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Traditional Chinese medicine for insomnia: Recommendation mapping of the global clinical guidelines

Ziying Ye [a,b], Honghao Lai [a,b], Jinling Ning [a,b], Jianing Liu [c], Jiajie Huang [c], Sihong Yang [d,e], Jiayue Jin [f,g], Yajie Liu [f], Jie Liu [f], Hui Zhao [d,e,**], Long Ge [a,b,h,i,*]

[a] Evidence-Based Social Science Research Center, School of Public Health, Lanzhou University, Lanzhou, China
[b] Department of Social Medicine and Health Management, School of Public Health, Lanzhou University, Lanzhou, China
[c] School of Nursing, Gansu University of Chinese Medicine, Lanzhou, China
[d] Institute of Basic Research of Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing, China
[e] China Center for Evidence Based Traditional Chinese Medicine, Beijing, China
[f] Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing, China
[g] Beijing University of Chinese Medicine, Beijing, China
[h] Key Laboratory of Evidence Based Medicine and Knowledge Translation of Gansu Province, Lanzhou, China
[i] World Health Organization Collaborating Centre for Guideline Implementation and Knowledge Translation, Lanzhou, China

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ABSTRACT

Ethnopharmacological relevance: Traditional Chinese Medicine (TCM) represents a rich repository of empirically-developed traditional medicines. The findings call for more rigorous study into the efficacy, safety, and mechanisms of action of TCM remedies to strengthen the evidence base.

Aim of the study: To systematically review the quality of insomnia clinical practice guidelines that involve TCM recommendations and to summarize the certainty of evidence supporting the recommendations, strength, and consistency of recommendations, providing valuable research references for the development of future insomnia guidelines.

Materials and methods: We systematically searched PubMed, Web of Science, Embase, CNKI, Wanfang, Chinese Biomedical Literature Database, Chinese Medical Association, Chinese Sleep Research Society, Medsci, Medlive, British National Institute of Health and Clinical Excellence (NICE), and the International Guidelines Collaboration Network (GIN) for clinical practice guidelines on insomnia from inception to March 5, 2023. Four evaluators conducted independent assessments of the quality of the guidelines by employing the AGREE II tool. Subsequently, the guideline recommendations were consolidated and presented as evidence maps.

Results: Thirteen clinical practice guidelines addressing insomnia, encompassing 211 recommendations (consisting of 127 evidence-based and 84 expert consensus recommendations), were deemed eligible for inclusion in our analysis. The evaluation results revealed an overall suboptimal quality, with the "scope and purpose" domain achieving the highest score (58.1%), while the "applicability" domain garnered the lowest score (13.0%). Specifically, it was observed that 74.8% (n = 95) of the evidence-based recommendations were supported by evidence of either very low or low certainty, in contrast to the expert consensus recommendations, which accounted for 61.9% (n = 52). We subsequently synthesized 44 recommendations into four evidence maps, focusing on proprietary Chinese medicines, Chinese medicine prescriptions, acupuncture, and massage, respectively. Notably, Chinese herbal remedies and acupuncture exhibited robust support, substantiated by high-certainty evidence, exemplified by interventions such as Xuefu Zhuyu decoction, spleen decoction, body acupuncture, and ear acupuncture, resulting in solid recommendations. Conversely, proprietary Chinese medicines needed more high-certainty evidence, predominantly yielding weak recommendations. As for other therapies, the level of certainty was predominantly categorized as low or very low. Recommendations about magnetic therapy, bathing, and fumigation relied primarily on expert consensus, needing more substantive clinical research evidence, consequently forming weak recommendations. Hot ironing and acupoint injection recommendations were weakly endorsed, primarily based on observational studies. Furthermore, interventions like qigong, gua sha, and

* Corresponding author. Evidence-Based Social Science Research Center, School of Public Health, Lanzhou University, Lanzhou, China.
** Corresponding author. Institute of Basic Research of Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing, China.
E-mail addresses: huizh_519@126.com (H. Zhao), gelong2009@163.com (L. Ge).

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moxibustion displayed a relatively limited number of clinical studies, necessitating further exploration to ascertain their efficacy.

Conclusions: Our analysis revealed a need for substantial improvement in the quality of all the included guidelines related to insomnia. Notably, recommendations for Traditional Chinese Medicine (TCM) treatments predominantly rely on low-certainty evidence. This study represents a pioneering effort in the utilization of recommendation mapping to both present and identify existing gaps in the evidence landscape within TCM therapies, thus setting the stage for future research initiatives. The evidence supporting TCM therapy recommendations must be fortified to achieve a more substantial level of recommendation and higher certainty. Consequently, there exists a critical and pressing demand for high-quality clinical investigations dedicated to TCM, with a specific focus on ascertaining its long-term efficacy, safety, and potential side effects in the context of insomnia treatment. These endeavors are poised to establish a robust scientific foundation to inform the development of TCM therapy recommendations within the insomnia guidelines.

1. Introduction

Insomnia, a prevalent sleep disorder, is characterized by inadequate sleep duration, inferior sleep quality, challenges initiating or maintaining sleep, and difficulties resuming sleep after awakening (Black and Grant, 2014). Studies have associated insomnia with various health complications, including depression, diminished concentration, metabolic syndrome, pain, and cognitive impairments. Prolonged insomnia profoundly impacts individuals' health. Epidemiological research has linked insomnia with type 2 diabetes, dementia, stroke, and chronic kidney disease (Buysse, 2013; Benbir et al., 2015; Hung et al., 2018; Gibson et al., 2023). Due to shifting lifestyle habits and mental health concerns, the prevalence of insomnia is escalating.

Conventional treatments for insomnia primarily involve medications and behavioral therapies. However, prolonged use of medications is associated with an increased risk of adverse effects (Schroeck et al., 2016; Grau and Plener, 2018). Behavioral therapy, while effective, has limitations such as lengthy intervention durations, reduced patient adherence, and financial implications for treatment (Schroeck et al., 2016; Hung et al., 2018; Grau and Plener, 2018; Gibson et al., 2023). TCM, an essential component of complementary and alternative medicine, demonstrates distinct advantages in treating insomnia (Dopheide, 2020). TCM is recognized for its capacity to ameliorate insomnia symptoms and enhance sleep quality concurrently (Zhang et al., 2019; Singh and Kaur, 2020) and is noted for its safety (Cheng et al., 2020), positioning it as one of the treatments for insomnia. Clinical practice guidelines (CPG) are instrumental in standardizing medical praxis and bridging between the quintessential research evidence and extant practice (Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, 2011). Guidelines of high quality, grounded in the most compelling evidence, act as a reliable bedrock for steering clinical practice in TCM for insomnia treatment.

In recent years, the evolution of TCM guidelines for treating insomnia has seen remarkable acceleration. However, the lucidity of the foundational evidence requires further elucidation. This investigation aimed at the prevailing status of TCM treatment recommendations in insomnia guidelines, utilizing a cross-sectional assessment, and harnessed the power of recommendation evidence maps to summarize the results visually.

Evidence mapping is a method premised on integrated evidence, bolstering systematic and swift collation, appraisal, and categorization (Hetrick et al., 2010; Miake-Lye et al., 2016; Madera Anaya et al., 2019). The recommendation evidence map will summarize, review, and disseminate existing data and identify research gaps. It will guide future research and facilitate the development of credible guidelines and practical implementation (Lotfi et al., 2021).

Our cross-sectional analysis of the certainty of evidence, support, and strength of TCM recommendations in insomnia guidelines provides a valuable reference for future TCM treatment of insomnia clinical research and formulating guidelines.

2. Methods

2.1. Inclusion and exclusion criteria

We included CPG if they met the following criteria: 1) A complete guideline text, published in English or Chinese; 2) CPG addressed issues about the diagnosis, assessment, treatment, care, or management of insomnia, with no restrictions on the classification of insomnia or patients; 3) CPG contains recommendations regarding TCM or Chinese and Western Integrative Medicine interventions, with no restriction on the type of recommendations, including evidence-based recommendations and expert consensus.

The following literatures will be excluded: 1) Interpretations or translations of guidelines; 2) Antecedent versions of the guideline; 3) Recommendations devoid of reference to TCM.

2.2. Literature search strategy

We used a highly sensitive strategy presented in Table A1 to systematically search the following databases: PubMed, EMBASE, Web of Science, China National Knowledge Infrastructure (CNKI), Wang Fang Database, Chinese Biomedical Literature (CBM) Database, Medsci, and Medlive. Public search engine Google and the reference lists of eligible guidelines were also employed to identify more potential CPG.

2.3. Data extraction

Two independent reviewers (YZY and NJL) screened the titles and abstracts, and evaluated the full texts of articles and their eligibility for inclusion in this study. We resolved all disagreements through discussions with a third author (LHH). Data were extracted and recorded on a standardized data extraction form, including publication information (title, publication year, country, developers, evidence grading criteria, criteria for grading recommendation, type of recommendation for TCM, and funding), Chinese medicine therapy recommendations and corresponding evidence (strength of recommendation, certainty of evidence, type and amount of evidence supporting the recommendation, content of the recommendation TCM evidence, and TCM category).

2.4. Quality appraisal of guidelines

Four trained reviewers (YZY, NJL, HJJ, LJN) independently assessed the methodological quality of the included guidelines using the AGREE II (Appraisal of Guidelines for Research and Evaluation II) instrument (Paschalis et al., 2020), which consists of 23 items in six domains: 1) scope and purpose; 2) stakeholder involvement; 3) rigour of development; 4) clarity of presentation; 5) applicability; and 6) editorial independence (Brouwers et al., 2010). We rated each item using a 7-point scale ranging from 1 (absence of them) to 7 (exceptional quality of item). Domain scores were calculated by summing up scores for each item and each reviewer, then standardizing it as a percentage of the maximum possible score. The formula is as follows:

$$\text{Scaled domain score} = \frac{\text{obtained score-minimum possible score}}{\text{maximum possible score} - \text{minimum possible score}} \times 100\%$$

The comprehensive evaluation scores for each domain were the basis for guideline recommendations. As the AGREE II does not include explicit cut-off levels to determine levels of overall guideline quality, we applied a 3-step cut-off system according to the previous study) Recommended: all fields score >60%; ii) Recommended with modifications: three or more fields score >30%, some <60%; iii) Not recommended: three or more fields score <30% (Linn et al., 2022). We utilized the intraclass correlation coefficient to measure the consistency during the quality appraisal of the guidelines among the four evaluators. ICC >0.75 means high consistency (Zhou and Feng, 2018).

