世界中医药学会联合会国际组织标准

编制说明

Formulation Explanations

一、工作简况

主要起草单位：山东中医药大学附属眼科医院、山东省眼病防治研究院、中国中医科学院眼科医院、温州医科大学附属眼视光医院、上海交通大学附属上海市第一人民医院

参与起草单位：湖南中医药大学第一附属医院、中国人民解放军总医院、广西中医药大学第一附属医院、长春中医药大学附属医院、北京中日友好医院、中国中医科学院广安门医院、天津中医药大学第一附属医院、甘肃省中医院、上海中医药大学附属龙华医院、天津市眼科医院、山西省眼科医院、浙江大学医学院附属第二医院、广东省中医院、云南大学附属医院、天津医科大学眼科医院、枣庄市中医医院、辽宁中医药大学第二附属医院、上海交通大学医学院附属第九人民医院、海南省眼科医院、成都中医药大学附属医院、香港大学、香港理工大学、台北市立联合医院、新加坡中华医院、新加坡国立大学、加拿大天泉中医诊所

主要起草人：毕宏生、谢立科、瞿佳、许迅、宋继科、胡媛媛

参与起草人（按姓氏拼音排序）：

中　国：陈向东、陈小鸟、郝小波、郝晓凤、鞠援、金明、康玮、梁凤鸣、梁丽娜、路雪婧、吕帆、罗向霞、刘新泉、李丽华、李俊红、倪海龙、庞龙、彭华、曲毅、田庆梅、吴烈、魏瑞华、王哲、杨永升、左韬、张丰菊、周激波、钟兴武、郑燕林、赵健、何明光（中国香港）、翁林仲（中国台湾）

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日　本：仝选甫

二、指南起草过程简介

（如：何时启动，如何开展调研，如何征求各利益相关方的意见，召开了哪些审稿会，标准审定委员会讨论或投票情况等）

1 指南编制原则

《国际中医临床实践指南 近视》（以下简称“本指南”）制定遵循了“循证为举，共识为主，经验为鉴”的原则，指南的编制程序、方法和结构，借鉴了国际上通用的临床实践指南的制定方法，不仅保证了指南制作的科学性，又体现了中

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医药临床实践特色。本指南编制全程基于证据检索和广泛的专家意见调研，并层层深入研讨和分析，所有过程和环节均可以溯源，实现了有据可循。

2 主要工作过程

2.1 启动部署阶段

本指南已在世界中医药学会联合会立案和申请后确定指南名称和具体内容，目前《国际中医临床实践指南 近视》在世界中医药学会联合会立项（SCM NP 2023-179）。

2.2 起草阶段

2.2.1 指南研发计划的制定和实施步骤的落实

本指南工作组根据分配任务，制定了指南研究计划，确定了编制时间节点，征求了有关专家意见，召开专家讨论会，完善研究计划，落实指南制定具体实施步骤。

2.2.2 组织管理

通过负责人召集，与相关专业领域专家电话及信息沟通确定项目组成员。

2.2.3 避免利益冲突

凡参与制定工作的成员均已声明未存在利益冲突，未发现任何明确和本指南主题相关商业、专业或其他方面的利益，以及所有可能被本指南成果影响的利益冲突情况。

2.2.4 确定本指南主题和目的

本指南的制定以中医外治法及中医药辨证论治为主，彰显中医药诊治近视的特色，力求完成一部可操作性强、流程规范的临床实践指南。本指南制定的目的在于进一步规范近视的中医临床诊断与治疗，为国际中医师提供中医药治疗策略与方法。

工作组在前期完成了对 20 名来自国内外临床一线医生对近视结局指标的评分和对本指南拟解决临床问题的调研。通过对调研结果分析发现，对于近视临床一线医生比较关注的结局指标主要为：屈光度、眼轴长度等。而对于本指南拟解决的问题则主要集中在如何更好的为国际中医师提供中医药诊治近视的策略与方法。根据前期的调研，工作组对本疾病领域的 5 名老专家进行了面对面访谈，访谈内容主要从专家治疗儿童青少年的总体思路、辨证论治及诊疗措施等方面进行。2023 年 12 月，本指南获得了世界中医药学会联合会国际组织标准的立项通知。

