

# PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Extension for Chinese Herbal Medicines 2020 (PRISMA-CHM 2020)

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**Abstract:** Chinese Herbal Medicines (CHM) are the most common interventions of traditional Chinese medicine (TCM), typically administered as either single herbs or formulas. Systematic reviews (SRs) are essential references for evaluating the efficacy and safety of CHM treatments accurately and reliably. Unfortunately, the reporting quality of SRs with CHM is not optimal, especially the reporting of CHM interventions and the rationale of why these interventions were selected. To address this problem, a group of TCM clinical experts, methodologists, epidemiologists, and editors has developed a PRISMA extension for CHM interventions (PRISMA-CHM) through a comprehensive process, including registration, literature review, consensus meeting, three-round Delphi survey, and finalization. The

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PRISMA checklist was extended by introducing the concept of TCM Pattern and the characteristics of CHM interventions. A total of twenty-four items (including sub-items) are included in the checklist, relating to title (1), structured summary (2), rationale (3), objectives (4), eligibility criteria (6), data items (11), synthesis of results (14, 21), additional analyses (16, 23), study characteristics (18), summary of evidence (24), and conclusions (26). Illustrative examples and explanations are also provided. The group hopes that PRISMA-CHM 2020 will improve the reporting quality of SRs of CHM.

*Keywords:* Chinese Herbal Medicine; Extension; PRISMA; Reporting Quality; Recommendation; Review.

## Introduction

As modern medical models evolve, traditional Chinese medicine's (TCM) impact worldwide is increasing, and there is a pressing need to further develop the unique aspects of its clinical practice (Zhang *et al.*, 2012). TCM is unique in its principles, comprehensive theory, and the variety of its interventions (Jiang *et al.*, 2010). Chinese herbal medicine (CHM), an essential part of TCM and the typical representative of TCM interventions, is currently recognized more and more as having profound value because of its demonstrated curative effects (Xiong *et al.*, 2013; Lin *et al.*, 2015). CHM interventions include Chinese medicinal substances and CHM formulas (Wu *et al.*, 2007). Chinese medicinal substances (e.g., single herbs) mainly originate from natural sources, including plants, animals, minerals, and some chemical or biological products. CHM formulas (e.g., "Fu-Fang" in Chinese) are combinations of Chinese medicinal substances that are either individual prescriptions or fixed formulas, often classic, now sometimes patented (Ma and Liu, 2015). In clinical practice, the selection of CHM interventions is determined based on TCM theory described as "principles, methods, formulas, and herbs" (e.g., "Li-Fa-Fang-Yao" in Chinese); the core of diagnosis is Pattern differentiation (e.g., "Bian-Zheng-Lun-Zhi" in Chinese) (Cheng *et al.*, 2017; Zhang *et al.*, 2019b). Generally, the effectiveness of a CHM intervention highly depends on the accuracy of TCM Pattern differentiation (Wu *et al.*, 2015).

In terms of evaluating the efficacy of an intervention, systematic reviews (SRs), possibly including meta-analyses (MA), are essential evidence. They can summarize large bodies of relevant original studies and then integrate independent results (Cook *et al.*, 1997). Since the first SR with CHM interventions was published in 1997 (He and Hou, 1997), an increasing number of SRs have been conducted (Ma *et al.*, 2011). Chen M *et al.* have analyzed 218 SRs of CHM published in Chinese journals from 1998 to 2008 and found that 82.1% were of CHM formulas (e.g., patent formulas and individualized prescriptions), 10.1% were of Chinese medicinal substances (e.g., single herbs and herbal extracts), and 7.8% were of both formulas and herbs (Chen *et al.*, 2012). Recently, we have reviewed 109 Cochrane SRs of CHM published during 1999–2017, of which 29.4% studied single herbs, 22.9% studied CHM formulas, and 47.7% evaluated a broad category of CHM formulas and herbs (Zhang *et al.*, 2019a).

The value of an SR largely depends on the completeness and transparency of the reporting (Moher *et al.*, 2008). Unfortunately, the quality of reporting is not optimal, especially with regard to the completeness of CHM interventions and underlying rationale reporting (Li *et al.*, 2007; Zhang *et al.*, 2007; Yang *et al.*, 2015). Although the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) Statement and its extensions have substantially improved the reporting quality of SRs (Moher *et al.*, 2009; Sun *et al.*, 2018), the PRISMA checklists do not include CHM-specific items and do not adequately take into account TCM-related rationales. As a result, this valuable TCM-specific information is often missing or inconsistently reported in SRs of CHM. Without this information, SRs of CHM cannot provide the details from primary studies, such as the type, composition, dose, dosage form, and duration of CHM formulas used, necessary to compare whether interventions are the same and also necessary to design and carry out further experiments (Zhang *et al.*, 2019a). It is also difficult for readers to understand whether the conclusions are based on the same formula or different formulas. Therefore, we set out to extend the PRISMA guidelines to the specific reporting of SRs of studies testing CHM interventions.

### Development of PRISMA-CHM

PRISMA-CHM was developed based on the methodological framework for guideline development recommended by the EQUATOR (Enhancing the Quality and Transparency of Health Research) Network (Moher *et al.*, 2010). The standard PRISMA Checklist was used as a starting point, and the development of this extension has been a comprehensive process, including seven steps as follows:

- (1) Registration: “PRISMA-CHM” was registered on the EQUATOR Network on 18 August 2016 (Bian, 2016).
- (2) Literature review: The main objective of the scoping review was conducted to assess the reporting quality of SRs with CHM published before 1 January 2018, particularly evaluating whether necessary information related to CHM was adequately reported (Zhang *et al.*, 2019a). These results guided the preliminary drafting of the items which should be extended. The review also suggests a list of authors who had published SRs of CHM as potential participants for the Delphi survey.
- (3) Preparation of Extension checklist: A working group of PRISMA-CHM was established in January 2017. Referring to the results of the scoping review and CONSORT Extension for CHM formulas 2017 (Cheng *et al.*, 2017), the working group members drafted the initial extension items.
- (4) Face-to-face consensus meeting: A total of eleven experts, including senior TCM practitioners, clinicians in Chinese and Western medicine, methodologists of reporting guidelines and systematic reviews, epidemiologists, and editors attended a one-day face-to-face meeting in Lanzhou, China, on 19 July 2017. During the meeting, the study background and the drafted checklist were discussed with the revision of each item followed. Finally, the checklist including 25 items and subitems was confirmed for the Delphi exercise.

- (5) Three rounds of Delphi survey: An invitation letter, including a detailed explanation of the objectives and workflow of the Delphi process, and a consent form were sent to the expert. Once the expert had accepted our invitation and given consent for their comments to be shared, the Delphi questionnaire was immediately sent out by a personalized email account. A three-round Delphi survey was conducted from November 2017 to April 2018. In total, 35 experts accepted the invitation; 65.7% (23/35) finished all three rounds of the Delphi survey, while the remaining 34.3% (12/35) completed one or two rounds.

In the survey, participants were asked to score each item using a 5-point Likert scale ranging from “of no importance” to “very important” (Norman, 2010; Cummins and Gullone, 2000). Specifically, in the first round, the experts were invited to score all initially extended items as well as to suggest any additional potentially relevant items. The second round included any items that did not reach consensus and any new items from the first round. The third round involved items that did not reach consensus during the previous rounds. Following each round, item scores were calculated with the formula of  $100\% * (1 * N_5 + 0.75 * N_4 + 0.5 * N_3 + 0.25 * N_2) / (N_5 + N_4 + N_3 + N_2 + N_1)$ , where  $N_i$  represents the number of respondents who chose specific “ $i$ ” on the scale of “1 to 5.” Items with a score greater than or equal to 75% were included. Both the consensus level and the weight of responses were considered (Chen *et al.*, 2017). An anonymized summary of the results of each round was sent to all participants through emails, together with the questionnaire of the next round. The survey was sent and collected with a specific email account, which was administrated by two researchers (RT and XZ). Anonymity and confidentiality of responses were ensured. Through the Delphi exercise, a total of 24 included items and subitems were moved forward to the advisory group for discussion.

