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Prebiotics and Probiotics as Operationalized Within Siddha, Ayurveda, Unani, Traditional Chinese Medicine, Kampo, and Homeopathy-Adjacent Products: A PRISMA-P Protocol for Systematic Review, Evidence Mapping, and Meta-analysis in irritable bowel syndrome

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ABSTRACT

Background: "Probiotic" and "prebiotic" are modern technical categories with consensus definitions that require specific material features (e.g., live microorganisms in adequate amounts for probiotics; selective utilization by host microorganisms for prebiotics). Retroactively claiming that traditional medical systems "had probiotics" is conceptually invalid unless explicit mapping rules are stated and applied consistently. Fermented foods are further complicate comparability because microbial composition and dose are often unstandardized, making naive pooling with standardized probiotic products inappropriate.

Objective: To prospectively define a strict intervention taxonomy and eligibility framework for identifying and synthesizing clinical evidence on microbiome-directed interventions explicitly situated within Siddha, Ayurveda, Unani, Traditional Chinese Medicine (TCM), Japanese traditional medicine (e.g., Kampo), and "homeopathy-adjacent" marketed products, and to conduct meta-analysis only where interventions and outcomes are comparable.

Methods: This protocol follows PRISMA-P guidance and is intended for PROSPERO registration. Final reporting will follow PRISMA 2020. We will first produce an evidence map across the targeted medical systems, then perform meta-analysis for coherent strata (primarily randomized controlled trials in adults with irritable bowel syndrome (IBS) receiving standardized probiotic or prebiotic interventions). Risk of bias will be assessed using RoB 2 for randomized trials and ROBINS-I for non-randomized designs. Random-effects meta-analysis will be used as default, with pre-specified sensitivity analyses separating fermented foods from standardized probiotic products.

Expected outputs: (i) an evidence map and intervention taxonomy; (ii) a narrative synthesis across systems and intervention classes; (iii) meta-analyses where appropriate; and (iv) GRADE certainty ratings for key outcomes..

Keywords: *probiotic; prebiotic; synbiotic; postbiotic; fermented foods; Siddha; Ayurveda; Unani; Traditional Chinese Medicine; Kampo; homeopathy; irritable bowel syndrome; systematic review; meta-analysis; PRISMA*

1. INTRODUCTION

Siddha medicine, deeply rooted in South Indian traditions and sharing philosophical foundations with Ayurveda, represents one of humanity's oldest holistic medical systems. This ancient healing tradition adopts a comprehensive perspective on health that emphasizes the fundamental interconnection between human physiology and natural rhythms [1], [2]. At the heart of this system lies the recognition that health is not merely the absence of disease but rather a dynamic state of balance achieved through harmonious alignment with the temporal patterns governing biological existence [3], [4].

Central to Siddha medicine's approach is the understanding of circadian rhythms—endogenous biological cycles operating

Modern microbiome therapeutics use terms with constraints, not metaphors. A probiotic is not "anything fermented," and a prebiotic is not "any fiber." Consensus definitions require probiotics to contain live microorganisms administered in adequate amounts and associated with a health benefit, and prebiotics to be substrates selectively utilized by host microorganisms that confer a health benefit [8,9]. Related constructs include synbiotics (live microorganisms plus a selectively utilized substrate together) [10] and postbiotics (inanimate microorganisms and/or their components conferring a health benefit) [11]. Fermented foods form a distinct category and are not automatically equivalent to probiotics [12].

Traditional medical systems (Siddha, Ayurveda, Unani, TCM, Kampo) are epistemically distinct frameworks that sometimes intersect with fermentation and diet-therapy. Intersection is not identity. The central methodological risk for this review is anachronistic translation: re-labeling within-system constructs as "probiotic" or "prebiotic" without demonstrating that the intervention matches modern criteria and is delivered in a comparable manner. This protocol therefore foregrounds mapping rules, system-attribution rules, and an intervention taxonomy separating fermented foods from standardized probiotic products.

