

Clinical research report on traditional Chinese patent medicines and traditional Chinese classic famous prescriptions (2022)

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Abstract

Objective: The paper is to comprehensively summarize and analyze the basic situation and methodological quality of clinical randomized controlled trials (RCTs) of traditional Chinese patent medicines and traditional Chinese classic famous prescriptions published in 2022, to provide evidence and reasonable suggestions for the advancement of clinical research and the formulation of policies and guidelines.

Methods: The Evidence Database System of clinical evidence-based evaluation of traditional Chinese medicine was searched, and data from China National Knowledge Infrastructure (CNKI), PubMed, and other databases were supplemented. The search duration was from January 1, 2022, to December 31, 2022. RCTs of traditional Chinese patent medicines and traditional Chinese classic famous prescriptions were included as the source of clinical evidence, and published information, sample size, intervention, control measures, treatment course, methodological quality, and key link report were analyzed and evaluated.

Results: A total of 1,464 RCTs of traditional Chinese patent medicines were included, which comprised 667 types of traditional Chinese patent medicines; “traditional Chinese patent medicines + Western medicine vs. Western medicine” was the most widely used intervention and control setting, involving 417 RCTs (28.48%). A total of 245 RCTs of traditional Chinese classic famous prescriptions were included, comprising 55 types of traditional Chinese classic famous prescriptions. “Decoction + conventional treatment vs. conventional treatment” was the most widely used intervention and control setting, with 87 RCTs (35.51%). Published RCTs on traditional Chinese patent medicines and traditional Chinese classic famous prescriptions were limited by the study design and implementation. Most “allocation concealment” and “blinding of patients and personnel” were rated as medium to high risk. There are insufficient reports on key research links such as experimental registration and ethical approval.

Conclusions: The number of RCTs on traditional Chinese patent medicines has decreased in 2022, but there has been a slight improvement in the research quality and impact. There are relatively few studies on traditional Chinese classic famous prescriptions. Measures must be taken to improve clinical trial design, implementation, and reporting. Methodological experts should be invited to provide professional technical guidance on the trial design. In the research implementation process, attention should be paid to quality control, particularly the standardization of the randomized execution.

Keywords: Chinese patent medicine, Evidence-based medicine, Randomized controlled trials, Traditional Chinese classic famous prescriptions

Graphical abstract: <http://links.lww.com/AHM/A126>.

Introduction

Chinese patent medicine, an important part of traditional Chinese medicine, has the advantages of easy storage, transport, application, more stable quality control, and a wide range of applications^[1,2]. The classic famous prescriptions of traditional Chinese medicine are included in the Catalog of Ancient Classic prescriptions jointly formulated by the National Administration of Traditional

Chinese Medicine and the National Medical Products Administration, which is the natural crystallization of thousands of years of practical experience in the clinical application of traditional Chinese medicine^[3,4]. With the development of medicine in China, traditional Chinese patent medicines and traditional Chinese classic famous prescriptions have played an increasingly important role in the treatment of diseases, and a large number of

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Received 22 December 2023 / Accepted 6 June 2024

How to cite this article: Wang DL, Shi ML, Hu HY, Ma YC, Peng DH, Zhang JH, Fauci AJ, Ji ZC. Clinical research report on traditional Chinese patent medicines and traditional Chinese classic famous prescriptions (2022). *Acupunct Herb Med* 2024;4(3):306–319.

DOI: 10.1097/HM9.000000000000122

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clinical randomized controlled trials (RCTs) have been conducted^[5-7]. However, the quality of these studies is debatable, and there are loopholes in the trial design and methodological problems in the design and implementation processes that affect the authenticity and reliability of the research results^[8-10]. Therefore, it provides a comprehensive summary and analysis of the basic situation and methodological quality of RCTs of traditional Chinese patent medicines and traditional Chinese classic famous prescriptions in 2022, with the objective of providing evidence and reasonable suggestions for the development of clinical research and formulation of policies and guidelines.

Methods

Search strategy

RCTs of Chinese patent medicine in the Evidence Database System (EVDS) clinical trial database, China National Knowledge Infrastructure (CNKI), Wanfang database (WF), VIP database (VIP), Chinese Biomedical Literature Database (SinoMed), PubMed, and Web of Science were searched from January 1, 2022, to December 31, 2022 [Supplement 3, <http://links.lww.com/AHM/A125>].

Inclusion criteria

Type of study: RCT; Patients: Study subjects were not restricted; Intervention and comparison: The intervention and comparison of Chinese patent medicine were performed using the test group (Chinese patent medicine, Chinese patent medicine + other interventions). The Chinese patent medicine dose form was not limited and the control group was Chinese patent medicine, other intervention, Chinese patent medicine + other interventions, blank control, or placebo. Outcomes: the evaluation indices were not restricted.

Exclusion criteria

Exclusion criteria were as follows: nonrandomized studies, repeatedly published studies, no full-text or incomplete studies, dissertations, and conference paper.

Study screening and data extraction

The literature included in the EVDS was exported by the system and manually sorted according to the required items. The database literature was reviewed using Note Express software, read independently, and screened according to inclusion and exclusion criteria. Disagreements were resolved through discussions. A data collection table was created using Excel to extract published information, disease type, sample size, intervention measures, evaluation indicators, and other information included in the RCT.

Quality assessment

The quality of the RCTs was assessed using the Cochrane Risk of Bias (ROB) assessment tool^[11,12], which includes seven aspects: (1) random sequence generation, (2) allocation concealment, (3) blinding of patients and

personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective reporting, and (7) other biases. The assessment results were presented as “low risk” “high risk” or “unclear risk.”

Results

Chinese patent medicine

Overview of the literature publication

In 2022, a total of 1,464 RCTs of Chinese patent medicine were published, including 1,420 Chinese RCTs, 44 English RCTs, and 213 RCTs involving Chinese medicine syndromes. Thirty-one provinces and autonomous regions in China were covered. The top three regions in terms of RCT publications were Henan (242 articles), Guangdong (114 articles), and Zhejiang (103 articles). The participating units included tertiary hospitals, secondary hospitals, primary hospitals (township hospitals), medical schools, scientific research institutions, and private hospitals. In the Chinese literature, the literature on tertiary hospitals as the first unit represented 75.00% (1,098/1,464). Of the first units in the English literature, 88.64% (39/44) were tertiary hospitals. By 2022, the top three research participants were the China Academy of Chinese Medical Sciences and its affiliated hospitals (24), Henan University of Science and Technology and its affiliated hospitals (22), Beijing University of Chinese Medicine and its affiliated hospitals, and Guangzhou University of Chinese Medicine and its affiliated hospitals (17 each). The ranking of the participating institutions (top 10) is shown in Figure 1.

Publication of journals

In 2022, 327 journals published RCTs on Chinese patent medicine, of which 18 were Chinese core journals in Peking University, with 109 articles (7.45%). *The China Journal of Traditional Chinese Medicine* published the most number of articles (35 articles). There were 125 journals in the China Science Citation Database (CSCD), with 467 articles (31.90%), and *Modern Medicine and Clinical Medicine* published the most number of articles (40 articles). The top 10 Chinese journals in terms of publication volume were *New Chinese Medicine*, *Chinese Journal of Clinical Rational Drug Use, Drugs & Clinic*, *Chinese Archives of Traditional Chinese Medicine*, *Clinical Research and Practice*, *Medical Journal of Chinese People's Health*, *Inner Mongolia Journal of Traditional Chinese Medicine*, *Liaoning Journal of Traditional Chinese Medicine*, *The Journal of Medical Theory and Practice*, and *Journal of Practical Traditional Chinese Medicine* (Table 1). There were 30 English journals, 28 of which were included in the SCI, with impact factors (IF) ranging from 1.1 to 7.9. The journal with the highest IF was *Phytomedicine* (IF: 7.9, 1 article) (Table 1).

