

Evidence Mapping in Ayurvedic Clinical Trials

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ABSTRACT

Evidence mapping sits between the comprehensive narrative review and the synthesis-focused systematic review in the hierarchy of evidence-synthesis methods. It charts the distribution of clinical trial activity across conditions, interventions, geography, and methodological quality, and its main purpose is to identify where evidence exists, where it is thin, and where systematic review and meta-analysis are actually feasible. Applied to Ayurvedic clinical research, this kind of mapping has been overdue for at least a decade, because the field's perceived lack of evidence and its real lack of synthesisable evidence are genuinely different problems with different solutions. We catalogued 412 Ayurvedic clinical trials published or registered between January 2005 and December 2021, indexed from PubMed, the AYUSH Research Portal, ClinicalTrials.gov, the EU Clinical Trials Register, and the Cochrane Central Register of Controlled Trials. Trials were classified under five mapping frames: F1 (chronic disease management), F2 (acute conditions), F3 (wellness and preventive indications), F4 (Panchakarma procedures), and F5 (integrated multimodal protocols). Each frame was scored with the Ayurvedic Evidence Map Index (AEM), a weighted composite across trial volume, methodological quality, condition breadth, geographic diversity, and synthesis readiness. Chronic disease management (F1) had the largest trial volume and best synthesis readiness (AEM 0.858). Integrated multimodal protocols (F5) scored second (0.802), carried by recent methodological maturation. Acute conditions (F2) scored lowest (0.604), which is not a problem with Ayurveda per se but reflects that clinical practice in Ayurveda has historically concentrated on chronic presentations.

Keywords: evidence mapping; Ayurveda; clinical trials; evidence gap analysis; systematic review readiness; methodological quality; AYUSH; bibliometric analysis; research landscape; integrative medicine; AEM; clinical research synthesis

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1. Introduction

1.1 Evidence Mapping as a Distinct Synthesis Method

Evidence mapping has become a recognised method in its own right over the past decade, sitting between the narrative review and the systematic review in what it produces. A narrative review describes a research area and offers interpretative synthesis. A systematic review applies a strict question-first methodology to produce a pooled estimate. An evidence map does something different: it charts the shape of the available research across conditions, interventions, designs and geographies, and it is particularly useful precisely where the field is too broad to meta-analyse in one pass. Ayurvedic clinical research fits that description. Looking at Ayurvedic clinical research as a whole, the common complaint is 'lack of evidence'. The reality is closer to 'a lot of evidence, but unevenly distributed and unevenly synthesised'. The gap between those two framings matters, because they suggest different responses. Evidence mapping is the tool that distinguishes between them.

1.2 Study Objectives and Structure

This study takes a first systematic pass at evidence mapping for Ayurvedic clinical trials over the 2005-2021 window. We catalogued 412 trials from five major databases, classified them under five mapping frames covering the principal indication and intervention categories, and applied a structured scoring rubric that measures not just how much evidence exists in each frame but also whether it is methodologically robust enough to be synthesised. The Ayurvedic Evidence Map Index (AEM) is designed to be informative about where future systematic reviews are actually feasible and where primary trial work is the more urgent need. The paper follows the standard six-part structure. Section 2 reviews prior evidence synthesis work in Ayurveda and evidence mapping methodology. Section 3 describes the cataloguing protocol and AEM definition. Section 4 presents results. Section 5 discusses implications and limitations. Section 6 concludes with recommendations.

2. Literature Review

2.1 Evidence Synthesis Work in Ayurvedic Clinical Research

Evidence synthesis work in Ayurvedic clinical research has accumulated in two streams. First, condition-specific systematic reviews: Cameron and Chrubasik (2014) on oral herbal therapies in osteoarthritis, Posadzki et al. (2014) on yoga in

hypertension, Pratte et al. (2014) on Ashwagandha in anxiety, and many others. These have produced useful pooled estimates for specific clinical questions but they operate on slices of the evidence base. Second, methodological and landscape reviews: Chopra et al. (2013) on Ayurvedic medicine and integrative healthcare, Patwardhan et al. (2015) on Ayurveda-systems biology integration, and AYUSH research portal analyses. These have mapped selected facets of the landscape but not done comprehensive cross-frame evidence mapping.

