Journal of Traditional Chinese Medical Sciences 12 (2025) 201–209

Contents lists available at ScienceDirect

Journal of Traditional Chinese Medical Sciences

journal homepage: www.elsevier.com/locate/jtcms

Advancing global healthcare: Methodological innovations for integrating Chinese medicine

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ARTICLE INFO

Article history:
Received 29 May 2024
Received in revised form
28 February 2025
Accepted 3 March 2025
Available online 7 March 2025

Keywords:
Integrative medicine
Chinese medicine
Research methodology
Global healthcare
Evidence based medicine

ABSTRACT

Chinese medicine, with its rich historical roots and holistic approach, has been a fundamental aspect of healthcare in East Asia and is now gaining global recognition. Founded on centuries of empirical knowledge and philosophical insight, Chinese medicine draws heavily from classical texts to guide its practices in herbal medicine and acupuncture. Despite its cultural and historical significance, integrating Chinese medicine into global healthcare systems presents challenges, notably the need for evidence-based practices to enhance credibility, ensure patient safety, and foster broader acceptance within the medical community. This paper explores how Chinese medicine can adopt evidence-based practices by incorporating principles of Western medicine into its research methodologies. It reviews the origins and philosophical foundations of Chinese medicine, examining its reliance on classical texts and empirical methods. The paper also highlights the differences between the personalised approach of Chinese medicine, which tailors treatments to individual needs, and the standardised protocols typical of Western medicine. Additionally, it addresses methodological challenges in Chinese medicine research, such as inconsistent diagnostic criteria and insufficient design rigour. To bridge these gaps, innovative research methodologies that respect the unique variability of Chinese medicine are needed. By adopting evidence-based practices and rigorous scientific validation, Chinese medicine can enhance its legitimacy and facilitate its integration into the global healthcare landscape.

1. Introduction

Chinese medicine has long served as a cornerstone of healthcare in East Asia and is increasingly recognised worldwide. With a deep-rooted tradition of holistic health and wellness, Chinese medicine is founded on centuries of empirical knowledge and philosophical insights, preserved and transmitted through classical texts detailing practices in herbal medicine and acupuncture. These texts serve as both repositories of ancient wisdom and foundations for contemporary practice, ensuring that insights from generations of practitioners remain accessible. While this experience-based practice has evolved over centuries, fully integrating Chinese medicine into the global healthcare system requires adopting evidence-based practices. This transition is essential for enhancing credibility, ensuring patient safety, improving treatment efficacy, and fostering wider acceptance within the global clinical community.

2. Origins and philosophical foundations

Chinese medicine traces its origins back to prehistoric times, with foundational texts such as *The Yellow Emperor's Canon of Medicine* (*Huang Di Nei Jing*) dating back to the 3rd century Before the Common Era (BCE). This seminal text, presented as a dialogue between the mythical Yellow Emperor and his ministers, discusses fundamental principles of health, disease, and treatment. It introduces core concepts such as yin and yang, the five elements (wood, fire, earth, metal, and water), and qi, or vital energy. *The Yellow Emperor's Canon of Medicine* emphasises the importance of balance between yin and yang and the harmonious flow of qi in maintaining health. Disease, in this context, results from disruptions in this balance, and treatments aim to restore harmony primarily through herbal medicine and acupuncture.

Chinese medicine's evolution reflects humanity's enduring pursuit of health and well-being, grounded in meticulous observation and the transmission of knowledge through classical texts. Foundational texts like *The Compendium of Materia Medica* (*Ben Cao Gang Mu*) and *The Yellow Emperor's Canon of Medicine* exemplify this integration of empirical practice with theoretical insights,

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Peer review under responsibility of Beijing University of Chinese Medicine.

https://doi.org/10.1016/j.jtcms.2025.03.001

ensuring that Chinese medicine remains a vital and effective healthcare system deeply enriched by its historical and literary heritage.

2.1. Herbal medicine: the materia medica tradition

Herbal medicine forms a cornerstone of Chinese therapeutic practice, deeply interwoven with Chinese history and culture. One of the earliest pharmacological texts is *The Shennong's Herbals* (*Shen Nong Ben Cao Jing*), attributed to the mythical Shennong and compiled around the 1st century of the Common Era (CE). This text categorises herbs into three grades based on their healing properties and potential toxicity, representing an empirical approach to herbal therapy.

Another significant text, *Treatise on Cold Damage* (*Shang Han Lun*), written by ancient physician Zhang Zhongjing during the Eastern Han Dynasty (circa 206 $_{BCE}$–220 $_{CE}$), has profoundly shaped Chinese medical theory and practice. This text provides a framework for diagnosing and treating illnesses caused by pathogenic cold, a leading environmental factor in disease. *Treatise on Cold Damage* is structured around six channels (*liu jing*), pathways through which pathogenic factors invade the body. These channels correspond to six stages of disease progression, each with specific symptoms and treatment strategies. Treatments often involve herbal combinations to expel pathogens, harmonise the internal environment, and restore balance. Classic formulas such as Guizhi decoction and Mahuang decoction are still widely used today.

The practice of herbal medicine involves plants, minerals, and animal products, with formulas tailored to individual patients. Over time, practitioners extensively documented the effects of these substances, refining their use through centuries of clinical practice. *The Compendium of Materia Medica* by Li Shizhen, published in the 16th century, further expanded this knowledge by describing over 1800 substances and their medicinal uses. This comprehensive work epitomises the empirical nature of Chinese herbal medicine, where accumulated experience and observation guide treatment.

2.2. Acupuncture: the art of needle therapy

Acupuncture, another fundamental aspect of Chinese medicine, involves inserting fine needles into specific points on the body to regulate the flow of qi. The earliest references to acupuncture appear in *The Yellow Emperor's Canon of Medicine*, which outlines the meridian system—a network through which qi flows. This text describes 365 acupuncture points, each associated with distinct therapeutic effects. *The Miraculous Pivot* (*Ling Shu*) section of *The Yellow Emperor's Canon of Medicine* is devoted entirely to acupuncture, providing detailed descriptions of meridians, acupuncture points, needle techniques, and therapeutic effects. It introduces concepts such as qi flow, the importance of balance within the body, and methods to manipulate qi through needling.

