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Review Article

# The efficacy, safety, effectiveness, and cost-effectiveness of ultrasound and shock wave therapies for low back pain: a systematic review

Jesús Seco, MD, PhD[a,b], Francisco M. Kovacs, MD, PhD[b,c,*], Gerard Urrutia, MD[b,d,e]

[a]*Department of Nursing and Physical Therapy, Institute of Biomedicine (IBIOMED), University of León, Ponferrada, Spain*
[b]*Spanish Back Pain Research Network, Paseo Mallorca 36, 07012 Palma de Mallorca, Spain*
[c]*Scientific Department, Fundación Kovacs, Palma de Mallorca, Paseo Mallorca 36, 07012 Palma de Mallorca, Spain*
[d]*Iberoamerican Cochrane Center-Servei d'Epidemiologia Clínica i Salut Pública, Institut d'Investigació Biomèdica Sant Pau, Hospital de Sant Pau, C/ Sant Antoni Maria Claret, 167, 08025 Barcelona, Spain*
[e]*CIBER Epidemiología y Salud Pública (CIBERESP), Spain*

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**Abstract**

**BACKGROUND CONTEXT:** Shock wave and especially ultrasound are commonly used to treat low back pain (LBP) in routine practice.

**PURPOSE:** To assess the evidence on the efficacy, effectiveness, cost-effectiveness, and safety of ultrasound and shock wave to treat LBP.

**STUDY DESIGN:** Systematic review.

**METHODS:** An electronic search was performed in MEDLINE, EMBASE, and the Cochrane Library databases up to July 2009 to identify randomized controlled trials (RCTs) comparing vibrotherapy with placebo or with other treatments for LBP. No language restrictions were applied. Additional data were requested from the authors of the original studies. The risk of bias of each study was assessed following the criteria recommended by the Cochrane Back Review Group.

**RESULTS:** Thirteen studies were identified. The four RCTs complying with the inclusion criteria included 252 patients. Two of the three RCTs on ultrasound had a high risk of bias. For acute patients with LBP and leg pain attributed to disc herniation, ultrasound, traction, and low-power laser obtained similar results. For chronic LBP patients without leg pain, ultrasound was less effective than spinal manipulation, whereas a shock wave device and transcutaneous electrical nerve stimulation led to similar results. Results from the only study comparing ultrasound versus a sham procedure are unreliable because of the inappropriateness of the sham procedure, low sample size, and lack of adjustment for potential confounders. No study assessed cost-effectiveness. No adverse events were reported.

**CONCLUSION:** The available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. High-quality RCTs are needed to assess their efficacy versus appropriate sham procedures, and their effectiveness and cost-effectiveness versus other procedures shown to be effective for LBP. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. 

*Keywords:* Low back pain; Ultrasound; Vibrotherapy; Shock wave; Systematic review; Effectiveness

## Introduction

Nonspecific or common low back pain (LBP) is defined as pain between the costal margins and the inferior gluteal folds, which may be associated with pain referred down to the leg (''leg pain''), and is usually accompanied by painful limitation of movement [1]. Diagnosing common LBP implies that the pain is not related to conditions such as fractures, spondylitis, direct trauma, or neoplastic, infectious, vascular, metabolic, or endocrine-related processes [1].

FDA device/drug status: Not applicable.

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Gerard Urrutia is a PhD candidate at the Public Health and Research Methodology Programme, Universitat Autonoma de Barcelona (UAB).

* Corresponding author. Departamento Científico, Fundación Kovacs, Paseo Mallorca 36, 07012 Palma de Mallorca, Spain. Tel.: (34) 971-720809; fax: (34) 971-720774.

*E-mail address*: kovacs@kovacs.org (F.M. Kovacs)

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Two forms of mechanical vibration are used for treating LBP. Ultrasound is the term used when the frequency of vibration is above 20,000 Hz and generates heat. Ultrasound penetrates the tissue in a focused directional manner, transmitting heat deep into the tissue. It is believed that ultrasound can increase local metabolism and blood circulation, enhance the flexibility of connective tissue, and accelerate tissue regeneration, potentially reducing pain and stiffness, while improving mobility [2,3]. Shock wave is a form of treatment that applies vibration at a low frequency (10, 50, 100, or 250 Hz), causing an oscillatory pressure. Several devices have been designed to provide ''shock waves,'' such as ''FairMed,'' ''muscle relaxation machines,'' and vibratory platforms. Shock wave is commonly referred to as ''vibrotherapy,'' but it will be referred to as shock wave hereafter because both shock wave and ultrasound use vibration with a therapeutic goal and, therefore, strictly speaking, both could be referred to as ''vibrotherapy.''

The most recent evidence-based guidelines for the treatment of LBP do not recommend shock wave or ultrasound [4–6]. Nevertheless, ultrasound is commonly used in routine clinical practice for musculoskeletal problems, including LBP [7–9]. Approximately 50% of UK physiotherapists, 65% of US physiotherapists, and 94% of Canadian physiotherapists use it [10]. In the United States, 55% of primary care practitioners recommend ultrasound as a form of treatment [11]. Moreover, the most recent Cochrane review on ultrasound suggests that it might be useful for treating knee osteoarthritis, although firm conclusions could not be drawn because of the low quality of the trials included [12].

No systematic reviews on shock wave have been published, and the last one on ultrasound for LBP did not find any randomized clinical trials. However, it dates back to 2001 [13], and new evidence may have been published since then.

Therefore, the objective of this study was to systematically review the evidence on the efficacy, safety, effectiveness, and cost-effectiveness of ''ultrasound/shock wave'' versus placebo or other treatments, for treating pain and disability in LBP patients with or without radiculopathy.

## Materials and methods

The protocol of this study was approved by and registered in the Spanish Ministry of Health's (''Fondo de Investigación Sanitaria'' FIS 03/0908) and the Spanish Back Pain Research Network's databases.

### *Search and study selection*

An electronic search of studies was performed in CENTRAL (The Cochrane Library 2009; Issue 4), MEDLINE (1966–2008), and EMBASE (1980–2008). The search strategy was designed to ensure maximum sensitivity and did not apply language restrictions. It is shown in the Appendix.

Studies were included in this review if they were randomized controlled trials (RCTs); compared ultrasound or shock wave with any kind of active or inert procedure; included patients with LBP with or without radicular or referred pain down to the leg (''leg pain''); and assessed at least one of the following variables: pain severity, disability, quality of life, daily activities, impact on work, patient satisfaction, medication use, side effects, health resources employed, and total costs. No language restrictions were applied.