2.5. Categorization of TCM recommendations

We have referred to the 2013 Handbook of Chinese Medical Techniques (Popular Edition) (State Administration of Traditional Chinese Medicine, 2018) to classify TCM therapy, culminating in identifying 14 categories, including pharmacotherapy and acupuncture. In the event of inconsistent evidence certainty grading and recommendation strength methodologies employed in the guidelines, we shall categorize the evidence certainty into quartet gradations: high, moderate, low, and very low, in adherence to the GRADE approach. We will distill the strength of recommendation into three categories: strong, weak, and not recommended. The specific outcomes of this categorization are illustrated in Table A2.

Table 1
Characteristics of 13 included guidelines.

Clinical practice guideline	Year	Developers	Country/ region	Grading system	Evidence base	Type of recommendation for Chinese medicine	Funding
Clinical Practice Guidelines of Insomnia Disorder (Ministry of Science and Technology, 2016 "eleventh Five-Year" national science and technology support plan key topics of psychological disorders prevention research and demonstration project research group, 2016)	2016	GAMH-CATCM	China	TCM grading system	OB	10 Evidence-based recommendations	Government
TCM clinical guidelines of insomnia research group (WHO/WPO) (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016)	2016	GAMH-CATCM	China	TCM grading system	RCT	13 Evidence-based recommendations and 34 Expert Consensus	Not reported
Guidelines for the diagnosis and treatment of insomnia in China (Chinese Sleep Research Society, 2017)	2017	CSRA	China	AASM Methodology	Expert opinion	15 Expert Consensus	Not reported
The diagnosis and treatment of Insomnia Disorders (Guangdong Provincial Association of Chinese Medicine, 2022)	2022	GDACM	China	AASM Methodology	Expert opinion	22 Expert Consensus	Not reported
Clinical Diagnosis and Treatment Guidelines of Mental Diseases for Integrated Chinese and Western Medicine – Non-organic Insomnia (China Association of Chinese Medicine, 2021)	2021	CATCM-NB	China	Recommendations for Clinical Evidence Grading on TCM Based on Evidence Body	Expert opinion	14 Evidence-based recommendations	Not reported
Diagnosis and Treatment Guidelines of Insomnia Disorders with the Integrated Traditional Chinese and Western Medicine (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)	2023	FAH-HUCM	China	GRADE	RCT	67 Evidence-based recommendations	Government
Evidence-based Guidelines of Clinical Practice with Acupuncture and Moxibustion Insomnia (China Association for Acupuncture and Moxibustion, 2014)	2014	CSAM	China	GRADE	OB	6 Evidence-based recommendations	Government
Hong Kong Chinese Medicine Clinical Practice Guideline for Cancer Palliative Care: Pain, Constipation, and Insomnia (Lam et al., 2019)	2019	HKBU-SCM	China	TCM grading system	OB	7 Expert Consensus	Government
European guideline for the diagnosis and treatment of insomnia (Riemann et al., 2017)	2017	ESRE	Europe	GRADE	OB	3 Evidence-based recommendations	Institution
Hong Kong Chinese medicine clinical practice guideline for insomnia (Zhong et al., 2020)	2020	HKBU-SCM	China	TCM grading system	SR, MA	8 Evidence-based recommendations 5 Expert Consensus	Institution
Clinical guideline for the treatment of primary insomnia in middle- aged and older adults (Shekelle et al., 2001)	2014	UT Austin SON	United States	USPSTF	RCT, OB	2 Evidence-based recommendations 1 Expert Consensus	Institution
VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF CHRONIC INSOMNIA DISORDER AND OBSTRUCTIVE SLEEP APNEA (Department of Veterans Affairs Department of Defense, 2019)	2014	USAMC OEBP	United States	GRADE	SR, MA	3 Evidence-based recommendations	Not reported
Clinical Practice Guidelines for the Management of Patients with Insomnia in Primary Care (Guideline Development Group for the Management of Patients with insomnia in Primary Care, 2009)	2009	MoH Spain	Spain	SIGN	SR, MA	1 Evidence-based recommendations	Institution

2.6. Statistical analysis

We executed statistical analysis of quantitative data and guideline-based information using Microsoft Office 2021 and calculated ICC via SPSS V.26.0. We used R 4.3.1 to map the evidence to illustrate current research trends and identify gaps. In the bubble plot, each intervention had two-dimensional information, including the x-axis (the certainty of the recommendation), y-axis (the number of recommendations), and bubble color (recommendation strengths). In addition, we use radar plots to illustrate the AGREE II scores for each domain of the guidelines for comparison.

3. Results

3.1. Search and description of studies

After removing 25 duplicates, 628 titles and abstracts were further screened. Finally, 13 guidelines were included. Table 1 provides more detailed information on the included guidelines. The selection flow used in this research is displayed in Appendix (Fig. S1). The included guidelines originated from four distinct countries or regions and had their initial publication in 2009. Financial backing varied, with three guidelines supported by government funding, three by institutional resources, and five that did not disclose funding details. The prominent developing organizations were the Guang 'anmen Hospital of the Chinese Academy of TCM and the Hong Kong Baptist University School of Chinese Medicine. Various evidence grading systems were utilized in the guidelines. Predominantly, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system (Atkins et al., 2004) and Liu Jianping's traditional medicine evidence grading recommendations (Liu, 2007) were employed to assess the certainty of evidence and the strength of recommendations. Additionally, two clinical practice guidelines utilized the American Academy of Sleep Medicine (AASM) grading methodology (Colquhoun et al., 2014; Guangdong Provincial Association of Chinese Medicine, 2022). One implemented Liu's team's TCM evidence grading recommendations (Chen et al., 2019), the Scottish Intercollegiate Guidelines Network (SIGN) evidence grading system (Harbour and Miller, 2001), and the United States Preventive Services Task Force (USPSTF) grading criteria (U.S. Preventive Services TASK FORCE, 2018). Regarding TCM treatment recommendations, three guidelines (Chinese Sleep Research Society, 2017; Lam et al., 2019; Guangdong Provincial Association of Chinese Medicine, 2022) relied solely on expert consensus, and three others (Shekelle et al., 2001; Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016) incorporated a blend of expert consensus and information derived from ancient Chinese medicine books.

GAMH-CATCM: Guang 'anmen Hospital, Chinese Academy of TCM; CSRA: China Sleep Research Association; GDACM: Guangdong TCM Society; CATCM-NB: Chinese Academy of TCM, Neurology Branch; FAH-HUCM: The First Affiliated Hospital of Henan University of Chinese Medicine; CSAM: Chinese Society of Acupuncture and Moxibustion; HKBU-SCM: Hong Kong Baptist University School of Chinese Medicine; ESRE: European Sleep Research Society; UT Austin SON: The University of Texas at Austin School of Nursing; USAMC OEBP: U.S. Army Medical Command Office of Evidence-Based Practice; MoH Spain: Ministry of Health of Spain; TCM grading system: Professor Liu Jianping's proposal for grading evidence in traditional medicine; Evidence Grading on TCM Based on Evidence Body: Clinical evidence grading criteria for TCM proposed by Prof. Liu Jianping's team; AASM Methodology: American Academy of Sleep Medicine Evidence Rating System; GRADE: Grading of Recommendations Assessment, Development and Evaluation Grading Criteria; USPSTF: U.S. Preventive Services Task Force Evidence Grading Criteria and Strength of Recommendations; SIGN: The Scottish Intercollegiate Guidelines Network Guidelines Network; RCT: randomized controlled trial, OB: observational trial; SR: systematic review; MA: meta-analysis.

3.2. Methodologic quality assessment

3.2.1. Consistency

The ICC value for the assessment results using AGREE II was 0.931, indicating an excellent internal agreement of the four assessors.

3.2.2. Overall quality assessment of guideline

The AGREE II each domain scores are available in Table A4. For the 13 guidelines, the average AGREE II scores corresponding to the six domains were respectively: Scope and purpose (58.1%), Stakeholder involvement (32.2%), Rigour of development (26.2%), Clarify of presentation (50.4%), Applicability (13.1%), Editorial independence (39.3%). Domain 1 ("scope and purpose") and Domain 4 ("clarity of expression") scored above the median. Seven guidelines (China Association for Acupuncture and Moxibustion, 2014; Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016; Ministry of Science and Technology, 2016 "eleventh Five-Year" national science and technology support plan key topics of psychological disorders prevention research and demonstration project research group, 2016; China Association of Chinese Medicine, 2021; Chinese Sleep Research Society, 2017; Guangdong Provincial Association of Chinese Medicine, 2022; The First Affiliated Hospital of Henan University of Chinese The First Affiliated Hospital of Henan University of Chinese Medicine, 2023), received insufficient scores, and therefore, we do not recommend their use. Conversely, six English guidelinesGuideline Development Group for the Management of Patients with insomnia in Primary Care (2009); Shelley Baker et al., 2014; Riemann et al. (2017); Department of Veterans Affairs Department of Defense, 2019; Lam et al. (2019); Zhong et al. (2020) guidelines achieved a comparatively high score amongst the thirteen guidelines, which obtained high scores among the thirteen analyzed guidelines and could serve as a methodological benchmark for future insomnia guideline development. Regarding methodology, the quality of evidence-based guidelines outshone those based on expert consensus in Chinese medicine, with the highest-scoring trio of guidelines being evidence-based and in English. Fig. 1 A compares scores across six domains for every guideline. Average scores ranged from 25.1% to 54.6% (Fig. 1 B).

