BMJ Open Mapping of systematic reviews on traditional medicine across health conditions: a protocol for a systematic map

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ABSTRACT

Introduction Traditional medicine (TM) is an important part of healthcare either as the main healthcare system or as a complement to conventional medicine. The effectiveness of TM has been assessed in clinical trials that have been synthesised into thousands of systematic reviews (SRs). This study is commissioned by the World Health Organization (WHO) and is aimed at providing a systematic map of SRs of TM interventions across health conditions, as well as identifying gaps in the research literature in order to prioritise future primary research. Methods and analysis This is the protocol for a systematic map of SRs reported in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P). We will search 17 electronic databases to identify SRs of TM. The literature search covers the last 5 years, from January 2018 to December 2022. At least two independent reviewers will perform the database search, screening of eligible SRs, data extraction and quality assessments using the A MeaSurement Tool to Assess Systematic Reviews (AMSTAR 2). The characteristics and extent of SRs will be analysed according to disease classification, and type of TM intervention, and visualised by means of (interactive) graphical maps.

Ethics and dissemination Ethical approval is not required as this is a systematic map of published studies. The findings of the study will be disseminated through online-available maps, presentations and scientific publications.

PROSPERO registration number CRD42023416355.

INTRODUCTION

Traditional medicine (TM) is an important part of healthcare either as the main healthcare system or as a complement to conventional medicine, also known as complementary medicine, complementary medicine, traditional and complementary medicine, etc. 1-4 According to the National Center for Complementary and Integrative Health, complementary medicine includes natural products (medicinal plants and

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The rigorous systematic methodology will be applied to identify and evaluate the relevant research literature on traditional medicine (TM) interventions across health conditions.
- ⇒ A broad range of TM modalities and disease classifications will be covered and discussed in the mapping.
- ⇒ The date range of literature database search will be limited to specific given time frame.
- ⇒ Despite the wide coverage of databases and the use of robust search strategies, relevant systematic reviews could be missed.

relevant products), nutritional products, dietary supplements, mind and body practices, psychological therapies, acupuncture, stimulation therapies and manual therapies.⁵ TM is widely used in nearly all nations worldwide. TM modalities, for which evidence of effectiveness and safety is available, can play an important role in achieving universal health coverage. 67 Many nations have identified the need for evidence and data to inform policies, standards and regulatory frameworks for the safe, cost-effective and effective use of TM.85

In evidence-based medicine (EBM), systematic reviews (SRs) using rigorous methodology are considered the gold standard for synthesising the available evidence of effectiveness and safety for a particular intervention and a particular condition. ¹⁰ The EBM concept has substantially altered and influenced the clinical practices in various fields and influenced clinicians, educators and politicians in their healthcare-related work. Without SRs, decision-making processes would frequently be based only on a selection of research that may not be representative of the field's entire body of knowledge. Therefore, facilitating



the production of further high-quality SRs is essential for establishing the best available evidence to support decision-making in healthcare.

Evidence mapping is a recent methodology that allows the categorisation and graphical presentation of the evidence synthesised in SRs, highlighting the extent and distribution of evidence as well as research gaps in a particular area. Hence, evidence mapping is gradually gaining interest among researchers and stakeholders who use scientific evidence to support research, evidence-based practice and decision-making in healthcare.

In recent years, the number of published SRs of some TM modalities has increased significantly. ^{12–14} It is, therefore, timely to systematically map the available SR literature in order to assess its extent and nature, as well as to identify gaps. This study is commissioned by the WHO Global Centre on Traditional Medicine (WHO: 2023/SCI/RFH/ERP/00029) and aimed at producing a systematic map of available SRs in the area of TM. This map will provide valuable insights into the existing SRs for TM, identify knowledge and evidence gaps in the research literature, and inform the development of future evidence syntheses and primary research.

Objectives

The objectives of this study are as follows:

- 1. Identify the extent, key characteristics and quality of existing SRs on TM and their distribution across multiple health conditions.
- 2. Identify gaps in the TM evidence found through the available SRs.
- 3. Discuss priorities for future evidence syntheses and primary research in TM.

