid injections in people with acute low back pain without sciatica. [27]

Harms:

We found no RCTs.

Comment:

Clinical guide:
Epidural corticosteroid injections may be associated with serious adverse effects and should only be administered under specific indications. Epidural corticosteroid injections are only indicated for people who are on a waiting list for surgery with leg-dominant pain and root irritation. Epidurals are most effective for potential surgical candidates; however, even in such cases, epidural injections lead to only marginal benefit. Epidurals give a short period of improvement and are ineffective in the long term. Epidural corticosteroid injections are not effective for those with only acute back pain and no leg pain.

QUESTION What are the effects of non-drug treatments for acute low back pain?

OPTION ADVICE TO STAY ACTIVE

Symptom improvement
Compared with bed rest Advice to stay active is more effective at reducing pain at 3 to 12 weeks post episode (moderate-quality evidence).

Functional improvement
Compared with no advice or traditional medical treatment (including analgesics as required, advice to rest, and "let pain be your guide") Advice to stay active with or without other treatments may be more effective than traditional medical treatment alone (including analgesics as required, advice to rest, and "let pain be your guide") at reducing chronic disability at up to 1 year. However, evidence was weak and the size of effects was unclear (very low-quality evidence).

Compared with bed rest Advice to stay active is more effective at improving functional outcomes at 3 to 12 weeks post episode (moderate-quality evidence).

Return to work
Compared with no advice or traditional medical treatment (including analgesics as required, advice to rest, and "let pain be your guide") Advice to stay active with or without other treatments may be more effective than traditional medical treatment alone (including analgesics as required, advice to rest, and "let pain be your guide") at reducing sick leave. However, evidence was weak and the size of effects was unclear (very low-quality evidence).

Compared with bed rest Advice to stay active seems to be more effective than bed rest at reducing initial sick leave and sick leave at 3 to 4 weeks and 12 weeks in people with acute low back pain (moderate-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found one systematic review (search date 1996, 6 RCTs, 1957 people). [28]

Advice to stay active versus no advice or traditional medical treatment:
The review did not pool data, but reported consistent findings among included RCTs. [28] The review compared advice to stay active with or without other treatments versus those other treatments alone. The review found that advice to stay active significantly reduced sick leave (significance not assessed; reported as significant) and reduced chronic disability at up to 1 year compared with traditional medical treatment (including analgesics as required, advice to rest, and "let pain be your guide"). See comment. [28]

Advice to stay active versus bed rest:
See benefits of bed rest, p 26 .

Harms:

Advice to stay active versus no advice or traditional medical treatment:
The review [28] gave no information on adverse effects.

Advice to stay active versus bed rest:
See harms of bed rest, p 26 .

Comment:

Limitations in methods preclude meaningful quantification of effect sizes. Advice to stay active was provided either as a single treatment or in combination with other interventions such as back schools, a graded activity programme, or behavioural counselling.

The distinction between placebo effects and specific treatment effects is often ill-defined in non-pharmaceutical treatment trials. Thus, the selection of a comparison group often requires considerable thought to ensure that the placebo intervention does not share some of the specific therapeutic components of the experimental intervention. This issue is more of a concern when placebos are designed to resemble the experimental intervention. In some placebo-controlled trials, the placebo treatment is actually used in clinical practice as a treatment. [10]

OPTION MULTIDISCIPLINARY TREATMENT PROGRAMMES (ACUTE LOW BACK PAIN)

Symptom improvement
Compared with usual care We don't know whether graded activity is more effective at 26 weeks at reducing pain intensity as we found insufficient evidence (very low-quality evidence).

Functional improvement

Compared with usual care We don't know whether graded activity is more effective at improving functional status as we found insufficient evidence (very low-quality evidence).

Return to work
Compared with usual care People undergoing graded activity (even when combined with workplace intervention) may occasionally take longer to return to work (very low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found one RCT assessing the effects of a multidisciplinary treatment programme in people with acute low back pain analysed in two publications. [29] [30] The RCT (196 people with low back pain who had been on sick leave for 2–6 weeks) randomised people initially to a workplace intervention (96 people) or usual care (100 people). [29] At 8 weeks after the start of the person's sick leave, people (112 people) underwent a second round of randomisation to either graded activity or usual care.

One report analysed the effects of the combination of graded activity plus workplace intervention (27 people) versus the effects of either treatment alone and usual care as a group (85 people): the study did not correct for the effects of the workplace intervention or graded activity in the control comparator group. [29] At 12 months' follow-up, the study found no significant difference in the number of days off work between groups receiving both the workplace intervention and graded activity compared with those receiving either treatment alone or usual care (median number of days off work: 143 with combined treatment *v* 126 without combined treatment; P = 0.49). The RCT also found no significant difference between groups in pain intensity and functional status (improvement in pain intensity [measured using a visual analogue scale, where 0 = no pain and 10 = severe pain]: 2.9 with combined treatment *v* 3.3 without combined treatment; improvement in functional status [measured using Roland Morris questionnaire]: 8.3 with combined treatment *v* 8.7 without combined treatment; number of people in analysis not reported; both comparisons reported as not significant; P values not reported).

The second analysis of this study assessed the effects of graded activity versus usual care. [30] At 26 weeks, the RCT found that people in the graded activity group had a small, but significant, worsening in pain intensity compared with the usual-care group (mean improvement from baseline on a 10-point visual analogue scale: 92 people analysed: 3.7 with graded activity *v* 3.2 with usual care; reported by the authors to be a significant difference in favour of usual care; P value not reported). [30] People undergoing graded activity took significantly longer to return to work compared with those receiving usual care (intention-to-treat analysis: median time taken to return to work: 139 days with graded activity *v* 111 days with usual care; HR 0.52, 95% CI 0.32 to 0.86; P <0.01). However, there was no significant difference between groups in functional status (mean improvement from baseline on Roland Morris questionnaire: 91 people analysed: 7.9 with graded activity *v* 7.5 with usual care; reported as not significant; P value not reported). The RCT reported that, of the 55 people assigned to graded activity, 27 received workplace intervention, and of the 57 assigned to usual care, 26 received the workplace intervention. Subgroup analysis of those who had not received workplace intervention (59 people) found no significant difference in median number of days taken to return to work between graded activity and usual care (HR 0.86, 95% CI 0.40 to 1.84; P = 0.69). The RCT did not carry out a subgroup analysis for those who received the workplace intervention. Graded activity comprised physiotherapist-supervised exercise programmes (26 sessions lasting 1 hour/week) emphasising return to work based on operant conditioning principles. The workplace intervention consisted of ergonomic workplace assessment, modifications plus case management, and additional treatments (physiotherapy, manual therapy, Cesar therapy, and chiropractor care). The results presented should be interpreted with caution. The number of people who received both the workplace intervention and graded activity is unclear. Of the 55 people randomised to graded activity, 19 did not receive the clinical intervention, and, of the 36 people receiving graded activity, it is unclear how many had previously received the workplace intervention and were followed up for 12 months.

Harms:

The RCT gave no information on adverse effects. [29] [30]

Comment:

There was a considerable time lag between randomisation and the start of the graded activity programme, which, together with poor compliance in this group, could explain the observed delay in return to work. [30]

Clinical guide:
Multidisciplinary rehabilitation programmes are typically expensive and may not be necessary for uncomplicated acute low back problems. Multidisciplinary programmes typically include treatments provided by two or more healthcare providers with different professional training to obtain different

perspectives and approaches to recovery. The term multidisciplinary does not imply a mandatory roster of specialists and does not dictate the nature of the treatment.

OPTION MULTIDISCIPLINARY TREATMENT PROGRAMMES (SUBACUTE LOW BACK PAIN)

Return to work

Compared with usual care Multidisciplinary treatment, with or without a workplace visit, may be more effective than usual care at reducing sick leave in people with subacute low back pain. However, evidence was weak and interventions varied between studies (very low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found two systematic reviews (search date 2002, 2 RCTs, 233 people with subacute low back pain, duration between 4 weeks and 3 months; [31] 1998–2006, 2 RCTs, 928 people with subacute low back pain, duration 5–12 weeks). [32]

The first review found that multidisciplinary treatment, including a workplace visit, significantly reduced sick leave compared with usual care (time to return to work: 10 weeks with multidisciplinary treatment *v* 15 weeks with usual care in first RCT; RR for return to work rate 2.4, 95% CI 1.2 to 4.9 in second RCT). [31] However, both studies identified in the review were of low quality; methodological deficiencies included lack of blinding, reporting of co-interventions, and unclear reporting of loss to follow-up.

The second review included two studies excluded from the first review as not being multidisciplinary (see comments). [32] The first included RCT (457 people, low back pain 8–12 weeks) included in the review used an intervention of light mobilisation and individualised information on prognosis and activity in the setting of a university clinic, while the control was people in primary care. [32] The review reported that the intervention group had an earlier return to work at 1 year (OR 1.60; CI, P value, and absolute numbers not reported), but differences between groups diminished over the second year (reported as not significant; P value not reported). In the third year, sick leave was 127.7 days with the intervention compared with 169.6 days with control (statistical analysis between groups not reported). In the second included study (489 people, described as subchronic low back pain, initial sick leave of 5–11 weeks), consecutive people were assigned by alternate allocation to intervention or control. Control was not specified in the review. The intervention group received a light mobilisation programme based on education and advice, and monitoring of conventional treatment. The review reported that the intervention significantly improved return to work compared with control at 5 years (based on data from an insurance office: 81% with intervention *v* 66% with control; absolute numbers not reported; P <0.001). The review reported that during the follow-up period, 72% of people in the intervention group and 74% of people in the control group had sickness absence because of low back pain (statistical analysis between groups not reported). However, this study was by alternate allocation and the results should be interpreted with caution. [32]

Harms:

The reviews gave no information on adverse effects. [31] [32]

Comment:

The first review included inpatient and outpatient programmes that were multidisciplinary. [31] To be multidisciplinary they had to consist of a physician's consultation plus either a psychological, social, or vocational intervention, or any combination. Trials in which rehabilitation was exclusively or predominantly medical were excluded, and back schools were also excluded from the review. [31] However, multidisciplinary programmes do not always include a psychosocial aspect as is evident in the second review. [32] The second review defined multidisciplinary interventions as those involving two or more healthcare disciplines. [32]

Clinical guide:

Multidisciplinary rehabilitation programmes are typically expensive and may not be necessary for uncomplicated acute low back problems. Multidisciplinary programmes are typically taken to comprise treatments provided by two or more healthcare providers with different professional training to obtain different perspectives and approaches to recovery. The term multidisciplinary does not imply a mandatory roster of specialists and does not dictate the nature of the treatment.

