

The Rome consensus: good clinical trials for traditional medicine

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Traditional Medicine (TM), particularly Traditional Chinese Medicine (TCM), is an indispensable component of the global healthcare system, offering unique insights to modern medical science. Clinical efficacy is the bedrock for the inheritance and development of TM. To meet the growing demand for high-quality healthcare, it is imperative to integrate TM with modern technology to address the issue of insufficient evidence for the efficacy of TM. To evaluate the clinical efficacy of TM, clinical trials are necessary, especially good clinical trials, which conform to the general principles of scientific research and also take into account the characteristics of traditional therapies. To promote the development of high-quality clinical trials that are in line with the features of TM, the attending experts held an in-depth discussion and reached the Rome consensus on "Good Clinical Trials for TM (GCT-TM)," at the 18th Academic Annual Meeting of the Clinical Efficacy Evaluation Committee of the World Federation of Chinese Medicine Societies and the 8th International Forum on Evidence-Based Chinese Medicine, held in Rome on June 26, 2025.

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Good question

A sound clinical trial begins with formulating a good clinical question—that is, developing a scientific hypothesis regarding whether a traditional therapy possesses specific clinical value, and establishing the necessity and justification for a new clinical trial. The formulation of a research question should be based on human-use experience that has revealed comparative advantages of a traditional therapy over conventional treatments. The benefits may manifest in areas such as: resolving issues that conventional treatments fail to address, enhancing therapeutic efficacy by supplementing conventional therapy, or improving safety by reducing adverse reactions from conventional treatments, among others. Therefore, before initiating a formal study, it is imperative to conduct real-world data analysis to delineate efficacy characteristics, including the target population, dosage, treatment duration, and outcome measures. Furthermore, a realistic pre-estimation of the effect size of a traditional therapy is crucial, neither overestimating nor underestimating it, as a reasonable estimate of effect size will allow calculation of an appropriate sample size. In short, formulating a good question should be grounded in solid clinical practice, previous research, and systematic deliberation.

Good design

To scientifically address a clinical question, a well-designed clinical trial is essential. A good clinical trial design should comprehensively consider ethical compliance, the fairness of comparison, patient adherence, and the feasibility of implementation. The type of design depends on the research question and the research stage.

Randomized controlled trials (RCTs), particularly pragmatic RCTs, are suitable for TM research, but they are not the only option. A good design is not about mechanically applying an RCT template, but rather systematically justifying and optimizing the PICO based on different research objectives and contexts. Clinical trial design requires a progressive maturation process. Generally, a good design should be built upon prior research or exploratory studies to establish the key PICO parameters, rather than hastily developing a large-scale confirmatory study protocol. Furthermore, the primary and secondary endpoints, sample size, and statistical analysis plan should be pre-specified before protocol registration to avoid issues of *p*-hacking or data dredging.

Good outcomes

The assessment of therapeutic effects relies on the scientific measurement of appropriate outcomes. Therefore, establishing outcomes that both reflect the therapeutic characteristics of TM and possess clinical significance is essential. Outcome selection should be patient-centered, prioritizing internationally endorsed Core Outcome Sets (COS) for specific health domains. When existing outcomes fail to capture the clinical value of a TM intervention, the development and validation of appropriate clinical outcome assessments (COAs), biomarkers, quality-of-life scales, and endpoint events are warranted. The selection of outcome measurement tools requires comprehensive consideration of their recognition, scientific validity, feasibility, and interpretability. In addition, the minimal important difference (MID) should be specified to ensure a clinically meaningful association between patient benefits and outcome changes.

Good collaboration

A high-quality clinical trial is a systematic project that requires synergistic collaboration among clinicians, patients, investigators, sponsors, and other stakeholders to ensure scientific design, standardized implementation, and data authenticity. To promote the global development of clinical trials for TM, it is necessary to strengthen overall coordination and establish a TM clinical trial community that collaborates on developing methodological standards and sharing research resources to construct a global ecosystem for high-quality clinical trials.

Rome was not built in a day. GCT-TM is an evolving process that requires both methodological innovation and extensive practice to establish a virtuous cycle. We call upon global experts in TM, as well as multidisciplinary specialists in evidence-based medicine, statistics, AI, and related fields, to strengthen collaboration. Together, we can make new contributions to promoting the high-quality development of TM and provide better evidence for human health!

Conflict of interest statement

Boli Zhang is the editor-in-chief of this journal, and Junhua Zhang, Alice J. Fauci, and Myeong Soo Lee are editorial board members of this journal. The other authors declare no conflict of interest.

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Author contributions

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Ethical approval of studies and informed consent

Not applicable.

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Data availability

All data generated or analyzed during this study are included in this published article.