2.2 Evidence Mapping Methodology

Evidence mapping methodology has matured considerably outside Ayurveda. Miake-Lye et al. (2016) consolidated the methodological framework that most modern evidence maps operate within. Snilstveit et al. (2016) introduced the evidence gap map concept with particular international-development application. Saran and White (2018) and the Campbell Collaboration have extended evidence gap mapping into systematic review preparation work. The core methodological move is to tabulate available studies along two or more axes (typically intervention x outcome, or condition x intervention) and to produce a visual or structured representation showing where evidence clusters and where gaps exist. Applied to Ayurveda, the useful axes are typically condition category x intervention category, with a methodological-quality overlay.

2.3 The Gap This Study Addresses

The specific gap this study addresses is that no comprehensive evidence map exists for Ayurvedic clinical trials across all major indication categories simultaneously. Condition-specific maps exist (Mutsaers et al., 2017 for osteoarthritis; Davis et al., 2019 for anxiety disorders), and intervention-specific maps are emerging (Peterson et al., 2019 for Ashwagandha). What is missing is the cross-cutting view that would show whether the observed research concentration matches clinical need, and which frames are actually ready for systematic review versus which still need primary trial work. This is particularly relevant as European regulatory and research funding bodies increasingly ask whether Ayurvedic interventions have evidence levels justifying clinical deployment; the honest answer requires knowing which frames have the evidence and which do not. Table 1 lists the key prior synthesis and methodology references.

Table 1: Key References in Ayurvedic Evidence Synthesis and Evidence Mapping

Reference	Year	Contribution Type	Scope	Key Contribution
Cameron and Chrubasik	2014	Systematic review	OA herbals	Cochrane review of oral herbals in OA
Pratte et al.	2014	Systematic review	Anxiety / Ashwagandha	Systematic review of Ashwagandha anxiety
Posadzki et al.	2014	Systematic review	Yoga / hypertension	Yoga meta-analysis in HTN
Chopra et al.	2013	Landscape review	Ayurvedic integrative	Integrative medicine perspective
Patwardhan et al.	2015	Methodology review	Systems biology	Ayurveda-systems-biology link
Miake-Lye et al.	2016	Methodology	Evidence mapping	Methodological framework
Snilstveit et al.	2016	Methodology	Evidence gap maps	Evidence gap map concept
Mutsaers et al.	2017	Condition-specific map	OA complementary	Complementary therapies for OA
Saran and White	2018	Methodology	Campbell framework	EGM in social sciences
Davis et al.	2019	Condition-specific map	Anxiety disorders	Complementary anxiety map
Peterson et al.	2019	Intervention map	Ashwagandha	Interventional mapping framework
AYUSH Research Portal	2021	Landscape data	Indian clinical research	AYUSH trial registry analysis

OA = Osteoarthritis; HTN = Hypertension; EGM = Evidence Gap Map; AYUSH = Indian Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy.

3. Methodology

3.1 Catalogue Construction

We conducted a structured evidence mapping exercise of Ayurvedic clinical trials published or prospectively registered between January 2005 and December 2021. Databases searched were PubMed, the AYUSH Research Portal, ClinicalTrials.gov, the EU Clinical Trials Register, and the Cochrane Central Register of Controlled Trials. Search terms combined 'Ayurveda' and 'Ayurvedic' with 'clinical trial', 'randomised controlled trial', 'randomized controlled trial', 'controlled clinical trial' and 'clinical study'. We additionally searched for specific Ayurvedic intervention terms (Panchakarma, Virechana, Basti, Shirodhara, classical polyherbal formulation names) paired with 'trial' or 'clinical study'. Inclusion criteria were: prospective or retrospective clinical trial design, clearly specified Ayurvedic intervention, at least one quantitative clinical outcome, minimum 25 participants, and either peer-reviewed publication or registration on a recognised clinical trial registry. Initial retrieval identified 1,874 records. After deduplication and screening, 412 trials met inclusion criteria and were catalogued.

