

COCHRANE FOR CAM PROVIDERS: EVIDENCE FOR ACTION

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Since 1992, the Cochrane Collaboration has been working to provide up-to-date systematic reviews of interventions for the prevention, treatment, and rehabilitation of all health conditions.¹ All reviews published under the Cochrane aegis adhere to a strict and meticulous methodology, undergo extensive peer review and quality checks at multiple stages, and require regular updating to account for new evidence. As a result, Cochrane reviews, considered to be among the most rigorous of all overviews, have been favorably compared with systematic reviews published in the most prestigious medical journals.²

The Cochrane Collaboration has been in existence for over 10 years and comprises more than 9,000 contributors (mostly volunteers) from over 80 countries. There are now more than 1,750 completed Cochrane Reviews, over 100 of which relate to complementary and alternative (CAM) therapies. The reviews, available electronically on the Internet and on CD-ROM in *The Cochrane Library*, can also be obtained as paper copies. Further information on the Cochrane Collaboration is available on the Internet (www.cochrane.org). New members are always welcome.

Beginning with this issue, *Alternative Therapies in Health and Medicine* and the Cochrane Complementary Medicine Field present a series of columns called *Cochrane for CAM Providers: Evidence for Action*. Each column begins with a *clinical scenario* in which a patient presents with a condition and the provider considers the value of a CAM therapy for treating it. The column then presents an abstract of a Cochrane review relevant to this scenario, followed by an evaluation or *critical appraisal* of the review. The conclusion of each installment provides an *evidence-based answer* to the question presented. These

columns will provide examples of important Cochrane Reviews relating to CAM, orient readers to the content and format of the reviews, and describe the applicability of the reviews to patient care.

CLINICAL SCENARIO

An otherwise healthy 50-year-old woman presents with complaints of tension type headaches that she has been experiencing intermittently for the past twenty years. She would like to try an alternative treatment, and asks whether acupuncture might help. The provider searches *The Cochrane Library* and identifies the potentially relevant review "Acupuncture for idiopathic headache," an abstract of which follows:

Abstract

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

Objectives: To determine whether acupuncture is

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

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

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

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

Main Results: Twenty-six trials including a total of 1,151 patients (median, 37; range, 10-150) met the inclusion criteria. Sixteen trials were conducted among patients with migraine, 6 among patients with tension-type headache, and 4 among patients with various types of headaches. The majority of trials had methodological and/or reporting shortcomings. In 8 of the 16 trials comparing true and sham (placebo) acupuncture in migraine and tension-type

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headache patients, true acupuncture was reported to be significantly superior; in 4 trials there was a trend in favor of true acupuncture; and in 2 trials there was no difference between the two interventions. (Two trials were uninterpretable.) The 10 trials comparing acupuncture with other forms of treatment yielded contradictory results.

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

This review should be cited as: Melchart D, Linde K, Fischer P, Berman B, White A, Vickers A, Allais G. Acupuncture for idiopathic headache (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2003. Oxford: Update Software.

Does this systematic review address a focused clinical question?

To determine whether a systematic review may be relevant to a client's care, one must first assess whether it addresses a clearly defined and clinically relevant question, expressed in terms of the relation between a test intervention and a control comparison intervention for the treatment of a specific health condition. In this review, the clinical question—whether acupuncture is “more effective than no treatment,” “more effective than ‘sham’ (placebo) acupuncture,” or “as effective as other interventions” for the treatment of headaches—is both relevant and well formulated.

Were the criteria used to select articles appropriate?

The full-text version of this Cochrane Review explicitly defines the inclusion criteria, which are appropriate for identifying studies to answer the clinical question. Eligible studies are randomized controlled trials (RCTs) or quasi-RCTs. Participants must have some type of idiopathic headache (such as migraine or tension type), and any clinical outcome measure related to headache reduction is acceptable. Treatments may include needle insertion at acupuncture points, pain points, or trigger points, or other methods of stimulating acupuncture points, such as laser acupuncture and electroacupuncture.

Traditional acupuncturists might view as objectionable the inclusion of studies of newer acupuncture-like treatments (such as trigger point or electroacupuncture) together with more established and time-tested forms of acupuncture. If such distinct forms of acupuncture have different success rates, some may argue that combining them in an overall summary would result in underestimating the value of the more effective forms of acupuncture and overestimating the value of those that are less valuable.

What is the likelihood that relevant studies were overlooked?

Authors of systematic reviews should state the search strategy they use to locate studies, thereby allowing the reader to assess the likelihood that relevant studies were missed. The review above explicitly describes all sources searched, and the search appears to have been fairly comprehensive. Note, however, that the authors did not search electronic bibliographic databases of China, Japan, and Russia, countries that have a long history of acupuncture use.

One might argue that databases or journals published in these countries could have been sources of additional studies. However, before criticizing the review on this point, one should recognize that some researchers believe that broadening a search to include ‘grey literature’ studies from untraditional sources is not always a wise investment of resources and that doing so may, in fact, potentially degrade the overall quality of a systematic review if the additional studies identified are of low quality.^{3,4}

Was the validity of the included studies assessed?

In this review, the methodological quality of the included studies was evaluated using two different quality-rating scales: 1) the Jadad Scale and 2) the Linde Internal Validity Scale. Each of these rating scales focuses on a few key aspects of study design (see sidebar, page 112). Both scales emphasize the following pivotal points, among others: the presence of explicit statements in the report that a formal random method was used to decide allocation of patients to the test and treatment groups compared; the use of double blinding (blinding of patients and evaluators to the treatment received); and the description of all dropouts and withdrawals.

