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Protocol for a Scoping Review of Traditional Medicine Research Methods, Methodologies, Frameworks and Strategies

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Corresponding author:

Jennifer Hunter

drjenniferhunter@healthresearchgroup.com.au

Author Affiliation:

Health Research Group Pty. Limited.

Hunter, J¹; Ijaz, N²; Grant, S³; Templeman, K⁴.

ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 November 2023 and was last updated on 17 November 2023.

INTRODUCTION

Review question / Objective This scoping review aims to summarize and characterize the range of research approaches (i.e., methods, methodologies, frameworks and strategies) used to study TM systems and practices and describe the ‘paradigmatic alignment’ of these research approaches with the TM being studied.

Background In the 2014-2023 Traditional Medicine Strategy, the World Health Organization (WHO) recommended that traditional medicine (TM) “research should use methods which are generally accepted in the evaluation of health services” (1). TM is often rooted in paradigms whose underlying ontologies, epistemologies and

practices – that is, ways of being, knowing and doing – differ from more dominant biomedical paradigms. This can pose challenges for TM researchers when the dominant research paradigms do not closely align with the TM being studied.

The term paradigm has been applied across various fields and disciplines and is widely used to characterize “the entire constellation of beliefs, values, techniques, and so on shared by the members of a given community” (2). Grounded in the work of research methodologists, who have extensively explored the concept of a ‘research paradigm’ in recent decades, this Scoping Review defines paradigms to encompass three central elements: ontology (understandings about how reality is constituted); epistemology (how knowledge is acquired and constructed), and

practice (e.g., methodologies or techniques used within a paradigmatic community) (3,4). This definition also echoes the work of Indigenous scholars, who characterize ‘worldview’ to include ‘ways of being, knowing and doing’ (5,6): a threefold construct analogous to the present work’s differentiation between ontology, epistemology and practice within the concept of ‘paradigm’.

Discussion continues about which research approaches are best suited to studying TM. Scholars in the biomedical (7,8) and TM fields (9–11), as well as Indigenous scholars (12,13), have critiqued the limitations of many dominant health research norms. In parallel, biomedical paradigms are shifting away from a reductionist understanding of disease and health towards person-centered care, biopsychosocial models, systems-based thinking, and complexity science. This has led to the development of approaches to research and evidence syntheses that are better suited to evaluating healthcare interventions, including many TM systems and modalities, that are characterized by high intervention complexity. Indeed, the past 20 years have witnessed an exponential growth in TM research and evidence syntheses. However, systematic literature reviews examining the grounding of this research within TM paradigms, which are multiple and diverse, are lacking.

Rationale Scoping review methods will be applied for this descriptive, exploratory review, which seeks neither to evaluate the evidence for TM nor to conduct a bibliometric analysis or exhaustive literature review (14). In line with JBI guidance, an a priori conceptual framework – provisionally termed ‘paradigmatic alignment’ (see: Eligibility criteria) – will guide the review sub-questions, eligibility criteria, search strategy, data extraction, and analysis plan (14). Conceptual frameworks may be a “critical element in effectively focusing the review and designing the methods to respond to the knowledge question” (15).

This scoping review and its conceptual framework represent an important step towards exploring how various approaches to TM research may align with the diverse global range of TM paradigms (including knowledges, concepts, theories, beliefs, and practices). The findings from this review will be used to inform additional reviews on related topics, such as enablers and barriers to TM research. It is anticipated the review will also be relevant to the field of TM research and health research more broadly. The inclusion of a wide range of research approaches, research domains, and TM types, aims to optimize the utility of the findings equally for researchers and for communities, practitioners, decision-makers, and policy.

METHODS

Strategy of data synthesis Searches of electronic databases will be staggered. This will begin with a protocol-driven searches designed for the English language on the following databases: Academic Search Complete, Allied and Complementary Medicine Database (AMED), Anthropology Plus, CINAHL Complete, EBM Reviews - Cochrane Methodology, Humanities Source Ultimate, MEDLINE, PsycINFO, Psychology and Behavioral Sciences Collection, Sociology Source Ultimate, and the WHO Global Index Medicus databases (African Index Medicus (AIM), Index Medicus for the Eastern Mediterranean Region (IMEMR), Index Medicus for the South-East Asia Region (IMSEAR), Latin American and Caribbean Health Sciences Literature (LILACS), and Western Pacific Region Index Medicus (WPRO)).

