

# Australian Journal of Acupuncture and Chinese Medicine

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# Australian Journal of Acupuncture and Chinese Medicine

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# Australian Journal of Acupuncture and Chinese Medicine

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The primary focus of the Journal is publishing peer-reviewed articles that will enhance quality and diversity in acupuncture and Chinese medicine clinical practice and/or research and stimulate the exchange of ideas about clinical practice and the role of acupuncture and Chinese medicine in contemporary health care.

Peer-reviewed papers include research articles, clinical trials, systematic reviews, case reports and case series, as well as general and theoretical papers. The Journal also publishes brief reports on current research, book reviews, conference reports and other articles relevant to the Journal's objectives.

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# Editorial

This issue of AJACM (volume 3, issue 1) is packed with systematic reviews, articles, research summaries, conference reports and book reviews and is one of our biggest issues yet. Our aim is to provide our readers and subscribers with the latest in research findings, clinical practice and professional issues, an aim which I believe the Journal is achieving. To this end, we will be distributing an anonymous survey at the next Australasian Acupuncture and Chinese Medicine Annual Conference (AACMAC) at Sydney in May, in order to get some detailed feedback on what you want in the Journal.

The first article in this issue is a systematic review of the Chinese literature on research of the effect of acupuncture on migraine, co-authored by our editor, Zhen Zheng. While there is a global expansion of Chinese medicine, access by English speakers to the wealth of Chinese research literature has been minimal. This paper represents, I believe, one of the first studies to specifically address that issue in the format of a systematic review.

The second article is an exploration of Chinese medicine epistemics (knowledge systems). The authors, one Chinese and one Australian, contest some of the assumptions in the West concerning early notions of reality and being, and how these affected the early developments of Chinese medical concepts and methods. Those interested in a scholarly understanding of Chinese medical thought will find this article thought provoking.

The next paper, by Hong Xu and her colleague, has a clinical focus. The well-known *Shang Han Lun* formula – *Ban Xia Xie Xin Tang* for treating glomus – is evaluated for its clinical usage and further modification. The ability of master practitioners to use a few formulae with the knowledge to modify them for a range of specific complaints is integral to developing clinical skill.

The fourth article is a condensed version of a Cochrane Systematic Review on the Chinese herbal research on primary dysmenorrhea that was published in late 2007. Xiaoshu Zhu and co-authors have permitted us to reproduce the review of this very commonly presented clinical condition. Reviews such as this and the previous acupuncture study give us confidence in treating such conditions, and are also useful in informing

potential patients of the ability of herbal medicine and acupuncture to treat many common conditions.

Central to the development of a profession is education. To this end, the next article directs readers to the growing use of computer technology. The paper describes the four-stage quality assurance model SOPE and how it is used in the development of online materials for a subject on herbal pharmacology at an Australian university.

There are also book reviews, conference reports and clinical research summaries that will keep you up to date on the Australian and international scene.

Since the last issue in December 2007, we have had a number of important events occur in Australia. On the conference front, an international conference, the Third International Congress of Complementary Medicine Research (ICCMR) was held in Sydney in March. While the scope of the conference was broad, Chinese medicine and acupuncture were an integral component of the program. On the research front, the National Health and Medicine Research Council (NHMRC) complementary medicine grants were recently released. In the area of Chinese medicine and acupuncture, Professor Alan Bensoussan (University of Western Sydney) was successful in receiving a grant of \$590 200 for the clinical and physiological evaluation of Chinese herbal medicine for constipation predominant irritable bowel syndrome. The other recipient was Associate Professor Patricia Armati (University of Sydney), who will receive \$326 207 to investigate the neural mechanism of laser acupuncture in pain relief using rat peripheral nervous tissue models. Also released were the National Institute of Complementary Medicine (NICM) Collaborative Centre grants, a State and Commonwealth venture to increase the capacity for research into complementary medicine. The University of Sydney (representing a consortium of eight universities) was successful in obtaining \$734 000 to establish a national approach to evaluating Chinese medicine, including acupuncture and Chinese herbal medicine.

Finally, congratulations to the Division of Chinese Medicine at RMIT University, one of the only two organisations globally that have been recognised through the Wang Ding Yi Cup International Prize by the World Federation of Chinese

Medicine Societies (WFCMS). The conferring ceremony was held at the Great Hall of the People (the Chinese Parliament) on 15 April 2008. This award is recognition of RMIT's contribution to Chinese medicine education, research, clinical training and promotion of the internationalisation of Chinese medicine over a period of 15 years.

Readers are reminded to consider submitting manuscripts to the Journal, including letters to the editor and case studies,

as we need your support to continue to make the Journal a valuable resource for professional and clinical knowledge. I think I have accosted you in this editorial with enough acronyms to last a lifetime! Please read and enjoy, and we look forward to publishing an even bigger and better issue in late 2008.

*Chris Zaslawski*  
*Deputy Editor*

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## Letters to the Editor

One of our readers recently contacted Sherman Gu regarding his case report, 'Thoracic Outlet Syndrome Treated with Acupuncture, Manual Techniques and Self-stretching Exercises', which was published in volume 2, issue 1 (2007) of AJACM. The reader had utilised some of the treatments described by Gu and enquired whether he could recommend any additional treatment for thoracic outlet syndrome (TOS). Gu's response is reprinted below.

Dear —,

I am pleased to hear that your patient is benefiting from the article I wrote.

You might instruct the patient to perform the following stretch exercises adapted from Travell and Simons, one of the references listed at the end of my article.

The patient is in the supine position; if the TOS is on the left side, then anchor his affected side arm by placing it behind the trunk. Put his other hand on the back of the head with the head in 45° rotation away from the affected side, and stretch the neck and shoulder gently and slowly. Repeat the same manoeuvre with the head in the position of 45° rotation

toward the affected side or neutral position (face up). The stretching can be repeated three or four times in each direction and performed in two or three sessions daily until the patient is pain free.

The details of the stretch can be obtained from the following:

Travell J, Simons D. Myofascial pain and dysfunction: the trigger point manual (Vol. 1). Baltimore, MD: Williams & Wilkins; 1983. p. 362–63.

Regards,  
Sherman Gu

# Acupuncture for Migraine: A Systematic Review of Chinese Literature

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## ABSTRACT

**Introduction:** Acupuncture is widely used for the treatment of migraine, but its effectiveness is inconclusive based on findings of two recent systematic reviews. However, these reviews included very few studies conducted in Asian countries. Research papers published in Chinese are yet to be reviewed to determine their role in the overall understanding of the effectiveness and safety of acupuncture for migraine. **Objectives:** Is acupuncture more effective than no treatment, sham/placebo acupuncture, or as effective as other interventions for migraine? **Methods:** *Search Strategies:* Electronic search was performed in the two most comprehensive Chinese e-databases, *Vi Pu* and *Wan Fang*. **Keywords** used were a combination of acupuncture, headache, migraine, Chinese medicine, electroacupuncture and point-stimulation. *Selection Criteria:* Randomised, controlled trials comparing acupuncture with any type of control interventions and reporting at least one of the clinically related outcome measures for migraine were selected. *Data Collection and Analysis:* Characteristics of the studies were extracted by two independent reviewers. Reporting quality and validity were assessed using the Jadad Scale, Internal Validity Scale and Oxford Pain Validity Scale. STRICTA was used to assess the reporting quality of acupuncture treatment. RevMan 4.2 was used for data analysis. **Results:** Seventeen studies with a total of 2097 participants (median 91; range 62–216) met the inclusion criteria. Ten studies compared acupuncture alone with western medications. The remaining seven trials compared a combined therapy of acupuncture and other therapies with western medications. None of the studies compared acupuncture with no-treatment control or sham/placebo acupuncture. None of the 17 studies was considered of high quality. Studies indicated that acupuncture alone was superior to western medications (RR 1.55, 95% CI 1.27 to 1.88). In comparison to studies included in the other two reviews, the Chinese studies in this review had a larger sample size and acupuncture treatments were more frequent. **Conclusion:** There is moderate evidence that acupuncture is more effective than western pharmacotherapy. Due to the poor quality and validity of included studies, this conclusion requires further assessment. Data from Chinese literature should be included in future systematic reviews.

**KEYWORDS** systematic review, acupuncture, migraine, headache.

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## Introduction

Migraine is a common, disabling, and typically unilateral headache disorder with symptoms such as nausea, vomiting, phonophobia or photophobia. Approximately 16% of Australians suffer from migraine.<sup>1</sup> Direct and indirect costs of migraine as a whole in Australia from 1989 to 1990 were estimated to be between 302 and 721 million dollars.<sup>2</sup>

Current treatments for migraine focus on symptomatic management using anti-inflammatory medications, opioids and ergots. These western medications have provided some relief, but not without risks, such as drug overuse with resultant headache exacerbation. More and more migraine sufferers seek complementary therapies, including acupuncture, for relief. A recent Italian study reported that the percentages of complementary and alternative medicine users in chronic and episodic migraine sufferers were 50% and 27%, respectively.<sup>3</sup>

The role of acupuncture in migraine treatment, however, remains uncertain.<sup>4</sup> Currently available systematic reviews (SRs) on this topic have focused on published studies from western countries, with few studies in Asian languages.<sup>4-6</sup> Thus, the majority of Asian studies were neglected, possibly due to language difficulties and a lack of access to the relevant databases.<sup>4</sup> In China, acupuncture is widely used and data from this region need to be taken into consideration in determining the effectiveness and safety of acupuncture for migraine.

## Objectives

Through systematically reviewing Chinese literature, the objectives of this review were to determine whether acupuncture was:

1. more effective than no treatment;
2. more effective than 'sham/placebo' acupuncture; and
3. as effective as other interventions for migraine.

## Methods

### CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

#### TYPES OF STUDIES

Studies with a randomised and controlled design were included. Quasi-randomised studies (e.g. by the order of admission or date of birth) were also included. Ongoing or unpublished studies were excluded.

#### TYPES OF PARTICIPANTS

Participants were migraine patients diagnosed according to standard criteria, such as those recommended by the Ad Hoc Committee of the National Institute of Neurological Diseases and Blindness<sup>7</sup> or the International Headache Society (IHS).<sup>8</sup>

Studies that did not separate migraine patients from those with other types of headache, such as tension-type headache, were excluded.

#### TYPES OF INTERVENTION

Studies that involved needle insertion at acupuncture points, tender points, or trigger points, and other invasive methods of stimulating these points (e.g. electroacupuncture) were included. Studies examining non-invasive acupuncture, such as laser acupuncture or acupressure, were excluded, so were studies utilising point-injection alone. Studies comparing a combined therapy of acupuncture and Chinese herbal medicine or Tuina with a control group were included because acupuncture was often used together with other therapies in clinical practice.

Control interventions considered were:

- no treatment,
- sham or placebo acupuncture, or
- other active treatments.

Studies comparing different modalities of acupuncture were excluded, for instance, those comparing manual acupuncture with electroacupuncture. Studies without a valid control group, meaning that the effect of acupuncture could not be assessed (for instance, comparing acupuncture with acupuncture plus Qigong), were also excluded.

#### TYPES OF OUTCOME MEASURES

Included studies should report at least one clinically related outcome for migraine, such as frequency or intensity of migraine or number of respondents. Trials reporting only physiological or laboratory parameters as outcome measures, such as electroencephalogram, were excluded.

We extracted data of the 'global response' to treatment. Response was defined as at least 50% improvement in our review. We estimated whether 50% improvement was met from the description provided by the authors. For instance, Lao<sup>9</sup> recorded the reduction of migraine index (MI) during the third month after the end of the treatment. The MI reduction between 90% and 100% was considered as 'cured', between 55% and 89% as 'marked improvement', between 20% and 54% as 'improvement' and less than 20% as 'no effect'. The participants in the first two groups were considered to be respondents in our review. Most studies did not report the immediate and the long-term effects separately. For instance Zhou<sup>10</sup> defined 'improvement' as more than 50% reduction of MI in the three months after the end of the treatment. Consequently, the 50% improvement in our review refers to the global response to acupuncture at 0–12 months after the treatment, and is not specific to either the immediate effect or the long-term effect. Relative risks and their 95% confidence intervals were calculated.

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

‘Acupuncture (针灸)’, ‘electroacupuncture (电针)’, ‘Chinese medicine (中医药疗法)’, ‘point-stimulation (穴位刺激)’, ‘headache (头痛)’ and ‘migraine (偏头痛)’ were the keywords searched in the two largest Chinese electronic databases, *Vi Pu* (重庆维普, www.cqvip.com, inception 1989) and *Wan Fang* (万方数据, www.wanfangdata.com.cn, inception 1982) for papers published from the inception of the databases to August 2006.

METHODS

ELIGIBILITY

Of 266 papers found, 177 were either not RCTs, used Chinese herbs as the active intervention, or did not have a valid control intervention. A further 55 papers were excluded because they reported other types of headache. Two authors (YYW and ZZ) assessed the remaining 34 papers. Two were excluded because non-invasive acupuncture was used and seven were excluded due to the use of point-injection alone as the treatment. A further eight were eliminated for not providing any clinically relevant outcome measures. Finally, a total of 17 studies were included and analysed. The following flowchart illustrates the process of identifying studies (Figure 1).

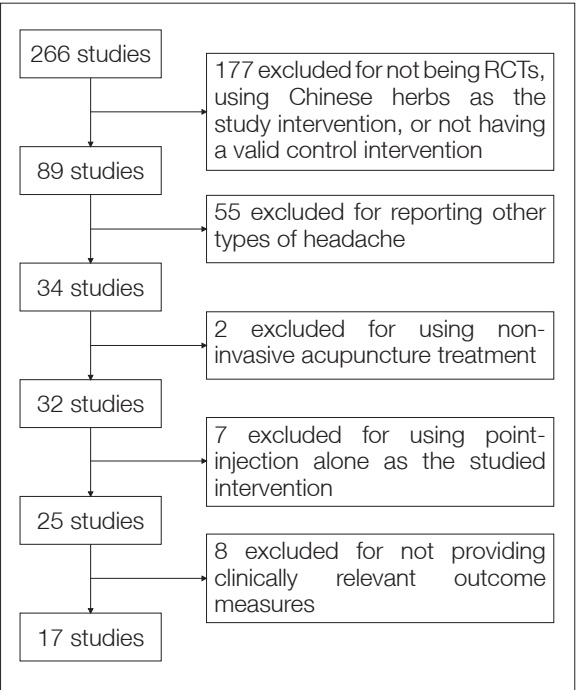


FIGURE 1 A flowchart illustrating the process of study identification

DATA EXTRACTION

Information on participants, randomisation, blinding interventions, outcome measures and results were extracted using the standard form adopted by Melchart and colleagues.<sup>4</sup> One reviewer (YYW) extracted the data. Another reviewer (ZZ) checked the extraction according to the pre-defined form. Differences between the reviewers were resolved through discussion.

ASSESSMENT OF QUALITY

The quality of included studies was assessed independently by two reviewers using the Jadad Scale,<sup>11</sup> the Internal Validity Scale (IVS),<sup>12</sup> and the Oxford Pain Validity Scale (OPVS).<sup>13</sup> The former two scales have been used in several SRs on acupuncture.<sup>4,14</sup> Studies scoring three or more points on the Jadad scale are considered of high quality, which is 60% of the maximum score. OPVS was designed specifically to examine the internal validity of trials in the field of pain research.<sup>13</sup> Points awarded for each item of the Jadad Scale, IVS and OPVS are listed in order for each trial in Table 1. In addition, the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) were used to assess the reporting quality of acupuncture interventions.<sup>15</sup>

Concealment of allocation is the process of concealing assignments of the interventions. We adopted the method recommended by the Cochrane Collaboration to assess whether allocation concealment was adequate, uncertain, inadequate or not mentioned, and scored A, B, C and D, appropriately.<sup>16</sup> This method has been used by other systematic reviews.<sup>4,17-19</sup> ‘A’ refers to studies adopting correct concealment methods, such as using centralised randomisation or sequentially numbered, sealed, opaque envelopes. If studies do not report any concealment approach, ‘B’ should be coded. Category C includes the use of case record numbers, dates of birth or days of the week, and any procedure that is entirely transparent before allocation, such as an open list of random numbers. ‘D’ refers to studies that clearly state that allocation concealment was not used.

DATA ANALYSIS

RevMan 4.2 was used for meta-analysis. If significant heterogeneity among the trials was detected with the  $I^2$  statistic ( $I^2 \geq 50\%$ ), a random-effects model was used. Otherwise, a fix-effects model was used. For continuous data, weight or standard mean difference was used; for dichotomy data, relative risk was used.

We adopted the method described by van Tulder and colleagues in 2003 for the qualitative assessment of the overall evidence. This method classifies the evidence into strong, moderate, limited, conflicting or no evidence, depending on the quality, number and results of the studies.<sup>20</sup>

TABLE 1 Characteristics of included studies

| Author and date         | Intervention                                                      | Sample population*                        | Outcomes#                    | Follow-up | Drop-out |
|-------------------------|-------------------------------------------------------------------|-------------------------------------------|------------------------------|-----------|----------|
| Zhou JH (2005)          | Acupuncture vs western medication                                 | Acu: <i>n</i> = 35<br>WM: <i>n</i> = 35   | ▲                            | 6 months  | No       |
| Wang B (2004)           | Acupuncture vs western medication                                 | Acu: <i>n</i> = 125<br>WM: <i>n</i> = 61  | ▲                            | N/A       | No       |
| Cui R, et al. (2004)    | Acupuncture vs western medication                                 | Acu: <i>n</i> = 48<br>WM: <i>n</i> = 38   | ▲                            | 3 months  | No       |
| Feng SL, et al. (2003)  | Acupuncture vs western medication                                 | Acu: <i>n</i> = 35<br>WM: <i>n</i> = 27   | ▲                            | 2 months  | No       |
| Zhang YC, et al. (2002) | Acupuncture vs western medication                                 | Acu: <i>n</i> = 106<br>WM: <i>n</i> = 110 | ■                            | 1 year    | No       |
| Liu KY, et al. (2001)   | Acupuncture vs western medication                                 | Acu: <i>n</i> = 43<br>WM: <i>n</i> = 43   | ▲ and frequency and duration | 1 month   | No       |
| Li W, et al. (1998)     | Acupuncture vs western medication                                 | Acu: <i>n</i> = 70<br>WM: <i>n</i> = 32   | ▲                            | N/A       | Yes      |
| Chen XS (1997)          | Acupuncture vs western medication                                 | Acu: <i>n</i> = 45<br>WM: <i>n</i> = 30   | ■                            | 6 months  | No       |
| Zhou LS (2003)          | Acupuncture vs western medication                                 | Acu: <i>n</i> = 43<br>WM: <i>n</i> = 20   | ▲                            | 3 months  | No       |
| Lao JX (2003)           | Electronic acupuncture vs western medication                      | Acu: <i>n</i> = 87<br>WM: <i>n</i> = 61   | ▲                            | 2 months  | No       |
| Wang JL, et al. (2004)  | Acupuncture plus Chinese medicine injection vs western medication | Acu: <i>n</i> = 60<br>WM: <i>n</i> = 60   | ■                            | 6 months  | No       |
| Liu Y, et al. (2002)    | Acupuncture plus acupoint injection vs western medication         | Acu: <i>n</i> = 54<br>WM: <i>n</i> = 52   | ■                            | 8 weeks   | No       |
| Lu ZQ (2004)            | Acupuncture plus massage vs western medication                    | Acu: <i>n</i> = 54<br>WM: <i>n</i> = 30   | ■                            | 6 months  | Yes (16) |

| Number and percentage of respondents: Treatment vs Control                                                                                    | Quality                                                             | Allocation concealment <sup>†</sup> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------|
| Treatment: 21/35, 60%<br>Control: 9/35, 25.7%                                                                                                 | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0-0-1<br>OPVS: 0-3-2-0-1-1-0-1   | C                                   |
| Treatment: 100/125, 80%<br>Control: 36/61, 59%                                                                                                | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-1-0-0-1<br>OPVS: 0-3-2-0-1-1-0-1     | B                                   |
| Treatment: 28/48, 58.3%<br>Control: 17/38, 44.7%                                                                                              | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-1-0-0-1<br>OPVS: 0-3-2-0-1-0-0-1     | C                                   |
| Treatment: 23/35, 65.7%<br>Control: 7/27, 25.9%                                                                                               | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0-0-1<br>OPVS: 0-3-2-0-1-0-0-1   | B                                   |
| Treatment: 63/106, 59.4%<br>Control: 24/110, 21.8%                                                                                            | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0-0-0-1<br>OPVS: 0-3-2-0-1-1-0-1     | B                                   |
| Treatment: 33/43, 76.7%<br>Control: 25/43, 58.1%<br>Frequency: $0.3 \pm 1.4$ vs $2.6 \pm 1.6$<br>Duration: $2.54 \pm 1.37$ vs $14.7 \pm 15.6$ | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-1-0-0-1<br>OPVS: 0-3-2-0-1-1-1-1     | B                                   |
| Treatment: 37/70, 52.9%<br>Control: 15/32, 46.9%                                                                                              | Jadad: 1-0-0-0-0<br>IVS: 0.5-0-0-0-0-0.5<br>OPVS: 0-3-2-0-1-1-0-1   | C                                   |
| Treatment: 30/45, 66.7%<br>Control: 16/30, 53.3%                                                                                              | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-1-0-0-1<br>OPVS: 0-3-2-0-1-1-0-1     | B                                   |
| Treatment: 40/43, 93%<br>Control: 15/20, 75%                                                                                                  | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0-0-1<br>OPVS: 0-3-2-0-1-0-0-1   | B                                   |
| Treatment: 41/87, 47.1%<br>Control: 14/61, 23%                                                                                                | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0-0-1<br>OPVS: 0-3-2-0-1-1-0-1   | B                                   |
| Treatment: 37/60, 61.7%<br>Control: 19/60, 31.7%                                                                                              | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0-0-1<br>OPVS: 0-3-2-0-1-0-0-1   | C                                   |
| Treatment: 41/54, 75.9%<br>Control: 32/52, 61.5%                                                                                              | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0--0-1<br>OPVS: 0-3-2-0-1-1-0-1  | B                                   |
| Treatment: 35/46, 76.1%<br>Control: 12/26, 46.2%                                                                                              | Jadad: 1-0-0-0-0<br>IVS: 0.5-0-0.5-0-0-0.5<br>OPVS: 0-3-2-0-1-1-0-1 | B                                   |

*continued on next page*

TABLE 1 Characteristics of included studies (continued)

| Author and date        | Intervention                                              | Sample population*                        | Outcomes <sup>#</sup> | Follow-up | Drop-out |
|------------------------|-----------------------------------------------------------|-------------------------------------------|-----------------------|-----------|----------|
| Shao Y, et al. (2005)  | Electronic acupuncture plus massage vs western medication | Acu: <i>n</i> = 35<br>WM: <i>n</i> = 33   | ▲                     | 6 months  | No       |
| Wang LQ, et al. (2004) | Acupuncture plus hyperbaric oxygen vs western medication  | Acu: <i>n</i> = 63<br>WM: <i>n</i> = 28   | ●                     | 1 year    | No       |
| Liu XL, et al. (2002)  | Acupuncture plus hyperbaric oxygen vs western medication  | Acu: <i>n</i> = 256<br>WM: <i>n</i> = 158 | ■                     | N/A       | No       |
| Zhang YK (2005)        | Acupuncture plus medication vs western medication         | Acu: <i>n</i> = 60<br>WM: <i>n</i> = 60   | Headache index        | No        | No       |

\* Acu: acupuncture, WM: western medications

<sup>#</sup> ▲ refers to four categories of self-defined 'global response', named 'cured', 'marked improvement', 'improvement' and 'no effect'. According to the definition, the participants in the 'cured' and 'significantly improved' categories had more than 50% improvement when compared with the baseline and were considered as respondents in this review. ■ refers to three categories of self-defined 'global response', named 'cured', 'effective' and 'ineffective'. According to the definition, the participants in the 'cured' category had more than 50% improvement, and were considered as respondents in this review. ● refers to four categories of self-defined 'global response', named 'cured', 'marked improvement', 'improvement' and 'no effect'. According to the definition, the participants in the 'cured', 'significantly improved' and 'improved' categories had more than 50% improvement, and were considered as respondents in this review.

## METHODOLOGICAL ASSESSMENT

### DESCRIPTION OF THE STUDIES

Table 1 summarises the characteristics of the 17 studies. Sixteen trials adopted the IHS criteria for the diagnosis of migraine, and one trial used the Ad Hoc Committee's criteria.<sup>21</sup> A total of 2097 participants (median 91; range 62–414) were included in our review.

All studies compared acupuncture with western medication treatments. Ten studies used acupuncture alone. Six studies used a combined therapy of acupuncture with acupoint injection,<sup>22</sup> with intravenous injection of a purified Chinese herb,<sup>23</sup> with Chinese Tuina,<sup>24,25</sup> or with hyperbaric oxygen.<sup>26,27</sup> The remaining study compared acupuncture plus western medication with western medication alone.<sup>23,28</sup> None of the studies compared acupuncture with no-treatment control or sham/placebo acupuncture.

### QUALITY ASSESSMENT

The median Jadad score was 2 (range 1–2) out of a possible score of 5; the median IVS was 2.0 (range 1.5–2.5) out of 6; and the median OPVS was 8 (range 7–9) out of 16. None of the 17 studies had more than 60% of a maximum score of Jadad, IVS or OPVS.

All 17 trials were described as randomised studies. Six studies in which the method of randomisation was briefly mentioned used the order of admission or date of birth to allocate participants, and can be considered as quasi-randomised studies. Consequently, 'C Inadequate' was coded for these six studies. The remaining twelve studies were in Category B because it is unclear if and how the allocation concealment was conducted. Detailed information about allocation concealment was absent in eleven studies, one trial only merely stated that the sortition method was used.<sup>9</sup>

Furthermore, no study reported details regarding the process of blinding. The participants were not blinded to the treatment allocation because western medications were the control intervention. The blinding of assessors was not reported in any of the studies. All studies gained one point for reporting drop-outs. In two studies, a drop-out rate of less than 10% was reported.<sup>21,25</sup> The remaining studies did not have any drop-outs.

Only two trials<sup>28,29</sup> presented means and standard deviations of the outcome measures and were awarded one point for data presentation in OPVS.

| Number and percentage of respondents: Treatment vs Control                                                                       | Quality                                                           | Allocation concealment† |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-------------------------|
| Short-term: Treatment: 26/35, 74.3%<br>Control: 25/33, 75.8%<br>After 6 months: Treatment: 26/35, 74.3%<br>Control: 17/33, 51.5% | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0-0-1<br>OPVS: 0-3-2-0-1-1-0-1 | C                       |
| Treatment: 53/63, 84.1%<br>Control: 33/56, 58.9%                                                                                 | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0-0-1<br>OPVS: 0-3-2-0-1-1-0-1 | B                       |
| Treatment: 103/256, 40.2%<br>Control: 50/158, 31.6%                                                                              | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-1-0--0-1<br>OPVS: 0-3-2-0-1-1-0-1  | C                       |
| Treatment: 9.1 ± 2.07<br>Control: 11.7 ± 3.04                                                                                    | Jadad: 1-0-0-0-1<br>IVS: 0.5-0-0.5-0-0-1<br>OPVS: 0-3-2-0-1-1-0-1 | B                       |

† A: indicates adequate concealment of the allocation (e.g. by telephone randomisation, or use of consecutively numbered, sealed, opaque envelopes). B: indicates uncertainty about whether the allocation was adequately concealed (e.g. where the method of concealment is not known). C: indicates that the allocation was definitely not adequately concealed (e.g. open random number lists or quasi-randomisation, such as alternate days, odd/even date of birth, or hospital number). D: indicates the score was not assigned, i.e. allocation concealment was not used.

In contrast to the poor reporting quality of study designs, most of the studies achieved satisfactory results in STRICTA, reporting quality of intervention, which is not assessed by any other measurements. All 17 trials gave detailed information for acupuncture rationale, needling techniques, treatment regimes, co-interventions and control interventions; however, none of the studies gave details of practitioner backgrounds (Table 2).

ACUPUNCTURE INTERVENTION

Twelve trials used formula acupoints. One trial employed formula acupoints plus Ashi points.<sup>21</sup> The remaining four used semi-structured acupuncture treatment, including formula plus complementary acupoints based on traditional Chinese medicine (TCM) syndrome differentiation.<sup>9,25,26,30</sup> The principles of acupuncture point selection were clearly stated in 16 studies, including dispelling wind,<sup>22,23,25</sup> dredging meridian and activating Qi and blood,<sup>27,28,31-33</sup> and regulating the liver.<sup>9,10,21,24,26,29,34,35</sup> Deqi (a feeling of numbness, heaviness, distension or radiation) was reported in all 17 studies.

The median treatment period was 30 days (range 5–56 days) with an average of 30 treatment sessions (range 5–40). In 13 studies, participants were treated with acupuncture daily. Three studies gave five or six treatment sessions weekly<sup>21,30,35</sup> and in the remaining study, treatment was given once every three days.<sup>31</sup>

The top five acupoints used in the 17 trials were GB 8 *Shuaigu*, GB 20 *Fengchi*, LI 4 *Hegu*, LR 3 *Taichong*, and Ex-HN 5 *Taiyang*.

CONTROL INTERVENTION

All 17 trials used western medications as the control intervention. Participants took prophylactics daily. These drugs were categorised as Ca<sup>++</sup> channel blocker (Nimodipine), antihistamines (Flunarizine), anticonvulsants (Carbamazepine) and analgesics (Rotudin, a combination of analgesics and unnamed herbs). In two studies, participants were instructed to use NSAID (Indomethacin and Brufen) daily,<sup>25,28</sup> which is not a standard western pharmacotherapy for prophylactic treatment of migraine. They were excluded from the meta-analysis.

In six trials, Ergotamine, Cafergot or Ibuprofen was used for acute attacks in the control group only.<sup>10,21,22,24-26,31</sup>

OUTCOME MEASURES

All studies reported the use of at least one of the clinical-related outcome measures, such as frequency, intensity, and duration of migraine. However, apart from two studies which presented the means and standard deviations of clinical data,<sup>28,29</sup> the remaining fifteen reported the number of participants in the ‘cured’, ‘marked improvement’, ‘improvement’ and ‘no effect’ categories. None of the studies mentioned the use of a diary to record patients’ migraine.

FOLLOW-UP

Follow-up was not clearly mentioned in three studies, and one trial did not include a follow-up period. Fourteen studies had a follow-up period ranging from one month to one year after treatment with a median of 4.5 months. Performance of the participants during the follow-up period was not reported separately from that immediately after acupuncture.

Side effects of acupuncture and western medications were not reported.

Results

ACUPUNCTURE VS WESTERN MEDICATIONS

In total, ten studies with 1094 participants were included in this analysis. All 10 studies reported positive results (Figure 2); however, the  $I^2$  statistic (61.4%) indicated significant heterogeneity. Thus, a random-effects model was applied in the data analyses. The results significantly favoured acupuncture as an intervention (RR 1.55; 95% CI 1.27 to 1.88). Only one study<sup>29</sup> presented the details of frequency and duration of migraine in mean and SD (frequency per month:  $0.3 \pm 1.4$  vs  $2.6 \pm 1.6$ ; duration in hours:  $2.54 \pm 1.37$  vs  $14.7 \pm 1.56$ ). This study also provided the number of participants in the sub-groups of ‘cured’, ‘marked improvement’, ‘improvement’ and ‘no effect’. The number of respondents in the study was chosen for the meta-analysis.

ACUPUNCTURE PLUS WESTERN MEDICATION VS WESTERN MEDICATION

There was only one study in the comparison. Zhang (2005) compared acupuncture plus western medication with the same western medication alone (Brufen). In total, 120 participants

were randomised into two groups with 1:1 ratio. After 30 treatment days, the acupuncture group ( $9.1 \pm 2.07$ ) was found to be statistically significantly better than the western medication alone group ( $11.7 \pm 3.04$ ) in headache index, a combined measure of frequency and intensity of headache.

ACUPUNCTURE PLUS OTHER TCM THERAPIES VS WESTERN MEDICATIONS

Four studies compared a combined therapy of acupuncture and other Chinese medicine (CM) therapies, including acupoint injection,<sup>22</sup> intravenous injection of a purified Chinese herb<sup>23</sup> and Tuina<sup>24,25</sup>, respectively, with western medications. Lu<sup>25</sup> combined acupuncture with Chinese Tuina to compare with treatment with Indomethacin (NSAID) (25 mg twice a day for 30 days), an invalid pharmacological treatment for migraine. In fact, frequent use of NSAIDs could lead to migraine from medicine overuse.<sup>36</sup> Consequently, this study was not included in the meta-analysis.

Shao<sup>24</sup> is the only study that presented both short-term data and the six-month follow-up data. The results indicated that acupuncture with massage produced a long-term effect, although the short-term effect was not better than western medications. To be consistent with the data extracted from other studies, the follow-up data were included in the meta-analysis.

The fixed-effects model was used because the  $I^2$  statistic was 43.1%. Figure 3 shows that acupuncture plus other CM therapies were significantly better than western medications control (RR 1.48, 95% CI 1.22 to 1.81).

