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Clinical research report on Chinese patent medicines and classic traditional Chinese medicine prescriptions (2023)

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ABSTRACT

Objective Randomized controlled trials (RCTs) of Chinese patent medicines and classic traditional Chinese medicine prescriptions were systematically reviewed from both Chinese and English journals published in 2023. A preliminary summary and evaluation were conducted on the generation and translation of clinical evidence for these treatments. This analysis aims to inform future research on clinical efficacy evaluation and guide the rational application of evidence.

Methods RCTs of Chinese patent medicines and classic traditional Chinese prescriptions published in 2023 were comprehensively retrieved from the Artificial Intelligence Clinical Evidence Database for Chinese Patent Medicine (AICED-CPM), with supplementary searches conducted in China National Knowledge Infrastructure (CNKI), Wanfang Data, Chinese Science and Technology Journal Database (VIP), Chinese Biomedical Literature Database (SinoMed), Cochrane Library, PubMed, Embase, and Web of Science. The study characteristics and methodological quality of these RCTs were systematically analyzed and evaluated.

Results A total of 1 443 RCTs of Chinese patent medicines were included, comprising 1 399 Chinese articles and 44 English articles. Additionally, 334 RCTs of classic traditional Chinese medicine prescriptions were found, with 331 published in Chinese and 3 in English. 196 567 participants were included, covering 585 types of Chinese patent medicines (487 oral, 61 injectable, and 37 topical) and 179 classic traditional Chinese medicine prescriptions. The involved studies encompassed 22 types of diseases, with research primarily focusing on diseases of the circulatory system, the respiratory system, and the genitourinary system. The sample sizes ranged from 18 to 3 777 participants, and most studies were conducted at a single center. Methodologically, the implementation of allocation concealment and blinding remained insufficiently emphasized.

Conclusion Overall, compared with 2022, both the number of RCT publications and their methodological quality have improved in 2023, with heightened attention to research on

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diseases of the genitourinary system. However, quality control and standardized management in the design and implementation processes still require enhancement to produce more high-quality clinical evidence and accelerate the translation and application of this evidence.

1 Introduction

Traditional Chinese medicine is based on the principle of preventing illness before it occurs, and when illness does arise, preventing its progression. This approach provides significant advantages in the prevention and treatment of various diseases [1]. Chinese patent medicines and classic traditional Chinese medicine prescriptions are crucial components of traditional Chinese medical treatment. Chinese patent medicines are distinguished by their convenience, readily identifiable components, notable therapeutic effects, and high patient compliance [2, 3]. Classic traditional Chinese medicine prescriptions embody a wealth of knowledge derived from China's long history of disease prevention and treatment, characterized by meticulous formulation and reliable efficacy [4]. Currently, with the widespread clinical application of Chinese patent medicines and classic traditional Chinese medicine prescriptions, the number of related randomized controlled trials (RCTs) has grown rapidly [5-8]. However, design flaws and methodological issues in the design and implementation process undermine the authenticity and reliability of the research results [9]. Therefore, it is increasingly important to conduct scientifically rigorous studies to obtain high-quality evidence on efficacy and safety [10, 11].

This study provides a statistical analysis and evaluation of the clinical research evidence on Chinese patent medicines and classic traditional Chinese medicine prescriptions published in 2023. The goal is to offer evidence-based support for the rational and safe use of these treatments in clinical practice, promote the transformation of traditional Chinese medicine clinical research and decision-making models, and serve as a reference for future related clinical studies and the translation of evidence into practice [12].

2 Data and methods

2.1 Search strategy

The Artificial Intelligence Clinical Evidence Database for Chinese Patent Medicine (AICED-CPM) (https://admin.tcmevd.com/index#/login) was searched, supplemented by searches of China National Knowledge Infrastructure (CNKI), Wanfang Data, Chinese Science and Technology Journal Database (VIP), Chinese Biomedical Literature Database (SinoMed), Cochrane Library, PubMed, Embase, and Web of Science for RCTs on Chinese patent medicines and classic traditional Chinese medicine prescriptions. The search period covered January 1, 2023 to December 31, 2023. The detailed search strategy can be found in Supplementary Table S1.

2.2 Inclusion criteria

(i) Type of study: RCTs. (ii) Patients: study subjects were not restricted. (iii) Intervention and comparison: the intervention for the test group consisted of Chinese patent medicine/classic traditional Chinese medicine prescriptions or a combination of Chinese patent medicine/classic traditional Chinese medicine prescriptions with other interventions, with no restrictions on the dosage form of the Chinese patent medicine. The control group interventions included Chinese patent medicine/classic traditional Chinese medicine prescriptions, other interventions, a combination of Chinese patent medicine/classic traditional Chinese medicine prescriptions with other interventions, a blank control, or a placebo. (iv) Outcomes: the evaluation indices were not restricted.

2.3 Exclusion criteria

Exclusion criteria were as follows: repeatedly published studies, non-randomized controlled studies, studies with inaccessible full texts or incomplete data, conference papers, and dissertations.

2.4 Study screening and data extraction

For literature on the target topics already included in the AICED-PCM [13], the system exported relevant structured data, which were then organized and structured according to the required entries. The supplementary database literature was independently reviewed by two researchers using NoteExpress, who screened the literature according to pre-established inclusion and exclusion criteria. Any discrepancies were resolved through discussion with a third researcher. Information was extracted based on five key aspects: participants, interventions, comparisons, outcomes, and study design.

2.5 Quality assessment

The quality of the RCTs was assessed using the Cochrane Risk of Bias (RoB) assessment tool [14, 15], which includes seven aspects: (i) random sequence generation, (ii) allocation concealment, (iii) blinding of patients and personnel, (iv) blinding of outcome assessment, (v) incomplete

outcome data, (vi) selective reporting, and (vii) other biases. The assessment results were presented as “low risk” “high risk” or “unclear risk.”