Other influential texts include *The Classic of Difficult Issues* (*Nan Jing*), *Systematic Classic of Acupuncture and Moxibustion* (*Zhen Jiu Jia Yi Jing*), and *Great Compendium of Acupuncture and Moxibustion* (*Zhen Jiu Da Cheng*). *The Classic of Difficult Issues*, written around the 2nd century CE, supplements *The Yellow Emperor's Canon of Medicine*, elaborating on acupuncture theories, pulse diagnosis, and the organ-meridian interplay. It clarifies complex and ambiguous points from the Inner Canon, with a focus on diagnostics and acupuncture. *Systematic Classic of Acupuncture and Moxibustion*, written by Huangfu Mi in the 3rd century CE, is one of the earliest comprehensive texts dedicated to acupuncture and moxibustion. This text systematically introduces the twelve primary and eight extraordinary meridians, detailing their pathways, connections, and functions, alongside numerous acupuncture points, their indications, and techniques. It includes illustrations and diagrams to help practitioners locate points accurately and provides in-depth guidance on needling techniques, moxibustion methods, and clinical applications for various diseases.

These ancient writings provide both a theoretical and practical framework for acupuncture, detailing meridians (channels), acupuncture points, needle techniques, and the underlying philosophy of this healing art. Acupuncture evolved through continuous experimentation and clinical observation, with practitioners developing various techniques and tools, such as the nine classical needles, to address different conditions.

3. The practice of Chinese medicine outside its origin

Chinese medicine, with its holistic approach and centuries-old traditions, has extended far beyond its origins in East Asia to become a significant component of alternative and complementary medicine worldwide, partially facilitated by centuries of migration. Its practices, including acupuncture, herbal medicine, and Tuina (therapeutic massage), have gained popularity due to their perceived effectiveness in treating various ailments.

The international prominence of Chinese medicine began to rise in the 20th century, particularly following President Richard Nixon's visit to China in 1972, which sparked Western interest in acupuncture. Since then, practitioners in countries such as the United States, Canada, Australia, and various European nations have adopted Chinese medical practices. The World Health Organisation (WHO) has recognised acupuncture as an effective treatment for certain conditions and, in 2021, published benchmarks for acupuncture practice. These benchmarks were established by representatives from the WHO's African Region, Region of the Americas, Eastern Mediterranean Region, European Region, South-East Asia Region, and Western Pacific Region.[1]

This global expansion has led to a diverse, multicultural practice of Chinese medicine. Practitioners often combine traditional Chinese techniques with local medical practices, creating unique hybrids tailored to patient needs. While this cross-cultural exchange enriches the practice, it also highlights the importance of establishing clear guidelines and standards. In several countries, governments have formally recognised Chinese medicine within their healthcare systems, often establishing regulatory frameworks to ensure practitioners are properly trained and qualified. For example, in Australia, Chinese medicine practitioners must be registered with the Chinese Medicine Board of Australia. Similar regulatory frameworks exist in New Zealand, Singapore, and parts of North America. Such standardised registration and regulation uphold safety, efficacy, and professional integrity.

However, in most countries outside East Asia, Chinese medicine is not centrally or nationally regulated. The establishment of regulatory and accreditation bodies outside East Asia has been instrumental in promoting standards and professionalism among Chinese medicine practitioners. For instance, the Chinese Medicine Board of Australia set rigorous standards for education, clinical practice, ethical conduct and competency framework for practitioners who wish to practice Chinese medicine or acupuncture in Australia. These registration requirements ensure that practitioners are suitably trained and meet appropriate professional standards before they are allowed to practice in the community, enhancing Chinese medicine's credibility in the society.

Registered practitioners are recognised as professionals who adhere to a code of conduct and ethical standards. This professional recognition strengthens the credibility of Chinese medicine within the broader healthcare system and among patients. It also fosters greater collaboration between Chinese medicine practitioners and those of conventional Western medicine, leading to more

integrated and comprehensive patient care. In many countries, registration and regulation are prerequisites for including Chinese medicine in health insurance plans, which facilitates broader access to Chinese medical treatments and makes them more affordable and widely available. However, varying standards for training and education in Chinese medicine across countries present challenges in establishing uniform registration criteria worldwide.

4. Prioritising evidence-based practice

Chinese medicine is increasingly integrated into conventional healthcare systems as a complementary therapy. Hospitals, clinics, and healthcare providers incorporate acupuncture and herbal medicine into treatment options, particularly for managing chronic pain, stress, and other conditions where conventional treatments may have limited effectiveness.[2–6] This integration not only expands treatment options but also promotes a more holistic approach to health. Today, Chinese medicine thrives by blending traditional knowledge with modern scientific research. Classical texts continue to guide diagnosis and treatment, while modern practitioners engage in rigorous research to validate and expand these practices. Studies on the pharmacological properties of herbs and the physiological effects of acupuncture bridge the gap between ancient wisdom and modern science, affirming the efficacy of Chinese medicine within the global healthcare landscape.

4.1. Advancing credibility and professional excellence

Western medicine is grounded in evidence-based practice principles, relying on rigorous scientific research and clinical trials to validate treatment methods. For Chinese medicine to achieve comparable credibility, it must demonstrate efficacy through systematic, reproducible research. Integrating evidence-based practices into Chinese medicine involves conducting randomised controlled trials (RCTs), systematic reviews, and meta-analyses to evaluate the effectiveness of various treatments. Such studies provide robust evidence that supports or refutes therapeutic claims made by traditional practices. Over the past few decades, substantial scientific research has supported the efficacy of various Chinese medical practices. Acupuncture, in particular, has been extensively studied and is now widely accepted for managing pain, reducing nausea, and treating specific musculoskeletal conditions.[2,7–10] This scientific validation has played a key role in legitimising Chinese medicine within the broader medical community. By adopting evidence-based practices, practitioners can substantiate traditional Chinese medical wisdom with scientific data, thereby enhancing legitimacy and acceptance among healthcare professionals and patients alike.