Disease types and distribution

Number of disease studied in each system

According to the latest International classification of diseases 11th revision (ICD-11) disease classification

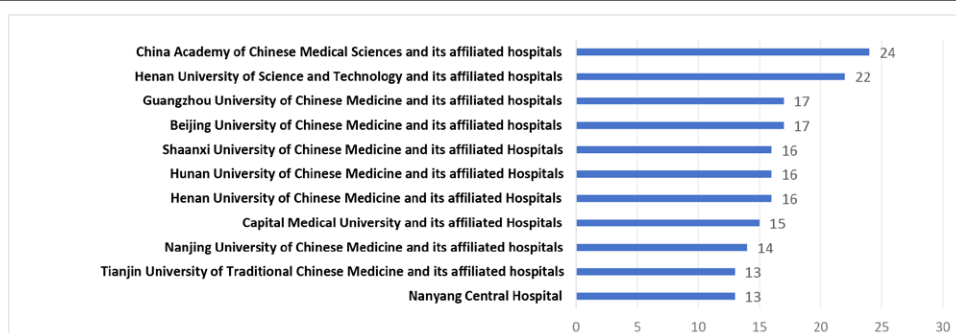


Figure 1. Ranking of institutions in Chinese patent medicine in 2022 (top 10).

Table 1

Publications in English journals on clinical research of Chinese patent medicines in 2022 (refer to 2022 IFs, IF ≥5.0) and ranking of Chinese journals involved in publishing RCTs on traditional Chinese patent medicine in 2022 (≥20 articles)

Journal name (n = IF)	Number of RCTs
<i>Phytomedicine</i> (7.9)	1
<i>Obstetrics and Gynecology</i> (7.2)	1
<i>Circulation-cardiovascular Quality and Outcomes</i> (6.9)	1
<i>Journal of Orthopaedic Translation</i> (6.6)	1
<i>Frontiers in Cellular and Infection Microbiology</i> (5.7)	1
<i>Sleep</i> (5.6)	1
<i>Frontiers in Pharmacology</i> (5.6)	2
<i>Bioscience Trends</i> (5.5)	1
<i>Journal of Ethnopharmacology</i> (5.4)	7
<i>New Chinese Medicine</i>	68
<i>Chinese Journal of Clinical Rational Drug Use</i> *	47
<i>Drugs & Clinic</i> *	40
<i>Chinese Archives of Traditional Chinese Medicine</i> *†	35
<i>Clinical Research and Practice</i>	26
<i>Medical Journal of Chinese People's Health</i>	25
<i>Inner Mongolia Journal of Traditional Chinese Medicine</i>	24
<i>Liaoning Journal of Traditional Chinese Medicine</i> *	23
<i>The Journal of Medical Theory and Practice</i>	22
<i>Mental, Behavioural or Neurodevelopmental Disorders</i>	42
<i>Pregnancy, Childbirth or the Puerperium</i>	42
<i>Traditional Medicine Conditions</i>	42

IF: Impact factor; RCT: Randomized controlled trial.

*China Science Citation Database indexed journals.

†Peking University Chinese Core Journal.

statistics, the RCTs on traditional Chinese patent medicine published in 2022 involved 22 types of disease, with circulating system diseases being the highest (253, 17.28%), followed by respiratory system diseases (172, 11.75%, including nine novel coronavirus pneumonia studies) and digestive system diseases (158, 10.79%; Table 2).

Table 2

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

Disease type	Number of RCTs
Diseases of the circulatory system	253
Diseases of the respiratory system	172
Diseases of the digestive system	158
Diseases of the genitourinary system	156
Diseases of the nervous system	149
Endocrine, nutritional or metabolic diseases	114
Neoplasms	95
Certain infectious or parasitic diseases	90
Diseases of the musculoskeletal system or connective tissue	74
Mental, behavioral, or neurodevelopmental disorders	42
Pregnancy, childbirth, or the puerperium	42
Traditional medicine conditions	42

ICD-11: International classification of diseases 11th revision; RCT: Randomized controlled trial.

Disease distribution

Regarding the circulatory system, angina pectoris was the most common disease (68, 4.64%). Regarding the respiratory system, the highest number of publications were on chronic obstructive pulmonary disease (30, 2.05%). Regarding the nervous system, the highest number of publications was on ischemic stroke (81, 5.53%). Regarding the urogenital system, the largest number of publications were on nephrotic syndrome (9, 0.61%).

The most researched diseases (the top 10 articles) were ischemic stroke (81, 5.53%), angina pectoris (68, 4.64%), heart failure (44, 3.01%), coronary heart disease (35, 2.39%), diabetes (33, 2.25%), chronic obstructive pulmonary disease (30, 2.05%), diabetes nephropathy (28, 1.91%), pneumonia (28, 1.91%), lung cancer (22, 1.50%), and hepatitis B (21 articles, 1.43%). Compared with 2021, the proportion of research on angina pectoris, diabetes, heart failure, and other diseases had increased, while attention on the musculoskeletal system or connective tissue diseases such as rheumatoid arthritis had decreased. The annual distribution of diseases in RCTs on traditional Chinese patent medicine is shown in Figure 2.

