

VU Research Portal

Noninvasive physical treatments for chronic recurrent headache (Cochrane Review)

Bronfort, G.; Nielsen, N.; de Haas, M.; Evans, R.; Goldsmith, C.; Assendelft, W.J.J.; Bouter, L.M.

published in

Cochrane Library
2009

DOI (link to publisher)

[10.1002/14651858.CD001878.pub2](https://doi.org/10.1002/14651858.CD001878.pub2)

document version

Publisher's PDF, also known as Version of record

[Link to publication in VU Research Portal](#)

citation for published version (APA)

Bronfort, G., Nielsen, N., de Haas, M., Evans, R., Goldsmith, C., Assendelft, W. J. J., & Bouter, L. M. (2009). Noninvasive physical treatments for chronic recurrent headache (Cochrane Review). *Cochrane Library*, 2004(3). <https://doi.org/10.1002/14651858.CD001878.pub2>

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

E-mail address:

vuresearchportal.ub@vu.nl

Non-invasive physical treatments for chronic/recurrent headache (Review)

Brønfort G, Nilsson N, Haas M, Evans RL, Goldsmith CH, Assendelft WJJ, Bouter LM



**THE COCHRANE
COLLABORATION®**

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2009, Issue 1

<http://www.thecochranelibrary.com>



TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	2
OBJECTIVES	3
METHODS	3
RESULTS	7
DISCUSSION	15
AUTHORS' CONCLUSIONS	16
ACKNOWLEDGEMENTS	17
REFERENCES	18
CHARACTERISTICS OF STUDIES	22
DATA AND ANALYSES	40
ADDITIONAL TABLES	40
APPENDICES	65
WHAT'S NEW	67
HISTORY	67
DECLARATIONS OF INTEREST	67
SOURCES OF SUPPORT	67
INDEX TERMS	67

[Intervention Review]

Non-invasive physical treatments for chronic/recurrent headache

Gert Brønfort¹, Niels Nilsson², Mitchell Haas³, Roni L Evans¹, Charles H Goldsmith⁴, Willem JJ Assendelft⁵, Lex M Bouter⁶

¹Wolfe-Harris Center for Clinical Studies, Northwestern Health Sciences University, Bloomington, MN, USA. ²Center for Biomechanics, Odense University, Odense M, Denmark. ³Center for Outcomes Studies, Western States Chiropractic College, Portland, OR, USA. ⁴Department of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, Canada. ⁵Department of Public Health and Primary Care, Leiden University Medical Centre, Leiden, Netherlands. ⁶Executive Board of VU University Amsterdam, Amsterdam, Netherlands

Contact address: Gert Brønfort, Wolfe-Harris Center for Clinical Studies, Northwestern Health Sciences University, 2501 West 84th Street, Bloomington, MN, 55431, USA. gbronfort@nwhealth.edu.

Editorial group: Cochrane Pain, Palliative and Supportive Care Group.

Publication status and date: Edited (no change to conclusions), published in Issue 1, 2009.

Review content assessed as up-to-date: 14 November 2002.

Citation: Brønfort G, Nilsson N, Haas M, Evans RL, Goldsmith CH, Assendelft WJJ, Bouter LM. Non-invasive physical treatments for chronic/recurrent headache. *Cochrane Database of Systematic Reviews* 2004, Issue 3. Art. No.: CD001878. DOI: 10.1002/14651858.CD001878.pub2.

Copyright © 2009 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Non-invasive physical treatments are often used to treat common types of chronic/recurrent headache.

Objectives

To quantify and compare the magnitude of short- and long-term effects of non-invasive physical treatments for chronic/recurrent headaches.

Search strategy

We searched the following databases from their inception to November 2002: MEDLINE, EMBASE, BIOSIS, CINAHL, Science Citation Index, Dissertation Abstracts, CENTRAL, and the Specialised Register of the Cochrane Pain, Palliative Care and Supportive Care review group. Selected complementary medicine reference systems were searched as well. We also performed citation tracking and hand searching of potentially relevant journals.

Selection criteria

We included randomized and quasi-randomized controlled trials comparing non-invasive physical treatments for chronic/recurrent headaches to any type of control.

Data collection and analysis

Two independent reviewers abstracted trial information and scored trials for methodological quality. Outcomes data were standardized into percentage point and effect size scores wherever possible. The strength of the evidence of effectiveness was assessed using pre-specified rules.

Main results

Twenty-two studies with a total of 2628 patients (age 12 to 78 years) met the inclusion criteria. Five types of headache were studied: migraine, tension-type, cervicogenic, a mix of migraine and tension-type, and post-traumatic headache. Ten studies had methodological quality scores of 50 or more (out of a possible 100 points), but many limitations were identified. We were unable to pool data because of study heterogeneity.

For the prophylactic treatment of migraine headache, there is evidence that spinal manipulation may be an effective treatment option with a short-term effect similar to that of a commonly used, effective drug (amitriptyline). Other possible treatment options with weaker evidence of effectiveness are pulsating electromagnetic fields and a combination of transcutaneous electrical nerve stimulation [TENS] and electrical neurotransmitter modulation.

For the prophylactic treatment of chronic tension-type headache, amitriptyline is more effective than spinal manipulation during treatment. However, spinal manipulation is superior in the short term after cessation of both treatments. Other possible treatment options with weaker evidence of effectiveness are therapeutic touch; cranial electrotherapy; a combination of TENS and electrical neurotransmitter modulation; and a regimen of auto-massage, TENS, and stretching. For episodic tension-type headache, there is evidence that adding spinal manipulation to massage is not effective.

For the prophylactic treatment of cervicogenic headache, there is evidence that both neck exercise (low-intensity endurance training) and spinal manipulation are effective in the short and long term when compared to no treatment. There is also evidence that spinal manipulation is effective in the short term when compared to massage or placebo spinal manipulation, and weaker evidence when compared to spinal mobilization.

There is weaker evidence that spinal mobilization is more effective in the short term than cold packs in the treatment of post-traumatic headache.

Authors' conclusions

A few non-invasive physical treatments may be effective as prophylactic treatments for chronic/recurrent headaches. Based on trial results, these treatments appear to be associated with little risk of serious adverse effects. The clinical effectiveness and cost-effectiveness of non-invasive physical treatments require further research using scientifically rigorous methods. The heterogeneity of the studies included in this review means that the results of a few additional high-quality trials in the future could easily change the conclusions of our review.

PLAIN LANGUAGE SUMMARY

Non-invasive physical treatments for chronic/recurrent headaches

Various physical treatments are often used instead of, or in addition to, medications to treat headaches. Evidence from controlled trials suggests that several non-invasive physical treatments may help prevent chronic/recurrent headaches. Spinal manipulation may be effective for migraine and chronic tension-type headache. Both spinal manipulation and neck exercises may be effective for cervicogenic headache. Weaker evidence suggests that other treatments may also be effective: pulsating electromagnetic fields and transcutaneous electrical nerve stimulation (TENS) for migraine, and therapeutic touch, cranial electrotherapy, TENS, and a combination of self-massage/TENS/stretching for tension-type headache. Although none of these treatments has conclusive evidence for effectiveness, all appear to be associated with little risk of serious adverse effects.

BACKGROUND

Headache is an extremely common complaint in the industrialized world, with a 1-day prevalence in the general population of approximately 16% (Rasmussen 1991). Migraine affects 10% to 12%

of the population annually (Stewart 1992), while tension-type headache affects over 38% (Schwartz 1998). Although headache is normally a benign disorder and most cases are moderate or mild,

the human and socioeconomic impact is considerable due to lost work days and days with reduced work efficiency (Pryse-Phillips 1992; Schwartz 1998). The financial cost of headaches is huge. It is estimated that 57% of headache-related lost work days in the US are attributable to migraines, while 43% are due to tension-type and other headaches (Schwartz 1997). Migraine alone costs American employers about US\$13 billion per year because of missed workdays and impaired work function (Hu 1999).

There are several headache treatment approaches. Often, headaches are treated pharmacologically, but many patients also receive various forms of physical treatment (Eisenberg 1998; Rasmussen 1992). Physical treatments include massage, trigger point therapy, reflexology, spinal manipulation, therapeutic heat or cold, and exercise therapy, among others. Several systematic reviews have assessed the effectiveness of different forms of physical treatments for chronic/recurrent headache (Bronfort 2001; Gross 2002; Holroyd 1990; Hurwitz 1996; Klawansky 1995; McCrory 2001; Melchart 2001; Vernon 1999). These reviews address different types of therapies and headaches and, consequently, come to somewhat different conclusions. This makes it difficult for health-care providers to make up-to-date evidence-based decisions regarding which physical treatments to consider. This Cochrane review updates one of the above-mentioned systematic reviews (Bronfort 2001) and represents the most comprehensive evaluation to date of the evidence regarding the efficacy of physical treatments for all types of headaches.

OBJECTIVES

The objectives of the review were to quantify and compare the magnitude of short- and long-term effects of specific non-invasive physical treatments for chronic/recurrent headaches classified according to the International Headache Society (IHS) diagnostic criteria (IHS 1988). The levels of evidence in support of these treatments were determined based on pre-specified rules.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) and quasi-randomized studies (e.g., allocation by date of birth, hospital record number, or alternation). RCTs and quasi-randomized studies were analyzed separately. Study reports could be in any language.

Types of participants

We included persons of any age with chronic/recurrent headaches including, but not limited to, episodic and chronic tension-type headache, cluster headache, cervicogenic headache, and migraine, classified according to the IHS criteria (IHS 1988). Some studies were anticipated to pre-date or not adhere to the 1988 IHS classification system.

Types of interventions

Included studies had to assess the effect of one or more types of non-invasive physical treatments. These included, but were not limited to, therapeutic heat or cold; traction; electrical modalities, such as transcutaneous electrical nerve stimulation (TENS), interferential therapy, electromagnetic therapy, microcurrent, ultrasound, and laser; exercise; spinal manipulation or mobilization; massage; reflexology; stretching; and trigger-point therapy. Acupuncture and psychological interventions such as biofeedback and relaxation were excluded. A separate Cochrane review has been devoted to acupuncture (Melchart 2001), and psychological interventions will be addressed in future reviews (see, e.g., Nicholson 2004). These treatments were, however, included as comparison therapies in studies that also featured non-invasive physical treatments. In general, acceptable comparator groups included placebo, no treatment (e.g., wait-list control), and any other type of active intervention.

Types of outcome measures

The trials must have reported on at least one patient-rated outcome measure such as headache pain intensity, headache index, frequency, duration, improvement, analgesic use, activities of daily living, quality of life, functional health status, or patient satisfaction. Data on costs and side effects of treatment, if available, were reported in the review.

Search methods for identification of studies

We identified studies by a comprehensive computerized search of MEDLINE (January 1966 to November 2002), EMBASE (January 1974 to November 2002), BIOSIS (January 1996 to November 2002), CINAHL (January 1980 to November 2002), Science Citation Index (January 1974 to December 1990), Dissertation Abstracts (July 1980 to November 2002), the Cochrane Central Register of Controlled Trials (CENTRAL; Issue 3, 2002), and the Specialised Register of the Cochrane Pain, Palliative Care and Supportive Care Collaborative Review Group (2002). Additionally, studies were identified through complementary medicine reference systems such as Chirofars/MANTIS (March 1992 to November 2002), the Index to Chiropractic Literature (ICL; January 1985 to November 2002), and the Chiropractic Research

Archives/Abstracts Collection (CRAC; January 1984 to December 1990). Finally, we performed citation tracking; hand searched non-indexed physical therapy, chiropractic, osteopathic, and manual medicine journals; hand searched non-indexed dissertations; and examined references found in relevant publications.

In MEDLINE, a published search strategy for identifying RCTs (Dickersin 1994) was applied in combination with specific search terms, without language restriction. The full MEDLINE search strategy, which was adapted for use in the other electronic databases, is provided in [Appendix 1](#).

Data collection and analysis

Study identification

The two main reviewers (GB and NN) independently selected trials to be included in the review based on the explicit search strategy. The reviewers were too familiar with the relevant RCTs to conduct blinded reviews. Differences in the results of selection were resolved by discussion between the two reviewers; a third reviewer (WJJA or LMB) was consulted if disagreements could not be resolved. Articles were initially selected on the basis of the abstracts; if a determination could not be made based on the abstracts, the full articles were retrieved.

Data extraction

Explicit information about patient demographics, type of headache, clinical characteristics, interventions, and outcome measures were recorded using standardized abstracting forms. Two non-blinded reviewers (NN and GB) independently extracted and recorded relevant data from each article. All original data on outcomes were standardized into percentage point and effect size (ES) scores whenever possible. Efforts were made to contact authors if there was uncertainty about important aspects of methods or data in the published report.

Categorization of short- and long-term outcomes

Short-term follow up was defined as outcomes evaluated up to 3 months after the initial study treatment. Long-term follow up was defined as outcomes evaluated more than 3 months after onset of study therapy.

Assessment of methodological quality

The methodological scoring of the trials was performed by two reviewers independently (NN and GB). In addition to the short methodological quality checklist developed by Jadad et al (Jadad 1996), we used a critical evaluation list of 20 methodological items and their operational definitions to assess methodological quality.

This list (see below for the operational definitions used) represents a modification of previously used instruments (Assendelft 1996a; Koes 1991). Fourteen of the items were used to compute a validity score, and six related to descriptive information. The validity items included assessment of study group comparability at baseline, adequacy of randomization process, reliability and validity of outcome measures, blinding of patients and treatment providers, bias in measurement of outcomes, attention bias, definition of tested hypothesis, impact of dropouts and missing data, intention-to-treat analysis, and adjustments for number of statistical tests used. Differences in scores were resolved by discussion between the two reviewers (NN and GB); a third reviewer was consulted if disagreements could not be resolved.

The critical evaluation list contains 20 methodological items (A-T), of which 14 (B-G, J, L-N, P-S) have been classified as internal validity (V) items and six (A, H, I, K, O, and T) as informativeness (I) items. The following is a description of each item in the list, accompanied by operational definitions, where needed.

Scoring: A 'YES' score (+) is used only when all described individual item criteria are met. 'NO' (-) is used only when it is clear from the article that none of the described individual item criteria are met. 'UNCLEAR/PARTLY' (p) is used when the documentation or description is insufficient to answer 'YES' or 'NO' as to whether any or all of the described individual item criteria are met. If an item did not apply, it was scored 'NOT APPLICABLE' (na). The validity score (VS) was derived by dividing 100 by the number of applicable validity items (maximum of 14).

A. Are the inclusion and exclusion criteria clearly defined? (I-item)

YES: Inclusion and exclusion criteria are stated explicitly.

UNCLEAR/PARTLY: Inclusion and/or exclusion criteria are not clearly defined.

NO: Inclusion/exclusion criteria are not described.

B. Is it established that the groups are comparable at baseline, or if different, are appropriate adjustments made during the statistical analysis? (V-item)

YES: Comparability is established by tabulating important predictor variables, including baseline value of main outcome, demographic variables, duration and severity of condition, and other known prognostic indicators such as patient expectations. If comparability is not established, then analysis of co-variance or equivalent is used.

UNCLEAR/PARTLY: Baseline comparability is established for some, but not all, of the important predictor variables.

NO: Baseline comparability is not established and appropriate statistical adjustments are not made.

C. Is the randomization procedure adequately described and appropriate? (V-item)

YES: The randomization process is described (e.g., randomly generated list, opaque envelopes), the method used (simple, block, stratification, minimization, etc.) is appropriate, and allocation concealment is established explicitly.

UNCLEAR/PARTLY: One or two of the aforementioned three

criteria are met.

NO: Information given indicates that randomization was used, but none of the aforementioned three criteria are met.

D. Is it established that at least one main outcome measure was relevant to the condition under study, and were adequate reliability and validity established? (V-item)

YES: At least one of the primary outcomes is patient-oriented (e.g., pain, functional disability), and its reliability and validity documented or generally accepted.

UNCLEAR/PARTLY: Documentation of reliability or validity are absent for an outcome measure that is not generally accepted.

NO: Neither relevance, reliability, nor validity is established.

E. Are patients blinded to the degree possible, and did the blinding procedure work? (V-item)

YES: Optimal blinding is used and effectiveness of the blinding procedure is documented.

UNCLEAR/PARTLY: Either optimal blinding or effectiveness of blinding is not documented.

NO: Neither optimal blinding nor its effectiveness is documented.

NOT APPLICABLE: Trial may not be blinding (e.g., a comparison of a drug and a physical treatment).

F. Is it established that treatment providers were blinded to the degree possible, and did the blinding procedure work? (V-item)

YES: Optimal blinding is used and effectiveness of the blinding procedure is documented.

UNCLEAR/PARTLY: Either optimal blinding or effectiveness of blinding is not documented.

NO: Neither optimal blinding or effectiveness of blinding is documented.

NOT APPLICABLE: Trial may not be blinding (e.g., a comparison of a drug and a physical treatment).

G. Is it established that assessment of the primary outcomes was unbiased? (V-item)

YES: Subjects were not influenced by study personnel. It is established that assessors were blinded, when relevant.

UNCLEAR/PARTLY: Unclear or no documentation of unbiased assessment of outcomes.

NO: It is established or highly likely that patients were influenced by providers or investigators on how they scored their own outcomes, or it is not established that an assessor was blinded when applicable.

H. Is the post-intervention follow-up period adequate and consistent with the nature of the condition under study? (I-item)

YES: Minimal acceptable post-intervention follow-up period for acute conditions is 1 month and for chronic conditions 3 months.

UNCLEAR/PARTLY: A minimum of 2 weeks post-intervention follow-up period for acute conditions and 1 month for chronic conditions.

NO: Shorter than 2 weeks post-intervention follow-up period for acute conditions and 1 month for chronic conditions.

NOT APPLICABLE: May not apply to study (e.g., crossover designs)

I. Are the interventions described adequately? (I-item)

YES: All interventions follow a defined protocol. It is possible from the description in the article or reference to prescribe or apply the same treatment in a clinical setting.

UNCLEAR/PARTLY: Unclear or incomplete description of one or more of the interventions.

NO: Very inadequate or no description of one or more of the interventions.

J. Were differences in attention bias between groups controlled for and explicitly described? (V-item)

YES: Documentation that time, provider enthusiasm, and number of intervention sessions are equivalent among study groups.

UNCLEAR/PARTLY: No documentation that time, provider enthusiasm, and number of intervention sessions are equivalent among study groups.

NO: Evidence that time, provider enthusiasm, and number of intervention sessions are clearly not equivalent among study groups.

NOT APPLICABLE: Pragmatic trials.

K. Is comparison made to existing efficacious or commonly practiced treatment options? (I-item)

YES: Comparison is made to existing efficacious or commonly practiced treatment options.

UNCLEAR/PARTLY: Equivocal information.

NO: Comparison is not made to existing efficacious or commonly practiced treatment options.

NOT APPLICABLE: Placebo-controlled and non-management trials.

L. Is the primary study objective (hypothesis) clearly defined a priori in terms of group contrasts, outcomes, and time points? (V-item)

YES: The primary study objective (hypothesis) is clearly defined a priori in terms of group contrasts, outcomes, and time points.

UNCLEAR/PARTLY: The primary study objective (hypothesis) is only partially defined a priori. Information is lacking about either group contrasts, outcomes, or time points.

NO: The primary study objective (hypothesis) is not defined a priori in terms of either group contrasts, outcomes, or time points.

M. Is the choice of statistical tests of the main results appropriate? (V-item)

YES: The main analysis is consistent with the design and the type of the outcome variables used.

UNCLEAR/PARTLY: The main analysis is not clearly described or only partially consistent with the design and the type of the outcome variables used.

NO: The main analysis is clearly inconsistent with the design and/or the type of the outcome variables used.

N. Is it established at randomization that there is adequate statistical power ($1 - \beta = 0.8$, with $\alpha = 0.05$) to detect an a priori determined clinically important between-group difference of the primary outcomes, including adjustment for multiple tests and/or outcome measures? (V-item)

YES: Adequate statistical power documented.

NO: No documentation of adequate statistical power.

O. Are confidence intervals or data allowing confidence intervals to be calculated presented? (I-item)

YES: Confidence intervals are presented or can be calculated.

UNCLEAR/PARTLY: Confidence intervals are presented or can be calculated for only some of the main outcomes.

NO: Confidence intervals are not presented and cannot be calculated from available data.

P. Are all dropouts described for each study group separately and accounted for in the analysis of the main outcomes? (V-item)

YES: Analysis of impact of dropouts or worst-/best-case analysis reported.

UNCLEAR/PARTLY: Incomplete analysis of impact of dropouts.

NO : Analysis of impact of dropouts not performed or reported.

NOT APPLICABLE: Dropout rate less than 5%.

Q. Are all missing data described for each study group separately and accounted for in the analysis of the main outcomes? (V-item)

YES: Analysis of impact of missing data reported.

UNCLEAR/PARTLY: Incomplete analysis of impact of missing data.

NO: Analysis of impact of missing data not performed or reported.

NOT APPLICABLE: Missing data less than 5%.

R. If indicated, was intention-to-treat analysis used? (V-item)

YES: All patient data analyzed according to group or initial random allocation. In studies with documented full compliance with allocated treatments and no differential co-intervention between groups, a YES score can apply.

UNCLEAR/PARTLY: Unclear from article whether intention-to-treat analysis was used and how.

NO: No intention-to-treat analysis used when applicable.

NOT APPLICABLE: Single-session studies (e.g., studies with one intervention and outcomes collected in same session).

S. Were adjustments made for the number of statistical tests (two or more) when establishing a cut-off point for p-level for each test? (V-item)

YES: Appropriate adjustments made (e.g., Bonferroni's or similar type of adjustment).

