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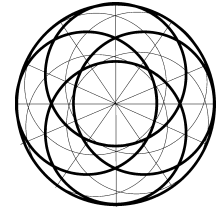
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Complementary and alternative medicine for the prevention and treatment of migraine headache: an overview of systematic reviews

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Abstract

Background Complementary and alternative medicine (CAM) is very popular among migraineurs.

Objectives The aim of this article is to summarise and critically evaluate the evidence from systematic reviews (SRs) of CAM for the prevention and treatment of migraine headache.

Method Ten electronic databases were searched from 1946 to August 2014. Retrieved papers were also hand-searched for relevant references. Systematic reviews were eligible for inclusion if they reported the prevention and treatment of migraine headache using any type of CAM. Oxman criteria were used to appraise the methodological quality of the included SRs.

Results Thirty-three SRs, with a total of 45 886 migraine sufferers, were included in the analyses. The majority (64%) of the SRs were of high methodological quality (mean Oxman score=4.87, SD=3.96). Most (60.6%) SRs arrived at positive conclusions (16 of which were of high quality); two (6.0%) SRs arrived at negative conclusions (of which one was of high quality), and 11 (33.3%) arrived at equivocal conclusions (of which four were of high quality). The majority of the high-quality SRs (Oxman score=6–9) were based on moderate-quality RCTs. For multiple SRs, unanimously positive conclusions were reached for acupuncture and biofeedback. There was conflicting evidence regarding the effectiveness of homeopathy, herbal medicines such as *Petasites hybridus* and *Tanacetum parthenium* L., and spinal manipulative therapy.

Conclusion The evidence from SRs evaluating the effectiveness of CAM for the prevention or treatment of migraine headache is mostly positive. However, several caveats should be taken into account, and only for acupuncture and biofeedback are the conclusions unanimously positive.

Keywords

Complementary and alternative medicine • effectiveness • migraine • systematic reviews

Introduction

Migraine is considered to be a brain dysfunction of multisensory modulatory networks involving light, sound and smell, with the disturbance affecting processing of normal neural signals.^{1,2} The aetiology and pathogenesis is complex and might involve

genetic, neurovascular, neuro-hormonal and environmental factors.^{3,4} Other contributors include a disturbed energy metabolism reflected in a drop in phosphocreatine (CP) and an observed increase in lactate.⁵ There is also a growing body of evidence to suggest that migraine pathophysiology may, in part, include dysfunction of subcortical structures

such as diencephalic and brainstem nuclei that can modulate the activation of the trigeminovascular system.⁶ A recent study also suggests that migraine may be a risk factor for structural changes in the brain.⁷ Migraine affects more than 324 million adults worldwide,⁸ and is associated with significant pain, disability, absenteeism and poor QoL as well as high societal and economic costs.⁹

Complementary and alternative medicine is an 'umbrella' term reflecting a wide variety of modalities that can be operationally defined as the 'diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, satisfying a demand not met by orthodoxy, or diversifying the conceptual framework of medicine'.¹⁰ The prevalence of CAM use among patients with migraine ranges from 31.4%¹¹ to 84%,¹² with acupuncture (58.3%), massage (46.1%) and relaxation techniques (42.4%) being the most popular therapies.¹³ The reasons for this popularity are complex but presumed effectiveness and safety of CAM play a crucial role.¹⁰ Some migraineurs may also perceive conventional drugs/medicine as ineffective and/or burdened with unacceptable adverse-effects and, as a result, seek alternatives.¹⁴

There is an abundance of RCTs of CAM for the treatment or prevention of migraine. The results of these trials are often evaluated and synthesised in systematic reviews (SRs). Several of these SRs arrive at conclusions that are far from uniform, thus creating ambiguity. To date, no attempts have been made to summarise and rigorously appraise the data from SRs of CAM for migraine. This article aims to review and critically evaluate the evidence from SRs of CAM for the prevention and/or treatment of migraine headache.

Methods

The recent Preferred Reporting Items for Systematic Reviews & Meta Analyses (PRISMA) guidelines¹⁵ and the *Cochrane Handbook for Systematic Reviews of Interventions*¹⁶ were used to lend a framework for the reporting structure of this systematic review.

Data sources

In addition to hand-searches, 10 electronic databases were inspected from 1946 to August 2014 for pertinent reviews, including: AMED (Ebsco), CINAHL (Ebsco), The Cochrane Library, EMBASE (Ovid), Google Scholar, ISI Web of Knowledge, ISI Web of Science, MEDLINE (Ovid), PsycARTICLES (Ovid), and Scopus. A detailed search strategy for MEDLINE is presented in Box 1.

Study selection

In this systematic review, we included all SRs evaluating the effectiveness of CAM for the treatment

- 1 exp HEADACHE DISORDERS/OR exp Migraine Disorders/OR HEADACHE/OR (headacheormigrain or cephalgiorcephalalg).mp.
- 2 (Alternative adj3 (healormedic or remedotherap or treatment)).ti, ab.OR(Complementaryadj3(heal or medicorremed or theraportreatment)).ti,ab. OR (integratadj3(heal or medicorremed or theraportreatment)).ti,ab. OR CAM.ti,ab. OR exp Complementary Therapies/
- 3 review.ti

Box 1 Detailed search strategy for MEDLINE (Ovid)

and/or prevention of migraine in children and/or adults. Only SRs of RCTs published in the English language were eligible for inclusion. To avoid confusion, reviews that depended upon previous SRs for their primary data (i.e. update SRs) were included. We defined SRs as articles that use repeatable inclusion and exclusion criteria for primary studies as well as comprehensive and reproducible literature searches.¹⁷ Non-systematic reviews, MSc or PhD theses or abstracts were excluded.^{18,19}

The following CAM modalities were considered admissible in the present review: acupuncture and associated techniques, Alexander Technique, Ayurvedic medicine, aromatherapy, (Bach) flower remedies, biofeedback, chiropractic, herbal medicine, homeopathy, hypnosis, massage, meditation, naturopathy, osteopathy, qigong, spirituality/spiritual healing, tai chi, TCM and yoga. We excluded dietary supplements, physical exercise, physiotherapeutic or psychotherapeutic modalities from our analyses as these were not considered to be part of CAM.

