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Development of CORE-CM core outcome domain sets for trials of Chinese medicine for lumbar spinal stenosis

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ABSTRACT

Objectives Most Asian countries have employed Chinese medicine (CM) and Western medicine to treat lumbar spinal stenosis (LSS). Evidence synthesis and comparison of effectiveness are difficult since outcomes examined and presented through trials possess heterogeneity. This study aimed to solve the outcome problems for CM clinical trials in LSS by building a core outcome set (COS).

Methods To achieve an agreement on a set of core outcome domains, a four-phase study was carried out. First, we identified candidate outcome domains by systematically reviewing trials. In addition, we identified outcome domains associated with patients by conducting semistructured interviews with patients. Next, outcome domains were processed through a national two-round Delphi survey, in which 18 patients and 21 experts were recruited. Finally, the above domains were converted as a core outcome domain set based on a consensus meeting, in which 24 stakeholders were recruited.

Results Seventeen outcome subdomains were identified by the systematic review and interviews. The Delphi survey assigned a priority to four outcome domains in the first round and four outcomes additionally in the second round. The core outcome domains were determined through discussion and redefinition of outcomes in the consensus meeting: pain and discomfort, health-related quality of life, lumbar function, activities of daily living, measures of walking, patient global assessment, adverse events and CM-specific outcomes.

Conclusion COS-CM-LSS is likely to enhance the consistency of outcomes reported in clinical trials. In-depth research should be conducted for the exploration of the best methods to examine the above outcomes.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We used a mixed-method approach to determine which outcomes would be included in the CORE outcome domain sets for trials of Chinese medicine for lumbar spinal stenosis (CM-LSS).
⇒ In this investigation, we incorporated the perspectives of different stakeholders, including patients, physicians and researchers.
⇒ The participants were sampled based on duration and socioeconomic status, disease severity, as well as LSS manifestations, which ensures that the core domains are generalisable to LSS people.
⇒ CM or integrated medicine studies have been mostly used there, which limits the results since stakeholders are distributed in different geographical areas.

INTRODUCTION

Lumbar spinal stenosis (LSS) arises from spinal anatomical or functional narrowing with a negative effect on the spinal cord and nerve roots, characterised by pain and discomfort in legs, buttocks and lumbar spine, as well as disability of walking capacity.[1] The above discomfort and pain can be increased by walking and alleviated through sitting or lumbar flexion.[2] LSS affects a global population of nearly 103 million[3] and 11% of the elderly in the USA.[4] Most LSSs are treated non-operatively, with physical therapy, analgesia and activity modification as the first-line therapies, whereas patients subjected to limited activities and continuous pain are likely to be an alternative in terms of surgery.[5]

Chinese medicine (CM), a non-surgical treatment, is critical in the treatment of LSS. Acupuncture and acupotomy contribute to the LSS patients on pain, symptoms and functional outcomes up to 6 months post-treatment.[6 7] Moreover, CM alone or combined treatment is likely to more pronouncedly alleviate pain and ameliorate functional outcomes than conventional therapies.[8] Furthermore, manual therapy in combination with exercises under supervision can improve walking capacity, symptoms and pain in comparison to exercises.[9]

A review of clinical trials of LSS found inconsistency between results reporting or measuring instrument application under one outcome and poorly defined outcomes.[10] An important effect of the above inconsistencies is to limit the potential of robust

meta-analysis. In a network meta-analysis of conservative treatment of LSS, only four results were analysed, while the other results could not be analysed due to the limited data or no meta-analysis to determine the outcome, or the variety of definitions of an outcome.[8] Existing problems, supported by most CM trials, include poorly defined outcomes, insufficient evidence of instruments, selective reporting of outcomes or no criteria for selection for core outcomes.[11] Data that cannot be interpreted or used cause unacceptable and unethical waste of research. Selective reporting of results and associated reporting biases may also occur if consistent results are not specified in advance.[12]