UNCLEAR/PARTLY: Insufficient adjustment or lack of adequate information about adjustment.

NO: Adjustments were indicated but not performed.

NOT APPLICABLE: Indicated adjustments were incapable of changing main result/outcome of study, or study involved only one test at one time point.

T. Are the main study conclusions valid? (I-item)

YES: A priori testable hypotheses are tested and prioritized appropriately in the conclusions.

UNCLEAR/PARTLY: A priori testable hypotheses are only partially tested and/or prioritized appropriately in the conclusions.

NO: A priori testable hypotheses are not tested and prioritized appropriately in the conclusions.

Quantitative analysis of trial results

Statistical pooling was planned in the case of two or more studies with comparable interventions, study groups (including headache type), and outcomes. The pooling methods chosen were fixed or random effects models as indicated, with effect sizes (ESs) in the form of weighted mean differences (WMDs) as the effect measure. It was further planned for the point estimates and 95% confidence intervals of each trial to be plotted, for statistical homogeneity to be tested, and for potential sources of variation to be examined in the case of strong statistical evidence of heterogeneity ($p < 0.1$).

Effect sizes between the non-invasive physical treatment groups and the comparison groups were calculated for the end of the treatment intervention phase and at the main post-treatment follow up. ESs were computed as described by Cohen (Cohen 1988) and Glass (Glass 1981): difference in treatment and control group means divided by the pooled standard deviation. In the absence of these statistics, ESs were calculated from T-scores, and F-values and confidence intervals, provided sample sizes were given (Friedman 1968; Glass 1981). ESs for differences in proportions were estimated using probit transformation (Friedman 1968). Correction for ES estimate bias associated with small sample sizes ($n < 50$) was accomplished using the method described by Hedges and Olkin (Hedges 1985). If confidence intervals could not be directly calculated for ESs, they were estimated using p-values and sample sizes (Hedges 1985).

Outcome scales were normalized to a 100-percentage-point scale. The percentage point difference was computed as the between-group mean difference.

Regardless of the degree of statistical heterogeneity, the impact of specific differences among trials was examined. Subgroup analyses were planned for (a) trials comparing non-invasive physical treatments with other conservative types of treatment; and (b) trials comparing different types of non-invasive physical treatments, by type of headache.

Levels of evidence

The criteria we used to determine the level of evidence of efficacy were adapted from those developed by the US Agency for Health Care Policy and Research panel that evaluated the efficacy of various treatments for acute low back pain (Bigos 1994). Our system evaluated the evidence taking into account: (a) type of comparison therapy; (b) methodological quality (validity scores); (c) the number of studies; (d) ES magnitude; and (e) statistical significance or ES confidence limits (95% confidence intervals). Table 1 provides detailed definitions of the five levels of evidence and the terms efficacy, inefficacy, superiority, inferiority, similarity, and equivalence. The terms 'superior' and 'inferior' always indicate efficacy/inefficacy. Similarity to an efficacious treatment indicates efficacy. Similarity to a placebo, no treatment, or a component of a combination therapy indicates inefficacy. No conclusion about

efficacy can be reached for the case of similarity to a treatment of currently unknown efficacy.

We defined the five levels of evidence as follows:

- Strong: Two or more high-quality studies (VS = 50 or higher); evidence of superiority, inferiority, or similarity; and statistical significance or appropriate confidence limits.
- Moderate: One high-quality study (VS = 50 or higher); evidence of superiority, inferiority, or similarity; and statistical significance or appropriate confidence limits.
- Limited: At least one lower-quality study (VS < 50); evidence of superiority, inferiority, or similarity; and statistical significance or appropriate confidence limits.
- Preliminary: Study findings did not meet the criteria for strong, moderate, or limited because of considerations of statistical significance or confidence limits.
- Conflicting: Findings among studies that could be pooled were inconsistent.

We recognize the arbitrariness of using a particular magnitude of ES in the determination of levels of evidence, because there is no consensus on what constitutes a clinically important difference between treatment options. We address the ES cutpoint issue in a sensitivity analysis below. All eligible RCTs were considered regardless of their results.

Statistical pooling of two or more trials was considered if they were homogeneous in terms of patient population, interventions, outcomes, and follow-up time points. For determination of the outcome of each RCT, we considered patient-rated pain intensity or the headache index as the primary outcome. We considered frequency, duration, headache improvement, and medication use the most important secondary outcomes.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Thirty-six original trials assessing non-invasive physical treatments were identified by our literature search. Fourteen were excluded for various reasons (see 'Characteristics of excluded studies' table). Twenty-two studies with a total of 2628 patients (age 12 to 78 years) met the inclusion criteria for this review. One was classified as a quasi-randomized trial ([Tuchin 2000](#)); the remaining 21 were RCTs. The included trials assessed five categories of headache: migraine, tension-type, cervicogenic, mixed migraine and tension-type, and post-traumatic. It was not possible to map the trials in the last two categories to any of the International Headache Society (IHS) diagnoses ([IHS 1988](#)). Ten studies used the IHS criteria for diagnosis and classification ([Boline 1995](#); [Bove 1998](#);

[Jull 2002](#); [Marcus 1998](#); [Nelson 1998](#); [Nilsson 1997](#); [Sherman 1998](#); [Sherman 1999](#); [Tuchin 2000](#); [Whittingham 1997](#)). The non-invasive physical treatments evaluated included spinal manipulation, mobilization, massage, therapeutic touch, therapeutic exercise, cold packs, and electrical modalities (including pulsating electromagnetic fields [PEMF], cranial electrotherapy, interferential therapy, transcutaneous electrical nerve stimulation [TENS], and ultrasound), and different combinations of physical treatments. Comparison groups included other non-invasive treatments, treatments excluded from this review (acupuncture, rest, relaxation, and biofeedback), medication, placebo, wait-list, and no-treatment control. The main outcome measures abstracted from the studies were headache pain intensity, headache frequency, headache hours, headache duration, medication use, and improvement. Follow-up periods varied from immediately post-treatment to 36 months post-treatment. We attempted to contact the authors of four RCTs to acquire additional data for analysis. We were successful in obtaining such data in two cases ([Tuchin 2000](#); [Whittingham 1997](#)); however, we were unsuccessful in contacting the authors in the other two cases ([Parker 1980](#); [Reich 1989](#)).

Seven trials (total n = 1593) assessed four types of non-invasive physical treatments for migraine headache: spinal manipulation ([Nelson 1998](#); [Parker 1980](#); [Tuchin 2000](#)), physical treatment combinations ([Marcus 1998](#)), TENS ([Reich 1989](#)), and pulsating electromagnetic fields (PEMF) ([Sherman 1998](#); [Sherman 1999](#)). Four to 16 treatments were given over a period of 2 to 8 weeks. One study did not specify the number of treatments or the treatment period ([Reich 1989](#)).

Eight trials (total n = 1504) assessed five types of non-invasive physical treatments for tension-type headache: spinal manipulation ([Boline 1995](#); [Bove 1998](#); [Hoyt 1979](#)), physical treatment combinations ([Ahonen 1984](#); [Carlsson 1990](#)), cranial electrotherapy ([Solomon 1989](#)), a combination of TENS and electrical neurotransmitter modulation ([Reich 1989](#)), and therapeutic touch ([Keller 1986](#)). One to 12 treatments were performed over 1 to 6 weeks. ([Reich 1989](#) did not specify the number of treatments or the treatment period.)

Six trials (total n = 461) assessed five types of non-invasive physical treatments for cervicogenic headache: spinal manipulation ([Ammer 1990](#); [Howe 1983](#); [Jull 2002](#); [Nilsson 1997](#); [Whittingham 1997](#)), massage ([Nilsson 1997](#)), exercise therapy ([Jull 2002](#)), mobilization ([Bitterli 1977](#)), and physical treatment combinations ([Ammer 1990](#); [Jull 2002](#)). One to 12 treatments were provided over a period of 1 to 6 weeks.

Two trials (total n = 85) assessed two types of non-invasive physical treatments for headaches that could not be classified according to IHS categories. One trial assessed post-traumatic headache ([Jensen 1990](#)) and compared mobilization to cold packs. Two treatments

were given over 2 weeks. One trial assessed mixed headache (migraine/tension-type) (Solomon 1985) and compared cranial electrotherapy to placebo immediately after one treatment.

Risk of bias in included studies

The two methodological quality scores are reported for each study in Table 2 (A-H), Table 3 (J-P), and Table 4 (R-Z). Limitations of individual higher-quality trials (validity score = 40 or more) are described below, under 'Results'.

Effects of interventions

Results are organized by headache type. The study design, interventions, outcome measures, and results, as reported by study investigators, are described for each study in the 'Characteristics of included studies' table. We used these data to calculate effect sizes and percentage point differences for the purpose of this review. Summaries of effect sizes and percentage point differences for the various treatment comparisons and outcomes are provided in Table 5 through Table 6 (according to headache type). A positive effect size favors the treatment group over the comparison group. In the following discussion of individual studies, results for the primary systematic review outcomes (headache pain and/or headache index) are described first for each study, followed by results for secondary outcomes. Effect sizes (ESs) and 95% confidence intervals (CIs) are also reported.

In many cases, even relatively high-quality trials (validity score = 40 or more) had limitations that may affect the interpretation of study results; these limitations are discussed below. Studies with lower quality scores are acknowledged as having substantial limitations, which are specifically described in Table 2 through Table 4.

Migraine headache (IHS category 1)

See Table 5 for a summary of treatment comparisons and results for migraine headache.

Spinal manipulation therapy

Three trials evaluated the effect of spinal manipulation therapy (SMT): Nelson 1998 (n = 218, validity score [VS] = 91), Parker 1980 (n = 88, VS = 67), and Tuchin 2000 (n = 127, VS = 38). Nelson 1998 (n = 218, VS = 91) compared SMT to the commonly used and efficacious drug amitriptyline (Bank 1994); the same study also compared a combination of SMT plus amitriptyline to amitriptyline alone. The 8 weeks of treatment consisted of 14 sessions of SMT and/or 100 mg of amitriptyline per day. Our analysis showed similar reductions in headache index (ES -0.1; 95% CI -0.5 to 0.3) and pain medication use (ES -0.2; 95% CI -0.6 to 0.2) in the SMT and amitriptyline groups during the last 4 weeks of treatment. However, during the 4-week post-treatment period, patients in the SMT group recorded a significantly greater

reduction in headache index than patients in the amitriptyline group (ES 0.4; 95% CI 0.0 to 0.8); pain medication use was again similar in the two groups (ES 0.2; 95% CI -0.2 to 0.6). The combination of SMT plus amitriptyline was no better than amitriptyline alone for headache index or medication use at either time point (see Table 5 for effect sizes).

This study had several limitations that may affect the interpretation of these findings. One concern is the substantial loss of patients to follow up (28%). The missing data analysis performed may not have fully compensated for the loss of data. Moreover, the withdrawal of amitriptyline at the end of treatment in this study is inconsistent with normal clinical practice, and the return of the amitriptyline patients to near baseline values on the main outcomes at 4 weeks post-treatment could be due to a medication rebound effect, making the apparent advantage of the SMT group less obvious. Similarly, this may explain why the SMT plus amitriptyline combination therapy did not outperform amitriptyline alone.

In Parker 1980 (n = 88, VS = 67), SMT provided by chiropractors was compared to (a) SMT provided by medical doctors or physical therapists and (b) mobilization provided by medical doctors or physical therapists. Treatment was provided in up to two sessions per week for 8 weeks. At 8 weeks post-treatment, we found that

SMT provided by chiropractors was more favorable than mobilization for headache pain intensity (ES 0.4; 95% CI -0.2 to 1.0), but not for disability, duration, or frequency (ES for all three outcomes 0.1; 95% CI -0.5 to 0.7).

There was no description of dropouts in this study, and there is substantial uncertainty about the data integrity and statistical analysis, so the likelihood of bias is an issue. We were unable to access the original data. Based on the magnitude of the group difference, the chiropractic SMT group appeared to be superior to the medical doctors/physical therapist SMT group on pain intensity, but no F-ratios were presented. When the authors combined data from the two SMT groups, the effect was similar to the mobilization group on all outcomes (based on imputed effect sizes from F-ratios). There was inadequate statistical power to detect a clinically important effect size. The data provided did not allow us to calculate ESs for the comparison of the two SMT groups with one another, or for the comparison of SMT provided by medical doctors/physical therapists with mobilization by medical doctors/physical therapists.

[Tuchin 2000](#) (n = 127, VS = 38) compared SMT with detuned interferential therapy (placebo electrotherapy). Patients received SMT up to 16 times over 8 weeks; frequency of placebo therapy was unspecified. There was no statistically significant difference between SMT and placebo for headache pain at 8 weeks post-treatment (ES -0.4; 95% CI -0.8 to 0.1). However, SMT resulted in statistically significant lower headache frequency (ES 0.5; 95% CI 0.1 to 0.9), duration (ES 0.5; 95% CI 0.1 to 0.9), and medication use (ES 0.6; 95% CI 0.3 to 1.0).

The three studies were too dissimilar for their results to be pooled. Summary of levels of evidence:

- There is preliminary evidence that SMT and amitriptyline have a similar effect in reducing headache index during 8 weeks of treatment, and moderate evidence that SMT is superior to amitriptyline for the same outcome during the 4-week post-treatment period. There is preliminary evidence that the treatments result in similar reduction of non-prescription pain medication use at both time points (evidence from one trial: [Nelson 1998](#)).
- There is preliminary evidence that SMT plus amitriptyline is at best similar to amitriptyline alone (evidence of inefficacy) for headache index and pain medication use at both time points (evidence from one trial: [Nelson 1998](#)).
- There is preliminary evidence that SMT is superior to mobilization for pain, and that the interventions are similar for disability, frequency, and duration at 8 weeks post-treatment. However, the efficacy of mobilization is unknown (evidence from one trial: [Parker 1980](#)).
- There is limited evidence that SMT is at best similar to sham interferential therapy (evidence of inefficacy) for reducing headache intensity at 2 months post-treatment, and limited evidence that SMT is superior to the sham therapy for reducing headache frequency, duration, and non-prescription pain

medication use at the same time point (evidence from one trial: [Tuchin 2000](#)).

Pulsating electromagnetic fields

Two trials evaluated the effect of pulsating electromagnetic fields (PEMF): [Sherman 1998](#) (n = 12, VS = 50) and [Sherman 1999](#) (n = 48, VS = 39).

[Sherman 1998](#) (n = 12, VS = 50) compared PEMF to placebo PEMF using a crossover trial design. Each 2-week treatment period consisted of ten 1-hour sessions during which the interventions were applied to the medial thigh. Patients who received PEMF experienced a greater reduction in the number of headaches per week after 2 weeks of treatment than patients who received placebo PEMF (ES 1.1; 95% CI -0.2 to 2.3).

This small pilot study had 12 participants, of which three patients in the PEMF group inadvertently received treatments at half the intended intensity. This study was intended only to provide information about the feasibility of performing an adequately powered trial.

In a subsequent larger study ([Sherman 1999](#); n = 48, VS = 39), the same group of investigators compared PEMF to placebo PEMF using a parallel-group design. Each 2-week treatment period consisted of ten 1-hour sessions during which the interventions were applied to the medial thigh. The PEMF group experienced a significantly greater decrease in headache activity index scores than did the placebo PEMF group at 1 month post-treatment (ES 0.9; 95% CI 0.2 to 1.5).

The two studies were too dissimilar for their results to be pooled. Summary of levels of evidence:

- There is preliminary evidence that PEMF is superior to placebo PEMF in reducing headache frequency after 2 weeks of treatment (evidence from one trial: [Sherman 1998](#)).
- There is limited evidence that PEMF is superior to placebo PEMF on the headache activity score at 1 month post-treatment (evidence from one trial: [Sherman 1999](#)).

Physical treatment combinations

Two trials evaluated physical treatment combinations: [Marcus 1998](#) (n = 88, VS = 33) and [Reich 1989](#) (n = 392, VS = 29).

[Marcus 1998](#) (n = 88, VS = 33) compared a combination of home exercise, stretching, and heat/ice to biofeedback/relaxation. The 4-week treatment schedule included a home regimen twice per day and weekly 1-hour treatment sessions with a therapist. Significantly fewer patients in the home exercise, stretching, and heat/ice group experienced a 50% reduction in headache index score (mean headache severity over 2 weeks) compared to the relaxation and biofeedback group following 4 weeks of treatment (ES -0.8; 95% CI -1.3 to -0.3). The mean reduction in the headache index score from baseline was also significantly less for the home exercise, stretching, and heat/ice group (ES -0.6; 95% CI -1.1 to -0.1).

[Reich 1989](#) (n = 392, VS = 29) compared electrical modalities

including TENS and electrical neurotransmitter modulation to relaxation, biofeedback, and an unspecified combination of two of these three treatments. Treatment lasted 4 weeks. It is unclear how many treatments were provided on average. It appears that some patients got fewer than and some more than 15 treatment sessions. Follow up was after 4 weeks of treatment and 36 months later. Effect sizes could not be calculated from the data. However, group differences in percentage points suggest that a combination of TENS and electrical neurotransmitter modulation is inferior to biofeedback and superior to relaxation for reduction of headache pain following 4 weeks of treatment and 36 months later. Using omnibus statistical tests, Reich found significant differences in headache pain and duration between groups, with the relaxation group having the worst and the biofeedback group the best outcomes.

Spinal manipulation therapy

Two trials evaluated spinal manipulation therapy (SMT) for tension-type headache (TTH): [Boline 1995](#) (n = 150, VS = 91) and [Hoyt 1979](#) (n = 22, VS = 44).

[Boline 1995](#) (n = 150, VS = 91) compared SMT to the commonly used efficacious drug amitriptyline ([Holroyd 2001](#)) for chronic TTH. Treatment lasted 6 weeks. The SMT group had two 20-minute sessions per week including SMT, 5 to 10 minutes of moist heat and 2 minutes of light massage. For the amitriptyline group, the medication dosage was 10 mg per day in the first week, 20 mg per day in the second week, and 30 mg per day each week thereafter. At the end of a 6-week treatment period, the SMT group had higher pain intensity (ES -0.4; 95% CI -0.8 to 0.0) but reported fewer side effects. The two therapies were similar for headache frequency (ES -0.3; 95% CI -0.7 to 0.1) and non-prescription medication use (ES -0.2; 95% CI -0.6 to 0.2) at this same time point. However, 4 weeks post-treatment, the SMT group performed significantly better in terms of headache pain intensity (ES 0.6; 95% CI 0.2 to 1.0), frequency (ES 0.5; 95% CI 0.1 to 0.9), and non-prescription medication use (ES 0.5; 95% CI 0.1 to 0.9).

There is a concern with the medication intervention in this trial. The withdrawal of amitriptyline at the end of treatment is inconsistent with normal clinical practice, and the return of these patients to near baseline values at 4 weeks post-treatment could be due to a medication rebound effect, making the reported advantage of the SMT group less valid.

[Hoyt 1979](#) (n = 22, VS = 44) compared SMT to two no-treatment controls (palpation and rest). Each intervention consisted of a single 10-minute session. Significantly more pain reduction was observed in the SMT group than in the other groups immediately following treatment (ES 1.8; 95% CI 0.4 to 3.2 for both comparisons). Since the study assessed only the immediate effects of a single treatment, it provides little information about the role

The two studies were too dissimilar for their results to be pooled. Summary of levels of evidence:

- There is limited evidence that a combination of home exercise, stretching, and heat/ice is inferior to biofeedback/relaxation for reducing pain severity following 4 weeks of treatment (evidence from one trial: [Marcus 1998](#)).
- There is preliminary evidence that a combination of TENS and electrical neurotransmitter modulation is inferior to biofeedback and superior to relaxation for reduction of headache pain after 4 weeks of treatment and 36 months later (evidence from one trial: [Reich 1989](#)).

Tension-type headache (IHS category 2)

See [Table 7](#) for a summary of treatment comparisons and results for tension-type headache.

of SMT in the management of chronic/recurrent headache.

The two studies were too dissimilar for their results to be pooled. Summary of levels of evidence:

- There is moderate evidence that SMT is inferior to amitriptyline for pain intensity during 6 weeks of treatment. There is also preliminary evidence for similarity of the treatments for frequency and non-prescription medication use during treatment. However, for the 4-week post-treatment period, there is moderate evidence showing that SMT is superior to amitriptyline for pain intensity, frequency, and non-prescription pain medication use (evidence from one trial: [Boline 1995](#)).
- There is limited evidence indicating that SMT is superior to no treatment (palpation or rest) for pain reduction immediately after a single treatment (evidence from one trial: [Hoyt 1979](#)).

Cranial electrotherapy

One trial evaluated cranial electrotherapy (CE): [Solomon 1989](#) (n = 112, VS = 42) compared CE to placebo CE. Patients received 20-minute treatments for individual headache episodes using a home headache suppressor unit for 6 to 10 weeks. At the end of this period, participants receiving the active CE had significantly greater improvements in pain intensity than those receiving placebo CE (ES 0.4; 95% CI 0.0 to 0.8).

There is an important limitation. It is uncertain what impact the group differences in important baseline characteristics (e.g., duration in hours of headaches) had on the final outcomes in this trial.

Summary of levels of evidence:

- There is limited evidence showing that CE is superior to a placebo CE for pain intensity after 6 to 10 weeks of treatment (evidence from one trial: [Solomon 1989](#)).

Therapeutic touch

One trial evaluated therapeutic touch: [Keller 1986](#) (n = 60, VS = 50) compared one session of therapeutic touch (intention to heal by near-touching) plus rest and deep breathing to placebo therapeutic touch plus rest and deep breathing. Large and statistically significant lower pain ratings were observed 5 minutes (ES 1.1; 95% CI 0.5 to 1.6) and 4 hours (ES 0.8; 95% CI 0.2 to 1.3) post-treatment in patients receiving therapeutic touch.