- (6) Finalization of the checklist and preparation of explanation and elaboration (E&E) document: After the advisory group review, the checklist was finalized in accordance with the final results of the Delphi survey. The meaning and rationale for each extension item, and relevant examples were prepared accordingly. Some examples were edited by removing citations or Web addresses, or by spelling out abbreviations. The checklist with E&E document was circulated to advisory group members for further comments.
- (7) Finalization of the guideline and manuscript: During consultations with advisors, the wording and presentation of the checklist and the E&E document were further discussed and revised. The checklist of PRISMA-CHM and its E&E document were finalized following the revision by the advisory group. The working group members finalized the manuscript on 30 October 2019.

### Highlights of PRISMA-CHM

PRISMA-CHM introduces the key concepts of TCM Patterns and the features of CHM interventions, including single herbs and formulas. It aims to optimize reporting of SRs that focus on studies of CHM interventions for specific conditions and Patterns (if any). The

checklist of PRISMA-CHM includes 24 extension items and subitems, namely title (1a and 1b), abstract (2), rationale (3a and 3b), objectives (4), eligibility criteria (6a, 6b, 6c, and 6d), data items (11a, 11b, 11c, and 11d), synthesis of results (14, 21), additional analyses (16), study characteristics (18a, 18b, 18c and 18d), additional analysis (23), summary of evidence (24), and conclusions (26). The checklist is presented in Table 1. Explanations of corresponding items are given below, and examples of good reporting are provided in Table 2. There is no modification to the PRISMA flow diagram.

## Explanations of PRISMA-CHM Items

### *Item 1: TITLE*

PRISMA-CHM item: 1a. Specify the name of the CHM intervention, in terms of 1) Chinese medicinal substance(s), and/or 2) CHM formula(s). 1b. State whether the review targets 1) Western medicine–defined disease(s), or 2) Western medicine–defined disease(s) with specific TCM Pattern(s), or 3) TCM Pattern(s).

Explanation: For SRs, a self-explanatory title ideally reflecting the PICOS approach (participants, interventions, comparators, outcomes, and study design) can make vital information easily accessible to readers. In terms of CHM intervention(s), we suggest authors to report the specific name of the single herb or CHM formula studied, either in English translation or Chinese Pinyin, such as “Cordyceps Sinensis,” “Yinchenhao decoction.” If an SR targets a large category of CHM treatments (e.g., both single herbs and formulas), authors can use a general term of “Chinese herbal medicines” or “herbal medicines and formulas.” In these circumstances, if the CHMs being studied can be assigned to a specific category based on TCM therapeutic principles and methods, authors are advised to report the principles or categories, such as “Chinese herbal medicines of supplementing Qi and nourishing Yin.” If an SR targets a large category of pharmacological interventions including CHM, it is not necessary to mention the CHM in the title.

In clinical practice, Pattern differentiation plays an important role in determining the CHM prescriptions. Therefore, whether the CHM intervention(s) targets a disease(s) and/or Pattern(s) in an SR should be clarified in the title. For example, if the SR targets a specific type of Pattern, its particular name should be reported, such as “damp-heat and blood-stasis syndrome.” If the SR is planning to include many types of Patterns, the keyword of Patterns, such as “TCM syndromes/Patterns” or “Pattern-based,” etc., should be in the title (Li *et al.*, 2012).

### *Item 2: STRUCTURED SUMMARY*

PRISMA-CHM item: Provide the name and form of the CHM intervention(s) used, and the TCM Pattern applied (if any).

Explanation: A comprehensive abstract can provide critical information that enables readers to understand the scope, processes, and findings of an SR and to decide whether to

Table 1. Checklist of Items for Reporting Systematic Reviews of Chinese Herbal Medicines\*

Section/Topic	Item Number	PRISMA Checklist Item	Extension for CHM	Reported on Page Number
TITLE				
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1a. Specify the name of the CHM intervention, in terms of (1) Chinese medicinal substance(s), and/or (2) CHM formula(s). 1b. State whether the review targets (1) Western medicine-defined disease(s), or (2) Western medicine-defined disease(s) with specific TCM Pattern(s), or (3) TCM Pattern(s).	
ABSTRACT				
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Provide the name and form of the CHM intervention(s) used, and the TCM Pattern applied (if any).	
INTRODUCTION				
Rationale	3	Describe the rationale for the review in the context of what is already known.	3a. State the rationale of using particular CHM intervention(s) to target the specific disease(s) and/or TCM Pattern (if any), ideally in terms of TCM theory. 3b. State the importance of the review.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	State whether the CHM intervention(s) targets a Western medicine-defined disease, a TCM Pattern, or a Western medicine-defined disease with a specific TCM Pattern.	

**Table 1. (Continued)**

Section/Topic	Item Number	PRISMA Checklist Item	Extension for CHM	Reported on Page Number
METHODS				
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.		
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6a. As applicable, state whether participants with a specific TCM Pattern will be included, in terms of (1) diagnostic criteria, and (2) inclusion and exclusion criteria. All criteria utilized should be universally recognized, or reference(s) where detailed explanation(s) can be found should be given. 6b. Specify the detailed requirements of CHM intervention(s), considering (1) types, such as whether CHM formulas are fixed, individualized, or patent proprietary; (2) composition, such as main herb(s) in a CHM formula; (3) dosage form, such as decoction, granules, powder; and (4) treatment duration. 6c. Specify the types of control group(s), if any, such as placebo control, active control, other treatment control or blank control. 6d. State whether TCM-related outcome(s) will be included, and if so, describe the change of degree and scope of symptoms and signs related to TCM Pattern differentiation.	

**Table 1. (Continued)**

<b>Section/Topic</b>	<b>Item Number</b>	<b>PRISMA Checklist Item</b>	<b>Extension for CHM</b>	<b>Reported on Page Number</b>
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.		
Search	8	State full electronic search strategy for at least one database, including any limits used, such that it could be repeated.		
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).		
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.		
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	11a. State details of the participants with a specific TCM Pattern (if any), considering (1) diagnostic criteria; and (2) baseline characteristics. 11b. State details of the CHM intervention(s), including (1) name, source, and dosage form; (2) name, source, processing method, and dosage of each medical substance, if applicable, names of the parts of the substances; (3) quality control information; (4) dosage,	



Table 1. (Continued)

Section/Topic	Item Number	PRISMA Checklist Item	Extension for CHM	Reported on Page Number
			administration route and time; (5) information about the production method, authentication method, and safety assessment, if any; (6) for CHM formulas, the principles, rationale, and interpretation of forming and/or modifying the formula; and (7) for patented proprietary CHM formulas, the name of the product and manufacturer.	
			11c. State details of any placebo of CHM used, considering (1) if/how it is physically identical and pharmacologically inert; (2) administration route, regimen, and dosage; (3) success of blinding, if any.	
			11d. State the TCM-related outcome (if any), considering (1) name and measuring methods; (2) measuring time points and length of follow-up, if applicable.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.		
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).		