A primary benefit of evidence-based practice is its emphasis on patient safety. In Western medicine, treatments undergo rigorous testing to identify potential side effects and contraindications. Chinese medicine can adopt similar standards to ensure treatments are safe and effective. This includes pharmacovigilance, which monitors the safety of herbal medicines and other traditional therapies, and establishing standardised protocols for their use. Herbal medicine, a core component of Chinese medicine, can pose risks if not properly regulated, as some herbs may interact adversely with pharmaceutical drugs or become toxic if misused. Evidence-based guidelines help mitigate these risks by providing clear instructions on dosage, administration, and contraindications. This systematic approach to safety protects patients and enhances trust in Chinese medicine as an effective, reliable healthcare option. Table 1 illustrates the key differences between Chinese and Western medicine.

4.2. Fostering greater acceptance within the global healthcare community

Evidence-based practice provides a common language and framework for collaboration among practitioners of different medical traditions, fostering mutual respect and understanding. Integrating Chinese medicine into mainstream healthcare enhances patient care by offering complementary treatment options. Conditions that are challenging to manage solely with conventional medicine, such as chronic pain or certain autoimmune disorders,[11,12] may benefit from a holistic approach that incorporates both Western and Chinese medical practices. This integration is possible when Chinese medicine adheres to the same rigorous standards of evidence and quality as Western medicine.

5. Challenges in integrating the classical practice of Chinese medicine and Western medicine

Despite its increasing integration into global healthcare systems, research in Chinese medicine faces several challenges and limitations that hinder its full acceptance and integration into mainstream medical practice.

5.1. The conflict between personalised practice in Chinese medicine and standardised practice in Western medicine

Chinese medicine and Western medicine represent two distinct paradigms of healthcare, each with unique principles and practices. One of the fundamental differences lies in the approach to treatment: Chinese medicine emphasises personalised care tailored to an individual's unique condition, while Western medicine often relies on standardised treatment protocols. This difference is especially evident when comparing practices like modifying herbal compositions and selecting acupuncture points in Chinese medicine, based on the concept of pattern differentiation (*Bian Zheng*), to the more uniform, evidence-based practices in Western medicine. Fig. 1 illustrates the key elements of Chinese and Western medicine practices.

Table 1
Key differences between Chinese medicine and Western medicine.

Aspect	Chinese medicine	Western medicine
Treatment approach	Personalised, tailored to the individual's unique condition	Standardised, evidence-based treatment protocols
Diagnosis method	Pattern differentiation	Diagnosis based on clinical evidence and standardised tests
Prescription of medications	Customized herbal formulas based on patient's condition (pattern differentiation)	Standardised drug prescriptions based on clinical trials
Treatment flexibility	Herbal compositions and acupuncture points modified per case	Fixed dosages and treatment regimens
Variability in treatments	High, due to individualised approach	Low, aiming for consistent outcomes
Scientific validation	Challenging due to variability	Easier due to standardisation and reproducibility
Educational approach	Relies heavily on practitioner's experience and expertise	Protocol-driven, standardised training across practitioners

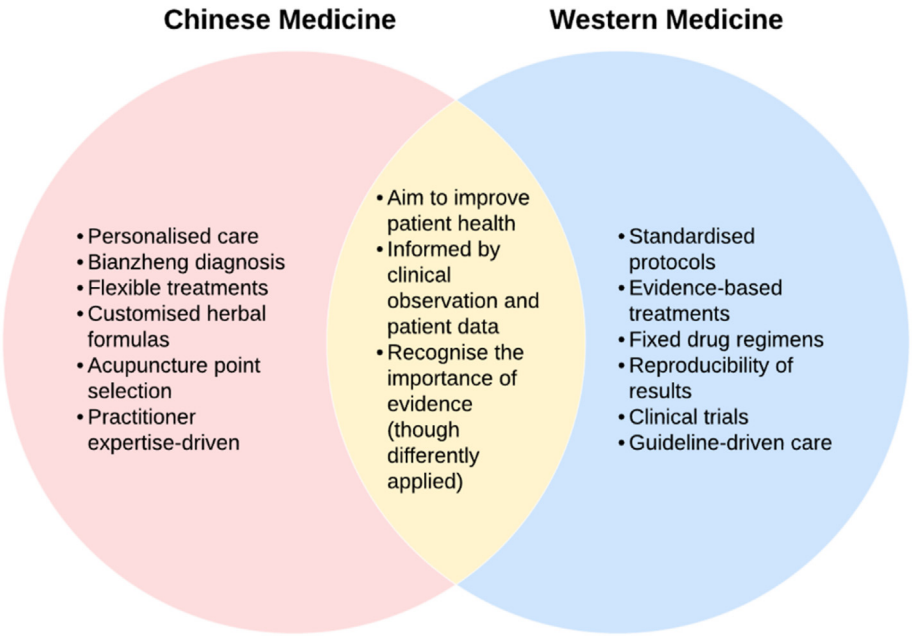

Fig. 1. Key elements of Chinese *vs.* Western medicine practice.

In Chinese medicine, pattern differentiation is central to diagnosis and treatment. It involves a detailed assessment of the patient's symptoms, constitution, and overall balance of yin and yang, qi, and blood. Based on this assessment, practitioners create a highly individualised treatment plan that may include customised herbal formulas and specific acupuncture points tailored to the patient's unique condition. Chinese medicine practitioners often modify herbal prescriptions to suit each patient's individual needs. A single herb can have different effects depending on its combination with other herbs, dosage, and the patient's specific condition. This flexibility allows for a dynamic and responsive treatment approach but also introduces variability that challenges standardisation. Similarly, the selection of acupuncture points is personalised, with practitioners choosing points based on the patient's specific symptoms and overall health status, as determined through pattern differentiation. This individualised approach aims to restore balance and promote healing uniquely suited to the patient's condition.

Western medicine emphasises standardised treatment protocols developed through rigorous scientific research and clinical trials. These protocols are designed to be broadly applicable and reproducible, ensuring that patients receive treatments proven effective through evidence-based studies. As a result, drugs are prescribed based on standardised dosages and treatment regimens extensively tested in clinical trials. These standards ensure consistency and predictability in treatment outcomes, minimising variability and reducing the risk of adverse effects. However, there has been increasing recognition of sex and racial biases in patient enrollment in previous RCTs, leading to uneven treatment efficacy among different sexes, ages, and racial backgrounds.[13–15] In response, the U.S. National Institutes of Health now requires the inclusion of both males and females in pre-clinical studies. Thus, Western medical practice is guided by clinical guidelines developed by professional organisations and health authorities. These guidelines are based on the best available evidence and are intended to standardise care across practitioners and healthcare settings.