The data screening and selection process was performed by the first reviewer (PP), and verified and validated by the second (MK), third (MSL), fourth (AA) and fifth reviewer (EE).

Outcome measures

The main outcomes were limited to the intensity and duration of migraine headache.

Data extraction

Two reviewers (PP and MK) performed the data extraction independently of each other. An *a priori* defined data extraction form was used to obtain the following information: first authors' names and publication date, prevention or treatment focus, population, mean age or age range, total number of primary RCTs, quality of primary studies as judged by the authors of the primary studies (i.e. poor, moderate, high), whether meta-analysis had been conducted, quality of SR (i.e. Oxman score²⁰), overall result, direction of conclusion as judged by the present authors (i.e. positive, negative or equivocal), whether the SR had mentioned adverse effects (AEs), authors' conflicts of interest (COI), source of funding (SOF)

(mentioned or not mentioned), and any comments relating to primary or secondary research.

Risk of bias/quality assessments

We used the Oxman criteria for judging the methodological quality of review papers.²⁰ This is a standardised tool that evaluates the quality of SRs across nine domains, including: reporting of search strategy, comprehensiveness of searches, repeatable eligibility criteria, avoidance of selection bias, presence or absence of a validity assessment tool, appropriate use of the validity assessment tool, robustness of data analysis and synthesis and supportiveness of conclusions. Each domain is then scored as 1 (fulfilled), 0 (partially fulfilled), or -1 (not fulfilled). The final score ranges between -9 and 9. A result of 1 or less means the SR has extensive flaws; 2-3 indicates major flaws, 4-5 minor flaws, and 6-9 minimal or no flaws. This process was carried out by two reviewers (PP, MK) independently of each other.

Data synthesis

The results are presented as a narrative, and are supported by descriptive tables.

Results

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Study description

The search generated a total of 419 records, with 33 SRs meeting our inclusion criteria (Figure 1). The number of primary studies included within each SR ranged from one to 28 (mean=9.42; SD=7.58). The key findings from the included SRs are presented in Table 1. Table 2 summarises the methodological quality of the included SRs. Table 3 indicates the direction of the conclusions as a function of the quality of SRs and that of the primary studies (i.e. RCTs). Table 4 encapsulates the quality of the SR as a function of CAM modality.

Description of included interventions

A wide variety of CAM modalities were evaluated, including auricular acupuncture (AA) (n=1), acupuncture (AT) (n=12), biofeedback (BFB) (n=2), chiropractic (n=1), herbal medicines such as *Ginkgo biloba* (n=1), *Petasites hybridus* (n=3), *Tanacetum parthenium* L. (n=6) and Tianshu capsule (a combination of 38 various constituents) (n=1), homeopathy (n=3), hyperbaric oxygen therapy (HBOT) (n=1),

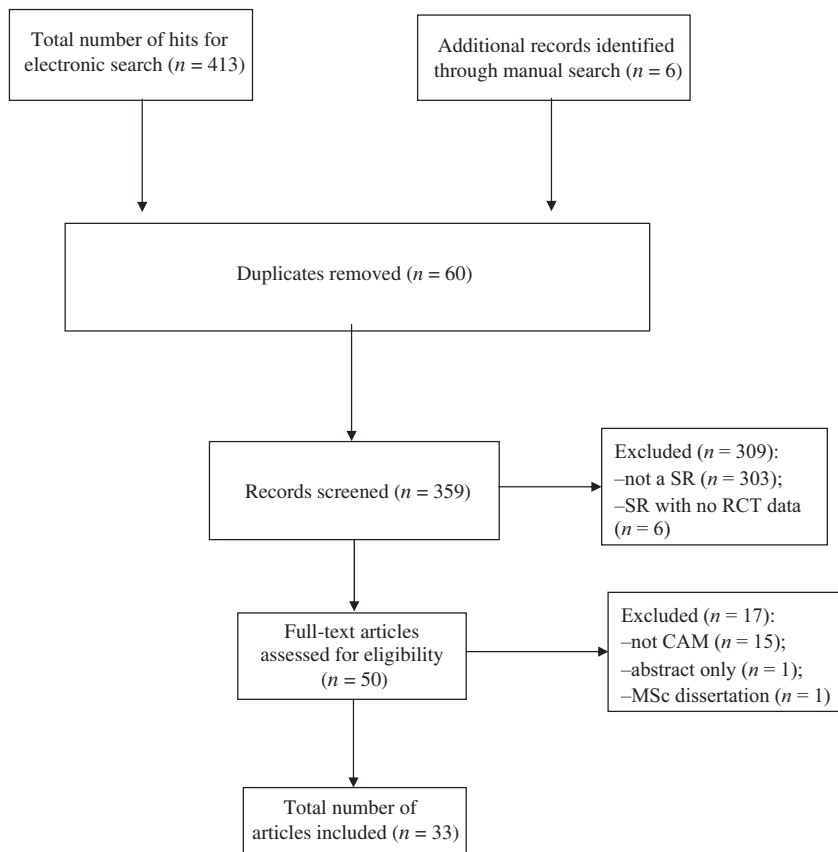


Figure 1 Flow diagram for included systematic reviews (SR).

