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REVIEW

Challenges in Traditional Chinese Medicine Clinical Trials: How to Balance Personalized Treatment and Standardized Research?

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Abstract: Randomized controlled trials (RCTs), as the highest level of evidence and the gold standard in clinical research, occupy a central position in modern medical research due to their stringent variable control and high internal validity. However, their vacuum-like research environment and standardized treatment approaches face significant challenges in traditional Chinese medicine (TCM), which emphasizes Treatment Tailored to Individual and Treatment Based on Syndrome Differentiation, focusing on personalized treatment according to a patient's constitution, age, gender, and lifestyle, and diagnosis based on specific syndromes. This approach lacks systematic modern clinical research and unified standards, conflicting with RCTs' standardized design, thus limiting TCM trials and posing serious challenges to its modernization and internationalization. This study systematically collected and categorized data on the registration status, study type, design, interventions and control measures, research objectives, primary outcome measures of registered trials by searching the ClinicalTrials.gov using TCM-related keywords. It reveals the current status and distribution patterns of TCM clinical registration trials. Evidence suggests that TCM clinical trials urgently need to seek a balance between standardized research and individualized treatment to address the limitations of RCTs in the TCM field, like implementation difficulties and the neglect of individual differences. To address this, the paper proposes an innovative research framework centered on pragmatic RCTs, highlighting randomization based on patient preferences to gather real-world evidence. Additionally, it suggests constructing a multidimensional core information set for standardized diagnosis of TCM syndromes by integrating disease and syndrome data to enhance diagnostic scientificity and increase the credibility and international acceptance of TCM clinical trials. The introduction of this framework effectively integrates the traditional characteristics of TCM with modern scientific methods, providing essential theoretical support and innovative solutions for the design and implementation of TCM clinical research, thereby enhancing TCM's role in global health.

Keywords: traditional Chinese medicine, TCM, clinical research, randomized controlled trials, RCT, TCM clinical trials, personalized treatment, standardized research

Introduction

Clinical trials are studies designed to answer specific questions (involving human subjects or related samples, such as tissues or blood, requiring human intervention research).[1] They are a crucial component of medical research, systematically evaluating the efficacy, safety, and effects of a particular drug or treatment in humans. This process translates theoretical mechanisms into clinical practice, providing a scientific basis for medical decision-making.

RCTs, regarded as the gold standard in clinical trials, utilize random assignment and strict selection criteria to allocate participants into different study groups. This method reduces selection bias and confounding factors, thereby enhancing the internal validity of the study results. RCTs typically employ placebo controls, blinding, and objective outcome measures to improve the reliability and interpretability of evidence. However, RCTs also have limitations, such as high

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costs, implementation challenges, and the potential to overlook individual differences. These limitations are particularly pronounced in the field of TCM.[2]

TCM has a long-standing history of clinical practice but lacks systematic clinical research and standardized guidelines, leading to conflicts between TCM and modern clinical research. For example, Chinese herbal compound formulas, the primary form of TCM clinical treatment, have been widely used in practice. Since the first report of a randomized controlled trial of Chinese herbal medicine was published in 1982, tens of thousands of clinical trial reports related to these formulas have been documented. In the absence of unified standards at that time, these trials were not fully standardized, however, their quality was often suboptimal. Although standards such as the Consolidated Standards of Reporting Trials (CONSORT) for Chinese Herbal Medicine Formulas,[3] the extended CONSORT for Acupuncture interventions (Standards for Reporting Interventions in Clinical Trials of Acupuncture, STRICTA),[4] and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) for TCM have been introduced,[5] the quality of TCM clinical trial reporting has not significantly improved. During a bottleneck period of several decades, the stagnation in establishing comprehensive standards has undoubtedly hindered the further development of TCM clinical trials. International skepticism and criticism have also significantly impeded the application and promotion of TCM in clinical practice and patient care. Though the unified standard for reporting Chinese herbal compound clinical trials (CONSORT Extension for Chinese Herbal Medicine Formulas, CONSORT–CHM Formulas, 2017) has incorporated TCM syndrome differentiation and specific characteristics of Chinese herbal formulas,[3] expanding sections on various aspects such as the abstract, background, objectives, participants, interventions, outcome measures, generalizability, and interpretation, the practical implementation of these new standards is still limited. The lack of comprehensive systemic standards for TCM remains unresolved, and the foundational weaknesses in TCM clinical research, such as unclear research objectives, inappropriate methodological choices, inadequate quality control during implementation, non-standardized result presentation, and insufficient evidence translation and application,[6] ultimately reflect the shortfall in TCM standardization. The establishment and implementation of TCM clinical standards require the concerted efforts of experts and scholars across various fields and represent a long-term endeavor. It necessitates the development of clinical practice guidelines, a shared quality standard database for TCM, and the establishment of quality evaluation and certification systems for high-quality Chinese herbal varieties.[7] These efforts aim to fully realize the clinical efficacy of TCM, give rise to ongoing theoretical development, mitigate conflicts, and integrate with modern international clinical research.

