

OS06.05

Clinical Evidence of Chinese Herbal Medicine for Treatment of Idiopathic Sudden Sensorineural Hearing Loss from Chinese Literature



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Purpose: To provide a comprehensive summary of all clinical evidence on Chinese herbal medicine (CHM) for idiopathic sudden sensorineural hearing loss (ISSHL) published in Chinese literature.

Methods: We systematically searched randomized clinical trials (RCTs), clinical controlled trials (CCTs), case series (CSs) and case reports (CRs) which reported CHM for ISSHL through four main Chinese electronic databases from their inception to March 2014. We bibliometrically analyzed the studies and assessed the methodological quality of RCTs using the Cochrane risk of bias tool.

Results: A total of 299 clinical studies with involving 22,237 participants were identified including 150 RCTs, 42 CCTs, 80 CSs and 27 CRs. The number of publications increased obviously per year from 1995, with the peak in 2011. Among 145 different herbal formulae tested, the most popular prescribed herbal formulae were Longdan Xiegan decoction and Tongqiao Huoxue decoction, and the top three frequently used Chinese herbs were Rhizoma Chuanxiong, Radix Bupleuri and Radix Puerariae Lobatae. The most frequently reported outcome was improvement of hearing in 286 (95.7%), followed by improvement of tinnitus (139, 46.5%), improvement of dizziness (99, 33.1%). Among the 150 RCTs, randomization methods were described in only 12 trials (8.0%). No trial reported allocation concealment and only four mentioned blinding. Among 146 RCTs (97.3%) and 37 CCTs (88.1%) reporting improvement of hearing as the outcome measurement, all showed significant difference favoring CHM. Of 16 trials reporting adverse events, only five trials reported mild adverse events related to CHM and the remaining stated that none had occurred.

Conclusion: The quantity of clinical research on CHM for ISSHL is substantial, but methodological quality of RCTs is generally suboptimal. Future clinical studies would need to report structurally and based on the CONSORT and TREND Statements. Quality of life, adverse events, depression and anxiety should be addressed as outcome measures.

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Empirical evidence for outcome reporting bias in randomized clinical trials of acupuncture: comparison of registered records and subsequent publications



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Purpose: To evaluate the consistency between the registered records and subsequent publications regarding outcomes and other data, and to determine whether outcome reporting bias favored significant primary outcomes.

Methods: We systematically searched 15 registries from their inception to January 2014 to identify randomized clinical trials (RCTs) on acupuncture that the status was listed as 'completed'. The subsequent publications were retrieved by searching PubMed and three Chinese databases. Basic characteristics and the registration information were extracted from registered records and publications. We performed comparisons regarding primary outcomes and other data between the registered records and publications to assess the consistency and selective outcome reporting.

Results: Eighty-eight trials on acupuncture with 96 publications were identified. Only 19.3% (17/88) were registered before the start of the trial. The trial registered number was not reported in 36 publications (25.9%). A comparison of registered and published primary outcomes could be conducted in 71 publications (74.0%), and the inconsistency of the primary outcomes was identified in 44.4% (32 of 71), mainly involving in registered primary outcome omitted in the publications (22/32, 68.75%), followed by registered primary outcome reported as secondary outcome in the publications (15/32, 46.9%). 71.4% (15 of 21) had a discrepancy that favored statistically significant primary outcomes while 28.6% (6 of 21) favored nonsignificant primary outcomes. Furthermore, the other inconsistencies between the registry records and publications involved in inclusion criteria (54.7%), exclusion criteria (47.9%), and control (22.9%).

Conclusion: We find that the proportion of retrospective registration for RCTs on acupuncture is high, selective outcome reporting is prevalent, and the change of primary outcomes intends to favor results with statistical significance. These discrepancies in outcome reporting may lead to biased and misleading results of RCTs on acupuncture. To ensure publication of reliable and unbiased results, further promotion and implementation of trial registration is still needed.

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Key elements of defining integrative medicine - a potential checklist for reporting^{*}



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Purpose: Drawing from the experience of experts in different geographical areas, including USA, UK, Australia, and China, this review identified the key elements which could be used to define IM and to explore developing a checklist for reporting IM in clinical trials.

Methods: A total of 54 sources were searched (including websites of governments, key authorities, representative clinical sites, academic journals, relevant textbooks) to identify definitions of IM from the four countries from 1990 - 2014. Key elements characterizing IM were extracted and categorized in a thematic approach in order to identify items to consider when reporting IM in research studies.

Results: Seventeen definitions were identified and extracted from 17 sources. The remaining thirty seven sources did not provide a definition of IM. The most common key elements which defined IM were: practitioner-patient relationship; using aspects of both CAM and conventional medicine; goals of health and healing; holistic approach; and optimum treatment. Integration was also defined at three levels: theoretical, diagnostic and therapeutic. A potential check list of items is proposed for reporting IM in clinical studies.

Conclusion: This paper identifies the key elements which define IM and provides a potential reporting guide for developing IM clinical trials which could be used in narrative/systematic reviews. Further debate, discussion and input is now needed from the research and clinical IM communities to further advance this agenda. Integrative medicine (IM, also called integrative healthcare) is a frequently used term, but there is no standard definition. Drawing from the experience of authors in four different countries (US, UK, Australia and China), this review aims to identify key elements to define IM; and begin to develop a potential checklist for reporting IM which could be developed for research purposes.

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A change of perspective: treatment for period pain using acupuncture alters how women view their menstrual cycle



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Purpose: Primary dysmenorrhea affects at least half of all women at some stage during their reproductive life (Latthe 2006). Due to its prevalence many women feel that period pain is a normal part of the menstrual cycle, this is often reinforced by views from friends, family and other medical professionals. In this study we sought to investigate if participating in a clinical trial using traditional Chinese medicine (TCM) acupuncture to treat primary dysmenorrhea changed women's attitudes in regards to their menstrual cycle and the normality of pain and other symptoms.

Methods: A purposive sample of 12 women from New Zealand who participated in a recent clinical trial investigating the effectiveness of three months of TCM acupuncture on the symptoms of primary dysmenorrhea. Women were invited to participate in one on one semi structured interviews. Transcripts were analyzed using thematic analysis.

Results: The overarching theme that emerged from the data analysis was "a change of perspective" which captured how participants felt participation in the study changed their perspective on their health, both in general and in relation to their menstrual cycle. Three major related themes were found; "Period Pain, a normal part of being a woman", "Treating more than just cramps" and "Making sense of my menstrual cycle". The themes include how women felt that the acupuncture wasn't only treating their period pain but affected a range of their menstrual symptoms. Women also felt that the explanations given by their acupuncturists about their period was different from what they had been told previously and this changed their perceptions on what a normal period was and how pain wasn't inevitable.

Conclusion: Based on this small sample, women who received TCM acupuncture found the TCM framework provided them with another way to view their body. This changed their perspective on their menstrual cycle and period pain.

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