Since the study assessed only the effects within hours of the application of a single treatment, it provides little information about the role of this treatment in the management of chronic/recurrent headache. The study was also limited by lack of blinding of the therapist.

Summary of levels of evidence:

- There is moderate evidence that therapeutic touch is superior to placebo therapeutic touch for pain reduction within a few hours of a single treatment (evidence from one trial: [Keller 1986](#)).

Physical treatment combinations

Four trials evaluated physical treatment combinations: [Ahonen 1984](#) (n = 22, VS = 40), [Bove 1998](#) (n = 75, VS = 58), [Carlsson 1990](#) (n = 48, VS = 21), and [Reich 1989](#) (n = 311, VS = 29).

[Ahonen 1984](#) (n = 22, VS = 40) compared a combination of massage, ultrasound, and hot packs to acupuncture. Treatment lasted 3 weeks. The combination therapy group received three sessions of massage and parafango (warm paraffin and mud), followed by five sessions of massage and ultrasound. The acupuncture group received four sessions of care. For pain reduction, the combination therapy was similar to acupuncture at the end of treatment (ES -0.1; 95% CI, -1.0 to 0.8) and 20 weeks later (ES 0.2; 95% CI -0.7 to 1.1); at 8 weeks post-treatment the combination therapy was inferior (ES -0.6; 95% CI -1.5 to 0.3). The group differences were not statistically significant. This study was substantially underpowered, producing highly uncertain results.

[Bove 1998](#) (n = 75, VS = 58) compared a combination of SMT and massage to placebo laser plus massage. The treatment regimen was eight 15-minute sessions over 4 weeks. High-velocity, low-amplitude SMT was administered. Massage consisted of deep friction massage and trigger point therapy to the muscles of the neck and shoulders. For headache intensity, outcomes favored the comparison group, although no significant differences were found at 1 week (ES -0.3; 95% CI -0.8 to 0.2) or 3 months (ES -0.4; 95% CI -0.9 to 0.1) after treatment. There were no notable differences between groups for daily analgesic use or headache hours at the two time points (see [Table 7](#) for ESs).

The authors concluded that SMT alone does not have a positive effect on episodic tension-type headache. By its design, the trial did not assess the isolated effect of SMT; rather, it examined the combined effect of SMT and soft tissue massage. Whether there is an interaction that results from combining SMT with soft tissue massage is unknown. A more appropriate conclusion would

have been that SMT, when combined with soft tissue massage, is no better than soft tissue therapy alone for episodic tension-type headache. This conclusion neither supports nor refutes the efficacy of SMT as a separate therapy.

[Carlsson 1990](#) (n = 48, VS = 21) compared a regimen of relaxation, auto-massage, TENS, and stretching to acupuncture. The regimen group received 10 to 12 sessions given over 8 to 12 weeks, and the acupuncture group received 4 to 10 sessions over 2 to 8 weeks. The combination group experienced significantly less headache pain intensity 4 to 9 weeks post-treatment (ES 0.7; 95% CI 0.1 to 1.3). No significant differences were observed between groups for headache frequency (ES -0.1; 95% CI -0.7 to 0.4).

[Reich 1989](#) (n = 311, VS = 29) compared electrical modalities including TENS and electrical neurotransmitter modulation with relaxation, biofeedback, and an unspecified combination of two of these three treatments. Treatment lasted 4 weeks. It is unclear how many treatments were provided on average. It appears that some patients got fewer than and some more than 15 treatment sessions. Effect sizes could not be calculated from the data. Follow up was after 4 weeks of treatment and 36 months later. Significant differences in headache pain and frequency were noted between groups using omnibus statistical tests, with the relaxation group doing the worst and the biofeedback group doing the best. The biofeedback group had better outcomes than the combination electrical modalities group. The multi-modal group had similar outcomes to the combination group.

The four studies were too dissimilar for their results to be pooled. Summary of levels of evidence:

- There is preliminary evidence that a regimen of massage, ultrasound, and hot packs is similar in effect to acupuncture at the end of 3 weeks of treatment for pain reduction, inferior to acupuncture at 8 weeks, and similar at 20 weeks post-treatment (evidence from one trial: [Ahonen 1984](#)).
- There is moderate evidence showing that SMT added to massage is at most similar in effect to placebo laser added to massage (evidence of inefficacy) for headache intensity 1 week after a 4-week treatment period, and preliminary evidence that the combination of SMT and massage is inferior at 3 months following treatment. There is preliminary evidence of similarity for duration and daily analgesics at the two time points (evidence from one trial: [Bove 1998](#)).
- There is limited evidence that a regimen of auto-massage, TENS, and stretching is superior to acupuncture for pain relief 4 to 9 weeks post-treatment. There is preliminary evidence that the treatments are similar for headache frequency at the same time point (evidence from one trial: [Carlsson 1990](#)).
- There is preliminary evidence that a combination of TENS and electrical neurotransmitter modulation is similar to biofeedback and to relaxation for reduction of headache pain after 4 weeks of treatment. There is preliminary evidence that the combination therapy is inferior to biofeedback and superior to relaxation for pain reduction 36 months later (evidence from one

trial: [Reich 1989](#)).

Cervicogenic headache (IHS category 11.2)

See [Table 8](#) for a summary of treatment comparisons and results for cervicogenic headache.

Spinal manipulation therapy

Five studies evaluated spinal manipulation therapy (SMT) for cervicogenic headache: [Bitterli 1977](#) (n = 30, VS = 29), [Howe 1983](#) (n = 27, VS = 25), [Jull 2002](#) (n = 200, VS = 75), [Nilsson 1997](#) (n = 54, VS = 65), and [Whittingham 1997](#) (n = 105, VS = 54).

[Bitterli 1977](#) (n = 30, VS = 29) compared 3 weeks of SMT, mobilization, and a wait-list control. The SMT group averaged 3.8 sessions and the mobilization group 3.2 sessions. At the end of treatment, patients receiving SMT had greater pain reduction than those receiving mobilization (ES 0.4; 95% CI -0.5 to 1.4) or those put on a wait-list (ES 0.6; 95% CI -0.4 to 1.5). Results were not statistically significant (insufficient power). Three months after treatment, there was no difference between SMT and mobilization (ES -0.1; 95% CI -1.0 to 0.8).

The study by [Howe et al \(Howe 1983\)](#) (n = 27, VS = 25) compared SMT plus NSAIDs to NSAIDs alone for neck-related headache (IHS category 11.2). Treatment was provided for up to 3 weeks, but the number of treatments was not specified. More patients receiving one session of SMT plus NSAIDs reported improvement than those receiving NSAIDs alone (ES 0.5; 95% CI -0.5 to 1.5); this difference was not statistically significant. There were no differences between the two groups after 1 week (ES 0.1; 95% CI -0.9 to 1.1) or 3 weeks of care (ES -0.1; 95% CI -1.1 to 0.9).

[Jull 2002](#) (n = 200, VS = 75) compared 6 weeks of SMT (high- and low-velocity), exercise (endurance, isometric, and stretching), a combination of the two, and a no-treatment control. At 1 week and 12 months post-treatment, the SMT group showed significantly more reduction in pain intensity (ES [with 95% CI] at 1 week 0.7 [0.3 to 1.2]; at 12 months 0.4 [0.0 to 0.8]) and headache frequency (ES 0.7; 95% CI 0.3 to 1.1 at both time points) than the no-treatment control group. SMT performed little better than no treatment in terms of headache duration (see [Table 8](#) for ESs). Compared to exercise, SMT showed similar reductions in pain (ES [with 95% CI] at 1 week -0.1 [-0.5 to 0.3]; at 12 months -0.2 [-0.6 to 0.2]), headache frequency (ES [with 95% CI] at 1 week -0.2 [-0.6 to 0.2]; at 12 months -0.1 [-0.5 to 0.3]), and headache duration (ES [with 95% CI] at 1 week 0.3 [-0.2 to 0.8]; at 12 months 0.1 [-0.3 to 0.5]); these results were not statistically significant.

In this study, numerous statistical tests were performed at several time points without adjustments for the increased likelihood of spurious results.

[Nilsson 1997](#) (n = 54, VS = 65) compared SMT to massage plus placebo laser. There were six sessions of care in 3 weeks. SMT con-

sisted of standard 'diversified' manipulation in the lower cervical region and 'toggle recoil' in the upper region. The massage group received deep friction massage and trigger point therapy. There was a significantly greater decrease in pain intensity (ES 0.6; 95% CI 0.1 to 1.1) and headache hours (ES 0.5; 95% CI 0.0 to 1.0) in the SMT group at 1 week post-treatment. The advantage for SMT in number of pain killers (pills per day) was not significant (ES 0.3; 95% CI -0.2 to 0.8).

This extended trial is unorthodox in that the decision to recruit more patients was made after the original analyses of the data for the purpose of increasing statistical power. No pre-specifications were made regarding separate analyses of the data and no statistical adjustments were made for multiple looks at the data.

[Whittingham 1997](#) (n = 105, VS = 54) compared SMT with placebo SMT. 'Toggle recoil' manipulation was administered to the upper cervical region three times per week for 3 weeks. Placebo manipulation consisted of treatment to the same region with a deactivated mechanical instrument. There were significant differences in favor of SMT after 3 weeks of treatment for pain intensity (ES 2.2; 95% CI 1.7 to 2.7), disability (ES 1.0; 95% CI 0.6 to 1.5), and number of headache locations (ES 1.1; 95% CI 0.7 to 1.5).

This study was designed as a crossover trial, but due to the presence of both carryover and time effects, only the first phase of the trial contributed to the conclusions.

The five studies were too dissimilar for their results to be pooled. Summary of levels of evidence:

- There is preliminary evidence that SMT is superior to mobilization and to a wait-list control for pain reduction after 3 weeks of treatment, and similar to mobilization at 3 months post-treatment (evidence from one trial: [Bitterli 1977](#)).
- There is preliminary evidence that SMT plus NSAIDs is superior to NSAIDs alone for headache improvement after 1 treatment, and similar to NSAIDs at the end of 1 week and 3 weeks of treatment (evidence from one trial: [Howe 1983](#)).
- There is moderate evidence that SMT is superior to no treatment in reducing headache pain and frequency 1 week and 12 months following 6 weeks of treatment. There is also preliminary evidence that SMT is similar to no treatment for headache duration (evidence from one trial: [Jull 2002](#)).
- There is preliminary evidence that SMT is at most similar to exercise for headache pain and frequency. There is moderate evidence showing that SMT is at least similar to exercise for headache duration at both time points (evidence from one trial:

Jull 2002).

- There is moderate evidence showing SMT is superior to massage plus placebo laser for pain and headache hours at 1 week following 3 weeks of care, and SMT is at least similar to massage plus placebo laser for medication use (evidence from one trial: Nilsson 1997).

- There is moderate evidence indicating that SMT is superior to placebo SMT for pain, disability, and number of headache sites after 3 weeks of treatment (evidence from one trial: Whittingham 1997).

Massage

One trial evaluated the effect of massage: Nilsson 1997 (n = 54, VS = 65) compared massage plus placebo laser to SMT. There were six sessions of care in 3 weeks. The massage group received deep friction massage and trigger point therapy. SMT consisted of standard 'diversified' manipulation in the lower cervical region and 'toggle recoil' in the upper region. There was a significantly smaller decrease in pain intensity (ES -0.6; 95% CI -1.1 to -0.1) and headache hours (ES -0.5; 95% CI -1.0 to 0.0) for the massage group at 1 week post-treatment. The difference between groups for number of pain killers (pills per day) was not significant (ES -0.3; 95% CI -0.8 to 0.2).

This extended trial is unorthodox in that the decision to recruit more patients was made after the original analyses of the data for the purpose of increasing statistical power. No pre-specifications were made regarding separate analyses of the data and no statistical adjustments were made for multiple looks at the data.

Summary of levels of evidence:

- There is moderate evidence that massage plus placebo laser is inferior to SMT for pain and headache hours at 1 week following 3 weeks of care. There is also preliminary evidence that the treatments are at most similar for medication use (evidence from one trial: Nilsson 1997).

Exercise therapy

One trial evaluated the effect of exercise therapy (Jull 2002; n = 200, VS = 75). This study compared 6 weeks of exercise therapy (endurance, isometric, and stretching), SMT (high- and low-velocity), a combination of the two, and a no-treatment control. At 1 week and 12 months post-treatment, the exercise group showed significantly greater reductions in pain intensity and headache frequency than did the no-treatment control group. Effect sizes (with 95% CIs) were: for pain intensity at 1 week, 0.8 (0.3 to 1.2); for pain intensity at 12 months, 0.6 (0.2 to 1.0); and for headache frequency, 1.0 (0.5 to 1.4) for both time points. Exercise performed no better than no treatment in terms of headache duration (see Table 8 for ESs). Compared to SMT, exercise showed similar reductions in pain (ES [with 95% CI] at 1 week 0.1 [-0.3 to 0.5]; at 12 months 0.2 [-0.2 to 0.6]), headache frequency (ES [with 95%

CI] at 1 week 0.2 [-0.2 to 0.6]; at 12 months 0.1 [-0.3 to 0.5]), and headache duration (ES [with 95% CI] at 1 week -0.3 [-0.8 to 0.2]; at 12 months -0.1 [-0.5 to 0.3]); these results were not statistically significant.

In this study, numerous statistical tests were performed at several time points without adjustments for the increased likelihood of spurious results.

Summary of levels of evidence:

- There is moderate evidence for short-term and long-term absolute efficacy indicating that exercise is superior to no treatment in reducing headache pain and frequency 1 week and 12 months following 6 weeks of treatment. There is preliminary evidence that exercise is similar to no treatment for headache duration at the two time points (evidence from one trial: Jull 2002).

- There is moderate evidence showing that exercise is at least similar to manipulation for headache pain and frequency 1 week and 12 months following 6 weeks of treatment. There is also preliminary evidence for similarity in headache duration at the two time points (evidence one trial: Jull 2002).

Mobilization

One trial evaluated mobilization: Bitterli 1977 (n = 30, VS = 29) compared 3 weeks of mobilization, SMT, and a wait-list control. The mobilization group averaged 3.2 sessions and the SMT group averaged 3.8 sessions. At the end of treatment, patients receiving mobilization had less pain reduction than those receiving SMT (ES -0.4; 95% CI -1.3 to 0.5). There was also no difference between mobilization and wait-list control at the end of treatment (ES 0.1; 95% CI -0.8 to 1.0). Results were not statistically significant (insufficient power). Three months after treatment, there was no difference between mobilization and SMT (ES 0.1; 95% CI -0.8 to 1.0).

Summary of levels of evidence:

- There is preliminary evidence that mobilization is inferior to spinal manipulation for pain reduction at the end of 3 weeks of treatment, and similar to manipulation 3 months later (evidence from one trial: Bitterli 1977).

- There is preliminary evidence that mobilization is similar to a wait-list control at the end of 3 weeks of treatment (evidence from one trial: Bitterli 1977).

Physical treatment combinations

Two trials evaluated physical treatment combinations: Ammer 1990 (n = 45, VS = 50) and Jull 2002 (n = 200, VS = 75).

Ammer 1990 (n = 45, VS = 50) compared three regimens: SMT plus pulsed galvanic current applied to the neck; massage with herbal moist pack applied to the neck and shoulders; and a combination of ultrasound and UV light applied to the neck with direct galvanic current applied to the neck and forehead. All treatment

was provided in 10 sessions over 2 weeks. At the end of treatment, there were no statistically significant differences between groups on patient-rated headache improvement (insufficient power) (ES [95% CI] versus galvanic current + ultrasound/UV light 0.4 [-0.4 to 1.1]; versus massage + herbal pack 0.5 [-0.3 to 1.3]). There were no important differences between the latter two groups (ES 0.1; 95% CI -0.6 to 0.9).

The results of this trial are limited by the use of a non-validated outcome measure of patient-rated improvement, thus making magnitude of within- and between-group differences difficult to compare with those from other trials.

Jull 2002 (n = 200, VS = 75) compared 6 weeks of SMT (high- and low-velocity), exercise (endurance, isometric, and stretching), a combination of SMT and exercise interventions, and a no-treatment control. SMT plus exercise versus no treatment: At 1 week and 12 months post-treatment, the combination therapy produced significantly better reduction of headache pain intensity (ES [95% CI] at 1 week 0.8 [0.4 to 1.2]; at 12 months 0.6 [0.2 to 1.0]), frequency (ES [95% CI] at 1 week 0.7 [0.3 to 1.1]; at 12 months 0.7 [0.3 to 1.2]), and duration (ES 0.5; 95% CI 0.1 to 0.9 for both time points). SMT plus exercise versus exercise alone: There were no significant differences for headache pain (ES [95% CI] at 1 week, 0.0 [-0.4 to 0.4]; at 12 months, -0.1 [-0.5 to 0.3]) or frequency (ES -0.2; 95% CI -0.6 to 0.2 for both time points). SMT plus exercise was significantly better than exercise alone only for headache duration (ES [95% CI] at 1 week 0.5 [0.1 to 0.9]; at 12 months 0.4 [0.0 to 0.8]). SMT plus exercise versus SMT alone: There were no notable differences between the groups for pain, frequency, or duration at either 1-week or 1-year time points (ES ranged between 0.3 and -0.1; 95% CIs not statistically significant; see Table 8).

In this study, numerous statistical tests were performed at several time points without adjustments for the increased likelihood of spurious results.

The two studies were too dissimilar for their results to be pooled. Summary of levels of evidence:

- There is preliminary evidence that SMT plus galvanic current is superior to a combination of galvanic current, ultrasound, and UV light and to a combination of massage and moist herbal packs for headache improvement at the end of 2 weeks of treatment. There is preliminary evidence that the latter two groups are similar in effect (evidence from one trial: Ammer 1990).
- There is moderate evidence showing that SMT plus exercise is superior to no treatment in reducing headache pain, frequency, and headache duration at 1 week and 12 months following 6 weeks of treatment. (evidence from one trial: Jull 2002).
- There is preliminary evidence that the SMT plus exercise is similar to exercise alone for headache pain at 1 week following treatment, and moderate evidence that the combination is at most similar to exercise alone at 12 months after treatment. There is moderate evidence that SMT plus exercise is at most

similar to exercise alone for frequency at the two time points.

However, there is moderate evidence showing that the combination is superior to exercise alone for headache duration at the two time points (evidence from one trial: Jull 2002). This means, that except for headache duration, there is no advantage to adding SMT to exercise over exercise alone (evidence of inefficacy).

- There is preliminary evidence that SMT plus exercise is similar to SMT alone for headache pain intensity, frequency, and duration at the 2 time points (evidence from one trial: Jull 2002). This means there is no advantage to adding exercise to SMT over SMT alone (evidence of inefficacy).

Headache not classifiable (IHS category 13)

See Table 6 for a summary of treatment comparisons and results for headache not classifiable.

Cranial electrotherapy for mixed headache (migraine/tension-type)

One trial evaluated cranial electrotherapy (CE): Solomon 1985 (n = 62, VS = 19) compared a single 15-minute session of CE-perceived stimulus, CE-subliminal stimulus, and placebo (detuned) CE. There was significantly lower pain intensity in the CE-perceived stimulus group than in the placebo CE group immediately following one treatment (ES 0.7; 95% CI 0.1 to 1.3). There was no significant difference between CE-subliminal stimulus and placebo (ES 0.1; 95% CI -0.5 to 0.7); there was lower pain intensity in the CE-perceived stimulus versus the CE-subliminal (ES 0.6; 95% CI -0.1 to 1.3). The study was underpowered. It was not possible to extract data allowing separate analysis of migraine and/or tension-type headache.

Summary of levels of evidence:

- There is limited evidence for absolute efficacy showing that CE-perceived stimulus is superior to placebo CE for pain intensity immediately following one treatment. There is preliminary evidence that perceived stimulus CE is superior to subliminal stimulus CE (evidence from one trial: Solomon 1985).
- There is preliminary evidence of similarity between CE-subliminal stimulus and placebo CE following one treatment (evidence from one trial: Solomon 1985).

Mobilization for post-traumatic headache

One trial (Jensen 1990; n = 23, VS = 46) compared mobilization to cold packs. Mobilization consisted of mobilization of specific segments of the cervical and upper thoracic spine in combination with 'muscle-energy' techniques. Cold packs were applied to neck and shoulders for 15 to 20 minutes. There were two sessions per week for 2 weeks. Mobilization patients did significantly better in regards to headache pain intensity 3 weeks after treatment (ES 1.1;

95% CI 0.1 to 2.0). There was no statistically significant difference 8 weeks after treatment (ES 0.4; 95% CI -0.5 to 1.2).

Interventions in both groups were performed by the principal investigator and lead author of the study, making bias likely.

Summary of levels of evidence:

- There is limited evidence that mobilization is superior to cold packs in reducing pain intensity 3 weeks following 2 weeks of treatment, and preliminary evidence that mobilization is superior 8 weeks after treatment (evidence from one trial: [Jensen 1990](#)).

Sensitivity analyses

Originally, sensitivity analyses were planned to examine the impact of changing the validity scores using both our 20-item scale and the Jadad scale. The correlation of the scores between the two scales was 0.42. We decided that the Jadad scale was not suited to form the basis of alternative evidence rules, so only one set of sensitivity analyses was conducted to evaluate the effect of changing the methodological quality scores required for each level of evidence (see [Table 2](#), [Table 3](#), [Table 4](#)).

Validity score

We examined the effect of changing the validity score requirement for a specific evidence level ± 10 points (100-point quality scale) for the review's primary outcomes, headache pain and headache index.

