

# Therapeutic ultrasound for acute ankle sprains

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A substantive amendment to this systematic review was last made on 28 November 2001. Cochrane reviews are regularly checked and updated if necessary.

## Abstract

**Background:** Ultrasound is used in the treatment of a wide variety of musculoskeletal disorders.

**Objective:** To evaluate the effects of ultrasound therapy in the treatment of acute ankle sprains.

**Search strategy:** We searched the Cochrane Musculoskeletal Injuries Group Specialised Register (July 2004), the Cochrane Central Register of Controlled Trials (The Cochrane Library Issue 2, 2004), MEDLINE (1966 to July 2004), EMBASE (1983 to July 2004), CINAHL (1982 to July 2004), and PEDro - the Physiotherapy Evidence Database (<http://ptwww.cchs.usyd.edu.au/pedro/>) (accessed 17/09/04). We also searched the Cochrane Rehabilitation and Related Therapies Field database, reference lists of articles, and contacted colleagues.

**Selection criteria:** Randomised trials were included if the following conditions were met: at least one study group was treated with active ultrasound; participants had acute lateral ankle sprains; and outcome measures included general improvement, pain, swelling, functional disability, or range of motion. Final selection of papers was conducted by two authors independently.

**Data collection and analysis:** Two authors independently assessed quality using a standardised checklist and extracted data. Relative risks together with 95 per cent confidence intervals were calculated for dichotomous outcomes and weighted or, where different scales were used, standardised mean differences together with 95 per cent confidence intervals for continuous outcome measures. Pooling of data was undertaken where there was clinical homogeneity in terms of participants, treatments, outcomes, and follow-up time points.

**Main results:** Five trials were included, involving 572 participants. Four of these trials were of modest methodological quality and one placebo-controlled trial was considered to be of good quality. None of the four placebo-controlled trials (sham ultrasound) demonstrated statistically significant differences between true and sham ultrasound therapy for any outcome measure at seven to 14 days of follow up. The pooled relative risk for general improvement was 1.04 (random-effects model, 95% confidence interval 0.92 to 1.17) for active versus sham ultrasound. The differences between intervention groups were generally small, between zero and six per cent for most dichotomous outcomes. However, one trial reported relatively large differences for pain-free status (20%) and swelling (25%) in favour of ultrasound.

**Reviewers' conclusions:** The extent and quality of the available evidence for the effects of ultrasound therapy for acute ankle sprains is limited. The results of four placebo-controlled trials do not support the use of ultrasound in the treatment of ankle sprains. The magnitude of treatment effects are generally small and of limited clinical importance. As yet, only few trials are available and no conclusions can be made regarding any optimal dosage schedule for ultrasound therapy, and

whether such a schedule would improve the reported lack of effectiveness of ultrasound for ankle sprains.

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## Background

Acute soft tissue injuries of the ankle (simple stretching, partial rupture or complete rupture of at least one ligament) are extremely common. Ankle sprains may be associated with long-term complaints of pain, functional disability and absence from work ([Makuloluwe 1977](#); [Williamson 1986](#)). Despite their importance, there is still debate regarding the management of acute ankle sprains. Standard treatment usually comprises of rest, ice, compression, and leg elevation, but additional treatment is often considered to be necessary ([Oakland 1993](#); [Williamson 1986](#)).

Ultrasound has been used in the treatment of musculoskeletal conditions for many years. Ultrasound equipment consists of a generator and transducer. The generator produces electromagnetic energy with a frequency of 0.5 to 3.5 MHz, which is converted by the transducer to mechanical energy with a similar frequency and intensity of up to 3 watts/cm<sup>2</sup> ([Ebenbichler 1994](#)). Laboratory research has demonstrated that the application of ultrasound results in the promotion of cellular metabolic rate and increased visco-elastic properties of collagen ([Maxwell 1992](#)). In animal studies, an exposure to 1 MHz ultrasound at 50 joules/cm<sup>2</sup> is reported to be sufficient to increase tissue temperature ([Hykes 1985](#)). This rise in temperature is assumed to be the mediating mechanism for tissue repair, the enhancement of soft tissue extensibility, promotion of muscle relaxation, augmentation of blood flow, and alleviation of inflammatory reactions of soft-tissue ([Falconer 1990](#); [Hayes 1992](#); [Kitchen 1990](#); [Maxwell 1992](#); [Van der Heijden 1991](#)).

Based on these experimental findings, ultrasound is used in physical therapy to relieve pain, reduce swelling, and improve joint immobility in a wide variety of musculoskeletal disorders including ankle sprains. Despite the theoretical benefits and widespread use, conclusive evidence on the effectiveness of ultrasound therapy in patient care is not yet available.

## Objectives

The objective of this systematic review of controlled trials was to determine whether ultrasound therapy is more effective than reference treatments (placebo intervention, no treatment, or other types of interventions) in people with acute ankle sprains with respect to the following outcomes: general recovery, improvement of pain relief, swelling, functional disability, and range of motion.

## Criteria for considering studies for this review

### Types of studies

Randomised controlled trials (RCTs) were considered. Also considered were controlled trials (CCTs) using a pseudo-randomised treatment allocation such as alternating allocation; allocation based on birth date, hospital number, or day of inclusion.

While only results from full trial reports were included, other trials reported only in abstract or incompletely were sought for reference purposes. There were no language restrictions.

### Types of participants

Trials that included people with pain, swelling and/or functional disability caused by acute ankle ligament injuries were considered.

### Types of intervention

Trials with at least one group treated with active ultrasound therapy were considered. Comparisons with placebo interventions were allowed as well as comparisons with no treatment or other types of interventions such as exercise therapy, immobilisation, laser therapy, or medication. Trials in which all intervention groups received ultrasound as a co-intervention were excluded as well as studies comparing phonophoresis with ultrasound (as this does not provide a contrast to ultrasound).