METHODS AND ANALYSIS

Registration

This protocol is registered in PROSPERO—the International Prospective Register of Systematic Reviews, under registration number: CRD42023416355. It was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA) checklist. Ethical approval is not required as this is a systematic map of published studies.

Eligibility criteria

The study objectives and eligibility criteria for inclusion of studies will be guided by the Participants-Interventions-Comparators-Outcomes-Studies (PICOS) as shown in table 1.

According to the PICOS (table 1), the following eligibility criteria for the inclusion of studies will be applied:

- Describing the characteristics of patients with a diseaserelated health condition that can be categorised under the International Classification of Diseases 11th Revision.
- 2. Describing TM interventions that are applied within the modalities of herbal medicine, acupuncture, moxibustion, cupping, manual therapies, mind-body thera-

Table 1 Participants-Interventions-Comparators-Outcomes-Studies (PICOS)

PICOS	Descriptions
Participants	Patients treated for any disease-related health condition in all age groups.
Interventions	TM interventions that are applied within the modalities of herbal medicine, acupuncture, moxibustion, cupping, manual therapies, mind-body therapies or aromatherapy.
Comparators	Placebo, conventional medical treatment, standard care, other active therapy or waiting-list control.
Outcomes	The extent, distribution and quality of SRs of different TM interventions and their distribution across a broad range of disease classifications.
Studies	Peer-reviewed SRs of randomised and non- randomised clinical trials evaluating the effectiveness of a TM intervention.
SR. systematic	review: TM. traditional medicine.

pies or aromatherapy. Considering the broad scope of TM included in this systematic map, the inclusion of these intervention modalities is defined and narrowed as follows:

- Herbal medicine: Any type of orally administered herbal medicine is eligible, including decoction and herbal patent medicine. Herbal injections or topical medications are not considered.
- Acupuncture: Acupuncture in any form of stimulation is included. Studies on acupuncture types such as pharmacopuncture, acupotomy, and auricular acupuncture, thread-embedding acupuncture are excluded.
- Moxibustion: Any form of moxibustion, direct or indirect, is eligible.
- Cupping: Any form of cupping, wet or dry cupping, is eligible.
- Manual therapies: Therapies that include manual manipulation involving TM meridians and points such as Tuina/Chuna, and acupressure are eligible.
- Mind-body therapies: TM-related mind-body therapies such as Yoga, Tai Chi and Qi Gong are eligible.
- Aromatherapy: Any form of aromatherapy is eligible.
- 3. Using a placebo, conventional medical treatment, standard care, other active therapy or waiting-list control as a comparator.
- 4. Report on at least one disease-related health outcome after a TM intervention.
- 5. Peer-reviewed SRs of clinical studies that evaluate the effectiveness of a TM intervention will be included. Hence, to be included, SRs should (a) perform a comprehensive search in at least two core databases; (b) describe the methodology in detail, including search strategies and eligibility criteria and (c) conduct a

