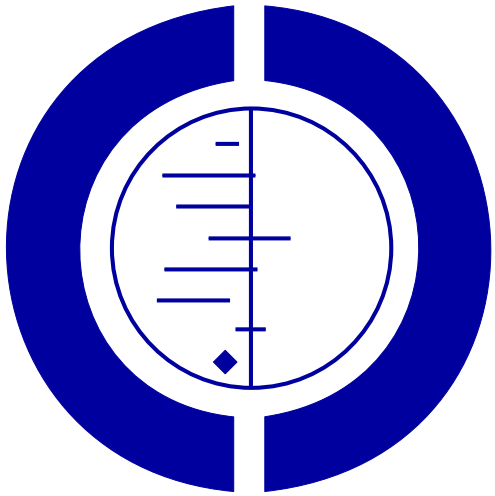
Acupuncture for idiopathic headache (Review)

Melchart D, Linde K, Berman B, White A, Vickers A, Allais G, Brinkhaus B



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ABSTRACT

Background
Acupuncture is widely used for the treatment of headache, but its effectiveness is controversial.

Objectives
To determine whether acupuncture is:

- more effective than no treatment
- more effective than 'sham' (placebo) acupuncture
- as effective as other interventions used to treat idiopathic (primary) headaches.

Search strategy
Electronic searches were performed in MEDLINE, EMBASE, the Cochrane Controlled Trials Register, and the database of the Cochrane Field for Complementary Medicine. We also contacted researchers in the field and checked the bibliographies of all articles obtained.

Selection criteria
Randomized or quasi-randomized clinical trials comparing acupuncture with any type of control intervention for the treatment of idiopathic (primary) headaches were included.

Data collection and analysis
Information on patients, interventions, methods, and results was extracted by at least two independent reviewers using a pre-tested standard form. Results on headache frequency and intensity were summarized descriptively. Responder rate ratios (responder rate in treatment group/responder rate in control group) were calculated as a crude indicator of results for sham-acupuncture-controlled trials. Quantitative meta-analysis was not possible due to trial heterogeneity and insufficient reporting.

Main results
Twenty-six trials including a total of 1151 patients (median, 37; range, 10-150) met the inclusion criteria. Sixteen trials were conducted among patients with migraine, six among patients with tension-type headache, and four among patients with various types of headaches. The majority of trials had methodological and/or reporting shortcomings. In eight of the 16 trials comparing true and sham (placebo) acupuncture in migraine and tension-type headache patients, true acupuncture was reported to be significantly superior; in four trials there was a trend in favor of true acupuncture; and in two trials there was no difference between the two interventions. (Two trials were uninterpretable.) The 10 trials comparing acupuncture with other forms of treatment yielded contradictory results.

Authors' conclusions
Overall, the existing evidence supports the value of acupuncture for the treatment of idiopathic headaches. However, the quality and amount of evidence are not fully convincing. There is an urgent need for well-planned, large-scale studies to assess the effectiveness and cost-effectiveness of acupuncture under real-life conditions.

BACKGROUND

Idiopathic headaches are a major source of morbidity (Schwartz 1998; Göbel 1994; Pryse-Phillips 1992; Rasmussen 1991) and cause substantial costs (Ferrari 1998). Acupuncture is widely used for headache treatment and may be applied as a single modality or as part of a more complex treatment program (Richardson 1986; Millman 1977; Woollam 1998). Despite this popularity, there is still a debate within academic medicine about whether acupuncture has 'specific' effects, that is, effects over and above placebo.

It is difficult to evaluate the health effects of acupuncture because treatment can take a variety of forms. In formula acupuncture, fixed points are used for patients with a defined Western medical diagnosis. In more traditional forms of treatment, acupuncturists vary points depending on traditional Chinese medical diagnoses. As a result, patients with the same Western diagnosis may be treated with different sets of acupuncture points.

Systematic reviews on the use of acupuncture for chronic pain in general (Patel 1989; ter Riet 1989a; ter Riet 1990) and headaches in particular (ter Riet 1989b; ter Riet 1989c; ter Riet 1989d) were published in 1989 and 1990. Since that time a number of new trials have been performed, and agreement has been reached on a classification of headaches (IHS 1988). Therefore, an up-to-date review of the available clinical evidence was deemed necessary.

OBJECTIVES

To determine whether acupuncture is:

- more effective than no treatment
- more effective than 'sham' (placebo) acupuncture
- as effective as other interventions used to treat idiopathic (primary) headaches.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomized and quasi-randomized (e.g., by alternation or date of birth) clinical trials were included.

Types of participants

Trials conducted among patients with idiopathic headaches (migraine, tension-type headache, cluster headache, or imprecisely classified chronic or recurrent primary headaches) were included. Trials focusing explicitly on patients with facial pain were excluded.

Types of intervention

The treatments considered were:

- needle insertion at acupuncture points, pain points, or trigger points
- other methods of stimulating acupuncture points (e.g., laser acupuncture, electro-acupuncture).

Control interventions considered were:

- no treatment
- placebo (sham acupuncture)
- other treatment.

Trials that compared only different forms of acupuncture were excluded.

Types of outcome measures

Studies were included if they reported at least one clinical outcome related to headache (e.g., pain intensity, global assessment of headache). Trials reporting only physiological or laboratory parameters were excluded, as were trials with outcome measurement periods of less than 4 weeks (from the start of treatment to final observation).

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Pain, Palliative and Supportive Care Group methods used in reviews.

The following sources were searched:

- MEDLINE 1966 to April 2000
- EMBASE 1989 to April 2000
- the database of the Cochrane Field for Complementary Medicine
- the Cochrane Controlled Trials Register 2000, Issue 1
- individual trial collections and private databases
- bibliographies of review articles and included studies.

The search terms used for the electronic databases were '(acupuncture or acupressure)' and '(headache or migraine)'.

METHODS OF THE REVIEW

ELIGIBILITY
All references identified by the literature search were screened by two reviewers. As a first step, we tried to identify all articles on

acupuncture treatment of recurrent headaches that reported original data. Of the 102 studies so identified, 58 were excluded because they did not mention a control condition. The eligibility of the remaining 44 studies was then assessed in detail by at least two reviewers. Eighteen studies were excluded (for reasons, see the table describing the 'Characteristics of excluded studies'). Disagreements occurred for three studies (Annal 1992; Borglum-Jensen 1979; Lenhard 1983). These disagreements were resolved by discussion, with the result that all three studies were excluded (for the reasons, see the table describing the 'Characteristics of excluded studies').

DATA EXTRACTION

Information on patients, methods, interventions, outcomes, and results was extracted independently by at least two reviewers using a pre-tested form. We tried to obtain additional information from the first authors or the corresponding authors of the primary studies as necessary.

Trials were categorized by headache type (migraine and migrainous disorders, tension-type headache, mixed [patients with different types of headache within one trial]), and by the type of control intervention used (no treatment, sham acupuncture, other treatment).

ASSESSMENT OF QUALITY

The quality of reports/methodological quality of included trials was assessed by at least two independent reviewers using two scales.

The scale by Jadad et al. (Jadad 1996) has items on:

- random allocation (1 point if allocation was described as randomized + 1 point if an adequate method to generate the random sequence was described)
- double-blinding (1 point if there was a statement that patients and evaluators were blinded + 1 point when the blinding procedure was described and adequate)
- reporting of dropouts/exclusions (1 point if dropouts and withdrawals, as well as the reasons, were listed independently for each treatment group)

The maximum score is 5. Studies scoring 3 or more points were considered high quality. The points achieved for each of the above three items are listed in order for each study in the table describing the 'Characteristics of included studies' (e.g., for a trial getting full points on each item, the score would be 2-2-1). A summary of the scores for all the included trials is also provided in Table 01.

The second scoring method (the internal validity scale = IVS) was developed by a member of the review team (KL) and has been used in several systematic reviews of complementary medicine (Linde 1996a; Linde 1996b; Linde 1997). This instrument has six items:

- method of allocation to groups
- concealment of allocation
- baseline comparability
- blinding of patients
- blinding of evaluators
- likelihood of selection bias after allocation to groups by dropouts, etc.

Each item is scored as 0 (criterion not met or insufficient information provided), 0.5 (criterion partially met), or 1 (criterion met). The points achieved for each of the six items are listed in order for each trial in the table describing the 'Characteristics of included studies' (e.g., for a trial getting full points on each item, the score would be 1-1-1-1-1-1). A summary of the scores for all the included trials is also provided in Table 02.

For the calculation of quality scores only the information provided in the publications or written reports was used. Disagreements between reviewers were resolved by discussion.

The quality of acupuncture was assessed by a reviewer (GA) who is a specialist in both in acupuncture and headache. This individual has trained in Europe in both traditional Chinese acupuncture and Western acupuncture (reflexotherapy) and practices using both methods. He was provided with copies of the methods sections of the reports, with all indications of authorship and source, as well as the introduction, results, and discussion sections, deleted. The acupuncturist was first asked how he would treat the patients included in the study. His options were 'exactly or almost exactly the same way', 'similarly', 'differently', 'completely differently', or 'could not assess' due to insufficient information (on acupuncture or on the patient). He was then asked to rate his degree of confidence that acupuncture was applied in an appropriate manner on a 100-mm visual scale (with 0% = complete absence of evidence that the acupuncture was appropriate, and 100% = total certainty that the acupuncture was appropriate). The latter method was proposed by a member of the review team (AW) and has been used in a review of clinical trials of acupuncture for back pain (Ernst 1998). In the table describing the 'Characteristics of included studies' the acupuncturist's assessment is summarized under 'Methods' (e.g., 'similarly/70%' for a trial where the acupuncturist would treat 'similarly' and is 70% confident that acupuncture was applied appropriately). A summary of the scores assigned to all the included trials is also provided in Table 03. For updates of this review we plan to involve additional acupuncturists in these assessments.

SUMMARIZING THE RESULTS

The pre-defined main outcome measure for quantitative analysis was the number of days with headache per month in the last follow-up period. Other pre-planned outcomes included intensity of pain, duration and frequency of headache attacks, and medication use. The type and timing of outcome measures were so inconsistent and the presentation of results so often insufficient that it was not possible to calculate effect size estimates for the majority of the trials that should have, in principle, contributed data. Therefore,

we extracted the available data on frequency and pain intensity for the earliest available measurement (last phase of treatment up to a maximum of 2 months after treatment) and the latest follow-up (at least 2 months after end of treatment) and summarized it in tabular form (see Table 04 and Table 05).

We also extracted data on global 'response' to treatment. If there were no global response data, data on frequency or headache indices were used. Response was defined as at least 33% improvement (as trials typically used either 33% or 50% improvement from baseline as a cut-off to define response). Rate ratios (proportion of responders in the true acupuncture group/proportion of responders in the sham acupuncture group) and their 95% confidence intervals were calculated. Due to the great clinical heterogeneity we refrained from calculating pooled estimates.

Because it had been anticipated that a quantitative meta-analysis might not be possible, at least two independent reviewers voted in the following categories as a crude estimate of the overall outcome of each study:
-2 = control group better than acupuncture (significant)
-1 = control group better than acupuncture (trend)
0 = no difference
1 = acupuncture better than control group (trend)
2 = acupuncture better than control group (significant)
Disagreements occurred for only two studies (Dowson 1985; Carlsson 1990). In both cases, the least favorable score was used.

DESCRIPTION OF STUDIES

Twenty-six studies with a total of 1151 patients (median, 37; range, 10-150) met the inclusion criteria. Sixteen trials were conducted among patients with migraine, six among patients with tension-type headache patients, and four among patients with various types of headaches. One of the migraine trials was conducted among children. Eight trials used the criteria of the International Headache Society (IHS 1988) to classify headache syndromes, two used the Ad Hoc Committee's criteria (Ad Hoc 1962), and the pediatric trial used the Prensky criteria (Prensky 1979).

