

Traditional Chinese Medicine Constitution and Functional Decline in Older Adults: A Systematic Review with Synthesis Without Meta-analysis (SWiM)

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2026100132

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 October 2026 and was last updated on 31 October 2026.

INTRODUCTION

Review question / Objective To systematically identify, appraise, and synthesise observational evidence on the association between traditional Chinese medicine (TCM) constitution types and functional decline outcomes in older adults; to characterise the quantity, methodological quality, and comparability of the available evidence (assessment tools, classification rules, reference groups, and handling of mixed constitutions); and to quantify methodological and substantive evidence gaps to guide future large-scale multicentre empirical investigations on multidimensional functional decline, pathway mechanisms, and risk prediction in older adults.

Rationale Emerging observational studies suggest that biased TCM constitution types are associated with functional decline in older adults, but the evidence base has never been systematically

synthesised: no published systematic review or meta-analysis was identified that addresses constitution (as classified by standard questionnaires) and functional outcomes in older populations prior to protocol registration. One systematic review protocol on constitution and frailty is registered and ongoing (PROSPERO CRD420251248833). Existing syntheses in adjacent fields cover syndrome differentiation (zheng) rather than constitution, or intervention efficacy. Given marked heterogeneity in constitution instruments, merging rules for "yes/tendency" classifications, reference groups, and outcome tools, plus frequent absence of extractable effect estimates, a meta-analysis is not currently justified; a structured synthesis without meta-analysis (SWiM) is therefore planned.

Condition being studied TCM constitution (nine-category classification per the 2009 standard: CCMQ; elderly edition CCMQ-EE; Body Constitution Questionnaire BCQ) in relation to

geriatric functional decline: frailty and pre-frailty, sarcopenia, ADL/IADL disability, physical performance, malnutrition, and sleep quality.

METHODS

Search strategy Databases: PubMed, Embase, Web of Science, Cochrane Library, CNKI, Wanfang, SinoMed, VIP; searches from inception to search date, restricted to Chinese and English. Supplementary methods: reference-list checking (citation snowballing), scanning of publications by core constitution-research groups, screening of an existing review reference pool, and a grey-literature log. Full-text-unobtainable records are retained and counted, never silently dropped. Screening: two reviewers independently screen titles/abstracts and full texts against a pre-frozen decision manual with adjudication by a third party; calibration on 32 pre-labelled records before formal screening, and a 50-record pilot requiring Cohen's kappa ≥ 0.6 before title/abstract screening; "await full text" liberally applied where abstracts are insufficient.

Search strings (line-by-line, per database):

[PubMed]

((("body constitution"[tiab] OR "body constitutions"[tiab] OR CCMQ[tiab] OR "TCM constitution"[tiab] OR "traditional Chinese medicine constitution"[tiab] OR "constitution of traditional Chinese medicine"[tiab] OR "constitution identification"[tiab] OR "Body Constitution Questionnaire"[tiab] OR BCQ[tiab]) OR ("constitution"[tiab] OR "constitution type"[tiab] OR "constitution types"[tiab] OR "constitutional"[tiab]) AND ("traditional Chinese medicine"[tiab] OR "traditional Chinese"[tiab] OR TCM[tiab] OR "Chinese medicine"[tiab]))) AND ("Aged"[Mesh] OR elderly[tiab] OR "older adults"[tiab] OR "older people"[tiab] OR "older persons"[tiab] OR geriatric*[tiab] OR "oldest old"[tiab] OR "community-dwelling"[tiab] OR "old age"[tiab])) AND (frailty[tiab] OR frail[tiab] OR prefrail*[tiab] OR sarcopeni*[tiab] OR "activities of daily living"[tiab] OR "physical function"[tiab] OR "functional decline"[tiab] OR "functional status"[tiab] OR "physical performance"[tiab] OR malnutrition[tiab] OR "nutritional status"[tiab] OR "nutrition risk"[tiab] OR "sleep quality"[tiab] OR insomnia[tiab] OR "muscle strength"[tiab] OR "grip strength"[tiab] OR handgrip[tiab] OR "gait speed"[tiab] OR mobility[tiab] OR disability[tiab] OR "instrumental activities"[tiab])

[Embase]