Lowering the score 10 points would increase the level of evidence from 'limited' to moderate' for:

- Efficacy of SMT compared to no treatment for tension-type headache ([Hoyt 1979](#));
- Efficacy of cranial electrotherapy compared to placebo for tension-type headache ([Solomon 1989](#)); and
- Efficacy of mobilization compared to cold packs for post-traumatic headache ([Jensen 1990](#)).

Raising the score 10 points would reduce the level of evidence from 'moderate' to 'limited' for:

- Efficacy of therapeutic touch compared to placebo therapeutic touch for tension-type headache ([Keller 1986](#));
- Inefficacy of adding manipulation compared to massage for tension-type headache ([Bove 1998](#)); and
- Efficacy of SMT compared to placebo SMT for cervicogenic headache ([Whittingham 1997](#)).

Overall, the sensitivity analyses showed that changing the rules of evidence, in regard to the validity scores, would have had limited impact on the overall conclusions of this review.

Effect size

We examined the effect of lowering or raising the point estimate of the ES used in determining a clinically important difference

(classified as superiority or inferiority) for the review's primary outcomes, headache pain and headache index.

Increasing the ES criterion from ± 0.4 to ± 0.5 resulted in the following changes:

- Moderate evidence of inefficacy of SMT compared to an efficacious drug for tension-type headache during the treatment phase would be raised to preliminary evidence of efficacy ([Boline 1995](#)).
- Moderate evidence of efficacy for SMT compared to no treatment would become preliminary evidence of inefficacy for cervicogenic headache at the 1-year follow-up point ([Jull 2002](#)).
- Preliminary evidence of efficacy for SMT compared to mobilization would become preliminary evidence of similarity with a therapy of unknown efficacy for migraine headache ([Parker 1980](#)).
- Preliminary evidence of efficacy for SMT compared to mobilization would become preliminary evidence of similarity with a therapy of unknown efficacy for cervicogenic headache ([Bitterli 1977](#)).
- Preliminary evidence of efficacy for mobilization compared to cold packs would become preliminary evidence of similarity with a therapy of unknown efficacy for post-traumatic headache ([Jensen 1990](#)).

Decreasing the ES criterion from ± 0.4 to ± 0.3 did not change the evidence from any of the studies.

Overall, the sensitivity analyses involving the effect size showed that changing the rules of evidence, in regard to the threshold for what was arbitrarily considered a group difference of clinical importance, would have had relatively limited impact on the main conclusions of this review.

DISCUSSION

Clinical heterogeneity of the trials in terms of headache type, patient characteristics, interventions, comparison therapies, and outcome measures prevented us from applying statistical pooling in this review. IHS diagnostic categories 3-10 and 12 were not represented in any of the included trials.

Two trials could not be classified according to IHS diagnostic categories. [Jensen 1990](#) included patients with post-traumatic headache, but apparently not as a result of head injury, and was, therefore, not classifiable. In the study by Solomon et al, ([Solomon 1985](#)) it was not possible to extract data allowing separate analysis of migraine, tension-type headache, or the combination of the two.

None of the studies reviewed evaluated the cost-effectiveness of the interventions for chronic/recurrent headaches.

Limitations of the review

A possible limitation of the current review is publication bias, of which there are several potential sources (Dickersin 1990). No effort was made to identify unpublished research, which is more likely to have negative outcomes (Cook 1993; Rosenthal 1979). However, it is recognized that attempts to retrieve unpublished data from trials are also likely to be biased (Rosenthal 1979). The search strategy may have missed important studies not currently indexed, but by including citation tracking of non-indexed journals we should have kept such omissions to a minimum. Optimally, reviews should include all trials regardless of language (Dickersin 1987; Gregoire 1995; Moher 1996). Although an attempt was made to identify trials in all languages, the possibility that some relevant trials may have been overlooked must be acknowledged. Furthermore, the reliability of different methodological scoring systems is a source of uncertainty (Oxman 1991). Conclusions regarding the weight of evidence are dependent on the choice of quality scoring system and on the exact definition of the evidence classification system used (Moher 1995). Therefore, in addition to our preferred 20-item scale, described above, we employed a commonly used methodological assessment tool, namely the five-point scoring system developed by Jadad (Jadad 1996). This scale addresses three areas: randomization, double-blinding, and description of dropouts, which, if not addressed adequately, may be important sources of bias. The correlation between the total scores of the two scoring systems was 0.42. The explanation for the relative low correlation may be the proportionally high weight placed on the importance of blinding both patients and treatment provider in the Jadad scale compared to our 20-item scale. Complete blinding for some of the treatments (e.g., spinal manipulation and massage) is inherently impossible or difficult to achieve.

Adverse reactions

The results of the trials included in this review do not suggest that any of these therapies are associated with important risks of severe adverse reactions. Side effects have been addressed mostly for spinal manipulation. Individual estimates and the results of retrospective surveys consistently suggest a risk of serious cerebrovascular complication of approximately one per one million cervical manipulations (Haldeman 1999; Terrett 1992). Overall, serious or severe complications from spinal manipulation seem to be very rare, but because underreporting in the literature is a likely phenomenon, and because some reports may have wrongly attributed side effects to SMT when not established (Powell 1993), the existing estimates are associated with substantial uncertainty at this time and can only be improved when data become available from well designed prospective studies (Assendelft 1996b).

Magnitude of effects

Interpretation of the results of RCTs has traditionally focused on the statistical significance, whereas the clinical importance of differences between treatment and control has frequently been ignored. Very little is known about what is considered by patients to be a minimal clinically important change in headache outcome measures such as pain and disability. However, a key question needed to interpret the results of clinical trials is whether the measured standardized group difference in outcomes (effect size) is clinically important. Sometimes, the minimal clinically important difference is arbitrarily stipulated by investigators. Usually, authors assume that if the mean difference between a treatment and control is appreciably less than the smallest pre-determined important change, then the treatment had little or no effect. Conversely, it is also assumed that if the observed mean difference between treatments was substantially larger than the smallest important change, most or all patients benefited from the treatment. This is not necessarily true.

Benefit depends not only on differences between group means, but also on the distribution of outcomes among patients within each treatment group. Members of an international clinical significance consensus group recently addressed this topic in a series of publications (Guyatt 1998; Guyatt 2000; Guyatt 2002). They concluded that no single approach to interpreting findings from RCTs and systematic reviews is perfect. Authors too often draw inappropriate conclusions when they declare treatment ineffectiveness based solely on presence or absence of statistical differences between a test treatment and a control. To inform decisions about management of individual patients, it may be much more appropriate to think in terms of available treatment options which have shown a meaningful clinical effect, rather than choosing or discarding specific therapies based on mean group differences of undefined clinical importance.

Systematic reviews

Several previously published systematic reviews have assessed the effect of different non-invasive therapies for chronic/recurrent headache. Except for migraine, which was not covered in the reviews by Hurwitz et al (Hurwitz 1996), Vernon et al (Vernon 1999), McCrory et al (McCrory 2001), and Gross et al (Gross 2002), the conclusions of these reviews are similar to ours. Hurwitz 1996 and Gross 2002 focused primarily on the effectiveness of manual treatment for neck pain but also reviewed what they defined as neck-related headache using different criteria. The acupuncture review by Melchart et al (Melchart 2001) came to conclusions similar to ours regarding the effect of certain combinations of physical treatments for tension-type headache.

AUTHORS' CONCLUSIONS

Implications for practice

The evidence for efficacy or inefficacy of the different non-invasive physical treatments for the various types of headaches rests on separate individual trials. Thus the strength of the evidence never exceeded the moderate level. Ten studies had methodological quality scores equal to or greater than 50, but many limitations were identified. A few additional high-quality randomized controlled trials (RCTs) in the future could easily change the conclusions of our review. Based on trial results, the non-invasive physical treatments studied appear to be associated with little risk of serious adverse effects. Their relative cost-effectiveness is not known.

For the prophylactic treatment of migraine headache, there is evidence from a high-quality study that spinal manipulation may be an effective treatment option with a short-term effect similar to that of a commonly used, effective drug (amitriptyline). There were fewer side effects associated with spinal manipulation. Combining the two treatments does not seem to offer an advantage. Weaker evidence from a lower-quality study showed that spinal manipulation was ineffective in reducing pain, but was superior to a sham interferential therapy for reducing headache frequency, duration, and medication use. Other possible treatment options with weaker evidence of effectiveness in pain reduction are pulsating electromagnetic fields in comparison to placebo; and a combination of transcutaneous electrical nerve stimulation (TENS) and electrical neurotransmitter modulation in comparison to relaxation training.

For the prophylactic treatment of chronic tension-type headache, evidence from a high-quality study shows that a commonly used drug provides more pain reduction in the short term than spinal manipulation. There were fewer side effects associated with the spinal manipulation. However, spinal manipulation appears superior to the drug after cessation of treatment by providing a sustained short-term effect. Evidence from another high-quality study shows that adding spinal manipulation to massage for episodic tension-type headache is not effective. Therapeutic touch may result in immediate short-term pain reduction. Other possible treatment options with weaker evidence of effectiveness in pain reduction are cranial electrotherapy compared to placebo therapy; a combination of TENS and electrical neurotransmitter modulation in comparison to relaxation training; and a regimen of auto-massage, TENS, and stretching in comparison to acupuncture.

For the prophylactic treatment of cervicogenic headache, there is evidence from a high-quality study that both neck exercise (low-intensity endurance training) and spinal manipulation are effective in reducing headache intensity and frequency in the short and long term in comparison to no treatment. Except for reduction in headache duration, there is no advantage to combining the two therapies. From two more high-quality studies there is evidence that spinal manipulation is effective in the short term in improving pain and other secondary headache outcomes in comparison

to massage or placebo spinal manipulation. Weaker evidence from a lower-quality study showed that spinal manipulation was more effective for pain reduction in the short term than spinal mobilization or no treatment.

There is currently insufficient evidence to draw conclusions regarding the efficacy of any non-invasive physical treatments for patients with a mix of migraine and tension-type headache.

There is some evidence that spinal mobilization may have better short-term reduction in pain intensity than cold packs in the treatment of post-traumatic headache.

No single approach to interpreting findings from RCTs and systematic reviews is perfect. To inform decisions about the management of individual patients, it may be more appropriate to think in terms of available treatment options that have shown a meaningful clinical effect, rather than choosing or discarding specific therapies solely based on mean group differences of undefined clinical importance.

Implications for research

The heterogeneity of the studies included in this review means that the results of a few additional high-quality RCTs in the future could easily change the conclusions of our review.

More trials are needed to establish a firmer basis for considering these treatments as viable options. The clinical effectiveness and the relative cost-effectiveness of the commonly used therapies for which there is some evidence of effect need to be researched further. The results of the studies included in this review suggest that non-invasive physical treatments pose little risk of serious adverse effects. However, future studies should make a concerted effort to systematically document side effects and ensure that they are comprehensively reported. In particular, there is a need to compare long-term effects of non-invasive physical treatments with the effects of first-line efficacious medications in the prophylactic management of the different types of chronic/recurrent headaches. It is recommended that future trials follow specific guidelines concerning inclusion/exclusion criteria, classification of headaches, and outcome measurements for headache trials (IHS 1995; IHS 2000) so that trial results may be pooled. Future trials should also follow the updated CONSORT statement on reporting in scientific journals (Moher 2001), which would help ensure the reliability and validity of quality assessments. To better inform decisions about patient management, trials should include not only evaluation of the differences between group means, but also assessment of the distribution of outcomes within each treatment group.

ACKNOWLEDGEMENTS

We sincerely appreciate the contributions of Douglas McCrory (lead editor for headache) and Rebecca Gray (assistant review

group co-ordinator) of the Cochrane Pain, Palliative Care and Supportive Care review group. They provided critical constructive suggestions for improvements to the review and invaluable help in the copy-editing of the final draft. Jennifer Hart at Northwestern Health Sciences University is acknowledged for her dedicated help in verification of data tables and entry of the review into Review Manager (RevMan).

REFERENCES

References to studies included in this review

Ahonen 1984 *{published data only}*

Ahonen E, Hakumäki M, Mahlamäki S, Partanen J, Riekkinen P, Sivenius J. Acupuncture and physiotherapy in the treatment of myogenic headache patients: pain relief and EMG activity. In: Bonica JJ, Lindblom U, Iggo A editor(s). *Advances in Pain Research and Therapy*. Vol. 5, New York: Raven Press, 1983:571–6.

* Ahonen E, Hakumäki M, Mahlamäki S, Partanen J, Riekkinen P, Sivenius J. Effectiveness of acupuncture and physiotherapy on myogenic headache: a comparative study. *Acupuncture & Electro-Therapeutics Research* 1984;**9**(3): 141–50.

Ammer 1990 *{published data only}*

Ammer K, Rathkolb O. Physical therapy in occipital headaches [Physikalische Therapie bei Hinterhauptkopfschmerzen]. *Manuelle Medizin* 1990;**28**: 65–8.

Bitterli 1977 *{published data only}*

Bitterli J, Graf R, Robert F, Adler R, Mumenthaler M. Objective criteria for the evaluation of chiropractic treatment of spondylotic headache [Zur Objektivierung der manualtherapeutischen Beeinflussbarkeit des spondylogenen Kopfschmerzes]. *Nervenarzt* 1977;**48**(5):159–62.

Boline 1995 *{published data only}*

Boline PD, Kassak K, Bronfort G, Nelson C, Anderson AV. Spinal manipulation vs. amitriptyline for the treatment of chronic tension-type headaches: a randomized clinical trial. *Journal of Manipulative & Physiological Therapeutics* 1995; **18**(3):148–54.

Bove 1998 *{published data only}*

Bove G, Nilsson N. Spinal manipulation in the treatment of episodic tension-type headache: a randomized controlled trial. *JAMA* 1998;**280**(18):1576–9.

Carlsson 1990 *{published data only}*

* Carlsson J, Augustinsson LE, Blomstrand C, Sullivan M. Health status in patients with tension headache treated with acupuncture or physiotherapy. *Headache* 1990;**30**(9): 593–9.

Carlsson J, Fahlcrantz A, Augustinsson LE. Muscle tenderness in tension headache treated with acupuncture or physiotherapy. *Cephalalgia* 1990;**10**(3):131–41.

Carlsson J, Rosenhall U. Oculomotor disturbances in

patients with tension headache treated with acupuncture or physiotherapy. *Cephalalgia* 1990;**10**(3):123–9.

Carlsson J, Wedel A, Carlsson GE, Blomstrand C. Tension headache and signs and symptoms of craniomandibular disorders treated with acupuncture or physiotherapy. *The Pain Clinic* 1990;**3**(4):229–38.

Howe 1983 *{published data only}*

Howe DH, Newcombe RG, Wade MT. Manipulation of the cervical spine--a pilot study. *Journal of the Royal College of General Practitioners* 1983;**33**(254):574–9.

Hoyt 1979 *{published data only}*

Hoyt WH, Shaffer F, Bard DA, Benesler JS, Blankenhorn GD, Gray JH, et al. Osteopathic manipulation in the treatment of muscle-contraction headache. *Journal of the American Osteopathic Association* 1979;**78**(5):322–5.

Jensen 1990 *{published data only}*

Jensen OK, Nielsen FF, Vosmar L. An open study comparing manual therapy with the use of cold packs in the treatment of post-traumatic headache. *Cephalalgia* 1990;**10**(5): 241–50.

Jull 2002 *{published data only}*

Jull G, Trott P, Potter H, Zito G, Niere K, Shirley D, et al. A randomized controlled trial of exercise and manipulative therapy for cervicogenic headache. *Spine* 2002;**27**(17): 1835–43.

Keller 1986 *{published data only}*

Keller E, Bzdek VM. Effects of therapeutic touch on tension headache pain. *Nursing Research* 1986;**35**(2):101–6.

Marcus 1998 *{published data only}*

Marcus DA, Scharff L, Mercer S, Turk DC. Nonpharmacological treatment for migraine: incremental utility of physical therapy with relaxation and thermal biofeedback. *Cephalalgia* 1998;**18**(5):266–72.

Nelson 1998 *{published data only}*

Nelson CF, Bronfort G, Evans R, Boline P, Goldsmith C, Anderson AV. The efficacy of spinal manipulation, amitriptyline and the combination of both therapies for the prophylaxis of migraine headache. *Journal of Manipulative & Physiological Therapeutics* 1998;**21**(8):511–9.

Nilsson 1997 *{published data only}*

Nilsson N. A randomized controlled trial of the effect of spinal manipulation in the treatment of cervicogenic

- headache. *Journal of Manipulative & Physiological Therapeutics* 1995;**18**(7):435–40.
- * Nilsson N, Christensen HW, Hartvigsen J. The effect of spinal manipulation in the treatment of cervicogenic headache. *Journal of Manipulative & Physiological Therapeutics* 1997;**20**(5):326–30.
- Parker 1980** {published data only}
- * Parker GB, Pryor DS, Tupling H. Why does migraine improve during a clinical trial? Further results from a trial of cervical manipulation for migraine. *Australian & New Zealand Journal of Medicine* 1980;**10**(2):192–8.
- Parker GB, Tupling H, Pryor DS. A controlled trial of cervical manipulation of migraine. *Australian & New Zealand Journal of Medicine* 1978;**8**(6):589–93.
- Reich 1989** {published data only}
- Reich BA. Non-invasive treatment of vascular and muscle contraction headache: a comparative longitudinal clinical study. *Headache* 1989;**29**(1):34–41.
- Sherman 1998** {published data only}
- Sherman RA, Robson L, Marden LA. Initial exploration of pulsing electromagnetic fields for treatment of migraine. *Headache* 1998;**38**(3):208–13.
- Sherman 1999** {published data only}
- Sherman RA, Acosta NM, Robson L. Treatment of migraine with pulsing electromagnetic fields: a double-blind, placebo-controlled study. *Headache* 1999;**39**(8):567–75.
- Solomon 1985** {published data only}
- Solomon S, Guglielmo KM. Treatment of headache by transcutaneous electrical stimulation. *Headache* 1985;**25**(1):12–5.
- Solomon 1989** {published data only}
- Solomon S, Elkind A, Freitag F, Gallagher RM, Moore K, Swerdlow B, et al. Safety and effectiveness of cranial electrotherapy in the treatment of tension headache. *Headache* 1989;**29**(7):445–50.
- Tuchin 2000** {published data only}
- Tuchin PJ, Pollard H, Bonello R. A randomized controlled trial of chiropractic spinal manipulative therapy for migraine. *Journal of Manipulative & Physiological Therapeutics* 2000;**23**(2):91–5.
- Whittingham 1997** {published data only}
- Whittingham W. *The efficacy of cervical adjustments (toggle recoil) for chronic cervicogenic headaches [PhD dissertation]*. Melbourne (Australia): Royal Melbourne Institute of Technology, 1997.
- References to studies excluded from this review**
- Ahmed 2000** {published data only}
- Ahmed HE, White PF, Craig WF, Hamza MA, Ghoname EA, Gajraj NM. Use of percutaneous electrical nerve stimulation (PENS) in the short-term management of headache. *Headache* 2000;**40**(4):311–5.
- Airaksinen 1992** {published data only}
- Airaksinen O, Pontinen PJ. Effects of the electrical stimulation of myofascial trigger points with tension headache. *Acupuncture & Electro-Therapeutics Research* 1992;**17**(4):285–90.
- Gray 1994** {published data only}
- Gray RJ, Quayle AA, Hall CA, Schofield MA. Physiotherapy in the treatment of temporomandibular joint disorders: a comparative study of four treatment methods. *British Dental Journal* 1994;**176**(7):257–61.
- Iwata 1998** {published data only}
- Iwata JL, Multack RF. Treatment of ocular tension-type headache using osteopathic manipulative treatment (OMT). *Journal of the American Osteopathic Association* 1998;**98**(7):388.
- Kaliappen 1987** {published data only}
- Kaliappen L, Kaliappen KV. The efficacy of yoga therapy in the treatment of migraine and tension headaches. *Journal of the Indian Academy of Applied Psychology* 1987;**13**(2):95–100.
- Kaliappen 1992** {published data only}
- Kaliappen L, Kaliappen KV. Efficacy of yoga therapy in the management of headaches. *Journal of Indian Psychology* 1992;**10**(1-2):41–7.
- Karppinen 1999** {published data only}
- Karppinen K, Eklund S, Suoninen E, Eskelin M, Kirveskari P. Adjustment of dental occlusion in treatment of chronic cervicobrachial pain and headache. *Journal of Oral Rehabilitation* 1999;**26**(9):715–21.
- Lemstra 2002** {published data only}
- Lemstra M, Stewart B, Olszynski WP. Effectiveness of multidisciplinary intervention in the treatment of migraine: a randomized clinical trial. *Headache* 2002;**42**(9):845–54.
- MacNeil 1995** {published data only}
- MacNeil MS. Therapeutic touch and tension headaches: a Rogerian study. *Masters Abstracts International* 1995;**33**(5):1492.
- Sargent 1986** {published data only}
- Sargent J, Solbach P, Coyne L, Spohn H, Segerson J. Results of a controlled, experimental, outcome study of nondrug treatments for the control of migraine headaches. *Journal of Behavioral Medicine* 1986;**9**(3):291–323.
- Scharff 1996** {published data only}
- Scharff L, Marcus DA, Turk DC. Maintenance of effects in the nonmedical treatment of headaches during pregnancy. *Headache* 1996;**36**(5):285–90.
- Schokker 1990** {published data only}
- Schokker RP, Hansson TL, Ansink BJ. The result of treatment of the masticatory system of chronic headache patients. *Journal of Craniomandibular Disorders* 1990;**4**(2):126–30.
- Sethi 1981** {published data only}
- Sethi BB, Trivedi JK, Anand R. A comparative study of relative effectiveness of biofeedback and shavasana (yoga) in tension headache. *Indian Journal of Psychiatry* 1981;**23**(2):109–14.

