

Clinical Evidence Map of Traditional Chinese Medicine for Treating Menopausal Hypertension

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Abstract: This study systematically summarizes the clinical research methods and efficacy of Traditional Chinese Medicine (TCM) in treating menopausal hypertension to provide clinical reference. Databases including CNKI, PubMed, and Cochrane Library were searched up to April 30, 2025, with evidence summarized via figures, tables, and text. A total of 164 randomized controlled trials (RCTs) and 3 meta-analyses were included. Over 70% of studies had sample sizes ranging from 60 to 100 cases, with treatment protocols mainly combining TCM and Western medicine, where oral herbal decoctions were the most common intervention and control groups typically received Western antihypertensive medications. Outcome indicators primarily focused on blood pressure and clinical efficacy rates. However, included RCTs demonstrated high risk of bias due to inadequate allocation concealment and insufficient blinding procedures, while meta-analyses received poor methodological evaluations owing to lack of protocol registration and incomplete literature searches. Current research exhibits significant flaws in study design, lacks comparative studies between different TCM treatment regimens, and demonstrates insufficient reporting of key outcome indicators, which collectively restrict the credibility and applicability of research findings. Limitations must be addressed to provide more robust evidence-based support for TCM in the prevention and treatment of menopausal hypertension.

1. Introduction

Menopause is a critical turning point in a woman's life cycle. Due to ovarian function decline and decreased estrogen levels, patients experience endocrine disorders, making them more susceptible to hypertension on top of a series of menopausal syndromes such as hot flashes, night sweats, insomnia, and irritability. Studies have found that postmenopausal women have a doubled risk of developing hypertension compared to men of the same age^[1]. At the same time, the incidence of cardiovascular events also increases, further aggravating their physical discomfort and psychological burden, seriously affecting their quality of life and health, which urgently requires a high degree of clinical attention and resolution. Current Western medical treatment is mainly based

on antihypertensive drugs combined with hormone replacement therapy, regulation of autonomic nervous system dysfunction, and lifestyle improvement. However, patients' blood pressure often fluctuates significantly, the use of clinical antihypertensive drugs can easily cause hypotension, and hormone replacement therapy may bring risks such as venous thrombosis, pulmonary embolism, and stroke ^[1-3], leading to a decrease in treatment adherence and limited efficacy. Therefore, comprehensive management for patients with menopausal hypertension is needed, and exploring integrated and personalized intervention methods has become a top priority.

Traditional Chinese Medicine (TCM) has unique advantages with its holistic concept and individualized treatment based on syndrome differentiation, and its multi-target, multi-pathway intervention effects show great potential in the treatment of menopausal hypertension. In TCM theory, menopausal hypertension can be classified under categories such as vertigo and headache. Its core pathogenesis is mainly summarized as "deficiency of kidney essence, where water fails to nourish wood," which in turn leads to "hyperactivity of liver yang." Clinical studies have confirmed that the combination of Chinese and Western medicine can reduce blood pressure fluctuations, improve menopausal symptoms and hormone levels, and has a good safety profile ^[4-6].

However, there is currently a lack of systematic analysis of the efficacy of clinical research related to this disease. As an emerging method for evidence synthesis and visualization, an evidence map can clearly display the distribution characteristics, main results, evidence quality, and existing gaps in research ^[7]. This study aims to provide strong evidence-based support for the development of TCM treatment for this disease by constructing the first clinical evidence map for TCM in the treatment of menopausal hypertension, comprehensively and systematically collecting, evaluating, and integrating existing clinical research evidence, and analyzing its progress and shortcomings.

2. Materials and Methods

2.1 Search Strategy A systematic search was conducted in the China

CNKI, Wanfang, VIP, SinoMed, PubMed, Web of Science, Cochrane Library, and Embase databases for literature on the treatment of menopausal hypertension with Traditional Chinese Medicine. The search period was from the inception of each database to April 30, 2025. search terms included menopausal hypertension, perimenopausal hypertension, Traditional Chinese Medicine, TCM, Chinese medicine, Chinese herbal medicine, herbal medicine, formula, granule, powder, tablet, capsule, pill, mixture, drink, paste, injection, etc, as shown in Figure 1.

2.2 Inclusion Criteria

The study had to meet the diagnostic criteria for menopausal hypertension; the study type was a randomized controlled trial (RCT) or a meta-analysis of RCTs; the intervention measures for the experimental group included Chinese medicine injections, single Chinese herbs, or Chinese medicine compounds (with no restrictions on the specific dosage form), and the intervention measures for the control group included Western medical treatment, a Chinese medicine placebo, or a blank control.