The personalised approach of Chinese medicine frequently diverges from the standardised protocols of Western medicine, creating an inherent tension between the two. Western medicine's reliance on standardisation aims to ensure that all patients receive the same evidence-based care, improving consistency and safety. However, Chinese medicine's individualised approach can adapt to the nuances of each patient's condition, potentially offering more tailored and effective treatments. The variability inherent in personalised Chinese medicine treatments poses challenges for scientific validation. Western medical research, which prioritises reproducibility and standardisation, finds it difficult to evaluate treatments that change from patient to patient. This lack of standardisation can lead to scepticism about the efficacy of Chinese medicine within the Western medical community. Integrating Chinese medicine into predominantly Western healthcare systems requires reconciling these differing approaches. Standardised protocols are more accessible to regulate, monitor, and reimburse through insurance systems. In contrast, the individualised nature of Chinese medicine treatments complicates these processes, making integration more challenging.

The personalised practice of Chinese medicine relies heavily on the practitioner's expertise and experience in pattern differentiation, in contrast to the more protocol-driven approach in Western medicine, where standardised training ensures consistency across practitioners. Balancing these different educational and practice paradigms is a significant challenge.

5.2. Common methodological challenges in Chinese medicine research

5.2.1. Diagnostic criteria

Chinese medicine and Western medicine have fundamentally different approaches to diagnosing and understanding diseases. Chinese medicine employs a holistic diagnostic framework that includes concepts such as yin and yang, qi, and the five elements. Diagnosis is made through pattern differentiation, which assesses the patient's overall condition, including physical symptoms, emotional state, and lifestyle factors. Western medicine, on the other hand, relies on objective, quantifiable criteria to diagnose diseases, often involving laboratory tests, imaging studies, and well-defined clinical criteria based on specific symptoms and biomarkers. Diseases are categorised based on pathophysiological

Table 2
Comparison of RCT design features in Western and Chinese medicine research.

RCT design features	Chinese medicine research	Western medicine research
Randomization	Often lacks robust randomisation protocols	Strong emphasis on random assignment of participants
Control groups	Often absent or poorly defined control groups	Well-defined control groups (e.g., placebo, standard treatment)
Blinding	Blinding is challenging, especially when two different treatment methods are compared (e.g., herbs *vs.* acupuncture)	Uses single, double, or triple blinding to reduce bias
Placebo use	Placebos (e.g., sham acupuncture, sham herbs) are more challenging to design	Placebo controls (e.g., sugar pills, sham treatments)
Sample size	Often small, reducing the generalisability of findings	Typically large, enhancing statistical power
Trial duration	Varies between patients based on outcome improvements or lack thereof	Fixed
Replication	Difficult due to personalised treatments and variability	Easier to replicate due to standardised protocols
Bias reduction	Greater risk of bias due to treatment transparency and practitioner knowledge	Strong protocols to minimise selection and observer bias
Adjunctive use	Often used in combination with Western medicine	Rarely used alongside other treatments

Note: RCT: randomised controlled trial.

mechanisms and standardised diagnostic codes, such as the International Classification of Diseases (ICD).

Chinese medicine research often defines and categorises diseases differently, without using Western diagnostic methods. This inconsistency makes it difficult to directly compare research outcomes with those from Western medicine studies. For example, a condition like “headache” may be approached and treated based on entirely different underlying principles and categories in Chinese medicine compared to Western medicine. The lack of standardised diagnostic criteria in Chinese medicine can result in treatments being tested on heterogeneous patient groups with varying underlying conditions,[16] complicating research findings' generalisability and reproducibility. In contrast, Western medical research strives for homogeneity in patient selection to ensure that outcomes can be attributed specifically to the intervention being tested. Western medical research emphasises evidence-based practice, requiring rigorous validation through reproducible studies. In contrast, the holistic and individualised nature of Chinese medicine diagnosis complicates the design of standardised studies which can affect its perceived scientific rigor and broader acceptance within the medical community. Table 2 compares RCT design features in Western and Chinese medicine research.

It is not uncommon for many Chinese medicine-related RCT studies to focus on the Western medical diagnosis of conditions or diseases, emphasising the standardisation of acupuncture or Chinese herbal medicine treatments. However, these studies often overlook the necessity of adopting different Chinese medicine (CM) treatment plans based on varying CM patterns, which can impact treatment efficacy. Chinese medicine diagnosis and pattern differentiation are essential for CM therapy planning and delivery to ensure patients receive correct and appropriate treatments for their conditions. Conducting clinical research without acknowledging the importance of Chinese medicine diagnosis and pattern differentiation, and solely applying a single CM formulation to all research subjects, can easily lead to false-negative conclusions, suggesting that Chinese medicine therapy is ineffective for the condition of interest. Therefore, investigating the effectiveness of acupuncture or Chinese herbal medicine therapy for specific medical conditions or diseases using a single treatment or prescription plan, rather than basing it on CM clinical diagnostic patterns and adopting varied CM approaches, cannot adequately demonstrate the clinical effectiveness of CM for these conditions. Fig. 2 showcases the overlapping challenges in Chinese medicine research.

