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

**H. Vernon, C. S. McDermaid, C. Hagino**
Canadian Memorial Chiropractic College, Toronto, Canada

**SUMMARY. Objectives: To conduct a systematic review of the randomized controlled clinical trials (RCTs) of complementary/alternative (CAM) therapies in the treatment of non-migrainous headache (i.e. excluding migraine, cluster and organic headaches). Design: Systematic review with quality scoring and evidence tables. Main outcome measures: Number of RCTs per therapy, quality scores, evidence tables. Results: Twenty-four RCTs were identified in the categories of acupuncture, spinal manipulation, electrotherapy, physiotherapy, homeopathy and other therapies. Headache categories included tension-type (under various names pre-1988), cervicogenic and post-traumatic. Quality scores for the RCT reports ranged from approximately 30 to 80 on a 100 point scale. Conclusion: RCTs for CAM therapies of the treatment of non-migrainous headache exist in the literature and demonstrate that clinical experimental studies of these forms of headache can be conducted. Evidence from a sub-set of high quality studies indicates that some CAM therapies may be useful in the treatment of these common forms of headache.**


## INTRODUCTION

Tension-type headache (TTH) is the most prevalent form of adult benign headache. Recent population-based studies have estimated its prevalence as 35–40% of the adult population in Western societies.[1-3] TTH contributes to a large burden of disability, resulting in lost work-days, diminished quality of life, and considerable health care costs to both governments and institutional payers.[3,4] Individual sufferers share in these costs, because the predominant approach to treatment of TTH is the use of over-the-counter analgesic medications[4] for symptomatic relief.

The etiology of TTH is unclear at present. Older models of painful cranial muscular contraction, possibly induced by psychological tension, have been rejected.[5-8] In 1988, the International Headache Society (IHS) promulgated a classification of headaches[9] which did not endorse any particular etiological mechanism for TTH, and, as such, recommended changing the name of this condition from 'tension headache' to the current form of 'tension-type headache'. The IHS classification includes two categories: headaches less frequently than 15 per month are known as episodic TTH, while the term chronic TTH is reserved for the small minority (about 3%)[3,4] who suffer headache more frequently than every other day. The IHS-based definition of TTH is given in Figure 1.

Cervicogenic headache (CH) is a recently validated type of headache,[9-11] although its existence

**Howard Vernon**
Canadian Memorial Chiropractic College 1900 Bayview Ave Toronto, ON M4G 3E6 Canada

**1) Tension-Type Headache:**

A. At least 10 previous headache episodes fulfilling criteria B to D.
B. Headache lasting from 30 minutes to 7 days.
C. At least two of the following criteria:
   i. Pressing /tightening (non-pulsatile) quality
   ii. Mild or moderate intensity (may inhibit, but does not prohibit activity)
   iii. Bilateral location
   iv. No aggravation by walking, stairs or similar routine physical activity.
D. Both of the following:
   i. No nausea or vomitting (anorexia may occur)
   ii. One of photo-or phonophobia may be present, but not both.

**2) Cervicogenic Headache:**

A. Pain localized to the neck and occipital region. May project to forehead, orbital region, temples, vertex or ears.
B. Pain is precipitated or aggravated by special neck movements or sustained postures.
C. At least one of the following:
   i. Resistance to or limitation of passive neck movements
   ii. Changes in neck muscle contour, texture, tone or response to active and passive stretching and contraction
   iii. Abnormal tenderness of neck muscles.
D. Radiological examination reveals at least one of the following:
   i. Movement abnormalities in flexion/extension
   ii. Abnormal posture
   iii. Fractures, congenital abnormalities, bone tumours, rheumatoid arthritis or other distinct pathology (not spondylosis or osteochondrosis).

**Fig. 1** Criteria for tension-type headache and cervicogenic headache from the IHS classification[7]

had been proposed by investigators in the manual medicine field for many decades.[12,13] Nilsson,[14] using the criteria established by the IHS[9], reported the prevalence of cervicogenic headache in a Scandinavian population to be approximately 16%. There is still some confusion in the clinical profiles of TTH and CH. The IHS-based definition of CH is given in Figure 1.

A lack of clarity also exists for the etiology of CH; however, by definition, it must involve pain referred to the head originating from structures in the cervical spine. The upper cervical spine has been particularly implicated, principally as the upper cervical spinal cord and lower brain stem share a common input of pain afferent fibres from the trigeminal and upper cervical sensory systems.[15]

A number of systematic reviews and meta-analyses have been reported on treatments for headache.[16–22] The interventions studied in these reviews have been confined to pharmacological therapies and cognitive/behavioural therapies. The majority of these reviews have been for treatments of migraine-type headache. Bogaards and ter Kuile's recent meta-analytic review of treatments for 'recurrent tension headache'[18] confined itself to the following categories of intervention: pharmacological, cognitive therapy, relaxation therapy, EMG biofeedback therapy and combinations, although some CAM therapies (acupuncture and physiotherapy) were regarded as control or 'pseudo-placebo' treatments. No primary complementary/alternative (CAM) therapies were included. It appears that no systematic review of CAM therapies for non-migrainous headaches currently exists in the literature.

Since the publication of Eisenberg's important article describing the usage of CAM therapies by Americans[23] interest in the topic within orthodox medical circles has grown and the use of CAM therapies in society has increased considerably. CAM therapy utilization rates in sufferers of TTH are poorly understood. Several studies cite the proportion of patients seeking chiropractic care for headache to be approximately 3–10% of patients in practice.[24,25]

Our group is pursuing a number of clinical studies in TTH and CH, with a particular interest in non-pharmacologic therapies which have been used for non-migrainous headaches. In the non-pharmacologic group there are two main categories of therapies. The first of these includes psychologically-based treatments involving cognitive or behavioural therapies such as biofeedback and counselling. The second of these categories involves CAM therapies, including acupuncture, chiropractic, physiotherapy, massage, homoeopathy and others. This report will confine itself to this latter category.