**Table 1. (Continued)**

Section/Topic	Item Number	PRISMA Checklist Item	Extension for CHM	Reported on Page Number
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I <sup>2</sup> ) for each meta-analysis.	When combining trial results from different studies, describe whether CHM intervention(s) matched the TCM Pattern(s) of participants, if applicable.	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).		
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Describe methods of subgroup analyses in terms of the CHM intervention(s) and participants, considering at least (1) the types, compositions, dosage, dosage form, and treatment duration of the CHM intervention(s); and (2) participants with different TCM Patterns, if any.	
<b>RESULTS</b>				
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.		
Study characteristics	18	For each study, state characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	18a. State characteristics of participants with a specific TCM Pattern (if any), including diagnostic criteria and baseline data. 18b. State characteristics of the CHM intervention(s), including (1) name, source, and dosage form; (2) name, source, processing method, and dosage of each	

**Table 1. (Continued)**

Section/Topic	Item Number	PRISMA Checklist Item	Extension for CHM	Reported on Page Number
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	<p>medical substance; (3) quality control information; (4) dosage, administration route and time; (5) information about the production method, authentication method, and safety assessment, if available; (6) for CHM formulas, how the formula has been modified, if applicable; and (7) for patent proprietary CHM formulas, the name of the product and manufacturer.</p> <p>18c. State characteristics of the placebo of CHM (if any), including (1) whether physically identical and pharmacologically inert; (2) administration route, regimen, and dosage; and (3) success of blinding.</p> <p>18d. State characteristics of the TCM-related outcome (if any), including (1) name and measuring methods; (2) measuring time points and length of follow-up.</p>	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.		

**Table 1. (Continued)**

<b>Section/Topic</b>	<b>Item Number</b>	<b>PRISMA Checklist Item</b>	<b>Extension for CHM</b>	<b>Reported on Page Number</b>
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Give results of each meta-analysis based on the consistency of PICOS, considering (1) participants with TCM Patterns, if any; (2) CHM intervention(s); (3) comparators (e.g. CHM placebo); and (4) TCM-related outcome(s), if any.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).		
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Give results of subgroup analyses based on the different categories of CHM intervention(s) and participants with TCM Patterns (if any), if done.	
<b>DISCUSSION</b>				
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers).	Summarize how the CHM intervention(s) worked on different TCM Pattern(s) or Western medicine-defined disease(s) with specific TCM Pattern(s). Interpret the main findings in terms of TCM theory, if applicable.	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).		

Table 1. (Continued)

Section/Topic	Item Number	PRISMA Checklist Item	Extension for CHM	Reported on Page Number
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	When the review targets TCM Pattern(s), or Western medicine-defined disease(s) with specific TCM Pattern(s), a general interpretation of the results about the relationship of the CHM intervention(s) and TCM Pattern(s) should be provided.	
FUNDING				
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.		

Notes: CHM = Chinese herbal medicines; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-analyses; TCM = traditional Chinese medicine.  
 \* Both original PRISMA items and CHM extensions are provided. We strongly recommend reading this checklist in conjunction with the PRISMA 2009 Explanation and Elaboration for important clarifications on all original items of the PRISMA Statement (Liberati *et al.*, 2009).

**Table 2. Available Published Examples of Reporting for SRs of CHM**

PRISMA-CHM Items	Examples
<b>Item 1: TITLE.</b>	
1a. Specify the name of the CHM intervention, in terms of (1) Chinese medicinal substance(s), and/or (2) CHM formula(s).	<p>(1) “Yinchenhao decoction in the treatment of cholestasis: A systematic review and meta-analysis.” (Chen <i>et al.</i>, 2015).</p> <p>(2) “Chinese herbal medicines of supplementing Qi and nourishing Yin combined with chemotherapy for non-small cell lung cancer: A meta-analysis and systematic review.” (Shen and Jiang, 2019).</p> <p>(3) “Cordyceps sinensis (a traditional Chinese medicine) for treating chronic kidney disease.” (Zhang <i>et al.</i>, 2014).</p>
1b. State whether the review targets (1) Western medicine-defined disease(s), or (2) Western medicine-defined disease(s) with specific TCM Pattern(s), or (3) TCM Pattern(s).	<p>(1) “Efficacy and safety of Chinese herbal medicine for chronic prostatitis associated with damp-heat and blood-stasis syndromes: a meta-analysis and literature review.” (Wang <i>et al.</i>, 2016).</p> <p>(2) “Prescription of Chinese Herbal Medicine in Pattern-Based Traditional Chinese Medicine Treatment for Depression: A Systematic Review.” (Yeung <i>et al.</i>, 2015).</p>
<b>Item 2: STRUCTURED SUMMARY.</b>	
2. Provide the name and form of the CHM intervention(s) used, and the TCM Pattern applied (if any).	<p>(1) “Objective: The aim of this meta-analysis and systematic review is to evaluate the safety and efficacy of Chinese herbal medicine (CHM) for chronic prostatitis (CP) associated with damp-heat and blood-stasis syndromes. Methods: An electronic search of 13 databases up to May 2016 was screened to identify randomized controlled trials comparing the safety and efficacy of CHM for the treatment of CP associated with damp-heat and blood-stasis syndromes. Studies reporting on effective rates, and symptom index of Chinese medicine for chronic prostatitis (SI-CM) scores as outcomes Results: Oral CHMs were significantly more effective than placebo at reducing NIH-CPSI scores, with a mean difference of <math>-1.39</math> (95% CI: <math>-1.87</math> to <math>-0.92</math>, <math>P = 0.00001</math>) Conclusion: Our novel analysis demonstrates that CHM ranks highest in terms of improvement of CP associated with damp-heat and blood-stasis syndromes” (Wang <i>et al.</i>, 2016).</p>
<b>Item 3: RATIONALE.</b>	
3a. State the rationale of using particular CHM intervention(s) to target the specific disease(s) and/or TCM Pattern (if any), ideally in terms of TCM theory.	<p>(1) “Introduction. Chinese herbal medicine (CHM) is one of the oldest medical treatments in the world and it is a common form of complementary and alternative medicine therapy for major depressive disorder (MDD). Previous studies have been conducted to examine the efficacy of CHM for</p>
3b. State the importance of the review.	

Table 2. (Continued)

PRISMA-CHM Items	Examples
	<p>depression; however, limited information is available on Pattern-based CHM treatment. According to the traditional Chinese medicine (TCM) theory, eight major parameters, yin and yang, external and internal, hot and cold, and excess and deficiency, are used to describe the Patterns of bodily disharmony. Additional systems, such as qi, blood, and body fluid differentiation and zang fu (organ) differentiation are also used. In terms of the TCM theory, the onset of depression is often due to “damages” by extreme emotions. To the best of our knowledge, no systematic review has been conducted on Pattern-based CHM treatment for depression. It is important to review the current application of Pattern differentiation in CHM treatment for depression.” (Yeung <i>et al.</i>, 2015)</p> <p>(2) “Background. Description of the condition: Schizophrenia is a severe mental disorder. In Traditional Chinese medicine (TCM) there is not an exact equivalent disease to (what Western countries consider) schizophrenia. Description of the intervention: Wendan decoction (WDD), also Wendan Tang or Warm Gallbladder decoction, is one of the classical Chinese herb formulae for schizophrenia-like symptoms. WDD, was firstly recorded in Yao’s Collection of Effective Prescriptions (A.D. 580), and then fully described in Valuable Prescriptions for Emergency (A.D. 652) (Shi 2001). WDD is typically composed of Rhizoma Pinelliae (Qty: 6g) and Radix Glycyrrhizae (3g). The herbs and their dosages in the formula can be changed to treat different symptoms (modified WDD). How the intervention might work: There is an essential principle of treatment based on syndrome differentiation in TCM theory and clinical practice. The target of WDD is to regulate Qi, resolve phlegm, purify the gallbladder and harmonise the stomach. Why it is important to do this review: Wendan decoction is a classical TCM prescription for spirit disorders and has been used to treat schizophrenia-like symptoms for hundreds of years. This is an important area for which there should be a maintained review that can be updated in the light of new emerging evidence.” (Deng and Xu, 2017)</p>

Table 2. (Continued)