## Types of outcome measures

Trials using at least one of the following five types of outcome measures were considered for inclusion: 1) general improvement (patient perceived benefit, proportion/percentage of participants recovered, etc); 2) improvement of pain (visual analog scale, ordinal scale, pain questionnaire); 3) swelling; 4) functional disability (ability to walk, sick leave, re-uptake of sports, limitations of activities of daily living); or 5) range of motion.

## Search strategy for identification of studies

See: [Cochrane Bone, Joint and Muscle Trauma Group](#) search strategy

We searched the Cochrane Musculoskeletal Injuries Group Specialised Register (September 17th 2004), the Cochrane Controlled Trials Register (The Cochrane Library Issue 2, 2004), MEDLINE (1966 to July 2004, week 1), EMBASE (1983 to July 2004, week 28), CINAHL (1982 to July 2004, week 2), and PEDro - the Physiotherapy Evidence Database (<http://ptwww.cchs.usyd.edu.au/pedro/>) (accessed 17/09/04). We also searched the Cochrane Rehabilitation and Related Therapies Field database using the search term 'ultrasound' (April 1999), reference lists of articles, and contacted colleagues. No language restrictions were applied. No further attempts were made to collect unpublished data.

In MEDLINE (OVID Web) the following search strategy was combined with the first two stages of the optimal trial search strategy ([Alderson 2004](#)). This search was modified for use in other databases.

- 1. Ankle Injuries/
- 2. Ankle/ or Ankle Joint/ or Lateral Ligament, Ankle/
- 3. or/1-2
- 4. "Sprains and strains"/
- 5. ankle\$1.tw.
- 6. and/4-5
- 7. or/3,6
- 8. Ultrasonics/
- 9. (ultrasound or ultrasonic\$1).tw.
- 10. or/8-9
- 11. and/7,10

## Methods of the review

Two authors independently applied the selection criteria to the publications identified by the search strategy described above. During consensus meetings, remaining disagreements were discussed and a third author was consulted in cases of remaining disagreement.

- Assessment of methods (quality assessment)
- All publications included in the review were blinded for authors, affiliation, source, and results. Subsequently, the quality of methods was independently assessed by two authors using ten criteria for internal validity:
  - a. generation of a random sequence;
  - b. concealment of treatment allocation;
  - c. baseline similarity;
  - d. blinding of care provider;
  - e. co-interventions;
  - f. adherence to interventions;
  - g. blinding of participants;
  - h. proportion/percentage of withdrawals;
  - i. blinding of outcome assessment;
  - j. similarity in the timing of outcome assessment, follow-up assessments scheduled at equal time points in all intervention groups.

This list is based on the Amsterdam-Maastricht Consensus List for Quality Assessment, a consensus of two frequently used checklists designed by Koes et al ([Koes 1991](#)) and Verhagen et al ([Verhagen 1998](#)). The list includes the Jadad criteria ([Jadad 1996](#)). The checklist is recommended for use in systematic reviews on back pain by the Editorial Board of the Cochrane Collaboration Back Review Group ([Van Tulder 1997](#)). Detailed guidelines for the assessment of each validity criterion were made available to the authors.

For each criterion, both authors checked whether incomplete information hampered assessment of methods. Where there was insufficient information, the criterion was scored as 'don't know' (?). If sufficient information was provided the criterion was scored as either 'yes' ('+' for adequate methods) or 'no' ('-' for inadequate methods, potential bias). Assessment would have been based on all available information for those trials with more than one report if this had occurred. Disagreements were dealt with as stated above.

The trials were ranked according to the number of positively scored validity criteria. It was intended to use the quality assessment results for sensitivity analyses comparing the results of studies with relatively good method scores with the results of potentially flawed studies. Two cut-off points for good quality scores were given in the protocol: at least five items positively scored, and based on the median number of positively scored items.

- Data extraction
- For each publication, two authors independently extracted all necessary details using standardised forms. Details were recorded for:
  - eligibility criteria;

- interventions;
- outcome measures;
- length of follow up;
- adverse reactions;
- sample size;
- statistical analysis (intention-to-treat);
- data presentation.

For the primary outcome measures (general improvement, improvement of pain, range of motion, swelling, and functional disability), specific details were collected to allow statistical pooling of the results.

- Analysis
- Whenever possible, success rates and other outcomes were calculated according to the intention-to-treat principle. To evaluate differences in outcome, relative risks (relative benefits) together with 95 per cent confidence intervals were calculated for dichotomous outcomes. In addition, differences between intervention groups were calculated for dichotomous outcomes such as the proportion of participants able to walk, or the proportion of participants with sufficient improvement of pain. Weighted or, where different scales have been used, standardised mean differences together with 95 per cent confidence intervals (CI) were stipulated in the protocol for continuous outcome measures. For continuous outcome measures (e.g. visual analogue scales for pain severity), results for differences in improvement between groups were used in preference to differences between post-treatment values.

Statistical pooling of results (meta-analysis) was done in order to obtain some quantitative information on the efficacy of ultrasound therapy. The Cochrane Q-test was used to test for statistical homogeneity. In the case of statistical heterogeneity ( $p < 0.10$ ), and after consideration of the value of I squared, potential sources of heterogeneity were explored. The following variables were considered: type of control treatment, application of co-interventions, total validity score, and separate aspects of validity (blinding, randomisation procedure, and drop-out rate). Pooled estimates of outcome were computed for subgroups of trials that showed statistical homogeneity and sufficient clinical homogeneity with respect to participants, interventions, outcomes, and follow-up time points using a random-effects model ([DerSimonian 1986](#); [Fleiss 1993](#)).

