

# From TCM–conventional medicine combination to integration: the driving role of evidence-based research

Jian-ping Liu<sup>1,2,✉</sup>

<sup>1</sup> Center for Evidence-Based Medicine, Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu, 610075, China

<sup>2</sup> Center for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, Beijing, 100029, China

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For over 70 years, the integration of traditional Chinese and conventional medicine has evolved from early cooperation into a national policy, reaffirmed in the 2026 National Health Plan.<sup>1</sup> Historically, conventional medicine has also been referred to as Western medicine. A key task for researchers today is to advance this field from experience-based to evidence-based practice.

## 1. From combination to integration: a conceptual evolution

The integration of traditional Chinese and conventional medicine is far from being a one-size-fits-all concept. Initially, the term combination referred to the two systems operating in parallel. In diagnostic practice, pairing conventional disease classifications (such as The International Statistical Classification of Diseases and Related Health Problems 10th Revision, ICD-10) with Chinese pattern differentiation is now routine, yielding a binary framework in which the same disease may present with varying patterns and vice versa. Therapeutically, the combined use of both modalities is the most common clinical approach. In the research arena, established methodologies, including good laboratory practice (GLP), good clinical practice (GCP), randomized controlled trials (RCTs), and systematic reviews, are now standard features of clinical investigations of traditional Chinese medicine (TCM).

Several clinical models exemplify this combination. In one, conventional diagnosis is paired with Chinese therapy, such as acupuncture, for Bell's palsy as an alternative to corticosteroids. In another, both diagnostic systems and therapeutic approaches are used together, an approach known as disease-pattern integration; a typical example is the combination of antiviral therapy with herbs that promote the free flow of liver-qi and relieve stagnation, used for viral hepatitis presenting with liver-qi stagnation and lowered function of the spleen. In a third, conventional medicine takes the lead, while TCM plays an adjunctive role, as seen in acupuncture for stroke rehabilitation. In a fourth, specific conventional treatments such as chemotherapy are supplemented with herbal formulas for cancer, combined with individualized Chinese decoctions selected according to pattern differentiation. Although these models have achieved encouraging results, they remain essentially additive; the two systems operate in parallel rather than as an integrated whole.

By contrast, integration signifies a deeper fusion that goes beyond mere addition. It places the patient at the center, aiming to merge the holistic, pattern-based perspective of TCM with the diagnostic precision and specific interventions of conventional medicine, thus shaping a novel healthcare model.

Internationally, the evolution of the term integrative medicine reflects a similar shift toward deeper synergy. As defined in authoritative reviews, integrative medicine is a healing-oriented paradigm that emphasizes whole-person health, while accounting for lifestyle and environmental interactions.<sup>2</sup> It is not simply the addition of traditional or complementary therapies to standard care; rather, it represents an evidence-informed synthesis of diverse approaches designed to comprehensively evaluate and support patient recovery.

This model requires practitioners to adopt a whole-person perspective, recognizing that health is determined by a range of factors, including biological, psychological, social, spiritual, and environmental, and acknowledging the therapeutic value of a strong patient-clinician relationship. This aligns with the three core elements of evidence-based medicine: the best research evidence, clinical expertise, and patient preferences. Moreover, integrative medicine provides patients with agency through actionable interventions such as dietary advice, physical activity, and stress reduction, transforming the dynamics from passive receipt of care to active participation. Ultimately, this is not a mere substitution of one set of tools for another but a profound shift in outlook—from treating a disease that happens to affect a person to caring for a person who has a disease.

## 2. Evidence-based methods: the cornerstone of integrative medicine

The conceptual advances in integrative medicine require robust scientific validation. A key question is how to convincingly establish whether integration offers advantages over combination therapy or monotherapy. Evidence-based medicine provides a methodological foundation, yet applying evaluation standards originally developed for single-agent drugs to complex integrative regimens is clearly inadequate. Therefore, we need to advance and adapt our methodological toolkit accordingly.

### 2.1. Leveraging real-world studies and pragmatic RCTs

Traditional explanatory randomized controlled trials (eRCTs) are conducted under tightly controlled, idealized conditions, with a focus on internal validity. However, their findings often fail to translate to the complexities

✉ Corresponding author.

E-mail address: [Liujp@bucm.edu.cn](mailto:Liujp@bucm.edu.cn) (JP. Liu)

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of routine clinical practice. In contrast, real-world studies (RWS) and pragmatic RCTs (pRCTs) evaluate overall effectiveness in everyday clinical settings, offering stronger external validity and better suitability for assessing complex integrative interventions. Tools such as Pragmatic-Explanatory Continuum Indicator Summary-2 (PRECIS-2) can help researchers shift trial design toward pragmatism across ten key dimensions, including participant selection, intervention flexibility, and outcome measurement,<sup>3</sup> making the results more directly applicable to clinical decision-making.