PRISMA-CHM Items	Examples
Item 4: OBJECTIVES.	
4. State whether the CHM intervention(s) targets a Western medicine–defined disease, a TCM Pattern, or a Western medicine–defined disease with a specific TCM Pattern.	<p>(1) “The objectives of this paper were (1) to summarize the commonly diagnosed TCM Patterns in patients with insomnia and (2) to find out the current practice of Pattern-based TCM treatments for insomnia.” (Yeung <i>et al.</i>, 2012).</p> <p>(2) “Objectives: To assess the effects (harms and benefits) of tongxinluo capsule for unstable angina. Specific comparisons were made between tongxinluo capsule with or without other treatments, compared with other treatments, placebo or no-treatment controls.” (Wu <i>et al.</i>, 2006).</p>
Item 6: ELIGIBILITY CRITERIA.	
6a. As applicable, state whether participants with a specific TCM Pattern will be included, in terms of (1) diagnostic criteria, and (2) inclusion and exclusion criteria. All criteria utilized should be universally recognized, or reference(s) where detailed explanation(s) can be found should be given.	<p>(1) “Types of participants: We included adults and children (any age) diagnosed with mumps by positive signs and symptoms. The diagnosis of mumps was made on the basis of TCM diagnostic criteria, issued by the State Administration of Traditional Chinese Medicine standards. TCM diagnostic criteria for mumps include a history of exposure to mumps and symptoms beginning with fever and then swelling of the parotid glands, which may be unilateral (one side) or bilateral (both sides). The parotid glands are located in front of the ear, indistinctly outlined, elastic to palpation, painful and tender, with swelling of the parotid gland orifices. The white blood cell count is normal or slightly low and the lymphocyte count is slightly increased.” (Shu <i>et al.</i>, 2015).</p>
6b. Specify the detailed requirements of CHM intervention(s), considering (1) types, such as whether CHM formulas are fixed, individualized, or patent proprietary; (2) composition, such as main herb(s) in a CHM formula; (3) dosage form, such as decoction, granules, powder; and (4) treatment duration.	<p>(1) “Types of interventions and comparisons: Only studies that tested Jian Ling Decoction (JLD) used alone versus antihypertensive drugs, or JLD combined with antihypertensive drugs versus antihypertensive drugs were included. Interventions in the control group included antihypertensive drugs. The duration of treatment was required to be at least 2 weeks. According to the principle of similarity of the TCM formula, 39 modified JLD should contain at least six of eight herbs used in JLD, and only a few herbs could be added into the JLD based on the TCM syndrome theory. However, the resulting prescription should contain the following four principal drugs: Achyranthes Root (Niuxi, Achyranthis Bidentatae Radix), Hematite (Daizheshi, Haematitum), Fossilized Mammal Bones (Longgu, Os Draconis) and Oyster Shell (Muli, Concha Ostreae).” (Xiong <i>et al.</i>, 2015a).</p>
6c. Specify the types of control group(s), if any, such as placebo control, active control, other treatment control or blank control.	



Table 2. (Continued)

PRISMA-CHM Items	Examples
6d. State whether TCM-related outcome(s) will be included, and if so, describe the change of degree and scope of symptoms and signs related to TCM Pattern differentiation.	<p>(1) “Types of outcome measures: Secondary outcomes: Traditional Chinese Medicine (TCM) outcomes: the tongue picture, pulse picture and symptoms.” (Feng <i>et al.</i>, 2013).</p> <p>(2) “Types of outcome measures: The primary outcomes were defined as categorical or continuous blood pressure (BP) and secondary outcomes were TCM symptoms and syndromes. As shown in tables 1 and 2, the efficacy of Zhen Wu Decoction (ZWD) on categorical BP and TCM symptoms and syndromes were classified into three grades based on the evaluation criteria from the Guidelines of Clinical Research of New Drugs of Traditional Chinese Medicine (GCRNDTCM).” (Xiong <i>et al.</i>, 2015b).</p>
Item 11: DATA ITEMS.	
11a. State details of the participants with a specific TCM Pattern (if any), considering (1) diagnostic criteria; and (2) baseline characteristics.	<p>(1) “Data extraction and management: We used a standard extraction form (Appendix 5) to collect data from each included trial and categorise into the following items: (1) General information: publishing status, language, authors, article title, journal title and year, volume, issue, page and funding source. (2) Participants: diagnostic criteria, total number and number in comparison groups, baseline characteristics, age, gender, inclusion criteria, exclusion criteria and study setting. (3) Intervention: type of preparation, dose, regimen, cointervention, withdrawals, loss to follow-up. (4) Outcome: primary outcomes, secondary outcomes and other outcomes at the end of treatment and/or the end of follow up. The adverse events recorded will also be extracted. (5) Data analysis: study data in detail, statistical methods for data analysis.” (Jin <i>et al.</i>, 2016).</p>
11b. State details of the CHM intervention(s), including (1) name, source, and dosage form; (2) name, source, processing method, and dosage of each medical substance, if applicable, names of the parts of the substances; (3) quality control information; (4) dosage, administration route and time; (5) information about the production method, authentication method, and safety assessment, if any; (6) for CHM formulas, the principles, rationale, and interpretation of forming and/or modifying the formula; and (7) for patented proprietary CHM formulas, the name of the product and manufacturer.	
11c. State details of any placebo of CHM used, considering (1) if/how it is physically identical and pharmacologically inert; (2) administration route, regimen, and dosage; (3) success of blinding, if any.	
11d. State the TCM-related outcome (if any), considering (1) name and measuring methods; (2) measuring time points and length of follow-up, if applicable.	
Item 14: PLANNED METHODS OF ANALYSIS.	
When combining trial results from different studies, describe whether CHM intervention(s) matched the TCM Pattern(s) of participants, if applicable.	<p>(1) “Every type of herbal medicine was individually compared with a control (for example placebo) regardless of route of administration, dose, or preparation. In Chinese prescriptions a difference of even</p>

Table 2. (Continued)

PRISMA-CHM Items	Examples
<p>Item 16: ADDITIONAL ANALYSES. Describe methods of subgroup analyses in terms of the CHM intervention(s) and participants, considering at least (1) the types, compositions, dosage, dosage form, and treatment duration of the CHM intervention(s); and (2) participants with different TCM Patterns, if any.</p>	<p>one herb could make a different formula and have different effects. We decided not to do meta-analysis if the interventions were different.” (Liu <i>et al.</i>, 2016).</p> <p>(2) “Data synthesis: We synthesized the results in meta-analysis when there was no important clinical heterogeneity. Separate analyses were conducted for different ginseng type, different populations (healthy individuals, MCI, dementia) and different dementia types (AD, VD, mixed dementia or other type)” (Geng <i>et al.</i>, 2010).</p> <p>(1) “Subgroup analysis and investigation of heterogeneity: We carried out the following subgroup analyses to explore possible sources of heterogeneity, for primary outcomes only. 1. Duration of treatment (such as Aloe vera used for three, five or seven days, etc). 2. Types of Aloe vera products (such as a thin slice or the juice of Aloe vera and Aloe-derived products).” (Zheng <i>et al.</i>, 2014).</p> <p>(2) “Subgroup analysis and investigation of heterogeneity: The protocol stated that where data were available, subgroup analyses would be conducted to determine the evidence of different types of Chinese herbal formulation, that is, standard formulation and individualised formulation, in order to investigate heterogeneous results. Since the data were unavailable, subgroup analysis was not undertaken.” (Li <i>et al.</i>, 2016).</p> <p>(3) “Subgroup analysis and investigation of heterogeneity: We planned to perform subgroup analyses under the heading of “children (16 years old or under) with eczema versus adults with eczema”, and “application of intervention based on Chinese medicine syndrome differentiation versus non-individualisation formula” where there were at least moderate levels of heterogeneity across the included studies. We investigated the sources of heterogeneity including participant factors (e.g. age, diagnosis, sex, race, comorbidity), treatment factors (e.g. dosage, formulation), study factors (e.g. concordance rates, quality of reporting), and quality control for the Chinese herbal preparations (e.g. source, purity, preparation facilities) to explain such differences.” (Zhang <i>et al.</i>, 2007).</p>