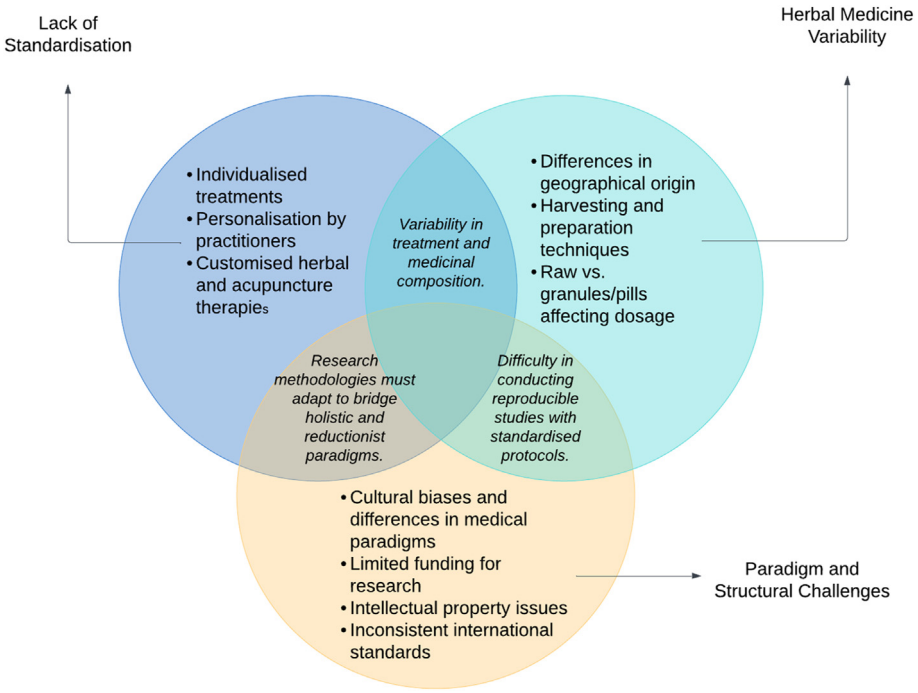

Fig. 2. Overlapping challenges in Chinese medicine research.

5.2.2. Design rigor

High-quality research in medical science generally relies on RCTs, which are widely regarded as the gold standard for evaluating the efficacy and safety of treatments. RCTs are designed to minimise bias and provide robust, reliable data by randomly assigning participants to either a treatment group or a control group. This random assignment ensures that any observed effects can be attributed to the intervention itself rather than to external factors. By randomly assigning participants (e.g., to a treatment *vs.* a control group), RCTs eliminate selection bias and balance both known and unknown confounding variables between groups. The RCT design also facilitates replication by other researchers, which is essential for validating results and establishing the reliability of findings.

A key limitation in Chinese medicine research is the rigour of control groups and randomisation in clinical trials. In RCTs, the control group receives either a placebo, a standard treatment, or no intervention, providing a baseline for comparing the effects of the new treatment. This setup helps isolate the impact of the intervention. However, a "no treatment" control group is often absent in Chinese medicine clinical trial manuscripts. Additionally, Chinese medicine is increasingly used as an adjunct treatment to manage symptoms in patients with chronic or incurable diseases, such as severe asthma, that Western medicine alone has not controlled effectively.[17] Many studies on Chinese medicine lack the rigour associated with RCTs due to small sample sizes, which limits statistical power and generalizability. Larger, well-designed studies are needed to provide more robust evidence. However, the absence of proper control and randomisation makes it difficult to systematically review treatment efficacy, even when adjustments for small sample sizes are made.[18] Table 3 lists the key challenges in Chinese medicine research.

Controlling for confounding variables and using proper blinding and random assignment in Chinese medicine research can better demonstrate a causal relationship between the intervention and the observed outcomes. Blinding involves keeping participants, researchers, and sometimes data analysts unaware of group assignments, reducing the risk of bias in outcome reporting and assessment. Blinding may be single (only participants are unaware), double (both participants and researchers are unaware), or triple (participants, researchers, and analysts are unaware). Ensuring proper blinding in Chinese medicine studies can be challenging. Practitioners and patients are often aware of whether they are administering or receiving real treatment or a placebo, leading to potential biases. Double-blind study arrangements, where both the practitioner and patient are unaware of the treatment being given, are especially difficult to implement in Chinese medicine research.

Randomisation and blinding help reduce biases such as selection bias and observer bias, improving the accuracy and generalizability of findings. For example, sham herbs, granules, or pills are sometimes used as controls. However, designing placebo controls for practices like acupuncture can be challenging. Sham acupuncture, which may use needles that do not penetrate the skin or are placed at non-therapeutic points, is commonly used as a placebo, but its effectiveness as a true control is debated. This complication can affect the interpretation of study results and raise questions about the validity of findings. In such cases, sham acupuncture points placed close to the therapeutic ones may be considered, though this requires the practitioner to have refined technical competency.

5.2.3. Standardisation

Another significant challenge in Chinese medicine research is the lack of standardisation in treatments, even for identical diagnoses. Chinese medicine emphasises individualised treatment based on a holistic assessment of the patient, which contrasts with the standardised protocols typical of Western medicine. This personalisation makes it difficult to develop standardised treatment protocols for research, leading to variability in study designs and outcomes.

Variability in herbal medicine can be challenging to control, even within the same country. The composition and quality of herbal medicines may vary significantly depending on factors such as geographical origin, harvesting methods, and preparation techniques. This variability complicates efforts to ensure consistency in studies and to replicate results. When using raw herbs, preparation methods can alter the chemical composition of the decoction, which can significantly impact patient outcomes. Using therapeutic-grade granules extracted from single herbs or pills made from multiple herbs may help standardise doses within treatment groups and allow for broader practitioner use.

5.2.4. Paradigm differences

Cultural biases and differing medical paradigms present additional challenges in Chinese medicine research. The Western scientific paradigm emphasises reductionism and quantifiable outcomes, whereas Chinese medicine is based on a holistic approach that considers the interplay of mind, body, and environment. Bridging these paradigms requires developing new research methodologies that can accommodate the holistic nature of

Table 3
Key challenges in Chinese medicine research.