Table 1 Systematic reviews of CAMs for migraine

| First author (year) | Intervention(s) | P/T | Population (mean age or age range) | N* | Quality of RCTs | Meta-analysis | Oxman score ²⁶ for quality of SR | Overall result (quote) | Direction of conclusion | Mention of adverse effects | Conflicts of interest | Source of funding | Comment |
|-------------------------------|---|-----|------------------------------------|----|-----------------|---------------|---|---|-------------------------|----------------------------|-----------------------|-------------------|--|
| Agosti (2006) ²⁵ | Herbal medicine (<i>Petasites hybridus</i>) | P | 293 adults (28.6 years) | 2 | High | No | 5 | 'There is to date moderate evidence of effectiveness for a 3–4 months daily treatment with 150 mg Petasites root extract Petadolex in the prophylaxis of migraine.' | (+) | Yes | Mentioned | Not mentioned | No independent replications of RCTs which used the same herbal extract |
| Astin (2002) ²⁶ | SMT | T | 430 adults (not given) | 3 | Low | No | 9 | 'It is unclear from the findings of this SR whether or not SMT is an effective treatment for headache disorders' | (+/-) | Yes | Not mentioned | Mentioned | SR included any type of headaches including cervicogenic and TTH |
| Bennett (2008) ⁴¹ | HBOT | P/T | 201 adults (38.8 years) | 9 | Low to moderate | Yes | 9 | 'There was some evidence that HBOT was effective for the termination of acute migraine in an unselected population' | (+) | Yes | Mentioned | Mentioned | All trials were of small samples and some included cluster headaches |
| Brockow (2000) ²⁷ | Naturopathy (SCIs) | T | 80 adults (not given) | 1 | Low | No | 2 | 'The low number and quality of the available studies precludes firm conclusions on the clinical effectiveness of SCIs' | (+/-) | Yes | Not mentioned | Not mentioned | Poor quality SR based on one RCT (for migraine) |
| Bronfort (2001) ⁴² | SMT | P/T | 201 adults (not given) | 2 | Moderate | No | 8 | 'SMT has an effect comparable to commonly used first-line prophylactic prescription medications for TTH and migraine headache' | (+) | Yes | Not mentioned | Mentioned | Three out of five authors were DCs |

Table 1 (Continued)

| First author (year) | Intervention(s) | P/T | Population (mean age or age range) | N* | Quality of RCTs | Meta-analysis | Oxman score ²⁰ for quality of SR | Overall result (quote) | Direction of conclusion | Mention of adverse effects | Conflicts of interest | Source of funding | Comment |
|-------------------------------|--|-----|---|----|-----------------|---------------|---|--|-------------------------|----------------------------|-----------------------|-------------------|---|
| Bronfort (2004) ⁴³ | SMT ^a | P/T | 430 adolescents and adults (39.3 years) | 3 | Low | No | 8 | 'For the prophylactic treatment of migraine headache, there is evidence that SMT may be an effective treatment option with a short-term effect similar to that of a commonly used, effective drug (amitriptyline)' | (+) | Yes | Mentioned | Mentioned | SR included other types of headaches and treatment regimens; conclusions not fully supported |
| Bryans (2011) ²⁸ | Chiropractic care ^b | T | 292 adults (40 years) | 7 | Moderate | No | 7 | 'For migraine, SMT and multimodal multidisciplinary interventions including massage are recommended for management of patients with episodic or chronic migraine.' | (+) | Yes | Mentioned | Mentioned | COI has the potential to distort the findings |
| Chaibi (2011) ⁴⁴ | Manual therapies ^c | P/T | 706 adults (37.7 years) | 7 | Moderate | No | 1 | 'Massage therapy, physiotherapy, relaxation and chiropractic SMT might be equally efficient as propranolol and topiramate in the prophylactic management of migraine' | (+) | No | Not mentioned | Mentioned | Conventional treatments were included alongside CAM modalities |
| Damen (2006) ⁴⁵ | Thermal BFB, relaxation, AT ^d | P/T | 179 children (11.6 years) | 11 | Moderate | No | 6 | 'A few non-pharmacological treatments such as relaxation may be effective as prophylactic treatment for migraine in children' | (+) | No | Mentioned | Mentioned | A wide range of CAM modalities were examined; SR also included CCTs, conclusions for BFB were (-) |
| Ernst (1999) ⁴⁶ | Homeopathy | P/T | 284 adults (not given) | 4 | Moderate | No | 5 | 'The trial data available to date do not suggest that homeopathy is effective in the prophylaxis of migraine or headache beyond a placebo effect' | (-) | No | Not mentioned | Not mentioned | One primary RCT included TTH |

Table 1 (Continued)

| First author (year) | Intervention(s) | P/T | Population (mean age or age range) | N* | Quality of RCTs | Meta-analysis | Oxman score ²⁰ for quality of SR | Overall result (quote) | Direction of conclusion | Mention of adverse effects | Conflicts of interest | Source of funding | Comment |
|-------------------------------|---|-----|--------------------------------------|----|------------------|---------------|---|--|-------------------------|----------------------------|-----------------------|-------------------|---|
| Ernst (2000) ²² | Herbal medicine (<i>Tanacetum parthenium</i> L.) | P | 246 children and adults (9-72 years) | 6 | High | No | 6 | 'Feverfew is likely to be effective in the prevention of migraine' | (+) | Yes | Not mentioned | Not mentioned | Trials included different doses and herb preparations; only one RCT had a reasonably large sample |
| Griggs (2006) ²⁹ | AT | T | 1107 adults (not given) | 13 | Low | No | 1 | 'No solid conclusions or advice can be given' | (+/-) | No | Not mentioned | Not mentioned | SR focused on methodological limitations of AT trials |
| Linde (2009) ⁴⁷ | AT | P/T | 4419 adults (39 years) | 22 | Moderate to high | Yes | 9 | 'Available studies suggest that AT is at least as effective as, or possibly more effective than, prophylactic drug treatment, and has fewer adverse effects' | (+) | Yes | Mentioned | Mentioned | There was statistically significant heterogeneity ($P < 0.05$) in nine out of 25 analyses |
| Madsen (2009) ³⁰ | AT | T | 302 adults (not given) | 1 | High | Yes | 5 | 'A small analgesic effect of AT was found, which seems to lack clinical relevance and cannot be clearly distinguished from bias' | (+/-) | No | Mentioned | Mentioned | No formal quality assessments were attempted |
| Manias (2000) ³¹ | AT | T | 1088 adults (not given) ^c | 20 | Low to moderate | No | -4 | 'AT offers benefits in the treatment of headaches' | (+) | No | Not mentioned | Not mentioned | SR also included patients with TTH or cluster headaches |
| Melchart (1999) ³² | AT | T | 805 children and adults (37.3 years) | 15 | Low to moderate | Yes | 9 | 'The existing evidence suggests that acupuncture has a role in the treatment of recurrent headaches' | (+) | No | Mentioned | Mentioned | The majority of trials were small and of limited quality |
| Melchart (2001) ⁴⁸ | AT | P/T | 1151 adults (not given) ^c | 16 | Low to moderate | No | 0 | 'Overall, the existing evidence supports the value of acupuncture for the treatment of idiopathic headaches' | (+) | No | Not mentioned | Mentioned | Significant heterogeneity of the included trials |