Table 2 Search strat TM intervention	Search terms
Overall traditional medicine	"Medicine, Traditional" [MH] OR "Complementary Therapies" [MH] OR "Medicine, Korean Traditional" [MH] OR "Medicine, Chinese Traditional" [MH] OR "Medicine, Mongolian Traditional" [MH] OR "Medicine, Tibetan Traditional" [MH] OR "Medicine, Kampo" [MH] OR "Medicine, African Traditional" [MH] OR "Medicine, Ayurvedic" [MH] OR "Medicine, Persian" [MH] OR "Medicine, Arabic" [MH] OR "Traditional medicine*" [TIAB] OR Ayurved* [TIAB] OR "alternative medicine" [TIAB] OR "alternative therapies" [TIAB] OR "complementary medicine" [TIAB] OR "complementary therapies" [TIAB] OR "integrative medicine" [TIAB] OR "integrated medicine" [TIAB] OR "traditional Chinese medicine" [TIAB] OR "Chinese medicine*" [TIAB] OR "traditional Korean medicine" [TIAB] OR Kampo [TIAB] OR "Persian medicine" [TIAB] OR "traditional African medicine" [TIAB] OR "traditional medicine in America*" [TIAB] OR "Oriental medicine*" [TIAB] OR "traditional Oriental medicine" [TIAB] OR TCM [TIAB] OR KM [TIAB]
Herbal medicine	"Herbal Medicine" [MH] OR Phytotherapy [MH] OR "Drugs, Chinese herbal" [MH] OR "herbal medicine" [TIAB] OR "medicinal plants" [TIAB] OR herb* [TIAB] OR prescription [TIAB] OR decoction [TIAB] OR tang [TIAB] OR capsule [TIAB] OR powder [TIAB] OR botanic* [TIAB]
Acupuncture	Acupuncture[MH] OR "Acupuncture Points" [MH] OR "Acupuncture Therapy" [MH] OR "Dry Needling" [MH] OR Electroacupuncture [MH] OR "Electric Stimulation Therapy" [MH] OR "Acupuncture, Ear" [MH] OR Auriculotherapy [MH] OR "Bee Venoms" [MH] OR Apitherapy [MH] OR acupuncture [TW] OR acupoint* [TW] OR needle* [TW] OR needling [TW] OR electroacupuncture [TW] OR electroacupuncture [TW] OR "electric stimulation therap*" [TIAB] OR pharmacopuncture [TW] OR pharmacoacupuncture [TW] OR "herbal injection" [TIAB] OR "ear point" [TIAB] OR threadembedding [TIAB] OR needle embedding [TIAB] OR "embedding therapy" [TIAB] OR "catgut embedding" [TIAB] OR "catgut implantation" [TIAB] OR "bee venom* therapy" [TIAB] OR apitherapy [TIAB] OR "trigger point*" [TIAB] OR acupotom* [TIAB] OR "needle-knife" [TIAB] OR miniscalpel [TIAB]
Manual therapies	Chiropractic[MH] OR "Manipulation, Chiropractic" [MH] OR Acupressure [MH] OR tuina [TIAB] OR "tuina" [TIAB] OR chiropractic [TIAB] OR "Chinese manipulation" [TIAB] OR chiropractic [TIAB] OR acupressure [TIAB]
Moxibustion	Moxibustion[MH] OR moxibustion[TIAB] OR moxa[TIAB] OR mugwort[TIAB]
Cupping	Bloodletting[MH] OR "Cupping Therapy"[MH] OR bloodletting[TIAB] OR "blood letting"[TIAB] OR cupping[TIAB] OR "pricking blood therapy"[TIAB] OR Hijama[TIAB] OR "ba guan"[TIAB] OR baguan[TIAB] OR schröpfen[TIAB]
Mind-body therapies	Yoga[MH] OR yoga[TIAB] OR Asana[TIAB] OR Pranayama[TIAB] OR Dhyana[TIAB] OR Panchakarma[TIAB] OR Meditation[MH] OR meditation[TIAB] OR "Tai ji"[MH] OR "Tai ji"[TIAB] OR Taiji[TIAB] OR "Tai chi"[TIAB] OR taichi[TIAB] OR "Tai ji quan"[TIAB] OR "Tai chi chuan"[TIAB] OR Qigong[MH] OR qigong[TIAB] OR "qi gong"[TIAB] OR "chi gong"[TIAB] OR "chi kung"[TIAB] OR "chi gung"[TIAB]
Aromatherapy	Aromatherapy[MH] OR odorants[MH] OR aroma*[TIAB] OR aromatherap*[TIAB] OR "aroma therapy"[TIAB] OR oil[TIAB] OR oils[TIAB]
Reviews	"Meta-Analysis as Topic"[MH] OR "Review Literature as Topic"[MH] OR "Systematic Reviews as Topic"[MH] OR "Systematic Review"[PT] OR Meta-Analysis[PT] OR "meta analy*"[TIAB] OR review*[TIAB] OR meta-analysis[TIAB] OR metareview*[TIAB] OR "systematic map"[TIAB]

quality assessment of included primary studies using a validated tool. SRs that include both randomised controlled trials and non-randomised trials will be included. SRs that use either a narrative synthesis and/ or meta-analysis will be included. The following SRs will be excluded: (a) published as abstract only, thesis or dissertation; (b) SRs of studies other than intervention studies such as diagnostic methods, animal and preclinical studies, safety/pharmacovigilance studies, and pharmacokinetic or pharmacodynamic trials and (c) and SRs with network meta-analysis; SRs of studies other than treatment-related interventions, such as preventive intervention studies other than those for disease complication prevention.