The core outcome set (COS) includes standardised outcomes. It has been found as the minimal measurement and report criterion in terms of the respective trial for a specific health area,[13] increasing outcome reporting consistency, accountability and transparency. Outcomes, which conform with certain standards and are examined in studies under a particular condition, can reduce this research waste, such that the bias of reporting can be prevented. The above outcomes can ensure that existing research reporting outcomes is able to be integrated into meta-analyses with certain significance.[14] The review of the Core Outcome Measures in Effectiveness Trials (COMET) database and searching OMERACT for COSs of trauma and orthopaedics ensured the lack of COS on LSS.[15]

This study presents a multiple-stakeholder, Chinese nationally endorsed, consensus-based CORE outcome set suitable for CM intervention trials in adults with LSS (CORE-CM-LSS), as well as its development.

METHOD

The study protocol was registered in the COMET database (https://www.comet-initiative.org/Studies/Details/1363), whereas the protocol was not published. The development of our COS was reported and consistent with the COS-STAndards for Reporting[16] as well as COS-STAndards for Development[17] guidelines (online supplemental table S1 and S2). This is a further study underlying COS development for low back pain (LBP), and the COS focused on specific LBP due to LSS which is treated by CM.

Scope and design

Study advisory group (SAG) was formed, in which a wide variety of stakeholders, two orthopaedists, one acupuncture and Tuina expert, one patient, one methodologist, one clinical trial researcher, as well as one statistician were invited. SAG confirmed the outcome set that serves as a candidate in terms of data analyses and explanation, process coordination and Delphi survey. Furthermore, some of them participated in the consensus process.

Following SAG, this COS's scope is clarified as follows: setting: randomised controlled trials (RCTs); health condition: symptomatic LSS.[1] Target interventions are CM for LSS, which comprise acupuncture, Tuina (CM massage), Gongfa (CM exercise), bloodletting, cupping, oral herbal medicine, local washing or compressing with CM. Furthermore, CM alone or CM combined with other conventional treatments were involved.

This study fell into three vital sections to obtain consensus on the outcome domains that were to be examined, which were completed in the proper sequence. The following inquiries were answered, including which outcome domains are likely to benefit LSS patients, which outcomes are more important, as well as which results should be included in the COS.

All participants declared no interest conflict during the study. Patients contributed to the design of the study and were involved in the stages of patients' interview and consensus meeting.

Systematic literature review

A list of outcomes was established through Systematic literature review (SLR). Moreover, the results of the SLR were partly published to assess the effectiveness of non-pharmaceutical Chinese medical therapies alone or in combination for the treatment of LSS.[18]

Eligible trials

The RCTs of the LSS patients diagnosed by clinical symptoms of neurogenic claudication and imaging findings were included, no matter whether LSS patients have complicating diseases. Interventions included the treatment with CM alone or treatment including CM. The control intervention involved routine treatment (eg, injection therapy, physical therapy, exercise therapy, health education, self-management), or a combination of the above. There were no restrictions on publication type, language or status.

Literature search and selection

The trials were identified by searching RCT and spinal stenosis terms from CNKI, VIP, WangFang, Sinomed, PubMed, Cochrane Library and EMBASE online databases, from their inception to 1 January 2022 (search strategy in online supplemental table S3). Grey literature and reference lists of included literature were searched. Furthermore, the authors of included literature were contacted to identify eligible trials.

The EndNote V.20 managed literature and excluded the duplicate ones. Eligibility was evaluated initially by two independent reviewers (including Y-NS and Y-JZ) through reading abstracts and titles, and the trials were included after the full texts were read. Any disagreements would be addressed through discussions when the full text was critically reviewed, or through consultation with a third author (CY).

Data collection and analyses

The data from eligible trials were extracted independently and inputted into Microsoft EXCEL for management. Extracted data included the first authors, contact information, outcome measurement instruments (OMI) (name

and measuring time frame), comparator, intervention, sample size, country and year of publication. If response rate or composite index outcomes exited in trials, the criteria and classification of them were recorded.