3 Results

3.1 Chinese patent medicine

3.1.1 Overview of published literature In 2023, a total of 1 443 clinical RCTs on Chinese patent medicines were published, including 1 399 in Chinese and 44 in English. A flowchart of the literature screening process is shown in Figure 1. RCTs on Chinese patent medicines were conducted across 31 provinces, municipalities, and autonomous regions in China. The top three regions in terms of RCT publication volume were Henan Province (230 articles), Jiangxi Province (132 articles), and Shandong Province (127 articles). The participating institutions included tertiary hospitals, secondary hospitals, primary hospitals (township health centers), medical schools, research institutions, and private hospitals. Among the Chinese-language publications, 78.56% (1 098/1 399) had a tertiary hospital as the leading institution, while in the English-language publications, 100% (44/44) were led by tertiary hospitals. The geographical distribution of RCTs on Chinese patent medicines is shown in Figure 2.

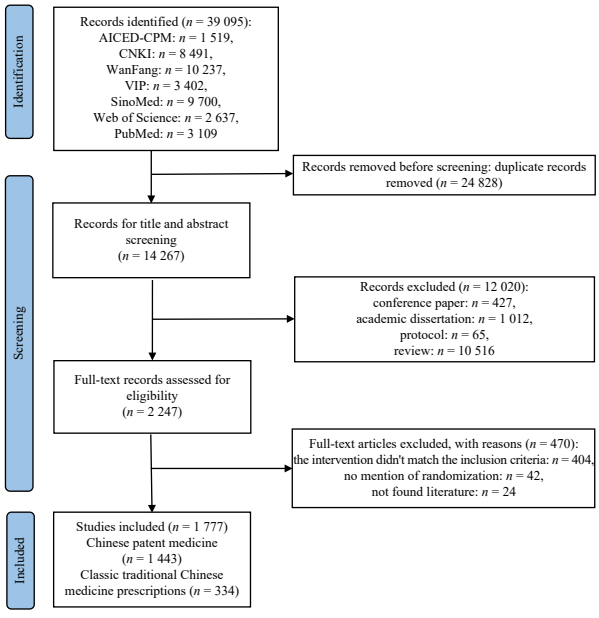

Figure 1 Literature screening flowchart

3.1.2 Overview of publication journals In 2023, RCTs on Chinese patent medicines were published across 301 journals. Among them, 276 were Chinese-language journals, including 30 journals indexed in the Peking University Chinese Core Journals list, which published 149

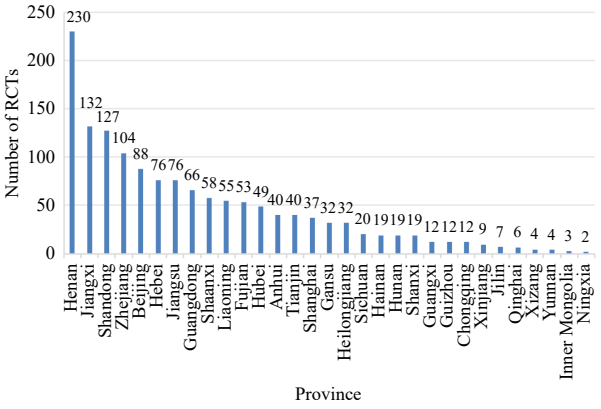

Figure 2 The geographical distribution of RCTs on Chinese patent medicines

articles (10.65%). The journal *Chinese Archives of Traditional Chinese Medicine* had the highest number of publications, with 27 articles. A total of 113 journals indexed in the Chinese Science Citation Database (CSCD) published 441 articles (31.52%), with *Drugs & Clinic* having the most publications at 75 articles. The top 10 Chinese-language journals by publication volume were *Drugs & Clinic*, *Journal of New Chinese Medicine*, *Chinese Journal of Clinical Rational Drug Use*, *Clinical Research and Practice*, *Journal of Practical Traditional Chinese Medicine*, *Medical Journal of Chinese People's Health*, *Chinese Archives of Traditional Chinese Medicine*, *Practical Clinical Journal of Integrated Traditional Chinese and Western Medicine*, *Modern Diagnosis and Treatment*, and *Liaoning Journal of Traditional Chinese Medicine*. Chinese-language journals with 20 or more publications are listed in Table 1. A total of 25 English-language journals were involved, with 24 of them indexed by SCI. The impact factors (IF) of these journals ranged from 0.4 to 22.5. The journal with the highest IF was *JAMA Internal Medicine* (IF 22.5, 1 article). Details of the publications in English-language journals are presented in Table 2.

3.1.3 Disease types and distribution (i) Number of diseases types. According to the latest International Classification of Diseases (ICD) 11th Revision, the RCTs on Chinese patent medicines published in 2023 covered 22 disease categories. The circulatory system diseases had the highest number of publications (217 articles, 15.04%), followed by the respiratory system diseases [216 articles, 14.97%, including 16 studies on coronavirus diseases 2019 (COVID-19)], and the genitourinary system diseases (184 articles, 12.75%). The top 10 RCTs of Chinese patent medicines involving diseases classified according to ICD-11 are shown in Table 3.

(ii) Disease distribution. A statistical analysis of disease names involved in RCTs on Chinese patent medicines published in 2023 revealed the following: in the circulatory system diseases category, coronary heart disease had the highest number of publications (70 articles, 4.85%); in the respiratory system diseases, chronic

Table 1 Ranking of Chinese-language journals by the number of publications related to RCTs on Chinese patent medicines in 2023 (≥20 articles)

Journal	Number of RCTs
Drugs & Clinic	75
Journal of New Chinese Medicine	73
Chinese Journal of Clinical Rational Drug Use	37
Clinical Research and Practice	30
Journal of Practical Traditional Chinese Medicine	28
Medical Journal of Chinese People's Health	28
Chinese Archives of Traditional Chinese Medicine	27
Practical Clinical Journal of Integrated Traditional Chinese and Western Medicine	26
Modern Diagnosis and Treatment	26
Practical Clinical Journal of Integrated Traditional Chinese and Western Medicine	26
Modern Diagnosis and Treatment	26
Liaoning Journal of Traditional Chinese Medicine	23
Nei Mongol Journal of Traditional Chinese Medicine	23
Women's Health Research	23
Chinese Journal of Modern Drug Application	22
Chinese Medicine Modern Distance Education of China	21

Table 2 Publications in English-language journals on RCTs of Chinese patent medicines in 2023 (with 2023 IF ⩾ 5.0)