Table 1 (Continued)

| First author (year) | Intervention(s) | P/T | Population (mean age or age range) | N* | Quality of RCTs | Meta-analysis | Oxman score ²⁰ for quality of SR | Overall result (quote) | Direction of conclusion | Mention of adverse effects | Conflicts of interest | Source of funding | Comment |
|---------------------------------|---|-----|---------------------------------------|----|------------------|---------------|---|---|-------------------------|----------------------------|-----------------------|-------------------|---|
| Nestoriuc (2007) ³³ | BFB | T | 2229 adults (37.1 years) | 28 | Low to moderate | Yes | 8 | 'This MA documents the short- and long-term outcome of BFB for migraine in adults' | (+) | Yes | Not mentioned | Not mentioned | No tests for heterogeneity of PICO |
| Orr (2014) ⁴⁹ | Herbal medicine (<i>P. hybridus</i> , <i>Ginkgo biloba</i>) | P/T | 1043 children and adults (6-65 years) | 8 | Low to moderate | No | -6 | 'There is growing interest in the use of nutraceuticals for pediatric migraine prophylaxis' | (+/-) | Yes | Mentioned | Mentioned | Grade A quality of evidence in favour of butterbur, and low quality evidence for ginkgo |
| Owen (2004) ³⁴ | Homeopathy | T | 193 adults (not given) | 3 | Moderate | No | 2 | 'There is insufficient evidence to support or refute the use of homeopathy for managing...migraine headache' | (+/-) | No | Not mentioned | Not mentioned | Two RCTs fail to exhibit the difference beyond placebos |
| Pittler (2000) ²⁴ | Herbal medicine (<i>T. parthenium</i> L.) | P | 196 adults (not given) | 4 | Moderate to high | No | 3 | 'The efficacy of feverfew for the prevention of migraine has not been established beyond reasonable doubt' | (+/-) | Yes | Mentioned | Mentioned | The most rigorous RCT found no difference between feverfew and placebo |
| Pittler (2004) ²³ | Herbal medicine (<i>T. parthenium</i> L.) | P | 343 adults (not given) | 5 | Moderate to high | No | 7 | 'There is insufficient evidence from randomised, double-blind trials to suggest an effect of feverfew over and above placebo for preventing migraine' | (+/-) | Yes | Mentioned | Mentioned | Dosage and preparations of feverfew differed; no safety concerns were raised |
| Posadzki (2011) ³⁵ | SMT | T | 430 adults (not given) | 3 | Low | No | 7 | 'Current evidence does not support the use of SMT for the treatment for migraine headaches' | (-) | Yes | Not mentioned | Not mentioned | Small number of low-quality RCTs |
| Saranitzky (2009) ⁵⁰ | Herbal medicine (<i>T. parthenium</i> L.) | P/T | 486 adults (18-65 years) | 6 | High | No | 6 | 'Currently available research examining feverfew for migraine prophylaxis is promising' | (+) | No | Mentioned | Mentioned | Length of treatment ranged from 4 to 8 months |

Table 1 (Continued)

| First author (year) | Intervention(s) | P/T | Population (mean age or age range) | N* | Quality of RCTs | Meta-analysis | Oxman score ²⁰ for quality of SR | Overall result (quote) | Direction of conclusion | Mention of adverse effects | Conflicts of interest | Source of funding | Comment |
|-------------------------------|--|-----|---|----|------------------|---------------|---|---|-------------------------|----------------------------|-----------------------|-------------------|---|
| Schetzek (2013) ²¹ | AT, LA, homeopathy, SMT, herbal medicine (<i>T. parthenium</i> L., <i>P. hybridus</i>) | T | Unspecified number of children and adults (not given) | 13 | Low | No | -4 | 'The limited evidence of CAM therapy in pediatric headache is also in part caused by methodologic problems' | (+/-) | Yes | Not mentioned | Not mentioned | SR also included SRs; 11 RCTs were of dietary supplements |
| Scott (2006) ⁵¹ | AT | P/T | 3004 adults (not given) | 25 | Low to moderate | Yes | 7 | 'The current evidence suggests that AT is significantly superior to waiting list, at least as good as sham AT, and of comparable efficiency to several proven drug therapies' | (+) | Yes | Not mentioned | Not mentioned | No subgroup analyses; small median sample size (<i>n</i> =63) |
| Sun (2008) ³⁶ | AT | T | 2241 adults (38.5 years) | 17 | Moderate | Yes | 6 | 'Needing AT is superior to sham AT and medication therapy in improving headache intensity, frequency, and response rate' | (+) | Yes | Mentioned | Mentioned | Significant heterogeneity of the MA (<i>I</i> ² >90%); TTH and migraine were pooled in one analysis |
| Vickers (2012) ³⁷ | AT | T | 17922 adults (not given) ^e | 4 | High | Yes | 7 | 'AT is effective for the treatment of chronic pain and is therefore a reasonable referral option' | (+) | No | Mentioned | Mentioned | Lack of formal validity/risk of bias assessments |
| Vogler (1998) ⁵² | Herbal medicine (<i>T. parthenium</i> L.) | P/T | 216 children and adults (9-71 years) | 5 | Moderate to high | No | 6 | 'The clinical effectiveness of feverfew in the prevention of migraine has not been established beyond reasonable doubt' | (+/-) | Yes | Not mentioned | Not mentioned | Three out of the four crossover RCTs had no washout period |
| Wang (2008) ⁵³ | AT | P/T | 2097 adults (not given) | 17 | Low | Yes | 6 | 'There is moderate evidence that AT is more effective than western pharmacotherapy' | (+) | Yes | Mentioned | Not mentioned | No placebo-controlled RCTs were included |

