Effectiveness of acupuncture for the treatment and rehabilitation of accident-related musculoskeletal disorders

A systematic review of the literature

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ERRATA

A number of references were inadvertently omitted from the reference list in the first version of this report and the date of the 1981 article on neck pain by Coan was cited incorrectly as 1982 in the text. These errors have now been corrected.
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EXECUTIVE SUMMARY

Objective

The aim of this systematic review was to provide a comprehensive assessment of the effectiveness of acupuncture for the treatment and rehabilitation of accident-related musculoskeletal disorders.

The Accident Compensation Corporation (ACC) commissioned the review.

Background

Musculoskeletal disorders affect the bones, joints, ligaments, tendons, muscles or other related soft tissues of the body. A key cause of musculoskeletal disorder is injury. Injury can occur when external force is exerted on the body such as during a fall or motor vehicle crash, or through the cumulative effects of repetitive, stressful, vigorous, or awkward movements. Musculoskeletal disorders caused by injury include fractures, bruising, muscle sprains, strains, tears and pulls, and disorders associated with inflammation or irritation of muscle membranes or tissues attached to bone.

The term acupuncture derives from the Latin word for “needle puncture”. It refers to the many different therapies in which points of the body are stimulated by inserting needles into tissue, or by other techniques like finger pressure or tapping needles on the surface of the skin (Dale 1997). Acupuncture is thought to have first developed in China. Since the early 1970s, with the opening up of diplomatic and cultural contact between China and the West, especially the US, the popularity and use of acupuncture therapies has increased markedly in Western countries (White and Ernst 1999a).

Several injury-related musculoskeletal conditions are claimed to respond well to acupuncture. Examples include soft tissue injury (e.g., sprained ankle), tennis and golfer’s elbow, torticollis (also known as “wryneck”), rotator cuff tendinitis, traumatic bruising of a rib or rib fracture, trigger point pain arising from whiplash, pain due to faulty posture, tenosynovitis of the wrist, post-traumatic pain in the thumb, and trigger finger (Baldry 1989; Weaver 1998).

Search strategy and study selection

Inclusion criteria were determined in consultation with ACC staff. Only randomised controlled trials, or systematic reviews or meta-analysis of randomised controlled trials, were eligible for inclusion in the review. Study subjects were people sustaining musculoskeletal complaints as a consequence of personal injury by accident. This included injuries caused by external force, as well as by gradual process. The intervention of interest was acupuncture (all types that involve needling), where this was the sole modality in the treatment of injuries. Comparators were no intervention, placebo or sham acupuncture, or other standard therapeutic interventions. To be included, studies had to cover groups where > 90% of patients had acute or chronic pain consistent with musculoskeletal injury, or presented results separately for patients with injury-related conditions.

Bibliographic and review databases, including Medline, Embase and the Cochrane Controlled Trials Register, were searched using the search strategies outlined in Appendix 1. Major New Zealand and international library catalogues, health technology assessment agencies, evidence-based website compilations, current controlled trials websites, guidelines websites, and acupuncture societies were also searched for relevant studies. Searches were not limited to any language or publication date. The major searching was done in mid-January 2002, and an update carried out on April 24, 2002. A complete list of the sources searched for this review is given in Appendix 2.

Results

There were 254 articles identified by the search strategy. From the examination of abstracts, some 98 full text articles were obtained and considered against the criteria set down for the review. As a result,
six studies, all randomised controlled trials, were found to meet all the inclusion criteria. These six trials were fully appraised and summarised in the form of evidence tables.

An additional 38 studies (30 RCTs and eight systematic reviews or meta-analyses) assessing the effectiveness of acupuncture for the treatment of musculoskeletal disorders are also described in the report. Although these studies fell short of meeting the inclusion criteria for the review, it was decided to summarise their features to enable readers to compare them with the included studies.

All studies meeting the inclusion criteria were appraised using modified SIGN (Scottish Intercollegiate Guidelines Network) methodology checklists (see examples in Appendix 3).

Overview of included trials

The types of musculoskeletal disorders covered by the six included RCTs were:

- lateral elbow pain (three RCTs)
- patellofemoral pain syndrome (one RCT)
- rotator cuff tendinitis (two RCTs).

The reported results from all six included RCTs generally favoured acupuncture, although there are methodological limitations to the studies.

Lateral elbow pain

Lateral elbow pain (also known as “lateral epicondylitis”, “epicondylalgia” or “tennis elbow”) is typically classified as a work or sports-related overuse or overload pain disorder of the arm (Green et al. 2002).

The first of the three included trials for lateral elbow pain concluded that acupuncture was more effective than ultrasound for reducing subjective pain, but not grip-strength or functional ability assessed four weeks post-treatment (Davidson et al. 2001). The failure to identify a statistically significant difference between the two treatments for the grip-strength and functional ability measures may be a product of the small size, and therefore low power, of the study. The trial was a pilot study containing less than 10 patients in each group.

The second lateral elbow pain trial compared traditional acupuncture with superficial acupuncture and found traditional acupuncture to be superior to superficial (sham) acupuncture for the “short-term symptomatic treatment” of lateral elbow pain (Haker and Lundeberg 1990). No statistically significant between-group differences in treatment outcomes were found at three and 12 month follow-up (although 13/86 patients had dropped out of the study by three months).

The third lateral elbow pain trial compared traditional acupuncture with a kind of sham acupuncture that included deep, rather than superficial, needling (Fink et al. 2002). All participants in the study were recruited using newspaper advertisements and all were screened to ensure they had experienced no marked variation in their complaint in the previous month. At two weeks post-treatment, the true acupuncture group was found to have improved significantly compared to the sham group for all three main outcome measures (strength, pain, and upper extremity disability score). At two months post-treatment, the true acupuncture group still had significantly better upper extremity disability scores than the sham group, although there was no longer any differences for strength or pain. The authors of the study concluded that the therapeutic effect of true acupuncture was “dominant” in the first two weeks following treatment.

Patellofemoral pain syndrome

Patellofemoral pain syndrome is considered to be an overuse or overload injury associated with repeated weight-bearing impact and is characterised by diffuse knee pain often exacerbated by squatting, kneeling, sitting in certain positions or getting up after long periods of sitting (Jensen et al. 1999).
The one included trial on patellofemoral pain syndrome compared acupuncture to no treatment. Results of the study indicated that the acupuncture group experienced significantly greater improvements in knee function, and that these differences persisted for 12 months post-treatment. However, it is unclear how much these improvements may have been the result of the non-specific effects of treatment, rather than the specific effects of needling.

Rotator cuff tendinitis

The rotator cuff is a group of tendons surrounding the shoulder joint. The tendons can become inflamed or tear following activities that involve repeated raising of the arm above the head, such as swimming, weight lifting or tennis.

Of the two trials for patients with rotator cuff tendinitis, the results of one must be interpreted with caution (Dyson-Hudson et al. 2001), as its patients came from a somewhat unusual group, namely wheelchair-using spinal cord injury patients. As well, the number of participants in the trial was small (only 18 completed the trial) and the comparison therapy was Trager Psychophysical Integration, seemingly not a common therapy for rotator cuff tendinitis.

The other rotator cuff tendinitis trial by Kleinhenz et al. (1999) found true acupuncture to be significantly more effective than sham acupuncture in improving shoulder function when assessed immediately after the course of treatment. Unfortunately, loss to follow-up hampered the ability of the trial to reliably determine if these differences endured over the long-term (i.e., three months post-treatment).

Conclusions

Given the very small number of eligible RCTs identified, and their heterogeneity, it is not possible for this review to reach any strong conclusions about the effectiveness of acupuncture for the treatment and rehabilitation of musculoskeletal injuries.

Acupuncture is considered by practitioners to be useful for treating a wide range of musculoskeletal disorders, including many common disorders thought to be caused primarily by injury. However, RCTs have investigated acupuncture’s effectiveness for treating only a very limited subset of these disorders. This may partially reflect a lack of emphasis in traditional acupuncture theory on distinguishing between injury and non-injury-related musculoskeletal disorder. For many acupuncturists, the location and nature of the musculoskeletal pain, along with any associated dysfunction or restriction of movement, appear to be the main criteria used for selecting sites for needle placement and other technical features of acupuncture therapy. Whether or not the condition being treated is the result of injury does not appear to be especially relevant.

Another reason why few trials have focused exclusively on injury-related disorders may be the difficulty of reliably identifying the causes of musculoskeletal complaints, or being clear about the extent to which a disorder may be caused by injury as opposed to other factors. Many musculoskeletal disorders, especially those involving chronic pain, may be multi-factorial in origin and have a complex aetiology, such as trauma overlaid with degeneration due to osteoarthritis or osteoporosis.

It is to be hoped that in the future, researchers will give greater priority to conducting trials of needle acupuncture with groups of patients who are all considered to have the same kind of injury-related musculoskeletal disorder. The work to date on lateral elbow pain, limited as it is, helps to show what may be possible. Internationally, similar effort, and more, needs to be put into conducting a range of trials on the other common musculoskeletal injuries that clinical experience suggests are likely to benefit markedly from acupuncture therapy.
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<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>95% CI</td>
<td>95% Confidence Interval</td>
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<tr>
<td>ALTENS</td>
<td>Acupuncture-Like Transcutaneous Electrical Nerve Stimulation</td>
</tr>
<tr>
<td>DASH</td>
<td>Disabilities of the Arm, Shoulder and Hand</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>NHP</td>
<td>Nottingham Health Profile</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>NSAID</td>
<td>Non-Steroidal Anti-Inflammatory Drug</td>
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<tr>
<td>NZ</td>
<td>New Zealand</td>
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<tr>
<td>OP</td>
<td>Outpatient</td>
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<tr>
<td>OPVS</td>
<td>Oxford Pain Validity Scale</td>
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<tr>
<td>OR</td>
<td>Odds Ratio</td>
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<td>RR</td>
<td>Relative Risk</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<tr>
<td>TENS</td>
<td>Transcutaneous Electrical Nerve Stimulation</td>
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<tr>
<td>VA(P)S</td>
<td>Visual Analogue (Pain) Scale</td>
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GLOSSARY OF TERMS

**Acupuncture-like transcutaneous electrical nerve stimulation** - electrical stimulation applied to traditional acupuncture points through the surface of the skin using carbon rubber pad electrodes.

**De qi** - see teh chi.

**Electroacupuncture** - needling of acupuncture points combined with electrical stimulation delivered through the needles.

**Gradual process injury** - injury caused by the cumulative effects of repetitive, stressful or awkward movements.

**Injury** - damage inflicted on the body by an external force or the cumulative effects of repetitive, stressful or awkward movements.

**Meridians** - in Chinese medicine, channels in the body through which qi circulates.

**Moxibustion** - a traditional method of applying heat to acupuncture points, or acupuncture needles, by burning small pieces of the dried leaf of the herb mugwort.

**Musculoskeletal** - pertaining to the muscles and skeleton.

**Needling** - insertion of acupuncture needles, typically filiform stainless steel needles, into tissue.

**Qi** - in Chinese medicine, an invisible vital energy or life force circulating within or across the body.

**Sham acupuncture** - needling the wrong acupuncture points, inserting needles only superficially, or tapping the skin with blunt needles or other implements in an effort to generate the appearance of giving true acupuncture.

**Trauma** - a wound or injury, either physical or psychic.

**Transcutaneous electrical nerve stimulation** - electrical stimulation applied to the surface of the skin through carbon rubber pad electrodes.

**Teh chi** - in Chinese medicine, sensations of soreness, numbness, heaviness or distention produced during acupuncture.
**Introduction**

**OBJECTIVES OF THIS REVIEW**

To systematically identify and appraise international evidence for the effectiveness of acupuncture in the treatment and rehabilitation of musculoskeletal disorders caused by injury.

**STRUCTURE OF REPORT**

This report is divided into four sections. The next section, Background, describes features of acupuncture and musculoskeletal injury relevant to this review. The Review Methodology section describes the search strategy, inclusion and exclusion criteria, and outcomes considered for this review. The Results section describes the randomised controlled trials (RCTs), systematic reviews and meta-analyses that fulfilled the eligibility criteria for the review. As well, this section presents detailed evidence tables summarising each appraised study’s methods, results, limitations, and authors’ conclusions. Shorter evidence tables are also provided for selected studies that did not fully meet the review’s inclusion criteria. The final section, Discussion, presents key conclusions and briefly discusses methodological limitations and future research requirements in the area.
Background

MUSCULOSKELETAL DISORDERS AND INJURY

Musculoskeletal disorders affect the bones, joints, ligaments, tendons, muscles or other related soft tissues of the body. Common symptoms and signs include persistent or intermittent pain, restricted movement and interference with the activities of daily living.

Many factors can underlie the development of musculoskeletal pain or impairment. They include bone and muscle degeneration and weakening as a result of ageing, nutritional deficiencies, obesity, infections, or systemic conditions such as rheumatoid arthritis.

Another key cause of musculoskeletal disorder is injury. Injury can occur when external force is exerted on the body such as during a fall or motor vehicle crash, or through the cumulative effects of repetitive, stressful, vigorous, or awkward movements.

Examples of musculoskeletal disorders caused by injury include fractures, bruising, muscle sprains, strains, tears and pulls, and inflammation or irritation of muscle membranes or tissues attached to bone.

The focus of this review is the use of acupuncture for the treatment of these and other kinds of injury-related musculoskeletal disorders.

ORIGINS OF ACUPUNCTURE

The term acupuncture derives from the Latin for “needle puncture”. It refers to the different therapies in which points of the body are stimulated by inserting needles into tissue, or by other techniques like applying finger pressure or tapping needles on the surface of the skin (Dale 1997).

Acupuncture is thought to have developed first in China. Texts referring to techniques of traditional Chinese acupuncture therapy date back at least 2000 years (White and Ernst 1999a). Variations of acupuncture have also been used in other Asian countries, including Japan, Korea and Vietnam, for at least 1500 years. Acupuncture has been known in Western Europe for more than three centuries and in North America for over 150 years (Birch and Kaptchuk 1999).

Since the early 1970s, with the opening up of diplomatic and cultural contact between China and the West, especially the US, the popularity and use of acupuncture has increased markedly in Western countries.

MODELS OF PRACTICE

Acupuncture has been described as a heterogeneous field of enormous complexity, with a great diversity of explanatory models, models of practice and acupuncture techniques (Birch and Kaptchuk 1999). However, two broad approaches are widely recognised in the literature (White and Ernst 1999a).

The first is the traditional Chinese approach. This is based on theories describing flows and blockages of vital energy or qi (pronounced “chi”). Needling or other forms of stimulation of acupuncture points are considered to provide access to energy circulating through the body along channels known as meridians, yielding therapeutic benefits for a wide range of conditions. Often the acupuncture treatment provided by therapists adhering to the traditional Chinese approach will be individualised according to the patient’s symptoms and signs, as interpreted within the theories of Chinese medicine (Leake and Broderick 1998). The treatment may also include herbal preparations and advice on lifestyle and diet.
The second broad approach is “modern” acupuncture, also known as “medical acupuncture”. This is commonly used by medical practitioners and other therapists trained in Western biomedicine. Here diagnosis is more likely to be based on conventional history taking and physical examination, with acupuncture seen as just one of several therapeutic options that could be offered to the patient. Practitioners of modern acupuncture are generally less likely to adhere to the traditional Chinese theories relating to energy flows, believing instead that acupuncture stimulates nerve endings (White and Ernst 1999a).

**VARIATIONS OF ACUPUNCTURE TECHNIQUE**

There are many different varieties and styles of acupuncture technique spanning both the traditional and modern models of practice. Broadly speaking, they can be categorised into two groups:

- therapies that involve the insertion of thin, solid, dry needles into tissue (sometimes referred to as “needling”)
- therapies that involve other “non-needling” acupuncture techniques.

Needling techniques include variations where the needles are stimulated either manually or electrically (electroacupuncture), or both.¹

Non-needling acupuncture techniques include the stimulation of acupuncture points or other areas of the body with finger pressure (acupressure) or suction (cupping). Heat can also be applied to acupuncture points by burning small pieces of the dried mugwort plant on the surface of the skin, a technique known as moxibustion. Lasers or electric current delivered through surface electrodes may also be used to stimulate acupuncture points (Leake and Broderick 1998).

Practitioners of needle acupuncture may have contrasting, even conflicting, ideas about which points of the body are active acupuncture points (acupoints), the ideal level of intensity and duration of acupuncture stimulation, the gauge of acupuncture needles that should be used, and the appropriate depth of needle insertion (Birch and Kaptchuk 1999; Filshie and Cummings 1999).

Many practitioners of needle acupuncture aim to produce in the patient the sensation known as “teh chi” (or “de qi”); a feeling of numbness, heaviness, tingling, soreness or distension brought on by needling (Birch and Kaptchuk 1999).

**PHYSIOLOGICAL PROCESSES UNDERLYING ACUPUNCTURE’S EFFECTS**

Various explanations have been suggested for acupuncture’s effects.

Traditional Chinese acupuncture theories posit that acupuncture promotes the optimal flow of life force energy or qi.

Western scientific theories are based on findings from experimental studies in human biology and physiology.

The gate control theory posits that acupuncture needling produces a form of alternative sensory stimulation that restricts or conceals the perception of pain and other sensory stimulation arising in the body from other sources (van Tulder et al. 2001).

¹ “Dry needling”, as in acupuncture, can be contrasted with “wet needling”, which is typically the use of hollow hypodermic needles to inject substances into the body.
According to the theory of diffuse noxious inhibitory control, the pain sensation of an initial noxious stimulus (e.g., a muscle injury) is modified or blocked by the introduction of a second potentially noxious stimulus (i.e., acupuncture). The second noxious stimulus activates the brainstem and descending pathways to block background ‘noise’, including the initial stimulus (van Tulder et al. 2001; Weaver 1998).

A third theory, and the one given perhaps the greatest support in recent studies, is that acupuncture either stimulates nerve endings in the skin or peripheral nerves in muscles. This, in turn, results in impulses being sent to three separate areas of the central nervous system; the spinal cord, the midbrain and the hypothalamus/pituitary areas of the brain, triggering the production of endorphins, serotonin, acetylcholine and other pain blocking substances (Vickers 2001; Weaver 1998). Studies have observed that the physiological responses obtained from acupuncture are the same as those generated by vigorous exercise involving strong muscle contractions (Leake and Broderick 1998).

There is also some evidence from biological studies suggesting acupuncture may alter immune system responses (National Institutes of Health Consensus Development Panel on Acupuncture 1997).

**TYPES OF MUSCULOSKELETAL DISORDERS TREATED WITH ACUPUNCTURE**

Surveys of acupuncturists in the UK show that acupuncture is used in the treatment of a wide range of complaints and conditions. These include emotional and psychological conditions, arthritis, digestive disorders, headache and migraine, respiratory conditions such as asthma, cardiovascular conditions, and various forms of addiction (including tobacco smoking). However, the most common general category of conditions treated by acupuncturists is musculoskeletal pain, stiffness or trauma, especially in the back and neck region (White and Ernst 1999a).

Acupuncture texts list several injury-related musculoskeletal conditions thought to respond well to acupuncture. Examples include soft tissue injury (e.g., sprained ankle), tennis and golfer’s elbow, torticollis (also known as “wryneck”), rotator cuff tendinitis, traumatic bruising of a rib or rib fracture, trigger point pain arising from whiplash, pain due to faulty posture, tenosynovitis of the wrist, post-traumatic pain in the thumb, and trigger finger (Baldry 1989; Weaver 1998).
Methodology

CRITERIA USED TO LOCATE AND INCLUDE STUDIES FOR THIS REVIEW

The following review criteria were determined in consultation with ACC.

**Design**

Only studies using one of the following designs were eligible for inclusion in the review:
- randomised controlled trial (RCT), or pseudo-randomised controlled trial (alternate allocation or some other method)
- systematic review or meta-analysis of all relevant randomised controlled trials.

These designs correspond to level III-1 and above of the Australia National Health and Medical Research Council revised hierarchy of evidence (Australia National Health and Medical Research Council 1999).

**Subjects**

People who sustain musculoskeletal disorder as a consequence of personal injury by accident. This includes acute injuries caused by external force, as well as gradual process injuries.

**Intervention**

Acupuncture (all types that involve needling) as a sole modality in the treatment of injuries.

**Comparators**

No intervention (e.g., acupuncture compared to a group on a waiting list to receive acupuncture).

Placebo or “sham” acupuncture (e.g., needles placed in an area close to but not in acupuncture points).

Other standard therapeutic interventions (e.g., physiotherapy, medication).

**Outcomes**

Outcome measures at follow-up of at least one month included at least one of the following:
- pain/symptom control
- global improvement/recovery
- functional status (disability)
- return to work (return to work status, number of days of work)
- independence (consumption of health/rehabilitation services).
**Inclusion criteria**

Study contains > 90% of patients with acute or chronic pain consistent with musculoskeletal injury; or study reports results separately for patients with and without acute or chronic pain consistent with musculoskeletal injury.

Study includes follow-up assessment at least one month after the end of the course of treatment.

**Exclusion criteria**

The following types of studies were not considered for inclusion in the review:

- studies where the therapeutic effectiveness of acupuncture was being assessed specifically for patients with the following conditions: infection, metastatic disease, neoplasm, osteoporosis, rheumatoid arthritis, asthma, post-operative pain, chemotherapy induced or post-operative nausea and vomiting, dental pain, dysmenorrhea, menstrual cramps, failure to progress in labour, stroke, substance (including alcohol and smoking) abuse/addiction, cerebral palsy, headaches/migraine, sore throat
- studies of non-needle acupuncture
- studies using an experimental pain model
- non-randomised controlled trials and controlled before and after studies
- studies where any study participant was under 16 years of age
- studies that primarily considered the adverse outcomes of acupuncture treatment
- studies for which only an abstract was available
- studies in the form of a case presentation
- studies presented as a letter.

Research papers were also excluded if they:

- studied primarily healthy volunteers
- reported only animal studies
- reported a pilot study that was subsequently superceded by a published full study
- did not clearly describe their methods and/or results, or had significant methodological weaknesses.