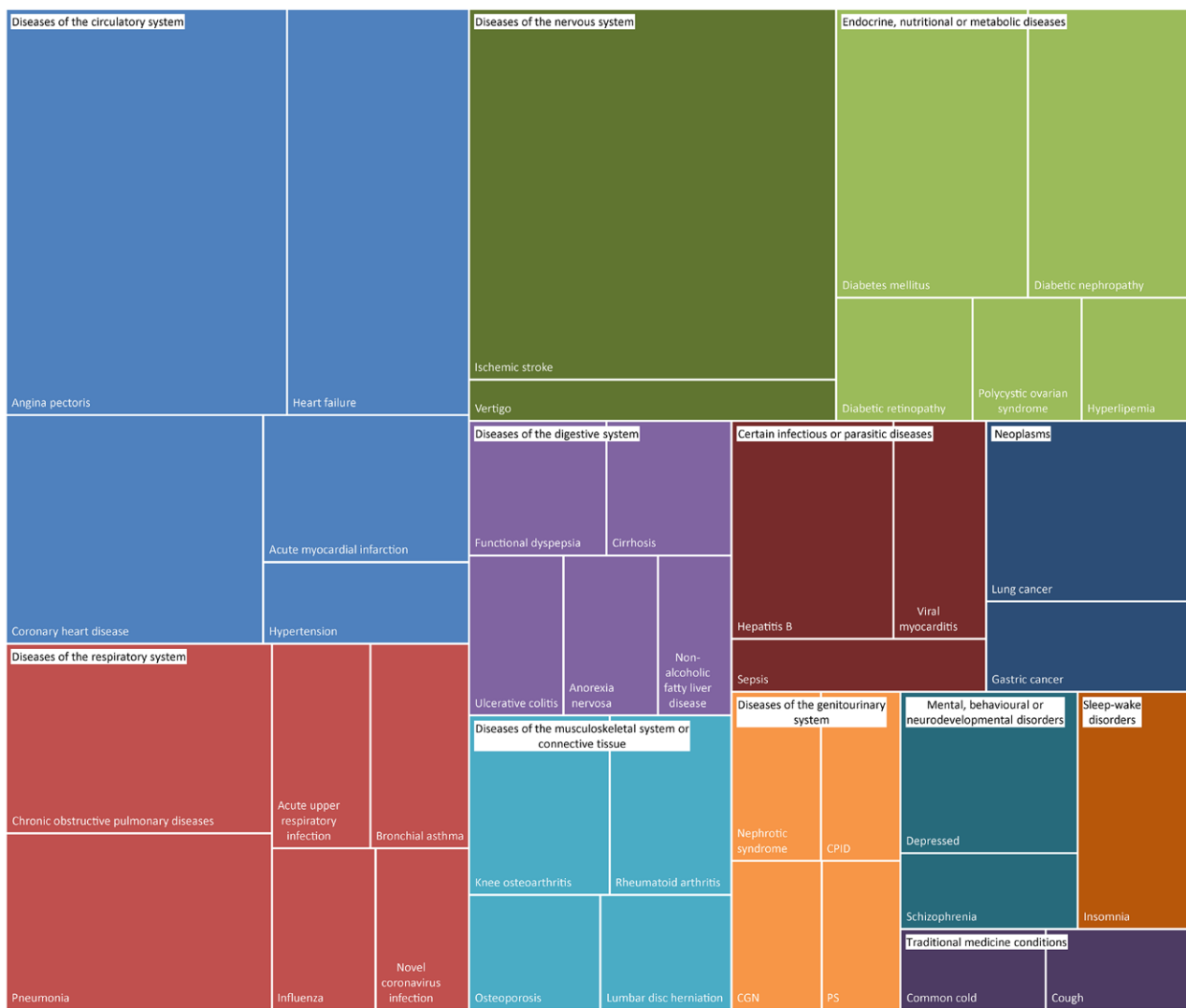


Figure 2. Distribution of diseases in clinical research of traditional Chinese patent medicines in 2022. CGN: Chronic glomerulonephritis; CPID: Chronic pelvic inflammatory disease; PS: Perimenopausal syndrome.

Situation of traditional Chinese patent medicine

There were 667 types of traditional Chinese patent medicines (556 types of oral traditional Chinese patent medicines, 72 traditional Chinese medicine injections, and 39 for external use) involved in the RCTs, and the treatment mainly focused on circulatory and respiratory diseases. The top 10 oral traditional Chinese patent medicines with the highest number of publications included Corbrin capsules (28), Shexiang Baoxin pills (27), Tripterygium wilfordii polysaccharide tablets (16), Liuwei Dihuang pills (16), compound Danshen Dropping pills (14), Tongxinluo capsules (14), Angong Niu Huang pills (13), Shugan Jieyu capsules (13), Huaqihuang granules (12), and Qishen Yiqi dropping pills (12) (Table 3). The top 10 traditional Chinese medicine injections in terms of publication volume include Danhong injection (24 articles), Shenfu injection (21 articles), Shenmai injection (20 articles), Xingnaojing injection (16 articles), injectable salvianolic acid salts (16 articles), Salviae miltiorrhizae and Ligustrazine hydrochloride injection (15 articles), Tanreqing injection (15 articles), Ginkgo biloba extract injection (14 articles), Ginkgo biloba diterpenoid lactone glucosamine injection (13 articles), Danshen injection (12 articles), and Huangqi

injection (12 articles) (Table 4). The top three traditional Chinese patent medicines for external use with the highest number of publications included Kangfuxin liquid (23), compound *Phellodendron* solution (10), and moist-exposed burn ointment (9).

Intervention and control design

The RCTs included 1,414 two-arm trials, 42 three-arm trials, and 8 four-arm trials. The two-arm trials involved 58 intervention and control designs, including 417 articles (28.48%) of “traditional Chinese patent medicines + Western medicine *vs.* Western medicine” 389 articles (26.57%) of “traditional Chinese patent medicines + Western medicine + conventional treatment *vs.* Western medicine + conventional treatment” and 238 articles (16.26%) of “traditional Chinese patent medicines + conventional treatment *vs.* conventional treatment”. The number of intervention and control design of RCTs of traditional Chinese patent medicines in 2022 (number of researches ≥ 10) as shown in Figure 3. Among the 44 English RCTs, 26 were designed with placebo control, 17 with positive control, and one with blank controls.

Table 3**The number of studies on each variety of oral Chinese patent medicine in 2022 (number of publications ≥ 10)**

Drug name (<i>n</i> = number of RCTs)	Disease type
Corbin capsule (28)	Diseases of the genitourinary system
Shexiang Baoxin pill (27)	Diseases of the circulatory system
Tripterygium wilfordii Polysaccharide tablet (16)	Immune system diseases
Liuwei Dihuang pill (16)	Traditional medicine conditions
Compound Danshen Dropping pill (14)	Diseases of the circulatory system
Tongxinluo capsule (14)	Diseases of the circulatory system
Angong Niuhuang pill (13)	Diseases of the nervous system
Shugan Jieyu capsule (13)	Traditional medicine conditions
Huaiqihuang granule (12)	Traditional medicine conditions
Qishen Yiqi Dropping pill (12)	Diseases of the circulatory system
Xiaoer Chiqiao Qingre granule (11)	Diseases of the respiratory system
Shufeng Jiedu capsule (10)	Diseases of the respiratory system

RCT: Randomized controlled trial.

Table 4**The number of studies on each variety of traditional Chinese medicine injection in 2022 (number of publications ≥ 10)**

Drug name (<i>n</i> = number of RCTs)	Disease type
Danhong injection (24)	Diseases of the circulatory system
Shenfu injection (21)	Certain infectious or parasitic diseases
Shenmai injection (20)	Diseases of the circulatory system
Xingnaojing injection (16)	Diseases of the nervous system
Injectable Salvianolic Acid salts (16)	Diseases of the circulatory system
Salviae miltiorrhizae and Ligustrazine Hydrochloride injection (15)	Diseases of the circulatory system
Tanreqing injection (15)	Diseases of the respiratory system
Ginkgo Biloba Extract injection (14)	Diseases of the nervous system
Ginkgo Biloba Diterpenoid Lactone Glucosamine injection (13)	Diseases of the nervous system
Danshen injection (12)	Diseases of the circulatory system
Huangqi injection (12)	Neoplasms
Compound Kushen injection (11)	Neoplasms

RCT: Randomized controlled trial.

Overview of large sample and multicenter research

The study involved a total of 159,635 patients, with a sample size ranging from 26 to 2,265 in each study, with an average sample size of 109. More than half of the studies had a sample size of less than 100 cases (859, 58.67%); 515 studies had a sample size of 100–199 cases (35.18%), 81 had 200–499 cases (5.53%), and only nine studies had a sample size of more than 500 cases (<1%). The results of a study with a sample size of more than 500 patients are presented in Table 5.