Witucki 1994 {published data only}

Witucki MP. A controlled comparison of aerobic exercise and behavioral treatment for recurrent tension headache. *Dissertation Abstracts International* 1994;**55**(5-B):1998.

Additional references**Assendelft 1996a**

Assendelft WJ, Koes BW, van der Heijden GJ, Bouter LM. The effectiveness of chiropractic for treatment of low back pain: an update and attempt at statistical pooling. *Journal of Manipulative & Physiological Therapeutics* 1996;**19**(8):499–507.

Assendelft 1996b

Assendelft WJ, Bouter LM, Knipschild PG. Complications of spinal manipulation: a comprehensive review of the literature. *Journal of Family Practice* 1996;**42**(5):475–80.

Bank 1994

Bank J. A comparative study of amitriptyline and fluvoxamine in migraine prophylaxis. *Headache* 1994;**34**(8):476–8.

Bigos 1994

Bigos S, Bowyer O, Braen G, Brown K, Deyo R, Haldeman S, et al. *Acute low back problems in adults. Clinical Practice Guideline No. 14. AHCPR Publication No. 95-0642.* Rockville (MD): Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, December 1994.

Bronfort 2001

Bronfort G, Assendelft WJ, Evans R, Haas M, Bouter LM. Efficacy of spinal manipulation for chronic headache: a systematic review. *Journal of Manipulative & Physiological Therapeutics* 2001;**24**(7):457–66.

Cohen 1988

Cohen J. *Statistical power analysis for the behavioral sciences.* 2nd Edition. Hillsdale, NJ: Lawrence Erlbaum Associates, Inc., 1988.

Cook 1993

Cook DJ, Guyatt GH, Ryan G, Clifton J, Buckingham L, Willan A, et al. Should unpublished data be included in meta-analyses? Current convictions and controversies. *JAMA* 1993;**269**(21):2749–53.

Dickersin 1987

Dickersin K, Chan S, Chalmers TC, Sacks HS, Smith H Jr. Publication bias and clinical trials. *Controlled Clinical Trials* 1987;**8**(4):343–53.

Dickersin 1990

Dickersin K. The existence of publication bias and risk factors for its occurrence. *JAMA* 1990;**263**(10):1385–9.

Dickersin 1994

Dickersin K, Scherer R, Lefebvre C. Identifying relevant studies for systematic reviews. *BMJ* 1994;**309**(6964):1286–91.

Eisenberg 1998

Eisenberg DM, Davis RB, Ettner SL, Appel S, Wilkey S, Van Rompay M, et al. Trends in alternative medicine use

in the United States, 1990–1997: results of a follow-up national survey. *JAMA* 1998;**280**(18):1569–75.

Friedman 1968

Friedman H. Magnitude of experimental effect and a table for its rapid estimation. *Psychological Bulletin* 1968;**70**(4):245–51.

Glass 1981

Glass GV, McGaw B, Smith ML. *Meta-analysis in social research.* Beverly Hills, CA: Sage Publications, 1981.

Gregoire 1995

Gregoire G, Derderian F, Le Lorier J. Selecting the language of the publications included in a meta-analysis: is there a Tower of Babel bias?. *Journal of Clinical Epidemiology* 1995;**48**(1):159–63.

Gross 2002

Gross AR, Kay TM, Kennedy C, Gasner D, Hurley L, Yardley K, et al. Clinical practice guideline on the use of manipulation or mobilization in the treatment of adults with mechanical neck disorders. *Manual Therapy* 2002;**7**(4):193–205.

Guyatt 1998

Guyatt GH, Juniper EF, Walter SD, Griffith LE, Goldstein RS. Interpreting treatment effects in randomised trials. *BMJ* 1998;**316**(7132):690–3.

Guyatt 2000

Guyatt GH, Haynes RB, Jaeschke RZ, Cook DJ, Green L, Naylor CD, et al. Users' Guides to the Medical Literature: XXV. Evidence-based medicine: principles for applying the Users' Guides to patient care. *JAMA* 2000;**284**(10):1290–6.

Guyatt 2002

Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR. Methods to explain the clinical significance of health status measures. *Mayo Clinic Proceedings* 2002;**77**(4):371–83.

Haldeman 1999

Haldeman S, Kohlbeck FJ, McGregor M. Risk factors and precipitating neck movements causing vertebral artery dissection after cervical trauma and spinal manipulation. *Spine* 1999;**24**(8):785–94.

Hedges 1985

Hedges LV, Olkin I. *Statistical methods for meta-analysis.* Orlando, FL: Academic Press, 1985.

Holroyd 1990

Holroyd KA, Penzien DB. Pharmacological versus non-pharmacological prophylaxis of recurrent migraine headache: a meta-analytic review of clinical trials. *Pain* 1990;**42**(1):1–13.

Holroyd 2001

Holroyd KA, O'Donnell FJ, Stensland M, Lipchik GL, Cordingley GE, Carlson BW. Management of chronic tension-type headache with tricyclic antidepressant medication, stress management therapy, and their combination: a randomized controlled trial. *JAMA* 2001;**285**(17):2208–15.

Hu 1999

Hu XH, Markson LE, Lipton RB, Stewart WF, Berger ML. Burden of migraine in the United States: disability and economic costs. *Archives of Internal Medicine* 1999;**159**(8): 813–8.

Hurwitz 1996

Hurwitz EL, Aker PD, Adams AH, Meeker WC, Shekelle PG. Manipulation and mobilization of the cervical spine. A systematic review of literature. *Spine* 1996;**21**(15):1746–60.

IHS 1988

Headache Classification Committee of the International Headache Society. Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. *Cephalalgia* 1988;**8 Suppl 7**:1–96.

IHS 1995

Schoenen J. Guidelines for trials of drug treatments in tension-type headache. First edition: International Headache Society Committee on Clinical Trials. *Cephalalgia* 1995;**15**(3):165–79.

IHS 2000

Tfelt-Hansen P, Block G, Dahlföf C, Diener HC, Ferrari MD, Goadsby PJ, et al. Guidelines for controlled trials of drugs in migraine: second edition. *Cephalalgia* 2000;**20**(9): 765–86.

Jadad 1996

Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary?. *Controlled Clinical Trials* 1996;**17**(1):1–12.

Klawansky 1995

Klawansky S, Yeung A, Berkey C, Shah N, Phan H, Chalmers TC. Meta-analysis of randomized controlled trials of cranial electrostimulation. Efficacy in treating selected psychological and physiological conditions. *Journal of Nervous & Mental Disease* 1995;**183**(7):478–84.

Koes 1991

Koes BW, Assendelft WJ, van der Heijden GJ, Bouter LM, Knipschild PG. Spinal manipulation and mobilisation for back and neck pain: a blinded review. *BMJ* 1991;**303** (6813):1298–303.

McCrory 2001

McCrory DC, Penzien DB, Hasselblad V, Gray RN. *Evidence report: behavioral and physical treatments for tension-type and cervicogenic headache*. Des Moines (IA): Foundation for Chiropractic Education and Research, 2001. Product No.: 2085.

Melchart 2001

Melchart D, Linde K, Berman B, White A, Vickers A, Allais, et al. Acupuncture for idiopathic headache. *Cochrane Database of Systematic Reviews* 2001, Issue 1. [DOI: 10.1002/14651858.CD001218]

Moher 1995

Moher D, Jadad AR, Nichol G, Penman M, Tugwell P, Walsh S. Assessing the quality of randomized controlled

trials: an annotated bibliography of scales and checklists. *Controlled Clinical Trials* 1995;**16**(1):62–73.

Moher 1996

Moher D, Fortin P, Jadad AR, Juni P, Klassen T, Le Lorier J, et al. Completeness of reporting of trials published in languages other than English: implications for conduct and reporting of systematic reviews. *Lancet* 1996;**347**(8998): 363–6.

Moher 2001

Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;**357**(9263):1191–4.

Nicholson 2004

Nicholson R, Penzien D, McCrory DC, Gray RN, Nash J, Dickersin K. Behavioral therapies for migraine. (Protocol). *Cochrane Database of Systematic Reviews* 2004, Issue 1. [DOI: 10.1002/14651858.CD004601]

Oxman 1991

Oxman AD, Guyatt GH, Singer J, Goldsmith CH, Hutchison BG, Milner RA, et al. Agreement among reviewers of review articles. *Journal of Clinical Epidemiology* 1991;**44**(1):91–8.

Powell 1993

Powell FC, Hanigan WC, Olivero WC. A risk/benefit analysis of spinal manipulation therapy for relief of lumbar or cervical pain. *Neurosurgery* 1993;**33**(1):73–9.

Pryse-Phillips 1992

Pryse-Phillips W, Findlay H, Tugwell P, Edmeads J, Murray TJ, Nelson, RF. A Canadian population survey on the clinical, epidemiologic and societal impact of migraine and tension-type headache. *Canadian Journal of Neurological Sciences* 1992;**19**(3):333–9.

Rasmussen 1991

Rasmussen BK, Jensen R, Schroll M, Olesen J. Epidemiology of headache in a general population—a prevalence study. *Journal of Clinical Epidemiology* 1991;**44**(11):1147–57.

Rasmussen 1992

Rasmussen BK, Jensen R, Olesen J. Impact of headache on sickness absence and utilisation of medical services: a Danish population study. *Journal of Epidemiology & Community Health* 1992;**46**(4):443–6.

Rosenthal 1979

Rosenthal R. The file drawer problem and tolerance for null results. *Psychological Bulletin* 1979;**86**(3):638–41.

Schwartz 1997

Schwartz BS, Stewart WF, Lipton RB. Lost workdays and decreased work effectiveness associated with headache in the workplace. *Journal of Occupational & Environmental Medicine* 1997;**39**(4):320–7.

Schwartz 1998

Schwartz BS, Stewart WF, Simon D, Lipton RB. Epidemiology of tension-type headache. *JAMA* 1998;**279** (5):381–3.

Stewart 1992

Stewart WF, Lipton RB, Celentano DD, Reed ML.
Prevalence of migraine headache in the United States.
Relation to age, income, race, and other sociodemographic
factors. *JAMA* 1992;**267**(1):64–9.

Terrett 1992

Terrett AGJ, Kleynhans AM. Cerebrovascular complications
of manipulation. In: Haldeman S editor(s). *Principles and
practice of chiropractic*. 2nd Edition. East Norwalk, CT:
Appleton & Lange, 1992:579–598.

Vernon 1999

Vernon H, McDermaid CS, Hagino C. Systematic review
of randomized clinical trials of complementary/alternative
therapies in the treatment of tension-type and cervicogenic
headache. *Complementary Therapies in Medicine* 1999;**7**(3):
142–55.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ahonen 1984

Methods	Design: parallel, 2 groups. Baseline: 2 weeks. Treatment: 3 weeks. Post-treatment follow up: 8 and 20 weeks. Randomization method: Not described. Jadad quality score: 1/5. Internal validity score: 40/100
Participants	Myogenic headache associated with tension-neck syndrome (n = 22) Inclusion: chronic persistent headache. Recruitment: patients admitted to neurological outpatient unit. Location: university hospital, Finland. % Female: 82. Mean age: 42 years. Mean length of HA history: 6 years
Interventions	G1 (n = 12): acupuncture using Shuai-ku, Feng-chih, T'ien-chu, Feng-men, Hsin-yu, Chuan-his, and 2 pressure points in neck. No report whether De Chi achieved. 4 sessions, over 3 weeks. G2 (n = 10) 3 sessions parafango (warm paraffin and mud), plus massage, then 5 sessions of massage and ultrasound over ergonomic advice. Total of 8 sessions over 3 weeks
Outcomes	Headache pain measured with VAS (0-100) during each week of baseline and treatment, and then at 8 and 20 weeks post-treatment Headache pain intensity: At the end of 3 weeks of treatment, G2 was more favorable than G1 (G1 = 33.0 [38.1]; G2 = 29.0 [28.5] [NS]). At 8 weeks post-treatment, mean headache pain intensity was lower in G2 than in G1 (G1 = 47.0 [31.2]; G2 = 30.0 [25.3] [NS]). At 20 weeks post-treatment, G1 was lower than G2 (G1 = 28.0 [31.2]; G2 = 33.0 [28.5] [NS])
Notes	Loss to follow up: not specified. Side effects: not specified

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Ammer 1990

Methods	Design: parallel, 3 groups. Baseline: immediately before treatment. Treatment: 2 weeks. Post-treatment follow up: at end of treatment. Randomization method: not described. Jadad quality score: 1/5. Internal validity score: 50/100
Participants	Cervicogenic-like occipital headache (predating IHS criteria) (n = 45). Inclusion: HA \leq 4 months. Presence of blocked neck motion and trigger points. Recruitment: ambulatory patients in clinic. Location: research outpatient clinic in Austria. % Female: 65. Median age: 52 years. Age range: 23-78. Mean weeks since onset: 3
Interventions	G1 (n = 15): spinal manipulative therapy + pulsed galvanic current to neck for 2 weeks (10 sessions). G2 (n = 15): direct galvanic current to forehead/neck plus ultrasound and UV-light over neck muscles for 2 weeks (10 sessions). G3 (n = 15): Moist herbal pack + massage of neck and shoulders for 2 weeks (10 sessions)

Ammer 1990 (Continued)

Outcomes	Main outcomes: patient-rated headache improvement (1-4). Pain scores and number of trigger points assessed by examiners Headache improvement: At the end of 2 weeks of treatment, scores were similar for all three groups (G1 = 1.9 [0.9]; G2 = 2.2 [0.9]; G3 = 2.3 [0.8] [NS])	
Notes	Loss to follow up: 7/45 (16%). Five patients in G1 and 2 in G2 discontinued treatment after 5 sessions because they were symptom-free. Side effects: not specified	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Bitterli 1977

Methods	Design: parallel, 3 groups. Baseline: prior to treatment. Treatment: 3 weeks. Post-treatment follow up: 3 months. Randomization method: drawing a lot. Jadad quality score: 2/5. Internal validity score: 29/100	
Participants	Cervicogenic-like headache (predating IHS criteria) (n = 30). Inclusion: Primary complaint of cervicogenic headache, several months' duration. Recruitment: patients attending neurological outpatient clinic. Location: neurological outpatient clinic, Switzerland. Mean age: 31 years. Age range: 16-23. % Female: 80	
Interventions	G1 (n = 10): spinal manipulative therapy for 3 weeks (3.8 sessions). G2 (n = 10): mobilization for 3 weeks (3.2 sessions). G3 (n = 10): 3-week waiting list, then spinal manipulative therapy for 3 weeks	
Outcomes	Average headache pain intensity measured on 100-mm VAS. Headache pain intensity: At the end of the 3-week treatment period, G1 was more favorable than G2 and G3 (G1 = 27.8 [30.4]; G2 = 39.5 [23.6]; G3 = 43.5 [25.4] [NS]). At 12 weeks post-treatment, G1 and G2 were similar (G1 = 35.7 [38.4]; G2 = 32.5 [18.0] [NS])	
Notes	Loss to follow up: 7/30 (23%) missing pain ratings at 3 months post-treatment (G1 3/10, G2 2/10, G3 2/10). Side effects: not specified	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Boline 1995

Methods	Design: parallel, 2 groups. Baseline: 2 weeks. Treatment: 6 weeks. Post-treatment follow up: 4 weeks. Randomization method: 1:1 computer-generated list and sealed envelopes. Jadad quality score: 3/5. Internal validity score: 91/100
Participants	Tension-type headache (TTH). Mix of mostly chronic but also episodic TTH (n = 150). Inclusion: Headache episode \geq 1/week for \geq 3 months, age 18-70, migraine was allowed if TTH was the predominant headache type. Recruitment: media advertising. Location: outpatient chiropractic research clinic in Minnesota, USA. Mean age: 42 years. Age range: 18 to 69. % Female: 62. Years since onset: 14 (mean). Number of headache episodes per week: 12 (mean)
Interventions	G1 (n = 75): high-velocity, low-amplitude spinal manipulative therapy. Two 20-minute sessions per week for 6 weeks preceded by 5-10 minutes of moist heat + 2 minutes of light massage to neck. G2 (n = 75): amitriptyline therapy. 10 mg per day in first week, 20 mg per day in second week and 30 mg per day each week thereafter. Patients were required to take the amitriptyline 80% of the days to be included in the analysis. Patients in both groups were allowed to use over-the-counter pain medication on an as-needed basis throughout the study
Outcomes	<p>Patient diaries (filled in 4x/day during 12 weeks of study) rated headache pain intensity (0-20), frequency (no. of HAs/week), and OTC medication use (no. of pills per day). SF-36 functional status was measured at baseline and at post-treatment follow-up. All outcomes results were adjusted for baseline differences</p> <p>Headache pain intensity: During the 6-week treatment period, G2 was superior to G1 (G1 = 4.3; G2 = 3.2; difference = 1.1 [95% CI 0.2 to 2.0]). However, during the 4-week post-treatment period, G1 was superior to G2 (G1 = 3.8; G2 = 5.2; difference = 1.4 [95% CI 0.5 to 2.3])</p> <p>Headache frequency: During the 6-week treatment period, G2 was more favorable than G1 (G1 = 8.6; G2 = 6.8; difference = 1.9 [95% CI -0.4 to 4.3]). However, during the 4-week post-treatment period, G1 was superior to G2 (G1 = 7.6; G2 = 11.8; difference = 4.2 [95% CI 1.9 to 6.5])</p> <p>Medication use: During the 6-week treatment period, G2 was more favorable than G1 (G1 = 1.4; G2 = 1.1; difference = 0.3 [95% CI -0.3 to 0.9]). During the 4-week post-treatment period, G1 was superior to G2 (G1 = 1.3; G2 = 2.2; difference = 0.9 [95% CI 0.3 to 1.5])</p>
Notes	Loss to follow-up: 24/150 (16%). A best-/worst-case analysis did not change the results. Side effects: In G1 4% reported side effects in the form of neck soreness and stiffness after treatment. In G2 82% reported side effects, including dry mouth, drowsiness, or weight gain

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Bove 1998

Methods	Design: parallel, 2 groups. Baseline: 2 weeks. Treatment: 4 weeks. Post-treatment follow-up: 13 weeks. Randomization method: blinded drawing of ticket/lot. Jadad quality score: 3/5. Internal validity score: 58/100
Participants	Episodic tension-type headache (n = 75). Inclusion: Headache episode = 5 but fewer than 15 per month. Age range: 20-60. Typical headache intensity 25-85/100. Recruitment: newspaper advertising. Location: outpatient chiropractic research clinic, Denmark. Mean age: 38 years. Age range: 20-59. % Female: 65

Bove 1998 (Continued)

Interventions	G1 (n = 38): soft-tissue therapy and high-velocity, low-amplitude cervical spinal manipulative therapy. Eight 15-minute sessions were given over 4 weeks. The soft-tissue treatment consisted of deep friction massage (including trigger point therapy if indicated) of the superficial and deep muscles of the neck and shoulder girdle. G2 (n = 37): soft-tissue therapy as described above plus low power (placebo) laser treatment. Eight 15-minute sessions were given over 4 weeks	
Outcomes	<p>The main outcome measures were number of headache hours/day, mean headache intensity per headache episode (0 to 100-mm VAS), and medication use</p> <p>Headache pain intensity: There were relatively small differences between the two groups 1 week after 4 weeks of treatment (G1 = 38.0; G2 = 34.0), and during the 13-week post-treatment follow-up period (G1 = 35.0; G2 = 26.0)</p> <p>Headache duration: There were relatively small differences between the two groups 1 week after 4 weeks of treatment (G1 = 1.5; G2 = 1.9), and during the 13-week post-treatment follow-up period (G1 = 2.1; G2 = 2.2)</p> <p>Medication use: There were relatively small differences between the two groups 1 week after 4 weeks of treatment (G1 = 0.4; G2 = 0.6), and during the 13-week post-treatment follow-up period (G1 = 0.5; G2 = 0.6)</p>	
Notes	Loss to follow-up: 5/75 (7%). Side effects: not specified.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Carlsson 1990

Methods	Design: parallel, 2 groups. Baseline: 3 to 8 weeks. Treatment: 2 to 12 weeks. Post-treatment follow-up: 4 to 9 weeks and 7 to 12 months. Randomization method: sealed envelope. Jadad quality score: 3/5. Internal validity score: 21/100	
Participants	Tension headache (study predated IHS criteria) (n = 48). Inclusion: NIH criteria. Recruitment: from outpatient neurology and neurosurgery clinics at hospital. Location: Goteborg, Sweden. Mean age: 35 years. Age range: 18-60. % Female: 100	
Interventions	G1 (26): relaxation, automassage, cryotherapy, TENS, and stretching, and education regarding causative factors and control of these factors. 10-12 sessions given over 8-12 weeks. G2 (22): classical Chinese acupuncture points (GB 20, GB 21, LI 4), De Chi achieved. 4-10 sessions over 2-8 weeks	
Outcomes	<p>Headache intensity (1-5 scale and 0 to 100-mm VAS) at baseline and 4-9 weeks post-treatment follow up. 0 to 100-mm VAS also measured at 7 to 12 months post-treatment. Improvement of headache intensity persisted unchanged 7-12 months after treatment. Headache frequency (1-5 scale) at baseline and 4-9 weeks post-treatment. Between-group statistical tests not performed. Analyses based on change in outcomes from baseline to 4-9 weeks post-treatment</p> <p>Headache pain intensity: At 4-9 weeks post-treatment, G1 was superior to G2 (G1 = -1.2 [0.9]; G2 = -0.5 [1.0] [SS])</p> <p>Headache frequency: At 4-9 weeks post-treatment, G2 was more favorable than G1 (G1 = 3.7 [0.8]; G2</p>	