**SEARCH STRATEGY**

A systematic method of literature searching and selection was employed in the preparation of this review.

Searches were not limited to any language or publication date. The major searching was done in mid-January 2002, and an update carried out on April 24, 2002.

**Principal sources of information**

The following databases were searched (using the search strategies outlined in Appendix 1):

Bibliographic databases
Medline
Embase
Cinahl
Current Contents
Science/Social Science Citation Index
Cochrane Controlled Trials Register
Amed – Allied and Complementary Medicine
Index New Zealand
Mantis – Manual, Alternative & Natural Therapy Index

Review databases
Best Evidence
Cochrane Database of Systematic Reviews
Database of Abstracts of Reviews of Effectiveness
Health Technology Assessment database
NHS Economic Evaluation database

Other
Major New Zealand and international library catalogues, health technology assessment agencies, evidence-based website compilations, current controlled trials websites, guidelines websites, and acupuncture societies were searched for relevant studies.

Hand searching of journals or contacting of authors for unpublished research was not undertaken in this review. A complete list of the sources searched for this review is given in Appendix 2.

Search terms used

Index terms from Medline/Healthstar (MeSH terms): acupuncture, meta-analysis, randomized controlled trials, placebos, random allocation, controlled clinical trials, randomized controlled trial [publication type], controlled clinical trial [publication type].

Index terms from Embase: acupuncture, randomized controlled trial, double blind procedure, randomization, placebo, single blind procedure, meta-analysis.

Additional index terms used for Cinahl: random assignment.

The above index terms were used as keywords in databases where they were not available and in those databases without controlled vocabulary.

Additional keywords (not standard index terms) were used in all databases: acupuncture, random*, double blind, single blind, placebo*, systematic* near review*, systematic* near overview.

Because the literature on randomised controlled trials of acupuncture was relatively small, it was possible to scan through all references retrieved by the search strategy and select relevant references manually. This avoided lengthening the search strategies considerably to encompass the many different subject terms and additional keywords for all possible variants of the musculoskeletal injury concepts.

Case reports, correspondence, news items and interviews were excluded in those databases where these were searchable using index terms or the “publication type” identifiers.

STUDY SELECTION

There were 254 articles identified by the search strategy. From the examination of abstracts, some 98 full text articles were obtained and considered against the criteria set down for the review. As a result of this consideration six studies, all randomised controlled trials, were found to meet all the inclusion criteria. These six trials were fully appraised and summarised in the form of evidence tables. The references for these trials, as well as other cited publications are presented in the References.

Another 38 studies (30 RCTs and eight systematic reviews or meta-analyses) assessing the effectiveness of acupuncture for the treatment of musculoskeletal disorders are also described in the
report. These studies fell short of meeting the inclusion criteria for the review, but it was decided to summarise their features to enable readers to compare them with the included studies.

**APPRAISAL OF STUDIES AND PREPARATION OF EVIDENCE TABLES**

Eligible studies were appraised using modified SIGN (Scottish Intercollegiate Guidelines Network) methodology checklists (see example in Appendix 3). The evaluation criteria are defined by a series of questions covering study internal validity.

Evidence tables for included randomised controlled trials present key information summaries employing the column headings described below:

- **source of the study** including authors, year published, and country of origin
- **population** including patient inclusion and exclusion criteria, and randomisation procedure
- **intervention, outcome measures and follow-up** including a description of the active and control treatments given, the duration and frequency of treatment, blinding, primary outcome measures used to assess improvement in pain and function, withdrawals and drop-outs
- **results** including summary of the findings of the study, relevant statistical data and author conclusions
- **comments** including description of study limitations and internal validity issues arising from the study appraisal.

Briefer, less detailed evidence tables are provided for the excluded RCTs, systematic reviews and meta-analyses.

Systematic reviews and meta-analyses were described and critiqued in terms of their search strategy, inclusion/exclusion criteria, data synthesis and key results or conclusions.

**LIMITATIONS OF THE REVIEW**

This study has used a structured approach to review the literature. However, there were some inherent limitations with this approach. Namely, systematic reviews are limited by the quality of the studies included in the review and the review’s methodology.

The review has been limited to the published academic literature, and has not appraised unpublished work. Restriction to the published literature may lead to bias since the unpublished literature tends to consist of studies not identifying a significant result.

Studies included in the review were initially selected by examining the abstracts of these articles. Therefore, it is possible that some studies were inappropriately excluded prior to examination of the full text article.

The review is limited to studies examining the effectiveness of needle acupuncture. It does not cover studies where the main treatment being assessed is a non-needling acupuncture technique (e.g., laser acupuncture or acupressure). This is consistent with other systematic reviews and aimed at trying to limit the heterogeneity of the different acupuncture treatments compared in the review (Bradnam and Larmer 2001; van Tulder et al. 1999).

All studies included in this review were conducted outside New Zealand, and therefore, their generalisability to the New Zealand population and context may be limited and needs to be considered.

This review was confined to an examination of the effectiveness of the interventions and did not consider the acceptability, or any ethical, economic or legal considerations associated with these interventions. Interventions were not assessed in terms of their impact on general quality of life.
Data extraction, critical appraisal and report preparation was performed by two researchers. Although the two researchers appraised the articles included in this review, they did not cross-validate the data extraction and appraisal process.

This review was conducted over a limited timeframe (January 2002 – June 2002).

The review has benefited from the advice provided by two consultant peer reviewers. However, it has not been exposed to wider peer review.

For a detailed description of interventions and evaluation methods, and results given in the studies appraised, the reader is referred to the original papers cited.

LIMITATIONS OF ACUPUNCTURE RANDOMISED CONTROLLED TRIALS

Principles of evidence-based medicine dictate that the randomised controlled trial (RCT) is the most appropriate clinical research methodology for scientifically evaluating the therapeutic effects of acupuncture.

Control and comparison groups

RCTs compare the therapeutic outcomes of acupuncture treatment with the therapeutic outcomes of other forms of treatment, or control or placebo treatments (Filshie and Cummings 1999). In general, three different types of RCT design have been used to examine the effectiveness of acupuncture:

- acupuncture therapy compared to no therapy
- acupuncture therapy compared to another kind of therapy
- acupuncture therapy compared to placebo control or sham acupuncture.

Randomised controlled trials comparing acupuncture therapy to no treatment are useful for determining the likely treatment effects of acupuncture. In these trials, half of a group of patients receives acupuncture and the other half do not, usually by being put on a waiting list for treatment.

Trials where acupuncture is compared with another form of therapy are useful for showing whether or not acupuncture works better or worse than conventional approaches (e.g., physiotherapy, NSAIDs).

However, neither of these two kinds of trial designs are useful for differentiating between the non-specific and specific effects of acupuncture. Specific effects are those produced by needling, while the non-specific (placebo) effects are those produced by the remainder of the therapeutic encounter. This includes the personality of the therapist, the degree of empathy and concern shown by the therapist, the expectations of the patient about the value and likely effectiveness of therapy, and the degree of physical contact and relaxation patients experience during the therapy.

The non-specific effects of a therapy such as acupuncture can be powerful. According to some studies, the non-specific effects of therapy may even be enough to stimulate the release of endogenous opioids (Filshie and Cummings 1999; Kleinhenz et al. 1999).

In the last three decades of acupuncture research, especially in the West, there has been a concern with reliably demonstrating how much of the therapeutic effects of acupuncture derive from the non-specific effects of therapy, and how much, if any, derive directly from the effects of needling recognised acupuncture points.

RCTs have therefore been designed comparing acupuncture therapy with various placebo treatments that seek to replicate the non-specific effects of acupuncture without providing the specific effects (i.e., appropriate needling).
One common placebo control technique used in these studies is to give patients some kind of mock conventional therapy. Examples include deactivated laser devices, or transcutaneous electrical nerve stimulation (TENS) machines that give all the appearance of functioning normally, but which in fact deliver no electric current. However, these placebo therapies may not necessarily replicate the non-specific effects of acupuncture, since they are not acupuncture-like techniques. For one thing, they do not involve the visible use of needles by the therapist.

Another common placebo control technique is so-called “sham” acupuncture. Sham acupuncture aims to look and feel like acupuncture to the patient, but in contrast to “true” acupuncture, provide minimal or no needling effects. Common sham acupuncture techniques include needling areas of the body not considered to be therapeutically active, or needling very superficially on the surface of the skin in areas of the body considered therapeutically active (Leake and Broderick 1998). Other techniques include pressing or tapping (but not inserting) blunt needles on acupuncture points (usually on the patient’s back so they cannot see the treatment being performed), or using blunt needles that retract into the handle attached to the needle when pressed against the patient’s skin (Kleinhenz et al. 1999).

The suitability of using sham acupuncture to control for the non-specific effects of true acupuncture has been widely questioned. There is evidence from physiological studies suggesting that the specific effects of acupuncture may be stimulated by many different types of needling, whether deep or superficial, and in many different areas of the body, not just those traditionally regarded as “true” acupuncture points. Sham procedures may therefore generate specific therapeutic effects intermediate to those produced by “true” acupuncture and no-treatment. One review of the clinical effects of acupuncture for the treatment of chronic pain has concluded that acupuncture is effective in relieving pain in 60-75 percent of patients; sham acupuncture needling in off-site positions of the body reduces pain in 50 percent of patients, and placebo techniques (needles pressed or tapped on the skin, or inactive electrodes or lasers used) reduces pain in 30 percent of patients (Lewith and Machin 1983).

There is also evidence suggesting that the areas of the body selected to receive sham acupuncture may also be an important determinant in the level of specific effects produced by sham acupuncture. A recent review of acupuncture trials found that improvements from baseline of 35 percent or more were reported for placebo patients in 24/30 acupuncture RCTs where the placebo (sham) needling was in the same segment of the body as the active (true) needling. This compared with reported improvements from baseline of 35 percent or more for placebo patients in only 6/30 acupuncture RCTs where the placebo (sham) needling was in a different segment of the body from the active (true) needling (Vickers 2001).

Given these factors, interpreting the findings of RCTs comparing true acupuncture with sham acupuncture is difficult. Both sham and true acupuncture may have specific effects, making it harder, not easier, to reliably define the specific effects of true acupuncture (Filshie and Cummings 1999; Grant et al. 1999; Kleinhenz et al. 1999; Leake and Broderick 1998; Thomas and Lundberg 1994).

The need for future acupuncture trials to devise better, more reliable techniques to control for the non-specific effects of needling is widely acknowledged in the literature. However, it is also accepted that acupuncture, like many other therapies, involves physical contact between therapist and patient, as well as the use of needles and other devices or materials that can be readily observed or felt by the patient. Consequently, it may be difficult, if not impossible, to devise satisfactory control interventions that reliably mimic the non-specific effects of acupuncture while delivering none of the specific effects, yet still appearing (and feeling) to patients like an authentic form of needle acupuncture.

**Blinding**

Another key methodological problem in acupuncture trials is the difficulty of blinding therapists and study participants to the type of intervention. Unlike some therapies, such as giving drugs, the type of acupuncture, whether true, sham or placebo, cannot be concealed from the therapist delivering it. Nor in many cases can it easily (or ethically) be concealed from the patient. The status of the kind of therapy being offered may therefore influence the confidence and authority with which it is provided by the therapist, as well as how much patients believe the treatment they are receiving is credible and effective. Some trials exclude patients who have previously received acupuncture in an effort to partly control for these influences.
Lack of blinding also introduces the potential for bias if the therapist is involved in evaluating the results of treatment. To address this issue, outcome measures in many acupuncture trials are undertaken by a blinded assessor. The assessor does not deliver the therapy and is unaware of the treatment group to which patients have been allocated.
Results

TYPES OF MUSCULOSKELETAL DISORDERS EXAMINED IN TRIALS

Examination of all the abstracts and retrieved documents obtained for this review showed that randomised controlled trials assessing the effectiveness of acupuncture have been undertaken for patients with the following specific categories of musculoskeletal disorder:

- capsulitis (“frozen shoulder”)
- carpal tunnel syndrome
- cervical spondylosis
- fibromyalgia
- lateral elbow pain (“tennis elbow”)
- myofascial pain
- osteoarthritis
- plantar fasciitis
- patellofemoral pain syndrome
- rheumatoid arthritis
- rotator cuff tendinitis
- sciatica
- temporomandibular pain
- whiplash.

Other RCTs were also identified in which the therapeutic effectiveness of acupuncture was assessed using groups of patients with heterogeneous types of musculoskeletal diagnoses or conditions located in a single anatomical region of the body. The three main regions covered in these studies were:

- low back
- neck
- shoulders.

No RCTs were found examining acupuncture’s effectiveness for treating any of the many other common injury-related musculoskeletal disorders, such as fractures, occupational overuse syndrome (OOS), torn ligaments, or contusions.

EXCLUDED CONDITIONS

Trials where all subjects had capsulitis, rheumatoid arthritis or temporomandibular pain were automatically excluded from the review, as these conditions were considered either to have an uncertain aetiology or unlikely in the vast majority of cases to be caused by injury.

In consultation with the client for the review, it was also determined that trials where all subjects had cervical spondylosis, fibromyalgia, myofascial pain and osteoarthritis should also be excluded, as,
again, these conditions were considered either to have an uncertain aetiology or unlikely in the vast majority of cases to be caused by injury.²

IDENTIFYING ELIGIBLE STUDIES

All remaining RCTs were assessed using abstracts or the full text of retrieved documents to determine their eligibility for inclusion in the review. In addition, systematic reviews and meta-analyses of randomised controlled trials evaluating the therapeutic effectiveness of acupuncture for these same conditions were also assessed against the review’s inclusion and exclusion criteria.

RCTs and systematic reviews or meta-analyses were subsequently excluded for the following reasons:
- the type of acupuncture being assessed did not involve dry needling but instead involved non-needling techniques such as laser acupuncture, massage of acupuncture points, acupuncture-like transcutaneous electrical nerve stimulation (ALTENS), or wet needling including the injection of substances into acupuncture points
- the trial compared only two or more kinds of acupuncture therapy
- the intervention being assessed was acupuncture in combination with another treatment modality (such as physiotherapy), rather than acupuncture as the sole treatment modality
- final patient follow-up assessments were conducted less than one month after the end of the course of acupuncture treatment
- the trial did not appear to include > 90% of patients with acute or chronic pain consistent with musculoskeletal disorder caused by personal injury accident or gradual process, or did not present results separately for patients with these kinds of musculoskeletal disorders.

As a result of this process, six RCTs and no systematic reviews or meta-analyses were considered to qualify for full appraisal in this review.

The types of musculoskeletal disorders covered by the six included RCTs were:
- lateral elbow pain (three RCTs)
- patellofemoral pain syndrome (one RCT)
- rotator cuff tendinitis (two RCTs).

None of the RCTs covering the following specific musculoskeletal disorders qualified for inclusion in the review:
- carpal tunnel syndrome³
- plantar fasciitis
- sciatica
- whiplash.

² A recent UK review of acupuncture studies grouped osteoarthritis, rheumatoid arthritis and fibromyalgia together under the heading “rheumatic disease" (Vickers 2001).

³ A review undertaken by the US’s National Institutes of Health using a consensus development conference approach concluded that acupuncture may be useful for relieving pain in carpal tunnel (National Institutes of Health Consensus Development Panel on Acupuncture 1997). However, only one RCT on carpal tunnel syndrome was identified for the present review and this assessed the effectiveness of laser acupuncture, not needle acupuncture (Aigner and Fialka 1998; Aigner et al. 1999). No published RCTs assessing the effectiveness of needle acupuncture for carpal tunnel syndrome appear to exist.
None of the RCTs, systematic reviews or meta-analyses covering the following heterogeneous groups of regional musculoskeletal pain disorders qualified for inclusion in the review:

- low back pain
- neck pain
- shoulder pain.

Several of these back, neck and shoulder pain studies met all the review’s inclusion criteria, except for the requirement that they included > 90% of patients with acute or chronic pain consistent with a musculoskeletal disorder caused by injury, or, alternatively, presented results separately for patients with these kinds of disorders.

**OVERVIEW OF INCLUDED TRIALS**

Following is a summary of the six randomised controlled trials that met the inclusion criteria for the review. More detailed information on each study is provided in the evidence tables.

**Diagnoses/conditions**

Three of the included trials were on patients with lateral elbow pain (Davidson et al. 2001; Fink et al. 2002; Haker and Lundeberg 1990). Lateral elbow pain is typically classified as a work or sport-related overuse or overload pain disorder of the arm associated with strenuous or repetitive tasks (Green et al. 2002). Other names for the condition include “lateral epicondylitis”, “epicondylalgia” or “tennis elbow”.

One of the included trials was on groups of patients with patellofemoral pain syndrome (Jensen et al. 1999). Patellofemoral pain syndrome is characterised by diffuse knee pain that is often exacerbated by squatting, kneeling, sitting in certain positions or getting up after long periods of sitting. Although the precise aetiology of patellofemoral pain syndrome is unknown, it is typically classified as an overuse or “overload” injury associated with repeated weight-bearing impact (e.g., distance running). The condition is thought to be especially common in young adult sports people and is one of the most common diagnoses given at sports medicine clinics (ibid.).

Two of the included trials covered groups of patients with rotator cuff tendinitis (Dyson-Hudson et al. 2001; Kleinhenz et al. 1999). The rotator cuff is a group of tendons surrounding the shoulder joint. The tendons can become inflamed or tear following activities that involve repeated raising of the arm above the head, such as swimming, weight lifting or tennis.

**Study designs**

One of the trials compared acupuncture with no treatment (Jensen et al. 1999).

One of the trials compared acupuncture with placebo or sham needling that did not involve penetration of the skin (Kleinhenz et al. 1999). Another of the trials compared acupuncture to superficial subcutaneous needle insertion (Haker and Lundeberg 1990). It was decided to define this subcutaneous needle insertion as a type of sham acupuncture. The trial by Fink et al. (2002) compared acupuncture to a type of sham acupuncture that involved needling to a depth identical to true acupuncture, but at non-acupuncture points.

The remaining two trials compared acupuncture to another type of treatment. One compared acupuncture with ultrasound (Davidson et al. 2001) and the other compared acupuncture with Trager Psychophysical Integration, a bodywork and movement re-education technique (Dyson-Hudson et al. 2001).
Features of acupuncture therapy

There was little consistency in the type of needling and needle placement used in the five trials. Two trials appeared to use a standardised protocol of needle placement and needling stimulation for all patients (Davidson et al. 2001; Fink et al. 2002). Another appeared to individualise the type of needling and placement of needles according to the requirements of each patient (Jensen et al. 1999). The remaining trials used what was commonly described as “classical acupuncture”, meaning needling at traditional Chinese acupuncture points. One of these studies used both traditional and non-traditional points (Dyson-Hudson et al. 2001).

In five of the six trials, it was stated that the acupuncture therapy was continued until patients experienced “teh chi” or “de-qi”; a sensation associated with feelings of numbness, heaviness, tingling, soreness or distension (Davidson et al. 2001; Fink et al. 2002; Haker and Lundeberg 1990; Jensen et al. 1999; Dyson-Hudson et al. 2001).

There was some uniformity in the number, duration and frequency of acupuncture treatments used in the trials. In three of the trials, subjects received eight acupuncture treatment sessions. In the other three trials, subjects received 10 sessions. The length of treatment sessions in all six trials was between 20 and 30 minutes. Treatment sessions were typically delivered over a period of three to four weeks, with two to three sessions given each week.

Blinding, sample size, outcome measures and follow-up

All six trials included the use of a blinded outcome assessor.

Two of the three trials involving the use of sham acupuncture techniques sought to achieve patient blinding (Fink et al. 2002; Kleinhenz et al. 1999).

The size of the study populations in two of the six trials was very small (i.e., less than 25 subjects at baseline). Both these trials were classified by their authors as pilot studies (Davidson et al. 2001; Dyson-Hudson et al. 2001). The size of the study populations in the remaining four trials ranged from 40 to 86.

Various outcome measures were used in the trials. These included measures based on patient self-reported pain levels, disability or global improvement as well as measures based on results of physical examinations by blinded assessors.

The length of post-treatment follow-up varied across the trials. The maximum follow-up period in the two pilot trials was four weeks in one (Davidson et al. 2001) and five weeks in the other (Dyson-Hudson et al. 2001). The remaining trials had maximum follow-up periods ranging from three months post-treatment (Kleinhenz et al. 1999) to 12 months (Jensen et al. 1999; Haker and Lundeberg 1990). In some trials with longer follow-up periods, a sizeable minority of subjects dropped out or could not be traced.

Study results

The reported results from all six trials generally favoured acupuncture.

In the one trial comparing acupuncture with no treatment for patellofemoral pain syndrome, scores for knee function and pain improved significantly at 12 months post-treatment for the acupuncture group compared to the no treatment group (Jensen et al. 1999). However, whether this improvement was the result of the specific effects of acupuncture (i.e., needling) or the non-specific effects (the placebo effect) cannot be determined with this kind of study design.

The three trials comparing true acupuncture with sham needling (Fink et al. 2002; Haker and Lundeberg 1990; Kleinhenz et al. 1999) each found that patients in the true acupuncture group had greater levels of improvement in pain levels or function immediately or up to two weeks after the course of treatment ended. One of the trials with lateral elbow pain patients also found the true
acupuncture group had a significantly better upper extremity disability score than the sham acupuncture group at two month follow-up (Fink et al. 2002). However, no statistically significant differences in pain levels or function were identified at three month follow-up in the other trial with lateral elbow pain patients (Haker and Lundeberg 1990). The three month follow-up data for the trial with rotator cuff tendinitis patients is unreliable, as it was based on data from only 67 percent of the original study population (Kleinhenz et al. 1999).

