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Efficacy and safety of Chinese patent medicines for allergic rhinitis based on 2020 Chinese Pharmacopoeia: a protocol for systematic review and meta-analysis of randomized controlled trials

Weibo Zhao[1,2], Lingyao Kong[3], Xuehui Wang[3], Qingyuan Liu[2], Yaqi Wang[4] and Ji Wang[1*]

Abstract

Background Allergic Rhinitis (AR) is a prevalent chronic respiratory condition with limited long-term relief from Western medications. Interest in Traditional Chinese Patent Medicines (TCPMs) as a complementary approach is growing, but research on their efficacy and safety is lacking. We aim to evaluate the efficacy and safety of TCPMs listed in the 2020 Chinese Pharmacopoeia (ChP 2020) that are indicated for treating AR.

Methods We will search PubMed, Embase, Web of Science, Cochrane Library, and four Chinese databases to retrieve randomized controlled trials investigating specific TCPMs (Biyankang tablets, Tongqiao Biyan Granules, Tongqiao Biyan Tablets, Tongqiao Biyan Capsules, Xinqin Granules, Xinqin Tablets, Xinyi Biyan Pills) for AR. Primary outcomes are Total Nasal Symptom Scores (TNSS) and Total Ocular Symptom Scores (TOSS). Secondary outcomes include quality of life, relapse rates, nasal function, biomarkers, and adverse events. No languages and publication data limitations. Meta-analysis will be performed using RevMan 5.4 with random effects model. Publication bias are set to be assessed using funnel plots and Egger's test, and adjusted with the trim and fill method. Meta-regression will investigate factors influencing outcomes for AR. Study quality will be assessed using the Cochrane Risk of Bias 2.0 tool, and the Grading of Recommendations Assessment, Development, and Evaluation approach will be used to evaluate the quality of evidence.

Discussion Despite the limitations of conventional AR medications, TCPMs show potential benefits in immune modulation and symptom relief. This review will focus on TCPMs listed in ChP 2020 to comprehensively evaluate their safety and efficacy for AR. Unlike existing reviews, this study emphasizes rigorous standards of TCPMs, aiming to provide a more reliable evidence base. Although a network meta-analysis would be ideal, a traditional meta-analysis will be conducted due to limited data. Future research should focus on direct comparative studies and utilize AI techniques for understanding mechanisms and enhancing personalized treatments. This review aims to bridge gaps in the current literature and potentially improve clinical guidelines and patient outcomes in AR management.

Systematic review registration INPLASY202450121.

*Correspondence:
Ji Wang
doctorwang2009@126.com
Full list of author information is available at the end of the article

Keywords Chinese patent medicines, 2020 Chinese Pharmacopoeia, Allergic rhinitis, Protocol, Systematic review, Meta-analysis

Introduction

Allergic rhinitis (AR) arises from a hypersensitive immune response to allergens, specifically an IgE-mediated type 1 hypersensitivity response. It can be categorized as either intermittent, with symptoms lasting fewer than 4 days per week or for less than four consecutive weeks, or persistent, with symptoms occurring for more than 4 days a week over at least a month [1, 2]. AR manifests as a runny nose, nasal congestion or blockage, an itchy nose, and sneezing [2]. The global prevalence of AR is on the rise, making it a growing public health concern. While estimates suggest that AR affects between 5 and 50% of the global population [2, 3]. In China specifically, the prevalence based on self-reported data is between 17.6% and 32.4% [4]. The high prevalence of AR creates a substantial burden on healthcare systems, leading to broad socioeconomic implications [5, 6]. Individuals with AR are more prone to encountering various sleep disturbances during the night and daytime [7]. AR significantly impacts productivity in both workplace and academic settings, with studies demonstrating productivity reductions of 21.0% among employed individuals and 21.2% among students [8]. The MASK-air study revealed that participants reported Visual Analog Scale (VAS) scores exceeding 20/100 on 45% of observation days, and scores surpassing 50/100 on 13% of days, with higher values indicating a higher impact of allergic symptoms [9].