Challenge	Description	Impact on research
Lack of treatment standardization	Individualised treatments based on holistic assessment of patients rather than standard protocols	Difficult to create consistent treatment protocols, leading to variability in outcomes and study designs
Herbal medicine variability	Quality and composition of herbs can vary by geographical origin, harvesting methods, and preparation techniques	Difficult to ensure consistency in studies and to replicate results
Preparation methods	Different preparation techniques for herbs (e.g., raw *vs.* granules/pills) can lead to variations in chemical compositions	Variability in patient outcomes, making results difficult to standardise
Paradigm differences	Western reductionist scientific approach *vs.* Chinese holistic, mind-body-environment interplay	Challenges in developing research methodologies bridging the two paradigms
Funding limitations	Chinese medicine research often receives less funding compared to conventional Western medical research	Smaller study sizes, limited research scope, affecting robustness and generalisability
Publication bias	Positive results are more likely to be published than negative or inconclusive results	Skews research landscape, limiting visibility of balanced evidence
Intellectual property challenges	Communal and historical nature knowledge base complicates securing patents	Limits investment in research and development, reducing progress in standardisation
International standards variability	Differences in standards of practice, education, and research across countries	Leads to inconsistencies in research quality and comparability of findings

Chinese medicine. Positive study results are more likely to be published than negative or inconclusive findings, a bias that can be particularly pronounced in fields like Chinese medicine, where positive results are eagerly sought to gain acceptance within mainstream medical communities.

Different countries have varying standards for practice, education, and research, leading to inconsistencies in the quality and conduct of research. Research in Chinese medicine often receives less funding compared to conventional medical research, which can limit the scale and scope of studies, affecting both the quality and quantity of research outputs. The traditional knowledge underpinning Chinese medicine is often communal and historical, making it difficult to navigate intellectual property laws and secure patents. This lack of patent protection can deter investment in research and development.

6. Move forward

Based on the current research and knowledge gaps,[19–40] adopting evidence-based practices can significantly enhance the efficacy of Chinese medical treatments and acceptance by the international community, especially Western medical doctors. By rigorously testing traditional therapies through clinical trials, practitioners can identify the most effective treatments and refine their techniques. This process enables the development of standardised treatment protocols that can be consistently applied in clinical practice, ensuring that patients receive the highest quality of care. Additionally, evidence-based practices encourage ongoing research and innovation. As new evidence emerges, Chinese medicine can evolve to incorporate the latest scientific discoveries, thereby continuously improving treatment outcomes. This dynamic approach contrasts with the static nature of traditional practices and aligns more closely with the progressive, adaptive nature of Western medicine.

To improve the quality of research on the efficacy of Chinese medicine treatments, it is essential to combine the strengths of both Chinese and Western medicine paradigms. Collaboration among practitioners of Chinese and Western medicine, along with medical scientists in RCTs, can foster mutual understanding and integration.[19] Hybrid models that incorporate the personalised aspects of Chinese medicine within a research framework that allows for some level of standardisation could help bridge the gap. For instance, standardised protocols could be developed for common conditions while permitting individual modifications based on patient-specific assessments. Pragmatic clinical trials,[20] which allow for some flexibility in treatment, may be particularly suited to evaluating Chinese medicine. Bayesian Adaptive Trials enable trial procedures, such as dosage or patient selection criteria, to be modified based on interim results.[21] This flexibility accommodates the dynamic adjustments often made in Chinese medicine, such as modifying herbal compositions or acupuncture points based on ongoing assessments of the patient's condition. Sequential Multiple Assignment Randomized Trials allow for multiple stages of treatment adjustments, aligning with the iterative process of pattern differentiation in Chinese medicine.[22] Patients can be re-randomized to different treatments based on their responses, reflecting the tailored and evolving nature of Chinese medicine.

While acupuncture and herbal remedies are widely used, their mechanisms and outcomes require thorough investigation and documentation to establish a solid scientific foundation. Innovative research methodologies that account for the variability of Chinese medicine can help validate its practices within the Western scientific paradigm. Identifying specific biomarkers associated with Chinese medicine treatments can provide objective, quantifiable measures of treatment effects. For example, tracking changes in inflammatory or hormonal markers in response to herbal therapies or acupuncture can provide measurable outcomes.[23] Genomic profiling can aid in understanding the genetic basis of individual responses to Chinese medicine treatments. Genome-wide association studies (GWAS) can investigate the genetic factors influencing individual responses, leading to personalised medicine approaches that tailor treatments based on genetic profiles.[24] Employing research methods standard in Western medicine can help bridge the gap between these two distinct paradigms, ensuring that Chinese medicine practices are rigorously tested and scientifically validated. This includes adapting and applying basic research methods such as *in vitro* studies, *in vivo* animal models, pharmacokinetic and pharmacodynamic studies, as well as advanced molecular and genomic techniques.[3,4,25–29] Researchers can use cell cultures to study the effects of individual herbs or combinations on specific cell lines, helping to identify active compounds, elucidate mechanisms of action, and determine effects on cellular processes such as proliferation, apoptosis, and differentiation.[4,27] High-throughput screening techniques can rapidly identify potential therapeutic agents from the wide range of substances used in Chinese medicine. Using classical animal models of diabetes, cancer, or cardiovascular disease allows researchers to evaluate the therapeutic effects of Chinese medicine formulations. Techniques like RNA sequencing (RNA-seq) can analyse changes in gene expression following Chinese medicine treatments,[29,30] revealing molecular pathways and biological processes influenced by the treatment. Proteomics and metabolomics studies can identify changes in protein and metabolite levels in response to Chinese medicine, elucidating the complex biochemical effects of herbal formulations and acupuncture on the body.

Chinese medicine has long been recognised for its emphasis on preventive care, aiming to maintain health and prevent disease through holistic approaches such as herbal medicine, acupuncture, dietary adjustments, and lifestyle modifications. However, preventive treatments often require extended periods to demonstrate efficacy, necessitating long follow-up periods in RCTs. Unlike treatments for acute conditions, the benefits of preventive measures may take years or even decades to become apparent, complicating the design and execution of RCTs and increasing costs and the potential for participant dropout, which can affect a study's validity and reliability. Innovative trial designs, such as adaptive trials or pragmatic trials, could allow for interim analyses and adjustments. Additionally, leveraging long-term health data through observational studies and integrating these with RCT data can provide a more comprehensive evaluation of preventive treatments. Preventive care aims to maintain overall health and balance, which can be difficult to quantify with standard biomedical endpoints. Outcomes such as improved quality of life, enhanced immune function, or reduced incidence of illness are multifactorial, complicating the assessment of efficacy. Developing composite outcome measures that capture a range of health indicators, both objective (e.g., biomarkers, clinical measurements) and subjective (e.g., quality-of-life assessments, patient-reported outcomes), can provide a more holistic evaluation of preventive treatments. Additionally, integrating qualitative research methods to capture patients' experiences and perspectives can enrich the understanding of preventive care benefits. In preventive care RCTs, it is important to ensure that the control group does not miss essential preventive measures. Using active comparator trials, where the intervention is compared to an existing standard of care, can address ethical concerns while still providing valuable comparative data. Crossover designs, where participants receive both intervention and control treatments sequentially, can also help mitigate these issues.