2.3 Exclusion Criteria

Literature irrelevant to the topic; animal studies, reviews, clinical experience, clinical research protocols, theoretical discussions, health reports, etc.; meta-analyses that included non-randomized controlled trials, cohort studies, case-control studies, and other types of research; books, conference proceedings, and achievement reports; duplicate publications; and literature for which the full text

was unavailable, as shown in Figure 1.

2.4 Literature Screening and Data Extraction

Two researchers independently screened the literature. The retrieved literature was imported into NoteExpress software in bibliographic format to remove duplicates. The titles and abstracts were read for initial screening based on inclusion and exclusion criteria. If a decision could not be made, the full text was read for a second screening. If a decision still could not be made or there was a disagreement, it was discussed with a third party.

2.5 Methodological Quality Assessment of Literature

The Cochrane Handbook for Systematic Reviews of Interventions was used to assess the risk of bias in the included RCTs, The AMSTAR 2 tool was used to assess the risk of bias in the included meta-analyses, which consists of 16 items, including the PICO principle, establishment of research methods before the systematic review, types of included studies, comprehensiveness of the search strategy, and dual literature screening and data extraction. Each item was rated as "partial yes," "no," or "yes," and the literature quality was classified into four levels: "high," "medium," "low," and "critically low" [8]. The above assessments were conducted by two researchers separately, and any disagreements were resolved by discussion with a third party.

2.6 Statistical Analysis

WPS Office was used for statistical analysis and chart creation. The evidence distribution characteristics were presented through bubble charts.

3. Results

3.1 Literature Screening Process

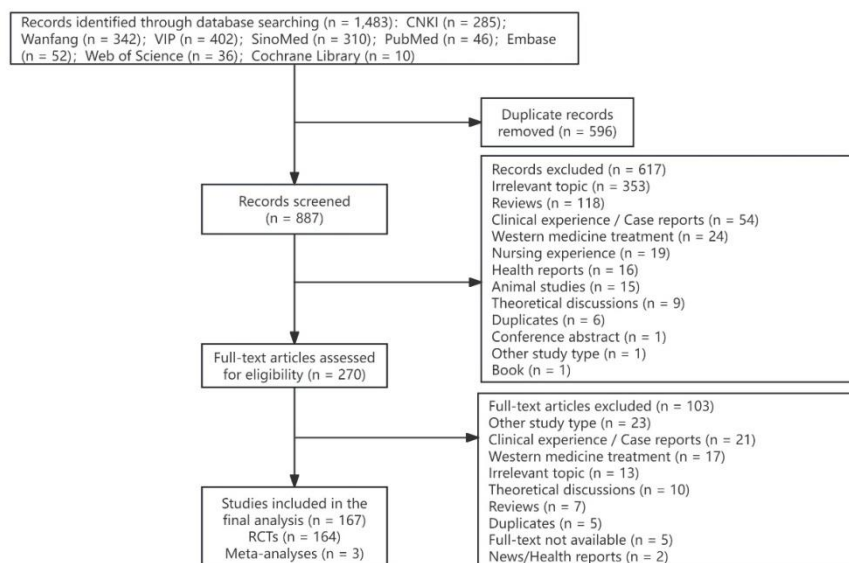


Figure 1 Literature screening process

3.2 Characteristics of the Literature

(1) Publication Trend Among the included literature, the overall number of publications shows a fluctuating upward trend. Notably, from 2009 to 2012, the number of publications increased significantly from 6 to 12, showing a high growth rate. The number of publications peaked in 2022.

(2) Hypertension Grading In the statistics of publications related to hypertension, publications focusing on Grade 1-3 hypertension are the most numerous, totaling 83 articles with a percentage of 50.61%; followed by those on Grade 1-2 hypertension, which amount to 62 articles accounting for 37.80%; publications on Grade 1 hypertension number 14, representing 8.54%; those on High-Normal to Grade 1 hypertension are 2 articles, making up 1.22%; publications on Grade 2 hypertension stand at 3 articles with a percentage of 1.83%; while there are 0 publications on Grade 3 hypertension.

(3) Sample Size Statistical analysis revealed that the sample sizes of clinical randomized controlled trials were mainly concentrated in the range of 60-100 cases (116 articles, 71%). The minimum sample size was 40 cases^[9-11], and the maximum was 300 cases^[12].