Carlsson 1990 (Continued)

	= 3.6 [1.1] [NS])	
Notes	Loss to follow up: 10/62 (16%), 4 from G1, and 6 from G2. Side effects: a few patients reported a slight vasovagal reaction with first acupuncture treatment	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Howe 1983

Methods	Design: parallel, 2 groups. Baseline: prior to treatment. Treatment: number not specified. Post-treatment follow up: after first treatment and then 1 and 3 weeks later. Randomization method: sealed envelopes. Jadad quality score: 2/5. Internal validity score: 25/100	
Participants	Subgroup of 52 neck pain patients who presented with neck-related, chronic, non-specified headache (n = 27). Inclusion: Pain in the neck, arm, or hand due to cervical spine lesion, 50% had headaches. Recruitment: patients routinely attending surgery. Location: two-person general practice in the UK. Mean age: not specified. Age range: 15-65. % Female: not specified	
Interventions	G1 (n = 14): NSAID (azapropazone) + high-velocity, low-amplitude cervical spinal manipulative therapy. Majority of patients received 1-2 treatments. G2 (n = 13): NSAID (azapropazone). Dosage and time not reported	
Outcomes	Patient-rated degree of improvement (absent, same, better, or worse). This measure was transformed into a percentage of patients reporting being improved Headache improvement: Immediately after the first treatment, G1 was more favorable than G2 (G1 = 29%; G2 = 15% [p-value = 0.13]). At the end of 1 week of treatment, results were similar (G1 = 64%; G2 = 58% [p-value = 0.87]). At the end of 3 weeks of treatment, G2 was more favorable than G1 (G1 = 92%; G2 = 100% [p-value = 0.45])	
Notes	Loss to follow up: not specified. Side effects: no information given	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Hoyt 1979

Methods	Design: parallel, 3 groups. Baseline: immediately before treatment. Treatment: 1 session. Post-treatment follow up: immediately after treatment. Randomization method: not reported. Jadad quality score: 1/5. Internal validity score: 44/100	
Participants	Chronic muscle tension headache (predating IHS criteria) (n = 22). Inclusion: dull, non-throbbing, bilateral headaches recurring over months or years with posterior neck discomfort. Recruitment: not specified. Location: not specified. Mean age: not specified. Age range: not specified. % Female: not specified	
Interventions	G1 (n = 10): palpatory examination of cervical spine + high-velocity, low-amplitude cervical manipulation + soft-tissue procedures. One 10-minute session. G2 (n = 6): palpatory examination of cervical spine without manipulation. One session. G3 (n = 6): rest supine for 10 minutes, one session	
Outcomes	Patient-rated headache pain intensity (0-7 scale) immediately pre- and post-treatment Headache pain intensity: Immediately after one treatment, G1 was superior to G2 and G3 (G1 = 1.9; G2 = 0.0; G3 = 0.0 [F-value = 17.2; p < 0.0001])	
Notes	Loss to follow up: not specified. Side effects: No information given	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Jensen 1990

Methods	Design: parallel, 2 groups. Baseline period: 5 weeks. Treatment period: 2 weeks. Post-treatment follow up period: 3 weeks. Randomization method: envelopes. Jadad quality Score: 3/5. Internal validity score: 46/100	
Participants	Post-traumatic headache (n = 23). Inclusion: post-traumatic headache symptoms 9-12 months after diagnosis of concussion. Recruitment: patients who had been diagnosed with concussion/suspected concussion were contacted by telephone; those with post-traumatic headache were invited to participate. Location: County hospital, Aarhus, Denmark. Mean age: 32 years (based on the 19 who completed the study). Age range: 18-60. % Female: 63 (based on the 19 who completed the study)	
Interventions	G1 (n = 11): manual therapy to cervical and upper thoracic spine. Included specific mobilization ('soft passive movements of joint at outer range of motion') 'often' in combination with muscle energy technique. 2 sessions (1/week). G2 (n = 12): Cold pack to neck and shoulders for 15-20 minutes. 2 sessions (1/week)	
Outcomes	Patient diaries recorded headache pain index (based on headache intensity [VAS] 4x/day for 7 days). Analysis based on change in outcomes from baseline (weeks 1 and 5 of baseline period) to week 1 of treatment, and weeks 1, 2, and 7 post-treatment Headache pain intensity: At 3 weeks post-treatment, G1 was superior to G2 (G1 = -305.7 [329.5]; G2 = 67.4 [362.4] [SS]). At 8 weeks post-treatment, G1 was more favorable than G2 (G1 = -87.6 [404.8]; G2 = 53.4 [370.5] [NS])	
Notes	Loss to follow-up: 4/23 (17%). Side effects: not specified.	

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Jull 2002

Methods	Design: multi-center, 2x2 factorial. Baseline: 2 weeks. Treatment: 6 weeks. Post-treatment follow up: 1 week, 3, 6 and 12 months. Randomization method: permuted block, with strata for length of headache history and city of residence. Jadad quality score: 3/5. Internal validity score: 75/100	
Participants	Cervicogenic headache (n = 200). Inclusion: Headache \geq 1/week duration 2 months-10 years. Recruitment: referral from GP, advertisements. Location: 5 centers located in capital cities in Australia. Mean age: 37 years. Age range: 18-60. % Female: 70	
Interventions	G1 (n = 51): manipulative therapy as described by Maitland, including low-velocity joint mobilization and high-velocity, low-amplitude manipulation of cervical spine. 8-12 sessions. G2 (n = 52): therapeutic exercise including low-load endurance exercises to train muscle control of cervical-scapular region, postural correction exercises, cervical isometric exercises with rotary resistance, and muscle lengthening exercises as needed. 8-12 sessions. G3 (n = 49): G1 + G2. 8-12 sessions. G4 (n = 48): Control group; no physical treatment intervention	
Outcomes	Headache intensity (VAS 0-10), headache frequency (no. of HA days/week), and headache duration (no. of hours/HA/week). Analyses based on change in outcomes from baseline to 1 week post-treatment Headache pain intensity: G1, G2, and G3 were superior to G4 at 1 week post-treatment (G1 = 3.0 [2.2]; G2 = 3.3 [2.7]; G3 = 3.4 [2.7]; G4 = 1.4 [2.0]) and at 12 months post-treatment (G1 = 2.3 [2.6]; G2 = 2.8 [2.6]; G3 = 2.7 [2.2]; G4 = 1.3 [2.4]) Headache frequency: G1, G2, and G3 were superior to G4 at 1 week post-treatment (G1 = 2.1 [2.0]; G2 = 2.4 [1.5]; G3 = 2.0 [1.7]; G4 = 0.8 [1.7]) and at 12 months post-treatment (G1 = 2.3 [1.9]; G2 = 2.5 [1.7]; G3 = 2.1 [1.6]; G4 = 1.0 [1.6]) Headache duration: G3 was superior to G4 at 1 week post-treatment (G1 = 3.5 [3.9]; G2 = 2.2 [3.6]; G3 = 4.3 [4.4]; G4 = 2.1 [3.7]) and 12 months post-treatment (G1 = 3.0 [4.9]; G2 = 2.4 [4.6]; G3 = 4.3 [4.6]; G4 = 2.0 [4.4])	
Notes	Loss to follow up: 7/200 (3.5%). Side effects: 6.7% of headaches experienced by patients during treatment period (group not specified) were reportedly provoked by treatment	

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Keller 1986

Methods	Design: parallel, 2 groups. Baseline: immediately prior to treatment. Treatment: 5 minutes. Post-treatment follow up: 5 minutes and 4 hours post-treatment. Randomization method: random number table. Jadad quality score: 3/5. Internal validity score: 50/100
Participants	Tension headache (n = 60). Inclusion: Dull persistent head pain, usually bilateral, with feelings of heaviness, pressure or tightness; no headache medication within 4 hours prior to study entry. Recruitment: 1) university student clinic, 2) university student and staff population, and 3) radio, newspaper and bulletin board advertisements in general population. Location: US. Mean age: 30 years. Age range: 18-59. % Female: 75
Interventions	G1 (n = 30): Therapeutic touch with intention to heal plus rest and deep breathing; 1 session. G2 (n = 30): Placebo touch without intention to heal plus rest and deep breathing; 1 session
Outcomes	Pain using 3 subscales from McGill-Melzack Pain Questionnaire: Pain Rating Index, Number of Words Chosen, and Present Pain Intensity (0-10) measured immediately prior to treatment, and 5 minutes and 4 hours post-treatment. Data for all patients not presented at 4 hours post-treatment follow up Present Pain Intensity: 5 minutes after one treatment, G1 was superior to G2 (G1 = 0.76; G2 = 1.82; difference = 1.1 [p < 0.005]). 4 hours post-treatment, G1 was again superior to G2 (G1 = 0.54; G2 = 1.40; difference = 0.9 [p-value < 0.01])
Notes	Loss to follow up: Not specified. Side effects: not specified 15 subjects in G2 and 5 subjects in G1 used additional treatments for headache relief during the 4-hour post-treatment follow-up period. When these subjects were removed from analysis, statistically significant differences were found in favor of G1 for all three pain scales

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Marcus 1998

Methods	Design: parallel, 2 groups. Baseline: 2 weeks. Treatment: 4 weeks. Post-treatment follow up: not specified. Randomization method: not specified. Jadad quality score: 1/5. Internal validity score: 33/100
Participants	Migraine headache (n = 88). Inclusion: Migraine headache +/- aura using IHS classification, >= 1/week or >= 5 days/month. Recruitment: newspaper advertisement, posters. Location: US. Mean age: 37 years. Age range: 20-58. % Female: 100
Interventions	G1 (n = 43): postural correction, cervical range-of-motion exercises, isometric neck strengthening exercises, self-mobilization exercises, whole body stretching and conditioning, and 'flare up' management techniques (heat, ice, distraction, oscillatory movements, trigger point treatment). Patients instructed to perform program 2x/day. Four weekly 1-hour treatment sessions. G2 (n = 45): progressive muscle relaxation, breathing exercises, and thermal biofeedback training. Patients instructed to perform program 2x/day. Four weekly 1-hour treatment sessions

Marcus 1998 (Continued)

Outcomes	<p>Patient diaries at baseline and post-treatment recorded daily headache severity and medication use (severity rated 4x/day). A headache index (HI) score was calculated by taking the mean headache severity score over 2 weeks. $\geq 50\%$ reduction in HI considered clinically important. Subjects achieving $\geq 50\%$ reduction in HI scores were followed up at 3, 6, and 12 months. Treatment success maintained in both groups; however, no between-group analysis done. HI analyses based on change in outcome from baseline to after 4 weeks of treatment</p> <p>Headache index: After 4 weeks of treatment, G2 was superior to G1 (G1 = -0.4; G2 = -1.0 [$p < 0.01$]).</p> <p>Proportion 50% improved: After 4 weeks of treatment, G2 was superior to G1 (G1 = 13%; G2 = 51% [$p < 0.001$])</p>
Notes	<p>Loss to follow up: 19/88 (22%). 13 in G1 (10 did not start treatment) and 6 in G2 (5 did not start treatment). Side effects: not specified</p>

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Nelson 1998

Methods	<p>Design: parallel, 3 groups. Baseline: 4 weeks. Treatment: 8 weeks. Post-treatment follow-up: 4 weeks. Randomization method: computer-generated 1:1:1 allocation, sealed opaque envelopes. Jadad quality score: 3/5. Internal validity score: 91/100</p>
Participants	<p>Chronic migraine headache (n = 218). Inclusion: ≤ 4 episodes/month, duration ≤ 1 year. Recruitment by newspaper advertising to outpatient chiropractic research clinic in Minnesota, USA. Mean age: 38 years. Age range: 18-65. % Female: 79. 87% of all patients had more than 5 years' duration of migraine</p>
Interventions	<p>G1 (n = 77): high-velocity, low-amplitude cervical spinal manipulation. 14 sessions. Each session started with 5-10 minutes of light massage +/- trigger point therapy. G2 (n = 70): amitriptyline therapy. The dosage of 25 mg/day for the first week was increased to 50 mg/day the next week and to 75 mg/day the next week, ending with a maximum of 100 mg/day after 3 weeks. G3 (n = 71): G1 + G2</p>
Outcomes	<p>Main outcome: headache index = pain intensity (0-10)/day x 7 (0-70) during 4-week baseline, last 4 weeks of treatment, and during the 4-week follow up. Secondary outcomes were OTC medication use at all time points, and SF-36 functional status measured at baseline and at post-treatment follow up. All outcome results were adjusted for baseline differences in the analysis</p> <p>Headache index: During the last 4 weeks of the treatment, scores were similar in all 3 groups, although slightly more favorable in G1, (G1 = 9.8 [6.3]; G2 = 9.1 [6.3]; G3 = 9.8 [6.3]). At 4 weeks post-treatment, G1 was superior to G2, and G3 (SS) (G1 = 9.8 [7.0], G2 = 12.6 [7.0]; G3 = 12.6 [7.0]).</p> <p>Medication use: During the last 4 weeks of treatment, scores were similar among groups, but slightly more favorable in G2 (G1 = 1.1 [1.1]; G2 = 0.9 [1.0]; G3 = 1.1 [1.1]). At 4 weeks post-treatment, G1 was superior to G3 (SS) (G1 = 1.1 [1.3], G2 = 1.4 [1.3]; G3 = 1.7 [1.5])</p>
Notes	<p>Loss to follow-up: 56/218 (26%). Alternative analysis with imputed data based on a missing data analysis did not change the trial results and conclusions. Side effects: 58% of patients in G2 and G3 reported side effects including dry mouth, drowsiness, or weight gain; 10% withdrew from treatment due to side</p>

Nelson 1998 (Continued)

	effects. Side effects for G1 were infrequent and mild (neck soreness). No patients withdrew due to side effects	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Nilsson 1997

Methods	Design: prospective, parallel, 2 groups. Baseline: 1-2 weeks. Treatment: 3 weeks. Post-treatment follow up: 1 week. Randomization method: labeled tickets prepared in advance, randomly drawn by project secretary. Jadad quality score: 3/5. Internal validity score: 65/100	
Participants	Cervicogenic headache (n = 54). Inclusion: Headache \geq 5 days/month, duration \geq 3 months, no effect of migraine medication, no prior spinal manipulation, headache located in occipital region with or without forward radiation, patient able to identify neck movements or postures that aggravate headaches, decreased passive range of motion of cervical spine, typical headache intensity 25-85/100. Recruitment: advertisements in local press. Location: outpatient clinic, Denmark. Median age: 37 years. Age range: 20-60. % Female: 57	
Interventions	G1 (n = 28): high-velocity, low-amplitude spinal manipulation; toggle recoil technique in upper cervical spine, diversified technique in lower cervical spine. 6 sessions. G2 (n = 26): deep friction massage including trigger point therapy to the posterior muscles of shoulder girdle and upper thoracic and lower cervical region plus low-level laser (no therapeutic effect). 6 sessions	
Outcomes	Patient diaries recorded headache episode intensity (0-100 VAS), number of headache hours/day, and number of pain killers/day during 1-week baseline period and 1 week post-treatment follow-up period. Analyses based on change in outcomes from baseline to post-treatment follow up Headache pain intensity: At the end of 4 weeks of treatment, G1 was superior to G2 (G1 = 17.0; G2 = 4.2; difference = 12.8 [p = 0.04]) Medication use: At the end of 4 weeks of treatment, G1 was more favorable than G2 (G1 = 0.7; G2 = 0.3; difference = 0.4 [p = 0.14]) Headache duration: At the end of 4 weeks of treatment, G1 was superior to G2 (G1 = 3.2; G2 = 1.6; difference = 1.6 [p = 0.03])	
Notes	Loss to follow-up: 1/54 (2%). Side effects: None reported. Special note: 15/54 participants were enrolled at a later date (after some statistical analyses had been performed) and had 1 week of baseline instead of 2 weeks	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Parker 1980

Methods	Design: prospective, parallel, 3 groups. Baseline: 2 months. Treatment: 2 months. Post-treatment follow up: 2 months. Randomization method: not specified. Jadad quality score: 1/5. Internal validity score: 67/100
Participants	Migraine headache (n = 85). Inclusion: Diagnosis of migraine headache (predates IHS criteria). Recruitment: media. Location: Australia. Mean age: 41 years. Age range: 12-55. % Female: 61
Interventions	G1 (n = 30): cervical spine manipulation ('movement of joint beyond normal limitations') + other spinal manipulation, all provided by chiropractors. Up to 2 sessions per week. G2 (n = 27): cervical spine manipulation + other 'manipulatory techniques', all provided by medical doctors or physical therapists. Up to 2 sessions per week. G3 (n = 28): cervical spine mobilization ('small oscillatory movements to a joint within its normal range') + other spinal mobilization, all provided by medical doctors or physical therapists. Up to 2 sessions per week
Outcomes	Patient diaries ('migraine form') filled out after each migraine attack recording headache frequency, headache duration (hours/attack), headache intensity (VAS 0-10); disability (1-5). Analyses based on group differences in change scores in outcomes from baseline to post-treatment follow up Outcomes at 8 weeks post-treatment: Headache intensity: G1 = 2.1; G2 = 0.6; G3 = 0.7 (group differences NS). Headache frequency: G1 = 3.5; G2 = 1.2; G3 = 3.0 (group differences NS) Headache duration: G1 = 5.1; G2 = 0.1; G3 = 3.0 (group differences NS) Headache disability: G1 = 0.9; G2 = 0.3; G3 = 0.6 (group differences NS).
Notes	Loss to follow up: 3/85 (4%). Side effects: not specified. In the trial, several contrasts were made and F-ratios were given: G1 vs. G2 + G3, and G1 + G2 vs. G3. The means for the group combinations were not reported

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Reich 1989

Methods	Study design: parallel, 4 groups. Baseline: 4 weeks. Treatment: ?. Post-treatment follow up: 1, 8, 24, and 36 months. Randomization method: not specified. Jadad quality score: 0/5. Internal validity score: 29/100
Participants	Vascular/migraine and muscle contraction headache (n = 703 uncertain). Inclusion: Either vascular or muscle contraction headache (could not have both). Recruitment: physician referral. Location: US. Mean age: not specified. Age min: 18. % Female: 58 (of the 703 who completed study)
Interventions	G1 (n = 173) relaxation, including cognitively oriented psychotherapy, hypnosis, or progressive muscle relaxation. G2 (n = 161): electrical modalities, including TENS and electrical neurotransmitter modulation. G3 (n = 178): biofeedback (thermal or EMG). G4 (n = 191): multi-modal group (a combination of two of the above groups). Each group received either \leq 15 treatment sessions, or \geq 15 treatment

Reich 1989 (Continued)

	sessions	
Outcomes	<p>Patient diaries recorded daily headache pain (1-5) measured 6x/day, and medication use. Diaries kept for 4-week periods at baseline, immediately following treatment, eight months, 24 months, and 36 months. Analysis stratified by number of treatments (≤ 15 and > 15) and type of headache (migraine or tension-type). Results presented in graphs and difficult to interpret. Repeated measures analyses found statistically significant results between groups for pain and weekly headache hours. Combination of treatments in G4 not specified. No means or variability estimates were given; means estimated from graphs</p> <p>Headache pain intensity (migraine): G1 performed the worst and G3 performed the best at the end of 4 weeks of treatment (G1 = 2.7; G2 = 2.0; G3 = 1.4), and 36 months post-treatment (G1 = 3.0; G2 = 2.4; G3 = 1.8)</p> <p>Headache duration (migraine): G1 performed the worst and G3 performed the best at the end of 4 weeks of treatment (G1 = 8.0; G2 = 3.5; G3 = 1.0), and 36 months post-treatment (G1 = 13.0; G2 = 7.0; G3 = 1.5)</p> <p>Headache pain intensity (tension-type): G1 performed the worst and G3 performed the best at the end of 4 weeks of treatment (G1 = 2.5; G2 = 2.2; G3 = 1.8), and 36 months post-treatment (G1 = 2.9; G2 = 2.3; G3 = 1.7)</p> <p>Headache duration (tension-type): G1 performed the worst and G3 performed the best at the end of 4 weeks of treatment (G1 = 10.0; G2 = 5.0; G3 = 1.0), and 36 months post-treatment (G1 = 15.0; G2 = 8.0; G3 = 1.5)</p>	
Notes	Loss to follow up: not specified.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Sherman 1998

Methods	Design: 2 groups, double-blind crossover. Baseline: 3-6 weeks. Treatment: 2 weeks then crossed over to other group for 2 weeks. Post-treatment follow up: 3 weeks and 1-6 months. Randomization method: sealed envelope. Jadad quality score: 3/5. Internal validity score: 50/100
Participants	Migraine (n = 12). Inclusion: Migraine headaches as defined by IHS, multi-year history of headache. Recruitment: from patients at military center. Location: US Army Medical Center. Mean age: 50. Age range: 33-63. % Female: 83
Interventions	G1 (n = 7): pulsating electromagnetic field (PEMF) applied to medial thigh. 10 sessions (1 hour/day, 5 days/week). G2 (n = 5): placebo (inactive PEMF). 10 sessions (1 hour/day, 5 days/week). Note: G1 and G2 represent patients who received that treatment first, prior to crossing over to other treatment
Outcomes	<p>Patient diaries recorded number of headaches per week measured during baseline and 2-week treatment period. Analyses based on change in outcomes from baseline to after 2 weeks of treatment</p> <p>Number of headaches/week: After 2 weeks of treatment, G1 was less favorable than G2 (G1 = 2.3 [1.5]; G2 = 0.8 [0.9] [NS])</p>

Sherman 1998 (Continued)