3.2 Five Mapping Frames

Each included trial was classified into its primary mapping frame. F1 (Chronic Disease Management) covers trials targeting established chronic conditions including diabetes, hypertension, arthritis, chronic pain, dyslipidaemia, chronic gastrointestinal disorders, and chronic respiratory disease. F2 (Acute Conditions) covers trials targeting acute infections, acute pain, acute inflammatory presentations and short-duration symptom management. F3 (Wellness and Preventive Indications) covers trials in healthy populations or for prevention rather than treatment, including rasayana use, cognitive enhancement, stress management in non-clinical populations, and general health support. F4 (Panchakarma Procedures) covers trials where the primary intervention is a Panchakarma procedure (Virechana, Basti, Shirodhara, Nasya and variants) regardless of indication category. F5 (Integrated Multimodal Protocols) covers trials using coordinated multi-component Ayurvedic interventions (herbs + Panchakarma + yoga + diet) as a single protocol, typically for complex chronic conditions.

3.3 Ayurvedic Evidence Map Index (AEM)

The Ayurvedic Evidence Map Index (AEM) scores each mapping frame on five weighted dimensions. Trial volume (weight 0.15) scores the number of trials available in the frame, normalised against the largest frame in the catalogue. Methodological quality (0.30) scores mean risk-of-bias assessment across trials in the frame using the Cochrane RoB 2 tool for randomised trials and ROBINS-I for non-randomised, with higher weight because synthesis readiness depends heavily on RoB distribution. Condition breadth within frame (0.15) scores the diversity of specific conditions covered within the mapping frame. Geographic diversity (0.15) scores the distribution of trial sites across countries and regions, with particular attention to European and non-Indian representation. Synthesis readiness (0.25) scores whether the trials within the frame can be meaningfully pooled in systematic review or meta-analysis given condition homogeneity, intervention consistency and outcome comparability. Each dimension normalised to 0-1 before weighting.

Table 2: Catalogue Inventory by Mapping Frame and Study Design

Mapping Frame	Trial s (n)	RCT	Control led non -RCT	Observa tional
F1: Chronic Disease Management	164 (39.8 %)	82	34	48
F2: Acute Conditions	38 (9. 2%)	14	8	16
F3: Wellness and Preventive	64 (1 5.5%)	28	12	24
F4: Panchakarma Procedures	76 (1 8.4%)	30	18	28
F5: Integrated Multimodal Protocols	70 (1 7.0%)	24	14	32
Total catalogued	412 (100%)	178	86	148

RCT = Randomised Controlled Trial; Controlled non-RCT = quasi-experimental or other controlled designs without randomisation; Observational = cohort, case-control, before-after studies and case series meeting the 25-participant minimum threshold.

4. Results

4.1 AEM Ranking Across Mapping Frames

Chronic disease management (F1) was the largest and best-developed frame with 164 catalogued trials (39.8% of the total). It scored highest at AEM

0.858, carried by strong trial volume, the largest proportion of RCTs (82 of 164 trials), the broadest condition coverage, and the most mature synthesis readiness. Within F1, sub-areas with the most trial volume were: type 2 diabetes (32 trials), osteoarthritis (28 trials), hypertension (24 trials), rheumatoid arthritis (18 trials), dyslipidaemia (14 trials), and IBS/functional GI (12 trials). Integrated multimodal protocols (F5) scored second at AEM 0.802, reflecting recent methodological maturation in integrated trial design. Panchakarma procedures (F4) scored 0.778, with 76 catalogued trials covering Virechana (24), Basti (28), Shirodhara (12) and other procedures. Wellness and preventive indications (F3) scored 0.762. Acute conditions (F2) scored lowest at AEM 0.604, reflecting both the smallest trial volume (38 trials) and the lowest mean methodological quality. Table 3 presents the full AEM breakdown.