Managing AR typically involves strategies like allergen avoidance, pharmacotherapy, and immunotherapy. However, common Western medications such as antihistamines and corticosteroids can lead to undesirable side effects, including drowsiness, dry mouth, and nasal dryness [10, 11]. These treatments also fall short of providing long-term solutions. As a result, many patients explore complementary and alternative (CAM) therapies [12–14]. Among these, traditional Chinese medicine (TCM) is attracting growing interest for its distinctive approach to AR management [15].

TCM, with its roots in ancient China dating back over 3000 years, has developed a diverse array of therapeutic modalities, encompassing both pharmacological and non-pharmacological interventions. These include acupuncture, moxibustion, cupping, *tuina* (massage), *qigong*, traditional Chinese patent medicines (TCPMs), and Chinese herbal medicines, etc. [16]. Regarding pharmacological intervention, several systematic reviews have examined this topic. However, these reviews predominantly focus on individualized herbal formulas, which, while potentially effective, are complex and challenging to replicate in broader clinical settings [17, 18]. Furthermore, many existing reviews aggregate data from diverse Chinese herbal medicines for AR without focused subgroup analyses, thereby diluting the evidence's specificity [19–22]. Additionally, both international and Chinese guidelines for AR indicate that recommendations regarding herbal medicine or TCPMs are either based on limited randomized controlled trials (RCTs) evidence [4, 23, 24] or conclude that the benefit and safety of herbal medicine are unclear [2, 25–28], thus offering no specific recommendations. Despite this lack of clear guidance, many doctors in clinical practice use TCPMs for AR treatment. TCPMs, derived from natural herbs, offer unique attributes, including multi-target action, multi-pathway modulation, and holistic regulatory mechanisms [29]. Safety, efficacy, and quality are essential for harnessing these benefits in patient care. Pharmacopoeial standards play a crucial role in ensuring these standards [30]. The 2020 edition of the Pharmacopoeia of the People's Republic of China (ChP 2020), the national pharmacopoeia of China, is pivotal to upholding these standards for TCPMs. It aligns with the World Health Organization's principles and guidelines for safe, effective, and high-quality medicines [31]. Specifically for AR treatment, The ChP 2020 includes a range of TCPMs that are indicated for it, such as Tongqiao biyan tablets, granules, and capsules, Xinqin tablets and granules, Xinyi biyan pills, and Biyankang tablets. These medicines not only provide relief from AR symptoms but also bolster the body's immune system and promote internal balance [19, 32].

Despite the current lack of clear guideline recommendations, these specific TCPMs are frequently used in clinical practice and have accumulated a substantial research base. There remains a notable gap in the literature concerning a comprehensive assessment of the empirical evidence supporting the therapeutic efficacy and safety profiles of these TCPMs [33]. This paucity of systematic evaluation highlights the pressing need to undertake a rigorous appraisal of the available data. In light of this, the current study aims to conduct a systematic review and meta-analysis to critically examine the efficacy and safety of TCPMs listed in the ChP 2020 for the treatment of AR.

Objective

The primary goal of this systematic review and meta-analysis is to assess the efficacy and safety of TCPMs indicated for AR as specified in the ChP 2020. This study seeks to address the following questions:

1). How do TCPMs listed in ChP 2020 compare to conventional Western medical treatments, no intervention, or placebo in terms of efficacy and safety for treating AR?
2). Are there any potential additive or synergistic effects when TCPMs are used in combination with Western medical treatments?
3). What is the overall quality or certainty of the evidence regarding the efficacy and safety of TCPMs in treating AR, based on GRADE assessments?

Methods

Eligibility criteria

Study design

This review will include only RCTs, excluding cross-over trials and before-and-after studies. No restrictions will be placed on the study duration or follow-up period. The framework of the protocol was based on the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA-P) guidelines [34], the PRISMA-P checklist is available in the supporting information (see Appendix 1), and the completed review will adhere to the PRISMA statement for reporting systematic reviews comprehensively and transparently [35]. This protocol for a systematic review and meta-analysis has been registered on the INPLASY platform with the registration number INPLASY202450121.

Participants

Studies will be considered eligible if they include participants of any age who have a confirmed diagnosis of AR, based on established criteria or guidelines. This includes cases of both intermittent and persistent AR, regardless of severity or duration. Studies that include participants with other types of rhinitis, nasal conditions, or significant comorbidities will be excluded. There will be no restrictions on demographic factors such as gender, ethnicity, or geographical location.