3.3. Evidence of TCM therapy

As summarized in Table 2, pharmacotherapy, acupuncture, and tuina recommendations were supported by several randomized controlled trials and systematic reviews. Archaic Chinese medical texts and the wisdom of experienced practitioners form the primary basis of Chinese herbal formulae, which lack substantial evidence from clinical research. Expert opinion forms the basis for recommending magnetotherapy and fumigation. Therefore, there are significant evidence gaps in this area. Herbal prescription treatments predominantly provide high-certainty evidence. Non-pharmacological interventions and herbal prescriptions mainly yield moderate-certainty evidence. Table A5 shows three treatment modalities with an even distribution of low and very low certainty evidence. Of 211 recommendations, 127 were supported by evidence and 84 by expert consensus. As depicted in Fig. 2A, when we broke down the certainty of these evidence-based recommendations, we found that very low-certainty evidence accounted for 29.13% (n = 37), low-certainty 45.67% (n = 58), and moderate-certainty 18.90% (n = 24). High certainty evidence accounted for only 6.30% (n = 8). In terms of expert consensus, very low certainty recommendations were 60.71% (n = 51), low certainty recommendations 10.71% (n = 9), medium certainty recommendations 9.52% (n = 8), and high certainty recommendations 19.05% (n = 24). It is interesting to note that 13 strong recommendations were based on low certainty evidence. These recommendations came from three Chinese guidelines related to acupuncture and herbal formula treatments. For evidence-based recommendations,

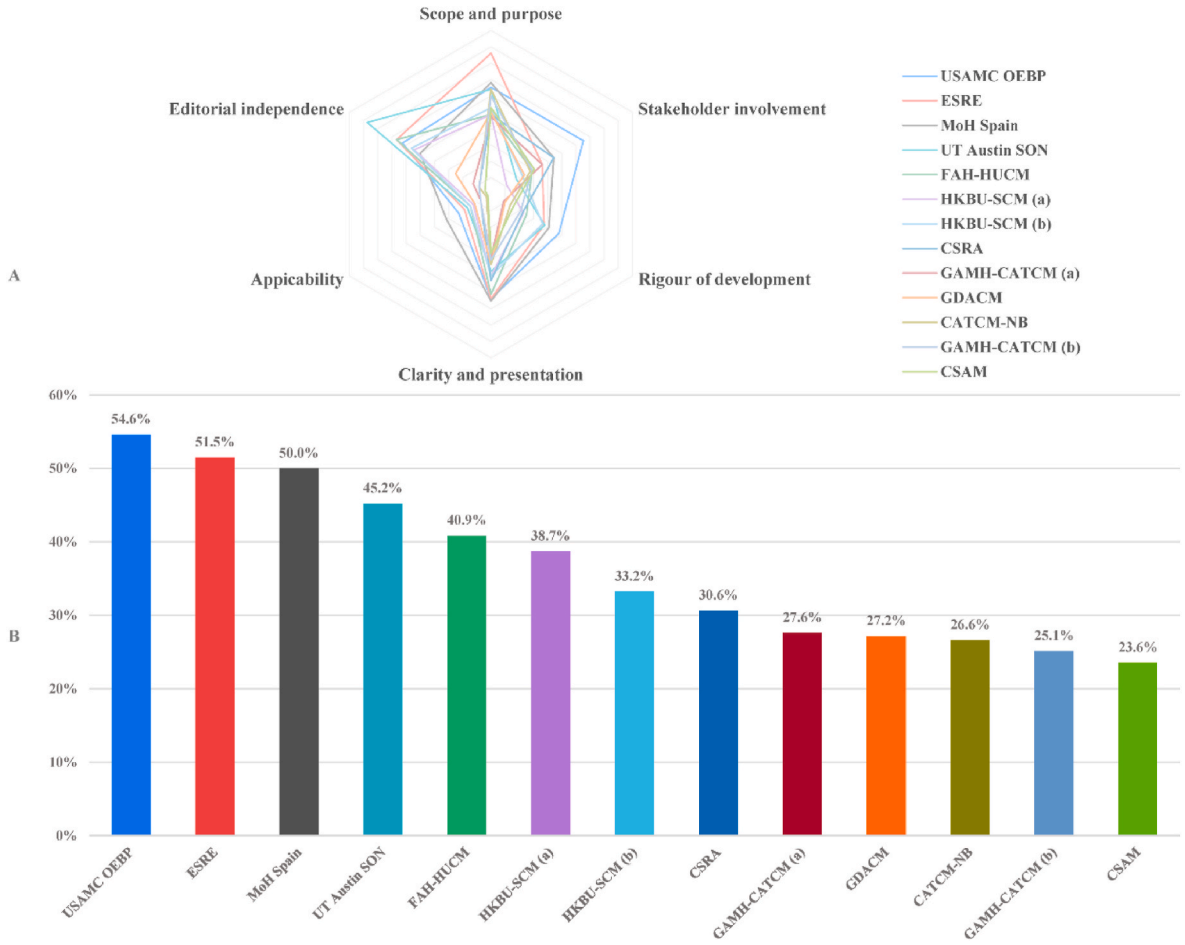

Fig. 1. The distribution of scores in 6 domains of the 13 guidelines and average scores.

strong recommendations represented 37.01% (n = 47), weak recommendations 57.48% (n = 73), and not recommendations 5.51% (n = 7). For expert consensus recommendations, strong recommendations were 19.05% (n = 16), weak recommendations 73.81% (n = 62), and not recommendations 7.14% (n = 6), as shown in Fig. 2B. Prescription treatments with herbal medicines mainly formed the basis for the strong recommendations, whereas non-pharmacological treatments primarily underpinned the weak recommendations. Not recommendations came from English guidelines covering five therapies: drugs, acupuncture, Tui Na, moxibustion, and Qigong. The main reason for not recommending TCM for insomnia was insufficient evidence to support using TCM to treat insomnia. The guideline development team needed to be much more confident in the quality of the original research evidence, even though they recognized the effectiveness of TCM.

3.4. *Proprietary Chinese medicine recommendations for insomnia*

Fig. 3 shows two guidelines (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016; The First Affiliated Hospital of Henan University of Chinese Medicine, 2023) detailing eight critical recommendations for treating CPG using proprietary Chinese medicines. These include: (1) Nourishing blood and clearing brain granules (Weak recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016)); (2) Bailemian capsule (Weak recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016)); (3) Spleen-invigorating pill (Weak recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016)); (4) Comfort Sleep Capsules (strong recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)); (5) Soothe the liver and relieve depression capsule (strong recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)); (6) Tianwang Tonic Heart Pill (strong recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)); (7) Wu Ling Capsules (Weak recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)); (8) Zao Ren An Shen Capsules (Weak recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)).

Among the proprietary Chinese medicines, the Tianwang Tonic Cardiac Dan appeared most frequently in the recommendations (5 times), followed by the Bailemian capsule and GuiPi Wan (4 times). Zaoren Anshen Capsule appeared three times. Anshen Tonic Cerebral Liquid and nine other kinds appeared twice, and Sweet Dream oral liquid and 18 others appeared once. More details can be found in Table A6.

3.5. *Recommendations for Chinese herbal tonics for insomnia*

Fig. 4 presents the 14 paramount recommendations from 5 guidelines for herbal prescription therapy (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016; Zhong et al., 2020; China Association of Chinese Medicine, 2021; Guangdong Provincial Association of Chinese Medicine, 2022; The First Affiliated Hospital of Henan University of Chinese Medicine, 2023). These crucial recommendations for herbal prescription therapy are as follows: (1) Self-designed sour dates and tranquilization soup (strong recommendation (Chinese Medicine Clinical Practice Guidelines for

Table 2
Evidence of Chinese medicine for insomnia guidelines.

Types of TCM Therapy	Number of recommendations	Number of Evidence	Sources of Evidence	Total number included in the study
Drug therapy	124	260	12 RCT; 249 OB; 66 Expert Opinions	24,193
Acupuncture therapy	57	175	8 SR and MA; 14 RCT; 153 OB	13,866
Tui Na Therapy	7	21	3 SR and MA; 2 RCT; 16 OB	4171
Qigong Therapy	5	4	1 RCT; 3 OB	377
Gua Sha Therapy	4	3	1 RCT; 2 OB	214
Moxibustion	4	8	1 RCT; 7 OB	634
Compress therapy	2	7	1 RCT; 6 OB	494
Bath Therapy	2	0	0	0
Magnetic Therapy	1	0	0	0
Hot ironing therapy	1	2	2 OB	176
Acupressure	1	4	1 RCT; 3 OB	327
Acupoint Injection Therapy	1	19	19 OB	1285
Fumigation therapy	1	0	0	0
Medicinal food therapy	1	1	1 OB	112

RCT: randomized controlled trial, OB: observational trial; SR: systematic evaluation; MA: meta-analysis.

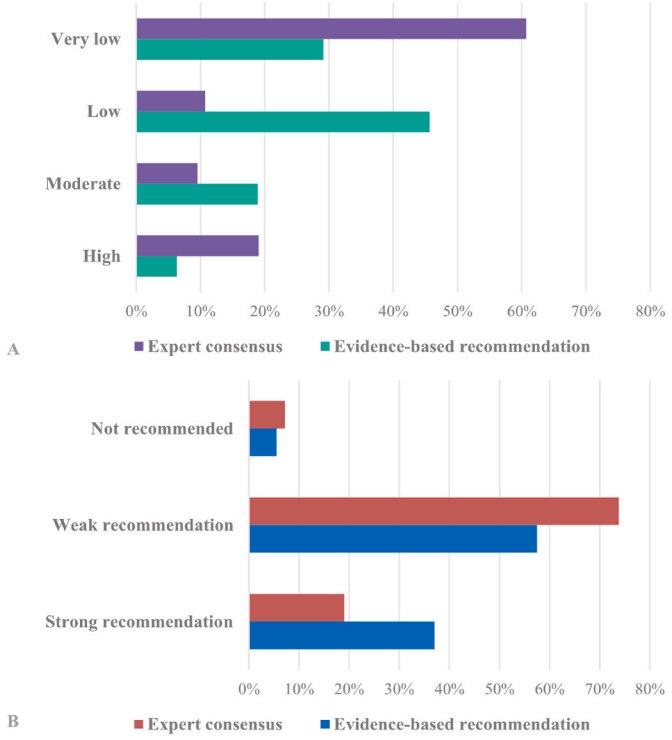

Fig. 2. Certainty of evidence for TCM recommendation and Recommended strength of TCM therapy.