Journal	IF	Number of RCTs
JAMA Internal Medicine	22.5	1
Journal of the National Comprehensive Cancer Network	14.8	1
JAMA Network Open	10.5	1
Pharmacological Research	9.1	1
Chinese Medical Journal	7.4	1
Phytomedicine	6.7	4
Phytotherapy Research	6.1	1

obstructive pulmonary disease (COPD) was the most frequently studied (40 articles, 2.77%); in the genitourinary system diseases, diabetic nephropathy led in publication volume (32 articles, 2.22%); and in the nervous system diseases, ischemic stroke had the most publications (89 articles, 6.17%). The diseases with the highest research focus (the top 10 by publication volume) were as follows: ischemic stroke (89 articles, 6.17%), coronary heart disease (70 articles, 4.85%), COPD (40 articles, 2.77%), diabetic nephropathy (32 articles, 2.22%), type 2 diabetes mellitus (26 articles, 1.80%), chronic heart failure (25 articles, 1.73%), fractures (23 articles, 1.59%), influenza (21 articles, 1.46%), acute upper respiratory tract infection (20 articles, 1.39%), and osteoarthritis (19 articles, 1.32%). The annual distribution of diseases in RCTs on Chinese patent medicines is shown in Figure 3.

Table 3 RCTs on Chinese patent medicine involving ICD-11 disease classification (top 10)

Disease type	Number of RCTs
Diseases of the circulatory system	217
Diseases of the respiratory system	216
Diseases of the genitourinary system	184
Diseases of the nervous system	145
Neoplasms	98
Diseases of the digestive system	95
Certain infectious or parasitic diseases	68
Diseases of the musculoskeletal system or connective tissue	65
Endocrine, nutritional or metabolic diseases	60
Traditional medicine conditions	46

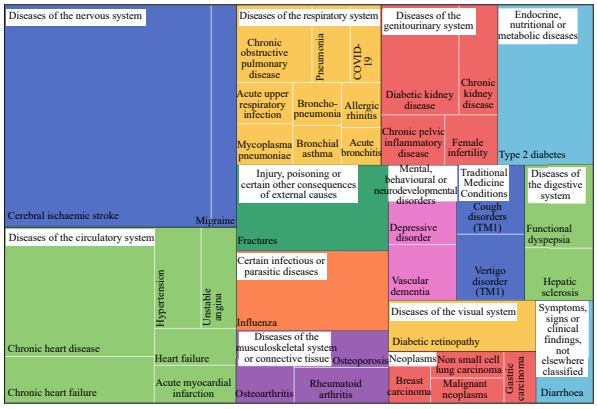

Figure 3 Distribution of diseases in RCTs on Chinese patent medicines in 2023

3.1.4 Situation of Chinese patent medicine The included RCTs involved 585 types of Chinese patent medicines, comprising 487 oral formulations, 61 injectable forms, and 37 topical preparations, primarily targeting circulatory and respiratory system diseases.

The top 10 oral Chinese patent medicines with the highest number of publications included Shexiang Baoxin Pill (麝香保心丸) (23 articles), Child Chiqiao Qingre Granule (小儿豉翘清热颗粒) (21 articles), Corbrin Capsule (百令胶囊) (20 articles), Fufang Danshen Dropping Pill (复方丹参滴丸) (17 articles), Qishen Yiqi Dripping Pill (芪参益气滴丸) (16 articles), Shensong Yangxin Capsule (参松养心胶囊) (15 articles), Huangkui Capsule (黄葵胶囊) (15 articles), Tripterygium Glycosides Tablet (雷公藤多苷片) (14 articles), Suhuang Zhike Capsule (苏黄止咳胶囊) (13 articles), and Tongxinluo Capsule (通心络胶囊) (13 articles).

The top 10 traditional Chinese medicine Injections in terms of publication volume include Fufang Kushen Injection (复方苦参注射液) (23 articles), Salviae Miltiorrhizae and Ligustrazine Hydrochloride Injection (丹参川芎嗪注射液) (16 articles), Xingnaojing Injection (醒脑静注射液) (15 articles), Danshen Injection (丹参注射液) (12 articles), Danhong Injection (丹红注射液) (12 articles), Tanreqing Injection (痰热清注射液) (12 articles), Shenfu Injection (参附注射液) (11 articles), Ginkgo Biloba Extract Injection (银杏叶提取物注射液) (11 articles), Gastrodin Injection (天麻素注射液) (10 articles), and Paclitaxel Injection (紫杉醇注射液) (10 articles). Topical Chinese patent medicines with five or more published studies included: Compound Phellodendron Solution (复方黄柏液涂剂) (17 articles), Kangfuxin Liquid (康复新液) (9 articles), Moist-exposed Burn Ointment (湿润烧伤膏) (5 articles), and Tongluo Qutong Plaster (通络祛痛膏) (5 articles). The ranking of research quantities for various types of Chinese patent medicines is presented in Table 4 and 5.

Table 4 Ranking of research quantities for various oral Chinese patent medicines in 2023 (≥10 articles)

Drug	Number of RCTs
Shexiang Baoxin Pill	23
Child Chiqiao Qingre Granule	21
Corbrin Capsule	20
Fufang Danshen Dropping Pill	17
Qishen Yiqi Dripping Pill	16
Shensong Yangxin Capsule	15
Huangkui Capsule	15
Tripterygium Glycosides Tablet	14
Suhuang Zhike Capsule	13
Tongxinluo Capsule	13
Dingkun Pill (定坤丸)	11
Guizhi Fuling Pill (桂枝茯苓丸)	11
Lianhua Qingwen Capsule (连花清瘟胶囊)	11
Qili Qiangxin Capsule (芪苈强心胶囊)	11
Yangxue Qingnao Particles (养血清脑胶囊)	10

Table 5 Ranking of research quantities for various injectable Chinese patent medicines in 2023 (≥10 articles)

Drug	Number of RCTs
Fufang Kushen Injection	23
Salviae Miltiorrhizae and Ligustrazine Hydrochloride Injection	16
Xingnaojing Injection	15
Danshen Injection	12
Danhong Injection	12
Tanreqing Injection	12
Shenfu Injection	11
Ginkgo Biloba Extract Injection	11
Gastrodin Injection	10
Paclitaxel Injection	10

3.1.5 Intervention and control design The RCTs included 1 408 two-arm trials, 32 three-arm trials, and 3 four-arm trials. The two-arm trials involved 42 intervention and control designs, including 521 articles (36.11%) with the design "Chinese patent medicines + western medicine vs. western medicine", 349 articles (24.19%) with "Chinese patent medicines + western medicine + conventional treatment vs. western medicine + conventional treatment", and 209 articles (14.48%) with "Chinese patent medicines + conventional treatment vs. conventional treatment".