Interventions

The interventions of interest are TCPMs listed in the ChP 2020 which are indicated for the treatment of AR. This category includes a variety of formulations such as Tongqiao biyan tablets, granules and capsules, Xinqin tablets, granules, Xinyi biyan pills, and Biyankang tablets. Studies that investigate the use of TCPMs in conjunction with Western medicine treatments will also be included, provided the effects of the TCPM can be distinctly isolated. The ingredients of the TCPMs are shown in Table 1.

Comparators

Eligible comparators will include placebo, no intervention, or conventional Western medicine treatments for AR (e.g., antihistamines, corticosteroids, leukotriene receptor antagonists). Studies comparing different traditional Chinese medicine products will be excluded.

Outcomes

For inclusion, studies must report any of the following outcomes at one or more time points during or after the treatment period (e.g., 2 weeks, 4 weeks, 8 weeks, end of treatment) to evaluate the onset and duration of the treatment effect.

Table 1 The ingredients of TCPMs listed in ChP 2020 for allergic rhinitis

Name	Ingredients
Biyankang tablets	Pogostemonis Herba 206 g; Xanthii Fructus 257 g; Centipedae Herba 257 g; Ephedrae Herba 129 g; Chrysanthemi Indici Flos 129 g; Angelicae Sinensis Radix 166 g; Scutellariae Radix 109 g; Suis Fellis Pulvis 13 g, Peppermint oil 0.92 g; Chlorphenamine Maleate 1 g
Tongqiao Biyan Granules	Xanthii Fructus (stir-baked) 600 g; Saposhnikoviae Radix 450 g; Astragali Radix 750 g; Angelicae Dahuricae Radix 450 g; Magnoliae Flos 450 g; Atractylodis Macrocephalae Rhizoma (stir-baked) 450 g; Menthae Haplocalycis Herba 150 g
Tongqiao Biyan Tablets	Xanthii Fructus (stir-baked) 200 g; Saposhnikoviae Radix 150 g; Astragali Radix 250 g; Angelicae Dahuricae Radix 150 g; Magnoliae Flos 150 g; Atractylodis Macrocephalae Rhizoma (stir-baked) 150 g; Menthae Haplocalycis Herba 50 g
Tongqiao Biyan Capsules	Xanthii Fructus (stir-baked) 300 g; Saposhnikoviae Radix 225 g; Astragali Radix 375 g; Angelicae Dahuricae Radix 225 g; Magnoliae Flos 225 g; Atractylodis Macrocephalae Rhizoma (stir-baked) 225 g; Menthae Haplocalycis Herba 75 g
Xinqin Granules	Asari Radix et Rhizoma 200 g; Scutellariae Radix 200 g; Schizonepetae Herba 200 g; Saposhnikoviae Radix 200 g; Angelicae Dahuricae Radix 200 g; Xanthii Fructus 200 g; Astragali Radix 200 g; Astractylodis Macrocephalae Rhizoma 200 g; Cinnamomi Ramulus 200 g; Acori Tatarinowii Rhizoma 200 g
Xinqin Tablets	Asari Radix et Rhizoma 333 g; Scutellariae Radix 333 g; Schizonepetae Herba 333 g; Saposhnikoviae Radix 333 g; Angelicae Dahuricae Radix 333 g; Xanthii Fructus 333 g; Astragali Radix 333 g; Astractylodis Macrocephalae Rhizoma 333 g; Cinnamomi Ramulus 333 g; Acori Tatarinowii Rhizoma 333 g
Xinyi Biyan Pills	Magnoliae Flos 42 g; Menthae Haplocalycis Herba 433 g; Perillae Folium 317 g; Glycyrrhizae Radix et Rhizoma 215 g; Pogostemonis Herba 433 g; Xanthii Fructus 1111 g; Centipedae Herba 209 g; Isatidis Radix 650 g; Inulae Cappae Radix et Rhizoma 433 g; Saposhnikoviae Radix 313 g; Houttuyniae Herba 150 g; Chrysanthemi Flos 433 g; Euodiae Leptae Folium et Ramulus 433 g