ACUPUNCTURE PLUS OTHER THERAPY VS WESTERN MEDICATION

Two studies of 503 participants combined acupuncture with hyperbaric oxygen to compare with western medication.<sup>26,27</sup>

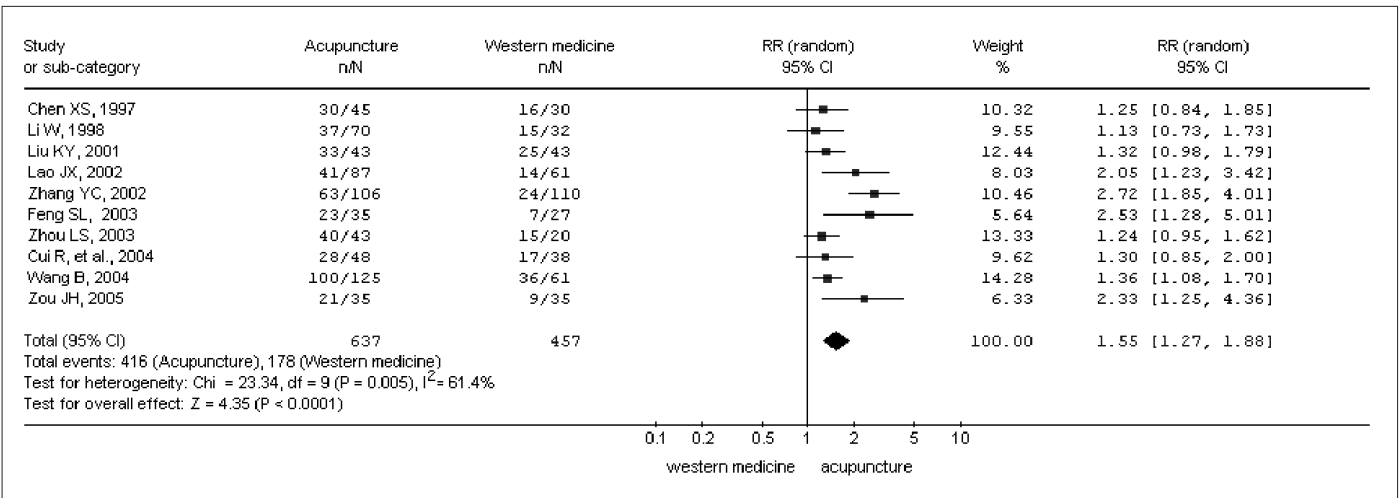


FIGURE 2 Global responses to the treatments – acupuncture versus western medications

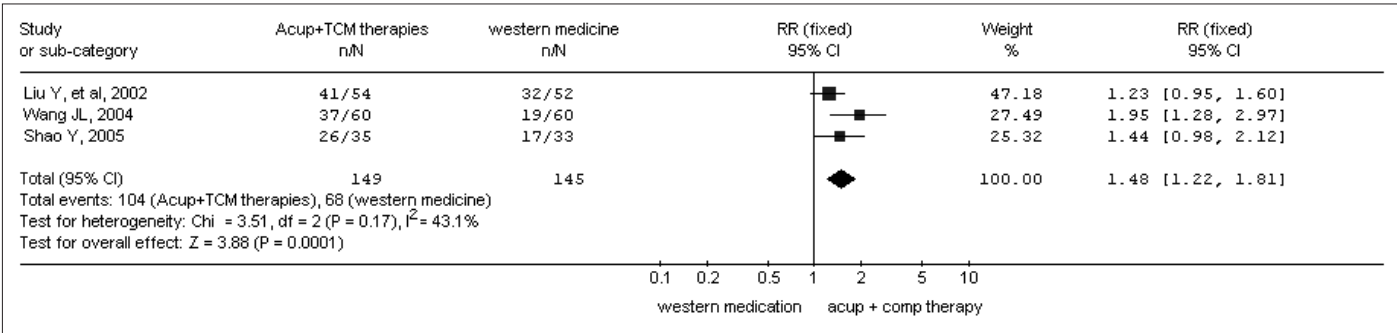


FIGURE 3 Global responses to the treatments – acupuncture with other traditional Chinese medicine versus western medications

Significant heterogeneity was indicated by the I<sup>2</sup> statistic (84.7%), and a random-effects model was applied. Figure 4 indicates that the combined therapy was not statistically significantly better than the western medication controls (RR 1.22, 95% CI 0.87 to 1.7).

A COMPARISON OF OUR REVIEW WITH THE OTHER TWO SRS

A comparison of findings from our review with those in the two previous SRs<sup>4,6</sup> is presented in Table 3. The majority of studies included in the two existing SRs were published in English or European languages. In general, studies published in China had larger sample sizes, were of poorer quality, had acupuncture treatment more frequently and had pharmacotherapy controls only. All studies included in our review emphasised that the Deqi sensation was achieved during treatment. Only 9 out of 26 trials reported Deqi in Melchart et al’s review,<sup>4</sup> and 10 out of 25 in Scott and Deare’s review.<sup>6</sup>

Twenty three percent of the Chinese trials (four out of 17 studies) used semi-standardised acupuncture treatment based on Chinese medicine syndrome differentiation. In comparison, 44% of the trials reported in English and European literature adopted this method.

Trials published in English and European languages used sham/placebo acupuncture, waiting list, western medicine or physiotherapy as the control interventions; blinding of participants was common in the sham acupuncture-controlled trials. All of the 17 Chinese studies used western medications as a control. Except for two studies,<sup>25,28</sup> all drugs used in these 17 trials were recommended migraine medication<sup>37</sup> and were similar to those of trials in the other SRs

Discussion

This review of Chinese literature was conducted to determine the effect of acupuncture on migraine when compared with sham acupuncture, no treatment and other therapies. No relevant studies were identified for the first two comparisons. There is moderate evidence from Chinese literature supporting the value of acupuncture for the treatment and prevention of migraine when compared with western medications. Furthermore, combining acupuncture with other modalities of Chinese medicine is superior to western medications.

The major limitation of our SR is that we were not able to identify papers published prior to the 1980s because the inceptions of the two databases – *Vi Pu* (重庆维普) and *Wan*

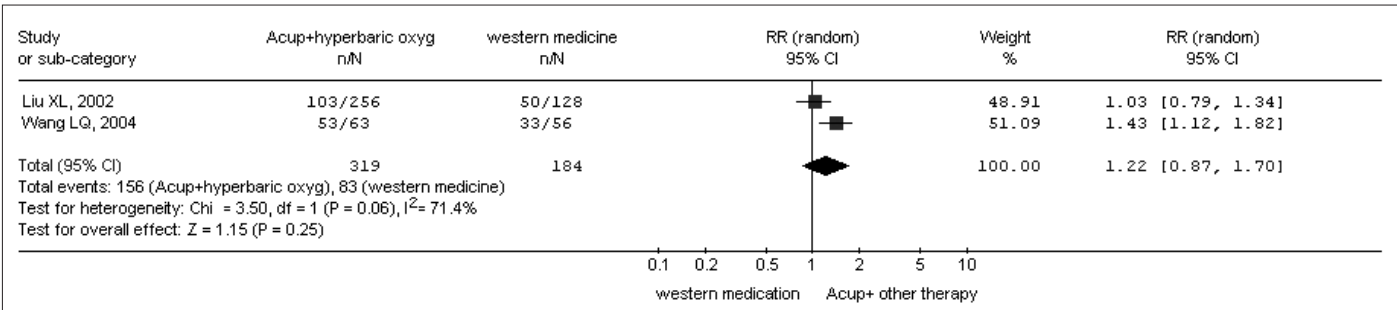


FIGURE 3 Global responses to the treatments – acupuncture and other therapy versus western medications

TABLE 2 Study and control interventions of included studies

| Author and date         | Study intervention                                                | Type of acupuncture treatment                                                                             | Acupuncture points and needling                                                                                                                                                                             |
|-------------------------|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Zhou JH (2005)          | Acupuncture alone                                                 | Formula acupuncture (dredging meridian and activating Qi and blood)                                       | GB 8, GB 19, TE 20. Deqi mentioned.                                                                                                                                                                         |
| Wang B (2004)           | Acupuncture alone                                                 | Formula acupuncture (dredging meridian and activating Qi and blood)                                       | GV 15, GV 16, GV 17; dividing the distance between GV 16 and GB 12 into 6 equal sections, then needling the points dividing the sections. Deqi mentioned.                                                   |
| Cui R, et al. (2004)    | Acupuncture alone                                                 | Formula acupuncture (regulating the liver)                                                                | GB 8, GB 20, GB 39, GB 41, LI 4, LR 3, KI 12. Deqi mentioned.                                                                                                                                               |
| Feng SL, et al. (2003)  | Acupuncture alone                                                 | Formula acupuncture plus complementary point based on TCM syndrome differentiation                        | Empirical points: 1st point: 0.5 cun above GB 8; 2nd/3rd points: 1 cun left or right of the 1st point. Complementary points: BL 23, KI 3, LR 3, or SP 9, ST 8, ST 40 or GB 20, GB 34, LR 3. Deqi mentioned. |
| Zhang YC, et al. (2002) | Acupuncture alone                                                 | Formula acupuncture (dredging meridian and activating Qi and blood)                                       | TE 21. Deqi mentioned.                                                                                                                                                                                      |
| Liu KY, et al. (2001)   | Acupuncture alone                                                 | Formula acupuncture (regulating the liver)                                                                | Ex-HN 5, GB 8, GB 20, GB 34, GB 41, LR 3, TE 5, ST 36, start and end points of lower sensory area in Head acupuncture. Deqi mentioned.                                                                      |
| Li W, et al. (1998)     | Acupuncture alone                                                 | Formula acupuncture (regulating the liver) plus Ashi points                                               | GV 20, GB 20, GB 39, LR 2. Complementary points: Ashi points. Deqi mentioned.                                                                                                                               |
| Chen XS (1997)          | Acupuncture alone                                                 | Formula acupuncture (regulating the liver)                                                                | Ex-HN 5, GB 20, LR 3, ST 8, TE 5. Deqi mentioned.                                                                                                                                                           |
| Zhou LS (2003)          | Acupuncture alone                                                 | Formula acupuncture (regulating the liver)                                                                | TE 5, GB 8, GB 41, GB 44, TE 3, TE 19. Deqi mentioned.                                                                                                                                                      |
| Lao JX (2003)           | Electrical acupuncture alone                                      | Formula acupuncture (regulating the liver) plus complementary point based on TCM syndrome differentiation | GB 4, TE 23. Complementary points: Ex-HN 5, GB 20, LU 7, or KI 3, LR 3 or LI 4, LR 2, or GB 8, ST 40. Deqi mentioned.                                                                                       |
| Wang JL, et al. (2004)  | Acupuncture plus intravenous injection of a purified Chinese herb | Formula acupuncture (dispelling wind)                                                                     | Ex-HN 5, GB 8, GB 20, LI 4, LR 3, TE 3. Deqi mentioned.                                                                                                                                                     |
| Liu Y, et al. (2002)    | Acupuncture plus acupoint injection                               | Formula acupuncture (dispelling wind)                                                                     | GV 20, Ex-HN 5, GB 8, GB 20, LI 4, LU 7, ST 8, TE 23. Deqi mentioned.                                                                                                                                       |
| Lu ZQ (2004)            | Acupuncture plus massage                                          | Formula acupuncture (dispelling wind) plus complementary point based on TCM syndrome differentiation      | Ex-HN 5, GV 14 GV 20, GB 20. Complementary points: LI 4, ST 40 or KI 3, LR 3 or LI 4, SP 6 or LU 9, ST 36. Deqi mentioned.                                                                                  |
| Shao Y, et al. (2005)   | Electrical acupuncture plus massage                               | Formula acupuncture (regulating the liver)                                                                | Ex-HN 5, GB 4, GB 20, GB 38, GB 41, LR 3, PC 6, TE 23. Deqi mentioned.                                                                                                                                      |
| Wang LQ, et al. (2004)  | Acupuncture plus hyperbaric oxygen                                | Formula acupuncture (regulating the liver) plus complementary point based on TCM syndrome differentiation | GB 4, GB 20, TE 19, TE 23. Complementary points: BL 17, SP 10, or BL 12, BL 60, or SP 6, ST 40, or BL 23, KI 3. Deqi mentioned.                                                                             |
| Liu XL, et al. (2002)   | Acupuncture plus hyperbaric oxygen                                | Formula acupuncture (dredging meridian and activating Qi and blood)                                       | Ex-HN 5, LI 4, LI 11, LU 4. Deqi mentioned.                                                                                                                                                                 |
| Zhang YK (2005)         | Formula acupuncture plus medication                               | Formula acupuncture (dredging meridian and activating Qi and blood)                                       | GB 8, GB 20, LI 4, LR 3. Deqi mentioned.                                                                                                                                                                    |

Key: bid = twice per day; tid = three times per day; qd = four times per day.

| Other treatment                                                                    | Treatment regime                                              | Practitioner background | Control intervention                                                                                                                                                |
|------------------------------------------------------------------------------------|---------------------------------------------------------------|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No                                                                                 | 1/day for 30 days                                             | N/A                     | Nimodipine (Ca channel blocker) 40 mg, tid                                                                                                                          |
| No                                                                                 | 1/3 days for 30 days                                          | N/A                     | 1. Cafergot 2 tabs for acute migraine attacks; if not effective within 30 mins, take another 1–2 tablets; max 6 tab/day.<br>2. Nimodipine 30 mg bid for 30 days.    |
| No                                                                                 | 6/week for 3 weeks                                            | N/A                     | Nimodipine 40 mg, tid and oryzanol 20 mg, tid                                                                                                                       |
| No                                                                                 | 5/week for 8 weeks                                            | N/A                     | Nimodipine 40 mg, t.i.d                                                                                                                                             |
| No                                                                                 | 1/day for 5 days                                              | N/A                     | Flunarizine (antihistamines) 10 mg, q.d for 5 days                                                                                                                  |
| No                                                                                 | 1/day for 30 days                                             | N/A                     | Nimodipine 30 mg, tid for 30 days                                                                                                                                   |
| No                                                                                 | 6/week for 3 weeks                                            | N/A                     | Carbamazepine (anticonvulsants) 100 mg, tid for 21 days                                                                                                             |
| No                                                                                 | 1/day for 20 days                                             | N/A                     | Nimodipine 30 mg, tid for 20 days                                                                                                                                   |
| No                                                                                 | 1/day for 40 days                                             | N/A                     | Ergotamine 1 mg for acute migraine attacks; if not effective, take another 2 mg after 30 mins; maximal dose 6 mg/day                                                |
| No                                                                                 | 1/day for 10 days, then rest 5 days; totally repeated 3 times | N/A                     | Rotudin 30 mg tid for 10 days, then rest 5 days; totally repeat 3 times                                                                                             |
| Ligustrazine Hydrochloride (川芎嗪) 100 mL i.v. drip qd for 15 days                   | 1 /day for 15 days                                            | N/A                     | Flunarizine 5 mg, qd                                                                                                                                                |
| Acupoint injection using stauntoniae (野木瓜皂甙) on Ex-HN 5 or GB 16, 2 mL for 8 weeks | 1/day for 10 days, then rest 2 day, lasting 8 weeks           | N/A                     | Flunarizine 5 mg, qd for 8 weeks; cafergot for acute migraine attacks.                                                                                              |
| Tuina                                                                              | 1/day for 30 days                                             | N/A                     | 1. Ergotamine 1–2 mg for acute migraine attacks, if not effective, take another 2 mg after 30 mins; max 6 mg/day.<br>2. Indomethacin (NSAID) 25 mg bid for 30 days. |
| Tuina along the gallbladder meridian on the head for 15 min                        | 1/day for 10 days, then rest 3 days, totally 3 phases.        | N/A                     | Flunarizine 5 mg, qd Acute migraine attack, take ibuprofen 1–2 tablets.                                                                                             |
| Hyperbaric oxygen                                                                  | 1/day for 10 days                                             | N/A                     | 1. Cafergot (1–2 tabs for first symptoms).<br>2. Nimodipine 40 mg tid and Flunarizine (antihistamines) 5 mg, tid for 10 days.                                       |
| Hyperbaric oxygen                                                                  | 1/day for 10 days                                             | N/A                     | Somiton (a combination of analgesics and unnamed herbs) 500 mg, tid, oryzanol 10 mg, tid, and VB1 10 mg, tid for 7 days                                             |
| Brufen 400 mg, t.i.d for 30 days                                                   | 1/day for 30 days                                             | N/A                     | Brufen 400 mg, tid for 30 days                                                                                                                                      |

*Fang* (万方数据) – were 1989 and 1982 respectively. These two databases are the most comprehensive Chinese e-databases and include all the academically credible journals and theses published in China in the area of science and technology. Although studies published before the 1980s are not included in these databases, it is unlikely we have missed many published papers in this area. Apart from two of the 17 papers being published in 1997 and 1998, the remaining fifteen studies were published after 2001.

None of the 17 studies in our review were included in the other two SRs,<sup>4,6</sup> indicating that a large body of research was not considered when the conclusions were drawn. Given that the Chinese studies have larger sample sizes than those conducted in western countries, potentially yielding a higher weighting in a meta-analysis, it is even more important to include such studies.

A search indicated that only one journal included in our review

(*Zhongguo Zhenjiu*) was indexed in PubMed (from 2005). Three studies<sup>16-18</sup> in our review were published in this journal before 2005 and so were not included in PubMed. This confirms the view expressed by the authors of the other two SRs that there is a lack of access to the Asian literature.<sup>4,6</sup>

In this review, we encountered the same difficulty that faced the authors of the other two SRs. Ideally, we should use the number of days with migraine per month or changed intensity or duration of migraine at the end of the treatment as the main outcome measure for quantitative analyses as recommended by the IHS.<sup>38</sup> Only two papers presented means and standard deviations of these outcome measures.<sup>28,29</sup> Due to detailed clinical data being unavailable, the number of respondents was used for meta-analyses. There are differences in the definition of respondents; 50% was used in our and Melchart et al's reviews, and 33% in Scott and Deare's review. Such a reduction of data limits our understanding of the exact effects of acupuncture on the frequency, intensity and duration of migraine.

TABLE 3      A comparison of our review (overall data) and two other systematic reviews of acupuncture for migraine

|                                                    | Our review                                                                                           | Melchart et al.                                                                                                        | Scott and Deare                                                                                                       |
|----------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Sample size (median)                               | 91                                                                                                   | 37                                                                                                                     | 63                                                                                                                    |
| Frequency of treatment (sessions per week)         | 5–7                                                                                                  | 1–2                                                                                                                    | mostly 1–2                                                                                                            |
| Deqi sensation                                     | 17/17 trials reported                                                                                | 9/26 trials reported                                                                                                   | 10/25 trials reported                                                                                                 |
| Jadad, median (range)                              | 2 (1–2)                                                                                              | 1.5 (1–4)                                                                                                              | 2.3 (1–5)                                                                                                             |
| IVS                                                | 2 (1.5–2.5)                                                                                          | 2.5 (1–4)                                                                                                              | 3 (0.5–6)                                                                                                             |
| Acupoint selection                                 | 23% of the studies chose acupoints according to Chinese medicine individual syndrome differentiation | N/A                                                                                                                    | 44% of the studies chose acupoints according to Chinese medicine individual syndrome differentiation                  |
| Control intervention                               | Western medications                                                                                  | Physiotherapy (massage and relaxation), sham/placebo acupuncture, waiting list, western medications, standard GP care. | Physiotherapy (massage and relaxation), sham/placebo acupuncture, waiting list, western medications, standard GP care |
| Respondent rate                                    | 50%                                                                                                  | 50%                                                                                                                    | 33%                                                                                                                   |
| Relative risk (acupuncture vs western medications) | 1.55 (1.27–1.88)<br>Favours acupuncture                                                              | N/A                                                                                                                    | 1.38 (1.08–1.76)<br>Favours acupuncture                                                                               |

Similar pharmacological treatments were used as the control interventions in our review and Scott and Deare's. The effect size identified in our review (1.55) is comparable with the value reported by Scott and Deare (1.38). Considering the different definitions for respondents, Chinese trials have a higher success rate. It is unknown whether the higher success rate is due to publication bias reported by Vickers and colleagues,<sup>39</sup> lower quality, or the differences in acupuncture treatment protocol.

The reporting quality and internal validity are generally poor, as confirmed by three different scales. All 17 studies compared acupuncture with western medications, and participants could not be blinded to treatment allocation. Furthermore, no trial described whether the acupuncturists were blinded to outcome assessment or whether an independent assessor/evaluator was employed. No trials reported the detailed process of randomisation or the reasons for drop-out.

Another major shortcoming of the Chinese literature is the assessment of the outcomes. First, the effect of acupuncture on acute attacks was not investigated. Second, the Chinese trials neither presented detailed clinical data nor separated the immediate effect from the long-term effect. As a result, we cannot determine the duration of the effect of acupuncture on migraine. Third, although many included studies claimed that they assessed the time-profile and intensity of migraine, none of the studies described either the use of a diary, a method recommended by the IHS,<sup>40</sup> or how the data were recorded. The poor reporting quality and lower internal validity might have contributed to the over-estimation of the effect size.

Most Chinese trials implemented nearly daily treatment, which is much more frequent than the treatments provided in studies included in the other two SRs.<sup>4,6</sup> It is unknown whether frequent treatment is associated with better results. Except for one study using empirical points alone, the remaining 16 trials selected traditional acupoints and provided the basis for point selection. All of them are in accordance with the classic literature. From the available data, we cannot conclude how frequent the treatment should be and which formula is the best. The ideal acupuncture treatment, in terms of frequency of treatment and acupoint selection, should be investigated in the future.

## Conclusion

### IMPLICATIONS FOR RESEARCH

Acupuncture shows promising effects on migraine. There is moderate evidence that acupuncture alone or combined with western medications is more effective than western medication for the prevention and treatment of migraine. However, the poor quality of the available studies and a lack of detailed data greatly reduced the level of overall evidence. Future

## Clinical Commentary

This review indicates that acupuncture alone or when combined with other therapies is 1.2 to 1.5 times more effective than western medications for the treatment of migraine. Formula-based acupuncture is used in the majority of studies. The most frequently used acupoints are GB8 *Shuaigu*, GB20 *Fengchi*, LI4 *Hegu*, LR3 *Taichong* and Ex-HN5 *Taiyang*. The findings of this review need to be interpreted with caution as the quality of the included studies is poor.

studies should improve the reporting quality and trial design and present detailed data of the outcome measures. Profiles of the side effects of acupuncture should also be recorded. Furthermore, it is important to include trials published in Chinese in meta-analyses.

### IMPLICATIONS FOR CLINICAL PRACTICE

Acupuncture might be an effective prophylactic treatment for migraine. It can be used either alone or in conjunction with western medications.

## Acknowledgments

### POTENTIAL CONFLICTS OF INTEREST

None. The authors recently completed a randomised, controlled clinical trial of acupuncture for migraine.

### CONTRIBUTION OF REVIEWERS

YYW and ZZ contributed to the development of the protocol, paper selection, data extraction and assessment of quality. YYW, ZZ and CX contributed to interpretation of the data and writing of the manuscript.

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# Chinese Medicine and the *Yi Jing*'s Epistemic Methodology

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## ABSTRACT

Traditional Chinese medicine and contemporary biomedicine have developed methodologies that observe and investigate the human body from different epistemological perspectives. Their conceptual differences have been a recurring topic in the West. The contribution of our article to this topic draws on the ontological and epistemological insights found in the *Yi Jing* (*Book of Changes*). Readers will already be familiar with the argument that Chinese medicine has been profoundly influenced by the *Yi Jing*'s use of yin-yang theory. This paper offers a fresh perspective by examining the *Great Commentary*'s *dao-xiang-qi* cosmology. '*Dao-xiang-qi*' stands for abstract principles, emergent manifestations, and concrete objects, respectively, and this triadic conception of reality leads to an analysis of the human body from a holistic, process-oriented epistemology. The interpretations of reality and being contained in the *Yi Jing* were developed by careful and detailed observation over time, and have deeply influenced China's philosophical and scientific traditions, including medicine. The effect of the *dao-xiang-qi* (way-image-vessel) triad on Chinese medicine has led to its characteristic *dao xiang* epistemic: investigations of human health and illness focus on the living body and result in a more functional or process-oriented epistemic. Relatively speaking, biomedical investigations are guided by a *qi*-vessel epistemic that places more importance on objective, physicalist information and on quantitative and concrete data. The purpose of this paper is to explore the *Yi Jing*'s influence on medical epistemics and the influence of *dao-xiang-qi* for Chinese medical investigations and methodologies. The paper does not attempt an analysis of biomedical epistemics but inevitably the discussion touches on issues pertaining to the integration of Chinese medicine and biomedicine occurring in recent times. Integration presupposes some degree of philosophical and methodological commonality and to that extent we draw attention to the ontological and epistemological assumptions of both medicines.

**KEYWORDS** biomedicine, Chinese medicine, epistemology, integration, materialism, methodology, ontology, *Yi Jing* (*Book of Changes*).

## Introduction

During the nineteenth and early twentieth centuries, the survival of China's traditional medical practices seemed doubtful as they struggled to compete with the evidence, advances and technologies of the emerging western medical sciences. But then, in the late 1950s, Mao Zedong declared Chinese medicine 'a great treasure house' and its continued existence was ensured. The integration of contemporary

scientific medicine and traditional medicines has become part of a global health strategy promoted by the World Health Organization as recently as 2002,<sup>1</sup> and in China the integration of Chinese medicine and biomedicine has already occurred to a large extent.<sup>2,3</sup> Since 1958 the highest levels of Chinese government have actively pursued unification, or more recently, integration, as 'national policy . . . backed by

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strong public support'.<sup>4,5</sup> Official government policy has also encouraged modernisation and scientisation, so that today Chinese medicine must highlight its status as an icon of Chinese culture and at the same time, measure up to scientific scrutiny.<sup>6</sup>

Western sciences pursue the investigation of material and objective phenomena and the label 'scientific materialism' defines this endeavour. Scientific enquiry uses empirical and analytic-deductive methods that rely on objective technologies and quantifiable data, and favour reductionism and linear causality. Scientific observations therefore tend to deal with phenomena that can be recorded and quantified in an objective way. Its methods of investigation attempt to reduce variables, utilise repeatable experiments, and apply measurement and analysis to isolated factors and individual components. Some recent scientific theories (systems, quantum, complexity, bio-coherence) may challenge these broad principles, but in the meantime, biomedicine also utilises scientific methods of investigation and analysis.

The qualitative nature of early Chinese sciences, including medicine, generally emphasised relational and functional patterns rather than quantitative or physicalist information. Being less concerned with the physical details of body organs and tissues, medical investigations instead produced a 'sophisticated analysis of how functions were related on many levels, from the vital processes of the body to the emotions to the natural and social environment of the patient, always with therapy in mind'.<sup>7</sup> Chinese medical theories codified these relational qualities. They assumed principles of holism embracing complexity, the connectedness and interaction of all things, and the non-separability of body and mind. As for contemporary biomedicine, Chinese medicine's methodologies were largely empirical. But the Chinese were concerned with whole systems, dynamic complexity over time, interactivity, and subjectivity. They were also concerned as to whether nature could be fully comprehended by rational, empirical investigation and this led to an abiding interest in the idea that the scale of nature and the cosmos is too large, its texture too subtle and fine, too closely intermeshed for phenomena to be fully predictable. 'This proposition denies that the physical world can be fully penetrated by study, or fully described in words or numbers'.<sup>8</sup>

Yin-yang theory is the core of early Chinese philosophy, and all China's ancient sciences were formed from and deeply influenced by it. The pragmatic application of relational, contingent concepts such as yin-yang is characteristic of the Chinese medical tradition, a tradition that is closely related to the onto-cosmological framework of the *Yi Jing* (易经, *Book of Changes*), the oldest and most famous of China's ancient classics. To further examine the *Yi Jing*'s influence, we discuss

its *dao xiang qi* (道象器, way-image-vessel) cosmology, and the consequent theories of being (ontology) and of knowing (epistemology) that connect all phenomena. *Dao-xiang-qi* has important epistemological and methodological consequences for investigating the world and human life. References to contemporary scientific medicine are given to highlight those consequences and some of the problems for integration.

The *Yi Jing* investigates material and immaterial reality using symbols and metaphors that afford insight into the principles governing life and the cosmos. The text's yin-yang method, with its analogic-inductive reasoning, is a more appropriate tool for this enterprise than the analytic-deductive logic of the Greek tradition and contemporary sciences. The *Yi Jing*'s symbols, metaphors and interpretations are based on *guan* (观, comprehensive observation). *Guan* requires the observation and contemplation of nature's 'organic relationships . . . [and] a long period of time to make correct adjustment and to achieve a neatness and simplicity that would cover the totality of nature and life'.<sup>9</sup>

The early forms of Daoism, Confucianism and medicine that arose in China before the Qin Dynasty (221–206 BCE) developed in distinct ways over the next two millennia, but all three drew from the *Yi Jing*'s onto-cosmological assumptions and methods. Historically, Chinese medical texts frequently acknowledge the importance of the *Yi Jing* for medicine. In the Tang Dynasty (618–906 CE), Sun Si-Miao said: 'If you don't understand the changes, you cannot practice medicine.' [不知易，不足以言太医。]<sup>10</sup> In 1624 Zhang Jie-Bin said:

Medicine and the *Yi Jing* are the same. [This is because] Nature/heaven and the human body conform to the same laws, namely, the principles of yin-yang. And though medical practice is complicated, we can use yin-yang to summarise and analyse all its permutations. [医易相同。天人一理也，一此阴阳也。医道虽繁，而可一言以蔽之者，曰：阴阳而已。]<sup>11</sup>

The high regard traditionally accorded *Yi Jing* is more than convention. In the next section, we examine the influence of its *dao-xiang-qi* triad for the philosophical assumptions concerning the nature of reality and being, and the approach to 'knowing'. Following that, we explore how these assumptions and concepts have influenced the Chinese medical tradition.

## *Yi Jing* epistemics: *dao-xiang-qi*

The *Yi Jing*'s triadic analysis guides its investigation of all phenomena. The result is a sophisticated synthesis, or 'natural law', that applies to all of creation. The *Yi Jing* categorises the essences of the myriad beings, and a being's behaviour in the world is largely determined by the category (类, *lei*) to which it belongs. The concept of *lei* also plays a significant role in the *Nei*

*Jing Su Wen*, where phenomena are systematically associated with the five phases (五行, *wuxing*) by, for example, describing things as 'of the category of fire' (类火, *lei huo*).<sup>12</sup> In the *Yi Jing*, *lei* is linked to the notion of a common origin, meaning the *dao*. In both cases these are not logical statements of fact so much as probabilistic or analogic-inductive observations.

#### DAO 道: 'WHAT IS ABOVE THE FORM IS CALLED THE DAO.'

The *Yi Jing* achieves its 'penetrating syntheses'<sup>9</sup> of categories, changes and natural law by the application of its *dao-xiang-qi* onto-epistemic and yin-yang analytic method. Its analysis of categories, changes and transformations connects and integrates all of creation, and its methods and interpretations have served as primary resources for the investigation of all phenomena, material and immaterial. For the *Yi Jing* and early Chinese onto-cosmology, nothing is greater than heaven and earth, and in all areas of early Chinese theorising, nothing is bigger and nothing is smaller than yin-yang.

According to the *Nei Jing*, yin and yang are the 'way' (*dao*, or 'natural law') of heaven and earth. In *Su Wen* (chapter 5: *Yin Yang Ying Xiang Da Lun* – 'Great Treatise on the Interactions and Manifestations of Yin and Yang'), the comprehensiveness of yin-yang theory for cosmology, the environment, human physiology, diet, emotions, illness, ageing, and so on, is explained. This is yin-yang natural law as it applies to human life, including the relationships, manifestations and interactions within and between macrocosmic (nature) and microcosmic (human life) phenomena. Because human life is one kind of natural phenomena it must also follow the way of yin-yang. So yin-yang has provided an effective guiding principle for Chinese medicine since earliest times. In the *Nei Jing* it is used extensively to discuss the connections between nature and human life and health (also see, for example, *Su Wen*, chapter 3: *Sheng Qi Tong Tian Lun* – 'On Human Life's Union with Heaven/Nature').

When arranged in the earlier heaven (先天, *xian tian*) sequence, the *Yi Jing*'s eight trigrams (八卦, *ba gua*) represent the universal potential before space, time, and movement – the *dao*. The *xian tian* arrangement is the cosmogenic principle and the source of the later heaven sequence. Similarly, the relation of the *dao*-way to *qi*-vessels is that of universal principles to local particulars, abstract to concrete.<sup>2,13</sup>

According to the *Yi Jing* and its *Great Commentary* (大传, *Da Zhuan*), the *dao* (道, the way) is not visible – it is before time and without substance; the *qi* (器, vessel, tool or container) is visible – it is subsequent in time, it has substance and a determined shape. The *xiang* (象, image) can be observed but does not have a determined shape; it is the emergent manifestation of the *dao*. Wang Bing (8th c. CE) said: '*Xiang* means something

becomes apparent and can be seen,'<sup>14</sup> meaning: the observable indications of yin-yang law are called *xiang*.