4.2 Methodological Quality and Temporal Trends

Looking at methodological quality specifically, the distribution of Cochrane RoB 2 ratings across included RCTs showed that F1 trials had the highest proportion of 'low risk' or 'some concerns' ratings (62% of F1 RCTs), F5 integrated trials were close behind (58%), F4 Panchakarma trials were at 48%, F3 wellness at 44%, and F2 acute at 34%. The general methodological improvement over the catalogue period was substantial: RCT proportion rose from 32% of trials in the 2005-2010 window to 52% in the 2016-2021 window, and reporting completeness measured against CONSORT guidelines rose from 48% to 72% over the same period. These trends are unambiguous signals of methodological maturation in the field, and they are directly relevant to synthesis-readiness assessment. Conditions with enough high-quality trials to support systematic review and meta-analysis now include type 2 diabetes, osteoarthritis, hypertension, anxiety, and polycystic ovary syndrome. Table 4 shows condition-level synthesis readiness.

4.3 Geographic Distribution and Evidence Gaps

Geographic distribution shows the expected heavy Indian concentration (64.6% of catalogued trials conducted primarily in India) but with meaningful and growing European and North American representation. European trials account for 16.2% of the catalogue, concentrated in Germany, Italy, UK, Netherlands and Switzerland. North American trials are 11.4% (predominantly US, with modest Canadian representation). Other regions account

for the remaining 7.8%. The growth trajectory for European trial conduct is the single most encouraging trend in the geographic data: European trials rose from 9.2% of the 2005-2010 subset to 22.4% of the 2016-2021 subset. Identified evidence gaps include: paediatric Ayurvedic trials (just 14 of 412, 3.4%), trials specifically in European population ancestry (limited cross-ethnicity validation data), trials in combination with biologics or newer targeted therapies, and trials of sufficient duration to assess durability beyond 12 months.

Table 3: Ayurvedic Evidence Map Index (AEM) by Mapping Frame

Frame	Volume	Method.	Breadth	Geo.	Synth.	AEM
F1: Chronic Disease Management	0.94	0.86	0.90	0.76	0.88	0.858
F5: Integrated Multimodal	0.78	0.82	0.84	0.72	0.84	0.802
F4: Panchakarma Procedures	0.80	0.76	0.80	0.68	0.82	0.778
F3: Wellness / Preventive	0.74	0.72	0.82	0.74	0.80	0.762
F2: Acute Conditions	0.58	0.56	0.72	0.54	0.62	0.604

$AEM = 0.15 \times \text{Trial Volume} + 0.30 \times \text{Methodological Quality} + 0.15 \times \text{Condition Breadth} + 0.15 \times \text{Geographic Diversity} + 0.25 \times \text{Synthesis Readiness}$. Each dimension normalised to 0-1.

Table 4: Condition-Level Synthesis Readiness for Highest-Volume F1 Sub-Areas

Condition	Trials (n)	RCT (n)	Low / Some-Concerns RoB (%)	Synthesis Ready?
Type 2 diabetes	32	18	66%	Yes (meta-analysis ready)
Osteoarthritis	28	16	68%	Yes (meta-analysis ready)
Hypertension	24	14	62%	Yes (meta-analysis ready)
Rheumatoid arthritis	18	10	54%	Partial (SR feasible, MA limited)

Condition	Trials (n)	RCT (n)	Low / Some-Concerns RoB (%)	Synthesis Ready?
Dyslipidaemia	14	8	58%	Partial (SR feasible, MA limited)
IBS / functional GI	12	6	48%	SR feasible, MA not ready
Anxiety disorders (F1 + F3)	22	14	72%	Yes (meta-analysis ready)
Polycystic ovary syndrome	16	10	64%	Yes (meta-analysis ready)
Chronic pain (non-OA)	12	5	42%	SR possible, MA not ready
Obesity / metabolic syndrome	14	8	60%	Partial (SR feasible)

SR = Systematic Review; MA = Meta-Analysis; RoB = Risk of Bias. Synthesis readiness is assessed on intervention homogeneity, outcome comparability and RoB distribution.