OPTION SPINAL MANIPULATION

Symptom improvement

Compared with placebo or sham treatment Spinal manipulative therapy may be more effective than sham therapy at reducing pain at 6 weeks. However, results were inconsistent between studies and varied by the analysis undertaken. We don't know whether spinal manipulative therapy is more effective than placebo or sham therapy at reducing pain in the longer term (very low-quality evidence).

Functional improvement
Compared with placebo or sham treatment We don't know whether spinal manipulation and chiropractic adjustment are more effective than placebo or sham therapy at improving disability in either the short or long term (low-quality evidence).

Compared with specific back exercise Spinal manipulation may be less likely than McKenzie treatment to increase disability at 5 days and at 4 weeks (low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found two systematic reviews (search dates 2000, 39 RCTs; [33] 2006, 4 RCTs, 149 people [10]) and one subsequent RCT. [34]

Spinal manipulation versus placebo or sham treatment:
The first review found that spinal manipulative therapy significantly reduced pain in the short term (<6 weeks) compared with sham therapy, but found no significant difference in the longer term (short-term difference in pain on 100-mm visual analogue scale: 10 mm, 95% CI 2 mm to 17 mm). [33] The review found no significant difference in either short-term or long-term disability between groups (difference in disability on Roland Disability Questionnaire: short term: +2.8 mm, 95% CI –0.1 mm to +5.6 mm; long term: further data not reported).

The second review identified 4 RCTs (149 people) evaluating the analgesic effects of spinal manipulation estimated by placebo-controlled trials in people with non-specific low back pain. [10] In this review, RCTs using a placebo consisting of what might now be considered to be an active treatment were excluded (see muscle relaxants, p 3 ; see comment). The review extracted data on outcomes from the first assessment after the end of therapy, because the review considered that this time point was where the largest analgesic effects would be observed. It did not include a description of individual interventions used in each RCT. The review found no significant difference between spinal manipulation and placebo in pain (pain measured by analgesic efficacy [100-point scale]: 4 RCTs, 149 people; RR presented graphically; absolute numbers and figures for point estimate of RR and CI not reported; individual RCTs in analysis not reported; see comment). [10] One RCT (192 people) included in the second review compared chiropractic adjustments, muscle relaxants, and placebo, and found no significant difference in disability at 4 weeks among groups. [14]

The subsequent RCT (101 people) compared manipulation plus standard care (general advice and paracetamol, diclofenac, or dihydrocodeine as required, other treatments not allowed) versus standard care alone for 2 weeks. [34] Manipulation was initiated within 24 hours of randomisation, with people undergoing a maximum of 5 sessions within 2 weeks. Manipulation was performed by a specialist in manual medicine, chiropractice, and rheumatology; a specialist in physical medicine; or an osteopath. The RCT found no significant difference between groups in pain at 14 days or 6 months (pain measured by 11-point box scale [BS-11]; 14 days: difference +0.5, 95% CI –0.2 to + 1.2; P = 0.13; 6 months: difference +0.6, 95% CI –0.4 to +1.6; P = 0.22). It found no significant difference between groups in analgesic consumption at 14 days (calculated as diclofenac mg equivalents: difference –18, 95% CI –43 to +7; P = 0.17). There was no significant difference between the proportion of people who were pain free at 6 months (22/50 [44%] with manipulation plus standard care *v* 30/51 [59%] with standard care alone; difference −15%, 95% CI −34% to +4%; P = 0.17). [34]

Spinal manipulation versus other treatments:
The review found no significant difference in pain or function between spinal manipulative therapy and general-practitioner care, physiotherapy, exercises, or back school (results presented graphically). [33]

Spinal manipulation versus back exercises:
See benefits of back exercises, p 22 .

Harms:

Spinal manipulation versus placebo or sham treatment:
The systematic reviews gave no information on adverse effects. [33] [10] Another systematic review assessed harms of spinal manipulation. [35] In RCTs identified by the review that used a trained therapist to select people and perform spinal manipulation, the risk of serious complications was low, with an estimated risk of vertebrobasilar strokes of 1/20,000 to 1/1,000,000 people and risk of cauda equina syndrome of less than 1/1,000,000 manipulations. [36]

One systematic overview of non-pharmacological therapies reported that 5 systematic reviews consistently found that serious adverse events after spinal manipulation (such as worsening lumbar disc herniation or the cauda equina syndrome) were very rare. [37]

In the subsequent RCT, two serious adverse events occurred in the experimental group (4%) and two in the control group (4%). [34] In the manipulation group, there was one person with acute pancreatitis and one person with an acute loss of motor and sensory function of the left lumbar segment L5 due to a herniated disk after randomisation, but before any manipulation treatment was initiated. In the standard care group, one person had a symptomatic cholelithiasis and one person had a femoroacetabular impingement syndrome. The RCT reported that neither of these events seemed to be related to the allocated treatment strategies. [34]

Spinal manipulation versus other treatments:
The review gave no information on adverse effects related to treatment. [33]

Spinal manipulation versus back exercises:
See harms of back exercises, p 22 .

Comment: Spinal manipulation is not advised in people with severe or progressive neurological deficit. [38] The first review included RCTs that compared manipulation or mobilisation for low back pain with another treatment or control (the review noted that manipulation differed from mobilisation in that manipulation focused on a different range of motion of the involved joint — the review reported that both hands-on treatments were included in the review). [33] The second review did not specify what was included under the term spinal manipulative therapy. [10]

The distinction between placebo effects and specific treatment effects is often ill-defined in non-pharmaceutical treatment trials. Thus, the selection of a comparison group often requires considerable thought to ensure that the placebo intervention does not share some of the specific therapeutic components of the experimental intervention. This issue is more of a concern when placebos are designed to resemble the experimental intervention. In some placebo-controlled trials, the placebo treatment is actually used in clinical practice as a treatment. [10]

The lack of identification of RCTs in each analysis in the second review and the lack of descriptions of trials are omissions that make interpretation of results very difficult. [10] On the basis of published studies, there is little evidence of benefit of spinal manipulation.

OPTION ACUPUNCTURE

Symptom improvement
Compared with sham needling or other treatments We don't know whether acupuncture is more effective at reducing pain as we found insufficient evidence (very low-quality evidence).

Functional improvement
Compared with sham needling or other treatments We don't know whether acupuncture is more effective at improving functional status as we found insufficient evidence (very low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits: We found one systematic review (search date 2003; see comment) that identified three RCTs of acupuncture in people with acute low back pain. [39] The review did not pool data. The first included RCT (40 people) found no significant difference in pain or function (measured immediately after the session) between one session of acupuncture on the SI3 acupoint bilaterally, and sham needling of the same point (see comment). The second included RCT (60 people) found no significant difference in pain between acupuncture and naproxen. The third identified RCT (100 people with low back pain, 5 days to 6 months' duration, worse in cold or rainy weather), which was of poor methodological quality, compared acupuncture plus moxibustion (burning a herb at the end of the needle) plus Chinese herbal medicine versus Chinese herbal medicine alone, making it difficult to draw reliable conclusions on the effects of acupuncture alone.

Harms: One systematic review (search date 1996) found that serious, rare, adverse effects included infections (HIV, hepatitis, bacterial endocarditis) and visceral trauma (pneumothorax, cardiac tamponade). [40]

Comment: The first included RCT was reported in abstract form only. The authors of the systematic review obtained additional material from the authors of the RCT. [39] The review concluded that, because of the small sample sizes and low methodological quality of the studies, the data did not allow firm conclusions about the effectiveness of acupuncture in acute low back pain. [39] Many studies of acupuncture are either non-English language papers (which we excluded) or were published in difficult-to-access journals, and thus were not available to review.

OPTION BACK SCHOOLS

Symptom improvement
Compared with placebo or usual care We don't know whether back schools are more effective at improving pain as we found insufficient evidence (very low-quality evidence).

Functional improvement
Back schools plus usual treatment compared with usual treatment alone Back schools plus usual treatment may be no more effective at improving functional status (very low-quality evidence).

Return to work
Compared with placebo or usual care We don't know whether back schools are more effective at reducing sick leave as we found insufficient evidence (very low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits: We found one systematic review (search date 2003, 4 RCTs, see comment below) [41] and one subsequent RCT. [42]

The review did not pool data because of data deficiencies and heterogeneity of trial design. [41] The review assessed the quality of included RCTs against standard criteria and categorised them as being of higher or lower methodological quality (high quality: score of 6 or more on a methodological scale of 0–10). One low-quality RCT (217 people working in a car factory, pain with or without radiation; see comment) identified by the review compared back school, combined physiotherapy (including manual therapy), and placebo (short waves at the lowest intensity). The review found that back school significantly reduced the duration of sick leave compared with placebo (mean days until recovery: 14.8 with back school *v* 28.7 with placebo; median days of absence from work: 20.5 with back school *v* 26.5 with placebo; P value not reported). It found no significant difference between groups in pain at 6 weeks or recurrences during 1 year (P values not reported). A second high-quality RCT (170 people attending a private outpatient clinic, reporting inability to work and receiving compensation) identified by the review compared back school plus usual treatment versus usual treatment alone (including rest, analgesics, NSAIDs as appropriate, daily physiotherapy) and measured outcomes at 8 weeks, 6 months, and 12 months. The review found no significant differences between groups in pain, functional status, median time to return to work, or compensated recurrences over 1 year. A third low-quality RCT (56 people attending a general practitioner, in pain with or without radiation to the thigh; see comment) identified by the review compared back school versus a control treatment (advice not to strain the back, analgesics when required). The review found no significant difference between groups in the proportion of people pain free at 1, 3, or 6 weeks. The fourth high-quality RCT (975 people referred to a spine clinic, on sick leave from work for 8–12 weeks, in pain with or without radiation; see comment) identified by the review compared back school versus usual care. The review found that back school significantly reduced sick leave compared with usual care at 200 days and 5 years (200 days: 30% with back school *v* 60% with usual care; 5 years: 19% with back school *v* 34% with usual care; P values not reported).

