

INPLASY

Theory-informed frameworks, dimensions, and indicators for process evaluation of acupuncture as a complex intervention: a scoping review protocol

INPLASY202690042

doi: 10.37766/inplasy2026.9.0042

Received: 9 September 2026

Published: 9 September 2026

Wang, YY; Hao, QZ; Hu, XY; Yin, H; Li, X; Han, M; Cao, HJ; Liu, JP.

Corresponding author:

Jianping Liu

20240941073@bucm.edu.cn

Author Affiliation:

Hospital of Chengdu University of
Traditional Chinese Medicine;
Beijing University of Chinese
Medicine.

ADMINISTRATIVE INFORMATION**Support** - Longitudinal Development Fund.**Review Stage at time of this submission** - The review has not yet started.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202690042**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 September 2026 and was last updated on 9 September 2026.**INTRODUCTION**

Review question / Objective Primary objective: To systematically identify, map, and theoretically organise frameworks, models, dimensions, indicators, tools, and reporting items used to evaluate the processes of acupuncture as a complex intervention, and to develop an evidence-informed architecture that distinguishes a shared core from routine clinical-practice and RCT-specific modules.

Review questions:

- 1.Which theories, frameworks, and models have been proposed or applied to evaluate acupuncture intervention processes?
- 2.Which dimensions, constructs, indicators, operational definitions, and data-collection methods have been used?
- 3.Which tools, scales, checklists, or quality-control instruments have been developed or applied, and what measurement properties are reported?
- 4.How are implementation, mechanisms of impact, context, fidelity, adaptation, and causal assumptions conceptualised and assessed?

5.Which implementation-science models are suitable for acupuncture, for which functions and at which ecological or organisational levels?

6.Which constructs are shared between routine clinical practice and RCTs, and which require setting-specific modules?

7.Where are the principal conceptual, measurement, implementation, and reporting gaps?

Background Acupuncture is a multicomponent intervention whose delivery and effects may depend on diagnostic reasoning, point selection and modification, needling technique and stimulation, de qi and other participant responses, practitioner competence, therapeutic interaction, co-interventions, service organisation, and wider context. Outcome evaluation alone cannot determine whether acupuncture was delivered as intended, through which mechanisms change occurred, or why outcomes differ between patients, practitioners, sites, and study designs. Process evaluation examines implementation, mechanisms of impact, and context, but

acupuncture-relevant concepts and measures are dispersed across clinical trials, qualitative studies, fidelity and quality-control research, measurement studies, implementation studies, methodological papers, guidelines, consensus work, and reporting initiatives.

Rationale Existing reviews predominantly address effectiveness, safety, or intervention-reporting completeness and do not provide an integrated theory-informed map of acupuncture process evaluation. Generic complex-intervention and implementation-science models offer different functions and cannot be treated as interchangeable checklists. Routine clinical practice permits diagnosis-led adaptation and is shaped by continuity, workflow, payment, access, and organisational integration, whereas RCTs additionally require protocol specification, bounded tailoring, practitioner training, comparator differentiation, contamination control, blinding-related behaviour, and explicit process-outcome linkage. Mapping these elements is necessary to support later Delphi consensus, operationalisation, and empirical testing of an acupuncture-sensitive process-evaluation system.

METHODS

Strategy of data synthesis Information sources and search concepts:

From database inception to the final search date, the review will search PubMed, Web of Science Core Collection, the Cochrane Library, the JBI evidence resource available to the team, China National Knowledge Infrastructure (CNKI), Wanfang Data, VIP Database, and China Biology Medicine (CBM). Search concepts will combine acupuncture and related modalities with process evaluation, complex intervention, implementation, mechanism, context, fidelity, adherence, dose, reach, acceptability, adaptation, quality control, standardisation, theory, framework, model, indicator, instrument, measurement, and reporting guidance. Controlled vocabulary and free-text terms will be adapted to each source. Backward and forward citation searching and targeted searches for named frameworks and tools will supplement database searches.

Synthesis:

Publication characteristics will be summarised descriptively. Each distinct framework/model will form one analytic record and will be classified by primary function, theoretical provenance, construct coverage, acupuncture-specific adaptation, and applicability to routine practice, RCTs, or both. Constructs and indicators will be charted in long format and mapped deductively to implementation,

mechanisms, and context while retaining inductively derived acupuncture-specific categories. Frameworks will be assessed for functional complementarity rather than ranked solely by frequency. MRC guidance will provide the organising structure; logic modelling, realist context-mechanism-outcome reasoning, CFIR, fidelity/adaptation approaches, Proctor implementation outcomes, RE-AIM, and Normalization Process Theory will be considered where they contribute distinct analytic functions. No meta-analysis of clinical effectiveness will be conducted.

Eligibility criteria Population:

Recipients of acupuncture-related interventions and stakeholders involved in their design, delivery, evaluation, implementation, governance, or use, including practitioners, researchers, service managers, caregivers, and guideline or policy personnel.

Concept:

Sources must explicitly propose, apply, define, measure, or report at least one theory, framework, model, dimension, indicator, tool, operational definition, data-collection method, quality-control approach, or reporting item relevant to implementation, mechanisms, context, fidelity, dose, reach, acceptability, adaptation, treatment adequacy, practitioner factors, participant responses, therapeutic interaction, or process quality in acupuncture.

Context:

Any clinical, research, community, educational, or health-system setting, without restriction by country, care sector, or disease area.

Evidence types:

Primary qualitative, quantitative, and mixed-methods studies; trials and protocols with a distinct process component; methodological and measurement studies; theory/framework/model/tool development; guidelines, consensus and Delphi studies; reporting-guideline research; and relevant systematic or scoping evidence syntheses.