*Xiang* reveals the existence of the *dao*'s governing potentials and activities, including yin-yang law; it is the bridge linking invisible (道, *dao*) and visible (器, *qi*). So when the changes and transformations of yin and yang become apparent, this produces *xiang*. *Xiang* (象) means manifestation, image and symbol, and since the Song Dynasty (960–1279 CE), the term has been used in its modern sense of 'phenomenon'.<sup>13</sup>

All macrocosmic and microcosmic phenomena are modelled on the *xiang*-manifestations. Heaven and earth are associated with two kinds of *xiang*: 'images' and 'symbols' (象, *xiang*) belong to heaven, and 'forms' (形, *xing*) belong to earth. The *Great Commentary* says:

In heaven perfecting symbols 象; on earth perfecting forms 形: change and transformation become apparent. . . . What is above form is called the 'Way'; what is below form is called the 'vessel'.<sup>13,15</sup>

#### QI 器: 'WHAT IS BELOW THE FORM IS CALLED THE QI-VESSEL'

According to the *Great Commentary*: 'What may be seen is spoken of as [象, *xiang*]. What has physical form is spoken of as [器, *qi*].'<sup>16</sup>

Whilst the *dao* (道) is without substance and before time, *qi* (器) is substantial and subsequent in time, and the binome, *daoqi* (the way and vessel), expresses the relationship of that between the abstract and concrete. In the *Yi Jing*, *qi*-vessel refers to 'everything that does not depend on human consciousness but is the objective object of all sensation and awareness. . . . [The] Chinese notion of *qi*-vessel is very close to . . . the Western notion of matter [except that it] lacks the traditional Western mechanistic interpretation of matter'.<sup>13</sup> While *xiang*-manifestation and *qi*-vessel are both perceptible things in the world, the *qi*-vessel has a determined shape and can be seen and felt. The *xiang*, as emergent manifestation or process-event, does not have a determined shape.

Early Chinese philosophy tends to assume that the *dao* (abstract principles) exists before and produces the material world, and all phenomena come from the *dao*.<sup>17</sup> So in the *Yi Jing*, the *dao* is the governor, *qi* is the result, and *xiang* is the interface between *dao* and *qi* – if there is no *dao* there can be no *xiang* and no *qi*. Conversely, it is difficult to maintain that the *dao* exists independently of phenomena. In other words, if there can be no abstract principle apart from concrete phenomena, then from *qi*-vessel the *xiang* must appear, and the *xiang* must have the *dao* working behind it. Whilst Chinese philosophy emphasises the first direction, our understanding in fact comes

from the second because it is based on the observation of natural phenomena. As the PRC Marxist historian Fan Wenlan (1893–1969) explained: 'The *dao* is the rule of nature extracted from all physical things.'<sup>18</sup>

In any case, *dao-xiang-qi* cannot be separated: they are not independent, they are not divisible entities or parts of existence, and the *Yi Jing*'s epistemic tradition recognises all three aspects (*dao*, *xiang* and *qi*), and both levels (above and below the 'form'). To that extent, the clear differentiation between the physical and the metaphysical made by Aristotle is much less distinct in the Chinese tradition.

Guided by the *Yi Jing*'s onto-epistemic, Chinese medical traditions explore human life phenomena, including visceral (脏, *zang*) functions and manifestations (脏象, *zang xiang*). The *zang* are deep inside the body and the *xiang* are their observable manifestations. Over time, comprehensive observation and the understanding of reality, including *xiang*-manifestation, meant that Chinese medical methodologies are characterised by *zang xiang xue* (脏象学) – medical investigation with a functional perspective based on observable phenomena – rather than by a *zang qi xue* (脏器学) – the reductive physicalist perspective of anatomical and micro-anatomical investigations.

## Dao-xiang-qi and Chinese medicine's epistemic methods

### DAO: YIN-YANG METHOD

From the discussion so far, we see China's early theories of being and knowing propose the *dao* as the undifferentiated potential behind all of creation, and yin and yang as the expression of the *dao* in nature. On the human scale, yin and yang are unified to form a new individual at conception; disease arises when yin and yang are disordered, and death occurs when essence *qi* (精气, *jing qi*) is exhausted and yin and yang separate. Today, Chinese medicine's basic theories, diagnostic frameworks and therapeutic methods still embrace the yin-yang epistemic method. But its encounters with external knowledge systems and advances have forced Chinese medicine to undertake extensive revisions to scientise and systematise its methods and practices. Additionally, there are the political pressures to unify, merge, or integrate with its biomedical counterpart.<sup>5</sup>

Traditional Chinese medicine and contemporary biomedicine both observe and investigate human physiology and pathology, but their philosophical assumptions and methodologies are fundamentally different. Here we will distinguish the two by the epistemic methods identified above: the *zang xiang xue* and *zang qi xue*.

### XIANG: ZANG XIANG XUE

The differences between *zang qi* (脏器) and *zang xiang* (脏象) research objects and methodologies are fundamental. Reductive physicalism and *zang qi* investigations have little to do with the *xiang*, and of course no need for the *dao*. As an example of *zang qi* methodology, the biomedical anatomy tradition reflects the onto-epistemic of scientific materialism – anatomical research methods provide knowledge of objective physical structures.

Historically, however, the object of enquiry is the corpse without life phenomena. Lu Mao-xiu's (1818–1886) famous rebuttal of Wang Qing-ren's (1768–1831) *Correcting the Errors in the Forest of Medicine* decried the 'moral turpitude and medical irrelevance of direct anatomical investigations'.<sup>19</sup> Although Wang's criticisms of the medical classics in favour of anatomical investigations could be viewed as the beginning of 'modern' Chinese medicine, his revisions in fact seem ill-informed and redundant today.<sup>20</sup> Lu gave voice to the prevailing (traditional) attitude towards the *zang qi* level of inquiry, noting the obvious problems of examining lifeless body structures.

Although the methods and technologies of today's medical sciences are so much more advanced and successful, the *zang-qi* onto-epistemic still operates to guide research issues, interpretations and outcomes. From the point of view of the *dao-xiang-qi* onto-epistemic, it is not possible to acquire knowledge of human life by relying on *qi*-vessel data alone because the investigation of isolated body structures and substances remains at the level of *zang-qi* physicalism, where the essence (精, *jing*) is exhausted, *qi* movement (气机, *qi ji*) has ceased, and both the body form and consciousness (形神, *xing-shen*), and yin and yang have separated.

The term '*zang-qi*' is not much used in Chinese medicine and mention of it in the *Nei Jing* is very rare, but Chinese medicine does recognise all three aspects of the *dao-xiang-qi* model. Its investigations, however, are focused primarily on the *zang xiang* aspect – the emergent manifestations of the integrated systems and processes of human life. Specifically, traditional Chinese medicine's human systems and processes include the five viscera (五脏, *wu zang*) and their associated hollow organs (腑, *fu*), the five offices or sense organs (五官, *wu guan*), five body tissues (五体, *wu ti*), five spirits (五神, *wu shen*), and five minds (五志, *wu zhi*). In health, all the body's systems and processes are well-integrated, and all aspects of *qi* movement, including the five phase relationships of engendering (生, *sheng*) and restraining (克, *ke*), are appropriate and orderly. Orderly *qi* movement produces the harmonious function of yin and yang and unifies the body form (形, *xing*) and mind (神, *shen*). *Zang xiang* theory therefore applies not only to internal organs, but also to their systemic influences, structures, and substances, external

senses and tissues, consciousness, perceptions, movements and transformations. In other words, *zang xiang* leads to a holistic analysis of the living body and whole person.

#### QI: ANCIENT ANATOMY

We know the Chinese performed detailed anatomical dissections because even in the *Nei Jing* the body's internal structures are described along with their positions, size, length, capacity, and so on. Many of the organs and measurements given in the *Nei Jing Ling Shu* (chapters 31 and 32) are the same or very close to those we observe today. Why Chinese medicine did not pursue a materialist-physicalist (*zang-qi*) approach to its investigations is a question that Joseph Needham and Nathan Sivin have frequently approached and refined. Readers will be familiar with the arguments that China's socio-political structures stymied technological and scientific innovation to some extent, and that traditions respecting one's ancestors and parents meant that one's body should not be dismembered or dissected. Sivin has challenged the relevance of the question itself for an unbiased enquiry into Chinese 'sciences'.

In our opinion, the *Yi Jing*'s onto-hermeneutic perspective served as a guiding principle in the *Nei Jing* and has been a critical influence for the epistemic methodologies informing Chinese medicine's theoretical developments. Today, Chinese medicine still observes the living body as integrated process-systems that depend on orderly *qi* movement, the harmonious interaction of *qi* and blood, and the dynamic balance of yin and yang. Its interventions attempt to restore and maintain those movements and interactions. Therapeutic adjustments at that level are believed to create optimum circumstances whereby *xing* (形) and *shen* (神) are unified, the *jing-qi-shen* (精气神) are strong and well integrated, the *wu xing* (五行) relationships are orderly, and human life unfolds.

## Conclusion

The scale and complexity of nature, its fine textures and subtleties, were the subject of investigation in China before recorded history. In addressing these issues, the *Yi Jing*'s sophisticated analyses and syntheses provide an onto-hermeneutic framework that has profoundly influenced Chinese thinking. Furthermore, the *Yi Jing* is the philosophical root of Chinese medicine, and historically its *dao-xiang-qi* onto-epistemic is embedded in the development of Chinese medicine's theoretical and clinical methodologies. Chinese medicine recognises all three aspects of the *dao-xiang-qi* triad, not only *zang-qi* physicalism, and even today, the *Yi Jing*'s yin-yang methodology deeply penetrates its theoretical concepts and clinical practices.

The *Yi Jing*'s yin-yang epistemic method encompasses and connects all phenomena because it contains the *dao* and expresses 'natural law'. In light of the *Yi Jing*'s onto-hermeneutics, the nature and activities of life may be observed at the point of emergence (*xiang*) between the *dao* and *qi* aspects of reality, and medicine must account for basic and essential life categories and activities (the yin-yang balance, unified *xing-shen*, the *jingluo*, *qi* movement, *mingmen*, and so on). In this paper we have argued that, comparatively speaking, a biomedical focus is primarily within the parameters of *zang-qi* physicalism, and its epistemic methods therefore emphasise information on material structures and components. Inevitably, *zang xiang* (脏象) functional and *zang qi* (脏器) physicalist perspectives have developed different theories about health and disease, and herein lies the difficulty in comparing and integrating the two medical traditions.

Guided by their onto-hermeneutic traditions, Chinese medical and biomedical researchers and practitioners employ different

## Clinical Commentary

This paper does not discuss particular disease states, treatment strategies or prescriptions. Instead it raises some of the epistemological and methodological issues faced by Chinese medicine as it appraises its place in the contemporary healthcare industry, absorbs the impact of biomedical advances and technologies, and realigns its traditional assumptions to conform to a more scientised investigation of human health and disease. The paper notes that the 'integration' of Chinese medicine into contemporary healthcare delivery systems consists of the 'biomedicalisation' of its interventions and conceptual frameworks.

The onto-cosmological frameworks of medicine have important methodological consequences for investigating the human form, the object of treatment. The changes and revisions Chinese medicine has undergone in recent decades have caused a shift away from the more process-oriented and contingent methods that developed early in its history and are closely related to its traditional view of being and reality.

TABLE 1 Glossary of terms

|       |                               |                                            |
|-------|-------------------------------|--------------------------------------------|
| 八卦    | <i>ba gua</i>                 | eight trigrams                             |
| 大传    | <i>Da Zhuan</i>               | the <i>Yi Jing's Great Commentary</i>      |
| 道     | <i>dao</i>                    | the way, or law of nature                  |
| 道器    | <i>dao qi</i>                 | the way and vessel                         |
| 道象器   | <i>dao xiang qi</i>           | way image vessel                           |
| 腑     | <i>fu</i>                     | yang (hollow) organs                       |
| 观 (觀) | <i>guan</i>                   | comprehensive observation                  |
| 精     | <i>jing</i>                   | essence                                    |
| 经络    | <i>jing luo</i>               | channels and collaterals                   |
| 精气    | <i>jing qi</i>                | essence Qi                                 |
| 精气神   | <i>jing-qi-shen</i>           | essence-Qi-spirit                          |
| 克     | <i>ke</i>                     | restrain, check                            |
| 类 (類) | <i>lei</i>                    | kind, category                             |
| 灵枢    | <i>Ling Shu</i>               | 'Miraculous Pivot'                         |
| 命门    | <i>ming men</i>               | life gate                                  |
| 内经    | <i>Nei Jing</i>               | (Huangdi's) <i>Internal Classics</i>       |
| 气 (氣) | <i>qi</i>                     | Qi                                         |
| 器     | <i>qi</i>                     | vessel, container                          |
| 气机    | <i>qi ji</i>                  | Qi movement; Qi dynamic                    |
| 认识方法  | <i>renshi fangfa</i>          | epistemic method                           |
| 认识论   | <i>renshilun</i>              | epistemology                               |
| 三宝    | <i>san bao</i>                | three gems/treasures; <i>jing-qi-shen</i>  |
| 生     | <i>sheng</i>                  | life, movement, engendering                |
| 生气通天论 | <i>Sheng Qi Tong Tian Lun</i> | 'On Human Life's Union with Heaven/Nature' |
| 素问    | <i>Su Wen</i>                 | 'Plain Questions'                          |
| 五官    | <i>wu guan</i>                | five offices or sense organs               |
| 五神    | <i>wu shen</i>                | five spirits                               |
| 五体    | <i>wu ti</i>                  | five body tissues                          |
| 五脏    | <i>wu zang</i>                | five viscera                               |
| 五志    | <i>wu zhi</i>                 | five minds                                 |
| 五行    | <i>wu xing</i>                | five phases                                |
| 先天    | <i>xian tian</i>              | earlier heaven                             |
| 象     | <i>xiang</i>                  | image, manifestation, process-event        |
| 形     | <i>xing</i>                   | form                                       |
| 形神    | <i>xing-shen</i>              | body form and spirit-mind                  |

|            |                                       |                                                                               |
|------------|---------------------------------------|-------------------------------------------------------------------------------|
| 易经<br>(易經) | <i>Yi Jing</i> or<br><i>I Ching</i>   | <i>Book of Changes, I Ching</i>                                               |
| 阴阳应象<br>大论 | <i>Yin Yang Ying<br/>Xiang Da Lun</i> | 'Great Treatise on the Interactions<br>and Manifestations of Yin and<br>Yang' |
| 脏          | <i>zang</i>                           | internal yin viscera                                                          |
| 脏器学        | <i>zang qi xue</i>                    | medical investigation with a<br>quantitative-materialist perspective          |
| 脏象学        | <i>zang xiang xue</i>                 | medical investigation with a<br>functional-processual perspective             |

methodologies appropriate to their favoured perspectives of reality. But today, the criteria and methodologies of biomedicine are applied to investigate, evaluate and validate Chinese medicine. Science is used to research Chinese medicine's therapeutic interventions and to correct and modernise its theoretical content. Thus, the integration of biomedicine and Chinese medicine in reality means that biomedicine is practised according to its own epistemic methods, whereas Chinese medicine is practised according to biomedical and Chinese epistemic methods – despite their fundamental differences.

If we employ the *Yi Jing's dao-xiang-qi* onto-epistemic to evaluate biomedicine, we find it is primarily concerned with developing our knowledge of human anatomy, physiology and pathology at the level of *qi*-vessel physicality. Even though biomedical research is advancing rapidly, it remains conceptually bound to materialist-physicalist ontologies and interpretations, and in our opinion, research that neglects the *xiang* (象) and *shen* (神) cannot reflect the complexity and subtlety of human life. This is why some areas of *zang-xiang xue* (such as 三宝, *san bao*; 命门, *mingmen*; and 经络, *jingluo*) are unlikely to be investigated, or have proved so difficult to investigate, using scientific methods.

The fundamental differences between Chinese medicine and biomedicine constitute the basis for on-going intellectual and political tensions between the two, and to some extent within our medical and healthcare industries.<sup>21</sup> We contend that the dissimilarity of their respective epistemic and ontological assumptions is significant, and that the 'modernisation' and 'integration' of Chinese medicine cannot be realised by simply discarding its philosophical underpinnings and adopting biomedical epistemics and technologies.

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# Modern Applications of Modified *Ban Xia Xie Xin Tang* and Their Development

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## ABSTRACT

Traditional Chinese medicine (TCM) classic formulae have evolved over hundreds of years; however, their applications and modifications can be further developed. The classic formula *Ban Xia Xie Xin Tang* (Pinellia Decoction to Drain the Epigastrium; BXXXT), which was originally prescribed by Zhang Zhong-Jing in the Han dynasty (150–219), can be modified and used flexibly in treating various abdominal disorders. In the Qing dynasty (1644–1911), Wu Ju-Tong (1758–1836) wrote the book *Wen Bing Tiao Bian* (*Systematised Identification of Warm Pathogen Diseases*), outlining his eight modifications to BXXXT based on Ye Tian-Shi's (1667–1746) clinical applications of BXXXT and its patterns. Ye applied BXXXT in two main ways. The first involved the use of bitter, pungent, dispersing and purging herbs to treat damp heat; the second was used to purge *jue yin* and unblock *yang ming* in order to treat various symptoms caused by Liver wood attacking Stomach earth. Wu followed Ye's methodology and developed eight modifications to BXXXT. These can treat summer heat-damp (*shu shi*), lurking summer heat (*fu shu*) and damp-warm (*shi wen*) conditions. They can also treat *jue yin* Liver conditions or Liver Qi attacking Stomach patterns. This article discusses the use of Wu Ju-Tong's eight modifications. Modern clinical cases including nausea, vomiting, abdominal distension, stomach ache, diarrhoea and infertility have been used as examples to illustrate the flexible use of BXXXT.

**KEYWORDS** Chinese herbal formula, *Ban Xia Xie Xin Tang*, *Wen Bing*, abdominal disorders, patterns of disharmony.

## Introduction

*Ban Xia Xie Xin Tang* (BXXXT) is derived from the *Shang Han Lun* ('Treatise on Cold Damage Diseases', clause 149) and is used for *shang han chai hu* syndrome, where purging was wrongly applied.<sup>1</sup> It was originally developed to regulate focal distension and epigastric fullness due to the accumulation of endogenous pathogenic cold and heat in the gastrointestinal organs, with an underlying deficiency of Spleen and Stomach. Appearance of glomus below the heart with no pain is defined

as *pi* syndrome (痞, gastric stuffiness). *Jin gui yao lue* – nausea, vomiting and diarrhoea (clause 10) – indicate that nausea, intestinal rumbling and *pi* can be treated with BXXXT. According to Ye Tian-Shi's (1667–1746) *Wen Bing Lun* ('Treatise on Warm Pathogen Diseases'), the pathogenesis of *wen bing* damp-heat stasis in the middle *jiao* can be treated with bitter and purging herbs. The formula BXXXT treats exterior damp-heat. In *Lin Zheng Zhi Nan Yi An* ('Guide to Clinical

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Cases'), BXXXT was frequently used for treating summer-damp, damp-heat, malaria and dysentery. Wu Ju-Tong edited Ye Tian-Shi's cases and in his *Wen Bing Tiao Bian* developed eight BXXXT modifications based on Ye's basic methods of applying BXXXT.<sup>2</sup>

Wu Ju-Tong (1758–1836) made a significant contribution to *Wen Bing Xue* (the Study of Warm Pathogen Diseases) and is renowned for his formulae and *San Jiao Bian Zheng* (Triple Energizer Pattern Identification). A devoted follower, he studied and further developed Ye Tian-Shi's theory. His modifications of BXXXT provide a different therapeutic perspective to the Cold Damage Diseases of the era of Zhang Zhong-Jing (150–219), some 1500 years earlier.<sup>3</sup>

### BXXXT and the eight modifications

The original formula BXXXT is from *Shang Han Lun*: *Banxia* (*Rhizoma Pinelliae ternatae*), 9 g; *Huangqin* (*Radix Scutellariae*), 9 g; *Ganjiang* (*Rhizoma Zingiberis officinalis*), 9 g; *Renshen* (*Radix Ginseng*), 9 g; *Zhigancao* (*Radix Glycyrrhizae uralensis*, prepared), 9 g; *Huanglian* (*Rhizoma Coptidis*), 3 g; *Dazao* (*Fructus Zizyphi jujubae*), 4 pieces.<sup>4</sup> Formula actions include harmonising Stomach and descending rising Stomach Qi, dispersing stasis and removing *pi*. The pattern treated is Stomach Qi disharmony. Symptoms and signs include *pi* below the heart that is painless, dry retching or nausea and vomiting, intestinal rumbling and diarrhoea, thin yellow and greasy tongue coating, wiry rapid pulse.<sup>4</sup>

*Pi* is Qi that is blocked, with fullness but no pain, and a soft sensation when pressed. Due to the accumulation of cold and

heat, the movement of Qi is disrupted, resulting in dry retching or nausea and vomiting. Abdominal pain, intestinal rumbling and diarrhoea also occur. Cold and heat need to be removed, ascending and descending Qi function needs to be restored and the Spleen and Stomach must be tonified.<sup>5</sup>

The formula uses the bitter, cold, descending and purging natures of *Huanglian* (*Rhizoma Coptidis*) and *Huangqin* (*Radix Scutellariae*) to remove the heat; the pungent and warm qualities of *Ganjiang* (*Rhizoma Zingiberis officinalis*) and *Banxia* (*Rhizoma Pinelliae ternatae*) to unblock stasis and to disperse the cold; the sweet and warm nature of *Renshen* (*Radix Ginseng*), *Gancao* (*Radix Glycyrrhizae uralensis*) and *Dazao* (*Fructus Zizyphi jujubae*) to benefit Qi and to tonify deficiency. The seven herbs, which utilise cold and hot, bitter descending and pungent dispersing to tonify Qi and harmonise the middle *jiao*, naturally reset the balance.

The herbal compositions of the eight modifications of BXXXT<sup>6</sup> are listed in Table 1. The frequencies of the use of specific herbs in the original and eight modified formulae are listed in Table 2. Their indications are illustrated in Figure 1. These modifications reflect the understanding and methodology of Ye, including Wu Ju-Tong's personal understanding. All have been successfully applied clinically.

### Case studies

#### CASE 1: USING BXXXT TO TREAT PHLEGM QI STAGNATION<sup>7</sup>

A 36-year-old male had consumed excessive alcohol for a long time, resulting in alcohol-damp damaging the Spleen and Stomach, which in turn weakened the transport and transformation functions of Spleen and led to disharmony

TABLE 1 The composition of *Ban Xia Xie Xin Tang* (BXXXT) and its eight modifications

| Rx No.* | Original BXXXT formula herbs |            |           |          |           |        |         | Added herbs |             |          |                                                               |
|---------|------------------------------|------------|-----------|----------|-----------|--------|---------|-------------|-------------|----------|---------------------------------------------------------------|
|         | Ban Xia                      | Huang Lian | Huang Qin | Ren Shen | Gan Jiang | Da Zao | Gan Cao | Zhi Shi     | Sheng Jiang | Bai Shao | Others                                                        |
| M1      | ✓                            | ✓          | ✓         |          |           |        |         | ✓           |             |          | <i>Xinren</i>                                                 |
| M2      | ✓                            | ✓          | ✓         |          |           |        |         | ✓           | ✓           |          |                                                               |
| M3      |                              | ✓          | ✓         | ✓        | ✓         |        |         | ✓           |             | ✓        |                                                               |
| M4      |                              | ✓          |           | ✓        | ✓         |        |         | ✓           | ✓           |          | <i>Muli</i>                                                   |
| M5      | ✓                            | ✓          | ✓         |          |           |        |         | ✓           | ✓           | ✓        |                                                               |
| M6      |                              | ✓          | ✓         |          | ✓         |        |         |             |             | ✓        | <i>Jinyinhua</i> , Charcoaled <i>Shanzha</i> , <i>Muxiang</i> |
| M7      | ✓                            | ✓          | ✓         | ✓        | ✓         |        |         | ✓           | ✓           |          |                                                               |
| M8      | ✓                            | ✓          | ✓         | ✓        | ✓         |        |         | ✓           |             |          |                                                               |

\* Rx No. = Case study formulae as outlined in Figure 1

TABLE 2      The frequencies of use of specific herbs in the original *Ban Xia Xie Xin Tang* and eight modified formulae

|                    | BXXXT | M1 | M2 | M3 | M4 | M5 | M6 | M7 | M8 | F* |
|--------------------|-------|----|----|----|----|----|----|----|----|----|
| Huanglian          | ✓     | ✓  | ✓  | ✓  | ✓  | ✓  | ✓  | ✓  | ✓  | 9  |
| Huangqin           | ✓     | ✓  | ✓  | ✓  |    | ✓  | ✓  | ✓  | ✓  | 8  |
| Zhishi             |       | ✓  | ✓  | ✓  | ✓  | ✓  |    | ✓  |    | 7  |
| Banxia             | ✓     | ✓  | ✓  |    |    | ✓  |    | ✓  | ✓  | 6  |
| Ganjiang           | ✓     |    |    | ✓  | ✓  |    | ✓  | ✓  | ✓  | 6  |
| Renshen            | ✓     |    |    | ✓  | ✓  |    |    | ✓  | ✓  | 5  |
| Shengjiang         |       |    | ✓  |    | ✓  | ✓  |    | ✓  |    | 4  |
| Baishao            |       |    |    | ✓  |    | ✓  | ✓  |    |    | 3  |
| Xinren             |       | ✓  |    |    |    |    |    |    |    | 1  |
| Dazao              | ✓     |    |    |    |    |    |    |    |    | 1  |
| Gancao             | ✓     |    |    |    |    |    |    |    |    | 1  |
| Muli               |       |    |    |    | ✓  |    |    |    |    | 1  |
| Jinyinhua          |       |    |    |    |    |    | ✓  |    |    | 1  |
| Charcoaled Shanzha |       |    |    |    |    |    | ✓  |    |    | 1  |
| Muxiang            |       |    |    |    |    |    | ✓  |    |    | 1  |

\* M1–8 = Case study formulae as outlined in Figure 1. F = frequencies of use of specified herbs.

of middle *jiao* Qi, generating phlegm. The phlegm further affected lifting and descending functions of the middle *jiao* Qi, and resulted in *pi* with nausea, vomiting and diarrhoea three to four times a day. He had no significant improvement after receiving previous treatments. The tongue body was red, tongue coating white, pulse wiry and slippery.

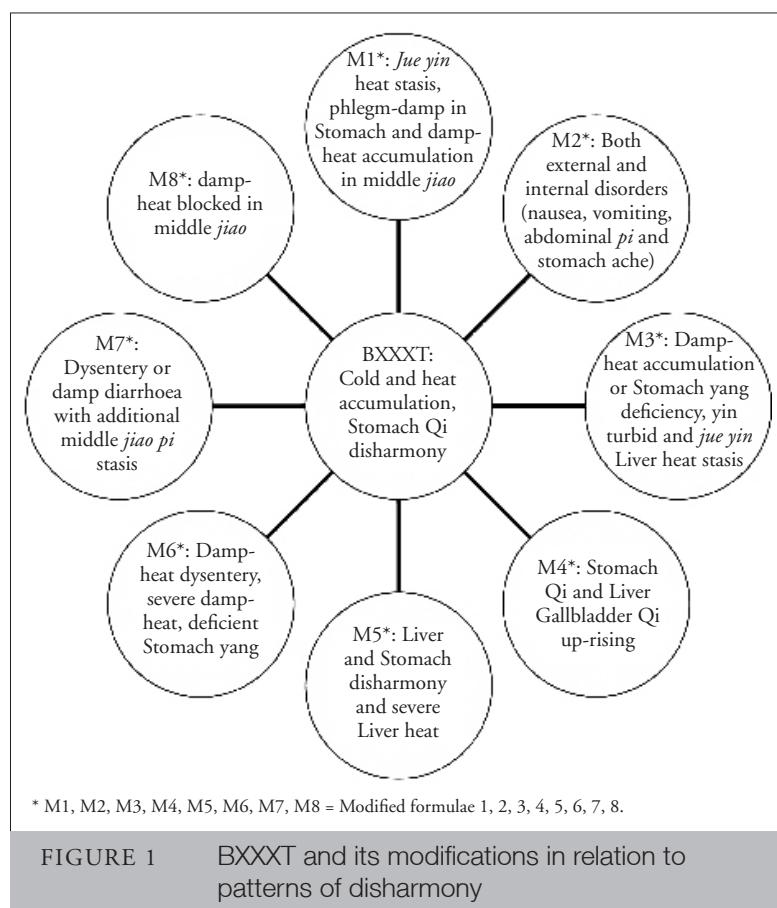
The symptoms were due to phlegm Qi blockage resulting in *pi*. BXXXT can be used. Modified BXXXT was prescribed, using *Banxia* (*Rhizoma Pinelliae ternatae*), 12 g; *Ganjiang* (*Rhizoma Zingiberis officinalis*), 6 g; *Huanglian* (*Rhizoma Coptidis*), 6 g; *Huangqin* (*Radix Scutellariae*), 6 g; *Dangshen* (*Radix Codonopsis pilosulae*), 9 g; *Dazao* (*Fructus Zizyphi jujubae*), 7 pieces; *Zhigancao* (*Radix Glycyrrhizae uralensis*, prepared), 9 g. After taking one dose, the patient passed lots of white sticky mucus in his stools. Nausea and vomiting reduced significantly. After taking the second dose, the *pi* and diarrhoea were both reduced. After taking four doses he completely recovered. Professor Liu Du-Zhou commented that this was a case of *tan-qi-pi* (phlegm-Qi-*pi*), traditionally treated with BXXXT.<sup>7</sup>

CASE 2: USING BXXXT TO TREAT REFLUX<sup>8,9</sup>

For two years, a 32-year-old male had suffered from vomiting in the evening the food consumed the same morning, or vomiting

in the morning the food consumed the night before. He also complained of recent, frequent nausea and vomiting once daily or every second day. Apart from food, he also vomited a large amount of acid. Normally he experienced tastelessness and had no appetite. He felt depressed and had abdominal bloating after food, acid regurgitation, lower back pain, cool extremities, frequent and excessive urination. He had deep-red lips, red tongue body, thin white and slippery tongue coating, and deep-weak-thready pulse.

The diagnosis was earth deficiency with wood attacking and adversely affecting the movement of Stomach Qi. Treatment principles were to control the Liver and harmonise the Stomach. Four doses of formula BXXXT were prescribed, containing *Zuojinwan* (Left Metal Pill), 9 g; *Banxia* (*Rhizoma Pinelliae ternatae*), 9 g; *Renshen* (*Radix Ginseng*), 9 g; *Huanglian* (*Rhizoma Coptidis*), 6 g; *Huangqin* (*Radix Scutellariae*), 6 g; *Ganjiang* (*Rhizoma Zingiberis officinalis*), 6 g; *Wuzhuyu* (*Fructus Evodiae rutaecarpae*), 6 g; *Zhigancao* (*Radix Glycyrrhizae uralensis*, prepared), 3 g; *Dazao* (*Fructus Zizyphi jujubae*), 3 pieces. Once the treatment started, the patient only had mild nausea and vomiting twice, vomiting clear fluid, phlegm, saliva and a small amount of food. No acid taste or acid reflux occurred but he regularly experienced excessive saliva. It took a long time for his extremities to become warmer; his urination



was still excessive and frequent. His lip and tongue colour changed to normal, but his tongue coating was still thin, white and wet. The BXXXT formula was modified to exclude *Huangqin* (*Radix Scutellariae*) and *Huanglian* (*Rhizoma Coptidis*); and the following were added: *Fuzi* (*Radix lateralis Aconiti carmichaeli*, prepared) [Note: this herb is currently not legally available to Australian TCM practitioners – Ed.], 9 g; *Chaobaizhu* (*Rhizoma Atractylodis macrocephalae*), 9 g; *Buguzhi* (*Fructus Psoraleae corylifoliae*), 9 g; *Roudoukou* (*Semen Myristicaceae fragrantis*, Wei), 6 g; *Rougui* (*Cortex Cinnamomi cassiae*), 1.2 g (separate pack); *Renshen* (*Radix Ginseng*), 9 g. With the treatment of one dose every three days continuing for ten doses, the patient recovered.

#### CASE 3: USING BXXXT TO TREAT CHRONIC HEPATITIS WITH *PI* AND BLOATING<sup>10</sup>

A male, 42 years old, suffered from poor appetite, fatigue and tiredness, two to four sticky and loose bowel movements per day, abdominal bloating and flatulence. He had been previously diagnosed with chronic hepatitis. Current lab tests showed relatively normal liver function. The patient had been taking different western medicines and herbs for the symptoms with no effect. Current symptoms were poor appetite, slightly

bitter taste in the mouth, stomach and abdominal fullness and distension after food, dry retching and bad breath, abdominal bloating that was more severe in the afternoon, difficulty with flatulence, irritability, a wariness of speaking and engaging in outdoor activities, poor sleep (only sleeping two to four hours per night) and occasionally pain in the area of the liver. He was short and obese. The tongue coating was white/yellow with moisture, and the pulse was deep and strong though slightly weak at the right *guan* position.

The diagnosis was chronic stomach and intestinal functional disorder but with mixed cold and heat, yin/yang disharmony and lifting/descending disharmony. Zhang Zhong-Jing's BXXXT was used to harmonise. Contents of prescription were *Dangshen* (*Radix Codonopsis pilosulae*), 9 g; *Banxia* (*Rhizoma Pinelliae ternatae*, Qing), 9 g; *Ganjiang* (*Rhizoma Zingiberis officinalis*), 4.5 g; *Zhigancao* (*Radix Glycyrrhizae uralensis*, prepared), 4.5 g; *Huangqin* (*Radix Scutellariae*), 9 g; *Huanglian* (*Rhizoma Coptidis*), 3 g; *Dazao* (*Fructus Zizyphi jujubae*), 4 pieces. After taking the formula, the patient gradually improved. After finishing forty doses over a few months he identified five areas of improvement. The first improvement was better appetite, no stomach bloating and stuffiness after food and with mild abdominal bloating occurring only occasionally. The second improvement was enhanced energy levels, with the patient enjoying walking and participating in outdoor activities without feeling tired. The third was improved bowel movements, which were lessened to once a day and in most cases with lots of wind passing out with the bowel movement. The fourth was that pain in the area of the liver disappeared in general, with mild pain occurring occasionally but disappearing quickly. The fifth was improved sleep with the ability to sleep for more hours each night. A chronic disorder for so many years had benefited from this treatment. Later the patient was given a formula to nourish Heart and calm *shen* (spirit), due to a difficulty in falling asleep.

