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

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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

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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

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jep.2023.117601.

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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