The goal of this report was to present an analysis of the randomized clinical trials of the efficacy of CAM treatments for non-migrainous headache. We have defined 'non-migrainous headache' as excluding migraine (with or without aura), cluster and any organic types of headache. In this study, we employed standardized methods for literature searching and evaluating the quality of the relevant studies.

## METHODS

### Literature review

A literature search was conducted of MEDLINE (English-language, 1966 to mid-1998), PsycInfo and CINHAL databases. The MEDLINE search strategy is given in Figure 2. Once these searches were obtained, supplementary searches of citations and reference lists in other systematic literature reviews, as well as author queries, were undertaken.

### Inclusion criteria

From the total initial citation lists, a screening process was undertaken by the senior author to identify the study design as one of the following: clinical trial, case series, case report or letter to the editor. Only randomized controlled trials (RCTs) were retained for analysis in this report. Relevant RCTs were defined as prospective studies with a sample of adult headache sufferers in which at least two groups were randomly allocated to receive one or more interventions. Studies involving exclusively migraine, cluster or organic types of headache were excluded. A small number of studies included both tension (-type) and migraine groups, and were included in the review. In some reports, older terminology such as 'muscle contraction' or 'tension' headache was used and these studies were included.

Studies were included in the review if they reported clinical outcomes related to headache activity (i.e. headache index, severity, frequency, medication usage). Studies which reported only physiological outcomes (EMG measurements only, blood chemistry, eye function), without clinical measures were not included. Papers had to be published in the English language.

### Quality scoring

Data abstraction and quality reviews were independently conducted by two reviewers (CM and CH), using a standardized abstraction form and a quality review protocol modified from van Tulder et al.[26] (further details are available from the authors on request). This quality review protocol was deemed most appropriate for our purposes as it was devised for reviewing clinical trials of non-medical treatments for spinal pain. As such, items pertaining to medications (dosages, side effects, monitoring via blood samples, etc.), which would be relevant to drug trials and which appear in other quality review schemes,[17,27] were excluded to prevent quality decrements from unfairly being applied to the CAM studies.

The reviewers were not blinded to the source of the citations. While there is evidence that a difference may exist between blinded and unblinded reviews, the differences demonstrate little consistency in direction of bias or its magnitude.[28]

The reviewers included one clinician (CM) as well as a non-clinician methodologist (CH). The reviewers' scores were assessed for consistency with the Intraclass Correlation Coefficient. The standard error of the mean of the difference scores was calculated to determine the absolute level of difference between the reviewers' scores.

Evidence tables were constructed to include author(s), year of publication, study duration, sample size, headache type (as well as use of IHS classification) and a review of the outcome of the trial, specifically whether a positive or negative result was obtained when comparing the experimental to the comparative or control treatment(s). No statistical pooling was attempted.

The quality review protocol contains eighteen items answered by 'yes, no, don't know' scores. The latter two response categories were collapsed, making the scoring dichotomous. No weighting factor was used. Scores, therefore, range from 0–18, and were converted to percentages for ease of interpretation and reporting. A rating of 0–40% was deemed to indicate 'poor' quality; ratings of 40–60% were deemed 'moderately high' and ratings above 60% were deemed to indicate 'high' quality.

## RESULTS

The MEDLINE search resulted in 444 citations. Three hundred and forty-nine of these were excluded immediately because they were irrelevant to our study, involved migraine headaches or involved studies of behavioural or cognitive-type treatments. Of the remaining 95 citations related to CAM, 73 were not RCTs, giving a total of 22 RCTs. The PsychInfo and CINHAL searches revealed no additional RCTs. Citation searches revealed one additional RCT.[29] One RCT[30] was identified in the recent literature. Five additional reports did not deal directly with clinical outcomes but were investigations of physiological measures,[31–34] or, in one case, did not involve symptomatic subjects.[35] They were excluded from the review.

The 24 studies included in this review were organized into groups according to the primary modality of treatment. This was straightforward for studies involving acupuncture, spinal manipulation and homeopathy. The category of 'physiotherapy' was less straightforward. Studies investigating electrical

1 randomized controlled trial.pt.
2 controlled clinical trial.pt.
3 randomized controlled trials.sh.
4 random allocation.sh.
5 double blind method.sh.
6 single blind method.sh.
7 1 or 2 or 3 or 4 or 5 or 6
8 (animal not human).sh.
9 7 not 8
10 clinical trial.pt.
11 exp clinical trials/
12 (clin$ adj25 trial$).ti,ab.
13 ((singl$or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
14 placebos.sh.
15 placebo$.ti,ab.
16 random$.ti,ab.
17 research design.sh.
18 of/10–17
19 18 not 8
20 19 not 9
21 comparative study.sh.
22 exp evaluation studies/
23 follow up studies.sh.
24 prospective studies.sh.
25 (control$ or prospective$ or volunteer$).ti,ab.
26 or/21–25
27 26 not 8
28 26 not (9 or 20)
29 9 or 20 or 28
30 exp headache/
31 headache.ti,ab.
32 headache/ci
33 30 or 31
34 33 not 32
35 exp alternative medicine/
36 exp plants, medicinal/
37 exp plant oils/
38 exp plant extracts/
39 exp formularies, homeopathic/
40 ((complementary or unconventional or folk or alternative) adj25 (med$ or ther$ or treat$ or care)).ti,ab.
41 exp holistic health/
42 exp physical therapy/
43 (physical ther$ or physiother$).ti,ab.
44 exp osteopathy/or exp osteopathic medicine/
45 (chiropract$ or naturopath$ or osteopath$ or homeopath$ or acupunct$).ti,ab.
46 or/35–45
47 29 and 34 and 46
48 limit 47 to english language
49 47 not 48