Table 2. (Continued)

PRISMA-CHM Items	Examples
Item 18: STUDY CHARACTERISTICS.	
18a. State characteristics of participants with a specific TCM Pattern (if any), including diagnostic criteria and baseline data.	(1) "Of the 296 studies on CHM for depression, 61 of them examined Pattern-based treatment. A total of 27 different TCM Patterns were identified in the 61 studies. We analyzed the most commonly studied TCM Patterns: liver qi depression, liver depression and spleen deficiency, dual deficiency of the heart and spleen, and liver depression and qi stagnation and liver-kidney yin deficiency. (Table 1) The criteria were based on the TCM Syndrome Diagnostic Standard ( $N = 7$ ), New Guidelines for TCM Clinical Research ( $N = 3$ ), TCM Diagnostic Standard for Depression ( $N = 2$ ), Chinese Professional Association of Integrative Medicine Diagnostic Criteria for Mental Disorders, Version 1991/2001 ( $N = 3$ ), Chinese Classification and Diagnostic Criteria of Mental Disorders ( $N = 1$ ), and TCM textbooks ( $N = 13$ ). However, none of the studies described other details of the diagnostic procedure and the background of practitioners who made the Pattern diagnosis." (Yeung <i>et al.</i> , 2015).
18b. State characteristics of the CHM intervention(s), including (1) name, source, and dosage form; (2) name, source, processing method, and dosage of each medical substance; (3) quality control information; (4) dosage, administration route and time; (5) information about the production method, authentication method, and safety assessment, if available; (6) for CHM formulas, how the formula has been modified, if applicable; and (7) for patent proprietary CHM formulas, the name of the product and manufacturer.	(1) "Characteristics of included studies: Yuan 2013 Interventions: Treatment group 1 received Chinese herbal medicines combined with Western medicines. (1) The Chinese medicine formula included Mongolian Milkcatch Root 30 g, Chinese Angelica 10 g, Gordon Enryale Seed 18 g (2) Formula changes: Abdominal pain: White Paeony Root 15 g, Licorice Root 10 g were added (3) Decoction: po, twice per day. (4) Western medicines were received at the same time, including progesterone 10–20 mg, im, once per day. Treatment group 2 received Chinese herbal medicines alone. Same as above, Mongolian Milkcatch Root 30 g, Chinese Angelica 10 g, Gordon Enryale Seed 18 g Control group was treated with Western medicines alone. Same as above, progesterone 10–20 mg, im, once per day, Dydrogesterone tablets 10–20 mg, po, once per day, until 10th–12th week, vitamin E, 100 mg, po, twice per day, tranexamic acid tablets 1–2 g, iv, once per day, until bleeding stopped." (Li <i>et al.</i> , 2016).
18c. State characteristics of the placebo of CHM (if any), including (1) whether physically identical and pharmacologically inert; (2) administration route, regimen, and dosage; and (3) success of blinding.	
18d. State characteristics of the TCM-related outcome (if any), including (1) name and measuring methods; (2) measuring time points and length of follow-up.	(1) "Characteristics of included studies: Chang 2005, Yu 2005: Outcomes: Outcomes were judged based on the changing of symptoms and body signs and divided into the following categories: (1) Recovery: TCM

Table 2. (Continued)

PRISMA-CHM Items	Examples
Item 21: SYNTHESSES OF RESULTS.	<p>symptoms disappeared or almost disappeared, signs scores reduced more than 95%; (2) Marked improvement: TCM symptoms markedly improved, TCM signs scores reduced more than 70%; (3) Improvement: partial TCM signs improved, signs scores reduced more than 30% but less and 70%; (4) No improvement: TCM signs no improvement or worse, signs scores reduced less than 30%; (5) TCM signs.</p> <p>Outcomes: (5) TCM signs: 3 signs including fever, chill and lack of sweat were better in the intervention group than in the control group; no difference between the 2 groups was found for the other 5 symptoms including headache, cough, etc.” (Zhang <i>et al.</i>, 2007).</p>
<p>Give results of each meta-analysis based on the consistency of PICOS, considering (1) participants with TCM Patterns, if any; (2) CHM intervention(s); (3) comparators (e.g. CHM placebo); and (4) TCM-related outcome(s), if any.</p>	<ol style="list-style-type: none"> <li data-bbox="666 838 1146 1180">(1) “Interventions: The intervention measures (Traditional Chinese Medicinal herbs, TCMHs) consisted of the patent herbal medicine or the self-produced herbal compound, often including seven to 15 kinds of herbs (listed in Table 1), but some authors did not specify the dosage of the herbs due to commercial or technological secrets. The medicinal herbs used in the intervention groups and the control group were different in each trial (see Table 1 for details). Therefore, we could not carry out a meaningful subgroup analysis on the herbs, or pool the trial data in a meta-analysis.” (Gan <i>et al.</i>, 2010).</li> <li data-bbox="666 1188 1146 1329">(2) “In the event of substantial clinical or methodological or statistical heterogeneity, we planned not to report study results as meta analytically pooled effect estimates. Participants: One trial did not specify the diagnostic criteria” (Liu <i>et al.</i>, 2013).</li> <li data-bbox="666 1336 1146 1709">(3) “Secondary outcomes: Improvement in menopausal symptoms: one study assessed the improvement in menopausal symptoms in relation to TCM diagnostic Pattern scores. Pooling would be inappropriate for head-to-head comparisons using different herbal formulations (Analysis 4.1). It showed evidence of a difference between comparisons with different CHM formulations in favour of the experimental formula, Geng Mei Ning (RR 1.52; 95% CI 1.16 to 2.00; 1 RCT, 231 women) (Analysis 4.2). Formula compositions in detail are provided in the Characteristics of included studies tables.” (Zhu <i>et al.</i>, 2016).</li> </ol>

Table 2. (Continued)

PRISMA-CHM Items	Examples
<p>Item 23: ADDITIONAL ANALYSES.</p> <p>Give results of subgroup analyses based on the different categories of CHM intervention(s) and participants with TCM Patterns (if any), if done.</p>	<ol style="list-style-type: none"> <li>(1) “Subgroup analysis and investigation of heterogeneity: We could not perform subgroup analyses because we could not include a sufficient number of comparable and homogeneous clinical trials in this review.” (Gan <i>et al.</i>, 2013).</li> <li>(2) “Subgroup analysis: The test for subgroup differences by duration of treatment did not reach statistical significance overall (<math>P = 0.06</math>). Results of the subgroup analysis based on the incidence of second degree phlebitis were similar and an obvious advantage could be found comparing external application of Aloe vera for varied durations of treatment with no treatment the results of the subgroup analysis according to the varied durations showed that external application of Aloe verawas effective for prevention of phlebitis compared with no treatment but the overall heterogeneity was not substantially decreased between subgroups. The pre-planned subgroup analysis for types of Aloe vera products (such as a thin slice or the juice of Aloe vera and Aloe derived products)’ was not conducted because of insufficient data.” (Zheng <i>et al.</i>, 2014).</li> </ol>
<p>Item 24: SUMMARY OF EVIDENCE.</p> <p>Summarize how the CHM intervention(s) worked on different TCM Pattern(s) or Western medicine-defined disease(s) with specific TCM Pattern(s). Interpret the main findings in terms of TCM theory, if applicable.</p>	<ol style="list-style-type: none"> <li>(1) “Discussion: This is the first systematic review to investigate the efficacy and safety of Chinese herbal medicine (CHM) for the treatment of Chronic prostatitis (CP) associated with damp-heat and blood-stasis syndromes. Our findings from 18 RCTs suggested that CHM was superior to placebo for CP associated with damp-heat and blood-stasis syndromes. From the point of view of TCM, CP belongs to “Turbid Semen”, “Stranguria”, and “Gonorrhea”. TCM theory also states that there are four kinds of general syndromes, including downward flow of damp-heat, blood stasis due to qi stagnation, stagnation of liver-qi, and deficiency of kidney-yang. TCM believes that the damp-heat and blood-stasis syndrome is the most common compound syndrome differentiation. Thus, this CP is frequently treated through clearing away the damp-heat in the lower energizer and promoting blood circulation to prevent blood stasis.” (Wang <i>et al.</i>, 2016).</li> <li>(2) “Discussion: According to the TCM theory, bleeding haemorrhoids occur in the human body mostly</li> </ol>