References identified through the electronic search were screened. The full text of those that were eligible was assessed for inclusion criteria independently by two authors (JS and GU). Disagreements were resolved by consensus with a third author (FMK). References of potential additional studies were searched for in the reference section of the studies included.

### *Risk of bias assessment and data analysis*

When necessary, unpublished data were requested from the authors of the original studies. Details are shown in Tables 1–3.

Following the recommendations of the Cochrane Back Review Group, the risk of bias of the studies included was independently assessed by two of the reviewers (JS and GU), and it was agreed that any disagreements would be solved by consensus with the third author [14]. According to these criteria, a study was rated as having a ''low risk of bias'' when it met at least 6 of the 12 proposed criteria. For studies that compared procedures that did not allow masking of therapists and patients, these two criteria were scored as ''not applicable.'' For the latter, the maximum possible score was 10, and they were considered as having a ''low risk of bias'' if they scored $\geq$5. However, studies with serious flaws were considered as having a ''high risk of bias'' independently of their score [14].

Data extraction was undertaken independently and in duplicate, using standardized forms. For each study, data on pain severity, disability, quality of life, daily activities, impact on work, patient satisfaction, medication use, side effects, health resources employed, and total costs, were searched for, and all data on all the variables gathered in each individual study were extracted.

A quantitative synthesis of data (meta-analysis) was not possible because of the variability of outcome measures and heterogeneity of the methods used across the studies. Therefore, a qualitative analysis of data was performed, based on the methodological quality of the trials included and consistency of their findings.

### *Role of the funding sources*

The funding institutions had no role in the design and conduction of the study; data collection, management, analysis, and interpretation; preparation, review, and approval

Table 1
Characteristics of the studies that were included

| Study | Methods | Participants | Interventions | Outcomes |
|---|---|---|---|---|
| Ansari, 2006 (Iran) [18] | RCT. An orthopedist who was unaware of the treatment schedule selected patients who were referred to a single physiotherapist. She allocated patients using sealed opaque envelopes withdrawn by chance.<br>Single blind (patients). | Fifteen patients with chronic nonspecific low back pain without radiating pain. Five dropped out because of noncompliance and discontinuation of treatment, and only 10 were analyzed.<br>Patients were not comparable at baseline in age (ultrasound: 35.5±13.8 y; placebo: 26.4±11.3 y), gender (ultrasound: all men; placebo: two men and three women), and body mass index (ultrasound: 28.3±2.9 kg/m$^2$; placebo: 23.8±5.2 kg/m$^2$) (p=.032). | All treatments were applied over a period of 3 wk, 3 days a week (10 sessions in total).<br>Therapeutic ultrasound (n=5): using 1 MHz with a 5-cm$^2$ sound head at an intensity of 1.5 W/cm$^2$, in continuous mode, on the right and left sides of the posterior lumbar region, for 8 min.<br>Placebo group (n=5): The same ultrasound device was used, but it was switched off. The application pattern (in terms of duration and location) was the same as in the active group.<br>Co-interventions: Patients were advised to continue previous treatment but not to initiate any new treatments or take new analgesics. No exercise programs were prescribed. | Follow up: 3 wk.<br>Functional Rating Index (0–100): 10 items (pain, sleeping, personal care, travel, work, activity, frequency of pain, lifting, walking, and standing).<br>Lumbar range of motion: extension, flexion, and lateral flexion.<br>Electroneurophysiological evaluation:<br>• H reflex latency and $H_{max}/M_{max.}$<br>• Impedance of less than 10 kΩ<br>• Rectangular pulses (p), duration 0.5 ms, rate 1p/3s<br>• In the soleus muscle<br>• In both sides. |
| Unlu, 2008 (Turkey) [17] | RCT. All patients were sequentially recruited by the same physiatrist, who also performed clinical assessments during follow-up visits.<br>No details about randomization.<br>Single blind (outcome assessor). | 60 patients (18 men and 42 women) with a mean age of 44.5 y (range, 20–60 y) with acute low back and sciatica or femoral neuralgia symptoms for less than 3 mo because of the herniation of one or more lumbar discs, documented by magnetic resonance imaging.<br>No dropouts.<br>No significant baseline differences between groups. | All treatments were applied over a period of 3 wk; once a day, 5 days a week (15 sessions in total).<br>Lumbar traction (n=20): standard motorized traction therapy system (15 min per session).<br>Therapeutic ultrasound (n=20): using 1 MHz with a 5-cm$^2$ sound head, at an intensity of 1.5 W/cm$^2$, in continuous mode, on the right and left sides of the posterior lumbar region, for 8 min.<br>Low-power laser (n=20): a Gal-Al-As diode, at a power output of 50 mV and wavelength of 830 nm. The dose at each point was 1 J. Time: 4 min at each point.<br>Co-interventions: ''Other co-interventions were not allowed during the treatment period.'' | Follow-up: 4 and 12 wk after treatment.<br>Lumbar range of motion: lateral flexion and Schober test.<br>Muscular tenderness on palpation of paravertebral muscles.<br>Straight leg raising test (≤70° in the affected leg).<br>Pain (low back pain and radiating leg pain) (VAS 0–100).<br>Roland Disability Questionnaire (0–24).<br>Modified Oswestry Disability Index (0–50). |
| Mohseni-Bandpei, 2006 (UK) [16] | RCT. Patients were assigned a number according to a block-style randomization scheme. | 120 patients aged between 18 and 55 y with pain between L1 and L5 and the sacroiliac joints for ≥3 mo, | Treatment sessions lasted for ≈20 min. | Follow-up: End of treatment (3–4 wk), in person, and 6 mo later, through a postal questionnaire. |