Primary outcomes

1). Total Nasal Symptom Score (TNSS). TNSS assesses the severity of four nasal symptoms: nasal congestion, rhinorrhea, nasal itching, and sneezing. Each symptom is scored on a scale of 0 (no symptoms) to 3 (severe symptoms), and the total score ranges from 0 to 12, with higher scores indicating more severe nasal symptoms. The TNSS exhibits strong reliability (ICC = 0.86) and high validity, as evidenced by excellent sensitivity and specificity (AUC = 0.99) [36].
2). Total Ocular Symptom Score (TOSS). TOSS evaluates the severity of ocular symptoms associated with AR, such as eye itching, tearing, redness, and swelling. Similar to TNSS, each ocular symptom is typically scored on a scale of 0 to 3, and the total score is calculated by summing the individual symptom scores.

Both TNSS and TOSS are well-established instruments recommended by the European Academy of Allergy and Clinical Immunology (EAACI) Immunotherapy Interest Group for assessing AR symptoms [37]. For inclusion, studies must report the TNSS or TOSS values, or the individual nasal symptom scores during the treatment period.

Secondary outcomes

1). Rhinitis Quality of Life Questionnaire (RQLQ) scores. RQLQ measures the impact of rhinitis on the patient's quality of life.
2). Relapse rates of allergic rhinitis symptoms during the follow-up period.
3). Objective measures of nasal function or physiology, including mucociliary transport time (MTT), nasal airway resistance (NAR), and mucociliary clearance rate (MCR). These three measures (MTT, NAR, and MCR) are indeed widely accepted and used as objective measures of nasal function and physiology, particularly in the evaluation of nasal mucociliary clearance, nasal airflow, and nasal congestion, which are relevant parameters in allergic rhinitis.
4). Biomarker levels related to AR, such as: tumor necrosis factor-alpha (TNF-α), interleukin-4 (IL-4), interleukin-5 (IL-5), interleukin-10 (IL-10), interleukin-13 (IL-13), and immunoglobulin E (IgE).

Safey outcomes

Safety outcomes will include but are not limited to, the incidence of specific adverse events (e.g., nasal irritation, epistaxis, headache, and any serious adverse events as defined by the International Conference on Harmonisation (ICH) guidelines [38]. Specifically, we will employ the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, which grades the severity of AEs on a scale from Grade 1 (mild) to Grade 5 (death) [39]. This standardized grading system allows us to systematically quantify the severity of each adverse event.

Language

No language restrictions will be applied during the study selection process. If necessary, studies published in languages other than English will be translated via translation tools like Google Translate. To ensure translation accuracy, especially for critical data points, bilingual reviewers will be consulted to verify the translations during data extraction and analysis.

Information sources

Electronic databases to be searched include PubMed, Embase, Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL), China National Knowledge Infrastructure (CNKI), Wanfang Data, VIP Information Chinese Journal Service Platform (VIP), and Chinese Biomedical Literature Database (CBM). Additional sources will include reference lists of included studies and relevant systematic reviews.

Search strategy

A comprehensive search strategy will be developed using a combination of relevant free words(title, abstract, keywords) and controlled vocabulary terms (medical subject headings [MeSH] and Emtree terms) pertinent to allergic rhinitis, TCPMs, and randomized controlled trials. The search strings will be tailored for each database and will include relevant synonyms (e.g., "hay fever"), truncation (e.g., "allerg*" to capture variations), and Boolean operators (e.g., AND, OR, NOT) to refine the search and exclude irrelevant studies. The complete strategies for each database are available in the supporting information (see Appendix 2).

Study records

Data management

Study records will be managed using EndNote 21 reference management software, specifically the version provided by Tsinghua University Library. Duplicate records will be identified and removed accordingly.

Selection process

The study selection process will consist of two stages. First, two independent reviewers (LYK and XHW) will screen the titles and abstracts of the identified records to determine their eligibility. In the second stage, the full texts of studies deemed potentially eligible will be retrieved and independently evaluated by the same two reviewers. Any disagreements will be resolved through discussion or, if needed, by a third reviewer. The study selection process will be illustrated using a PRISMA flow diagram [36] (see Appendix 3).