Table 2. (Continued)

PRISMA-CHM Items	Examples
Item 26: CONCLUSIONS. When the review targets TCM Pattern(s), or Western medicine-defined disease(s) with specific TCM Pattern(s), a general interpretation of the results about the relationship of the CHM intervention(s) and TCM Pattern(s) should be provided.	caused by Damp-Heat syndrome (TCM jargon), so some herbs can be used to eliminate damp and heat in the patient's viscera. Cortex Dictamni has obvious effects of both clearing heat and drying dampness, and Radix Sophorae Flavescentis can help increase the effectiveness of clearing heat and drying dampness." (Gan <i>et al.</i> , 2010).  (1) "Conclusion: Chinese herbal medicine (CHM) is not associated with increased adverse events or discontinuations compared with placebo. The novel data we present here demonstrate that CHM ranks the highest in terms of improvement of Chronic prostatitis (CP) associated with damp-heat and blood-stasis syndrome. In conclusion, this meta-analysis of 13 RCTs comparing CHM and placebo shows that CHM can be used safely and effectively for the treatment of CP associated with damp-heat and blood-stasis syndrome." (Wang <i>et al.</i> , 2016).

read the full report. As some readers cannot access the full paper, reading abstracts may be the only option for gleaning research results (Beller *et al.*, 2013). For an SR on CHM, whether the intervention(s) targets a WM-defined disease, a TCM Pattern, or a WM-defined disease with specific TCM Pattern(s) should be clarified in the abstract. As a structured abstract is highly recommended, we advise authors to give the specific name of studied CHM and Pattern (if any) in the contents of *Objective* (or *Purpose*). More detailed information on CHM interventions, participants with Pattern(s), and TCM-related outcome (if any) could be reported in the parts of *Methods* and *Results* (or *Findings*). In many abstracts of SRs, however, the term "Chinese herbal medicines" is the most common. This vagueness and incompleteness forces readers to read the full report to find the results; however, as mentioned, in some cases this is not possible, and the information is then completely lost.

### Item 3: RATIONALE

PRISMA-CHM item: 3a. State the rationale of using particular CHM intervention(s) to target the specific disease(s) and/or TCM Pattern (if any), ideally in terms of TCM theory. 3b. State the importance of the review.

Explanation: The underlying rationale of how the research question was addressed helps readers evaluate the review and its significance (Liberati *et al.*, 2009). For any SR of CHM, it is ideal to provide the context for readers from the perspective of TCM theory; this

context has four aspects: First, authors might describe the disease(s) and/or Pattern(s) studied based on TCM knowledge, considering the cause, onset, pathological mechanism, treatment principle(s), and relevant TCM Pattern(s). Second, authors might introduce the CHM intervention(s) according to the TCM knowledge, giving the name (e.g., English, Latin or Chinese Pinyin), source, dosage form, composition (e.g., name and dosage of each medical substance in a formula), explanation of forming the formula, principles of modifying the formula (if any), etc. Third, authors might interpret the mechanism by which the intervention(s) address the disease(s) and/or Pattern(s) according to TCM theory, such as “Pattern differentiation,” “principles, methods, formulas, and herbs,” and “correspondence between formula and Pattern” (Zhang *et al.*, 2019b). It is also preferable to include reference(s) to a pilot study or other literature reviews; as well as any evidence of the benefits and side effects or harms of the CHM intervention(s). Fourth, the authors could state the importance of the review and report whether this is a new review or an update of a previously published review.

To ensure clear reporting, we recommend authors to reference a structured *Background* used in the Cochrane reviews. It mainly comprises four parts: “Description of the condition;” “Description of the intervention;” “How the intervention might work;” and “Why it is important to do this review” (Li *et al.*, 2009). Authors could use this four-point framework to present rationale based on biomedical science findings, TCM theory, or both.

#### *Item 4: OBJECTIVE*

PRISMA-CHM item: State whether the CHM intervention(s) targets a Western medicine-defined disease, a TCM Pattern, or a Western medicine-defined disease with a specific TCM Pattern.

Explanation: The *Objective* is the critical scientific question that the review was designed to answer, it should be stated precisely. To improve the explicitness of review objectives, the components of “PICOS” should be reported in this section. In particular, whether the CHM intervention(s) studied targets a TCM Pattern should be reported and, if so, which Pattern. Readers can then quickly decide whether this is of interest to them.

#### *Item 6: ELIGIBILITY CRITERIA*

PRISMA-CHM item: 6a. As applicable, state whether participants with a specific TCM Pattern will be included, in terms of (1) diagnostic criteria, and (2) inclusion and exclusion criteria. All criteria utilized should be universally recognized, or reference(s) where detailed explanation(s) can be found should be given. 6b. Specify the detailed requirements of CHM intervention(s), considering (1) types, such as whether CHM formulas are fixed, individualized, or patent proprietary; (2) composition, such as main herb(s) in a CHM formula; (3) dosage form, such as decoction, granules, powder; and (4) treatment duration. 6c. Specify the types of control group(s), if any, such as placebo control, active control, other treatment control, or blank control. 6d. State whether TCM-related outcome(s) will be

included, and if so, describe the change of degree and scope of symptoms and signs related to TCM Pattern differentiation.

Explanation: Well-reported eligibility criteria allow interested readers to assess the applicability of the review and to use the results properly (Tricco *et al.*, 2018). Pattern differentiation is used more frequently in CHM interventional trials than in non-herbal TCM interventional trials (e.g., moxibustion, cupping) (Liu, 2007). If the Pattern concept is involved in the selection of participants, how the TCM Pattern is diagnosed and what criteria are used for including and excluding participants should be reported (Cheng *et al.*, 2019). Due to the various types of Patterns and their features, and due to the inherent nature of TCM, the diagnostic criteria originating from different references might differ. Citing nationally or internationally recognized Pattern diagnosis criteria in an SR is crucial. Commencing from the 1980s, more and more standard diagnostic criteria for TCM Patterns and specific Patterns of a disease have been developed, such as the Reference Criteria of Deficiency Syndrome Diagnosis (Shen, 1983), and the Diagnosis Criteria of Blood Stasis (Li *et al.*, 2014). If standardized diagnostic criteria of the Pattern are not available, we recommend authors to explain how the criteria used in the review were developed or to provide the reference(s), where detailed explanations can be found.

For CHM treatments in clinical trials, many aspects could influence the application of the intervention. For example, the effectiveness of a fixed CHM formula may not be as good as of an individualized CHM formula based on Pattern differentiation. We recognize that types and compositions of CHMs could differ significantly between trials. Traditionally, there are three types of CHM formulas, namely fixed, individualized, and proprietary patented. For compositions of individualized CHM formulas, the principal herbs of the prescription, at least, should be reported. Also, we advise authors to report the dose, dosage form, and treatment duration of CHM interventions in the criteria of intervention selection. If the characteristics of CHM intervention(s), such as the quality, safety, and efficacy, are provided in the original trials, it is better for this information to be extracted in detail.