(4) Intervention Measures As shown by the statistical results, Chinese herbal decoctions had the highest number of publications (84 articles, 51.22%), followed by oral Chinese patent medicines (21 articles, 12.65%), external therapies of TCM (15 articles, 9.15%), and combined TCM therapies (10 articles, 6.11%), as shown in Table 1.

Table 1 Intervention measures in the TCM treatment of menopausal hypertension trial group

Category	Intervention	Number of Publications	Percentage (%)
Oral Chinese Medicine	Chinese Herbal Decoction	84	51.22
	Chinese Medicine Granules	14	8.54
	Chinese Medicine Capsules	7	4.27
	Chinese Medicine Powder	5	3.05
	Chinese Medicine Mixture/Syrup	3	1.83
	Chinese Medicine Pills	2	1.22
	Chinese Medicine Tablets	1	0.61
Chinese Patent Medicine	Oral Chinese Patent Medicine	21	12.80
	Chinese Patent Medicine Injection	1	0.61
External TCM Therapies	Acupuncture	6	3.66
	Bundled TCM Interventions	4	2.44
	Auricular Acupressure	2	1.22
	Acupoint Application	1	0.61
	Acupoint Catgut Embedding	1	0.61
Combined TCM Therapies	Meridian Scraping+Auricular Acupressure	1	0.61
	Oral Herbal Decoction+Acupuncture	6	3.66
	Oral Herbal Decoction+Auricular Acupressure	1	0.61
	Oral Herbal Decoction+Foot Bath Therapy	1	0.61
	Oral Herbal Decoction+Meridian Scraping	1	0.61
	Oral Herbal Decoction+Hyperbaric Oxygen Therapy	1	0.61
Diet Therapy	Dietary Therapy	1	0.61

This study included 116 articles that used self-prescribed formulas to treat menopausal hypertension. A total of 67 oral chinese decoction for menopausal hypertension were involved, among which Erxian Decoction/Granules and Xuzao Gengping Granules/Powder had the most literature reports (14 each, accounting for 12.07% respectively), followed by Qiju Dihuang Pills (6 articles, 5.17%), Ningmai Anshen Granules and Zishen Ningxin Capsules (4 each, 3.45% respectively), 4 oral chinese decoction including Liuwei Dihuang Decoction, Qianyang

Mixture, Qinggan Huoxue Decoction and Xiaoyao Powder (3 each, 2.59% respectively), 4 oral chinese decoction including syndrome differentiation and treatment, Guidi Baihe Soup, Shugan Jieyu Capsule and Zhengan Xifeng Decoction (2 each, 1.72% respectively), and the remaining 49 oral chinese decoction all had only 1 literature report (0.86% respectively).

A total of 22 articles on Chinese patent medicine preparations were included, involving 11 types of Chinese patent medicines. Among them, Songling Xuemai Kang Capsule has the largest number of publications, totaling 9 articles with a percentage of 40.9%; Wuling Capsule, Shensong Yangxin Capsule, and Xiaoyao Pill have the same number of publications, each with 2 articles accounting for 9.1% respectively; Jiawei Xiaoyao Pill, Kuntai Capsule, Liuwei Dihuang Pill, Qiju Dihuang Pill, Tianmeng Capsule, Zhenju Antihypertensive Tablet, and Gastrodin Injection have the same number of publications, each with 1 article representing 4.5% respectively.

(5) Outcome Indicators The outcome indicators in this study were mainly divided into the following 14 categories: Blood pressure; Ambulatory blood pressure; Efficacy rate; TCM syndrome score; Modified Kupperman scale; Quality of life scales; Safety indicators; Sex hormone; Adverse reactions; Clinical efficacy; Vascular endothelial function; Neuroendocrine indicator; Serum inflammatory factor; Pittsburgh Sleep quality index scale.

Among the included RCTs, blood pressure (119 articles), ambulatory blood pressure (54 articles), efficacy rate (90 articles), TCM syndrome score (68 articles), modified Kupperman Index (41 articles), quality of life scales (24 articles), safety indicators (31 articles), sex hormones (42 articles), adverse reactions (17 articles), and clinical efficacy (70 articles) were the main outcome indicators of interest. Therefore, a plot of outcome indicators was created for Chinese herbal decoctions (frequency ≥ 2) and all Chinese patent medicines, as shown in Figure 2.