The unique characteristics of TCM diagnostics and treatment lie in its Holistic Concept, Treatment Based on Syndrome Differentiation, and Formula Modification Based on Symptom Changes. These principles are fundamentally at odds with the standardized interventions required in RCT.[8] In spite of evidence-based TCM has established several standardized treatment protocols, for adult influenza, these protocols categorize the condition into mild, severe, and recovery phases based on symptom severity and further classify them according to specific syndromes. Among the mild phase, Wind-Heat Invading the Defense Level (exterior syndrome caused by pathogenic wind-heat, manifesting as fever, sore throat, and floating pulse), Wind-Cold Tightening the Exterior (exterior syndrome due to wind-cold pathogens, characterized by chills, headache, and absence of sweating), Exterior Cold with Interior Heat (pathological state with cold pathogens on the body surface and heat accumulation internally), and Accumulation of Heat-Toxin in the Lung (severe inflammatory lung condition caused by intense pathogenic heat) are treated with Yin Qiao San, Shu Feng Jie Biao Fang, Da Qing Long Tang, and a combination of Ma Xing Shi Gan Tang and Jin Hong Tang, respectively. In the severe phase, Pathogenic Qi Obstructing the Lung (respiratory dysfunction due to pathogenic factors blocking lung function) and Vital Qi about to Collapse (Vital Qi is weakened and on the verge of collapse) are treated with Xuan Bai Cheng Qi Tang combined with Shen Huang Granules to clear heat and purge the lung. Internal Sinking of Toxic Heat (progression of severe heat-toxin pathogens into deeper physiological layers), Interior Blockage with Exterior Collapse (complex crisis combining organ dysfunction and Yang Qi depletion) is treated with Shen Fu Tang to rescue the body by Tonifying Qi and Enriching Blood. The recovery period is characterized by the main pathological mechanism of Deficiency of Both Qi and Yin (dual depletion of vital energy and body fluids), which is treated with Shashen Maidong Tang by Tonifying Qi and Nourishing Yin (therapeutic strategy for replenishing energy and fluids simultaneously).[9] In actual clinical practice, however, physicians often make flexible adjustments to prescriptions based on their personal experience and expertise, introducing new variables into the treatment process.