In any clinical trial, a control group is essential for evaluating the efficacy of an intervention(s); it also affects the results and conclusions that can be drawn from the review. There are several types of comparisons that could be included in a CHM study, such as no intervention, placebo, or active intervention (Bian *et al.*, 2006). Among these, placebo-control design has appeared in many CHM interventional trials, although creating a quality placebo of CHM is extraordinarily difficult because the herbs often have special colors, tastes, and smells (Dube *et al.*, 2007; Qi *et al.*, 2008). In RCTs of CHM formulas, a description of the placebo is required to be reported in detail. Thus, when an SR includes placebo controls, we remind authors to carefully assess the reporting of placebo quality (e.g., physical identical and pharmacological inert) in the included trials.

In terms of reporting outcomes from trials, some standards of TCM studies recommend including both Western medicine-specific outcomes and TCM-specific outcomes (Dai *et al.*, 2019; Fu *et al.*, 2016). For clinical trials with CHM, the efficacy of studied CHM(s) may not be evaluated properly if no TCM-related outcomes (e.g., TCM Pattern) were included (Liu *et al.*, 2013). Therefore, in SRs of CHM, authors should state whether TCM-related outcome(s) will be included or not. If yes, descriptions of how to ensure the TCM indicator(s) are sufficiently



consistent in the review should be highlighted. At a minimum, the criteria for relevant measurement(s) should be considered because even the same TCM Pattern-outcome could be assessed with varying methods in different studies (Bian *et al.*, 2008).

#### *Item 11: DATA ITEMS*

PRISMA-CHM item: 11a. State details of the participants with a specific TCM Pattern (if any), considering (1) diagnostic criteria; and (2) baseline characteristics. 11b. State details of the CHM intervention(s), including (1) name, source, and dosage form; (2) name, source, processing method, and dosage of each medical substance, if applicable, names of the parts of the substances; (3) quality control information; (4) dosage, administration route and time; (5) information about the production method, authentication method, and safety assessment, if any; (6) for CHM formulas, the principles, rationale, and interpretation of forming and/or modifying the formula; and (7) for patented proprietary CHM formulas, the name of the product and manufacturer. 11c. State details of any placebo of CHM used, considering (1) if/how it is physically identical and pharmacologically inert; (2) administration route, regimen, and dosage; (3) success of blinding, if any. 11d. State the TCM-related outcome (if any), considering (1) name and measuring methods; (2) measuring time points and length of follow-up, if applicable.

Explanation: It is essential to list all variables in detail. Inadequate reporting directly affects the quality of study characteristics (Item 18), hinders accurate comparison, and may influence the validity of the results, particularly in the meta-analysis (Item 21). All of these variables invite skepticism as to the validity of the results. The aim to improve the transparency of reporting data of PICO, item 11 (data items) is extended to include the reporting recommendations for Pattern-related criteria about participants (if any), CHM interventions, and their placebo design, as well as TCM-related outcomes (if any). Specifics are as follows:

As emphasized in the previous Extension items, the reporting of TCM Pattern(s) should be adequate if the Pattern is a criterion in participant selection. Specifically, the diagnostic criteria of Pattern(s) used should be collected from each trial included in the SR. Also, the baseline characteristics of Pattern groups (e.g., participant number) are recommended for inclusion. For trials that adopted TCM-related outcomes, such as symptoms and signs assessed by TCM diagnostic methods, or TCM Pattern(s) the extraction data of outcomes should include name, measurement, and time points.

The CHM intervention(s) is the core of any SR of CHM studies, therefore it should be described in as much detail as possible. In addition to the general information of name, source, dose, dosage form, composition, administration route, and time, information about quality and safety control are highly recommended (Wu *et al.*, 2007). We understand that some details may not be easily obtained, and authors often describe such missing information as “not reported” in the results section (e.g., Item 18. study characteristics). Nevertheless, complete information is essential for avoiding bias in an SR. To ensure that information will be complete, researchers should design data items accordingly.

The TIDieR checklist is a detailed guideline for intervention reporting that could be referred to for designing the form of data extraction (Hoffmann *et al.*, 2014).

#### *Item 14: PLANNED METHODS OF ANALYSIS*

PRISMA-CHM item: When combining trial results from different studies, describe whether CHM intervention(s) matched the TCM Pattern(s) of participants, if applicable.

Explanation: The decision as to whether or not to combine data involves statistical, clinical, and methodological considerations. The consistency of PICOS across the included trials is a significant consideration that influences the decision of whether to conduct a meta-analysis (Dixon *et al.*, 2005). For the SRs of CHM, unfortunately, primary heterogeneity originates from differences between CHM interventions used in various clinical studies (Hu *et al.*, 2011). Thus, authors of the SRs need to design the method(s) of data analysis in combination with caution before the data extraction, using either meta-analysis or narrative synthesis (Guise *et al.*, 2017). For example, if an SR targets a large category of CHM formulas for a disease, authors could not easily perform a pooled analysis as they need to identify the same intervention among various CHMs very carefully.

As with the intervention, if TCM Pattern(s) will be involved in an SR, authors are also not allowed to combine results from various studies with different or uncertain diagnostic criteria. The diagnostic criteria of a Pattern are of importance for (i) clarifying the scope of target populations, and (ii) establishing correspondence with the CHM intervention(s) (Jiang *et al.*, 2012). Because each CHM formula is designed based on Pattern differentiation, authors should identify the consistency of the diagnostic criteria of included Pattern(s). There may not be a “right” or “wrong” choice concerning synthesis in an SR because such decisions are likely to be complex due to the diversity and uniqueness of CHM formulas and whether they match TCM Patterns. Therefore, authors should transparently report their critical decisions and rationale (Guise *et al.*, 2017).

#### *Item 16: ADDITIONAL ANALYSES*

PRISMA-CHM item: Describe methods of subgroup analyses in terms of the CHM intervention(s) and participants, considering at least (1) the types, compositions, dosage, dosage form, and treatment duration of the CHM intervention(s); and (2) participants with different TCM Patterns, if any.

Explanations: Subgroup analyses address whether the effects vary according to specific (usually clinical) characteristics. For the unique features of CHM interventions and TCM Patterns, authors may opt to conduct subgroup analyses to determine whether the results of SRs are robust. To make the reporting recommendation more practical, we suggest authors to consider at least the following factors when planning to perform subgroup analyses. For CHM interventions, include: (1) type of CHM, such as different products of one single herb, individualized or patent CHM formula; (2) composition of CHM, such as different parts of single herbs, and different herbal combinations in CHM formulas; (3) dosage of CHM, such as various doses of studied interventions; (4) dosage

form of CHM, such as pill, powder, and injection; and (5) treatment duration of CHM (Cheng *et al.*, 2017).

In general, the specifics of subgroup analysis depend on the review objective and the characteristics of interventions and participants. These include but are not limited to the above items. Thus, we recommend authors to propose any pre-assumptions in the subgroup analysis, even when data is possibly missing or unclear and to report those processes. It is important to inform readers whether these subgroup analyses were performed, their rationale, and which were pre-specified.

#### *Item 18: STUDY CHARACTERISTICS*

PRISMA-CHM item: 18a. State characteristics of participants with a specific TCM Pattern (if any), including diagnostic criteria and baseline data. 18b. State characteristics of the CHM intervention(s), including (1) name, source, and dosage form; (2) name, source, processing method, and dosage of each medical substance; (3) quality control information; (4) dosage, administration route and time; (5) information about the production method, authentication method, and safety assessment, if available; (6) for CHM formulas, how the formula has been modified, if applicable; and (7) for patent proprietary CHM formulas, the name of the product and manufacturer. 18c. State characteristics of the placebo of CHM (if any), including (1) whether physically identical and pharmacologically inert; (2) administration route, regimen, and dosage; and (3) success of blinding. 18d. State characteristics of the TCM-related outcome (if any), including (1) name and measuring methods; (2) measuring time points and length of follow-up.