Seventeen trials were 'placebo'-controlled. Eleven of these used 'sham' needling, i.e., needling of points distant from acupuncture points or superficial needling; the remaining six used other procedures that did not involve penetration of the skin. Four trials compared acupuncture with drug treatment, two with physiotherapy, one with combined relaxation and massage, and one with a traditional Chinese drug combination. One three-armed trial compared acupuncture, no treatment, and a biobehavioral treatment program. The acupuncture interventions used varied considerably. In three trials the test intervention was not needle acupuncture but laser acupuncture (Ho 1999; Lavies 1998) or transcutaneous electric nerve stimulation (TENS) at acupuncture points (Heydenreich 1989a); one trial had both a needle acupuncture group and a TENS at acupuncture points group (Heydenreich 1989b). In eight studies the rationale behind the choice of points was traditional Chinese medicine; seven gave other reasons; 10 were unclear about their rationale; and in one trial points were chosen based only on local tenderness. Basic information on the qualification and experience of trial acupuncturists was provided in only 10 cases. The achievement of DeChi, an irradiating feeling said to indicate effective needling, was rarely reported.

All of the 17 'placebo'-controlled trials attempted to blind patients. At least five of these trials did not fully inform patients that one group would receive 'sham' acupuncture (patients were told that two 'types' of acupuncture would be compared). In at least two further trials in which the sham intervention did not involve needling (Dowson 1985; Shi 2000) it seems likely that a similar procedure was followed (otherwise it would not have been possible to blind patients).

The median treatment period was 8 weeks (range, 6 to 26) with eight treatment sessions (range, 6 to 12; one trial allowed for the possibility of 3 courses of treatment with 10 sessions each). In the 21 trials that followed up patients after completion of the treatment phase the median follow-up time was 26 weeks (range, 3 to 104).

The most commonly reported outcomes were headache frequency (days with headache or number of headache attacks) and pain intensity, but in many studies results were reported in insufficient detail. Subjective mood, quality of life, medication use, and disability were reported in a minority of trials (sometimes these outcomes seem to have been monitored, but were not reported). Eighteen trials used headache diaries for outcome assessment, and four used point measurements (patients rating outcomes retrospectively at a defined time point). The remaining four trials did not describe the method of headache assessment used.

We attempted to contact the authors of 20 studies; 13 responded. These contacts provided very little relevant additional information with one exception in which the author provided individual patient data (Vincent 1990).

METHODOLOGICAL QUALITY

The majority of the trials had methodological and/or reporting shortcomings. Allocation concealment was described in only three trials: one used a central telephone call randomization scheme, and two used sealed envelopes. The author of a fourth trial told us that he had used sealed envelopes. The median Jadad score was 1.5 (range, 1 to 5) from a possible maximum score of 5 (see Table 01), and the median internal validity score was 2.5 (range, 1 to 5) from a possible maximum score of 6 (see Table 02). The success of blinding was tested in two trials (both suggested successful blinding). Reporting of dropouts and withdrawals was satisfactory in only half of the trials. Eight trials did not list inclusion criteria,

and 14 did not describe co-interventions. The reporting of the complex headache data was poor. The quality scores achieved by a given study did not always agree with our subjective impression of its quality.

We have particular doubts about four studies (Heydenreich 1989a; Heydenreich 1989b; Lehmann 1991; Gao 1999), all of which reported extremely positive results, but were insufficiently described (see the table describing the 'Characteristics of included studies' for details). In addition to a general lack of detail in reporting, neither Heydenreich et al. (Heydenreich 1989b) nor Lehmann et al. (Lehmann 1991) provided information about dropouts. Furthermore, the control therapy used by Heydenreich et al. (Heydenreich 1989b) may not have been appropriate (long-term use of the ergotamine compound used in the study could arguably aggravate, rather than alleviate, headache). Finally, while it is stated that the patients included by Lehmann et al. (Lehmann 1991) had migraine, their reported mean baseline frequency of 22 headache days per month is hardly compatible with this diagnosis. Gao et al. (Gao 1999) reported that 24 of 32 patients treated with acupuncture were cured (defined as 'symptoms disappear completely without recurrence for 1 year'). Although the acupuncture intervention in this study seems to have been very well done, such a success rate is hard to believe. The unblinded study does not report how headache was monitored or whether there were dropouts and withdrawals. Furthermore, as the duration of disease was from 1 month to 15 years, it seems doubtful whether all patients truly suffered from migraine.

One trial (Kubiena 1992) which seemed well designed from a methodological perspective failed completely on a practical level: a large proportion of patients dropped out in the early phase of the trial.

The evaluating acupuncturist (GA) found himself unable to assess the quality of acupuncture in seven trials as the description was insufficient (see Table 03). In five trials he would have treated in a different manner or completely differently, in seven trials similarly, and in six trials in exactly the same way. The degree of confidence that acupuncture was applied appropriately ranged from 10% to 95%.

RESULTS

The trials were highly heterogeneous regarding patients, acupuncture and control interventions, and type and timing of outcome measures. In addition, data were often presented in insufficient detail (e.g., without standard deviations, and with only some of multiple outcomes presented). Therefore, we did not perform a quantitative meta-analysis.

SHAM-CONTROLLED TRIALS IN PATIENTS WITH MIGRAINE:

A total of 11 trials compared acupuncture and sham acupuncture among patients with migraine. Two (Baust 1978; Dowson 1985) found no effects over sham acupuncture, three (Henry 1986; Weinschütz 1993; Ho 1999) showed trends in favor of acupuncture, and in five trials (Ceccherelli 1992; Heydenreich 1989a; Pintov 1997; Vincent 1989; Weinschütz 1994) the patients in the acupuncture group did significantly better than those in the sham acupuncture group. In the remaining trial (Kubiena 1992) a positive trend was claimed by the authors, but this study was judged to be uninterpretable by both of the reviewers who assessed it because of the very high dropout rate.

Table 04 provides an overview of the results regarding the number of days with headache, or frequency of attacks, and intensity. Most trials reported differences in favor of acupuncture for at least one outcome, but the size of effects and the outcomes actually influenced varied considerably. Headache duration and medication use were rarely reported in an interpretable way. Seven trials provided data on numbers of responders (Baust 1978; Ceccherelli 1992; Henry 1986; Heydenreich 1989a; Ho 1999; Weinschütz 1993; Weinschütz 1994). For two further trials such data were either available for headache frequency (Dowson 1985) or could be calculated from individual patient data on headache-free days (Vincent 1990).

SHAM-CONTROLLED TRIALS IN PATIENTS WITH TENSION-TYPE HEADACHE:

In a cross-over study Hansen et al. (Hansen 1985) found that headache indices were significantly better after the true acupuncture phase than after the sham acupuncture phase. No other outcomes were reported. Tavola et al. (Tavola 1992) found no significant differences between acupuncture and placebo (n = 30). However, all three reviewers assessing this trial interpreted the data presented as showing a trend in favor of acupuncture (e.g., headache frequency decreased 44% in the acupuncture group versus 21% in the control group; medication use decreased 58% in the acupuncture group versus 28% in the control group). Johansson et al. (Johansson 1991) reported that acupuncture was significantly more effective than sham acupuncture, but no actual data were presented. A small, methodologically rigorous pilot study (White 1996) did not find significant differences between acupuncture and sham acupuncture, but the results were uninterpretable due to large baseline differences between the two groups (in favor of the sham acupuncture group) and the extremely small sample size (n = 10).

TRIALS COMPARING ACUPUNCTURE WITH ANOTHER TREATMENT AND NO TREATMENT IN PATIENTS WITH MIGRAINE:

In the only methodologically reliable, completed trial (Hesse 1994) comparing acupuncture with a drug treatment (metoprolol), the authors claimed that both treatments were equally effective, but all three reviewers rating this study concluded that there was a trend in favor of metoprolol in terms of efficacy. However,

metoprolol also had more side effects. In the other two completed trials (Heydenreich 1989b; Lehmann 1991), both needle and electro-acupuncture were significantly more effective than drug treatment, but doubts about the validity of these trials seem justified (see above, under Methodological quality of included studies).

In the trial by Doerr-Proeske et al. (Doerr-Proske 1985) a biobehavioral program was found to be more effective than acupuncture (difference not statistically significant in a trial with only 10 patients in each group). This trial also included a no-treatment (waiting-list) arm; the patients in this group did slightly worse than those receiving acupuncture.

Gao et al. (Gao 1999) compared acupuncture and a traditional Chinese drug prescription in 64 migraine patients. The authors report extremely positive results. Our reservations about the trial are summarized above, in the section on the Methodological quality of included studies, and in the table describing the 'Characteristics of included studies'.

TRIALS COMPARING PHYSIOTHERAPY AND ACUPUNCTURE IN PATIENTS WITH TENSION-TYPE HEADACHE:
Carlsson et al. (Carlsson 1990) found individualized physiotherapy more effective than acupuncture both for headache intensity and mental well-being. In the small trial by Ahonen et al. (Ahonen 1984), acupuncture was considered at least as effective as physiotherapy.

SHAM-CONTROLLED TRIALS IN PATIENTS WITH VARIOUS TYPES OF HEADACHES:
Lavies (Lavies 1998) did not find significant differences between laser-acupuncture and placebo laser-acupuncture in a cross-over trial in 12 patients suffering from migraine and tension-type headache. However, due to large baseline differences between the two groups this trial is hardly interpretable. Shi et al. (Shi 2000) found clinically relevant differences between true acupuncture and placebo laser-acupuncture both after treatment and at 6 months follow-up in pain intensity, disability, complaints, and depressive mood; however they neither present the headache diagnoses of the patients participating nor any between-group inferential statistics.

ACUPUNCTURE VERSUS DRUG TREATMENT IN PATIENTS WITH VARIOUS TYPES OF HEADACHES:
Loh et al. (Loh 1984) found acupuncture slightly more effective than individualized drug treatment. Eight of 23 acupuncture patients were classified as responders compared to 4/25 patients in the medication group. Patients could cross over to the alternative treatment after 3 months. Eleven of 23 patients originally receiving acupuncture chose this option, compared to 18/25 patients originally receiving medication.

ACUPUNCTURE VERSUS MASSAGE AND RELAXATION IN PATIENTS WITH MIGRAINE OR TENSION-TYPE HEADACHE:
Wylie et al. (Wylie 1997) found a greater reduction of headache scores with combined massage and relaxation compared to acupuncture in patients with tension-type headache (n = 40) or migraine (n = 27). The data presented in the paper, however, suggest that the effects differed considerably for tension-type headache patients (those receiving massage and relaxation had much greater reduction) and migraine patients (those receiving acupuncture had much greater reduction) (see Table 05).

LONG-TERM EFFECTS OF ACUPUNCTURE (see also Table 04 and Table 05):
Thirteen trials had follow-up periods of at least 6 months after therapy. The majority of these trials have to be interpreted with caution due to loss to follow-up (Kubiena 1992, Carlsson 1990), major reporting deficiencies (Dowson 1985; Shi 2000; Weinschütz 1993; Weinschütz 1994; Ahonen 1984) or doubtful overall validity (Gao 1999; Heydenreich 1989a; Heydenreich 1989b; Lehmann 1991). The results of the two most rigorous trials (Vincent 1990; Tavola 1992) suggest that improvements after acupuncture can persist more than 6 months after the cessation of therapy.

LINKING VOTE COUNTS AND QUALITY ASSESSMENTS:
Of the seven interpretable studies with a Jadad score of 3 or more, two migraine trials were trend-positive compared to placebo (Henry 1986; Ho 1999), one was not different from placebo (Baust 1978), and one was trend-negative compared to standard treatment (Hesse 1994). For tension-type headache one trial was rated positive (Hansen 1985), and one trend-positive compared to placebo (Tavola 1992). One trial of laser acupuncture with both migraine and tension-type headache patients showed no difference from placebo (Lavies 1998).

Among the five interpretable trials scoring 4 points or more on the internal validity scale, one migraine trial was positive (Vincent 1989) and one trend-positive (Henry 1986) compared to placebo, while one trial was trend-negative compared to standard treatment (Hesse 1994). For tension-type headache one trial was positive (Hansen 1985) and one trend-positive (Tavola 1992) compared to placebo.

Finally, if only interpretable trials were considered in which the acupuncturist was at least 70% sure that acupuncture was appropriate, there were, for migraine, three positive (Ceccherelli 1992; Vincent 1989; Weinschütz 1994) and two trend-positive trials (Ho 1999; Weinschütz 1994) compared to placebo. Another trial (Gao 1999) was rated positive compared to traditional Chinese drug treatment. For tension-type headache there were again one positive (Hansen 1985) and one trend-positive trial (Tavola 1992). A further sham-controlled trial in which the headache diagnoses were not described was positive (Shi 2000).