The number of intervention and control design of RCTs on Chinese patent medicines in 2023 (with the number on articles ⩾ 10) is shown in Figure 4. Among the 44 English RCTs, 24 used a placebo control, and one used a blank control design.

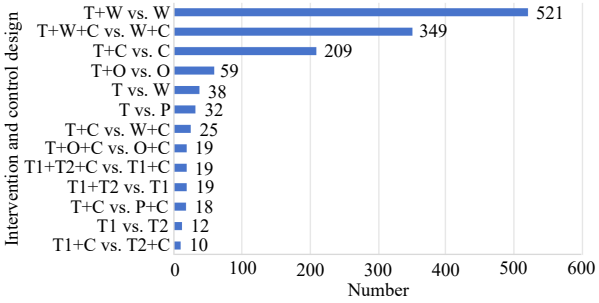

Figure 4 Intervention and control design of RCTs on Chinese patent medicine in 2023

T, Chinese patent medicine. W, western medicine. C, conventional treatment. O, other interventions. P, placebo.

3.1.6 Overview of large sample and multicenter research The study involved a total of 166 527 patients, with sample sizes ranging from 18 to 3 777 per study, and an average sample size of 155. More than half of the studies had a sample size of fewer than 100 cases (853 articles, 59.11%); 485 studies had a sample size of 100 – 199 cases (33.61%), 93 studies had 200 – 499 cases (6.44%), and only 12 studies had a sample size of more than 500 cases (< 1%). The results of the study with a sample size of more than 500 patients are presented in Table 6.

A total of 74 multicenter RCTs (5.13%) were conducted, involving 61 types of oral Chinese patent medicines, 5 types of topical Chinese patent medicines, and 5 types of traditional Chinese medicine Injections. The primary diseases studied were respiratory system diseases (including 7 studies on COVID-19), circulatory system diseases, and genitourinary system diseases. The number of centers involved ranged from a minimum of 2 to a maximum of 124. Six studies were identified as multicenter but did not specify the number of centers. The highest number of articles involved collaborations with 4 centers (9 articles). The Chinese patent medicines and diseases involved of the RCTs with more than 15 participating centers, are detailed in Table 7.

Table 6 Chinese patent medicines and diseases involved in RCTs with a sample size ⩾ 500 cases in 2023

Drug	Disease	Number of RCTs	Sample size
Tongxinluo Capsule [16]	Myocardial infarction	1	3 777
Reyanning Mixture (热炎宁合剂) [17]	COVID-19	1	2 830
Zishen Yutai Pill (滋肾育胎丸) [18]	Female infertility	1	2 265
Xuebijing Injection (血必净注射液) [19]	Sepsis	1	1 817
Yunnan Baiyao Capsule (云南白药胶囊) [20]	Fracture	1	1 122
Lianhua Qingwen Capsule [21]	COVID-19	1	815
Shuanghuanglian Oral Liquid (双黄连口服液) [22]	Oral ulcers	1	750
Shexiang Baoxin Pill [23]	Coronary heart disease	1	716
Xuebijing Injection [24]	Pneumonia	1	675
Fufang Furong Effervescent Suppositories (复方芙蓉泡腾栓) [25]	Vaginitis	1	600
Xueshuantong Injection (血栓通注射液) [26]	Ischemic stroke	1	550
Tongmai Yangxin Pill (通脉养心丸) [27]	Arrhythmia	1	500

Table 7 Distribution of multicenter RCTs involving Chinese patent medicines and diseases in 2023 (number of centers ⩾ 15)

Drug	Disease	Number of center	Number of RCTs
Tongxinluo Capsule [16]	Myocardial infarction	124	1
Shexiang Baoxin Pill [23]	Coronary heart disease	97	1
Xuebijing Injection [19]	Sepsis	45	1
Huamoyan Granule (滑膜炎颗粒) [28]	Osteoarthritis	22	1
Fufang Kushen Injection [29]	Lung cancer	20	1
Xuanfei Zhisou Mixture (宣肺止嗽合剂) [30, 31]	Acute bronchitis	19	2
Xuanfei Zhisou Mixture [30]	Cough (TM1)	19	1
Zishen Yutai Pill [18]	Female infertility	19	1
Xiyanping Injection [32]	Acute tonsillitis	18	1
Lianhua Qingwen Capsule [21]	COVID-19	17	1
Suhexiang Pill (苏合香丸) [33]	COVID-19	17	1
Danlong Oral Liquid (丹龙口服液) [34]	COPD	16	1

3.1.7 Quality assessment In terms of methodological quality, 25.80% of the studies in the Chinese literature had issues with "random sequence generation", primarily due to random grouping without specifying the implementation methods. Only 1.79% of the studies reported implementing "allocation concealment", 4.72% reported subject blinding, 14.08% implemented blinding in outcome assessment, and 64.05% had "other biases". A total of 233 studies (16.65%) used blinding, of which 66 reported subject blinding, and 197 reported blinding in outcome assessment. Thirty studies (2.14%) simultaneously used both blinding methods. A quality assessment of the Chinese RCTs' methodology is shown in Figure 5.

In the English literature, 29.55% of the studies had issues with "random sequence generation", 43.18% of the studies reported implementing "allocation concealment", 59.09% reported subject blinding, 50.00% implemented blinding in outcome assessment, and 4.55% had "other biases". A quality assessment of the methodology of the English RCTs is shown in Figure 6.