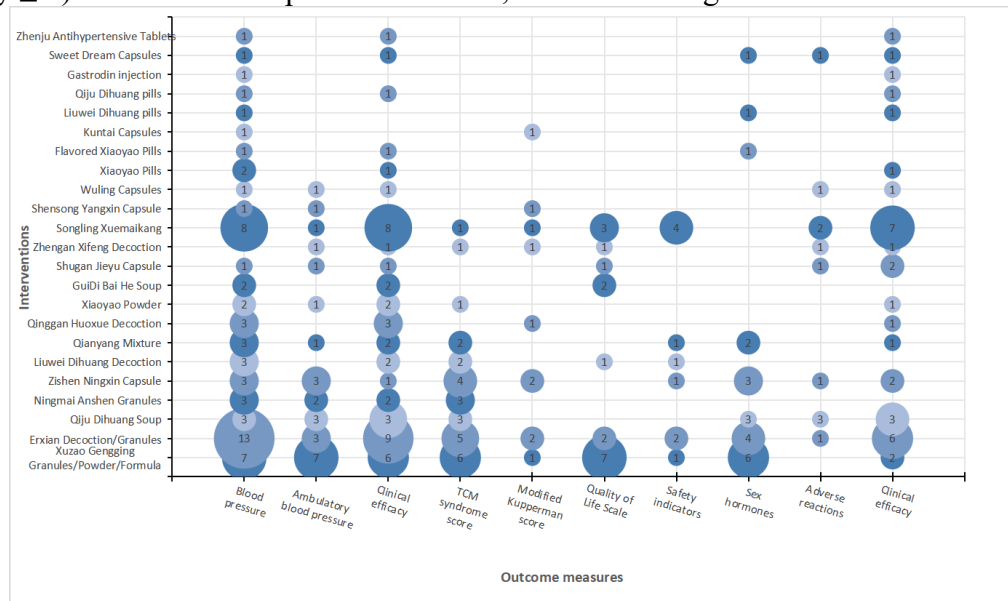


Figure 2 Outcome indicators of randomized controlled trials of traditional Chinese medicine for the treatment of menopausal hypertension

4. Methodological Quality Assessment

4.1 Methodological Quality Assessment of RCTs

The methodological quality of the 164 included RCTs was assessed, as shown in Figure 3. 1) Random sequence generation: 70 studies were fully randomized, including 60 using a random number table, 4 using random software, 3 using random numbers, 1 using systematic randomization,

and 1 using drawing lots, all rated as "low risk". 7 studies were quasi-randomized, including 6 based on the order of consultation or admission, and 1 using a coin toss (the protocol specified that once one group reached 40 subjects, the remaining subjects were automatically assigned to the other group, violating the principles of RCTs), rated as "high risk". 87 studies only mentioned "random" or did not specify the allocation method, rated as "unclear risk". 2) Allocation concealment: 158 studies did not explicitly mention it, rated as "unclear risk"; only 6 used sealed envelopes for concealment, rated as "low risk". 3) Blinding of participants and personnel: For 158 studies, there was insufficient information to determine if blinding was used, rated as "unclear risk"; 1 study was double-blind, rated as "low risk"; 5 were single-blind, rated as "high risk". 4) Blinding of outcome assessment: All studies failed to mention relevant information, with insufficient information to judge "yes" or "no", thus all were rated as "unclear risk". 5) Incomplete outcome data: 137 studies (83.5%) had no missing data, and 15 had missing data but the proportion was small and the reasons were explained, rated as "low risk"; 11 studies had a large proportion of missing data or did not report the reasons, and 1 lacked outcome indicators, rated as "high risk". 6) Selective reporting: 163 studies reported the declared indicators according to the pre-specified plan, rated as "low risk"; 1 study did not fully report the declared indicators, rated as "high risk". 7) Other biases: It was not possible to determine if other biases existed in any of the studies, so all were rated as "unclear risk".