In the subsequent RCT (220 people), people were randomly assigned to receive a behavioural videotape or a control videotape (each about 20 minutes in length). [42] The behavioural video indicated that people with acute low back pain may require several weeks of decreased activity while healing. However, after this period, moderate activity and exercises were the best treatment. Return to work as soon as possible was also emphasised. The control video described proper technique and posture when performing daily activities but did not target beliefs or self-management skills. Other than the videotape, usual care was provided to each person. At 12 months' follow-up, the RCT found no significant differences between groups in outcomes (as measured by short form-36 scores [P value not reported], Oswestry Disability Index [P = 0.36], fear avoidance beliefs [FABs] questionnaire [P = 0.32], Pain and Impairment Relationship Scale [P = 0.70], or Spielberger's State-Trait Anxiety Inventory [P = 0.79]). The behavioural participants viewed the videotape significantly more frequently during the final 3 months of the study than did controls (0.86 times with behavioural video *v* 0.55 times with control video; P = 0.008). [42] However, results were based on 111/220 (55%) people initially randomised, so results should be interpreted with caution.

Harms: The review and subsequent RCT gave no information on adverse effects. [41] [42]

Comment: The systematic review included RCTs in which a back-school type intervention was included. A back school was defined as consisting of an educational and skills-acquisition programme, including exercises, in which all lessons were given to groups of people and supervised by a paramedical therapist or medical specialist. [41] The back-school programmes in the 4 included RCTs varied considerably between trials, as did the included populations, making generalisations difficult. Three

RCTs included people with radiating back pain (not further defined), but subgroup analysis of back pain without radiation was not possible. [41] With the explosion in the ways in which information can be disseminated, formal back schools have become far less common than they were previously. The emphasis currently focuses more on general education, often through less-traditional methods such as the internet. In a future update, we will include education on low back pain as a separate intervention.

The distinction between placebo effects and specific treatment effects is often ill-defined in non-pharmaceutical treatment trials. Thus, the selection of a comparison group often requires considerable thought to ensure that the placebo intervention does not share some of the specific therapeutic components of the experimental intervention. This issue is more of a concern when placebos are designed to resemble the experimental intervention. In some placebo-controlled trials, the placebo treatment is actually used in clinical practice as a treatment. [10]

OPTION BEHAVIOURAL THERAPY

Symptom improvement

CBT compared with usual care We don't know whether CBT is more effective than traditional care (analgesics plus back exercises until pain subsides) at reducing low back pain at 9 to 12 months as we found insufficient evidence (very low-quality evidence).

CBT plus generic back exercise compared with no exercise or CBT alone CBT plus neuromuscular training may be more effective at reducing pain intensity at 7 days (low-quality evidence).

CBT plus back exercise compared with back exercise alone We don't know whether CBT plus generic back exercise is more effective than generic back exercise alone at improving pain or severity at up to 6 months' follow-up in people with subacute low back pain (low-quality evidence).

Functional improvement

CBT compared with usual care We don't know whether CBT is more effective than traditional care (analgesics plus back exercises until pain subsides) at improving perceived disability at 9 to 12 months as we found insufficient evidence (very low-quality evidence).

CBT plus generic back exercise compared with no exercise or CBT alone CBT plus neuromuscular training may be no more effective at improving disability at 12 months' follow-up (low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

CBT versus usual care:
We found one systematic review (search date 1995, 1 RCT, 107 people). [25] The poor-quality RCT identified by the review found that CBT significantly reduced pain and perceived disability compared with traditional care (analgesics plus back exercises until pain had subsided) at 9 to 12 months' follow-up (mean score on pain drawing: 1.98 with CBT *v* 3.06 with control; mean claimed impairment: 4.84 with CBT *v* 6.25 with control; scales not defined; P values not reported). [25]

CBT plus back exercise versus no exercise or versus CBT:
See benefits of back exercises, p 22 .

CBT plus back exercise verses exercise alone:
See benefits of back exercises, p 22 .

Harms:

CBT versus usual care:
The review did not report on harms. [25]

CBT plus back exercise versus no exercise or versus CBT:
See harms of back exercises, p 22 .

CBT plus back exercise verses exercise alone:
See harms of back exercises, p 22 .

Comment: None.

OPTION ELECTROMYOGRAPHIC BIOFEEDBACK

We found no direct information from RCTs about the effects of electromyographic biofeedback in people with acute low back pain.

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits: We found no systematic review or RCTs of electromyographic biofeedback in people with acute low back pain.

Harms: We found no evidence on harms.

Comment: None.

OPTION LUMBAR SUPPORTS

Symptom improvement
Compared with no lumbar support An elastic lumbar belt may be more effective than no belt at improving pain (measured by visual analogue scale) at 30 and 90 days in people with subacute low back pain lasting 1 to 3 months. However, evidence was weak (very low-quality evidence).

Functional improvement
Compared with no lumbar support An elastic lumbar belt may be more effective than no belt at improving functional capacity (measured by EIFEL score) at 30 and 90 days in people with subacute low back pain lasting 1 to 3 months. However, evidence was weak (very low-quality evidence).

Note
We found no evidence from RCTs in people with <30 days of low back pain.

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits: We found one RCT (197 people with subacute low back pain, episode lasting 1−3 months), which compared an elastic lumbar belt (with crossed bands and posterior metallic reinforcement) versus control (no belt). [44] The RCT found that the lumbar belt significantly improved functional capacity (as measured by the EIFEL score) at 30 and 90 days (reduction from baseline, score 0−24; 30 days: 5.4 with belt *v* 4.0 with no belt; P = 0.022; 90 days: 7.6 with belt *v* 6.1 with no belt; P = 0.023). The RCT found that the lumbar belt significantly improved pain (as measured by a visual analogue scale [VAS]) at 30 and 90 days (reduction from baseline, VAS 0−100 mm; 30 days: 26.8 with belt *v* 21.3 with no belt; P = 0.038; 90 days: 41.5 with belt *v* 32.0 with no belt; P = 0.002). It also found a significant reduction in the proportion of people who took medication during the trial (no medication: 60.8% with belt *v* 40% with no belt; P = 0.029; absolute numbers not reported). The RCT was not blinded and people in the control group were asked not to purchase a lumbar belt or to wear a lumbar belt during the study. [44]

Harms: Harms associated with prolonged lumbar support use include possible muscle atrophy, sweating, and discomfort. The RCT did not report on adverse effects. [44]

Comment: Supportive studies for usage usually address comfort over biomechanical advantage or protection.

OPTION MASSAGE

Symptom improvement
Compared with placebo massage, sham massage, no massage, or usual care Massage (with or without usual care) may be more effective than usual care alone or placebo massage at improving pain at short-term follow-up (1 week) in people with acute low back pain, but we don't know about at longer term follow-up, and evidence was weak (very low-quality evidence).

Specific back exercise compared with passive treatments A combined analysis of educational booklets, bed rest, ice packs, and massage may be less effective at 7 days than McKenzie treatment at reducing pain (low-quality evidence).

Functional improvement
Compared with placebo massage, sham massage, no massage, or usual care We don't know whether massage is more effective at improving function at short-term follow-up (1 week) in people with acute low back pain (very low-quality evidence).

Specific back exercise compared with passive treatments A combined analysis of educational booklets, bed rest, ice packs, and massage may be less effective than McKenzie treatment at 7 days but not at 4 weeks at reducing disability (low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

Massage versus placebo massage, sham massage, no massage, or usual care:
We found one systematic review (search date 2008, 13 RCTs). [45] The review included massage in both acute and chronic low back pain. Of the 13 RCTs included in the review, two RCTs met our inclusion criteria. The types of massage technique, duration, and frequency of treatments varied among the studies.

The first three-armed RCT (60 people) included in the review compared massage (20 people) versus an inert control group comprising placebo massage therapy (20 people) and waiting list control (20 people). Massage was applied with a mechanical device (one 30-minute session of deep cross-friction massage with the aid of a copper myofascial T-bar [roptrotherapy] applied to the lumbar pelvic region). The review reported that massage was significantly better than placebo and no treatment (waiting list) for reducing pain and improving function at 1 week (mean pain measured by 100-mm visual analogue scale [VAS]; massage *v* placebo massage: SMD −1.08, 95% CI −1.74 to −0.41; massage *v* waiting list: reported as significant; P value not reported; mean function measured by Oswestry Disability Index; massage *v* placebo massage: SMD −2.52, 95% CI −3.37 to −1.67; massage *v* waiting list: reported as significant; P value not reported). [45] The review noted that allocation sequence generation and concealment were unclear and the study was not blinded.