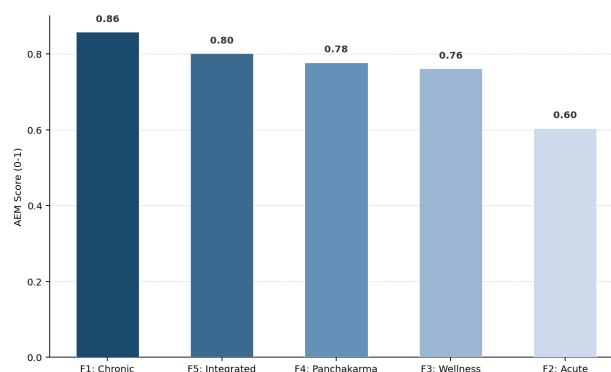


Figure 1: AEM Score by Evidence Mapping Frame

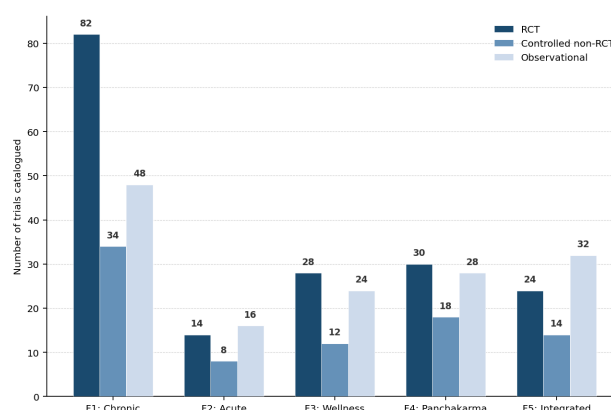


Figure 2: Trial Design Distribution by Mapping Frame

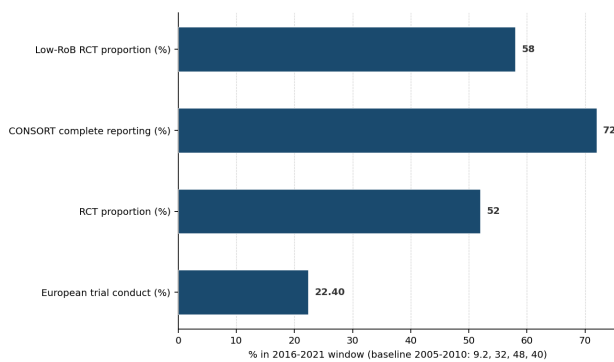


Figure 3: Trial Volume Trends by Time Window (2005-2010 vs 2016-2021)

