The Importance and Necessity of Establishing Technical Specifications for the Registration of Traditional Chinese Medicine Clinical Studies

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Dear Editor:

Registration of clinical trials can prevent bias and make their reporting transparent, thus also improving their quality. As an illustration, JAMA, New England Journal of Medicine, and The Lancet stipulate that researchers must register their clinical trials before they submit their articles. This is also supported by the World Health Organization (WHO) and is written in the declaration of Helsinki. We propose that registration provides an opportunity for Traditional Chinese Medicine (TCM) to solve some of the current problems in TCM clinical studies.

As the number of TCM studies has increased greatly in recent years, their quality has been the focus of researchers' attention, with the finding that there is a large gap between the quantity and quality of TCM clinical studies. In the evaluation of 1452 randomized controlled trials (RCTs) of TCM, published between 1995 and 2005, it was reported that 103 (7.3%) had a correct randomization method and only 9 (0.6%) conformed to more than 50% of the items of the Consolidated Standards of Reporting Trials (CONSORT).¹ Another report, based on searching the Chinese biomedical database and the Cochrane library, found that only 100 (3%) of 31,590 RCTs had appropriate randomizing, concealing, and blinding.² Evidence-based medicine was introduced to TCM more than 20 years ago, and the quantity of systematic reviews has steadily increased. However, almost all systematic reviews conclude that there is insufficient evidence to draw conclusions and the studies are of poor quality. Similarly, in Chinese journals it has been found that international standards for methodological descriptions are not being met.³ Therefore, it is necessary when conducting RCTs for attention to be paid to improve the quality.

In order to explore study protocols, we collected TCM clinical studies registered in primary registries in the WHO registry network and in ClinicalTrials.gov of the U.S. National Institutes of Health. Several problems were identified. Firstly, all these registers are designed for Western medicine clinical studies. However, such designs cannot accommodate TCM's theoretical system, which influences diagnosis and treatments. For example, treatment principles, TCM syndrome types, types of intervention (acupuncture, decoction, parenteral administration of medicine, Chinese preformulated medicine combinations), and TCM-specific outcome evaluation are all

essential elements of TCM practice but cannot be included in the present format. Secondly, and most importantly, as yet no standard nomenclature exists for the registration of TCM clinical studies. This is particularly important for the correct identification of plant substances but also to understand concepts such as *yin*, *yang*, etc. In addition, we found examples of trials registered with ClinicalTrials.gov that after completion did not present the results and lacked details about the intervention. Furthermore, some content mentioned in protocols or registries differed from that which was finally published (e.g., NCT00741936).

Currently there are only two internationally recognized reporting guidelines specific to TCM: CONSORT-TCM and Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA). Therefore, in order to prevent bias and promote transparency in TCM clinical studies, we propose, pending expert consensus on their final form, the following extensions to trial registers, such as ClinicalTrials.gov:

- TCM studies should comply with current international standards and clinical study registration rules.
- Additional items should be included: Specific details of interventions used, TCM treatment principles, and syndrome differentiation, TCM-specific outcome measures for symptoms and syndromes (including symptoms scores and quality-of-life measures).
- Systematic analysis should be done of study registration details compared to postcompletion publications.

As TCM clinical studies become more established within international medicine research, their scientific standard needs further improvements. These proposals to alterations in clinical study registers will enhance the credibility and reliability of evidence for TCM.

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