In the two trials comparing acupuncture to another type of treatment, the therapeutic effectiveness of acupuncture was reported to be either equivalent to or better than the other form of treatment. In the trial comparing acupuncture with ultrasound for the treatment of patients with lateral elbow pain, one study found similar improvements at four week post-treatment follow-up for acupuncture and ultrasound, although acupuncture was concluded to be more effective for reducing pain (Davidson et al. 2001). The study comparing acupuncture with Trager Psychophysical Integration therapy for spinal cord injury wheelchair users with rotator cuff lesions found statistically significant reductions in pain intensity scores at the five week follow-up for both treatments compared to baseline groups (Dyson-Hudson et al. 2001). Between group analysis found no significant differences in pain scores between the two treatment groups.

OVERVIEW OF EXCLUDED TRIALS

A total of 30 RCTs were identified where the study subjects all had some form of musculoskeletal disorder, where the form of acupuncture being assessed involved needling, and where the trial compared acupuncture either with no treatment, with placebo or sham acupuncture, or with another kind of treatment modality (e.g., physiotherapy).

However, all of these RCTs had to be excluded from the review for one or more the following reasons:

- the intervention being assessed was acupuncture in combination with another treatment modality (such as physiotherapy), rather than acupuncture as the sole treatment modality
- final follow-up assessment was undertaken less than one month after the end of the course of acupuncture treatment
- the trial did not appear to include > 90% of patients with acute or chronic pain consistent with musculoskeletal disorder caused by personal injury accident or gradual process, did not present results separately for patients with these kinds of musculoskeletal disorder, or did not give enough information to determine whether or not subjects were experiencing injury-related conditions.

It was decided, nonetheless, to present brief evidence tables for these 29 excluded RCTs, as it was felt these might be usefully contrasted with the included trials.

Specific musculoskeletal disorders

Four of the excluded trials covered patients with a single specific musculoskeletal disorder.

Lateral elbow pain

As discussed, lateral elbow pain is an overload disorder of the arm, also known as epicondylalgia or tennis elbow. The trial by Molsberger and Hille (1994), also reported in Molsberger (1986), compared the effects of a single treatment of traditional acupuncture with a single treatment of sham acupuncture (a pencil-like probe with no puncture of skin at non-traditional acupuncture points) for treating chronic unilateral tennis elbow pain in 48 volunteers. The trial had a post-treatment follow-up period of only 72 hours. The authors concluded that true acupuncture was significantly more effective than sham acupuncture for pain relief.

The trial by Wang (1997) included 60 patients with lateral elbow pain and compared the effectiveness of acupuncture plus B12 injection with B12 injection alone. The original report of this study could not be retrieved for this report, but features of the study have been summarised by Green et al. (2002) in their systematic review. They indicate that the trial found no statistically significant differences between the two treatment groups when assessed for symptoms immediately after treatment.
Plantar fasciitis

This condition is characterised by inflammation of the connective tissue at the bottom of the foot and is thought to be often the result of standing, walking or running for long periods, especially on hard surfaces (i.e., an overuse injury). Symptoms include pain in the bottom of the foot (ball, arch, and/or heel), exacerbated by weight bearing.

The trial by Vrchota et al. (1991) compared the effectiveness of treating plantar fasciitis patients with true acupuncture, sham acupuncture and conventional sports medicine approach. However, the study did not quite meet the inclusion criteria for the review because the post-treatment follow-up period was only three weeks. The trial found that at the end of the treatment period, and at follow-up, the “true” acupuncture group experienced a significantly greater decrease in pain (as recorded in their daily pain logs) than the sports medicine group.

Rotator cuff tendinitis

As discussed, rotator cuff tendinitis is inflammation of the tendons surrounding the shoulder joint associated with repeated raising of the arm above the head. The trial by Berry et al. (1980) compared the effectiveness of acupuncture, steroid injections, ultrasound and placebo treatments for treating pain in patients with a rotator-cuff lesion. Assessments were made immediately after the course of treatment. There was no long-term follow-up. The trial identified statistically significant improvements in pain scores in all study groups, but there were no statistically significant differences between the groups.

Sciatica

This is pain in the large sciatic nerve which runs from the lower back down through the buttocks and the back of each leg. The usual cause of sciatica is pressure imposed on the nerve by a herniated intervertebral disc, where the disc protrudes from its normal position. The herniation may sometimes be caused by injury.

Duplan et al. (1983) compared the effectiveness of acupuncture using nine traditional acupuncture points with sham acupuncture at non-traditional acupuncture points for treating 30 patients hospitalised for acute sciatica. Outcomes were measured immediately after five days of treatment, with long-term follow-up. The true acupuncture group reported statistically significant improvements in pain, but the sham group did not.

Regional pain studies

A total of 25 trials examined the effectiveness of acupuncture for treating musculoskeletal pain located in a defined anatomical region of the body. The majority of these trials focused on pain in the low back region.

Low back pain

There is a great deal of uncertainty in the medical literature about the aetiological factors, including injury events, responsible for mechanical low back pain (Baldry 1989). Even where degenerative changes of the spine are found radiologically, injury may still be responsible for symptoms.

Fourteen excluded RCTs assessed the effectiveness of acupuncture for treating groups of patients with low back pain of diverse or uncertain origin. Some of the patients in these trials had back pain that could have been caused by injury.

Two of the RCTs compared acupuncture with no treatment (waiting list) (Coan et al. 1980; Thomas and Lundeberg 1994). Results of both studies favoured acupuncture over no treatment.

Six trials compared acupuncture to other kinds of treatments (Cherkin et al. 2001; Garvey et al. 1989; Grant et al. 1999; Gunn et al. 1980; Kittang et al. 2001; Lehmann et al. 1986). The other treatments included therapeutic massage, lidocaine injections, and TENS. One of these trials found acupuncture to be less effective than therapeutic massage (Cherkin et al. 2001). Two trials found equal
improvements in all treatment groups, including acupuncture (Grant et al. 1999; Lehmann et al. 1986). One trial found equal improvements in pain/stiffness for acupuncture and naproxen, but lower use of analgesics (short-term) as well as fewer episodes of back pain in the acupuncture group (Kittang et al. 2001).

Two studies found acupuncture to be superior to other treatments, either used alone compared with lidocaine injections (Garvey et al. 1989) or in combination with standard clinic therapy compared to standard therapy alone (Gunn et al. 1980).

Three trials compared acupuncture to placebo treatments (e.g., mock TENS) (Carlsson and Sjölund 2001; Lehmann et al. 1986; MacDonald et al. 1983). In two of the three trials, acupuncture was concluded to be superior to placebo.

Four trials compared acupuncture to sham acupuncture (e.g., off-site needling, superficial needling, etc.) (Edelist et al. 1976; Grobglas 1993; Mendelson et al. 1983; Von Mencke et al. 1989). Two of these studies concluded that true acupuncture was no more effective than sham acupuncture. The other two found true acupuncture to be superior to sham.

Neck pain

Four excluded RCTs assessed the effectiveness of acupuncture for treating groups of patients with neck pain of diverse or uncertain origin. Again, radiologically detectable degenerative changes may or may not be causally associated with symptoms.

Coan et al. (1981) compared acupuncture treatment (including electroacupuncture) with no treatment for patients with cervical spine pain syndromes. At the 12 week follow-up assessment, 80 percent of the acupuncture group reported an improvement, compared to 13 percent of the no treatment group.

The majority of patients in the study by David et al. (1998) had postural neck pain, chronic whiplash injury, or occupationally-related neck pain (e.g., VDU operators). The remainder were diagnosed as having neck pain related to cervical spondylosis. The study compared medical acupuncture (including local needling of trigger points, as well as regional and distal needling) to standard physiotherapy mobilisation techniques. At six week follow-up, statistically significant improvements were identified in both the acupuncture and physiotherapy groups for measures of neck mobility and pain.

Patients in the study by Irnich et al. (2001) either had diagnoses of myofascial pain syndrome or whiplash. The three arm trial compared a treatment package made up of traditional Chinese medicine and ear acupuncture and dry needling of local myofascial trigger points with conventional massage and sham laser acupuncture. Three months after treatment, no significant differences were detected between the three groups for the primary outcome measure – pain associated with neck movement as assessed by VAS. However, acupuncture was superior for most secondary outcomes.

Petrie and Hazelman (1986) compared traditional acupuncture with sham TENS for a group of patients with chronic cervical pain, including a majority with degenerative disease of cervical spine. They found no statistically significant differences between the two groups either at the end of treatment or at one month follow-up.

Shoulder pain

Three excluded RCTs assessed the effectiveness of acupuncture for patients with shoulder pain of diverse aetiology. All three designs compared acupuncture with sham acupuncture, although the types of sham acupuncture techniques differed.

Batra et al. (1985) compared electroacupuncture given at traditional acupuncture points with sham electroacupuncture at non-traditional points. After treatment, the majority of the true acupuncture group assessed their pain as “much better”, whereas only one member of the sham acupuncture group rated their pain as “much better”.

The trial by Moore and Berk (1976) included patients with periarticular disease (tendinitis or bursitis) or osteoarthritis and compared acupuncture at traditional sites with non-penetrating superficial needling
at the same sites. Statistically significant improvements in shoulder discomfort were found for both groups, but no statistically significant differences were found between the groups.

Von Mencke et al. (1988) found that after seven treatments traditional acupuncture was superior to sham acupuncture for pain reduction and most orthopaedic tests.

Multiple pain sites

Four excluded RCTs assessed the effectiveness of acupuncture in groups of patients with musculoskeletal pain in diverse anatomical regions. Three compared acupuncture with sham acupuncture, while one compared acupuncture with TENS.

Patients in the trial by Cheng and Pomeranz (1986) had musculoskeletal conditions such as osteoarthritis, low back pain, whiplash, tendinitis, epicondylitis, capsulitis, and fibrositis. Standard electroacupuncture at traditional acupuncture points was compared with acupuncture-like TENS (ALTENS) at the same points, with results from long-term follow-up showing ALTENS had a statistically significantly higher success rate than electroacupuncture.

Gallacchi et al. (1981) compared the effects of needle acupuncture at traditional Chinese acupuncture points with sham acupuncture at the same points, sham acupuncture at non-traditional points, as well as various types of radiation at traditional acupuncture points. Patients were diagnosed as having chronic tendomyotic cervical and lumbar syndromes. Improvements were found in all groups. There were no statistically significant differences between groups.

Participants in the trial by Godfrey and Morgan (1978) had a mix of diagnoses including degenerative disc disease, osteoarthritis, and lumbosacral strain. Pain sites included back, neck, knee, shoulder, hip, and elbow. Acupuncture at traditional acupoints was compared with sham acupuncture at non-traditional acupoints. Immediately following the course of treatment, both the true and sham acupuncture groups improved, though there were no statistically significant differences in improvement between the groups.

Junnila (1982) compared the effects of acupuncture at traditional acupoints with a sham acupuncture technique where fingernail pricks were given at points approximately 2.5 cm away from traditional acupoints. Trial subjects had headaches, neck and shoulder pain, low back pain and osteoarthritis. Patients in the true acupuncture group indicated an 80 percent reduction in pain assessed by VAS, compared to a 30 percent reduction in the sham acupuncture group. These differences were statistically significant.

OVERVIEW OF EXCLUDED SYSTEMATIC REVIEWS AND META-ANALYSES

As already indicated, no systematic reviews or meta-analyses were found that fully met the inclusion criteria for this review.

Several good quality systematic reviews and meta-analyses have appraised RCTs examining the effectiveness of acupuncture for treating musculoskeletal disorders. However, none of these reviews or meta-analyses aimed specifically to assess acupuncture’s effectiveness for treating musculoskeletal disorders caused only by injury.

The one systematic review that comes close to fulfilling all the inclusion criteria is the review by Green et al. (2002) of acupuncture’s effectiveness for treating lateral elbow pain. This is one of a series of reviews of interventions for lateral elbow pain undertaken for the Cochrane Collaboration. The review included trials that did not involve needling (e.g., laser acupuncture), as well as interventions that involved a combination of acupuncture and other therapies (e.g., vitamin B12 injection). The review also included trials with nil or only short-term post-treatment follow-up periods. The review identified four included RCTs. The review determined that these four trials provided insufficient evidence to either support or refute the use of acupuncture in the treatment of lateral elbow pain. It called for further trials examining acupuncture’s effectiveness for treating tennis elbow pain using robust methodologies and adequate sample sizes.
Four good quality systematic reviews or meta-analyses have assessed the effectiveness of acupuncture for treating musculoskeletal pain in certain anatomical regions of the body. However, none of these reviews specifically focus on musculoskeletal pain caused only by injury. In all cases, the reviews included RCTs where all or some patients had degenerative musculoskeletal conditions, particularly osteoarthritis.

Van Tulder et al. (1999) (also see van Tulder et al. 2001), undertook a systematic review of the effectiveness of acupuncture for the management of acute and chronic low back pain. The review excluded RCTs where subjects had low back pain caused by specific pathologic entities such as infection, metastatic diseases, neoplasm, osteoporosis, rheumatoid arthritis, or fractures. Eleven RCTs were included. While eight of the RCTs concluded that acupuncture was effective, the reviewers considered that positive effects were demonstrated in only two of these studies. The reviewers concluded that there was no convincing scientific evidence that acupuncture was effective in the management of acute and chronic low back pain.

Ernst and White (1998) conducted a meta-analysis of RCTs assessing acupuncture’s effectiveness for treating any type of back pain in humans. Back pain was acknowledged not to be a distinct entity but an ill-defined category of complaints with diverse causes. Trials in which one form of acupuncture was compared with another were excluded. Twelve RCTs were finally included in the review. In most of these studies, the post-treatment follow-up period was considered inadequate. Results of a meta-analysis of outcome data for nine of the studies that presented suitable outcome data favoured acupuncture as a treatment for back pain. Omission of the three other RCTs was considered unlikely to seriously undermine the accuracy of the meta-analysis. The authors concluded that the RCTs showed acupuncture to be superior to various control interventions, but that data for sham-controlled, evaluator-blinded studies did not show acupuncture to be superior to placebo. The review called for further trials to determine the extent to which acupuncture works through specific effects or non-specific effects.

Results from another systematic review of acupuncture’s effectiveness for the treatment of chronic low back pain were not summarised in an evidence table. This is because it was not comprehensive, overlooking several eligible RCTs (Strauss 1999).

White and Ernst (1999b) undertook a systematic review of RCTs assessing acupuncture’s effectiveness for treating acute or chronic neck pain. RCTs that assessed the effects of non-needling acupuncture (e.g., laser) were included. Studies comparing one form of acupuncture with another were excluded. A total of 14 RCTs were selected for inclusion. The methodological quality of the studies was considered to be generally disappointing. The results of only three of the eight higher quality studies favoured acupuncture. The authors concluded that acupuncture was superior to waiting-list controls, but whether this was due to the non-specific or specific effects of acupuncture was unclear given the current state of the evidence.

Smith et al. (2000) completed a systematic review of the analgesic efficacy of acupuncture compared to placebo for back and neck pain. RCTs that assessed the effects of non-needling acupuncture were included. Trials comparing acupuncture with other active treatments were excluded. Thirteen RCTs were included, 11 for chronic back or neck pain and two for acute low back pain. Trials were rated as generally of poor quality, especially because of lack of blinding and small group sizes. Higher rated trials were more likely to be unfavourable to acupuncture. The authors concluded that acupuncture was no more effective than placebo for treating back and neck pain. There was insufficient evidence to determine if pain relief is an early outcome or a late outcome of acupuncture treatment.

Three further good quality systematic reviews or meta-analyses were identified that assessed the effectiveness of acupuncture for treating pain in diverse anatomical regions of the body. These reviews included RCTs on musculoskeletal pain (e.g., osteoarthritis or rheumatoid arthritis pain, non-specific low back pain) as well as RCTs on pain from conditions such as angina, migraine, neuralgia, cystitis, dysmenorrhoea, or herpes.

A systematic review by Ezzo et al. (2000) examined all English language RCTs assessing the effectiveness of acupuncture for treating people with chronic pain, defined as pain lasting longer than three months. A total of 51 RCTs were included. Several of these were RCTs focusing on musculoskeletal pain located in anatomical regions like the back, neck or shoulders. The review
concluded that there was limited evidence that acupuncture was better than no treatment (waiting list) for the treatment of chronic pain. Trials in which patients received six or more acupuncture treatment sessions were found to be significantly associated with positive outcomes. However, it was considered the level of evidence was insufficient to determine how effective acupuncture was compared to placebo, sham acupuncture or standard care.

The meta-analysis by Patel et al. (1989) of 14 RCTs evaluating the use of acupuncture for the treatment of chronic pain included trials covering musculoskeletal pain in the back, neck and shoulder, as well as headache pain. The authors found trials in which acupuncture was compared to conventional treatment was more favourable to acupuncture than trials against placebo. However, they concluded that reliable data on the effectiveness of acupuncture therapy should come from robust triple blind randomised clinical trials.

The meta-analysis of acupuncture’s effectiveness for treating chronic pain by ter Riet et al. (1990) included 51 RCTs and non-randomised controlled trials. These covered pain in musculoskeletal regions such as the neck, lower back and shoulder, as well as migraine headache, post-herpetic pain, pancreatitis and angina. The authors determined that no high quality studies of the effectiveness of acupuncture for treating chronic pain were available. They therefore were unable to draw any definitive conclusions regarding the efficacy of acupuncture for treating chronic pain.

LATERAL ELBOW PAIN

This section presents evidence tables for the included and excluded studies examining acupuncture’s effectiveness in the treatment of lateral elbow pain.

As described earlier, lateral elbow pain is commonly described as an overuse or overload pain disorder of the arm. Other names for the condition include “lateral epicondylitis”, “epicondylalgia” or “tennis elbow”. Minor and often unrecognised trauma of the extensor muscles of the forearm is thought to precede the development of the condition in many cases Green et al. (2002). Lateral elbow pain is generally a self-limiting condition, meaning that many patients will improve irrespective of the type of treatment they receive.

Three RCTs examining the effectiveness of needle acupuncture for the treatment of lateral elbow pain met all the criteria for inclusion in this review. One compared acupuncture with ultrasound (Davidson et al. 2001), one compared traditional acupuncture with superficial acupuncture at non-traditional points (Haker and Lundeberg 1990), and one compared traditional acupuncture with needling of similar depth at non-traditional points (Fink et al. 2002). Evidence tables for these three studies are presented in Table 1, pages 26-29.

A third RCT, undertaken in Italy by (Grua et al. 1999), appeared very likely to meet all the inclusion criteria for the review. However, despite concerted efforts and contact with a number of agencies, it was not possible to obtain a copy of the full report of the study. The study compared the effects of acupuncture and ultrasound in 40 patients with lateral elbow pain, following patients up for six months post-treatment. In the abstract the authors report that both acupuncture and ultrasound were significantly effective for reducing pain and improving function, but that acupuncture was significantly more effective than ultrasound. These differences were stated to be “permanent” and maintained at the six month follow-up assessment. The abstract supplied no information about blinding procedures, including whether or not independent blinded outcome assessors were used during the trial.

Two further needle acupuncture RCTs were excluded; one because it only had a 72 hour post-treatment follow-up period (Molsberger and Hille 1994; also reported in Molsberger 1986), and the other because the active therapy was acupuncture in combination with B12 injection, and there was no follow-up assessment (Wang 1997). Brief evidence tables for these studies are presented in Table 2, page 30.

A very recently completed systematic review of acupuncture’s effectiveness for treating lateral elbow pain was excluded from the review because it included RCTs where acupuncture was not the sole treatment modality and RCTs where final post-treatment follow-up assessments were conducted less than one month after the end of the course of treatment (Green et al. 2002). A brief summary of this systematic review is provided in Table 3, page 31.
Limitations of included studies

The authors of all three included RCTs determined that acupuncture was effective in the treatment of lateral elbow pain. However, the trial in which acupuncture was found to be superior to ultrasound was a pilot study containing only 17 subjects (Davidson et al. 2001).

All three trials included blinded outcome assessors, but patients were blinded to the type of therapy being provided in only one of the trials (Fink et al. 2002).