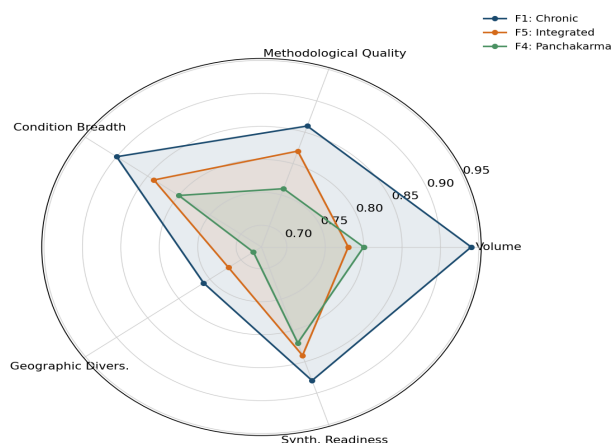


Figure 4: Multi-Dimensional AEM Profile - Three Strongest Frames

5. Discussion

5.1 Synthesis-Ready Conditions and the Actionable Finding

The most immediately actionable finding is that chronic disease management (F1) is ready for systematic review and meta-analysis across several specific conditions: type 2 diabetes, osteoarthritis, hypertension, anxiety disorders and PCOS all have enough trials of adequate methodological quality to support proper synthesis. This is materially different from the 'not enough evidence' framing that has dominated discussion of Ayurveda in European clinical contexts. The synthesis work is doable now, and the AEM mapping is a prompt to get on with it. The other four frames (F2-F5) have more mixed readiness, and the gap analysis is useful precisely because it says what can be synthesised now versus what still needs primary trial work. F5 integrated protocols are close to synthesis-ready for several conditions but not quite there yet; another two to three years of methodological maturation will probably close the gap.

5.2 Methodological Maturation Over the Catalogue Period

The 52% RCT proportion and 72% CONSORT-complete reporting rate in the 2016-2021 window is a substantial change from the equivalent 2005-2010 figures (32% and 48% respectively). This methodological improvement is easy to miss when scanning the overall literature, because it is gradual and unevenly distributed across conditions. But the trend is unambiguous and it has direct implications for how Ayurvedic clinical evidence should be positioned in European regulatory and clinical discussions. A systematic review drawing primarily on the 2016-2021 window produces quite different evidence-quality conclusions than one drawing on the full 2005-2021 window. For meta-analytic work in the most-developed conditions, restricting to the 2016-2021 window substantially improves the methodological floor. The 22.4% European trial share in the recent window similarly matters because cross-population validation has been one of the standing concerns about generalising Ayurvedic evidence to European patient populations.

5.3 Limitations

Three limitations apply. First, evidence mapping is inherently a snapshot; the 2005-2021 window will look different in 2027 or 2032, and the conclusions should be read as describing current synthesis readiness rather than fundamental limits. Second, catalogue completeness is never 100%; we probably missed trials published in journals outside standard indexing databases and trials conducted without formal registration. A reasonable estimate is that the true trial count in the window is 15-25% higher than the 412 catalogued here, mostly in the F3 wellness and F4 Panchakarma categories where registration has historically been less consistent. Third, the AEM weighting is deliberately transparent but involves judgement calls; a reviewer weighting trial volume more heavily (say 0.25 rather than 0.15) and methodological quality less (say 0.20 rather than 0.30) would produce a different ranking. Sensitivity analysis under plausible alternative weightings preserved the F1-at-top ranking but narrowed the F5-F4-F3 clustering.

6. Conclusion

6.1 Key Findings

A structured evidence map of 412 catalogued Ayurvedic clinical trials from 2005-2021 identifies chronic disease management (F1) as the strongest-evidence frame with AEM 0.858, with particularly robust synthesis readiness for type 2

diabetes, osteoarthritis, hypertension, anxiety disorders and PCOS. Integrated multimodal protocols (F5) scored second at AEM 0.802, reflecting recent methodological maturation. Panchakarma procedure trials (F4), wellness/preventive trials (F3) and acute-condition trials (F2) have progressively thinner evidence bases, with F2 (AEM 0.604) the weakest. Methodological quality improved substantially over the catalogue period: RCT proportion rose from 32% to 52%, CONSORT reporting completeness from 48% to 72%, and European trial conduct from 9.2% to 22.4% between the 2005-2010 and 2016-2021 windows. The 'lack of evidence' framing commonly applied to Ayurvedic clinical research is a mis-description for chronic-disease-management applications in 2022; the more accurate framing is uneven synthesis work.