The RoB in Chinese RCTs was higher than in English RCTs. Most Chinese RCTs were rated as high risk in terms of blinding of patients and personnel, as well as other

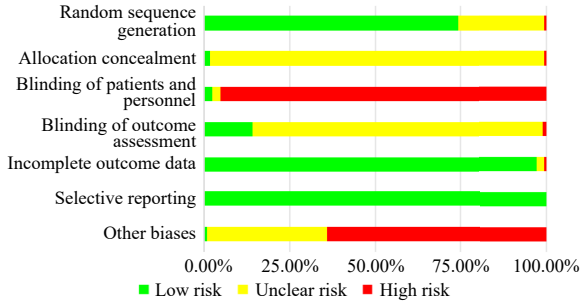

Figure 5 Quality assessment of the RCTs' methodology in Chinese

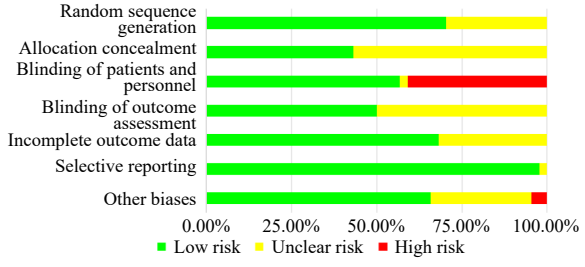

Figure 6 Quality assessment of the RCTs' methodology in English

biases, but were rated as low risk regarding incomplete outcome data and selective reporting of study results. The quality of RoB evaluation in English RCTs was generally high, with only a few articles reporting a high risk of blinding patients, personnel, and other biases. This suggests that the overall quality of Chinese patent medicine RCTs was compromised, primarily due to unreported blinding and other biases.

3.1.8 Ethics approval and protocol registration Of the 1 443 RCTs, 926 articles (882 Chinese studies and 44 English studies) reported ethical approval, and 56 articles (19 Chinese studies and 37 English studies) reported registration information. This indicates a significant gap in ethical considerations in current clinical studies.

3.1.9 Domestic and foreign Chinese patent medicine RCT registration situation According to the 2023 data from the Drug Clinical Trial Registration and Information Publicity Platform of the National Medical Products Administration, 67 Chinese patent medicine RCTs were registered involving 63 types of new Chinese medicine drugs, 50 were ongoing, and 17 were completed [35]. Information regarding RCT registration was obtained from the National Medical Products Administration Drug Clinical Trial Registration and Information Publicity Platform in 2023 (Supplement Table S2).

Searches were conducted on the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) and the Clinical Trials Registration Platform of the National Institutes of Health (NIH) of the United States. A total of 109 RCTs involving Chinese patent medicines were registered in 2023 (Supplementary Table S3).

3.2 Classic traditional Chinese medicine prescriptions

3.2.1 Overview of published literature In 2023, a total of 334 clinical RCTs on classic traditional Chinese prescriptions were published, including 331 in Chinese and 3 in English. A flowchart of the literature screening process is shown in Figure 1. RCTs on classic traditional Chinese medicine prescriptions were conducted across 28 provinces, municipalities, and autonomous regions in China. The top three regions in terms of RCT publication volume were Henan Province (50 articles), Shandong Province (31 articles), and Jiangxi Province (26 articles). The participating institutions included tertiary hospitals, secondary hospitals, primary hospitals (township health centers), medical schools, research institutions, and private hospitals. Among the publications, 70.06% (234/334) had a tertiary hospital as the leading institution. The geographical distribution of RCTs on classic traditional Chinese medicine prescriptions is shown in Figure 7.

3.2.2 Overview of publication journals In 2023, RCTs on classic traditional Chinese medicine prescriptions were published across 145 journals. Among them, 142 were

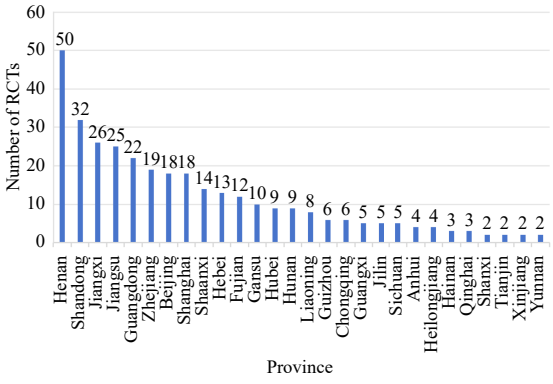

Figure 7 The geographical distribution of RCTs on classic traditional Chinese medicine prescriptions

Chinese-language journals, including 10 journals indexed in the Peking University Chinese Core Journals list, which published 20 articles (5.97%). The *Liaoning Journal of Traditional Chinese Medicine* had the highest number of publications, with 7 articles. A total of 42 journals indexed in CSCD published 82 articles (24.78%), with *Journal of Sichuan of Traditional Chinese Medicine* having the highest number of publications (7 articles). The top 10 Chinese-language journals by publication volume were *Journal of Practical Traditional Chinese Medicine*, *Guangming Journal of Chinese Medicine*, *Inner Mongolia Journal of Traditional Chinese Medicine*, *Henan Traditional Chinese Medicine*, *New Chinese Medicine*, *Liaoning Journal of Traditional Chinese Medicine*, *Journal of Sichuan of Traditional Chinese Medicine*, *Practical Clinical Journal of Integrated Traditional Chinese and Western Medicine*, *Chinese Journal of Clinical Rational Drug Use*, and *Chinese Medicine Modern Distance Education of China*. The top 10 Chinese-language journals by publication volume are listed in Table 8.

Table 8 Ranking of Chinese-language journals by publication volume for RCTs on classic traditional Chinese medicine prescriptions in 2023 (top 10)

Journal	Number of RCTs
Journal of Practical Traditional Chinese Medicine	20
Guangming Journal of Chinese Medicine	18
Inner Mongolia Journal of Traditional Chinese Medicine	10
Henan Traditional Chinese Medicine	8
New Chinese Medicine	8
Liaoning Journal of Traditional Chinese Medicine	7
Journal of Sichuan of Traditional Chinese Medicine	7
Practical Clinical Journal of Integrated Traditional Chinese and Western Medicine	7
Chinese Journal of Clinical Rational Drug Use	6
Chinese Medicine Modern Distance Education of China	6

A total of 3 English-language journals were involved, with 2 of them indexed by SCI. The IF of these journals

ranged from 1.0 to 1.99. The journal with the highest IF was *Journal of Traditional Chinese Medicine* (IF 1.99, 1 article). Details of the publications in English-language journals are presented in Table 9.