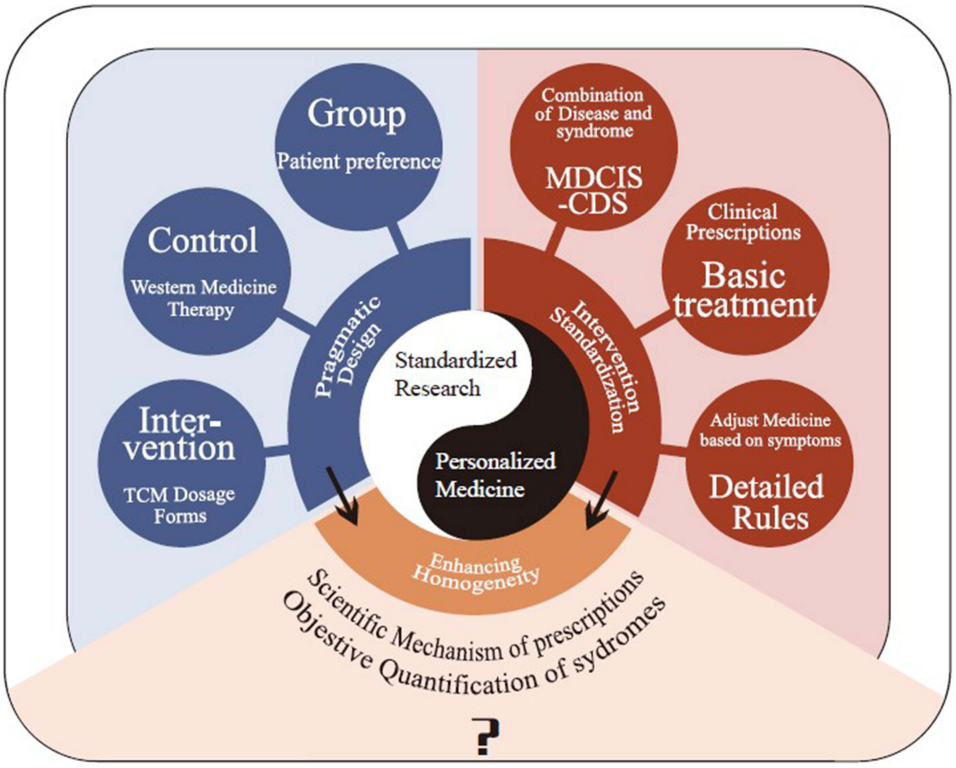

Figure 1 Personalized medicine and Standardized research.
Abbreviations: TCM, Traditional Chinese Medicine; MDCIS-CDS, Multidimensional Core Information Set for Combined Disease and Syndrome Diagnosis.

Resolving the conflict between the variability inherent in TCM treatment and the uniformity required in clinical research holds great significance. Not only would this advance the modernization of TCM, but it would contribute to global health initiatives. By optimizing clinical trial design, the efficacy and safety of TCM can be better assessed, thereby enhancing its acceptance and application within global healthcare systems. This study reviews and categorizes TCM-related clinical trials registered on clinicaltrials.gov over the past three years. The objective is to summarize experiences, identify current challenges, and provide practical references for the design of TCM clinical trials (the database is public offering a free open license for unrestricted use by both domestic and international researchers, with all data confirmed to be anonymous) (Figure 1).

Practical Research Design

The statistical data from this study indicate that from January 1, 2021, to January 1, 2024, most registered clinical trials relating to TCM remain in the recruitment phase, with experimental studies being predominant, totaling 213 (Figure 2). In terms of intervention measures, Chinese medicines, especially granules, are widely used (Figure 3), suggesting that research in the field of TCM clinical trials are steadily advancing, although a significant proportion of studies have yet to progress to subsequent stages.

Regarding research design methods, most TCM clinical trials follow the principles of randomization, parallel control, and blinding. Among these, 188 experimental studies employ randomized designs (Supplementary Table 1). In recent years, RCT has remained the mainstream design method in TCM research, reflecting a gradual alignment with modern scientific research paradigms to enhance its scientific rigor and credibility. However, achieving a balance between individualized treatment and standardized RCTs is crucial for optimizing TCM research, enhancing its credibility, and promoting its modernization and internationalization. The main challenges in TCM trial design lie in reconciling conflicts with traditional RCTs, such as dealing with complex medical environments, the potential for fully randomized grouping

