Authors' objectives
To evaluate the effectiveness of ultrasound therapy in the treatment of musculoskeletal disorders.

Searching
Published and full trial reports (including dissertations) were retrieved by a computerised search of MEDLINE (1966 to July 1997) and EMBASE (1983 to July 1997). The first two stages of the search strategy of the UK Cochrane Centre were used to identify controlled clinical trials and this strategy was combined with a search for ultrasound therapy, musculoskeletal disorders, and physical therapy. The Cochrane Controlled Trials Register and the database of the Field Rehabilitation and Related Therapies were screened using the search term "ultrasound". References from all retrieved trials, and relevant reviews and meta-analysis were also screened. No language restrictions were applied.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and controlled clinical trials (CTs) in which an alternative method of treatment allocation were used were included if they met the inclusion criteria regarding intervention, study population and outcome measures.

Specific interventions included in the review
Active ultrasound either alone or in combination with other active treatments was compared with placebo interventions including sham ultrasound, no treatment and the following other types of active interventions either alone or in combination: electrotherapy, hydrocortisone injection, laser therapy, exercise therapy, tolmetin, ice packs, paraffin, short-wave diathermy, placebo gel, felbinac gel, immobilisation, medication, megapulse, TENS, iontophoresis and histamine injections. Comparisons of phonophoresis and ultrasound therapy were excluded.

Participants included in the review
Patients with pain and/or restriction of range of motion associated with the following musculoskeletal disorders were included: lateral epicondylitis; soft-tissue shoulder disorders; degenerative rheumatic disorders; ankle distortions; temporomandibular joint pain or myofascial pain; and a variety of other musculoskeletal disorders. Patients with pressure sores, pain after tooth extractions, post partum perineal pain, or wound healing were excluded.

Outcomes assessed in the review
The following four types of outcome measures were assessed: general improvement; improvement of pain; improvement of functional disability; or improvement of range of motion.

How were decisions on the relevance of primary studies made?
Publications were blinded for authors, affiliation, source, and results.

Two reviewers independently applied the validity criteria to studies published in English or German. Disagreements were resolved by consensus with any continuing disagreements being resolved by a third reviewer. Studies published in other languages required the help of a translator or native speaker.

Assessment of study quality
Validity was assessed using the following criteria from the Amsterdam-Maastricht Consensus List for Quality Assessment: adequacy of method of randomisation; degree of concealment of treatment allocation; similarity of intervention groups at baseline; blinding of care provider and use of placebo; avoidance or standardization of cointerventions; acceptable adherence to intervention in all groups; patient blinded to allocation intervention (placebo or naive patients); withdrawal/drop-out rate described and acceptable; outcome assessor blinded; and comparability of timing of outcome assessment in both groups.
Criteria were scored as adequate methods, inadequate methods, or unclear. The sum of positively scored items denoted the validity score. Publications were blinded for authors, affiliation, source, and results.

Two reviewers independently applied the validity criteria to studies published in English or German. Disagreements were resolved by consensus with any continuing disagreements being resolved by a third reviewer. Studies published in other languages required the help of a translator or native speaker.

**Data extraction**

Two reviewers independently extracted the following data onto standardised forms: selection criteria; interventions; outcome measures; length of follow-up; adverse reactions; study size; analysis and data presentation. Disagreements were resolved by consensus with any continuing disagreements being resolved by a third reviewer. Success rates for each study group were estimated using general improvement of symptoms. Differences in success rates and 95% confidence intervals (CI) between study groups were estimated, as was the number-needed-to-treat (NNT). For outcomes evaluated on an ordinal or continuous scale, 95% CI were calculated for differences between groups in change since baseline or for differences between post-treatment values. Effect size was computed using Cohen's method.

**Methods of synthesis**

*How were the studies combined?*

Studies were grouped according to type of musculoskeletal disorder addressed.

Pooled estimates were calculated using a random-effects model when there was clinical homogeneity with respect to diagnosis, interventions, and outcome measures and for studies of sufficiently high validity (scoring five or more points on validity criteria).

*How were differences between studies investigated?*

Results were considered separately from studies scoring five or more on validity criteria. Clinically important differences were considered to exist if difference in success rates between groups exceeded 20% (NNT < 5) or effect size exceeded 0.5.

Results from data extraction were used to consider and evaluate clinical heterogeneity across studies. Statistical heterogeneity was assessed using the Breslow-Day statistic (chi-squared). Results from studies published in languages other than English or German that required translation and data extraction by only one translator were considered separately.