Notes	Three patients in G1 inadvertently received half power treatments. Side effects: not specified Data are presented for the patients who received either treatment first, as 5/6 patients (active PEMF first) declined to cross over	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Sherman 1999

Methods	Design: prospective, parallel, 2 groups. Baseline: 1 month. Treatment: 2 weeks. Post-treatment follow up: 1 month. Randomization method: computer-generated algorithm. Jadad quality score: 4/5. Internal validity score: 39/100	
Participants	Migraine (n = 48). Inclusion: Migraine headaches as defined by IHS. Recruitment: not specified. Location: not specified. Mean age: 46 years. Age range: not specified. % Female: 81 (based on the 42 individuals who completed study)	
Interventions	G1 (n = 27): pulsating electromagnetic field (PEMF) applied to medial thigh. 10 sessions (1 hour/day, 5 days/week). G2 (n = 21): placebo (inactive PEMF). 10 sessions (1 hour/day, 5 days/week)	
Outcomes	Diaries recording headache frequency, duration, intensity (VAS 0-10), and headache-related medication use. Composite scores indicating 'headache activity' calculated from change in outcomes from baseline to 4 weeks post-treatment Headache activity index: After 2 weeks of treatment, G1 was superior to G2 (G1 = 3.5 [1.0]; G2 = 2.6 [1.0] [SS])	
Notes	Loss to follow up: 6/48 (13%). Three were dropouts (2 active treatment group, 1 placebo group) and 3 patients experienced only tension-type headaches during study and were removed from analyses. Side effects: not specified	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Solomon 1985

Methods	Design: parallel, 3 groups. Baseline: immediately pre-treatment. Treatment: one session. Post-treatment follow up: immediately post-treatment. Randomization method: not described. Jadad quality score: 0/5. Internal validity score: 19/100	
---------	---	--

Solomon 1985 (Continued)

Participants	Migraine (22/62) or muscle-contraction headache (33/62) or both (8/62) (n = 62). Inclusion: not specified. Recruitment: patients presenting to headache unit at time of headache asked to participate. Location: headache unit of medical center, New York. Age mean/median: not specified. Age range: not specified. % Female: not specified	
Interventions	G1 (n = 18): Cranial electrotherapy-perceived stimulus max at 4 milliamp. One 15-minute session. G2 (n = 18): Cranial electrotherapy-subliminal stimulus max at 4 milliamp. One 15-minute session. G3 (n = 22): detuned cranial electrotherapy (placebo). One 15-minute session	
Outcomes	Patient-rated pain severity (1-10 scale) measured immediately pre- and post-treatment Headache pain intensity improvement: Immediately after one treatment, G1 was superior to G3 (G1 = 2.1 [1.9]; G2 = 1.0 [1.5]; G3 = 0.9 [1.5])	
Notes	Loss to follow up: 4/62 (6%) due to 'technical reasons'. Side effects: no information given Raw data were extracted from tables to calculate change scores from baseline to post-treatment. Standard deviations on the change scores were then calculated	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Solomon 1989

Methods	Design: parallel, 2 groups, double-blind, placebo-controlled. Baseline: before each treatment. Treatment: 6-10 weeks (minimum of 4 episodes of headache). Post-treatment follow up: after each treatment and at end of 6- to 10-week treatment period. Randomization method: not described. Jadad quality score: 1/5. Internal validity score: 42/100	
Participants	Muscle contraction headache (n = 112). Inclusion: Tension-type headache with or without migraine headache, 4 episodes/month for 1 year. Age > 18. Recruitment: from private practice or clinic practices. Location: Multi-center, US. Age mean/median: mean of 42 years. Age range: 20-70. % Female: not specified	
Interventions	G1 (n = 57): cranial electrotherapy (CE), given at max tolerance (1-4 milliamps). Automatic shut off after 20 minutes. G2 (n = 55): placebo CE. Automatic shut-off after 70 seconds, but meter registered 1-4 milliamps for 20 minutes. All patients instructed in use of pain suppressor unit at home when experiencing a headache episode. Each session lasted 20 minutes. If necessary a second 20-minute session was allowed	
Outcomes	Patient diaries rated pain intensity (0-10 scale) before and after use of stimulator unit. Global rating of improvement at end of study on 4-level ordinal scale (highly to not effective). Headache pain intensity analysis based on change in outcome from baseline to the end of 4-6 weeks of treatment Headache pain intensity: At the end of 4-6 weeks of treatment, G1 was superior to G2 (G1 = 2.1 [2.1]; G2 = 1.2 [2.1] [SS]) % of patients rating CE effective: At the end of 4-6 weeks of treatment, G1 was superior to G2 (G1 = 36%; G2 = 16% [p = 0.006])	

Solomon 1989 (Continued)

Notes	Loss to follow up: 12/112 (11%) because of lack of headaches that could be evaluated. Side effects: 6/57 in G1 (active) and 7/55 in G2 (placebo) noted side effects (e.g. nausea, dizziness, rash). For G1 the most common symptom was irritation at the electrode sites. G1 had longer duration in hours of headaches at baseline than G2	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Tuchin 2000

Methods	Design: Prospective, parallel, 2 groups. Baseline: 2 months. Treatment: 2 months. Post-treatment follow up: 2 months. Randomization method: participants were 'randomly allocated' based on the first letter of the participant's surname by an 'impartial research assistant'. Jadad quality score: 1/5. Internal validity score: 38/100	
Participants	Migraine (n = 127). Inclusion: Headache ≥ 1 x/month. Had to have ≥ 5 of the following: 1) inability to continue normal activities or need to seek quiet, dark area, 2) pain in temples, 3) throbbing pain, 4) nausea, vomiting, aura, photophobia or phonophobia, 5) migraine precipitated by weather changes, 6) migraine aggravated by head or neck movements, 7) previous diagnosis of migraine by specialist, 8) family history of migraine. Recruitment: radio and newspaper advertisements. Location: chiropractic research center, Macquarie University, Sydney, Australia. Mean age: 39 years. Age range: not specified. % Female: 68	
Interventions	G1 (n = 83): high-velocity, low-amplitude spinal manipulative therapy; area of spine not specified. Up to 16 treatments. G2 (n = 40): detuned interferential therapy. Number of sessions unspecified	
Outcomes	Patient diaries recorded intensity (VAS 0-10 scale), headache frequency (no. episodes/month), duration (no. of hours per episode), and disability (no. of hours before able to return to normal activities) for 6-month study period. Analyses based on change in outcomes from baseline to post-treatment period Headache pain intensity: At 8 weeks post-treatment, G2 was more favorable than G1 (G1 = 1.1; G2 = 1.7 [p > 0.05]) Headache duration: At 8 weeks post-treatment, G1 was superior to G2 (G1 = 8.5; G2 = 2.8 [p < 0.01]) Headache frequency: At 8 weeks post-treatment, G1 was superior to G2 (G1 = 3.0; G2 = 0.4 [p < 0.005]) Medication use: At 8 weeks post-treatment, G1 was superior to G2 (G1 = 11.5; G2 = 3.9 [p < 0.001])	
Notes	Loss to follow up: 4/127 (3%). Side effects: 2 patients from G1 withdrew from study due to side effects, including soreness and increased migraine headache Tuchin et al correctly used analysis of covariance to adjust for differences in baseline values. The change scores from baseline and post-treatment have been abstracted and the effect sizes have been calculated based on the change scores and the p-values	
Risk of bias		
Item	Authors' judgement	Description

Tuchin 2000 (Continued)

Allocation concealment?	No	C - Inadequate
-------------------------	----	----------------

Whittingham 1997

Methods	Design: 2 groups, blinded, placebo-controlled, crossover. Powered at 80% for first phase, parallel-group design. Baseline: 3 weeks. Treatment: 3 weeks. Washout: 3 weeks. Crossover treatment: 3 weeks. Washout: 3 weeks. Post-treatment follow up: 8 and 12 months. Randomization method: drawing allocated file numbers out of a hat. Jadad quality score: 3/5. Internal validity score: 54/100
Participants	Cervicogenic headache (n = 105). Inclusion criteria: > 6 months' duration, \geq 4 episodes/month. Recruitment by advertising in daily newspaper, university newsletter, and radio. Location: outpatient chiropractic research clinic in Melbourne, Australia. Mean age: 41 years. Age range: 17-81. % Female: 60. 64% had HA duration of > 10 years
Interventions	G1 (n = 56): spinal manipulative therapy (toggle recoil) to upper cervical spine. 3 sessions/week for 3 weeks. G2 (n = 49): Placebo (deactivated mechanical adjusting instrument to upper cervical spine). 3 sessions/week for 3 weeks
Outcomes	Measured before and after each treatment phase: Main outcome: Pain drawing of head and neck with pain intensity (0-100) and number of headache locations. Secondary outcomes: Neck Disability Index (NDI), Sickness Impact Profile (SIP), cervical spine range of motion, and pressure algometry. Patient diaries recorded headache intensity, number and duration of episodes, and medication use Headache pain intensity: (from pain drawings) At the end of 3 weeks of treatment, G1 was superior to G2 (G1 = 23.9 [28.5]; G2 = 77.7 [20.1] [SS]) Headache disability (NDI subscale): At the end of 3 weeks of treatment, G1 was superior to G2 (G1 = 1.6 [1.5]; G2 = 2.9 [0.9] [SS]) Number of headache locations: At the end of 3 weeks of treatment, G1 was superior to G2 (G1 = 2.0 [2.3]; G2 = 5.6 [4.1] [SS])
Notes	3/105 (3%) lost to follow-up. Carry-over and time effects present. Trial result evaluated on outcomes from first phase. Unexplained inconsistency between main outcomes and diary data. Effectiveness of blinding not evaluated adequately. Side effects: None from either treatment

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

CE = cranial electrotherapy; CI = confidence interval; EMG = electromyographic; G = (treatment) group; GP = general practitioner; HA = headache; HI = headache index; IHS = International Headache Society; NIH = National Institutes of Health; NS = not statistically significant ($p > 0.05$); NSAID = non-steroidal anti-inflammatory drug; OTC = over-the-counter; PEMF = pulsating electromagnetic field; SS = statistically significant ($p \leq 0.05$); TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; UV = ultraviolet; VAS = visual analog scale

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Ahmed 2000	Intervention of interest: invasive physical treatment
Airaksinen 1992	Condition studied: change in trigger points
Gray 1994	Condition studied: change in TMJ symptoms
Iwata 1998	Condition studied: visual disturbance/symptoms
Kaliappen 1987	Intervention of interest: yoga/relaxation
Kaliappen 1992	Intervention of interest: yoga/relaxation
Karppinen 1999	Intervention of interest: invasive physical treatment
Lemstra 2002	Non-invasive treatment could not be isolated from multimodal intervention
MacNeil 1995	No quantitative data available. Intervention of interest: therapeutic touch
Sargent 1986	Intervention of interest: relaxation/biofeedback
Scharff 1996	Follow-up data on patients from Marcus 1998; could not be analyzed
Schokker 1990	Condition studied: change in TMJ symptoms
Sethi 1981	Intervention of interest: yoga/relaxation
Witucki 1994	Intervention of interest: aerobic exercises

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Definition of levels of evidence

Level of evidence of efficacy or inefficacy	# RCTs with validity score ≥ 50	# RCTs with validity score < 50	Notes
Strong	≥ 2	-	<p>Absolute efficacy: A treatment was superior(1) to a placebo or no-treatment control with $p < 0.05$.</p> <p>Relative efficacy: A treatment was superior(1) to a comparison therapy with $p < 0.05$, or superior(1)/similar(2)/equivalent(3) to an established efficacious treatment with LCL > -0.4. A combination therapy was superior(1) to one of its components with $p < 0.05$.</p> <p>Absolute inefficacy: A treatment was inferior(4) to a placebo or no-treatment control with $p < 0.05$, or inferior(4)/similar(2)/equivalent(3) to a placebo or no-treatment control with UCL < 0.4.</p> <p>Relative inefficacy: A treatment was inferior(4) to a comparison therapy with $p < 0.05$. A combination therapy was inferior(4) to one of its components with $p < 0.05$, or inferior(4)/similar(2)/equivalent(3) to one of its components with UCL < 0.4.</p>
Moderate	1	-	As above.
Limited	-	≥ 1	As above.

Table 1. Definition of levels of evidence (Continued)

Preliminary			Standards for classification above were not met for either statistical significance or confidence limits
Conflicting			The evidence from RCTs that could be pooled was conflicting.
Key to terms:			(1) Superior: $ES \geq 0.4$. (2) Similar: $-0.4 < ES < 0.4$. (3) Equivalent: $0.4 > ES$, LCL, & UCL > -0.4 . (4) Inferior: $ES \leq -0.4$.

Table 2. Methodological quality of included studies A -H (+ = yes; - = no; p = unclear)

Validity items	Ahonen 1984	Ammer 1990	Bitterli 1977	Boline 1995	Bove 1998	Carlsson 1990	Howe 1983	Hoyt 1979
Group comparability	p	+	p	+	p	-	p	p
Randomization procedure	-	-	p	p	p	p	p	-
Outcome measure	+	p	+	+	+	+	p	p
Patient blinding	na	na	-	na	na	na	na	na
Treatment provider blinding	na	na	na	na	na	na	na	na
Unbiased outcomes assessment	-	-	p	p	p	p	-	p
Attention bias	-	p	-	na	p	-	-	p
A priori hypothesis	p	+	p	+	p	-	-	+

Table 2. Methodological quality of included studies A -H (+ = yes; - = no; p = unclear) (Continued)

Appropri- ate statistical tests	-	+	p	+	p	-	p	p
Ade- quate statis- tical power	-	-	-	+	+	-	-	-
Dropouts analysis	na	na	-	+	p	p	-	na
Missing data analysis	na	na	-	+	p	-	-	na
Intention- to-treat analysis	+	+	-	+	+	-	+	na
p-level adjustments	+	-	na	+	-	-	-	na
Total valid- ity % score	40	50	29	91	58	21	25	44
Informa- tiveness Items								
Defined in- clusion and exclusion criteria	P	P	P	+	+	+	P	P
Adequate follow-up period	+	-	+	p	+	+	-	-
Defined in- tervention protocol	+	+	p	+	p	+	p	+
Compar- ison to ex- isting treat- ment	p	-	-	+	+	+	-	-
Confidence intervals	p	-	+	+	+	p	+	-

Table 2. Methodological quality of included studies A -H (+ = yes; - = no; p = unclear) (Continued)

Appropriate conclusions	p	+	p	+	+	p	-	+
Jadad scale item								
Randomization procedure	0	0	2	2	2	2	2	0
Patient and treatment provider blinding	0	0	0	0	0	0	0	0
Dropouts analysis	1	1	0	1	1	1	0	1
Total Jadad score	1	1	2	3	3	3	2	1

Table 3. Methodological quality of included studies J-P (+ = yes; - = no; p = unclear)

Validity items	Jensen 1990	Jull 2002	Keller 1986	Marcus 1998	Nelson 1998	Nilsson 1997	Parker 1980
Group comparability	p	+	p	+	+	p	p
Randomization procedure	p	+	p	-	p	p	-
Outcome measure	+	+	+	+	+	+	+
Patient blinding	na	na	p	na	na	na	na
Treatment provider blinding	na	na	na	na	na	na	na
Unbiased outcomes assessment	p	p	p	p	p	p	p
Attention bias	-	-	p	-	na	+	+

Table 3. Methodological quality of included studies J-P (+ = yes; - = no; p = unclear) (Continued)

A priori hypothesis	p	+	+	p	+	+	+
Appropriate statistical tests	+	+	+	-	+	+	+
Adequate statistical power	-	+	-	-	+	-	-
Dropouts analysis	p	+	p	p	+	na	p
Missing data analysis	-	p	-	-	+	na	p
Intention-to-treat analysis	+	+	na	p	+	+	+
p-level adjustments	-	-	-	-	+	-	+
Total validity % score	46	75	50	33	91	65	67
Informative-ness Items							
Defined inclusion and exclusion criteria	p	+	p	p	+	+	+
Adequate follow-up period	p	+	-	-	p	-	+
Defined intervention protocol	p	+	+	+	+	+	p
Comparison to existing treatment	-	+	-	+	+	+	-
Confidence intervals	+	+	-	-	+	+	-
Appropriate conclusions	p	p	p	p	+	p	p

Table 3. Methodological quality of included studies J-P (+ = yes; - = no; p = unclear) (Continued)

Jadad scale item							
Randomization procedure	2	2	2	0	2	2	0
Patient and treatment provider blinding	0	0	0	0	0	0	0
Dropouts analysis	1	1	1	1	1	1	1
Total Jadad score	3	3	3	1	3	3	1

Table 4. Methodological quality of included studies R-Z (+ = yes; - = no; p = unclear)

Validity items	Reich 1989	Sherman 1998	Sherman 1999	Solomon 1985	Solomon 1989	Tuchin 2000	Whittingham 1997
Group comparability	-	-	-	-	p	+	+
Randomization procedure	-	p	p	-	-	-	p
Outcome measure	+	+	+	p	+	+	+
Patient blinding	na	p	+	p	p	na	p
Treatment provider blinding	na	+	+	-	na	na	na
Unbiased outcomes assessment	p	-	p	p	p	p	p
Attention bias	-	+	+	-	na	-	p
A priori hypothesis	p	+	p	p	p	-	-

Table 4. Methodological quality of included studies R-Z (+ = yes; - = no; p = unclear) (Continued)

Appropriate statistical tests	+	p	-	-	+	-	+
Adequate statistical power	-	-	-	-	-	-	+
Dropouts analysis	-	na	-	-	p	+	na
Missing data analysis	-	na	-	-	-	p	p
Intention-to-treat analysis	p	-	-	p	p	p	-
p-level adjustments	-	na	-	na	-	-	-
Total validity % score	29	50	39	19	42	38	54
Informative-ness Items							
Defined inclusion and exclusion criteria	p	p	p	p	p	+	+
Adequate follow-up period	+	na	p	-	-	p	na
Defined intervention protocol	-	p	+	+	+	+	+
Comparison to existing treatment	+	-	p	+	-	-	+
Confidence intervals	-	p	+	+	+	+	+
Appropriate conclusions	p	p	p	p	p	-	+
Jadad scale item							

Table 4. Methodological quality of included studies R-Z (+ = yes; - = no; p = unclear) (Continued)

Random-ization procedure	0	2	2	0	0	0	2
Patient and treatment provider blinding	0	0	2	0	0	0	0
Dropouts analysis	0	1	0	0	1	1	1
Total Jadad score	0	3	4	0	1	1	3

Table 5. List of comparisons: migraine headache (* - sign favors comparison group)

Intervention	Comparison	Outcome measure	Study	Time points	Group difference*	Difference % points*	Effect size (ES)*	ES CI	95%	ES calc method
Home exercise, stretching, and heat/ice	Biofeedback thermal	Headache index								
		(scale 0-4)	Marcus1998 (n = 88)	After 4 weeks of treatment	-0.6	-16	-0.6	-1.1 to -0.1		From p-value
		Proportion 50% improved								
		1-100	Marcus1998 (n = 88)	After 4 weeks of treatment	-38.0	na	-0.8	-1.3 to -0.3		Probit transformation
SMT	Amitriptyline	Headache index								
		(scale 0-70)	Nelson 1998 (n = 218)	During last 4 weeks of treatment	-0.7	-1	-0.1	-0.5 to 0.3		SMD

Table 5. List of comparisons: migraine headache (* - sign favors comparison group) (Continued)

		(As above)	(As above)	4 weeks post-treatment	2.8	4	0.4	0.0 to 0.8	SMD
		Medication use							
		(no. pills/day)	Nelson 1998 (n = 218)	During last 4 weeks of treatment	-0.2	na	-0.2	-0.6 to 0.2	SMD
		(As above)	(As above)	4 weeks post-treatment	0.3	na	0.2	-0.2 to 0.6	SMD
SMT	SMT + amitriptyline	Headache index							
		(scale 0-70)	Nelson 1998 (n = 218)	During last 4 weeks of treatment	0.0	0	0.0	-0.4 to 0.4	SMD
		(As above)	(As above)	4 weeks post-treatment	2.8	4	0.4	0.0 to 0.8	SMD
		Medication use							
		(no. pills/day)	Nelson 1998 (n = 218)	During last 4 weeks of treatment	0.0	na	0.0	-0.4 to 0.4	SMD
		(As above)	(As above)	4 weeks post-treatment	0.6	na	0.4	0.0 to 0.8	SMD
SMT + amitriptyline	Amitriptyline	Headache index							
		(scale 0-70)	Nelson 1998 (n = 218)	During last 4 weeks of treatment	-0.7	-1	-0.1	-0.5 to 0.4	SMD
		(As above)	(As above)	4 weeks post-treatment	0.0	0	0.0	-0.4 to 0.4	SMD

Table 5. List of comparisons: migraine headache (* - sign favors comparison group) (Continued)

		Medication use							
		(no. pills/day)	Nelson 1998 (n = 218)	During last 4 weeks of treatment	-0.2	na	-0.2	-0.6 to 0.2	SMD
		(As above)	(As above)	4 weeks post-treatment	-0.3	na	-0.2	-0.6 to 0.2	SMD
SMT (chiropractors)	Spinal mobilization (medical doctors/physical therapists)	Headache pain intensity							
		(scale 0-10)	Parker 1980 (n = 85)	8 weeks post-treatment	1.4	14	0.4	-0.2 to 1.0	Imputed from f-value
		Headache frequency							
			Parker 1980 (n = 85)	8 weeks post-treatment	0.5	na	0.1	-0.5 to 0.7	Imputed from f-value
		Headache duration							
			Parker 1980 (n = 85)	8 weeks post-treatment	2.1	na	0.1	-0.5 to 0.7	Imputed from f-value
		Headache disability							
		(scale 0-5)	Parker 1980 (n = 85)	8 weeks post-treatment	0.3	6	0.1	-0.5 to 0.7	Imputed from f-value
SMT (medical doctors/physical therapists)	Spinal mobilization (medical doctors/physical therapists)	Headache pain intensity							

Table 5. List of comparisons: migraine headache (* - sign favors comparison group) (Continued)

	ical therapists)								
		(scale 0-10)	Parker 1980 (n = 85)	8 weeks post-treatment	-0.1	-1	?	?	?
		Headache frequency							
			Parker 1980 (n = 85)	8 weeks post-treatment	-1.8	na	?	?	?
		Headache duration							
			Parker 1980 (n = 85)	8 weeks post-treatment	-2.9	na	?	?	?
		Headache disability							
		(scale 0-5)	Parker 1980 (n = 85)	8 weeks post-treatment	-0.3	-6	?	?	?
SMT (chiropractors)	SMT (medical doctors/physical therapists)	Headache pain intensity							
		(scale 0-10)	Parker 1980 (n = 85)	8 weeks post-treatment	1.5	15	?	?	?
		Headache frequency							
			Parker 1980 (n = 85)	8 weeks post-treatment	2.3	na	?	?	?
		Headache duration							

Table 5. List of comparisons: migraine headache (* - sign favors comparison group) (Continued)

			Parker 1980 (n = 85)	8 weeks post- treatment	5.0	na	?	?	?
		Headache disability							
		(scale 0-5)	Parker 1980 (n = 85)	8 weeks post- treatment	0.6	12	?	?	?
TENS and electri- cal neuro- transmit- ter modu- lation	Biofeed- back ther- mal	Headache pain inten- sity							
		(scale 1-5)	Reich 1989 (n = 392)	End of 4 weeks of treatment	-0.6	-12	?	?	?
		As above	As above	36 months post- treatment	-0.6	-12	?	?	?
		Headache duration							
		(0-168)	Reich 1989 (n = 392)	End of 4 weeks of treatment	-2.5	na	?	?	?
		As above	As above	36 months post- treatment	-5.5	na	?	?	?
TENS and electri- cal neuro- transmit- ter modu- lation	Relaxation	Headache pain inten- sity							
		(scale 1-5)	Reich 1989 (n = 392)	End of 4 weeks of treatment	0.7	14	?	?	?