**Fig. 2** MEDLINE search strategy

therapies alone and as the primary modality were placed in the 'electrotherapy' category. Studies included in the 'physiotherapy' category, involved multiple modalities, including electrotherapy in some. Table 1 gives the breakdown of number of RCTs by treatment category. The largest group involved studies of acupuncture, with no other group having more than five distinct trials. In the manipulation group, one of the trials was reported twice, with different sample sizes. We conducted

**Table 1 RCTs by type of treatment**

| Treatment | # of studies |
|---|---|
| Acupuncture | 8 |
| Manipulation | 6 |
| Electrotherapy | 4 |
| Physiotherapy | 3 |
| Massage | 1 |
| Homeopathy | 1 |
| Other | 1 |
| Total | 24 |

quality reviews on each of these reports separately.

Twenty-two of the trials involved tension headache subjects. Only two reports (one trial)[36,37] involved CH. Only one study involved post-traumatic headache (PTTH) subjects.[38] Subjects in these three trials received spinal manipulation as compared to soft tissue therapy (for the CH trials) or ice therapy (in the PTTH trial).

The quality raters' scores achieved a reliability coefficient of 0.72 ($P$ = 0.0015). Scores were not statistically significantly different from one another ($t = -1.5$, $P = 0.14$) and the 95% CI of the mean difference between scores was 1.9–0.3. Given this level of consistency, we averaged the two raters' scores for a final trial quality score.

## Quality reviews

### Acupuncture trials

The quality scores for the eight acupuncture trials ranged from 44 to 69, with an average score of 58 and a median of 61. The quality scores for the four high quality trials ranged from 61 to 69%. These trials were published during 1979–1996. The total number of subjects reported in these trials is 99, with an average of about 25 subjects per trial. Three of these trials[29,39,40] were sham-controlled, with an average treatment duration of 52.5 days. The other trial,[41] compared acupuncture to physiotherapy. Tavola et al.[40] reported a 'negative' outcome, in that the acupuncture treatment was no better than the placebo, while Ahonen et al.[41] reported significant improvement in the acupuncture and physiotherapy groups, with no difference between the two groups. Two trials[29,39] reported a significant difference favouring acupuncture over sham placebo with regard to the frequency of headaches, but these two trials have a combined total of 39 subjects, thus precluding any definitive conclusions.

The quality scores for the other four trials ranged from 44 to 50 (moderately high quality).[42–45] They were published from 1984 to 1991. The total number of subjects in these reports was 173, with an average of 43 per trial. Only one of these studies was sham-controlled,[44] while one used a no-treatment control.[45] The average duration of treatment was 99 days. Three of these studies reported a positive benefit in that acupuncture was shown to be better than sham-control for frequency,[44] better than no-treatment control[45] and better than medication.[43] On the other hand, Johansson et al.[45] did not demonstrate differences between acupuncture and an occlusal splint for TMJ-related tension headache and Carlsson et al.[42] reported that subjects receiving physiotherapy obtained greater benefit than acupuncture.

In summary, (see Tables 2 and 3) the total number of TTH subjects reported in the literature receiving acupuncture is 264. The treatment durations of these studies range from 6 to 12 weeks. Five (63%) of these studies were controlled (4/5 employed sham controls). Two of four higher quality studies reported negative results, although, with the small sample sizes in all of these trials, the likelihood of a type II error is quite high. Acupuncture has been shown in at least one study (low quality) to be more beneficial than medication over a 3 month period, and equivalent to an occlusal splint in the treatment of TMJ-related tension-type headache. Acupuncture does not appear to be more effective than a course of physiotherapy.

### Spinal manipulation trials

Three RCTs of spinal manipulation for TTH,[30,46,47] two for cervicogenic headache[36,37] and one for 'post-traumatic headache'[38] were identified. The quality scores ranged from 56–80%, with a mean score of 67.5%.

Table 4 reviews these trials. No trial included an exclusively sham or placebo-type control group, so that the 'efficacy' of spinal manipulation treatment cannot yet be determined. With respect to determining the effectiveness of spinal manipulation, comparative treatments include soft-tissue mobilization,[46] resting briefly,[46] ice pack,[38] amitriptyline[47] and soft tissue therapy.[30,36,37] A total of 286 subjects were included in these reports.

There is some inconsistency with regard to the diagnostic classifications used in these studies. The report by Hoyt et al.[46] involved a single manipulative session provided to nine subjects with a concurrent 'muscle contraction' headache (versus 13 other control subjects). Jensen et al.'s[38] study was conducted on a small group of subjects with 'post-traumatic headache'. Boline et al.'s[47] and Bove and Nilsson's[30] studies were the only ones to explicitly include 'tension-type headache' according to the IHS criteria.[9] The former study included a 6 week intervention phase and a 4 week follow-up, while the latter study involved 4 weeks of treatments with no follow-up phase. Nilsson's study[36,37] was conducted on subjects with cervicogenic headache.

As no high quality studies exist which employed an exclusive placebo or sham-control group, the efficacy of SMT for TTH or CH cannot be determined. Four high quality studies do exist which compare SMT to other forms of therapy, although two of them have relatively small sample sizes. Three of these studies report a benefit of SMT.