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2.2.5 采用 PICO 原则确定检索策略

检索策略分为电子检索和手工检索，电子检索中文数据库包括中国科技成果数据库、山东科技成果数据库、中文科技期刊数据库、中国期刊全文数据库、中国学位论文数据库、中国学术会议论文数据库、中国学术会议论文库（全文）、中国科技经济新闻数据库、山东省成果查新报告数据库、山东省立项查新报告数据库、中国专利数据库、中国科技成果交易信息数据库、INTERNET 网络搜索、中国生物医药库；英文数据库包括科学文摘、美国政府研究报告、法国全国科研中心文摘通报、博士论文数据库、会议数据库、欧洲专利文摘数据库、德温特世界专利索引、美国专利全文、日本专利文摘数据库、世界知识产权组织专利数据库、工程索引、科学引文索引、Science Direct Elsevier 数据库、INTERNET 网络搜索、Medline、Pubmed 等。手工检索主要包括诊疗指南、标准、规范、药品说明书、专利说明书、相关中西医眼科教材和专著，同时搜集未公开发表的科研报告、学位论文、会议论文等灰色文献，检索国家卫生健康委员会、教育部等政府部门的近视和眼健康相关政策文件。检索时间均从建库截止至 2023 年 12 月。中文检索词包括：近视、能近怯远、目不能远视、近觑，以及中医、祖国医学、针刺、针灸、电针、针、灸、推拿、按摩、方药、中药、方剂、离子导入、耳穴、耳针、贴敷、穴、穴位、中医外治、梅花针、明目，结合“治未病”、“未病先防”、“预防”，英文检索词包括#1 myopi*, myopia, shortsight, short-sighted, short-sightedness, short sight, short sightedness, near-sight, near-sighted, near-sightedness, near sight, near sighted, near sightedness, refractive errors-refract, et al.

2.2.6 证据筛选和资料提取

完成文献检索后，两位研究者通过阅读标题和摘要独立对文献进行了初步筛选，随后根据这些初筛后研究的全文进行了复筛，如存在分歧，则通过讨论或咨询第三方解决。

旨在研究某种干预延缓近视发生发展的证据均被纳入。纳入的研究类型包括：随机对照试验、队列研究、横断面研究、指南或专家共识等。针对的人群为 3-18 岁的儿童。任何可以体现延缓近视发生发展的指标都可以作为结局指标被纳入。无法获取全文的会议摘要被排除了。

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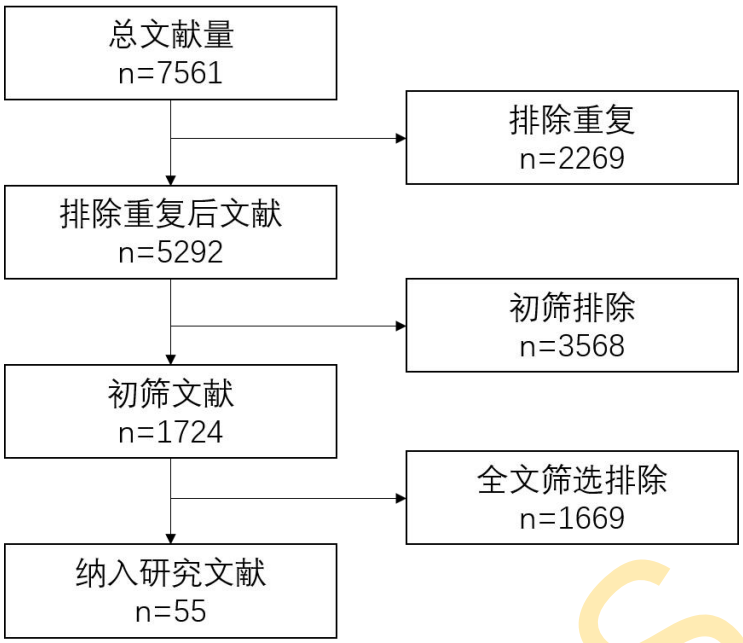

图 1 证据筛选流程图

2.2.7 证据综合

应用 ReviewManager5.3 对研究类型相同、干预措施相同、结局指标相同、数据类别相同的随机对照试验原始研究的数据进行整合分析。观察指标采用区间估计，计数资料用优势比（odds ratio, OR）及其 95%置信区间（confidenceinterval, CI）表示；单位统一的计量资料用均数差（meandifference, MD）及其 95%CI 表示。