Insomnia Group, Academy of Chinese Medicine, 2016)); (2) Lily Warming Gall Bladder Soup (strong recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016)); (3) Addition of warm gall bladder soup (strong recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016)); (4) Radix Aconiti Lizhong Tang (strong recommendation (Guangdong Provincial Association of Chinese Medicine, 2022)); (5) Gentian and Liver Soup (strong recommendation (Guangdong Provincial Association of Chinese Medicine, 2022)); (6) Plus-flavored Free and Easy San (strong recommendation (China Association of Chinese Medicine, 2021)); (7) Huang Lian Wenzhi Tang (strong recommendation (China Association of Chinese Medicine, 2021)); (8) Warm Gall Bladder Soup (Weak recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)); (9) Gui Spleen Soup (strong recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)); (10) Chai Hu plus Long Bone Oyster Soup (strong recommendation); (11) Sour date soup (Weak recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023)); (12) Gentian Liver Relief Soup (strong recommendation (Zhong et al., 2020)); (13) Huang Lian Agaricus Soup (strong recommendation (Zhong et al., 2020)); (14) Ginseng to the Spleen Soup (Weak recommendation (Zhong et al., 2020)).

3.6. *Recommendations for acupuncture for insomnia*

This comprehensive list provides recommendations for acupuncture, a TCM therapy, to treat insomnia, as drawn from six different clinical practice guidelines (China Association for Acupuncture and Moxibustion, 2014; Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016; Department of Veterans Affairs Department of Defense, 2019; Zhong et al., 2020; China Association of Chinese Medicine, 2021). Fig. 5 encapsulates 17 robust acupuncture recommendations underpinned by solid evidence.

(1) Acupuncture at points like Heart Yu, Gall Bladder Yu, Diaphragm Yu, Qi Hai, Shenting, Si Shen Cong, Ben Shen, Shen Men, Sanyinjiao is recommended with the use of tonic and diarrhea methods (strong recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016));
(2) Similarly, targeting Liver Yu, Xingma, Daling, Hegu, Taichong, Zhongyuan, Fenglong, Neiguan, Shenting, Sishencong, Benshin, Baihui, Shenmen, Sanyinjiao is suggested with the use of tonic and diarrhea methods (strong recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016));
(3) Acupuncture points Tai Chong, Feng Long, Shenting, Si Shen Cong, Ben Shen, Shen Men, and Sanyinjiao are recommended (strong recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016));
(4) Points like Zhongshang, Fusanli, Yinlingquan, Neiguan, Shenting, Sishencong, Benshin, Shenmen, and Sanyinjiao are suggested (strong recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016));
(5) Acupuncture points Xin Yu, Jue Yin Yu, Spleen Yu, Tai Chong, Tai Bai, Zhong Yuan, Foot San Li, Shen Men, Shen Ting, Sichong, Ben Shen, Sanyin Jiao are advised with the use of Ping Tie and Ping Di method (strong recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016));
(6) Points Xin Yu, Ren Yu, Zhao Hai, Tai Xi, Shenting, Si Shen Cong, Ben Shen, Shen Men, and Sanyin Jiao are recommended (strong

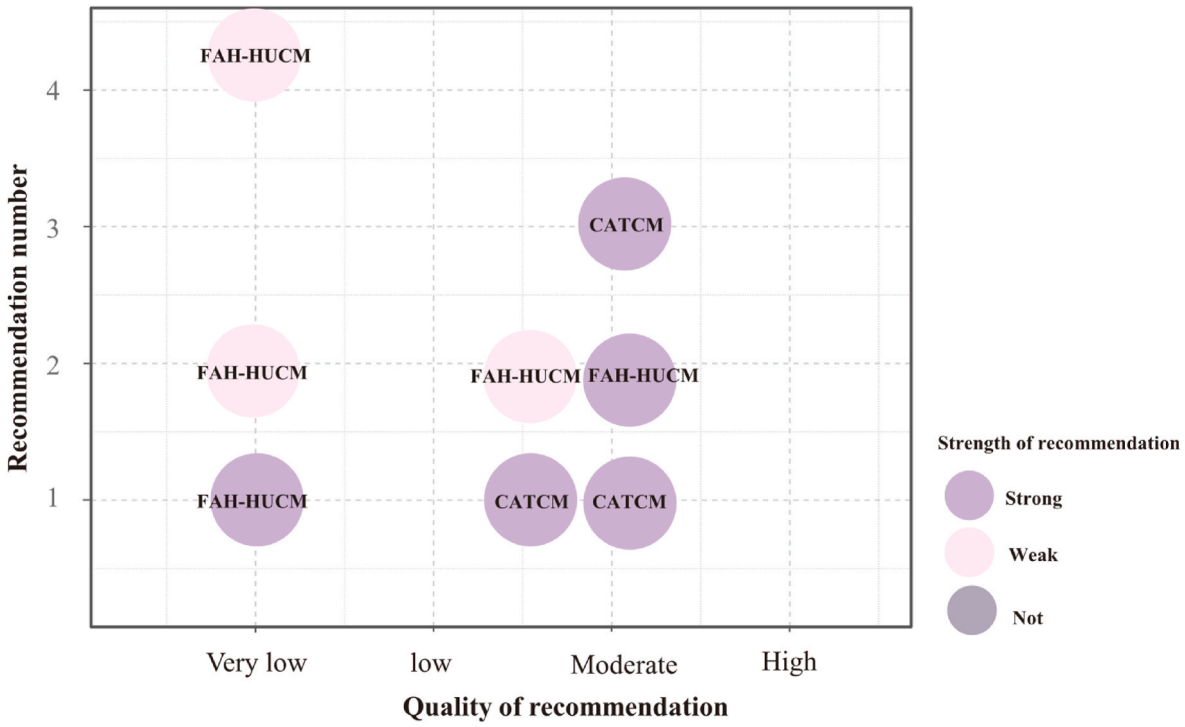

Fig. 3. Evidence diagram for Proprietary Chinese medicine treatment recommendations.

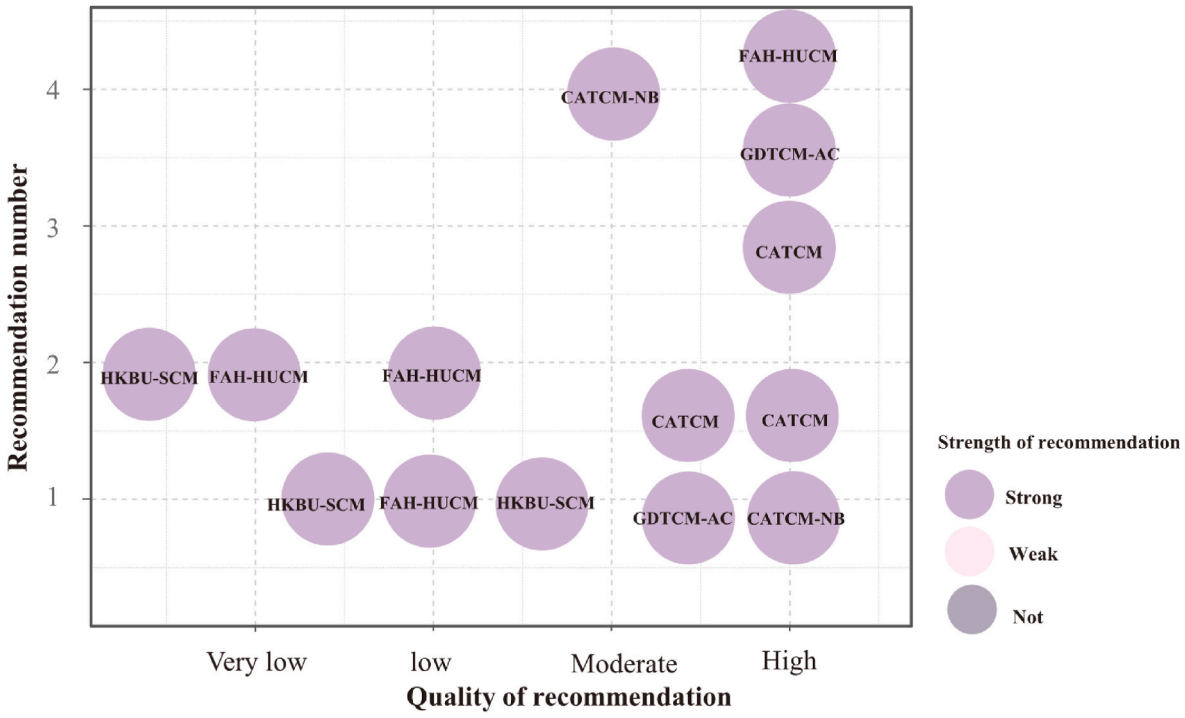

Fig. 4. Evidence diagram of recommendations for treatment with Chinese herbal formulas.

recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016));

(7) Main points are Shouhai, Shenwei, Shenmen, Sanyinjiao, Ann-mian, and Sishencong. Matching points vary depending on different conditions like Liver stagnation and fire, phlegm and heat disturbing the heart, blood stasis, deficiency of the heart and spleen, heart and kidney disconnection, and heart and gall bladder deficiency. Different operation methods are suggested (strong recommendation (China Association of Chinese Medicine, 2021));

(8) To improve sleep quality in insomnia patients, the milli-needle acupuncture method is recommended (Weak recommendation (China Association for Acupuncture and Moxibustion, 2014));

(9) Auricular pressure pill therapy is suggested to improve sleep duration and quality, especially for chronic insomnia patients, as a complement to milli-needle acupuncture (Weak