A total of 83 multicenter RCTs (5.67%) involved 84 types of oral traditional Chinese patent medicines and five types of traditional Chinese medicine injections for circulatory system diseases, respiratory system diseases (including three studies on coronavirus disease 2019 [COVID-19]), and genitourinary system diseases. The minimum number of centers was two and the maximum number was 97. Twenty-six studies (31.33%) involved traditional Chinese medicine syndrome. Table 6 shows the RCTs involving traditional Chinese

patent medicines and diseases conducted across more than 15 centers.

Quality assessment

In terms of methodological quality, 27.18% of the studies in the Chinese literature had the problem of “random sequence generation” mainly referring to random grouping without specifying the implementation methods. Only 3.59% of the research reports implemented “allocation concealment” 4.01% of the research reports were subject-blinded, 17.68% of the research reports implemented the blind evaluation method for the results, and 61.20% of the research reports had “other biases”. A total of 269 (18.94%) research reports used blinding, of which 57 were subject-blinded, and 251 were blinded to the results. Thirty-nine studies (2.75%) simultaneously used both blinding methods. A quality assessment of the Chinese RCTs’ methodology is shown in Figure 4. In the English literature, 11.36% of

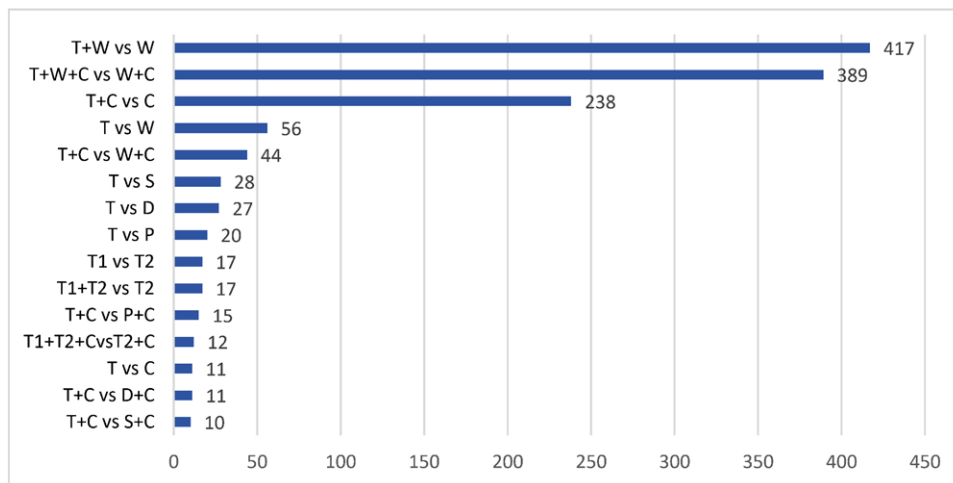


Figure 3. Intervention and control design of RCTs on traditional Chinese patent medicine in 2022. C: Conventional treatment; D: Decoction; P: Placebo; RCT: Randomized controlled trial; T: Traditional Chinese patent medicine; W: Western medicine.

Table 5

Sample size of ≥ 500 in RCTs on traditional Chinese patent medicine in 2022

Drug name	Disease	Number of RCTs	Sample size
Zishen Yutai pill ^[13]	Barrenness	1	2,265
Naoxintong capsule ^[14]	Ischemic stroke	1	1,899
Xinsuning capsule ^[15]	Premature ventricular contraction	1	861
Shexiang Baoxin pill ^[16]	Stable coronary artery disease	1	776
Naoxinqing pill ^[17]	Cerebral arterial thrombosis	1	654
Songling Xuemaikang capsule ^[18]	Primary hypertension	1	628
Motherwort injection ^[19]	Postpartum uterine rehabilitation	1	600
Yinqiao Qingre pill ^[20]	Common cold	1	598
Tongmai Yangxin pill ^[21]	Primary, stable, microvascular angina pectoris	1	577

RCT: Randomized controlled trial.

the studies had the problem of “random sequence generation” 43.18% of the research reports implemented “allocation concealment” 59.09% of the research reports were subject-blinded, 68.18% of the research reports implemented the blind evaluation method for results, and 11.36% of the research reports had “other biases”. A quality assessment of the methodology of the English RCTs is shown in Figure 5.

The ROB in the Chinese RCTs was higher than that in the English RCTs. Most Chinese RCTs were rated high risk in terms of blinding of patients and personnel and other biases and low risk in terms of incomplete outcome data and selective reporting of study results. The quality of ROB evaluation in English RCTs was high, and only a few articles reported a high risk of blinding patients, personnel, and other biases. This indicates that the quality of the literature was generally poor due to unreported blinding and other biases in RCTs on Chinese patent medicine.

Ethics approval and protocol registration

Of the 1,464 RCTs, 916 (874 Chinese studies and 42 English studies) reported ethical approval, and 53 (21 Chinese studies and 32 English studies) reported

registration information, indicating that there is still a large gap in terms of ethical considerations in the current clinical studies.

Domestic and foreign Chinese patent medicine RCT registration situation

According to the drug clinical trial registration and information publicity platform of the National Medical Products Administration, 2022, 49 Chinese patent medicine RCTs were registered in 2022, involving 47 types of new Chinese medicine drugs; 43 were carried out, five were completed, and one was suspended voluntarily^[26]. For RCT registration, information was obtained from the National Medical Products Administration Drug Clinical Trial Registration and Information Publicity platform in 2022 [Supplement 1, <http://links.lww.com/AHM/A125>].

The World Health Organization International Clinical Trials Registry Platform and the Clinical Trial Registration Platform of the National Institutes of Health of the United States were searched. There were 19 RCT registrations for traditional Chinese patent medicines in 2022 [Supplement 2, <http://links.lww.com/AHM/A125>].

Table 6

Multicenter RCTs involving Chinese patent medicine and disease distribution in 2022 (number of centers ≥15)

Drug name	Disease	Number of center	Number of RCTs	Sample size
Shexiang Baoxin pill ^[16]	Coronary artery disease	97	1	776
Xinsuning capsule ^[15]	Premature ventricular contraction (Phlegm-heat disturbing Xin syndrome)	39	1	861
Naoxinqing pill ^[17]	Cerebral arterial thrombosis	23	1	1,899
Zishen Yutai pill ^[13]	Barrenness	19	1	2,265
Bidouyan mixture ^[22]	Acute sinusitis in children	17	1	443
Songling Xuemaikang capsule ^[18]	Primary hypertension	17	1	628
Shenqu Xiaoshi oral liquid ^[23]	Functional dyspepsia in children	17	1	356
Yangxin Dingji capsule ^[24]	Premature ventricular contraction	16	1	231
Jintiange capsule ^[25]	Primary osteoporosis	16	1	400

RCT: Randomized controlled trial.