| | | | | |
|---|---|---|---|---|
| | Single blind (outcome assessor). | without sciatic pain, nerve root compression, or disc herniation.<br>Mean (SD) age (assessment after treatment completion/6 mo later): 34.8 (10.2) y/37.2 (10.6) y. Men, n (%): 22 (39%)/24 (43%).<br>112 patients were assessed after treatment completion and 73 patients were assessed 6 mo later.<br>No significant baseline differences between groups. | Spinal manipulation (n=56): a dynamic, short-lever, high-velocity thrust was applied exerting a force on the lumbar spine and sacroiliac joint. Four sessions (range, two to seven sessions), once or twice per week.<br>Ultrasound (n=56): a frequency of 1 MHz; continuous pattern ultrasound was applied to the lower back, on the painful area; an intensity of between 1.5 and 2.5 W/cm$^2$; 5–10 min depending on the size of the treatment area; six sessions (range, 3–11), once or twice per week.<br>Co-interventions: A written set of exercises were generated by the PhysioTools computer package, and the physiotherapist selected some of them for each patient. Medications (eg, NSAID, pain killers, muscle relaxants) were allowed and registered in both groups. | Pain intensity during the last week (VAS 0–10) [42].<br>Disability (Oswestry Disability Index) [43].<br>Range of motion (modified-modified Schober test) [44].<br>Surface electromyography of multifidus and iliocostalis: Median frequency, and median frequency slope (rate of shift calculated from the median frequency calculated for every second of recording, which was considered to be an index of muscle fatigue).<br>Muscle endurance (Biering-Sorensen test) [45]. |
| Barker, 2008 (United Kingdom) [15] | RCT. Noninferiority trial.<br>Randomization was performed using a random numbers table with permuted blocks.<br>Consecutively numbered, sealed, opaque envelopes were used.<br>Single blind (assessors). | Among 120 eligible adult patients older than 18 y, with low back pain for ≥3 mo and no leg pain, 60 were referred to a single physiotherapy department.<br>Mean (SD) age: 53.4 (±11.5) y, 50% men.<br>Six (10%) patients withdrew (one in the TENS group and five in the FairMed).<br>No significant baseline differences between groups. | All treatments were applied over a period of 3 wk.<br>TENS (n=27): Continuous trains at high frequency (80 Hz, using square-wave 100-μs pulses). Two surface electrodes (5 cm×5 cm$^2$ TPN 40 each) were placed in or adjacent to the painful area at a distance of 5 to 20 cm apart. The intensity was adjusted to produce a tingling sensation that was approximately two to three times the sensory threshold.<br>FairMed device (n=27): Subjects were asked to use the device for 30-min sessions.<br>Co-interventions: No co-interventions were allowed.* | Follow-up: 3 wk.<br>Pain (VAS) [46].<br>Disability (Oswestry Disability Index v. 2.1) [47], functional physical tests [48] (5-min walking distance, 1-min stair climb, and 1-min standing up from and sitting down on a chair).<br>Emotional functioning (Hospital Anxiety and Depression Scale) [49].<br>Fear of movement (Tampa Scale for Kinesiophobia) [50].<br>Catastrophizing (Pain Coping Scale) [51].<br>Self-efficacy beliefs (Pain Self-Efficacy Questionnaire) [52].<br>Global rating of patient reported improvement and satisfaction (Patient Global Impression of Change scale) [53].<br>Adverse events. |

VAS, visual analog scale; SD, standard deviation; NSAID, nonsteroidal anti-inflammatory drug; TENS, transcutaneous electrical nerve stimulation.

* Personal communication from Ms Barker.

Table 2
Risk of bias of the studies included [14]

| Sources of risk of bias | | Ansari (2006) [18] | Unlu (2008) [17] | Mohseni-Bandpei (2006) [16] | Barker (2008) [15] |
|---|---|---|---|---|---|
| A | 1. Was the method of randomization adequate? | Yes* | Unsure (not described) | Yes† | Yes |
| B | 2. Was treatment allocation concealed? | Yes* | Unsure | Yes† | Yes |
| C | Was knowledge of the allocated interventions, adequately prevented during the study? | | | | |
| | 3. Was the patient blinded to the intervention? | Unsure‡ | Not applicable | Not applicable | Not applicable |
| | 4. Was the care provider blinded to the intervention? | Not applicable | Not applicable | Not applicable | Not applicable |
| | 5. Was the outcome assessor blinded to the intervention? | No | Yes | Yes | Yes |
| D | Were incomplete outcome data adequately addressed? | | | | |
| | 6. Was the dropout rate described and acceptable? | No | Yes§ | Yes (immediately after the end of treatment)<br>No (at 6 mo)‖ | Yes¶ |
| | 7. Were all randomized participants analyzed in the group to which they were allocated? | No | Yes | Yes (immediately after the end of treatment)<br>No (at 6 mo) | Yes |
| E | 8. Are reports of the study free of suggestion of selective outcome reporting? | Yes | Yes | Yes | Yes |
| F | Other sources of potential bias: | | | | |
| | 9. Were the groups similar at baseline regarding the most important prognostic indicators? | No | Yes | Yes | Yes |
| | 10. Were co-interventions avoided or comparable? | Yes* | Yes | Yes† | Yes# |
| | 11. Was the compliance acceptable in all groups? | Yes | Yes | Yes | Yes |
| | 12. Was the timing of the outcome assessment in all groups similar? | Yes | Yes | Yes | Yes |
| | Total | 6/11** | 8/10 | 10/10 (for results from assessment immediately after treatment)<br>8/10 (for results at 6 mo)** | 10/10 |

TENS, transcutaneous electrical nerve stimulation.

* Details not available in the article, which were provided by Dr Nouredin Ansari on request from the authors of this review.

† Details not available in the article, which were provided by Dr Mohseni-Bandpei on request from the authors of this review.

‡ No co-interventions were allowed (data provided by Ms Barker and Dr Fairbank on request from the authors of this review).

§ Although patients were supposed to be masked, sham intervention did not cause heat (whereas active ultrasound does). This might have compromised patients' blindness.

‖ No patients dropped out; all patients were analyzed.

¶ The sample was established anticipating for ≤20% losses to follow-up. Immediately after treatment, eight of 112 patients (6.6%) were lost to follow-up. At the 6-month assessment (through a postal questionnaire), 47 patients (42%) were lost. Although a sensitivity analysis assuming different values for these patients was not performed, there was no crossover, and all patients were analyzed in the group they had been assigned to.

# One patient in the TENS group (of 28), and five (of 32) in the FairMed dropped out. Although a sensitivity analysis assuming different values for these patients was not performed, there was no crossover, and all patients were analyzed in the group they had been assigned to.

** Despite this score, this study had serious flaws implying a high risk of bias.

of the manuscript; or in the decision to submit the article for publication.

## Results

The electronic search provided 1,419 references, which led to the identification of 13 studies potentially eligible for inclusion in this review [15–27]. Twelve focused on ultrasound [16–27], and one on a shock wave device [15]. Nine studies were excluded: two because they turned out to not be randomized studies [20,21], one because it used sham ultrasound (a dose close to 0–0.1 W/cm$^2$—intermittently and without generating a heat effect) as a ''placebo'' treatment to be compared with usual treatment and exercise [19], and six because they used ultrasound in combination with other treatments in all the groups, making it impossible to isolate its effect [22–27].