('body constitution'/exp OR 'body constitution':ti,ab,kw OR ccmq:ti,ab,kw OR 'tcm constitution':ti,ab,kw OR 'traditional chinese medicine constitution':ti,ab,kw OR 'constitution identification':ti,ab,kw OR 'body constitution questionnaire':ti,ab,kw OR bcq:ti,ab,kw OR ((constitution:ti,ab,kw OR 'constitution type':ti,ab,kw) AND ('traditional chinese medicine':ti,ab,kw OR 'chinese medicine':ti,ab,kw))) AND (aged/exp OR elderly:ti,ab,kw OR 'older adults':ti,ab,kw OR 'older people':ti,ab,kw OR geriatric*:ti,ab,kw OR 'community dwelling':ti,ab,kw OR 'oldest old':ti,ab,kw) AND (frailty:ti,ab,kw OR frail:ti,ab,kw OR prefrail*:ti,ab,kw OR sarcopeni*:ti,ab,kw OR 'activities of daily living':ti,ab,kw OR 'instrumental activities':ti,ab,kw OR 'physical function':ti,ab,kw OR 'functional decline':ti,ab,kw OR 'functional status':ti,ab,kw OR 'physical performance':ti,ab,kw OR malnutrition:ti,ab,kw OR 'nutritional status':ti,ab,kw OR 'nutrition risk':ti,ab,kw OR 'sleep quality':ti,ab,kw OR insomnia:ti,ab,kw OR 'muscle strength':ti,ab,kw OR 'grip strength':ti,ab,kw OR handgrip:ti,ab,kw OR 'gait speed':ti,ab,kw OR mobility:ti,ab,kw OR disability:ti,ab,kw) AND ([english]/lim OR [chinese]/lim)

[Web of Science]

TS= (("body constitution" OR "TCM constitution" OR "traditional Chinese medicine constitution" OR CCMQ OR "constitution identification" OR "Body Constitution Questionnaire" OR BCQ OR (constitution* SAME ("traditional Chinese medicine" OR "Chinese medicine")) AND (elderly OR "older adults" OR "older people" OR geriatric* OR "community-dwelling" OR "oldest old") AND (frailty* OR frail OR prefrail* OR sarcopeni* OR "activities of daily living" OR "physical function" OR "functional decline" OR "functional status" OR "physical performance" OR malnutrition OR "nutritional status" OR "nutrition risk" OR "sleep quality" OR insomnia OR "muscle strength" OR "grip strength" OR handgrip OR "gait speed" OR mobility OR disability OR "instrumental activities"))

[Cochrane Library]

((("body constitution" OR "TCM constitution" OR "traditional Chinese medicine constitution" OR CCMQ OR "constitution identification" OR "Body Constitution Questionnaire" OR BCQ):ti,ab,kw AND (frailty OR sarcopeni* OR "activities of daily living" OR "physical function" OR "functional decline" OR malnutrition OR "sleep quality" OR insomnia OR "grip strength" OR disability):ti,ab,kw AND (elderly OR "older adults" OR geriatric* OR aged):ti,ab,kw)

[CNKI]

SU=('中医体质'+ '体质辨识'+ '体质量表'+ '中医体质量表'+ '九种体质'+ '平和质'+ '气虚质'+ '阳虚质'+ '阴虚质'+ '痰湿质') AND SU=('老年'+ '老年人'+ '高龄'+ '社区老年'+ '老年住院') AND SU=('衰弱'+ '衰弱前期'+ '肌少症'+ '肌肉衰减'+ '日常生活活动'+ 'ADL'+ '日常生活能力'+ '躯体功能'+ '功能衰退'+ '功能下降'+ '营养不良'+ '营养风险'+ '睡眠质量'+ '睡眠障碍'+ '失眠'+ '握力'+ '步速')

[万方]

主题:("中医体质" OR "体质辨识" OR "体质量表" OR "九种体质" OR "气虚质" OR "阳虚质" OR "阴虚质" OR "痰湿质") AND 主题:("老年" OR "高龄") AND 主题:("衰弱" OR "肌少症" OR "肌肉衰减" OR "日常生活活动" OR "日常生活能力" OR "躯体功能" OR "功能衰退" OR "营养不良" OR "睡眠质量" OR "失眠" OR "握力" OR "步速")

[SinoMed]