Table 1 (Continued)

| First author (year) | Intervention(s) | P/T | Population (mean age or age range) | N* | Quality of RCTs | Meta-analysis | Oxman score ²⁰ for quality of SR | Overall result (quote) | Direction of conclusion | Mention of adverse effects | Conflicts of interest | Source of funding | Comment |
|---------------------------|-----------------------------------|-----|--|----|-----------------|---------------|---|---|-------------------------|----------------------------|-----------------------|-------------------|---|
| Xia (2013) ³⁸ | Herbal medicine (Tianshu capsule) | T | 937 adolescents and adults (14-57 years) | 10 | Moderate | Yes | 6 | 'Tianshu capsule had better efficacy in the treatment of migraine with fewer adverse effects' | (+) | Yes | Not mentioned | Not mentioned | All primary RCTs were conducted in China, six RCTs used Tianshu capsule in combination with 'other' drugs |
| Yeh (2014) ³⁹ | AA | T | 89 adults (not given) | 1 | Moderate | Yes | 7 | 'Our findings suggest that auricular therapy can be used as an adjunct therapy for pain management' | (+) | Yes | Mentioned | Mentioned | Primary RCT lacked power calculations and ITT and was considered an outlier |
| Zhou (2013) ⁴⁰ | TCM | T | 2246 adults (not given) | 20 | Low | Yes | 7 | 'More multi-center, large-scale, double-blind RCTs are needed to provide a higher level of evidence for systematic TCM reviews' | (+/-) | Yes | Not mentioned | Mentioned | Lack of formal quality appraisal of primary RCTs; small overall effect size |

AA, auricular acupuncture; AT, acupuncture therapy; BFB, biofeedback; CCT, controlled clinical trial, DC, doctor of chiropractic; HBOT, hyperbaric oxygen therapy; LA, laser acupuncture; MA, meta-analysis; N*, number of RCTs related to CAM for migraine; PICO, population, intervention, comparators, outcomes; P/T, prevention/treatment; SCIs, subcutaneous CO₂ insufflations; SMT, spinal manipulative therapy; SR, systematic review; TCM, traditional Chinese medicine; TTH, tension-type headache.

^aSR included other types of non-invasive physical treatments including therapeutic touch, cranial electrotherapy, transcutaneous electrical nerve stimulations (TENS), auto-massage, stretching and exercises.

^bChiropractic care of migraines also included massage, exercise, relaxation, nutritional counselling and trigger point therapy.

^cSystematic review also included massage therapy, physiotherapy, relaxation and chiropractic SMT.

^dSystematic review also included dietary approaches/supplements, sleep advice and coping strategies.

^eEstimate pertains to the total number of patients included in this SR (and not solely to migraines).

Table 2 Quality ratings for included systematic reviews of CAMs for migraine

| First author (year) | Search methods? (a) | Search comprehensive? (b) | Inclusion criteria? (c) | Bias avoided? (d) | Validity criteria? (e) | Validity assessed? (f) | Methods for combining studies? (g) | Appropriately combined? (h) | Conclusions supported? (i) | Total |
|---------------------------------|---------------------|---------------------------|-------------------------|-------------------|------------------------|------------------------|------------------------------------|-----------------------------|----------------------------|-------|
| Agosti (2006) ²⁵ | 1 | 1 | -1 | 0 | 1 | 1 | 1 | 0 | 1 | 5 |
| Astin (2002) ²⁶ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 |
| Bennett (2008) ⁴¹ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 |
| Brockow (2000) ²⁷ | 1 | 1 | 1 | -1 | 0 | 0 | 0 | 0 | 0 | 2 |
| Bronfort (2001) ⁴² | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 8 |
| Bronfort (2004) ⁴³ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 8 |
| Bryans (2011) ²⁸ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 7 |
| Chaibi (2011) ⁴⁴ | 0 | 1 | 0 | -1 | 1 | 1 | -1 | 0 | 0 | 1 |
| Damen (2006) ⁴⁵ | 1 | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 1 | 6 |
| Ernst (1999) ⁴⁶ | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 5 |
| Ernst (2000) ²² | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 6 |
| Ernst (2006) ²⁹ | 0 | 1 | 1 | -1 | 1 | 1 | -1 | -1 | 0 | 1 |
| Griggs (2006) ²⁹ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 |
| Linde (2009) ⁴⁷ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 |
| Madsen (2009) ³⁰ | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 5 |
| Manias (2000) ³¹ | 0 | 0 | 1 | -1 | -1 | -1 | -1 | -1 | 0 | -4 |
| Melchart (1999) ³² | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 |
| Melchart (2001) ⁴⁸ | 0 | 1 | 0 | -1 | -1 | -1 | 1 | 0 | 1 | 0 |
| Nestoriuc (2007) ³³ | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 8 |
| Orr (2014) ⁴⁹ | -1 | -1 | 1 | -1 | -1 | -1 | -1 | -1 | 0 | -6 |
| Owen (2004) ³⁴ | 1 | 1 | 1 | -1 | 1 | 1 | -1 | -1 | 0 | 2 |
| Pittler (2000) ²⁴ | 1 | 1 | 1 | -1 | 1 | 1 | -1 | -1 | 1 | 3 |
| Pittler (2004) ²³ | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 7 |
| Posadzki (2011) ³⁵ | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 7 |
| Saranitzky (2009) ⁵⁰ | 1 | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 1 | 6 |
| Schetzek (2013) ²¹ | 1 | 1 | -1 | -1 | -1 | -1 | -1 | -1 | 0 | -4 |
| Scott (2006) ⁵¹ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 7 |
| Sun (2008) ³⁶ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 6 |
| Vickers (2012) ³⁷ | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 7 |
| Vogler (1998) ⁵² | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 6 |
| Wang (2008) ⁵³ | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 0 | 6 |
| Xia (2013) ³⁸ | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | -1 | 6 |
| Yeh (2014) ³⁹ | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 7 |
| Zhou (2013) ⁴⁰ | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 7 |

