
Systematic review of randomized clinical trials of complementary/alternative therapies in the treatment of tension-type and cervicogenic headache

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Authors' objectives

To evaluate complementary/alternative (CAM) therapies in the treatment of non-migrainous headache.

Searching

MEDLINE (from 1966 to mid-1998), PsycINFO, and CINAHL were searched for studies published in the English language. Full details of the MEDLINE search were presented. Additional studies were located by searching the citations and reference lists in systematic reviews, and by contacting authors.

Study selection

Study designs of evaluations included in the review

Randomised controlled trials (RCTs), in which at least two groups were randomly allocated to receive one or more interventions, were eligible.

Specific interventions included in the review

The inclusion criteria were not defined in terms of the intervention. The following CAM therapies were studied: acupuncture; spinal manipulation; electrotherapy, including transcutaneous electrical nerve stimulation (TENS); physiotherapy, involving multiple modality combinations of relaxation, stretching, TENS, ice therapy, massage and ultrasound, exercise, education and medication; massage; homeopathy; an analgesic/counter-irritant ointment (Tiger Balm); and therapeutic touch. These therapies were compared with each other, either alone or in combinations with the following: sham, placebo or no-treatment controls; occlusal splint; medication; soft-tissue therapy; amitriptyline; relaxation therapy; rest; ice; biofeedback; and paracetamol (1 g). The duration of acupuncture therapies ranged from 30 to 120 days, the number of spinal manipulations ranged from 1 to 12, the number of electrotherapy sessions ranged from 1 to at least 15, the duration of physiotherapy treatments ranged from 60 to 90 days, and the duration of homeopathy was 12 weeks. Both Tiger Balm and therapeutic touch were evaluated after one application for concurrent headache.

Participants included in the review

Adult headache sufferers were eligible. Non-migrainous headache was defined as those other than migraine (with or without aura), cluster and organic types of headache. Studies involving both tension-type and migrainous groups were included, as were studies reporting participation of those with 'muscle contraction' or 'tension' headaches; those involving only migraine, cluster or organic headaches were excluded. The participants in most studies were predominantly patients with tension headaches; there was a minority of patients suffering from cervicogenic or post-traumatic headaches.

Outcomes assessed in the review

Studies reporting clinical outcomes related to headache activity were eligible, whilst those reporting only physiological outcomes were excluded.

How were decisions on the relevance of primary studies made?

The senior author screened the total citations lists to identify RCTs.

Assessment of study quality

Validity was assessed using an 18-item quality protocol modified from van Tuldor et al. (see Other Publications of Related Interest no.1). The validity criteria were: specification of eligibility criteria; random allocation; groups similar at baseline; interventions described explicitly; provider blinded; cointerventions described and limited; compliance monitored; patients blinded; assessor blinded; outcome measures relevant; adverse effects monitored; drop-out rates

described and acceptable; short-term follow-up; long-term follow-up; timing of outcome assessments; sample size described; intention to treat analysis; and point estimates and measure of dispersion. Quality scores were converted to percentages; studies scoring over 60% were classified as high quality, 40 to 60% as moderately high, and less than 40% as poor. Two reviewers, not blinded to the source of the citation, independently assessed and scored validity. Consistency between reviewers' scores was assessed using the Interclass Correlation Coefficient.

Data extraction

Two reviewers independently extracted the following data using a standardised data extraction form: author and year of publication; study duration; sample size; headache type and IHS classification (see Other Publications of Related Interest no.2); and outcome, i.e. whether a positive or negative result was obtained when comparing the experimental to the control treatment. Consistency between reviewers' scores was assessed using the Interclass Correlation Coefficient.

Methods of synthesis

How were the studies combined?

The studies were grouped according to the primary treatment modality and combined in a narrative review.

How were differences between studies investigated?

Where applicable, the results from high-quality studies were reported separately.

Results of the review

Twenty-four RCTs involving 1,472 patients were included .

The agreement between quality raters was high (reliability coefficient 0.72; $p=0.0015$) and scores were averaged for the review.

Acupuncture (8 RCTs): the quality score ranged from 44 to 69%.

1. High-quality trials (4 RCTs with 99 patients): the quality scores ranged from 61 to 69%, and the average treatment duration was 52.2 days. Three RCTs compared acupuncture with sham treatment and reported inconsistent results: 1 RCT reported equivalence of outcome, the other 2 small RCTs reported a significant reduction in headache frequency with acupuncture but involved only 39 patients.