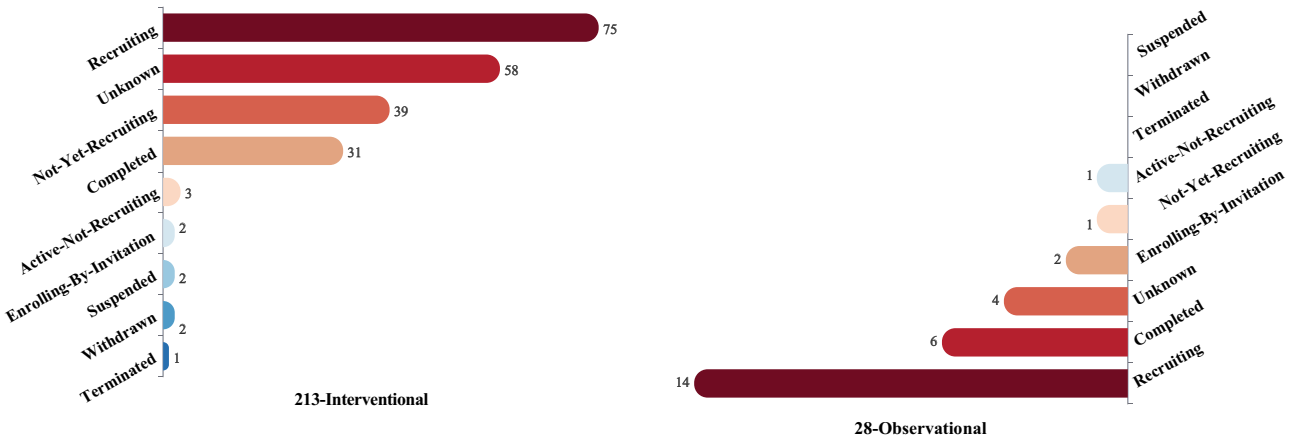

Figure 2 Research types and status.

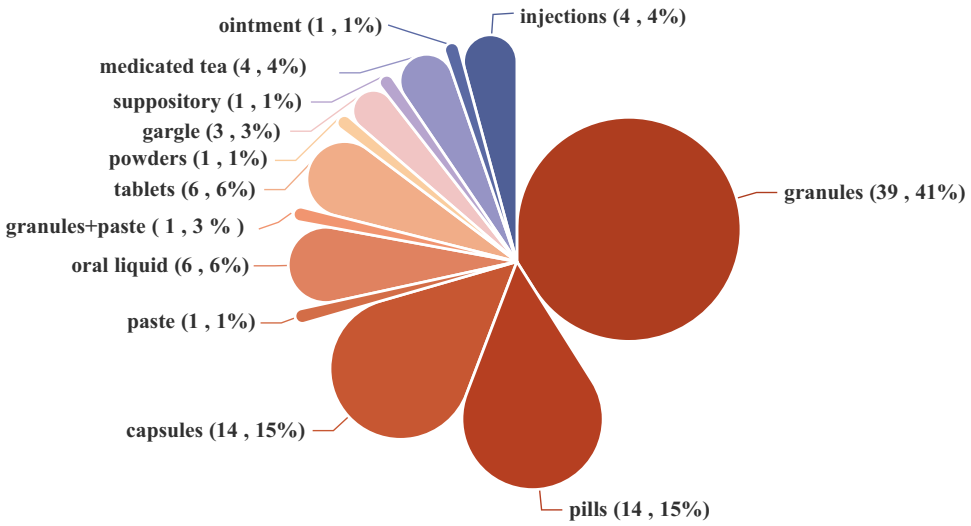

Figure 3 Dosage forms of TCM patent.

to conflict with patient preferences, difficulties in implementing placebo controls, and issues of confounding between intervention and control groups.

Therefore, when selecting research designs, the classic RCT poses certain difficulties in practical application within TCM clinical trials due to its idealized and controlled experimental environment. Based on the aforementioned data, TCM trial designs should innovate upon the classic RCT framework by adopting pragmatic trial methods to better accommodate real-world clinical settings. Pragmatic trials, which measure the effectiveness of interventions in clinical practice through real-world evidence,[10–13] aim to retain the holistic concepts, syndrome differentiation, and flexible treatment adjustments to prescriptions based on symptoms in TCM, making them more suitable for TCM clinical trials. On the one hand, TCM is often used to treat chronic diseases, emphasizing a People-Centered Approach (clinical philosophy prioritizing individual patient characteristics over standardized protocols) and focusing on the improvement of the patient's overall condition and symptoms. On the other hand, TCM has a clear and specific natural endpoint, which is the balance of Yin and Yang. Consequently, pragmatic RCT designs can methodologically mitigate the conflicts between TCM clinical trials and classic RCTs.