After data extraction, the measurement instruments were categorised by SAG into outcome subdomains and domains, and the respective outcome was defined by SAG following the COMET criteria.[19 20] Besides, SAG removed the duplicates and standardised the similar or overlapping outcomes. Information and purpose of an instrument (ie, to evaluate physical function, or pain intensity) was confirmed by original prescription, from either method or results parts, and considered into right subdomains. Any disagreements were resolved by consulting a third author (CY).

The number of instruments of the respective trial and subdomain and outcome domains of all trials was obtained. The frequency and percentages of categorical instruments and outcomes were conducted with SPSS V.18.0.

The semistructured interview

The additional associated outcome domains were elicited through qualitative semistructured interviews of patients.

Participants

The LSS patients previously or currently under CM treatment were recruited. While the LSS patients due to trauma or congenital spinal disease, having hearing or communication problems, or refusing to join the interviews were excluded.

We employed convenient and purposeful sampling methods based on several ages, gender, years of LSS and imaging findings related to the hospital outpatients from seven territories of China (predefined features in online supplemental table S4). Features were defined by the SAG to ensure diversity represented. The qualitative data were analysed, while the interviews continued, and the sampling was ended following data saturation criteria, based on the definition from two consecutive interviews without any additional subdomain.

Interview process

Interviews were carried out face to face in outpatient or via remote video software (WeChat) and recorded by qualified researchers (CY). Explanation and information consent should be given to patients before the interviews. We initiated the interview with questions (eg, 'what outcomes are important or most concern to you, or how do you determine the effectiveness of treatment, or what aspect they would like to get better improvement'). A list of subdomains from SLR was provided as the outline when patients could not answer or had no ideas about the important outcomes. After patients completed reading the list, another open-ended question was asked to allow patients to provide additional outcomes.

Data analysis

The additional outcomes and the demographic and medical information of patients were collected. The words expressed by patients were analysed through qualitative content analysis. For an overall perspective and familiarity with the content, the recorded interviews were listened to and the transcripts were reviewed and reread. The two researchers (Y-NS and YA) first carried out the initial assessment individually before being mapped into the initiative list in three steps. Specifically, sentences and paragraphs were found, abstracted and then coded as meaning units. The codes were organised into subjects under the context of COMET outcomes subdomains; the codes of each topic fell into initial COMET outcome domains. Subsequently, the draft outcomes domains of the two researchers were combined and compared. Afterwards, outcomes subdomains with similar names were examined, and those with the same content were grouped together. Any discrepancies were resolved with discussion.

Expert consensus

Panel participants

A group of participants specialised in CM, integrated Chinese and Western medicine, nursing, orthopaedics, acupuncture, Tuina, pain management, rehabilitation and clinical researchers were recruited in the Delphi survey, and the professional and geographical distribution of panellists was considered. Furthermore, all SAG members engaged in the consensus meeting via WeChat conference instead of face to face due to the COVID-19 pandemic.

It was expected to select 30 participants based on a snowball sampling method. The experts were preliminarily identified by reviewing the authors of high-impact papers and recommended by the preliminary stakeholders. The patients were selected following a pool of outpatients. All participants completed round 1 were invited to join round 2 of Delphi.

Identifying important outcomes in Delphi Survey

In rounds 1 and 2, for the respective outcome, panellists were recruited for assigning scores between 1 (of no importance) and 9 (of high importance), where 1–3 represents that it is 'of no importance to be included in the COS', 4–6 represents that it is 'of importance but no critical importance to be included in the COS' and 7–9 represents that it is 'of critical importance to be included in the COS'.[21] In round 1, participants were recruited to add new outcome(s), if they regarded it/them as important.

We removed outcomes reaching consensus thresholds between rounds for the minimisation of attrition. Predefined 'consensus in' thresholds are reached if >80% of the panellists scores 7–9 and ≤15% scores 1–3; 'consensus out' thresholds are met if >80% of the panellists scores 1 to –3 and ≤15% of the panellists scores 7–9. This threshold is consistent with those set for other core

outcomes, protecting minority stakeholders' different views from the rejection by a greater stakeholder group.[22]

The outcomes that scored neither consensus in nor out were retained to the next round. The newly added outcomes by the participants that existed in the preliminary list were removed. Otherwise, the new outcomes were entered in the next round for scoring. Feedback was presented between the 1st and 2nd rounds, with average scores of outcomes.