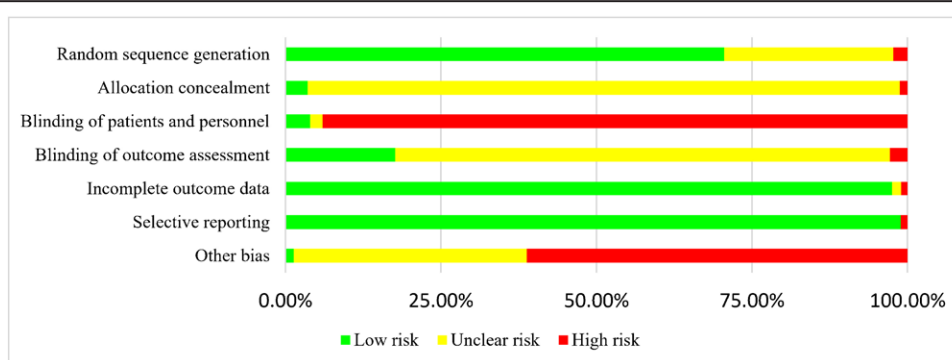


Figure 4. Quality assessment of the RCTs' methodology in Chinese. RCT: Randomized controlled trial.

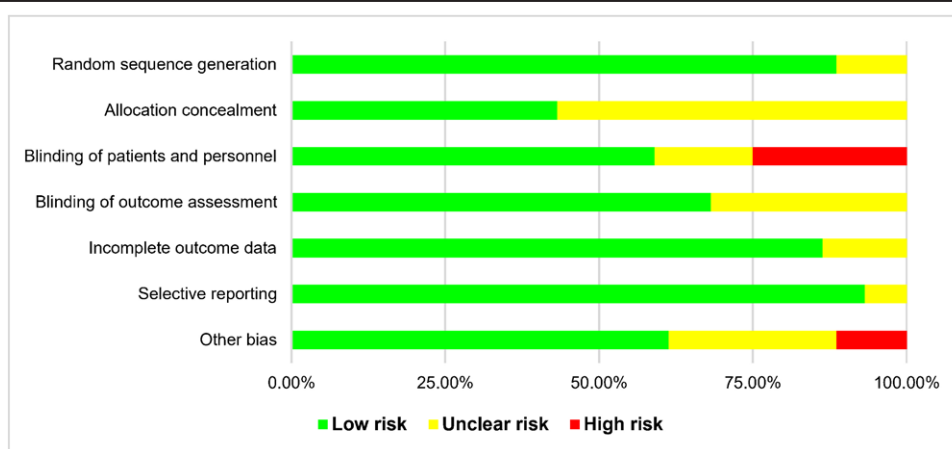


Figure 5. Quality assessment of the RCTs' methodology in English. RCT: Randomized controlled trial.

Discussion

Analysis of RCTs of Chinese patent medicine in 2022

The number of RCTs on Chinese patent medicine decreased this year compared to the previous year. In 2022, an RCT on traditional Chinese patent medicines included 1,464 articles, 96.99% of which were published in Chinese journals and 3.01% of which were in English journals. The number of published articles decreased by 33.91% compared to that in 2021 (2215) and increased by 13.93% compared to that in 2020 (1285). The number of English journals increased significantly^[27]. The

number of RCTs on Chinese patent medicine in the Chinese core journals of Peking University decreased in 2021. This shows that the development of traditional Chinese medicine tends to have globalized, and researchers worldwide are paying more attention to patented Chinese medicine. In addition, domestic researchers have paid more attention to the writing and publication of English reports on clinical trials of Chinese patent drugs. The longer publication cycle of English articles may be one of the reasons for the decrease in the number of RCTs on Chinese patented drugs in 2022.

In terms of research hotspots, circulatory system diseases and respiratory system diseases remained the research hotspots, and the ranking of articles on the digestive system improved compared to that in 2021. There were a large number of articles on ischemic stroke, angina pectoris, acute ischemic stroke, coronary heart disease, chronic obstructive pulmonary disease, and diabetes nephropathy. Widely researched Chinese patent medicines included the Corbrin capsule, Shexiang Baoxin pill, and Danhong injection, which are related to hotspot diseases^[28–31]. However, if we focus on hot areas, we may neglect other therapeutic areas, which can easily lead to duplication of clinical research and waste of clinical resources. Injections of Chinese patent medicines have received widespread attention for the treatment of circulatory and nervous system diseases. They have a high value in clinical research and show a good development trend.

In terms of the research scale, the sample size range was relatively large, but small sample studies (sample size <100) remained to be the main focus. In multicenter studies, attention to the types of syndromes decreased compared to that in 2021^[27]. In the future, the cooperation of multiple research centers is needed to jointly conduct large sample and multicenter clinical research, which is conducive to providing high-quality clinical evidence in the field of traditional Chinese medicine.

Quality analysis of the RCTS on Chinese patent medicines in 2022

Through a comprehensive analysis, it was found that the quality of the Chinese articles was medium, while that of English articles was high. In terms of the intervention control design, the observation of the efficacy of the combination of Chinese and Western medicine was the main focus. The intervention settings in clinical research were not standardized, and there was a lack of positive control and placebo control. In terms of the methodological quality, issues such as allocation concealment and blinding application, did not receive sufficient attention. In terms of ethical approval and experimental registration, the reporting rate of English RCTs was relatively high, while the reporting rate of Chinese RCT increased by 6.79% compared to that in 2021; the reporting rate of experimental protocol registration increased by 1.21% compared to that in 2021^[27]. Compared to English RCTs, the reporting rate of Chinese ECT RCTs remained insufficient, which is the main reason for the high risk of other biases in the literature.

Suggestions and summary of future clinical research of Chinese patent medicine

Overall, the number of RCTs decreased this year, but there has been a slight improvement in research quality and impact. Measures must be taken to improve clinical trial design, implementation, and reporting. It is recommended to invite methodological experts to provide professional technical guidance during experimental design, based on evidence-based traditional Chinese medicine theory, to improve the quality of the scheme design^[32–34]. Researchers need to pay attention to the registration of the test scheme of traditional Chinese

patent medicine RCTs and management norms in the implementation process to improve the quality of clinical trials of Chinese medicine. During research implementation, attention should be paid to process quality control, especially the standardization of randomized execution, which must be continuously improved to avoid the problem of “pseudo-randomness”^[34].

Traditional Chinese classic famous prescriptions

Overview of the literature publication

In 2022, 245 RCTs, including 244 Chinese RCTs and one English RCT, were published on traditional Chinese classic prescriptions.

The regions conducting these RCTs included 28 provinces, cities, and autonomous regions in China. The top three regions in terms of RCT publication volume were Henan province (49 articles), Liaoning province (23 articles), and Jiangxi province (19 articles). The research participation units included tertiary hospitals, secondary hospitals, primary hospitals (township health centers), medical colleges, research institutions, and private hospitals. Among them, studies with tertiary hospitals as the first unit represented 70.61% (173/245). In 2022, the top three research participants in the RCT publication volume of traditional Chinese classic famous prescriptions were Liaoning University of Traditional Chinese Medicine and its affiliated hospitals (11 articles), Guangzhou University of Chinese Medicine and its affiliated hospitals (eight articles), and Shaanxi University of Chinese Medicine and its affiliated hospitals (seven articles). The ranking of participating institutions (top 10) is shown in Figure 6.