## Description of studies

- Search results
- The search yielded eight potentially relevant trials on ultrasound therapy for acute ankle sprains. Five trials were identified in MEDLINE ([Makuloluwe 1977](#); [Nyanzi 1999](#); [Pellow 2001](#); [Van Lelieveld 1979](#); [Williamson 1986](#)). Reference checking and searches in other databases resulted in the identification of two additional trials ([Middlemast 1978](#); [Oakland 1993](#)). One abstract ([Bradnock 1995](#)) was obtained separately via the handsearching of recent conference abstracts from orthopaedic conferences, published in journals (Helen Handoll, personal communication).
- Trial selection

- The two authors selecting trials for inclusion initially agreed on the status of five out of the eight trials on ankle sprains. After a consensus meeting, agreement was reached for two remaining trials. As a result, five trials that met all the selection criteria were included in the review and the other three were excluded. Of the three excluded studies one used detuned (sham) ultrasound as a placebo intervention in comparison with manual therapy ([Pellow 2001](#)), one only evaluated (biomechanical) aspects of gait pattern after one treatment with ultrasound and thus did not meet our inclusion criterion regarding types of outcome measures ([Bradnock 1995](#)), one included a variety of soft-tissue injuries but did not report separate results for ankle sprains ([Middlemast 1978](#)).
- Included trials
- Four trials conducted in Britain were published in English ([Makuloluwe 1977](#); [Nyanzi 1999](#); [Oakland 1993](#); [Williamson 1986](#)), and one conducted in Denmark was published in Danish ([Van Lelieveld 1979](#)).

All studies involved participants with acute ankle sprains of relatively short duration. Four of the five studies compared ultrasound therapy with sham ultrasound (machine turned off) ([Nyanzi 1999](#); [Oakland 1993](#); [Van Lelieveld 1979](#); [Williamson 1986](#)). In three studies ultrasound therapy was compared with other treatment modalities: immobilisation by elastoplast ([Makuloluwe 1977](#)), felbinac gel ([Oakland 1993](#)), and electrotherapy ([Van Lelieveld 1979](#)).

[Nyanzi 1999](#) included 58 participants with inversion injuries of the ankle (time since injury less than 100 hours). Ultrasound therapy (three sessions on three consecutive days) was compared to sham ultrasound (treatment head electronically disabled). Outcome was assessed at day one, two, three and 14. Outcome measures were: pain (10 cm visual analog scale); swelling (ankle joint circumference); range of motion during dorsiflexion and plantar flexion (degrees); ability to bear weight (% body weight).

[Makuloluwe 1977](#) compared the effectiveness of ultrasound therapy (four to 10 treatments) with immobilisation with elastoplast in 80 participants with mild to moderate ankle sprains. In some cases an ice pack was applied before the first ultrasound treatment to reduce swelling. Recovery (yes/no) was assessed after one to two weeks.

[Oakland 1993](#) included 220 participants with acute injuries to the lateral ankle ligament (time since injury less than 48 hours). Ultrasound therapy (four treatments during one week) in combination with felbinac gel was compared with sham ultrasound in combination with felbinac gel and with ultrasound therapy in combination with placebo gel. Outcome was assessed at three, five, and seven days after randomisation. Participants scored pain on movement on a 100 mm visual analogue scale. Investigators assessed swelling, pain, and general severity on a five point ordinal scale and the ability to bear weight on a four point ordinal scale. Success rates were calculated as the proportion of people showing a moderate or marked improvement.

[Van Lelieveld 1979](#) compared ultrasound therapy (10 treatments during two weeks) with sham ultrasound and with electrotherapy. Sixty participants with acute ankle sprains (time since injury zero to four days) were included in the study. Outcomes were assessed daily for 15 days after randomisation. Main outcome measures were: swelling (ankle joint circumference); range of motion (three point ordinal scale); pain (six point ordinal scale); and the ability to walk 20 meters without limping (yes/no).

[Williamson 1986](#) randomised 154 participants with acute inversion injuries of the lateral ligament of the ankle joint (time since injury less than 48 hours) to treatment with either true or sham ultrasound. The length of follow up was three to four weeks. Outcome was assessed using a combined clinical score (0 to 15 points) consisting of five factors (each scored on a three point scale): subjective assessment of swelling; participant's discomfort; degree of limp; pain on inversion; and pain on plantar flexion. Success rates were computed as the number of "cured" participants who scored either zero or one point.

All available details on study populations, interventions, drop-out rates, outcomes, and adverse reactions are presented in the table 'Characteristics of included studies'.

## Methodological quality

The results of the quality appraisal are presented below. The total validity scores for the studies (based on total number of positively scored items and out of a possible total of ten) were: seven points for [Nyanzi 1999](#); five points for [Oakland 1993](#), [Van Lelieveld 1979](#) and [Williamson 1986](#); and two points for [Makuloluwe 1977](#). Thus the median number of positively scored items was five.

- Results of quality assessment (see [Table 01](#))
- Insufficient information was provided on several important methodological aspects (see Table 1: criteria, scored '?'). This impeded a good evaluation of the study design and mainly concerned methods used for the concealment of treatment allocation (b), similarity of intervention groups at baseline (c), and adherence to the intervention (f). Procedures used for the generation of a random sequence (a), blinding of participants (g), and timing of follow-up assessment (j) were positively evaluated in at least four out of five publications.

As well as a lack of information on trial methodology, there were inadequate details of the interventions (dosage and frequency of the treatment was often unclear), and outcome. In particular, continuous outcomes, including point estimates and measures of dispersion, were often inadequately reported and results were often presented graphically in terms of percentages without the denominators.