Grouping by Patient Preferences

Classic RCTs enhance homogeneity by using fully random group assignments, effectively avoiding selection bias. However, TCM RCTs often occur in TCM departments of hospitals where patients seek TCM treatments, exhibiting

a clear subjective preference. Fully random group assignments may conflict with patient preferences, making it difficult to obtain informed consent for non-TCM interventions.[14,15] Blinding patients can also lead to high dropout rates due to the low efficacy of placebos.[16,17] Difficulties in recruitment and high dropout rates may contribute to the long duration of TCM clinical trials.[6,18,19] For instance, in a randomized study on acupuncture for dysmenorrhea by Witt et al,[20] a patient preference-based randomization was used. Patients willing to be randomized were assigned to acupuncture or control groups, while those unwilling were included in a non-randomized acupuncture group, addressing compliance issues caused by going against patient preferences and ensuring the effective completion of the trial.

Control with Standard Western Medical Treatment

RCTs generally use placebo controls and emphasize blinding to reduce bias.[21] Although placebo/blinding methods are often used in TCM clinical trials, practical challenges exist in TCM research. The diverse types of TCM interventions make creating placebos difficult, especially for herbal decoctions, whose smell, color, and taste are hard to replicate. Acupuncture and moxibustion, tuina (Chinese therapeutic massage), and auricular acupoints therapy involve direct patient interaction, making sham placebo treatments challenging. Ethical concerns also make it difficult for patients to accept placebo treatments. Therefore, we recommend using standard clinical treatments as controls,[22] which can avoid risks associated with ineffective placebo treatments, reduce the pressure of informed consent and increase the generalizability of trial results. In a study by Chen et al on Chinese medicine combined with tiotropium bromide for stable chronic obstructive pulmonary disease (COPD),[23] tiotropium bromide commonly used for COPD treatment, was used as a control. This ensured that both the Chinese medicine and control groups were effective, reducing adverse reaction risks and demonstrating significant effects of Chinese medicine in improving sputum symptoms in stable COPD patients. Coincidentally, in a study on electroacupuncture for female stress urinary incontinence,[24] a pragmatic placebo needle similar to the Streitberger device was used, where both groups experienced skin stimulation, achieving a blinding effect.

Enhancing TCM Intervention Methods

In experimental research involving Western medicine, it is relatively straightforward to maintain consistency in dosage forms and administration routes between experimental and control groups, whether using placebo or active drug controls. However, ensuring the comparability between experimental TCM and control groups (in terms of drug structure, mechanism of action, dosage form, and administration method) presents a significant challenge.[25,26] Traditional Chinese herbal decoctions have drawbacks such as time-consuming preparation, storage difficulties, strong taste, and unpleasant flavor, as well as challenges in creating placebos.[27–29] Therefore, we recommend transforming TCM into granules, capsules, or other forms, which not only standardizes TCM interventions and enhances consistency in drug action but also improves patient adherence by eliminating the need for self-preparation of herbal decoctions.[30,31]

Standardization of Interventions

The complexity and dynamic nature of TCM interventions are rooted in the understanding of diseases, syndromes, and symptoms across three levels. This complexity is reflected in the dynamic adjustment of treatment plans, the combined use of multiple treatment modalities, and the multi-dimensional intervention in patient discomfort. Thereupon, employing complex interventions,[32] which do not strictly define the details of implementation and allow clinicians to perform individualized syndrome differentiation within a certain scope. This approach aligns with the principles emphasised by TCM on the Integration of the Four Diagnostic Methods (the comprehensive use of inspection, listening and smelling, inquiry, and palpation in diagnosis), Treatment in Accordance with Three Categories of Etiologic Factors (treatment customization according to individual constitution, seasonal changes, and geographical factors), and Treatment Based on Syndrome Differentiation. Nevertheless, the number and scope of intervention components can vary greatly, making it crucial to standardize interventions to limit their complexity. Standardizing interventions goes beyond formal standardization to include standardization of diagnostic thinking.

Standardizing Syndrome Diagnosis

Appropriate inclusion and exclusion criteria are prerequisites for standardized diagnosis in TCM clinical trials. We suggest continuing to use patient inclusion strategies that meet both Western and Chinese medical standards, while adding specific TCM syndromes as inclusion criteria to further refine standards.[33] This approach ensures disease homogeneity while allowing for a degree of individualized expression. Optimizing the integration of Chinese and Western medical inclusion and exclusion criteria essentially involves standardizing syndrome diagnosis.