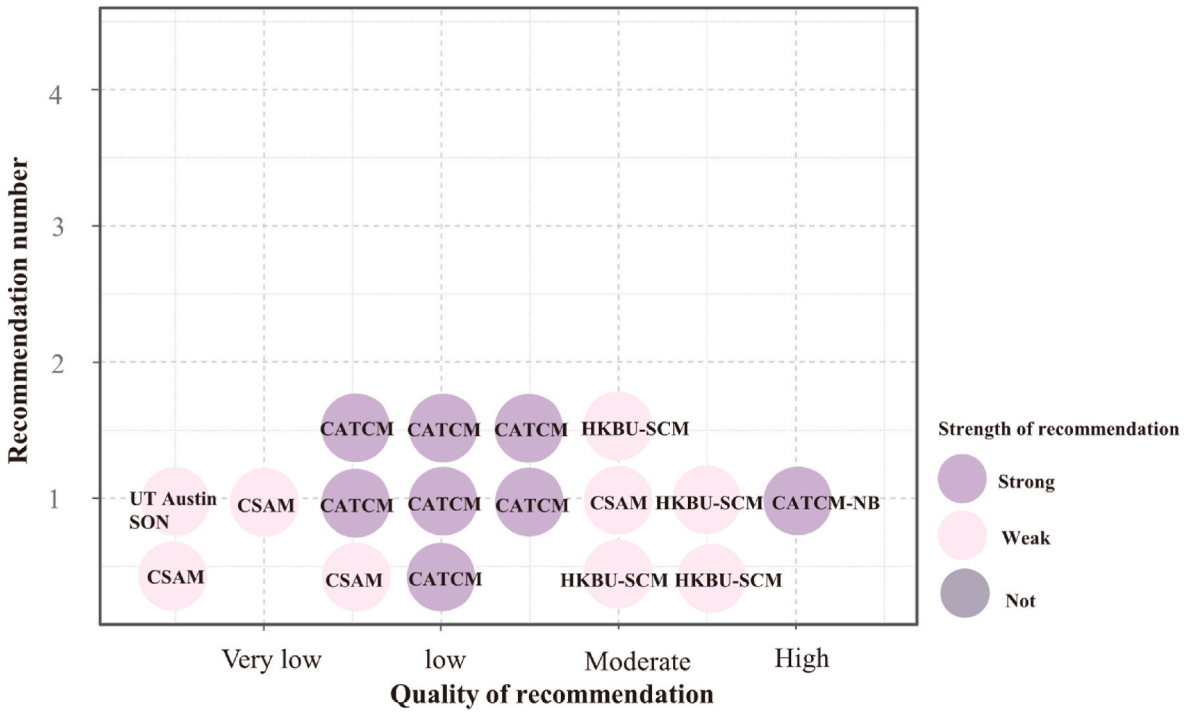

Fig. 5. Evidence map for acupuncture treatment recommendations.

recommendation (China Association for Acupuncture and Moxibustion, 2014));

(10) Milli-needle acupuncture method is recommended for insomnia patients with daytime dysfunction (Weak recommendation (China Association for Acupuncture and Moxibustion, 2014));

(11) For patients with difficulty in falling asleep, waking problems, and lack of deep sleep, the method of tonic and diarrhea among the veins is suggested (Weak recommendation (China Association for Acupuncture and Moxibustion, 2014));

(12) For those with difficulty in sleeping, skin acupuncture therapy can be used for the bladder meridian and the dou chakra (Weak recommendation (China Association for Acupuncture and Moxibustion, 2014));

(13) Shenmen, Sanyinjiao, and Baihui suggested acupuncture points (Weak recommendation (Lam et al., 2019));

(14) Points Shen Shenhua, Sanyinjiao, Baihui, Sishencong, Neiguan, Suisanli, Zhaohai, and Sheeting are recommended for insomnia (Weak recommendation (Zhong et al., 2020));

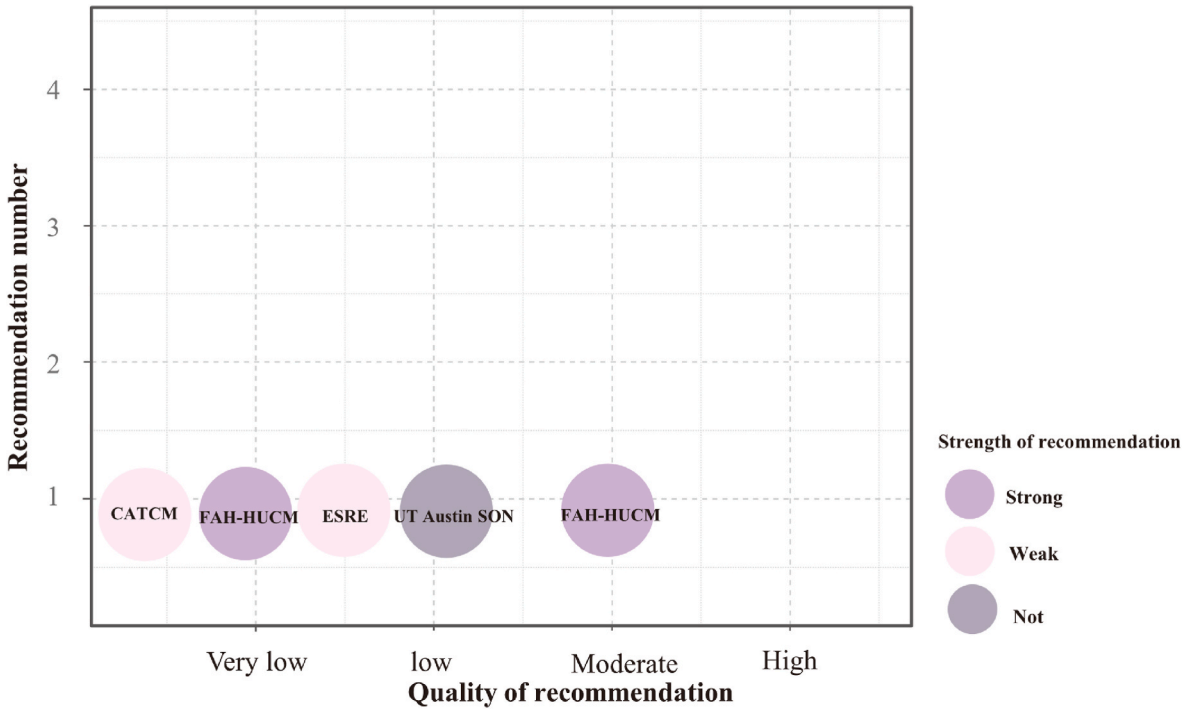

Fig. 6. Evidence map for Tui Na treatment recommendations.

(15) Ear points Hovenia, Jiao Shen, Sen Men, Zhen, Heart, Spleen, Liver, Kidney are recommended for treating insomnia (Weak recommendation (Zhong et al., 2020));
(16) Commonly used points for electroacupuncture are Baihui, Yintang, Feosanli, Yanglingchuan, Neihuan, Sanyinjiao, and Sishencong (Weak recommendation (Zhong et al., 2020));
(17) Use of auricular grain acupuncture is recommended for the treatment of chronic insomnia (Weak recommendation (Department of Veterans Affairs Department of Defense, 2019)).

3.7. Recommendations for tui Na for insomnia

Fig. 6 demonstrates the five main recommendations for tui na therapy in 4 of the clinical practice guidelines (Shekelle et al., 2001; Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016; Riemann et al., 2017; The First Affiliated Hospital of Henan University of Chinese Medicine, 2023). These recommendations include.

(1) For applying Tui Na, several critical points on the head, abdomen, waist, and extremities are suggested, each requiring specific massage techniques such as pushing, kneading, wiping, pressing, and rubbing. These methods aim to stimulate the points and promote overall health (weak recommendation (Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016));
(2) Tui Na is recommended for insomnia patients based on TCM evidence. This treatment is suggested to improve sleep quality, extend total sleep time, and reduce waking frequency. Additionally, it can help to relieve anxiety and depression symptoms and improve cognitive function (strong recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023));
(3) For elderly patients struggling with insomnia, non-pharmacological treatments based on TCM, including Tui Na, are recommended to improve sleep quality. It signifies that Tui Na can be a beneficial approach for older adults, who might be more sensitive to the side effects of medication (strong recommendation (The First Affiliated Hospital of Henan University of Chinese Medicine, 2023));
(4) Foot reflexology, a technique that involves applying specific pressure to points on the feet that correspond to different body organs and systems, is suggested as a potential therapeutic approach to insomnia. However, this recommendation is considered weaker, possibly indicating the need for more research or variability in patient responses (weak recommendation (Riemann et al., 2017));
(5) Massage therapy, while shown to improve sleep parameters in elderly hospitalized patients, is not currently recommended for the general elderly population. The guideline suggests that more studies are needed to establish its effectiveness within this wider population (not recommended (Shekelle et al., 2001; Zhao et al., 2023)).

4. Discussion

4.1. Principal findings

According to our AGREE II evaluation results, existing clinical practice guidelines for insomnia that include TCM interventions must be of higher quality. The domains of “scope and purpose” and “clarity of presentation” achieved high scores, with most guidelines reflecting the explicit developmental objective, clinical problems, target groups, and recommendations. Nonetheless, there are still four areas that require further improvement. Undoubtedly, the scores in the domains of ‘applicability’ and ‘rigour of development’ are below average.

Our evidence mapping analysis revealed that: (1) TCM drug therapies, substantiated by rigorous clinical trials, are often preferred due to their superior evidence certainty compared to non-drug therapies; (2) approaches such as magnetic and fumigation therapies, despite extensive evidence gaps, demand additional rigorous clinical investigation to affirm their efficacy; (3) therapies like hot ironing, acupuncture point injection, and application, reliant on observational trials, should be interpreted cautiously given the high risk of bias and unreliable evidence. Randomized controlled trials could be a future avenue; (4) while acupuncture and tui na therapy have a systematic reviews/meta-analyses evidence base, the efficacy of other non-pharmacological interventions remains indeterminate, necessitating further exploration through high-quality randomized controlled trials involving qigong, gua sha, and moxibustion. As regards the strength of recommendations, high certainty recommendations come mainly from domestic guidelines, and recommendations from international guidelines tend to focus on non-pharmacological treatments for which the certainty of evidence could be higher, despite endorsements from the guideline development working group. Merely 2.84% of drug therapy recommendations were underpinned by high-certainty evidence, and the majority (77.52%) needed more detailed dosage and treatment duration information, thus lacking robust supporting evidence. Moreover, the limited maximum follow-up period of one month restricts the extrapolation of drug safety evidence over longer durations. We found variations in the certainty and strength of some of the recommendations. This may be due to the guideline developers’ need to understand the methodological system.