The trial comparing traditional acupuncture with superficial acupuncture had long-term post-treatment follow-up assessment scheduled at three months and 12 months (Haker and Lundeberg 1990). However, 13 of the original 86 clinic patients included in the study at baseline had dropped out or withdrawn from the study by three month follow-up.
### Table 1. Lateral elbow pain – Evidence table of included randomised controlled trials

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Population</th>
<th>Intervention, outcome measures and follow-up</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davidson et al. (2001)</td>
<td>17 subjects who had been carefully screened through history taking and physical examination.</td>
<td><strong>Intervention</strong>&lt;br&gt;G1: 8 treatments x 20 minutes, standardised protocol of acupuncture, with teh chi.&lt;br&gt;G2: 8 treatments x 10 minutes, standardised protocol of ultrasound.&lt;br&gt;&lt;br&gt;<strong>Duration</strong>&lt;br&gt;2-3 treatments per week.&lt;br&gt;&lt;br&gt;<strong>Baseline comparability</strong>&lt;br&gt;Mean age for G1 was 49 years and for G2 46 years. G1 comprised 4 males and 4 females, G2 3 males and 6 females. Prior to the first treatment, VAS scores for G1 were slightly less than G2 (39.6 vs. 46.5). Pain-free grip strength scores were more for G1 than G2 (10.3 vs. 6.1). DASH disability scores were slightly lower for G1 than G2 (36.4 vs. 38.0).&lt;br&gt;&lt;br&gt;<strong>Blinding</strong>&lt;br&gt;Outcome assessors: Yes&lt;br&gt;Patients: No&lt;br&gt;Therapist: No&lt;br&gt;&lt;br&gt;<strong>Primary outcome(s)</strong>&lt;br&gt;Pain-free grip strength (measured by dynamometer). Pain level VAS (Visual Analogue Pain Scale). DASH upper extremity disability questionnaire (30-items assessing functional ability in everyday activities).&lt;br&gt;&lt;br&gt;<strong>Follow-up</strong>&lt;br&gt;Four week follow-up to administer DASH upper extremity disability questionnaire, VAPS and pain-free grip strength prior to each treatment.&lt;br&gt;&lt;br&gt;<strong>Drop-outs</strong>&lt;br&gt;One subject dropped out of G2 and failed to complete the 8 treatment sessions. Analysis involved only the 16 remaining subjects.</td>
<td>Both treatments (acupuncture and ultrasound) were found to be effective in improving all outcome measures (p&lt;0.05).&lt;br&gt;&lt;br&gt;Analysis of variance for between-group differences showed that acupuncture was more effective than ultrasound at reducing pain, as subjectively assessed by patients using VAS (F(2,14) = 5.287, p&lt; 0.05).&lt;br&gt;&lt;br&gt;There were no significant differences between the two treatments in the effects on pain-free grip strength or DASH.</td>
<td>Authors describe the trial as a pilot study.&lt;br&gt;No placebo control group.&lt;br&gt;Non-dominant side affected more in study group than is generally thought to be the case for this condition.&lt;br&gt;Very small sample size. This may have resulted in Type II errors. Authors calculated a total sample size of 168 would be required to achieve a power value of 0.90 for VAS. For the DASH measure, this increased to a required sample of 1,570 because of the small effect.</td>
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Table 1.  Lateral elbow pain – Evidence table of included randomised controlled trials (continued)

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Population</th>
<th>Intervention, outcome measures and follow-up</th>
<th>Results</th>
<th>Comments</th>
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<tr>
<td>Fink et al. (2002) Germany &quot;Chronic epicondylitis&quot;</td>
<td>45 subjects recruited by newspaper advertising. Screened initially by telephone and then during clinical examination. Screening selected only patients who reported no marked change in their complaint after previous treatments and no marked variation in their complaint in the previous 4 weeks. 40/45 had received treatments such as local anaesthesia, exercise, immobilisation or NSAIDs.</td>
<td>Intervention G1: 10 treatments x 25 minutes, standardised protocol of classical acupuncture at selected local, regional and distant acupoints, six needles in all, with teh chi. Needles inserted down to the musculature and twisted at the start of treatment. G2: 10 treatments x 25 minutes, standardised protocol of “sham” acupuncture at points at least 5cms away from classical acupuncture points and their interconnecting lines (meridians) and also clear of painful trigger points. Type of needle insertion identical to G1.</td>
<td>Both treatments (true acupuncture and sham acupuncture) associated with significant improvements in outcome measures at 2 weeks and 2 months. Analysis of between group differences found true acupuncture group improved significantly compared to sham group at 2 weeks for all three outcomes (strength G1=128.2, G2=92.7; pain G1=8.0, G2=12.3; DASH score G1=14.4, G2=25.2; p&lt; 0.05).</td>
<td>No age limit for patient inclusion. Sham acupuncture used in this trial involves deep rather than superficial needling.</td>
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<td>Inclusion criteria Chronic lateral epicondylitis of the elbow (duration &gt; 3 months); unilateral localisation; no age limit.</td>
<td>Duration 2 treatments per week.</td>
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<td>Baseline comparability Mean age for G1 was 52.5 years and for G2 51.6 years. No statistically significant difference between groups at baseline with respect to maximal strength, pain intensity and functional impairments. However, real acupuncture group had lower (better) mean scores than sham group for all three outcome parameters.</td>
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<td>Blinding Outcome assessors: Yes Therapist: No</td>
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Table 1. Lateral elbow pain – Evidence table of included randomised controlled trials (continued)

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<thead>
<tr>
<th>Author, year, country</th>
<th>Population</th>
<th>Intervention, outcome measures and follow-up</th>
<th>Results</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Fink et al. (2002)</td>
<td>Germany</td>
<td>“Chronic epicondylitis”</td>
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<td></td>
<td></td>
<td>Randomisation procedure List of random numbers.</td>
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<td></td>
<td></td>
<td>Allocation concealment Not reported.</td>
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<td></td>
<td></td>
<td>Primary outcome(s) Maximal strength measured with a specially designed device for testing the isometric strength of the forearm extensors. Pain intensity, rated using a six-point verbal rating scale for pain at rest, in motion, during exertion, duration and frequency of pain. Functional impairment measured using DASH upper extremity disability questionnaire [30-items assessing functional ability in everyday activities].</td>
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<td>Follow-up 2 weeks and 2 months post-treatment.</td>
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<td>Drop-outs 3 subjects did not attend or discontinued treatment, and a further 2 did not attend or were excluded prior to the 2 month follow-up (thus G1 n=20, G2 n=20 at 2 month follow-up).</td>
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<td></td>
<td>However, sham acupuncture led to significantly less improvement in DASH score for sub-group with high or varying occupational strain, cf. Sub-group with low occupational strain (p&lt; 0.05). Authors observe that therapeutic effect of true acupuncture was “dominant” at the start of the follow-up period. Authors conclude that acupuncture with correct location. and stimulation based on traditional Chinese theories “seems to alleviate pain and improve function” in chronic epicondylitis,</td>
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</table>
### Table 1. Lateral elbow pain – Evidence table of included randomised controlled trials (continued)

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Population</th>
<th>Intervention, outcome measures and follow-up</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haker and Lundeberg (1990) Sweden</td>
<td>“Lateral epicondylalgia”</td>
<td>86 clinic patients with lateral elbow pain, either self-referred or referred by a physician or physiotherapist. Patients attributed their symptoms to sport (29/86), work (27/86), other activities (20/86), trauma (1/86), non-specific causes (5/86). Most had tried other treatments.</td>
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<td>Inclusion criteria</td>
<td>Pain over the lateral epicondyle produced by 2 of 4 diagnostic tests and a pain duration of &gt; 1 month.</td>
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<td>Exclusion criteria</td>
<td>Dysfunction in the shoulder, neck and/or thoracic region; local arthritis, generalised polyarthritis; neurological abnormalities; radial nerve entrapment.</td>
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<td>Randomisation procedure</td>
<td>“Consecutive cases were randomly assigned”</td>
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<td></td>
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<td>Allocation concealment</td>
<td>Not reported.</td>
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<td>Intervention</td>
<td>G1: (n=44) classical “deep” acupuncture including Teh Chi at 5 traditional Chinese acupuncture points. 10 sessions, 20 mins each. G2: (n=38) superficial subcutaneous needle insertion at 5 traditional Chinese acupuncture points. No Teh Chi. 10 sessions, 20 mins each. Duration of treatment period</td>
<td>Not stated but average of 2-3 sessions per week.</td>
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<td></td>
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<td>Baseline comparability</td>
<td>Two groups regarded as similar regarding afflicted arm, cause of pain, and previous treatment.</td>
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<td></td>
<td></td>
<td>Blinding</td>
<td>Outcome assessors: Yes Patients: No Therapist: No</td>
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<tr>
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<td>Follow-up</td>
<td>10 treatments, 3 months, and 12 months.</td>
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<td>Drop-outs</td>
<td>4 of the 86 patients dropped out after two weeks in the study and were not included in the statistical analysis. A further 4 withdrew at end of treatment period, while 5 withdrew after 3 month follow-up.</td>
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<td>Immediately after the 10th and final treatment, 22/44 in G1 reported “excellent or good” results, cf. 8/38 in G2 (subjective outcome) (p &lt;0.01). No significant differences at 3 and 12 month follow-ups.</td>
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<td>Immediately after the 10th and final treatment, pain threshold on gripping balloon “significantly increased” in G1 compared with G2 (p &lt; 0.05). No significant differences at 3 and 12 month follow-ups.</td>
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<td>Immediately after the 10th and final treatment, a smaller number of G1 group suffered pain when lifting 3kg cf. G2 (p &lt; 0.05). “This was the only separate clinical sign showing a difference between groups.” No significant differences at 3 and 12 month follow-ups.</td>
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<td>For this review, the superficial needling used in this trial was considered equivalent to “sham” acupuncture.</td>
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<td>13/86 patients withdrew or dropped out prior to 3 month follow-up.</td>
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</table>
Table 2. Lateral elbow pain – Evidence table of excluded randomised controlled trials

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Population</th>
<th>Intervention, outcome measures and follow-up</th>
<th>Results</th>
<th>Reasons excluded and comments</th>
</tr>
</thead>
</table>
| Molsberger and Hille (1994)  
Also see Molsberger (1986) Germany  
“Chronic tennis elbow pain” | 48 volunteer patients with chronic unilateral tennis elbow pain, mean pain duration 15 months.  
Inclusion criteria  
Pain for more than 2 months, fluent in German.  
Exclusion criteria  
Current therapy involving pain killers, systemic bone or joint disorders [e.g., rheumatoid arthritis], overt psychiatric illness, previous acupuncture. | Intervention  
G1: Acupuncture (traditional acupuncture point, eliciting de qi). Single treatment session only.  
G2: Sham acupuncture with pencil-like probe (no puncture of skin) at non-traditional site, with suggestion that true acupuncture had occurred. Single treatment session only.  
Follow-up  
After treatment and during next 3 days (72 hours). | True acupuncture (G1) was significantly more effective than sham acupuncture (G2) for the measured outcomes:  
G1’s pain score [measured by VAS] reduced on average by 56% and that of G2 reduced by 15%.  
19/24 of G1 reported pain relief of at least 50%, compared with 6/24 for G2.  
Average duration of pain relief for G1 was 20.2 hours, compared with 1.4 hours in G2. | Excluded  
Post-treatment follow-up period < 1 month. |
| Wang (1997) 
“Tennis elbow”  
N.B. The full report of this trial could not be retrieved. All information shown here is derived from the systematic review by Green et al. (2002). | 60 people with lateral elbow pain, duration of condition 10 days-18 months.  
Inclusion criteria  
Not reported.  
Exclusion criteria  
Not reported. | Intervention  
G1: Acupuncture plus B12 injection.  
G2: B12 injection alone. | No statistically significant differences between the two treatment groups when assessed for symptoms immediately after treatment (G1: 4/30 still had symptoms; G2: 9/30 still had symptoms). | Excluded  
Acupuncture not the sole treatment modality; post-treatment follow-up period < 1 month. |
Table 3. Lateral elbow pain – Evidence table of excluded systematic reviews and meta-analyses

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Topic and search strategy</th>
<th>Inclusion criteria and outcomes of interest</th>
<th>Results</th>
<th>Reasons excluded and comments</th>
</tr>
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<tbody>
<tr>
<td>Green et al. (2002)</td>
<td>Topic: Acupuncture for lateral elbow pain. Search Medline, Cinahl, Embase and Scisearch, Cochrane Clinical Trials Register, Musculoskeletal Review Group’s specialist trial database (1966-June 2001). No language restrictions.</td>
<td>Inclusion criteria: Randomised and pseudo randomised trials; adults with lateral elbow pain; acupuncture (either with or without needling) compared to placebo or another intervention. Outcomes of interest: Pain, function, disability, quality of life, strength, participant satisfaction with treatment, adverse effects.</td>
<td>4 RCTs were included. Data from trials could not be combined in a meta-analysis due to flaws in study designs and clinical differences between trials. Insufficient evidence to either support or refute the use of acupuncture in the treatment of lateral elbow pain. Results from two small trials show needle acupuncture to be of short-term benefit (less than 24 hours) for pain. Further trials using appropriate methods and adequate sample sizes are needed before conclusions can be reached about acupuncture’s effectiveness for treating tennis elbow.</td>
<td>Excluded: Assessed RCTs with post-treatment follow-up &lt; 1 month; assessed RCTs with non-needling acupuncture; assessed RCTs where acupuncture was not the sole treatment modality.</td>
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</table>
PATELLOFEMORAL PAIN SYNDROME

This section contains the evidence table for the one included RCT examining acupuncture’s effectiveness for the treatment of patellofemoral pain syndrome (Jensen et al. 1999) (see Table 4 overleaf).

As discussed, patellofemoral pain syndrome is characterised by diffuse knee pain that is often made worse by squatting, kneeling, sitting in certain positions or getting up after long periods of sitting. The precise causes of the condition have yet to be precisely defined, though it is commonly classified as an overload injury associated with repeated weight-bearing impact, such as occurs during distance running.

Limitations of the included study

The Jensen et al. (1999) trial compared acupuncture with no treatment, concluding that relatively greater improvements occurred in the acupuncture group, with these greater improvements generally being maintained at long-term follow-up. Having no placebo or sham acupuncture group makes it difficult to determine the extent to which these differences are due to the specific effects of needling.

Although 13/75 subjects dropped out during treatment or did not return follow-up data, missing data was substituted with worst case results.
Table 4. Patellofemoral pain syndrome – Evidence table of included randomised controlled trials

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<thead>
<tr>
<th>Author, year, country</th>
<th>Topic and search strategy</th>
<th>Inclusion criteria and outcomes of interest</th>
<th>Results</th>
<th>Reasons excluded and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jensen et al. (1999)</td>
<td>Norway “Patellofemoral pain syndrome”</td>
<td>75 people recruited by advertising and case-finding in orthopaedic and physiotherapy practices. Patellofemoral pain syndrome defined as pain in one or both knees during activity or rest, without another specific disorder.</td>
<td>Baseline global score for CKRS (for worst knee) increased for acupuncture group compared to no treatment group at 5 months (acupuncture 71.9, controls 66.1, NS) and at 12 months (acupuncture 75.2, controls 61.7; p=0.005). Substitution of missing data with worst case results resulted in global CKRS of 68.1 for acupuncture group and 54.4 for controls (p=0.03). 14/32 of acupuncture patients assessed as free of pain at 12 months, cf. 3/29 of control group (p=0.007). 17/32 of acupuncture patients assessed as having no or slight limitation to activity at 12 months, cf. 7/29 of controls (p=0.04). Authors conclude that increased physical activity now made possible by acupuncture relieving pain. This may have been why relatively greater improvements were seen in the acupuncture group.</td>
<td>No placebo or sham acupuncture group used. Other treatments (e.g., physiotherapy and analgesics) allowed during trial.</td>
</tr>
<tr>
<td>75 people recruited by advertising and case-finding in orthopaedic and physiotherapy practices. Patellofemoral pain syndrome defined as pain in one or both knees during activity or rest, without another specific disorder.</td>
<td></td>
<td>Intervention: G1: Acupuncture based on individual diagnosis undertaken by the author; 2 sessions per week, 20-25 mins per session. Needles were manipulated until de-qi was obtained. G2: No treatment. Duration of treatment period 4 weeks. Baseline comparability: Subjects in acupuncture group were younger and slimmer, but this not regarded as clinically important. Blinding: Outcome assessors: Yes Patients: No Therapist: No Primary outcome(s): 1. Cincinnati Knee Rating System (CKRS) (evaluating symptoms of pain, swelling, giving-way, function. Max score = 100). 2. Stairs-Hopple Test – jumping on stairs using one leg. 3. Quadriceps atrophy – measurement of thigh circumference. 4. Self-rated pain after testing – using 10-cm VAS. Subjects also reported use of analgesic medication (including NSAIDs) in last 7 days, and any physiotherapy treatment. Follow-up: 6 weeks after inclusion (acupuncture group only), then at 5 months and 12 months (both groups). Drop-outs: 5 dropped out before first follow-up assessment. A further 9 subjects did not return CKRS questionnaire at 12 month follow-up. 14/32 of acupuncture patients assessed as free of pain at 12 months, cf. 3/29 of control group (p=0.007). 17/32 of acupuncture patients assessed as having no or slight limitation to activity at 12 months, cf. 7/29 of controls (p=0.04). Authors conclude that increased physical activity now made possible by acupuncture relieving pain. This may have been why relatively greater improvements were seen in the acupuncture group.</td>
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<td>Inclusion criteria: Aged 18-45; pain in one or both knees during activity or at rest consistent with patellofemoral pain syndrome; no other more specific knee disorder diagnosed or found; still able to participate in active daily life. Exclusion criteria: Received acupuncture in last 12 months; steroid treatment in last 3 months.</td>
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<td>Randomisation procedure: Randomly allocated in groups of 4. Allocation concealment: Not reported.</td>
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</table>
PLANTAR FASCIITIS

This section presents the evidence table for the one excluded RCT examining acupuncture’s effectiveness for the treatment of plantar fasciitis (Vrchota et al. 1991) (see Table 5 overleaf).

Plantar fasciitis is pain in the heel region associated with inflammation of the connective tissue at the bottom of the foot. The condition is believed to be an overuse injury resulting from standing, walking or running for long periods, especially on hard surfaces. Weight bearing exacerbates the condition.

**Limitations of the excluded study**

This trial by Vrchota et al. (1991) narrowly missed qualifying as an included study because it had a post-treatment follow-up period of only three weeks, not four. Therefore, its findings may still have some relevance for the current review.

The study compared the effects of electroacupuncture with sham acupuncture and conventional sports medicine therapy (stretching, ice, NSAIDs). At the end of the treatment period, and at follow-up, the electroacupuncture group was found to have experienced a significantly greater decrease in pain than the sports medicine group.
Table 5. Plantar fasciitis – Evidence table of excluded randomised controlled trials

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Topic and search strategy</th>
<th>Inclusion criteria and outcomes of interest</th>
<th>Results</th>
<th>Reasons excluded and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vrchota et al. (1991)</td>
<td>US “Plantar fasciitis pain”</td>
<td>43 patients with plantar fasciitis who responded to newspaper advertisements asking for study subjects. Inclusion criteria: Diagnosis of plantar fasciitis by history and physical examination. Exclusion criteria: None specified.</td>
<td>Intervention: G1: Electroacupuncture (traditional acupuncture points); G2: Sham acupuncture with minimal intensity electrostimulation (superficial acupuncture of non-traditional points); G3: Sports medicine therapy (decreased training; stretching exercises; ice applied after exercise; regular taking of NSAID – salsalate). Follow-up: 3 weeks post-treatment.</td>
<td>All groups improved over the study period. At the end of the treatment period, and follow-up, the “true” acupuncture group (G1) experienced a significantly greater decrease in pain (as recorded in their daily pain logs) compared with the sports medicine group (G3). At follow-up, the true acupuncture group also had significantly less pain, as assessed by a physician, than both the sports medicine and sham acupuncture groups. There were no statistically significant differences between the three groups in physician-assessed heel tenderness.</td>
</tr>
</tbody>
</table>
ROTATOR CUFF TENDINITIS

This section presents evidence tables for the two included RCTs (Table 6, pages 37 and 38) and one excluded RCT (see Table 7, page 39) examining acupuncture’s effectiveness for treating rotator cuff tendinitis.

Rotator cuff tendinitis is a condition where the tendons of the rotator cuff surrounding the shoulder joint become inflamed or tear as a result of repeated raising of the arm above the head during activities such as swimming, weight lifting and tennis.

Limitations of the included studies

The study by Dyson-Hudson et al. (2001) was undertaken with a special population of patients, namely individuals with spinal cord injury who used wheelchairs. This may limit its generalisability beyond wheelchair users. In addition, the study had only 24 subjects, six of whom (i.e., 25 percent) dropped out before the end of the treatment period. On top of this, the Trager Psychophysical Integration therapy used as a comparison treatment in the trial appears not to be a widely used therapy, meaning the results of the trial probably has potential relevance to only a small minority of health providers.