## Results

Data were extracted on all relevant outcome measures: general improvement, pain, swelling, functional disability, and range of motion. The results of all outcomes are presented in the outcomes column of the 'Characteristics of included studies' table.

Two types of comparisons are presented below: comparisons between true and sham ultrasound, and comparisons between ultrasound therapy and other treatment modalities.

- Ultrasound therapy versus sham ultrasound
- All four trials with a validity score of five points or more included an intervention group receiving sham ultrasound. None of these trials demonstrated statistically significant differences between true and sham ultrasound therapy for any outcome measure ([Nyanzi 1999](#); [Oakland 1993](#); [Van Lelieveld 1979](#); [Williamson 1986](#)). The studies varied with respect to the type of ultrasound (pulsed or continuous). Sufficient information on other treatment parameters (frequency or intensity) was only provided in [Oakland 1993](#) and [Nyanzi 1999](#).
- General improvement
- For three studies results of dichotomous measures of general improvement were available at seven days after randomisation, measured as: moderate or marked improvement ([Oakland 1993](#)); pain-free status ([Van Lelieveld 1979](#)); cured as indicated by a combined clinical score of zero or one point ([Williamson 1986](#)). The differences in success rates ranged between 0 and 20 per cent with the success rate in the control group ranging between 55 and 85 per cent. The three studies were relatively homogenous in terms of study populations and follow-up time points. The pooled relative risk (relative benefit) for general improvement was 1.04 (random-effects model, 95% confidence interval (CI) 0.92 to 1.17) for the comparison between true and sham ultrasound. The pooled difference in general improvement was 3.0 per cent (95% CI -6% to 12%). Differences across these

studies in the application of co-interventions, validity score, or separate aspects of validity had no influence on outcome.

- Pain
- Data on continuous or ordinal outcome measures of pain were incomplete. [Oakland 1993](#) did not demonstrate significant differences between groups with a moderate or marked response on pain with either true or sham ultrasound (follow up at seven days: 89% versus 79%, difference 10%; 95% CI -2% to 22%). [Nyanzi 1999](#) found no significant differences in pain scores on a visual analog scale between true and sham ultrasound (follow up at 14 days: 0.9; SD 1.4 versus 0.7; SD 1.4).
- Swelling
- Incomplete data were presented on continuous outcome measures of swelling. In [Van Lelieveld 1979](#), more participants treated with ultrasound had less than 0.5 cm difference in ankle circumference after seven days (65% versus 40%, 95% CI for the difference between groups: -5% to 55%). The difference in ankle circumference between true and sham ultrasound was small and not statistically significant in [Nyanzi 1999](#) (at 14 days: 51.3 cm; SD 2.5 versus 51.6 cm; SD 2.2).
- Functional disability
- Two studies presented dichotomous data on the ability to walk or bear weight at seven days ([Oakland 1993](#); [Van Lelieveld 1979](#)). The differences between intervention groups were small (5% to 6%) and not statistically significant. The pooled relative risk (relative benefit) was 1.09 (random-effects model, 95% CI 0.92 to 1.30). The pooled difference for functional disability was 6% (95% CI -6% to 19%). [Nyanzi 1999](#) reported only a small difference between true and sham ultrasound for the ability to bear weight at 14 days (% body weight in the affected leg): 44.7%; SD 5.6 versus 45.1%; SD 4.6.
- Range of motion
- [Van Lelieveld 1979](#) reported range of motion as an outcome measure but reported incomplete data (there were no standard deviations). [Oakland 1993](#) reported that problems with measurement had precluded presenting results for this outcome. [Nyanzi 1999](#) reported small differences in range of motion (degrees) between true and sham ultrasound (follow up at 14 days) for dorsiflexion: 36.8 degrees; SD 11.1 versus 38.6 degrees; SD 9.6, and plantar flexion: 36.3 degrees; SD 11.0 versus 31.7 degrees; SD 11.8.
- Comparisons between ultrasound therapy and other treatment modalities
- One study reported superior effects of ultrasound therapy compared with immobilisation with elastoplast ([Makuloluwe 1977](#)). The difference in success rate was 19 per cent at seven days (46% versus 27%); 95% CI -2% to 40%). The validity of these findings may be limited considering the relatively poor validity score of this study (two points).

The comparison between ultrasound therapy and felbinac gel resulted in small and non-significant differences (-1% to 5%), see the 'Characteristics of included studies' table ([Oakland 1993](#)).

In [Van Lelieveld 1979](#) the beneficial effects of electrotherapy appeared to be larger than those of ultrasound therapy: with respect to swelling (less than 0.5 cm) difference -20%; 95% CI -46% to 6%), ability to walk (difference -25%; 95% CI -55% to 5%), and recovery (pain-free status) difference -15%; 95% CI -38% to 8%). These differences were not statistically significant.

- Adverse reactions



- Four of the five studies did not provide information on adverse reactions, the issue only being addressed by [Oakland 1993](#). Eight out of 73 participants allocated to ultrasound therapy (plus placebo gel) reported 11 non-serious adverse reactions including gastrointestinal events and skin reactions. In one person, treatment was discontinued due to skin reactions and the person withdrawn from the trial.

## Discussion

The results of this review show that there is little evidence for the effectiveness of ultrasound therapy for acute ankle sprains. Five trials met the selection criteria. Four placebo-controlled trials could not detect statistically significant or clinically important differences between true and sham ultrasound for any outcome measure: general improvement, pain, swelling, functional disability or range of motion. The number of studies was relatively small and only one was of good methodological quality. Due to differences in the definition of outcome measures statistical pooling of results was only sensible for some comparisons and for which data from only two or three studies could be used. These pooled estimates also resulted in small and non-significant differences between true and sham ultrasound.