#### CASE 4: BXXXT TREATMENT FOR INFERTILITY<sup>9</sup>

A female, 29 years old, had had a miscarriage three years ago, following a three-month pregnancy and without any clear cause. She had not been pregnant since. Western medical examinations could not identify any pathology. No significant abnormality was found for her or her husband. She had taken Spleen tonifying and Kidney *jin* nourishing herbs without success. She often experienced lower abdominal coldness, stomach fullness with acid regurgitation, and diarrhoea 1–2 times daily. Her menstrual cycle was normal. Tongue body was red, coating thin, yellow and greasy.

Diagnosis was accumulated cold and heat and blocked *bao mai*. Treatment principles were to remove cold and heat, regulate Qi and warm the channels. Modified BXXXT was

prescribed, including *Banxia* (*Rhizoma Pinelliae ternatae*), 12 g; *Dangshen* (*Radix Codonopsis pilosulae*), 12 g; *Xiangfu* (*Rhizoma Cyperi rotundi*), 12 g; *Huangqin* (*Radix Scutellariae*), 9 g; *Ganjiang* (*Rhizoma Zingiberis officinalis*), 9 g; *Chenpi* (citrus peel), 9 g; *Huanglian* (*Rhizoma Coptidis*), 3 g; *Zhigancao* (*Radix Glycyrrhizae uralensis*, prepared), 3 g; *Dazao* (*Fructus Zizyphi jujubae*), 3 pieces. After taking five doses of herbs the patient's acid regurgitation reduced significantly, the tongue coating became thin, yellow and slightly greasy, and other symptoms remained unchanged. The above formula was then modified, removing *Huangqin* (*Radix Scutellariae*) and adding *Baizhu* (*Rhizoma Atractylodis macrocephalae*) and *Sangjisheng* (commonly used dosage: 9–15 g). After a few months the patient informed the doctor that her period had not come for more than 40 days and a test showed that she was pregnant. A boy was born after a full-term pregnancy.

#### CASE 5: BXXXT PLUS XIAO CHAI HU TANG (MINOR BUPLEURUM DECOCTION) TO TREAT STOMACH ACHE

(From Wen-Xuan Zhang's (WXZ) clinical record.)

A female, 31 years old, had stomach ache occurring regularly for two years due to work-related stress, family issues and a long-term unstable mood state. The pain always started when the patient was hungry or experiencing negative emotions. Stomach ache had occurred daily recently, sometimes occurring as spasm pain. There was Stomach *pi*, no appetite, and nausea upon waking in the morning. Other symptoms included irritability and a bitter taste in the mouth, chest fullness and discomfort, and sleeplessness; the tongue was red, coating thin yellow, pulse wiry and slightly rapid.

This was a typical BXXXT and *Xiao Chai Hu Tang* pattern, with emotional depression, accumulated heat in the Liver Gallbladder attacking the Stomach and Stomach Qi blockage. Five doses of the following were prescribed: *Banxia* (*Rhizoma Pinelliae ternatae*), 12 g; *Shengjiang* (*Rhizoma Zingiberis officinalis recens*), 10 g; *Huanglian* (*Rhizoma Coptidis*), 6 g; *Huangqin* (*Radix Scutellariae*), 10 g; *Zhishi* (*Fructus immaturus Citri aurantii*), 10 g; *Chaihu* (*Radix Bupleuri*), 10 g; *Baishao* (*Radix Paeoniae lactiflorae*), 12 g; *Zhigancao* (*Radix Glycyrrhizae uralensis*, prepared), 6 g. The patient reported that, after taking the first dose, her stomach ache was relieved and after taking five doses, the above-mentioned symptoms all disappeared. Her appetite also increased. She was advised to control her mood and avoid eating too much at each meal. The following simplified formula was given, including *Banxia* (*Rhizoma Pinelliae ternatae*), 12 g; *Shengjiang* (*Rhizoma Zingiberis officinalis recens*), 10 g; *Huanglian* (*Rhizoma Coptidis*), 6 g; *Zhishi* (*Fructus immaturus Citri aurantii*), 10 g; *Chaihu* (*Radix Bupleuri*), 10 g; *Baishao* (*Radix Paeoniae lactiflorae*), 12 g; *Zhigancao* (*Radix Glycyrrhizae uralensis*, prepared), 6 g.

#### CASE 6: BXXXT AND WU LING SAN (FIVE-INGREDIENT POWDER WITH PORIA) TO TREAT DIARRHOEA

(From WXZ's clinical record.)

A male, 35 years old, experienced diarrhoea for a year. The western medical diagnosis was colitis. Watery diarrhoea occurred 3–4 times every morning; this was aggravated with work-related stress. The patient could not drink beer or cold drinks as watery diarrhoea occurred immediately after. Abdominal pain occurred before the diarrhoea. There was Stomach *pi* and the patient was tired with irritability, dry mouth, deep red tongue, yellow and slightly greasy tongue coating, and deep, wiry and slightly rapid pulse. *Li Zhong Tang* (Decoction to regulate the middle *jiao*), *Ge Gen Qin Liang Tang* (Decoction with *Radix Puerariae*, *Radix Scutellariae* and *Rhizoma Coptidis*) and *Bu Zhong Yi Qi Tang* (Decoction to tonify the middle *jiao* and augment the Qi) granule formulae were used and the diarrhoea increased.

Diagnosis was depressed wood attacking earth and Liver heat with Stomach cold. This was a BXXXT and *Wu Ling San* pattern. Five doses were prescribed of *Banxia* (*Rhizoma Pinelliae ternatae*), 12 g; *Ganjiang* (*Rhizoma Zingiberis officinalis*), 10 g; *Shengjiang* (*Rhizoma Zingiberis officinalis recens*), 10 g; *Huanglian* (*Rhizoma Coptidis*), 6 g; *Huangqin* (*Radix Scutellariae*), 3 g; *Zhishi* (*Fructus immaturus Citri aurantii*), 10 g; *Fuling* (*Sclerotium Poriae cocos*), 15 g; *Guizhi* (*Ramulus Cinnamomi cassiae*), 10 g. After taking five doses he only had one bowel movement per day, which tended to be loose but not watery and his abdominal pain and *pi* symptoms disappeared. His tongue was red, coating greasy and slightly yellow; pulse was wiry and slightly rapid. A modified formula was given, including *Banxia* (*Rhizoma Pinelliae ternatae*), 12 g; *Ganjiang* (*Rhizoma Zingiberis officinalis*), 10 g; *Huanglian* (*Rhizoma Coptidis*), 6 g; *Huangqin* (*Radix Scutellariae*), 3 g; *Fuling* (*Sclerotium Poriae cocos*), 15 g; *Guizhi* (*Ramulus Cinnamomi cassiae*), 10 g. Bowel movements became normal after taking 14 doses. Two months later, watery diarrhoea occurred three to four times a day after drinking a lot of beer. He was given the first formula for seven doses and the diarrhoea stopped. He was prescribed BXXXT plus *Li Zhong Tang* (Decoction to regulate the middle *jiao*). He then fully recovered.

## Discussion

### THE COMPOSITION OF BXXXT AND ITS EIGHT MODIFICATIONS

The herbs commonly used by Wu Ju-Tong for treating *pi* and its related pattern are: *Huanglian* (*Rhizoma Coptidis*), *Huangqin* (*Radix Scutellariae*) (to clear heat and dry damp), *Zhishi* (*Fructus immaturus Citri aurantii*) (to regulate and descend Qi), *Banxia* (*Rhizoma Pinelliae ternatae*) (to dispel damp and descend Qi), *Ganjiang* (*Rhizoma Zingiberis officinalis*), *Renshen*

## Clinical Commentary

The classic formula *Ban Xia Xie Xin Tang* (BXXXT) was designed to treat the mixed pattern of heat and cold which results in Qi moving up and down incorrectly and damp heat accumulation. This treatment method is particularly useful for treating Liver/Stomach disharmony. The common causes of this disharmony are stress and improper diet, which cause Qi stagnation and damp heat and/or cold accumulation. By comparing the original and modified formulae and analysing modern cases, it is clear that *Ban Xia Xie Xin Tang* can be modified and used flexibly in treating a variety of abdominal disorders, including nausea and vomiting, abdominal distension, infertility, stomach ache and diarrhoea.

(*Radix Ginseng*) and *Shengjiang* (*Rhizoma Zingiberis officinalis recens*) (to warm and tonify the middle). The main patterns of *pi* are cold and heat accumulation and Stomach Qi disharmony (see Figure 1).

### BXXXT AS A FORMULA FOR TREATING JUE YIN DISEASE

Wu Ju-Tong put a note under the modified *Renshen* XXT, stating that the formula included strong pungent and warm, together with strong bitter and cold herbs, and should have been used as a standard method for treating *jue yin* channel disorder. The Liver and Gallbladder are close in location, which is different to the other *zang* and *fu* in TCM. The Liver prefers warmth and the Gallbladder prefers cold. Zhang Zhong-Jing's *Wu Mei Wan* (*Prunus Mume* pill) and XXT provided a good basis for future development. Wu Ju-Tong's notes indicate that BXXXT and *Wu Mei Wan* (*Mume* pill) should be in one category because they used the basic rule of combining formulae for *jue yin* disease. His *Xiao Chai Hu Tang* (Decoction of minor *Bupleurum*) is another example of a base formula, using pungent, cool, bitter and cold together with pungent and warm herbs to treat *shao yang* disease and treat both the Liver and Gallbladder.

Given that BXXXT is a formula for *jue yin* disease, how do we understand the symptoms of *pi*, nausea and vomiting in relation to BXXXT? Wu Ju-Tong further explained the reasons for choosing the pungent-warm and cold-bitter combined method to treat this type of disease. An example of this in TCM is *nue* (malaria) with a disturbed Stomach that causes adverse Stomach Qi. This occurs because Stomach is a yang *fu* dependant on yin. It should be sending the Qi downwards, but not up. Nausea, vomiting and *pi* are therefore due to Stomach Qi rebelling. This reflects the Liver and Gallbladder influencing the Stomach adversely. Early TCM scholars considered nausea a Liver symptom, but nowadays it is usually considered a Stomach symptom. Wu Ju-Tong believed that nausea, vomiting and *pi* were caused by a blockage of the

Stomach Qi and the Stomach not sending Qi downwards. The Liver attacking the Stomach causes these symptoms; therefore, BXXXT is used to treat the Liver.

*Shang Han* academics generally believe that BXXXT is the main formula for regulating Stomach and Intestine cold and heat mixed disorder. Based on Ye's cases in the use of BXXXT to purge the Liver and unblock the Stomach, Wu Ju-Tong determined that BXXXT should be used for *jue yin* disease as a standard method. This is an important development of the traditional view and makes a substantial contribution to clinical practice.

### WU JU-TONG'S APPLICATIONS OF YE TIAN-SHI'S BXXXT

After reviewing Ye's cases, Wu Ju-Tong, in his book *Wen Bing Tiao Bian*, developed *Renshen* XXT (clause 54) and then *San Ren Tang* (Three Kernels Decoction, clause 55). He wrote that, while *Renshen* XXT uses heavy herbs to remove evils from the lower *jiao*, the *San Ren Tang* uses light herbs to remove evils from the upper *jiao*. He further commented that in cases of *wen bing* summer damp-heat, these formulae could be utilised. *Banxia* (*Rhizoma Pinelliae ternatae*) is the key herb for treating phlegm-damp turbidity. Herbs that clear damp-heat and regulate Qi are essential in modified BXXXT formulae, indicating that damp-heat is the main pathogen associated with the modified formulae.

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# SOPE: A Model for Developing Online Materials in Chinese Herbal Medicine Education

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## ABSTRACT

The application of online materials to support classroom teaching may increase the flexibility of students' access to course information and facilitate communication between teachers and students. Quality assurance is the key to the development of online materials. Chinese medicine degree training has recently been introduced into higher education systems of the western world. We have recently adapted a four-stage model (SOPE), including strategic planning, operational practice, product implementation, and evaluation, into the development of online materials for a Chinese medicine subject – Pharmacology of Chinese Medicine. Following this model, information on 350 individual Chinese herbs has been presented at RMIT's Distributed Learning System to facilitate learning and teaching. This paper describes the process of this development with a focus on activities and their quality criteria at the four stages. Findings from this study demonstrate the applicability of the SOPE model in the development of online materials for primary healthcare practitioner training, such as Chinese medicine. Further study is required to conduct formal evaluation of the proposed model and its effective implementation in other educational disciplines.

**KEYWORDS** quality assurance, case study, Chinese medicine education.

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## Introduction

The application of information technology (IT) in education has had a significant impact on educational practice. Online materials are particularly important to support classroom teaching. Online materials may increase students' access to the course information and facilitate communication between teachers and students outside of class time.<sup>1</sup> However, issues concerning the cost-effectiveness, quality of learning, and value-adding in learning are yet to be fully addressed.<sup>2</sup> Such concerns have negatively impacted on the acceptance of online resources,<sup>3</sup> particularly for primary healthcare practitioner training such as Chinese medicine.

Chinese medicine has a long history dating back thousands of years<sup>4</sup> and has been introduced into higher education systems of western countries. In Australia alone, four publicly funded universities offer degree programs in acupuncture and Chinese herbal medicine.<sup>5</sup> However, Chinese medicine education has encountered some difficulties in accessing English resources, as the majority of Chinese medicine literature is in Chinese. There are limited high-quality online resources that can be used in these programs.

The term 'quality' has various definitions that need to be interpreted within specific contexts.<sup>6,7</sup> Within the context of education, quality is a multi-faceted, multi-level, and dynamic description that reflects the specific objectives of a program.<sup>7</sup> Educational quality assurance involves a number of sequential steps that contribute to the overall learning outcome.<sup>8</sup> It is an ongoing and continuous process of management and evaluation to ensure consistency and to meet stated targets and anticipated outcomes by an institution.<sup>7,9</sup> Specifically, for the development of online materials, the steps may include determining learning objectives, understanding student needs, and developing course materials that address relevant pedagogic requirements. Much has been written about quality assurance of higher education

and online learning.<sup>10-14</sup> The essential elements for designing online teaching materials include gathering data (e.g. learner characteristics and needs), developing materials (e.g. selecting materials), producing materials (e.g. instructional methodology combined with technology) and evaluating materials (e.g. checking and revising for the fitness of purpose).<sup>10,11,14</sup>

The process of planning, developing and evaluating is frequently discussed in the literature related to online material design.<sup>10,15</sup> The SOPE model is an improved system representing strategic planning (S), operational practice (O), product implementation (P), and evaluation (E). The accessibility of IT is essential for this process. The requirements of IT in the SOPE development include access to a knowledge base for construction, suitability of the learning context, and usability as a management tool.<sup>16,17</sup> This four-stage process has been used in the online material development for a Chinese medicine course – Pharmacology of Chinese Medicine. This course is designed to teach students the principles of Chinese materia medica and the characteristics of a number of individual Chinese herbs, which consist of actions, meridians entered, dosage range, processing, and contraindications/cautions. This paper attempts to provide a case study on the development of online materials for the course of Pharmacology of Chinese Medicine at RMIT University to illustrate the SOPE model.

## Methods

The implementation of the SOPE model into Pharmacology of Chinese Medicine involved the development team identifying the activities for each stage and their relevant quality criteria. The four stages of this model are shown in Figure 1 and are elaborated below.

### STRATEGIC PLANNING

Aspects of educational mode, teaching objectives, learner characteristics/needs, and instructional strategy (i.e. methods

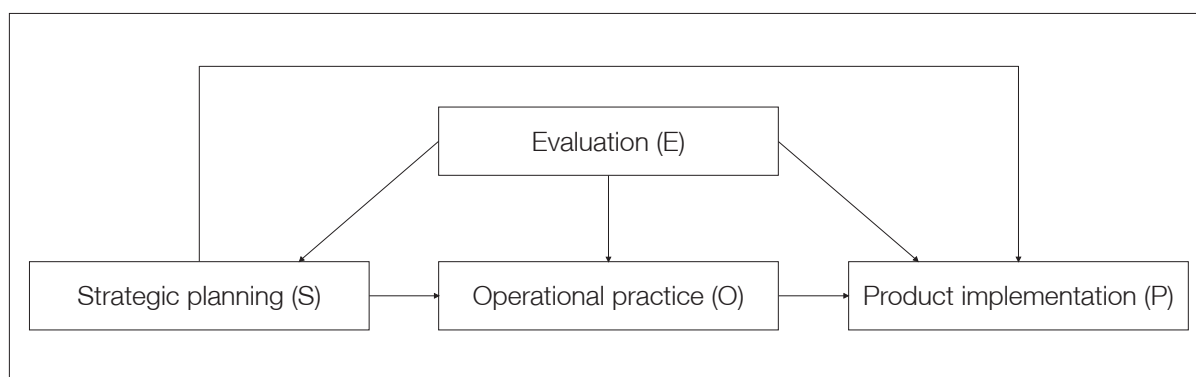


FIGURE 1 The SOPE model for the development of online materials

to support students in pursuing learning goals) should all be taken into account throughout the process. At this stage, the team developed strategies to achieve teaching objectives with consideration of students' characteristics. The quality criteria considered included capability-oriented curriculum, attainability and adaptability.

### OPERATIONAL PRACTICE

This stage involved five steps: classifying thematic topics (i.e. categorising herbs), selecting materials, producing materials (i.e. writing introductions and summaries of categorised herbs), producing media objects (i.e. taking pictures of individual herbs), and managing data. The peer review process was involved at every step. The quality criteria for each step are described below.

#### TOPIC SELECTION

1. Appropriateness: does each unit (topic) contribute to the learning objectives of the subject?
2. Sequence<sup>12</sup>: are the topics sequenced in the order of subject knowledge development?

#### MATERIAL SELECTION

1. Readability<sup>10</sup>: is the chosen material appropriate to the students' level?
2. Relevancy: is the material related to the core theme of the subject?
3. Reliability: is the material retrieved from a reliable source?
4. Currency: is the chosen material of interest to learners and is the information up-to-date?

#### SCRIPT PRODUCTION

1. Accuracy: is the information accurately presented and is the language error-free?
2. Clarity: is the material logically sequenced and presented in an organised manner?
3. Strategy-oriented format: is the material written in a way that embodies a target instructional strategy or a learning strategy?<sup>10</sup>

#### MEDIA SELECTION AND PRODUCTION

1. Types of media object: are the chosen media objects most appropriate to facilitate learning?
2. Quality of the media: are the colour, size, and sound quality of the media object suitable for specific topics and intended learning activities?
3. Size of images: has quality IT access been made readily available to learners?
4. Practicality: are students able to access the online material using different IT platforms?
5. Learning support: have media objects been designed to facilitate efficient and effective learning?

### DATA MANAGEMENT

1. Structural template<sup>10</sup>: is the format of structure standardised to increase user satisfaction?
2. Presentation template<sup>10</sup>: is information to be presented in a consistent format to simplify the learning process?
3. Material formatting<sup>10</sup>: what font, colour and background texture are chosen for the presentation?

### PRODUCT IMPLEMENTATION

The main task at this stage is the presentation of materials. The following criteria were used to facilitate the online presentation:

1. Consistency of web/content layout: the instructional material for each unit is in the same format to improve user-friendliness.
2. Sequence of content<sup>15</sup>: content within each instructional topic is in logical order for learning enhancement.
3. Clarity of material presentation: all the texts, graphics and pictures are well organised and clearly presented.
4. Minimisation of human errors: particular efforts should be made to reduce human errors, such as making wrong links or typographical or other mistakes.

As RMIT University provides all the enrolled students with access to the Distributed Learning System (DLS), DLS is selected as the media for delivery of online teaching materials.

### EVALUATION

Evaluation is an essential component of every stage of the development. This is an ongoing process that includes expert review, staff appraisal within or across institutions, as well as student feedback. In the current project, informal evaluation from students and staff was used to assess the application of online materials to support classroom teaching as an outcome from the SOPE process.

## Results

### STRATEGIC PLANNING

The purpose of the development of online materials for Pharmacology of Chinese Medicine was to facilitate study in the Double Degree Program of Bachelor of Applied Science (Chinese Medicine/Human Biology) at RMIT University. The online learning process was developed to supplement face-to-face learning as opposed to replacing class learning. The development of the online material for Pharmacology of Chinese Medicine has successfully addressed the following criteria: (a) Capability-oriented curriculum by offering hyper-links to the herbs for the purpose of herb identification; (b) Attainability by providing a user-friendly learning environment; and, (c) Adaptability by giving the opportunity of self-development and catering to different learning styles.

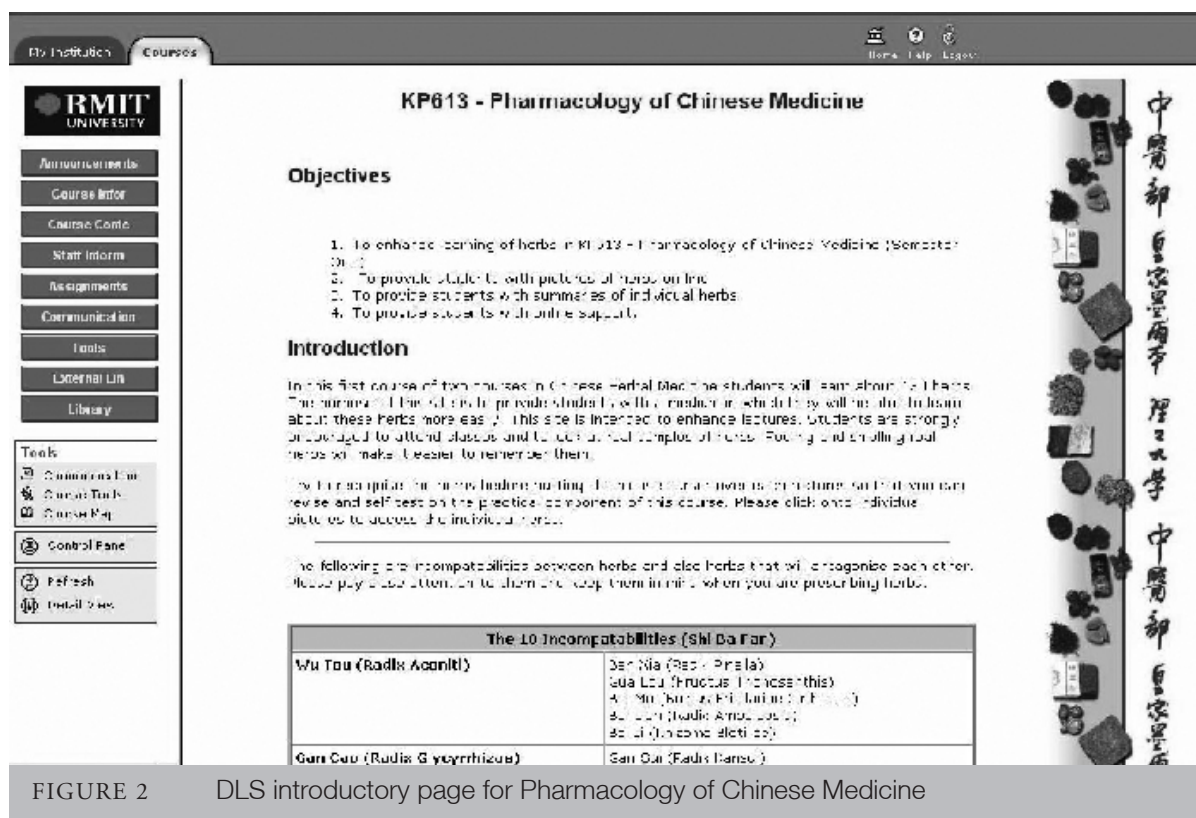


FIGURE 2 DLS introductory page for Pharmacology of Chinese Medicine

## OPERATIONAL PRACTICE

As part of the capability-driven curriculum development, online material needs to contribute to the building of graduate capabilities. Besides the provision of major course content, other subject matters such as images, graphics, and external links to additional information require deliberation to ensure that such elements are coherent with the overall design. During this stage, peer reviews<sup>8</sup> were conducted to ensure quality of the materials prepared. This was undertaken by peers in the program team, including two key academic staff for the course, an IT expert and the Head of Division of Chinese Medicine, who provided comments and feedback. Their comments were reflected in the revision of the relevant online materials.

## PRODUCT IMPLEMENTATION

The third stage is to focus on uploading the developed materials to the RMIT intranet via a File Transfer Protocol (FTP). The online materials have been presented with a user-friendly interface. Students and staff are able to obtain easy access to the desired information. Online tutorials (i.e. user's guide) and technical support are available. Provisions have been made to ensure two-way teacher–student communication via e-mail, forum or other forms of communication. A specific staff member has been appointed to update and maintain the currency of the materials, to provide technical support for staff and students as well as to maintain technology stability.

Currently, essential information, including high quality digital images of 350 commonly used Chinese herbs, has been constructed as online materials. Figure 2 and Figure 3 illustrate how the design of lecture notes was integrated with computer technology to provide students the maximum learning outcome through a more flexible and self-paced learning process. All students enrolled in the Pharmacology of Chinese Medicine course are provided with access to the course materials through the DLS at RMIT University. All the online information has been presented at the DLS Learning Hub website: <https://dls.rmit.edu.au/learninghub/hub.asp> (login required).

## EVALUATION

Informal feedback on the online materials has been gathered from students and staff, and it was indicated that such online materials are effective complements to classroom learning and teaching, particularly to enhance the learning of herbal identification at students' own pace and in their own time. Students and staff also made a number of suggestions for further improvements, which have been taken into consideration for more effective use of the online materials in both classroom and outside scheduled teaching time. A formal and systematic evaluation will be undertaken to determine student and staff views on the value and effectiveness of using these online materials in Chinese medicine learning and teaching.

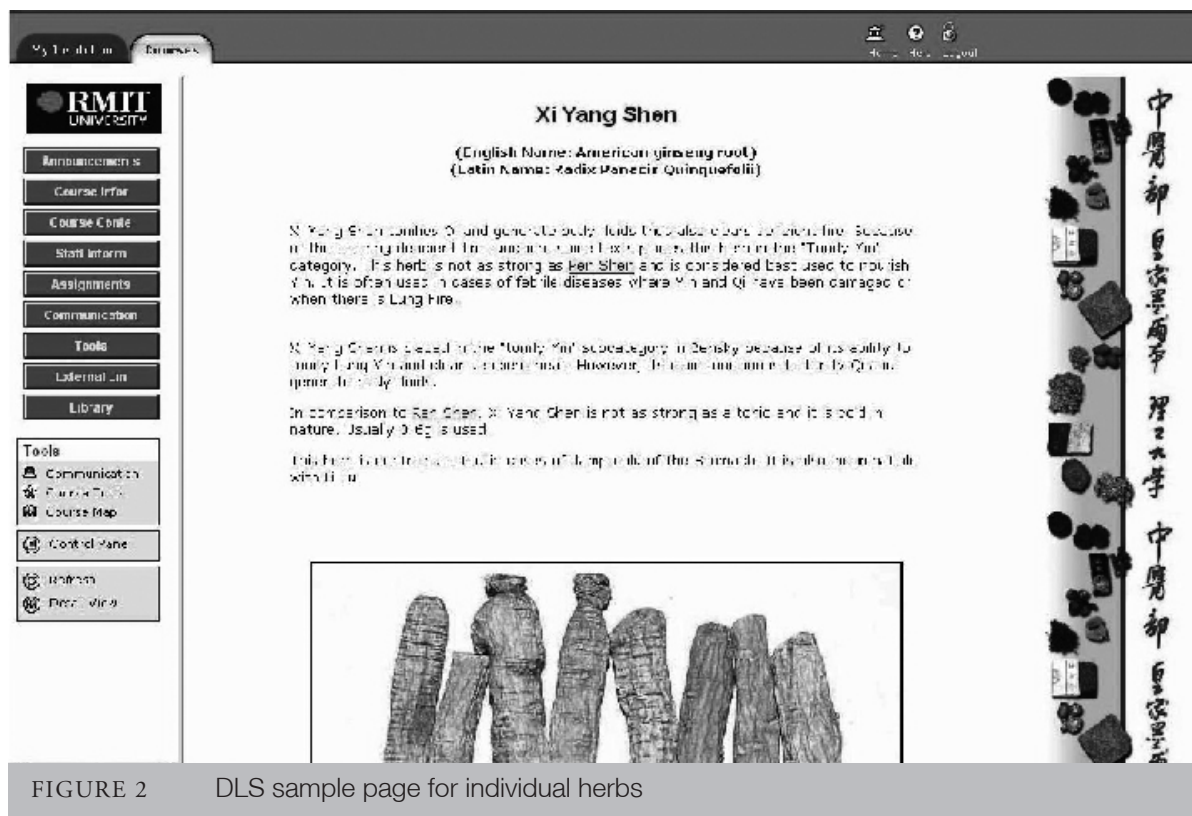


FIGURE 2 DLS sample page for individual herbs

## Comments and conclusion

The increasing popularity of complementary and alternative medicine, including Chinese medicine, has resulted in the introduction of numerous degree programs in the tertiary education systems of western countries. Significant efforts have been made to address challenges to this development, including appropriate application of teaching technology such as IT into Chinese medicine education. This paper describes the process that has been developed and applied in the development of online Chinese herbal medicine teaching materials.

This project showed that online materials with an appropriate and user-friendly interface can be an effective supplementary learning and teaching method for the subject area of Chinese medicine pharmacology. It is clearly demonstrated that the information and standardised images of herbal medicine, with convenient student accessibility, are of great benefit to learning in this topic, either during self-directed learning hours, tutorials, attending a teaching clinic for supervised clinical practice, or preparation for the assessments. The project is a pilot to build such a platform which will have the capacity and technical capability for the development of other online teaching, such as incorporation of recent research findings on specific herbal medicine into this information portal and multi-site real-time real case studies for student training and professional

development. This will be a valuable contribution to the profession as many of the practitioners have limited time to undertake professional development activities during business hours. Obviously, the information and resources in this format are not intended to be used by consumers independently, as they do not have adequate background to make appropriate clinical judgment for the use of herbal medicines.

Online materials have been successfully used as supplements to traditional learning and teaching in healthcare education, such as dental<sup>18</sup> and histology<sup>19</sup> courses. Within the blended learning context, online materials provide students with a flexible, non-linear and diverse learning environment. This emerging educational mode creates unlimited potential for access to education. However, rigorous quality assurance procedures are prerequisites for the fulfilment of these potentials. The development of the SOPE model was an attempt to address quality assurance concerns associated with online material development. A case study on the course Pharmacology of Chinese Medicine was presented to illustrate the quality assurance process that was embedded into this development by creating a set of practical criteria as check-lists throughout a four-stage process. The SOPE model may serve as a point of reference for health education online material development.

Evaluation is a critical stage of the SOPE model and requires much time and effort for ongoing improvement. To date, informal feedback on the online materials from the stakeholders, including undergraduate students and academic staff, has been addressed to advance the contents. However, formal evaluation has yet to be conducted. This may hinder the quality improvement of online materials and limit the application of the SOPE model to other courses. Therefore, further study will be extended to the following three areas. Firstly, the SOPE model needs to be further validated. Secondly, formal evaluation from students and staff will need to be conducted through a structured and systematic approach. Thirdly, the framework of the SOPE model will be applied to other subject areas of health education.

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## AUTHORS' CONTRIBUTION

QW, AY, AR and CX conceived and executed the project, participated in the interpretation of data and drafted the manuscript. SM participated in the design of the online component of the study and contributed to drafting the manuscript. AZ contributed to the conception of the study and to the revision of intellectual contents of the manuscript. All authors read and approved the final manuscript.

## COMPETING INTERESTS

The authors declare that they have no competing interests.

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# Chinese Herbal Medicine for Primary Dysmenorrhoea: A Systematic Review

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## ABSTRACT

**Background:** Conventional treatment for primary dysmenorrhoea has a failure rate of 20% to 25% and may be contraindicated or not tolerated by some women. Chinese herbal medicine may be a suitable alternative. **Objectives:** To determine the efficacy and safety of Chinese herbal medicine for primary dysmenorrhoea when compared with placebo, no treatment, and other treatment. **Main results:** Thirty-nine randomised controlled trials involving a total of 3475 women were included in the review. A number of the trials were of small sample size and poor methodological quality. Results for Chinese herbal medicine compared to placebo were unclear as data could not be combined (3 RCTs). Chinese herbal medicine resulted in significant improvements in pain relief (14 RCTs; RR 1.99, 95% CI 1.52 to 2.60), overall symptoms (6 RCTs; RR 2.17, 95% CI 1.73 to 2.73) and use of additional medication (2 RCTs; RR 1.58, 95% CI 1.30 to 1.93) when compared to use of pharmaceutical drugs. Self-designed Chinese herbal formulae resulted in significant improvements in pain relief (18 RCTs; RR 2.06, 95% CI 1.80 to 2.36), overall symptoms (14 RCTs; RR 1.99, 95% CI 1.65 to 2.40) and use of additional medication (5 RCTs; RR 1.58, 95% CI 1.34 to 1.87) after up to three months of follow-up when compared to commonly used Chinese herbal health products. Chinese herbal medicine also resulted in better pain relief than acupuncture (2 RCTs; RR 1.75, 95% CI 1.09 to 2.82) and heat compression (1 RCT; RR 2.08, 95% CI 2.06 to 499.18). **Reviewers' conclusions:** The review found promising evidence supporting the use of Chinese herbal medicine for primary dysmenorrhoea; however, results are limited by the poor methodological quality of the included trials.