**Table 2 Evidence table for high quality acupuncture studies**

| Authors | Headache type | Sample size | Study duration | Treatment groups (*n*) | Results | Side effects | Quality scores |
|---|---|---|---|---|---|---|---|
| Tavola et al., 1992[40] | tension-type headache (IHS) | 30 | 60 days | (1) ACUP = 15<br>(2) SHAM = 15 | *Pre-Post Tx reduction F*<br>(1) 44.3%<br>(2) 21.4%<br>NS<br>*Pre-Post Tx* reduction S<br>(1) 58.3%<br>(2) 27.8%<br>NS<br>*Post-Tx F* | Not mentioned | 69 |
| White et al., 1996[29] | episodic tension-type headache (IHS) | 10 (pilot study) | 45 days | (1) ACUP = 4<br>(2) SHAM = 5 | (1) 9/28 weeks HA-free<br>(2) 3/36 weeks HA-free<br>*Pre-Tx F:* | None | 69 |
| Borglum-Jensen et al., 1979[39] | not specified (non-migraine) | 29 | 60 days | (1) ACUP = 19<br>(2) SHAM = 10 | (1) 34.6 (17) /60 days<br>(2) 26.9 (16)<br>*Post-Tx F:*<br>(1) 25.7 (17)<br>(2) 23 (15)<br>$P < 0.05$<br>*Pre-Tx F:* | None | 64 |
| Ahonen et al., 1984[41] | 'myogenic headache' | 22 | 30 days | (1) ACUP = 12<br>(2) SHAM = 10 | (1) (2)<br>daily 6 5<br>>1/week 6 4<br>1/week 0 1<br><3 month 0 0<br>*Post-Tx F:*<br>(1) (2)<br>daily 5 3<br>> 1/week 2 5<br>1/week 3 1<br><3/month 2 1<br>NS | Not mentioned | 61 |
| Totals or average | | 91 | 48 days | | | | 66 |

(*n*) = sample size in each treatment group; (*IHS*) = inclusion based on criteria of the International Headache Society Classification.[9] Treatment types: ACUP = acupuncture; SHAM = sham placebo treatment; SPLINT = occlusal splint; CONTR = no-treatment control; P/T = physical therapy or physiotherapy; MEDS = medication; MANIP = chiropractic spinal manipulation; STT = soft tissue therapy; AMIT = amitriptyline; RELAX = relaxation therapy; TENS = transcutaneous electrical nerve stimulation; ELEC. STIM. = electrical stimulation; LO- = low level; BIOF = biofeedback; ATTEN. = attention control. Outcomes *Tx* = treatment; *HA* = headache; *S* = severity; *F* = frequency; *mm* = millimetres on a visual analogue scale; severity: Global relief: *mod* = moderate; *sev* = severe; *v. sev.* = very severe Frequency: *sev* = several, *hi* = high; *mod* = moderate; *min* = minimal; *improv.* = improvement; ≥ = statistically significantly better than; = means: not statistically significantly better than. *NS* = not significant; * = 0.05; ** = 0.01; *** = 0.001.

In these studies SMT is more effective than ice pack applications and soft tissue therapy in post-traumatic and CH. SMT appears to be as effective as amitriptyline in producing short-term benefit for TTH; however, there may be a longer term benefit with SMT once the treatments are withdrawn. In one study, the addition of SMT to a group already receiving therapeutic levels of deep massage did not improve outcomes in TTH sufferers beyond the level obtained by a group receiving the massage and a placebo treatment. This study is the only one to report no additional benefit from SMT.

## Electrotherapy studies

Four RCTs were obtained which investigated electrotherapy as the sole modality. Three studied transcutaneous electrical nerve stimulation (TENS) and one used a form of 'cranial electrotherapy'. The latter study and two of the TENS studies[48-50] were placebo-controlled, while the other study[51] compared TENS to relaxation therapy, biofeedback and a combination of all three treatments. The quality scores for these studies ranged from 39 to 61%, with an average score of 50%. Only one study achieved a rating which would qualify it as of 'high' quality.[48] The studies by Reich[51] and Solomon et al.[48] included both tension-type and migraine sufferers, while the studies by Airaksinen and Pontinen[49] and Solomon and Guglielmo[50] involved only tension-type headache. Airaksinen and Pontinen[49] investigated the short-term changes in pressure pain threshold at 'trigger points' in TTH sufferers

