

Stricter reporting for Chinese medicine clinical trials

August 7 2018



Ten years in the making, the updates aim to improve transparency, consistency and full disclosure of Chinese herbal medicine formula studies. Credit: Valentina Gabdrakipova | 123rf

The CONSORT (Consolidated Standards of Reporting Trials) Statement is an evidence-based set of recommendations for reporting the results of

randomized controlled trials testing clinical interventions. First developed by the international medical community in 1996, it was extended in 2007 to include guidelines for reporting the results of acupuncture trials.

Now, new recommendations have been added to the CONSORT Statement 2010 for reporting the results of [randomized controlled trials](#) involving Chinese herbal medicine (CHM) formulas. Ten years in the making, the updates aim to improve transparency, consistency and full disclosure of CHM formula studies.

CHM formulas usually contain more than two Chinese medical substances. They are prepared based on a patient's 'pattern': the summation of the cause, nature and location of pathological changes at a certain stage of disease.

The CONSORT Statement updates stipulate that diagnostic criteria must be specified when tested therapies target a pattern. Practitioners must also describe the specific contents of CHM formulas, including the dosage of each herb, the quality control methods applied, and the formula's safety profile.

The updates include a recommendation for using critical keywords in study reports to facilitate indexing CHM-related studies and searching for them.

"We were interested in this topic because tens of thousands of clinical reports on traditional Chinese medicine have been published but with poor general quality," says Zhaoxiang Bian of Hong Kong Baptist University's School of Chinese Medicine.

"Inadequate reporting not only compromises the values of Chinese herbal medicine, but also may affect reviewers' and readers' judgments

about the efficacy and safety of traditional Chinese medicine, inviting scepticism and criticism. As a result, clinical practice and patient care suffer," he explains.

The updates have undergone comprehensive feedback and review from researchers and practitioners. English, traditional Chinese and simplified Chinese versions of the recommendations were published in the *Annals of Internal Medicine*; the first time since the journal's launch in 1927 that three different language versions of a paper have been published.

The team next plans to introduce these updates to traditional Chinese medicine practitioners, researchers, peer reviewers and journal editors through a series of workshops and conferences. They will continue to gather feedback on the updates for future revisions.

More information: Chung-wah Cheng et al. CONSORT Extension for Chinese Herbal Medicine Formulas 2017: Recommendations, Explanation, and Elaboration, *Annals of Internal Medicine* (2018). [DOI: 10.7326/M16-2977](https://doi.org/10.7326/M16-2977)

Provided by Hong Kong Baptist University

Citation: Stricter reporting for Chinese medicine clinical trials (2018, August 7) retrieved 19 April 2024 from <https://medicalxpress.com/news/2018-08-stricter-chinese-medicine-clinical-trials.html>

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