DISCUSSION

Overall, the existing evidence supports the value of acupuncture for the treatment of idiopathic headaches. However, the quality and amount of evidence are not fully convincing. The majority of the trials comparing true and sham acupuncture in migraine and tension-type headache patients show at least a trend in favor of true acupuncture. But most trials were small and were either inadequately reported or had methodological flaws. Moreover, the trials varied greatly with respect to the precise nature of the acupuncture intervention and the method of outcome assessment. When the responder rates in sham-controlled trials were plotted graphically against an estimate of precision (funnel plot) the display was asymmetrical suggesting publication bias or other biases.

There is insufficient evidence to assess how acupuncture compares to no treatment and whether it is as effective as other headache treatments.

Our findings are similar to those of two recent systematic reviews on a variety of behavioral and physical treatment modalities, including acupuncture, for migraine (Goslin 1999) and tension-type headache (McCrory 2000).

We searched a number of different sources to identify all trials relevant to our subject. We were not able to identify any unpublished studies. Also, our literature search yielded only one eligible trial from China and none from Russia, where acupuncture is widespread. The literature from these countries is only partially covered by most databases; it is therefore possible that unidentified eligible trials from these countries exist. However, evidence from Russia and China has to be interpreted with caution since it has been shown, using acupuncture as an example, that researchers from these countries publish positive results almost exclusively (Vickers 1998).

Widespread insufficient reporting made both assessment of methodological quality and data extraction difficult and sometimes even impossible. Concealment of allocation to groups was rarely described, and reporting of dropouts and withdrawals was often incomplete. Only two of the blinded trials tested the success of blinding. Testing the success of blinding in sham-controlled trials seems important, as a proportion of patients might find out to which group they had been allocated. Telling potential participants in a sham-controlled trial that two forms of acupuncture will be compared may help with recruitment and aid blinding; it is, however, ethically dubious. Quality scoring for blinding of evaluators proved difficult in our review since evaluation was mostly done by the patients themselves in headache diaries. Consequently, a trial in which patients were blinded might be considered as double-blind (patients and evaluators blind). However, for our scoring methods those collecting the headache diaries also had to be blinded for the trial to be considered double-blind.

Assessing migraine and tension-type headaches in a clinically meaningful manner is a complex issue. Frequency, intensity, duration, medication needs, accompanying symptoms, mood, social functioning, daily activity, and work days lost are all relevant indicators. The heterogeneous outcome measurement methods used in the included trials and the lack of detail in the presentation of results precluded the calculation of effect size estimates for these outcomes. The responder rates we have calculated have to be interpreted with extreme caution and should only be seen as a very crude indicator of the overall tendency of results. For one thing, response was not defined in a uniform way in the included trials. In addition, dichotomous outcomes like responder rate, when used in small trials, are associated with very large confidence intervals, indicating very low statistical power and precision. This explains why our vote counts and our narrative summary provide a slightly more optimistic result than the analysis of responder rates.

In a previously published version of this review (Melchart 1999) we presented a pooled estimate for the responder rate ratios in the sham-controlled trials. On reconsidering the great heterogeneity of the trials regarding patients, test and control interventions, measurement methods, responder definitions, internal and external validity, and the asymmetrical funnel plots, we decided to refrain from any pooling of the data in this updated version. In the peer review process for this review, it was suggested that we should include a sensitivity analysis including only trials scoring at least 3 points on the Jadad scale. As we have refrained from pooling results, formal sensitivity analyses incorporating quality scores were not possible. When we linked our vote count and the three different quality assessment methods (Jadad scale, internal validity scale, and appropriateness of acupuncture) the results were rather contradictory. Based on the Jadad scale (Jadad 1996), the results seem less positive for migraine, while the trials in which the confidence in the appropriateness of acupuncture was rated highly had more positive findings. Given the high degree of heterogeneity of the trials and the relatively crude nature of the available quality assessment methods and of the vote counts, the results of these sensitivity approaches should not be overinterpreted.

AUTHORS' CONCLUSIONS

Implications for practice

Due to the clinical heterogeneity and the poor methodological quality of the included studies, straightforward recommendations for clinical practice cannot be made. Overall, some forms of acupuncture seem to be beneficial, but it is unclear which treatment strategies (points, type of stimulation, frequency, etc.) and which providers may be most promising for particular groups of patients.

Though not risk-free (Norheim 1996; Ernst 1995), acupuncture seems to be relatively safe in the hands of qualified providers. Therefore, we conclude that headache patients who want to try acupuncture should not be discouraged. Existing provision of

acupuncture to headache patients also seems justified. Whether acupuncture should be more widely recommended and, if so, which particular type of acupuncture should be offered, are questions that cannot be answered at present.

Implications for research

The widespread use of acupuncture, the promising results, and the often insufficient quality of the available studies warrant further research. Larger sham-controlled trials are needed to confirm (or refute) the available evidence that the effects of acupuncture in headache sufferers are truly specific. However, as sham acupuncture might have specific effects of its own, or could at least be a more potent placebo than the provision of a pill, the evidence derived from such trials may underestimate the benefits of acupuncture (Sanchez-Araujo 1998). More pragmatic trials comparing acupuncture with no prophylactic treatment and other prophylactic interventions are needed to evaluate effectiveness and cost-effectiveness under real-life conditions. Long-term observational studies would be useful to determine how long the effects of acupuncture last and which patients are most likely to benefit from treatment. Because acupuncture is applied in different manners by different acupuncturists, it is necessary to investigate practice patterns to ensure that future randomized trials test acupuncture strategies that are truly widespread in practice.

Trials of acupuncture clearly need larger sample sizes. At present, sample size calculations for comparisons of acupuncture versus sham acupuncture or no treatment could be based on the responder rates obtained in our study set. On average, the response rates in the studies reviewed were about 60% in the treatment groups and about 40% in the sham groups. To detect such a difference with 90% power (alpha level 0.05, two-sided test), 140 patients per group should be included in a trial. Smaller sample sizes could be possible if other outcomes (such as number of days with headache) are employed as primary outcome measures. Furthermore, future trials should follow specific guidelines concerning inclusion criteria, classification of headaches, control of co-interventions, and outcome measurements for headache trials (IHS 1991; IHS 1995), and should follow general guidelines for reporting trials (Begg 1996). Because the current evidence on the question of whether acupuncture mainly affects the frequency of headache attacks or their intensity is not completely consistent, both outcomes should be carefully monitored in future trials.

NOTES

This review was scheduled for an update in spring 2004. The authors and editors decided to postpone the update until 2005 as a number of highly relevant, large-scale trials were close to completion or publication. Trials published since the completion of the original review that appear to meet the inclusion criteria are now listed in the 'Studies awaiting assessment' section of the 'References to studies'; these will be fully evaluated as part of the forthcoming update. In addition, the authors are aware of six trials now underway whose results will probably be published in 2005; these trials will also be evaluated for the update. They are now listed and briefly described in the 'Characteristics of ongoing trials' table. A full update of the review is expected late in 2005.

POTENTIAL CONFLICT OF INTEREST

Adrian White and Gianni Allais were involved in two trials included in this review. Both trials were reviewed by other reviewers.

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* *Indicates the major publication for the study*

TABLES

Characteristics of included studies

Study	**Ahonen 1984**
Methods	Allocation: randomized Concealment: unclear Blinding: not blinded Dropouts/withdrawals: unclear Observation period: baseline?; treatment?; follow-up 28 w Quality scales: Jadad: 1-0-0; IVS: 1-0-0.5-0-0-0 Acupuncturist's assessment: similarly/60%
Participants	Number of patients included/analyzed: 22?/22 Condition: myogenic headache Demographics: mean age 46 years (acu) and 37 (control); 82% female Setting: neurological outpatient department of university hospital in Finland Time since onset of headaches: 5.7 years
Interventions	Acupuncture points: GB8, GB20, BL10, BL12, BL15, Chuanxi and pressure points on the neck No information on acupuncturist(s)

Characteristics of included studies (*Continued*)

	DeChi achieved?: no information Number of treatment sessions: unclear (10 minutes each) Frequency of treatment sessions: no information Control intervention: physiotherapy (parafango, massage, ultasound)
Outcomes	Method for outcome measurement: point measurement (no diaries); only data for follow-up presented Responder rates: 7/12 (acu) vs. 3/10 (physiotherapy) Frequency: 5/12 (acu) vs. 2/10 (physiotherapy) with one or fewer headache days/week Intensity: not reported Duration: not mentioned Medication: decreased in 6/12 (acu) vs. 4/10 (physiotherapy)
Notes	Author's conclusion: both treatments similarly effective Reviewer's conclusion: both treatments similarly effective Comments: insufficient reporting; unclear whether there were dropouts/withdrawals, poor outcome measurement; sample size too small to assess equivalence of the two therapies
Allocation concealment	B

Study	**Baust 1978**
Methods	Allocation: randomized Concealment: unclear Blinding: patient, evaluating physician Dropouts/withdrawals: no information Observation period: individualized period of observation (10 intervals between migraine attacks in the baseline period) Quality scores: Jadad: 1-2-0; IVS: 1-0-0-1-1-0 Acupuncturist's assessment: similarly/35%
Participants	Number of patients included/analyzed: 44?/44? Condition: migraine ('therapy-resistant') Demographics: no information Setting: unclear, Germany Time since onset of headaches: 75% of patients > 5 years
Interventions	Acupuncture points: if pain mainly frontal: GB 14, Ex3, LI 4; temporal: Ex9, GB 20, TE5; occipital: GV 15, BL 10, BL 60 Information on acupuncturists: n = 2, no information on experience and qualification DeChi achieved?: no information Number of treatment sessions: 6 Frequency of treatment sessions: every 2 days Control group intervention: placebo points 2-3 cm distant from true points
Outcomes	Method for outcome measurement: patient diary, all analyses focus on an index (integrating frequency, intensity and duration) Responder rates: 14/23 (acu) vs. 14/21 (sham) No information on frequency, intensity, duration or medication
Notes	Author's conclusion: good response in both groups, no difference between groups Reviewer's conclusion: good response in both groups, no difference between groups Comments: insufficient data presentation; variable observation period; patients were not told that they could get a placebo
Allocation concealment	B

Study	**Carlsson 1990**
Methods	Allocation: randomized

Characteristics of included studies (*Continued*)

	Concealment: sealed envelope Blinding: not blinded Dropout/withdrawals: bias possible (8 dropouts in acu, 2 in physiotherapy group) Observation period: baseline 3-8 w; treatment 2-8 w; follow-up 7-12 m Quality scales: Jadad: 1-0-1; IVS: 1-0.5-0.5-0-0-0.5 Acupuncturist's assessment: completely differently/10%
Participants	Number of patients included/analyzed: 62/52 Condition: chronic tension headache (Ad Hoc) Demographics: mean age 34 years; all female Setting: hospital/outpatient department, Sweden Time since onset of headaches: mean 9 years
Interventions	Acupuncture points: local points: GB 20, GB 21; distal points: LI 4 Information on acupuncturists: n = 2; no further information DeChi achieved?: yes Number of treatment sessions: 5 to 10 sessions of 20 minutes each Frequency of treatment sessions: 1-2/week Control intervention: individualized physiotherapy (10-12 sessions of 30 to 45 minutes each, including relaxation, automassage, TENS, cryotherapy, coping techniques)
Outcomes	Method for outcome measurement: point measurement (no diary) Responder rates: not mentioned Frequency: reduced in both groups ($p < 0.01$ in acu, $p < 0.001$ in physiotherapy group) Intensity: mean VAS scores 40 +/- 34 (acu) vs. 28 +/- 22 (physiotherapy) after treatment and 52 +/- 32 (acu) vs. 29 +/- 22 (physiotherapy) at follow-up Duration: not mentioned Medication: not mentioned Other: overall function improved in both groups, mental well-being only in physiotherapy group
Notes	Author's conclusion: other therapy significantly better Reviewer's conclusion: other therapy significantly better Comments: multiple publication; dropouts different between groups; control group got more therapy than acupuncture group
Allocation concealment	A