Promoting standardized diagnosis in TCM clinical trials begins with constructing a Multidimensional Core Information Set for Combined Disease and Syndrome Diagnosis (MDCIS-CDS), which quantifies symptoms to make syndrome differentiation explicit, objective, and scientific. MDCIS-CDS provides researchers with a standardized syndrome diagnosis framework, helping them establish standardized comprehensive treatment plans for patients at the outset of a study. During the study, it assists researchers in tracking changes in participants' syndromes and adjusting treatment plans accordingly to enhance specificity and effectiveness.[34] Drawing on internationally recognized methods for constructing core outcome sets,[35] MDCIS-CDS can be developed through: a) incorporating a Minimal Core Symptom Set (MiCSS) for syndromes, such as Based on symptoms like chest tightness, greasy skin and hair, coughing up phlegm, chest pain, and chest oppression, individuals exhibiting these symptoms are classified as having the phlegm-stasis interjunction coronary heart disease, as done by Ren Liu et al;[36] b) standardizing methods for collecting signs such as tongue and pulse information, reducing personal experience bias in manual collection through the use of tongue and pulse measurement devices and artificial intelligence,[37] which decreases subjectivity in interpreting tongue and pulse data; c) collecting multidimensional laboratory multimodal biochemical imaging objective indicators to deeply explore specific biomarkers across multiple omics. Modern research has found that TCM syndrome differentiation in diseases exhibits individual differences in genomics,[38,39] proteomics and other omics, and identifying specific biomarkers across these omics can effectively enhance the recognition and acceptance of TCM syndrome diagnosis.

Furthermore, a subgroup dynamic-static parallel group design can be employed.[40] In this approach, patients are first divided into a TCM group and a control group based on the disease or a specific stage of the disease, and the TCM group is further divided into subgroups according to Syndrome (pathological profile integrating cause, location, and nature of disease). The advantage of this method lies in its adherence to the principle of treatment based on syndrome differentiation, allowing for precise patient classification that ensures compatibility with the characteristics of TCM. Additionally, subgroup research reveals the specificity and variability of treatment efficacy among different patients, accommodating both dynamic and static factors and embodying the principle of Treatment in Accordance with Three Categories of Etiologic Factors, thereby enhancing treatment specificity. At the same time, to prevent excessive classification leading to unbalanced grouping and significant intergroup differences, the categories of syndromes should be appropriately limited. This can be achieved by referencing methods such as the Eight-Principle, Six Meridians, and Triple Energizer Differentiation, focusing on the target disease of the study and incorporating syndrome elements like nature, location, and mechanism of the disease. For instance, a clinical trial on TCM for stable angina categorized patients into two types,[41] Phlegm-Stasis Intermingling Type (a pathological state combining phlegm-dampness and blood stasis, leading to Qi stagnation and microcirculatory dysfunction; clinically manifests as masses, fixed pain, or chronic inflammation) and Qi Deficiency with Blood Stasis Type (a pathological state where insufficient Qi fails to propel blood circulation, resulting in stagnant blood flow; clinically manifests as chronic fatigue, fixed pain, and purple-dark tongue), based on the Western medicine diagnosis of stable angina and combined with TCM syndromes, providing different herbal compound treatments.

Standardizing Treatment Protocols

The purpose of standardized syndrome diagnosis is to set a comprehensive treatment plan based on the research objective, using the disease or a specific phase of the disease as a unit and syndromes as the basis. This plan can consist of a single foundational formula for the entire disease or multiple foundational formulas targeting different syndromes of the disease. It is crucial to note that once the overall treatment plan is established, it should not be altered. Given the vast number of TCM formulas and their flexible modifications, it is inefficient to conduct clinical research on every formula.

Therefore, we recommend starting with empirically validated formulas from renowned TCM practitioners. Given the current limitations in developing animal models for TCM syndromes and pharmacological studies, it is advisable to prioritize early human data from clinical trials of Chinese herbal medicine over solely relying on animal experiments for better evidence quality.[42] These formulas, refined over extended periods of clinical application, target specific diseases and syndromes with proven therapeutic effectiveness and safety. They also serve as a foundation for subsequent experimental studies to elucidate their mechanisms of action, such as therapeutic targets, which enhances the homogeneity and generalizability of TCM clinical trials.[43,44] Another example is, in a clinical study evaluating the effectiveness of Chinese medicine in treating anovulatory infertility,[45] infertility resulting from six different etiologies was unified under the core pathogenesis of Insufficiency of Kidney Qi (a pathological state marked by declining Kidney Qi, which governs growth, reproduction, bone health, and fluid metabolism; manifests as low back pain, hearing loss, frequent urination, or developmental delays in children), and all cases were treated with Bushen CuLuan Tang (Kidney-Tonifying and Ovulation-Promoting Decoction), resulting in effective outcomes.