Table 9 Publications in English-language journals on RCTs of classic traditional Chinese medicine prescriptions in 2023

Journal	IF	Number of RCTs
Journal of Traditional Chinese Medicine	1.99	1
Medicine	1.3	1
World Journal of Clinical Cases	1.0	1

3.2.3 Disease types and distribution (i) Number of diseases studied in each system. According to the latest ICD-11 disease classification statistics, the RCTs on classic traditional Chinese medicine prescriptions published in 2023 covered 19 disease categories. The respiratory system diseases had the highest number of publications (51 articles, 15.27%), followed by the digestive system diseases (46 articles, 13.77%) and the circulatory system diseases (44 articles, 13.17%) (Table 10).

Table 10 RCTs on classic traditional Chinese medicine prescriptions involving ICD-11 disease classification (⩾ 10 articles)

Disease type	Number of RCTs
Diseases of the respiratory system	51
Diseases of the digestive system	46
Diseases of the circulatory system	44
Endocrine, nutritional or metabolic diseases	34
Diseases of the musculoskeletal system or connective tissue	30
Diseases of the nervous system	21
Diseases of the genitourinary system	20
Injury, poisoning or certain other consequences of external causes	18
Traditional medicine conditions	12

(ii) Disease distribution. A statistical analysis of disease names involved in RCTs on classic traditional Chinese medicine prescriptions published in 2023 revealed the following: in the respiratory system diseases category, COPD had the highest number of publications (20 articles, 5.99%); in the digestive system diseases, chronic gastritis was the most frequently studied (7 articles, 2.10%); in the disease of the circulatory system, disease of the coronary heart led in publication volume (11 articles, 3.29%); and in the disease of the endocrine system, type 2 diabetes had the most publications (25 articles, 7.49%).

The diseases with the highest research focus (with the number of articles ⩾ 5) were as follows: type 2 diabetes (25 articles, 7.49%), COPD (20 articles, 5.99%), fractures (17 articles, 5.09%), coronary heart disease (11 articles, 3.29%), pneumonia (9 articles, 2.69%), hypertension (9 articles, 2.69%), ischemic stroke (9 articles, 2.69%), chronic gastritis (7 articles, 2.10%), and bronchiectasis (7 articles, 2.10%). Diseases of the circulatory system and respiratory system were the primary research hotspots. The annual distribution of diseases in RCTs on classic traditional Chinese medicine prescriptions is shown in Figure 8.

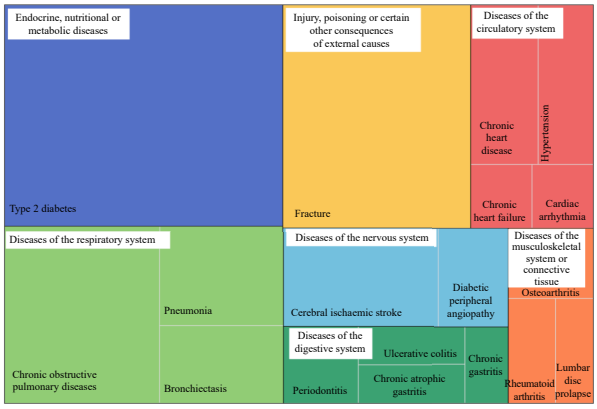

Figure 8 Distribution of diseases in RCTs of classic traditional Chinese medicine prescriptions in 2023

3.2.4 Situation of classic traditional Chinese medicine prescriptions The included RCTs involved 179 types of classic traditional Chinese medicine prescriptions, primarily targeting respiratory and circulatory system diseases.

The top 10 classic traditional Chinese medicine prescriptions by publication volume included Taohong Siwu Decoction (桃红四物汤) (20 articles), Huangqi Guizhi Wuwu Decoction (黄芪桂枝五物汤) (13 articles), Qingjin Huatan Decoction (清金化痰汤) (11 articles), Banxia Xiexin Decoction (半夏泻心汤) (9 articles), Huanglian Wendan Decoction (黄连温胆汤) (9 articles), Gegen Qinlian Decoction (葛根芩连汤) (8 articles), Qingfei Huatan Decoction (清肺化痰汤) (8 articles), Shenling Baizhu Powder (参苓白术散) (7 articles), Shentong Zhuyu Decoction (身痛逐瘀汤) (7 articles), Zhenwu Decoction (真武汤) (7 articles), and Zhigancao Decoction (炙甘草汤) (7 articles). The ranking of research quantities for various classic traditional Chinese medicine prescriptions is presented in Table 11.

3.2.5 Intervention and control design The RCTs included 318 two-arm trials, 12 three-arm trials, and 4 four-arm trials. The two-arm trials involved 16 intervention and control designs, including 91 articles (27.25%) with the design "classic traditional Chinese medicine prescriptions + conventional treatment vs. conventional treatment", 87 articles (26.05%) with "classic traditional Chinese medicine prescriptions + western medicine vs. western medicine", and 75 articles (22.46%) with "classic

Table 11 Ranking of research quantities for various classic traditional Chinese medicine prescriptions in 2023 (top 10)

Prescription	Number of RCTs
Taohong Siwu Decoction	20
Huangqi Guizhi Wuwu Decoction	13
Qingjin Huatan Decoction	11
Banxia Xiexin Decoction	9
Huanglian Wendan Decoction	9
Gegen Qinlian Decoction	8
Qingfei Huatan Decoction	8
Shenling Baizhu Powder	7
Shentong Zhuyu Decoction	7
Zhenwu Decoction	7

traditional Chinese medicine prescriptions + western medicine + conventional treatment vs. western medicine + conventional treatment".

The number of intervention and control designs of RCTs of classic traditional Chinese medicine prescriptions in 2023 (with the number of articles ⩾ 10) is shown in Figure 9.

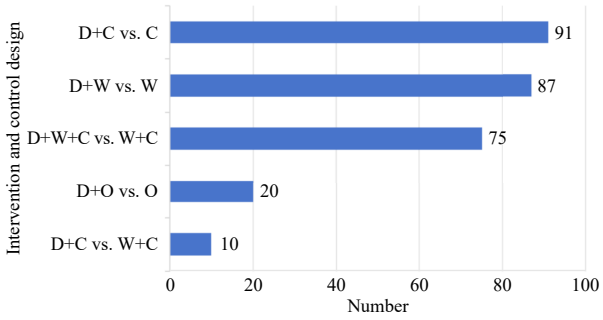

Figure 9 Intervention and control design of RCTs on classic traditional Chinese medicine prescriptions in 2023

D, classic traditional Chinese medicine prescriptions. W, western medicine. C, conventional treatment. O, other interventions.

