

Quality Requirements for Real-World Studies of Traditional Chinese Medicine

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Traditional Chinese Medicine (TCM) has its own theory and methods for recognition and treatment of diseases that are very different from those of modern (Western) medicine. The history of TCM shows a great increase in clinical experience, but not much scientific reformation in thousands of years [1]. Although the effectiveness of TCM has been recognized around the world, the Western medical system cannot explain the concepts of TCM, such as the lines, distribution, and function of *meridians*. Disparities in the theoretical foundations of TCM and Western medicine have made it difficult to integrate these two systems in the development of medicine.

Randomized Controlled Trials of TCM

Evidence-based Medicine (EBM) was introduced in China in 1996 [1]; since then Chinese investigators have tried to conduct randomized controlled trials (RCTs) of TCM following EBM standards. For example, during 2007 and 2012 a total of 1341 clinical trial articles, including 387 articles on complex TCM interventions (decoctions, acupuncture, moxibustion, and massage), were published in the two main TCM journals, *Chinese Journal of Integrated Traditional and Western Medicine* and *Journal of Traditional Chinese Medicine* [2]. However, most RCTs of TCM were not consistent with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement. In a review of 3159 RCTs of TCM published before 2009, only 12%, 7%, and 19% of the articles in Chinese journals followed adequate methods of randomization, allocation, and blinding, respectively, compared with 25%, 26%, and 60% of those in English journals [3]. Other aspects of poor methodological quality included small sample size, lack of rationale for interventional components, lack of long-term outcomes, lack of compliance data, ambiguous component interaction, incomplete follow-up information, failure to quantitatively report the efficacy, and failure to include data on baseline characteristics or all side effects' profiles [1-3].

A TCM prescription usually involves a mixture of different bioactive compounds that have diverse functions and effects. Also, the prescription recipe highlights the overall condition of the individual patient and rather than focusing on a particular course of disease it applies a more holistic approach to treatment [1]. This might be a major reason why the RCTs of TCM cannot adhere to many items of the CONSORT requirements. On the other hand, the one-disease-one-drug concept in Western medicine might not be sufficient for the complexity of (chronic) disease occurrences and their therapies. Thus, complex herbal medicines may be able to play a significant role and result in efficient and safe prevention and treatment for such diseases or patterns [4].

Since the 1950s, the Chinese government has issued a series of national guidelines on TCM. However, few standards for the efficacy of TCM have been implemented, and description of usage, dosage, efficacy, and properties of TCMs are mainly based on TCM theories, not in accordance with EBM from modern scientific research [1]. Since 2005, recommendations to reflect the specificity of TCM research have

been revised according to the CONSORT check list and a series of draft CONSORT check lists for TCM intervention trials have been published [5].

Real-World Studies for TCM

Real-world study (RWS) (or real-world research) integrates patient-centered, data-oriented, and problem-driven techniques [6]. RWS enhances clinical practice and can be regarded as an applied stage between clinical practice and clinical trial. There are two main categories of RWS, pragmatic and observational (prospective or retrospective) [6,7]. To carry out valid and reliable research, in the stages of preparation, analyses, and reporting we should consider the data collection plan, identification of appropriate databases, clear outcome definition, bias minimization by rational study design, and data analysis using suitable statistical methods with adjustment for potential confounders or sensitivity analysis. However, till now, no RWS guidelines have been issued by Chinese TCM authorities. It is absolutely essential that specific ethical guidelines should be developed by the Chinese medicine regulatory authorities as called for by Wang [6].

Due to lack of institute facilities or research capacity in clinical settings in China, RCTs for TCM may be difficult to conduct, particularly if related to TCM theory. Also, because the narrow designs of RCTs remove important characteristics of patients, that is, real-life factors and comorbidities, responses in routine care patients may not be captured [8]. However, as information technology becomes widely utilized, after a large database has been accumulated, investigators are likely to access available data and conduct RWS without a *priori* specific research questions [9]. Then, RWSs may complement RCTs and provide opportunities to use real-life evidence to help guide patient care decisions, contributing greatly to promote TCM and the integration of TCM with Western medicine.

As with RCTs for TCM, however, the quality of RWS for TCM or integrated TCM should be seriously taken into account. Some of the EBM requirements like the CONSORT check list for TCM, even though not finalized, may be applicable to RWS for TCM. Other reporting guidelines are also good references for developing RWS guidelines including the statement on reporting studies using observational routinely-collected health data [9], the GRADE system (Grading of Recommendations, Assessment, Development and Evaluation) [10], the recommendations

for reporting adverse drug reactions of TCM by a Chinese EBM Center [11], standards for reporting clinical trials of acupuncture [12], and the quality standards for real-world research [7]. Clinicians and investigators who are trying to promote TCM have a responsibility to improve their research quality by following related requirements.

Although much research on TCM and integrative TCM and Western medicine has been conducted, still, the main publications are in Chinese journals, and only a few are listed on PubMed with English abstracts. We encourage Chinese researchers to publish their RWS articles (including the research protocols) in English in international journals. This sort of reporting practice will help improve their research ability by requiring them to understand and follow the global standards in Western medicine and will help propagate TCM with enhanced clinical implementation.

Conclusion

We believe that not only RCTs, but also RWS of TCM in clinical and community settings with adherence to EBM requirements, would benefit from quality improvement and could then provide more useful information for the health of people all over the world. We also appeal to the Chinese health authorities and relevant TCM associations to expedite the process of developing ethical and efficacy guidelines for conducting RWS. To solve clinical problems and increase knowledge about TCM, well-designed and completely reported RWS will help in the scientific reformation of TCM and to integrate TCM with Western medicine.

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