Acupuncture and Herbal Medicine

The Rome consensus: good clinical trials for traditional medicine

Junhua Zhang[1,2], Boli Zhang[1,2,*], Alice J. Fauci[2,3], Myeong Soo Lee[4], L. Susan Wieland[5], Iman Majd[6], Terje Alræk[7,8], Linda Zhong[9], Sergio Bangrazi[10], Aldo Liguori[10], Jingqing Hu[1], Yanming Xie[11], Jianyuan Tang[12], Zhongqi Yang[13], Paolo Landini[14], Annalisa Bucchi[14], Weian Yuan[15], Kam Wa Chan[16], Filomena Petti[10], Carlo Maria Giovanardi[17], Jialiang He[18], Rui Gao[19], Baohe Wang[20], Yuhong Huang[21], Jia Liu[11], Fang Lu[19], Jianan Guo[18], Pasquale Ricci[22], Bo Pang[1,2,*]

[1]Tianjin University of Traditional Chinese Medicine, Tianjin, China; [2]Joint Sino-Italian Laboratory of Traditional Chinese Medicine, Italian National Institute of Health, Rome, Italy; [3]Italian National Institute of Health, Rome, Italy; [4]KM Science Research Division, Korea Institute of Oriental Medicine, Daejeon, Korea; [5]Division of Integrative Physiology, Department of Biochemistry and Cellular & Molecular Biology, Georgetown University School of Medicine, Washington, DC, USA; [6]Osher Center for Integrative Medicine, Department of Family Medicine, University of Washington, Seattle, WA, USA; [7]School of Health Sciences, Kristiania University of Applied Sciences, Oslo, Norway; [8]National Research Center in Complementary and Alternative Medicine (NAFKAM), Department of Community Medicine, Faculty of Health Sciences, UiT The Arctic University of Norway, Tromsø, Norway; [9]School of Biological Sciences, Nanyang Technological University, Singapore; [10]Paracelso Institute, Rome, Italy; [11]Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing, China; [12]Affiliated Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu, China; [13]The First Affiliated Hospital of Guangzhou University of Traditional Chinese Medicine, Guangzhou, China; [14]Department of Biosciences, University of Milan, Milan, Italy; [15]Shuguang Hospital of Shanghai University of Traditional Chinese Medicine, Shanghai, China; [16]School of Chinese Medicine, Hong Kong Baptist University, Hong Kong, China; [17]Italian Federation of Acupuncture Societies (FISA), Italy; [18]Italian Institute of Traditional Chinese Medicine, Italy; [19]Xiyuan Hospital of China Academy of Chinese Medical Sciences, Beijing, China; [20]The Fourth Affiliated Hospital of Tianjin University of Traditional Chinese Medicine, Tianjin, China; [21]The Second Affiliated Hospital of Tianjin University of Traditional Chinese Medicine, Tianjin, China; [22]Department of Life Sciences, Health and Health Professions, "Link Campus University," Rome, Italy

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.

*Corresponding author. Boli Zhang, E-mail: zhangbolipr@163.com; Bo Pang, E-mail: pangbo@tjutcm.edu.cn.

Received 31 July 2025 / Accepted 01 August 2025

Copyright © 2025 Tianjin University of Traditional Chinese Medicine. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

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.

Funding

None.

Author contributions

Junhua Zhang and Bo Pang are the main drafters of the manuscript. Boli Zhang, Alice J. Fauci, Myeong Soo Lee, L. Susan Wieland, Iman Majd, Terje Alræk, Linda Zhong, Aldo Liguori, Kam Wa Chan, Carlo Maria Giovanardi, Jialiang He, Baohe Wang, Yuhong Huang, Jia Liu, and Pasquale Ricci revised and provided critical version of the manuscript. Sergio Bangrazi, Paolo Landini, Annalisa Bucchi, Filomena Petti, and Jianan Guo helped with organization and dissemination. Jingqing Hu, Yanming Xie, Jianyuan Tang, Zhongqi Yang, Weian Yuan, Rui Gao, and Fang Lu helped with the methodological normalization. All authors contributed to the revision of the manuscript and approved the final manuscript.

Ethical approval of studies and informed consent

Not applicable.

Acknowledgments

None.

Data availability

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