The remaining four studies were included in this systematic review [15–18]. They included a total of 242 patients, and their characteristics are shown in Table 1. There was no disagreement between reviewers with regard to data extraction and the assessment of risk of bias.

Across the studies, ultrasound was compared with a sham procedure (a deactivated device that was moved across the painful area, but which did not produce heat) [18], lumbar traction [17], low-power laser [17], and spinal manipulation

Table 3
Summary of results

| Study | Pain | Disability | Mobility | Other |
|---|---|---|---|---|
| Ansari 2006 [18] | Not assessed | FRI (%): mean (SD)<br>•Ultrasound: before treatment, 56.5 (20.35); after treatment, ***34.5 (13.5)***<br>•Placebo: before treatment, 46.95 (14.38); after treatment, 39.9 (16.5) | Range of motion (degree): mean (SD)<br>Flexion<br>• Ultrasound: before treatment, 117.4 (2.5); after treatment, 128.6 (14.3)<br>• Placebo: before treatment, 103.4 (13.39); after treatment, 109.2 (10.6)<br>Extension<br>• Ultrasound: before treatment, 23.8 (4.15); after treatment, 30 (6.4)<br>• Placebo: before treatment, 27.2 (3.03); after treatment, 29 (4.2)<br>Right lateral flexion<br>• Ultrasound: before treatment, 20.2 (7.3); after treatment, 28 (8.6)<br>• Placebo: before treatment, 22.6 (5.2); after treatment, 26 (4.8)<br>Left lateral flexion<br>• Ultrasound: before treatment, 22 (7.77); after treatment, 28 (7.1)<br>• Placebo: before treatment, 23.8 (6.53); after treatment, 28.4 (4) | Electromyography features: mean (SD)<br>Right $H_{max}/M_{max}$<br>• Ultrasound: before treatment, 0.36 (0.07); after treatment, 0.36 (0.08)<br>• Placebo: before treatment, 0.38 (0.04); after treatment, 0.42 (0.01)<br>Left $H_{max}/M_{max}$<br>• Ultrasound: before treatment, 0.34 (0.1); after treatment, 0.35 (0.09)<br>• Placebo: before treatment, 0.41 (0.05); after treatment, 0.44 (0.03)<br>Right latency (ms)<br>• Ultrasound: before treatment, 27.32 (1.1); after treatment, 27.7 (1.1)<br>• Placebo: before treatment, 26.4 (2.7); after treatment, 26.5 (2.7)<br>Left latency (ms)<br>• Ultrasound: before treatment, 27.7 (0.9); after treatment, 28.1 (1.7)<br>• Placebo: before treatment, 26.11 (2.8); after treatment, 26.5 (2.5) |
| Unlu 2008 [17] | LBP (VAS 0–100): mean (SD):<br>• Traction: before treatment, 58.2 (18.1); at 3 mo, 31.3 (16.4)<br>• Laser: before treatment, 54.0 (17.0); at 3 mo, 30.0 (16.8)<br>• Ultrasound: before treatment, 51.7 (18.7); at 3 mo, 26.9 (15.2)<br>Radicular pain (VAS 0–100): mean (SD)<br>• Traction: before treatment, 59.6 (15.4); at 3 mo, 29.5 (16.7)<br>• Laser: before treatment, 53.1 (25.9); at 3 mo, 23.6 (17.7)<br>• Ultrasound: before treatment, 56.0 (15.3); at 3 mo, 25.2 (13.9) | RDQ: mean (SD)<br>• Traction: before treatment, 14.2 (4.3); at 3 mo, 8.9 (4.0)<br>• Laser: before treatment, 12.5 (5.0); at 3 mo, 6.7 (4.5)<br>• Ultrasound: before treatment, 13.4 (4.5); at 3 mo, 8.6 (6.0)<br>MODQ: mean (SD)<br>• Traction: before treatment, 19.3 (5.3); at 3 mo, 14.9 (4.9)<br>• Laser: before treatment, 18.4 (7.1); at 3 mo, 13.6 (6.2)<br>• Ultrasound: before treatment, 19.6 (6.4); at 3 mo, 14.4 (5.9) | Lateral flexion: mean (SD)<br>• Traction: before treatment, 47.0 (3.3); at 3 mo, 46.1 (4.2)<br>• Laser: before treatment, 47.0 (5.1); at 3 mo, 45.2 (4.7)<br>• Ultrasound: before treatment, 49.1 (4.5); at 3 mo, 47.8 (3.2)<br>Schober test: mean (SD)<br>• Traction: before treatment, 4.0 (0.9); at 3 mo, 4.2 (0.8)<br>• Laser: before treatment, 4.1 (0.9); at 3 mo, 4.3 (0.9)<br>• Ultrasound: before treatment, 4.2 (1.0); at 3 mo, 4.5 (0.9) | Muscular tenderness (0–4): mean (SD)<br>• Traction: before treatment, 0.7 (0.9); at 3 mo, 0.3 (0.5)<br>• Laser: before treatment, 0.8 (0.8); at 3 mo, 0.5 (0.6)<br>• Ultrasound: before treatment, 1.2 (1.1); at 3 mo, 0.5 (0.7)<br>Straight leg raising test (degree): median (SD)<br>• Traction: before treatment, 55.2 (7.1); at 3 mo, 57.5 (13.8)<br>• Laser: before treatment, 55.2 (9.6); at 3 mo, ***65.0 (5.7)***<br>• Ultrasound: before treatment, 54.4 (8.9); at 3 mo ***57.0 (10.5)*** |
| Mohseni-Bandpei 2006 [16] | VAS<br>• Baseline data: mean (SD):<br>Manipulation: 65 (19)<br>Ultrasound: 63 (19) | ODI (%)<br>• Baseline data: mean (SD):<br>Manipulation: 30.8 (12.7) | Lumbar flexion (mm)<br>• Baseline data: mean (SD):<br>Manipulation: 47 (13)<br>Ultrasound: 51 (11) | Median frequency multifidus (Hz) (mean):<br>• Baseline data: mean (SD):<br>Manipulation: 105 (16) |

(*Continued*)