Publication of journals

RCTs published on traditional Chinese classic famous prescriptions in 2022 included 108 journals. There were 107 Chinese journals, of which six were included in the core Chinese journals of Peking University, and nine articles were published (3.69%). The volume of publications in *Lishizhen Medicine* and *Materia Medica Research* was the highest (two articles). The CSCD included 24 journals, with 41 articles published (16.73%). *Journal of Emergency in Traditional Chinese Medicine* had the highest number of published articles (4). The top 10 Chinese journals in terms of volume of publication were the *Guangming Journal of Chinese Medicine*, *Journal of Practical Traditional Chinese Medicine*, *Chinese Medicine Modern Distance Education of China*, *New Chinese Medicine*, *Inner Mongolia Journal of Traditional Chinese Medicine*, *Medical Journal of Chinese People's Health*, *Henan Traditional Chinese Medicine*, *Chinese Journal of Clinical Rational Drug Use*, *Clinical Research and Practice*, *Capital Food Medicine*, *Medical Diet and Health*, *Smart Healthcare*, and *Journal of Emergency in Traditional Chinese Medicine*. The top 10 Chinese journals in terms of volume of publication are listed in Table 7. One English journal, *the Journal of Traditional Chinese Medicine*, had an IF of 2.6.

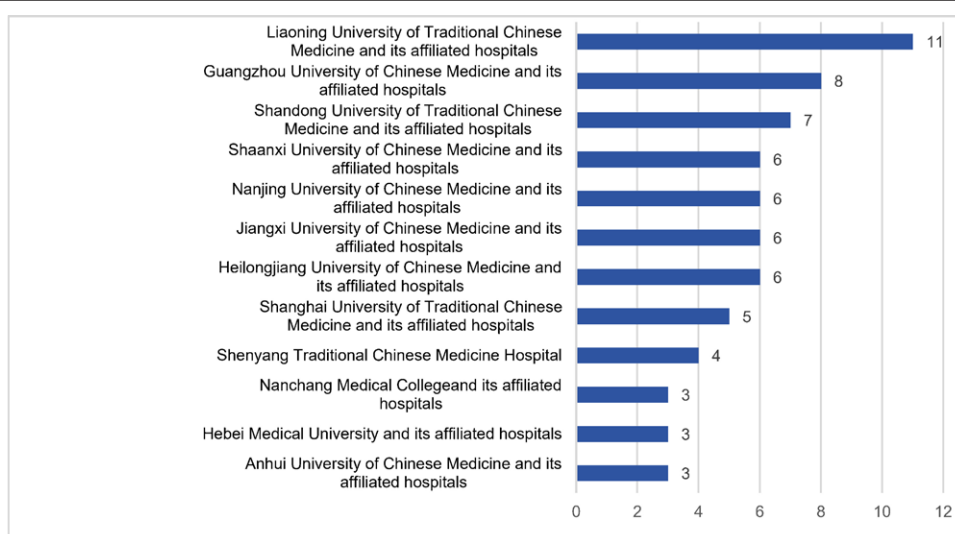


Figure 6. Ranking of institutions in the traditional Chinese classic famous prescriptions in 2022 (top 10).

Disease types and distribution

Number of studies of disease in each system

According to the latest ICD-11 disease classification statistics, the RCTs on traditional Chinese classic famous prescriptions published in 2022 involved 14 types of diseases, with circulating system diseases ranked the highest (56 articles, 22.86%), followed by endocrine, nutritional, and metabolic diseases (40 articles, 16.33%), and digestive system diseases (39 articles, 15.92%), as shown in Table 8.

Distribution of the disease

According to the statistics of the diseases involved in RCTs on traditional Chinese classic famous prescription

Table 7

Ranking of Chinese journals related to the publication of RCTs in 2022 on traditional Chinese classic famous prescriptions (top 10)

Journal name	Number of RCTs
Guangming Journal of Chinese Medicine	24
Journal of Practical Traditional Chinese Medicine	16
Chinese Medicine Modern Distance Education of China	16
New Chinese Medicine	11
Inner Mongolia Journal of Traditional Chinese Medicine	8
Medical Journal of Chinese People's Health	7
Henan Traditional Chinese Medicine	5
Chinese Journal of Clinical Rational Drug Use*	4
Clinical Research and Practice	4
Capital Food Medicine	4
Medical Diet and Health	4
Smart Healthcare	4
Journal of Emergency in* Traditional Chinese Medicine	4

RCT: Randomized controlled trial.

*China Science Citation Database indexed journals.

in 2022, regarding the circulatory system, heart failure (21, 8.57%) and angina pectoris (16, 6.53%) were the most popular. Regarding the endocrine system, diabetic peripheral neuropathy had the highest number of publications (11 articles, 4.49%). Regarding the nervous system, vertigo had the highest number of articles (9, 3.67%), while regarding the digestive system, the number of articles with gastritis was the highest (6, 2.45%). Among these, 69 (28.16%) RCTs classified the TCM syndrome types of the studied diseases.

Most researched diseases (the top 10 articles) were heart failure (21, 8.57%), angina pectoris (16, 6.53%), hypertension (12, 4.90%), diabetes and peripheral neuropathy (11, 4.49%), pneumonia (9, 3.67%), vertigo (9, 3.67%), diabetes mellitus (8, 3.27%), coronary heart disease (7, 2.86%), diabetes nephropathy (7, 2.86%), and fracture (7, 2.86%). Circulating system diseases, endocrine, nutritional, or metabolic diseases, and digestive system diseases were the research hotspots. The annual

Table 8

RCTs on traditional Chinese classic famous prescriptions involving ICD-11 disease classification (top 10)

Disease type	Number of RCTs
Diseases of the circulatory system	56
Endocrine, nutritional or metabolic diseases	40
Diseases of the digestive system	39
Diseases of the respiratory system	22
Diseases of the genitourinary system	17
Diseases of the nervous system	17
Injury, poisoning, or certain other consequences of external causes	16
Neoplasms	15
Diseases of the musculoskeletal system or connective tissue	14
Traditional medicine conditions	9

ICD-11: International classification of diseases 11th revision; RCT: Randomized controlled trial.