4.2. Comparison with other studies

Researchers have employed the AGREE II evaluation in evaluating insomnia guidelines, including those covering complementary alternative therapies (Ng and Parakh, 2021; Zhao et al., 2023) and all-inclusive insomnia guidelines (Zhu et al., 2022). nevertheless, no studies have specifically examined the utilization of TCM therapies in the context of insomnia guidelines. Numerous evidence mapping studies on TCM therapies exist. However, none explicitly focus on insomnia: such as post-stroke sleep disorders (Su et al., 2022), type 2 diabetes (Wang et al., 2022), ulcerative colitis (Sun et al., 2021), stroke (Choi et al., 2022), and gastric cancer (Lu et al., 2021).

4.3. Strengths and limitations

This study is the first cross-sectional investigation of the certainty of evidence for treating insomnia in TCM. This study represents a groundbreaking exploration, employing an evidence mapping approach to visually represent the published insomnia guidelines concerning recommendations for TCM treatments. A systematic and comprehensive literature search of national and international literature databases and guideline websites was conducted to ensure the inclusion of all published clinical practice guidelines on TCM treatment of insomnia. It is worth noting that the entire review process, from literature screening to data extraction to methodological quality assessment, was conducted independently by two to four researchers. Our findings are reliable. However, our research has some limitations. This study was limited to publicly available Chinese and English guidelines. It did not include guidelines in other languages or unpublished guidelines, which may lead to publication bias. The certainty of recommendations may have been biased by incorrectly classifying some recommendations into inappropriate levels of evidence because the certainty of evidence classification of recommendations was not validated. Furthermore, it is essential to note that the validity of the evidence supporting the use of TCM for insomnia is subject to change with ongoing research. This suggests that newly published evidence may have yet to be considered. Consequently, there is a need for regular updates of the results to incorporate emerging research findings. It is essential to emphasize that evidence mapping exclusively encompasses recommendations

substantiated by dependable evidence, thereby inherently constraining the scope of evidence mapping.

4.4. Potential interpretations of findings

The low scores in the "applicability" domain can be attributed to overlooking potential facilitators and barriers in the implementation process. Identifying barriers is vital for formulating practical recommendations, and paying attention to this may reduce adherence to the guidelines (Horbar et al., 2004; Langlois et al., 2016; Hill et al., 2020). Future efforts should focus on developing guidelines and implementing and scientific methodological framework to improve guideline implementation (Huang et al., 2023; Lai et al., 2023). This approach will effectively strengthen the implementability of the recommendations (Huang et al., 2023). "rigour of development" also scored poorly. Most guidelines should have mentioned the frequency of updates and criteria for evidence selection. In future efforts, it is imperative to strictly adhere to the guideline development methodology, strengthen the optimization of the guideline development methodology tailored to the unique characteristics of Chinese medicine, and accelerate the establishment of an evidence evaluation system tailored to the specific characteristics of Chinese medicine (Lai et al., 2023). For the future, strict adherence to guideline development methods is essential. In addition, to improve outcomes, it is crucial to ensure that guidelines stay in line with the latest clinical evidence as it develops and grows. Existing studies recommend that guidelines revising every three to five years to maintain consistency with the latest evidence (Shekelle et al., 2001).

Recent evidence corroborates the significant improvement of sleep quality in patients due to non-pharmacological TCM therapies (Liu et al., 2022; Zhuang et al., 2022). However, these clinical trials often grapple with methodological quality and risk bias, necessitating future large-sample randomized controlled trials to appraise the long-term efficacy, safety, and potential side effects of TCM for insomnia. While several meta-analyses testify to the positive impact of TCM on insomnia (Guo et al., 2013; Dong et al., 2017; Yin et al., 2017; Guo et al., 2018), the efficacy has yet to be fully endorsed due to methodological limitations (Huang et al., 2020), calling for future high-quality systematic evaluations and meta-analyses to provide robust and objective evidence. Some recommendations relate to Chinese herbal formulas. However, the need for standardized manufacturing procedures hinders their global applicability. There is also a lack of comprehensive standard operating procedures (SOP) for the non-pharmaceutical part of the recommendations, which hinders effective implementation in clinical practice. Future recommendations should enhance and refine these segments.

TCM holds a deep-rooted position within the framework of Chinese culture and often takes precedence as the preferred therapeutic approach for insomnia in China. Conversely, in many foreign countries, TCM is regarded as one among various therapeutic modalities within the realm of complementary and alternative medicine. Consequently, recommendations about TCM frequently exhibit vagueness, rendering them insufficient in offering comprehensive clinical guidance. Implementing rigorous, large-scale, randomized controlled trials for non-pharmacological treatments within TCM poses considerable challenges. Historically, non-pharmacological therapies within TCM have traversed an evolutionary trajectory in the Western context, commencing with initial skepticism, gradually transitioning to acceptance, and culminating in widespread recognition (Guo et al., 2017). There is a significant difference between the clinical perspectives of Chinese and Western medicine. Chinese medicine has a unique "holistic view," This contrasts with Western medicine's emphasis on "research evidence." This makes the Western medical evidence grading system unsuitable for evaluating TCM evidence (Xia et al., 2022). The utilization of contemporary evidence grading systems may compromise the quality of TCM interventions. Certain scholars promote the continuous validation and evaluation of evidence derived from ancient literature and expert opinions in TCM within real-world settings. This approach aims to obtain authentic evidence and establish a clinical research methodology system that aligns harmoniously with the evolution of TCM (Shi et al., 2023). In the forthcoming times, it is imperative to enhance collaboration between experts in evidence-based methodology in TCM and clinicians, particularly in clinical research within TCM (Chen et al., 2020). This collaborative effort will elevate the quality and standards of research, thereby bolstering the evidence base for insomnia therapy in TCM.

Clinical practice guidelines should stem from a comprehensive evaluation of the evidence, which serves as the cornerstone of evidence-based medicine. Ensuring congruity between evidence certainty and recommendations' strength is vital in crafting trustworthy guidelines (Yao et al., 2021a). When confronted with evidence of low or negligible quality, it is judicious for guidelines to exercise caution and refrain from providing recommendations. This approach helps prevent the possibility of misleading practitioners (Yao et al., 2021b). Notably, during the period spanning from 2007 to 2012, a significant proportion, precisely 55.5%, of the strong recommendations issued by the World Health Organization were founded upon evidence characterized by low or very low certainty (Alexander et al., 2014). This phenomenon can be attributed to their limited familiarity with the GRADE methodology (Alexander et al., 2016). Future guidelines should strengthen the rigor of the development process and enhance the training of professionals, particularly those in TCM, in applying the GRADE methodology.

5. Conclusion

The findings from our study underscore the pressing need for enhanced quality across guidelines concerning insomnia. Consequently, it is imperative that, in future guideline development endeavors, strict adherence to established methodologies is maintained, with particular attention paid to the domain of "rigour of development" and "applicability". Our recommendation evidence map elucidates that recommendations related to Traditional Chinese Medicine (TCM) treatments predominantly occupy the lower spectrum of evidence certainty, often manifesting as weak recommendations, underpinned by a notably feeble evidence base. In order to address this issue effectively, we must undertake robust clinical investigations encompassing a variety of Traditional Chinese Medicine (TCM) interventions, thereby yielding research evidence of higher quality. Simultaneously, there exists a critical need to expedite the establishment of an evidence evaluation system explicitly tailored to the distinctive attributes of TCM. Furthermore, it is warranted to intensify efforts to optimize methodological research, spanning the entire spectrum from evidence generation to recommendation formulation.

CRediT authorship contribution statement

Ziying Ye: Writing – original draft, Methodology, Formal analysis. **Honghao Lai:** Writing – review & editing, Methodology. **Jinling Ning:** Formal analysis. **Jianing Liu:** Formal analysis. **Jiajie Huang:** Formal analysis. **Sihong Yang:** Writing – review & editing, Methodology. **Jiayue Jin:** and **Yajie Liu:** provided some helpful suggestions in this paper. All authors read and approved the publication of this study. **Jie Liu:** proposed the framework of this paper. **Hui Zhao:** proposed the framework of this paper. **Long Ge:** proposed the framework of this paper, Writing – review & editing.

Declaration of competing interest

The authors declare no conflict of interest.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

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References

Alexander, P.E., Bero, L., Montori, V.M., Brito, J.P., Stoltzfus, R., Djulbegovic, B., Neumann, I., Rave, S., Guyatt, G., 2014. World Health Organization recommendations are often strong based on low confidence in effect estimates. J. Clin. Epidemiol. 67, 629–634. https://doi.org/10.1016/j.jclinepi.2013.09.020.

Alexander, P.E., Gionfriddo, M.R., Li, S.-A., Bero, L., Stoltzfus, R.J., Neumann, I., Brito, J. P., Djulbegovic, B., Montori, V.M., Norris, S.L., Schünemann, H.J., Thabane, L., Guyatt, G.H., 2016. A number of factors explain why WHO guideline developers make strong recommendations inconsistent with GRADE guidance. J. Clin. Epidemiol. 70, 111–122. https://doi.org/10.1016/j.jclinepi.2015.09.006.

Atkins, D., Eccles, M., Flottorp, S., Guyatt, G.H., Henry, D., Hill, S., Liberati, A., O'Connell, D., Oxman, A.D., Phillips, B., Schünemann, H., Edejer, T.T.-T., Vist, G.E., Williams, J.W., Jr, GRADE Working Group, 2004. Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches the GRADE Working Group. BMC Health Serv. Res. 4, 38. https://doi.org/10.1186/1472-6963-4-38.