2. Other trials (4 RCTs with 173 patients): the quality scores ranged from 44 to 50%, and the average treatment duration was 99 days. Control interventions were: sham (1 RCT), no-treatment or occlusal splint control (1 RCT), medication (1 RCT) and physiotherapy (1 RCT). Three RCTs reported less frequent headaches in the acupuncture treatment groups.

3. Tension-type headaches (264 patients): results were inconsistent.

Spinal manipulation (6 RCTs with 286 patients): the quality scores ranged from 56 to 80%. The efficacy of spinal manipulation could not be determined.

Patients suffered from: tension-type headache (3 RCTs), cervicogenic headache (2 RCTs) and post-traumatic headache (1 RCT). No trial included an exclusively sham or placebo-type control and five different control therapies were used. There was some inconsistency regarding diagnostic classification.

Electrotherapy (4 RCTs, including 507 patients with tension-type headaches): the quality scores ranged from 39 to 61%. Three RCTs (1 high and 2 moderately high quality) reported greater benefit from electrotherapy than placebo.

Physiotherapy (3 RCTs with 147 patients): the quality scores ranged from 33 to 58%. Physiotherapy involved multi-modality programmes (all including TENS) making it impossible to determine the effect of individual treatment components. Control therapies were: acupuncture, attention control, and medication and biofeedback. All 3 RCTs reported greater benefit from additional physiotherapy.

Massage: no RCTs were found.

Homeopathy (1 RCT with 98 patients, of which approximately half had tension-type headache): the quality score was high (86%). The study was methodologically rigorous with double-blinded placebo control. No difference in efficacy between treatments was found.

Tiger Balm (1 RCT with 57 patients): the quality score was high (72%). Tiger Balm and paracetamol produced significantly greater pain relief than a topic placebo for one episode of headache. There was no difference between Tiger Balm and paracetamol.

Therapeutic touch (1 RCT with 60 patients): the quality score was moderately high (47%). After a 5-minute intervention, those patients who received the intervention experienced twice as much pain relief as the control group, both immediately and after 4 hours.

The included studies were hampered by a lack of provider blinding, monitoring of adverse effects, long-term follow-up and intention to treat analysis.

Authors' conclusions

The existing RCTs on the use of CAM therapies in the treatment of non-migrainous headache demonstrate that clinical experimental studies of these forms of headaches can be conducted. Evidence from a subset of high-quality studies indicates that some CAM therapies may be useful in the treatment of these common forms of headache.

CRD commentary

The aims were stated, and inclusion criteria were defined in terms of study design, outcomes and participants. Several relevant sources were searched, but by limiting the search to English language publications other relevant studies may have been omitted. In addition, there was no attempt to locate unpublished studies, thus raising the possibility of publication bias. Primary studies were restricted to RCTs, the methods used to formally assess and score validity were described, and the results of the validity assessment were reported. Relevant data were presented in tabular format, the methods used to extract data were described, and the agreement between data extractors were reported. Given the small number of trials in each intervention category, a narrative review was appropriate, and evidence from higher-quality trials was highlighted in this narrative. The narrative review was well structured and presented.

The evidence presented supports the authors' conclusions.

Implications of the review for practice and research

Practice: The authors state that there appears to be sufficient evidence to support the application of electrotherapy to cranial muscles. There is evidence that homeopathy is not effective for tension-type headache. For other treatments, there are too few trials or trials with contradictory findings to comment definitively on efficacy.

Research: The authors state that in future studies, headache patients should be carefully selected according to explicit inclusion and exclusion criteria, as specified by the International Headache Society classification guidelines. In addition, every effort should be made to blind treatment allocation from all parties not directly involved in the treatment (particularly the assessors), and long-term follow-up should be included.

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Bibliographic details

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Other publications of related interest

1. van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain. *Spine* 1997;22:2128-56. 2. International Headache Society Committee on Clinical Trials. Guidelines for Trials of Drug Treatments in Tension-type Headache. *Cephalgia* 1995;15:165-79.

Indexing Status

Subject indexing assigned by NLM

MeSH

Acupuncture Therapy; Cervical Vertebrae /physiopathology; Chronic Disease; Complementary Therapies /methods; Confidence Intervals; Female; Follow-Up Studies; Headache /diagnosis /therapy; Health Surveys; Humans; Male; Manipulation, Spinal; Pain Measurement; Physical Therapy Modalities; Randomized Controlled Trials as Topic; Tension-Type Headache /diagnosis /physiopathology /therapy; Treatment Outcome

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