Study	**Ceccherelli 1992**
Methods	Allocation: randomized Concealment: unclear Blinding: patients Dropout/withdrawals: no dropouts or withdrawals Observation period: baseline unclear; treatment 10 w; follow-up only in patients with good response Quality scores: Jadad: 1-0-0; IVS: 1-0-0.5-1-0-1 Acupuncturist's assessment: similarly/70%
Participants	Number of patients included/analyzed: 30?/30 Condition: migraine without aura Demographics: mean age 40 years; 9 (fe), 6 (m) in acu group; 15 fe in sham group Setting: unclear, Italy Time since onset of headaches: 179 +/- 127 months (control group: 226 +/- 140)
Interventions	Acupuncture points: BL 2, BL10, BL 60, GB 3, GB 20, GV 11, GV 20, LR 3, CV 13 Ex HN1, ST 8 (on non-painful side) No information on acupuncturist(s) DeChi achieved?: no information Number of treament sessions: 10

Characteristics of included studies (*Continued*)

	Frequency of treatment sessions: 1/week Control intervention: placebo acupuncture (complex procedure without real needling suggesting superficial anesthesia to the patient)
Outcomes	Method for outcome measurement: headache diary Responder rates: 13/15 (acu) vs. 5/15 (sham) Frequency: 7 +/- 12 (acu) vs. 34 +/- 50 (sham) hours pain per week No information on intensity, duration or medication
Notes	Author's conclusion: acupuncture better (significantly) Reviewer's conclusion: acupuncture better (significantly) Comments: patients probably not completely informed that they might get a placebo; unusual sham technique; sex differences between groups; no interpretable follow-up data
Allocation concealment	B

Study	**Doerr-Proske 1985**
Methods	Allocation: randomized Concealment: unclear Blinding: not blinded Dropouts/withdrawals: no information Observation period: 2 months diagnostic; baseline 1 m; treatment 2 m; follow-up 1 m Quality scales: Jadad: 1-0-0; IVS: 1-0-0-0-0-0 Acupuncturist's assessment: completely differently/20%
Participants	Number of patients included/analyzed: 30?/30? Condition: migraine (therapy-resistant) Demographics: mean age 39 years; 77% female Setting: unclear, Germany Time since onset of headaches: > 2 years (inclusion criterion); 23/30 > 10 years
Interventions	Acupuncture points: Extra 2, GB2, TE5 Information on acupuncturist: n = 1; anesthesiologist trained in acupuncture DeChi achieved?: no information Number of treatment sessions: 10 Frequency of treatment sessions: 1/week? Control 1: waiting-list Control 2: psychological biobehavioral treatment program
Outcomes	Method for outcome measurement: diary Responder rates: not mentioned Frequency: decreased by 24% (acu) vs. 10% (waiting-list) vs. 43% (psychological) after treatment and by 32% (acu) vs. 38% (psychological) at follow-up Intensity: measured only by days with a defined intensity Duration: not mentioned Medication: weighted number of drugs 10.2 (acu) vs. 9.9 (waiting-list) vs. 1.8 (psychological) after treatment and 8.2 (acu) vs. 1.6 (psychological) at follow-up
Notes	Author's conclusion: psychological treatment better (trend) than acupuncture better (trend) than waiting-list Reviewer's conclusion: psychological treatment better (trend) than acupuncture better (trend) than waiting-list Comment: very small sample size; no information on whether there were dropouts/ withdrawals
Allocation concealment	B

Study	**Dowson 1985**
Methods	Allocation: randomized

Characteristics of included studies (*Continued*)

	Concealment: sealed envelope Blinding: patients Dropouts/withdrawals: major bias unlikely Observation period: baseline 4 w; treatment 6 w; follow-up 24 w Quality scores: Jadad: 2-0-0; IVS: 1-0.5-0.5-0.5-0-0.5 Acupuncturist's assessment: insufficient information for an assessment
Participants	Number of patients included/analyzed: 48/39 Condition: migraine, migrainous headaches Demographics: mean age 39 years; 83% female Setting: practice, UK Time since onset of headaches: at least 1 year
Interventions	Acupuncture points: point selection according to location of pain (modified after 2-3 sessions if no response) No information on acupuncturist(s) DeChi achieved?: yes Number of treatment sessions: 6 Frequency of sessions: 1/week Control intervention: mock transcutaneous nerve stimulation
Outcomes	Method for outcome measurement: diary, but only presentation of dichotomized data (33% improvement interpreted as positive response) Responder rates: not measured Frequency: 11/25 responders (acu) vs. 13/23 (sham) Intensity: 14/25 responders (acu) vs. 7/23 (sham) Duration: not presented Medication: not presented
Notes	Author's conclusion: at best acupuncture slightly better Reviewer's conclusion: at best acupuncture slightly better Comments: insufficient presentation of results (no data on follow-up at all); unusual (probably not very sensitive) method of analysis; patients probably not fully informed about use of placebo
Allocation concealment	A

Study	**Gao 1999**
Methods	Allocation: randomized Concealment: unclear Blinding: not blinded Dropouts/withdrawals: unclear Observation period: no baseline; follow-up 12 months Quality scales: Jadad: 1-0-0; IV: 1-0-0-0-0-0 Acupuncturist's assessment: exactly the same way/95%
Participants	Number of patients included/analyzed: 64?/64 Condition: migraine Demographics: age range 15-58 years; 72% female Setting: unclear, China Time since onset of headaches: 1 month - 15 years
Interventions	Acupuncture points: point selection according to traditional Chinese medicine No information on acupuncturist(s) DeChi achieved?: no information Number of treatment sessions: 1-3 courses of 10 sessions Frequency of treatment sessions: 4-5/week Control intervention: a traditional Chinese medicine of unclear composition, ergotamine for acute attacks
Outcomes	Method for outcome measurement: unclear

	Responder rates: after 1 year, 24/32 (acu) vs. 11/32 (control) 'cured' (= symptoms disappear completely without recurrence for 1 year) and further 6 (acu) vs. 9 (control) 'improved' No information on frequency, intensity, duration or medication
Notes	Author's conclusions: acupuncture statistically significantly superior Reviewer's conclusion: acupuncture statistically significantly superior Comment: insufficiently reported study; proportion of 'cures' hard to believe
Allocation concealment	B

Study	**Hansen 1985**
Methods	Allocation: randomized cross-over Concealment: unclear Blinding: patients and data-collecting investigator Dropouts/withdrawals: 7 of 25 patients were excluded before the code was broken (bias possible but not likely) Observation period: baseline 3 w; treatment 3 w; interval 3 w; treatment 3 w; post-treatment 3 w Quality scales: Jadad: 1-1-1; IVS: 1-0-0.5-1-1-0.5 Acupuncturist's assessment: similarly/70%
Participants	Number of patients included/analyzed: 25/18 Condition: chronic tension headache Demographics: mean age 36 years; 67% female Setting: university neurology outpatient department in Denmark Time since onset of headaches: 1.5-60 years
Interventions	Acupuncture points: needling bilaterally GB 20, LI 4, BL 60 No information on acupuncturist(s) DeChi achieved?: yes Number of treatment sessions: 6 (15 minutes each) Frequency of treatment sessions: 2/week Control intervention: sham acupunture close to the true points (depth 2-4 mm)
Outcomes	Method for outcome measurement: diary (a headache index for each phase was calculated) Responder rates (at least 33% decrease in headache index) calculated from individual patient data for the pre-cross-over period: 4/9 (acu) vs. 2/9 (sham) Headache index reduction compared to baseline: 31% (acu) vs. 21% (sham; $p < 0.05$) No information on frequency, intensity, duration or medication
Notes	Author's conclusion: acupuncture significantly better Reviewer's conclusion: acupuncture significantly better Comments: poor outcome measurement; no explicit listing of inclusion criteria; blinding credible; patients not informed about use of placebo; limited clinical relevance because of short duration
Allocation concealment	B

Study	**Henry 1986**
Methods	Allocation: randomized Concealment: unclear Blinding: patient, evaluating neurologist Dropouts/withdrawals: major bias unlikely (at least until end of treatment phase) Observation period: baseline unclear; treatment probably 3 months?; follow-up 3 m after therapy (second follow-up after 6 m) Quality scores: Jadad: 1-2-0; IVS: 1-0-1-1-1-0 Acupuncturist's assessment: differently/45%
Participants	Number of patients included/analyzed: 30/26

Characteristics of included studies (*Continued*)

	Condition: migraine (Ad Hoc) Demographics: mean age 34 years; 73% female; Setting: unclear, France Time since onset of headaches: 12.6 +/- 1.5 years (placebo: 13.8 +/- 10.6)
Interventions	Acupuncture points: LI 4, ST36, BL 2, BL 10, BL 60, LR3 needling with electrostimulation Information on acupuncturist: n = 1, no further information DeChi achieved?: no information Number of treatment sessions: 8 sessions of 30 minutes each Frequency of treatment sessions: 6x one/week, 2x one/month Control intervention: dry needling 1 cm away from points used in acupuncture group (same metamere)
Outcomes	Method for outcome measurement: migraine index, global assessments (after 3 months) Responder rates: 11/20 (acu) vs. 3/10 (sham) Frequency: 12/20 (acu) vs. 3/10 (sham) improved Intensity: 11/20 (acu) vs. 2/10 improved Duration: 8/20 (acu) vs. 4/20 improved Medication: 7/20 (acu) vs. 4/10 improved
Notes	Author's conclusion: trend in favor of acupuncture Reviewer's conclusion: trend in favor of acupuncture Comments: no use of a diary; many losses to follow-up, therefore follow-up data uninterpretable
Allocation concealment	B

Study	**Hesse 1994**
Methods	Allocation: randomized Concealment: unclear Blinding: patients and evaluators Dropouts/withdrawals: bias unlikely Observation period: baseline 4 w; treatment 17 w; no follow-up Quality scales: Jadad: 1-1-1; IVS: 1-0-1-0.5-1-0.5 Acupuncturist's assessment: completely differently/50%
Participants	Number of patients included/analyzed: 85/77 Condition: migraine with or without aura (IHS) Demographics: mean age 45 years; 84% female Setting: outpatient pain clinic in Denmark Time since onset of headaches: mean 23 years
Interventions	Acupuncture points: needling at individually most tender trigger points and placebo tablets Information on acupuncturist: n = 1, no further information DeChi achieved?: no information Number of treatment sessions: individualized Duration of treatment sessions: needling for a few seconds only Control intervention: beta blocker metroprolol and placebo stimulation (touch with blunt end of the needle)
Outcomes	Method for outcome measurement: diary Responder rates: not mentioned Frequency: both groups with significant reduction; 0.7 (95% CI, -1.6 to 2.7) more attacks in acu group Intensity: global rating of migraine attacks 0.3 (95% CI, 0.1 to 0.5) better in metoprolol group Duration: attacks 2.4 hours (95% CI, -1.8 to 6.5 hours) longer in acu group Medication: not mentioned Side effects: 3 (acu) vs. 18 (metoprolol)
Notes	Author's conclusion: acupuncture equipotent to metoprolol Reviewer's conclusion: trend in favor of metoprolol (efficacy; fewer side effects with acupuncture)

Characteristics of included studies (*Continued*)

	Comments: rigorous trial; sham acupuncture procedure possibly distinguishable; unusual acupuncture technique
Allocation concealment	B

Study	**Heydenreich 1989a**
Methods	Allocation: randomized Concealment: unclear Blinding: patients? Dropouts/withdrawals: unclear Observation period: baseline 8 w; treatment 12 w; follow-up 6 months Quality scores: Jadad: 1-0-0; IVS: 1-0-1-0-0-0 Acupuncturist's assessment: insufficient information for an assessment
Participants	Number of patients included/analyzed: 40?/40? Condition: migraine Demographics: mean age 41 years; 90% female Setting: outpatient department, university hospital, East Germany Time since onset of headaches: mean 18.5 years (control: 16.6)
Interventions	Acupuncture points: PuTens (transcutaneous electrical nerve stimulation at acupuncture points) mainly at LR3, KI6, SP6, ST36 or 44, BL60 or 62, LU7, P6, TE5, LI4, SI3, local pain points No information on acupuncturist(s) DeChi achieved?: no information Number of treatment sessions: 12 sessions of 20 to 30 minutes each Frequency of treatment sessions: 1/week Control intervention: placebo 3 cm distant from true points
Outcomes	Method for outcome measurement: diary?, only follow-up data presented Responder rates: 16/20 (acu) vs. 3/20 (sham) Frequency: 81% (acu) vs. 25% (sham) reduction Intensity: 39% (acu) vs. 8% (sham) reduction Duration: not mentioned Medication: not reported
Notes	Author's conclusion: PuTens significantly better Reviewer's conclusion: PuTens significantly better Comments: lack of detail in the presentation makes a valid assessment of the quality of the study almost impossible - doubts seem justified
Allocation concealment	B