The second RCT (61 people) included in the review compared the addition of massage to usual care (not described in the RCT) versus usual care alone. Massage was acupressure with a specific oil for 8 sessions with relaxation with a digital electronic muscle stimulator on acupoints before the massage. The RCT found that massage plus usual care significantly improved pain at short-term follow-up but not function (pain measured by VAS, mean difference −0.38, 95% CI −0.54 to −0.22; function measured by range of measures such as flexion, walking time, daily activities, mean difference −0.10, 95% CI −0.21 to +0.01). [45] The review reported that the acupuncture massage group had 39% greater reduction in pain intensity than the usual care group at 1 week after the end of treatment (P = 0.0001). It reported that electrical stimulation on acupuncture points followed by acupressure with aromatic lavender oil had no significant effects on housework, work, or leisure time. The review reported that allocation concealment was not clear, participants and carers were not blinded to intervention and assessment, co-interventions were not described, and 16% of people were lost to follow-up.

Massage versus back exercises:
See benefits of back exercises, p 22 .

Harms:

Massage versus placebo massage, sham massage, no massage, or usual care:
The review gave no information on adverse effects. [45]

Massage versus back exercises:
See harms of back exercises, p 22 .

Comment:

The review defined massage as soft tissue manipulation using the hands or a mechanical device (examples include Shiatsu, Rolfing [soft tissue manipulation], Swedish massage, reflexology, craniosacral therapy, as part of physiotherapy, copper myofascial T-bar). [45] Massage could be applied to any body part (lumbar region only or to the whole body) and any technique could be used (e.g., cyriax, friction, kneading, and hacking).

OPTION TEMPERATURE TREATMENTS (SHORT-WAVE DIATHERMY, ULTRASOUND, ICE, AND HEAT)

Symptom improvement
Heat wrap compared with placebo or non-heated wrap Heat wrap is more effective at improving pain relief at 5 days (moderate-quality evidence).

Heat wrap compared with oral analgesic Heat wraps may be more effective than paracetamol (acetaminophen) at improving pain at 1 to 4 days (low-quality evidence).

Heat wrap compared with NSAID (ibuprofen) Heat wraps may be more effective at improving pain at 1 and 4 days (low-quality evidence).

Heat wrap plus NSAID compared with NSAID alone Heat wrap plus NSAID (not specified; taken on an as required basis) may be more effective than NSAID alone (taken on an as required basis) at reducing pain at days 2, 3, and 4 post treatment. However, evidence was weak (very low-quality evidence).

Heat wrap plus education compared with education alone Heat wrap plus education may be more effective at reducing pain intensity but not pain relief at 14 days (low-quality evidence).

Heat wrap alone compared with McKenzie treatment We don't know whether heat wrap is more effective at relieving pain at 2 to 7 days as we found insufficient evidence (low-quality evidence).

Functional improvement
Heat wrap compared with placebo or non-heated wrap Heat wrap is more effective at improving disability at 5 days (moderate-quality evidence).

Heat wrap compared with oral analgesic Heat wraps may be more effective than paracetamol (acetaminophen) at improving disability at 4 days (low-quality evidence).

Heat wrap compared with NSAID (ibuprofen) Heat wraps may be more effective at improving disability at 4 days (low-quality evidence).

Heat wrap plus education compared with education alone Heat wrap plus education may be more effective at improving disability at 14 days (low-quality evidence).

Heat wrap alone compared with McKenzie treatment We don't know whether heat wrap is more effective at improving function at 2 to 7 days as we found insufficient evidence (low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found one systematic review (search date 2005, 5 RCTs, 856 people with acute or subacute low back pain) [46] and two subsequent RCTs [47] [48] assessing the effects of heat treatments on acute low back pain. The review reported that only a small proportion of the data were suitable for pooling (pooling was not possible for most outcomes and comparisons). We found no review or RCTs on the effects of short-wave diathermy, ultrasound, or cold therapies in people with acute low back pain.

Heat wrap versus placebo or non-heated wrap:
The review found that heat wrap therapy significantly improved pain relief, reduced pain, and improved disability at 5 days compared with placebo or non-heated wrap (pain relief [scale range 0–5, higher score favours heat]: 2 RCTs, 258 people; WMD 1.06, 95% CI 0.68 to 1.45; pain [measured using a visual analogue scale, range 0–100, lower score favours heat]: 1 RCT, 90 people; WMD –32.20, 95% CI –38.69 to –25.71; disability [measured using Roland Morris questionnaire, lower score favours heat]: 2 RCTs, 258 people; WMD –2.12, 95% CI –3.07 to –1.18). [46]

Heat wrap versus paracetamol (acetaminophen):
The review found that heat wrap significantly improved pain relief at both 1 and 4 days' treatment, and improved disability at 4 days' treatment compared with paracetamol (acetaminophen) (1 RCT, 226 people; pain relief at 1 day: WMD 0.90, 95% CI 0.50 to 1.30; pain relief at 4 days: WMD 0.74, 95% CI 0.31 to 1.17; disability at 4 days: WMD 2.00, 95% CI 0.86 to 3.14). [46]

Heat wrap versus NSAID (ibuprofen):
The review found that heat wrap significantly improved pain relief at both 1 and 4 days' treatment and improved disability at 4 days' treatment compared with ibuprofen (1 RCT, 226 people; pain relief at 1 day: WMD 0.65, 95% CI 0.25 to 1.05; pain relief at 4 days: WMD 1.05, 95% CI 0.62 to 1.48; disability at 4 days: WMD 2.20, 95% CI 1.11 to 3.29). [46]

Heat wrap plus NSAID versus NSAID alone:
The second subsequent RCT (30 people) compared heat wrap therapy plus oral analgesics (NSAIDs; not specified) as required versus control (oral analgesics [NSAIDs] as required alone). [48] The heat wrap therapy had to be used once a day for at least 4 hours on 4 consecutive days. The heat-delivering device was a single-use commercial product designed like a belt, which wrapped around the stomach and delivered heat to the low back area, providing at least 8 hours of continuous heat at a constant temperature of 40 °C. Both groups were investigated on 5 successive days. Pain was assessed as part of an overall questionnaire that was based on other published validated questionnaires. The RCT found that the heat wrap significantly reduced pain in the evening of the third day (P = 0.20) and fourth day (P = 0.042) and significantly reduced the proportion of people who woke with pain on the second day (P = 0.016), third day (P = 0.002), and fourth day (P = 0.001; all results presented graphically; absolute numbers not reported). The RCT reported that of 38 people enrolled in the study, only 30 completed all measurements. It was unclear whether the additional 8 participants had been initially randomised. The RCT reported that assignment to the two groups followed a randomisation list in the order that people were recruited by the orthopaedist; no further details were reported. [48]

Heat wrap plus education versus education alone:
The first subsequent RCT (43 people) compared topical heat wrap (worn during daytime hours for 3 consecutive days) plus education versus education alone. [47] At 14 days after initial treatment, the RCT found that combined treatment of heat wrap plus education significantly reduced pain intensity and significantly improved disability compared with education alone (difference between groups adjusted for sex, age, baseline pain intensity, and pain medication use: pain intensity: –1.75, 95% CI –3.33 to –0.18; P = 0.030: disability: –4.33, 95% CI –8.41 to –0.27; P = 0.038). The RCT found that heat wrap plus education significantly increased pain relief at 4 days compared with education alone, but the difference between groups was not significant at 14 days (difference between groups adjusted for sex, age, baseline pain intensity, and pain medication use: 4 days: 1.13, 95% CI 0.11 to 2.14; P = 0.03: 14 days: +0.80, 95% CI –0.33 to +1.93; P = 0.157). Pain intensity was measured as a change in a visual analogue scale (VAS [where 0 = no pain and 10 = pain as bad as it could be]) and disability was measured using the Roland Morris questionnaire. Education comprised distribution of written material describing low back pain covering, for example, the recognition and treatment of symptoms.

Heat wrap alone versus McKenzie treatment:
The review found no significant difference between heat wrap and McKenzie treatment in pain relief or function at 2 or 7 days' follow-up (1 RCT, 50 people; pain relief [higher score favours heat]; 2 days: 1.40 with heat wrap *v* 1.00 with McKenzie treatment; WMD +0.40, 95% CI –0.15 to +0.95; 7 days: 2.30 with heat wrap *v* 2.00 with McKenzie treatment; WMD +0.30, 95% CI –0.68 to +1.28; function: 2 days: –0.90 with heat wrap *v* –0.20 with McKenzie treatment; WMD –0.70, 95% CI –2.09 to +0.69; 7 days: –2.80 with heat wrap *v* –2.30 with McKenzie treatment; WMD –0.50, 95% CI –2.72 to +1.72). [46]

Harms:

Heat wrap versus placebo or non-heated wrap:
The review reported that skin pinkness, which resolved quickly, was reported as an adverse effect of heat wrap therapy. [46] The first subsequent RCT reported that no serious adverse effects were associated with heat wrap treatment. [47]

Heat wrap versus paracetamol (acetaminophen):
For harms associated with paracetamol, see harms of analgesics, p 9 .

Heat wrap versus NSAID (ibuprofen):
For harms associated with ibuprofen, see harms of NSAIDs, p 5 .

Heat wrap plus NSAID versus NSAID alone:
The RCT gave no information on adverse effects. [48]

Heat wrap plus education versus education alone:
The RCT gave no information on adverse effects. [47]

Heat wrap alone versus McKenzie treatment:
The review gave no information on specific adverse effects for this comparison. [46]

Comment: Of the 5 RCTs identified in the review, one was in people with acute low back pain, and 4 were in people with subacute low back pain. [46] Four RCTs declared receipt of industry funding.

OPTION TRACTION

We found no clinically important results from RCTs about the effects of traction in people with acute low back pain.

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits: We found no systematic review or RCTs of traction in people with acute low back pain.

Harms: We found no RCTs.

Comment: None.