Exclusions:

Effectiveness or safety studies without a structured process-evaluation contribution; biological-mechanism studies unrelated to delivery, participant response, or implementation; animal-only or laboratory evidence without a relevant process construct; and non-acupuncture sources when acupuncture-specific or directly transferable methodological information cannot be separated. Commentaries and non-systematic reviews will be excluded unless they introduce a new, explicitly described framework, model, tool, dimension, or indicator contribution.

Core and supplementary evidence tiers:
Core evidence will directly contribute acupuncture-specific process-evaluation concepts or methods. Supplementary evidence will meet eligibility criteria but primarily contribute transferable information on feasibility, acceptability, service delivery, implementation, or adjacent methodology. Tiering will occur after eligibility determination and will not be used to exclude sources.

Source of evidence screening and selection All definitive search results will be imported into the selected reference-management and screening software (NoteExpress V4.3.0.10414) and deduplicated using documented automated and manual procedures. Two reviewers will independently screen titles and abstracts against a pilot-tested manual. Potentially eligible reports will undergo independent duplicate full-text assessment. Disagreements will be resolved by discussion and, when necessary, adjudication by a third reviewer. Reasons for full-text exclusion will be recorded. Multiple reports from the same study or programme will be linked. Screening calibration will be undertaken on a prespecified sample before formal screening. The definitive selection process will be reported in a PRISMA-ScR flow diagram.

Data management Microsoft Excel (Version 2608 Build 16.0.20326.20072) will store search exports and deduplication decisions. Each included publication will receive a Publication ID; related reports will share a Study ID. A pilot-tested long-format charting form will capture bibliographic characteristics; theories/frameworks/models; constructs and indicators; tools and measurement properties; implementation, mechanism, context, fidelity, adaptation, practitioner/patient and relational factors; clinical-practice/RCT applicability; and reporting items. Two reviewers will independently chart or independently verify all decision-critical fields. Source terms, page/table/appendix locations, and standardised labels will be retained. Missing information will be coded as not reported, not applicable, or requiring author/source verification. The definitive dataset will be stored securely, with dated read-only checkpoints and a deviation log.

Reporting results / Analysis of the evidence The review will follow JBI methodological guidance and will be reported using PRISMA-ScR. Descriptive counts and percentages will characterise the evidence base. Framework/model records may be multiply coded for lifecycle stages, construct domains, and adaptations, while each will be assigned one primary functional family using a locked coding manual. Theory-informed analysis

will classify models as process models, determinant frameworks, implementation theories, evaluation frameworks, outcome frameworks, programme theories, or reporting frameworks. Reporting guidance will be distinguished from explanatory theory and measurement instruments. A shared-core-plus-modules architecture will be generated by integrating deductive MRC domains with inductively derived acupuncture-specific constructs. No effectiveness estimate, meta-analysis, or overall quality score will be produced. Formal methodological appraisal will not determine eligibility. If appraisal is added after registration, it will be recorded as an amendment and performed with evidence-type-appropriate tools; its results will inform interpretation rather than exclusion.

Presentation of the results Results will be presented using: (1) a PRISMA-ScR flow diagram; (2) a table of included-source characteristics; (3) a taxonomy of framework/model functional families; (4) an evidence map across intervention lifecycle stages; (5) a model-to-function matrix; (6) a construct/indicator matrix organised by implementation, mechanisms, context, and acupuncture-specific domains; (7) a catalogue of tools and reported measurement properties; (8) a comparison of shared, routine-practice, and RCT-specific modules; and (9) an evidence-gap map. The integrative architecture will be labelled evidence-informed and provisional, not a validated instrument.

Language restriction Searches will not be restricted by language. English- and Chinese-language sources will be assessed directly. Sources in other languages will be included when sufficient information can be obtained.

Country(ies) involved China.

Other relevant information Before this registration, the review team conducted an exploratory pilot on the same topic, including searches, screening, and preliminary charting, to understand the evidence landscape and refine the definitive protocol. The pilot informed the eligibility rules, framework taxonomy, charting fields, and proposed synthesis. Following registration, all searches, deduplication, duplicate selection, charting, and synthesis will be repeated de novo. The review will follow current JBI guidance for scoping reviews and PRISMA-ScR. The 2021 MRC framework for complex interventions and MRC process-evaluation guidance will inform the high-level analytic organisation. STRICTA, TIDieR, and CROP will inform reporting-related analyses but

will not substitute for process measurement or explanatory theory.

Keywords acupuncture; complex intervention; process evaluation; implementation science; programme theory; fidelity; context; scoping review.

Dissemination plans The definitive review will be submitted to a peer-reviewed international journal specialising in systematic review products and methodology. Findings may also be presented at academic conferences and will inform subsequent Delphi consensus and empirical studies within the doctoral programme.

Contributions of each author

Author 1 - Yiyang Wang - Conceived and designed the study, and will oversee the entire research process and contribute to drafting the manuscript.
Email: 1569421525@qq.com

Author 2 - Qiaozhen Hao - Will Contribute data collection and extraction and will perform cross-checking and verification data.
Email: 18801256305@163.com

Author 3 - Xinyu Hu - Is involved in the design process and will perform cross-checking and verification data.
Email: huxinyu200111@163.com

Author 4 - Heng Yin - Will Contribute data collection and extraction, and help English language polishing.
Email: yh@bucm.edu.cn

Author 5 - Xia Li - Will perform data collection and extraction, and help cross-checking and verification data.
Email: mglx1109@163.com

Author 6 - Mei Han - Is involved in critically revising the manuscript.
Email: hanmeizoujin@163.com

Author 7 - Huijuan Cao - Is involved in critically revising the manuscript.
Email: huijuancao327@hotmail.com

Author 8 - Jianping Liu - Is involved in critically revising the manuscript and raise the funding.
Email: liujp@bucm.edu.cn