3.2.6 Overview of large sample and multicenter research The study involved a total of 30 040 patients, with a sample size ranging from 30 to 507 per study, and an average sample size of 90. More than half of the studies had a sample size of fewer than 100 cases (236 articles, 70.66%); 91 studies had a sample size of 100 – 199 cases (27.25%), 6 studies had 200 – 499 cases (1.80%), and only 1 study had a sample size of more than 500 cases (less than 1%). The results of the study with a sample size of more than 200 patients are presented in Table 12.

A total of 10 multicenter RCTs (2.99%) were conducted. The primary diseases studied were musculoskeletal system or connective tissue system diseases. The number of centers involved ranged from a minimum of 2 to a maximum of 6. The highest number of articles involved collaborations with 2 centers (6 articles). The classic traditional Chinese medicine prescriptions and diseases involved in the RCTs are detailed in Table 13.

Table 12 Classic traditional Chinese medicine prescriptions and diseases involved in RCTs with a sample size ⩾ 200 cases in 2023

Prescription	Disease	Number of RCTs	Sample size
Wenjing Decoction [36]	Premature ovarian failure	1	507
Yihuoxuehuayu Decoction (益气活血化瘀汤) [37]	Migraine	1	242
Shenling Baizhu Powder [38]	COPD	1	210
Qingfei Huatan Decoction [39]	COPD	1	208
Shaoyao Gancao Decoction (芍药甘草汤) [40]	Gallstones	1	201
Yiwei Huoxue Decoction (益胃活血汤) [41]	Chronic gastritis	1	200
Sanshen Er'geng Decoction (三参二梗汤) [42]	Cough (TM1)	1	200

Table 13 Distribution of multicenter RCTs involving classic traditional Chinese medicine prescriptions and diseases in 2023

Prescription	Disease	Number of centers	Number of RCTs
Xiongzhi Decoction (芎芷煎) [37]	Migraine	6	1
Danggui Liuhuang Decoction (当归六黄汤) [43]	Prostate cancer	3	1
Juanbi Decoction (蠲痹汤) [44]	Lumbar disc herniation	3	1
Qingfei Huatan Decoction [39]	COPD	3	1
Dihuang Yinzi (地黄饮子) [45]	Vascular dementia	2	1
Qingjin Huatan Decoction [46]	COPD	2	1
Shuanghe Decoction (双合汤) [47]	Osteochondropathy	2	1
Sanbi Decoction (三痹汤) [48]	Ankylosing spondylitis	2	1
Xiaku Xiaoying Decoction (夏枯消瘿汤) [49]	Hashimoto's thyroiditis	2	1
Yanghe Decoction (阳和汤) [50]	Breast cancer	2	1

3.2.7 Quality assessment In terms of methodological quality, 26.35% of the included studies had issues with "random sequence generation", primarily due to random grouping without specifying the implementation methods. Only 1.80% of the studies reported implementing "allocation concealment", 3.89% reported subject blinding, 11.68% implemented blinding in outcome assessment, and 56.59% had "other biases". A total of 49 studies (14.67%) used blinding, of which 13 reported subject blinding, and 39 reported blinding in outcome assessment. Three studies (0.90%) simultaneously used both blinding methods. A quality assessment of the classic traditional Chinese medicine prescriptions RCTs' methodology is shown in Figure 10.

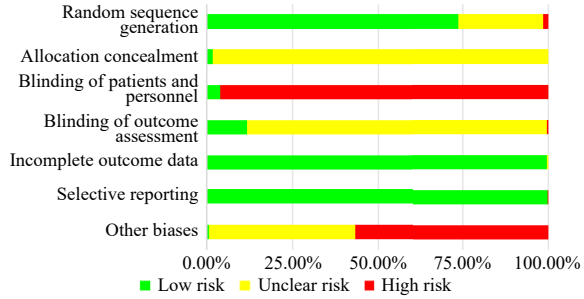

Figure 10 Quality assessment of RCTs' methodology for the classic traditional Chinese medicine prescriptions

3.2.8 Ethics approval and protocol registration Of the 334 RCTs, 197 articles (194 Chinese studies and 3 English studies) reported ethical approval, and 56 articles (1 Chinese study and 3 English studies) reported registration information. This indicates a significant gap in ethical considerations in current clinical studies.

4 Discussion

4.1 Chinese patent medicine

4.1.1 Analysis of RCTs on Chinese patent medicine in 2023 In 2023, a total of 1 443 RCTs on Chinese patent medicines were published, with 96.95% in Chinese and 3.05% in English. The publication volume decreased by 1.43% compared with 2022 (1 464 articles) and by 34.85% compared with 2021 (2 215 articles). The number of RCTs published in English journals remained the same as in 2022 but showed a significant increase compared with 2021. The research units were distributed across various provinces and cities nationwide, with the highest number of Chinese RCT publications from Henan, Jiangxi, and Shandong provinces, while English RCT publications were primarily concentrated in Beijing and Shanghai [51].

In 2023, the number of RCTs on Chinese patent medicines published in Peking University Chinese Core Journals increased significantly compared with 2022. Chinese-language journals remain central to publishing RCTs on Chinese patent medicines, though article distribution is highly concentrated in a limited number of these journals. The number of English-language journals publishing such research declined to 25 in 2023 from 30 in 2022, with no increase in publication output in high-impact factor journals. This continued limitation poses a major challenge to the international dissemination of Chinese patent medicine RCTs. Circulatory system diseases remained a research hotspot, while the ranking of publications on respiratory and genitourinary system diseases improved compared with 2022. There were a higher number of publications on ischemic stroke, coronary heart disease, COPD, diabetic nephropathy, and type 2 diabetes. The most frequently studied Chinese patent medicines in RCTs included Fufang Kushen Injection, Shexiang Baoxin Pills, Child Chiqiao Qingre Granules, and Corbrin Capsule, which are related to these hotspot diseases. In terms of research scale, sample sizes varied widely, but small-sample studies (sample size < 100) remained predominant. Although the number of multicenter studies decreased compared with 2022, the scale of these studies increased, with the largest involving 124 centers. Regarding intervention and control designs, the primary focus was on the efficacy of combined Chinese and western medicine therapies. Methodologically, issues such as allocation concealment and the application of blinding were still insufficiently addressed.