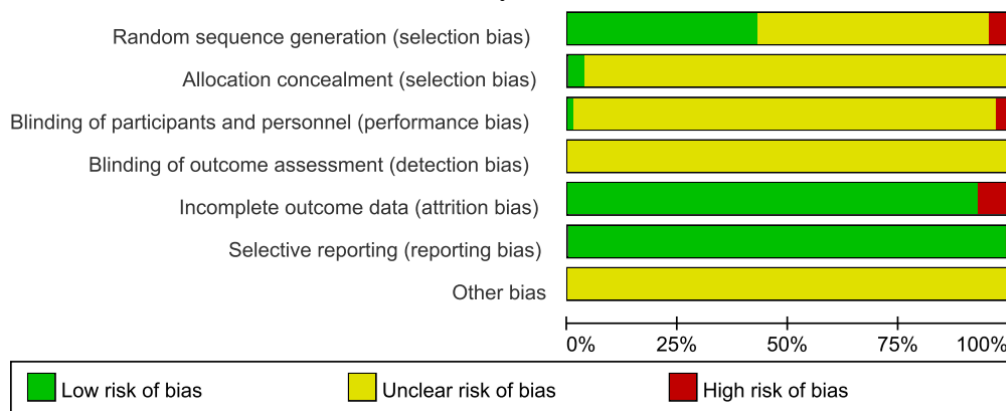


Figure 3 Proportion of items with bias risk in TCM-related RCTs

4.2 Quality Assessment of Meta-Analyses

The methodological quality of the 3 meta-analyses was assessed using the AMSTAR 2 scale. None of the 3 articles reported registration of their research protocol, nor did they assess or consider the potential impact of risk of bias on the final results. Two articles did not use appropriate tools to assess the risk of bias in the included studies. One article included too few studies and provided a severely inadequate description of them, while one article explored the heterogeneity of the results. Overall, the methodological quality of all 3 articles was rated as "critically low."

5. Discussion

5.1 Content Characteristics of the Literature

5.1.1 Research on Hypertension Grading

The results of this study show that the annual number of publications on TCM treatment for menopausal hypertension is on a fluctuating upward trend. Literature statistics show that only 1.22% of current studies focus on high-normal blood pressure, suggesting that clinical attention to this

condition may be low. The 2023 World Health Organization report pointed out that the burden of hypertension is increasing year by year, and prehypertension, as an early stage of hypertension, should receive more attention and early intervention^[13]. In addition to lifestyle improvements, the use of Traditional Chinese Medicine can help patients prevent disease before it arises and prevent its progression once it has occurred, further reducing the risk of hypertension and its associated cardiovascular and cerebrovascular events.

5.1.2 Research on Intervention Measures

The literature analysis shows that oral Chinese herbal decoctions and Chinese patent medicines are the main intervention methods, while the application of external therapies is relatively rare. Currently, the use of TCM formulas shows diversity in composition and dosage forms, with most being self-prescribed by clinicians. At the same time, formulas with the same name and prescriptions for the same syndrome type have significant differences in their components. Additionally, the inconsistent naming system for self-prescribed formulas makes standardized analysis difficult. Therefore, this study only conducted an in-depth exploration of the application of classic formulas and standardized Chinese patent medicines.

Regarding Chinese herbal decoctions: Erxian Tang was created in the 1950s by the famous TCM professor Zhang Bo-Ne. The formula consists of Yinyanghuo (Herba Epimedii), Xianmao (Rhizoma Curculiginis), Huangbai (Cortex Phellodendri), Zhimu (Rhizoma Anemarrhenae), Bajitian (Radix Morindae Officinalis), and Danggui (Radix Angelicae Sinensis), and has the effects of warming the kidney and supplementing essence, as well as nourishing yin and purging fire^[14]. Modern pharmacological studies have confirmed that active components in Erxian Tang, such as berberine, luteolin, and kaempferol, can act on key targets like ICAM-1, IL-6, and IL-1 β . Through a dual mechanism of improving vasodilation and inhibiting inflammatory responses, it achieves antihypertensive effects and effectively alleviates menopause-related symptoms^[15].

Regarding Chinese patent medicines: Songling Xuemai Kang Capsule is the most widely used, consistent with the recommendations of the 2024 "Expert Consensus on the Clinical Application of Songling Xuemai Kang Capsule for the Treatment of Primary Hypertension"^[16]. As a pure traditional Chinese medicine preparation, the main active ingredients of Songling Xuemai Kang Capsule include fresh pine needles, Gegen (Radix Puerariae), and pearl powder, which have the effects of calming the liver and suppressing yang, and tranquilizing the mind. Modern pharmacological studies indicate that this drug can exert an antihypertensive effect by regulating the renin-angiotensin-aldosterone system (RAAS), improving vascular endothelial function, and inhibiting inflammatory responses^[17–19]. Results from relevant meta-analyses show^[20,21] that combining Songling Xuemai Kang Capsule with ARB/CCB antihypertensive drugs can significantly improve the symptoms of TCM in patients with menopausal hypertension (OR=5.04).