The analysis was repeated with the inclusion only of trials reporting concealed allocation of interventions, low drop-out rates and blinding of outcome assessment.

**Results of the review**

Thirty-eight RCTs or CTs were included. Eighteen studies were placebo controlled. Total number of participants in trials was not reported though the smallest group size per study was reported.

Reviewers agreed on average on seven out of ten validity criteria in each study. Ten out of the thirty-one studies published in English or German and three out of the seven studies published in other languages scored five or more on validity criteria. Methodological shortcomings in the primary studies included the following: inadequacy of prognostic similarity at baseline, blinding of the therapist, and patient or outcome assessment; insufficient information reported on methodological aspects; inadequate data presentation; lack of long term follow-up; small sample size; and lack of study design with sufficient power to detect a clinically relevant difference.

Lateral epicondylitis (6 studies): all three placebo-controlled studies had a validity score of five or more and were considered to be clinically homogeneous. Breslow Day test chi-squared = 5.36, 0.1 < P < 0.05. Pooling of these three studies gave a difference in success rate of 15% (95% CI: -8%, 38%). NNT = 7. Proportion of positive studies 33%.

Other studies had low validity scores.

Soft-tissue shoulder disorders (7 studies): no study reported statistically significant results favouring ultrasound.
Validity scores ranged from 2 to 10 and 4 studies scored more than 5. For those studies with adequate validity scores only minor differences were reported for success rate. Clinical heterogeneity precluded pooling.

Degenerative rheumatic disorders (10 studies): no study scored more than four on validity. Results from these trials were inconsistent.

Ankle distortions (4 studies): three studies score five on validity but none found significant or clinically important differences between ultrasound and placebo.

Temporomandibular joint pain or myofascial pain (4 studies): no study scored at least five on validity. Differences between study groups were small.

Other diagnosis (7 studies): significant and clinically important differences favouring ultrasound were reported only for improvement of pain in patients with tendinitis or epicondylitis. The three studies published in other languages reported results similar to those published in English or German.

Three placebo-controlled trials examined heel pain, myofascial trigger points or lateral epicondylitis. The wide variation in diagnosis and outcomes measures precluded sensible pooling of results. Significant and important differences in favour of ultrasound were only reported for patient with tendinitis or epicondylitis but only for improvement of pain (effect size 0.55).

Ultrasound therapy in combination with exercise (13 studies): four studies score at least five on validity criteria but none reported statistically significant or clinically important effects for ultrasound added to exercise.

Repeating the analysis with the inclusion only of trials reporting concealed allocation of interventions, low drop-out rates and blinding of outcome assessment did not results in different conclusions.

**Authors’ conclusions**
As yet, there appears to be little evidence to support the use of ultrasound therapy in the treatment of musculoskeletal disorders. The large majority of 13 randomised placebo-controlled trials with adequate methods did not support the existence of clinically important or statistically significant differences in favour of ultrasound therapy. Nevertheless, the findings for lateral epicondylitis may warrant further investigation.

**CRD commentary**
This thorough and methodologically sound review was clearly presented.

The aims and inclusion criteria were clearly stated. Methods used to select primary studies, extract data and assess validity were described. The possibility of publication bias was discussed. Relevant detail of the included studies was presented in tabular format. Studies were grouped according to type of musculoskeletal disorder and the strength of evidence reported taking account of study validity. Studies were only combined where they were of adequate quality and clinically and statistically homogeneous. Where there was doubt as to the rigour of the methodology used this was mentioned. Sensitivity analysis was undertaken to investigate the effect of the value of the cut-off point for classifying studies as of adequate validity. The discussion included consideration of the methodological flaws in the primary studies.

The evidence presented supported the authors’ conclusions.

**Implications of the review for practice and research**
Practice: The authors state that there was weak evidence in favour of ultrasound therapy but no evidence or insufficient evidence of effectiveness of ultrasound therapy for soft-tissue shoulder disorders, degenerative rheumatic disorders, ankle distortions, temporomandibular joint pain or myofascial pain.

Research: The authors state that more attention should be directed towards the evaluation of other interventions for musculoskeletal disorders that may be more promising but have not been thoroughly evaluated, such as exercise therapy, multidisciplinary programmes, graded activity programmes, or cognitive behavioural therapies. The authors favour the introduction of guidelines for reporting of trials to prevent difficulties in quality assessment and to ensure
adequate data presentation and analysis.

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