In terms of ethics approval and trial registration, English-language RCTs had higher reporting rates. The ethics approval reporting rate for Chinese RCTs increased by 1.07% compared with 2022, while the reporting rate for trial protocol registration increased by 5.35% compared with 2022 [51].

4.1.2 Suggestions and summary of future clinical research of Chinese patent medicine Overall, the number of RCTs conducted in 2023 decreased, but there was an improvement in research quality and impact. However, further measures are needed to enhance the design, implementation, and reporting of clinical trials. It is recommended that methodological experts be invited to provide professional technical guidance during trial design, to improve the quality of protocols based on evidence-based traditional Chinese medicine theories [52-54]. Researchers should place greater emphasis on the registration of trial protocols and adherence to standardized management practices during the implementation of RCTs on Chinese patent medicines to improve the quality of clinical trials involving traditional Chinese medicine. During the research implementation process, attention must be paid to process quality control, with a particular focus on improving the rigor of randomization procedures to avoid issues such as pseudo-randomization [54].

4.2 Classic traditional Chinese medicine prescriptions

4.2.1 Analysis of RCTs of classic traditional Chinese medicine prescriptions in 2023 In 2023, a total of 334 RCT articles on classic traditional Chinese medicine prescriptions were published, with 331 articles in Chinese and 3 articles in English. The publication volume saw a significant increase compared with 2022 (245 articles). The research units were distributed across various provinces and cities nationwide, with the highest number of RCT publications from Henan, Shandong, and Jiangxi provinces. In terms of publication journals, the number of RCTs on classic traditional Chinese medicine prescriptions published in Peking University Chinese Core Journals and CSCD journals in 2023 increased compared to 2022, but the overall quantity remains low. The circulatory and digestive system diseases remained the research hotspots, while the ranking of publications on respiratory system diseases improved compared with 2022. There were a higher number of publications on type 2 diabetes, COPD, fractures, coronary heart disease, and pneumonia. The most frequently studied classic traditional Chinese medicine prescriptions in RCTs included Taohong Siwu Decoction, Huangqi Guizhi Wuwu Decoction, and Qingjin Huatan Decoction, which are related to these hotspot diseases. In terms of research scale, sample sizes varied widely, but small-sample studies (sample size < 100) remained predominant. Regarding intervention and control designs, the primary focus was on the efficacy of combined Chinese and western medicine therapies. Methodologically, issues such as allocation concealment and the application of blinding were still insufficiently addressed. In terms of ethics approval and trial registration, more than half of the RCTs on classic traditional Chinese medicine prescriptions reported ethics approval, but trial protocol registration was insufficiently emphasized.

4.2.2 Suggestions and summary of future clinical research of classic traditional Chinese medicine prescriptions Overall, the number of RCTs on classic traditional Chinese medicine prescriptions increased compared with 2022, but the total quantity remains low, and significant issues persist regarding research quality and impact. Careful attention must be paid to the rigor of trial design, as poor design can lead to biased evaluations of treatment effects. Additionally, researchers need to emphasize the importance of trial protocol registration and adherence to standardized management practices during the implementation of RCTs on classic traditional Chinese medicine prescriptions, to promote the generation of high-quality clinical evidence in traditional Chinese medicine.

Although the studies focus on classic traditional Chinese medicine prescriptions, they lack traditional Chinese medicine-specific indicators. It is recommended that researchers develop an evaluation index system aligned with the characteristics of traditional Chinese medicine, following the guidelines set by the Core Outcome Measures in Effectiveness Trials (COMET) initiative and Core Outcome Set (COS) standards. This would provide technical support for the scientific evaluation of the efficacy of classic traditional Chinese medicine prescriptions[55].

5 Conclusion

In 2023, a total of 1 443 RCTs on Chinese patent medicines, which was a decrease compared with 2022, but with a improved quality and impact. Conversely, RCTs on classic traditional Chinese medicine prescriptions reached 334 articles, marking a significant increase from 2022 yet remaining low in volume. Both categories predominantly featured small-sample studies (< 100 participants), exhibited inadequate allocation concealment and blinding, and focused on combined Chinese-western therapies, with circulatory diseases as a shared research hotspot. For Chinese patent medicines, English publications stabilized versus 2022, multicenter scale increased (though quantity declined), and ethics approval reporting rose. Classic traditional Chinese medicine prescriptions faced underreported trial registration and lacked traditional Chinese medicine-specific evaluation indicators.

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Competing interests

The authors declare no conflict of interest.

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中成药及中医经典名方临床研究报告（2023）

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【摘要】目的 通过检索和整理 2023 年发表在中、英文期刊的中成药与中医经典名方的随机对照试验，对中成药与中医经典名方临床证据的生产和转化进行阶段性总结和评价，为后续临床疗效评价研究的开展和证据的合理化应用提供参考。**方法** 基于智能化中成药临床证据数据库（AICED-CPM）收录，并补充检索中国知网（CNKI）、万方、维普（VIP）、中国生物医学文献服务系统（SinoMed）、Cochrane Library、PubMed、Embase、Web of Science 等数据库，全面获取 2023 年发表的中成药与中医经典名方的随机对照试验，对其研究特征和方法学质量进行分析、评价。**结果** 共检索中成药临床随机对照试验 1 443 篇（中文 1 399 篇，英文 44 篇），中医经典名方临床随机对照试验共 334 篇（中文 331 篇，英文 3 篇）；共包含 196 567 例受试者；包含中成药 585 种（口服中成药 487 种，中药注射剂 61 种，外用中成药 37 种），经典名方 179 种；涉及疾病类型 22 类，研究热点疾病为循环系统疾病、呼吸系统疾病与泌尿系统疾病；研究规模方面，纳入研究样本量最小为 18 例，最大为 3 777 例，多以单中心为主。方法学方面，分配隐藏、盲法的实施仍未被重视。**结论** 与 2022 年相比，2023 年 RCT 发文数量与方法学质量有所上升，对泌尿系统疾病研究的关注度有所提高，但研究设计和实施过程中的质量控制和规范化管理仍需要改善，以期产出更多高质量的临床证据，加快证据转化应用。

【关键词】中医药；中成药；中医经典名方；随机对照试验；循证医学