When data saturation is not reached for a research approach, TM type, or context, additional focused regional and/or language specific database searches will be conducted on the WHO Global Index Medicus databases, African Journals Online (AJOL), Applied Social Sciences Index and Abstracts (ASSIA), AYUSH Research portal, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journals Database (VIP), Digital Helpline for Ayurveda Research Articles (DHARA), Electronic (J-STAGE), eMarefa (Digital Arabic Database), Ethnic NewsWatch, Embase, Google Scholar, Indexing of Indian Medical Journals (INDMED), Japan Medical Abstracts Society (Ichushi-Web), Japan Science and Technology Information Aggregator, Korean studies Information Service System (KISS), Scopus, Thai Journals Online (ThaiJO), Wanfang Data, and Web of Science Core Collection.

Free-text and standardized search terms will reflect general overarching TM terms (e.g., “Traditional Medicine”, “Folk Medicine”, “Complementary Medicine”, “Integrative Medicine”), Indigenous health care approaches (e.g., “Bush Medicine”, “Indigenous Healing”, “Kahuna”, “Rongoa”), TM systems (e.g., “Ayurveda”, “Chiropractic”, “Kampo”, “Naturopathy”, “Osteopathy”, “Persian Medicine”, “Siddha”, “Traditional African Medicine”, “Traditional Chinese Medicine”, “Unani”, “Yoga”), overarching terms for botanicals and nutraceuticals (e.g., “Ethnopharmacology”, “Botanicals”, “Herbal Medicine”, “Jamu”, “Nutraceuticals”, “Phytotherapy”), and terms for individual TM modalities and therapies (e.g., “Acupuncture”, “Apitherapy”, “Balneotherapy”, “Cupping”, “Iridology”, “Meditation”, “Qi Gong”, “Shamanism”, “Shiatsu”, “Swedish Massage”, “Touch Therapy”, “Urine Therapy”, “Voodoo”). TM

terms will be combined with terms for research approaches (e.g., “methodology”, “methodological approach”, “research standard”, “effectiveness guidance document”, “framework”, “consensus statement”), terms for methodological approaches for evaluating complex phenomena (e.g., “program theory”, “logic theory”, “model validity”, “mixed method”, “realist”, “complexity science”, “implementation science”) and other relevant concepts (e.g., “epistemology”, “paradigm”, “Two-Eyed Seeing”).

The English-language TM terms will be informed by an operational definition of complementary, alternative and integrative medicine that was established for literature searching (16) and a TM typology proposed by Ijaz (17). Search terms will be adjusted according to the database syntax. Non-English-language searches will reflect, and expand upon, the search terms. Except for some of the additional, supplementary searches, databases will be searched from inception.

Protocol-driven database searches will be supplemented with documents known to the review team or provided by knowledge users via regional outreach and consultation, and through citation tracking, pearl growing/snowballing (18) and CLUSTER searching (19). All potential documents will be screened according to the review’s eligibility criteria.

Eligibility criteria

POPULATION

All populations engaged in any type of TM research (including animal studies) are included (e.g., consumers, patients, caregivers, practitioners, communities, researchers, funders, and other knowledge users). Populations not engaged in research or only engaged in research that does not include TM are excluded. However, populations engaged in both TM research and other research are included. Also excluded are other research or activities involving humans that do not pertain to health or health care, including self-care, along with research for other purposes such as veterinary, agriculture, or the environment.

CONCEPTS

TRADITIONAL MEDICINE. Any form of TM that aligns with the WHO’s definition of traditional medicine is included (1). The definition encompasses both codified and non-codified traditional and Indigenous medicine as well as complementary and integrative medicine modalities and approaches (17). To address the review’s conceptual framework of paradigmatic alignment, when determining data saturation an emphasis will be placed on TM whole systems (e.g., Anthroposophy, Ayurveda, Chiropractic, Homeopathy, Indigenous TM, Naturopathy,

Osteopathy, Siddha, Traditional East Asian Medicine, Unani, Yoga etc.) and their concomitant practices (e.g., acupuncture, apitherapy, balneotherapy, cupping, herbal medicine, massage, shamanism, tai chi etc.) (17). Lesser emphasis will be placed on therapeutic practices historically rooted in TM but now removed from their paradigmatic frameworks of origin (e.g., medical acupuncture, some herbs and dietary supplements). Excluded interventions are therapeutic approaches solely informed by biomedicine theory and practice, and drugs with natural ingredients or derivatives almost exclusively used in biomedical settings (e.g., digitalis for cardiac conditions or vitamin K for neonates) (20). Conventional biomedicine, when used alongside or integrated with TM, is included.