OPTION TENS

Symptom improvement
Compared with placebo We don't know whether TENS is more effective than placebo at improving pain in people with acute low back pain (very low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits: **TENS versus placebo:**
We found one systematic review (search date 2006), [10] which identified two RCTs reporting on the analgesic effects of TENS estimated by placebo-controlled trials in people with non-specific acute low back pain. In this review, RCTs using a placebo consisting of what might now be considered to be an active treatment were excluded (see benefits of muscle relaxants, p 3). The review extracted data on outcome from the first assessment after the end of therapy, because the review considered that this time point was where the largest analgesic effects would be observed. It did not include a description of individual interventions used in each RCT. The review found no significant difference between TENS and placebo in pain (measured by analgesic efficacy [100-point scale]) compared with placebo (2 RCTs, 121 people; RR presented graphically; absolute numbers and figures for point estimate of RR and CI not reported; individual RCTs in analysis not reported).

Harms: **TENS versus placebo:**
The review did not report on harms. [10]

Comment: None.

OPTION BACK EXERCISES

Symptom improvement
Generic back exercise compared with usual care or no treatment (acute low back pain of <6 weeks' duration) We don't know whether exercise is more effective at improving pain as we found insufficient evidence (very low-quality evidence).

Generic back exercise compared with non-exercise interventions (acute and subacute low back pain) We don't know whether exercise is more effective at improving pain as we found insufficient evidence (low-quality evidence).

Generic back exercise plus CBT compared with no exercise or CBT alone Neuromuscular training plus CBT may be more effective at reducing pain intensity at 7 days (low-quality evidence).

Generic back exercise compared with CBT plus exercise We don't know whether generic back exercise plus CBT is more effective than generic back exercise alone at improving pain or severity at up to 6 months' follow-up in people with subacute low back pain (low-quality evidence).

Specific back exercise compared with passive treatments McKenzie treatment may be more effective than a combined analysis of educational booklets, bed rest, ice packs, and massage at reducing pain at 7 days (low-quality evidence).

Specific back exercise compared with advice to stay active McKenzie treatment is no more effective at reducing pain intensity at 12 weeks (moderate-quality evidence).

Specific back exercise compared with flexion exercises We don't know whether McKenzie treatment is more effective at reducing pain at 8 weeks as we found insufficient evidence (low-quality evidence).

Specific back exercise compared with back school McKenzie treatment may be more effective at improving pain at 1 year (low-quality evidence).

Functional improvement
Generic back exercise compared with usual care or no treatment (acute and subacute back pain) We don't know whether exercise is more effective at improving function as we found insufficient evidence (very low-quality evidence).

Generic back exercise compared with non-exercise interventions (acute and subacute low back pain) We don't know whether exercise is more effective at improving function (low-quality evidence).

Generic back exercise plus CBT compared with no exercise or CBT alone Neuromuscular training plus CBT may be no more effective at improving disability at 12 months' follow-up (low-quality evidence).

Specific back exercise compared with passive treatments McKenzie treatment may be more effective at reducing disability at 7 days but not at 4 weeks compared with a combined analysis of educational booklets, bed rest, ice packs, and massage (low-quality evidence).

Specific back exercise compared with advice to stay active McKenzie treatment seems to increase disability at 12 weeks (moderate-quality evidence).

Specific back exercise compared with flexion exercises McKenzie treatment may be more effective at improving disability scores at 5 days (very low-quality evidence).

Specific back exercise compared with spinal manipulation McKenzie treatment may increase disability at 5 days and at 4 weeks (low-quality evidence).

Specific back exercise compared with NSAIDs We don't know whether McKenzie treatment is more effective at 3 months at improving short-term disability as we found insufficient evidence (low-quality evidence).

Return to work
Generic back exercise compared with usual care or no treatment (subacute low back pain of 6–12 weeks' duration) We don't know whether exercise is more effective at reducing absenteeism in the work place or at reducing time taken to return to work as we found insufficient evidence (very low-quality evidence).

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found three systematic reviews [49] [50] [51] and three subsequent RCTs. [52] [53] [43] The first review (search date 2004, 17 RCTs, see comment) included RCTs of back exercises versus placebo, no treatment, or other conservative treatments. [49] The second review (search date 2003, 6 RCTs, 518 people) included RCTs of McKenzie treatment versus passive treatment, advice to stay active, flexion exercises, spinal manipulation, back school, or strengthening. [50] The third review (3 RCTs, number of people included not clear) included RCTs of McKenzie treatment versus the NSAID ketoprofen, massage/advice, or passive movement/mobilisation. [51] The methodological quality of RCTs identified by the first review was assessed by the adequacy of 4 criteria: randomisation, allocation concealment, follow-up, and outcome blinding. [49] Studies were classed as high quality if they met all 4 criteria. The review identified 11 RCTs in people with acute back pain and 6 RCTs in people with subacute back pain; one RCT in each group was categorised as being of high quality. Methodological quality in the second and third reviews was based on the PEDro scale. [50] The second review identified 5 RCTs in people with acute low back pain, one RCT in people with subacute low back pain, and three RCTs in a mixed population of acute/subacute low back pain; all but one of the identified RCTs were high quality (score of 5+/10). [50] In the third review, two of the three RCTs identified were high quality (5+/10). [51] The first and second reviews identified 6 RCTs, one of which was also identified by the third review (see comment). The second and third reviews identified three RCTs assessing the effects of McKenzie treatment (see comment). [50] [51] All three reviews defined the included RCTs as either acute (<6 weeks' duration), subacute (6–12 weeks' duration), or duration not subgrouped (<12 weeks). The first review used both a qualitative rating system and a quantitative pooling of data where possible. [49] The second review pooled data (only statistically homogeneous RCTs) to compare the McKenzie treatment versus passive therapy (combined data on educational booklet, ice packs, massage, and bed rest) and advice to stay active (random effects model). [50] The third review transformed pain and disability scores to a score ranging from 0 to 100. To describe treatment effect for individual studies, mean and 95% confidence intervals were calculated for between-group differences (see comment). [51] The second review pooled data based on treatments, whereas the third review pooled data based on outcomes, and so, here, we report meta-analyses from only the second review.

Generic back exercise versus usual care or no treatment for acute low back pain (<6 weeks' duration):
The first review reported that 10 of 11 RCTs identified had non-exercise comparisons. [49] The review found no significant difference between generic exercise and no treatment in change in pain or function measured at the earliest follow-up (scale 0–100; pain: 3 RCTs, 491 people; WMD –0.59, 95% CI –12.9 to +11.51; function: 3 RCTs, 491 people; WMD –2.82, 95% CI –15.35 to +9.71; see comment). One high-quality RCT in an occupational setting found that mobilising home exercises were less effective than usual care, and one low-quality RCT in a healthcare setting found that a therapist-delivered endurance programme improved short-term functioning more than no treatment. Of the remaining 8 RCTs, 6 studies identified by the review found no statistically significant or clinically important difference between exercise therapy and usual care/no treatment, and the results of two RCTs were unclear. [49]

Generic back exercise versus usual care or no treatment for subacute low back pain (6–12 weeks' duration):
The first review reported that, in 6 included RCTs, 7 exercise groups (total number of exercise groups not reported) had a non-exercise comparison. [49] One high-quality and one low-quality RCT found that a graded exercise intervention reduced absenteeism outcomes in the workplace compared with usual care, and one low-quality RCT found improved functioning with exercise plus behavioural therapy compared with usual care. Two poor-quality RCTs found no difference in outcomes between exercise and the comparative treatments (including usual care), and one poor-quality RCT reported unclear results. One subsequent RCT (134 people with low back pain for at least 4 weeks before inclusion) compared graded exercise versus usual care. [52] The RCT found no significant difference in pain severity (11-point visual analogue scale [VAS]: 0 = no pain to 10 = very severe pain) or functional status (Roland Disability Questionnaire) between graded exercise

and usual care, although there were greater improvements in both outcomes with graded exercise (between-group difference at 12 months: pain severity [favours graded exercise]: –0.2, 95% CI –1.2 to +0.8; P = 0.67: functional status [favours graded exercise]: –0.6, 95% CI –2.8 to +1.5; P = 0.56). The RCT found that people assigned to the graded-exercise group returned to work faster than those assigned to usual care (median duration of first continuous period of sick leave after randomisation: 54 days with graded activity *v* 67 days with usual care; significance not assessed). Graded exercise consisted of twice-weekly exercise sessions lasting 60 minutes each until the people either achieved full return to work, or the maximum therapy duration of 3 months had been completed.

Generic back exercise versus non-exercise interventions for acute low back pain (<6 weeks' duration):
The first review found no significant difference between exercise and other conservative treatments (advice to stay active, education, and usual care) in change in pain or function measured at the earliest follow-up (scale 0–100; pain: 7 RCTs, 606 people; WMD +0.31, 95% CI –0.10 to +0.72; function: 6 RCTs, 534 people; WMD –1.34, 95% CI –5.5 to +2.81). [49] Results were similar at intermediate and long-term follow-up.

Generic back exercise versus non-exercise interventions for subacute low back pain (6–12 weeks' duration):
The first review found no significant difference between exercise and all other comparisons (including no treatment, usual care, advice to stay active, and education) in change in pain or function measured at the earliest follow-up (scale 0–100; pain: 5 RCTs, 608 people; WMD –1.89, 95% CI –4.91 to +1.13; function: 4 RCTs, 579 people; WMD –1.07, 95% CI –5.32 to +3.18). [49] Results were similar at intermediate follow-up. The review concluded that there was insufficient evidence to support or refute the effectiveness of exercise for pain or function in subacute low back pain.