**KEYWORDS** traditional Chinese medicine, dysmenorrhoea, review.

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## Background

Dysmenorrhoea is a common gynaecological complaint among adolescent girls and women of reproductive age and refers to the occurrence of painful cramps in the lower abdominal region during menstruation. It is usually classified into two subcategories: primary dysmenorrhoea occurs in the absence of an identifiable pathological condition;<sup>1</sup> when the period pain is associated with organic pathology such as endometriosis, it is defined as secondary dysmenorrhoea.<sup>2</sup>

Dysmenorrhoea can have a significant impact on women's lives. It can affect as many as 50% of women of reproductive age,<sup>3</sup> although, using different measurement methods and study populations, prevalence estimates vary from 60% to 85% of adolescent girls.<sup>4-6</sup>

The aetiology or cause of primary dysmenorrhoea has been the source of some debate. Experimental and clinical research has identified the over-production of uterine prostaglandins and vasopressin as contributing factors to the painful cramps.<sup>7,8</sup>

Principal pharmacological therapies include drugs that inhibit prostaglandins, such as non-steroidal anti-inflammatory drugs (NSAIDs); or that regulate hormones, such as oral contraceptive pills (OCPs). NSAIDs reduce myometrial activity (contraction of the uterus) by inhibiting prostaglandin F<sub>2</sub> (PGF<sub>2</sub>) synthesis and reducing vasopressin secretion. This may effectively reduce menstrual pain. However, these drugs provide no long-term relief as the treatment relieves symptoms on an episode-by-episode basis only. In addition, the failure rate of NSAIDs is often 20 to 25%<sup>9</sup> and these drugs may be contraindicated or not tolerated by some women.<sup>10</sup> In addition, gastrointestinal side effects can be particularly troublesome.<sup>3,11,12</sup> Emerging documents suggest many women are seeking alternatives to conventional medicine, including herbal medicine.<sup>13</sup>

Chinese herbal medicine (CHM) has been used for centuries in China. Recently, the practice of CHM has significantly permeated a broad cross-section of the western community.<sup>14</sup> CHM is currently used in public hospitals in China for the treatment of primary dysmenorrhoea. Case studies suggest that CHM may be effective in treating primary dysmenorrhoea; herbs may improve general wellbeing and also reduce recurrence of the condition over a three-month follow-up period.<sup>15</sup> However, the evidence describing the safety and efficacy of CHM for the treatment of primary dysmenorrhoea is important and there is a need for a systematic review of the available literature.

This review aims to identify randomised, controlled trials (RCTs) of CHM as treatment for women with primary dysmenorrhoea in order to establish the efficacy and safety of CHM.

## Objectives

To determine the efficacy and safety of CHM in the treatment of primary dysmenorrhoea when compared with a placebo, no treatment, conventional medical treatments (for example NSAIDs), heat compression or other TCM therapy (such as acupuncture, Chinese massage).

## Criteria for considering studies for this review

Any RCTs involving CHM for the treatment of primary dysmenorrhoea were considered for inclusion in the review. Interventions could include, but were not limited to, placebo, no treatment, conventional therapy, another type of CHM, acupuncture and heat compression.

At least one of the following primary outcomes was measured for a trial to be included. Data from each of the following outcomes were recorded, where available.

### PRIMARY OUTCOMES

- i. Change in menstrual pain intensity – measured by a visual analogue scale (VAS), or other validated scales, or measured as dichotomous outcomes.

### SECONDARY OUTCOMES

- i. Changes in overall severity of symptoms (other menstruation-related symptoms) – measured by changes in dysmenorrhoeic symptoms, treatment effectiveness that was either self-reported or observed or other similar measures;
- ii. Adverse effects – measured by any relevant incident and duration of any side effects;
- iii. Use of additional medication – measured as the proportion of women requiring no analgesics and continued routine activities;
- iv. Satisfaction of treatment as reported by patients – measured as the proportion of women who reported improvements or satisfaction, or both, with their treatment;
- v. Quality of life – measured by a validated scale, for example SF 36.

## Search strategy for identification of studies

The Cochrane MDSG search strategy was adopted. The following electronic databases were searched from their inception to the date given: Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2006, Issue 4), MEDLINE (1950 to January week 2 2007), EMBASE

(1980 to January week 2 2007), CINAHL (1982 to January week 1 2007), AMED (1985 to January week 1 2007).

Three electronic Chinese databases were examined. These were the China National Knowledge Infrastructure (CNKI) (1990 to January week 1 2007), Traditional Chinese Medicine Database System (TCMDS) (1990 to December 2006) and Chinese BioMedicine Database (CBM) (1990 to December 2006). The search identified a large number of trials on the use of CHM in the treatment of primary dysmenorrhoea. However, search results from the individual databases overlapped significantly. Only search results from CNKI were reported in this review as it is regarded as having wide coverage with full-text access.

## Methods of the review

### SELECTION OF STUDIES

The selection of trials for inclusion in the review, or exclusion from the review, was performed by two review authors (XZ and MP) employing the search strategy described previously. Since the majority of references were published in Chinese, two bilingual review authors (XZ and EW) translated the reports and extracted data onto hard-copy data sheets independently.

### QUALITY ASSESSMENT AND DATA EXTRACTION

All assessments on the quality of trials and further data extraction were performed independently by two review authors (XZ and MP). Any discrepancies were to have been resolved by a third review author (AB or CS); however, this was not necessary due to the lack of discrepancies.

All trials were assessed for methodological quality using the Jadad scale.<sup>16</sup> Furthermore, allocation concealment was scored according to the categories used by the Cochrane Collaboration: allocation concealment was adequate (A), unclear (B), inadequate (C) or allocation concealment was not used (D).

### ANALYSIS

Statistical analysis was performed in accordance with the guidelines developed by the Cochrane MDSG. Where possible, intention-to-treat data were extracted from trials and used in the analysis.

Statistical analysis was performed using the Review Manager software.<sup>17</sup> For dichotomous data, relative risk (RR) and associated 95% confidence interval (CI) were calculated using a fixed-effect model. Weighted mean difference (WMD) and 95% CI were calculated for continuous data using a fixed-effect model.

Statistical heterogeneity between trials was tested using a standard chi-squared test. Inconsistency across trials included in meta-analysis was measured using  $I^2$ . This describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error. As a general rule,  $I^2$  values of up to 25% provide evidence of low heterogeneity, a value of 50% is considered moderate heterogeneity and 75% or above is considered as high heterogeneity. In the presence of significant heterogeneity, the causes of heterogeneity were examined by pre-specified sub-group analysis and also sensitivity analysis, if possible. Where sub-group analysis failed to explain the heterogeneity, data were analysed using the random-effects model.

## Description of studies

### TRIALS

Using the search strategy described above, 39 RCTs involving treatment for primary dysmenorrhoea with CHM were identified. Figures 1 and 2 summarise the numbers of trials included in and excluded from the review. A description of the included trials can be found in Table 1.

Most of the studies were conducted in mainland China, except for one which was conducted in Taiwan, one in Japan and another in the Netherlands. Thirty-six of the included trials were published in Chinese and three were published in English.<sup>18-20</sup>

### PRINCIPLE OF HERBAL TREATMENT

In this review, nineteen of the included trials considered the traditional approach by making individualised treatment based on differentiated pattern(s) in TCM diagnosis. The criteria for differentiating the patterns of symptoms in most included trials were referred to the *Traditional Chinese Medicine Professional Statute: Criteria of Diagnosis and Therapeutic Effect of Diseases/Syndromes*, published by the State Administration of Traditional Chinese Medicine, China.<sup>21</sup> A number of other references, such as textbooks, were supplemented.<sup>22-25</sup>

### HERBAL INTERVENTION IN THE EXPERIMENTAL GROUP

The majority of included trials used complicated formulae with more than five or six herbs. However, two included trials tested a single herb, either in the form of a decoction or as a herbal extraction.<sup>20,26</sup>

Regardless of the variations in formulation, the herbs were mostly chosen from the following categories, which are set out in the Chinese herbal pharmacopoeia and textbooks: herbs 'regulating the Qi and Blood', 'warming the Interior', 'tonifying the Kidney and Liver' and 'reinforcing Qi and Blood'.<sup>27,28</sup>

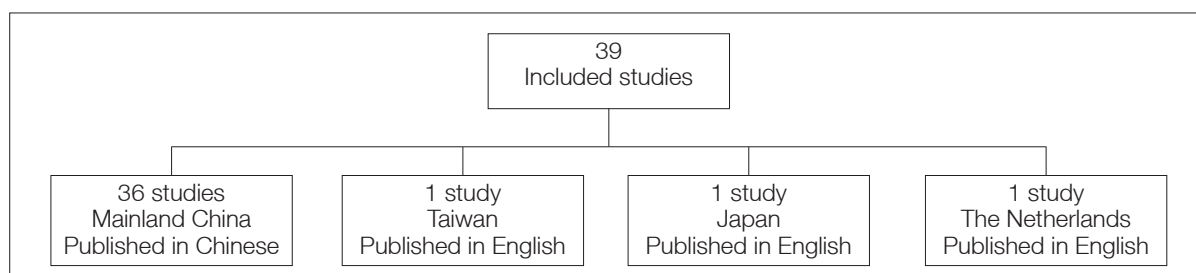


FIGURE 1 Trials included in the review

The most frequently evaluated herbs were: *Danggui* (*Radix Angelicae sinensis*, Chinese angelica root), *Chuanxiong* (*Chuanxiong Rhizoma*, Szechuan lovage root), *Chishao* (*Paeoniae Radix rubra*, red peony root), *Baishao* (*Paeoniae Radix alba*, white peony root), *Yimucao* (*Leonuri Herba*, Chinese motherwort), *Puhuang* (*Typhae Pollen*, cattail pollen), *Wulingzhi* (*Troglodytes Faeces*, flying squirrel faeces), *Niuxi* (*Radix Achyranthis bidentatae*, achyranthes root), *Danshen* (*Radix Salviae miltiorrhizae*, salvia root), *Chaihu* (*Radix Bupleuri*, Chinese thorowax root), *Xiangfu* (*Rhizoma Cyperi*, nut-grass rhizome), *Yanhusuo* (*Rhizoma Corydalis*, corydalis rhizome), *Aiye* (*Folium Artemisiae argyi*, mugwort leaf), *Wuzhuyu* (*Fructus Evodiae*, evodia fruit), *Huixiang* (*Fructus Foeniculi*, fennel fruit), *Rougui* (*Cortex Cinnamomi*, cinnamon bark), *Dihuang* (*Radix Rehmanniae*, rehmannia root), *Gouqizi* (*Fructus Lycii*, lycium fruit), *Dangshen* (*Radix Codonopsis*, codonopsis root), *Baizhu* (*Rhizoma Atractylodis macrocephalae*, atractylodes rhizome) and *Gancao* (*Radix Glycyrrhizae*, liquorice root).

Most trials considered timing of the clinical intervention based on phase of menstrual cycle. Herbal interventions were usually introduced from five to seven days prior to the onset of menstruation and continued for a period of approximately 10 to 15 days, which was until the first or second day of menstruation or throughout the whole bleeding period. One trial specified that the herbs should be given three days prior to bleeding and continued for a period of five days.<sup>29</sup>

## OUTCOME MEASURES

Outcome measures of change in pain intensity varied. Most included studies measured the pain intensity rating on an ordinal scale (for example, from poor to excellent) in combination with a dichotomous measure (for example, complete relief or ongoing pain). Pain relief was measured as the number of women with pain relief, reduced pain or no improvement compared with the total number of women in the treatment or control group; whether or not there was a relapse during the follow-up was also taken into consideration. The majority of trials that were conducted in mainland China fell into this group, which indicates such practice was compliant with the statute enacted by the State Administration of Traditional Chinese Medicine for measuring therapeutic efficacy of herbs in the treatment of primary dysmenorrhoea.<sup>21</sup>

A continuous numerical scale such as a visual analogue scale was rarely used in mainland China, but was used in three included studies from other countries or regions.<sup>18-20</sup> Tseng and colleagues used multiple scales to rate the degree of pain, such as the Short-form McGill Pain Questionnaire and the Menstrual Distress Questionnaire Short Form.

Only eight out of 39 included trials reported adverse effects. Seven trials<sup>18,19,30-34</sup> provided a thorough report, including data in the experimental and control groups. However, the rest had incomplete data. One trial<sup>18</sup> mentioned that headache was the most frequently reported side effect, with equal frequency in both experimental and control groups. The adverse effects were usually self-reported.

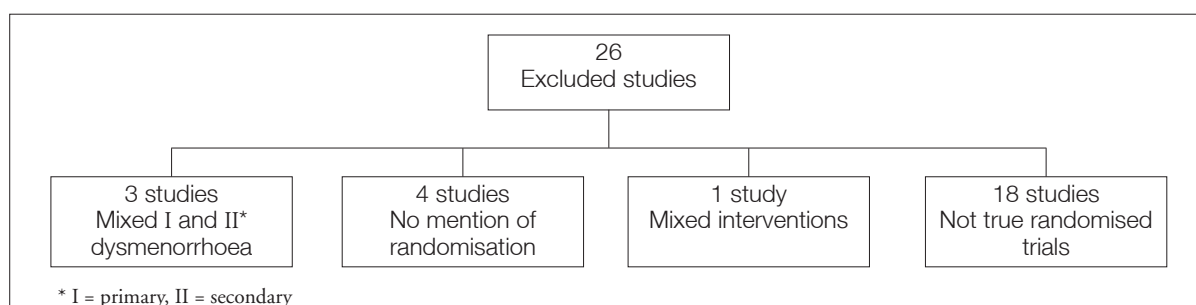


FIGURE 2 Trials excluded from the review

TABLE 1 Description of included studies

| Study        | Methods                                                                                                                                                                                      | Participants                                                                                                                                                                                                                                                              | Interventions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Deng (2003)  | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                           | $n$ (experimental) = 33; $n$ (control) = 30; Drop-outs/withdrawals: unstated; Diagnosis of dysmenorrhoea: stated; Age (experimental): 16–33; Age (control): 15–33.                                                                                                        | Self-designed formula ( <i>Jia Wei Muo Jie Pian</i> ) vs OTC ( <i>Yue Yue Shu</i> ).<br><i>Jia Wei Muo Jie Pian</i> : <i>Xuejie</i> ( <i>Sanguis Draconis</i> ), <i>Moyao</i> ( <i>Myrrha</i> ), <i>Puhuang</i> ( <i>Pollen Typhae</i> ), <i>Wulingzhi</i> ( <i>Excrementum Troglodyti seu Pteromi</i> ), <i>Sanleng</i> ( <i>Rhizoma Sparganii stoloniferi</i> ), <i>Erzhu</i> ( <i>Rhizoma curcumae</i> ), etc. 4 tablets, tid. 2 weeks prior to bleeding till 1st day of cycle.<br><i>Yue Yue Shu</i> : 1 sachet (10 g), bid. 1 week prior to bleeding till 1st day of cycle.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Deng (2005)  | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3–5 cycles of intervention + 3 cycles of follow-up.                         | $n$ (experimental) = 70; $n$ (control) = 70; Drop-outs/withdrawals: unstated; Age: 15–37 y. TCM Pattern: both groups were diagnosed as 'retention of cold', 'stagnation of Qi and blood', 'deficiency of liver and kidney', 'retention of dampness and heat'.             | Folker formula ( <i>Jiang Ji Jiu</i> ) vs OTC ( <i>Tian Qi Tong Jing Jiao Nang</i> ).<br><i>Jiang Ji Jiu</i> : rice wine 200 mL, <i>Shengjiang</i> ( <i>Rhizoma Zingiberis officinalis recens</i> ) 200 g, <i>Aiye</i> ( <i>Folium Artemisiae argyri</i> ) 200 g, <i>Yimucao</i> ( <i>Herba Leonuri heterophylli</i> ) 50 g, <i>Hen</i> 1000 g; modification of formula may be required. Stewing all ingredients, taking the soup and the chicken meat, one dose for 3 days. 3 days prior to bleeding, no chicken soup during menstruation, then started again on day 2 of cycle for 6 days.<br><i>Tian Qi Tong Jing Jiao Nang</i> : 6 pills, tid. 2 days prior to bleeding for 6 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Fan (1999)   | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles + 3 cycles of follow-up.                                           | $n$ (experimental) = 50; $n$ (control) = 48; Drop-outs/withdrawals: unstated; Age: 15–26 y. TCM Pattern: specified, 'stagnation of blood Qi and blood', 'retention of cold', 'deficiency of kidney deficiency'.                                                           | Self-designed formula ( <i>Huo Xue Zhen Tong Tang</i> ) vs Indomethacin + Atropome.<br><i>Huo Xue Zhen Tong Tang</i> : <i>Puhuang</i> ( <i>Pollen Typhae</i> ) 15 g, <i>Wulingzhi</i> ( <i>Excrementum Troglodyti seu Pteromi</i> ) 15 g, <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ) 30 g, <i>Danshen</i> ( <i>Radix Salviae miltorrhizae</i> ) 12 g, <i>Honghua</i> ( <i>Flos Carthami tinctorii</i> ) 12 g, <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ) 30–45 g, <i>Chailu</i> ( <i>Radix Bupleuri</i> ) 12 g. Modification might be required. Herbal decoction, one dose/day, 5 days prior to bleeding for a period of 7 days.<br>Indomethacin: 25 mg, tid; Atropome: 0.3 mg, tid. 20th day of cycle for a period of 7 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Guo (1997)   | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles + 3 cycles of follow-up.                                           | $n$ (experimental) = 35; $n$ (control) = 31; Drop-outs/withdrawals: unstated; Diagnosis of dysmenorrhoea: stated; Age: 15–26 y. TCM Pattern: unspecified, but mentioned the common reasons as 'stagnation of blood Qi and blood, retention of cold' etc.                  | Self-designed formula ( <i>Tong Jing San</i> ) vs OTC formula ( <i>Yue Yue Shu</i> ).<br><i>Tong Jing San</i> : <i>Xuejie</i> ( <i>Sanguis Draconis</i> ), <i>Rougui</i> ( <i>Cortex Cinnamomi cassiae</i> ), in a ratio of 3:1 and a form of powder, 3 g, bid. Mixed and dissolve with warm water, starting 24 hours prior to bleeding, till 3rd day of cycle.<br><i>Yue Yue Shu</i> (powder): 10 g, bid. 1 week prior to bleeding till day 3 of cycle.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Huang (2000) | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Parallel performance: no; Duration: 2 cycles of intervention + 2 cycles of follow-up. | $n$ (experimental) = 33; $n$ (control) = 25; Drop-outs/withdrawals: unstated; Diagnosis of dysmenorrhoea: stated; Age: 15–33 y. TCM Pattern: unspecified, only common patterns were 'stagnation of Qi and blood in the channels' and 'retention of cold in the channels'. | Self-designed formula (modified <i>Si Wu Tang</i> ) vs Indomethacin.<br>Modified <i>Si Wu Tang</i> based on patterns.<br>Stagnation of Qi and Blood: <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 15 g, <i>Chuanxiong</i> ( <i>Radix Ligustici</i> ) 10 g, <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ) 10 g, <i>Shudi</i> ( <i>Radix Rehmanniae glutinosae conquitae</i> ) 10 g, <i>Xiangfu</i> ( <i>Rhizoma Cypri rotundi</i> ) 10 g, <i>Taoren</i> ( <i>Semen Persicae</i> ) 15 g, <i>Honghua</i> ( <i>Flos Carthami tinctorii</i> ) 10 g.<br>Retention of Cold and Blood Stasis: <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 15 g, <i>Chuanxiong</i> ( <i>Radix Ligustici</i> ) 10 g, <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ) 10 g, <i>Shudi</i> ( <i>Radix Rehmanniae glutinosae conquitae</i> ) 10 g, <i>Taoren</i> ( <i>Semen Persicae</i> ) 15 g, <i>Honghua</i> ( <i>Flos Carthami tinctorii</i> ) 10 g, <i>Guizhi</i> ( <i>Ramulus Cinnamomi cassiae</i> ) 6 g, <i>Wuzhuyu</i> ( <i>Fructus Evodiae rutaecarpae</i> ) 6 g. Herbal decoction, one dose/day, as soon as bleeding started, for a period of 3 days.<br>Indomethacin: 25mg, as soon as bleeding started, for a period of 3 days. |
| Jiang (2000) | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                           | $n$ (experimental) = 40; $n$ (control) = 36; Drop-outs/withdrawals: unstated; Age: 14–25 y. TCM Pattern: unspecified, but the common pattern was 'stagnation of Qi and blood with retention of cold'.                                                                     | Self-designed formula ( <i>Li Qi Huo Xue Tang</i> ) vs Indomethacin.<br><i>Li Qi Huo Xue Tang</i> : <i>Dihuang</i> ( <i>Radix Rehmanniae glutinosae</i> ) 12 g, <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ) 12 g, <i>Gegen</i> ( <i>Radix Puerariae</i> ) 12 g, <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 10 g, <i>Chishao</i> ( <i>Radix Paeoniae rubrae</i> ) 10 g, <i>Zelan</i> ( <i>Herba Lycopi lucidi</i> ) 10 g, <i>Xiangfu</i> ( <i>Rhizoma Cypri rotundi</i> ) 10 g, <i>Huluba</i> ( <i>Semen Trigonellae foenigraeci</i> ) 10 g, <i>Danshen</i> ( <i>Radix Salviae miltorrhizae</i> ) 15 g, <i>Wuyao</i> ( <i>Radix Linderae strychnifoliae</i> ) 6 g, <i>Sharen</i> ( <i>Fructus Amomi</i> ) 6 g, <i>Wuzhuyu</i> ( <i>Fructus Evodiae rutaecarpae</i> ) 5 g. Herbal decoction, one dose daily, starting from 3 days prior to bleeding till bleeding ended, plus OCT ( <i>Wu Ji Bai Feng Wan</i> ) started as soon as bleeding stopped for a period of 10 days.<br>Indomethacin: 25mg, bid. 3 days before bleeding till bleeding ends.                                                                                                                                                                            |

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|                   |                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Kennedy<br>(2006) | Allocation concealment and randomisation: method stated (computer-generated opaque sealed envelope); Blinding: double blinded; Trial design: parallel; Duration: 3 cycles of intervention + 1 cycles of follow-up. | <i>n</i> (experimental) = 17; <i>n</i> (control) = 19; Drop-outs/withdrawals: stated, 3 dropped out before randomisation, 2 dropped out after randomisation due to either irregular menstruation or personal reasons. Their data were excluded (no intention-to-treatment performed). Diagnosis of dysmenorrhoea: stated; Age: 18–45 y. TCM Pattern: unspecified. | Self-designed formula vs Placebo.<br><br>Self-designed formula: <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ), <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ), <i>Chishao</i> ( <i>Radix Paeoniae rubrae</i> ), <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ), in a ratio of approximately 1:1.5:1.<br><br>Placebo: sugar beet fibre and maltodextrin indistinguishable in appearance.<br><br>Both groups took 3 tablets, bid, 2 days prior to bleeding for a period of 7 days. Rescue medication: Ibuprofen, 200 mg, 6 tablets/day maximum.                                                                                                                                                                                                                                                                                                  |
| Kotani<br>(1997)  | Allocation concealment and randomisation: method unstated; Blinding: double blind; Trial design: parallel; Duration: 2 cycles of observation + 2 cycles of intervention + 2 cycles of follow-up.                   | <i>n</i> (experimental) = 20; <i>n</i> (control) = 20; Drop-outs/withdrawals: unstated; Age: 14–45 y. TCM Pattern: stated, only included 'stagnation blood', 'deficiency', 'yin', and 'cold'.                                                                                                                                                                     | Classic Chinese formula ( <i>Tao Hong Si Wu San</i> ) vs Placebo.<br><br><i>Tao Hong Si Wu San</i> : <i>Danggui</i> ( <i>Angelicae sinensis radix</i> ); <i>Chishao</i> ( <i>Paeoniae rubrae radix</i> ); <i>Fuling</i> ( <i>Sclerotium Poriae cocos</i> ); <i>Cangzhu</i> ( <i>Atractylodis lanceae rhizoma</i> ); <i>Zexie</i> ( <i>Alismatis rhizoma</i> ); <i>Chuanxiong</i> ( <i>Chuanxiong rhizome</i> ), in a ratio of 3:4:4:4:4:3.<br><br>Placebo: no details.<br><br>Both groups took study materials 7.5 g, daily, for two cycles. Rescue medication: Diclofenac sodium 25 mg, 4 tablets/day maximum.                                                                                                                                                                                                                                        |
| Li<br>(1999)      | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Parallel performance: yes. Duration: 3 cycles of intervention + 3 cycles of follow-up.                      | <i>n</i> (experimental) = 44; <i>n</i> (control) = 36; Drop-outs/withdrawals: unstated; Age: 14–45 y. TCM Pattern: stated, 'stagnation of Qi and Blood'.                                                                                                                                                                                                          | Self-designed formula ( <i>Fu Ke Qian Jin Pian</i> ) vs OTC Chinese herbal formula ( <i>Tian Qi Jiao Nang</i> ).<br><br><i>Fu Ke Qian Jin Pian</i> : no details stated.<br><br><i>Tian Qi Jiao Nang</i> : no details stated.<br><br>Both group took 5 tablets of each study material, tid. 4–5 days prior to bleeding till day 2 of cycle.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Li<br>(2001)      | Allocation concealment and randomisation: method unstated; Blinding: single blinded; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                           | <i>n</i> (experimental) = 50; <i>n</i> (control) = 50; Drop-outs/withdrawals: unstated; Diagnosis of dysmenorrhoea: stated; Age (experimental): 15–35 y; Age (control): 15–33 y. TCM Pattern: unstated.                                                                                                                                                           | Self-designed formula ( <i>Tong Jing Wan</i> ) vs OTC Chinese herbal formula ( <i>Yuan Hu Zhi Tong Pian</i> ).<br><br><i>Tong Jing Wan</i> : <i>Xiaohuixiang</i> ( <i>Fructus Foeniculi vulgaris</i> ), <i>Rougui</i> ( <i>Cortex Cinnamomi cassiae</i> ), <i>Sanqi</i> ( <i>Radix Notoginseng</i> ), <i>Wulingzhi</i> ( <i>Excrementum Trogopteri seu Pteromi</i> ), <i>Puhuang</i> ( <i>Pollen Typhae</i> ), <i>Chenxiang</i> ( <i>Lignum Aquitariae</i> ), <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ), <i>Muxiang</i> ( <i>Radix Aucklandiae lappae</i> ), <i>Baizhu</i> ( <i>Rhizoma Atractylodis macrocephalae</i> ), made with certain ratio into pills. 2 g, tid.<br><br><i>Yuan Hu Zhi Tong Pian</i> : 5 tablets, tid.<br><br>Both groups started from 5 days prior to bleeding till day 2 of cycle.                                         |
| Li<br>(2004)      | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                 | <i>n</i> (experimental) = 40; <i>n</i> (control) = 40; Drop-outs/withdrawals: unstated; Age (experimental): 12–33 y; Age (control): 13–32 y. TCM Pattern: stated, only the pattern of 'retention of cold and blood stasis'.                                                                                                                                       | Self-designed formula ( <i>Nuan Gong Zhi Tong Tang</i> ) vs OTC ( <i>Yue Yue Shu</i> ).<br><br><i>Nuan Gong Zhi Tong Tang</i> : <i>Rougui</i> ( <i>Cortex Cinnamomi cassiae</i> ) 5 g, <i>Zhifuzi</i> ( <i>Radix lateralis Aconiti carmichaeli praeparata</i> ) 3 g, <i>Zishiying</i> ( <i>Fluoritum</i> ) 10 g, <i>Sanleng</i> ( <i>Rhizoma Sparganii stoloniferi</i> ) 10 g, <i>Erzhu</i> ( <i>Rhizoma Curcuma</i> ) 10 g, <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 10 g, <i>Xiangfu</i> ( <i>Rhizoma Cypri rotundi</i> ) 10 g, <i>Chuanxiong</i> ( <i>Radix Ligustici</i> ) 6 g, <i>Chishao</i> ( <i>Radix Paeoniae rubrae</i> ) 12 g, <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ) 12 g. 150 mL, bid.<br><br><i>Yue Yue Shu</i> : 1 sachet (10 g), bid.<br><br>Both groups started from 5 days prior to bleeding for a period of 7 days. |
| Liu<br>(2000)     | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                 | <i>n</i> (experimental) = 40; <i>n</i> (control) = 38; Drop-outs/withdrawals: unstated; Age: 14–31 y. TCM Pattern: unspecified.                                                                                                                                                                                                                                   | OCT Chinese herbal formula ( <i>Xiao Yao Wan</i> ) + Piroxicam vs Piroxicam.<br><br><i>Xiao Yao Wan</i> : <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ), <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ), <i>Chaihu</i> ( <i>Radix Bupleuri</i> ), <i>Fuling</i> ( <i>Sclerotium Poriae cocos</i> ), <i>Baizhu</i> ( <i>Rhizoma Atractylodis macrocephalae</i> ), <i>Gancao</i> ( <i>Radix Glycyrrhizae uralensis</i> ), <i>Weijiang</i> ( <i>Rhizoma Phragmitis communis</i> ), <i>Bohe</i> ( <i>Herba Menthae haplocalcis</i> ). 9 g, bid, in combination with Piroxicam, 20 mg, once daily.<br><br>Piroxicam: 20 mg, once daily.<br><br>Both groups started from 2 days prior to bleed for a period of 3 days.                                                                                                                             |