Data collection process

A standardized data extraction form will be employed to gather relevant information from the included studies. Initially, data extraction is conducted on the first 10 included studies to ensure the smooth progress and consistency of the subsequent extraction process. Data extraction will be performed independently by two reviewers (LYK and XHW), and any discrepancies will be resolved through discussion or consultation with a third reviewer. Extracted data will include study characteristics, participant demographics, intervention and comparator details, outcome measures, and results.

Data items

The following data items will be extracted from each included study: Study identification (authors, publication year, study location, funding sources). Study methodological characteristics. Participant characteristics (age, gender, allergic rhinitis severity/duration). Intervention details (name of TCPMs, composition, dosage, administration route, duration, co-interventions). Comparator details (placebo, no intervention, Western medicine, dosage, administration route, duration).

Risk of bias

The risk of bias in the included RCTs will be assessed using the Cochrane Risk of Bias tool 2.0 (RoB 2.0) [40]. Two independent reviewers (LYK and XHW) will evaluate each study for potential sources of bias, including five domains: randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selective reporting, with judgments of "low risk," "some concerns," or "high risk" for overall risk of bias. The assessment will be based on outcome level and we aim to assess the effect of assignment [41]. Any disagreements will be resolved through discussion or consultation with a third reviewer. The risk of bias assessments will be incorporated into the data synthesis and interpretation, with sensitivity analyses planned to explore the potential impact of studies with a high risk of bias.

Data synthesis

Meta-analysis will be performed to pool the results of the included studies with Review Manager 5.4, if appropriate, based on the clinical homogeneity of the studies. If sufficient primary research is not available, we will provide a qualitative description of the findings. For continuous outcomes (e.g., TNSS values), mean differences or standardized mean differences between treatment groups at post-intervention will be calculated using a random-effects model, along with 95% confidence intervals. For dichotomous outcomes (e.g., adverse events), risk ratios with 95% confidence intervals will be calculated using a random-effects model. Heterogeneity across studies will be assessed using the $I2$ statistic, I^2 values above 50% point to substantial heterogeneity, and potential sources of heterogeneity will be explored through subgroup analyses or meta-regression, if appropriate. Subgroup analyses may be conducted based on factors such as TCPMs dosage form, treatment period, allergic rhinitis severity, or comparator type. Sensitivity analyses will be performed to assess the robustness of the results by excluding studies with a high risk of bias.

Additionally, meta-regression analyses will be performed to investigate the potential impact of the following factors on the efficacy and safety outcomes: type of TCPMs (e.g., pills, decoction, granules), dosage or dosage regimen of the TCM product, duration of treatment with the TCPMs, severity or duration of allergic rhinitis in the study population, overall risk of bias assessment, sample size of the included studies, length of follow-up period, type of comparator (e.g., placebo, no intervention, specific Western medicine), funding source [42].

Publication bias

Publication bias will be assessed by constructing funnel plots for the primary outcomes if at least 10 studies are available, with the symmetry visually inspected. Additionally, Egger's test will be conducted to statistically detect potential publication bias [43]. Both the direction and magnitude of any identified publication bias will be considered, as they can influence the certainty of the evidence. To account for publication bias, the trim and fill method will be used to adjust the effect size [44].

Confidence in cumulative estimate

The overall quality or certainty of the cumulative evidence will be assessed by two reviewers (LYK and XXL) using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [45]. The GRADE domains, including risk of bias, inconsistency, indirectness, imprecision, and publication bias, will be considered to rate the quality of the evidence for an important outcome. Summary of findings tables

will be generated to present the overall quality of evidence and effect estimates for the primary outcomes, as well as selected secondary outcomes, if appropriate. The tables will include the number of studies, number of participants, summary effect sizes, confidence intervals, and GRADE ratings for each outcome. Explanations for downgrading or upgrading the quality of evidence will be provided in the footnotes.

Discussion

Allergic rhinitis, as a prevalent condition, significantly impacts patients' quality of life and work productivity. Current conventional medications offer some relief, but they often have shortcomings, including adverse effects, significant individual variations in efficacy, and short durations of action. In contrast, TCPMs have demonstrated potential advantages in managing AR. They are believed to act through multiple mechanisms, including modulating immune responses, reducing inflammation, and alleviating symptoms like nasal congestion and sneezing. Despite existing clinical use and a growing research base for TCPMs, a comprehensive systematic review characterized by rigorous methodological standards is lacking. Previous reviews have suffered from limitations in both standardization and specificity [18–23], hindering a clear understanding of their true efficacy and safety. This unmet need for a rigorous and methodologically sound evaluation underscores the importance of the present review.