Generic back exercise plus CBT versus no exercise or CBT alone:
The second subsequent RCT (106 men with low back pain during the 3 months before study enrolment) compared neuromuscular training plus CBT versus no exercise or CBT. [53] At 12 months, the RCT found that neuromuscular training plus CBT significantly decreased pain intensity (visual analogue scale [VAS]) for the 7 days before assessment compared with no treatment (80 people; change in VAS from baseline: from 9.9 to 5.5 with neuromuscular training plus CBT *v* from 11.8 to 10.2 with no treatment; P = 0.032). There was no significant difference between groups in intensity of back pain for the 2 months before assessment, although a greater improvement in pain was reported by the group receiving neuromuscular training plus CBT (80 people; change in VAS from baseline: from 15.3 to 8.6 with neuromuscular training plus CBT *v* from 15.8 to 14.3 with no treatment; P = 0.052). The RCT found no significant difference between treatments in disability (Oswestry Disability Index [ODI]) at 12 months (84 people; change in ODI from baseline: from 5.6 to 4.8 with neuromuscular training plus CBT *v* from 5.8 to 5.0 with no treatment; P = 0.88). Neuromuscular training plus CBT consisted of neuromuscular training plus counselling with cognitive-behavioural goals for improved lumbar stability (2 sessions/week, one of which was physiotherapist-led and the other independent): the exercise programme consisted of 10 generic exercises.

Generic exercise versus CBT plus exercise:
The third subsequent RCT (47 people with subacute low back pain) compared a control group who only received physiotherapy in the form of generic exercises versus an intervention group who received the exercise treatment plus a CBT programme. [43] The CBT programme was conducted by a psychologist and took place independently of the physiotherapy treatment. For pain intensity (measured by 10-point VAS), there were no significant differences between groups after the last physiotherapy session (P = 0.81), 3 months later (P = 0.12), or 6 months later (P = 0.075). For overall severity (measured by the question "how severe do you think your back problems are?" and scored 1–4), there was no significant difference between groups after the last physiotherapy session (P = 0.22), or at 3 months (P = 0.98), although there was a significant difference between groups at 6 months (P = 0.004). [43]

Specific back exercise (McKenzie treatment) versus usual care or no treatment:
The reviews identified no RCTs for this comparison. [50] [51]

Specific back exercise (McKenzie treatment) versus passive treatments (combined analysis of educational booklets, bed rest, ice packs, and massage):
The second review (4 RCTs, 681 people) found that McKenzie treatment significantly decreased pain and disability at 1 week compared with passive therapy (combined data on educational booklets, bed rest, ice packs, and massage) (2 RCTs, 470 people; pain: WMD –4.16, 95% CI –7.12 to –1.20; disability: WMD –5.22, 95% CI –8.28 to –2.16; absolute numbers and P values not reported). [50] However, there was no significant difference between groups in disability at 4 weeks (3 RCTs, 495 people; WMD –1.06, 95% CI –3.21 to +1.10; absolute numbers and P value not reported).

Specific back exercise (McKenzie treatment) versus advice to stay active:
The second review found a significant increase in disability after 12 weeks' treatment with the McKenzie treatment compared with advice to stay active (2 RCTs, 261 people; WMD [0–100 point scale] 3.85, 95% CI 0.30 to 7.39; absolute numbers not reported; P value not reported). [50] There was no significant difference between groups in pain intensity at 12 weeks (WMD +5.02, 95% CI –1.19 to +11.22; absolute numbers not reported).

Specific back exercise (McKenzie treatment) versus flexion exercises:
The second review did not pool data for this comparison because of clinical and statistical heterogeneity among studies. [50] The review identified two RCTs that met *Clinical Evidence* inclusion criteria. One high-quality RCT (149 people with acute low back pain with or without radiation) identified by the review found no significant difference between treatment groups in pain at 8 weeks (data presented graphically; reported as not significant; P value not reported). [54] One low-quality RCT (24 people) [55] identified by the review [50] found a greater improvement in mean disability scores (ODI) at 5 days' follow-up with McKenzie treatment compared with flexion exercise (data presented graphically in the RCT; no further details reported: mean difference [0 to 100-point scale] between groups reported in the review: –22 points, 95% CI –26 points to –18 points). [50] [55]

Specific back exercise (McKenzie treatment) versus back school:
The second review identified one RCT (100 people with acute or subacute low back pain and with or without radiating pain) that met *Clinical Evidence* inclusion criteria. [50] The RCT found that McKenzie treatment decreased pain at 1 year compared with back school (absolute numbers not reported; P <0.001). [56] A 5-year follow-up study of the RCT identified by the review found that McKenzie treatment significantly decreased the proportion of people on sick leave at 5 years compared with back school (24/47 [51%] with McKenzie treatment *v* 31/42 [74%] with back school; P <0.03). [57]

Specific back exercise (McKenzie treatment) versus spinal manipulation:
The second review identified one high-quality RCT (24 people with acute or subacute low back pain [58]) that met *Clinical Evidence* inclusion criteria. [50] The RCT did not carry out a statistical analysis. [58] The review found a significant increase in disability (ODI) with McKenzie treatment at 5 days and 4 weeks compared with spinal manipulation (mean difference [0 to 100-point scale]; 5 days: 17 points, 95% CI 8 points to 27 points; 4 weeks; 22 points, 95% CI 10 points to 33 points). [50]

Specific back exercise (McKenzie treatment) versus NSAIDs:
The third review (1 RCT, 260 people) found no significant difference in short-term disability between McKenzie treatment and the NSAID ketoprofen (follow-up at <3 months), although results favoured McKenzie treatment (mean AR –4.2, 95% CI –9.8 to +1.4; absolute numbers not reported). [51]

Harms:

Generic back exercise versus usual care or no treatment for acute low back pain:
The first review reported that few identified RCTs reported on harms (about 26% of RCTs). [49] Overall, in the review (which included RCTs on acute, subacute, and chronic low back pain), 12 RCTs reported mild negative reactions associated with the exercise programme, such as increased low back pain, and soreness in a minority of people; [49] although this is a natural and innocuous reaction, particularly in those starting an exercise programme for the first time or after prolonged inactivity. No further details were provided. The subsequent RCTs gave no information on adverse effects. [52] [53]

Generic back exercise versus usual care or no treatment for subacute low back pain:
See harms of back exercises versus usual care or no treatment for acute low back pain.

Generic back exercise versus non-exercise interventions for acute low back pain:
The review gave no information on adverse effects for this comparison (see harms of back exercises versus usual care or no treatment for acute low back pain). [49]

Generic back exercise versus non-exercise interventions for subacute low back pain:
The review gave no information on adverse effects for this comparison (see harms of back exercises versus usual care or no treatment for acute low back pain). [49]

Generic back exercises plus CBT versus no exercise or CBT alone:
The RCT gave no information on adverse effects. [53]

Generic exercise versus CBT plus exercise:
The RCT gave no information on adverse effects. [43]

Specific back exercise (McKenzie treatment) versus usual care or no treatment:
The reviews identified no RCTs for this comparison. [50] [51]

Specific back exercise (McKenzie treatment) versus passive treatments (combined analysis of educational booklets, bed rest, ice packs, and massage):
The review gave no information on adverse effects for this comparison. [50]

Specific back exercise (McKenzie treatment) versus advice to stay active:
The review gave no information on adverse effects for this comparison. [50]

Specific back exercise (McKenzie treatment) versus flexion exercises:
The review gave no information on adverse effects for this comparison. [50]

Specific back exercise (McKenzie treatment) versus back school:
The review gave no information on adverse effects for this comparison. [50]

Specific back exercise (McKenzie treatment) versus spinal manipulation:
The review gave no information on adverse effects for this comparison. [50]

Specific back exercise (McKenzie treatment) versus NSAIDs:
The review gave no information on adverse effects for this comparison (see review on NSAIDs). [51]

Comment:

There was considerable variation in the exercise programmes undertaken in RCTs identified by the reviews. In the first review, subgroup meta-analysis for different specific types of exercise, or comparisons against specific individual conservative treatments were not reported. [49] The review included RCTs of exercise, this being defined as "a series of specific movements with the aim of training or developing the body by a routine practice or as physical training to promote good physical health". Individual RCT outcome data for pain and function were converted to a scale from 0 to 100 points to allow the pooling of data. The review considered that a 20-point (out of 100) improvement in pain and a 10-point (out of 100) improvement in functional outcomes were clinically important differences. The review categorised populations of included RCTs as being healthcare (primary, secondary, or tertiary), occupational (occupational healthcare, in compensatory situations), and general or mixed (e.g., people recruited through advertisement for trials), to differentiate those studies in people in typical treatment settings (healthcare, occupational) from those in people who may not normally present for treatment. The review noted that, overall, the methodological quality of included RCTs was poor, with only 54% adequately describing the exercise intervention. The second review concluded that, when evaluating treatment effects of individual RCTs, the McKenzie approach was as effective at all follow-up times as an educational booklet, advice to stay active, and strengthening exercises. Comparisons with flexion exercises and spinal manipulative therapy yielded statistically significant differences favouring McKenzie treatment; however, no placebo-controlled trial was identified. [50] In the first subsequent RCT, it is not clear which component of the complex intervention — the graded activity instruction, the exercises, or the combination of both modalities — is the most important. Because no placebo therapy was used, the attention of the therapist may have had a role in the positive effects. [52] A possible criticism of generic-exercise studies is that all patients in the exercise groups receive the same treatment, regardless of a patient's preference for extension or flexion exercises. According to the McKenzie system, this type of pre-selection is essential to determine a directional preference for certain exercises.

Clinical guide:
For specific exercises, there is a growing, but still limited, evidence for short-term pain reduction and increased function. Given the methodological flaws mentioned above, and the lack of relevant detail of the primary studies, it is not possible to either support or oppose the use of exercise in patients with acute low back pain.

OPTION BED REST

Symptom improvement
Compared with advice to stay active Bed rest is less effective at reducing pain at 3 to 12 weeks post episode (moderate-quality evidence).

Functional improvement
Compared with advice to stay active Bed rest is less effective at improving functional outcomes at 3 to 12 weeks post episode (moderate-quality evidence).

Different lengths of bed rest compared with each other Three days and 7 days of bed rest may be equally effective at reducing pain intensity (low-quality evidence).

Return to work
Compared with advice to stay active Bed rest seems less effective than advice to stay active at reducing initial sick leave and sick leave at 3 to 4 weeks and 12 weeks in people with acute low back pain (moderate-quality evidence).