6. SRs that have been conducted in any setting, context or country worldwide.

Information sources

We will search 17 databases: PubMed, Embase, Cochrane Database of Systematic Reviews (CDSR), Allied and Complementary Medicine Database (AMED), Virtual Health Library (VHL), Web of Science, Scopus, China National Knowledge Infrastructure (CNKI), Wanfang database, Chinese Scientific Journal Database (VIP), Research Information Sharing Service (RISS), KoreaMed, Korean Studies Information Service System (KISS), Oriental Medicine Advanced Searching Integrated System (OASIS), Ichushi Web, Latin American

Table 3 Data extraction form	
Items	Extracted data details
General information	Study ID, first author, year of publication, country, review design, sample size
Patient information	Classification of disease according to ICD- 11, age category, gender
Study information	No and type of studies in the review, meta- analysis included
Intervention	Type of intervention(s)
Outcomes	Extent of SRs across specific health condition(s)
ICD-11, International Classification of Diseases 11th Revision; SR,	

and Caribbean Health Sciences Literature (LILACS) and Epistemonikos database.

Search strategy

systematic review.

The initial search strategy is developed for the PubMed database using subject headings, keywords, index terms and free-text words that describe TM interventions (see table 2). Search strategies for the other databases will be adapted and translated by modifying the vocabulary, search-field descriptor and topic focus as necessary. The literature time frame will be from the last 5 years, starting with January 2018 and ending with December 2022. No demographic, language or geographical restrictions will be imposed.

Selection process

Search results from multiple databases of the same language will be merged using EndNote reference management software and duplicates will be removed. Two reviewers will independently and in duplicate screen titles and abstracts to identify relevant studies for full-text review and will independently screen full texts for final inclusion. Disagreements will be resolved by consensus among reviewers through discussion. The number of studies identified, screened, included and excluded will be reported in a flow chart in accordance with the PRISMA guideline. ¹⁶

Data collection process

Two reviewers will independently extract data from each article in a piloted data extraction form. The data extraction form will be developed and piloted by all reviewers on five SRs before being applied. Items that are planned to be included in the data extraction form are listed in table 3. Discrepancies in the data extracted will be resolved by discussion and reaching consensus among the different reviewers.

Outcomes

The main outcome of this study is to produce a systematic map that visualises the extent and quality of SRs as well as their distribution across the various TM modalities

and disease classifications. The extent and quality of SRs will be mapped in relation to other outcomes such as across the different continents, countries, gender and age groups as well as the different types and number of clinical studies included in SRs, the number of meta-analyses in SRs, and the average sample sizes in SRs.

Quality assessment

Two reviewers will independently assess the methodological quality of each included SR using the A MeaSurement Tool to Assess Systematic Reviews (AMSTAR) 2 tool. 17 AMSTAR 2 is a 16-item assessment tool to evaluate the quality of SRs. The overall confidence in the SR will be rated as high, moderate, low or critically low, based on the seven critical domains that could affect the validity of the SRs. The seven domains include protocol preregistration, adequacy of search, justification of excluded studies, risk of bias, meta-analytical methods, considering bias when interpreting results and assessment of publication bias. Any disagreements in the ratings will be resolved by discussion and reaching a consensus. The quality assessments between pairs of reviewers will first be calibrated through the assessment of the first five included SRs and discussing discrepancies in the assessment before assessing the rest of the included studies.

Data analysis and presentation

For the main outcome, the extent of SRs will be calculated as total numbers and percentage of all SRs. The quality of SRs will be rated as high, moderate, low or critically low by means of the AMSTAR 2 tool. 17 Descriptive statistics such as average sample size and percentage of study designs will be carried out using R Statistical Software (V.4.1.2; R Core Team 2021. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. https://www.R-project. org/). Outcomes will be presented as a visual database of the nature and extent of SRs across specific disease classifications. For non-interactive data visualisation, bubble plots will be used as the main visualisation presentation of the systematic map. For interactive data visualisation, an evidence-gap map will be designed and generated using EPPI-Mapper to provide links that provide bibliographic data of the included studies. Furthermore, an overview of the main findings will be provided in a narrative form and will include an analysis of the gaps and under-researched areas, as well as discuss the priorities for new evidence syntheses and primary research on TM.