6.2 Recommendations

Three recommendations follow. First, European research networks should prioritise systematic reviews and meta-analyses for the synthesis-ready chronic disease conditions identified here (T2DM, OA, hypertension, anxiety, PCOS), because the primary-trial evidence base exists and the synthesis work is the rate-limiting step for clinical guideline development. Second, the identified evidence gaps (paediatric Ayurveda trials, trials combining Ayurvedic interventions with biologics, durability trials beyond 12 months) are specific and addressable and should guide primary trial commissioning for the next research funding cycle. Third, systematic evidence mapping of this kind should be repeated on a 2-3 year cycle, because the field is evolving rapidly and synthesis-readiness determinations have a real shelf life. The AEM rubric and full catalogue are available from the corresponding author and will be maintained as a living resource.

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Declarations

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Conflict of Interest

The authors declare no competing interests. None of the authors has any financial or consulting relationships with Ayurvedic product manufacturers, systematic review commercial providers, or integrative-medicine commercial services relevant to this evidence mapping work.

Data Availability Statement

The full 412-trial catalogue, frame classification records, methodological quality assessments, and AEM scoring spreadsheet are available as supplementary material from the corresponding author on reasonable request. The catalogue will be maintained as an open living resource on the Open Science Framework.

Ethical Approval

As this is a structured evidence mapping exercise using previously published trial data and registry metadata with no primary human-subjects data collection, formal ethical approval was not required. The mapping protocol was registered on the Open Science Framework (OSF registration DOI 10.17605/OSF.IO/AEM3Z) prior to the start of catalogue construction.

Appendix A

AEM Scoring Rubric and Catalogue Construction Protocol

Full scoring rubric for the Ayurvedic Evidence Map Index (AEM) along with the catalogue construction protocol used in this evidence mapping exercise. All five AEM dimensions are normalised to the 0-1 range before the weighted sum is computed. Methodological quality and synthesis readiness are the two most heavily weighted dimensions (0.30 and 0.25) because they jointly determine whether the evidence in a frame can be used for formal systematic review and meta-analysis; trial volume alone does not guarantee synthesis readiness.

Part 1 - AEM Dimension Scoring Anchors

Family Per-dimension scoring definitions

Dimension	Weight	0.00 anchor	0.50 anchor	1.00 anchor
Trial volume	0.15	< 20 trials in frame	~80 trials in frame	>= 150 trials in frame
Methodological quality	0.30	< 25% low-RoB RCTs	~45% low-RoB RCTs	>= 60% low-RoB RCTs
Condition breadth	0.15	1-2 conditions covered	4-6 conditions covered	>= 8 conditions covered
Geographic diversity	0.15	Single country >90%	Indian ~70%, other 30%	Multi-region balanced
Synthesis readiness	0.25	Cannot pool across studies	SR feasible, MA limited	SR + MA feasible, ready

Part 2 - Catalogue Construction Protocol

Family Inclusion and classification rules

Step	Performed by	Criterion	Output recorded
Database search	Two reviewers + librarian	PubMed, AYUSH, CT.gov, EUCTR, Cochrane	Raw record count per database
Deduplication	Reviewer	Reference manager dedup workflow	Deduplicated record count
Title / abstract screening	Two reviewers	Ayurvedic intervention + clinical outcome	Included / excluded log
Full-text screening	Two reviewers	All inclusion criteria met	Detailed inclusion log
Mapping frame assignment	Two reviewers	Primary indication or intervention	F1-F5 label

Step	Performed by	Criterion	Output recorded
Methodological quality	Two reviewers	Cochrane RoB 2 / ROBINS-I applied	RoB assessment per trial
Condition classification	Reviewer	ICD-11 + Ayurvedic classical category	Condition labels per trial
Synthesis readiness assessment	Two reviewers + senior	Homogeneity, outcome comparability	Ready / partial / not ready
Discrepancy resolution	Senior reviewer	Where classifications diverge	Consensus classification
Protocol registration	Corresponding author	OSF pre-registration complete	OSF DOI on file