Note
Bed rest has been associated with joint stiffness, muscle wasting, loss of bone mineral density, pressure sores, and venous thromboembolism.

For GRADE evaluation of interventions for low back pain (acute), see table, p 31 .

Benefits:

We found one systematic review (search date 2003, 11 RCTs, 1963 people; see comment). [59] The systematic review assessed the methodological quality of included RCTs against standard criteria and categorised them as being of low, moderate, or high risk of bias (see comment). [59]

Bed rest versus advice to stay active:
The systematic review included two RCTs at moderate/low risk of bias in a meta-analysis (see comment). The review found that advice to stay active significantly reduced pain and significantly improved functional status at 3 to 4 weeks' follow-up and at 12 weeks' follow-up compared with bed rest (pain: 2 RCTs, 400 people; 3–4 weeks: SMD 0.22, 95% CI 0.02 to 0.41; 12 weeks: SMD 0.25, 95% CI 0.05 to 0.45; functional status: 2 RCTs, 400 people; 3–4 weeks: SMD 0.29, 95% CI 0.09 to 0.49; 12 weeks: SMD 0.24, 95% CI 0.04 to 0.44). [59] The first RCT identified by the review found that advice to stay active significantly reduced sick leave at 3 to 4 weeks' follow-up and at 12 weeks' follow-up compared with bed rest (3–4 weeks: WMD 3.4 days, 95% CI 1.64 days to 5.16 days; 12 weeks: WMD 4.5 days, 95% CI 1.37 days to 7.63 days). The second RCT identified by the review found that bed rest increased initial sick leave compared with advice to stay active in people followed up at 12 weeks (86% with bed rest *v* 52% with advice to stay active; P <0.001). [59]

Different lengths of bed rest:
One included RCT (47 people) at low risk of bias found no significant difference in pain intensity between 3 days and 7 days of bed rest measured 2 days after the end of treatment. [59]

Bed rest versus exercise:
The review identified two RCTs at low risk of bias. [59] It reported that the first RCT found no significant difference between advice to rest in bed and exercise in pain or restrictions in activities of daily living at 6 weeks, 12 weeks, and 1 year of follow-up. [59] The review reported that the second RCT found no significant difference between advice to rest in bed and exercise in pain, functional status, or sick leave at 3 and 12 weeks' follow-up. [59]

Bed rest versus other treatments:
One included RCT at low risk of bias compared advice to rest in bed versus bed rest plus exercise plus education versus no instruction. The review found no significant difference in pain or restrictions of daily activities between any of the treatment groups (statistical analysis not reported). [59] The review reported that one other included RCT at high risk of bias found no difference in improvement on a combined pain, disability, and physical exam score between bed rest and manipulation, drug therapy, physiotherapy, back school, or placebo (statistical analysis not reported). [59]

Harms:

The review gave no information on adverse effects. [59] One previous systematic review assessing harms [28] found that adverse effects of bed rest included joint stiffness, muscle wasting, loss of bone mineral density, pressure sores, and venous thromboembolism (see review on thromboembolism).

Comment:

The review based classification of bias on 4 criteria: concealment of allocation, co-interventions, intention-to-treat analysis or losses to follow-up, and blinding of outcome assessor. [59] The review separately analysed: RCTs that included people with acute low back pain, with or without radiating pain, but excluded people with neurological deficits (called the acute simple low back pain group); RCTs that included people with verified neurological deficits (called the sciatica group); and RCTs that had included people with and without verified neurological deficits (called the mixed low back pain group). [59] We have only reported the results for the acute simple low back pain group here. However, within this group the proportion of people with radiating pain to the legs varied from none in some RCTs to 30% of the study population in others.

Bed rest versus advice to stay active:
In the analysis comparing advice to stay active versus bed rest for pain, one RCT that found significantly better pain outcomes for bed rest compared with advice to stay active was excluded from the meta-analysis: the RCT was categorised as being at high risk of bias, and the applicability of the included population (80 male combat trainees in an army hospital) to the general population

was questionable. [59] This RCT also found that bed rest significantly reduced length of sick leave compared with advice to stay active. [59]

GLOSSARY

Back school Traditionally, this is a series of group education sessions on low back pain. Sessions are usually supervised by a physiotherapist or physician and often include information on an exercise programme.

Cognitive behavioural therapy This aims to identify and modify people's understanding of their pain and disability using cognitive restructuring techniques (such as imagery and attention diversion) or by modifying maladaptive thoughts, feelings, and beliefs.

Electromyographic biofeedback A person receives external feedback of their own electromyogram (using visual or auditory scales), and uses this to learn how to control the electromyogram and hence the tension within their own muscles. Electromyogram biofeedback for low back pain aims to relax the paraspinal muscles.

Acupuncture Needle puncture of the skin at traditional "meridian" acupuncture points. Modern acupuncturists also use non-meridian points and trigger points (tender sites occurring in the most painful areas). The needles may be stimulated manually or electrically. Placebo acupuncture is needling of traditionally unimportant sites or non-stimulation of the needles once placed.

Cesar therapy Exercise programme to improve posture and so reduce back pain caused by poor posture.

Generic back exercise (low back pain) In this review, generic back exercise denotes undifferentiated exercise/movements performed in multiple directions or planes without emphasis on the person's pattern of pain or directional preference for pain control.

Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

McKenzie (direction-specific) exercise A method of physiotherapy that involves a comprehensive mechanical diagnosis and treatment to assess the effects on patient symptoms of end-range repetitive movements, static positioning, or both. The mechanical diagnosis enables physiotherapists to prescribe individual exercises in a specific preferred direction. The emphasis is on patient responsibility and self-treatment. Mobilisation techniques are used in more difficult mechanical cases until patients can perform the prescribed exercises on their own.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Multidisciplinary treatment Intensive physical and psychosocial training by a team (e.g., a physician, physiotherapist, psychologist, social worker, and occupational therapist). Training is usually given in groups and does not involve passive physiotherapy.

Sciatica Radicular leg pain emanating from irritation in one of the roots of the sciatic nerve and following the nerve's distribution.

Very low-quality evidence Any estimate of effect is very uncertain.

SUBSTANTIVE CHANGES

Analgesics (paracetamol, opioids) New evidence added. [19] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Back exercises New evidence added. [43] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Back schools New evidence added. [42] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Behavioural therapy New evidence added. [43] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Lumbar supports New evidence added. [44] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Massage New evidence added. [45] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Multidisciplinary treatment programmes (subacute low back pain) New evidence added. [32] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Muscle relaxants New evidence added. [10] [13] [18] Categorisation unchanged (Trade-off between benefits and harms).

NSAIDs New evidence added. [10] [19] [21] Categorisation unchanged (Trade-off between benefits and harms).

TENS New evidence added. [10] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Temperature treatments (short-wave diathermy, ultrasound, ice, and heat) New evidence added. [48] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Spinal manipulation One systematic review (149 people) [10] and one subsequent RCT (101 people) [34] added at this update. The review and RCT found no significant difference between spinal manipulation and placebo or usual care in pain. One further study added in harms which reports on adverse effects after spinal manipulation. [37] Categorisation of spinal manipulation changed from Likely to be beneficial to Unknown effectiveness.

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Greg McIntosh
Epidemiologist, Manager of Clinical Research
CBI Health Group Research Dept
Toronto, ON
Canada

Hamilton Hall
Medical Director
CBI Health Group
Toronto, ON
Canada

Competing interests: GM and HH declare that they have no competing interests.

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TABLE **GRADE evaluation of interventions for low back pain (acute)**

Important outcomes	Symptom improvement, functional improvement, return to work, adverse effects								
Number of studies (participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
What are the effects of oral drug treatments for acute low back pain?									
1 (68) [12]	Symptom improvement	Benzodiazepine muscle relaxants *v* placebo	4	−3	0	−1	0	Very low	Quality points deducted for sparse data, baseline differences, and incomplete reporting of results, and for poor-quality RCT. Directness point deducted for uncertainty about method of rating improvement
At least 9 RCTs (at least 1039) [10] [11] [13]	Symptom improvement	Non-benzodiazepine muscle relaxants *v* placebo	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for unclear interventions
1 (192) [14]	Functional improvement	Non-benzodiazepine muscle relaxants *v* placebo	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
4 (278) [11] [15] [16] [18]	Symptom improvement	Muscle relaxants *v* each other	4	−2	0	0	0	Low	Quality points deducted for incomplete reporting of results and weak methods (unclear scale assessment, comorbidity)
At least 4 (at least 724) [10] [19]	Symptom improvement	NSAIDs *v* placebo	4	−1	0	−2	0	Very low	Quality point deducted for incomplete reporting of results. Directness points deducted for inclusion of people with sciatica in 1 analysis and unclear interventions
8 (1768) [19] [20] [21]	Symptom improvement	NSAIDs *v* each other	4	−2	0	0	0	Low	Quality points deducted for incomplete reporting of results and weak methods in 2 RCTs
1 (323) RCT [21]	Functional improvement	NSAIDs *v* each other	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for small number of comparators
3 (297) [19]	Symptom improvement	NSAIDs *v* paracetamol (acetaminophen)	4	−2	0	−1	0	Very low	Quality points deducted for unclear allocation concealment and randomisation by military number in 1 RCT. Directness point deducted for restricted population in 2 RCTs
1 (80) [19]	Symptom improvement	NSAIDs *v* muscle relaxants	4	−2	0	−1	0	Very low	Quality points deducted for weak methods and sparse data. Directness point deducted for co-intervention (paracetamol)
1 (108) [19]	Symptom improvement	NSAIDs *v* non-drug treatments (physiotherapy or spinal manipulation)	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (40) [19]	Symptom improvement	NSAIDs *v* NSAIDs plus adjuvant treatment	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
2 (113) [25]	Symptom improvement	Analgesics *v* non-drug treatments	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for uncertainty about drugs in comparison
1 (119) [26]	Symptom improvement	Combination analgesics *v* analgesics alone	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for narrow range of comparators
What are the effects of non-drug treatments for acute low back pain?									