In terms of the parameters set for the current review, a major limitation of the Kleinhenz et al. (1999) trial is the lack of long-term (three months post-treatment) follow-up information for 33 percent of the study subjects. Consequently, while the study qualified for inclusion in the review because it collected long-term follow-up data, these data are in fact incomplete, meaning that conclusions based on them must at best be accepted with a degree of caution.
Table 6. Rotator cuff tendinitis – Evidence table of included randomised controlled trials

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<thead>
<tr>
<th>Author, year, country</th>
<th>Topic and search strategy</th>
<th>Inclusion criteria and outcomes of interest</th>
<th>Results</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Dyson-Hudson et al. (2001) US</td>
<td>“Wheelchair user’s shoulder pain in individuals with spinal cord injury”</td>
<td>24 wheelchair users (age 18-70yrs) with spinal cord injury and chronic (&gt;3 months) musculoskeletal shoulder pain (mostly rotator cuff in origin and believed to be the result of repetitive use injury). Exclusion criteria Suffered severe upper-extremity trauma, non-musculoskeletal shoulder pain, pregnancy, history of hospitalisation for psychopathology. Randomisation procedure Blocked randomisation – subjects with prior history of treatment with acupuncture or Trager were randomised separately using a coin toss. Allocation concealment Subjects told of treatment group assignment after baseline data collected.</td>
<td>Intervention G1: 10 treatment course (20-30 minutes per course) of acupuncture performed by licensed acupuncturists using both traditional and non-traditional acupuncture points – needles manually stimulated to produce de qi. G2: 10 treatment course of Trager Psychophysical Integration (a form of bodywork and movement reeducation) performed by certified practitioner. No set protocol. Duration of treatment period 5-9 weeks. Baseline comparability No significant differences between acupuncture and Trager groups at baseline. Blinding Outcome assessors: Yes Patients: No Therapist: No Primary outcome(s) Self-report questionnaire on activity level and intensity of shoulder pain (using PC-WUSPI – a visual analog scale - and verbal rating scales). Assessment of range of motion of shoulder (flexion, abduction, internal and external rotation by physical therapist). Follow-up 5 weeks after treatment endpoint. Drop-outs 18 of the 24 subjects completed the study (9 in acupuncture group and 9 in Trager group). Four withdrew during the first week of the baseline period, 2 withdrew during the treatment period. Those who withdrew had significantly smaller duration of shoulder pain than those who completed study. Statistical analyses only performed for the 18 who completed the study.</td>
<td>Significant reduction in mean pain intensity scores during the treatment period for both the acupuncture (53.4% reduction, p=.001) and Trager (53.8% reduction, p=.05) groups. At follow-up, subjects in acupuncture group experienced slight, but not statistically significant, increase in pain. Pain reduction continued for Trager group, though also not statistically significant. Statistically significant reduction in pain intensity scores for both acupuncture and Trager groups from beginning of treatment period to follow-up. Between group analysis found no significant differences in pain intensity scores at follow-up for the acupuncture and Trager groups. After treatment, 8/9 of the acupuncture group and 9/9 of the Trager group reported improvement in shoulder pain. The study obtained incomplete data on range of motion from subjects.</td>
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</table>
Table 6. Rotator cuff tendinitis – Evidence table of included randomised controlled trials (continued)

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Topic and search strategy</th>
<th>Inclusion criteria and outcomes of interest</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kleinhenz et al. (1999)</td>
<td>Male and female athletes aged 18-50 with shoulder pain (n=52). Injuries obtained in sports such as handball, volleyball, tennis, weightlifting, gymnastics, swimming, kayaking. [repetitive stress of rotator cuff tendons].</td>
<td>Inclusion criteria</td>
<td>Mean change in Modified Constant-Murley-score between baseline and after 4 weeks of treatment was 19.2 (SD 16.1, min –13, max 50) for the acupuncture group and 8.4 [SD 14.56, min –20, max 41] for the placebo-needling group – a statistically significant difference between the two groups (P=0.014; 95% CI: 2.3; 19.4). Of the 35/52 (67%) subjects who returned postal data at 3 month post-treatment follow-up, those in the acupuncture group had no statistically significant difference in pain intensity scores compared to 4 weeks post-treatment (4 weeks = 10.00 Constant-Murley-points, SD 4.54; 4 months = 8.89 C-M-points, SD 4.04). Those in the placebo needling group had further improvement (4 weeks = 6.47 Constant-Murley-points, SD 3.86; 4 months = 9.41 C-M-points, SD 4.64).</td>
<td>Patients were permitted to continue treatment with physiotherapy during the trial (but not use drugs or injections). Analysis of 3 month follow-up data based on only 67% subjects. Authors state these results should be regarded as preliminary. According to authors, placebo-needling may have caused acupressure effects.</td>
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<tr>
<td>Also see Streitberger et al. (2000)</td>
<td>Germany</td>
<td>Intention G1: 8 x 20 minute sessions of acupuncture on various acupoints. G2: 8 x 20 minute sessions of placebo-needling acupuncture on various acupuncture points without penetration of the skin using specially designed ‘placebo-needles’.</td>
<td>Duration of treatment period 4 weeks. Baseline comparability Statistical analysis revealed no relevant differences. Blinding Outcome assessors: Yes Patients: Yes Therapist: No Primary outcome(s) Changes in baseline shoulder function using Constant-Murley-score (items cover pain, activities of daily living, painless range of motion, power, with a maximum score of 100 denoting normal functioning).</td>
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<tr>
<td>&quot;Rotator cuff tendinitis&quot;</td>
<td>Inclusion criteria Rotator cuff disease due to sport; duration of disease more than 4 weeks; no acupuncture therapy in last 6 months; Constant-Murley-score under 81 points. Exclusion criteria Cervical or thoracic pain syndromes, previous operation of the shoulder, rupture of tendons, calcification in the rotator cuff, degeneration of gleno-humeral or acromio-clavicular joints, pregnancy. Randomisation procedure &quot;Central external randomisation&quot;. Allocation concealment No information.</td>
<td>Randomisation procedure &quot;Central external randomisation&quot;.</td>
<td>Mean change in Modified Constant-Murley-score between baseline and after 4 weeks of treatment was 19.2 (SD 16.1, min –13, max 50) for the acupuncture group and 8.4 [SD 14.56, min –20, max 41] for the placebo-needling group – a statistically significant difference between the two groups (P=0.014; 95% CI: 2.3; 19.4). Of the 35/52 (67%) subjects who returned postal data at 3 month post-treatment follow-up, those in the acupuncture group had no statistically significant difference in pain intensity scores compared to 4 weeks post-treatment (4 weeks = 10.00 Constant-Murley-points, SD 4.54; 4 months = 8.89 C-M-points, SD 4.04). Those in the placebo needling group had further improvement (4 weeks = 6.47 Constant-Murley-points, SD 3.86; 4 months = 9.41 C-M-points, SD 4.64).</td>
<td>Patients were permitted to continue treatment with physiotherapy during the trial (but not use drugs or injections). Analysis of 3 month follow-up data based on only 67% subjects. Authors state these results should be regarded as preliminary. According to authors, placebo-needling may have caused acupressure effects.</td>
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</table>
Table 7.  Rotator cuff tendinitis – Evidence table of excluded randomised controlled trials

<table>
<thead>
<tr>
<th>Author, year, country</th>
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<th>Intervention, outcome measures and follow-up</th>
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</thead>
<tbody>
<tr>
<td>Berry et al. (1980) UK</td>
<td>60 males and females attending hospital outpatients department for pain arising from the shoulder. Inclusion criteria Pain due to a rotator-cuff lesion. Included pain on resisted movements of the shoulder, with loss of passive movement, mainly abduction. Many had “painful arc syndrome”. Exclusion criteria “Frozen shoulder”, fracture, inflammatory arthritis, renal or hepatic disease, haemopoietic disorder, malignancy, mental disorder, gastro-intestinal disorders, pregnancy.</td>
<td>Intervention G1: Acupuncture with moxibustion. G2: Steroid injection plus placebo oral medication. G3: Steroid injection plus oral tolmetin sodium (anti-inflammatory drug). G4: Ultrasound (physiotherapy treatment). G5: Placebo oral medication plus placebo ultrasound. Follow-up Subjects assessed during and immediately after 4 week treatment period.</td>
<td>Over the four weeks treatment, there were statistically significant improvements in VAS pain readings for all five groups, but no statistically significant differences between the groups. Initially, 75% of all patients assessed their pain as “moderate” or “severe” and 25% said their pain was “mild”. After 4 weeks, none had “severe” pain, one third had “moderate” pain. There were no differences between treatment groups. Shoulder abduction significantly improved in all groups, but again there were no differences in the results for the 5 different groups.</td>
<td>Excluded Post-treatment follow-up period &lt; 1 month.</td>
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</table>
SCIATICA

Sciatica is pain in the large sciatic nerve running from the lower back down through the buttocks and the back of each leg. The pain can occur due to pressure imposed on the nerve by a herniated (protruding) intervertebral disc. A herniated disc, and thus sciatica, can sometimes be caused by injury.

This section presents evidence tables for the one excluded RCT examining acupuncture’s effectiveness for treating acute sciatica (Duplan et al. 1983) (see Table 8 overleaf). The study was excluded because it had an inadequate post-treatment follow-up period.
Table 8. Sciatica – Evidence table of excluded randomised controlled trials

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Population</th>
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</thead>
<tbody>
<tr>
<td>Duplan et al. (1983)</td>
<td>30 patients hospitalised for acute sciatica. Inclusion criteria: Severe sciatica originating from disc, acute phase of sciatica, hospitalisation because of no response to medical treatment. Exclusion criteria: Paralysing sciatic neuralgia, cauda equina involvement, symptoms from tumours, post-operative recurrence of sciatic neuralgia.</td>
<td>Intervention G1: Acupuncture using 9 traditional acupuncture points, 8 of which were detected electrically. G2: Sham acupuncture using 6 non-traditional sites. Follow-up: 5 days of treatment, with final assessment on the last day.</td>
<td>The Lasègue sign (angle between the leg and the flat part of a bed) improved significantly among the acupuncture group (G1). However, changes in several other objective signs were not statistically significant. Subjective measures of resting pain, pain after 10 minutes standing, duration of improvement, and analgesic consumption also all improved statistically significantly in G1. There were no statistically significant improvements in G2 for any of the objective or subjective outcome measures.</td>
<td>Excluded Post-treatment follow-up period &lt; 1 month. Note that analgesics were being taken by at least some subjects in both G1 and G2.</td>
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</table>
LOW BACK PAIN

This section presents evidence tables for the excluded studies examining acupuncture’s effectiveness for treating low back pain. These studies included groups of patients with various categories of musculoskeletal disorder producing back pain.

As discussed, none of these studies were considered to fully meet the criteria for inclusion in the review. They are presented here largely for the sake of comparison.

A number of low back pain RCTs were excluded during the early phases of the work for this review, either reviewing either abstracts or retrieved full reports. Reasons for exclusion included: results of the study were poorly reported or not reported at all; the type of acupuncture did not involve needling (e.g., laser acupuncture); the needling included wet needling (e.g., injections of substances) rather than dry needling; one standard type of acupuncture was compared with another.

After this, 14 back pain RCTs remained that potentially could be eligible for inclusion in the review (Carlsson and Sjolund 2001; Cherkin et al. 2001; Coan et al. 1980; Edelist et al. 1976; Garvey et al. 1989; Grant et al. 1999; Grobglas 1993; Gunn et al. 1980; Kittang et al. 2001; Lehmann et al. 1986; Macdonald et al. 1983; Mendelson et al. 1983; Thomas and Lundberg 1994; Von Mencke et al. 1989). It is these 14 back pain trials that are summarised in the evidence tables below (see Table 9, pages 43-53).

The systematic reviews and meta-analyses described in the evidence tables in this section were all excluded. This is because they primarily covered the same RCTs already excluded from the review for various reasons. The relevance of the conclusions of these reviews and meta-analyses specifically for injury-related back pain, as opposed to back pain not related to injury, or back pain of diverse or unknown origin, was therefore unclear (see Table 10, pages 54-56).

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4 It should be noted that several of these RCTs reported the results of radiological tests indicating that a high proportion of subjects had degenerative changes of the spine. These trials were frequently excluded on the basis of this information. However, a high proportion of the adult population normally develops radiological degenerative changes as they get older and back pain in people with radiological degenerative changes may still be caused or exacerbated by an injury event or process.
Table 9. Low back pain – Evidence table of excluded randomised controlled trials

<table>
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<tr>
<th>Author, year, country</th>
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<tr>
<td>Carlsson and Sjölund (2001), Sweden</td>
<td>50 consecutive adult patients (33 women and 17 men) with chronic lumbar or lumbosacral low back pain referred to outpatient pain clinic.</td>
<td><strong>Intervention</strong>&lt;br&gt;G1: Manual acupuncture. G2: Electroacupuncture. G3: Placebo stimulation (mock TENS with disconnected electrodes, and flashing lights visible to patient).&lt;br&gt;<strong>Follow-up</strong>&lt;br&gt;1 month and 6 months.</td>
<td><strong>Results</strong>&lt;br&gt;Independent assessment at 1 month showed a significantly higher proportion of subjects (16/34) in the acupuncture group (G1 + G2) had improvements compared with the placebo group (2/16 of G3).&lt;br&gt;At 6 months, this significant difference remained with 14/34 of G1+G2 showing improvements and only 2/16 of G3. There were also significantly greater improvements among the acupuncture group with regards to pain intensities (VAS) at 1 and 3 months, and in return to work, quality of sleep, and analgesic intake.&lt;br&gt;Authors concluded that acupuncture is effective in treating low back pain that is nociceptive in origin (but not neurogenic or psychogenic).</td>
<td>Excluded&lt;br&gt;Only a maximum of 78 percent of subjects had conditions that were likely to be due to injury (11 subjects had “severe structural changes” on X-ray, including old compression fractures, severe spondylarthrosis, and spinal stenosis).&lt;br&gt;Due to inadequate enrolment of subjects (partly because of increasing numbers of people who had previously experienced acupuncture), results for G1 and G2 were pooled for the statistical analyses.&lt;br&gt;Note that analgesic intake was used as an outcome measure, i.e., at least some subjects were taking analgesics during the trial (i.e., acupuncture was not sole modality treatment).</td>
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**Table 9. Low back pain – Evidence table of excluded randomised controlled trials (continued)**

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<tr>
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<tr>
<td>Cherkin et al. (2001)</td>
<td>People (HMO enrollees) aged 20 to 70 years who visited a primary care physician for low back pain (n=262).</td>
<td>Intervention: G1: Traditional Chinese acupuncture (n=94). G2: Therapeutic massage (n=78). G3: Self-care educational materials (n=90). Follow-up: 4, 10, and 52 weeks.</td>
<td>At 10 weeks follow-up, people in G2 (massage) had less dysfunction than those receiving acupuncture or self-care, and had less severe symptoms than those receiving self-care. Also, a higher proportion of patients in G2 subjectively rated their treatment as very helpful compared with the other two groups. After one year, massage was significantly more effective than acupuncture in reducing symptoms and dysfunction, but was not significantly more effective than self-care. A sub-study of 135 subjects from G1 and G2 indicated that subjects with higher expectations of the benefits of their assigned treatment were more likely to receive improved Roland disability scores than subjects with lower expectations of the benefits of their assigned treatment.</td>
<td>Excluded: No description of clinical conditions of study subjects, or whether or not they had experienced injuries. Because of large range of ages, likely to be a very heterogeneous group in terms of the disorders they had. Note also that use of medications was an outcome measure – i.e., at least some subjects were using medications during the trial, so acupuncture was not the sole treatment modality.</td>
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<td>Kalauokalani et al. (2001)</td>
<td>Inclusion criteria: Still had back pain 6 weeks after first visit. Exclusion criteria: Sciatica; underlying systemic or visceral disease; pregnancy; severe or progressive neurologic deficits; lumbar surgery within the past 3 years; recent vertebral fracture; serious comorbid conditions; bothersomeness of back pain rated as less than 4 on a scale from 0 to 10.</td>
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**Effectiveness of Acupuncture for the Treatment and Rehabilitation of Accident-Related Musculoskeletal Disorders**
Table 9. Low back pain – Evidence table of excluded randomised controlled trials (continued)

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Population</th>
<th>Intervention, outcome measures and follow-up</th>
<th>Results</th>
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<tbody>
<tr>
<td>Coan et al. (1980) US &quot;Low back pain&quot;</td>
<td>50 patients with low back pain, recruited by newspaper advertisements. Radiological abnormalities were found among 38 of the 43 participants who had X-rays, including degeneration with spur or osteophyte formation, narrowing of the intervertebral space, disc degeneration, scoliosis, spondylolisthesis. 4/50 had previous back surgery, 27/49 had sciatica, and 36/46 had muscle spasm.</td>
<td>Intervention: G1: Traditional Chinese acupuncture with electroacupuncture in some (n=23). G2: Waiting list – no treatment until at least eight weeks after trial started (n=16). G3: Inadequately treated patients (n=11) (this group was not originally planned as part of the study and was not randomised – was formed from members of G1 and G2 who decided either to discontinue treatment or not to begin it). Follow-up: G1: 10.3 weeks after enrolling for study (average of 4.5 weeks after average of 11.4 treatments); 40 weeks after enrolment. G2: 15 weeks after enrolment, before first acupuncture treatment; 25 weeks after enrolment (average of 7.4 weeks after average of 9.9 treatments); 40 weeks after enrolment. G3: 40 weeks after enrolment (average of 1.4 treatments).</td>
<td>After the first follow-up, 83% of the acupuncture group (G1) reported an improvement and none were worse. During the same time, 31% of the delayed treatment group (G2) reported an improvement and 20% said they were worse. In G1, there were reductions of 32% in pain hours, 51% in pain scores, 33% in the number of pain pills taken, and 19% in limitation of activity. In G2 there were reductions of 0-2% for the same outcomes. In the second follow-up of G2 (after acupuncture), 75% reported an improvement and none were worse. G2 also reported reductions of 52% in pain hours, 40% pain score, 62% in number of pills taken, 28% in limitation of activity. At the 40 weeks post-enrolment follow-up, the inadequately-treated group (G3) had virtually the same pain score as initially, whereas the pain scores of the other two groups remained around 30% lower than originally. Authors concluded that acupuncture was effective.</td>
<td>Excluded: A large proportion of sample had degenerative changes on X-ray. Although results at 40 weeks are presented individually for each patient, (with the X-ray diagnosis where available), there is no indication if treated back pain is related to any kind of injury event or process. Original design of 2 groups was changed during the trial so that drop-outs from both groups were combined into a third group that was also followed up at the end of the study. No statistical significance testing reported. Only some of G1 had electroacupuncture. Follow-up times were not consistent between and within the three groups (especially the first follow-up in G1 and G2). Some subjects in all three groups were taking analgesics during the trial.</td>
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### Table 9. Low back pain – Evidence table of excluded randomised controlled trials (continued)

<table>
<thead>
<tr>
<th>Author, year, country</th>
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<th>Intervention, outcome measures and follow-up</th>
<th>Results</th>
<th>Reasons excluded and comments</th>
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<tr>
<td>Edeist et al. (1976)</td>
<td>30 patients with low back pain treated at Mt. Sinai Hospital, Toronto.</td>
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<td>Canada</td>
<td>“Low back pain”</td>
<td>Inclusion criteria Failure to improve after conventional medical treatment (bed rest, analgesics, heat, physiotherapy) after “expected interval”. Patients “were felt to have” disc disease that was unsuitable for surgery.</td>
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<tr>
<td></td>
<td>Exclusion criteria Not stated.</td>
<td>Intervention</td>
<td>Follow-up</td>
<td>7/15 of the true acupuncture group (G1) showed improvements, as did 6/15 of the sham acupuncture group [i.e., there was no statistically significant differences between the two groups]. There were also no statistically significant differences between the groups for subjective improvements (7/15 of G1 compared with 6/15 of G2), or objective improvements (6/15 of G1 compared with 5/15 of G2).</td>
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<td>G1: Electroacupuncture at traditional acupuncture points, with Teh Chi.</td>
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<td></td>
<td>G2: Electroacupuncture at non-traditional sites, with no Teh Chi.</td>
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<td></td>
<td></td>
<td>Follow-up</td>
<td>Referred to orthopaedic surgeon for assessment after treatment (actual time not stated, though presumed to be soon after treatment).</td>
<td>Excluded Post-treatment follow-up period &lt; 1 month. Inference was that all subjects had “disc disease”, although there was no explicit discussion of what conditions the subjects had or whether these were due to injury.</td>
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Table 9. Low back pain – Evidence table of excluded randomised controlled trials (continued)

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<tr>
<td>Garvey et al. (1989)</td>
<td>US “Low-back strain”</td>
<td>63 patients with “low back strain”. Inclusion criteria Non-radiating low back pain with normal neurological examination, able to localise point of maximum tenderness. Normal lumbosacral roentgenograms. Continuing pain after at least 4 weeks initial treatment with NSAIDs, hot showers, avoidance of activity that aggravated pain. Exclusion criteria Tension signs.</td>
<td>Intervention All treatments were single trigger point treatments (after an isopropyl wipe). G1: Lidocaine (+ bacteriostatic). G2: Lidocaine + steroid. G3: Dry needle acupuncture. G4: Spray of vapocoolant + acupressure [with needle guard]. Follow-up 2 weeks post-injection.</td>
<td>A higher proportion of those who had injections without active medication (i.e., 63% of G3 plus G4) had improvements in pain compared with those whose injections contained medication (42% of G1 plus G2) [p value = 0.09]. Authors concluded that “trigger-point injection therapy is a useful method of treating low back strain when there is an area of maximum tenderness. …The critical factor in giving relief of pain is not the injected substance, but, rather, some type of mechanical stimulus to the trigger point.” (p. 964).</td>
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<tr>
<td>Grant et al. (1999)</td>
<td>UK “Chronic back pain in the elderly”</td>
<td>60 patients aged 60 or over with back pain recruited by inviting GPs to refer “suitable” patients. Inclusion criteria Back pain for at least 6 months. Exclusion criteria Being treated with anticoagulants, being treated with systemic corticosteroids, if they had dementia, or other severe concomitant disease.</td>
<td>Intervention G1: Acupuncture treatment (n=32). G2: TENS treatment (transcutaneous electrical nerve stimulation) (n=28). Follow-up 4 days, 3 months.</td>
<td>Significant improvements in both groups in terms of VAS [visual analogue pain scale], NHP [Nottingham Health Profile pain sub-scale] and analgesic tablet intake. No significant changes in spinal flexion in either group [except for acupuncture at 4 days].</td>
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<td><strong>Grobglas (1993)</strong></td>
<td>29 patients with acute low back pain, aged 31-91.</td>
<td><strong>Intervention</strong>&lt;br&gt;G1: Subcutaneous lidocaine injection followed by auricular acupuncture at the acupuncture point believed to be effective for lumbar pain.&lt;br&gt;G2: Subcutaneous lidocaine injection followed by auricular acupuncture on the ear lobe (a non-acupuncture point).&lt;br&gt;<strong>Follow-up</strong>&lt;br&gt;30 minutes, next day, 8 days.</td>
<td><strong>Results</strong>&lt;br&gt;At 8 days, significantly greater improvements in self-reported pain and hand-floor distance were found among those in G1 (experimental group) compared with the placebo group. (In addition, at 24 hours G1 patients had a significantly better Schöber index than G2 patients).</td>
<td><strong>Reasons excluded and comments</strong>&lt;br&gt;Excluded&lt;br&gt;Post-treatment follow-up period &lt; 1 month.&lt;br&gt;Auricular (ear) acupuncture rather than acupuncture on more proximal points. Some patients in both groups were taking medications such as NSAIDs and analgesics.</td>
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<td><strong>Gunn et al. (1980)</strong></td>
<td>56 male rehabilitation clinic patients with chronic low back pain.</td>
<td><strong>Intervention</strong>&lt;br&gt;G1: Needling of muscle motor points (stimulation of large diameter fibres) including electroacupuncture for some plus standard clinic therapy (n=29).&lt;br&gt;G2: Continuation of standard clinic therapy (n=27).&lt;br&gt;<strong>Follow-up</strong>&lt;br&gt;At discharge, 12 weeks after discharge and at time paper was written (average 27.3 weeks) (note though that the number and time of follow-up assessments varied to some degree).</td>
<td><strong>Results</strong>&lt;br&gt;In terms of a 4-point pain-work status scale, “the main result is that dry needling of muscle motor points was found to be clearly and significantly better than the control treatment in the three “status” analyses …and was on the verge of being significantly better in the “weeks of time loss” analysis” (p. 288).&lt;br&gt;For the pain-work status analyses of G1, the average improvement was one status point, and for the “weeks of wage loss” the improvement was half a week.</td>
<td><strong>Reasons excluded and comments</strong>&lt;br&gt;Excluded&lt;br&gt;Both groups continued with standard rehabilitation therapy (physiotherapy, remedial exercises, and occupational therapy), so acupuncture was not sole treatment modality; less than 90% of each group were likely to have injury as a cause of their condition (many had degenerative changes or conditions and the majority were described as having “myofascial pain”), and a significant proportion had previous surgery (5/29 of G1 and 3/27 of G2).&lt;br&gt;Note that muscle motor points were used, rather than traditional acupuncture points (although these tend to coincide).</td>
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Table 9. Low back pain – Evidence table of excluded randomised controlled trials (continued)