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| Liu (2003)  | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Parallel performance: yes; Duration: 2–3 days prior to bleeding or 1st day of bleeding for 7 days × 3 cycles of intervention + 3 cycles of follow-up. | $n$ (experimental) = 52; $n$ (control) = 38; Drop-outs/withdrawals: unstated; Age: 15–30 y. TCM Pattern: specified, pattern of ‘stagnation of blood’ only.                           | Self-designed formula ( <i>Wen Jing Tang</i> oral administration + <i>Xin Jie San</i> external administration) vs Indomethacin + Vit B6 + Hot water bottle.<br><br><i>Wen Jing Tang</i> : Rougui ( <i>Cortex Cinnamomi cassiae</i> ) 3 g, Chuanxiong ( <i>Radix Ligustici</i> ) 8 g, Dangshen ( <i>Codonopsis radix</i> ) 20 g, Danggui ( <i>Radix Angelicae sinensis</i> ) 10 g, Erzhu ( <i>Rhizoma Curcuma</i> ) 10 g, Danshen ( <i>Radix Salviae miltorrhizae</i> ) 15 g, Chuanniuxi ( <i>Radix Cyathulae officinalis</i> ) 10 g, Baishao ( <i>Radix Paeoniae latiflorae</i> ) 10 g, Yanhusuo ( <i>Rhizoma Corydalis</i> ) 10 g, Gancao ( <i>Radix Glycyrrhizae uralensis</i> ) 6 g. Herbal decoction, one dose daily.<br><br><i>Xin Jie San</i> : Xixin ( <i>Asari herba</i> ) 30 g, Baijiezi ( <i>Sinapis semen</i> ) 30 g, Mangxiao ( <i>Natrii sulfas</i> ) 30 g. All ingredients mixed, ground into powder and packed into 20 × 30 cm bag, sealed. Warmed up in microwave oven before applied on the lower abdominal region.<br><br>Indomethacin: 25 mg, tid. Vit B6 20 mg, tid. Hot water bottle in the lower abdominal region. Both groups started from 2–3 days prior to bleeding or 1st day of bleeding for a period of 7 days. |
| Liu (2004)  | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                           | $n$ (experimental) = 45; $n$ (control) = 40; Drop-outs/withdrawals: unstated; Age: 14–18 y. TCM Pattern: retention of coldness and stagnation of blood.                              | Self-designed formula administrated externally vs Classic formula ( <i>Wen Jing Tang</i> ) administrated orally.<br><br><i>Zi Ni Wai Fu Tong Jing Zhi Tong Fan</i> : Rougui ( <i>Cortex Cinnamomi cassiae</i> ) 30 g, Yanhusuo ( <i>Rhizoma Corydalis</i> ) 30 g, Ruxiang ( <i>Gummi Olibanum</i> ) 30 g, Moyao ( <i>Myrrha</i> ) 30 g, Dibiechong ( <i>Eupolyphaga seu Opisthaptalia</i> ) 30 g, Wuyao ( <i>Radix Linderae strychnifoliae</i> ) 30 g. All ingredients were dried and powdered, 20 g each time, mixed with rice wine as paste for external use on navel. Change once daily.<br><br><i>Wen Jing Tang</i> : no details. One dose daily.<br><br>Both groups started from 3 days prior to bleeding for a period of 5 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Liu (2005)  | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                           | $n$ (experimental) = 30; $n$ (control) = 30; Drop-outs/withdrawals: unstated; Age: 14–30 y. TCM Pattern: stated, retention of coldness and stagnation of blood.                      | Self-designed formula ( <i>Wen Jing Zhi Tong Yin</i> ) vs OTC Chinese herbal formula ( <i>Ai Fu Nuan Gong Tang</i> ).<br><br><i>Wen Jing Zhi Tong Yin</i> : Paojiang (Quick-fried <i>Rhizoma Zingiberis officinalis</i> ), Rougui ( <i>Cortex Cinnamomi cassiae</i> ), Danggui ( <i>Radix Angelicae sinensis</i> ), Chuanxiong ( <i>Radix Ligustici</i> ), Wulingzhi ( <i>Excrementum Troglodytes seu Pteromys</i> ), Puhuang ( <i>Pollen Typhae</i> ), Baishao ( <i>Radix Paeoniae latiflorae</i> ), Yanhusuo ( <i>Rhizoma Corydalis</i> ), Huainiuxi ( <i>Radix Achyranthis bidentatae</i> ), Xiaohuixiang ( <i>Fructus Foeniculi vulgaris</i> ), Xiangfu ( <i>Rhizoma Cypripedium rotundi</i> ), Gancao ( <i>Radix Glycyrrhizae uralensis</i> ), etc. No dosage stated in detail. Herbal decoction. 5 days prior to bleeding for a period of 7 days.<br><br><i>Ai Fu Nuan Gong Tang</i> : No dosage stated in detail. 3 days prior to bleeding for a period of 6 days.                                                                                                                                                                                                                                                                   |
| Luo (2002)  | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                           | $n$ (experimental) = 31; $n$ (control) = 31; Drop-outs/withdrawals: unstated; Age: 13–40 y. TCM Pattern: Stagnation of Qi and blood.                                                 | Self-designed formula ( <i>Tong Jing San</i> ) vs Indomethacin.<br><br><i>Tong Jing San</i> : Puhuang ( <i>Pollen Typhae</i> ) 15 g, Wulingzhi ( <i>Excrementum Troglodytes seu Pteromys</i> ) 12 g, Yanhusuo ( <i>Rhizoma Corydalis</i> ) 15 g, Xiangfu ( <i>Rhizoma Cypripedium rotundi</i> ) 10 g, Chuanniuxi ( <i>Radix Cyathulae officinalis</i> ) 10 g, Paojiang (Quick-fried <i>Rhizoma Zingiberis officinalis</i> ) 6 g, Xixin ( <i>Herba cum radice Asari</i> ) 3 g. Herbs were soaked for one hour, cooked for one hour, extracted into 200 mL decoction, 100mL, bid. Started from 7 days prior to bleeding till 1st day of cycle.<br><br>Indomethacin: 25 mg, tid. 3 days prior to bleeding till 1st day of cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Miao (2003) | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                           | $n$ (experimental) = 36; $n$ (control) = 27; Drop-outs/withdrawals: unstated; Age: 12–20 y. TCM Pattern: believed all clinical patterns related to ‘deficiency of kidney and liver’. | Self-designed formula ( <i>Niu Xi San</i> ) vs Acupuncture (LI4, and SP6 only)<br><br><i>Niu Xi San</i> : Niuxi ( <i>Chuan Niuxi</i> ( <i>Radix Cyathulae officinalis</i> ) or Huai Niuxi ( <i>Radix Achyranthis bidentatae</i> ) (not clear), Rougui ( <i>Cortex Cinnamomi cassiae</i> ), Chishao ( <i>Radix Paeoniae rubrae</i> ), Taoren ( <i>Semen Persicae</i> ), Yanhusuo ( <i>Rhizoma Corydalis</i> ), Danggui ( <i>Radix Angelicae sinensis</i> ), Muxiang ( <i>Radix Aucklandiae lappae</i> ), Danpi ( <i>Cortex Mouten radices</i> ), in a ration of 3:1:1:1:1:1:1:1:1, powdered, 9 g, mixed with warm water or wine, for a period of 5 days (unclear when the intervention started).<br><br>Acupuncture: needles remained for 30 min at each point, for a period of 5 days (unclear when the intervention started).                                                                                                                                                                                                                                                                                                                                                                                                              |
| Niu (1996)  | Allocation concealment and randomisation: method unstated; Blinding: single blinded; Trial design: parallel; Duration: 3 of intervention + 3 follow-up.                                                                                                      | $n$ (experimental) = 32; $n$ (control) = 21; Drop-outs/withdrawals: unstated; Age (experimental): 17–47 y; Age (control): 18–42 y. TCM Pattern: unstated.                            | Single herb ( <i>Glycyrrhiza uralensis</i> ) vs OTC ( <i>Yuan Hu Zhi Tong Pian</i> )<br><br><i>Glycyrrhiza uralensis</i> : no dosage details stated.<br><br><i>Yuan Hu Zhi Tong Pian</i> : 6 tablets, tid.<br><br>Both groups took the herb as soon as pain started, for 3 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

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| Qin<br>(2003)   | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                             | <i>n</i> (experimental) = 60; <i>n</i> (control) = 60; Drop-outs/withdrawals: unstated; Age (average): 14–40 y. TCM Pattern: unstated                                                                                                                                                                                   | Self-designed formula ( <i>Du Yi Wei Jiao Nang</i> ) vs OTC Formula ( <i>Yuan Hu Zhi Tong Jiao Nang</i> ) or added pain-relieving medication if required.<br><i>Du Yi Wei Jiao Nang</i> : no details given; 3 pills, tid.<br><i>Yuan Hu Zhi Tong Jiao Nang</i> : no details given.<br>Both groups started the herb from 1st day of cycle/bleeding for 7 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Shen<br>(2001)  | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                             | <i>n</i> (experimental) = 60; <i>n</i> (control) = 60; Drop-outs/withdrawals: unstated; Age (mean experimental): 26.63 y; Age (mean control): 25.1 y. TCM Pattern: stated, 'the retention of cold and stagnation of blood'.                                                                                             | Self-designed formula ( <i>Wen Jing Jian Tong Jiao Nang</i> ) vs OCT formula ( <i>Jiu Qi Jian Tong Wan</i> ).<br><i>Wen Jing Jian Tong Jiao Nang</i> : <i>Rougui</i> ( <i>Cortex Cinnamomi cassiae</i> ), <i>Jiuxiangchong</i> ( <i>Aspongopus</i> ), <i>Xiaohuixiang</i> ( <i>Fructus Foeniculi vulgaris</i> ), <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ), <i>Wulingzhi</i> ( <i>Excrementum Troglodyti seu Pteromidi</i> ), <i>Xiangfu</i> ( <i>Rhizoma Cypripidis rotundi</i> ), <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ), <i>Bingpian</i> ( <i>Borneol</i> ), ratio of herbal ingredients unstated; 4 pills, bid.<br><i>Jiu Qi Jian Tong Wan</i> : no details of herbal ingredients stated; 9 g, bid.<br>Both groups started herbs 7 days prior to period for a period of 5 days.                                                                                                                                                                                                                                                                          |
| Song<br>(2003)  | Allocation concealment and randomisation: method unstated; Blinding: single blinding; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                      | <i>n</i> (experimental) = 50; <i>n</i> (control) = 50; Drop-outs/withdrawals: unstated; Age (experimental): 15–35 y; Age (control): 14–36. TCM Pattern: stated, only the pattern of 'stagnation of Qi and Blood' was included.                                                                                          | Self-designed formula ( <i>Tong Jing Jiao Nang</i> ) vs Indomethacin.<br><i>Tong Jing Jiao Nang</i> : <i>Xuejie</i> ( <i>Sanguis Draconis</i> ), <i>Puhuang</i> ( <i>Pollen Typhae</i> ), <i>Wulingzhi</i> ( <i>Excrementum Troglodyti seu Pteromidi</i> ), <i>Chuannixi</i> ( <i>Radix Cyathulae officinalis</i> ), <i>Xiangfu</i> ( <i>Rhizoma Cypripidis rotundi</i> ), <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ), <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ), <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ), <i>Xixin</i> ( <i>Herba cum radice Asari</i> ), etc. as a capsule (no detailed dosage); 4 capsules, tid.<br>5 days prior to period for a period of 7 days.<br>Indomethacin: 25 mg, tid. 3 days prior to period for a period of 6 days.                                                                                                                                                                                                                                                                                                    |
| Sun<br>(2006)   | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                             | <i>n</i> (experimental) = 46; <i>n</i> (control) = 45; Drop-outs/withdrawals: unstated; Age (experimental): 13–35 y; Age (control): 12–35 y. TCM Pattern: specified, only the pattern of 'stagnation of blood and retention of cold'.                                                                                   | Self-designed formula ( <i>Tao Jing Ding Tong Tang</i> ) vs OTC Chinese herbal formula ( <i>Tian Qi Tong Jing Jiao Nang</i> ).<br><i>Tao Jing Ding Tong Tang</i> : <i>Guizhi</i> ( <i>Ramulus Cinnamomi cassiae</i> ) 15 g, <i>Xiaohuixiang</i> ( <i>Fructus Foeniculi vulgaris</i> ) 10 g, <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 10 g, <i>Chuanxiong</i> ( <i>Radix Ligustici</i> ) 15 g, <i>Xiangfu</i> ( <i>Rhizoma Cypripidis rotundi</i> ) 15 g, <i>Chaihu</i> ( <i>Radix Bupleuri</i> ) 10 g, <i>Yimucao</i> ( <i>Herba Leonuri heterophylli</i> ) 15 g, <i>Zelan</i> ( <i>Herba Lycopi lucidi</i> ) 15 g, <i>Wangbuliuxing</i> ( <i>Semen Vaccariae segetalis</i> ) 20 g, <i>Lulutong</i> ( <i>Fructus Liquidambaris taiwanianae</i> ) 15 g, <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ) 15 g, <i>Gancao</i> ( <i>Radix Glycyrrhizae uralensis</i> ) 5 g. Herbal decoction, bid.<br><i>Tian Qi Tong Jing Jiao Nang</i> : 4 pills, tid, half an hour before meals.<br>Both groups took herbs from 5 days prior to period for a period of 6 days. |
| Sun<br>(2004a)  | Allocation concealment and randomisation: randomised based on a random-number table, double-blinding; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                      | <i>n</i> (experimental) = 30; <i>n</i> (control) = 30; Drop-outs/withdrawals: unstated; Age: 15–23 y. TCM Pattern: unstated.                                                                                                                                                                                            | OTC formula ( <i>Gui Zhi Fu Ling Wan</i> no. 1) vs Placebo.<br><i>Gui Zhi Fu Ling Wan</i> no. 1: <i>Guizhi</i> ( <i>Ramulus Cinnamomi cassiae</i> ), <i>Fuling</i> ( <i>Sclerotium Poriae cocos</i> ), <i>Chishao</i> ( <i>Radix Paeoniae rubrae</i> ), <i>Danpi</i> ( <i>Cortex Mouten radialis</i> ), <i>Taoren</i> ( <i>Semen Persicae</i> ); 3 pills, tid.<br>Placebo: 3 pills, tid; no further details.<br>Both groups started herbs/placebo 3 days prior to period for a period of 7 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Sun<br>(2004b)  | Allocation concealment and randomisation: randomised based on a random number table, double-blinding; Duration: 3 cycles of intervention + 3 cycles of follow-up.                                                                                              | <i>n</i> (experimental) = 30; <i>n</i> (control) = 30; Drop-outs/withdrawals: unstated; Age: 15–23 y. TCM Pattern: unstated.                                                                                                                                                                                            | OTC formula ( <i>Gui Zhi Fu Ling Wan</i> no. 2) vs Placebo.<br><i>Gui Zhi Fu Ling Wan</i> no. 2: <i>Guizhi</i> ( <i>Ramulus Cinnamomi cassiae</i> ), <i>Fuling</i> ( <i>Sclerotium Poriae cocos</i> ), <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ), <i>Danpi</i> ( <i>Cortex Mouten radialis</i> ), <i>Taoren</i> ( <i>Semen Persicae</i> ); 3 pills, tid.<br>Placebo: 3 pills, tid; no further details.<br>Both groups started herbs/placebo 3 days prior to period for a period of 7 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Tseng<br>(2005) | Allocation concealment and randomisation: method unstated; Blinding: open trial; Trial design: parallel; Age: significant difference in mean age and PSS scores (variable) between two groups, but adjusted; Duration: 6 cycles of intervention; no follow-up. | <i>n</i> (experimental) = 70; <i>n</i> (control) = 60; 21 out of 130 dropped out because of irregular course of menstruation, failure of compliance, withdrawal of school; Age: adolescents/boarding school girls, age unspecified. TCM Pattern: unstated, only mentioned stagnation Qi and blood as general condition. | Rose tea vs No treatment.<br>Rose tea: 2 teacups per day made from 6 dry rosebuds steeped in 300 mL of hot water, taken for 12 days from one week prior to their menstrual period to the fifth menstrual day.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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| Wang (1996)  | Allocation concealment and randomisation: based on random number table; Blinding: single blinded; Trial design: parallel; Duration: 3 cycles + 3 cycles of follow-up.          | $n$ (experimental) = 23; $n$ (control 1) = 21; $n$ (control 2) = 16; Drop-outs/withdrawals: unstated; Age: high-school girls. TCM Pattern: specified, 'retention of cold and stagnation of Qi'. | Self-designed formula ( <i>Tong Jing Ling</i> ) rectal administration vs 1 OCT Chinese herbal formula ( <i>Tian Qi Tong Jing Jiao Nang</i> ) oral administration vs 2 Self-designed formula ( <i>Tong Jing Ling</i> ) oral administration.<br><br><i>Tong Jing Ling</i> : Guizhi ( <i>Ramulus Cinnamomi cassiae</i> ), Wuyao ( <i>Radix Linderae strychnifoliae</i> ), Xiangfu ( <i>Rhizoma Cypri rotundi</i> ), Yanhusuo ( <i>Rhizoma Corydalis</i> ), Muxiang ( <i>Radix Aucklandiae lappae</i> ), Kuncao, Wulingzhi ( <i>Excrementum Troglodyteri seu Pteromi</i> ), Chuanxiong ( <i>Radix Ligustici</i> ), etc. Either in suppository administration, 1 piece, rectal administration, bid, or in oral administration in capsule form, 5 pills, tid.<br><br><i>Tian Qi Tong Jing Jiao Nang</i> : 5 pills, tid. All groups started from 4–5 days prior to bleeding till day 2 of cycle (approximately 7 days).                                                                                                                                                           |
| Wang (2000)  | Allocation concealment and randomisation: Randomised, method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up. | $n$ (experimental) = 50; $n$ (control) = 50; Drop-outs/withdrawals: unstated; Age (experimental): 14–35 y; Age (control): 15–32 y. TCM Pattern: unspecified.                                    | Self-designed formula ( <i>Bu Shen Hua Yu Tang</i> ) vs OCT formula ( <i>Yue Yue Shu</i> )<br><br><i>Bu Shen Hua Yu Tang</i> : Bajietian ( <i>Radix Morindae officinalis</i> ) 15 g, Gouqizi ( <i>Fructus Lycii</i> ) 15 g, Xianlingpi ( <i>Herba Epimedii</i> ) 15 g, Shudi ( <i>Radix Rehmanniae glutinosae conquitae</i> ) 15 g, Baishao ( <i>Radix Paeoniae latiflorae</i> ) 20 g, Danggui ( <i>Radix Angelicae sinensis</i> ) 12 g, Honghua ( <i>Flos Carthami tinctorii</i> ) 12 g, Pubuang ( <i>Pollen Typhae</i> ) 12 g, Wulingzhi ( <i>Excrementum Troglodyteri seu Pteromi</i> ) 12 g, Chuanxiong ( <i>Radix Ligustici</i> ) 6 g, Xiangfu ( <i>Rhizoma Cypri rotundi</i> ) 9 g, Zhiqiao ( <i>Fructus Aurantii</i> ) 9 g, Gancao ( <i>Radix Glycyrrhizae uralensis</i> ) 6 g. Modification of formulation might be required. Herbal decoction, one dose daily, starting from 5 days prior to bleeding for a period of 7 days.<br><br><i>Yue Yue Shu</i> : no details of formula stated. 10 g, bid, started from 7 days prior to bleeding for a period of 10 days. |
| Wang (2003)  | Allocation concealment and randomisation: method unstated; Blinding: open labelled comparison; Duration: 3 cycles intervention + 3 follow-up.                                  | $n$ (experimental) = 52; $n$ (control) = 51; Drop-outs/withdrawals: unstated; Age (experimental): 14–35 y; Age (control): 15–32 y. TCM Pattern: specified.                                      | Tailored formulae based on clinical manifestation vs Acupuncture.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Wang (2006a) | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles intervention + 3 follow-up.                          | $n$ (experimental) = 172; $n$ (control) = 168; Drop-outs/withdrawals: unstated; Age: 14–23 y. TCM Pattern: unspecified.                                                                         | OCT Chinese herbal formula ( <i>Su Xiao Jiu Xin Wan</i> ) vs Indomethacin.<br><br><i>Su Xiao Jiu Xin Wan</i> : sublingual administration, 2–5 pills, tid, as soon as pain started for 4 days.<br><br>Indomethacin: 25 mg, tid, as soon as pain started for 4 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Wang (2006b) | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.             | $n$ (experimental) = 32; $n$ (control) = 24; Drop-outs/withdrawals: unstated; Age (experimental): 14–29 y; Age (control): 15–30 y. TCM Pattern: unspecified                                     | Modified self-designed formula ( <i>Tong Jing Ling</i> ) vs Indomethacin.<br><br><i>Tong Jing Ling</i> : Danggui ( <i>Radix Angelicae sinensis</i> ) 15 g, Baishao ( <i>Radix Paeoniae latiflorae</i> ) 15 g, Shengdi ( <i>Radix Rehmanniae glutinosae</i> ) 15 g, Danshen ( <i>Radix Salviae miltiorrhizae</i> ) 15 g, Chuanxiong ( <i>Radix Ligustici</i> ) 12 g, Honghua ( <i>Flos Carthami tinctorii</i> ) 12 g, Taoren ( <i>Semen Persicae</i> ) 9 g, Xiaohuixiang ( <i>Fructus Foeniculi vulgaris</i> ) 9 g, Guangmuxiang ( <i>Radix Aucklandiae lappae</i> ) 6 g. Modification of formulation might be required. Herbal decoction, 1 dose daily, 3 days prior to bleeding for a period of 6 days.<br><br>Indomethacin: 50 mg, bid, as soon as pain started for a period of 6 days.                                                                                                                                                                                                                                                                                  |
| Wu (2006)    | Allocation concealment and randomisation: method unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.             | $n$ (experimental) = 45; $n$ (control) = 45; Drop-outs/withdrawals: unstated; Age (experimental): 13–27 y; Age (control): 14–29 y. TCM Pattern: no specific statement.                          | Self-designed formula ( <i>Jia Wei Dang Gui Shao Yao San</i> ) vs Ibuprofen.<br><br><i>Jia Wei Dang Gui Shao Yao San</i> : Danggui ( <i>Radix Angelicae sinensis</i> ) 10–20 g, Chuanxiong ( <i>Radix Ligustici</i> ) 30 g, Baishao ( <i>Radix Paeoniae latiflorae</i> ) 15–30 g, Chishao ( <i>Radix Paeoniae rubrae</i> ) 10–20 g, Fuling ( <i>Sclerotium Poriae cocos</i> ) 10–20 g, Zexie ( <i>Rhizoma Alismatis orientalis</i> ) 10–20 g, Baizhu ( <i>Rhizoma Atractylodis macrocephalae</i> ) 10–20 g, Wuyao ( <i>Radix Linderae strychnifoliae</i> ) 10–20 g, Xiangfu ( <i>Rhizoma Cypri rotundi</i> ) 10–20 g, Yanhusuo ( <i>Rhizoma Corydalis</i> ) 10–20 g, Gancao ( <i>Radix Glycyrrhizae uralensis</i> ) 5–10 g. Herbal decoction, 150 mL, bid.<br><br>Ibuprofen: 200 mg, tid.<br><br>Both groups started from 3 days prior to bleeding for a period of 5 days.                                                                                                                                                                                                 |
| Ye (2004)    | Allocation concealment and randomisation: unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.                    | $n$ (experimental) = 30; $n$ (control) = 28; Drop-outs/withdrawals: unstated; Age (experimental): 15–27 y; Age (control): 14–28 y. TCM Pattern: unstated.                                       | Self-designed formula ( <i>Nv Jin Jiao Nang</i> ) vs Indomethacin.<br><br><i>Nv Jin Jiao Nang</i> : Danggui ( <i>Radix Angelicae sinensis</i> ), Baishao ( <i>Radix Paeoniae latiflorae</i> ), Chuanxiong ( <i>Radix Ligustici</i> ), Shudi ( <i>Radix Rehmanniae glutinosae gonquitae</i> ), Rougui ( <i>Cortex Cinnamomi cassiae</i> ), etc. 23 herbs in total, in pill-form; 3 pills, bid, 7 days prior to bleeding until the end of bleeding.<br><br>Indomethacin: 50 mg, tid, 1 day prior to bleeding until the end of bleeding.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

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|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yu<br>(2003)    | Allocation concealment and randomisation: unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.              | $n$ (experimental) = 35; $n$ (control) = 30; Drop-outs/withdrawals: unstated; Age (experimental): 12–32 y; Age (control): 13–30 y. TCM Pattern: both groups were diagnosed as 'retention of cold with blood stasis'.                                                   | Self-designed formula ( <i>Fu Mei Tong Jing Fang</i> ) vs OTC formula ( <i>Tian Qi Tong Jing Jiao Nang</i> ).<br><br><i>Fu Mei Tong Jing Fang</i> : <i>Zhifuzi</i> ( <i>Radix lateralis Aconiti carmichaeli praeparata</i> ) 6 g, <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ) 12 g, <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 12 g, <i>Moyao</i> ( <i>Myrrha</i> ) 9 g, <i>Erzhu</i> ( <i>Rhizoma Curcumae</i> ) 9 g, <i>Wulingzhi</i> ( <i>Excrementum Troglodyteri seu Pteromi</i> ) 9 g, <i>Puhuang</i> ( <i>Pollen Typhae</i> ) 9 g, <i>Rougui</i> ( <i>Cortex Cinnamomi cassiae</i> ) 5 g. Herbal decoction, extracted as 200 mL, bid.<br><br><i>Tian Qi Tong Jing Jiao Nang</i> : no details of formulation provided; 4 pills, tid.<br><br>Both groups started from 3 days prior to bleeding for a period of 5 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Zhang<br>(2000) | Allocation concealment and randomisation: unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.              | $n$ (experimental) = 35; $n$ (control) = 20; Drop-outs/withdrawals: unstated; Age (experimental): 16–22 y; Age (control): 15–23 y. TCM Pattern: unspecified, common patterns mentioned were 'deficiency of blood, blood stasis'.                                       | Self-designed formula (modified <i>Si Wu Tang</i> ) vs Heat compression.<br><br>Modified <i>Si Wu Tang</i> : <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ), <i>Chishao</i> ( <i>Radix Paeoniae rubrae</i> ), <i>Shendi</i> , <i>Chuanxiong</i> ( <i>Radix Ligustici</i> ), etc. 2–3 days prior to bleeding for a period of 10 days.<br><br>Heat compression: as soon as pain started till pain disappeared.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Zhang<br>(2001) | Allocation concealment and randomisation: unstated; Blinding: unstated; Trial design: parallel; Duration: 3–5 cycles of intervention + 3 cycles of follow-up.            | $n$ (experimental) = 60; $n$ (control) = 40; Drop-outs/withdrawals: unstated; Age: 14–26 y. TCM Pattern: unstated.                                                                                                                                                     | Self-designed formula (oral administration) + self-designed formula (external administration) vs Two different OTC formulae ( <i>Yuan Hu Zhi Tong Pian</i> and <i>Tong Jing Wan</i> , oral administration).<br><br>Self-designed formula (oral administration): <i>Guizhi</i> ( <i>Ramulus Cinnamomi cassiae</i> ) 9 g, <i>Ruxiang</i> ( <i>Gummi Olibanum</i> ) 9 g, <i>Chishao</i> ( <i>Radix Paeoniae rubrae</i> ) 9 g, <i>Zelan</i> ( <i>Herba Lycopi lucidi</i> ) 9 g, <i>Gancao</i> ( <i>Radix Glycyrrhizae uralensis</i> ) 9 g, <i>Xixin</i> ( <i>Herba cum radice Asari</i> ) 6 g, <i>Xiaohuixiang</i> ( <i>Fructus Foeniculi vulgaris</i> ) 6 g, <i>Chuanxiong</i> ( <i>Radix Ligustici</i> ) 6 g, <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ) 6 g, <i>Yimucao</i> ( <i>Herba Leonuri heterophylli</i> ) 15 g, <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 15 g, <i>Xiangfu</i> ( <i>Rhizoma Cypri rotundi</i> ) 15 g. Herbal decoction, one dose daily, 7 days prior to period till post menstruation.<br><br>Self-designed formula (external administration): <i>Baizhi</i> ( <i>Radix Angelicae</i> ) 6 g, <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 6 g, <i>Chishao</i> ( <i>Radix Paeoniae rubrae</i> ) 6 g, <i>Dahuang</i> ( <i>Radix et rhizoma Rhei</i> ) 6 g, <i>Huangdan</i> ( <i>Minium</i> ) mixed with sesame oil, in a paste, applied on 'Guan Yuan' outpoint during menstruation.<br><br><i>Yuan Hu Zhi Tong Pian</i> : 4 tablets, bid, 1st OCT started from 7 days prior to period for 7 days.<br><br><i>Tong Jing Wan</i> : 10 pills, bid, 2nd OCT in menstruation period for 3–5 days. |
| Zhu<br>(2001)   | Allocation concealment and randomisation: methods unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.      | $n$ (experimental) = 78; $n$ (control) = 39; Drop-outs/withdrawals: unstated; Age (experimental): 12–30 y; Age (control): 12.5–28 y. TCM Pattern: stated, 'stagnation of Qi and Blood, retention of cold, deficiency of Qi and Blood, deficiency of Liver and Kidney'. | Self-designed formula ( <i>Dong Gui Ai Ye Tang</i> ) vs Indomethacin and vitamin B6.<br><br><i>Dong Gui Ai Ye Tang</i> : <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 30 g, <i>Aiye</i> ( <i>Folium Artemisiae argyi</i> ) 15 g, <i>Hongtang</i> ( <i>Caulis Sargentodoxae cuneatae</i> ) 60 g; 600 mL herbal decoction daily, 3 days prior to bleeding for a period of 6 days.<br><br>Indomethacin: 25 mg, tid; vitamin B6, 20 mg, tid; 3 days prior to bleeding till bleeding stopped.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Zhu<br>(2002)   | Allocation concealment and randomisation: unstated; Blinding: unstated; Trial design: parallel; Duration: 3 cycles of intervention + 3 cycles of follow-up.              | $n$ (experimental) = 70; $n$ (control) = 62; Drop-outs/withdrawals: unstated; Age: 16–32 y. TCM Pattern: unstated.                                                                                                                                                     | Self-designed formula vs Indomethacin.<br><br>Self-designed formula: <i>Danshen</i> ( <i>Radix Salviae miltiorrhizae</i> ) 30 g, <i>Xiangfu</i> ( <i>Rhizoma Cypri rotundi</i> ) 10–15 g, <i>Shengjiang</i> (fresh <i>Rhizoma Zingiberis officinalis</i> ) 6 g. Herbs were cooked and extracted into 300 mL decoction, mixed with brown sugar (no dose provided), bid, 1 day prior to bleeding until 3rd day of cycle.<br><br>Indomethacin: 50 mg, tid, 3 days prior to bleeding until 3rd day of cycle.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Zhu<br>(2003)   | Allocation concealment and randomisation: blinding unstated; Trial design: parallel; Duration: 3 cycles of intervention or 6 cycles or 9 cycles + 3 cycles of follow-up. | $n$ (experimental) = 42; $n$ (control) = 42; Drop-outs/withdrawals: unstated; Age: 14–32 y. TCM Pattern: unspecified, but mentioned 'stagnation of blood in the medians' was most common pattern.                                                                      | Self-designed formula ( <i>Hua Yu Tong Mai Zhi Tong Tang</i> ) vs OCT ( <i>Yuan Hu Zhi Tong Jiao Nang</i> ).<br><br><i>Hua Yu Tong Mai Zhi Tong Tang</i> : <i>Danggui</i> ( <i>Radix Angelicae sinensis</i> ) 10 g, <i>Shishao</i> 12 g, <i>Baishao</i> ( <i>Radix Paeoniae latiflorae</i> ) 12 g, <i>Taoren</i> ( <i>Semen Persicae</i> ) 10 g, <i>Chuanxiong</i> ( <i>Radix Ligustici</i> ) 10 g, <i>Honghua</i> ( <i>Flos Carthami tinctorii</i> ) 10 g, <i>Xiangfu</i> ( <i>Rhizoma Cypri rotundi</i> ) 12 g, <i>Yanhusuo</i> ( <i>Rhizoma Corydalis</i> ) 15 g, <i>Yimucao</i> ( <i>Herba Leonuri heterophylli</i> ) 20 g, <i>Zelan</i> ( <i>Herba Lycopi lucidi</i> ) 15 g, <i>Xuejie</i> ( <i>Sanguis Draconis</i> ) 3 g, <i>Wulingzhi</i> ( <i>Excrementum Troglodyteri seu Pteromi</i> ) 15 g, <i>Gancao</i> ( <i>Radix Glycyrrhizae uralensis</i> ) 6 g. Herbal decoction, one dose daily.<br><br><i>Yuan Hu Zhi Tong Jiao Nang</i> : 3 pills, tid.<br><br>Both groups started from 4 days prior to bleeding for a period of 7 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

METHODOLOGICAL QUALITY OF  
INCLUDED STUDIESALLOCATION CONCEALMENT AND  
RANDOMISATION

Only two of the included trials described adequate methods of randomisation and allocation concealment, receiving an allocation score of A.<sup>18,32</sup> All other included trials received allocation scores of B or C. Poor compliance during clinical intervention was also noted.<sup>35</sup>

## BLINDING

Four included trials were single blinded;<sup>26,36-38</sup> three trials were double blinded.<sup>18,19,32</sup> The other included trials did not mention blinding at all.

## POWER CALCULATION

Only one included trial mentioned power calculation and stated that no formal statistical sample size calculation was made because this was a pilot study; it estimated a sample size for future study.<sup>18</sup>

INTENTION-TO-TREAT (ITT) ANALYSIS AND  
FOLLOW-UP

Only two included trials clearly reported the number of drop-outs and withdrawals,<sup>18,20</sup> although ITT analysis was not implemented, nor was it used in the other included trials. One trial reported that the exclusion of data from analysis was due to poor compliance and incomplete data; nevertheless, the information about drop-outs was unclear.<sup>39</sup>

Most included trials had two to three months of follow-up after the cessation of clinical intervention; four out of the 39 included trials did not report on any further follow-up.<sup>20,33,40,41</sup>

## Results

In summary, 39 randomised, controlled trials involving a total of 3475 women were included in the review. A number of the trials were of small sample size and poor methodological quality. Results for Chinese herbal medicine compared to placebo were unclear as data could not be combined (3 RCTs). Chinese herbal medicine resulted in significant improvements in pain relief (14 RCTs; RR 1.99, 95% CI 1.52 to 2.60), overall symptoms (6 RCTs; RR 2.17, 95% CI 1.73 to 2.73) and use of additional medication (2 RCTs; RR 1.58, 95% CI 1.30 to 1.93) when compared to use of pharmaceutical drugs (Figure 3). Self-designed Chinese herbal formulae resulted in significant improvements in pain relief (18 RCTs; RR 2.06, 95% CI 1.80 to 2.36), overall symptoms (14 RCTs; RR 1.99, 95% CI 1.65 to 2.40) and use of additional medication (5 RCTs; RR 1.58, 95% CI 1.34 to 1.87) after up to three months of follow-up when compared to commonly used Chinese herbal health products (Figure 4a–c). Chinese herbal

medicine also resulted in better pain relief than acupuncture (2 RCTs; RR 1.75, 95% CI 1.09 to 2.82) and heat compression (1 RCT; RR 2.08, 95% CI 2.06 to 499.18). For detailed and comprehensive analysis, please see the original publication at [www.thecochranelibrary.com](http://www.thecochranelibrary.com).

## Discussion

The review found promising evidence in the form of RCTs for the use of CHM in reducing menstrual pain in the treatment of primary dysmenorrhoea, with up to three months of effectiveness. No significant adverse effects were identified from the studies included in this review.

IMPACT OF AN INDIVIDUALISED  
APPROACH TO THE ROUTINE PRACTICE  
OF CHM

A key primary requirement of traditional treatment with CHM is that treatment needs to be tailored according to different patterns. Nineteen out of 39 included trials considered an inclusion criterion in relation to the TCM diagnostic pattern(s), and another 23 trials considered the influence of the pattern(s) (for example, a pattern was only treated by one correlating experimental herbal formula). In other words, the majority of included trials paid specific attention to the role of differentiated patterns defined in TCM diagnosis for primary dysmenorrhoea, because the patterns of primary dysmenorrhoea in TCM inform selection of treatment formulation. The patterns of 'stagnation of Qi and Blood', 'retention of Cold', 'deficiency of the Kidney and Liver' were the common diagnostic classifications of primary dysmenorrhoea in TCM diagnosis. In addition, 'stagnation of Blood' was the fundamental aetiology and pathological condition for primary dysmenorrhoea in TCM. This was in agreement with the majority of published diagnostic protocols in TCM.<sup>21,22,42,43</sup>

Overall, 23 trials used modified experimental Chinese herbal formulae in order to fit the different TCM diagnostic patterns, or selected a standard formula based on a defined specific pattern, that is, the individualised (tailored) treatment approach was employed. The results demonstrated promising evidence of effective pain relief for primary dysmenorrhoea. Whilst 16 trials did not consider a possible variation in patterns, the results still demonstrated the effectiveness of CHM in pain reduction with statistical significance. However, this review was unable to provide an explicit answer as to whether tailored treatment was more beneficial than standard formulae in the treatment of primary dysmenorrhoea.