2.2.8 证据分级

应用 GRAGE 对于证据数量充足的治法/药物/调摄防护方式等，采用 GRADE 方法对纳入的研究的有效性和安全性的证据体进行汇总和质量评价。证据数量不足、无法进行 Meta 分析的，秘书组制作共识意见表通过专家共识的推荐意见，将证据质量分为 A、B、C、D 4 个等级。在证据分级过程中，考虑 5 个降级因素：偏倚风险、不精确性、不一致性、不直接性以及发表偏倚，3 个升级因素：效应量大、合理的混杂可增加估计效应的可信度、剂量反应关系（负偏倚）。基于专家意见和后续的讨论达成共识，形成结果总结表，以呈现证据等级分级，最后通过证据总结表呈现证据，并参照 GRADE 系统对推荐级别的分级，结合专家意见，得到初步的推荐意见。

2.2.9 推荐意见

工作组开展了线上专家论证会进行了两轮名义组法专家意见调研。每轮名义组法专家共识会中强推荐≥50%或弱推荐+强推荐大于等于 70%的条目且没有专

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家提出异议的条目被直接纳入到指南中。未形成共识的条目进入第二轮会议中进行再次投票，最终指南内容针对专家意见进行证据重梳理、反馈和推荐意见修改。指南制订工作组基于纳入的证据，同时考虑了患者的偏好与价值观、干预措施的成本和利弊平衡，形成了指南问题清单和推荐意见。

2.2.10 撰写标准草案及论证

毕宏生、谢立科、瞿佳、许迅、宋继科、胡媛媛等草案执笔人对指南草案进行撰写，于 2024 年完成，其他指南起草组成员对指南草案进行修改整理。

2.3 征求意见阶段

2.3.1 问卷征求意见

本指南在制定过程中开展了 2 轮专家会议、2 轮专家调查问卷，针对每轮会议及调查问卷的反馈意见，工作组成员进行了详细记录，并结合专家意见，深入讨论，进行修改。

2.3.2 专家审核会征求意见

针对本指南的送审稿，召开了**次网络专家审核会，工作组负责人分别向专家汇报了本指南制定的情况和相关内容，以及向专家组提供了重点讨论的问题。每轮会议结束，工作组总结专家意见，并进行修改。

2.3.3 世界中医药学会联合会网站征求意见

本指南在世界中医药学会联合会网站公开征求意见。

三、主要技术内容介绍

（如：技术指标、参数、公式、性能要求、实验方法、检验规则等）的论据（包括试验、统计数据），修订标准时，应增加新、旧标准的对比。

1. 指南制定依据

本指南的制定依据美国医学研究所（Institute of Medicine，IOM）2011 年对临床实践指南的最新定义（基于系统评价的且对各种备选干预方式进行利弊评估后提出的最优指导意见）并遵循最新国际指南开发组织所颁布的指南制定步骤和相关评价标准确定了本指南的评价标准，旨在以循证医学思想为指导，注重中医药特色，对既往相关证据进行充分收集和评价。其次，在本指南制定过程中，技术内容主要遵循以下原则：

①针对证据分级的方法，总体思想认为来自多个随机临床试验的系统综述或单个高质量的随机对照临床试验的证据等级最高，观察性研究证据等级较低。

②针对推荐强度，主要基于 GRADE 内容进行推荐，同时提出在证据缺如或

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不能满足临床实际需求时，以专家共识推荐为主。

③专家共识是中医临床诊疗指南形成推荐意见的重要依据，基于此，本指南在起草过程中专家共识的形成主要基于改良的德尔菲法。

④本指南在实施前，除了需要对指南制定质量使用 AGREEⅡ工具进行评价外，还从指南的实施条件是否满足，是否符合实际医疗工作需要等方面进行了指南适用性与合规性预评价。