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<tr>
<td>Kittang et al. (2001)</td>
<td>60 general practice patients aged between 18 and 67 with acute low back pain.</td>
<td>Intervention G1: Standardised needle acupuncture treatment at specified acupuncture points, 4 treatments over 2 weeks. G2: Entero-soluble naproxen twice daily for 10 days. Follow-up 6 months (and 12 months for pain relapse and sick leave).</td>
<td>Over 6 months, there were no differences in pain or stiffness between the two groups. During the first week after start of treatment, use of analgesics was significantly less in acupuncture group than naproxen group. Acupuncture group had significantly fewer new episodes of pain (during 6 and 12 month follow-up). Over half those using naproxen (15/29) had gastro-intestinal side effects.</td>
<td>Excluded No description of clinical conditions, or whether or not subjects had experienced injuries. Patients in both G1 and G2 got general advice and were encouraged to do daily physical activity. At least some of subjects were using analgesics during the trial (use of analgesics being one of the outcome measures).</td>
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<td>Lehmann et al. (1986)</td>
<td>Patients admitted to inpatient rehabilitation programme at University of Iowa Orthopaedic Clinic with low back pain (n=53).</td>
<td>Intervention G1: Electroacupuncture plus core curriculum (education and exercise training). G2: TENS (transcutaneous electrical nerve stimulation) plus core curriculum. G3: TENS with dead battery (placebo) plus core curriculum. Follow-up 6 months.</td>
<td>Though 28/53 returned to “gainful activity” at 6 month follow-up, “the rate of return did not vary across the treatment groups”.</td>
<td>Excluded 48% had prior lumbar surgery, 49% had low back pain due to unknown aetiology. All groups were also given core curriculum – education and exercise training.</td>
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<td>“Low back pain”</td>
<td>Inclusion criteria: Low back pain that was disabling and had lasted at least 3 months (in fact, all had pain for at least 6 months). Exclusion criteria: Candidates for lumbar surgery, pregnancy, osteomyelitis of spine, discitis, tumours, ankylosing spondylitis, vertebral fractures, structural scoliosis.</td>
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<td>Macdonald et al. (1983)</td>
<td>17 patients, referred to pain relief clinic, Charing Cross Hospital, London, with chronic low back pain. Inclusion criteria: Low back pain for at least one year. Conventional methods of treatment had failed to provide sufficient relief. Diagnoses for the 17 patients were: anterior spondylitis (1), ankylosing spondylitis (1), degenerative disc lesion (3), idiopathic (3), non-articular rheumatism (1), osteoarthritis (2), prolapsed intervertebral disc (3), arachnoiditis following discogram (1), sacroiliac ligamentous strain (1), Scheuermann’s osteochondritis (1). Exclusion criteria: Not stated.</td>
<td>Intervention G1: Superficial needling in the skin and subcutaneous layers (approx. 4mm) at “trigger” points (with electroacupuncture if necessary) – aimed to elicit “feeling of warmth”. G2: Sham TENS (using inert electrodes) over trigger points. Follow-up: At beginning and end of each course of treatment. Participants in the acupuncture group (G1) had statistically significantly greater improvements than those in G2 for the following four outcomes: 1. pain relief after each treatment (77% vs. 30%) 2. activity pain score reduction (52% vs. 6%) 3. physical signs reduction (97% vs. 29%) 4. severity and pain area reduction (74% vs. 19%).</td>
<td>Excluded Post-treatment follow-up period &lt; 1 month; &lt;90% of subjects had conditions that were likely to be injury-related. All patients were asked to continue their existing drug regimens and other support as required. Some subjects in G1 had electroacupuncture, whereas others did not. Superficial needling may not be considered to be true acupuncture.</td>
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Table 9. Low back pain – Evidence table of excluded randomised controlled trials (continued)

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<td>Mendelson et al. (1983)</td>
<td>77 patient volunteers, diagnoses included: osteoarthritis; traumatic spondylolysis; disc lesion; sacroiliac joint disorder; backache (not otherwise specified). Inclusion criteria: &quot;Chronic low back pain&quot;, fluent in English, referred by doctor. Exclusion criteria: Litigation or compensation claims pending, overt psychiatric illness.</td>
<td>Intervention G1: 4 weeks traditional Chinese acupuncture (with feh chi), then: G2: 4 weeks sham (placebo) acupuncture of non-tender sites on back, acupuncture needles inserted superficially. (Crossover design) Follow-up: 4, 12, &amp; 16 weeks.</td>
<td>Authors concluded that placebo component of acupuncture treatment was more important than the physiological effects.</td>
<td>Excluded: 58/77 had osteoarthritis. 36 patients were taking analgesics and 27 were taking psychotropics during the trial.</td>
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<td>Thomas and Lundeberg (1994) Sweden “Chronic nociceptive low back pain”</td>
<td>Patients with “chronic nociceptive low back pain” who were recruited from a private physiotherapy clinic and a research clinic (n=43). Inclusion criteria: Sudden or insidious onset of low back pain, with or without trauma. Pain for 6 months or longer. Muscle spasm present. Postural changes affecting the intensity of pain. Diagnoses included: Osteoarthritis; intervertebral disc degeneration; chronic intervertebral disc prolapse with sciatica; chronic lumbar strain with sciatica; osteoporosis with dorsolumbar strain; central disc prolapse; chronic lumbar strain. Exclusion criteria: Major depressive illness or neurosis, previous back surgery, claudicating pain, evidence of sympathetic dysfunction.</td>
<td>Intervention: G1: Acupuncture with manual stimulation of needles. G2: Acupuncture with low-frequency electrical stimulation (2 Hz). G3: Acupuncture with high-frequency electrical stimulation (80 Hz). G4: No treatment (put on waiting list for later treatment). Follow-up: 6 months.</td>
<td>“A long-term improvement of patients suffering from nociceptive low back pain when treated with acupuncture in comparison with untreated controls, both after treatment and follow-up” p.67. Only those who had low-frequency electro-acupuncture had significant improvement at long-term follow-up.</td>
<td>Excluded: At least 18/40 had osteoarthritis/degeneration and only 11/40 of sample had “lumbar strain” (3 of these had osteoporosis as well).</td>
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### Table 9. Low back pain – Evidence table of excluded randomised controlled trials (continued)

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<tr>
<td>Von Mencke et al. (1989) Germany &quot;Lumbalgie / Ischialgie&quot; (lumbago / sciatic pain)</td>
<td>65 patients with lumbar or sciatic pain from an orthopaedic clinic, or referred by a specialist.</td>
<td>Inclusion criteria Various types of lumbar and sciatic pain and related syndromes (12 percent acute and 88 percent chronic). Exclusion criteria Neurological deficits, scoliosis, additional treatments, acute disc protrusion or prolapse, chronic degenerative disorders, neuritis.</td>
<td>Intervention G1: Traditional acupuncture using trigger points. G2: Acupuncture using non-traditional points (this group subsequently had traditional acupuncture – crossover design). Follow-up Final assessment at 7th or 8th treatment.</td>
<td>Pain intensity reduced by an average of 55% in G1 and 15% in G2 at the 7th treatment. After traditional acupuncture, pain intensity reduced for G2 to 42% of original (overall reduction of 58%). Both these improvements for traditional acupuncture were statistically significant. At the 7th treatment, there were statistically-significant improvements in the Schober index, and finger-floor-distance tests for G1, but not for G2. There were mixed results for the Lasègue sign.</td>
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### Table 10. Low back pain – Evidence table of excluded systematic reviews and meta-analyses

<table>
<thead>
<tr>
<th>Author, year, country</th>
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<th>Inclusion criteria and outcomes of interest</th>
<th>Results</th>
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<tr>
<td>Ernst and White (1998) UK Meta-analysis</td>
<td>Topic: Acupuncture for treatment of back pain. Search: Medline (1969-1996), Cochrane Controlled Trials Register (July 1997) and CISCOM (November 1996). Files of published articles were screened. Experts invited to identify published studies. Bibliographies of retrieved articles were reviewed for further references. Authors of articles published 1992-97 were contacted and asked to identify any other relevant articles. Authors of abstracts were contacted and asked to provide full reports.</td>
<td>Included studies RCTs only; dry needles inserted into skin and described as “acupuncture”; treatment of any type of back pain in humans; published in English, French, German, Spanish, Italian, or Polish. Excluded studies Trials in which one form of acupuncture was compared with another. Excluded studies: Trials in which one form of acupuncture was compared with another.</td>
<td>12 RCTs were included. The methodological quality rating was rated “good” or better in 10 out of 12 of the studies. The expert acupuncturists had diverging opinions about the adequacy of the acupuncture therapy provided in 11 of the 12 studies. In most studies, the follow-up period was considered inadequate. Meta-analyses of trial outcome data were performed for 9 of the studies that presented suitable outcome data. The results, based on a total of 377 patients included in the trials, favoured acupuncture as a treatment for back pain (OR 2.30, 95% CI, 1.28-4.13). Sub-group analysis showed that results of unblinded studies were more favourable towards acupuncture than blinded studies. The data shows acupuncture to be superior to various control interventions, though data for sham-controlled, evaluator-blinded studies did not show acupuncture to be superior to placebo.</td>
<td>Excluded: Assessed RCTs with post-treatment follow-up &lt; 1 month; assessed RCTs with non-needling acupuncture; assessed RCTs where acupuncture was not the sole treatment modality; study did not focus on musculoskeletal pain caused only by injury.</td>
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Table 10. Low back pain – Evidence table of excluded systematic reviews and meta-analyses (continued)

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<tr>
<td>Ernst and White (1998)</td>
<td>UK Meta-analysis</td>
<td>The assessment of acupuncture's effectiveness in this area is difficult for the following reasons:</td>
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<td>- there are many variations of acupuncture technique and they are not necessarily comparable</td>
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<td>- back pain is not a distinct entity but an ill-defined category of complaints with diverse causes</td>
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<td>- acute back pain can often disappear within days with or without treatment</td>
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<td>- there are numerous concomitant treatments for back pain.</td>
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<td>Included trials were heterogeneous in terms of study population, type of acupuncture used, outcome measures used, and length of follow-up. For this reason forming a firm judgement about the efficacy of acupuncture for treating back pain was considered problematic.</td>
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<td>Unblinded studies may have been more favourable towards acupuncture than blinded studies because patient and therapist expectations are important in terms of clinical outcomes.</td>
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<td>Acupuncture, like other hands-on therapies, may be associated with a powerful placebo effect.</td>
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<td>Further trials are required to determine whether acupuncture works through specific effects (i.e., of needling) or non-specific effects (i.e., the therapist-patient interaction and context).</td>
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<td>The optimal study in acupuncture for back pain should test acupuncture on a homogeneous subtype of back pain that has previously been suggested to respond favourably.</td>
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Table 10. Low back pain – Evidence table of excluded systematic reviews and meta-analyses (continued)

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<tr>
<td>van Tulder et al. (1999)</td>
<td>Topic: Effectiveness of acupuncture in the management of acute and chronic non-specific low back pain. Search: Medline (1966-96), Embase (1988-96) and the Cochrane Complementary Medicine Field databases. Bibliographies of retrieved articles were reviewed for further references. Screening of the Cochrane Library, Citation tracking of the RCTs identified. Study authors were not contacted.</td>
<td>Included studies: RCTs assessing the effectiveness of acupuncture involving needling; acupuncture compared with no treatment, or acupuncture compared with placebo or sham treatment, or acupuncture compared with conventional treatment; subjects with either subacute (12 weeks or less) or chronic (more than 12 weeks) nonspecific low back pain; use at least 1 of 4 following primary outcome measures: pain intensity, a global measure of improvement or recovery, functional status, return to work.</td>
<td>11 RCTs were included. Individual study results were not pooled as studies were regarded as clinically heterogeneous in terms of type and duration of disorder, the types of acupuncture used, and the outcome measures. Two out of 11 studies met the pre set score defining a “high quality” study (50 or more out of a max 100 points). Authors in 8 of the studies concluded that acupuncture was effective, whereas the reviewers concluded that positive effects were demonstrated in only 2 of these studies. In most studies, the number of needles, number and duration of sessions, and duration of the intervention period were not specified. Because the studies in this review were of poor quality, the effectiveness of acupuncture for low back pain is unclear.</td>
<td>Excluded: Assessed RCTs with post-treatment follow-up &lt; 1 month; assessed RCTs where acupuncture was not the sole treatment modality; study did not focus on musculoskeletal pain caused only by injury.</td>
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<td>Also see van Tulder et al. (2001)</td>
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<td>Netherlands Systematic review</td>
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NECK PAIN

This section presents evidence tables for the excluded studies examining acupuncture’s effectiveness for treating neck pain.

None of these studies fully met all the criteria for inclusion in the review, nonetheless they are presented here for the sake of comparison and discussion.

Several neck pain RCTs were excluded during the early phases of the work for this review. Reasons for exclusion included: results of the study were poorly reported or not reported at all; the type of acupuncture did not involve needling (e.g., laser acupuncture); the needling included wet needling (e.g., injections of substances) rather than simply dry needling; one standard type of acupuncture was compared with another.

After this, four neck pain RCTs remained that potentially were eligible for inclusion in the review (Coan et al. 1981; David et al. 1998; Irnich et al. 2001; Petrie and Hazleman 1986). However, all four were excluded because they either lacked sufficient post-treatment follow-up, because acupuncture was not the sole modality in the active treatment group, or because it was not possible to satisfactorily conclude from the data provided that more than 90 percent of subjects in the study had neck pain caused by injury. 5

Features of these four excluded neck pain trials are summarised in the evidence tables below (see Table 11, pages 58 and 59).

The one systematic review of acupuncture treatment for neck pain was excluded because it covered essentially all the RCTs already excluded individually from this review for various reasons. This made it unclear what relevance the findings of the systematic review had for specifically identifying acupuncture’s possible role in treating injury-related neck pain (see Table 12, page 60).

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5 Note that in some instances RCTs reported the results of radiological tests indicating that a high proportion of subjects had degenerative changes of the spine. Some trials were excluded on the basis of this information. However, a high proportion of the adult population develops radiological degenerative changes as they get older and neck pain in people with radiological degenerative changes may still be caused or exacerbated by an injury event or process.
Table 11. Neck pain – Evidence table of excluded randomised controlled trials

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<td>Coan et al. (1981) US “Cervical spine pain syndromes”</td>
<td>30 patients recruited through newspaper advertisements.</td>
<td><strong>Intervention</strong>&lt;br&gt;G1: Traditional acupuncture ± electroacupuncture ± moxibustion.&lt;br&gt;G2: On waiting list for at least 8 weeks.&lt;br&gt;<strong>Follow-up</strong>&lt;br&gt;12 weeks after start of study. For G1 this was a mean follow-up time of 8 weeks. It is therefore assumed that the follow-up was at least one month after the treatment ended.</td>
<td>At the 12-week assessment, 80% of the acupuncture group (G1) reported an improvement vs. 13% of G2. On average, G1 had a reduction of 68% mean pain hours per day (vs. no change for G2), 40% pain score (vs. no change for G2), and 54% fewer pain pills (vs. 10% for G2). G1 also experienced a 32% improvement in activity level (vs. 12% of G2).&lt;br&gt;The authors concluded “we believe that an 80% remission rate far outweighs the 33% placebo response rate expected in pain studies” (p. 329).</td>
<td>Excluded&lt;br&gt;A large proportion of sample had degenerative changes on X-ray. Although results at 12 weeks are presented individually for each patient, (with the X-ray diagnosis where available), there is no indication if treated neck pain is related to any kind of injury event or process.&lt;br&gt;No statistical significance testing of results reported.&lt;br&gt;Acupuncture treatment not standard for all patients in G1.</td>
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<tr>
<td>David et al. (1998) UK “Chronic neck pain”</td>
<td>70 adult patients with non-inflammatory neck pain of &gt; 6 weeks duration.</td>
<td><strong>Intervention</strong>&lt;br&gt;G1: Medical acupuncture including local needling of trigger points as well as regional and distal needling. G2: Physiotherapy – standard, localised, mobilisation techniques.&lt;br&gt;<strong>Follow-up</strong>&lt;br&gt;Immediately post-treatment (at 6 weeks) and at 6 months.</td>
<td>At 6 weeks, significant improvements occurred in both acupuncture and physiotherapy groups in terms of neck mobility, VAS, and neck pain questionnaire. At 6 months, no further improvements, or slight deterioration occurred for different outcomes in both groups.&lt;br&gt;Acupuncture was more effective in reducing pain among patients with higher baseline pain scores.</td>
<td>Excluded&lt;br&gt;Sample included an unspecified proportion of subjects with cervical spondylosis (generally considered to be a degenerative condition).&lt;br&gt;Note: no blinding, no placebo control group.</td>
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Table 11. Neck pain – Evidence table of excluded randomised controlled trials (continued)

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<td><strong>Irnich et al. (2001)</strong>&lt;br&gt;Germany&lt;br&gt;“Chronic neck pain”</td>
<td>177 patients aged 18-85 with painful restriction of cervical spine for &gt; 1 month, included patients with myofascial pain syndrome and whiplash.&lt;br&gt;Inclusion criteria: Painful restriction of cervical spine mobility for ≥ 1 month, no treatment for two weeks before entering the study.&lt;br&gt;Exclusion criteria: Previous surgery, dislocation, fracture, neurological deficits, systemic disorders, other contraindications.</td>
<td>Intervention&lt;br&gt;G1: Traditional Chinese medicine and ear acupuncture and dry needling of local myofascial trigger points. G2: Conventional Western massage. G3: Sham laser acupuncture.&lt;br&gt;Follow-up: 1 week, and 3 months after treatment.</td>
<td>At one week post-treatment, the effects of acupuncture were significantly better than those achieved with conventional massage, but not sham laser acupuncture. Acupuncture was the best treatment for patients with myofascial pain syndrome and those who had pain for longer than 5 years.&lt;br&gt;At 3 months after treatment, there were no significant differences between the groups for the primary outcome measure (pain associated with neck movement – VAS). Acupuncture was more effective than the other two interventions for most secondary outcomes (neck mobility, direction-related pain, quality of life SF-36 health survey).</td>
<td>Excluded: 73 percent of subjects had myofascial pain syndrome (32 percent had whiplash).&lt;br&gt;Authors comment that other studies have suggested that “between 55% and 90% of patients with chronic neck pain have the myofascial pain syndrome and 20% to 50% have suffered a whiplash injury” [p.1576].</td>
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<tr>
<td><strong>Petrie and Hazelman (1986)</strong>&lt;br&gt;UK&lt;br&gt;“Neck pain”</td>
<td>25 outpatients with chronic cervical pain.&lt;br&gt;Inclusion criteria: Pain arising from neck with or without radiation to the shoulders and/or occiput, present on a daily basis for at least 6 months.&lt;br&gt;Exclusion criteria: Peripheral synovitis, malignancy.</td>
<td>Intervention&lt;br&gt;G1: Acupuncture at traditional Chinese points with stimulation and with Teh Chi (n=13). G2: Sham TENS (n=12).&lt;br&gt;Follow-up: At end of treatment and then at 1 month.</td>
<td>There were improvements in both groups. However, no significant differences between the two groups were found at the end of treatment or at the 1 month follow-up for: MPQ (McGill Pain Questionnaire); VAS; STAI (State-trait Anxiety Inventory); objective assessment of neck mobility; patient rating of changes in pain.</td>
<td>Excluded: 64 percent of subjects (16/25) found to have degenerative disease of cervical spine on X-ray (no other clinical conditions or injury events were mentioned).&lt;br&gt;Note too that all 13 subjects in the acupuncture group were using NSAIDs or analgesics, as were 7/12 of the sham TENS group (i.e., acupuncture was not sole modality in most cases).&lt;br&gt;The trial did not last long enough for the planned 50 subjects to be recruited – small study sample.</td>
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Table 12. Neck pain – Evidence table of excluded systematic reviews and meta-analyses

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Topic and search strategy</th>
<th>Inclusion criteria and outcomes of interest</th>
<th>Results</th>
<th>Reasons excluded and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>White and Ernst (1999b) UK</td>
<td>Acupuncture treatment for neck pain. Search Medline (1966-97), Embase (1974-97), the Cochrane Library (1998) and CISCOM. Files of published articles were screened. Bibliographies of retrieved articles were reviewed for further references. No language restrictions.</td>
<td>Inclusion criteria RCTs only; for acupuncture used in the treatment of subjects with acute or chronic neck pain; either needle acupuncture, electroacupuncture or laser acupuncture. Exclusion criteria Trials in which one form of acupuncture was compared with another; trials in which no data or statistical comparison were provided; studies of subjects with headache or with pain in multiple sites. Quality of the studies was assessed using a modified version of the method described by Jadad and colleagues. Adequacy of the acupuncture treatment was not formally tested.</td>
<td>14 RCTs were included, of which 12 involved needling. The general methodological quality of the studies was assessed as disappointing. The results of the 14 studies were balanced between positive and negative. Of the 8 higher quality studies, five were negative and three were positive. Acupuncture was superior to waiting-list control, which could be due to placebo (non-specific) effects or needling (specific effects). Acupuncture was superior or equivalent to physiotherapy. Acupuncture did not appear to be superior when compared with control procedures (“sham acupuncture”). This may be because acupuncture performed at carefully selected points with precise techniques produces no better results than the generalised physiological response that may occur after random needling of the skin. The hypothesis that acupuncture is efficacious in the treatment of neck pain is not supported by current evidence. More, better designed trials are required.</td>
<td>Excluded Assessed RCTs with post-treatment follow-up &lt; 1 month; assessed RCTs with non-needling acupuncture; study did not focus on musculoskeletal pain caused only by injury.</td>
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</table>
SHOULDER PAIN

This section presents evidence tables for three excluded RCTs examining acupuncture’s effectiveness for treating shoulder pain (Batra et al. 1985; Moore and Berk 1976; Von Mencke et al. 1988) (see Table 13, pages 62 and 63).