Holistic understanding to diseases of TCM requires addressing diseases on three levels: disease, syndrome and symptoms. Among these, syndrome differentiation is the core, but it is also essential to consider positive symptoms that affect patients' quality of life. Therefore, TCM prescriptions must achieve a balance between syndrome-specific formulas and symptom-based modifications. Flexibility in prescription is a hallmark of TCM's individualized diagnosis and treatment; however, this flexibility should be guided by a defined framework. In syndrome differentiation and medication adjustments, explicit guidelines must be provided. Specifically, adjustments to prescriptions based on symptoms should clearly state the symptoms requiring modification, along with the specific herbal components and their dosages. This avoids ambiguity in prescription rules. For instance, in a multicenter randomized controlled study on TCM treatment of recurrent urinary tract infections,[46] syndrome scores were assigned based on patients' symptoms during treatment. Adjustments to the herbal formula were made according to the scores, enabling personalized treatment.

Conclusion and Outlook

Traditional Chinese Medicine (TCM) has a long-standing historical tradition of theory and practice, and their modernization is crucial for cultural preservation and global health. Therefore, this article attaches significance to the use of modern scientific methods, particularly clinical trials, to validate the efficacy and safety of TCM, thus promoting and preserving its cultural implications. It is recommended to employ pragmatic randomized controlled trials (RCTs) to gather real-world evidence, addressing the limitations of classical RCT designs in TCM research. This approach not only enhances the scientific rigor of studies by adhering to standardized research protocols but also preserves the core characteristics of TCM, such as individualized treatment, syndrome differentiation, and symptom-based adjustments, thereby integrating personalized care into standardized research frameworks.

However, current TCM clinical trials face several challenges. Initially, syndrome diagnosis and personalized medication lack internationally recognized standards, primarily due to the absence of clear quantitative criteria for the four diagnostic methods and key symptoms. Secondly, the credibility of clinical prescriptions is often questioned, as they are based on practical experience but lack sufficient theoretical support regarding their applicability to specific populations and formulation characteristics. Foundational mechanism research remains inadequate, particularly concerning the action targets of multi-component herbal formulas.

To address these issues, future research should focus on the development and refinement of syndrome biomarkers and objective measurement devices for primary symptoms, such as artificial intelligence, diagnostic instruments, and multi-omics technologies.[47] Additionally, complementary diagnostic and medical devices, such as wearable technology and symptom measurement tools,[48] will greatly aid in translating TCM diagnostic experience into concrete medical evidence. Furthermore, it is essential to conduct in-depth foundational research on renowned clinical prescriptions, utilizing modern technology to explore their effective targets and mechanisms in disease treatment, thereby continually advancing the modernization of TCM. Through these efforts, the international recognition and influence of TCM in the global health sector will be significantly enhanced, contributing more to human health endeavors.

This study, through a detailed statistical analysis of the current status and characteristics of TCM clinical registration trials, ultimately proposes the concept of using pragmatic RCTs to collect real-world evidence. This provides an

innovative framework for TCM clinical trials, effectively integrating traditional TCM features with modern scientific methods, thereby enhancing the reliability and feasibility of research. It offers crucial theoretical support and innovative solutions for the design and implementation of TCM clinical trials, as well as injects new vitality and perspectives into research and therapeutic practices in both domestic and international integrative medicine fields.