⑤按照国际指南报告标准 RIGHT 进行报告，推向国际。

⑥制定计划按照目前国际上发布的指南更新报告规范，在未来 2-3 年进行更新。

2. 指南制定技术路线

参考不同的国际临床实践指南制定组织有关临床实践指南制定过程和程序，结合世界中医药学会联合会国际组织标准发布相关规定，指南制定过程见图 3。

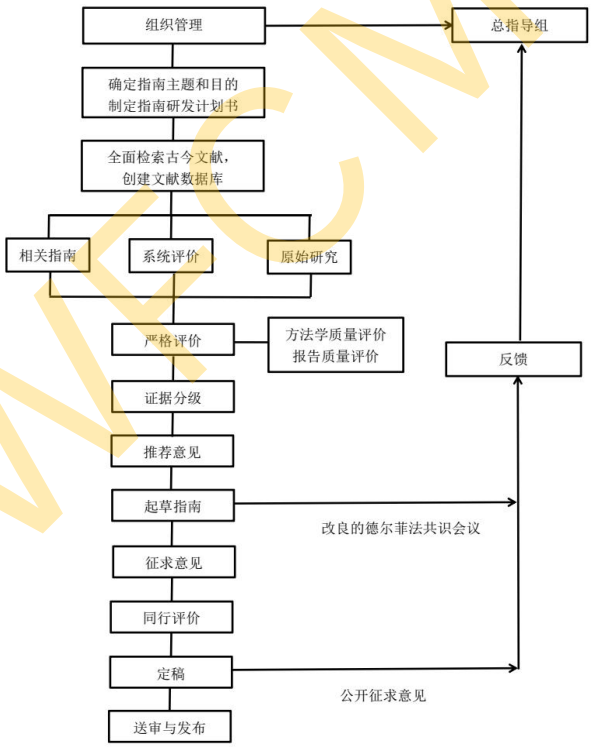

图 2.临床实践指南制定过程

3. 总体内容

本指南正文共设 10 部分，主要技术内容包括：第 1-3 部分明确了本指南的范围、规范性引用文件和术语定义；第 4-9 部分明确了近视的诊断、辨证、近视未病先防、近视既病防变、高度近视防控及调护指导；第 10 部分明确了本指南

附录和参考文献。

本指南以中医外治法为主，最大限度地将循证结果和专家共识相结合，将具有一定优势特色的中医药干预措施应用到近视的诊疗中。因此，在参照并实施本指南前，医师需掌握一定的中医药知识，在诊疗过程中应密切关注患者的各项指标变化。另外，由于受到使用者地域、民族、种族等因素的影响，具体诊疗过程应依照实际情况而定。

4. 与相关法律、法规、强制性标准和临床实践指南的关系

本指南所推荐的相关治疗药物，均遵循国家最新《国家基本医疗保险、工伤保险和生育保险药品目录》、《国家基本药物目录》和《中国药典》所记载的内容。

四、重大分歧意见的处理经过和依据

本指南在制定过程中，未出现重大分歧意见。

五、其他应说明的事项

无

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International organization standards of the World Federation of Chinese Medicine Societies.

Formulation Explanations

I. Job profile

Main drafting units: Affiliated Eye Hospital of Shandong University of Traditional Chinese Medicine, Shandong Academy of Eye Disease Prevention and Treatment, Eye Hospital of the Chinese Academy of Chinese Medical Sciences, Affiliated Eye and Vision Hospital of Wenzhou Medical University, and Shanghai First People's Hospital Affiliated to Shanghai Jiaotong University

Participating drafting units: First Affiliated Hospital of Hunan University of Traditional Chinese Medicine, General Hospital of the People's Liberation Army of China, First Affiliated Hospital of Guangxi University of Chinese Medicine, First Affiliated Hospital of Changchun University of Chinese Medicine, Beijing Sino-Japanese Friendship Hospital, Guang'anmen Hospital of Chinese Academy of Chinese Medical Sciences, First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine, Gansu Provincial Hospital of Traditional Chinese Medicine, Longhua Hospital Shanghai University of Traditional Chinese Medicine, Tianjin Eye Hospital, Shanxi Eye Hospital, Second Affiliated Hospital of Zhejiang University Medical College, Guangdong Provincial Hospital of Traditional Chinese Medicine, Affiliated Hospital of Yunnan University, Eye Hospital of Tianjin Medical University, Zaozhuang Hospital of Traditional Chinese Medicine, Second Affiliated Hospital of Liaoning University of Traditional Chinese Medicine, Ninth People's Hospital Affiliated to Shanghai Jiaotong University School of Medicine, Hainan Provincial Eye Hospital, Chengdu University of Traditional Chinese Medicine Affiliated Hospital, University of Hong Kong, Hong Kong Polytechnic University, Taipei City United Hospital, China Hospital Singapore, National University of Singapore, and Tian Quan Chinese Medicine Clinic