Study	**Heydenreich 1989b**
Methods	Allocation: randomized Concealment: unclear Blinding: no blinding Dropouts/withdrawals: unclear Observation period: baseline 8 w; 3 to 4 months treatment; 8 months follow-up Quality scores: Jadad: 1-0-0; IVS: 1-0-1-0-0-0 Acupuncturist's assessment: exactly the same way/90%
Participants	Number of patients included/analyzed: 150?/150? Condition: migraine Demographics: mean age 39 years; 84% female Setting: neurological outpatient department, university hospital, East Germany Time since onset of headaches: mean 15 years

Characteristics of included studies (*Continued*)

Interventions	Acupuncture points (group 1): needling of mainly LR3, KI6, SP6, ST36 or 44, BL60 or 62, LU7, P6, TE5, LI4, SI3 and local tender points (acu) Acupuncture points (group 2): transcutaneous nerve stimulation at the same points (Pu-Tens) No information on acupuncturist(s) DeChi achieved (group 1)?: no information Number of treatment sessions: 12 to 16 sessions (duration of sessions unclear) Frequency of treatment sessions: 1/week Control intervention: iprazochrom and dihydroergotocinmesylate for 3 to 6 months
Outcomes	Method for outcome measurement: unclear Responder rates: 38/50 (acu) vs. 42/50 (Pu-Tens) vs. 10/50 (medication group) Frequency: reduction by 80% (acu) vs. 76% (Pu-Tens) vs. 38% (medication group) Intensity: reduction by 45% (acu) vs. 44% (Pu-Tens) vs. 15% (medication group) Duration: not mentioned Medication: reduction by 76% (acu) vs. 79% (Pu-Tens) vs. 41% (medication group)
Notes	Author's conclusion: acupuncture and Pu-Tens significantly better than the tested medication Reviewer's conclusion: acupuncture and Pu-Tens significantly better than the tested medication Comments: insufficiently reported study of doubtful validity; no information on whether there was any loss to follow-up; extremely positive results for acupuncture and Pu-Tens
Allocation concealment	B

Study	**Ho 1999**
Methods	Allocation: randomized Concealment: unclear Blinding: patients and therapists Dropouts and withdrawals: no information Observation period: 6 weeks baseline; 8 weeks treatment; 3 months follow-up Quality scales: Jadad: 1-2-0; IVS: 1-0-1-1-0.5-0 Acupuncturist's assessment: exactly the same way/85%
Participants	Number of patients included/analyzed 52/52 Condition: Migraine (IHS) Demographics: mean age 38 years; 81% female Setting: pain outpatient department of a university hospital in Germany Time since onset of headaches: mean 18 years
Interventions	Acupuncture points: laser acupuncture at points chosen according to traditional Chinese medicine No information on acupuncturist(s) Number of treatment sessions: 8 (15 minutes each) Frequency of treatment sessions: 1/week Control intervention: sham laser acupuncture (device emitting only control light)
Outcomes	Method for outcome measurement: diary (data mainly presented as responder rate evaluated by time-series analysis) Responder rates: after treatment 5/25 (acu) vs. 1/27 (sham); at follow-up 9/25 vs. 4/27 No information on frequency, intensity, duration or medication Other: no effects on electrophysiological parameters (contingent negative variation and chatecholamines)
Notes	Author's conclusion: trend in favor of true laser acupuncture Reviewer's conclusion: trend in favor of true laser acupuncture Comment: probably rigorous, but insufficiently reported (in spite of double publication); no information on whether there were dropouts/withdrawals
Allocation concealment	B

Characteristics of included studies (*Continued*)

Study	**Johansson 1976**
Methods	Allocation: randomized Concealment: unclear Blinding: patients, evaluators Dropouts/withdrawals: no information Observation period: total observation period 8 weeks (no further information) Quality scales: Jadad: 1-1-0; IVS: 1-0-0-0.5-0.5-0 Acupuncturist's assessment: insufficient information for an assessment
Participants	Number of patients included/analyzed: 33?/33? Condition: tension headache Demographics: no information Setting: medical school, Sweden Time since onset of headaches: no information
Interventions	Acupuncture points: no information Information on acupuncturist: n = 1, 'fully trained and experienced specialist' DeChi achieved?: no information Number of treatment sessions: no information Frequency of treatment sessions: no information Control intervention: sham point at 1 cm distant from true points
Outcomes	Method for outcome measurement: unclear No numerical data presented
Notes	Author's conclusion: true acupuncture statistically significantly superior Reviewer's conclusion: impossible to assess Comment: only very short presentation available - insufficient detail makes reliable data extraction and assessment impossible
Allocation concealment	B

Study	**Kubiena 1992**
Methods	Allocation: randomized Concealment: unclear Blinding: patients Dropouts/withdrawals: extreme dropout (already early in the trial) Observation period: baseline 6 w; treatment 6 w; follow-up 2 yrs Quality scores: Jadad: 2-1-0; IVS: 1-0-0-1-0.5-0 Acupuncturist's assessment: insufficient information for an assessment
Participants	Number of patients included/analyzed: 30/18 (at end of treatment) Condition: migraine (IHS) Demographics: mean age 40 years; 97% female Setting: acupuncture outpatient clinic in Austria Time since onset of headaches: > 1 year
Interventions	Acupuncture points: 4-5 local and 4-5 distant points (chosen acc. to Vienna school) Information on acupuncturists: at least 2 acupuncturists; no further information DeChi acheived?: no information Number of treatment sessions: 10-15 Frequency of treatment sessions: 1/week Control intervention: points 1.5-2 cm away from acu points
Outcomes	Method for outcome measurement: diary Responder rates: 3/7 (of 15 originally randomized to acu) vs. 4/11 (of 15 originally randomized to sham) Data on frequency, intensity, duration and medication uninterpretable due to high number of dropouts

Characteristics of included studies (*Continued*)

Notes	Author's conclusion: trend in favor of acupuncture Reviewer's conclusion: uninterpretable Comments: ambitious study which reports sincerely its great logistical problems; uninterpretable because of data loss problems
Allocation concealment	B

Study	**Lavies 1998**
Methods	Allocation: randomized Concealment: unclear Blinding: patients and therapist Dropouts/withdrawals: unclear Observation period: baseline 6 w; treatment 6 w; follow-up 6 w; then cross-over Quality scores: Jadad: 2-2-0; IVS: 1-0-0-1-0.5-0 Acupuncturist's assessment: insufficient information for an assessment
Participants	Number of patients included/analyzed: 12?/12? Condition: migraine and/or tension-type headache Demograhics: no information Setting: unclear, UK Time since onset of headaches: no information
Interventions	Acupuncture points: laser acupuncture (Alfalaser) at LR3, ST36, LI4, GB20 Information on acupuncturist: n = 1 Number of treatment sessions: 6 Frequency of treatment sessions: 1/week Control intervention: sham laser acupuncture at same points
Outcomes	Method for outcome measurement: diary Responder rates: not mentioned Frequency: data uninterpretable due to large baseline differences No information on intensity, duration or medication Headache index: uninterpretable due to large baseline differences
Notes	Author's conclusion: no difference between true and sham laser acupuncture Reviewer's conclusions: results suggest no difference Comments: large baseline differences make any interpretation very difficult; insufficient reporting
Allocation concealment	C

Study	**Lehmann 1991**
Methods	Allocation: randomized Concealment: unclear Blinding: no blinding Dropouts/withdrawals: unclear Observation period: baseline 3 months; treatment 3 months; follow-up 12 months Quality scores: Jadad: 1-0-0; IVS: 1-0-0-0-0-0 Acupuncturist's assessment: insufficient information for an assessment
Participants	Numer of patients included/analyzed: 63?/63? Condition: migraine with or without aura Demographics: mean age 45 years; 65% female Setting: unclear, East Germany Time since onset of headaches: > 10 years
Interventions	Acupuncture (group 1): needle-acupuncture (acu); no information on points Acupuncture (group 2): electro-acupuncture (e-acu); no information on points

Characteristics of included studies (*Continued*)

	No information on acupuncturist(s) DeChi achieved?: no information Number of treatment sessions: 12 sessions with 20 minutes (acu) stimulation, respectively 1 minute per point (e-acu) Frequency of treatment sessions: 1/week Control intervention: Propanolol 75-150 mg/d
Outcomes	Method for outcome measurement: diary Responder rate: not mentioned Frequency: 7 (acu) vs. 5 (e-acu) vs. 18 (propanolol) days with headache Intensity: 54% (acu) vs. 72% (e-acu) vs. 8% (propanolol) reduction Duration: not reported Medication: 78% (acu) vs. 81% (e-acu) vs. < 50% (propanolol) reduction Other: acu and e-acu significantly better for work-days lost
Notes	Author's conclusion: acupuncture significantly better Reviewer's conclusion: acupuncture significantly better Comments: insufficiently reported study with questionable validity (inconsistent reporting on proceedings in case of lack of response; extremely positive results claimed; diagnosis of migraine hardly compatible with an average of 22 headache days per months; no report on dropouts in a study lasting 18 months)
Allocation concealment	B

Study	**Loh 1984**
Methods	Allocation: randomized Concealment: unclear Blinding: not blinded Dropouts/withdrawals: major bias unlikely Observation period: 3 months (with optional cross-over after 3 months) Quality scales: Jadad: 1-0-0; IVS: 1-0-0-0-0-0.5 Acupuncturist's assessment: differently/35%
Participants	Number of patients included/analyzed: 55/48 Condition: migraine, tension-type headache, both forms mixed Demographics: mean age 42; 69% female Setting: hospital outpatient department in UK Time since onset of headaches: mean 19 years
Interventions	Acupuncture points: brief, strong needling at local points in neck and temporal region of head (GB 20 and 21 in nearly all patients) and distal points (usually including LI4 and LR3). Minimum 6 points usually treated (no prophylactic migraine medication allowed). Information on acupuncturists: n = 2; no further information DeChi achieved?: yes Number of treatment sessions: no information Frequency of treatment sessions: no information Control intervention: individualized medication (mainly propranolol)
Outcomes	Method for outcome measurement: diary Responder rates: 8/23 (acu) vs. 4/25 (medication) No information on frequency, intensity, duration or medication Other: 11/23 patients in the acu group changed to medication after 3 months, while 18/25 patients in the medication group changed to acu
Notes	Author's conclusion: trend in favor of acupuncture Reviewer's conclusion: trend in favor of acupuncture Comments: strategy to choose medication unclear; only global assessments presented; positive response to acupuncture more likely in patients with local tender points

Characteristics of included studies (*Continued*)

Allocation concealment	B

Study	**Pintov 1997**
Methods	Allocation: probably alternation Concealment: probably inadequate Blinding: patients and nurses collecting questionnaires Dropout/withdrawals: no withdrawals or dropouts Observation period: baseline 10 w; treatment 10 w; follow-up 10 w Qualty scales: Jadad: 0-1-1; IVS: 0-0-0-0.5-0.5-1 Acupuncturist's assessment: insufficient information for an assessment
Participants	Number of patients included/analyzed: 22/22 Condition: migraine (Prensky criteria, no prophylactic treatment) Demographics: age 7 to 15 years; 58% female Setting: pediatric clinic in a medical center in Israel Time since onset of headaches: > 6 months (inclusion criterion)
Interventions	Acupuncture points: individually chosen, three needles upper and lower extremities No information on acupuncturist(s) DeChi achieved?: no information Number of treatment sessions: 10 Frequency of treatment sessions: 1/week Control intervention: superificial needling
Outcomes	Method for outcome measurement: diary, only post-treatment values reported Responder rates: not measured Frequency: 1.4 +/- 0.6 days (acu) vs. 9.3 +/- 1.5 days (sham) Intensity: 3.3 +/- 1.0 (acu) vs. 6.2 +/- 0.4 (sham) on VAS Duration: not reported Medication: not reported
Notes	Author's conclusion: acupuncture better (significantly) Reviewer's conclusion: acupuncture better (significantly) Comments: not truly randomized; insufficient description of acupuncture; extremely positive results, small standard deviations worrying
Allocation concealment	C