5.1.3 Research on Outcome Indicators

Outcome indicators are the key basis for scientifically and objectively reflecting the value of interventions. When constructing an evidence map for menopausal hypertension, it is necessary to systematically and comprehensively examine multi-dimensional indicators to ensure the scientific rigor, comprehensiveness, and clinical guiding value of the analysis^[22]. Through a systematic review, we found that the comprehensiveness of outcome indicators in studies on TCM for menopausal hypertension is insufficient, mainly in the following aspects: 1. Blood pressure monitoring: Studies show that the "non-dipping" phenomenon of nocturnal blood pressure is significantly associated with the risk of cardiovascular events^[23]. However, in this study, only 54 articles included ambulatory blood pressure monitoring, with a clear lack of attention to nocturnal

blood pressure monitoring. Therefore, blood pressure monitoring should not be limited to office and home measurements but should place greater emphasis on assessing the variability of nocturnal blood pressure. 2. Cardiovascular event monitoring: Cardiovascular events are key indicators reflecting the long-term prognostic impact of hypertension interventions. A growing body of research indicates that menopausal women have a significantly increased risk of cardiovascular events even at relatively low blood pressure thresholds. The INTERHEART study showed that, compared to age-matched men, hypertension increases the risk of myocardial infarction in older women. A meta-analysis of 3,568 heart failure cases showed that women who experience early menopause have a significantly higher risk of heart failure (HR 1.33; 95% CI 1.53). Another prospective study of 327 cases of spontaneous coronary artery dissection found that a large proportion of these patients had a history of hypertension^[23,24–26]. However, none of the studies included in our research mentioned cardiovascular event monitoring. 3. Arterial stiffness assessment: With the decline in estrogen levels, arterial stiffness in menopausal women increases significantly, which is closely related to cardiovascular risk^[27]. Only 2 articles in this study evaluated this indicator^[28,29]. 4. Psychological factors: Studies show that the incidence of anxiety and depression is higher in postmenopausal women, and these psychological states may lead to elevated blood pressure by activating the sympathetic nervous system^[30]. However, only 11 articles in this study recorded anxiety or depression scales as outcome measures, suggesting that researchers pay little attention to the psychological factors of menopausal patients. 5. Cognitive function: Cognitive decline is a potentially important outcome indicator for menopausal hypertension. Research indicates that menopausal hypertension can increase a woman's risk of dementia by 65%^[23]. Therefore, assessment in this area should be given importance in clinical research. 6. Other related factors: Obesity has become a major health issue in modern society. Studies have found that weight gain may be an important factor contributing to elevated blood pressure in menopausal women^[31]. However, the studies included in this paper have paid little attention to patients' weight. Future research should monitor and intervene on obesity-related indicators such as body mass index, waist circumference, waist-hip ratio, and body fat percentage. 7. Safety factors: Among the included literature, only 17 articles recorded adverse reactions; the rest did not mention them. Studies show that women report adverse reactions to certain antihypertensive drugs more frequently^[32]. Therefore, adverse reaction monitoring should be included as a standardized safety assessment indicator when designing clinical studies.

5.2 Methodological Quality Assessment of the Literature

The methodological quality assessment of RCTs shows that the overall quality of the literature is low. This is mainly because most studies did not adequately report the allocation concealment process, details of blinding implementation, basis for sample size estimation, or declarations of potential conflicts of interest, leading to them being rated as having an "unclear risk of bias." The methodological quality of the three meta-analyses was rated as critically low, primarily due to unregistered research protocols, inappropriate methods for assessing risk of bias, insufficient literature searches or search reporting, and failure to report funding sources for the included studies. These findings significantly reduce the credibility of the overall body of evidence and have a certain impact on the reliability and clinical applicability of the conclusions of the included studies^[33].

6. Conclusion

This study is the first to use the evidence map method to systematically summarize and analyze the current state of clinical research on Traditional Chinese Medicine (TCM) for the treatment of menopausal hypertension. It was found that TCM demonstrates clear clinical benefits in treating

menopausal hypertension, but the level of evidence is low. Future research should further standardize study protocols to improve research quality; increase focus on outcome indicators such as nocturnal blood pressure, cardiovascular events, arterial stiffness, psychological status, cognitive function, obesity, and safety to more comprehensively and accurately evaluate the efficacy of TCM. At the same time, efforts should be made to conduct long-term, multi-center, large-sample studies to provide more robust evidence-based support for the clinical application of TCM in treating hypertension.

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