None of these studies fully met all the criteria for inclusion in the review, as they either lacked sufficient post-treatment follow-up, or acupuncture was not the sole modality in the active treatment group, or it was not possible to satisfactorily conclude from the data provided that more than 90 percent of subjects in the study had shoulder pain caused by injury.
### Table 13. Shoulder pain – Evidence table of excluded randomised controlled trials

<table>
<thead>
<tr>
<th>Author, year, country</th>
<th>Population</th>
<th>Intervention, outcome measures and follow-up</th>
<th>Results</th>
<th>Reasons excluded and comments</th>
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<tbody>
<tr>
<td>Batra et al. (1985)</td>
<td>“Chronic shoulder pain” 28 patients aged 45-55 with chronic shoulder pain (for 6 months to two years).</td>
<td>Inclusion criteria Painful restriction of shoulder and arm movement. Early signs of “arthrosis” on X-ray. Exclusion criteria None reported.</td>
<td>Intervention G1: Electroacupuncture at traditional points, with “Teh chi”. G2: Electroacupuncture at non-traditional points (2cm away from actual points). Follow-up “During the first phase of treatment” (10 treatments in total) – actual time not specified.</td>
<td>After treatment, 9/14 of true acupuncture group (G1) assessed their pain as “much better” compared with 1/14 of the sham acupuncture (G2). 12/14 of G1 also had a large decrease in, or only occasional, use of analgesics (compared with 3/14 of G2). 6/14 of G1 returned to “usual” or “full” activity regarding range of motion of the shoulder joint (compared with 1/14 of G2).</td>
</tr>
<tr>
<td>Moore and Berk (1976)</td>
<td>“Chronic shoulder pain” 42 subjects, recruited through newspaper advertisements, with chronic shoulder pain.</td>
<td>Inclusion criteria Conditions included periarticular disease (tendinitis or bursitis) or osteoarthritis. Subjects were otherwise in good health. Exclusion criteria</td>
<td>Intervention G1: Acupuncture at traditional sites, manual manipulation. G2: Superficial needling at traditional sites (without skin penetration). Both G1 and G2 were further subdivided into “acupuncture-positive” and “acupuncture-negative” sub-groups. In these 2 sub-groups, either positive or negative statements about acupuncture were read out (respectively), and the physician talked either extensively or minimally with the participants during the treatment. Follow-up 1 week post-treatment.</td>
<td>There were statistically significant improvements in shoulder discomfort in both G1 and G2 (but no statistically significant differences between the two groups). Shoulder discomfort improved the least for subjects who had true acupuncture in an “acupuncture-negative” setting. Overall, range of motion scores did not improve significantly, and there were no significant differences between G1 and G2. For both G1 and G2, increasing hypnotic susceptibility scores were associated with greater improvements in shoulder discomfort (no statistical tests reported). Authors concluded that acupuncture produces only a placebo effect.</td>
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### Table 13. Shoulder pain – Evidence table of excluded randomised controlled trials (continued)

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<tr>
<th>Author, year, country</th>
<th>Population</th>
<th>Intervention, outcome measures and follow-up</th>
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<tr>
<td>Von Mencke et al. (1988) Germany “Shoulder pain”</td>
<td>75 patients with shoulder pain from an orthopaedic clinic or referred by a specialist. Inclusion criteria 64% had shoulder-arm syndrome, 27% had cervico-brachial syndrome, 9% had humero-scapular periarthritis. Exclusion criteria Neurological deficits, additional treatments, neoplasms, infections, polyneuritis.</td>
<td>Intervention G1: Traditional acupuncture using trigger points. G2: Acupuncture using non-traditional points (this group subsequently had traditional acupuncture – crossover design). Follow-up Final assessment at 7th or 8th treatment.</td>
<td>Pain intensity reduced by an average of 59% in G1 and increased by 9% in G2 at the 7th treatment. After traditional acupuncture, pain intensity reduced for G2 to 61% of original (overall reduction of 39%). Both these improvements for traditional acupuncture were statistically significant. 37/40 of G1 and 15/35 of G2 (before traditional acupuncture) agreed their condition had improved (a statistically-significant difference). At the 7th treatment, there were statistically-significant improvements for 12 of 16 orthopaedic tests for G1. At the same time for G2, 2 of the 16 tests had improved to statistically-significant levels.</td>
<td>Excluded Post-treatment follow-up period &lt; 1 month. Not clear what proportion of study participants had conditions caused by injury. All members of G1 and G2 were assessed at 7th treatment, but there was a high number of drop-outs by the 8th treatment. Less than half of G2 were assessed at the 7th treatment after they were treated with traditional acupuncture.</td>
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**EFFECTIVENESS OF ACUPUNCTURE FOR THE TREATMENT AND REHABILITATION OF ACCIDENT-RELATED MUSCULOSKELETAL DISORDERS**
MUSCULOSKELETAL PAIN – VARIOUS REGIONS

This section presents evidence tables for four excluded RCTs and three excluded systematic reviews or meta-analyses examining acupuncture’s effectiveness for treating musculoskeletal pain in diverse regions of the body (i.e., back pain, shoulder pain, neck pain, elbow pain, and so on).

None of the four RCTs fully met all the criteria for inclusion in the review (Cheng and Pomeranz 1987; Gallacchi et al. 1981; Godfrey and Morgan 1978; Junnila 1982). They either lacked sufficient post-treatment follow-up, or acupuncture was not the sole modality in the active treatment group, or it was not possible to satisfactorily conclude from the data provided that more than 90 percent of subjects in the study had musculoskeletal pain caused by injury (see Table 14, pages 65-67).

The one systematic review and two meta-analyses were excluded because they generally covered the same kinds of RCTs already excluded from the review for various reasons. Their relevance for clarifying the potential therapeutic effectiveness of acupuncture specifically for injury-related pain was therefore questionable (see Table 15, pages 68-71).
Table 14. Musculoskeletal pain in various regions – Evidence table of excluded randomised controlled trials

<table>
<thead>
<tr>
<th>Author, year, country</th>
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<tr>
<td>Cheng and Pomeranz (1986)</td>
<td>131 patients with chronic musculoskeletal pain.</td>
<td>Intervention: G1: Electroacupuncture at traditional acupuncture points. G2: Acupuncture-like TENS (ALTENS) at traditional acupuncture points (using carbon-impregnated rubber pads). Follow-up: Before each treatment session (most patients had 12 sessions); and 4-8 months after treatment ended (questions administered by telephone).</td>
<td>Initial assessments showed high success rates (&gt;25% improvement) for both treatments in terms of pain relief (85% of G1 and 94% of G2) and activity increase (86% of G1 and 85% of G2). At this initial stage, there were no statistically significant differences between the effectiveness of the two treatments. The long-term follow-up showed that ALTENS had statistically significantly higher success rates than standard electroacupuncture. Successful pain relief was experienced among 46% of G1 and 91% of G2. Successful activity increases were experienced among 39% of G1 and 90% of G2. At follow-up, only 24% of the electroacupuncture group was symptom-free, compared with 64% of the ALTENS group [this difference being statistically significant].</td>
<td>Excluded: No information given about what proportion of patients had different clinical conditions. Several of the conditions were obviously not injury-related. Electroacupuncture/ALTENS were explicitly sole modality treatments. Follow-up was by telephone, rather than face-to-face.</td>
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Table 14. Musculoskeletal pain in various regions – Evidence table of excluded randomised controlled trials (continued)

<table>
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<tr>
<th>Author, year, country</th>
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| Gallacchi et al. (1981) Switzerland | 121 rheumatology clinic patients with chronic tendomyotic cervical and lumbar syndromes (i.e., tendon and muscle involvement). | **Intervention**
All groups showed improvements in patient rating scales and practitioner rating, but no statistically significant differences between groups. | **Reasons excluded and comments**
Excluded
Post-treatment follow-up period < 1 month. Only small numbers in each group. Authors note that it is difficult to distinguish between vertebral and psychosomatic conditions in Western medicine, and that it may not be possible to apply Western statistical methods to Chinese diagnoses. |
Table 14. Musculoskeletal pain in various regions – Evidence table of excluded randomised controlled trials (continued)

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<tr>
<td>Godfrey and Morgan (1978) Canada “Musculoskeletal pain”</td>
<td>193 patients with musculoskeletal pain recruited from outpatient clinic at Wellesley Hospital in Toronto, physician referral and a public announcement. Inclusion criteria Chronic, dull, constant moderate pain (mean duration of pain was 75 months). Clinical conditions, mainly diagnosed by site and type of pain, included: degenerative disc disease (20%), osteoarthritis (24%), lumbosacral strain (8%), and 11 other diagnoses such as cervical strain, tennis elbow, bursitis. Sites of pain were: lumbosacral, cervical, knee, shoulder, hip, elbow, multiple sites. Exclusion criteria Findings of inflammatory process, organic problems requiring treatments other than pain relief.</td>
<td>Intervention G1: Acupuncture at traditionally appropriate sites. G2: Acupuncture at traditionally non-appropriate sites (sham acupuncture). Follow-up After the 3rd and 5th treatments (time period not specified).</td>
<td>After the third treatment, 62% of 173 subjects had reduced (physician assessed) pain. At this time 68% of G1 and 56% of G2 had reduced pain (a statistically non-significant difference). After the fifth treatment, 58% of the remaining 168 study participants had reduced pain (63% of G1 and 54% of G2 – again, not a significant difference). The authors concluded that the study does not support the “classical acupuncture theory”. Because of the lack of a “no treatment group”, they were uncertain what proportion of the observed reduction of pain was due to a placebo effect, and how much was due to endorphin release in response to needling.</td>
<td>Excluded Post-treatment follow-up period &lt; 1 month; at least 44% of diagnoses were degenerative conditions (disc disease or osteoarthritis).</td>
</tr>
<tr>
<td>Junnila et al. (1982) Finland “Chronic pain”</td>
<td>44 successive pain patients coming for acupuncture to the Halikko Health Center. Inclusion criteria Pain for at least one month (40 participants had pain for more than six months and 21 for over 5 years). Pain able to be treated with acupuncture on the back of the body or limbs. Diagnoses included headaches, neck and shoulder pain, low back pain, arthritis and osteoarthritis. Exclusion criteria None specified.</td>
<td>Intervention G1: Acupuncture at traditional acupuncture points. G2: Sham acupuncture (pricked with finger-nail) approx. 1 inch away from traditional acupuncture points. Follow-up 1 month after treatment ended (4 treatments once a week).</td>
<td>One month after treatment, 16/22 of the true acupuncture group (G1) and 5/22 of the sham acupuncture group (G2) believed they were symptom-free or “a lot better” (a statistically significant difference). At the same time, G1 experienced an 80% reduction on the pain scale (VAS) compared with 30% for G2 (also a statistically significant difference). Additionally, after treatment, 17/22 of G1 and 7/22 of G2 had reduced their analgesic intake or had given them up altogether (a statistically significant difference).</td>
<td>Excluded At least 48% of subjects had conditions (headaches and arthritis/osteoarthritis) unlikely to be caused by injury. Analgesic use continued among at least some participants throughout the trial.</td>
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Table 15. Musculoskeletal pain in various regions – Evidence table of excluded systematic reviews and meta-analyses

<table>
<thead>
<tr>
<th>Author, year, country</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Ezzo et al. (2000) US Systematic review</td>
<td>Acupuncture for treatment of chronic pain. Search Medline (1966-99), Cochrane Complementary Medicine Field Trials Registry, hand-searching of conference proceedings and abstracts, bibliographies from relevant papers. English language only.</td>
<td>Trials that were randomised, had a comparison group for which a between group analysis was presented, had a study population with pain longer than three months, used needles, had a measurement for pain relief.</td>
<td>There is limited evidence that acupuncture is better than no treatment (waiting list) for the treatment of chronic pain. It is too early to determine how effective acupuncture is compared to placebo, sham acupuncture or standard care. Existing studies have small sample sizes and are of poor quality. Two-thirds of the trials received a low-quality score. Low quality trials were significantly associated with positive results favouring acupuncture. Weaker study designs may bias study results in the direction of overestimating the positive effects of acupuncture treatment. Sham acupuncture may produce non-specific needling analgesic effects. Future trials using sham acupuncture should aim to develop sham techniques that minimise these non-specific effects. Future systematic reviews should not assume that acupuncture only controls for placebo effects. After controlling for study quality, trials which gave patients six or more acupuncture treatment sessions were significantly associated with positive outcomes. This may be due to chance, or because patients become more ‘invested’ in a positive outcome as they give more time and receive more treatment. It may also be due to the cumulative effects of repeated acupuncture treatments. Well-designed trials are required to determine whether different ‘doses’ of acupuncture produce different outcomes for patients with the same pain condition. The duration and intensity of de qi may also be important.</td>
<td>Excluded Assessed RCTs with post-treatment follow-up &lt; 1 month; study did not focus on musculoskeletal pain caused only by injury; study included RCTs covering non-musculoskeletal pain.</td>
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</table>
### Table 15. Musculoskeletal pain in various regions – Evidence table of excluded systematic reviews and meta-analyses (continued)

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<th>Results</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Patel et al. (1989)</td>
<td>Acupuncture for treatment of chronic pain.</td>
<td>Included studies RCTs evaluating use of acupuncture for the treatment of chronic pain. This included trials covering musculoskeletal pain in the back, neck and shoulder, as well as headache pain.</td>
<td>14 studies were included in the meta-analysis and their results pooled. Studies were not homogeneous according to the Q-statistic ($p&lt;0.01$). Acupuncture compared to conventional treatment was more favourable to acupuncture than trials against placebo. Patients did better in trials of classical (traditional Chinese medicine) where acupuncture points varied from treatment to treatment than in trials of 'formula acupuncture' at fixed acupuncture points. Non-blinded studies and large trials were more favourable to acupuncture than single-blinded studies and small studies. When data from individual trials were pooled, results favourable to acupuncture were obtained significantly more often than chance alone would allow. However, lack of blinding in trials may have biased results in favour of acupuncture, especially classical (traditional Chinese) acupuncture. Conclusive findings in favour of a therapy such as acupuncture can only be obtained from adequate triple blind randomised clinical trials.</td>
<td>Excluded Assessed RCTs with post-treatment follow-up &lt; 1 month; study did not focus on musculoskeletal pain caused only by injury. Study included RCTs covering headache pain.</td>
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Table 15. Musculoskeletal pain in various regions – Evidence table of excluded systematic reviews and meta-analyses (continued)

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<tr>
<td>Smith et al. (2000) UK</td>
<td><strong>Topic</strong> Acupuncture for neck and back pain. <strong>Search</strong> Medline (1966-98), Embase (1980-98), Cinahl (1982-98), Psychlit (1982-98), PubMed (1998), the Cochrane Library (1998), and the Oxford Pain Relief Database (1950-94). No language restrictions. Bibliographies of retrieved articles were reviewed for further references. Unpublished reports and abstracts not considered. Authors not contacted for original data.</td>
<td><strong>Inclusion criteria</strong> Full published reports of RCTs of traditional and non-traditional acupuncture for back or neck pain; acupuncture (with or without electrical stimulation) or laser acupuncture compared to an inactive control group; group size ≥ 10; pain outcomes reported. <strong>Exclusion criteria</strong> Trials comparing acupuncture with other active treatments. Quality of trials assessed using the Oxford Pain Validity Scale (OPVS) to assess validity of trials of interventions for pain. Dimensions include blinding, group size, outcome measures, baseline pain and internal sensitivity, data analysis, statistical analysis, handling of dropouts. Pain outcomes were categorised as either early (&lt; or = to 24 hrs after final acupuncture session) or late (&gt; 24 hrs after final acupuncture session).</td>
<td>13 RCTs were included, 11 for chronic back or neck pain and 2 for acute low back pain. The majority of trial were rated as poor quality. OPVS validity scores ranged from 4 to 14 out of possible 16. Points were most often lost for small group sizes and lack if blinding. Data pooling was not possible as trials were heterogeneous in terms of trial design, patient groups, needling points, acupuncture intervention and techniques for pain measurement. Sensitivity analysis showed no relationship between validity score and author’s conclusions, but showed significant relationship between validity scores and reviewers conclusions, with higher validity trials more likely to be unfavourable to acupuncture. Assessing the validity of trials using OPVS makes it possible to draw stronger overall conclusions compared to simply counting up the number of positive and negative trials. Acupuncture was no more effective than placebo.</td>
<td>Excluded Assessed RCTs with post-treatment follow-up &lt; 1 month; assessed RCTs with non-needling acupuncture; did not assess RCTs comparing acupuncture with other active treatments; assessed RCTs where acupuncture was not the sole treatment modality; study did not focus on musculoskeletal pain caused only by injury.</td>
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Table 15. Musculoskeletal pain in various regions – Evidence table of excluded systematic reviews and meta-analyses (continued)

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<tr>
<td>ter Riet et al. (1990)</td>
<td>Topic: Acupuncture for treatment of chronic pain. Search Medline (1963-88) and from Excerpta Medica (1981-98). Also screening of gray literature.</td>
<td>Included studies RCTs or controlled trials; needles were used, word “chronic” mentioned in title or abstract; patients stated to have had pain for at least 6 months. Excluded studies Trials involving only surface electrodes or laser acupuncture. All included studies were evaluated and scored using a list of 18 predefined methodological criteria covering four broad dimensions: comparability of prognosis; adequacy of intervention; adequacy of effect measurement; presentation of data.</td>
<td>51 RCTs and controlled trials were included in the meta-analysis. Included trials covered pain in musculoskeletal regions such as the neck, lower back and shoulder, as well as migraine headache, post-herpetic pain, pancreatitis and angina. 11 studies scored 50 points or more out of a possible 100 for the predefined methodological criteria, which the authors considered to indicate the “rather poor quality” of the trial reports reviewed. Results from top 11 studies were not pooled because the trials were too heterogeneous and of insufficient quality. There seem to be no high quality studies of the effectiveness of acupuncture for treating chronic pain. Consequently, no definitive conclusions can be drawn on the efficacy of acupuncture for treating chronic pain. Its efficacy therefore remains doubtful. Statistical pooling of study outcomes is not appropriate, as criteria are not yet available for deciding which modes of therapy, patients from different parts of the disease spectrum, and which trial end points are similar enough to be pooled. To improve the quality of acupuncture studies, future trials should have more homogeneous study groups, larger numbers of patients, fewer drop-outs, longer follow-up periods and make better use of sophisticated outcome assessment techniques.</td>
<td>Excluded Assessed RCTs with post-treatment follow-up &lt; 1 month; assessed RCTs where acupuncture was not the sole treatment modality; study did not focus on musculoskeletal pain caused only by injury; study included RCTs covering non-musculoskeletal pain. Assessed only RCTs covering chronic pain.</td>
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EFFECTIVENESS OF ACUPUNCTURE FOR THE TREATMENT AND REHABILITATION OF ACCIDENT-RELATED MUSCULOSKELETAL DISORDERS
Discussion

SUMMARY OF EVIDENCE

This report systematically reviewed relevant randomised controlled trials of acupuncture therapy in order to assess the effectiveness of acupuncture for the treatment and rehabilitation of musculoskeletal injuries.

Six RCTs met the inclusion criteria for the review, including the requirement that over 90 percent of trial subjects plainly had musculoskeletal disorders consistent with injury. In three of the trials, all the subjects had lateral elbow pain. In another two of the trials, all the subjects had rotator-cuff tendinitis. In the remaining trial, all the subjects had patellofemoral pain syndrome.

Other RCTs were identified where all the subjects had injury-related musculoskeletal disorders such as carpal tunnel syndrome, plantar fasciitis, sciatica or whiplash. However, none of these trials fully met the inclusion criteria for the review. The same was the case for RCTs assessing the effectiveness of needle acupuncture for treating patients with pain of diverse or unknown aetiology in the back, neck or shoulder.

Given the very small number of eligible RCTs identified, and their heterogeneity, it is not possible for this review to reach any strong conclusions about the effectiveness of acupuncture for the treatment and rehabilitation of musculoskeletal injuries. Acupuncture is considered by practitioners to be useful for treating a wide range of musculoskeletal disorders, including many common disorders thought to be caused primarily by injury. However, RCTs have investigated acupuncture’s effectiveness for treating only a very limited subset of these disorders.

Of the injury-related conditions covered to date in acupuncture RCTs, the most frequently studied has been lateral elbow pain. Altogether, six trials consisting entirely of patients with this condition have been published. However, only three of these qualified for inclusion in this review.

The first of these included trials for lateral elbow pain concluded that acupuncture was more effective than ultrasound for reducing subjective pain, but not grip-strength or functional ability assessed four weeks post-treatment. The failure to identify a statistically significant difference between the two treatments for the grip-strength and functional ability measures may be a product of the small size, and therefore low power, of the study. The trial was a pilot study containing less than 10 patients in each group (Davidson et al. 2001).

The second lateral elbow pain trial compared traditional acupuncture with superficial acupuncture and found traditional acupuncture to be superior to superficial (sham) acupuncture for the “short-term symptomatic treatment” of lateral elbow pain (Haker and Lundberg 1990). No statistically significant between-group differences in treatment outcomes were found at three and 12 month follow-up (although 13/86 patients had dropped-out of the study by three months).