Table 5. List of comparisons: migraine headache (* - sign favors comparison group) (Continued)

		As above	As above	36 months post-treatment	0.6	12	?	?	?
		Headache duration							
		(0-168)	Reich 1989 (n = 392)	End of 4 weeks of treatment	4.5	na	?	?	?
		As above	As above	36 months post-treatment	6.0	na	?	?	?
Electro-magnetic treatment	Placebo electro-magnetic treatment	Number of headaches/ week							
		na	Sherman1998 (n = 12)	After 2 weeks of treatment	1.5	na	1.1	-0.2 to 2.3	SMD
Electro-magnetic treatment	Placebo electro-magnetic treatment	Headache activity index (frequency, intensity, duration, and medication use)							
		(scale 1-5)	Sherman 1999 (n = 48)	4 weeks post-treatment	0.9	18	0.9	0.2 to 1.5	SMD
SMT	Placebo interferential	Headache pain intensity							
		(scale 0-10)	Tuchin 2000 (n = 127)	8 weeks post-treatment	-0.6	-6	-0.4	-0.8 to 0.1	p-values
		Headache duration							

Table 5. List of comparisons: migraine headache (* - sign favors comparison group) (Continued)

		(hours per episode)	Tuchin 2000 (n = 127)	8 weeks post-treatment	5.7	na	0.5	0.1 to 0.9	p-values
		Headache frequency							
		# per month	Tuchin 2000 (n = 127)	8 weeks post-treatment	2.6	na	0.5	0.1 to 0.9	p-values
		Medication use							
		# per month	Tuchin 2000 (n = 127)	8 weeks post-treatment	7.6	na	0.6	0.3 to 1.0	p-values

Table 6. List of comparisons: headache not classifiable (* - sign favors compar. group)

Intervention	Comparison	Outcome measure	Study	Time points	Group difference*	Difference % points*	Effect size (ES)*	ES 95% CI	ES calc method
Mobilization	Cold packs	Headache pain intensity reduction							
		?	Jensen 1990 (n = 23)	3 weeks post-treatment	373.1	na	1.1	0.1 to 2.0	SMD
		(As above)	(As above)	8 weeks post-treatment	141.0	na	0.4	-0.5 to 1.2	SMD
Cranial electrotherapy	Placebo cranial electrotherapy	Headache pain intensity improvement							
		(1-10)	Solomon 1985 (n = 62)	Immediately after 1 treatment	1.2	12	0.7	0.1 to 1.3	SMD

Table 6. List of comparisons: headache not classifiable (* - sign favors compar. group) (Continued)

Cranial electrotherapy	Sublim cranial electrotherapy	Headache pain intensity improvement							
		1-10)	Solomon 1985 (n = 62)	Immediately after 1 treatment	1.1	11	.6	-0.1 to 1.3	SMD
Sublim cranial electrotherapy	Placebo cranial electrotherapy	Headache pain intensity improvement							
		(1-10)	Solomon 1985 (n = 62)	Immediately after 1 treatment	0.2	2	0.1	-0.5 to 0.7	SMD

Table 7. List of comparisons: tension-type headache (* - sign favors comparison group)

Intervention	Comparison	Outcome measure	Study	Time points	Group difference*	Difference % points*	Effect Size (ES)*	ES CI	95%	ES calc method
Massage, ultrasound, and hot packs	Acupuncture	Headache pain intensity								
		(0-100)	Ahonen 1984 (n = 22)	End of 3 weeks of treatment	-4.0	-4	-0.1	-1.0 to 0.8		SMD
		As above	As above	8 weeks post-treatment	-17.0	-17	-0.6	-1.5 to 0.3		SMD
		As above	As above	20 weeks post-treatment	5.0	5	0.2	-0.7 to 1.1		SMD
SMT	Amitriptyline	Headache pain intensity								

Table 7. List of comparisons: tension-type headache (* - sign favors comparison group) (Continued)

		(0-20)	Boline 1995 (n = 150)	During 6 week treatment period	-1.1	-6	-0.4	-0.8 to 0.0	SMD
		(As above)	(As above)	During 4 week post-treatment period	1.4	7	0.6	0.2 to 1.0	SMD
		Headache frequency							
		(0-28)	Boline 1995 (n = 150)	During 6 week treatment period	-1.8	-6	-0.3	-0.7 to 0.1	SMD
		(As above)	(As above)	During 4 week post-treatment period	4.2	15	0.5	0.1 to 0.9	SMD
		Medication use							
		(no. of pills/day)	Boline 1995 (n = 150)	During 6 week treatment period	-0.3	na	-0.2	-0.6 to 0.2	SMD
		(As above)	(As above)	During 4 week post-treatment period	0.9	na	0.5	0.1 to 0.9	SMD
SMT + massage	Massage + placebo laser	Headache pain intensity							
		(scale 0-100)	Bove 1998 (n = 75)	1 week after 4 weeks of treatment	-4.0	-4	-0.3	-0.8 to 0.2	CIs and p-values
		(As above)	(As above)	13 weeks after 4 weeks of	-9.0	-9	-0.4	-0.9 to 0.1	CIs and p-values

Table 7. List of comparisons: tension-type headache (* - sign favors comparison group) (Continued)

				treatment					
		Headache duration							
		(0-24 hours/day)	Bove 1998 (n = 75)	1 week after 4 weeks of treatment	0.4	2	-0.1	-0.6 to 0.4	CI's and p-values
		(As above)	(As above)	13 weeks after 4 weeks of treatment	0.1	0	0.0	-0.5 to 0.5	CI's and p-values
		Medication use							
		(no. of pills/day)	Bove 1998 (n = 75)	1 week after 4 weeks of treatment	0.2	na	0.1	-0.4 to 0.6	CI's and p-values
		(As above)	(As above)	13 weeks after 4 weeks of treatment	0.1	na	0.0	-0.5 to 0.5	CI's and p-values
Relaxation, automassage, TENS, and stretching	Acupuncture	Headache pain intensity							
		(1-5)	Carlsson 1990 (n = 48)	4-9 weeks post-treatment	0.7	13	0.7	0.1 to 1.3	SMD
		Headache Frequency							
		(1-5)	Carlsson 1990 (n = 48)	4-9 weeks post-treatment	-0.1	-2	-0.1	-0.7 to 0.4	SMD
SMT	Spinal palpation	Headache pain intensity							

Table 7. List of comparisons: tension-type headache (* - sign favors comparison group) (Continued)

		(0-7)	Hoyt 1979 (n = 22)	Imme- diately af- ter 1 treat- ment	1.9	27	1.8	0.4 to 3.2	f-value
SMT	Rest	Headache pain inten- sity							
		(0-7)	Hoyt 1979 (n = 22)	Imme- diately af- ter 1 treat- ment	1.9	27	1.8	0.4 to 3.2	f-value
Therapeu- tic Touch	Placebo Therapeu- tic Touch	Present pain inten- sity							
		(0-5)	Keller 1986 (n = 60)	5 min- utes after 1 treatment	1.1	18	1.1	0.5 to 1.6	p-value
		(As above)	(As above)	4 hours af- ter 1 treat- ment	0.9	14	0.8	0.2 to 1.3	p-value
TENS and electri- cal neuro- transmit- ter modu- lation	Biofeed- back ther- mal	Headache pain inten- sity							
		(1-5)	Reich 1989 (n = 311)	End of 4 weeks of treatment	-0.4	-8	?	?	?
		As above	As above	36 months post- treatment	-0.6	-12	?	?	?
		Headache hours							
		(0-168)	Reich 1989 (n = 311)	End of 4 weeks of treatment	-4.0	na	?	?	?

Table 7. List of comparisons: tension-type headache (* - sign favors comparison group) (Continued)

		As above	As above	36 months post-treatment	-6.5	na	?	?	?
TENS and electrical neurotransmitter modulation	Relaxation	Headache pain intensity							
		(1-5)	Reich 1989 (n = 311)	End of 4 weeks of treatment	0.3	6	?	?	?
		As above	As above	36 months post-treatment	0.5	10	?	?	?
		Headache hours							
		(0-168)	Reich 1989 (n = 311)	End of 4 weeks of treatment	5.0	na	?	?	?
		As above	As above	36 months post-treatment	7.0	na	?	?	?
Cranial electrotherapy (CE)	Placebo CE	Headache pain intensity							
		Intensity reduction (0-10)	Solomon 1989 (n = 112)	End of 6-10 weeks of treatment	0.9	9	0.4	0.0 to 0.8	SMD
		% of patients rating CES effective							
		(0-100)	Solomon 1989 (n = 112)	End of 6-10 weeks of treatment	20.0	na	0.6	0.2 to 1.0	p-value

Table 8. List of comparisons: cervicogenic headache (* - sign favors comparison group)

Interven- tion	Compari- son	Outcome measure	Study	Time points	Group differ- ence*	Difference % points*	Effect size (ES)*	ES CI	95%	ES calc method
SMT + galv. cur- rent	Galv. cur- rent/ ultrasound	Headache improve- ment								
		(1-4)	Ammer 1990 (n = 45)	End of 2 weeks of treatment	0.3	8	0.4	-0.4 to 1.1		SMD
SMT + galv. cur- rent	Moist pack + massage	Headache improve- ment								
		(1-4)	Ammer 1990 (n = 45)	End of 2 weeks of treatment	0.4	11	0.5	-0.3 to 1.3		SMD
Galv. cur- rent/ ultrasound	Moist pack + massage	Headache improve- ment								
		(1-4)	Ammer 1990 (n = 45)	End of 2 weeks of treatment	0.1	2	0.1	-0.6 to 0.9		SMD
SMT	Mobiliza- tion	Headache pain inten- sity								
		(0-100)	Bitterli 1977 (n = 30)	End of 3 weeks of treatment	11.7	12	0.4	-0.5 to 1.4		SMD
		(As above)	(As above)	12 weeks post- treatment	-3.2	-3	-0.1	-1.0 to 0.8		SMD
SMT	Wait-list	Headache pain inten- sity								
		(0-100)	Bitterli 1977 (n = 30)	End of 3 weeks of treatment	15.7	16	0.6	-0.4 to 1.5		SMD

Table 8. List of comparisons: cervicogenic headache (* - sign favors comparison group) (Continued)

Mobiliza- tion	Wait-list	Headache pain inten- sity							
		(0-100)	Bitterli 1977 (n = 30)	End of 3 weeks of treatment	4.0	4	0.1	-0.8 to 1.0	SMD
SMT + NSAIDs	NSAIDs	Headache improve- ment							
		% of pa- tients im- proved	Howe 1983 (n = 27)	Imme- diately af- ter 1 treat- ment	14.0	na	0.5	-0.5 to 1.5	Probit transfor- mation
		(As above)	(As above)	End of 1 week of treatment	6.0	na	0.1	-0.9 to 1.1	Probit transfor- mation
		(As above)	(As above)	End of 3 weeks of treatment	-8.0	na	-0.1	-1.1 to 0.9	Probit transfor- mation
SMT	Exercise	Headache pain inten- sity							
		(0-10)	Jull 2002 (n = 200)	1 week post- treatment	-0.3	-3	-0.1	-0.5 to 0.3	SMD
		(As above)	(As above)	1 year post- treatment	-0.6	-6	-0.2	-0.6 to 0.2	SMD
		Headache frequency							
		(0-7 days/ week)	Jull 2002 (n = 200)	1 week post-treat- ment	-0.3	-4	-0.2	-0.6 to 0.2	SMD
		(As above)	(As above)	1 year post- treatment	-0.3	-4	-0.1	-0.5 to 0.3	SMD

Table 8. List of comparisons: cervicogenic headache (* - sign favors comparison group) (Continued)

		Headache duration							
		(0-24 hours/day)	Jull 2002 (n = 200)	1 week post-treatment	1.3	6	0.3	-0.1 to 0.8	SMD
		(As above)	(As above)	1 year post-treatment	0.7	3	0.1	-0.3 to 0.5	SMD
SMT	SMT + exercise	Headache pain intensity							
		(0-10)	Jull 2002 (n = 200)	1 week post-treatment	-0.4	-4	-0.1	-0.5 to 0.3	SMD
		(As above)	(As above)	1 year post-treatment	-0.4	-4	-0.2	-0.6 to 0.2	SMD
		Headache frequency							
		(0-7 days/week)	Jull 2002 (n = 200)	1 week post-treatment	0.1	1	0.0	-0.4 to 0.4	SMD
		(As above)	(As above)	1 year post-treatment	0.1	2	0.1	-0.3 to 0.5	SMD
		Headache duration							
		(0-24 hours/day)	Jull 2002 (n = 200)	1 week post-treatment	-0.8	-3	-0.2	-0.6 to 0.2	SMD
		(As above)	(As above)	1 year post-treatment	-1.3	-5	-0.3	-0.7 to 0.1	SMD
SMT+ exercise	Exercise	Headache pain intensity							

Table 8. List of comparisons: cervicogenic headache (* - sign favors comparison group) (Continued)

		(0-10)	Jull 2002 (n = 200)	1 week post- treatment	0.1	1	0.0	-0.4 to 0.4	SMD
		(As above)	(As above)	1 year post- treatment	-0.1	-1	-0.1	-0.5 to 0.3	SMD
		Headache frequency							
		(0-7 days/ week)	Jull 2002 (n = 200)	1 week post- treatment	-0.4	-5	-0.2	-0.6 to 0.2	SMD
		(As above)	(As above)	1 year post- treatment	-0.4	-6	-0.2	-0.6 to 0.2	SMD
		Headache duration							
		(0-24 hours/day)	Jull 2002 (n = 200)	1 week post- treatment	2.1	9	0.5	0.1 to 0.9	SMD
		(As above)	(As above)	1 year post- treatment	1.9	8	0.4	0.0 to 0.8	SMD
SMT	No treatment	Headache pain inten- sity							
		(0-10)	Jull 2002 (n = 200)	1 week post- treatment	1.6	16	0.7	0.3 to 1.2	SMD
		(As above)	(As above)	1 year post- treatment	1.0	10	0.4	0.0 to 0.8	SMD
		Headache frequency							
		(0-7 days/ week)	Jull 2002 (n = 200)	1 week post- treatment	1.3	18	0.7	0.3 to 1.1	SMD

Table 8. List of comparisons: cervicogenic headache (* - sign favors comparison group) (Continued)

		(As above)	(As above)	1 year post- treatment	1.3	19	0.7	0.3 to 1.1	SMD
		Headache duration							
		(0-24 hours/day)	Jull 2002 (n = 200)	1 week post- treatment	1.3	6	0.3	-0.1 to 0.8	SMD
		(As above)	(As above)	1 year post- treatment	1.0	4	0.2	-0.2 to 0.6	SMD
SMT + ex- ercise	No treatment	Headache pain inten- sity							
		(0-10)	Jull 2002 (n = 200)	1 week post- treatment	2.0	19	0.8	0.4 to 1.2	SMD
		(As above)	(As above)	1 year post- treatment	1.4	14	0.6	0.2 to 1.0	SMD
		Headache frequency							
		(0-7 days/ week)	Jull 2002 (n = 200)	1 week post- treatment	1.2	18	0.7	0.3 to 1.1	SMD
		(As above)	(As above)	1 year post- treatment	1.2	17	0.7	0.3 to 1.2	SMD
		Headache duration							
		(0-24 hours/day)	Jull 2002 (n = 200)	1 week post- treatment	2.1	9	0.5	0.1 to 0.9	SMD
		(As above)	(As above)	1 year post- treatment	2.3	9	0.5	0.1 to 0.9	SMD

Table 8. List of comparisons: cervicogenic headache (* - sign favors comparison group) (Continued)

Exercise	No treatment	Headache pain intensity							
		(0-10)	Jull 2002 (n = 200)	1 week post-treatment	1.8	18	0.8	0.3 to 1.2	SMD
		(As above)	(As above)	1 year post-treatment	1.5	15	0.6	0.2 to 1.0	SMD
		Headache frequency							
		(0-7 days/week)	Jull 2002 (n = 200)	1 week post-treatment	1.6	23	1.0	0.5 to 1.4	SMD
		(As above)	(As above)	1 year post-treatment	1.6	22	1.0	0.5 to 1.4	SMD
		Headache duration							
		(0-24 hours/day)	Jull 2002 (n = 200)	1 week post-treatment	0.0	0	0.0	-0.4 to 0.4	SMD
		(As above)	(As above)	1 year post-treatment	0.4	1	0.1	-0.3 to 0.5	SMD
SMT	Massage	Headache pain intensity							
		(0-100)	Nilsson 1997 (n = 54)	One week after 3 weeks of treatment	12.8	13	0.6	0.1 to 1.1	means and p-value
		Medication use							
		(no. of pills/day)	Nilsson 1997 (n = 54)	One week after 3 weeks of	0.4	na	0.3	-0.2 to 0.8	means and p-value

Table 8. List of comparisons: cervicogenic headache (* - sign favors comparison group) (Continued)

				treatment					
		Headache duration							
		(0-24 hours/day)	Nilsson 1997 (n = 54)	One week after 3 weeks of treatment	1.6	7	0.5	0.0 to 1.0	means and p-value
SMT	Placebo SMT	Headache pain intensity							
		(0-100)	Whittingham 1997 (n = 105)	End of 3 weeks of treatment	53.8	54	2.2	1.7 to 2.7	SMD
		Headache disability							
		(0-5)	Whittingham 1997 (n = 105)	End of 3 weeks of treatment	1.3	22	1.0	0.6 to 1.5	SMD
		Number of headache locations							
		na	Whittingham 1997 (n = 105)	End of 3 weeks of treatment	3.6	na	1.1	0.7 to 1.5	SMD

APPENDICES

Appendix I. MEDLINE search strategy

The full MEDLINE search strategy, which was adapted for use in the other electronic databases searched, was as follows:

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. or/1-6
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. or/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 prospectiv\$ 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. exp physical therapy/
32. transcutaneous electric nerve stimulation/
33. interferential therapy.ti,ab.
34. "biofeedback (psychology)"/feedback/ph
35. manipulation, spinal.sh.
36. chiropractic.sh.
37. osteopathic medicine.sh.
38. heat/tu
39. ultrasonic therapy.sh.
40. electromagnetic therapy.ti,ab.
41. microcurrent.ti,ab.
42. laser therapy.ti,ab.
43. lasers/tu
44. myofascial pain syndromes/th
45. traction.sh.
46. or/31-45
47. 30 and 46
48. 29 and 47

WHAT'S NEW

Last assessed as up-to-date: 14 November 2002.

Date	Event	Description
29 August 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 1, 2000

Review first published: Issue 3, 2004

DECLARATIONS OF INTEREST

Two authors, Gert Bronfort and Nils Nilsson, are also authors of studies included in this review ([Boline 1995](#); [Bove 1998](#); [Nilsson 1997](#)).

SOURCES OF SUPPORT

Internal sources

- Northwestern Health Sciences University, USA.
- Western States Chiropractic College, USA.

External sources

- University of Southern Denmark, Denmark.
- European Chiropractic Union, Switzerland.
- World Federation of Chiropractic (WFC), Canada.
- International Headache Society (for administrative costs associated with editorial review and peer review), Not specified.

INDEX TERMS

Medical Subject Headings (MeSH)

*Exercise Movement Techniques; *Physical Therapy Modalities; Chronic Disease; Headache [*therapy]; Headache Disorders [*therapy]; Recurrence

MeSH check words

Humans