Baker, Shelley, Bhatta, Sarmila, Bowden, Emily, Calaway, Valerie, 2014. Clinical guideline for the treatment of primary insomnia in middle-aged and older adults [WWW Document]. https://www.sandhillscenter.org/uploads/ngc10414.pdf.

Benbir, G., Demir, A.U., Aksu, M., Ardic, S., Firat, H., Itil, O., Ozgen, F., Yılmaz, H., Karadeniz, D., 2015. Prevalence of insomnia and its clinical correlates in a general population in Turkey: prevalence and correlates of insomnia. Psychiatr. Clin. Neurosci. 69, 543–552. https://doi.org/10.1111/pcn.12252.

Black, D.W., Grant, J.E., 2014. DSM-5™ guidebook: the essential companion to the diagnostic and statistical manual of mental disorders. In: DSM-5™ Guidebook: the Essential Companion to the Diagnostic and Statistical Manual of Mental Disorders, fifth ed. American Psychiatric Publishing, Inc., Arlington, VA, US. Fifth edition.

Buysse, D.J., 2013. Insomnia. JAMA 309, 706. https://doi.org/10.1001/jama.2013.193.

Chen, W., F, S., Jp, J., 2019. [Recommendations for clinical evidence grading on traditional Chinese medicine based on evidence body]. Chin. J. Integr. Tradit. West. Med. 39, 358–364.

Chen, Y., Liu, X., Wang, Y., 2020. [Western medical guidelines and traditional Chinese medical guidelines: lmprovingTogether through mutual learning]. Med. J. Peking. Union. Med. coll. Hosp. 11, 615–620.

Cheng, B., Liu, Yanfei, Tian, J., Gao, R., Liu, Yue, 2020. Complementary and Alternative Medicine for the treatment of insomnia: an overview of scientific evidence from 2008 to 2018. Curr. Vasc. Pharmacol. 18, 307–321. https://doi.org/10.2174/1570161117666190506111239.

China Association for Acupuncture and Moxibustion, 2014. [Evidence-based Guidelines of Clinical Practice with Acupuncture and Moxibustion Insomnia]. China Press Tradit Chin Med.

China Association of Chinese Medicine, 2021. [Clinical diagnosis and treatment guidelines of mental diseases for integrated Chinese and western medicine – non-organic insomnia]. https://www.cacm.org.cn/wp-content/uploads/2021/07.

Chinese Medicine Clinical Practice Guidelines for Insomnia Group, Academy of Chinese Medicine, 2016. [TCM clinical guidelines of insomnia research group (WHO/WPO)]. World. J. Sleep. Med. 3, 8–25.

Chinese Sleep Research Society, 2017. [Guidelines for the diagnosis and treatment of insomnia in China]. Chin. Med. J. 97, 1844–1856.

Choi, T.Y., Jun, J.H., Lee, H.W., Yun, J.M., Joo, M.C., Lee, M.S., 2022. Traditional Chinese medicine interventions in the rehabilitation of cognitive and motor function in patients with stroke: an overview and evidence map. Front. Neurol. 13, 885095 https://doi.org/10.3389/fneur.2022.885095.

Colquhoun, H.L., Levac, D., O'Brien, K.K., Straus, S., Tricco, A.C., Perrier, L., Kastner, M., Moher, D., 2014. Scoping reviews: time for clarity in definition, methods, and reporting. J. Clin. Epidemiol. 67, 1291–1294. https://doi.org/10.1016/j.jclinepi.2014.03.013.

Department of Veterans Affairs Department of Defense, 2019. VA/DoD clinical practice guideline for the management of chronic insomnia disorder and obstructive sleep apnea [WWW document]. https://www.healthquality.va.gov/guidelines/CD/insomnia/VADoDSleepCPGFinal508.pdf.

Dong, B., Chen, Z., Yin, X., Li, D., Ma, J., Yin, P., Cao, Y., Lao, L., Xu, S., 2017. The efficacy of acupuncture for treating depression-related insomnia compared with a control group: a systematic review and meta-analysis. BioMed Res. Int., 9614810 https://doi.org/10.1155/2017/9614810, 2017.

Dopheide, J.A., 2020. Insomnia overview: epidemiology, pathophysiology, diagnosis and monitoring, and nonpharmacologic therapy. Am. J. Manag. Care 26, S76–S84. https://doi.org/10.37765/ajmc.2020.42769.

Gibson, M.J., Lawlor, D.A., Millard, L.A.C., 2023. Identifying the potential causal role of insomnia symptoms on 11,409 health-related outcomes: a phenome-wide Mendelian randomisation analysis in UK Biobank. BMC Med. 21, 128. https://doi.org/10.1186/s12916-023-02832-8.

Grau, K., Plener, P.L., 2018. Psychopharmakotherapie bei Ein- und Durchschlafstörungen im Kindes- und Jugendalter: eine Übersicht. Z. Kinder JugenPsychiatr. Psychother. 46, 393–402. https://doi.org/10.1024/1422-4917/a000562.

Guangdong Provincial Association of Chinese Medicine, 2022. [The diagnosis and treatment of Insomnia Disorders]. https://www.ttbz.org.cn/StandardManage/Detail/67514/.

Guo, J., Wang, L.P., Liu, C.Z., Zhang, J., Wang, G.L., Yi, J.H., Cheng, J.L., 2013. Efficacy of acupuncture for primary insomnia: a randomized controlled clinical trial. Evid. Based. Complement. Alternat. Med., 163850 https://doi.org/10.1155/2013/163850, 2013.

Guo, Y., Zhao, H., Wang, F., Li, S.-N., Sun, Y.-X., Han, M.-J., Liu, B.-Y., 2017. Recommendations for acupuncture in clinical practice guidelines of the national guideline clearinghouse. Chin. J. Integr. Med. 23, 864–870. https://doi.org/10.1007/s11655-016-2750-4.

Guo, T., Jia, M., Jin, Y., Xu, N., Peng, T., 2018. Acupuncture for perimenopausal insomnia: a systematic review and meta-analysis protocol. Medicine (Baltim.) 97, e11083. https://doi.org/10.1097/MD.0000000000011083.

Harbour, R., Miller, J., 2001. A new system for grading recommendations in evidence based guidelines. BMJ 323, 334–336. https://doi.org/10.1136/bmj.323.7308.334.

Hetrick, S.E., Parker, A.G., Callahan, P., Purcell, R., 2010. Evidence mapping: illustrating an emerging methodology to improve evidence-based practice in youth mental health: evidence mapping in youth mental health. J. Eval. Clin. Pract. 16, 1025–1030. https://doi.org/10.1111/j.1365-2753.2008.01112.x.

Hill, J.E., Stephani, A.-M., Sapple, P., Clegg, A.J., 2020. The effectiveness of continuous quality improvement for developing professional practice and improving health care outcomes: a systematic review. Implement. Sci. 15, 23. https://doi.org/10.1186/s13012-020-0975-2.

Horbar, J.D., Carpenter, J.H., Buzas, J., Soll, R.F., Suresh, G., Bracken, M.B., Leviton, L. C., Plsek, P.E., Sinclair, J.C., 2004. Collaborative quality improvement to promote evidence based surfactant for preterm infants: a cluster randomised trial. BMJ 329, 1004. https://doi.org/10.1136/bmj.329.7473.1004.

Huang, J., Wu, M., Liang, S., Qin, X., Shen, M., Li, J., Huang, Y., 2020. A critical overview of systematic reviews and meta-analyses on acupuncture for poststroke insomnia. Evid Based Complement Alternat Med, 2032575. https://doi.org/10.1155/2020/2032575, 2020.

Huang, J., Lai, H.H., Sun, M.Y, liu, J., Zhao, W.L., Tang, W.J., Yang, S.H., Pan, B., Tian, J. W., Ma, X.T., 2023. [Interpretation of update on consolidated framework for implementation research (CFIR 2.0)]. Chin Gen Pract 26, 3863.

Hung, C.M., Li, Y.C., Chen, H.J., Lu, K., Liang, C.L., Liliang, P.C., Tsai, Y.D., Wang, K.W., 2018. Risk of dementia in patients with primary insomnia: a nationwide population-based case-control study. BMC Psychiatr. 18 https://doi.org/10.1186/s12888-018-1623-0.

Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, 2011. Clinical Practice Guidelines We Can Trust. National Academies Press (US), Washington (DC).

Lai, H.H., Sun, M.Y., Huang, J.J., Li, Y., Ning, J.L., Zhao, W.L., Yang, S.H., Tian, J.W., Chen, Y.L., Shang, H.C., Yang, K.H., Ge, L., 2023. [Development of the implementation framework of integrative Chinese medicine clinical practice guideline]. Med. J. Peking. Union. Med. Coll. Hosp. 14, 31–38.

Lam, W.C., Zhong, L., Liu, Y., Shi, N., Ng, B., Ziea, E., Bian, Z., Lu, A., 2019. Hong Kong Chinese Medicine clinical practice guideline for cancer palliative care: pain, constipation, and insomnia. Evid. Based. Complement. Alternat. Med., 1038206 https://doi.org/10.1155/2019/1038206, 2019.

Langlois, E.V., Becerril Montekio, V., Young, T., Song, K., Alcalde-Rabanal, J., Tran, N., 2016. Enhancing evidence informed policymaking in complex health systems: lessons from multi-site collaborative approaches. Health Res. Pol. Syst. 14, 20. https://doi.org/10.1186/s12961-016-0089-0.

Linn, D.D., Beckett, R.D., Faust, A.C., 2022. Use of the AGREE II instrument to evaluate critical care practice guidelines addressing pharmacotherapy. J. Eval. Clin. Pract. 28, 1061–1071. https://doi.org/10.1111/jep.13687.

Liu, J.P., 2007. [Composition of evidence body of traditional medicine and recommendations forIts evidence grading]. Chin. J. Integr. Tradit. West. Med. 1061–1065.

Liu, C.Y., Zhao, Y.N., Wang, X.Q., Qin, S., Wan, Q.Y., Zheng, S.Y., Wu, W.Z., 2022. Acupuncture combined with traditional Chinese medicine e-aid cognitive behavioral therapy for insomnia (TCM-eCBT-I) for chronic insomnia: study protocol for a randomized controlled trial. Trials 23. https://doi.org/10.1186/s13063-022-06012-6.