## 2.2. Conducting comparative effectiveness research (CER)

Given persistent constraints on healthcare resources, the question is no longer simply whether a therapy is effective, but whether it offers superior benefits or better cost-effectiveness relative to existing standard care. CER directly addresses this question by performing head-to-head comparisons of alternative treatment strategies in real-world clinical settings,<sup>4</sup> such as TCM versus conventional drugs, pharmacological versus non-pharmacological interventions, and Chinese versus ethnic minority medicines. Through systematic evaluation of benefits, risks, and costs, CER generates robust evidence to underpin reimbursement decisions and guide the development of clinical practice guidelines.

## 2.3. Transforming real-world data into usable evidence

Other approaches are available when RCTs are difficult to conduct. Retrospective treatment outcome (RTO) studies,<sup>5,6</sup> which collect patient-reported outcomes through interviews, can quickly identify therapies associated with good outcomes and generate hypotheses for subsequent testing. A more powerful option is to use real-world data, such as hospital electronic medical records, to conduct target trial emulation, an emerging method in integrative medicine evaluation. Chinese researchers have made important contributions in this area, building external control arms and carefully defining exposures and outcomes to convert real-world data into high-quality evidence suitable for causal inference. This approach has provided reliable assessments of the efficacy and safety of complex integrative interventions that would otherwise be difficult to study using conventional RCTs. These methodological advances have greatly broadened the scope of real-world research in TCM, producing evidence that is directly useful for clinical decision making.

## 3. Navigating challenges toward a patient-centered approach

The transition from combination to integration poses considerable challenges across multiple domains.

At the economic level, the substantial health benefits achieved by TCM at relatively modest costs present a fundamental challenge to an industry structured around high-margin patented pharmaceuticals. Thus, policymakers face a difficult trade-off between fostering innovation and safeguarding population health. In the regulatory and reimbursement arena, unresolved issues persist regarding the scope of insurance coverage, the criteria for approving compound formulations, and the translation of complex intervention evidence into policy frameworks. In clinical practice, the absence of standardized certification pathways for integrative practitioners and the lack of consistency in the quality of herbal decoction pieces and granules continue to impede the equitable delivery of integrative services.

The research challenges are perhaps the most acute. The most critical involves evaluating individualized treatment regimens and properly assessing complex interventions comprising multiple concurrent therapeutic components. However, these methodological questions are difficult to answer. Integrative medicine research needs to shift from validating add-on effects to clarifying the mechanisms of synergy—namely, how the combination of traditional Chinese and conventional medicine achieves results that exceed the sum of their parts. This necessitates study designs capable of clarifying mechanisms of action, identifying populations most likely to derive benefit, and systematically evaluating drug–drug interactions, with particular attention to potential antagonistic effects. Moreover, psychosocial and cultural variables

play a significant role in outcomes in integrative settings. Incorporating qualitative methodologies to explore patients' treatment experiences and value systems can enrich our understanding of what patient-centeredness truly means in this context.

Meeting these challenges demands increased investment in rigorous evidence-generating studies that produce actionable findings, as well as sustained collaboration among policymakers, clinicians, and researchers. The core attributes of integrative medicine can be divided into four dimensions: philosophical orientation, care delivery structure, process dynamics, and outcome focus (patient-centeredness). Collectively, these dimensions orient clinical research toward patients. Relative to disease-centered research, this patient-centered paradigm places greater emphasis on the whole person, physiological equilibrium, the mind-body interface, adjunctive and supportive interventions, and improvements in functional capacity and quality of life. A real-world model of complex intervention components suggests that effective integrative care must embody synergy, interaction, and dynamic adaptation with healthcare providers and patients as central actors. An optimal research portfolio should include a range of study types: effectiveness, safety, cost-effectiveness, patient preferences, satisfaction, and health services research. It is also important to ensure that the findings are translated into practice through consensus-building and implementation-focused strategies.

## 4. Looking ahead: toward a global vision for integrative medicine

In 2025, the World Health Organization released its ten-year strategy for traditional medicine (2025–2034),<sup>7</sup> outlining four strategic priorities: generating evidence, enabling safe and effective therapies through regulation, integrating traditional medicine into mainstream systems, and fostering international collaboration. These directions provide clear roadmaps.

A well-designed clinical study of integrated traditional Chinese and conventional medicine should reflect the core principles of integrative care, which can be grouped into seven interrelated concepts: prevention, prediction, participation, precision, health promotion, population health, and narrative medicine. Collectively, these concepts offer a comprehensive framework for research in this field.

The trajectory from cooperation to integration, from combination to synergy, and from empirical practice to evidence-based and now integrative evidence-based paradigms captures more than seven decades of progress in China's integrative medicine enterprise. It also carries significant implications for the current generation. With the new mandates set out in the National Health Fifteenth Five-Year Plan, it is reasonable to expect that, guided by evidence-based methods, integrative medicine will move beyond mere co-administration toward true fusion. What began as a distinctive Chinese experience has the potential to become a globally relevant model, offering contributions from China's experience to the global health community.

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Jian-ping Liu: Conceptualization, writing – original draft, and writing – review & editing.

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## Declaration of Competing Interest

Prof. Jian-ping Liu is the Co-Editor-in-Chief of *Evidence-Based Chinese Medicine and Technology Assessment*.

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