Scoring: each question is scored as 1, 0 or -1. The column headings denoting scoring are identified by the letters (a)-(i) in the explanatory notes below.

1 means that: (a) the review states the databases used, date of most recent searches and gives some mention of search terms; (b) the review reports how many data-bases and looks at other sources; (c) the review states the criteria used for deciding which studies to include in the overview; (d) the review reports how many studies were identified by searches, numbers excluded and appropriate reasons for excluding them; (e) the review states the criteria used for assessing the validity of the included studies; (f) the review reports validity assessment and did some type of analysis with it; (g) the report mentions that quantitative analysis was not possible and reasons that it could not be done; (h) the review performs a test for heterogeneity before pooling or does appropriate subgroup testing, appropriate sensitivity analysis or other such analysis; (i) the conclusions made by the author(s) are supported by the data and/or analysis reported in the review. 0 means that the above-mentioned criteria were partially fulfilled. -1 means that none of the above criteria were fulfilled. This is operationalisation of the Oxman criteria,²⁰ adapted from Posadzki, Ernst and Lee (2012).⁶²

Table 3 The direction of conclusion as a function of quality of systematic reviews and primary trials

| | The direction of conclusion (<i>n</i> of SRs) | | |
|----------------------------------|--|--------------|-----------------|
| | Positive (+) | Negative (-) | Equivocal (+/-) |
| Quality of SR (OS) | | | |
| Extensive flaws (≤ 1) | 3 | 0 | 3 |
| Major flaws (2-3) | 0 | 0 | 3 |
| Minor flaws (4-5) | 1 | 1 | 1 |
| Minimal or no flaws (6-9) | 16 | 1 | 4 |
| Quality of primary trials | | | |
| Low | 8 | 1 | 6 |
| Moderate | 14 | 1 | 5 |
| High | 5 | 0 | 4 |

OS, Oxman score;²⁰ SRs, systematic reviews.

Table 4 The quality of systematic reviews as a function of CAM modality

| Type of CAM | Quality of systematic review (Oxman score ²⁰) | | | |
|---|---|-------------------|-------------------|---------------------------|
| | Extensive flaws (≤ 1) | Major flaws (2-3) | Minor flaws (4-5) | Minimal or no flaws (6-9) |
| AA | 0 | 0 | 0 | 1 |
| AT | 4 | 0 | 1 | 7 |
| BFB | 0 | 0 | 0 | 2 |
| Chiropractic | 0 | 0 | 0 | 1 |
| HBOT | 0 | 0 | 0 | 1 |
| Homeopathy | 1 | 1 | 1 | 0 |
| Herbals (<i>Petasites hybridus</i>) | 2 | 0 | 1 | 0 |
| Herbals (<i>Tanacetum parthenium</i> L.) | 1 | 1 | 0 | 4 |
| Herbals (<i>Ginkgo biloba</i>) | 1 | 0 | 0 | 0 |
| Herbals (Tianshu capsule) | 0 | 0 | 0 | 1 |
| LA | 1 | 0 | 0 | 0 |
| Naturopathy (SCI) | 0 | 1 | 0 | 0 |
| Manual therapies | 1 | 0 | 0 | 0 |
| Relaxation | 0 | 0 | 0 | 1 |
| SMT | 1 | 0 | 0 | 4 |
| TCM | 0 | 0 | 0 | 1 |

AA, auricular acupuncture; AT, acupuncture therapy; BFB, biofeedback; HBOT, hyperbaric oxygen therapy; LA, laser acupuncture; SCI, subcutaneous CO₂ insufflations; SMT, spinal manipulative therapy; TCM, traditional Chinese medicine.

laser acupuncture (LA) (*n*=1), manual therapies (MT) (*n*=1), relaxation (*n*=1), spinal manipulative therapy (SMT) (*n*=5), subcutaneous CO₂ insufflations (SCI) (a part of naturopathic physical

medicine) (*n*=1) and traditional Chinese medicine (TCM) (*n*=1).

Description of included populations

Migraine sufferers included children (*n*=1), children and adults (*n*=5) and adults only (*n*=27). The total number of patients amounted to 45 886 (range=80-4419). One study did not report the number of included patients.²¹ Twenty-one SRs (63.6%) did not use a meta-analytic approach and 12 did.