**Table 3 Evidence table for lower quality acupuncture studies**

| Authors | Headache type | Sample size | Study duration | Treatment groups (*n*) | Results | Side effects | Quality scores |
|---|---|---|---|---|---|---|---|
| Hansen and Hansen 1985[44] | chronic tension headaches | 18 | 105 days (crossover) | (1) ACUP = 9<br>(2) SHAM = 9 | *Pre-TX F*[1]:<br>(1) = 42.2<br>(2) = 40.7<br>*Post-Tx F*:<br>(6 weeks)<br>(1) = 26.4*<br>(2) = 35.2<br>*Post-Tx F*:<br>(12 weeks[2])<br>(1) = 30.1<br>(2) = 30.9*<br>1 = primary measure is period index<br>2 = groups crossed-over | 1 subject had aggravation of pain from needling | 50 |
| Johansson et al., 1991[45] | muscle tension headache | 45 | 120 days | (1) ACUP = 15<br>(2) SPLINT = 15<br>(3) CONTR = 15 | *Pre-Tx S*:<br>(1) 52 mm<br>(2) 55 mm<br>(3) 50 mm<br>*Post-Tx S*:<br>(1) 27 mm*<br>(2) 29 mm<br>(3) 56 mm<br>NS between (1) and (2) | Not mentioned | 50 |
| Carlsson et al., 1990[42] | chronic tension-type HA (IHS) | 62 | 60–90 days | (1) ACUP = 23<br>(2) P/T = 29 | *Pre-Tx S*:<br>(%) (1) (2)<br>none 3 0<br>mild 3 3<br>mod. 17 29<br>sev. 59 58<br>v. sev. 17 10<br>*Post-Tx S*:<br>(%) (1) (2)<br>none 9 7<br>mild 9 38<br>mod. 39 41<br>sev. 35 14<br>v. sev. 9 0<br>* ***<br>*Pre-Tx F*:<br>(%) (1) (2)<br>none 0 0<br>1–2/months 7 0<br>1/week 7 7<br>sev/week 31 36<br>daily 55 58<br>*Post-Tx F*:<br>(%) (1) (2)<br>none 0 0<br>1–2/months 22 17<br>1/week 26 38<br>sev/week 3 14<br>daily 39 31<br>** *** | None | 50 |
| Loh et al., 1984[43] | 'muscle tension' = 7<br>migraine = 31<br>mixed = 10 | 48 | 120 days | (1) ACUP = 41<br>(2) MEDS = 36 | (1) improvement level:<br>great = 9/41<br>mod = 7/41<br>slight = 8/41<br>none = 17/41<br>(2) improvement level:<br>great = 3/36<br>mod = 1/36<br>slight = 5/36<br>none = 27/36<br>(Subjects may have received both Txs in series) | Not mentioned | 44 |
| Total or average | | 173 | 105 days | | | | 48 |

(*n*) = sample size in each treatment group; (*IHS*) = inclusion based on criteria of the International Headache Society Classification.[9] Treatment types: ACUP = acupuncture; SHAM = sham placebo treatment; SPLINT = occlusal splint; CONTR = no-treatment control; P/T = physical therapy or physiotherapy; MEDS = medication; MANIP = chiropractic spinal manipulation; STT = soft tissue therapy; AMIT = amitriptyline; RELAX = relaxation therapy; TENS = transcutaneous electrical nerve stimulation; ELEC. STIM. = electrical stimulation; LO- = low level; BIOF = biofeedback; ATTEN. = attention control. Outcomes *Tx* = treatment; *HA* = headache; *S* = severity; *F* = frequency; *mm* = millimetres on a visual analogue scale; severity: Global relief: *mod* = moderate; *sev* = severe; *v. sev.* = very severe Frequency: *sev* = several, *hi* = high; *mod* = moderate; *min* = minimal; *improv.* = improvement; ≥ = statistically significantly better than; = means: not statistically significantly better than. *NS* = not significant; * = 0.05; ** = 0.01; *** = 0.001.

**Table 4 Evidence table for spinal manipulation studies**

| Authors | Headache type | Sample size | Number of TXs | Treatment groups (*n*) | Results | Side effects | Quality scores |
|---|---|---|---|---|---|---|---|
| Hoyt et al., 1979[46] | 'muscle contraction' | 22 | 1 | (1) MANIP = 10<br>(2) MOB = 6<br>(3) REST = 6 | *Post-TX S:*<br>(1) –48%***<br>(2) 0<br>(3) 0 | Not mentioned | 56 |
| Jensen et al., 1981[38] | post-traumatic | 19 | 2 | (1) MANIP = 10<br>(2) ICE = 9 | *Post-Tx S:*<br>(1) –30.7/100 **<br>(2) + 6.7/100 | Not mentioned | 60 |
| Nilsson 1995[36] | cervicogenic | 39 | 6 | (1) MANIP = 20<br>(2) STT = 19 | *Post-Tx F:*<br>(1) – 3.4 (–59%)<br>(2) –2.1 (–45%)<br>*Post-Tx S:*<br>(1) –15 (–45%)<br>(2) –10 (–24%) | Not mentioned | 64 |
| Nilsson 1997[37] | cervicogenic | 53 | 6 | (1) MANIP = 28<br>(2) STT = 25 | *Post-Tx F:*<br>(1) –3.2* (–69%)<br>(2) –1.6 (–37%)<br>*Post-Tx S:*<br>(1) –17* (–36%)<br>(2) –4.2 (–17%) | Not mentioned | 72 |
| Boline et al., 1995[42] | tension-type headache (IHS) | 126 | 12 | (1) MANIP = 70<br>(2) AMIT = 56<br>(2) +5.0 | *Post-Tx F:*<br>(1) –3.8/28<br>(2) –4.0/28<br>*Follow-up F:*<br>(1) –1.0**<br>(2) 82.1%<br>*Post-Tx S:*<br>(1) –1.3/20<br>(2) –1.8/20**<br>*Follow-up S:*<br>(1) –.5**<br>(2) +2.0 | (1) 4.3% neck stiffness<br>(2) 82.1% dry mouth, drowsy, or weight gain | 75 |
| Bove and Nilsson, 1998[30] | tension-type headache (IHS) | 75 | 8 | (1) MANIP + STT = 38<br>(2) SHAM + STT = 37 | *Post-Tx F:*<br>(1) –1.5 hours<br>(2) –1.9 hours<br>*Post-Tx S:*<br>(1) No change<br>(2) No change | Not mentioned | 80 |
| Total or average | | 286 | 6 | | | | 68 |