7. Recommendations

There is a need to establish internationally recognised standards for clinical trials on herbal medicine and other traditional treatment methods to guide future research on the efficacy of Chinese medicine treatment strategies. Strengthening the WHO's Chinese Medicine Strategy and establishing a global consortium for acupuncture and Chinese herbal medicine practice is recommended. These consortia could develop, implement, and oversee standardised protocols and guidelines to ensure the credibility, safety, and efficacy of these treatments. Furthermore, these consortia could assist in developing international guidelines for conducting and publishing research on Chinese medicine and acupuncture to ensure consistency and comparability across global studies. The consortia might begin by conducting comprehensive reviews of existing clinical trial standards and identifying gaps specific to herbal medicine and other traditional treatments. To build consensus on essential clinical trial standards, the consortia could organise workshops and conferences to gather input from experts and practitioners worldwide. This input would assist in developing standardised protocols for clinical trials, including patient selection criteria, diagnostic methods incorporating both Chinese and Western medicine concepts, treatment protocols, outcome measures, and safety monitoring. Pilot testing and validation are critical to ensuring the feasibility and effectiveness of proposed standards. Pilot studies should be implemented in multiple countries to collect data and feedback to refine the guidelines. Validation studies will follow, ensuring that the standards are robust, reproducible, and applicable across different cultural and healthcare settings.

For successful implementation and dissemination, the consortia should develop training programs and materials to educate researchers, practitioners, and regulatory bodies on the new standards, providing ongoing support and resources to facilitate adoption. The finalised standards would be published in peer-reviewed journals and disseminated through WHO channels, international conferences, and professional networks. Monitoring compliance with these standards is essential for long-term success. The consortia should establish mechanisms for regular feedback from users, ensuring that the guidelines are reviewed and updated based on new evidence and emerging best practices.

A globally recognised and endorsed clinical trial protocol would ensure that clinical trials for herbal medicine and other traditional treatments are conducted with the same rigour and scientific validity as those for conventional therapies. This initiative would enhance the credibility and acceptance of these treatments within the global healthcare community, ultimately benefiting patients worldwide. A shared global database of Chinese herbal medicines that includes information on quality standards, active ingredients, toxicity data, and clinical trial efficacy should be developed. This would ensure practitioners worldwide have access to reliable information and help monitor adverse reactions or drug–herb interactions. Locally, researchers could establish joint initiatives between Chinese medicine practitioners and Western medical researchers to foster mutual understanding and integration of methodologies. Government agencies responsible for research standards could also create interdisciplinary committees to develop trial protocol guidelines, ensuring reliability in research methodology. Developing global e-learning and virtual health platforms for Chinese medicine practitioners to share best practices, case studies, and opportunities for continuous professional development would support a high standard of practice worldwide. These recommendations aim to provide clear and actionable insights that address the core issues discussed in this paper.

8. Conclusion

The adoption of evidence-based practices is essential for fully integrating Chinese medicine into the global healthcare system. This transformation will benefit patients and contribute to a more holistic and comprehensive approach to healthcare, bridging the gap between traditional wisdom and modern science. Research in Chinese medicine faces notable challenges due to methodological considerations, variability in standardisation, cultural perspectives, and regulatory complexities. Addressing these challenges requires a concerted effort to develop rigorous, culturally sensitive, and standardised research methodologies that respect the holistic nature of Chinese medicine while meeting the scientific rigour demanded by contemporary medical research.

Funding

There is no funding support for this study.

CRediT authorship contribution statement

Hui Chen: Conceptualisation, data curation, investigation, writing – original draft, and writing – review & editing. **Chi Eung Danforn Lim**: Conceptualisation, validation, visualisation, and writing – review & editing.

Declaration of competing interest

The authors declare that there are no conflicts of interest.

References

1. WHO. *WHO Benchmarks for the Practice of Acupuncture*; 2021. https://iriswhoint/bitstream/handle/10665/340838/9789240016880-engpdf?sequence=1. Accessed May 1, 2024.
2. Jiang W, Tang MZ, Yang LM, et al. Analgesic alkaloids derived from traditional Chinese medicine in pain management. *Front Pharmacol*. 2022;13:851508.
3. Luo Y, Wang CZ, Sawadogo R, Tan T, Yuan CS. Effects of herbal medicines on pain management. *Am J Chin Med*. 2020;48(1):1–16.
4. Li MY, Qin YQ, Tian YG, et al. Effective-component compatibility of Bufei Yishen formula III ameliorated COPD by improving airway epithelial cell senescence by promoting mitophagy *via* the NRF2/PINK1 pathway. *BMC Pulm Med*. 2022;22(1):434.
5. Yang XJ, Shi C, Bao TY, Zhang ZJ. Editorial: traditional Chinese medicine for depression and anxiety. *Front Psychiatr*. 2023;14:1217886.
6. Wild B, Brenner J, Joos S, et al. Acupuncture in persons with an increased stress level-Results from a randomized-controlled pilot trial. *PLoS One*. 2020;15(7):e0236004.
7. Elder C, Ritenbaugh C, Aickin M, et al. Reductions in pain medication use associated with traditional Chinese medicine for chronic pain. *Perm J*. 2012;16(3):18–23.
8. Brøndum L, Markfoged B, Finderup J. Acupuncture as a tool to reduce nausea in terminally ill patients. *Scand J Caring Sci*. 2022;36(4):1046–1053.
9. Nielsen A, Dusek JA, Taylor-Swanson L, Tick H. Acupuncture therapy as an evidence-based nonpharmacologic strategy for comprehensive acute pain care: the academic consortium pain task force white paper update. *Pain Med*. 2022;23(9):1582–1612.
10. Zhang JH, Li ZH, Li ZX, et al. Progress of acupuncture therapy in diseases based on magnetic resonance image studies: a literature review. *Front Hum Neurosci*. 2021;15:694919.
11. Zhong LL, Wang RS, Lam WC, et al. The combination of Chinese and western medicine in the management of rheumatoid arthritis: a real-world cohort study across China. *Front Pharmacol*. 2022;13:933519.
12. Shan YP, Zhang J, Ma YH, Zhang YM. The effects of acupuncture combined with western medicine in the treatment of neck, shoulder, lumbar and leg pain. *Am J Transl Res*. 2023;15(6):4246–4254.
13. Cooke CR, Erickson SE, Watkins TR, Matthay MA, Hudson LD, Rubenfeld GD. Age-, sex-, and race-based differences among patients enrolled versus not enrolled in acute lung injury clinical trials. *Crit Care Med*. 2010;38(6):1450–1457.
14. Daitch V, Turjeman A, Poran I, et al. Underrepresentation of women in randomized controlled trials: a systematic review and meta-analysis. *Trials*. 2022;23(1):1038.