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Singapore: Cheng Jingyu and Lin Qiuxia
Canada: Yu Weidong and Zhou Yue
Japan: Qi Xuanfu

II. Introduction to the drafting process of the guide

(e.g., when to start, how to conduct research, how to solicit input from stakeholders, peer review meetings held, discussions, or voting by the standards validation committee)

1. Principles for preparing guidelines

The International Guide to Clinical Practice of Traditional Chinese Medicine for Myopia (hereinafter referred to as "the Guide") was formulated in accordance with the principle of "evidence-based, consensus-based, and experience-oriented" medicine. The procedures, methods, and structure of the guidelines were developed based on commonly used international methods for formulating clinical practice guidelines. This not only ensured the scientific rigor of the guidelines, but also reflected the characteristics of the traditional Chinese medicine clinical practice. The entire preparation process for this guide was based on evidence retrieval and extensive expert opinion research and in-depth discussion and analysis. All processes and links can be traced back to their source, and evidence-based research has been conducted.

2. Main working process

2.1 Starting the deployment phase

The name and specific content of the Guide were determined after the case filing and application by the World Federation of Chinese Medicine Societies. The International Guide to Clinical Practice of Traditional Chinese Medicine for Myopia was recently established by the World Federation of Chinese Medicine Societies (SCM NP 2023-179).

2.2 Drafting phase

2.2.1 Guide development plan and implementation steps

According to the assigned tasks, the working group developed a guideline research plan, determined the timeline for compilation, solicited feedback from relevant experts, convened expert seminars, refined the research plan, and

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implemented the specific steps necessary for guideline formulation.

2.2.2 Organizational management

Determine project team members through person-in-charge calls and communication of information with experts in related fields.

2.2.3 Avoiding conflicts of interest

All members involved in the development process have declared no conflicts of interest. Additionally, they have not identified any clear commercial, professional, or other interests that are relevant to the subject matter of this guide and all conflicts of interest situations that may be affected by the results of this guide.

2.2.4 Determine the subject and purpose of this guide

The Guide was developed based on the external therapy and syndrome differentiation of traditional Chinese medicine (TCM), highlighting the characteristics of TCM in terms of diagnosing and treating myopia. The primary goal is to establish clinical practice guidelines with strong operability and standardized procedures. The purpose of the guide is to further standardize the TCM clinical diagnosis and treatment of myopia and provide TCM treatment strategies and methods for international TCM physicians.

In the early stages, the working group rated the myopia outcome indicators based on the evaluations provided by 20 clinical first-line physicians from domestic and international settings. The group also investigated the clinical problems that need to be addressed by the Guide. Analysis of the survey results revealed that the clinical first-line myopia doctors paid more attention to diopters and eye axis lengths as outcome indicators. The Guide primarily aims to provide international TCM practitioners with effective strategies and methods for diagnosing and treating myopia using TCM. Building on previous research, the working group conducted face-to-face interviews with five experts in this field, focusing on the treatment of children and adolescents, syndrome differentiation, diagnosis, and treatment measures. In December 2023, the Guide received approval from the international organization standards of the World Federation of Chinese Medicine Societies.

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2.2.5 Using the population, intervention, control, and outcome principle to determine the retrieval strategy