RESEARCH APPROACHES. The included ‘research approaches’ are the methods, methodologies, frameworks, and strategies applied in TM research. Methods are the techniques and tools used to gather, analyze or report research data. Research methodology theoretically outlines how research is conducted in a specified field. Research frameworks provide the rationale and/or guidelines for conducting research. Research strategies are organized plans to achieve a research goal that may be applied to a single research project or to a research program or field, including nationally or internationally.

PARADIGMATIC ALIGNMENT. The review’s conceptual framework – provisionally termed ‘paradigmatic alignment’ – refers to the ways different research and TM therapeutic paradigms align. This framework will be operationalized using the principle of Two-Eyed Seeing (Etuaptmumk) and the TM-specific use of the ‘model validity’ concept.

Research methodologists have extensively elaborated on a range of ‘research paradigms’ (e.g., positivism, constructivism, interpretivism, Indigenous research paradigms) and their suitability across different purposes and contexts (3,4). While no research methodology belongs absolutely or exclusively to a single research paradigm, some research approaches align well with certain research paradigms. For instance, quantitative methods tend to align with the positivist paradigm, whilst qualitative methods tend to align with constructivism and interpretivism (4). Further, it is well recognized that positivist and post-positivist research paradigms (and associated quantitative methodologies, like randomized controlled trials) are socio-politically privileged over other research paradigms (and approaches) (3,4,7). While the concept of a ‘therapeutic paradigm’ is widely used across biomedical and TM literatures, it is yet to be extensively theorized.

Notwithstanding, educationalists within multiple healthcare fields have elaborated on how therapeutic and disciplinary paradigms and their associated clinical practice are shaped by the ontologies and epistemologies of both the individual practitioner and their profession (21,22). Notably, the biomedical paradigm tends to hold greater political power globally than TM therapeutic paradigms (23).

Two-Eyed Seeing (Etuaptmumk) (24) is a principle wherein Indigenous, traditional and biomedical knowledges may equitably co-exist. This principle is closely related to the concepts of epistemic pluralism and epistemic equity. Epistemic pluralism refers to the co-existence of different epistemologies, typically within a context of differential power relations (25). Epistemic equity asserts that diverse epistemologies and their unique contributions should be fairly and appropriately valued according to their distinct contributions (25).

The TM-specific meaning of the term ‘model validity’, which affirms the importance of aligning clinical research methods and study designs with the TM being studied (9,26–29), will be used for this review. Over the past three decades, TM clinical researchers have developed and applied criteria for critically appraising the model validity of TM clinical research (26–29). ‘Model validity’ was also used as a conceptual framework in a scoping review of TM whole systems research (9). Model validity was described as “a theoretical construct, [that] represents a commitment to actively preserving these [TM] paradigms and practices in their own right” (9). Due to its broader applicability to of the included research approaches, this construct (9) will be used in this review. Additionally, this construct echoes the WHO’s commitment, articulated in the 2014–2023 TM Strategy, to “protect traditional knowledge” (1).

Examples of paradigmatic alignment relevant to this review are:

1. Community-based participatory research methods combined with culture-specific Indigenous methods such as Storytelling (30);
2. Indigenous-led research where Indigenous knowledge, ethnobotanical methods, and preclinical research are used side by side (31);
3. Innovative applications of preclinical methods to investigate herbal medicine synergism with reference to TM theories (32);
4. Pragmatic trials that adapt standard clinical trial methods and real-world data to study complex TM interventions as normally practiced (9);
5. Clinical trial eligibility criteria that requires dual biomedical and TM diagnoses (9);
6. Various TM-focused extensions to the CONSORT and PRISMA reporting guidelines; and

7. Guidelines for clinical practice or evidence synthesis that considers both TM knowledge and empirical research.

CONTEXTS

RESEARCH DOMAINS. Included are all TM research domains (e.g., basic science research, preclinical research, clinical research, health services research, health technology assessments, economic analyses, social sciences and ethnomedicine research, implementation research, or policy research). While research approaches that apply Indigenous research methodologies are included, research ‘of’ Indigenous peoples is only included if the focus is TM/Indigenous worldviews (e.g., ways of being, knowing and doing).

RESEARCH SETTINGS. All geographical locations, countries, and regions (irrespective of whether the TM being researched is part of a region’s own tradition), and cultural and health care settings (e.g., community, self-care, primary care, secondary care, integrative or traditional healthcare, clinical or non-clinical settings) are included.

Source of evidence screening and selection

Included evidence sources are primary and secondary research articles, viewpoint and opinion articles, and editorials published in peer-reviewed journals, grey literature (e.g., research theses, guidelines, white papers, reports, and policy documents), and books and book chapters. Conference proceedings, letters to journals, websites and other evidence sources are excluded unless this is the only or best available source. There are no language or date restrictions.