(*n*) = sample size in each treatment group; (*IHS*) = inclusion based on criteria of the International Headache Society Classification.[9] Treatment types: ACUP = acupuncture; SHAM = sham placebo treatment; SPLINT = occlusal splint; CONTR = no-treatment control; P/T = physical therapy or physiotherapy; MEDS = medication; MANIP = chiropractic spinal manipulation; STT = soft tissue therapy; AMIT = amitriptyline; RELAX = relaxation therapy; TENS = transcutaneous electrical nerve stimulation; ELEC. STIM. = electrical stimulation; LO- = low level; BIOF = biofeedback; ATTEN. = attention control. Outcomes *Tx* = treatment; *HA* = headache; *S* = severity; *F* = frequency; *mm* = millimetres on a visual analogue scale; severity: Global relief: *mod* = moderate; *sev* = severe; *v. sev.* = very severe Frequency: *sev* = several, *hi* = high; *mod* = moderate; *min* = minimal; *improv.* = improvement; ≥ = statistically significantly better than; = means: not statistically significantly better than. *NS* = not significant; * = 0.05; ** = 0.01; *** = 0.001.

(presumably as a measure of pain relief for concurrent headache), while the other three studies investigated the prophylactic benefit of a series or programme of treatments. A total of 507 tension headache subjects were included in these four studies (see Table 5).

At least one high quality RCT and two others of moderately high quality demonstrate that electrotherapy is more efficacious than placebo in the treatment of TTH. One moderately high quality study demonstrated that TENS is at least as effective as other cognitive/behavioural therapies in

**Table 5 Evidence table for electrotherapy studies**

| Authors | Headache type | Sample size | Study duration | Treatment groups (*n*) | Results | Side effects | Quality scores |
|---|---|---|---|---|---|---|---|
| Reich, 1989[51] | muscle contraction headache<br><br>(migraine also included but not analyzed here) | 331 | at least 15 weeks TX, 36 months follow-up | (1) RELAX<br>(2) TENS<br>(3) BIOF<br>(4) COMB | *Post-Tx S:*<br>(At discharge)<br>(1) –1.5/5<br>(2) –2.1/5<br>(3) –2.4/5 ***<br>(4) –2.1/5<br>*Post-Tx F:*<br>(At discharge)<br>(1) –20 hours<br>(2) –22 hours<br>(3) –30 hour ***<br>(4) –22 hours | Not mentioned | 44 |
| Solomon et al., 1989 [48] | tension headache | 100 | 6–10 weeks | (1) CRANIAL ELEC. STIM = 50<br><br>(2) SHAM = 50 | *Post-Tx S:*<br>(1) –2.1 (35%)*<br>(2) –1.2 (18%)<br>*Global relief:* (%)<br>(1) (2)<br>hi 12 4<br>mod 24 12<br>min 26 20<br>none 38 63<br>** | (1) 10.5%<br>(2) 12.7%<br>most frequency = irritation at electrode site | 61 |
| Airaksinen and Pontinen, 1992[49] | chronic tension headache | 14 (self-control) | 1 week, 2 sessions | (1) ELEC. STIM.<br><br>= 14<br>(2) SHAM = 14 | *Pre-Post Pressure Thresholds:* (kgs)<br>(1) pre = 2.83 (0.16)<br>post = 3.46 (0.21)<br>(2) pre = 3.34 (0.2)<br>post = 3.48 (2.1) | Not mentioned | 39 |
| Solomon and Guglielmo, 1985[50] | migraine = 21<br>muscle contraction = 33<br>combined = 8 | 62 | one treatment | (1) ACTIVE TENS = 18<br>(2) LO-TENS = 18<br>(3) SHAM = 22 | *Percent showing* clinically significant improvement (Muscle contraction headache)<br>(1) = 55%<br>(2) & (3) = 10% | Not mentioned | 56 |
| Total or Average | | 507 | | | | | 50 |

(*n*) = sample size in each treatment group; (*IHS*) = inclusion based on criteria of the International Headache Society Classification.[9] Treatment types: ACUP = acupuncture; SHAM = sham placebo treatment; SPLINT = occlusal splint; CONTR = no-treatment control; P/T = physical therapy or physiotherapy; MEDS = medication; MANIP = chiropractic spinal manipulation; STT = soft tissue therapy; AMIT = amitriptyline; RELAX = relaxation therapy; TENS = transcutaneous electrical nerve stimulation; ELEC. STIM. = electrical stimulation; LO- = low level; BIOF = biofeedback; ATTEN. = attention control. Outcomes *Tx* = treatment; *HA* = headache; *S* = severity; *F* = frequency; *mm* = millimetres on a visual analogue scale; severity: Global relief: *mod* = moderate; *sev* = severe; *v. sev.* = very severe Frequency: *sev* = several, *hi* = high; *mod* = moderate; *min* = minimal; *improv.* = improvement; ≥ = statistically significantly better than; = means: not statistically significantly better than. *NS* = not significant; * = 0.05; ** = 0.01; *** = 0.001.

reducing headache activity, although patient variables such as the duration of headache complaint and the number of treatments rendered have an impact on individual patient response.