Study	**Shi 2000**
Methods	Allocation: randomized Concealment: unclear Blinding: patients Dropouts/withdrawals: unclear Observation period: no baseline; 5-6 weeks treatment; 6 months follow-up Quality scores: Jadad: 1-0-0; IVS: 1-0-1-0.5-0-0 Acupuncturist's assessment: similarly/80%
Participants	Number of patients included/analyzed: 34?/34? Condition: 'chronic headache' Demographics: mean age 46 years; 74% female Setting: university outpatient department, Germany Time since onset of headaches: 5-20 years
Interventions	Acupuncture points: chosen individually according to principles of traditional Chinese medicine Information on acupuncturist: n = 1, qualified in traditional Chinese medicine DeChi achieved?: yes

Characteristics of included studies (*Continued*)

	Number of treatment sessions: 10-12, max. 25 minutes each Frequency of treatment sessions: 2/week Control intervention: sham laser acupuncture (device switched off)
Outcomes	Method for outcome measurement: point measurement Responder rate: not mentioned Frequency: not measured Intensity: after treatment 3.1 +/- 2.8 (acu) vs. 6.0 +/- 2.0 (sham); at 6 months 5.5 +/- 2.2 vs. 6.8 +/- 2.0 Duration: not measured Medication: at 6 months regular intake in 0/17 (acu) vs. 10/17 (sham) patients Other: acupuncture better for pain disability index, complaint list and activities of daily living
Notes	Author's conclusion: acupuncture better (significantly) Reviewer's conclusion: acupuncture better (clinically relevant) Comments: headache diagnoses and dropout rates not reported; no diary used; good presentation of results, but no between-group statistics presented
Allocation concealment	B

Study	**Tavola 1992**
Methods	Allocation: randomized Concealment: unclear Blinding: patients and data-collecting physician Dropouts/withdrawals: none Observation period: baseline 4 w; treatment 8 w; follow-up 12 months Quality scales: Jadad: 1-1-1; IVS: 1-0-1-1-1-1 Acupuncturist's assessment: (probably) exactly the same way/80%
Participants	Number of patients included/analyzed: 30/30 Condition: tension-type headache (Ad Hoc) Demographics: mean age 33 years; 87% female Setting: headache outpatient department of a university hospital in Italy Time since onset of headaches: mean 8 years
Interventions	Acupuncture points: individualized according to traditional Chinese medicine, possibility of changing points Information on acupuncturist: n = 1 DeChi achieved?: yes Number of treatment sessions: 8 (20 minutes each) Frequency of treatment sessions: 1/week Control intervention: sham (non-acupuncture points in the same regions)
Outcomes	Method for outcome measurement: diary Response rates: 13/15 (acu) vs. 9/15 (sham) Frequency: decreased 44% (acu) vs. 21% (sham) Intensity: not reported Duration: not reported Medication: decreased 58% (acu) vs. 22% (sham)
Notes	Author's conclusion: acupuncture not different from sham Reviewer's conclusion: acupuncture better (trend) than sham Comments: rigorous trial; acupuncture seems to be clearly better in all outcomes, but most differences are not statistically significant; surprisingly negative conclusions
Allocation concealment	B

Study	**Vincent 1989**
Methods	Allocation: randomized

Characteristics of included studies (*Continued*)

	Concealment: sealed envelope (information from author) Blinding: patients Dropouts and withdrawals: bias unlikely Observation period: baseline 4 w; treatment 6 w; follow-up 6 w, 4 m, and 1 yr Quality scores: Jadad: 1-0-0; IVS: 1-0-1-1-0-1 Acupuncturist's assessment: similarly/75%
Participants	Number of patients included/analyzed: 32/30 (6-week follow-up)/26 (1-year follow-up) Condition: classical or common migraine Demographics: mean 37 years; 84% female Setting: university outpatient department, UK Time since onset of headaches: mean 20 years
Interventions	Acupuncture points: classical points chosen individually by tenderness; 8 both local and distant points used No information on acupuncturist(s) DeChi achieved?: no information Number of treatment sessions: 6 sessions of 15 minutes each Frequency of treatment sessions: 1/week Control group intervention: superficial needling only, 2-3 cm from classical points
Outcomes	Method for outcome measurement: diary Responder rates (at least 33% reduction of headache days baseline vs. last 4 weeks of early follow-up) re-calculated from individual patient data: 7/15 (acu) vs. 6/15 (sham) Frequency: 3.7 (acu) vs. 3.5 (sham) pain-free days after treatment and 4.3 vs. 4.2 at follow-up Intensity: pain score 18.8 (acu) vs. 27.9 (sham) after treatment and 15.7 vs. 23.6 at follow-up Duration: not reported Medication: medication score 6.7 (acu) vs. 9.1 (sham) after treatment and 6.6 vs. 7.6 at follow-up
Notes	Author's conclusion: acupuncture significantly better Reviewer's conclusion: acupuncture significantly better Comments: major effect on intensity, but no relevant effect on number of pain-free days; credibility of blinding tested; rigorous trial; author provided individual patient data
Allocation concealment	A

Study	**Weinschütz 1993**
Methods	Allocation: randomized Concealment: unclear Blinding: patients Dropouts/withdrawals: unclear Observation period: baseline 6 w; treatment 8 w; follow-up 12 months Quality scores: Jadad: 1-0-0; IVS: 1-0-0.5-0.5-0-0 Acupuncturist's assessment: exactly the same way/95%
Participants	Number of patients included/analyzed: 40?/40? Condition: migraine with or without aura (IHS) Demographics: mean age 41 years; 90% female Setting: pain outpatient department of a university hospital, Germany Time since onset of headaches: mean 18 years
Interventions	Acupuncture points: up to 10 points chosen according to pain localization and modalities Information on acupuncturist: n = 1, experienced and qualified DeChi achieved?: yes Number of treatment sessions: 8 sessions of 15 minutes each Frequency of treatment sessions: 1/week Control intervention: sham acu (superficial needling 1-2 cm distant from true points)

Characteristics of included studies (*Continued*)

Outcomes	Method for outcome measurement: diary (data mainly presented as responder rate evaluated by time-series analysis) Responder rates: 13/20 (acu) vs. 8/20 (sham) (predefined main outcome measure number of attacks) Frequency: 10/20 (acu) vs. 3/20 (sham) responder after treatment and 13/20 vs. 8/20 at follow-up; mean reductions 37% vs. 26% (after treatment) and 45% vs. 40% (follow-up) Intensity: not reported Duration: 11/20 (acu) vs. 3/20 (sham) responders after treatment and 11/20 vs. 7/20 at follow-up Medication: not reported
Notes	Author's conclusion: trend in favor of acupuncture Reviewer's conclusion: trend in favor of acupuncture Comments: probably rigorous, but insufficiently reported (in spite of multiple publication); no information on whether there were dropouts/withdrawals
Allocation concealment	B

Study	**Weinschütz 1994**
Methods	Allocation: randomized Concealment: unclear Blinding: patients Dropouts/withdrawals: unclear Observation period: baseline 6 w; treatment 8 w; follow-up 12 months Quality scales: Jadad: 1-0-0; IVS: 1-0-0.5-0.5-0-0 Acupuncturist's assessment: exactly the same way/95%
Participants	Number of patients included/analyzed: 41?/41? Condition: migraine with or without aura (IHS) Demographics: mean age 38 years; 90% female Setting: pain outpatient department of a university hospital, Germany Time since onset of headaches: mean 18 years
Interventions	Acupuncture points: up to 10 points chosen according to pain localization and modalities Information on acupuncturist: n = 1, experienced and qualified DeChi achieved?: yes Number of treatment sessions: 8 sessions of 15 minutes each Frequency of treatment sessions: 1/week Control intervention: sham acu (superficial needling 1-2 cm distant from true points)
Outcomes	Method for outcome measurement: diary (data mainly presented as responder rate evaluated by time-series analysis) Responder rates: 15/20 (acu) vs. 8/21 (sham) Frequency: 9/20 (acu) vs. 1/21 (sham) responder after treatment and 15/20 vs. 8/21 at follow-up; mean reductions 45% vs. 20% (after treatment) and 51% vs. 31% (follow-up) Intensity: not reported Duration: 9/20 (acu) vs. 3/21 (sham) responders after treatment and 11/20 vs. 6/21 at follow-up Medication: not reported
Notes	Author's conclusion: acupuncture significantly better Reviewer's conclusion: acupuncture significantly better Comments: probably rigorous, but insufficiently reported (in spite of multiple publication); no information on whether there were dropouts/withdrawals; replication of Weinschütz 1993 (with additional needling of foot points)
Allocation concealment	B

Study	**White 1996**
Methods	Allocation: randomized

Characteristics of included studies (*Continued*)

	Concealment: central randomization (telephone call) Blinding: patients and evaluator Dropouts/withdrawals: bias unlikely Observation period: 3 w baseline; 6 w treatment; 3 w follow-up Quality scales: Jadad: 2-2-1; IVS: 1-1-0-1-1-0.5 Acupuncturist's assessment: similarly/25%
Participants	Number of patients included/analyzed: 10/9 Condition: tension-type headache (IHS) Demographics: mean age 57 years; 8 women Setting: unclear, UK Time since onset of headaches: 32 and 36 years on average
Interventions	Acupuncture points: 2 to 6 local points, LI4 Information on acupuncturist: n = 1, GP 'who recently attended a basic acupuncture course' DeChi achieved?: probably in most cases Number of treatment sessions: 6 Frequency of treatment sessions: 1/week Control intervention: sham acu (plastic guide tube and cocktail stick on 4 body regions without known acupuncture points)
Outcomes	Method for outcome measurement: diary with intensity, duration and medication. Questions on blinding.
Notes	Comments: this methodologically rigorous pilot study is uninterpretable due to relevant baseline differences; more pain-free weeks in true acupuncture group
Allocation concealment	A

Study	**Wylie 1997**
Methods	Allocation: randomized Concealment: unclear Blinding: post-treatment care Dropouts/withdrawals: unclear Observation period: baseline 4 w; treatment/follow-up unclear Quality scales: Jadad: 1-0-0; IVS: 1-0-0-0-0-0 Acupuncturist's assessment: insufficient information for an assessment
Participants	Number of patients included/analyzed: 67/? Condition: 27 migraine or migraine + tension-type headache, 40 tension-type headache (IHS) Demographics: mean age 38 years; 67% female Setting: headache outpatient department, UK Time since onset of headaches: mean 10 years
Interventions	Acupuncture points: chosen individually according to traditional Chinese medicine No information on acupuncturist(s) DeChi achieved?: no information Number of treatment sessions: 6 Frequency of treatment sessions: unclear Control intervention: massage and relaxation
Outcomes	Method for outcome measurement: diary Responder rates: not mentioned Frequency: mean number of attacks in migraine sufferers 1.7 (acu) vs. 2.7 (control) No information on intensity, duration or medication Headache index: migraine 9.2 (acu) vs. 19.3 (control); tension-type 16.8 (acu) vs. 6.2 (control) Other: a number of instruments were used to identify psychological factors predicting response (none convincingly identified)

Characteristics of included studies (*Continued*)

Notes	Author's conclusion: massage + relaxation significantly better Reviewer's conclusion: results seem to differ considerably among subgroups: in migraine, results favor acupuncture; in tension-type headache, massage + relaxation; overall, massage and control patients had a significantly lower headache index Comments: insufficiently reported
Allocation concealment	B