In accordance with the eligibility criteria, the evidence sources included in this review will:

1. Describe the range and characteristics of research approaches used to study TM systems and practices;
2. Critique TM research approaches;
3. Articulate a rationale for developing, implementing, or applying TM research;
4. Provide examples of TM-specific adaptations or alternatives to common biomedical research approaches and/or discuss the rationale; or
5. Provide guidance or strategies for TM research.

Excluded are:

1. Primary and secondary studies, including reviews of clinical practice guidelines, where there is absolutely nothing relevant to the review’s research question;
2. Reviews and other evidence sources that only evaluate intervention outcomes, mechanisms of action, and/or their study quality; and
3. Reviews, bibliometric analyses, and other evidence sources that do not report details about the research approaches.

Following calibration exercises, two reviewers will independently screen the titles and abstracts and the full papers of the shortlisted articles using Covidence systematic review software. Inter-rater reliability will be checked and reported using the Covidence functions. If inter-rater reliability is high (e.g., percentage agreement > 80%), and the number of citations to be screened is large (e.g., >10,000), rapid review methods may be applied where single reviewers screen articles and another rescreens the rejected articles. Disagreements will be resolved through consensus.

Data management Databases searches in RIS format will first be uploaded into EndNote 20 software for automatic duplicate identification, and then into Covidence systematic review software for duplicate identification, title/abstract screening, full-text screening, and data extraction of article characteristics. Data will then be exported in electronic spreadsheets. Taguette software will be used to support qualitative data analyses. Alternate comparable methods will be used when this is not feasible.

Following calibration exercises, one reviewer will extract the data into a pre-piloted data extraction form in Covidence systematic review software. Another reviewer will check the accuracy of the extracted data. Disagreements will be resolved through consensus. The study authors/investigators will be contacted for missing or additional data, or for clarification.

Reporting results / Analysis of the evidence JBI guidance for scoping reviews will inform the analysis (14). This will begin by describing the characteristics of the evidence sources (e.g., citation details, publication type and year, countries of authors, declarations), their relevance to the review questions, the research approaches discussed or applied across the research domains, and their application to different types of TM, populations, settings, regions, and countries. Substantial heterogeneity in the data is anticipated due to the broad, diverse sampling frame. Following data immersion, additional qualitative methods such as content analysis (33), thematic analysis (33), and ‘following the thread’ (34) will be used to further sort, code and categorize the data and describe its relevance to the review’s questions and conceptual framework.

Due to the review’s exploratory character, research sub-questions may be further refined within the conceptual framework as the analysis proceeds. This may include descriptions of how TM research rigor and quality is defined, determined and evaluated, and in what ways TM scholars are

discussing or applying the review’s concepts of interest.

Quality assessments and risk of bias assessments will not be conducted as it is not the purpose of this review. However, the JBI Critical Appraisal Tools (35), which includes guidance on text and opinion papers, will be applied prior to conducting an in-depth analysis of documents that were not published in a peer review journal. Additionally, information about how research quality is defined and applied in TM will be reported.

Presentation of the results Narrative and tabulated summaries of the findings of the document characteristics and the research approaches applied or discussed will be reported, along with figures when deemed useful. To facilitate knowledge user engagement, we aim to present illustrative exemplars representing different regions and TM disciplines. The PRISMA Extension for Scoping Reviews (36), along with relevant additional reporting requirements that are outlined in the updated PRISMA 2020 statement (36), will be followed.

Language restriction There are no language restrictions. All attempts will be made to translate relevant documents.

Country(ies) involved Reviewers from Canada and Australia will lead the study. The broader Review Team includes over 25 researchers located in 13 countries that combined represent all six WHO regions.

Keywords Traditional medicine; Complementary therapies; Research methods; Methodology; Epistemology; Paradigm; Scoping review.

Contributions of each author

Author 1 - Jennifer Hunter - Author 1. Conceptualization, Methodology, Validation, Writing - Original Draft, Writing - Review & Editing, Funding acquisition, Project Administration. drjenniferhunter@healthresearchgroup.com.au

Author 2 - Nadine Ijaz - Author 2. Conceptualization, Methodology, Validation, Writing - Original Draft, Writing - Review & Editing, Funding acquisition, Project Administration. nadine.ijaz@carleton.ca

Author 3 - Suzanne Grant - Author 3. Methodology, Validation, Writing - Review & Editing. s.grant@westernsydney.edu.au

Author 4 - Kate Templeman - Author 4. Methodology, Validation, Writing - Review & Editing, Project Administration. k.templeman@westernsydney.edu.au

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