One study did detect large and significant differences in favour of ultrasound therapy when compared with immobilisation using elastoplast ([Makuloluwe 1977](#)). However, this study was considered to be of relatively poor validity with a score of only two out of 10 points. Another pragmatic study comparing ultrasound with electrotherapy reported better results for electrotherapy with respect to improvements of swelling, pain, and ability to walk ([Van Lelieveld 1979](#)). The interpretation of these pragmatic studies is complicated as strong evidence for the effectiveness of most other interventions for ankle sprains is not yet available ([De Bie 1998](#)).

None of the trials included a follow-up period longer than one month. Ultrasound therapy is assumed to be most effective in the first phase of treatment ([Roebroeck 1998](#)) and long-term effects may not be expected. Indeed, the three trials with follow-up periods of two to four weeks showed that the large majority of participants had fully recovered by that time and any differences between intervention groups were negligible.

In 1995, Gam & Johannsen published a systematic review of 22 randomised clinical trials on the effectiveness of ultrasound therapy for musculoskeletal conditions ([Gam 1995](#)), which included two studies on ankle sprains ([Van Lelieveld 1979](#); [Williamson 1986](#)). While they did not present separate analyses for different musculoskeletal conditions, the general conclusion of their review was that there was little evidence for the effectiveness of ultrasound therapy, from well-designed trials.

We prefer to base conclusions regarding the effectiveness of ultrasound therapy on studies of adequate methodological quality. The Amsterdam-Maastricht Consensus list is one of the many scales and checklists that have been designed to assess quality of randomised trials ([Moher 1996](#)). Most of these scales and checklists, including the one we used, are based on generally accepted principles of intervention research. Some items in our checklist, particularly those concerning co-interventions and prognostic similarity, were associated with frequent disagreement among our authors and may need revision (e.g. more explicit instructions for scoring either positive or negative). Nevertheless, we consider quality assessment to be important and believe that relatively more weight should be attached to the outcomes of trials that reported adequate methods. Several studies have provided empirical evidence that trials with inadequate methods, particularly concerning concealment of treatment allocation and blinding, report different estimates of treatment effect ([Chalmers 1983](#); [Colditz 1989](#); [Schulz 1995](#)).

We chose an arbitrary cut-off point of five positive validity criteria to identify studies of adequate quality. Three placebo-controlled studies just met that cut-off point and one study ([Nyanzi 1999](#)) can be considered to be of good methodological quality with seven out of 10 points. An alternative scoring system was considered that included only three aspects of trial validity which are generally

considered to be important: concealed allocation of interventions (criterion b), low drop-out rate (criterion h), and blinding of outcome assessment (criterion i) (data not shown). This alternative analysis did not influence the ranking of studies according to validity scores and, consequently, did not result in different conclusions regarding the effectiveness of ultrasound therapy for ankle sprains.

Insufficient reporting of trial methods often hampered the quality assessment in this review. Journal style or editorial decisions may partly be the reason for the lack of information on important items. A more complete and informative trial report may result in higher validity scores but could also reveal additional flaws in design or conduct. Insufficient information frequently concerned not only aspects of trial validity but also diagnostic criteria, details concerning the study populations (athletes or sedentary people), treatment parameters including information on testing and calibration of ultrasound machines, and outcome measures. Future reviews will profit from the introduction of guidelines for the reporting of trials (CONSORT statement), which will prevent difficulties during quality assessment and ensure adequate data presentation and analysis ([Altman 1996](#); [Moher 2001](#)).

In the five studies included in the review, outcome measures were not uniform and the definitions of general improvement, pain, swelling, and functional disability varied across studies. Some of these measures have probably been designed on the basis of face validity and may have proved useful in clinical practice. Important characteristics of the outcome measures such as reproducibility, validity, responsiveness, or applicability were not described. A thorough assessment of the quality of outcome measures used in the five studies was, unfortunately, not feasible within the scope of this review.

Our review may not be entirely free from publication bias as we included only published trial reports. Retrieving unpublished data requires a huge effort that was not within the scope of this review. Publication bias may be prevented if investigators report the results of all studies undertaken and if journal editors base their decisions to publish on aspects of quality only and not on the strength and direction of results. However, considering the fact that it is usually small studies with negative results that are less likely to be published ([Dickersin 1990](#)), we do not think that inclusion of unpublished data would have strongly influenced the results of our review on the effectiveness of ultrasound therapy for ankle sprains.

In this review we included trial reports published in any language. Unfortunately we were unable to use the same authors for quality assessment of the studies published in English and Danish. The Danish paper ([Van Lelieveld 1979](#)) was assessed by another author, which may have resulted in a different interpretation of validity criteria. The findings of the Danish study were not systematically different from those published in English.

In our opinion it is important to consider not only the statistical significance of trial results but also the magnitude of treatment effect. Pooling of many small placebo-controlled studies or conducting very large trials will eventually produce statistically significant results but if the size of the treatment effect is small the costs of treatment may easily outweigh the benefits. Deciding on the magnitude of a clinically important difference is difficult and certainly arbitrary as it depends on several factors including the natural history, prevalence and severity of the condition, the reference treatment, potential adverse reactions and inconvenience of therapy, treatment preferences, and costs (including costs of personnel, equipment and time spent on therapy) ([Cook 1992](#)). Although the definition of a clinically important difference depends on the condition, research in patients with musculoskeletal disorders has shown that differences between study groups may be considered to be clinically important if they exceed 20 per cent ([Goldsmith 1993](#)).

