Acupuncture for tension-type headache: a meta-analysis of randomized controlled trials

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CRD summary
This well-conducted review suggested that acupuncture had limited efficacy (visible only at longer term follow-up) for reducing headache frequency in tension-type headache compared with sham acupuncture. The results were likely to be reliable, but further research was needed to assess other variations of needle-based acupuncture and subtypes of tension-type headache.

Authors' objectives
To evaluate the safety and efficacy of acupuncture for tension-type headaches.

Searching
The following databases were searched without language restriction from inception to August 2007: MEDLINE, EMBASE, CINAHL, PsycINFO and Cochrane Central Register of Controlled Trials. Search terms were mentioned but not reported. Further searches were carried out on ClinicalTrials.gov. Topic experts were contacted by email. Bibliographies of systematic reviews and eligible studies were scanned for additional studies.

Study selection
Only randomised controlled trials (RCTs) were eligible for this review. Studies had to compare needle-based acupuncture with sham acupuncture. The intervention was specified as needles inserted into traditional acupuncture points, stimulated electrically or with moxibustion. Dry-needling techniques were excluded as were trials comparing acupuncture with another active therapy. The populations were adults who met established criteria for tension-type headache. Studies were required to provide at least six sessions of treatment. Outcomes of interest were headache frequency, intensity or duration.

Included studies were mostly parallel RCTs, but two used a cross-over design. Studies had been carried out in Germany, England, Denmark, Italy and Australia and were performed in a mixture of settings including outpatient clinics, research departments and health centres. Participants' mean age ranged from 32.5 to 52.7 years (where reported). The percentage of males ranged from 13 per cent to 50 per cent (where reported). Most studies included chronic and episodic tension-type headache subtypes. The active intervention groups received either a standard protocol of acupuncture points plus optional points chosen by the practitioner or in one study acupuncture points as chosen by the practitioner. Sham conditions usually consisted of superficial needling at non-acupuncture points. Treatment duration ranged from three to 8 weeks, and six to 15 sessions. Outcomes were reported as headache index or period index scores, headache days via a diary, visual analogue scales and a von Korff pain intensity scale. Follow-up ranged from eight to 56 weeks.

Studies were evaluated by two independent reviewers and discrepancies were resolved by discussion.

Assessment of study quality
A modified version of the Jadad scale was used to assess methodological quality including a total of 11 items. Each study was then assigned a quality score between 0 and 5.

Validity assessment was carried out by two independent reviewers blinded to the country of origin, author and journal identity of each paper. Disagreements were resolved by moderated discussion.

Data extraction
A standardised data extraction form was used to record study characteristics and outcomes: headache days per month and headache intensity. Mean and standard deviation (SD) for headache days per month were extracted. The secondary outcome of headache intensity was defined as the score of subjective pain recorded on a numerical scale and extracted as mean (SD) where possible. Where outcomes were reported from both a headache diary and at examination the
average based on the diary data was selected. Where studies used a cross-over design, only data from the first period was used.

Data extraction was carried out by two independent reviewers blinded to the country of origin, author and journal identity of each paper. Disagreements were resolved by moderated discussion.

**Methods of synthesis**

Meta-analyses were performed using a random-effects model (DerSimonian and Laird) to produce weighted mean differences (WMDs) and associated 95% confidence intervals (CI) for the outcomes of interest. Sham and active acupuncture outcomes were compared. Further analyses explored differences at long-term follow-up (defined as follow-up between 20 and 25 weeks after randomisation). Publication bias was assessed based on visual inspection of funnel plots and plot symmetry was checked using the Egger linear regression method. Statistical heterogeneity was assessed using the X² test.

**Results of the review**

A total of eight RCTs (n=896) were included in this review (11 publications) of which five reported sufficient data to be included in meta-analyses. Sample sizes ranged from small pilot studies (n=10) to large multi-centre studies (n=409). Overall the methodological quality was reported as relatively high with all studies scoring between 3 and 4 out of 5. In all studies where blinding of patients was assessed, this was reported as having been successful. Publication bias did not seem to be present based on the funnel plot and Egger test.

There was no significant difference between active and sham acupuncture in the number of headache days per month during treatment, WMD -2.93 (95% CI: -7.49, 1.64; five studies). Statistically significant heterogeneity was noted (X²=119, p<0.00001). The forest plot was inspected visually and one outlier study removed (details not given). Re-analysis produced a non-significant WMD of -1.37 (95% CI: -2.93, 0.18) without significant statistical heterogeneity.

There was a significant difference in favour of active acupuncture in headache days per month at long-term follow up, WMD -1.83 (95% CI: -3.01, -0.64; four studies) without significant heterogeneity.

There was no significant difference between active and sham acupuncture in the headache intensity during treatment, WMD -7.24 (95% CI: -18.46, 3.99; three studies), however, there was a significant difference in favour of active acupuncture at long-term follow up, WMD -3.64 (95% CI: -6.55, -0.073; four studies). There was no statistically significant heterogeneity noted in either of these analyses.

Three trials reported adverse events data. No severe adverse events related to the active acupuncture were observed, but one severe exacerbation of headache occurred in the sham group. Adverse events (headache exacerbation/trigger, haematoma, dizziness) occurred in 16 per cent to 17 per cent of the active groups, and in four per cent to 17 per cent of the control groups where reported.

**Authors' conclusions**

This meta-analysis suggested that acupuncture had limited efficacy for reducing headache frequency in TTH when compared with sham acupuncture. Further research was needed to assess needle-based acupuncture that uses electrical or moxibustion for stimulation.

**CRD commentary**

This review addressed a clear question with appropriate inclusion criteria. The searches covered the major databases (although not Chinese language databases or AMED, a specialist complementary medicine resource as noted by the authors). Attempts were made to identify unpublished literature. Appropriate methods to reduce reviewer error and bias were used throughout and documented clearly, including validity assessment of the primary studies. The meta-analysis appeared to have been carried out appropriately. Statistical heterogeneity was both assessed and addressed, although no details were reported on which study was excluded from the primary outcome analysis. It was not clear why the reviewers chose to use WMD rather than standardised mean differences when analysing multiple numerical scales, but this was unlikely to have affected the overall results. Overall, the authors' conclusions were based on a well-
conducted review and were likely to be reliable.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that further research was needed to assess needle-based acupuncture that uses electrical or moxibustion for stimulation. Studies should also explore the responses in specific tension-type headache sub-types.

**Funding**

None stated.

**Bibliographic details**


**PubMedID**

18499526

**DOI**

10.1016/j.jpain.2008.03.011

**Indexing Status**

Subject indexing assigned by NLM

**MeSH**

Acupuncture Points; Acupuncture Therapy /adverse effects /methods /statistics & numerical data; Follow-Up Studies; Humans; Randomized Controlled Trials as Topic; Tension-Type Headache /therapy; Time Factors; Treatment Outcome

**AccessionNumber**

12008105798

**Date bibliographic record published**

03/02/2009

**Date abstract record published**

17/06/2009

**Record Status**

This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.