Identifying core outcomes in consensus meetings

A total of 9 LSS patients and 15 experts, most from previous study stages, were recruited in an online consensus meeting. One author (CHY), who is independent of the discussion and voting poll, moderated the meeting using the nominal group technique (NGT). The NGT refers to a meeting with a rigorous structure, which is carried out for allowing key stakeholders' identification and rating of a list of priorities; it also aims to ensure that the opinions of all participants are included.[23] The meeting aimed to reach an agreement in terms of a preliminary core set of 7–10 domains.

The NGT process started with the discussion of domains that were in consensus out or not a consensus with the purpose to discard them or move them into consensus in. Subsequently, the rest outcomes were investigated, redefined, kept or integrated into greater categories if an agreement was reached by most panellists. Anonymised votes were made in terms of agreements with domain placement. When the meeting was about to be completed, a draft preliminary core set of domains was made and then shown to the participants.

After the Delphi survey was completed, the outcomes of 'consensus in' and 'no consensus' were scored by using yes, no, or unsure for inclusion of the COS (yes for selected; no for not selected). In terms of outcomes to be included in the core domain set, a prespecified threshold of >80% on yes was set.

Patient and public involvement

None.

RESULTS

Identification of candidate outcomes

Outcomes from the SLR

A total of 5674 trials were identified through the SLR, 86 trials could be included after duplicates were removed, and abstract, title and full-text were screened (Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram in online supplemental figure S1). Eighty-six trials involved 6892 LSS patients (rang 26–200), with 80% (2980/6658, two trials did not report gender) female, aged from 33 to 72 years. Most trials compared a wide variety of CM treatments alone with placebo or routine treatment, and others compared the combination of CM treatment versus CM treatment alone or western treatment. Online supplemental table S4 lists the characteristics of the included trials in detail.

Table 1 lists a total of 86 trials that reported 54 different OMI. The number of OMIs was applied and reported, ranging from 1 to 6 (median 3). The most used OMI included response rates (64/86, 74.42%), various versions of JOA (42/86, 48.84%), Visual Analogue Scale (37/86, 43.02%), adverse events (AEs) (18/86, 20.93%), as well as measures of walking (12/86, 13.95%) (online supplemental table S5). Fifty per cent of OMI were patient-reported outcomes, and 30% were performance-based measurements. While the rest were clinician-based measurements (eg, CT and MRI).

SAG reviewed 54 OMI and identified 20 subdomain outcomes and 10 COMET domains (table 1). Among 86 trials, pain (98.8%; n=85) and function (97.7%; n=84) were the most frequently evaluated COMET domains, followed by AEs (22.1%; n=19), and Physiological index (12.8%; n=11). Three COMET domains (including resource use, mortality and infection) were not reported in any trial.

Patients interview

In this study, 18 interviews were carried out with LSS patients from seven territorial regions around China. Eight of the 18 interviews with them were done via the WeChat app. Online supplemental table S6 presents the demographic details of the participants. The content analyses of interview transcript and outcomes from open-ended questions indicated that 16 subdomain outcomes were identified and then classified into 11 COMET domains (table 2).

SAG identified subdomain outcomes as candidate outcomes from SLR and interviews, defined outcomes and constructed a final inventory of 17 outcomes[20 24–31] for the Delphi survey (table 3). Among candidate outcomes, physiological outcome was separated by SAG into biomarkers and radiographic changes. The biomarkers outcome was identified by SAG by combing inflammatory markers, haemorheological markers, immunological markers and physiological outcomes (figure 1).

Important outcomes identified from Delphi surveys

A total of 25 experts and 18 patients were recruited for online Delphi survey, and 21 experts and all patients responded and completed the first-round survey (participant characteristics detailed in online supplemental table S7). Delphi survey identified four outcome domains (including pain, function, activities of daily living (ADL) and quality of life (QOL)) in the first round, and another four outcome domains (including symptoms, measures of walking, global rating of change and AE) in the second round, all of which met the consensus threshold. Table 4 lists the scores for all candidate outcomes and 'consensus-in' outcomes. The 'consensus-in' outcomes drew the Delphi consensus threshold and employed the above for the development of several initial outcome domains to be covered in the core outcome domain set.