Table 3 (*Continued*)

| Study | Pain | Disability | Mobility | Other |
|---|---|---|---|---|
| | • Improvement: mean (95% CI): Difference in favor of manipulation at 6 mo follow-up: ***15.1 (7.6, 22.6)*** | Ultrasound: before treatment, 32.2 (14.9)<br>• Improvement: mean (95% CI): Difference in favor of manipulation at 6 mo follow-up: ***5.2 (2.6, 7.8)*** | • Improvement mean (95% CI): Differences in favor of manipulation between the end of treatment and the 6 mo follow-up: ***9.4 (5.5, 13.4)***<br>Lumbar extension (mm)<br>• Baseline data: mean (SD): Manipulation: 11 (7) Ultrasound: 10 (7)<br>• Improvement mean (95% CI): Differences in favor of manipulation between the end of treatment and the 6 mo follow-up: ***3.4 (1.0, 5.8)*** | Ultrasound: 99 (16)<br>• Improvement mean (95% CI): Differences in favor of manipulation between the end of treatment and the 6 mo follow-up: 6.8 (−1.2, 14.9)<br>Median frequency iliocostalis (Hz):<br>• Baseline data: mean (SD): Manipulation: 67 (7), Ultrasound: 72 (7)<br>• Improvement mean (95% CI): Differences in favor of manipulation between the end of treatment and the 6 mo follow-up: 2.4 (−2.5, 7.1)<br>Median frequency slope multifidus<br>• Baseline data: mean (SD): Manipulation: −0.65 (0.18), Ultrasound: −0.54 (0.25)<br>• Improvement mean (95% CI): Differences in favor of manipulation between the end of treatment and the 6 mo follow-up: ***0.3 (0.1, 0.5)***<br>Median frequency slope multifidus<br>• Baseline data: mean (SD): Manipulation: −0.35 (0.27), Ultrasound: −0.34 (0.37)<br>• Improvement mean (95% CI): Differences in favor of manipulation between the end of treatment and the 6 mo follow-up: 0.1 (−0.1, 0.5)<br>Co-interventions* (% of patients using each kind of drug)<br>• Manipulation: Pain killers (14%), NSAID (34%), muscle relaxant (0%), none (52%)<br>• Ultrasound: Pain killers (23%), NSAID (13%), muscle relaxant (2%), none (62%)Adverse events: None detected* |
| Barker 2008 [15] | (Change in outcome measures between baseline and 3 wk)<br>VAS; mean (SD)<br>• FairMed: −8 (18)<br>• TENS: −7 (14)<br>PSE; mean (SD) | (Change in outcome measures between baseline and 3 wk)<br>ODI (0–100); mean (SD)<br>• FairMed: −0.6 (8.7)<br>• TENS: −0.9 (5.1) | (Change in outcome measures between baseline and 3 wk)<br>Sit to stand; mean (SD)<br>• FairMed: 1.0 (2.1)<br>• TENS: 1.0 (2.2)<br>Stairs; mean (SD) | TSK; mean (SD)<br>• FairMed: −1.8 (5.8)<br>• TENS: −2.0 (7.7)<br>HAD-A; mean (SD)<br>• FairMed: −1.4 (2.7)<br>• TENS: −0.3 (3.0) |

- FairMed: 1.9 (7.8)
- TENS: 4.4 (7.5)

PCS; mean (SD)

- FairMed: −1.6 (5.4)
- TENS: 2.0 (7.7)

- FairMed: 0.4 (1.9)
- TENS: 0.5 (1.0)

Walking distance (meters in 5 min); mean (SD)

- FairMed: 3.1 (41.4)
- TENS: 9.1 (−6.4)

HAD-D; mean (SD)

- FairMed: −0.2 (2.0)
- TENS: −0.6 (1.9)

PGIC (%)

- FairMed: Improved: 27%, unchanged: 73%
- TENS: Improved: 45%, unchanged: 44%, worsened: 11%

Adverse events: None detected†

Electromyography parameters, H reflex (range, 25–32 ms); FRI, Functional Rating Index (range from better to worse; 0–100%); HADS-A, Hospital Anxiety and Depression Scale—Anxiety (range, 0–21); HADS-D, Hospital Anxiety and Depression Scale—Depression (range, 0–21); Median frequency multifidus (Hz): range 20 to 450 Hz; MODI, Modified Oswestry Disability Index (range from better to worse; 0–100%); ODI, Oswestry Disability Index (range from better to worse; 0–100%); PGIC, Patient Global Impression of Change scale; patients scored their ability to cope with pain, and to perform everyday activities, but results were only given categorized as "improved," "unchanged," or "worsened"; PCS, Pain Catastrophizing Scale (range, 0–52); PSE, Pain Self-Efficacy (range, 0–60); RDQ, Roland Disability Questionnaire (range from better to worse; 0–24); ROM, range of motion (range, degrees); Flexion (range, 0°–75°); Extension (range, 0°–30°); Lateral flexion (range, 0°–35°); Schober test (range, from −9 to +15 cm); Sit to stand (N°/min); SLRT, straight leg raising test (range, 0 to >70°); Stairs (N°/min); TSK, Tampa Scale for kinesiophobia (range, 17–60); VAS, visual analog scale (range from better to worse; 0–100); Walking distance (meters in 5 min); SD, standard deviation; 95% CI, 95% confidence interval; NSAID, nonsteroidal anti-inflammatory drug; TENS, transcutaneous electrical nerve stimulation.

Data in bold italics indicate the results that are statistically significant.

* Personal communication from Dr Mahseni-Bandpei (data in the original article were misprinted or absent).

† Personal communication from Dr Fairbank and Ms Barker (data absent in the original article).

[16]. Shock wave therapy was applied by using the "FairMed" device [15] and was compared with transcutaneous electrical nerve stimulation (TENS). Each of these interventions is described in detail in Table 1.

The three RCTs on ultrasound included a total of 182 patients, of whom 71 (39.0%) were men, with a mean (standard deviation) age of 37.5 (11.47) years [16–18]. The RCT on shock wave included 60 patients, of whom 30 (50%) were men, with a mean (standard deviation) age of 53.4 (11.5) years [15] (Table 1). In general, patients in these studies had moderate degrees of pain and disability.

All studies measured disability as an outcome measure, although instruments used to assess it varied across studies (Table 1). Other outcome measures were pain, mobility (flexion, extension, lateral flexion, and Schober test), physical functioning (sit to stand, climbing stairs, walking distance), electrophysiological parameters, pain self-efficacy, pain coping, kinesiophobia, anxiety, and depression scale (Table 1). Follow-up ranged between 3 weeks and 6 months, and losses to follow-up were 0% [17], 10% [15], 25.6% [16], and 33% [18] (Table 1).