## Physiotherapy trials

Three RCTs were identified involving multimodality physiotherapy treatment programmes. The quality scores for these trials ranged from 33 to 58% (low-to-moderately-high quality). The study with the highest rating (Carlsson et al.[52]) compared physiotherapy treatment to acupuncture. In this trial, 'physiotherapy' consisted of a variety of patient-initiated modalities, including relaxation techniques, stretching, TENS and ice therapy, as well as education regarding muscle tension and how to control it

**Table 6 Evidence table for physiotherapy studies**

| Authors | Headache type | Sample size | Study duration | Treatment groups (*n*) | Results | Side effects | Quality scores |
|---|---|---|---|---|---|---|---|
| Carlsson et al., 1990[33] | chronic tension headache | 62 | 60–90 days | (1) P/T = 29<br>(2) ACUP = 23 | *Post-Tx F:*<br>(1) reduced, $P<0.001$<br>(2) reduced, $P < 0.01$<br>*Post-Tx S:*<br>(1) –25 mm @ 4–9 weeks + 1 mm @ 7–12 months ***<br>(2) –1 mm @ 4–9 weeks + 12 mm @ 7–12 months | Not mentioned | 58 |
| Marcus et al., 1995[54] | migraine = 36%<br>tension = 28%<br>combined= 36%<br>(IHS) | 25 | 60 days | (1) P/T +BIOF = 11<br>(2) ATTEN CONTROL = 14 | *Post-Tx F:*<br>(1) –8.3 days<br>(2) –2.7 days (sig. ?)<br>*Post-Tx S:*<br>(2) –88.2%<br>(2) –32.7%<br>*Subjects with significant change:*<br>(1) 73%<br>(2) 27% | Not mentioned | 55 |
| Jay et al., 1988[53] | chronic muscle contraction headache | 60 | 90 days' Tx<br>90 days' follow-up | (1) MEDS + BIOF<br>(2) + P/T + TENS<br>(3) + P/T ONLY | *Post-Tx S:*<br>*WK* (1)(2)(3)<br>1 26 33 24<br>5 14 1.74.3<br>8 3 1 1.9<br>(2) and (3) > (1)<br>(2) = (3) | Not mentioned | 33 |
| Total or average | | 147 | 80 days | | | | 47 |

(*n*) = sample size in each treatment group; (*IHS*) = inclusion based on criteria of the International Headache Society Classification.[9] Treatment types: ACUP = acupuncture; SHAM = sham placebo treatment; SPLINT = occlusal splint; CONTR = no-treatment control; P/T = physical therapy or physiotherapy; MEDS = medication; MANIP = chiropractic spinal manipulation; STT = soft tissue therapy; AMIT = amitriptyline; RELAX = relaxation therapy; TENS = transcutaneous electrical nerve stimulation; ELEC. STIM. = electrical stimulation; LO- = low level; BIOF = biofeedback; ATTEN. = attention control. Outcomes *Tx* = treatment; *HA* = headache; *S* = severity; *F* = frequency; *mm* = millimetres on a visual analogue scale; severity: Global relief: *mod* = moderate; *sev* = severe; *v. sev.* = very severe Frequency: *sev* = several, *hi* = high; *mod* = moderate; *min* = minimal; *improv.* = improvement; ≥ = statistically significantly better than; = means: not statistically significantly better than. *NS* = not significant; * = 0.05; ** = 0.01; *** = 0.001.

'autogenically'. Both treatments produced positive benefit in mood state and overall health function as well as in the intensity and frequency of headaches. Physiotherapy produced greater gains in mood state and in reduced headache intensity.

In both other studies,[53,54] the physiotherapy modalities employed included TENS, heat, massage and ultrasound therapy to the painful areas, trigger point therapy, exercise therapies, biofeedback and education. In Jay et al.'s study[53] all subjects received amitriptyline medication. They reported that subjects receiving the additional physiotherapy treatments fared better than those receiving only the medication. Only the study by Marcus et al.[54] employed a control procedure consisting of education and 'skin-cooling' biofeedback. They reported that the combined physiotherapy group 'was more likely to experience significant headache relief' than the attention control group (72.7 vs 28.6%, $P<.03$).

In all three studies (see Table 6) various combinations of these 'physiotherapeutic' and 'cognitive/behavioural' therapies (as well as medications, in one study) were employed, making the determination of the effect of each of these components impossible. A total of 147 subjects were included in these three studies (two additional reports by Carlsson et al.[33,34] were on the same group of subjects and were excluded from this review).

The evidence from the three studies on TENS adds to the evidence of the studies reviewed above under 'electrotherapy'. There are no high quality studies to support the efficacy of any other form of 'physiotherapy' in the treatment of TTH. There is

**Table 7 Percentage of trials with deficiencies (based on reviewer agreement) (modified from van Tulder et al.[26])**

| Item | Per cent of trials |
|---|---|
| Eligibility criteria specified | 0 |
| Random allocation | 4 |
| Groups similar at baseline | 25 |
| Interventions explicitly described | 4 |
| Provider blinded | 50 |
| Co-interventions described and limited | 29 |
| Compliance monitored | 25 |
| Patient blinded | 24 |
| Assessor blinded | 8 |
| Outcome measures relevant | 4 |
| Adverse effects monitored | 33 |
| Drop-out rate described and acceptable | 25 |
| Short-term follow-up | 0 |
| Long-term follow-up | 42 |
| Timing of outcome assessments | 4 |
| Sample size described | 4 |
| Intention-to-treat | 58 |
| Point estimates and measure of dispersion | 8 |

some lower quality evidence supporting the effectiveness of combined physiotherapy regimens in treating TTH.

### Massage trials

No RCT was found on the effects of manual massage as the primary therapy for non-migrainous headache. The study by Bove and Nilsson[30] employed deep muscular massage to the trapezius and sub-occipital region as a control treatment. Subjects in both groups received this therapy, while they were randomly allocated to *additionally* receive spinal manipulation or sham treatment. As such, no randomized comparison of massage alone versus another treatment has been reported.