## Reviewers' conclusions

### Implications for practice

The number of trials evaluating the effectiveness of ultrasound therapy for acute ankle sprains was small. As yet, the results of four placebo-controlled trials do not support the use of ultrasound in the treatment of ankle sprains. The magnitude of most reported treatment effects is small and probably of limited clinical importance. Due to the limited amount of information on treatment parameters, no conclusions can be made regarding an optimal and adequate dosage schedule for ultrasound therapy or whether such a schedule would improve on the reported effectiveness of ultrasound for ankle sprains.

## Implications for research

Although the quality of methods of most available studies on ultrasound therapy for ankle sprains may be considered to be modest, the findings of the placebo-controlled studies consistently indicated small and non-significant treatment effects of ultrasound therapy. Therefore, future research should preferably be directed towards the evaluation of other interventions for ankle sprains, such as exercise therapy, or to interventions for the prevention of future or recurrent ankle sprains in those who are at a relatively high risk of ankle ligament injuries (e.g. taping, external ankle support devices, or health education interventions) ([Handoll 2002](#)).

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## Potential conflict of interest

None known.

## Notes

In a the first substantive update (Issue 1, 2002) one additional randomised clinical trial was included (Nyanzi 1999). The conclusions of the review remained unchanged.

## Tables

### Characteristics of included studies

Study	Makuloluwe 1977
Methods	Randomised clinical trial (no details of method). No blinding of patients, care providers and outcome assessment. Validity score: 2 out of 10 points.
Participants	Enfield, UK.80 patients with ankle sprains. Inclusion criteria: mild or moderate ankle sprains, pain on abduction or adduction of the foot.Exclusion criteria (X-ray): ankle fractures.
Interventions	Group 1: Ultrasound therapy: 1.5 W/cm <sup>2</sup> , 4 minutes, 4-10 sessions (n = 40). Length of treatment variable, depending on recovery.Group 2: Immobilisation by elastoplast (n = 40).Co-interventions: ice packs for

	some patients in the ultrasound group.
Outcomes	Length of follow up: 1 week At 1 week: success rate 46% (Group 1) versus 27% (Group 2), difference 19% (95% CI -2% to 40%) At 2 weeks: success rate 86% (Group 1) versus 59% (Group 2), difference 27% (95% CI 8% to 46%) Dropouts: none reported but values of percentages indicate incomplete outcome ascertainment. Adverse reactions: not described.
Notes	Authors' conclusion: ultrasound is more effective than immobilisation with elastoplast.
Allocation concealment	B
<b>Study</b>	<b>Nyanzi 1999</b>
Methods	Randomised clinical trial (use of computer generated randomisation scheme). Blinding of patients, care provider, and outcome assessor. Validity score 7 out of 10 points.
Participants	Southampton, UK. 58 patients with ankle ligament sprains. Inclusion criteria: inversion injury of the joint, time since injury < 100 hours, able to follow instructions, age 14 to 65 years. Exclusion criteria: previous similar injury within 1 year, multiple injuries, diabetic, extensive varicose veins, bony injuries. 59% male, 41% female, mean age 50 years.
Interventions	Group 1: pulsed ultrasound mark space ratio 1:4, 3 MHz, 0.25 W/cm <sup>2</sup> , 2 minutes, 3 treatments over 3 consecutive days (n = 29). Group 2: Sham ultrasound (n = 29) Co-interventions: elevate leg while resting, bear weight when active; Tubigrip support, paracetamol for those in need of analgesics.
Outcomes	Length of follow up: 14 days. - Pain (10 cm VAS, mean and SD), day 1: 4.9 ± 2.4 (1), 4.8 ± 2.6 (2); day 14: 0.9 ± 1.4 (1), 0.7 ± 1.4 (2). - Swelling (ankle joint circumference in cm, mean and SD), day 1: 50.8 ± 2.6 (1), 53.1 ± 2.6 (2); day 14: 51.3 ± 2.5 (1), 51.6 ± 2.2 (2). - ROM dorsiflexion (degrees, mean and SD), day 1: 14.3 ± 5.9 (1), 23.6 ± 11.3 (2); day 14: 36.8 ± 11.1 (1), 38.6 ± 9.6 (2). - ROM plantar flexion (degrees, mean and SD), day 1: 18.4 ± 5.4 (1), 17.4 ± 8.3 (2); day 14: 36.3 ± 11.0 (1), 31.7 ± 11.8 (2). - Ability to bear weight (% bodyweight, mean and SD), day 1: 36.7 ± 11.0 (1), 40.4 ± 9.2 (2); day 14: 44.7 ± 5.6 (1), 45.1 ± 4.6 (2). Dropouts: n = 7 (12.1%), 3 in group 1, 4 in group 2. All reported full recovery, and had no time to attend further assessments. Adverse reactions: not described.
Notes	Authors' conclusion: at the dose and duration used, ultrasound is no better than placebo in the management of acute ligament injuries.
Allocation concealment	B
<b>Study</b>	<b>Oakland 1993</b>
Methods	Randomised clinical trial (use of computer generated randomisation