Fig.1 shows mind map of this review

Scope Decision Gate

Candidate targets provided span fundamentally different populations, settings, and outcomes (hospital antibiotic-associated diarrhea prevention; microbiota modulation in healthy seniors; IBS symptom reduction; metabolic markers in pre-diabetes). Pooling across these questions would be incoherent. This protocol therefore focuses on a single primary scope and recommends separate protocols for other scopes.

Option A (Recommended): Gastrointestinal disorders - IBS-focused. Outcomes are symptom-based and commonly

reported; follow-up windows are typically weeks-to-months; trials exist allowing stratified synthesis.

Option B: Metabolic outcomes in pre-diabetes. Outcomes (HbA1c, fasting glucose) are standardized but follow-up should be longer (>=12 weeks) for meaningful HbA1c change.

Option C: Prevention of antibiotic-associated diarrhea (AAD) in hospitalized patients. Clinically important binary outcomes, but within-system attribution may be sparse and confounding by hospital practices is substantial.

Review

Protocol Governance and Reporting

This protocol is written for PROSPERO registration [3]. Final reporting will follow PRISMA 2020 [1], and protocol elements align with PRISMA-P [2].

Conceptual Mapping and Intervention Taxonomy

This review will not assume that traditional medical systems "have probiotics." Interventions will be classified using materially testable criteria, then analyzed within defensible comparability strata.

Modern Intervention Definitions Used for Classification

Probiotic intervention: Preparation contains live microorganisms administered intentionally in adequate amounts and associated with a health benefit [8]. Operational minimum for standardized probiotic product: organism identified at least to genus/species plus dose (e.g., CFU/day) or equivalent viability specification.

Prebiotic intervention: Substrate intended to be selectively utilized by host microorganisms, conferring a health benefit [9]. Operational minimum: identifiable substrate (e.g., inulin/FOS/GOS/resistant starch), dose, and route.

Synbiotic intervention: Combination of live microorganisms and selectively utilized substrate(s) together, aligned with ISAPP consensus definition [10].

Postbiotic intervention: Inanimate microorganisms and/or their components conferring a health benefit [11].

Fermented foods: Foods and beverages made through desired microbial growth and enzymatic conversion of food components; not assumed to be probiotic unless probiotic criteria are met [12].

Hard rule: fermented foods (variable microbiology; dose often unknown) will be analyzed separately from standardized probiotic products. Pooling is not permitted unless microbial composition and viable dose are quantified and comparable and sensitivity analyses support robustness.

Within-System Attribution Rules

A study will be classified as "within-system" only if at least one of the following is explicit: (i) intervention is named and justified using that system's theory; (ii) intervention is sourced from that system's materia medica or canonical preparation method; (iii) intervention is delivered as a canonical within-system preparation in a clinical context framed as that system's practice; or (iv) the product is positioned as belonging to that system and authors treat it within that tradition's clinical logic. Generic probiotic trials without explicit linkage will be excluded.

Homeopathy Conceptual Validity Rule

Classical homeopathic remedies are commonly ultradilute and are generally incompatible with containing viable microbes in measurable CFU; therefore, classical homeopathy will be excluded from probiotic/prebiotic intervention categories. Exception: products marketed as "homeopathic" that demonstrably contain viable microorganisms and/or measurable prebiotic substrate will be included and explicitly labeled as "homeopathy-adjacent marketing"; these will not be used to make claims about classical homeopathic theory.

Methods

Eligibility Criteria

Population: Adults (>=18 years) with irritable bowel syndrome (IBS) diagnosed by clinician assessment or recognized diagnostic criteria.

Intervention: Eligible interventions must meet modern classification criteria (probiotic, prebiotic, synbiotic, postbiotic, fermented food/beverage, fermented herbal preparation) and within-system attribution to Siddha, Ayurveda, Unani, TCM, Kampo/Japanese traditional medicine, or homeopathy-adjacent marketing.