("中医体质"[常用字段:主题] OR "体质辨识"[常用字段:主题] OR "体质量表"[常用字段:主题] OR "气虚质"[常用字段:主题] OR "阳虚质"[常用字段:主题] OR "阴虚质"[常用字段:主题] OR "痰湿质"[常用字段:主题]) AND ("老年人"[常用字段:主题] OR "高龄"[常用字段:主题]) AND ("衰弱"[常用字段:主题] OR "肌少症"[常用字段:主题] OR "日常生活活动"[常用字段:主题] OR "躯体功能"[常用字段:主题] OR "营养不良"[常用字段:主题] OR "睡眠障碍"[常用字段:主题] OR "失眠"[常用字段:主题] OR "握力"[常用字段:主题] OR "步速"[常用字段:主题])

[VIP]

M=(中医体质 OR 体质辨识 OR 体质量表 OR 九种体质 OR 气虚质 OR 阳虚质 OR 阴虚质 OR 痰湿质) AND M=(老年 OR 高龄) AND M=(衰弱 OR 肌少症 OR 肌肉衰减 OR 日常生活活动 OR 躯体功能 OR 功能衰退 OR 营养不良 OR 睡眠质量 OR 失眠 OR 握力 OR 步速).

Participant or population Population: older adults (mean age ≥ 60 years, or $\geq 80\%$ of participants aged ≥ 60 , or explicitly defined as older adults by the authors); general populations (community, general geriatric inpatients, health check-up, long-term care); disease-specific cohorts excluded.

Outcomes: ≥ 1 estimate of association (OR/RR/beta/r with CI or P; or direction-decidable significance tests) for ≥ 1 functional domain: frailty/pre-frailty, sarcopenia, ADL/IADL, physical performance (gait speed, TUG, SPPB, grip strength, balance), malnutrition, sleep quality.

Study designs: observational (cross-sectional, cohort, case-control); prediction-model studies reporting constitution-associated functional outcomes included as a study type.

Publications: peer-reviewed journal articles in Chinese or English; intervention studies, reviews, conference abstracts, and dissertations excluded (dissertations logged as grey literature for sensitivity discussion).

Intervention No intervention is evaluated (observational evidence). Exposure/Interest: TCM constitution determined by a standard instrument (CCMQ 2009, CCMQ-EE, BCQ, or other constitution questionnaires with reported reliability and validity) and used as an exposure/grouping variable (including "biased vs balanced" dichotomies); constitution merely as a covariate excluded.

Comparator Comparator: balanced (pinghezhi) constitution, non-biased constitution, absence of the target constitution, or another constitution as reported reference.

Study designs to be included Observational designs only: cross-sectional, cohort (prospective/longitudinal), and case-control studies. Prediction-model studies reporting constitution-associated functional outcomes will be included as a distinct study type. Intervention studies (RCTs, quasi-experimental, and trial protocols) will be excluded, as intervention evidence for TCM in frailty and sarcopenia is covered by our group's separately registered umbrella review (INPLASY202690099).

Eligibility criteria Population: older adults (mean age ≥ 60 years, or $\geq 80\%$ of participants aged ≥ 60 , or explicitly defined as older adults by the authors); general populations (community, general geriatric inpatients, health check-up, long-term care); disease-specific cohorts excluded.

Exposure/Interest: TCM constitution determined by a standard instrument (CCMQ 2009, CCMQ-EE, BCQ, or other constitution questionnaires with reported reliability and validity) and used as an exposure/grouping variable (including "biased vs balanced" dichotomies); constitution merely as a covariate excluded.

Comparator: balanced (pinghezhi) constitution, non-biased constitution, absence of the target constitution, or another constitution as reported reference.

Outcomes: ≥ 1 estimate of association (OR/RR/beta/r with CI or P; or direction-decidable significance tests) for ≥ 1 functional domain: frailty/pre-frailty, sarcopenia, ADL/IADL, physical

performance (gait speed, TUG, SPPB, grip strength, balance), malnutrition, sleep quality.

Study designs: observational (cross-sectional, cohort, case-control); prediction-model studies reporting constitution-associated functional outcomes included as a study type.

Publications: peer-reviewed journal articles in Chinese or English; intervention studies, reviews, conference abstracts, and dissertations excluded (dissertations logged as grey literature for sensitivity discussion).