The assessment of risk of bias is shown in Table 2. If such an assessment had been based only on the information available in the original report, the scores of two of the studies would have been significantly lower [16,18], and one of them would have been classified as having a high risk of bias [18]. Taking into account the additional information provided by the authors of the original studies, all of them scored as having a low risk of bias [15−18]. However, despite these scores, two of the studies had serious flaws and were considered as having a high risk of bias (Table 2) [16,18].

All studies were single blinded. Because of the nature of the interventions being compared, blinding of patients and therapists was considered to be feasible only in one study, which failed to do so [18]. Only the article on shock wave described the procedure for randomization and allocation concealment [15], but the authors of other two provided these data on request [16,18]. The study on shock wave was the only one for which one of the authors reported a potential conflict of interest [15].

In 60 acute patients with LBP and leg pain attributed to lumbar disc herniations, lumbar traction, ultrasound, and low-power laser led to the same results on pain and disability at 1 and 3 months, albeit the improvement in the straight leg raising test was approximately 7° greater in the laser group than in the ultrasound one (Table 3) [17].

The other three studies focused on chronic (≥3 months) non-specific LBP without leg pain. In a study with 15 patients, in which five were lost to follow-up, at 3 weeks disability had improved approximately 10% more in patients undergoing ultrasound than in those in whom a deactivated device was applied. This was the study with the lowest quality among those included in this review. It did not assess pain severity, and there were no differences in flexion, extension, lateral flexion, and the H reflex [18].

In a study with 112 patients, at 6 months, manipulation led to significantly greater improvements than ultrasound in: pain (an additional benefit of approximately 1.5 visual analog scale points), disability (approximately 5 Oswestry Disability Index points), flexion (modified-modified Schober test approximately 9 mm), extension (approximately 3 mm), and median frequency slope in the multifidus, whereas there were no differences between groups in the median frequency slope of surface electromyography signals for iliocostalis lumborum or in the median frequency for multifidus and iliocostalis muscles (Table 3) [16].

In a study with 60 patients, at 3 weeks, shock wave led to results that were similar to those from TENS with regard to pain, disability, kinesiophobia, pain self-efficacy, pain coping scale, health anxiety and depression scale, and physical functioning. In this study, the number of patients reporting variations in their perception of ability to cope with pain was greater in the TENS group than in the FairMed group: five (18%) more patients reported improvement, and three (11%) more reported worsening (Table 3) [15].

No data on costs or cost-effectiveness were gathered in these studies. No data on side effects or adverse events were reported but, on request, the authors of three of the studies reported that there were none [15,16,18].

## Discussion

Results from this review do not support the use of ultrasound or shock wave for treating patients with LBP and leg pain. Only one study included such patients in which leg pain was attributed to disc herniation and ultrasound was compared with low-power laser and traction [17]. Neither traction nor low-power laser has shown to be effective for LBP, with or without sciatica [28,29]. Therefore, results suggesting that ultrasound is equivalent to these procedures for patients with lumbar disc herniation cannot be seen as supporting the effectiveness of any of those techniques [17]. In fact, the clinical evolution of patients in that particular study may simply reflect the natural history of acute disc herniation (Table 3) [17].

Results from this review do not support the clinical use of ultrasound for patients with common LBP without leg pain, either. One study assessed the effect of ultrasound versus a sham procedure [18]. However, neither therapists nor outcome assessors were masked, and the sham procedure did not produce heat, which may have compromised patients' blindness. Moreover, it only included 15 patients, of whom five were lost at 3 weeks and whose data were not analyzed. The effect of potential co-interventions was not analyzed either. All these shortcomings imply that this study has a high risk of having been affected by multiple biases (Tables 1 and 2) [18], making it impossible to rule out the possibility that ultrasound may simply be acting as a placebo for LBP patients. In fact, this is consistent with results from previous systematic reviews on the effect of ultrasound for other musculoskeletal problems [30,31]. Another study, which also had a high risk of bias, compared ultrasound with spinal manipulation. In LBP patients, spinal manipulation has shown to lead to reductions in pain and disability that are either very small or nonexistent [5,32–35], and which might be attributed to placebo and other unspecific effects, because they are similar to those from a sham procedure [36]. Therefore, results from this study, which show that ultrasound is even less effective [16], cannot be seen as supporting its clinical use.

There is no evidence on the efficacy of shock wave when compared with a sham procedure. Therefore, it is impossible to rule out that any clinical effect attributed to this procedure is actually because of unspecific effects (eg, placebo, Hawthorne, etc). The only study on this procedure has found that, at 3 weeks, it is ''not inferior'' to TENS for patients with LBP and no leg pain (Table 3) [15]. However, as acknowledged by the authors of the original study [15], the evidence on the efficacy of TENS for LBP patients is limited and inconsistent [37], and therefore, results from this study cannot be seen as supporting the clinical use of shock wave therapy in routine practice [15].

Most differences in clinical evolution, which were found in the studies included in this review, are so small that they can be seen as clinically irrelevant [38,39]. The only exception is the evolution of pain at 3 weeks when comparing ultrasound with spinal manipulation, which favors the latter [16].

Publication bias generally favors positive results. Therefore, potential publication bias is not likely to affect the negative conclusions from this review.

As opposed to the study on shock wave [15], the quality of reporting of the studies on ultrasound was very poor [16–18]. Future studies in this area should follow the CONSORT recommendations on reporting for trials on nonpharmacologic interventions [40].

More than 200 treatment modalities are currently available for LBP patients, including many nonpharmacologic therapies. Most clinically and commercially available procedures have never shown to be effective, safe, and cost/effective, which raises ethical, clinical, and economic concerns [41]. The decision to finance or continue to finance a treatment should be based on solid evidence deriving from high-quality RCTs on its efficacy versus a sham procedure, and its effectiveness and cost-effectiveness versus other forms of treatment, as well as on results from post-marketing surveillance [41]. This should be particularly so in times of cost containment.

Conducting low-quality RCTs implies wasting effort, time, and resources that might have been used more efficiently. Similarly, comparing the effectiveness of procedures that have not previously shown to be better than placebo (or the corresponding sham procedure) may be useless because it is impossible to rule out that such a study would only compare the relative size of their placebo effects [41].

Therefore, sound studies comparing ultrasound and shock wave with appropriate sham procedures should be conducted before comparing them with other forms of treatment for LBP patients. These other forms of treatment should also have previously shown to be effective. Moreover, further studies should ensure a clear and standardized definition of the type of patients to be included, with detailed inclusion and exclusion criteria; standardized treatment protocols; masking of the randomization procedure, patients, treatment providers, outcome assessment, and statistical analysis; use of standardized instruments to measure clinically relevant outcomes; samples that are large enough to ensure statistical power to detect clinically meaningful differences; implementation of measures to minimize losses to follow-up and crossover; ''intention-to-treat'' and ''as-treated'' analyses; systematic report of co-interventions and adverse events; assessment of costs and cost-effectiveness across treatment groups; and quality of reporting.