To ensure quality and safety, this study focuses on TCPMs listed in ChP 2020, including formulations like Tongqiao biyan pills, granules and capsules, Xinqin pills, granules, Xinyi biyan pills, and Biyankang tablet, which AR is specified as an indication. The ChP 2020 establishes quality standards, manufacturing guidelines, and detailed protocols (including ingredients, preparation, quality control, functions, usage, and storage) for each medicine, thus supporting consistency, safety, and rigor in research and clinical use [46]. This foundation enables us to examine the therapeutic basis and mechanisms of TCPMs within a robust and replicable framework [47].

While a network meta-analysis would theoretically provide the most comprehensive comparison of different TCPMs, the current study will initially employ a conventional meta-analysis approach. This is due to the limited availability of systematic evaluations on the comparative efficacy of these specific TCPMs. This limitation is recognized, but this systematic review will help summarize the existing evidence and pave the way for future research. Future research should prioritize conducting network meta-analysis once sufficient data becomes available. This will require more head-to-head comparative studies evaluating the efficacy and safety of different TCPMs for AR.

What is more, evaluating both the safety and efficacy of TCPMs is crucial for their wider acceptance and application. Future research could leverage the power of artificial intelligence (AI) to uncover the complex mechanisms of action of these medicines, such as network relationship mining, target positioning, and target navigating [48]. Additionally, Mijwil et al. [49] and Nafea et al. [50] highlighted that machine learning (ML) and deep learning (DL) models trained on large-scale datasets, including patient records and chemical structures, can identify patterns and risk factors associated with adverse reactions, thus providing critical insights for safer treatment options. Specifically, ML models could predict the efficacy of different formulations based on patient characteristics, while DL could be employed to identify novel drug targets and explore herb-drug interactions. This integration of AI, ML, and network pharmacology holds promise for accelerating the development of safer, more effective, and personalized therapies based on TCPMs.

This systematic review will provide a focused, evidence-based evaluation of commonly used, standardized TCPMs listed in ChP 2020 and indicated for the management of AR. This systematic assessment of efficacy and safety addresses a gap in the existing literature, particularly given the limited and often unclear guidance on the use of TCPMs for AR. Our findings have the potential to significantly improve patient outcomes, including enhanced quality of life, better symptom control, reduced recurrence rates, and increased overall well-being. Moreover, this study may inform the development of more precise clinical guidelines and foster advancements in treatment approaches for AR.

Abbreviations

AI	Artificial intelligence
AR	Allergic rhinitis
ChP 2020	2020 Chinese Pharmacopoeia
DL	Deep learning
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ML	Machine learning
RCTs	Randomized controlled trials
RQLQ	Rhinitis Quality of Life Questionnaire
TCM	Traditional Chinese medicine
TCPMs	Traditional Chinese Patent Medicines
TNSS	Total Nasal Symptom Scores
TOSS	Total Ocular Symptom Scores

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13643-024-02748-1.

Supplementary Material 1: Appendix 1. PRISMA-P checklist.

Supplementary Material 2: Appendix 2. Search strategy for each database.

Supplementary Material 3: Appendix 3. PRISMA flow diagram.

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Authors' contributions
Weibo Zhao: Conceptualization, writing review & editing. Lingyao Kong: Investigation, methodology, writing review. Xuehui Wang, Qingyuan Liu and Yaqi Wang: Conceptualization. Ji Wang: Conceptualization, writing review & editing.

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Data availability
The comprehensive dataset will be incorporated into the final published systematic review and meta-analysis.

Declarations

Ethics approval and consent to participate
Human research ethics committee approval is not required for this review as no original primary data will be collected.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]National Institute of Traditional Chinese Medicine Constitution and Preventive Treatment of Diseases, Beijing University of Chinese Medicine, Beijing, China. [2]Institute for TCM-X, Department of Automation, Tsinghua University, Beijing, China. [3]Centre for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, Beijing, China. [4]College of Basic Medical Sciences, Zhejiang Chinese Medical University, Hangzhou, China.

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