The retrieval strategies were divided into electronic and manual methods. The Chinese databases included the China Science and Technology Achievement Database, Shandong Science and Technology Achievement Database, Chinese Science and Technology Periodical Database, China Periodical Full-Text Database, China degree thesis database, China Academic Conference Thesis Database, China Academic Conference thesis library (full text), China Science and Technology Economic News Database, Shandong Province Achievement Novelty Retrieval Report Database, Shandong Province Project Novelty Retrieval Report Database, China Patent Database, China Science and Technology Achievement Transaction Information Database, Internet search, and China Biological Medicine Database. The English databases included scientific abstracts, research reports from the United States (US) government, abstracts from French national research centers, doctoral dissertation databases, conference databases, European patent abstracts database, Derwent World Patent Index, full text of US patents, Japanese patent abstracts database, World Intellectual Property Organization patent database, engineering index, science citation index, Science Direct Elsevier database, Internet network search, Medline, and PubMed. The following data were manually retrieved: diagnosis and treatment guidelines, standards, specifications, drug instructions, patent instructions, related Chinese and Western medicine ophthalmology textbooks and monographs, unpublished research reports, degree papers, conference papers, and other gray literature. This also included policy documents related to myopia and eye health from the National Health and Health Commission, the Ministry of Education, and other government departments. The search period spanned from the date of database inception to December 2023. The following Chinese search terms were used: myopia, *Neng jin qie yuan*, the eyes cannot be far sighted, and *jin qu*; Chinese medicine, TCM, acupuncture, electroacupuncture, moxibustion, massage, prescriptions, Chinese medicines, prescriptions, iontophoresis, auricular points, auricular needles, application, acupoints, external therapy of TCM, plum-blossom needle, and

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eyesight; and “preventive treatment,” “prevention before disease onset,” and “prevention”. Meanwhile, the English search terms used were as follows: #1 myopi*, myopia, shortsight, short-sighted, short-sightedness, short sight, short sightedness, near-sight, near-sighted, near-sightedness, near sight, near sighted, near sightedness, and refractive errors-refract.

2.2.6 Evidence screening and data extraction

Upon completion of the literature retrieval, two researchers independently conducted a preliminary screening of the literature by reading the title and abstract. Subsequently, re-screening was conducted by reviewing the full texts of the preliminarily screened studies. Disagreements were resolved through discussions or consultations with a third party.

Studies examining interventions to delay the occurrence and development of myopia were included. Only randomized controlled trials (RCTs), cohort studies, cross-sectional studies, guidelines, and expert consensuses were selected for analysis. These studies involved children aged 3–18 years. Any index reflecting a delay in the occurrence and development of myopia can be included as an outcome index. Patients for whom full-text meeting summaries could not be obtained were excluded.

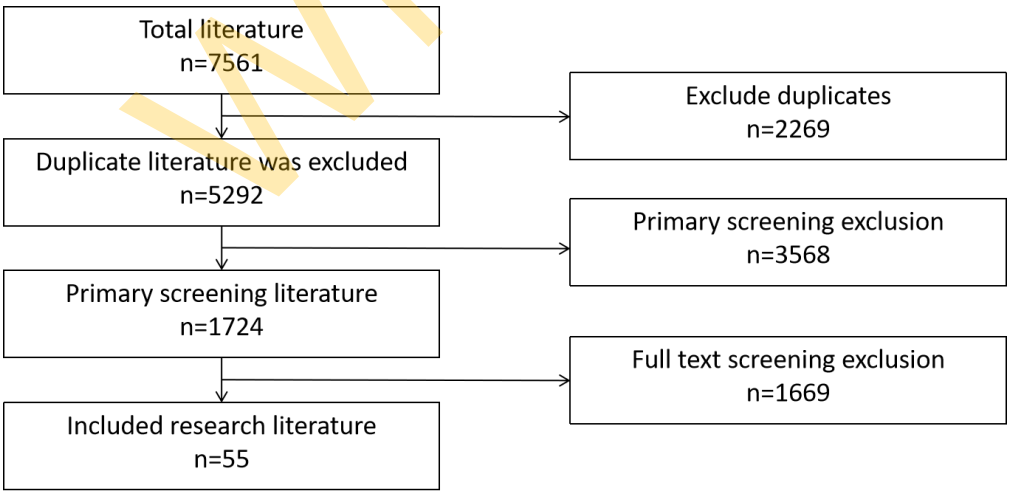

Figure 1. Evidence screening process

2.2.7 Evidence consolidation

Review Manager (version 5.3) was used to conduct an integrated analysis of data from original RCTs with the same study type, intervention, outcome index,

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and data type. The observation indices were estimated using intervals, and the enumeration data were expressed as odds ratios (OR) and 95% confidence intervals (CIs). The unified measurement data were expressed as the mean difference (MD) and 95% CIs.