Prevention systematic reviews

Four SRs²²⁻²⁵ focused on prevention only. All of these SRs evaluated the effectiveness of herbal medicines. Two SRs reached an equivocal conclusion^{23,24} and one a positive conclusion²² for *T. parthenium*; and one arrived at a positive conclusion for *P. hybridus*.²⁵

Treatment systematic reviews

Sixteen SRs^{21,26-40} focused on treatment only. Of these, one of which was examining several modalities that were single-counted,²¹ five reached a positive conclusion and four an equivocal conclusion for AT and associated techniques; one arrived at a positive conclusion for BFB; one arrived at an equivocal and one at a positive conclusion for herbal medicine (i.e. *T. parthenium* and *P. hybridus*, and Tianshu capsule, respectively); two arrived at equivocal conclusions for homeopathy; one arrived at equivocal conclusions for SCI; two arrived at an equivocal, one at a positive and one at a negative conclusion for SMT and chiropractic; and one arrived at an equivocal conclusion for TCM.

Prevention and/or treatment systematic reviews

Thirteen SRs⁴¹⁻⁵³ focused both on the prevention and treatment of migraine; several looked at a variety of modalities, that were single-counted. Of these SRs, five arrived at a positive conclusion for AT; one arrived at a positive conclusion for BFB; one reached a positive conclusion for HBOT; one arrived at a positive conclusion for homeopathy; one arrived at a positive conclusion for MT; one reached a positive conclusion for relaxation; two arrived at a positive conclusion for SMT; one arrived at a positive and one at an equivocal conclusion for *P. hybridus*; one arrived at a positive and one at an equivocal conclusion for *T. parthenium*, and one arrived at an equivocal conclusion for *G. biloba*.

Risk of bias of included systematic reviews

In general, the methodological quality of the included SRs was acceptable (mean=4.87, SD=3.96), ranging from -6 (poor) to 9 (excellent). The highest number of methodologically sound SRs focused on AT, followed by *T. parthenium* L., SMT and BFB.

The highest number of methodologically flawed SRs (Oxman score > 1) also related to AT (Table 4).

Outcomes

Overall, 20 (60.6%) SRs arrived at clearly positive conclusions, two (6.0%) SRs arrived at negative conclusions, and 11 (33.3%) arrived at equivocal conclusions. Twenty-one SRs had minimal or no flaws (Oxman score = 6–9). Nine SRs (27.2%) had major or extensive methodological flaws (Oxman score = 3 or less). Sixteen SRs that arrived at positive conclusions had minimal or no flaws. Fourteen SRs that arrived at positive conclusions were based on moderate quality RCTs (Table 3). There were no methodologically flawed SRs (i.e. Oxman score = 2–3) that drew either unanimously positive or negative conclusions. Thirteen high-quality SRs (Oxman score = 6–9) were based on moderate quality RCTs; nine were based on low-quality RCTs; and six were based on high-quality RCTs (Table 5).

In multiple SRs, positive conclusions were reached for AT ($n=9$), BFB ($n=2$), *P. hybridus* ($n=1$), *T. parthenium* L. ($n=2$) and SMT ($n=2$) (Table 6). Negative conclusions were reported for homeopathy ($n=1$) and SMT ($n=1$). Equivocal conclusions were reached for AT ($n=3$), homeopathy ($n=2$), *P. hybridus* ($n=2$), *T. parthenium* L. ($n=4$) and SMT ($n=2$). For other types of CAM, positive conclusions were drawn for AA, chiropractic, HBOT, manual therapies and relaxation (Table 7).

Other outcomes

Twenty-two (66.7%) SRs mentioned adverse effects (AEs) and 11 did not. Sixteen (48.4%) SRs disclosed the authors' conflicts of interest, whereas 17 did not. Nineteen (57.5%) SRs reported the source of funding and 14 did not.

Discussion

In the present SR, we aimed to summarise and evaluate the evidence from SRs of all forms of CAM for the prevention and treatment of migraine headache. Thirty-three SRs met our eligibility criteria. Of these, 30 (91%) focused both on prevention and treatment, or treatment alone, and 3 (9%) on prevention of migraine only. Twenty SRs reached positive conclusions (of which 80% were of high quality, with an Oxman score of 6–9); two SRs reached negative conclusions (of which 50% were of high quality), and 11 reached equivocal conclusions (of which 36.3% were of high quality).

A wide variety of CAM modalities were investigated in the included SRs. By far, the most frequently evaluated type of CAM was AT ($n=12$) followed by *T. parthenium* L. ($n=6$), SMT ($n=5$), *P. hybridus* ($n=3$), homeopathy ($n=3$) and BFB ($n=2$). One of each SR evaluated AA, chiropractic, *G. biloba*, HBOT, LA,

Table 5 The quality of systematic reviews (Oxman score) as a function of quality of primary data

| Quality of primary trials | Quality of systematic review (Oxman score ²⁰) | | | |
|---------------------------|---|-------------------|-------------------|---------------------------|
| | Extensive flaws (≤1) | Major flaws (2–3) | Minor flaws (4–5) | Minimal or no flaws (6–9) |
| Low | 5 | 1 | 0 | 9 |
| Moderate | 4 | 2 | 1 | 13 |
| High | 0 | 1 | 2 | 6 |

Table 6 Types of CAM modalities with multiple systematic reviews

| Type of CAM | Conclusion (n of systematic reviews) | | |
|---|---|--------------|-----------------|
| | Positive (+) | Negative (–) | Equivocal (+/–) |
| AT | 9 | 0 | 3 |
| BFB | 2 | 0 | 0 |
| Homeopathy | 0 | 1 | 2 |
| Herbals (<i>Petasites hybridus</i>) | 1 | 0 | 2 |
| Herbals (<i>Tanacetum parthenium</i> L.) | 2 | 0 | 4 |
| SMT | 2 | 1 | 2 |

AT, acupuncture therapy; BFB, biofeedback; SMT, spinal manipulative therapy.

manual therapies, relaxation, subcutaneous CO₂ insufflations, TCM and Tianshu capsule.