Lotfi, T., Stevens, A., Akl, E.A., Falavigna, M., Kredo, T., Mathew, J.L., Schünemann, H.J., eCOVID Collaborators, 2021. Getting trustworthy guidelines into the hands of decision-makers and supporting their consideration of contextual factors for implementation globally: recommendation mapping of COVID-19 guidelines. J. Clin. Epidemiol. 135, 182–186. https://doi.org/10.1016/j.jclinepi.2021.03.034.

Lu, C., Ke, L., Li, J., Wu, S., Feng, L., Wang, Y., Mentis, A.F.A., Xu, P., Zhao, X., Yang, K., 2021. Chinese medicine as an adjunctive treatment for gastric cancer: methodological investigation of meta-analyses and evidence map. Front. Pharmacol. 12, 797753 https://doi.org/10.3389/fphar.2021.797753.

Madera Anaya, M., Franco, J.V.A., Ballesteros, M., Solà, I., Urrútia Cuchí, G., Bonfill Cosp, X., 2019. Evidence mapping and quality assessment of systematic reviews on therapeutic interventions for oral cancer. Cancer Manag. Res. 11, 117–130. https://doi.org/10.2147/CMAR.S186700.

Miake-Lye, I.M., Hempel, S., Shanman, R., Shekelle, P.G., 2016. What is an evidence map? A systematic review of published evidence maps and their definitions, methods, and products. Syst. Rev. 5, 28. https://doi.org/10.1186/s13643-016-0204-x.

Ministry of Science and Technology "eleventh Five-Year" national science and technology support plan key topics of psychological disorders prevention research and demonstration project research group, 2016. [Clininal practice guidelines of insonmia disorder]. World. J. Sleep. Med. 3, 65–79.

Ng, J.Y., Parakh, N.D., 2021. A systematic review and quality assessment of complementary and alternative medicine recommendations in insomnia clinical practice guidelines. BMC Complement. Med. Ther. 21, 54. https://doi.org/10.1186/s12906-021-03223-3.

Paschalis, G., Alan, A., Keith, J.R., Robert, P.S., 2020. Appraisal of the current guidelines for management of cholangiocarcinoma-using the appraisal of guidelines research and evaluation II (AGREE II) instrument. Hepatobiliary Surg. Nutr. 9, 126–135.

Riemann, D., Baglioni, C., Bassetti, C., Bjorvatn, B., Dolenc Groselj, L., Ellis, J.G., Espie, C.A., Garcia-Borreguero, D., Gjerstad, M., Gonçalves, M., Hertenstein, E., Jansson-Fröjmark, M., Jennum, P.J., Leger, D., Nissen, C., Parrino, L., Paunio, T., Pevernagie, D., Verbraecken, J., Weeß, H.-G., Wichniak, A., Zavalko, I., Arnardottir, E.S., Deleanu, O.-C., Strazisar, B., Zoetmulder, M., Spiegelhalder, K., 2017. European guideline for the diagnosis and treatment of insomnia. J. Sleep Res. 26, 675–700. https://doi.org/10.1111/jsr.12594.

Schroeck, J.L., Ford, J., Conway, E.L., Kurtzhalts, K.E., Gee, M.E., Vollmer, K.A., Mergenhagen, K.A., 2016. Review of safety and efficacy of sleep medicines in older adults. Clin. Therapeut. 38, 2340–2372. https://doi.org/10.1016/j.clinthera.2016.09.010.

Shekelle, P.G., Ortiz, E., Rhodes, S., Morton, S.C., Eccles, M.P., Grimshaw, J.M., Woolf, S. H., 2001. Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? JAMA 286, 1461–1467. https://doi.org/10.1001/jama.286.12.1461.

Shi, X.Q., Li, H.Y., Zhou, J., Guo, J., 2023. [Grading criteria of evidence quality and recommendation strength in traditional ChineseMedicine/Integrated traditional Chinese and western medicine clinical practice guidelinesand expert consensus]. J. Tradit. Chin. Med. 64, 581–586.

Singh, P., Kaur, R., 2020. An integrated fog and Artificial Intelligence smart health framework to predict and prevent COVID-19. Glob. Transit. 2, 283–292. https://doi.org/10.1016/j.glt.2020.11.002.

State Administration of Traditional Chinese Medicine, 2018. [Compendium of medical technology manuals of traditional Chinese medicine 2013 popularized edition] [WWW Document]. http://www.natcm.gov.cn/yizhengsi/gongzuodongtai/2018-03-24/2690.html.

Su, Q., Zou, D., Gai, N., Li, H., Kuang, Z., Ni, X., 2022. Traditional Chinese medicine for post-stroke sleep disorders: the evidence mapping of clinical studies. Front. Psychiatr. 13, 865630 https://doi.org/10.3389/fpsyt.2022.865630.

Sun, Y.X., Wang, Xiao, Liao, X., Guo, J., Hou, W.B., Wang, Xin, Liu, J.P., Liu, Z.L., 2021. An evidence mapping of systematic reviews and meta-analysis on traditional Chinese medicine for ulcerative colitis. BMC Complement. Med. Ther. 21, 228. https://doi.org/10.1186/s12906-021-03387-y.

The First Affiliated Hospital of Henan University of Chinese Medicine, 2023. [Diagnosis and treatment guidelines of insomnia disorders with the integrated traditional Chinese and western medicine] [WWW document]. https://www.cacm.org.cn/wp-content/uploads/2023/01/03.

U.S. Preventive Services TASK FORCE, 2018. USPSTF.U.S. preventive services task force procedure manual [WWW Document]. In: https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual.

Wang, Y., Dai, Z., Wang, Q., He, Y., Peng, Y., Wu, M., Song, H., Ma, L., Zhang, Y., Li, N., 2022. Clinical application of traditional Chinese medicine therapy for type 2 diabetes mellitus: an evidence map. Evid. Based. Complement. Alternat. Med., 2755332 https://doi.org/10.1155/2022/2755332, 2022.

Xia, H., Zhao, Z., Guo, J., Huang, Q., 2022. [Traditional Chinese medicine related grading criteria for quality of evidence and strength ofrecommendations: a systematic review]. Chin. J. Med. Evidence-Based. Med. 22, 187–195.

Yao, L., Ahmed, M.M., Guyatt, G.H., Yan, P., Hui, X., Wang, Q., Yang, K., Tian, J., Djulbegovic, B., 2021a. Discordant and inappropriate discordant recommendations in consensus and evidence based guidelines: empirical analysis. BMJ 375, e066045. https://doi.org/10.1136/bmj-2021-066045.

Yao, L., Guyatt, G.H., Djulbegovic, B., 2021b. Can we trust strong recommendations based on low quality evidence? BMJ 375, n2833. https://doi.org/10.1136/bmj.n2833.

Zhang, H., Liu, P., Wu, X., Zhang, Y., Cong, D., 2019. Effectiveness of Chinese herbal medicine for patients with primary insomnia: a PRISMA-compliant meta-analysis: a PRISMA-compliant meta-analysis. Medicine (Baltim.) 98, e15967. https://doi.org/10.1097/MD.0000000000015967.

Zhao, F.Y., Xu, P., Kennedy, G.A., Conduit, R., Zhang, W.J., Wang, Y.M., Fu, Q.Q., Zheng, Z., 2023. Identifying complementary and alternative medicine recommendations for insomnia treatment and care: a systematic review and critical assessment of comprehensive clinical practice guidelines. Front. Public Health 11, 1157419. https://doi.org/10.3389/fpubh.2023.1157419.

Zhong, L.L.D., Shi, N., Sun, Y., Ng, B.F.L., Bian, Z., Lu, A., 2020. Hong Kong Chinese medicine clinical practice guideline for insomnia. Eur. J. Integr. Med. 39, 101193 https://doi.org/10.1016/j.eujim.2020.101193.

Zhou, H., Feng, G., 2018. [Methods for consistency evaluation in medical research]. Chronic. Pathematol. J. 19, 361–362+365.

Zhu, H., Li, M., Pan, B., Yang, Q., Cao, X., Wang, Q., Chen, Y., Ding, G., Tian, J., Ge, L., 2022. A critical appraisal of clinical practice guidelines on insomnia using the RIGHT statement and AGREE II instrument. Sleep Med. 100, 244–253. https://doi.org/10.1016/j.sleep.2022.08.023.

Zhuang, J., Wu, J., Fan, L., Liang, C., 2022. Observation on the clinical efficacy of traditional Chinese medicine non-drug therapy in the treatment of insomnia: a systematic review and meta-analysis based on computer artificial intelligence system. Comput. Intell. Neurosci., 1081713 https://doi.org/10.1155/2022/1081713, 2022.

Abbreviation

TCM: Traditional Chinese Medicine
NICE: British National Institute of Health and Clinical Excellence
GIN: International Guidelines Collaboration Network
AGREE II: Appraisal of Guidelines for Research and Evaluation
ICC: intraclass correlation coefficient
GRADE: Grading of Recommendations Assessment Development and Evaluation
AASM: American Academy of Sleep Medicine
SIGN: Scottish Intercollegiate Guidelines Network
USPSTF: United States Preventive Services Task Force
GAMH-CATCM: Guang 'anmen Hospital, Chinese Academy of TCM
CSRA: China Sleep Research Association
GDACM: Guangdong TCM Society
CATCM-NB: Chinese Academy of TCM, Neurology Branch
FAH-HUCM: The First Affiliated Hospital of Henan University of Chinese Medicine
CSAM: Chinese Society of Acupuncture and Moxibustion
HKBU-SCM: Hong Kong Baptist University School of Chinese Medicine
ESRE: European Sleep Research Society
UT Austin SON: The University of Texas at Austin School of Nursing
USAMC OEBP: U.S. Army Medical Command Office of Evidence-Based Practice
MoH Spain: Ministry of Health of Spain
TCM grading system: Professor Liu Jianping's proposal for grading evidence in traditional medicine
RCT: randomized controlled trial
OB: observational trial
SR: systematic review
MA: meta-analysis