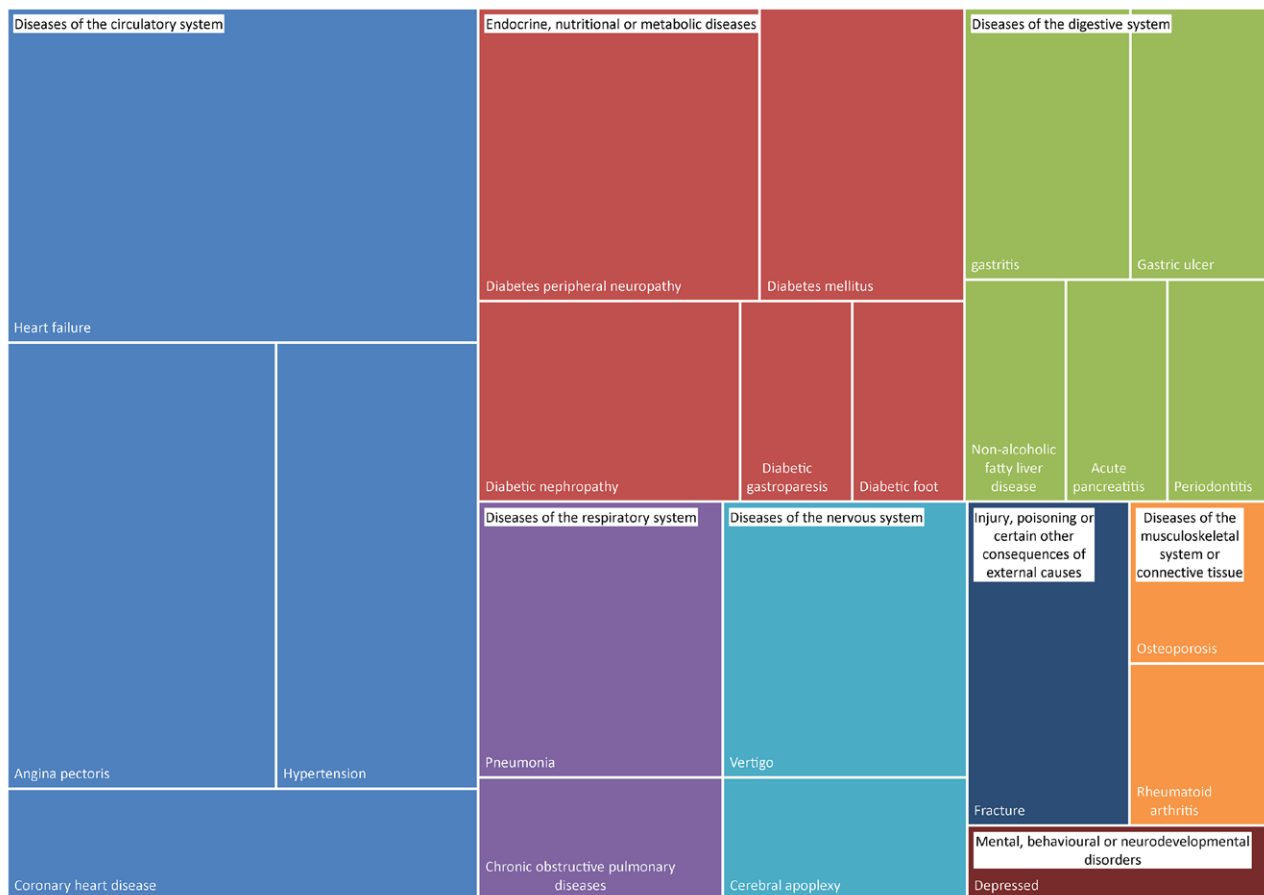


Figure 7. Distribution of diseases in clinical research of traditional Chinese classic famous prescriptions in 2022.

disease distribution in RCTs on traditional Chinese classic famous prescriptions is shown in Figure 7.

Situation of traditional Chinese classic famous prescriptions

There were 55 types of traditional Chinese classic famous prescriptions involved in RCTs, and the treatment was mainly for circulatory and endocrine system diseases. The top 10 traditional Chinese classic famous prescriptions in terms of publication volume included Taohong Siwu tang (23 articles), Banxia Xiexin tang (22 articles), Banxia Baizhu Tianma tang (21 articles), Zhenwu tang (21 articles), Qingjin Huatan tang (14 articles), Wendan tang (13 articles), Huangqi Guizhi Wuwu tang (12 articles), Gualou Xiebai Banxia tang (nine articles), Dangu Sini tang (eight articles), Guizhi Shaoyao Zhimu tang (eight articles), and Linggui Zhugan tang (eight articles) (Table 9).

Intervention and control design

The RCTs included 240 two-arm trials, 3 three-arm trials, and 2 four-arm trials. The two-arm trial involved 10 intervention and control designs, including 87 articles (35.51%) of “decoction + conventional treatment *vs.* conventional treatment” 71 articles (28.98%) of “decoction + Western medicine *vs.* Western medicine” and 50 articles (20.41%) of “decoction + Western medicine + conventional treatment *vs.* Western

medicine + conventional treatment”. In 2022, the number of RCTs on traditional Chinese classic famous prescriptions with intervention and control design exceeded 10, as shown in Figure 8.

Overview of the sample size

The study involved 22,176 patients, ranging from 30 to 300 cases, and had an average sample size of 91 cases; all were single-center studies. Studies with a sample size <100 cases represented more than half (161 studies, 65.71%) of the included studies; 79 studies had a sample size between 100 and 199 (32.24%), and only five studies had a sample size of >200 cases (2.04%). Studies with a sample size of >200 patients are presented in Table 10.

Quality assessment

In terms of quality assessment, 25.31% of the RCTs had the problem of “random sequence generation” mainly referring only to random grouping without a detailed explanation of the implementation methods. Only 0.41% of the research reports implemented “allocation concealment” 1.22% of the studies implemented subject blinding, 11.02% of the research reports implemented blind evaluation of results, and 72.24% of the research reports had “other biases”. Thirty (12.24%) research reports used blinding, of which three reports

Table 9**The ranking of research numbers for various varieties of traditional Chinese classic famous prescriptions in 2022**

Prescription name (n = number of RCTs)	Disease type
Taohong Siwu tang (23)	Neoplasms
Banxia Xiexin tang (22)	Endocrine, nutritional or metabolic diseases
Banxia Baizhu Tianma tang (21)	Diseases of the circulatory system; diseases of the nervous system
Zhenwu tang (21)	Diseases of the circulatory system
Qingjin Huatan tang (14)	Diseases of the respiratory system
Wendan tang (13)	Diseases of the circulatory system
Huangqi Guizhi Wuwu tang (12)	Endocrine, nutritional or metabolic diseases
Gualou Xiebai Banxia tang (9)	Diseases of the circulatory system
Danggui Sini tang (8)	Endocrine, nutritional or metabolic diseases
Guizhi Shaoyao Zhimu tang (8)	Diseases of the musculoskeletal system or connective tissue
Linggui Zhugan tang (8)	Diseases of the circulatory system
Danggui Buxue tang (7)	Endocrine, nutritional or metabolic diseases
Shashen Maidong tang (7)	Neoplasms
Banxia Houpo tang (5)	Diseases of the digestive system
Simiao Yongan tang (5)	Endocrine, nutritional or metabolic diseases
Xuanfu Daizhe tang (5)	Diseases of the digestive system
Zhuling tang (5)	Diseases of the genitourinary system
Gancao Xiexin tang (4)	Diseases of the digestive system
Taohe Chengqi tang (4)	Diseases of the digestive system
Wuwei Xiaodu yin (4)	Diseases of the genitourinary system

RCT: Randomized controlled trial.

used subject blinding but did not specifically describe the implementation plan, and 27 reports used result evaluation blinding. Quality evaluation of the RCT methodology for traditional Chinese classic famous prescriptions is shown in Figure 9.

Ethics approval and protocol registration

Of the 245 RCTs, 132 studies (131 Chinese studies and one English study) reported ethical approval and zero studies reported registration information. This indicates that there is still a significant gap in the international standardization of clinical research on traditional Chinese classic famous prescriptions.

Discussion

Analysis of the current situation of Chinese classic famous prescription RCTs

In 2022, 245 traditional Chinese classic famous prescription RCTs were published, including 244 Chinese RCTs and one English RCT. In terms of publishing journals, the number of RCTs on traditional Chinese classic famous prescriptions in Peking University's Chinese core journals and CSCD journals in 2022 was relatively small. The published literature was mainly in Chinese, and the number of Chinese classic famous prescription RCTs was smaller than the number of RCTs on Chinese patent medicine. This may be because the decoction used in Chinese classic famous prescriptions has certain traditional medical characteristics. There is no uniform standard for the

addition, reduction, and dose of drugs, and there are certain difficulties in the design of clinical research.