Abbreviations

RCT, Randomized controlled trials; TCM, Traditional Chinese Medicine; CONSORT, Consolidated Standards of Reporting Trials; STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture; CONSORT–CHM Formulas, CONSORT Extension for Chinese Herbal Medicine Formulas; COPD, Chronic obstructive pulmonary disease; MDCIS-CDS, Multidimensional Core Information Set for Combined Disease and Syndrome Diagnosis; MiCSS, Minimal core symptom set; Treatment Tailored to Individual, A principle emphasizing personalized treatment based on a patient's constitution, age, gender, and lifestyle differences; Treatment Based on Syndrome Differentiation, Diagnosis and treatment based on identifying and addressing the patient's specific syndrome or pattern of imbalance; Holistic Concept, The approach of considering the body as an integrated whole, emphasizing the interconnection between physical, emotional, and environmental factors in health and disease; Formula Modification Based on Symptom Changes, Modifying the treatment plan based on the changes in the patient's symptoms to better suit their current condition; Wind-Heat Invading the Defense Level, Exterior syndrome caused by pathogenic wind-heat, manifesting as fever, sore throat, and floating pulse; Wind-Cold Tightening the Exterior, Exterior syndrome due to wind-cold pathogens, characterized by chills, headache, and absence of sweating; Exterior Cold with Interior Heat, Pathological state with cold pathogens on the body surface and heat accumulation internally; Accumulation of Heat-Toxin in the Lung, Severe inflammatory lung condition caused by intense pathogenic heat; Qi (Vital Energy), Fundamental life force circulating through meridians, representing the vital energy or life force that flows through the body, essential for maintaining health and balance; Pathogenic Qi Obstructing the Lung, Respiratory dysfunction due to pathogenic factors blocking lung function; Vital Qi about to Collapse, Vital Qi is weakened and on the verge of collapse; Internal Sinking of Toxic Heat, Progression of severe heat-toxin pathogens into deeper physiological layers; Internal Blockage with External Collapse, Complex crisis combining organ dysfunction (internal blockage) and yang qi depletion (external collapse); Tonifying Qi and Enriching Blood, A therapeutic method to strengthen both Qi (vital energy) and Blood (circulating nourishment), addressing symptoms like fatigue, pale complexion, and weakness; Yin, one half of the yin-yang duality, representing qualities such as darkness, cold, passivity, and substance. It is crucial for maintaining balance and harmony within the body; Deficiency of Both Qi and Yin, Dual depletion of vital energy and body fluids; Tonifying Qi and Nourishing Yin, Therapeutic strategy for replenishing energy and fluids simultaneously; People-Centered Approach, Clinical philosophy prioritizing individual patient characteristics over standardized protocols; Acupuncture and Moxibustion, WHO-recognized TCM modality using needles (acupuncture) and heated herbs (moxibustion); Tuina (Chinese Therapeutic Massage), Manual therapy regulating Qi flow through specific manipulation techniques; Auricular Acupoints, Microsystem acupuncture points on the ear; Four Diagnostic Methods, Core diagnostic techniques: inspection, auscultation-olfaction, inquiry, palpation; Integration of the Four Diagnostic Methods, Holistic integration of diagnostic information from all four methods; Adaptation to Three Causes, Treatment customization according to individual constitution, seasonal changes, and geographical factors; Syndrome, Pathological profile integrating cause, location, and nature of disease; Eight-Principle, The fundamental framework of Chinese diagnosis: Yin-Yang, exterior-interior, cold-heat, deficiency-excess; Six Meridians, A foundational diagnostic framework in Shanghan Lun, classifying disease progression into six stages (Taiyang, Yangming, Shaoyang, Taiyin, Shaoyin, Jueyin) based on pathogenic depth and physiological responses; Triple Energizer Differentiation, Warm disease diagnosis focusing on three body cavities; Phlegm-Stasis Intermingling Type, A pathological state combining phlegm-dampness and blood stasis, leading to Qi stagnation and microcirculatory dysfunction; clinically manifests as masses, fixed pain, or chronic inflammation; Qi Deficiency with Blood Stasis Type, A pathological state where insufficient Qi fails to propel blood circulation, resulting in stagnant blood flow; clinically manifests as chronic fatigue, fixed pain, and purple-dark tongue; Insufficiency of Kidney Qi, A pathological state marked by declining Kidney Qi, which governs growth, reproduction, bone health, and fluid

metabolism; manifests as low back pain, hearing loss, frequent urination, or developmental delays in children; Prescribing Based on Syndrome Differentiation, Formula selection guided by identified syndrome patterns.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests in this work.

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