Table 1 Classification of outcome measurement instruments into subdomains and COMET outcomes

No	COMET domain outcome	No of 86 RCTs reporting COMET outcomes (%)	Subdomain outcome	No of 54 OMIs into subdomain outcomes (%)	OMI (n=54)
1	Function	85 (98.8)	Function ADL ROM Symptoms Measure of walking Global rating of change	10 (18.5) 3 (5.6) 1 (1.9) 1 (1.9) 3 (5.6) 3 (5.6)	JOA/improvement of JOA/mJOA/ODI/ mRMDQ/RMDQ/ ZCQ/SSS/self-made lumbar function evaluation scale/ physical function, role-physical, vitality of SF-36 ADL subscale of JOA, ODI or RMDQ Rang of lumbar spine extension Self-made symptoms rating scale SPWT/walking capacity/Pain-free walking distance Responder rates/Global Rating of Change Scale/general health of SF-36
2	Pain	84 (97.7)	Pain	6 (11.1)	VAS/NRS/UAB-PBS/pain subscale of JOA/pain subscale of SSS/bodily pain subscale of SF-36
3	AEs	19 (22.1)	AE	1 (1.9)	AE
4	Physiological	11 (12.8)	Inflammatory markers Haemorheological marker Immunological markers Physiological markers Radiographic changes	8 (14.8) 3 (5.6) 4 (7.4) 3 (5.6) 1 (1.9)	IL-6\IL-1B\TNF\CRP\IL-1\IL-4\IL-10\ ESR Blood viscosity/plasma viscosity/RBC haematocrit Changes in T lymphocyte subsets Hepatic and renal function tests/ Serum endothelin Parameters of CT
5	CM indictor	5 (5.8)	CM meridian/CM Zheng	2 (3.7)	Near-infrared imaging system on meridian CM Zheng scores
6	Mental health	4 (4.7)	Mental health	2 (3.7)	HADS/ mental health subscales of SF-36
7	Satisfaction	4 (4.7)	Satisfaction index	1 (1.9)	Satisfaction subscale of SSS
8	Quality of life	3 (3.5)	Quality of life	1 (1.9)	SF-36
9	Psychosocial	3 (3.5)	Psychosocial	1 (1.9)	Social function, role-emotional subscales of SF-36
10	Compliance	1 (1.2)	Adherence and attrition	1 (1.9)	Treatment Adherence index
11	Resource use	0 (0)	Resource use	0 (0)	NR
12	Mortality	0 (0)	Mortality	0 (0)	NR
13	Infection	0 (0)	Infection	0 (0)	NR

ADL, activities of daily living; AE, adverse event; CM, Chinese medicine; COMET, Core Outcome Measures in Effectiveness Trials; CRP, C reactive protein; HADS, Hospital Anxiety and Depression Scale; JOA, Japanese Orthopedic Association Score; mJOA, modified JOA; mRMDQ, modified Roland Morris Disability Questionnaire; NR, not reported; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index; OMI, Outcome Measurement Instruments; RBC, red blood cell; RMDQ, Roland Morris Disability Questionnaire; ROM, range of movement; SF-36, 6-Item Short Form Survey; SPWT, Self-Paced Walk Test; SSS, Spinal Stenosis Scale; TNF, tumour necrosis factor; UAB-PBS, University of Alabama at Birmingham- Pain Behavior Scale; VAS, Visual Analogue Scale; ZCQ, Zurich Claudication Questionnaire.

COS determined by consensus meetings

Consensus meeting summary

The participants redefined some outcomes from the list of 17 domains (table 4) in the NGT process. LSS patients were subjected to the pain accompanied by numbness or tingling in the lower legs or feet. Some severe limitations in activity resulted in the gradual worsening of pain over time. The severity of pain, walking disability underlying definition of symptoms outcome may overestimate or underestimate outcomes. Thus, the experts suggested that the overall symptom outcome can be replaced by the outcomes of pain, lumbar function, walking disability and ADL, respectively, which were evaluated easily and adequately.