Explanations: Details of the included studies, such as PICOS, are essential for readers to judge the validity of the results (Stewart *et al.*, 2015). We recommend authors to adequately describe the study characteristics based on their pre-designed data items (e.g., Item 11), especially details of CHM interventions and their controls. If some information is not, or is unclear, reported in the primary studies, reviewers can contact the trial authors to obtain missing information or confirm the data extracted for the review. If the information is still not received, this should be noted as “not reported” or “unclear” in the SRs. For the reporting of this item, we highly recommend authors to present the details in the form of Table(s), which can be shown in an appendix. Such a presentation ensures that all pertinent items are reported, and that missing or unclear information is also noted.

#### *Item 21: SYNTHESSES OF RESULTS*

PRISMA-CHM item: Give results of each meta-analysis based on the consistency of PICOS, considering (1) participants with TCM Patterns, if any; (2) CHM intervention(s); (3) comparators (e.g. CHM placebo); and (4) TCM-related outcome(s), if any.

Explanations: Data combinations depend on the consistency of PICOs. However, the primary sources of heterogeneity come from CHM interventions. In general, the effect of a CHM intervention is associated with several details, such as which specific parts of single herbs (e.g., root, leaf) are used, the types of CHM formulas (e.g., fixed, individualized), the components of CHM formulas (e.g., modified herbs), the processing

methods of each medical substance in CHM formulas (e.g. stir-frying, calcine), the dosage form (e.g., decoction, tablet), the amount of the dose, and treatment duration, etc. Authors should be made aware of any deviations from the planned analysis. If the pre-designed criteria of performing meta-analysis are not met, or the planned meta-analysis is not thought appropriate (see Item 14), the reasons should be clarified (Moher *et al.*, 2015). Also, the SWiM checklist, a reporting guideline for combining results without meta-analysis in SRs, could be referred to for presenting results in this section (Campbell *et al.*, 2020).

#### *Item 23: ADDITIONAL ANALYSES*

PRISMA-CHM item: Give results of subgroup analyses based on the different categories of CHM intervention(s) and participants with TCM Patterns (if any), if done.

Explanation: Authors should report any additional analyses, even those without statistical significance, and state whether or not they were pre-specified (see Items 16). If any pre-specified additional analyses were not conducted for the final result, authors should report the reasons (e.g., limited or insufficient data) to avoid selective outcome reporting bias (Hutton *et al.*, 2015). As discussed above, the features of CHM interventions are significant sources of heterogeneity, and additional analyses are often conducted to illustrate the data in SRs of CHM. However, it is essential to have a sufficient number of included trials for undertaking subgroup analyses.

#### *Item 24: SUMMARY OF EVIDENCE*

PRISMA-CHM item: Summarize how the CHM intervention(s) worked on different TCM Pattern(s) or Western medicine-defined disease(s) with specific TCM Pattern(s). Interpret the main findings in terms of TCM theory, if applicable.

Explanation: The authors should give a summary of the main findings of the review; for example, the efficacy of CHM herbs and/or formulas for a WM-defined disease, a TCM Pattern, or a WM-defined disease with a specific pattern(s) should be clarified. If applicable, we also advise authors to interpret the findings based on TCM theory (Bian *et al.*, 2014). In practice, one WM-defined disease may include several different TCM Patterns, and conversely, different WM-defined diseases may exhibit the same TCM Pattern in the course of their development (Chung *et al.*, 2016). Thus, the application of Pattern differentiation may “treat the same diseases with different CHM intervention(s),” or it may “treat different diseases with the same CHM therapy(ies).” The applicability of SR findings to different Patterns of the same disease or the same Pattern manifested as different diseases can be discussed.

#### *Item 26: CONCLUSIONS*

PRISMA-CHM item: When the review targets TCM Pattern(s), or Western medicine-defined disease(s) with specific TCM Pattern(s), a general interpretation of the results about the relationship of the CHM intervention(s) and TCM Pattern(s) should be provided.

Explanations: SRs of CHM sometimes cannot draw certain conclusions because of the low quality of original studies. For instance, in a sample of 109 Cochrane reviews of CHM, 103 (94.5%) reported uncertain conclusions due to the lack of reliable evidence for evaluation. 32 (29.4%) reviews tended to conclude that CHM interventions studied offer possible benefits, although the evidence was insufficient to draw definitive conclusions (Zhang *et al.*, 2019a). In these circumstances, we advise authors to make explicit recommendations for future research, such as implications for practice, or suggestions for clinical research in terms of PICOS. We believe SRs of CHM have great potential for guiding future clinical research. As the CHM intervention(s) is determined according to the TCM Pattern(s), authors should provide a summarized conclusion of the results about the relationship of the CHM intervention(s) and TCM Pattern(s) used in the SR. Also, a general interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence in terms of TCM Pattern is highly recommended.

## Discussion

PRISMA was devised to improve the reporting quality of systematic reviews and, indirectly, research of the studies being reviewed. Extensions have been made to PRISMA, giving specific guidance in areas of research that have special characteristics and needs. Recently, an extension of the PRISMA for acupuncture (PRISMA-A statement) has been published (Wang *et al.*, 2019), reflecting the increasing number of and interest in studies of TCM interventions. The most widely used TCM intervention is CHM, including herbs and formulas, and CHM have their characteristics that merit attention. Chief among these characteristics is the concept of TCM Pattern, which informs both diagnosis and treatment.

According to TCM theory, Pattern differentiation refers to the analysis and summarization of clinical symptoms obtained through the four diagnostic methods of TCM (inspection, auscultation and smell, inquiry, and pulse-taking and palpation). Using these methods, TCM practitioners diagnose and determine CHM prescriptions (Linde and Brinkhaus, 2017). In clinical practice, the efficacy of a CHM formula is highly dependent on the accuracy of Pattern differentiation. If the Pattern of a condition is wrongly diagnosed, the application of the TCM therapeutic principles will be incorrect, and its derivative formulas and herbs will be ineffective (Choi *et al.*, 2016). Therefore, in SRs of CHM, if the included clinical trials were conducted based on Pattern differentiation, the concept of TCM Pattern should be considered throughout the entire SR process with regard to the rationale of the review design, selection of diagnostic criteria, formulation of CHM intervention(s), selection of outcome measures and data interpretation, etc. These issues are discussed in this guideline of PRISMA-CHM. We hope that this CHM Extension will have important implications for future publications of SRs on CHM.

To maximize the clarity of this checklist, we provide explanations and examples for each item. It follows a format similar to that used in PRISMA E&E and its Extensions (Liberati *et al.*, 2009; Beller *et al.*, 2013). Using the reporting items of PRISMA-CHM may increase the word count of an SR (e.g., exceed the word limitation of journal requirements); however, we believe that the benefit of readers being able to critically appraise a clear,

complete, and transparent reporting outweighs the possible slight increase in the length of the report. By making the items more practical, we recommend authors to use appendices or “Web extras” for reporting detailed information, such as a data extraction form.

The value of a recommendation ultimately depends on its use (Schulz *et al.*, 2010; Chan *et al.*, 2013). For better dissemination of PRISMA-CHM, we will continue to introduce it through medical programs, workshops, and conferences. At the same time, use depends on relevance. Thus, we welcome comments and feedback to modify and periodically update the guideline. As we have registered this guideline on the EQUATOR Network (Bian, 2016), all relevant results and publication(s) will be shared as soon as they are available.

## Conclusion

The PRISMA-CHM aims to help authors report an SR with CHM interventions, both single herbs and formulas. We hope that these recommendations will promote both better reporting and better methodology design of SRs on CHM, especially for CHM formulas following TCM Pattern differentiation.

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