Patient and public involvement

This study describes the protocol for a systematic map of SR on TM as published in the scientific literature. Therefore, there is no involvement of patients in this work. We actively involved international experts in TM practice and research in developing the protocol, covering a diverse range of TM modalities such as acupuncture, manual manipulation, yoga, Tai Chi.

DISCUSSION

This systematic map will be the first comprehensive overview summarising the existing SRs of multiple TM interventions across a broad range of disease classifications and health conditions. The mapping will help us identify how TM has been examined with respect to the type of interventions and health conditions; thereby identifying gaps in the evaluation by SRs or only by SRs of low and critically low quality. The study will further enable us to identify knowledge gaps and clusters by comparing the key research findings identified in the available literature. We will also consult with other experts and key stakeholders to obtain further insights regarding the identification of knowledge gaps and the interpretation of our findings. This systematic map, therefore, will support the WHO and other healthcare policymakers in resource allocation decisions and inform the best use of TM interventions; and also support researchers to design high-quality clinical trials of the available evidence-based interventions and guide further research directions.

A strength of this study is that it will be performed by a large international and multidisciplinary team from nine countries, including South Korea, China (including Hong Kong), Japan, Norway, Canada, Australia, UK, the USA and Germany. The research team has extensive experience in the field of EBM and SR. Within this large research team, a technical expert group of researchers from the Korea Institute of Oriental Medicine, Norway's National Research Center in Complementary and Alternative Medicine, and other collaborating institutions will carry out all stages of this study. Additionally, experts from the WHO and the Pan American Health Organization will provide comments and advise the research team at each stage of the study. Other strengths of this study are the rigorous systematic methodology that will be applied and the broad range of TM modalities and disease classifications that will be mapped.

Due to the broad field of TM, it is an obvious limitation that this systematic map, after consultation with experts, will focus on a selection of the most applied TM modalities. Thereby, this systematic map will, thus, not provide an inclusive overview of SRs for all TM modalities worldwide. Furthermore, we expect that a high number (thousands) of SRs will meet the eligibility criteria for inclusion in this study. Based on this expected high number and the short timeframe of the study as commissioned by the WHO, it is not feasible to screen lists of included studies or consult other content experts in the TM field about other possible eligible SRs. Therefore, relevant SRs may be missed despite the wide coverage of databases and the use of robust search strategies. Another limitation of this study is that our findings are reliant on the information provided in the SRs, which may be affected by the reporting quality and may not reflect the actual research quality of the included primary studies. The fact that we will not perform a type of evidence analysis of the included TM interventions across the disease classifications could

be considered another limitation of this study, but is beyond the scope of a mapping review.

This study will provide valuable information regarding evidence of TM and possible evidence gap in the research literature. The study will lay a foundation to prioritise for future evidence syntheses in TM. Based on our findings and as a next step, further studies can be initiated and prioritised to analyse the evidence levels of TM interventions in more detail. The findings of this study will be used by the relevant national/international stakeholders, global health policy-makers, the WHO and the public.

ETHICS AND DISSEMINATION

Ethical approval is not required as this is a systematic map of published studies. The findings of the study will be disseminated through online-available maps, presentations and scientific publications under the guidance of WHO, complying with their internal clearance.

Study status

The study began in February 2023 with the performance of preliminary searches. Data extraction started in April 2023 and is estimated to be completed at the end of July 2023. Data analysis and reporting are planned for October 2023. The estimated study end date is planned at the end of year 2023.

Contributors LA, ES and MSL conceptualised and designed this work. MCJ refined the research question and eligibility criteria. LA drafted the original work. MSL, ES, MCJ, TA, BW, T-YC, JHJ, BL, YC, HWL and CY made significant contributions to the drafting of the protocol and provided critical revisions. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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