2.2.8 Classification of evidence

The GRAGE method was used to identify the treatments, drugs, interventions, and protection methods with sufficient evidence. Meanwhile, the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) method was used to summarize and evaluate the evidence supporting the effectiveness and safety of all included studies. When the available evidence was deemed insufficient for a meta-analysis, the secretariat prepared a consensus opinion form. The quality of evidence was divided into levels A, B, C, and D, according to expert consensus-based recommendations. During the classification process, five downgrading factors were assessed: risk of bias, imprecision, inconsistency, indirectness, and publication bias. Additionally, three upgrading factors, substantial effect size, and reasonable confounding factors were considered to enhance the credibility of the estimated effect and dose-response relationship, mitigating potential negative bias. Based on expert opinions and the consensus achieved in subsequent discussions, a summary table was made to present the evidence-level classification. Finally, the evidence was presented in an evidence summary table. Preliminary recommendation opinions were formulated by integrating the GRADE system's classification levels with expert opinions.

2.2.9 Recommendations

The working group conducted online expert seminars and two rounds of research on the opinions of legal experts in nominal groups. In each round of expert consensus meeting using the nominal group method, the items that received a strong recommendation (≥50%) or a combination of weak recommendation and strong recommendation (≥70%) with no objections from experts were directly included in the Guide. Items for which no consensus was reached were included in the second round of meetings for revoting. The final

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Guide incorporated a re-assessment of evidence, feedback from experts, and modifications to the recommendations based on expert opinions. The Guide Development Working Group created a list of guideline questions and recommendations based on the available evidence, taking into account patient preferences, values, and the costs and trade-offs associated with the interventions.

2.2.10 Writing standard draft and demonstration

Bi Hongsheng, Xie Like, Qu Jia, Xu Xun, Song Jike, Hu Yuanyuan, and other authors wrote the draft guide, which was completed in 2024. Other members of the guide-drafting group revised and organized the draft guide.

2.3 Stage of soliciting opinions

2.3.1 Questionnaires for comments

To develop the guide, two rounds of expert meetings and questionnaire-based surveys were conducted. In each round of meetings and after reviewing the feedback obtained from the questionnaires, the members of the working group documented the discussions in detail. These records combined with expert opinions were used to conduct in-depth discussions and make necessary revisions.

2.3.2 Expert review meeting for comments

Based on the content of the initial Guide, a series of network expert review meetings were held. The leader of the working group presented the process of developing the Guide, including other relevant matters, and the key issues discussed by the expert group. After each meeting, the working group summarized the expert opinions and made necessary modifications.

2.3.3 World Federation of Traditional Chinese Medicine Association website for comments

The Guide was made available for public comments at the World Federation of Chinese Medicine Association Website.

II. Introduction to the main technical content

This section includes technical indices, parameters and formulas, performance requirements, experimental methods, and testing rules as well as tests and statistical

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data. When revising the standards, a comparison between the new and old standards should be included.

1. Basis for the development of the Guide

The development of the Guide facilitated the establishment of the evaluation criteria based on the latest definition of clinical practice guidelines issued by the Institute of Medicine (IOM) in 2011. The IOM emphasized the conduct of systematic evaluation and consideration of the advantages and disadvantages of various alternative intervention methods. The development process adhered to the procedures and evaluation criteria set by the latest International Guideline Development Organization. The goal was to collect and evaluate relevant previous evidence under the guidance of evidence-based medicine, with a focus on the characteristics of TCM. During the process of formulating the Guide, the technical content mainly followed the principles below:

In terms of evidence classification, systematic reviews of multiple RCTs or a single high-quality randomized controlled clinical trial provide the highest level of evidence, while observational studies provide the lowest level of evidence.

For recommendation intensity, the recommendation was primarily based on the GRADE criteria. When the evidence was lacking or insufficient to meet clinical needs, expert consensus recommendations were used as the basis.

Expert consensus is an important basis for making recommendations for TCM clinical diagnosis and treatment guidelines. Therefore, the formation of expert consensus during the drafting of the guide was primarily based on the modified Delphi method.

Prior to the implementation of the Guide, the quality of guideline development was evaluated using the AGREE II tool. Additionally, a pre-evaluation of guideline applicability and compliance was conducted, focusing on whether the implementation conditions of the guideline were met and whether the guidelines aligned with the actual needs of medical practice.

⑤ Carry out the report according to the international Reporting Items for practice Guidelines in HealThcare checklist and submit it for international review.

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⑥ Plan to update the reporting guidelines in accordance with the current international guidelines and implement these changes in the next 2–3 years.