Important outcomes	Symptom improvement, functional improvement, return to work, adverse effects								
Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
Unclear (unclear) [28]	Return to work	Advice to stay active *v* no advice or traditional medical treatment	4	−1	0	−2	0	Very low	Quality point deducted for incomplete reporting of results. Directness points deducted for mixed comparison groups, use of co-interventions, and unclear effect sizes limiting generalisability
Unclear (unclear) [28]	Functional improvement	Advice to stay active *v* no advice or traditional medical treatment	4	−1	0	−2	0	Very low	Quality point deducted for incomplete reporting of results. Directness points deducted for mixed comparison groups, use of co-interventions, and unclear effect sizes limiting generalisability
1 (92) [29] [30]	Symptom improvement	Multidisciplinary treatment programme (for acute low back pain) *v* usual care	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for inclusion of co-interventions
1 (92) [29] [30]	Functional improvement	Multidisciplinary treatment programme (for acute low back pain) *v* usual care	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for inclusion of co-interventions
1 (92) [29] [30]	Return to work	Multidisciplinary treatment programme (for acute low back pain) *v* usual care	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for inclusion of co-interventions
4 (1179) [31] [32]	Return to work	Multidisciplinary treatment programmes (for subacute low back pain) *v* usual care	4	−3	0	−2	0	Very low	Quality points deducted for incomplete reporting of results, alternate allocation in 1 study, and weak methods (including blinding, co-interventions). Directness points deducted for no direct statistical analysis in 1 study and wide variation of interventions between studies
At least 5 (at least 250) [10] [33] [34]	Symptom improvement	Spinal manipulation *v* placebo/sham treatment	4	−1	−1	−1	0	Very low	Quality point deducted for incomplete reporting of results. Consistency point deducted for conflicting results (between studies, between short and long term). Directness point deducted for unclear interventions used
At least 2 (at least 192) [14] [33]	Functional improvement	Spinal manipulation *v* placebo/sham treatment	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for unclear interventions used
3 (200) [39]	Symptom improvement	Acupuncture *v* sham needling or other treatments	4	−3	0	−2	0	Very low	Quality points deducted for incomplete reporting of results and weak methodologies. Directness points deducted for uncertainty about benefit and for inclusion of other interventions
1 (40) [39]	Functional improvement	Acupuncture *v* sham needling	4	−3	0	−1	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and poor-quality RCT. Directness point deducted for uncertainty about benefit
4 (554) [41] [42]	Symptom improvement	Back schools *v* placebo or usual care	4	−2	0	−2	0	Very low	Quality points deducted for incomplete reporting of results and for inclusion of low-quality RCTs. Directness points deducted for disparities in programmes and populations between the groups affecting generalisability of results

Important outcomes	Symptom improvement, functional improvement, return to work, adverse effects								
Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
2 (281) [41] [42]	Functional improvement	Back schools plus usual treatment *v* usual treatment alone	4	−2	0	−2	0	Very low	Quality points deducted for sparse data and high withdrawal rate in 1 RCT. Directness points deducted for disparities in programmes and populations between the groups affecting generalisability of results
3 (1362) [41]	Time to return to work	Back schools *v* placebo or usual care	4	−1	0	−2	0	Very low	Quality point deducted for incomplete reporting of results. Directness points deducted for disparities in programmes and populations between the groups affecting generalisability of results
1 (107) [25]	Symptom improvement	CBT *v* usual care	4	−3	0	−1	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and poor-quality RCT. Directness point deducted for uncertainty about scales of measurement
1 (107) [25]	Functional improvement	CBT *v* usual care	4	−3	0	−1	0	Very low	Quality points deducted for sparse data, incomplete reporting of results and for poor-quality RCT. Directness point deducted for uncertainty about scales of measurement
1 (197) [44]	Symptom improvement	Lumbar support *v* no lumbar support	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and weak methods. Directness point deducted for restricted population (subacute low back pain)
1 (197) [44]	Functional improvement	Lumbar support *v* no lumbar support	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and weak methods. Directness point deducted for restricted population (subacute low back pain)
2 (121) [45]	Symptom improvement	Massage *v* placebo massage, sham massage, no massage, or usual care	4	−3	0	−1	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and weak methods. Directness point deducted for heterogeneity among interventions
2 (121) [45]	Functional improvement	Massage *v* placebo massage, sham massage, no massage, or usual care	4	−3	0	−1	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and weak methods. Directness point deducted for heterogeneity among interventions
3 (348) [46]	Symptom improvement	Heat wrap *v* placebo or non-heated wrap	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
2 (258) [46]	Functional improvement	Heat wrap *v* placebo or non-heated wrap	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
1 (226) [46]	Symptom improvement	Heat wrap *v* oral analgesic	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for narrow range of comparators
1 (226) [46]	Functional improvement	Heat wrap *v* oral analgesic	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for narrow range of comparators
1 (226) [46]	Symptom improvement	Heat wrap *v* NSAIDs	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for narrow range of comparators
1 (226) [46]	Functional improvement	Heat wrap *v* NSAIDs	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for narrow range of comparators

Important outcomes	Symptom improvement, functional improvement, return to work, adverse effects								
Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
1 (30) [48]	Symptom improvement	Heat wrap plus NSAIDs *v* NSAIDs alone	4	−3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and weak methods
1 (43) [47]	Symptom improvement	Heat wrap plus education *v* education alone	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (43) [47]	Functional improvement	Heat wrap plus education *v* education alone	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (50) [46]	Symptom improvement	Heat wrap alone *v* McKenzie treatment	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (50) [46]	Functional improvement	Heat wrap alone *v* McKenzie treatment	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
2 (121) [10]	Symptom improvement	TENS *v* placebo	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for unclear interventions
10 (at least 491) [49]	Symptom improvement	Generic back exercise *v* usual care or no treatment (acute back pain <6 weeks' duration)	4	−2	0	−1	0	Very low	Quality points deducted for incomplete reporting of results, and poor-quality RCTs. Directness point deducted for uncertainty about definition of exercises
10 (at least 491) [49]	Functional improvement	Generic back exercise *v* usual care or no treatment (acute back pain <6 weeks' duration)	4	−2	0	−1	0	Very low	Quality points deducted for incomplete reporting of results, and poor quality RCTs. Directness point deducted for uncertainty about definition of exercises
7 (at least 134) [49] [52]	Functional improvement	Generic back exercise *v* usual care or no treatment (subacute low back pain of 6–12 weeks' duration)	4	−2	−1	−1	0	Very low	Quality points deducted for incomplete reporting and for inclusion of poor-quality RCTs. Consistency point deducted for conflicting results. Directness point deducted for uncertainty about definition of exercises
7 (at least 134) [49] [52]	Return to work	Generic back exercise *v* usual care or no treatment (subacute back pain <6 weeks' duration)	4	−2	0	−1	0	Very low	Quality points deducted for incomplete reporting and for inclusion of poor-quality RCTs. Directness point deducted for uncertainty about definition of exercises
7 (606) [49]	Symptom improvement	Generic back exercise *v* non-exercise interventions (acute low back pain <6 weeks' duration)	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for uncertainty about definition of exercises
7 (534) [49]	Functional improvement	Generic back exercise *v* non-exercise interventions (acute low back pain <6 weeks' duration)	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for uncertainty about definition of exercises
5 (608) [49]	Symptom improvement	Generic back exercise *v* non-exercise interventions (subacute low back pain 6–12 weeks' duration)	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for uncertainty about definition of exercises
4 (579) [49]	Functional improvement	Generic back exercise *v* non-exercise interventions (subacute low back pain 6–12 weeks' duration)	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for uncertainty about definition of exercises

Important outcomes	Symptom improvement, functional improvement, return to work, adverse effects								
Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
1 (80) [53]	Symptom improvement	Generic back exercise plus CBT *v* no exercise or CBT alone	4	−1	0	−1	0	Low	Quality point deducted for sparse data. Directness points deducted for uncertainty about definition of exercises
1 (84) [53]	Functional improvement	Generic back exercise plus CBT *v* no exercise or CBT alone	4	−1	0	−1	0	Low	Quality point deducted for sparse data. Directness points deducted for uncertainty about definition of exercises
1 (47) [43]	Symptom improvement	Generic back exercise *v* CBT plus exercise	4	−1	0	−1	0	Low	Quality point deducted for sparse data. Directness point deducted for restricted population (subacute pain)
2 (470) [50]	Symptom improvement	Specific back exercise *v* passive treatments	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for composite outcome
4 (681) [50]	Functional improvement	Specific back exercise *v* passive treatments	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for composite outcome
2 (261) [50]	Symptom improvement	Specific back exercise *v* advice to stay active	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
2 (261) [50]	Functional improvement	Specific back exercise *v* advice to stay active	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
1 (149) [54]	Symptom improvement	Specific back exercise *v* flexion exercises	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (24) [55]	Functional improvement	Specific back exercise *v* flexion exercises	4	−3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and poor-quality RCT
1 (100) [56]	Symptom improvement	Specific back exercise *v* back school	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (24) [58]	Functional improvement	Specific back exercise *v* spinal manipulation	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (260) [51]	Functional improvement	Specific back exercise *v* NSAIDs	4	−1	0	−1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for narrow range of comparators
2 (400) [59]	Symptom improvement	Bed rest *v* advice to stay active	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
2 (400) [59]	Functional status	Bed rest *v* advice to stay active	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
2 (400) [59]	Return to work	Bed rest *v* advice to stay active	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
1 (47) [59]	Symptom improvement	Different lengths of bed rest *v* each other	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results

Type of evidence: 4 = RCT Consistency: similarity of results across studies.
Directness: generalisability of population or outcomes.
Effect size: based on relative risk or odds ratio.