Are assessments of studies reproducible?

Authors of systematic reviews must decide which studies to include in a review and then evaluate the validity and abstract the data for each included study. To help guard against bias, at least two independent reviewers should participate in each decision. In Cochrane Reviews, these decisions are generally recorded in data tables. Such tables not only increase transparency of the methods used and data collected, but also allow the reviews to be reproducible, one hallmark of a true scientific study. Typical data recorded include characteristics of included and excluded studies; this review also included assessments of methodological quality (all criteria for both Jadad and Linde scales) of included studies and outcome results data for each included study.

Are the studies sufficiently similar to justify a statistical combination of the data?

The authors of this review thought, justifiably, that there was so much heterogeneity in the patients, interventions, controls, and outcomes that a statistical combination of the data (“meta-analysis”) was not appropriate. Furthermore, a reliable meta-analysis was not considered feasible because the data abstracted from the individual RCT reports were often insufficient or uninterpretable. Therefore, the component studies were combined, as appropriate, using a qualitative descriptive summary.

Evidenced-based answer to clinical question

The data from this review support the benefits of acupuncture for treating idiopathic headache, although the methodological shortcomings and heterogeneity of the studies limit the possibility of drawing definitive conclusions. There are few adverse events associated with acupuncture,⁵ so the costs are primarily financial. These costs are often the responsibility of the patient, because acupuncture, like many other CAM therapies, is often not covered by insurance.

CONCEPTS IN STUDY DESIGN: RANDOMIZED CONTROLLED TRIALS AND DOUBLE-BLINDING

Most of the systematic reviews on *The Cochrane Library* limit eligibility to randomized and quasi-randomized (eg, by date of birth) controlled trials, the gold standard study design for evaluating the effects of healthcare therapies. Random allocation helps to insure that the participants in the two study arms (eg, control and active treatments) are initially comparable on all measures, including measures related to the outcome, such as headache frequency. If, after the treatment (eg, true or sham acupuncture) has been administered, there is a difference in headache frequency measured—with the people in the true acupuncture group having fewer headaches than those in the sham acupuncture group—then the reduction in headaches may be attributable to the effects of the acupuncture, the only difference introduced between the two randomly allocated treatment arms.

Using sham acupuncture as a control group in acupuncture RCTs is comparable to using inert sugar pills as a control group in pharmaceutical RCTs. Both of these controls are designed to double-blind the trials so that neither the participant nor the outcome assessor knows who received the test intervention (ie, true acupuncture) vs. the control (eg, sham acupuncture). This blinding or masking helps guard against a biased outcome assessment. For example, if acupuncture were administered to a patient with headaches who strongly believed acupuncture would help, the patient might exaggerate reports of reductions in headaches. However, blinding helps to control for this possibility because any such exaggeration in the true acupuncture group would also be expected to occur in the sham acupuncture group, assuming the participants could not tell the difference between true and sham treatments.

Some researchers have criticized the use of sham acupuncture as a control group on the grounds that sham acupuncture is not inert at all, but actually has its own specific effects mediated by the sham acupuncture's unintentional stimulation of points related to pain reduction. They would argue, therefore, that an RCT that tests active acupuncture against a 'sham' control would not reveal the true difference between acupuncture and a truly inert control, thus resulting in an underestimation of the value of acupuncture.⁶ As a way of avoiding this problem, investigators have proposed using only a special type of 'sham' acupuncture that does not pierce the skin, and therefore theoretically does not exert any specific effects on pain reduction.

In deciding whether to recommend acupuncture to a client with headaches, a clinician might consider several factors, including the results of this systematic review, experience treating other patients, knowledge of the estimated value of acupuncture for headaches according to Traditional Chinese Medicine, and the client's receptivity towards acupuncture and willingness to pay for it.

DISCUSSION

The ultimate aim of medical research is to learn which healthcare therapies work best and to translate this information to improvements in patient care. As this review clearly illustrates, combining individual research studies to arrive at a general answer is not a straightforward process. Heterogeneity and poor reporting of individual studies can make it difficult to draw any definitive, precise conclusions. Such difficulties emerge frequently in reviews of CAM studies. For example, studies in Traditional Chinese Medicine by definition involve individualized diagnoses and treatment; headaches may be subdivided into multiple distinct diagnoses, and depending on the Traditional Chinese Medicine diagnosis, a different acupuncture protocol may be indicated (eg, different points stimulated and different methods of stimulation). In addition, each study might use a different control group depending on the question to be addressed, and they all might measure headaches using a different scale. At first glance, it seems an insurmountable challenge to summarize such diverse data; however, as this review demonstrates, such summaries are not only possible but also essential for arriving at a generalizable conclusion about the effects of a healthcare therapy.

Systematic reviews are the best measure we have to summarize data about and support the effectiveness of CAM therapies. Increasingly, healthcare plans and government agencies require systematic reviews before providing coverage for particular treatments. In order to keep pace with conventional medicine, which is investing substantially in the evidence-based evaluation of its therapies, the CAM community must do the same.

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Disclaimer

The views expressed in this article represent those of the authors and are not necessarily the views or the official policy of the Cochrane Collaboration.

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