Information sources Eight databases will be searched from inception to the search date, with no language limit applied at search level (Chinese and English publications eligible): PubMed, Embase, Web of Science, Cochrane Library, CNKI, Wanfang Data, SinoMed, and VIP. Supplementary methods: reference-list checking (citation snowballing) of included studies, scanning of publications by core constitution research groups, screening of an existing narrative review reference pool, and a grey-literature log (dissertations and conference abstracts retrieved but excluded from main analysis). Searches will be executed within a two-day window across all databases; the exact search date will be recorded and reported.

Main outcome(s) Direction and consistency of association for each constitution-by-domain unit (nine TCM constitution types x six functional domains: frailty/pre-frailty, sarcopenia, ADL/IADL, physical performance, malnutrition, sleep quality), coded from extracted estimates as risk / protective / null / conflicting / descriptive-only, with strength grading (S2 = adjusted estimate with CI > S1 = minimally adjusted > S0 = significance test only), and cross-classified against methodological quality. No pooled effect estimates will be calculated.

Additional outcome(s) Evidence-gap metrics: proportion of studies assessing ≥ 3 functional domains concurrently; number and characteristics of constitution-based prediction models, including reporting of external validation and calibration; number of mediation/pathway studies and domains covered; reporting completeness of constitution classification rules ("yes vs tendency" merging rule, reference group definition, mixed-constitution handling); sample-size distribution and multicentre status.

Data management Search records from all eight databases will be exported with abstracts, deduplicated in EndNote followed by a manual second-pass check in Excel, and managed in a master screening ledger (one row per record, every

record receiving a screening decision; no silent drops). Full-text-unobtainable records will be retained and counted per PRISMA 2020. Two reviewers (ZW, HG) will independently screen titles/abstracts and full texts against a pre-frozen decision manual; calibration on 32 pre-labelled records before formal screening, and a 50-record pilot requiring Cohen's kappa ≥ 0.6 before title/abstract screening. Data extraction will use a standardised Excel workbook with drop-down coded fields (constitution instrument, merging rule, reference group, mixed-constitution handling), outcome-polarity anchoring to prevent direction-coding sign errors, and an auto-lookup column linking each effect estimate to its outcome's polarity. Independent double extraction with $\geq 95\%$ required numeric-field agreement; discrepancies resolved by discussion with third-party adjudication, all documented in a reconciliation ledger. Search logs (per-database strings, hit counts, export counts) will be maintained with automated conservation checks (sum of database exports = pooled records identified) before screening begins.

Quality assessment / Risk of bias analysis

Cross-sectional studies: JBI Checklist for Analytical Cross-Sectional Studies (8 items; "unclear" judged as 0, applying a conservative rule; studies classified high 7-8 / moderate 4-6 / low 0-3). Cohort and case-control studies: Newcastle-Ottawa Scale (NOS) with two pre-declared adaptations for constitution research: (1) exposure ascertainment = determination by a standard constitution instrument (self-report questionnaire scores 1; blinded physician judgement scores 2); (2) outcome ascertainment via validated functional scales without mandatory blinding unless assessor blinding is reported. Prediction-model studies will be assessed per their underlying design; model-specific quality (e.g., PROBAST domains) will be addressed narratively as a limitation rather than a formal tool. Two reviewers (ZW, HG) will assess independently; item-level agreement target $\geq 85\%$; disagreements resolved by discussion with third-party adjudication. Quality results will be cross-tabulated with association directions and used for stratification only—no quality-based exclusion of studies.

Strategy of data synthesis Synthesis without meta-analysis (SWiM) will be conducted per Campbell et al. (BMJ 2020;368:l6890; 9 reporting items) and reported per PRISMA 2020. Evidence will be grouped by six functional domains. Within each domain: (1) a study characteristics table (design, population, constitution instrument,

outcomes, quality); (2) a constitution-by-domain direction-quality matrix, each cell presenting association direction codes (risk/protective/null/conflicting) cross-classified with quality grading and estimate strength (S2/S1/S0); (3) narrative synthesis of direction, consistency, and quality constraints, with explicit reporting of heterogeneity in classification rules. Vote-counting is prohibited. When a study reports multiple indicators within the same domain, a pre-specified hierarchy of representative composite scales over single-item measures selects the primary estimate for the matrix. Pre-specified stratifications: constitution instrument (CCMQ/CCMQ-EE/BCQ), "yes/tendency" merging rule, reference group definition, mixed-constitution handling, and quality grade. Meta-analysis is pre-declared as not planned, justified by (1) instrument and classification-rule heterogeneity, (2) heterogeneous reference groups and outcome tools, (3) scarcity of extractable pooled-effect data, and (4) an already-registered dedicated meta-analysis on constitution and frailty (PROSPERO CRD420251248833).

