Perspectives

Acupuncture and Herbal Medicine

Improving the relevance and quality of clinical trials in traditional Chinese medicine

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Traditional Chinese Medicine (TCM) is an important part of the national healthcare systems and has the potential for transferability to other systems, with promising results for chronic pain, neurological disorders, and other conditions[1–2]. However, its credibility depends on the alignment of its holistic, individualized paradigm with international standards for trial design and reporting, careful formulation of relevant research questions, and movement toward patient and public involvement (PPI) and open science[3]. In the following sections, we expand on these points.

Keeping up with the standards

Although the first reporting standard, Consolidating Standards of Reporting Trials (CONSORT), was published in 1999, serious deficiencies in method and result reporting remain for clinical trials, including those related to traditional medicine[4]. A meta-epidemiological study of 476 acupuncture randomized controlled trials (RCTs) revealed that 65.3% failed to disclose conflicts of interest, and >50% omitted key details (eg, syndrome assessment protocols, randomization methods)[4]. "Spin," framing non-significant results as positive, is common, undermining result interpretability and synthesis into global systematic reviews[4].

Prospective registration (mandated by the International Committee of Medical Journal Editors [ICMJE] for trials enrolling first participants on or after July 1, 2005[5]) is inconsistently practised: 64.7% of TCM trials are unregistered and only 26.7% meet ICMJE's prospective standard[4]. Among registered trials (83.4% conducted in China *via* the Chinese Clinical Trial Registry [ChiCTR]), many lack critical details (eg, outcome measurement timelines), enabling selective reporting[6].

Nonetheless, general frameworks (eg, CONSORT) lack tailored provisions for TCM's unique elements: syndrome assessment, herbal quality control, and individualized intervention adaptation[4,7]. Existing TCM-specific extensions are limited in scope (eg, Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture [STRICTA], Case Report Guidelines [CARE] for Acupuncture), leaving researchers with unclear guidance on reporting field-specific nuances[8]. To address these gaps, comprehensive TCM-specific reporting guidelines extending CONSORT should be developed to cover syndrome assessment, herbal standardization, and intervention adaptation[7–8]. To improve completeness and reproducibility, journals should integrate these guidelines into their submission systems, requiring compliance for publication[4]. For trial registration, the prospective registration mandate of ICMJE should be strictly implemented, rejecting unregistered or retrospectively registered trials[5]. Routine audits of ChiCTR entries are also required to ensure completeness of TCM-specific details.

Asking the right questions

Core differences between TCM and RCTs manifest across key research dimensions (exemplified by the Population/Patient/Problem, Intervention, Comparison/Control, and Outcome [PICO] framework) but are not insurmountable. TCM defines populations by individualized "syndrome" (zhèng) patterns, delivers tailored interventions (eg, tailored herbal formulas and acupuncture protocols), and prioritizing holistic patient-centered outcomes, whereas RCTs rely on standardized disease classifications, uniform protocols, and objective surrogate markers rather than patient-reported outcomes (PROs), which may better reflect holistic treatment effects. These differences reflect contrasting paradigms: TCM's emphasis on individualization and wholeness, whereas RCTs focus on standardization and generalizability[1,9–11]. TCM further emphasizes the dynamic balance of the human body with its environment, requiring interventions to adapt to real-time syndrome fluctuations, whereas RCTs focus on isolating single disease/symptom effects with fixed, unmodifiable protocols to ensure internal validity[9–10]. These differences do not mean that TCM and RCTs are incompatible. Instead, they call for adaptive, syndrome-stratified, and pragmatic trial designs that

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How to cite this article: Duan YT, Franco JVA. Improving the relevance and quality of clinical trials in traditional Chinese medicine. Acupunct Herb Med 2026;6(2):139–140. doi: 10.1097/HM9.0000000000000196

Received 19 March 2026 / Accepted 31 March 2026

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maintain rigor while supporting individualized TCM practice. To address these paradigm differences, interdisciplinary work is needed to develop validated syndrome stratification tools, TCM-specific patient-reported outcome measures (PROMs), adaptive trial designs accommodating individualized TCM treatment, and statistical methods analyzing holistic effects[10]. It is also critical to mandate the use of evidence-based research approaches to avoid redundant studies and to ensure that trials align with existing systematic reviews and unmet clinical needs.

Meeting current expectations: open science and PPI

Open science standards emphasize transparent data management, public data sharing, reproducible analytical code, statistical scripts, and study protocols, along with full accessibility of research materials to enhance study reproducibility and transparency. However, such standards are rarely met in TCM trials: only 19.5% include a data sharing statement, with only 14.5% committing to sharing individual participant data (IPD) and 1.5% providing open-access links[4]. This violates, for instance, the *British Medical Journal* (BMJ)'s 2024 policy requiring anonymized IPD availability at publication[12], despite successful examples (eg, China's Science Data Bank hosting TCM trial data[13]). To improve data sharing, deposition of anonymized IPD should be mandated in recognized repositories (eg, Dryad and Science Data Bank) with stable digital object identifiers (DOIs)[12], eliminating vague "upon reasonable request" statements[14].

Furthermore, PPI is critical to ensure that trials address real-world needs; however, it is largely absent from TCM research. Globally, fewer than 20% of clinical trials included meaningful PPI[12], and TCM trials fare worse. Barriers include cultural perceptions of syndrome diagnosis as a "professional domain," resource gaps, and power imbalances[14]. Most TCM trials fail to meet the PPI disclosure requirements of top journals, leading to a misalignment between trial outcomes and patient needs[7,15]. To advance PPI, culturally adapted patients and public involvement are required, including patient involvement in syndrome validation and outcome co-design, with clear disclosure as per the BMJ guidelines[15].

Potential of TCM to enrich global healthcare is undeniable; however, it is highly dependent on the navigation of methodological differences, report strengthening, and transparency. These gaps are not inherent to TCM, but they reflect insufficient implementation and collaboration. Journals are central to driving change, which can be done by enforcing registration, mandating adapted reporting guidelines, and requiring open data and PPI disclosure, directly improving trial quality. Researchers and funding agencies can build a credible evidence base that respects the strengths of TCM while meeting global scientific rigor, benefiting patients worldwide.

Conflict of interest statement

The authors declare no conflict of interest.

Funding

None.

Author contributions

Yuting Duan contributed to writing-original draft. Juan Víctor Ariel Franco contributed to conceptualization, methodology, supervision, writing review and editing.

Ethical approval of studies and informed consent

Not applicable.

Acknowledgments

None.

Data availability

Not applicable.

Declaration of generative AI in scientific writing

The authors declare that no generative artificial intelligence (AI) technologies were used in the conception, drafting, or revision of this manuscript. All work was performed solely by the human authors.

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