Comparator: Placebo, usual care, no intervention, or active control.

Primary outcomes: Change in overall IBS symptom severity, preferably IBS Severity Scoring System (IBS-SSS) [13], or validated global symptom/responder outcome when IBS-SSS is not reported.

Secondary outcomes: Abdominal pain, bloating, stool frequency and stool form (Bristol Stool Form Scale when used) [14], IBS-specific quality of life, adverse events, and withdrawals. Microbiome outcomes (e.g., alpha/beta diversity, relative abundance) will be summarized narratively unless comparable.

Time window and language: English-language studies published 1 January 2020 through 31 December 2025.

Information Sources

MEDLINE (PubMed), Embase, Cochrane CENTRAL, Web of Science, Scopus.

Tradition- and region-relevant sources (searched for English records): CNKI, Wanfang, VIP, SinoMed/CBM (TCM); Ichushi-Web and J-STAGE (Japan); AYUSH Research Portal and IndMED (India/AYUSH).

Trial registries: ClinicalTrials.gov and WHO ICTRP.

Grey literature: conference proceedings and dissertations with extractable data; reference list screening.

Draft Search Strategy (PubMed)

The PubMed strategy will use a three-block structure: (Traditional system) AND (microbiome intervention) AND (IBS). Full line-by-line strategies for each database will be provided in an appendix.

Traditional-system block: (Siddha OR "Siddha medicine" OR Ayurveda OR Ayurvedic OR Unani OR Yunani OR "Greco-Arab" OR "Traditional Chinese Medicine" OR TCM OR "Chinese medicine" OR Kampo OR "Japanese traditional medicine" OR homeopathy OR homoeopathy OR homeopathic)

Microbiome-intervention block: (probiotic* OR prebiotic* OR synbiotic* OR symbiotic* OR postbiotic* OR "live microorganism* OR Lactobacillus OR Bifidobacterium OR Saccharomyces OR "fermented food*" OR fermentation OR kefir OR yogurt OR miso OR natto OR kombucha OR "fermented herbal")

IBS block: ("irritable bowel" OR IBS OR "functional bowel" OR abdominal pain OR bloating OR constipation OR diarrhea)

Combine: #1 AND #2 AND #3; Filters: Humans; English; 2020-2025.

Study Selection

we will independently screen titles/abstracts and full texts. Conflicts will be resolved by consensus or third-reviewer adjudication. Inter-rater agreement will be summarized using Cohen's kappa.

Data Extraction

Two reviewers will extract data using a piloted form capturing study descriptors, traditional-system attribution evidence, intervention taxonomy (including strain(s), CFU, dose, duration, fermentation details), outcomes, and adverse events.

Risk of Bias Assessment

Randomized trials will be assessed using RoB 2 [4]. Non-randomized comparative studies will be assessed using ROBINS-I [5].

Data Synthesis

An evidence map will be produced across traditions and intervention classes. Meta-analysis will be performed only where studies are sufficiently comparable (population, intervention class, and outcome).

Continuous outcomes will be synthesized using mean difference (MD) when scales match, or standardized mean difference (SMD; Hedges g) when scales differ. Dichotomous outcomes will use risk ratio (RR) when possible. Random-effects models will be the default, using REML for tau-squared. Hartung-Knapp adjustments will be considered for small numbers of studies [16,17].

Certainty of Evidence

Certainty will be rated with GRADE for primary and key secondary outcomes [6].

Conclusions

This protocol operationalizes a strict, non-anachronistic framework for evaluating microbiome-directed interventions as actually implemented within Siddha, Ayurveda, Unani, TCM, Kampo, and homeopathy-adjacent marketed products. Classification depends on modern consensus definitions and measurable intervention features, while inclusion depends on explicit within-system attribution. Evidence mapping will precede any pooling, and meta-analysis will be restricted to defensible comparability strata, with fermented foods analyzed separately from standardized probiotic products.

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