DeChi = irradiating sensation said to indicate effective needling

Characteristics of excluded studies

Airaksinen 1992	Intervention: electrical stimulation not necessarily at acupuncture points (myofascial trigger points)
Annal 1992	Intervention: transcutaneous electrical nerve stimulation not at acupuncture points
Borglum-Jensen 1979	Methods: random allocation unlikely
Domzal 1980	Not controlled trial
Dong 1994	Intervention: acupuncture vs. acupuncture
Formisano 1992	Neurophysiological study
Hansen 1982	Patients: condition chronic facial pain
Johansson 1991	Patients: condition facial pain
Junnilla 1983	Patients: study included patients with various chronic pain syndromes, including headache; however, headache patients were not presented as a separate subgroup, but only together with all other patients.
Lenhard 1983	Intervention: acupuncture + naloxone vs. acupuncture + placebo
Lundeberg 1988	Report of a series of studies with RCTs on other pain syndromes; only uncontrolled trial in headache patients
Okazaki 1975	Intervention: acupuncture vs. acupuncture
Pikoff 1989	Patients/outcome measures: study on acute headache
Sold-Darseff 1986	Methods: probably not randomized, only a subgroup had headache
Stone 1997	Patients: injured patients (secondary headaches)
Tekeoglu 1995	Intervention: electroacupuncture vs. music sound electroacupuncture
Turk 1990	Methods/intervention/outcomes: unclear method of allocation/acupuncture vs. laser-acupuncture/follow-up < 4 weeks
Vincent 1990	Methods/outcomes: multiple single case cross-over trials in which 4 true and 4 sham acupuncture treatments were randomly given in a 8-week observation period (therefore, no constant follow-up > 4 weeks)

Characteristics of ongoing studies

Study	**ARC Headache**
Trial name or title	ARC Headache = Acupuncture in Routine Care of Headache. Large trial being performed by the Insitute of Social Medicine, Epidemiology and Health Economics, Charité University Hospital, Berlin, Germany.
Participants	> 2000 patients with headache
Interventions	Acupuncture and wait-list control
Outcomes	Headache days, quality of life
Starting date	
Contact information	Dr. C. Witt: Claudia.Witt@charite.de

Characteristics of ongoing studies (*Continued*)

Notes	Status: Data under analysis

Study	**ART Migraine**
Trial name or title	ART Migraine = Acupuncture Randomized Trial in Patients with Migraine. Protocol published by Melchart D, Linde K, Streng A, Reitmayr S, Hoppe A, Brinkhaus B, et al. Acupuncture Randomized Trials (ART) in patients with migraine or tension-type headache - design and protocols. Forschende Komplementärmedizin und klassische Naturheilkunde 2003;10(4):179-84.
Participants	302 patients with migraine
Interventions	Acupuncture, minimal acupuncture, and wait-list control
Outcomes	Main outcome measure: Difference in days with moderate or severe headache between baseline and weeks 9 to 12 Secondary outcomes: migraine attacks, headache days, days with medication, response rate, quality of life, disability
Starting date	March 2002
Contact information	Dr. K. Linde: Klaus.Linde@lrz.tu-muenchen.de
Notes	Status: Completed and submitted for publication

Study	**ART TTH**
Trial name or title	ART TTH = Acupuncture Randomized Trial in Patients with Tension-Type Headache. Protocol published by Melchart D, Linde K, Streng A, Reitmayr S, Hoppe A, Brinkhaus B, et al. Acupuncture Randomized Trials (ART) in patients with migraine or tension-type headache - design and protocols. Forschende Komplementärmedizin und klassische Naturheilkunde 2003;10(4):179-84.
Participants	298 patients with tension-type headache
Interventions	Acupuncture, minimal acupuncture, and wait-list control
Outcomes	Main outcome measure: Difference in days with headache between baseline and weeks 9 to 12 Secondary outcomes: days with medication, response rate, quality of life, disability
Starting date	March 2002
Contact information	Dr. K. Linde: Klaus.Linde@lrz.tu-muenchen.de
Notes	Status: Data under analysis

Study	**GERAC Migraine**
Trial name or title	GERAC Migraine = German Acupuncture Trial in Migraine. Information on the study published by Molsberger A, Diener HC, Krämer J, et al. GERAC-Akupunktur-Studien - Modellvorhaben zur Beurteilung der Wirksamkeit. Deutsches Ärzteblatt 2002;99:A1819-24.
Participants	Recruitment target: n = 900 patients with migraine
Interventions	Acupuncture, sham acupuncture, and standard drug prophylaxis
Outcomes	
Starting date	
Contact information	Dr. A. Molsberger: a.molsberger@facm.de
Notes	Status: Recruitment completed; results probably available in 2005

Study	**GERAC TTH**
Trial name or title	GERAC TTH = German Acupuncture Trial in Tension-type Headache. Information on the study published by Molsberger A, Diener HC, Krämer J, et al. GERAC-Akupunktur-Studien - Modellvorhaben zur Beurteilung der Wirksamkeit. Deutsches Ärzteblatt 2002;99:A1819-24.

Characteristics of ongoing studies (*Continued*)

Participants	Recruitment target: n = 900 patients with tension-type headache
Interventions	Acupuncture, sham acupuncture, and standard drug prophylaxis
Outcomes	
Starting date	
Contact information	Dr. A. Molsberger: a.molsberger@facm.de
Notes	Status: Recruitment stopped early; results possibly available in 2005

Study	**PEP-COMP**
Trial name or title	PEP-COMP = Program for the Evaluation of Patient care with acupuncture - COMParative Trial
Participants	120 patients with migraine
Interventions	Acupuncture, metoprolol
Outcomes	Main outcome measure: Difference in days with moderate or severe headache between baseline and weeks 9 to 12 Secondary outcomes: migraine attacks, headache days, response rate, quality of life, disability
Starting date	October 2002
Contact information	Dr. K. Linde: Klaus.Linde@lrz.tu-muenchen.de
Notes	Status: Recruitment stopped early; results probably available in 2005

ADDITIONAL TABLES

Table 01. Assessment of methodological quality: Jadad scale

Study	Randomization	Double-blinding	Dropouts/Withdrawals	Sum score
Ahonen 1984	1	0	0	1
Baust 1978	1	2	0	3
Carlsson 1990	1	0	1	2
Ceccherelli 1992	1	0	0	1
Doerr-Proske 1985	1	0	0	1
Dowson 1985	2	0	0	2
Gao 1999	1	0	0	1
Hansen 1985	1	1	1	3
Henry 1986	1	1	0	3
Hesse 1994	1	1	1	3
Heydenreich 1989a	1	0	0	1
Heydenreich 1989b	1	0	0	1
Ho 1999	1	2	0	3
Johansson 1976	1	1	0	2

Table 01. Assessment of methodological quality: Jadad scale (*Continued*)

Study	Randomization	Double-blinding	Dropouts/Withdrawals	Sum score
Kubiena 1992	2	1	0	3
Lavies 1998	2	2	0	4
Lehmann 1991	1	0	0	1
Loh 1984	1	0	0	1
Pintov 1997	0	1	1	2
Shi 2000	1	0	0	1
Tavola 1991	1	1	1	3
Vincent 1989	1	0	0	1
Weinschütz 1993	1	0	0	1
Weinschütz 1994	1	0	0	1
White 1996	2	2	1	5
Wylie 1997	1	0	0	1

Table 02. Assessment of methodological quality: Internal validity scale

Study	Random allocation	Concealment	Baseline comparable	Patient blinding	Evaluator blinding	Handling dropouts	Sum
Ahonen 1984	1	0	0.5	0	0	0	1.5
Baust 1978	1	0	0	1	1	0	3
Carlsson 1990	1	0.5	0.5	0	0	0.5	2.5
Ceccherelli 1992	1	0	0.5	1	0	1	3.5
Doerr-Proske 1985	1	0	0	0	0	0	1
Dowson 1985	1	0.5	0.5	0.5	0	0.5	3
Gao 1999	1	0	0	0	0	0	1
Hansen 1985	1	0	0.5	1	1	0.5	4
Henry 1986	1	0	1	1	1	0	4
Hesse 1994	1	0	1	0.5	1	0.5	4
Heydenreich 1989a	1	0	1	0	0	0	2
Heydenreich 1989b	1	0	1	0	0	0	2
Ho 1999	1	0	1	1	1	0	4

Table 02. Assessment of methodological quality: Internal validity scale (*Continued*)

Study	Random allocation	Concealment	Baseline comparable	Patient blinding	Evaluator blinding	Handling dropouts	Sum
Johansson 1976	1	0	0	0.5	0.5	0	2
Kubiena 1992	1	0	0	1	0.5	0	2.5
Lavies 1998	1	0	0	1	1	0	3
Lehmann 1991	1	0	0	0	0	0	1
Loh 1984	1	0	0	0	0	0.5	1.5
Pintov 1997	0	0	0	0.5	0.5	1	2
Shi 2000	1	0	1	0.5	0	0	2.5
Tavola 1992	1	0	1	1	1	1	5
Vincent 1989	1	0	1	1	0	1	4
Weinschütz 1993	1	0	0.5	0.5	0	0	2
Weinschütz 1994	1	0	0.5	0.5	0	0	2
White 1996	1	1	0	1	1	0.5	4.5
Wylie 1997	1	0	0	0	0	0	1

Table 03. Assessment of acupuncture quality

Study	How would you treat?	How sure acu adeq.?
Ahonen 1984	similarly	60%
Baust 1978	similarly	35%
Carlsson 1990	completely differently	10%
Ceccherelli 1992	similarly	70%
Doerr-Proske 1985	completely differently	20%
Dowson 1985	could not assess	could not assess
Gao 1999	exactly the same way	95%
Hansen 1985	similarly	70%
Henry 1986	differently	45%
Hesse 1994	completely differently	50%
Heydenreich 1989a	could not assess	could not assess
Heydenreich 1989b	exactly the same way	90%
Ho 1999	exactly the same way	85%

Table 03. Assessment of acupuncture quality (*Continued*)

Study	How would you treat?	How sure acu adeq.?
Johansson 1976	could not assess	could not assess
Kubiena 1992	could not assess	could not assess
Lavies 1998	could not assess	could not assess
Lehmann 1991	could not assess	could not assess
Loh 1984	differently	35%
Pintov 1997	could not assess	could not assess
Shi 2000	similarly	80%
Tavola 1992	exactly the same way	80%
Vincent 1989	similarly	75%
Weinschütz 1993	exactly the same way	95%
Weinschütz 1994	exactly the same way	95%
White 1996	similarly	25%
Wylie 1997	could not assess	could not assess

Table 04. Migraine - true vs. sham interventions: Results for frequency and intensity

Study (diagnosis)	Frequency measure	< 2mo (true vs sham)	> 2mo (true vs sham)	Intensity measure	< 2mo (true vs sham)	> 2mo (true vs sham)	Vote count
Baust 1978 (Migraine)	attacks	not presented	not measured	visual analog scale	not presented	not measured	0
Ceccherelli 1992 (Migraine)	pain hours per week	11 +/- 11 vs. 35 +/- 28	not measured	scale 0-5	not presented	not measured	+2
Dowson 1985 (Migraine)	patients with 33% reduction	11/25 vs. 13/23	not presented	patients with 33% reduction	14/25 vs. 7/23	not presented	0
Hansen 1985 (TTH)	number of headache-free days	not presented	not measured	unclear	not presented	not measured	+2
Henry 1986 (Migraine)	reduction according to neurologist	12/20 vs. 3/10	not presented	reduction according to neurologist	11/20 vs. 2/10	not presented	+1
Heydenreich 1989a (Migraine)	patients with at least 40% reduction	18/20 vs. 6/20	17/20 vs. 3/20	mean % reduction compared to baseline	not presented	39% vs. 8%	+2
Ho 1999 (Migraine)	mean % headache days	24% vs. -2%	58% vs. 28%	unclear	not presented	not presented	+1

Table 04. Migraine - true vs. sham interventions: Results for frequency and intensity (*Continued*)