15. Taylor AL, Wright JT. Importance of race/ethnicity in clinical trials. *Circulation*. 2005;112(23):3654–3666.
16. Wang YL, Du RS, Cui H, et al. Acupuncture for acute migraine attacks in adults: a systematic review and meta-analysis. *BMJ Evid Based Med*. 2023;28(4):228–240.
17. Li H, Chen H, Morgan L, Li WH, Oliver BG. A narrative review of clinical studies of herbal treatment of difficult to manage asthma. *Compl Ther Clin Pract*. 2021;44:101433.
18. Lim CED, Ng RWC, Cheng NCL, Zhang GS, Chen H. Acupuncture for polycystic ovarian syndrome. *Cochrane Database Syst Rev*. 2019;7(7):CD007689.
19. Zhou M, Zhang HL, Li FL, et al. Pulmonary Daoyin as a traditional Chinese medicine rehabilitation programme for patients with IPF: a randomized controlled trial. *Respirology*. 2021;26(4):360–369.
20. Patsopoulos NA. A pragmatic view on pragmatic trials. *Dialogues Clin Neurosci*. 2011;13(2):217–224.
21. Giovagnoli A. The Bayesian design of adaptive clinical trials. *Int J Environ Res Publ Health*. 2021;18(2):530.
22. Kidwell KM, Almirall D. Sequential, multiple assignment, randomized trial designs. *JAMA*. 2023;329(4):336–337.
23. Li JS, Xie Y, Zhao P, et al. A Chinese herbal formula ameliorates COPD by inhibiting the inflammatory response *via* downregulation of p65, JNK, and p38. *Phytomedicine*. 2021;83:153475.
24. Uffelmann E, Huang QQ, Munung NS, et al. Genome-wide association studies. *Nat Rev Methods Primers*. 2021;1(1):59.
25. Han LI, Huang XM, Cai HY, et al. Mitochondrial dysfunction in a rat model and the related risk of metabolic disorders. *J Tradit Chin Med*. 2023;43(1):95–104.
26. Huang XM, Cai HY, Li H, et al. Cinnamon as dietary supplement caused hyperlipidemia in healthy rats. *Evid Based Compl Alter Med*. 2021;2021:9892088.
27. Xie ZS, Gao G, Wang H, et al. Dehydroabietic acid alleviates high fat diet-induced insulin resistance and hepatic steatosis through dual activation of PPAR-γ and PPAR-α. *Biomed Pharmacother*. 2020;127:110155.
28. Yin CS, Park HJ, Chung JH, Lee HJ, Lee BC. Genome-wide association study of the four-constitution medicine. *J Altern Compl Med*. 2009;15(12):1327–1333.
29. Li J, Peng C, Lai DJ, et al. PET-CT and RNA sequencing reveal novel targets for acupuncture-induced lowering of blood pressure in spontaneously hypertensive rats. *Sci Rep*. 2021;11(1):10973.
30. Shen J, Chen L, Cheng J, et al. Circular RNA sequencing reveals the molecular mechanism of the effects of acupuncture and moxibustion on endometrial receptivity in patients undergoing infertility treatment. *Mol Med Rep*. 2019;20(2):1959–1965.
31. Pan SY, Litscher G, Gao SH, et al. Historical perspective of traditional indigenous medical practices: the current renaissance and conservation of herbal resources. *Evid Based Compl Alter Med*. 2014;2014:525340.
32. Scheid V. The globalisation of Chinese medicine. *Lancet*. 1999;354:SIV10.
33. Fung FY, Linn YC. Developing traditional Chinese medicine in the era of evidence-based medicine: current evidences and challenges. *Evid Based Compl Alter Med*. 2015;2015:425037.
34. Liu YJ, Cheng YD. Combined development of traditional Chinese medicine and interventional medicine. *J Interv Med*. 2021;4(3):136–138.
35. Liu ZC, Zhao JM, Wang YT, Luo H. Comparative study on registration application of proprietary Chinese medicine in the Guangdong-Hong Kong-Macau Greater Bay Area of China. *J Pharm Policy Pract*. 2024;17(1):2325516.
36. Zhang X, Chung WCA, Lau CT, Wang NN. Reporting guidelines of Chinese medicine: current situation and future development. *J Tradit Chin Med Sci*. 2022;9(3):209–216.
37. Connor L, Dean J, McNett M, et al. Evidence-based practice improves patient outcomes and healthcare system return on investment: findings from a scoping review. *Worldviews Evidence-Based Nurs*. 2023;20(1):6–15.
38. Huang HY, Yang PL, Wang J, et al. Investigation into the individualized treatment of traditional Chinese medicine through a series of N-of-1 trials. *Evid Based Compl Alter Med*. 2018;2018:5813767.
39. The World Health Organization's decision about traditional Chinese medicine could backfire. *Nature*. 2019;570(7759):5.
40. Parveen A, Parveen B, Parveen R, Ahmad S. Challenges and guidelines for clinical trial of herbal drugs. *J Pharm BioAllied Sci*. 2015;7(4):329–333.