	scheme). Blinding of patients. Blinding of care providers and outcome assessment unclear. Validity score 5 out of 10 points.
Participants	Multicentre trial, UK.220 participants with acute ankle injuries. Inclusion criteria: injury of the lateral ankle ligament of at least mild severity, time since injury < 48 hours.Exclusion criteria: fractures, internal derangement of the joint, hypersensitivity for felbinac, abraded skin, asthma, metabolic joint diseases or rheumatic conditions, systematic connective tissue disorders, severe renal, hepatic, cardiovascular or dermatological disease, patients requiring analgesics or other NSAID, pregnant or lactating women, participants in other trials. 65% men, 35% women, mean age 28 years.
Interventions	Group 1: pulsed ultrasound: 3 MHz, 0.25-0.5 W/cm <sup>2</sup> , 2-3 minutes, 4 treatments over 7 days, in combination with felbinac gel: 2-3 applications every day (n = 75).Group 2: sham ultrasound in combination with felbinac gel (n = 72).Group 3: ultrasound in combination with placebo gel (n = 73).Co-interventions: none.
Outcomes	Length of follow up: 1 week- Pain on movement or at rest, swelling : mean change, no SD providedAt seven days (intention-to-treat):- Moderate or marked response of pain (investigator): 67/75 (1), 57/72 (2), 61/73 (3)Group 1 versus Group 2: 10% (95% CI -2% to 22%); Group 3 versus Group 2: 5% (95% CI -8% to 18%)- Able to bear full weight: 60/75 (Group 1), 53/72 (Group 2), 56/73 (Group 3) Group 1 versus Group 2: 6% (95% CI -7% to 20%); Group 3 versus Group 2: 3% (95% CI -11% to 17%)- Moderate or marked improvement of general severity: 65/75 (Group 1), 61/72 (Group 2), 61/73 (Group 3).Group 1 versus Group 2: 2% (95% CI -9% to 13%); Group 3 versus Group 2: -1% (95% CI -13% to 11%)dropouts: n = 30 at 3 days (14%), n = 59 at 5 days (27%), n = 81 at 7 days (37%). Adverse reactions: 20 non-serious adverse events: 7 (Group 1), 2 (Group 2), 11 (Group 3). One excluded (Group 3) due to adverse reactions.
Notes	Authors' conclusions: there were few significant differences between the intervention groups. The effectiveness of felbinac is similar to that of ultrasound therapy.
Allocation concealment	B
<b>Study</b>	<b>Van Lelieveld 1979</b>
Methods	Randomised clinical trial (computer generated random numbers). Blinding of patients and outcome assessment. No blinding of care provider. Validity score: 5 out of 10 points
Participants	Haslev, Denmark.All patients with acute ankle distortions referred to the X-ray department (n = 60).Inclusion criteria: time since injury 0-4 days, first distortion ever. 42% men, 58% women, mean age 23 to 29 years
Interventions	Group 1: continuous ultrasound: 0.5 W/cm <sup>2</sup> , 5-10 minutes, 5x/week, 2

	weeks (n = 20?).Group 2: electrotherapy: diadynamic current, pulse duration 10 msec, 50/100 Hz, 4-8 minutes (n = 20?).Group 3: sham ultrasound (n = 20?).Co-interventions: elastic bandages, crutches, leg elevation, plantar flexion exercises.
Outcomes	Length of follow up: 15 days.At baseline, and daily until maximum of 15 days:- swelling (joint circumference in cm), means, no SD - range of motion (1=20°, 2=40°, 3= > 40° restriction), means, no SD - pain (6-point scale), means, no SD- % patients with swelling < 0.5 cm at 7 days (n = ?): 13/20 (1), 17/20 (2), 8/20 (3)Group 1 versus Group 2: -20% (95% CI -46% to 6%); Group 1 versus Group 3: 25% (95% CI -5% to 55%)- % patients able to walk at 7 days (n = ?): 9/20 (Group 1), 14/20 (Group 2), 8/20 (Group 3)Group 1 versus Group 2: -25% (95% CI -55% to 5%); Group 1 versus Group 3: 5% (95% CI -26% to 36%)- % patients pain free at 7 days (n = ?): 15/20 (Group 1), 18/20 (Group 2), 11/20 (Group 3)Group 1 versus Group 2: -15% (95% CI -38% to 8%); Group 1 versus Group 3: 20% (95% CI -9% to 49%)Dropouts: 3 (2 did not complete treatment; 1 incorrect diagnosis).Adverse reactions: not described
Notes	Authors' conclusions: ultrasound therapy has no significant effect on the course of recovery.The assumption in the analyses of allocation of 20 patients to each group seems to be supported in the graphical representations.
Allocation concealment	B
<b>Study</b>	<b>Williamson 1986</b>
Methods	Randomised clinical trial (use of random numbers). Blinding of care provider, patients and outcome assessment. Validity score: 5 out of 10 points
Participants	Manchester, UK.All patients with ankle sprains attending the emergency department (n = 154).Inclusion criteria: time since injury < 48 hours, objective injury lateral ankle ligament; age 12 to 65 years. Exclusion criteria (X-ray): fractures, complete rupture with > 6 mm opening of the ankle mortice laterally or > 6 mm anterior displacement of the talus.
Interventions	Length of treatment: until recovery (clinical score 0 or 1 point)Group 1: ultrasound on alternate days (74). (Treatment parameters not described.)Group 2: sham ultrasound (80).Co-interventions: ice packs, exercises, Tubigrip support, crutches if needed.
Outcomes	Length of follow up: 4 weeksAt baseline and after 1 to 4 weeks:- Clinical score (0-15 points), median and ranges: swelling (0-3), patient's discomfort (0-3), limp (0-3), pain on inversion (0-3), pain on plantar flexion (0-3).- % patients 0 or 1 point: at 1 week (n = ?): 41/74 (Group 1) versus 44/80 (Group 2), difference 0% (95% CI -16% to 16%) at 2 weeks (n = ?): 67/74 (Group 1) versus 68/80 (Group 2), difference 5% (95% CI -5% to 15%)at 3 weeks (n = ?): 74/74 (Group 1) versus 76/80 (Group 2), difference 5% (95% CI 0% to 10%).at 4 weeks (n = ?): 100% all.Dropouts: n = 44 (29%)

	after three weeks. Adverse reactions: not described.
Notes	Authors' conclusions: ultrasound treatment does not hasten recovery after lateral ankle sprains. Data extrapolated from graphs.
Allocation concealment	B