### Homeopathy trials

Only one RCT was identified for homeopathic treatments of TTH. Walach et al.[55] reported on 98 subjects, about half of whom had chronic tension-type headaches and were randomly allocated to receive either an individualized homeopathic remedy or an inert, indistinguishable placebo for 12 weeks. This trial achieved a quality score of 86%, which was the highest in our series, chiefly as a result of the high methodologic rigour which included an appropriate sample size and double-blinded, placebo controls. This trial reported no difference between the two groups on any important clinical variables related to headache activity.

### Other remedies

One clinical trial was retrieved which investigated the use of an analgesic/counter-irritant ointment ('Tiger Balm') in the treatment of tension headache.[56] This study achieved a high quality rating of 72%. Fifty-seven tension headache subjects were randomly allocated to receive Tiger Balm, topical placebo or paracetamol (1000 mg dose) as a treatment for a concurrent headache. Both Tiger Balm and paracetamol produced greater pain relief than placebo in a single headache episode ($P < 0.05$) for up to 3 hours, with no difference between these two.

One study was found on the effects of 'therapeutic touch' on TTH[57] which achieved a quality score of 47%. The therapeutic benefit is purported to derive from the 'therapeutic intent' of the therapist. No manual contact is applied in this therapy. This trial involved the application of either true or 'placebo' therapeutic touch to 60 randomly allocated tension headache subjects who were experiencing a headache concurrently. Subjects in the 'experimental group' obtained twice as much pain relief as those in the control group immediately and 4 hours after the 5 minute intervention.

## Methodological aspects of the reviewed studies

Table 7 presents the results of the quality ratings per item of the rating checklist, based upon agreement between raters for 'no' or 'don't know'. Those items scoring higher than 30% represent critical deficiencies in this body of studies, most of which relate to internal validity.

# DISCUSSION

CAM therapies for non-migrainous headache appear to operate within several intersecting theoretical models. The more general of these involves the amelioration of pain states by activation of putative endogenous anti-nociceptive processes.[58–60] The mechanism by which these therapies may work could be described as 'systemic', and could include acupuncture and homoeopathy, as well as some of the relaxation techniques employed within 'physiotherapy'. These latter therapies are consistent with cognitive and behavioural therapies which have demonstrated effectiveness.[8,19,21,22]

A second mechanism appears to involve treatments targeted at the cervical spine or cranial muscles as putative sources of headache pain. The notion that headache pain may arise from the cervical spine is generally well accepted today, based upon the work of Kerr,[15] Sjaastad et al.[10,11] and Bogduk et al.[61–65] This work has contributed to the acceptance of a category of headache known as 'cervicogenic'.[9] The degree to which problems in the cervical spine may contribute to tension-type headache is still unresolved, from both theoretical and nosological perspectives. Cervical musculo-ligamentous dysfunction has been demonstrated in tension-type headache sufferers.[66] Despite the controversy, spinal manipulation, mobilization, massage, electrotherapy and other 'physiotherapeutic'

procedures such as exercise and postural education, target the soft tissues of cervical spine and craniocervical junction which may be producing referred head pain.

The other regional mechanism involves therapies directed to the cranial area, including electrotherapy to cranial skin and muscles as well as topical creams applied to the cranial skin, the purpose of which is to reduce local pain and muscle spasm.

These latter two mechanisms may be described as 'local' and appear to involve either the amelioration of possible referred cranial pain from cervical sources or the reduction of local cranial pain by counterirritation. In addition, these therapies might theoretically exert a relaxant effect on local musculature.

The findings of our review demonstrate that RCTs of CAM therapies for non-migrainous headache do exist, and that some of them have been conducted and reported at a sufficiently high level of rigour. There are some who claim that it is not possible to investigate the benefit of CAM therapies with RCTs, in that, in requiring an appropriate level of standardization and methodological rigour, compromises to the treatment context which may invalidate the results obtained are created.[20] While this may be true to some extent, it would appear that this is not an absolute circumstance. In fact, several of the trials have successfully incorporated sham/placebo treatments in order to investigate the efficacy of the primary treatment.

It has also been shown that investigators in these areas can develop well-designed, high-quality studies and recruit appropriately large samples of subjects interested in participating. As this development evolves, the database of outcomes for at least some of these treatment approaches should become large enough to conduct meta-analyses so that more robust evidence-based decisions can be made by practitioners.

It is noteworthy that one therapy, electrotherapy to cranial muscles, would appear to have sufficient strength of evidence to support its use in treating TTH. Additionally, for another therapy, homeopathy, there is at least one high-quality trial whose results might recommend against its use in TTH. For the other therapeutic modalities, the evidence base either contains too few trials or contains trials resulting in contradictory findings which preclude any definitive summary.

The methodological deficiencies cited in Table 7 indicate the areas where future clinical trials should be improved. Careful selection of headache subjects according to explicit inclusion and exclusion criteria following the IHS classification guidelines[9] should be employed. Provider and subject blinding may be difficult to achieve in studies of some CAM treatments, but every effort should be made to blind the treatment allocation from all parties not directly involved in the treatment, particularly the assessors. The issue of long-term follow-up must be dealt with in future trials in order to establish the true value of these treatments to society at large and their impact on the health-care system.

## CONCLUSION

We have reported on 24 published RCTs of acupuncture, spinal manipulative therapy, electrotherapy, physiotherapy, massage, homeopathy and 'other therapies' for non-migrainous headache.

Pooling of trial data would be the most desirable representation of the evidence; however, the small number of trials in each category, as well as the variability in outcome measures in the trials, precluded this type of analysis at present.

Quality issues that require attention in further trials include: similarly of groups at baseline, description of co-interventions, compliance monitoring, subject blinding (where possible), monitoring of adverse effects, describing drop-outs, long-term follow-up and intention-to-treat analysis.

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