## ADVERSE EFFECTS

Generally, the reviewed trials reported that CHMs for primary dysmenorrhoea were safe when compared with conventional

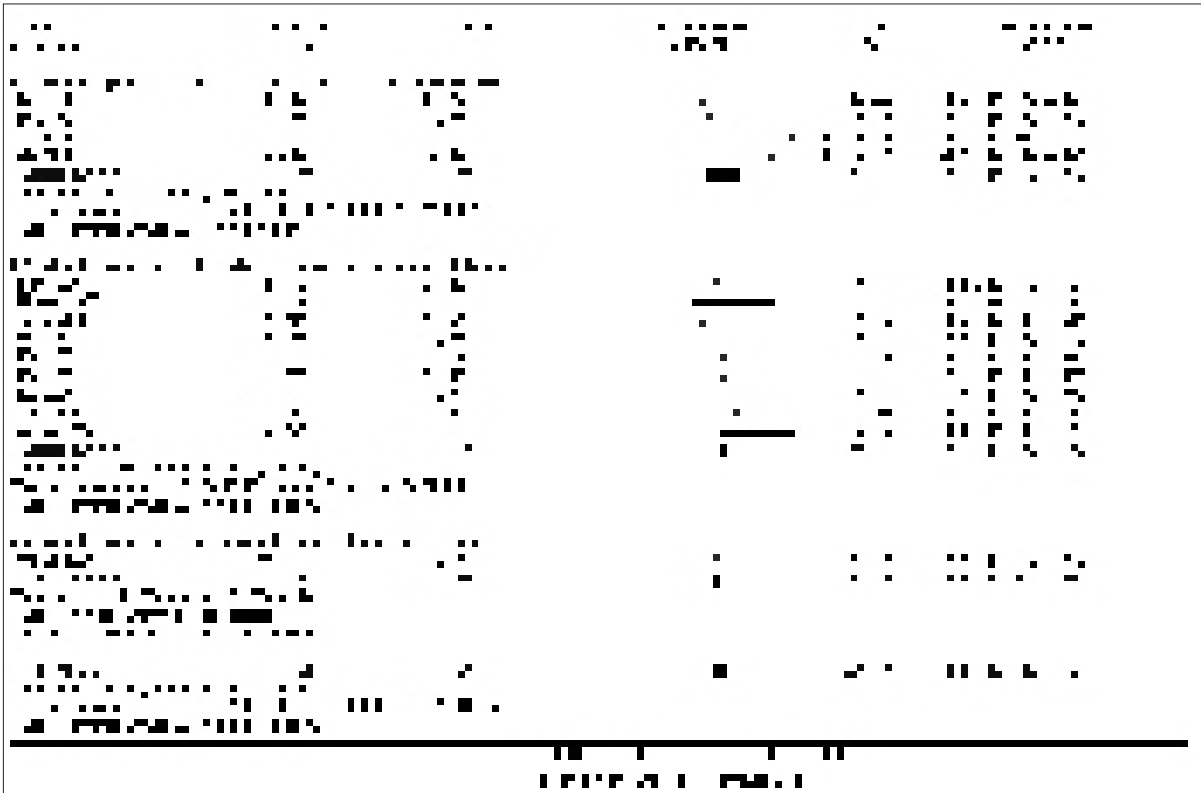


FIGURE 3a Meta-analysis results of Chinese herbal medicine for primary dysmenorrhoea when compared with conventional therapy (NSAIDs or over-counter products): Effects on pain reductions.

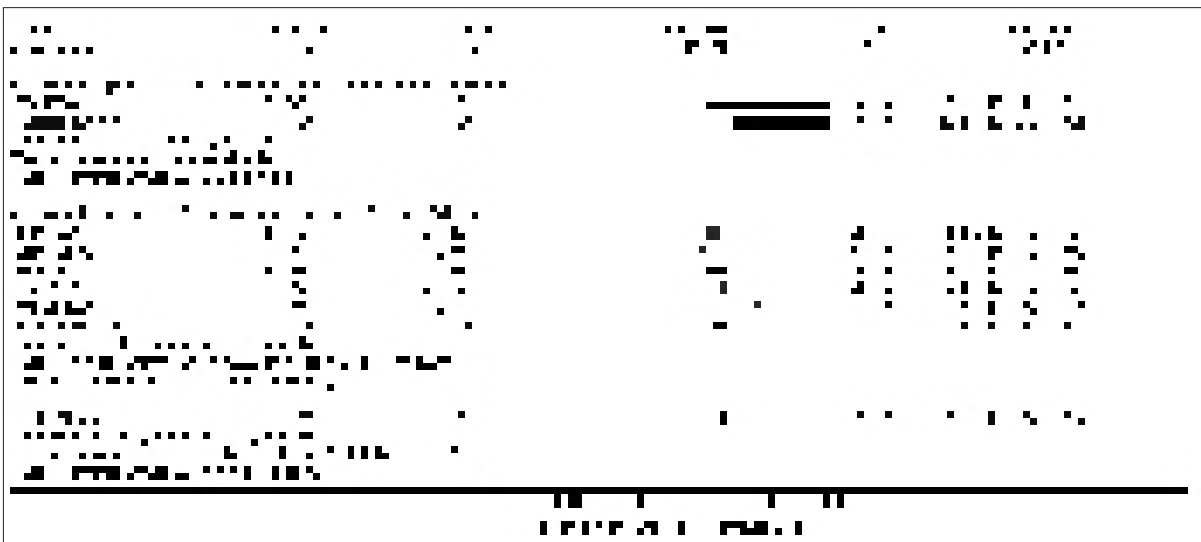


FIGURE 3b Meta-analysis results of Chinese herbal medicine for primary dysmenorrhoea when compared with conventional therapy (NSAIDs or over-counter products): Overall symptoms.

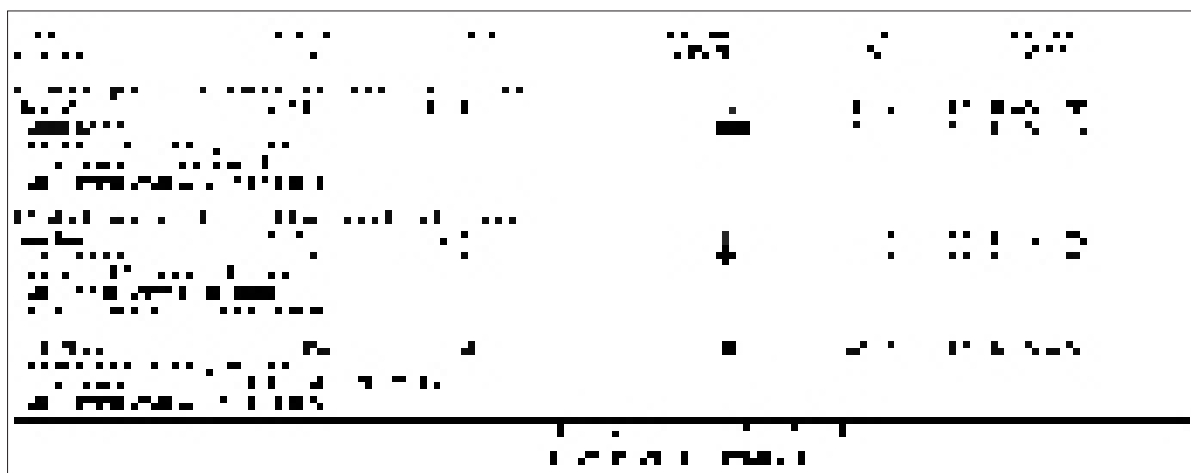


FIGURE 3c Meta-analysis results of Chinese herbal medicine for primary dysmenorrhoea when compared with conventional therapy (NSAIDs or over-the-counter products): Use of additional medication.

medicines. However, the attention to the safety of CHM in clinical practice was not addressed adequately in the reviewed trials. The measurement and reporting of adverse effects were poor; most trials neglected the fact that herbs are not risk free.

#### METHODOLOGICAL WEAKNESSES

The methodological quality of many trials included in this review was poor calibre. Only three out of the 39 trials clearly described their methods of randomisation and allocation concealment. The rest either did not state the methods or the methods were inadequate.

A consistent weakness of all the trials was their small sample size. Only one trial had more than one hundred participants. The small size reduces the likelihood of detecting any effect of an intervention in a single study, but given the similarities between studies, it makes meta-analysis of the data particularly valuable.

Placebo was seldom used in the trials (only three trials compared CHM with placebo). The lack of placebo trials affects the results, since typically a medicine's efficacy is established with placebo trials before comparisons are made with other drugs. With CHM this has not been the case. In addition, the lack of blinding in some trials had the potential to affect the results as it may give skewed results, if participants were aware of their treatment.

The measurement outcomes were generally subjective. Most of the trials collected the data by using descriptions of symptoms with no quantitative standards. Only four trials used numerical scales.

A possible publication bias has not excluded for this review as

the majority of trials reported positive effects of CHM in the treatment of primary dysmenorrhoea.

Overall, the review has found that an attempt towards evidence-based TCM practice has been made. However, more research trials with high-quality design are needed.

#### Reviewers' conclusions

The review found promising evidence for the use of Chinese herbal medicine in reducing menstrual pain in the treatment of primary dysmenorrhoea, compared to conventional medicine such as NSAIDs and the oral contraceptive pill, acupuncture and heat compression. No significant adverse effects were identified in this review. However, the findings should be interpreted with caution due to the generally low methodological quality of the included studies.

#### Acknowledgments

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#### POTENTIAL CONFLICT OF INTEREST

Xiaoshu Zhu recently completed a randomised, controlled trial of CHM for primary dysmenorrhoea. There are no other known potential conflicts of interest.

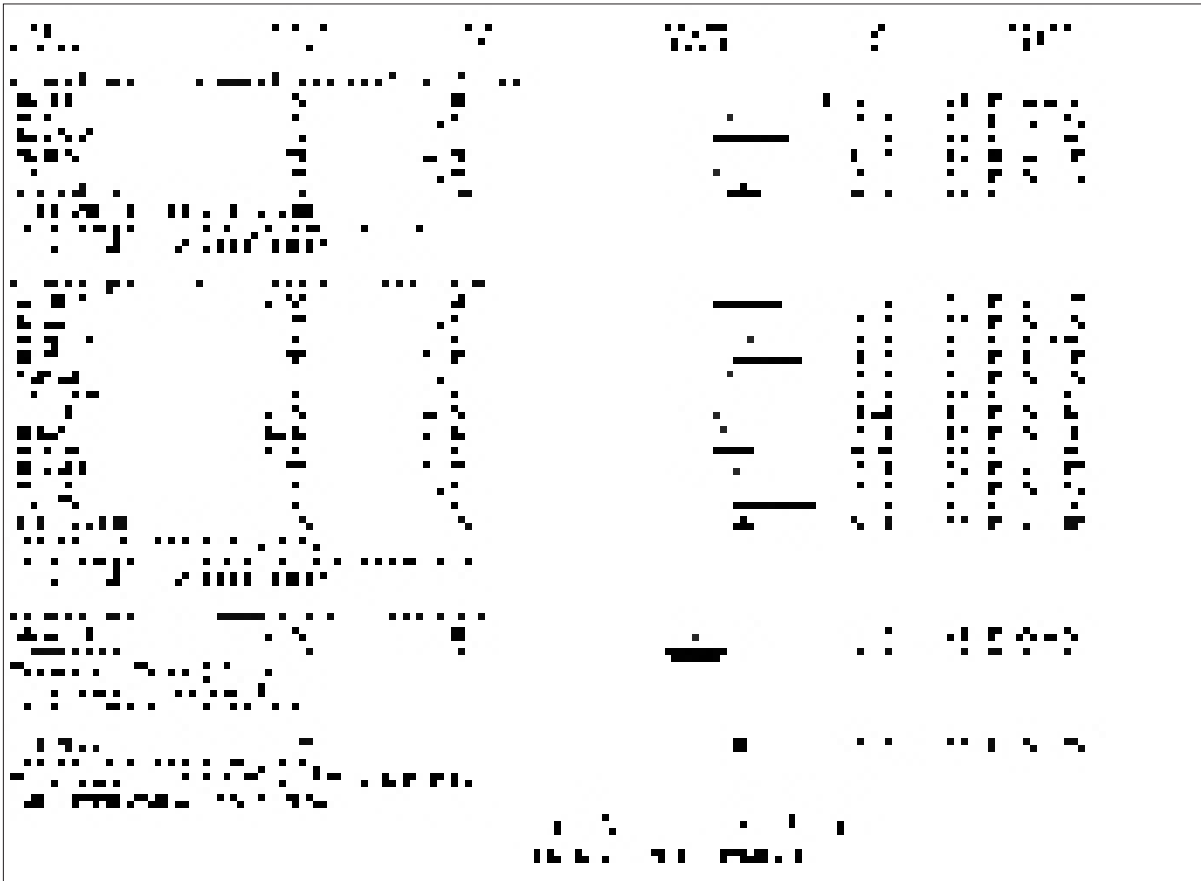


FIGURE 4a Meta-analysis results of self-designed Chinese herbal medicine for primary dysmenorrhoea when compared with over-the-counter or standard Chinese medicine herbal products: Effects on pain reduction.



FIGURE 4b Meta-analysis results of self-designed Chinese herbal medicine for primary dysmenorrhoea when compared with over-the-counter or standard Chinese medicine herbal products: Use of additional medication.

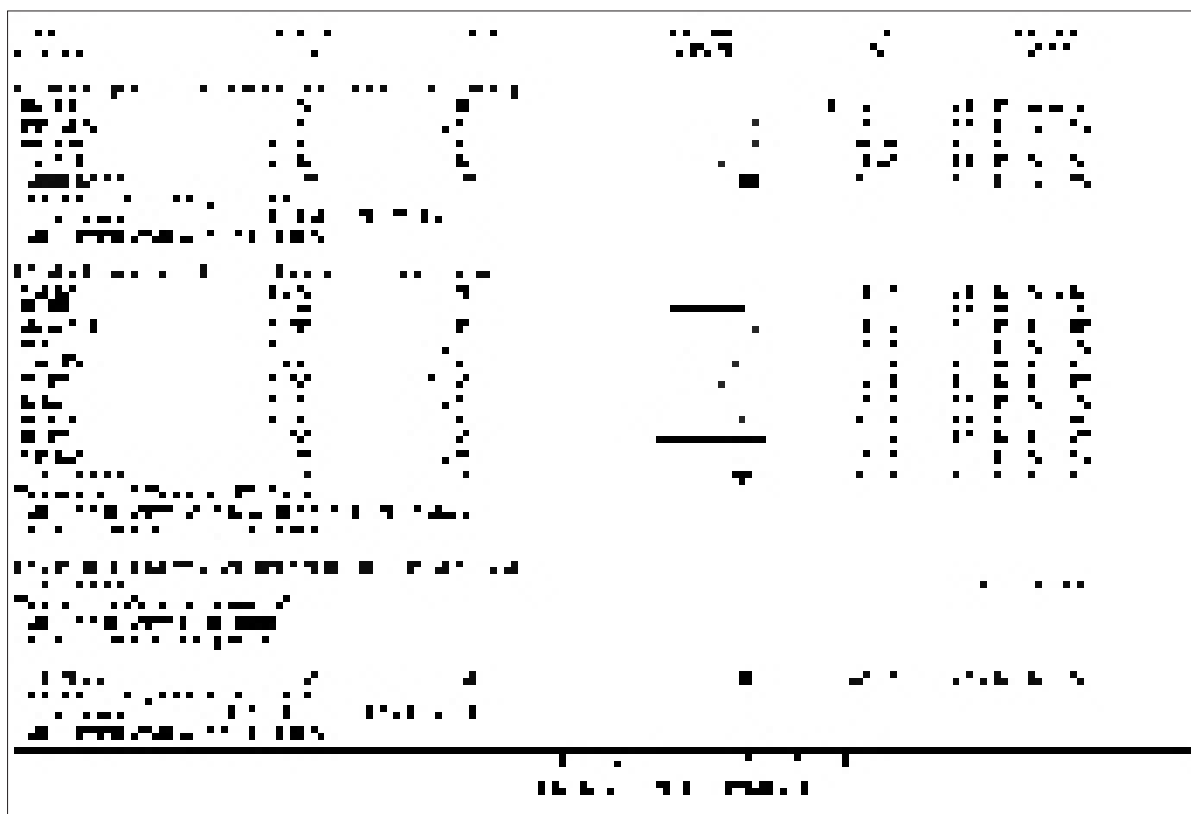


FIGURE 4c Meta-analysis results of self-designed Chinese herbal medicine for primary dysmenorrhoea when compared with over-the-counter or standard Chinese medicine herbal products: Overall symptoms.

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# Current Research and Clinical Applications

## Acupuncture as an Adjunct to Exercise-based Physiotherapy Does not Improve the Pain of Knee Osteoarthritis

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Osteoarthritis is the most likely underlying reason for knee pain in 70% of community-dwelling adults aged 50 or more.<sup>1</sup> A recent summary of systematic reviews by Smidt et al.<sup>2</sup> has concluded that exercise therapy, such as strengthening, stretching, and functional exercises, is effective for patients with knee osteoarthritis compared with no treatment. The chronic use of oral non-steroidal inflammatory drugs is discouraged because of their potential gastrointestinal side effects. A recent randomised, multi-centred and placebo-controlled clinical study by Foster et al.<sup>3</sup> indicates that the addition of acupuncture to a course of advice and exercise for knee osteoarthritis delivered by physiotherapists provides no additional improvement in pain. This study recruited 352 adult patients aged 50 or more with a clinical diagnosis of knee osteoarthritis from 37 physiotherapy centres accepting primary care patients referred from general practitioners within the Midlands and Cheshire regions of the United Kingdom between November 2003 and October 2005. The patients were randomised to receive advice and exercise only ( $n = 116$ ), advice and exercise plus true acupuncture ( $n = 117$ ), or advice and exercise plus non-penetrating acupuncture ( $n = 119$ ).

The acupuncture protocol was based on the concept of adequacy of

treatment, survey results, a consensus workshop and recommendations from traditional Chinese protocols.<sup>4</sup> For each individualised treatment session, six and ten acupuncture points from 16 commonly used local and distal points were selected. Local points were SP9 *Yinglingquan*, SP10 *Xuehai*, ST34 *Liangqiu*, ST35 *Dubi*, ST36 *Zusanli*, Ex-LE5 *Xiyan*, GB34 *Yanglingquan* and trigger points. Distal points included LI4 *Hegu*, TE5 *Waiguan*, SP6 *Sanyinjiao*, LR3 *Taichong*, ST44 *Neiting*, KI3 *Taixi*, BL60 *Kunlun* and GB41 *Zulinqi*. Sterilised disposable steel needles ( $30 \times 0.3$  mm) were used; the depth of insertion was 5–25 mm, depending on the points selected. Needles were manipulated to achieve the Deqi sensation (e.g. aching, warm or tingling sensation) and the therapists recorded the sensations in patients. The protocol permitted 25 to 35 minutes between insertion of the last needle and stopping treatment. The therapists revisited and manipulated the needles as appropriate. If the Deqi sensation was no longer present, the therapists were expected to use stronger manipulation, either rotation or thrust-and-withdraw techniques, to elicit it. Moxibustion, cupping, herbs or electroacupuncture were not allowed. The non-penetrating acupuncture was delivered through needles with a blunt tip. The shaft of these needles collapses into the handle,

creating an illusion of insertion. They meet the recommendations for acceptable controls for acupuncture research.<sup>5</sup> No attempt was made to elicit the Deqi sensation but participants were told they may experience sensations and to report what they felt. Researchers who collected, entered and analysed data were unaware of treatment allocation. By necessity the physiotherapists delivering the interventions were not blind to allocation.

The primary outcome observed was change in scores on the Western Ontario and McMaster Universities osteoarthritis index pain subscale (Likert 3.0)<sup>6</sup> at six months. Secondary outcomes included function, pain intensity and unpleasantness of pain at weeks 2 and 6, and months 6 and 12. The researcher recorded the number of patients in each group that achieved a clinically significant response according to criteria from the outcome measures in the Rheumatology and Osteoarthritis Research Society international initiative (OMERACT-OARSI). Side effects of treatment, adverse events and use of co-interventions were also recorded.<sup>7</sup>

The follow-up rate at month 6 was 94% and the baseline pain score was  $9.2 \pm 3.8$ . At six months, the reductions in pain score of patients receiving advice and exercise only, advice and exercise plus

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true acupuncture, and advice and exercise plus non-penetrating acupuncture were  $2.28 \pm 3.8$ ,  $2.32 \pm 3.6$ , and  $2.53 \pm 4.2$ , respectively. Mean differences in change scores between advice and exercise alone and each acupuncture group were 0.08 (95% confidence interval = -1.0 to 0.9) for advice and exercise plus true acupuncture and 0.25 (-0.8 to 1.3) for advice and exercise plus non-penetrating acupuncture ( $p > 0.05$ , by  $\chi^2$  test). Similarly, non-significant differences were observed at other follow-up points. However, there were small, statistically significant improvements in pain intensity and unpleasantness at weeks 2 and 6 for true acupuncture and at all follow-up points for non-penetrating acupuncture compared with advice and exercise alone. No adverse events occurred in the advice and exercise group or in the advice and exercise plus non-penetrating acupuncture group. Five adverse events were reported for participants receiving true acupuncture (pain, sleepiness, fainting, nausea and swelling around the treated knee).

### CLINICAL RELEVANCE

Patients with knee osteoarthritis prefer non-pharmacological options for pain relief and often choose complementary medicine approaches.<sup>8</sup> Acupuncture is one of the most popular options. However, clinical trials of acupuncture have been criticised for small sample sizes, inadequate blinding and lack of credible sham controls and long-term follow-up. Systematic reviews have concluded that acupuncture is more effective than placebo for osteoarthritis of the knee.<sup>4,9-11</sup> However, data on the benefits of adding acupuncture to other treatments, such as physiotherapy, for this population remain scant. In the present study by Smidt et al.,<sup>2</sup> acupuncture delivered by physiotherapists as part of an integrated package of health care with advice and exercise, for older adults with osteoarthritis of the knee, provided no additional improvement in pain scores compared with advice and exercise alone measured on the Western Ontario and

McMaster Universities osteoarthritis index at six and twelve months. This makes it different in several important aspects from those in previous trials of acupuncture for knee osteoarthritis which compared true acupuncture with sham acupuncture (including off-point needling),<sup>12</sup> ongoing stable medication,<sup>13</sup> waiting-list controls<sup>14,15</sup> or education alone.<sup>16</sup>

Smidt et al.<sup>2</sup> used fewer treatment sessions: six acupuncture treatments compared with 10–24 in previous studies.<sup>12-15</sup> The participants with a clinical diagnosis of knee osteoarthritis in this study are the patients seen in primary care, rather than those with a confirmed radiological diagnosis only, as used in other trials. Importantly, they used the credible acupuncture control of non-penetrating acupuncture at the same points as the true acupuncture rather than minimal depth needling at predefined distant non-acupuncture points. There is much debate within the acupuncture literature about the validity of sham acupuncture,<sup>17</sup> and given that a considerable proportion of participants in the non-penetrating acupuncture group reported sensations fitting the normal descriptions of Deqi, this intervention cannot be considered inert.

However, as the authors have pointed out, a potential limitation of this trial lies in its use of fewer treatment sessions than in previous studies of acupuncture practice, such as those from the United States<sup>16</sup> and Germany.<sup>15,18</sup> Nevertheless, the acupuncture protocols were developed to fit within current physiotherapy practice in the United Kingdom and the protocols met the minimum criteria for adequacy of acupuncture.

### CONCLUSIONS

The current study indicated that true acupuncture did not show any greater therapeutic benefit than a credible control procedure in patients with knee osteoarthritis; acupuncture was safe, with

few, minor adverse events; acupuncture provided no additional improvement in pain scores compared with a course of six sessions of physiotherapy-led advice and exercise. Small benefits in pain intensity and unpleasantness were observed in both acupuncture groups, making it unlikely that this was due to acupuncture needling effects, manual stimulation throughout treatment, and elicitation of the Deqi sensation. Further studies are warranted to investigate the underlying mechanisms of acupuncture, particularly the role of expectancy effects.

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# Acupuncture for Persistent Allergic Rhinitis

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This Australian study<sup>1</sup> was a randomised, single-blind, sham-controlled (sham needling) trial that investigated the effect of acupuncture on persistent allergic rhinitis (PAR). Eighty participants were randomised to either group and given 16 sessions of either acupuncture or invasive sham acupuncture (nearby non-acupoint sites with shallow needling). The primary acupoints used were LI 20 *Yingxiang*, Ex-HN 3 *Yintang* (midway between the medial eyebrows) and GB 20 *Fengchi*. In addition, Chinese medicine pattern differentiation was used to provide secondary acupoints: LI 4 *Hegu* for Lung Qi deficiency, ST 36 *Zusanli* for Spleen Qi deficiency and CV 6 *Qihai* for Kidney Qi deficiency patterns. Needle manipulation involving rotation (either supplementation or reduction) was applied and repeated at 10 minutes and prior to withdrawal of the needles. The primary outcome measure was self-assessed symptoms scores for nasal obstruction, sneezing, nasal itch and nasal discharge (rhinorrhoea). A secondary outcome measure was use of PAR relief medication.

Following eight weeks (two sessions per week) of treatment, results showed that the verum acupuncture resulted in a statistically significant reduction in the combined mean score of the nasal symptoms compared to the sham treatment at both the completion of the study and at follow-up of 12 weeks when compared to the sham acupuncture group. There was a significant reduction in use of PAR relief medication compared to baseline (within group comparison) at completion and at 12 weeks follow-up. This, however, was not significant when compared to the sham group (between-group comparison). Reported events included minor discomfort at the needling sites for 11 verum and eight sham acupuncture participants.

## CLINICAL SUMMARY

Sixteen sessions (two sessions per week) of needling should be administered to the acupoints LI 20 *Yingxiang*, Ex-HN 3 *Yintang* and GB 20 *Fengchi*. Pattern differentiation should be used to determine whether Lung, Spleen or Kidney Qi deficiency patterns are

present and the use of LI 4 *Hegu*, ST 36 *Zusanli* and CV 6 *Qihai* be administered if appropriate. Needle manipulation should be applied three times during the 25-minute treatment session. Patients should expect a decrease in symptoms such as nasal obstruction, sneezing and nasal itch with a greater reduction in nasal discharge (rhinorrhoea). These effects become apparent after eight sessions (at week 4). Patients may need to return for further treatment after a period of three months. Patients should also be informed that there may be some discomfort associated with the needling at some acupoint sites and that they may expect a reduction in the use of their PAR relief medication

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1. Xue CC, An X, Cheung TP, Da Costa C, Lenon GB, Thien FC et al. Acupuncture for persistent allergic rhinitis: a randomised, sham-controlled trial. *Med J Aust* 2007;187(6):337–41.

# Research Snapshots

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## ACUPUNCTURE ENHANCES IVF SUCCESS RATE

**OBJECTIVES:** To evaluate whether acupuncture improves rates of pregnancy and live birth when used as an adjuvant treatment to embryo transfer in women undergoing in vitro fertilisation.

**DESIGN:** Systematic review and meta-analysis. Eligible studies were randomised controlled trials that compared needle acupuncture administered within one day of embryo transfer with sham acupuncture or no adjuvant treatment, with reported outcomes of at least one of clinical pregnancy, ongoing pregnancy, or live birth. Two reviewers independently agreed on eligibility, assessed methodological quality and extracted outcome data.

**RESULTS:** Seven trials with 1366 women undergoing in vitro fertilisation were included in the meta-analyses. There was little clinical heterogeneity. Complementing the embryo transfer process with acupuncture was associated with significant and clinically relevant improvements in clinical pregnancy (odds ratio 1.65, 95% confidence interval 1.27 to 2.14; number needed to treat (NNT) 10 (7 to 17); seven trials), ongoing pregnancy (1.87, 1.40 to 2.49; NNT 9 (6 to 15); five trials), and live birth (1.91, 1.39 to 2.64; NNT 9 (6 to 17); four trials). The results were robust to sensitivity analyses on study validity variables. A pre-specified subgroup analysis restricted to the three trials with the higher rates of clinical pregnancy in the control group, however, suggested a smaller non-significant benefit of acupuncture (odds ratio 1.24, 0.86 to 1.77). **CONCLUSIONS:** The preliminary

evidence suggests that acupuncture given at the time of embryo transfer improves pregnancy and live births rates among women undergoing IVF. Manheimer reports a clinically relevant benefit and estimates that the number needed to treat is 10 in order to bring about one additional pregnancy. The subgroup analysis of three trials with higher pregnancy rates found a non-significant trend, suggesting the relative added value of acupuncture maybe reduced where baseline pregnancy rates are high. However, the numbers of women and trials included in the review is small, and further research is needed. This review is important because it paves the way for future clinical research to further examine the effect of acupuncture on pregnancy rates.

*Manheimer E, Zhang G, Udoff L, Haramati A, Langenberg P, Berman BM, Bouter LM. Effects of acupuncture on rates of pregnancy and live birth among women undergoing in vitro fertilisation: systematic review and meta-analysis. BMJ 2008;336(7643):545-9.*

## ACUPUNCTURE REDUCES DYSMENORRHOEA AND IMPROVES QUALITY OF LIFE

Dysmenorrhoea is the leading cause of time off school in adolescent girls and a common problem in women of reproductive age. The prevalence rates ranged from 18 to 81% depending on the measurement method used. **OBJECTIVES:** The aim of this clinical trial was to investigate the clinical effectiveness and cost-effectiveness of acupuncture in patients with

dysmenorrhoea. **STUDY DESIGN:** The trial was undertaken in Germany. In a randomised, controlled multi-centre trial plus non-randomised cohort, patients with dysmenorrhoea were randomised to acupuncture (15 sessions over three months) or to a control group (no acupuncture) who received acupuncture after three months. Patients who declined randomisation received acupuncture treatment. All subjects were allowed to receive usual medical care. Inclusion criteria included: age 18 or more years (age between menarche and menopause); primary dysmenorrhoea from the start of the menarche onwards or secondary dysmenorrhoea (for at least 12 months) with cramping pain during menstruation; written informed consent. Exclusion criteria were pain caused by inflammatory or malignant diseases. Each patient received a maximum of 15 acupuncture sessions. The number of needles and the acupuncture points used were chosen at the physicians' discretion. Only needle acupuncture (with disposable single-use needles and manual stimulation) was allowed; other forms of acupuncture treatment such as laser acupuncture were not permitted. **RESULTS:** Of 649 women (mean age  $36.1 \pm 7.1$  years), 201 were randomised. After three months, the average pain intensity (NRS 0-10) was lower in the acupuncture compared to the control group: 3.1 (95% CI 2.7; 3.6) vs 5.4 (4.9; 5.9), difference -2.3 (-2.9; -1.6);  $p < 0.001$ . In 11.8% of patients ( $n = 59$ ) a total of 70 side effects were reported after receiving acupuncture (74.3% minor local bleeding or haematoma, 10% pain (e.g. needling pain), 4.3% vegetative symptoms, and 11.4%

other). No life-threatening side effects were reported. The acupuncture group had better quality of life and higher costs (overall ICER €3011 per QALY). **CONCLUSION:** Additional acupuncture in patients with dysmenorrhoea was associated with improvements in pain and quality of life as compared to treatment with usual care alone and was cost-effective within usual thresholds. However, neither providers nor patients were blinded to treatment. Therefore, a bias due to unblinding cannot be ruled out.

Witt CM, Reinhold T, Brinkhaus B, Roll S, Jena S, Willich SN. *Acupuncture in patients with dysmenorrhea: a randomized study on clinical effectiveness and cost-effectiveness in usual care. Am J Obstet Gynecol. 2008;198(2):166.e1–8.*

#### NO DIFFERENCE BETWEEN DEEP OR SHALLOW NEEDLING

**OBJECTIVES:** The primary aim of this investigation was to compare the brain activation in response to deep and shallow acupuncture needling by utilising fMRI scans. **STUDY DESIGN:** Seventeen right-handed healthy volunteers were randomly allocated to receive either deep (8–12 mm) or shallow (1–2 mm) needling with Deqi on LI4 Hegu. Two fMRI scans were conducted to measure the increases (activations) and decreases (deactivations) in the blood oxygen level dependent (BOLD). **RESULTS:** The study demonstrated marked similarities in BOLD signal responses between two groups. **CONCLUSION:** There was no significant difference between the groups. This result was consistent with equivalent therapeutic outcomes claimed by the proponents of either Japanese or Chinese styles of acupuncture.

MacPherson H, Green G, Nevado A, Lythgoe MF, Lewith G, Devlin R, Haselfoot R and Asghar AUR. *Brain imaging of acupuncture: comparing superficial with deep needling. Neurosci Lett 2008;434(1):144–9.*

#### IS IT ALL ABOUT SEX?

A recent article in the journal *Acupuncture in Medicine* suggests that, because women experience repeated painful visceral events such as menses and labour during their life, this could cause increased sensitivity and prevalence to pain. The authors went on to explain that women exposed to experimental stimuli generally reported greater intensity than men did. They hypothesise that, due to this history of repeated pain, this could be a contributing factor for women and may be one of the reasons they are more likely to suffer or experience painful conditions such as fibromyalgia, temporomandibular dysfunction, migraine, rheumatoid arthritis and IBS.