The third lateral elbow pain trial compared traditional acupuncture with a kind of sham acupuncture that included deep, rather than superficial, needling (Fink et al. 2002). All participants in the study were recruited using newspaper advertisements and all were screened to ensure they had experienced no marked variation in their complaint in the previous month. At two weeks post-treatment, the true acupuncture group was found to have improved significantly compared to the sham group for all three main outcome measures (strength, pain, and upper extremity disability score). At two months post-treatment, the true acupuncture group still had significantly better upper extremity disability scores than the sham group, although there was no longer any differences for strength or pain. The authors of the study concluded that the therapeutic effect of true acupuncture was “dominant” in the first two weeks following treatment.
The systematic review of acupuncture’s effectiveness for treating lateral elbow pain by Green et al. (2002) included consideration of the trials by Davidson et al. (2001) and Haker and Lundeberg (1990). The review concluded that no therapeutic benefit lasting more than 24 hours following acupuncture treatment had been demonstrated in the lateral elbow pain RCTs published to date. However, it noted that this short-term pain relief “may be clinically significant if it allows improvement in function while the condition follows its natural history toward recovery” (ibid: 9).^6^ 

The trial by Fink et al. (2002) was published after the Green et al. (2002) systematic review was completed. It points to the possibility that acupuncture may have therapeutic benefits for lateral elbow pain up to two weeks post-treatment, or even longer, at least for some patients with chronic epicondylitis (> 3 months) who have not responded to other forms of treatment.

Of the two trials for patients with rotator cuff tendinitis, the results of one must be interpreted with caution (Dyson-Hudson et al. 2001), as its patients come from a somewhat unusual group, namely wheelchair-using spinal cord injury patients. As well, the number of participants in the trial was small (only 18 completed the trial) and the comparison therapy was Trager Psychophysical Integration, seemingly not a common therapy for rotator cuff tendinitis.

The other rotator cuff tendinitis trial by Kleinhenz et al. (1999) found true acupuncture to be significantly more effective than sham acupuncture in improving shoulder function when assessed immediately after the course of treatment. Unfortunately, loss to follow-up hampered the ability of the trial to reliably determine if these differences endured over the long-term (i.e., three months post-treatment).

The one other included trial on patellofemoral pain syndrome also favoured acupuncture. The trial compared acupuncture to no treatment, concluding that the acupuncture group experienced significantly greater improvements in knee function, and that these differences persisted for 12 months post-treatment. However, it is unclear how much these improvements may have been the result of the non-specific effects of treatment, rather than the specific effects of needling. Future trials comparing acupuncture with sham or placebo treatments for patellofemoral pain syndrome may be helpful for clarifying this question.

**DIRECTIONS FOR FUTURE RESEARCH**

While the six included trials in the current review all favoured acupuncture, more good quality randomised controlled trials are required before any strong conclusions can be reached about the benefits of acupuncture for treating the many different kinds of musculoskeletal disorders caused by injury.

To date, it has been rare for acupuncture trials to specifically investigate injury-related musculoskeletal disorders. Most trials addressing musculoskeletal disorder have included or excluded patients on the basis of clinical signs and symptoms, or diagnostic categories, rather than whether or not they have disorders that are clearly the result of an injury event or process.

This may partially reflect a lack of emphasis in traditional acupuncture theory on distinguishing between injury and non-injury-related musculoskeletal disorder. For many acupuncturists, the location and nature of the musculoskeletal pain, along with any associated dysfunction or restriction of movement, appear to be the main criteria used for selecting sites for needle placement and other technical features of acupuncture therapy. Whether or not the condition being treated is the result of injury does not appear to be especially relevant.^7^

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^6^ The National Institutes of Health Consensus Development Conference Statement on Acupuncture, issued in November 1997, concluded that acupuncture may be a useful adjunct or alternative treatment, or be included in a comprehensive management programme to relieve the pain of epicondylitis (tennis elbow) (National Institutes of Health Consensus Development Panel on Acupuncture 1997).

^7^ There is scope to undertake NZ-specific research describing the range of acupuncture-related therapeutic techniques currently used by different practitioners for treating musculoskeletal injuries. Part of this work could include seeking advice from experienced practitioners about the kinds of acupuncture techniques they consider to be most effective for treating injuries, and the range of therapeutic benefits they regard acupuncture to provide in...
Another reason why few trials have focused exclusively on injury-related disorders may be the difficulty of reliably identifying the causes of musculoskeletal complaints, or being clear about the extent to which a disorder may be caused by injury as opposed to other factors. Many musculoskeletal disorders, especially those involving chronic pain, may be multifactorial in origin and have a complex aetiology, such as trauma overlaid with degeneration due to osteoarthritis or osteoporosis. The aetiology of other conditions, including the extent to which they are injury-related, may be disputed or highly contentious.

It is to be hoped that in future researchers will give greater priority to conducting trials of needle acupuncture with groups of patients who are all considered to have the same kind of injury-related musculoskeletal disorder. The work to date on lateral elbow pain, limited as it is, helps to show what may be possible. Internationally, similar effort needs to be put into conducting a range of trials on the other common musculoskeletal injuries that clinical experience suggests are likely to benefit markedly from acupuncture therapy.

During the design, execution and interpretation of the findings of these studies, it will be important to bear in mind the following points and issues.

**General quality requirements**

To date, the quality of acupuncture trials covering musculoskeletal disorders has been variable. Future trials should aim to fulfil the following methodological requirements (adapted from Filshie and Cummings 1999):

- adequate choice and application of acupuncture treatment
- recruit a homogenous sample, using an explicit method of recruitment and clear inclusion and exclusion criteria
- use appropriate methods of randomisation and allocation concealment
- use valid outcome measures that are clearly defined and, where possible, objective
- use blinded independent observers to assess patient outcomes
- have an adequate follow-up period, not just assess outcomes immediately after the end of treatment
- use appropriate statistical analysis
- provide an adequate description in study reports of the kind of acupuncture procedure or “doses” used.

**Sample sizes**

Recent reviews of acupuncture research note that most chronic pain RCTs have been underpowered, with small study populations. This is thought to reflect at least in part the lack of a substantial international research infrastructure for acupuncture. Only in the last one to two years have clinical trials been designed with comparatively large samples. For example, a planned RCT examining acupuncture’s effectiveness for treating osteoarthritis of the knee will have 570 subjects in the study (Vickers 2001).

**Types of acupuncture therapy**

The RCTs covered in this review have used various types of acupuncture therapy, making it somewhat difficult to compare study results. At present there is no universal agreement or consensus on what “dose” of acupuncture is “best practice” for any given set of musculoskeletal symptoms or conditions.
RCTs of acupuncture therapy have used a wide range of different acupuncture approaches or styles, often reflecting diverging and competing theoretical orientations (Ernst 1999). Variations include the number of needles per treatment, the diameter of each needle, the depth of stimulation, the duration of stimulation, the type of stimulation or agitation given to needles, or whether the stimulation is electrical or manual or both (Filshie and Cummings 1999). This raises the question of whether it is appropriate to compare the results of one acupuncture trial with another, since, in theory at least, some forms of acupuncture therapy, or “doses” of acupuncture, may be more effective than others (Mayer 2000). Indeed, some reviewers have argued that the lack of evidence for the long-term effectiveness of acupuncture treatment stems from the use of poor or inadequate acupuncture techniques in acupuncture trials (e.g., too few treatments, too few needles, etc) (Longworth and McCarthy 1997).

Allied to this issue, the appropriateness of using standardised protocols for acupuncture treatment in clinical trials is also questioned. Some practitioners argue that providing identical acupuncture treatment to all subjects in a trial is likely to diminish the effects of acupuncture, since acupuncture is traditionally individualised to suit the needs of the patient as determined by the therapist (Bradnam and Larmer 2001; Leake and Broderick 1998; Mayer 2000).

**Sham acupuncture**

As well as variations in acupuncture treatment itself, a number of different sham acupuncture techniques have been employed by different RCTs. These include superficial needling or pressure at traditional or non-traditional sites, and normal depth needling at non-traditional sites. Studies suggest that some or all of these techniques may cause physiological effects and are therefore not acting as true control placebos. However, recently developed sham acupuncture techniques using blunt telescoping needles may enable future trials to avoid needle insertion as well as achieve effective patient-blinding (Park et al. 2001).

**Other comparison groups**

Other options chosen for comparison have been no treatment or other forms of true or sham treatments. No treatment has the advantage that it has no specific physiological effects, but patients and therapists cannot be blinded and if it is used as the only comparison group then the placebo (non-specific) effects of acupuncture cannot be estimated. The use of another kind of treatment as sole comparator has the advantage of testing which is the superior treatment, but often there are equal improvements in both groups, which may have occurred purely because the pain is self-limiting. In future studies it may be advisable to have at least three or four groups for comparison:

1) traditional acupuncture  
2) sham acupuncture  
3) no treatment/waiting list  
4) another treatment (should this comparison be required).

Of course, this type of trial requires a large number of participants and consequently more resources to achieve meaningful results.

**Blinding**

By its very nature, acupuncture is hard to disguise and blinding of both therapist and patient is difficult. Sham acupuncture if done well may achieve blinding among patients, but may not function as a true placebo control (see above). It is far more difficult to blind therapists in trials involving sham acupuncture. Where no treatment or another type of treatment are used for the comparison groups, it is obviously impossible to blind either patients or therapists. The only person involved in acupuncture trials who can be blinded relatively easily is an independent person who assesses patient outcomes without knowing to which study group patients have been allocated.
Variations in patient responses to acupuncture

Some people may be more predisposed than others to respond well to acupuncture. Reports from experimental studies with volunteers indicate that certain people exhibit a higher analgesic response to acupuncture needling than others, supporting the notion that the beneficial effects of acupuncture will not be experienced by every patient (Filshie and Cummings 1999; Vickers 2001; White 1999), or that some patients may be “strong reactors” to acupuncture, therefore requiring fewer needles, less stimulation and fewer treatments compared to patients who are “weak reactors” (Weaver 1998). Acupuncture texts emphasise the need to take these possible variations into account not only in everyday clinical practice but also when designing clinical trials (Baldry 1989). There is also the possibility that different types of pain (i.e., nociceptive, idiopathic, psychogenic, neuropathic) may respond differently to acupuncture treatment (Carlsson and Sjölund 2001), though this issue is not considered in most trials.

Randomisation

Randomisation of study participants into treatment and control groups makes sense in the Western medical paradigm where treatment is primarily chosen on the basis of clinical diagnosis. However, in traditional Chinese acupuncture, the most appropriate therapy is often selected on the basis of quite individual characteristics of the patient (Bradnam and Larmer 2001). Randomising subjects without consideration of these characteristics may affect the outcomes of the study.

Self-limiting conditions and chronicity

Many musculoskeletal disorders improve with time without any form of treatment. Pain of low back origin, for example, is often self-limiting with a high spontaneous recovery rate. A high proportion of back pain patients (up to 90 percent according to some studies) “improve” within one month regardless of treatment type, and only seven percent still complain of pain six months after experiencing a back pain injury (Longworth and McCarthy 1997). Partly in an attempt to control for this situation, some acupuncture trials deliberately include only patients with chronic musculoskeletal disorders of long-standing duration that have failed to respond to conventional conservative treatments. However, it is unclear how reliably the results from these trials can be generalised to all patients with the same disorder, regardless of the duration of their disorder or the extent to which other treatment options have been tried.

Use of analgesics during trials

Few of the acupuncture trials reviewed here explicitly stated that subjects were not taking analgesics, and in many trials a proportion of subjects apparently used analgesics during the study period. In fact, analgesic consumption was used as an outcome measure in a number of trials. There are obvious clinical and ethical issues to be considered when withdrawing analgesics for the purposes of a scientific study. However, it seems less than ideal, from a research point of view, to be continuing with one treatment for pain (usually in a non-standard way) while testing another mode of pain relief (i.e., acupuncture).

Sole modality or concomitant therapy

It is possible that acupuncture may give best results when used in conjunction with other conservative treatments, rather than as the sole treatment modality. In real-life clinical situations, for example, rehabilitation specialists may take a global approach to the treatment of low back pain, using a range of concomitant therapies, some as a main intervention and others as secondary interventions (Brosseau et al. 2002). However, this review did not seek to examine this issue, being concerned only with the effectiveness of acupuncture as a sole treatment modality.
References


Australia National Health and Medical Research Council (1999). A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra: NHMRC.


Appendix 1: Search strategies

MEDLINE

1. exp acupuncture/ (7312)
2. acupuncture.mp. (6901)
3. 1 or 2 (7850)
4. meta-analysis/ (3999)
5. meta-analysis.pt. (6071)
6. (meta-analy$ or metaanaly$).mp. (9477)
7. (systematic$ adj3 (review$ or overview)).mp. (3282)
8. randomized controlled trials/ or randomized controlled trial.pt. (169148)
9. placebos/ (21514)
10. random allocation/ (44901)
11. controlled clinical trials/ or controlled clinical trial.pt. (60824)
12. or/4-11 (266548)
13. (letter or news).pt. or case report/ (1464322)
14. 3 and 12 (659)
15. 14 not 13 (620)
16. from 15 keep (SELECTED REFERENCES) (121)

EMBASE

1. exp acupuncture/ (3924)
2. acupuncture.mp. (3781)
3. 1 or 2 (4104)
4. randomized controlled trials/ (60463)
5. Double Blind Procedure/ (37443)
6. Randomization/ (3634)
7. Placebo/ (30145)
8. Single Blind Procedure/ (3435)
9. meta-analysis/ (12698)
10. (meta-analy$ or metaanaly$).mp. (15611)
11. (systematic$ adj3 (review$ or overview)).mp. (2990)
12. or/4-11 (107120)
13. 3 and 12 (351)
14. letter.pt. or case report/ (641746)
15. 13 not 14 (331)
16. from 15 keep (SELECTED REFERENCES)(62)

CURRENT CONTENTS

1. acupuncture.mp. (1421)
2. (random$ or double blind or single blind or placebo$).mp. (242567)
3. (meta-analy$ or metaanaly$).mp. (12120)
4. (systematic$ adj3 (review$ or overview)).mp. (3329)
5. or/2-4 (252214)
6. 1 and 5 (380)
7. letter.pt. (363160)
8. 6 not 7
9. from 8 keep (SELECTED REFERENCES)(58)
CINAHL

1 exp ACUPUNCTURE/ (1041)
2 acupuncture.mp. (1161)
3 1 or 2 (1178)
4 Random Assignment/ (4257)
5 (random$ or double blind or single blind).mp. (19789)
6 PLACEBOS/ (1264)
7 Meta Analysis/ (2037)
8 (meta-analy$ or metaanaly$).mp. (2274)
9 (systematic$ adj3 (review$ or overview)).mp. (1925)
10 or/4-9 (21814)
11 3 and 10 (144)
12 letter.pt. (12993)
13 11 not 12 (142)
14 from 13 keep (SELECTED REFERENCES) (35)

AMED

1 exp acupuncture/ (5385)
2 acupuncture.mp. (5074)
3 1 or 2 (5537)
4 (random$ or single blind$ or double blind$).mp. (3469)
5 placebos/ (330)
6 meta-analysis/ (46)
7 (meta-analy$ or metaanaly$).mp. (190)
8 (systematic$ adj3 (review$ or overview)).mp. (191)
9 random allocation/ (282)
10 randomized controlled trials/ (476)
11 double blind method/ (282)
12 or/4-11 (3915)
13 3 and 12 (225)
14 (letter or news or interview).pt. (2100)
15 13 not 14 (224)
16 from 15 keep (SELECTED REFERENCES)(43)

SEARCHES FROM OTHER SOURCES

In other databases and sources without controlled vocabulary, combinations of the index terms and additional keywords from the above strategies were used in the search.
Appendix 2: Sources searched

BIBLIOGRAPHIC DATABASES

Medline
Embase
Cinahl
Cochrane Controlled Trials Register
Amed – Allied & Complementary Medicine
Science Citation Index
Social Science Citation Index
Current Contents
Index New Zealand
Mantis – Manual, Alternative, & Natural Therapy Index

REVIEW DATABASES

Cochrane Database of Systematic Reviews
Best Evidence
Database of Abstracts of Reviews of Effectiveness
NHS Economic Evaluation database
Health Technology Assessment database

HEALTH TECHNOLOGY ASSESSMENT ORGANISATIONS

Agency for Health Research & Quality (AHRQ)
British Columbia Office of Health Technology Assessment (BCOHTA)
Canadian Coordinating Office for Health Technology Assessment (CCOHTA)
German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information (DIMDI)
ECRI
EUROSCAN
Minnesota Health Technology Advisory Committee
Institute for Clinical Systems Improvement (ISCI)
International Society of Technology Assessment in Health Care (ISTAHC)
National Coordinating Centre for Health Technology Assessment (NCCHTA)
National Institute for Clinical Excellence (NICE)
Swedish Council on Technology Assessment in Health Care (SBU)
Veterans Affairs Technology Assessment Program (VATAP)

OTHER WEBSITES

New Zealand

New Zealand Ministry of Health
New Zealand Bibliographic database – Te Puna
UK
TRIPdatabase
Organised Medical Networked Information (OMNI)
Department of Health Publications
Current Controlled Trials
Scottish Intercollegiate Guidelines Network
British Medical Acupuncture Society
Focus on Alternative and Complementary Medicine
British Library Public Catalogue

Australia
Commonwealth Department of Health & Aged Care
National Health and Medical Research Council
Australian Medical Acupuncture Society

United States
Centers for Disease Control
National Guidelines Clearing House
Clinicaltrials.gov
American Academy of Medical Acupuncture
National Center for Complementary and Alternative Medicine
Society for Acupuncture Research
US National Library of Medicine catalog – Locatorplus

Canada
Health Canada
Acupuncture Foundation of Canada Institute

Other
Danish Medical Association of Acupuncture
Seville Regional Society of Acupuncture
World Congress on Low Back and Pelvic Pain
International Council of Medical Acupuncture and Related Techniques
World Health Organisation library and information catalogue
Google search engine
## Appendix 3: Checklists

SIGN (SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK)
METHODOLOGY CHECKLISTS

### Methodology Checklist 1: Systematic Reviews and Meta-analyses

<table>
<thead>
<tr>
<th>Evaluation criterion</th>
<th>How well is this criterion addressed?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study identification</strong></td>
<td>Include author, title, reference, year of publication</td>
</tr>
<tr>
<td>1.1 Does the review address an appropriate and clearly focused question?</td>
<td></td>
</tr>
<tr>
<td>1.2 Does the review include a description of the methodology used?</td>
<td></td>
</tr>
<tr>
<td>1.3 Was the literature search sufficiently rigorous to identify all relevant studies?</td>
<td></td>
</tr>
<tr>
<td>1.4 Was study quality assessed and taken into account?</td>
<td></td>
</tr>
<tr>
<td>1.5 Does the review include all the potential benefits and harms of the intervention?</td>
<td></td>
</tr>
<tr>
<td>1.6 Was it reasonable to combine the studies?</td>
<td></td>
</tr>
<tr>
<td>1.7 Do the conclusions flow from the evidence reviewed?</td>
<td></td>
</tr>
</tbody>
</table>

**Checklist completed by:**
### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th></th>
<th>How well was the study done to minimise bias?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Code ++, +, or −.</td>
</tr>
</tbody>
</table>

|   | If coded as +, or − what is the likely direction in which bias might affect the study results? |

|   | Are the results of this study directly applicable to the patient group targeted by this guideline? |

### SECTION 3: DESCRIPTION OF THE STUDY

<table>
<thead>
<tr>
<th></th>
<th>What types of study are included in the review?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Randomised Controlled Trials (RCT), Controlled Clinical Trials (CCT), Cohorts, Case Control Studies.</td>
</tr>
</tbody>
</table>

|   | What interventions are considered? |

<table>
<thead>
<tr>
<th></th>
<th>What outcome measures are used?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>i.e., benefits and harms.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Are potential confounding factors considered?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>This is particularly important where study types other than RCTs are included in the review.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>What are the characteristics of the study population?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>e.g., age, sex, disease characteristics of the population, disease prevalence.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>What are the characteristics of the study setting?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>e.g., rural, urban, hospital inpatient or outpatient, general practice, community.</td>
</tr>
</tbody>
</table>

### SECTION 4: GENERAL NOTES AND COMMENTS
## Methodology Checklist 2: Randomised Controlled Trials

### Study identification
Include author, title, reference, year of publication

### Checklist completed by:

### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>Evaluation criterion</th>
<th>How well is this criterion addressed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Does the study address an appropriate and clearly focused question?</td>
<td></td>
</tr>
<tr>
<td>1.2 Was the assignment of subjects to treatment groups randomised?</td>
<td></td>
</tr>
<tr>
<td>1.3 Were the treatment and control groups similar at the start of the trial?</td>
<td></td>
</tr>
<tr>
<td>1.4 Was an adequate concealment method used?</td>
<td></td>
</tr>
<tr>
<td>1.5 Were subjects and investigators kept ‘blind’ about treatment allocation?</td>
<td></td>
</tr>
<tr>
<td>1.6 Are all relevant outcomes measured in a standard, valid and reliable way?</td>
<td></td>
</tr>
<tr>
<td>1.7 Apart from the treatment under investigation, were the groups treated equally?</td>
<td></td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into the study are included in the analysis? Statistical power adequacy.</td>
<td></td>
</tr>
<tr>
<td>1.9 Were all the subjects analysed in the groups to which they were randomly allocated?</td>
<td></td>
</tr>
<tr>
<td>1.10 Degree of pharmaceutical company involvement.</td>
<td></td>
</tr>
</tbody>
</table>
## SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias?  
*Code ++, +, or −.*

2.2 If coded as +, or − what is the likely direction in which bias might affect the study results?

If the study reports an evaluation or comparison of diagnostic tests, please complete a diagnostic studies checklist before completing the next section.

## SECTION 3: DESCRIPTION OF THE STUDY

3.1 How many patients participated in the study?  
*Overall number, and in each arm of the study.*

3.2 What was the scale and direction of the measured effect?

3.3 What are the characteristics of the study population?  
*e.g., age, sex, disease characteristics of the population, disease prevalence.*

3.4 Are there any specific issues raised by this study?  
Make any general comments on the study results and their implications.