In conclusion, the main finding of this systematic review is that the available trials do not demonstrate the efficacy or effectiveness of ultrasound and shock wave for treating LBP, whether acute or chronic, with or without leg pain. This suggests that the resources assigned to fund these forms of treatment may be wasted and that the burden caused to patients (eg, visits to practitioners, time, costs, etc), may be unjustified. As a result, these procedures should only be used in the context of further research focused on assessing their efficacy, effectiveness, and cost-effectiveness, and their clinical use should be discouraged.

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## References

[1] Waddell G. The back pain revolution. Edinburgh, UK: Churchill Livingstone, 1998.

[2] Maxwell L. Therapeutic ultrasound: its effects on the cellular and molecular mechanisms of inflammation and repair. Physiotherapy 1992;78:421–6.

[3] Sweitzer RW. Ultrasound. In: Hecox B, Weisberg J, Tsega M, editors. Physical agents. CT: Appleton and Lange, 1994:163–92.

[4] Airaksinen O, Brox JI, Cedraschi C, et al. European guidelines for the management of chronic nonspecific low back pain. Eur Spine J 2006;15(Supplement 2):S192–300.

[5] Chou R, Huffman LH, American Pain Society, American College of Physicians. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/ American College of Physicians clinical practice guideline. Ann Intern Med 2007;147:492–504.

[6] van Tulder MW, Becker A, Bekkering T, et al., COST B13 working group on guidelines for the management of acute low back pain in primary care. European guidelines for the management of acute nonspecific low back pain in primary care. Eur Spine J 2006;15(Supplement 2):S169–91.

[7] Nussbaum EL. Ultrasound: to heat or not to heat—that is the question. Phys Ther Rev 1997;2:59–72.

[8] Roebroeck ME, Dekker J, Oostendorp RA. The use of therapeutic ultrasound by physical therapists in Dutch primary health care. Phys Ther 1998;78:470–8.

[9] Robertson VJ, Spurrit D. Electrophysical agents: implications of EPA availability and use in undergraduate clinical placements. Physiotherapy 1998;84:335–44.

[10] Lindsay DM, Dearness J, McGinley CC. Electrotherapy usage trends in private physiotherapy practice in Alberta. Physiother Can 1995;47: 30–4.

[11] Di Iorio D, Henley E, Doughty A. A survey of primary care physician practice patterns and adherence to acute low back problem guidelines. Arch Fam Med 2000;9:1015–21.

[12] Rutjes AW, Nüesch E, Sterchi R, et al. Therapeutic ultrasound for osteoarthritis of the knee or hip. Cochrane Database Syst Rev 2010;(1). CD003132.

[13] Brosseau L, Tugwell P, Wells GA, et al., Philadelphia Panel (Canada and the United States of America). Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for low back pain [with systematic review]. Phys Ther 2001;81: 1641–74.

[14] Furlan AD, Pennick V, Bombardier C, van Tulder M, Editorial Board of the Cochrane Back Review Group. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. Spine 2009;34:1929–41.

[15] Barker KL, Elliott CJ, Sackley CM, et al. Treatment of chronic back pain by sensory discrimination training. A Phase I RCT of a novel device (FairMed) vs. TENS. BMC Musculoskelet Disord 2008;9:97.

[16] Mohseni-Bandpei M, Critchley J, Staunton T, et al. A prospective randomized controlled trial of spinal manipulation and ultrasound in the treatment of chronic low back pain. Physiotherapy 2006;92: 34–42.

[17] Unlu Z, Tasci S, Tarhan S, et al. Comparison of 3 physical therapy modalities for acute pain in lumbar disc herniation measured by clinical evaluation and magnetic resonance imaging. J Manipulative Physiol Ther 2008;31:191–8.

[18] Ansari NN, Ebadi S, Talebian S, et al. A randomized, single blind placebo controlled clinical trial on the effect of continuous ultrasound on low back pain. Electromyogr Clin Neurophysiol 2006;46:329–36.

[19] Faas A, Chavannes AW, van Eijk JT, et al. A randomized, placebo-controlled trial of exercise therapy in patients with acute low back pain. Spine 1993;18:1388–95.

[20] Nwuga VC. Ultrasound in treatment of back pain resulting from prolapsed intervertebral disc. Arch Phys Med Rehabil 1983;64:88–9.

[21] Roman MP. A clinical evaluation of ultrasound by use of a placebo technic. Phys Ther Rev 1960;40:649–52.

[22] Koes BW, Bouter LM, van Mameren H, et al. Randomised clinical trial of manipulative therapy and physiotherapy for persistent back