2. Guide development technical route

The Guide was developed based on the relevant clinical practice guideline development processes and procedures of different international clinical practice guideline development organizations, in combination with the relevant provisions of the international organization standards released by the World Federation of Chinese Medicine Societies. The development process is shown in Figure 2.

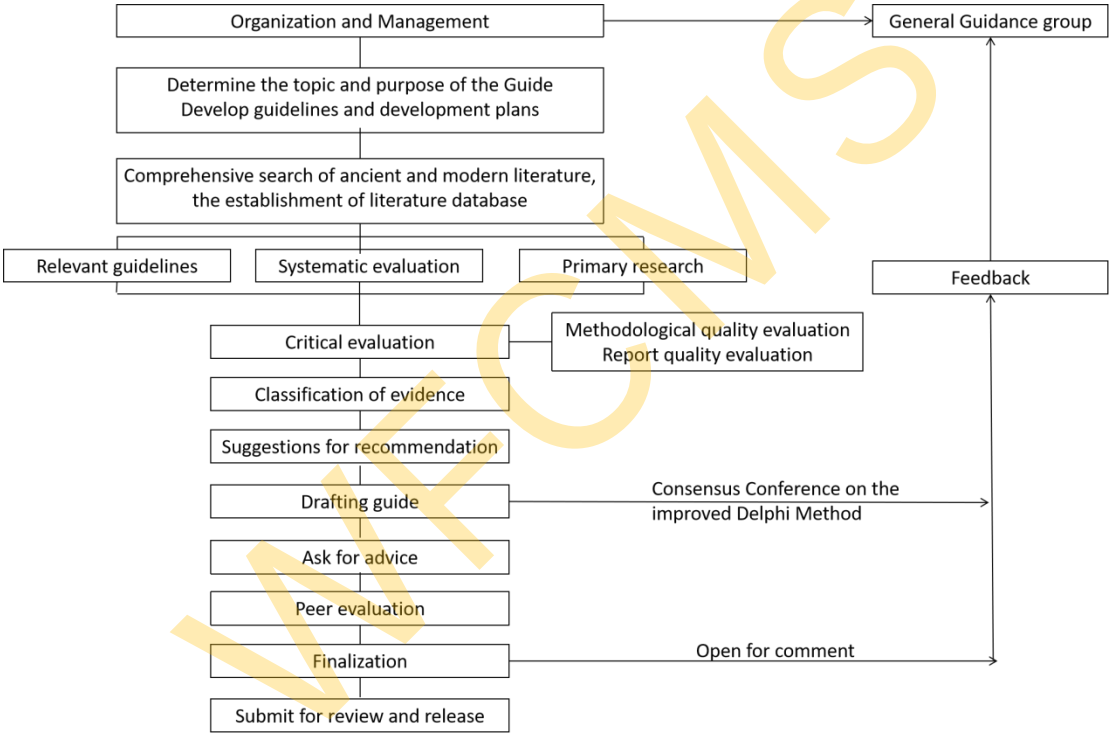

Figure 2. Process of developing clinical practice guidelines

3. General content

The Guide is organized into 10 parts, with the following technical contents: Parts 1–3 contain the scope of the Guide, normative reference documents, and definition of terms. Parts 4–9 comprise the diagnosis, syndrome differentiation, methods for preventing myopia, methods for preventing disease progression, preventive and control strategies for high myopia, and nursing guidance. Part 10 consists of the appendices and references.

The Guide focuses on external TCM therapies and combines evidence-based results and expert consensus. It also applies traditional Chinese medicine interventions, which offer unique advantages and characteristics, to the diagnosis and treatment of myopia. Therefore, physicians should have a foundational understanding of TCM and closely monitor the changes in various patient indicators during diagnosis and treatment. Additionally, due to the variations in geography, ethnicity, race, and other factors of the user, the specific diagnosis and treatment processes should be tailored to individual circumstances.

4. Relationship with relevant laws, regulations, mandatory standards, and clinical practice guidelines

The relevant therapeutic drugs recommended in the Guide are consistent with those listed in the latest National Catalogue of Drugs for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance, National Catalogue of Essential Drugs, and China Pharmacopoeia.

IV. Handling of major differences and basis

No significant differences were observed in the development of this Guide.

V. Other items to be clarified

None

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