In terms of research hotspots, this was similar to the RCT on Chinese patent medicine. Circulating and endocrine system diseases were the research hotspots. Hypertension, chronic heart failure, diabetes, peripheral neuropathy, angina pectoris, heart failure, and dizziness were studied, and many classic Chinese medicine prescriptions included Taohong Siwu tang, Banxia Xiexin tang, and Banxia Baizhu Tianma tang, which are related to hotspot diseases. It indicates that Chinese classic famous prescriptions have certain advantages and characteristics for treating these diseases. The distribution of research institutions covered most provinces in the country, and Henan, Liaoning, and Jiangxi provinces had the highest number of RCT publications. In terms of the study size, the sample size of the studies was varied, but most samples were still small (sample size <100). In the future, more clinical trials should be conducted in various fields of treatment to provide recognized and scientific clinical evidence for traditional Chinese medicine classic prescriptions.

Quality analysis of RCTs on Chinese classic famous prescriptions

The quality of RCTs on classic prescriptions was moderate. In terms of intervention and control design, the main focus was to observe the efficacy of a combination of Chinese and Western medicine. Concerning methodological quality, issues such as allocation concealment and blind applications did not receive sufficient attention.

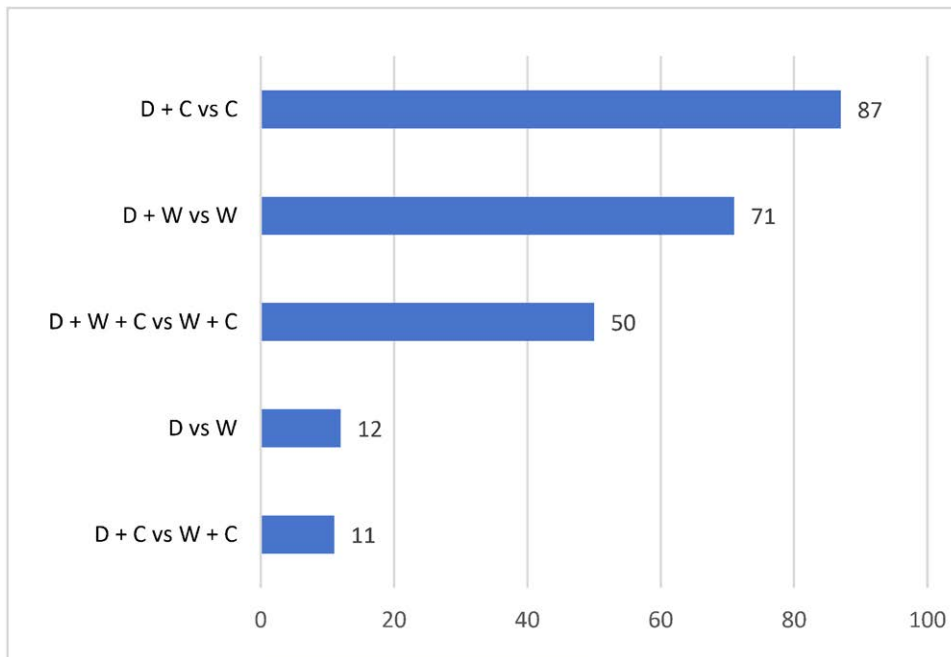


Figure 8. Intervention and control design of RCTs on traditional Chinese classic famous prescription in 2022. RCT: Randomized controlled trial.

Table 10

The RCTs with a sample size of ≥ 500 on traditional Chinese classic famous prescription varieties and diseases in 2022

Prescription name	Disease	Number of RCTs	Sample size
Danggui Sini tang ^[35]	Diabetic peripheral neuropathy	1	300
Shashen Maidong tang ^[36]	Pneumonia	1	280
Wendan tang ^[37]	Acute coronary syndrome	1	260
Simiao Yongan tang ^[38]	Acute myocardial infarction	1	260
Huangqi Guizhi Wuwu tang ^[39]	Diabetic peripheral neuropathy	1	200

RCT: Randomized controlled trial.

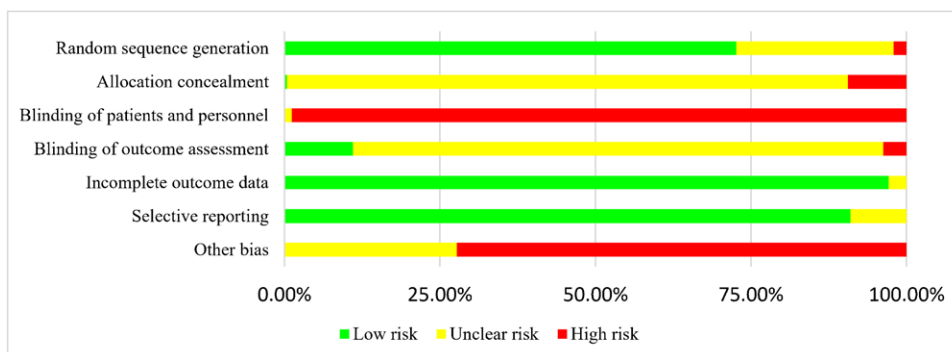


Figure 9. Quality assessment of the RCTs' methodology in traditional Chinese classic famous prescriptions. RCT: Randomized controlled trial.

In terms of ethical approval and trial registration, more than half of the RCTs reported ethical approval, while the registration process of trial plans did not receive sufficient attention.

Suggestions and summary of RCTs on Chinese classic famous prescriptions

Overall, the number of RCTs on famous traditional Chinese classic famous prescriptions in 2022 was relatively small, and the quality of clinical research in general

and attention were low. Attention must be paid to the rigor of the experimental design. Unreasonable designs can lead to bias in the evaluation of therapeutic effects. Researchers should also pay attention to the management norms in the registration and implementation process of the trial protocol of the traditional Chinese classic famous prescriptions to promote the production of high-quality clinical evidence. Although this research focused on traditional Chinese classic famous prescriptions, there is still a lack of characteristic indicators for traditional Chinese

medicine. It is recommended to develop an evaluation index system that conforms to the characteristics of traditional Chinese medicine according to the Core Outcome Measures in Effectiveness Trials development standards and the COS group standards to provide technical support for the scientific evaluation of the efficacy of traditional Chinese classic famous prescriptions^[40].

Conflict of interest statement

Junhua Zhang is the editorial board member of this journal, and other authors declare no conflict of interest.

Funding

This study was funded by Tianjin Science and Technology Bureau-Outstanding youth program-Methodological research on Intelligent Transformation of evidence in Traditional Chinese medicine (20JCJQJC00120) and Traditional Chinese Medicine Innovation Team and Talent Support Program National Traditional Chinese Medicine Multidisciplinary Interdisciplinary Innovation Team Project (ZYYCXTD-D-202204).

Author contributions

Danlei Wang and Menglong Shi participated in literature search and screening, data extraction, quality assessment, writing-original draft. Haiyin Hu participated in methodology, quality assessment, formal analysis, and writing review. Yucong Ma participated in methodology, quality assessment, formal analysis, and writing review. Dehui Peng participated in literature search and screening, data extraction. Junhua Zhang participated in research design. Alice Josephine Fauci was responsible for supervision, writing review & editing. Zhaochen Ji participated in research design, writing - review & editing.

Ethical approval of studies and informed consent

Not applicable.

Acknowledgments

None.

Data availability

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

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