and neck complaints: results of one year follow up. BMJ 1992;304: 601–5.
[23] Koes BW, Bouter LM, van Mameren H, et al. A blinded randomized clinical trial of manual therapy and physiotherapy for chronic back and neck complaints: physical outcome measures. J Manipulative Physiol Ther 1992;1:16–23.
[24] Hurwitz EL, Morgenstern H, Harber P, et al. The effectiveness of physical modalities among patients with low back pain randomized to chiropractic care: findings from the UCLA low back pain study. J Manipulative Physiol Ther 2002;25:10–20.
[25] Borman P, Keskin D, Bodur H. The efficacy of lumbar traction in the management of patients with low back pain. Rheumatol Int 2003;23: 82–6.
[26] Fernández-de-las-Peñas C, Fernández-Carnero J, Palomeque del cerro L, Miangolarra-Page JC. Manipulative treatment vs. conventional physiotherapy treatment in whiplash injury: a randomized controlled trial. J Whiplash and Related Disorders 2004;3: 73–90.
[27] Koldas Dogan S, Sonel Tur B, Kurtais Y, Atay MB. Comparison of three different approaches in the treatment of chronic low back pain. Clin Rheumatol 2008;27:873–81.
[28] Clarke J, van Tulder M, Blomberg S, et al. Traction for low-back pain with or without sciatica. Cochrane Database Syst Rev 2007;(2). CD003010.
[29] Yousefi-Nooraie R, Schonstein E, Heidari K, et al. Low level laser therapy for nonspecific low-back pain. Cochrane Database Syst Rev 2008;(2). CD005107.
[30] Robertson VJ, Baker KG. A review of therapeutic ultrasound: effectiveness studies. Phys Ther 2001;81:133–50.
[31] van der Windt DA, van der Heijden GJ, van den Berg SG, et al. Ultrasound therapy for musculoskeletal disorders. Pain 1999;81: 257–71.
[32] Cherkin DC, Sherman KJ, Deyo RA, et al. A review of the evidence for the effectiveness, safety, and cost of acupuncture, massage therapy, and spinal manipulation for back pain. Ann Intern Med 2003;138:898–906.
[33] Eisenberg DM, Post DE, Davis RB, et al. Addition of choice of complementary therapies to usual care for acute low back pain. A randomized controlled trial. Spine 2007;32:151–8.
[34] Ferreira ML, Ferreira PH, Latimer J, et al. Does spinal manipulative therapy help people with chronic low back pain? Aust J Physiother 2002;48:277–84.
[35] UK BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care. BMJ 2004;329:1377.
[36] Licciardone JCC, Stoll ST, Fulda KG, et al. Osteopathic manipulative treatment for chronic low back pain. A randomized controlled trial. Spine 2003;28:1355–62.
[37] Khadilkar A, Milne S, Brosseau L, et al. Transcutaneous electrical nerve stimulation for the treatment of chronic low back pain: a systematic review. Spine 2005;30:2657–66.
[38] Kovacs FM, Abraira V, Royuela A, et al. Minimal clinically important change for pain intensity and disability in patients with nonspecific low back pain. Spine 2007;32:2915–20.
[39] Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. Spine 2008;33:90–4.
[40] Boutron I, Moher D, Tugwell P, et al. A checklist to evaluate a report of a nonpharmacological trial (CLEAR NPT) was developed using consensus. J Clin Epidemiol 2005;58:1233–40.
[41] Carragee EJ, Deyo RA, Kovacs FM, et al. Clinical research. Is the spine field a mine field? Spine 2009;34:423–30.
[42] Waterfield J, Sim J. Clinical assessment of pain by visual analogue scale. Br J Ther Rehabil 1996;3:94–7.
[43] Fairbank J, Couper J, Davies J, et al. The Oswestry low back pain disability questionnaire. Physiotherapy 1980;66:271–3.
[44] William R, Blinkley J, Bloch R, et al. Reliability of the modified-modified Schober and double inclinometer methods for measuring lumbar flexion and extension. Phys Ther 1993;73:33–44.
[45] Biering-Sorensen F. Physical measurements as risk indicators for low back trouble over a one year period. Spine 1984;9:106–19.
[46] Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: a comparison of six methods. Pain 1986;27:117–26.
[47] Fairbank J, Pynsent P. The Oswestry Disability Index. Available at: http://www.chirogeek.com/001_Oswestry_20.htm. Accessed: August 31, 2010.
[48] Harding VR, Williams AC, Richardson PH, et al. The development of a battery of measures for assessing physical functioning of chronic pain patients. Pain 1994;58:367–75.
[49] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361–70.
[50] Vlaeyen JWS, Kole-Snijders AMJ, Rotteveel AM, et al. The role of fear of movement/(re)injury in pain disability. J Occup Rehabil 1995;5:235–52.
[51] Sullivan MJL, Bishop SC, Pivik J. The Pain Catastrophizing Scale: development and validation. Psychol Assess 1995;7:524–32.
[52] Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. Eur J Pain 2007;11:153–63.
[53] Guy W. ECDEU assessment manual for psychopharmacology. DHEW Publication No. ADM 76–338. Washington, DC: US Government Printing Office, 1976.

## Appendix

### Search strategy used for all reviews

*MEDLINE (PubMed)*

#2 "Low Back Pain"[Mesh]

#3 back pain[tw] OR lumbago[tw] OR backache[tw] OR spine pain[tw]

#4 #2 or #3 #7 "Electric Stimulation Therapy"[Mesh] NOT "Transcutaneous Electric Nerve Stimulation"[Majr] #9 electric stimulation[tiab] OR electrotherapy[tiab] OR electro therapy[tiab] OR short wave*[tiab] OR microwave*[tiab] OR ultrasound*[tiab] OR Laser*[tiab] OR magnetotherapy[tiab] OR pulsed radiofrequenc*[tiab] OR electro-acupuncture [tiab] OR electroacupuncture[tiab] OR electrostimulation [tiab] OR electrothermal[tiab] OR neuromodulation[tiab] OR intramuscular stimulation[tiab]

#10 #7 or #9

#11 transcutaneous electric nerve stimulation[ti] OR TENS[ti]

#12 #10 not #11

#13 #4 AND #12

#14 (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab]) NOT (animals[mh] NOT (humans[mh] AND animals[mh]))

#15 #13 AND #14

#16 ("1"[Publication Date] : "2009/12/31"[Publication Date]) AND (#13 AND #14)

#17 (#15) NOT #16

*CENTRAL (The Cochrane Library)*

#1 MeSH descriptor Low Back Pain explode all trees
#2 back pain OR lumbago OR backache OR spine pain
#3 (#1 OR #2)
#4 MeSH descriptor Electric Stimulation Therapy explode all trees #5 electric stimulation OR electrotherapy OR electro therapy OR short wave* OR microwave* OR ultrasound* OR Laser* OR magnetotherapy OR pulsed radiofrequenc* OR electro-acupuncture OR electroacupuncture OR electrostimulation OR electrothermal OR neuromodulation OR intramuscular stimulation
#6 (#4 OR #5)
#7 transcutaneous electric nerve stimulation:ti OR TENS:ti
#8 (#6 AND NOT #7)
#9 (#3 AND #8)
#10 (#9), from 1900 to 2009
#11 (#9 AND NOT #10)

*EMBASE (Ovid)*

1 exp Backache/
2 exp Low Back Pain/
3 back pain.mp.
4 back.ti.
5 lumbago.mp.
6 spine pain.mp.
7 1 or 2 or 3 or 4 or 5 or 6
8 exp electrostimulation therapy/
9 (electric stimulation or electrotherapy or electro therapy or short wave* or microwave* or ultrasound* or Laser* or magnetotherapy or pulsed radiofrequenc* or electro-acupuncture or electroacupuncture or electrostimulation or electrothermal or neuromodulation or intramuscular stimulation).ti,ab.
10 8 or 9
11 (transcutaneous electric nerve stimulation or TENS).ti.
12 10 not 11
13 7 and 12
14 random:.tw. or clinical trial:.mp. or exp health care quality/
15 13 and 14
16 limit 15 to yr="1974 - 2009"
17 15 not 16