Study (diagnosis)	Frequency measure	< 2mo (true vs sham)	> 2mo (true vs sham)	Intensity measure	< 2mo (true vs sham)	> 2mo (true vs sham)	Vote count
	reduction						
Johansson 1976 (TTH)	unclear	not presented?	not measured?	unclear	not presented?	not measured	+2
Pintov 1997 (Migraine)	migraine frequency	1.4 +/- 0.6 vs. 9.3 +/- 1.4	not presented	visual analog scale	3.3 +/- 1.0 vs. 6.2 +/- 0.4	not presented	+2
Shi 2000 (Mixed)	not measured?			numerical rating scale	3.1 +/- 2.8 vs. 6.4 +/- 2.0	5.5 +/- 2.2 vs. 6.8 +/- 2.0	+1
Tavola 1992 (TTH)	mean % episode frequency	44% vs. 21%	not presented	numerical rating scale	not reported	not reported	+1
Vincent 1989 (Migraine)	difference vs. baseline days with pain/4 weeks	2.7 +/- 04.8 vs. 0.7 +/- 2.9	4.9 +/- 4.6 vs. 3.4 +/- 2.9	mean intensity score	18.8 vs. 27.9	8.0 vs. 25.1	+2
Weinschütz 1993 (Migraine)	mean % headache days reduction	37% vs. 26%	45% vs. 40%	visual analog scale	not presented	not presented	+1
Weinschütz 1994 (Migraine)	mean % headache days reduction	45% vs. 20%	51% vs. 31%	visual analog scale	not presented	not presented	+2

Table 05. Acupuncture vs. other interventions: Results for frequency and intensity

Study (diagnosis)	Frequency measure	<2mo (acu vs. other)	>2mo (acu vs. other)	Intensity measure	<2mo (acu vs. other)	>2mo (acu vs. other)	Control	Vote count
Ahonen 1984 (TTH)	< 2 days/week with headache	5/12 vs. 2/10	not reported	visual analog scale	not reported	not reported	physiother-apy	0
Carlsson 1990 (TTH)	5-step rating scale	'reduced in both groups'	not reported	visual analog scale (baseline values acu 41 +/- 32, physiother-apy 52 +/- 22; all values extrapolated from figure)	40 +/- 34 vs. 28 +/- 22	52 +/- 32 vs. 29 +/- 22	physiother-apy	-2
Doerr-Proske 1985 (Migraine)	mean % reduction headache days	32% vs. 38%	not measured	mean % reduction	48% vs. 44%	not measured	biobe-havioral program	-1

Table 05. Acupuncture vs. other interventions: Results for frequency and intensity (*Continued*)

Study (diagnosis)	Frequency measure	<2mo (acu vs. other)	>2mo (acu vs. other)	Intensity measure	<2mo (acu vs. other)	>2mo (acu vs. other)	Control	Vote count
Gao 1999 (Migraine)	not measured?			not measured?			Chinese drugs	+2
Hesse 1994 (Migraine)	number of migraine attacks (mean difference acu vs. metoprolol, with 95% CI)	0.7 (-1.6 to 2.7)	not measured	3-point scale	0.3 (0.1 to 0.5)	not measured	metoprolol	-1
Heydenreich 1989b (Migraine) (needle acu vs. acupuncture-like TENS vs. drug therapy)	mean % reduction headache days	not presented	80% vs. 76% vs. 38%	unclear	not presented	45% vs. 44% vs. 15%	ipra-zochrom and dihydroergotoxinmesylate	+2
Lehmann 1991 (Migraine) (needle acupuncture vs. electro-acupuncture vs. propanolol)	days with headache	not presented	7 vs. 5 vs. 18	mean migraine index reduction	not presented	54% vs. 72% vs. 8%	propranolol	+2
Loh 1984 (Mixed)	unclear	not presented	not measured	unclear	not presented	not measured	drug therapy	+1
Wylie 1997 (Migraine)	migraine days	1.7 vs. 2.7	not measured	total pain index	61 vs. 154	not measured	massage & relaxation	+1
Wylie 1997 (TTH)	days with headache	not presented	not measured	total pain index	162 vs. 50	not measured	massage & relaxation	-2

ANALYSES

Comparison 01. True vs. sham acupuncture

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Response (earliest available date)			Relative Risk (Fixed) 95% CI	Totals not selected
02 Short-term response (within 2 months after treatment)			Relative Risk (Fixed) 95% CI	Totals not selected

03 Long-term response (follow-up > 2 months)	Relative Risk (Fixed) 95% CI	Totals not selected

INDEX TERMS

Medical Subject Headings (MeSH)

*Acupuncture Therapy; Evaluation Studies; Headache [*therapy]; Randomized Controlled Trials

MeSH check words

Humans

COVER SHEET

Title	Acupuncture for idiopathic headache
Authors	Melchart D, Linde K, Berman B, White A, Vickers A, Allais G, Brinkhaus B
Contribution of author(s)	All reviewers participated in the development of the protocol, the extraction and assessment of the primary studies, and the review of the final manuscript. The text was written by KL.
Issue protocol first published	1998/3
Review first published	2001/1
Date of most recent amendment	21 January 2005
Date of most recent SUBSTANTIVE amendment	27 November 2000
What's New	Changes made in this version of the review: 1) Eight citations added to 'Studies awaiting assessment'. 2) 'Characteristics of ongoing studies' table updated. 3) Published note added. 4) Very minor edits made to parts of the 'Methods of the review' and 'Results' sections. 5) List of authors updated.
Date new studies sought but none found	Information not supplied by author
Date new studies found but not yet included/excluded	07 December 2004
Date new studies found and included/excluded	Information not supplied by author
Date authors' conclusions section amended	Information not supplied by author
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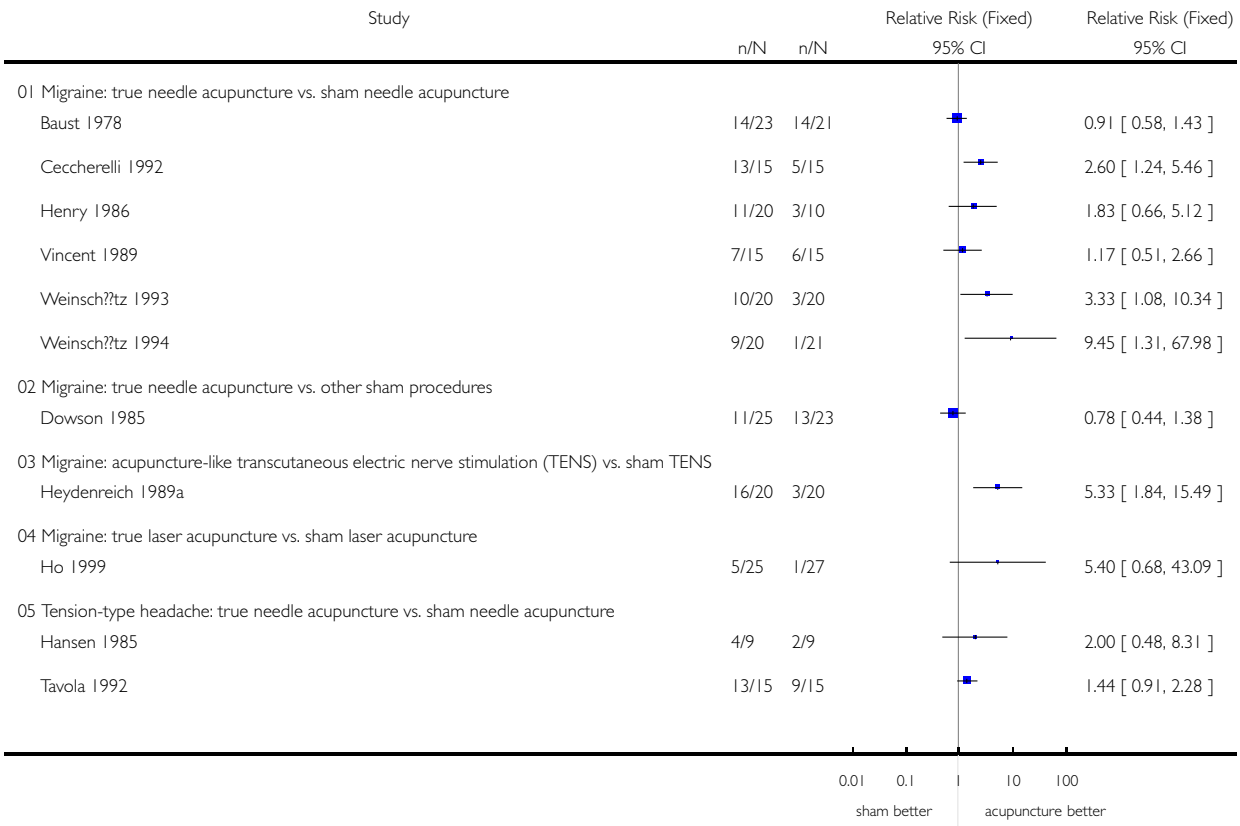
GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 True vs. sham acupuncture, Outcome 01 Response (earliest available date)

Review: Acupuncture for idiopathic headache

Comparison: 01 True vs. sham acupuncture

Outcome: 01 Response (earliest available date)

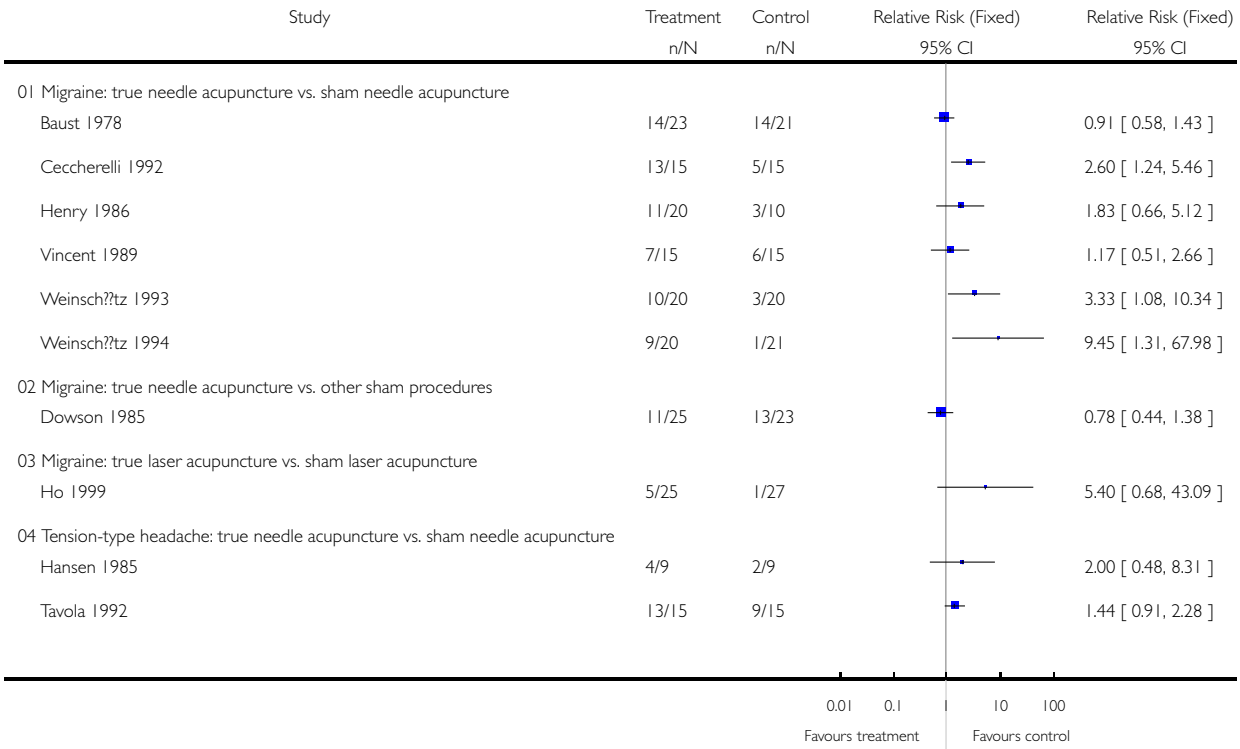


Analysis 01.02. Comparison 01 True vs. sham acupuncture, Outcome 02 Short-term response (within 2 months after treatment)

Review: Acupuncture for idiopathic headache

Comparison: 01 True vs. sham acupuncture

Outcome: 02 Short-term response (within 2 months after treatment)



Analysis 01.03. Comparison 01 True vs. sham acupuncture, Outcome 03 Long-term response (follow-up > 2 months)

Review: Acupuncture for idiopathic headache

Comparison: 01 True vs. sham acupuncture

Outcome: 03 Long-term response (follow-up > 2 months)