**ABBREVIATIONS AND ACRONYMS**

ROM: range of motion

SD: standard deviation

VAS: visual analog scale

**Characteristics of excluded studies**

Study	Reason for exclusion
Bradnock 1995	<p>Comparison of continuous ultrasound (45 kHz, 0.95 W), high frequency pulsed ultrasound (3 MHz, 2 W), and sham ultrasound in 47 patients with acute ankle sprains (1 treatment only).</p> <p>Reason for exclusion: outcome measures are related to gait pattern: stride length, swing phase, cadence ratio, walking speed. These outcome measures were not considered to be relevant for this review (aimed at pain, swelling, functional disability, general improvement).</p>
Middlemast 1978	<p>Comparison of pulsed ultrasound (1.5 MHz, 0.5 - 1 W/cm<sup>2</sup>), and thermotherapy (wax baths, infra-red, or short-wave diathermy) in 71 patients with soft tissue injuries.</p> <p>Study population consisted of patients with a variety of soft tissue injuries. Results for ankle sprains (n = 20, 28%) were not presented separately.</p>
Pellow 2001	<p>Comparison of manual therapy (ankle mortice separation adjustment), and 5 minutes of detuned ultrasound (8 sessions in 4 weeks) in 30 patients with subacute and chronic grade I or II ankle inversion sprains.</p>

**Additional tables**

**Table 01 Results of the quality assessment**

Criteria	Makuloluwe 1977	Nyanzi 1999	Oakland 1993	van Lelieveld 1979	Williamson 1986
a	?	+	+	+	+
b	?	?	?	?	?
c	?	?	?	?	?
d	-	+	?	-	+
e	?	+	+	+	?
f	?	?	?	?	?
g	-	+	+	+	+

h	+	+	+	?	?
i	-	+	?	+	+
j	+	+	+	+	+
total (+)	2	7	5	5	5

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#### **Makuloluwe 1977** *{published data only}*

Makuloluwe RT, Mouzas GL. Ultrasound in the treatment of sprained ankles. *Practitioner* 1977;218:586-8.

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\* indicates the major publication for the study

### References to studies excluded from this review

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### Van der Windt 2002

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## Graphs

### Graphs and Tables

To view a graph or table, click on the outcome title of the summary table below.

01 True versus sham ultrasound				
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
<a href="#">01 General improvement at 7 days</a>	3	341	Relative Risk (Random) 95% CI	1.04 [0.92, 1.17]
<a href="#">02 Ability to walk or bear weight at 7 days</a>	2	187	Relative Risk (Random) 95% CI	1.09 [0.92, 1.30]

## Cover sheet

### Therapeutic ultrasound for acute ankle sprains

**Reviewer(s)** Van der Windt DAWM, Van der Heijden GJMG, Van den Berg SGM, Ter Riet G, De Winter AF, Bouter LM

**Contribution of Reviewer(s)** DAWM van der Windt conceived, designed and co-ordinated the review, developed the search strategy and carried out the searches, screened search results and obtained papers, screened retrieved papers against inclusion criteria, carried out quality assessment and data abstraction, entered data into RevMan, carried out statistical analyses, and wrote the review. GJMG van der Heijden conceived and designed the review, developed the search strategy, contributed to the appraisal of quality and data abstraction, commented on statistical analyses and on drafts of the

review. S van den Berg designed the review, developed the search strategy and carried out the searches, screened search results and obtained papers, screened retrieved papers against inclusion criteria, carried out quality assessment and data abstraction, and commented on drafts of the review. G ter Riet contributed to the appraisal of quality and data abstraction, and commented on statistical analyses and on drafts of the protocol. AF de Winter contributed to the appraisal of quality and data abstraction, and commented on statistical analyses and on drafts of the protocol. LM Bouter conceived and supervised the review, and commented on drafts of the review.

<b>Issue protocol first published</b>	1999 issue 1
<b>Issue review first published</b>	1999 issue 4
<b>Date of last minor amendment</b>	05 November 2004
<b>Date of last substantive amendment</b>	28 November 2001
<b>Most recent changes</b>	<p>For this second update (Issue 1, 2005) the search was updated and no additional randomised clinical trials met the selection criteria. The conclusions of the review remain unchanged. The text has been modified to conform with the Cochrane Style Guide.</p> <p>The title has been changed from "Ultrasound therapy for acute ankle sprains" to "Therapeutic ultrasound for acute ankle sprains" to reflect current usage of 'therapeutic ultrasound' for therapy and 'diagnostic ultrasound' for diagnostics.</p>
<b>Date new studies sought but none found</b>	17 July 2004
<b>Date new studies found but not yet included/excluded</b>	01 February 2000
<b>Date new studies found and included/excluded</b>	01 September 2001
<b>Date reviewers'</b>	Information not supplied by reviewer

## conclusions section amended

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## Synopsis

Ultrasound is probably not effective in aiding the healing of ankle sprains

Ultrasound, or the use of high frequency sound pulses, is commonly used for treating acute ankle sprains. It is thought that the increase in temperature caused by ultrasound helps soft tissue healing. This review of trials found that ultrasound therapy does not seem to help to reduce pain and swelling, or to improve the ability to stand on the affected foot. Most injuries heal quickly within about two weeks, and ultrasound does not seem to hasten recovery. Most trial results do not support the use of ultrasound, as any differences in effect are very small.

## Keywords

Humans; Ankle Injuries[\*therapy]; Randomized Controlled Trials; Sprains and Strains[\*therapy]; \*Ultrasonic Therapy