Lund T, Lundberg T. *Is it all about sex? Acupuncture for the treatment of pain from a biological and gender perspective. Acupunct Med 2008;26(1):33–45.*

#### ACUPUNCTURE REDUCES PELVIC AND BACK PAIN IN PREGNANCY

**OBJECTIVES:** The objective of the study was to review the effectiveness of needle acupuncture in treating the common yet disabling problem of pelvic and back pain in pregnancy. **RESULTS:** Three studies met the inclusion criteria. Two trials with a small sample size examined mixed pelvic and back pain, and one larger trial was on pelvic pain only. The authors found in the two smaller studies that acupuncture as an adjunct to standard treatment was superior to standard treatment alone or physiotherapy in relieving mixed pelvic and back pain. In the larger study, they found that acupuncture in combination with standard care had greater relief than standard care alone or standard care and stabilising exercises. Reported adverse events were minor and few. The authors used a narrative synthesis due to significant clinical heterogeneity between trials. **CONCLUSION:** The authors concluded that limited evidence supports acupuncture in the treatment

of pelvic and back pain in pregnancy. Additional high-quality trials are needed to test the existing promising evidence for this relatively safe and popular complementary therapy.

Ee CC, Manheimer E, Pirota MV and White AR. *Acupuncture for pelvic and back pain in pregnancy review. Am J Obstet Gynecol 2008;198(3):254–9.*

#### BANXIA HOUPIU TANG PREVENTS PNEUMONIA AND RELATED MORTALITY IN ELDERLY PEOPLE WHO HAD DEMENTIA

**OBJECTIVES:** In this prospective, double-blinded, randomised, controlled trial, the authors evaluated whether the traditional Chinese herbal medicine formula *Banxia Houpu Tang* (BHT, *Banxia, Zhuling, Houpu, Zisu, Ganjiang*) prevented pneumonia and related mortality in elderly people who had dementia. **METHODS:** Ninety-five participants (mean age 84.0) with dementia due to cerebrovascular disease, Alzheimer's disease, or Parkinson's disease from two long-term care hospitals in Japan were randomly assigned to the BHT treatment ( $n = 47$ ) or the control group ( $n = 48$ ) and took BHT or placebo for 12 months. The occurrence of pneumonia, related mortality and the daily amount of self-feeding were recorded. **RESULTS:** Out of 92 patients who completed the study, four in the BHT group developed pneumonia, in comparison to 14 patients in the control group. The number of patients who died from pneumonia was one and six in the BHT and control groups, respectively. There was a statistically significant group difference. BHT reduced the risk of dementia patients developing pneumonia by 50% ( $p = 0.008$ ). No adverse events were observed from treatment with BHT. The BHT group also self-fed better than the control group did ( $p = 0.006$ ). **CONCLUSION:** BHT reduced the risk of pneumonia and pneumonia-related mortality in older patients with dementia.

Iwasaki K, Kato S, Monma Y, Niu K, Ohnri T, Okitsu R et al. *A pilot study of Banxia Houpu Tang, a traditional Chinese medicine, for reducing pneumonia risk in older adults with dementia.* *J Am Geriatr Soc* 2007;55(12):2035–40.

#### CHINESE HERBAL MEDICINE ELIMINATES LONG-STANDING MODERATE-TO-SEVERE ATOPIC DERMATITIS IN CHILDREN

**OBJECTIVES:** In this clinical study, the authors aimed to assess the efficacy and tolerability of a Chinese herbal medicine concoction (TCHM, *Jinyinghua, Bohe, Mudanpi, Cangzhu and Huangbai*) in children with long-standing moderate-to-severe atopic dermatitis (AD). **METHODS:** Following a two-week run-in period, 85 children (mean age 11.7 years) with AD were randomly allocated to receive a 12-week treatment of either TCHM or placebo. The SCORing of Atopic Dermatitis (SCORAD) score, Children's Dermatology Life Quality Index (CDLQI), allergic rhinitis score, and requirement for topical corticosteroid and oral antihistamine were assessed at the baseline and at weeks 4, 8, 12 and 16 after treatment. Adverse events, tolerability, haematological and biochemical parameters were also recorded during the study. **RESULTS:** The mean SCORAD score reduced significantly in both groups, from 58.3 to 49.7 in the TCHM group, and 56.9 to 46.9 in the placebo group. However, there was no significant group difference. The CDLQI in TCHM-treated patients was significantly improved and the amount of topical corticosteroid used was reduced by a third in the TCHM group, significantly better than the placebo-control group. The results maintained for one to three months after the end of the treatment. No serious adverse effects were reported. **CONCLUSIONS:** The TCHM concoction is well tolerated. It is efficacious in improving quality of

life and reducing topical corticosteroid use in children with moderate-to-severe AD.

Hon KLE, Leung TF, Ng PC, Lam MCA, Kam WYC, Wong KY et al. *Efficacy and tolerability of a Chinese herbal medicine concoction for treatment of atopic dermatitis: a randomized, double-blind, placebo-controlled study.* *Br J Dermatol* 2007;157(2):357–63.

#### CHAIGE QINGRE GRANULE IS EFFECTIVE FOR ACUTE UPPER RESPIRATORY TRACT INFECTION (AURTI) OF WIND HEAT SYNDROME

**OBJECTIVES:** In this double-blinded, randomised controlled trial, the authors aimed to evaluate the safety and efficacy of *Chaige Qingre Granule* (CQG), a traditional Chinese compound herbal medicine, in treating acute upper respiratory tract infection (AURTI) of wind heat syndrome. **METHODS:** In phase II, 60 patients with AURTI of wind heat syndrome were randomly allocated to receive CQG (*Chaihu, Gegan, Huangqin, Mahuang, Shigao, Xinren, Gancao*) or *Fufang Shuanghua Granule* (FSG, *Jingyinbua, Lianqiao, Chuangxinlian, Banlangen*). In phase III, 112 patients were randomly allocated to receive the two treatments. The two groups were treated for three days and four times daily. No other treatment was allowed. Clinical signs and symptoms, adverse effect, blood, urine and stool test, hepatorenal function and electrocardiogram were examined before and after the treatment. **RESULTS:** After treatment, the percentage of patients experiencing 75% reduction of fever and other symptoms were 93.10% and 96.55% in the CQG group and the control group, respectively, in phase II; and 92.11%, 92.59%, respectively, in phase III. There were no statistical differences between the two groups. No adverse effects were found in the trial.

**CONCLUSION:** CQG is as effective and safe in treating acute upper respiratory tract infection of wind heat syndrome as the commonly used Chinese herbal medicine FSG.

Chang J, Zhang Y, Mao B et al. *A double-blind, randomized controlled trial of Chaige Qingre Granule in treating acute upper respiratory tract infection of wind heat syndrome [Article in Chinese].* *Zhong Xi Yi Jie He Xue Bao* 2007;5(2):141–6.

#### WUWEIZI CONTAINING HERBAL FORMULA MAY HAVE A HEPATOPROTECTIVE EFFECT

**OBJECTIVES:** This study aimed to explore the immunomodulatory effect of a Chinese herbal formula, KY88 (*Wuweizi, Chaihu, Yinchenhao, Jinqiancao, Fuling, Zicao, Baishao, Huangbai, Huangqin, Tianhuafeng*), on Hepatitis B surface antigen carriers. **METHODS:** Thirty-three asymptomatic Hepatitis B surface antigen carriers took two capsules of KY88 daily for two weeks. Full blood tests and liver function tests were conducted before and after. **RESULTS:** The circulating monocyte count dropped significantly after KY88 from  $0.72 \times 10^9/L$  at the baseline to  $0.57 \times 10^9/L$  at the end of the two-week treatment. The count stayed at a lower level for 8 weeks after the treatment. White blood cell, neutrophil and lymphocyte, however, did not change significantly after the treatment. **CONCLUSION:** The results indicate that KY88 may reduce self-inflicted host immune response to HBV and has a hepatoprotective effect.

Yip AYS, Loo WTS, Chow LWC. *Fructus Schisandrae (Wuweizi) containing compound in modulating human lymphatic system – a Phase I minimization clinical trial.* *Biomed Pharmacother* 2007;61(9):588–90.

# Book Reviews

## Yin Lin Gai Cuo (Correcting the Errors in the Forest of Medicine)

Translated and commented on by Yuhsin Chung, Herman Oving and Simon Becker  
Blue Poppy Press, 2007  
ISBN 189184539X

## Blood Stasis: China's Classical Concept in Modern Medicine

Gunter Neeb  
Churchill Livingstone, 2007  
ISBN 044210185X

Two recent related but different publications concern the Chinese medical concept of blood stasis. The first book is a complete translation of the *Yi Lin Gai Cuo (Correcting the Errors in the Forest of Medicine)*, originally written by Wang Qin-Ren, with the English version being translated and commented on by Yuhsin Chung, Herman Oving and Simon Becker. The book has two sections, the first being a translation of the original text and the second being a review of the contemporary clinical uses of Wang Qin-Ren's formulae. The original text, which was first published in 1830, is best understood as a 'foundational work in modern Chinese medicine' that introduced a number of important Chinese herbal formulae for treating blood stasis, such as Xue Fu Zhu Yu (Mansion of Blood Stasis-expelling Decoction) and Bu Yang Huan Wu Tang (Yang Supplementing Five [tenths] Returning Decoction).

Book 1 has 35 sections, each relating to a specific issue. Sections 1–7 focus on the anatomical revisions that Wang Qin-Ren made after observing corpses and dismembered criminals. Wang Qin Ren theorised that the dried blood (that collected in the area above the diaphragm, which he called the mansion of blood) observed in corpses was the source of most disease. These

sections are a fascinating read, especially when comparing these concepts to modern anatomy. There are numerous reproductions of the organs and ducts that assist the reader to understand Wang Qin-Ren's developing thesis. Sections 8–11 introduce the herbal therapy for blood stasis and outline the pathoconditions treated by the three major herbal stasis-expelling formulae, namely Tong Huo Xue Tang (Orifice-freeing Blood-quickening Decoction), Xue Fu Zhu Yu Tang (Mansion of Blood Stasis-expelling Decoction) and Ge Xia Zhu Yu Tang (Infradiaphragmatic Stasis-expelling Decoction). Sections 12–35 cover a variety of pathoconditions, including hemiplegia, scourge toxin, tugging wind, pox, pregnancy and impediment.

The text also has much to contribute to the clinical use of the herbal formulae, especially with the inclusion of Book 2. Here the translators have collected a variety of modern clinical reports that bring to life and explain in detail the nuances associated with the use of eleven of Wang Qin-Ren's formulae. The composition, preparation and original indications and modifications are given for each formula. This is then followed by modern functions and indications and an in-depth formula analysis and discussion. Several case reports from the

Chinese medical literature then follow that bring to life the clinical complexity of each formula.

A bibliography and glossary of comparative terminology (Pinyin, Chinese character, Eastland Press, 'Practical Dictionary' and Blue Poppy Press) complete the text and allow the reader to cross-reference technical medical concepts across different publishing terminologies. The translators have succeeded in producing a very scholarly and detailed translation of the text, with bilingual printing (Chinese and English in Book 1) for the adept readers of modern Chinese. The ample commentaries and endnotes from the translators explain and elucidate many of the technical concepts and theories in the text. It is evident that the three translators bring together a unique skill set that includes academic, clinical and English writing skills to produce a text that sets the standard for future translations of Chinese medicine texts.

*Blood Stasis* by Gunter Neeb covers very similar ground but is a lot broader in outlook than the previous book. Whilst acknowledging the integral contribution from Wang Qin-Ren to the concept of blood stasis, the author draws on older and contemporary Chinese medicine texts to produce a clinical manual on the Chinese condition of blood stasis. Section 1

relays the theoretical, historical and background knowledge of the concept of blood stasis both from a western and, more importantly, a traditional Chinese medicine perspective. The aetiology, diagnostic and syndrome differentiation, as well as principles of treatment, are explained in a clear and rational manner. Chapter 7 outlines 46 medicinals that are commonly used for blood stasis. Tables are included, detailing the pharmacological effects of the medicinals, as well as the more traditional Chinese medical concepts of their effect on channels, organs and site of action. Also included are summaries of the effects of combining blood stasis medicinals (Pei Yao) with other medicinals, such as exterior-relieving and Qi-strengthening medicines. Chapter 8 then introduces 32 commonly used formulae, outlining their composition, application, action, explanation and, where appropriate, suggested acupuncture treatment. Chapter 9 follows with 20 cases studies from famous ancient and modern TCM

practitioners that further elucidate the clinical usage of the blood stasis-expelling formula. The author has contributed a commentary for each case study that further examines the clinical reasoning underlying each case.

Section 3 (Chapter 10) again includes a translation of Wang Qin-Ren's *Yi Lin Gai Cuo*. Whilst covering similar ground to the previous text, the lack of commentary precludes the reader from a comprehensive understanding of some of the technical concepts associated with the text. Indeed, it is interesting to compare the two translations! Also included are excerpts from six other Chinese medical texts that contribute to the further understanding of the concept. The author has also included 63 colour tongue slides and sublingual photographs that exemplify blood stasis.

Finally, there are nine appendices, including glossaries for both technical Chinese and western medicine terms,

and lists of Chinese medicinals and their western pharmacological actions. Appendices 4 and 5 consist of an index of medicinals and formulae, a bibliography, a listing of eminent Chinese physicians and their works, and a short bibliography of the author's publications.

Together these two texts present a formidable foundation for the study of blood stasis for the western Chinese medicine practitioner. The importance of the first book lies in its ability to allow access to and an in-depth understanding of an English translation of a primary medical text that has contributed to the contemporary practice of Chinese medicine. The second book amasses a broader and more clinical perspective. Together these two books complement each other and give a comprehensive and authentic basis for the understanding and treatment of blood stasis.

*Reviewed by Chris Zaslawski*

## Currents of Tradition in Chinese Medicine 1626–2006

Volker Scheid  
Eastland Press, 2007  
ISBN 9780939616565

Volker Scheid, in his second book, sets out to look at the problem of tradition and Chinese medicine. He tackles questions such as 'how can a medical tradition with cultural roots very different from those in the West survive and even thrive in places as far afield as the US and the UK in the twenty-first century?' Scheid's method is to look at how medicine was actually practised in imperial China. This study carries us on a journey stretching from 1626 to 2006.

Scheid first provides as good an overall general picture of the development of Chinese medicine from the Song period until now as you will find in the English language. He draws on works in Chinese and English. His training as a historian means that he is able to tease out what is important for us to know. Scheid denies being a Sinologist, but I believe his love of Chinese medicine and his deep attachment to China bring new depths of nuance to the areas of both Chinese medicine studies and Chinese studies in general.

He then dives into a specific group of practitioners in China. This group came to be known as the Menghe current. This is where Scheid's attention to detail and his erudite scholarship really drew me in and stunned me. Scheid traces the lineages in detail from primary sources. He must have spent years going through old records and diaries, which most people would have found boring. From these old pages he has made these revered and amazing practitioners of imperial China come to life and made them real characters who we can identify with, as well as picking out their faults. We see these people – warts and all – in their daily practice and their daily lives, while we learn how they actually practised.

For those of us trained in the West, I believe that we are handicapped during our training by not having the stories that make it all real. A lot of the concepts are new and very abstract. We have discussed theories without really knowing the people who were the bearers of these traditions. This work makes it real. This is a story that humanises Chinese medicine.

Menghe is an area of China in Jiangsu. Many of our Australia-trained practitioners would be familiar with Nanjing, which abuts the Menghe area. Scheid goes on to show that the Menghe current had a huge influence on the development of the particular type of Chinese medicine that we are familiar with today. People as familiar to us as the recently departed and revered John Shen claimed to be part of the Menghe lineage.

The book comprises fourteen chapters, being a weighty study of the area. It is divided into three parts.

Part 1 deals with late imperial China, which formally came to an end in 1911. This period is fascinating as it represents imperial China in its maturity. Scheid shows us how the scholar-physicians reached a position of pre-eminence in Qing society.

Here we meet several families and learn of the beginnings of the Menghe lineage as embodied by people such as the famous Fei Boxiong. The scholar-physicians were at their peak in terms of respect, status and wealth. This was the last time that practitioners of Chinese medicine did not have to deal with the problem of what to do with western medicine. The scholar-physicians as paragons of virtue were confident and had their place in

the sun. This was not because of some mystical force which they inherited, but through hard work, a lot of study and, as Scheid shows us, through the ability to carry out the project of what it is to be human. Medicine was seen to be the art of compassion. Dripping through every page of this book is the idea that the never-ending project of self-cultivation or self-improvement sits at the heart of what it is to be a good doctor. Ethics, morality and good old-fashioned virtue were essential components of the project of medical practice.

Part 2 deals with republican China (the period from the fall of the Qing Imperial Court in 1911 until the end of the Nationalist Party rule in 1949). This period sees Chinese medicine moving into Shanghai. Scheid the historian gives us vignettes of the growth of Shanghai, now the largest city in China. We see the origins of its dynamism in these chapters.

We learn a lot about that giant of his time, Ding Ganren, and his medical clan and lineage. This was an intense period of questioning, not just in Chinese medicine, but Chinese thought in general. This was a period of turmoil in intellectual circles, one in which Chinese medicine nearly did not survive. We see how the practitioners of Shanghai and elsewhere cleverly negotiated the survival of Chinese medicine.

Part 3 looks at contemporary China and how the Menghe practitioners of Chinese medicine have managed the years of rule by the Communist Party, which took power in 1949. Maoist China saw sharp twists and turns in the fortunes of Chinese medicine and we see this through the stories of the survivors of the Menghe lineage. From

difficult beginnings an institutional infrastructure for TCM was established. Scheid summarises the vicissitudes of medicine in China and brings us to the present day. Here we meet revered practitioners such as Qin Bowei, Zhang Cigong and Cheng Menxue.

In the epilogue, Scheid signals a warning, and seems to be yearning for the preservation of the ineffable. His discussion is a poignant reflection on the things that make Chinese medicine valuable and precious.

A lurch towards the 'McDonaldisation' of Chinese medicine would mean the loss of diverse currents of practice. That this may have already happened is another debate. Paul Unschuld has already said that he thinks Chinese medicine is dead. He argues that we have cut off the cultural roots, which means we are as fossils fighting a losing battle. Scheid shows that there may be ways to avoid this fate.

This work is a very useful study for any practitioner who wants to know where it all came from. We can see where some of our professional antecedents lie. Scheid also grapples intensely with the question

of how such an antiquated discipline is still valuable in a different place and time. His analysis concludes that medical practice stretches backwards and forwards in place and time, that the practices of our forebears are as relevant today as forever, and that we are part of that tradition whether we may like it or not. Lack of space means I cannot do justice to his arguments in this review.

In his first book, *Chinese Medicine in Contemporary China*, Scheid argued that diversity and plurality are essential features of medical practice. He was able to show that modern-day TCM has its origins in complex machinations involving the very survival of Chinese medicine.

Scheid brings a new flavour to historical analysis as he is still a practitioner, seeing patients daily, fitting in his research around his clinical work. This added dimension obviates the shortcomings in the work of some medical historians who do not actually understand Chinese medicine in depth.

I found it such a fascinating read that I am on my fifth go and still finding things to chew over.

This is not a clinical handbook. Rather, it provides an intellectual framework to what it is that we are practising. It gives us context, gives us a place and argues how we can be potent practitioners and effective members of our profession and our communities. Medicine is more than just a tool. It is also a 'thread that allows people to establish connections, a tool for creating identities, and a strategy for accumulating capital and extending influence.' Nathan Sivin, in the foreword, points out that medical currents are not just bodies of theory and method, but networks of people diversely motivated.

The notion of the self, in relation to others and as an agency of transformation, generates potency as a practitioner and as a human being.

I believe this work is a beginning for more people in our field to do scholarly research that looks at what we are really doing. There are so many unanswered questions. Most of the history of Chinese medicine has not been analysed at the micro level – the level of human lives. This is a good start.

*Reviewed by James Flowers*

## The Practice of Chinese Medicine

Second Edition  
Giovanni Maciocia  
Churchill Livingstone, 2007  
ISBN 9780443074905

The new edition of Giovanni Maciocia's *The Practice of Chinese Medicine* arrived at the clinic the other day. On opening the package, the first thing I noticed was that this book is almost a third thicker than the first edition. For those who have not read the first edition, it covered aetiology, channels, diagnosis, differentiation and treatment, prognosis and prevention, western differential diagnosis with Chinese medicine treatment strategies using acupuncture and Chinese herbal therapy for various common acute and chronic conditions.

This second edition is quite a shift from the previous one, first published twelve years ago. Expanded and updated, some of the chapters have new sections on pathology, treatment strategies and principles of point selection, as well as modern Chinese literature, reports of clinical trials and patient statistics from the author's own clinic. These have all added depth to the chapters. At the end of each section are summaries clearly outlining the important messages. Additional pictures and diagrams, as well as boxes with updated clinical notes

and important information related to the subject, make this new edition more user friendly.

Also new are the fourteen additional chapters that include depression, anxiety, goitre, hypertension, nausea and vomiting, acid reflux, stomach ulcers, urinary retention, interstitial cystitis, benign prostatic hyperplasia, prostatitis, fibromyalgia and erectile dysfunction. The chapter on mental-emotional problems has been expanded, from one chapter in the first edition to eight chapters in this edition, adding depth to this important area of clinical practice.

Other changes include the removal of all patent Chinese herbal products because the author is concerned with quality assurance and the use of banned or toxic contents or western drugs in some of the herbal products. Original herbal formulae containing banned products in some countries are however included, as the author feels that listing them allows the practitioners to see the functions of these herbs and gives them sufficient information to find appropriate

substitutes. In addition, the names of some chapters have been changed to reflect improved understanding of some clinical conditions.

The new edition is in hard cover and printed on quality paper, which is the norm for this publisher and author. The book is printed in a two-tone colour, making it easy and quick to identify important areas.

This well laid-out book with excellent texts is easy to use, and suitable for Chinese medicine students and practitioners. To quote from another new book edited by Hugh MacPherson, *Acupuncture Research*, 'One of the key characteristics of a profession is the ownership of a unique body of knowledge that informs professional practice and is constantly reviewed, renewed and augmented by the profession itself.' This beautifully presented text by Maciocia has clearly achieved this outcome.

*Reviewed by John Deare*

# Conference Reports

## Third International Congress on Complementary Medicine Research (ICCMR)

Sydney  
29 to 31 March 2008

**John Deare**

On the last weekend of March 2008, I represented the Australian Acupuncture and Chinese Medicine Association (AACMA) at the Third International Congress on Complementary Medicine Research (ICCMR), held at the Sydney Convention and Exhibition Centre. Complementary medicine is a complex and broad area, consisting of many modalities of health practice. The organising committee did their best not to be biased towards any therapy.

The program was extensive, ranging across the complementary medicine spectrum, from research to policy. About 600 delegates and speakers from Australia, New Zealand, USA, Canada, China, Hong Kong, India, Japan, Korea, Malaysia, Taiwan, UK, Germany, France, Norway, Denmark, Austria, Switzerland, Netherlands, Romania and Iran attended the conference.

The conference started with pre-conference workshops on Saturday at a number of universities and a hospital around Sydney. The workshop subjects covered herbal medicine and globalisation of traditional Chinese medicine (TCM), herbal medicines for brain and behaviour (from bench to bedside), TCM practices and research, chiropractic and mind-body medicine.

The vast volume of research on complementary medicine was presented at the plenary sessions and the concurrent symposia during the two-day conference. On Sunday you could have chosen from any of the following areas: TCM and acupuncture, complementary and alternative medicine (CAM) and cancer, safety and pharmaco-vigilance of herbal medicine, cross-disciplinary approaches to CAM evaluation, Ayurveda and other therapies for metabolic syndrome, the international harmonisation of CAM, or clinical trial methods. Monday continued the feast of choice with symposiums ranging from acupuncture and TCM, chiropractic and mind-body medicine, integrative medicine in action, CAM practice, evidence, herbal medicine quality and efficacy, paediatric CAM, social and qualitative research, Tai Chi and exercise therapy, pain/inflammation/psychobiology and integrating CAM into curricula and post-graduate training.

For me, perhaps the most interesting presentation that I saw was 'A review of meditation RCTs – important insights for future research'. Dr Manocha from the University of New South Wales undertook a review of RCTs published in English-language peer-reviewed journals. He concluded that there was

no strong or reliable evidence for its specific effect. The main problem was the definition of the term 'meditation', inadequate statistical analyses and poor methodology in the design of sham medication. This reminded me of the similar problems with acupuncture research.

At the closing session, Professor Bensoussan from the National Institute of Complementary Medicine outlined the main difficulties in complementary medicine research in Australia. Evidence is what is needed; however, less than 0.2% of the net sales of the complementary medicine industries was used for research. He praised the efforts of AACMA in establishing research grants to stimulate studies into Chinese medicine in this country, and thought AACMA had set a good example for other industries and complementary medicine professions.

As I got on the plane to come home, I have to admit that the mind was full, and I was wiped out from trying to take it all in.

## The Status and Future of Acupuncture Research: 10 Years Post NIH Consensus Conference

Baltimore, Maryland, USA  
8 to 11 November 2007

**Zhen Zheng, Caroline Smith and Chris Zaslowski**

### GENERAL INTRODUCTION

The Society for Acupuncture Research 2007 Conference was held from the 8th to the 11th of November 2007 in Baltimore, USA. The theme was to reflect on the achievements of acupuncture research in the ten years since the National Institutes of Health (NIH) published a consensus statement in 1997 on the safety and efficacy of acupuncture for a range of clinical conditions. The statement has since been considered as a White Paper to support the use of acupuncture in primary care and promote acupuncture clinical research in the United States and the world.

Data presented at the conference showed that since the publication of the Paper, the number of physicians who favour acupuncture in the US has increased from 50% to 80%, and the percentage of insurance companies giving rebates to acupuncture treatments has increased from 15% to 45%. More interestingly, in 1997, only 30% of acupuncture projects funded by the NIH had an acupuncturist on the team; by 2006, 100% of projects had research acupuncturists.

The four-day conference was stimulating and covered a range of topics, including research into acupuncture's mechanisms, clinical efficacy and qualitative studies.

More than 300 delegates from 20 countries took part in this special event. 250 abstracts were received by the conference organisers and 24 were accepted for oral presentations and 200 for posters. Three Australian researchers, all on the editorial board of this journal, presented at the conference. Each of

us agreed to summarise part of the conference and provide a brief report.

### CLINICAL EFFICACY OF ACUPUNCTURE

The second day of the conference focused on the latest scientific evidence from randomised controlled trials, systematic reviews and meta-analysis for a wide range of biomedical conditions. The scope was wide and included presentations from key researchers in the fields of osteoarthritis of the knee, back pain, headache and neck pain, women's health, cancer, mental health, respiratory disorders, gastrointestinal disorders, some neurological disorders, and a presentation from the German acupuncture research programs.

A key approach was to provide an overview of the evidence from clinical trials undertaken over the ten years since the NIH consensus statement. Several common themes emerged from many of the presentations. Firstly, conducting rigorous, high quality and robust randomised controlled trials remains a challenge. Secondly, we frequently heard from the presenters of a lack of a treatment effect between acupuncture and a sham acupuncture control. The majority of outcomes utilised in trials are clinically focused, and there is an absence of outcomes that reflect a more personal experience from treatment.

This stimulating day clearly demonstrated the contribution researchers have made over the past ten years towards developing an evidence base for acupuncture. However, the challenge remains given in many areas that our current research methodology

may not serve acupuncture well. There remains a need to consider the design of treatment protocols that reflect the everyday practice of acupuncture, and further careful consideration of appropriate study designs.

### BASIC RESEARCH

The third day of the conference focused on basic research of acupuncture. Latest research presented included the effects of acupuncture on chronic inflammation (Prof LX Lao), high blood pressure (Prof J Longhurst), female infertility (Dr E Stener-Victorin) and brain imaging (Drs Napadow and Harris).

In animals, electroacupuncture (EA) of 2 Hz on ST 36 *Zusanli*, ST 37 *Shangjuxu*, PC 5 *Jianshi* and PC 6 *Neiguan* reduced systolic blood pressure significantly more effectively than EA of 40 Hz or EA on LI 6 *Pianli* or LI 7 *Wenliu* did, indicating that the anti-hypertensive effect of EA is specific to acupuncture point and EA frequency. Frequency of EA is also an important factor on chronic inflammation. EA of 100 Hz produced a transient analgesic effect, whereas EA of 10 Hz included a long-term analgesic as well as anti-inflammatory effect.

I am most fascinated by the results of brain imaging research of acupuncture in humans. In healthy humans, each digit of our hand has its clear presentation in the somatosensory cortex of the brain. In patients with carpal tunnel syndrome, such presentation is unclear and the areas are merged so that the brain could not easily distinguish the sensation of one finger from another. After a course of acupuncture, patients reported reduced tingling and numbness and had enhanced

sensitivity in the affected hand. In such patients, the digit presentation in the brain became separated and mimicked the brain imaging of healthy humans.

A PET study on fibromyalgia patients showed that although both real and sham acupuncture reduced pain in these patients, the brain imaging induced by the two types of acupuncture interventions was different. Real acupuncture enhanced the efficiency of opioids in the brain regions related to pain whereas sham acupuncture did not.

As we are all aware, recently a few large clinical trials have found that real acupuncture produces a similar amount of pain relief to sham acupuncture (that is, needling shallowly on non-acupuncture points without Deqi). Results of such studies have led some people to believe that acupuncture is merely a powerful placebo. The above-mentioned PET study shows that the underlying mechanisms of real and sham acupuncture are rather different and the effect of acupuncture cannot be explained simply as placebo.

Basic research not only helps us understand how acupuncture works, but also guides our clinical practice by identifying ideal treatment parameters.

#### QUALITATIVE RESEARCH

The fourth and final day of the conference focused on the use of qualitative methods in acupuncture research. The first

presenter, Dr Claire Cassidy, argued that while clinical research was important for understanding how acupuncture works, it did not reflect the everyday experience in a real clinical setting. She acknowledged that measurable physiological changes were important, but the need to apply a mix of qualitative and quantitative methods in research would facilitate the whole exploration of the healing benefits of acupuncture. Both intention and expectation, she argued, must be factored into the design of studies. She then proceeded to layout a flow chart depicting the many 'decision points' inherent in the medical encounter even before "active" treatment begins and which affect outcome well after "active" treatment ceases. This perspective was also echoed by Hugh MacPherson, who argued the case for a 'whole system approach' for evaluating acupuncture. From this perspective, not only the specific effects of acupuncture contribute to the acupuncture effect, but also non-specific factors such as practitioner and patient beliefs, the clinical setting and the therapeutic relationship. Hugh is also a strong advocate for pragmatic trials which evaluate a treatment package, rather than parse out the specific effects of needling.

Charlotte Paterson also expressed a similar perspective. She presented some of the results of her research involving qualitative research methodology. Her presentation explored the views of patients who were enrolled in a clinical trial, and how dissimilar they were

when compared to the researcher's aims. Charlotte also argued the need for patient-centred outcomes in clinical trials, not just disease-focused measures.

The conference concluded with a presentation of the future directions of acupuncture research by Richard Hammerschlag from Oregon College of Oriental Medicine. Richard painted a futuristic picture of acupuncture research using an imaginary research institute. He then proceeded to extol the benefits of such an institute and said he hoped that such an institute would exist not too far in the future.

The conference closed with remarks from Rosa Schnyer (Co-president of SAR) who commented on the enormity of organising the event and thanked all the participants for attending. In retrospect, this was a 'once in a lifetime' event, where leading researchers from not only western countries like America and Australia, but also Korea, China and Japan, could meet, network and discuss the current state of acupuncture research. The SAR is to be congratulated on undertaking such an event. It also made us reflect on how the annual AACMA conference is also an important event for similar reasons. Without interaction and peer discussion the acupuncture profession will stagnate. Rigorous research, lively discussion and the generation of more questions than answers are sure indicators of a healthy, growing profession.

# Upcoming International Conferences

## 2008

- 23–25 May      Sydney, Australia  
**Australasian Acupuncture and Chinese Medicine Annual Conference (AACMAC)**  
Details: [www.acupuncture.org.au/AACMAC\\_2008.cfm](http://www.acupuncture.org.au/AACMAC_2008.cfm)
- 20–22 June      Wellington, New Zealand  
**New Zealand Register of Acupuncturists Annual Conference**  
Contact: [nzra@acupuncture.org.nz](mailto:nzra@acupuncture.org.nz)
- 27–29 June      Göttingen, Germany  
**International Congress for Biological Lasertherapy and Acupuncture**  
Details: [www.egla.de](http://www.egla.de); contact: [info@egla.de](mailto:info@egla.de)
- 14–18 August      Hong Kong, China  
**International Conference & Exhibition of the Modernization of Chinese Medicine Health Products**  
Details: [www.icmcm.com](http://www.icmcm.com)
- 14–17 October      Macau, China  
**5th International Congress of Traditional Medicine**  
World Federation of Chinese Medicine Societies (WFCMS)  
Details: [www.2008ictm.com](http://www.2008ictm.com)
- 16–20 October      Chicago, USA  
**American Association of Acupuncture & Oriental Medicine Annual Conference**  
Details: [www.aaaomonline.org](http://www.aaaomonline.org)
- 7–9 November      Beijing, China  
**WHO Congress on Traditional Medicine**

## 2009

- 22–24 May      Melbourne, Australia  
**Australasian Acupuncture and Chinese Medicine Annual Conference (AACMAC)**  
Details: [www.acupuncture.org.au/AACMAC\\_2009.cfm](http://www.acupuncture.org.au/AACMAC_2009.cfm)

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