Subgroup analysis No statistical subgroup analysis will be performed, as no pooled effect estimates will be calculated (SWiM design). Subgroup differences will instead be examined through pre-specified stratified tabulation of the direction-quality matrix within each functional domain, stratified by: (1) constitution instrument (CCMQ 2009 / CCMQ-EE / BCQ); (2) "yes vs tendency" classification merging rule; (3) reference group definition (balanced constitution / non-biased / other); (4) handling of mixed (jianjia) constitutions (independent dummy coding / principal-type assignment / separate group / exclusion); and (5) methodological quality grade (high / moderate / low). In addition, domain-level summaries will be presented separately for community-dwelling versus institutionalised/inpatient settings where data permit. These stratifications are descriptive and hypothesis-generating, without between-subgroup statistical testing.

Sensitivity analysis No pooled-estimate sensitivity analyses will be performed (SWiM design, no meta-analysis). Robustness of the direction-quality matrix will instead be examined descriptively through three pre-specified approaches: (1) quality-constrained synthesis—primary conclusions rest on moderate-to-high-quality studies, with low-quality studies presented separately; (2) estimate-strength-constrained synthesis—cells supported only by unadjusted estimates (S0/S1) are flagged and compared against cells supported by adjusted estimates (S2);

and (3) grey-literature sensitivity—dissertations and conference abstracts (logged but excluded from the main analysis) will be summarised narratively to assess whether their direction patterns differ from published journal articles, addressing publication access bias. Should any domain unexpectedly yield ≥ 8 -10 comparable adjusted estimates with compatible instruments, reference groups, and outcome definitions, a post-hoc exploratory meta-analysis may be considered and would be explicitly labelled as such and reported separately from the SWiM conclusions.

Language restriction Chinese and English.

Country(ies) involved China.

Other relevant information 1) Grey literature: dissertations and conference abstracts identified during searches will be logged (count and reason) but excluded from the main analysis; their direction patterns will be summarised narratively in the sensitivity discussion. 2) The complete line-by-line search strings for all eight databases (in original platform syntax, Chinese-database strings in Chinese) are appended to the search strategy section of this protocol and will be published in full with the completed review. 3) This review is part of the first author's doctoral thesis on TCM constitution and physiological function in older adults; the review is conducted and reported independently of any primary study, and no primary-data pooling will be performed. A separately registered umbrella review of TCM interventions for frailty and sarcopenia by the same group exists (INPLASY202690099); the present review addresses observational associations only, with no scope overlap.

Keywords TCM constitution; frailty; sarcopenia; activities of daily living; physical function; malnutrition; sleep; older adults; SWiM; systematic review.

Dissemination plans The completed review will be published in a peer-reviewed international journal and will simultaneously serve as the literature-research chapter of the first author's doctoral thesis at Beijing University of Chinese Medicine. The review will be reported per SWiM (9 items) and PRISMA 2020 checklists; the full line-by-line search strings, per-database search logs, and PRISMA flow counts will be published with the review or as open supplementary materials. Results will also be disseminated to clinical and academic audiences through conference presentation where appropriate. No participant-level data are involved.

Contributions of each author

Author 1 - zheng wang - conceptualization, methodology, development of the search strategy and pre-frozen decision manual, conduct of preliminary (scouting) searches, protocol drafting and registration, first reviewer for study screening, data extraction, and quality assessment, data synthesis, writing of the original manuscript, and project administration.

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Author 2 - hao guan - methodology, second (independent) reviewer for study screening, data extraction, and quality assessment, participation in calibration exercises, and critical revision of the protocol and manuscript.

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Author 3 - cheng ni - conceptualization, supervision, methodological oversight, adjudication of discrepancies where required, and critical revision of the protocol and manuscript for important intellectual content.

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