The Oxman criteria²⁰ were used to evaluate the methodological quality of the 33 SRs; 21 SRs were considered to be of high methodological quality, three had minor flaws, three had major flaws and six had extensive flaws. In general, the included SRs were of high methodological rigor. However, 22 high-quality SRs drew their conclusions on low-to-moderate quality evidence (Table 5), which may sound counterintuitive and undermine a reader's confidence. There were other issues with the SRs also, including significant heterogeneity of meta-analyses, small overall effect size, lack of sensitivity analyses or formal validity assessments, authors' COIs, and the inclusion of other types of headaches (e.g. TTH, cervicogenic) and treatment regimens (e.g. physiotherapy). With regards to the primary data, some RCTs lacked power calculations, wash-out periods, placebo-control arms, independent replications, large samples or standardised doses of treatment.

None of the multiple SRs reached negative conclusions for AT, BFB, *T. parthenium* L. and *P. hybridus*. The mechanisms of action of AT in migraine

Table 7 The direction of conclusion as a function of CAM modality

| Type of CAM | Conclusion (n of systematic reviews) | | |
|---|--------------------------------------|--------------|-----------------|
| | Positive (+) | Negative (-) | Equivocal (+/-) |
| AA | 1 | 0 | 0 |
| AT | 9 | 0 | 3 |
| BFB | 2 | 0 | 0 |
| Chiropractic | 1 | 0 | 0 |
| HBOT | 1 | 0 | 0 |
| Homeopathy | 0 | 1 | 2 |
| Herbals (<i>Petasites hybridus</i>) | 1 | 0 | 2 |
| Herbals (<i>Tanacetum parthenium</i> L.) | 2 | 0 | 4 |
| Herbals (<i>Ginkgo biloba</i>) | 0 | 0 | 1 |
| Herbals (Tianshu capsule) | 1 | 0 | 0 |
| LA | 0 | 0 | 1 |
| Naturopathy (SCI) | 0 | 0 | 1 |
| Manual therapies | 1 | 0 | 0 |
| Relaxation | 1 | 0 | 0 |
| SMT | 2 | 1 | 2 |
| TCM | 0 | 0 | 1 |

AA, auricular acupuncture; AT, acupuncture therapy; BFB, biofeedback; HBOT, hyperbaric oxygen therapy; LA, laser acupuncture; SCI, subcutaneous CO₂ insufflations; SMT, spinal manipulative therapy; TCM, traditional Chinese medicine.

pertain mainly to non-specific physiological effects and non-specific psychological (placebo) phenomena.⁵⁴ Even though AT is known to have short-term analgesic effects,³⁷ no uniformly accepted mode of action by which it could have persisting effects on chronic migraine sufferers exists.⁴⁷ Some self-regulatory techniques such as BFB/relaxation are believed to decrease muscle tension and (psychological) stress levels, and to increase cerebral blood flow and oxygen supply.⁵⁵ For *P. hybridus* and *T. parthenium*, the evidence is still unconvincing with more high-quality double-blind, placebo-controlled RCTs being recommended in all SRs.^{21-25,49,50,52} Our previous analyses⁵⁶ highlighted a high level of confusion regarding SRs of the effectiveness of SMT for headaches (including migraine), which is consistent with the present work. For SMT, two SRs arrived at positive conclusions, two reached equivocal conclusions and one arrived at negative conclusions. For homeopathy, one SR reached negative conclusions and two reached equivocal conclusions; there was no suggestion of benefits beyond placebo.⁵⁷ There is still insufficient evidence to recommend any of the other CAM modalities studied.

Given the good safety profile of AT, BFB/relaxation, *P. hybridus* and *T. parthenium* the risk-benefit ratio seems to be positive for these treatments. However, for homeopathy and SMT, the risk-benefit balance shifts more into the negative. More spe-

cifically, serious, sometimes fatal, vascular accidents have been associated with SMT of the cervical spine.^{58,59} Homeopathic remedies, when undiluted, are highly poisonous and can possibly cause serious adverse effects.⁶⁰

Previous research indicates that more than 50% of adults with migraine or severe headache that report the use of CAM do not discuss this use with their healthcare provider.¹⁴ Another study estimated that 31% of migraine sufferers in the USA had never sought medical attention for their condition.⁶¹ The reasons for this might be related to the adverse effects of prescription or over-the-counter drugs, or dissatisfaction with conventional care in reducing the frequency, intensity and duration of migraine.

This research has several limitations that need to be taken into account when interpreting its outcomes. Although extensive, our searches were limited to full-text papers published in English, so it is conceivable that articles published in other languages were missed. Furthermore, while reviewing SRs we might have neglected the methodological nuances of the original data. It has been repeatedly pointed out that all SRs are prone to inheriting publication bias within the primary data they include. There was also an overlap (double-counting) in terms of primary studies. For instance, nine SRs focused on AT and the majority of those relied on the same RCTs. We deliberately included SRs that relied on previous SRs for their primary data (i.e. update SRs). We did so because the problem of double-counting in overviews of SRs is unavoidable. For instance, almost always non-Cochrane SRs will include a large proportion of RCTs already included in Cochrane reviews and *vice versa*. Collectively, these limitations leave our conclusions less tangible.

Conclusions

A large number of SRs of CAM for the prevention and/or treatment of migraine exist. The evidence for the effectiveness of CAM in preventing or treating migraines is, in the majority of SRs, positive. Policy makers and clinicians should acknowledge the existence of several caveats, however. For instance, only for acupuncture and biofeedback are the conclusions unanimously positive, whereas for the remainder of CAM modalities, the evidence is still conflicting.

Conflict of interest None declared.

Details of the protocol for this systematic review were registered on PROSPERO and can be accessed at: <http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014013317>

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