Table 2 Subdomain and COMET outcomes identified from interviews

COMET domain outcome	Subdomain outcomes	No of 18 patients (%)	Example of interview transcript (Chinese words presented in English)
Function	Function	17 (94.4)	"*This waist does not seem to be as flexible as before……*"
	ADL	14 (77.8)	"*I felt hard to get dressed, brush teeth, wash face, or go to toilet……*"
	ROM	3 (16.7)	"*I felt hard to back straight or bend over (in some degrees)*"
	Symptoms	16 (88.9)	"*Pain is on my low back and legs, makes me hard to move anymore (or in certain distance)*"
	Measure of walking	16 (88.9)	"*I can't walk long way, I felt my legs do not work, and then I have to stop for a rest ……*"
	Global rating of change	2 (11.1)	"*I would like to feel wellbeing, ……, even for a while*"
Pain	pain	18 (100)	"*I cannot get into sleep due to pain when I tried to turn over on bed*"
Adverse events	AE	16 (88.9)	"*Is that (the treatment) safe? Are there any side effects?*"
Physiological	Inflammatory markers	0 (0)	nr
	Haemorheological markers	0 (0)	nr
	Immunological markers	0 (0)	nr
	Physiological markers	0 (0)	nr
	Radiographic changes	2 (11.1)	"*(Treatment) helps me release the narrowing of space and pressure of nerves, I would feel well*"
CM indicator	CM meridian	0 (0)	nr
	CM Zheng	1 (5.5)	"*Can Chinese medicine help to treat blood stasis pattern*?"
Mental health	Mental health	12 (66.7)	"*It always hurts and pain seems not to be relieved, so I felt some irritable, and worried as it is getting more serious*"
Satisfaction	Satisfaction index	1 (5.5)	"*I felt satisfied if it (treatment) can relieve my pain and help me walk long*"
Quality of life	Quality of life	5 (27.8)	"*Low back pain affects life, and the most impact of pain is on my quality of life*"
Psychosocial	Psychosocial	4 (22.2)	"*I was really worried because I was younger and worried about my professional longevity…….I couldn't hang out with my family, it was always a drag on my family, and I had to let them take care of me*"
Compliance	Adherence and attrition	1 (5.5)	"*You have to listen to the doctor, and the efficacy would be guaranteed*"
Resource use	Resource use	3 (16.7)	"*Treatment wastes lots of time on transportation and waiting, but I have to (do it) due to pain*"

ADL, activities of daily living; AE, adverse event; CM, Chinese medicine; COMET, Core Outcome Measures in Effectiveness Trials; nr, not reported; ROM, range of movement.

For pain outcome, several experts suggested that some patients felt discomfort rather than pain, so pain outcome was redefined 'pain' to 'pain and discomfort'. Furthermore, the physical function of LSS was redefined as lumbar function and walking function, and the latter referred to measures of walking or walking performance.

QOL, a board definition, was brought up for discussion. First, experts redefined QOL to health-related QoL (HRQoL), consisting of mental and physical health perceptions (eg, mood, energy level) and their correlates (eg, socioeconomic status, social support, functional status, as well a and health conditions and risks). The concept HRQoL presented potentially overlapping with some of the above domains. Thus, participants agreed and favoured the inclusion of physical, emotional and social life were covered in HRQoL for LSS patients.

Global rating of change was also discussed. The concept was felt to reflect disease activity and overarching global health status of the patient, specific to that patient. Based on the above discussion, the global rating of change was

Table 3 Candidate lumbar spinal stenosis outcomes and definitions

No	Candidate outcome	Definition	Resources
1	Pain	Experiencing an unpleasant physical sensation that aches, hurts in one or more joints or the spine; an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described for such damage.[29]	SLR+Int
2	Function	Being able to perform physical activities (includes lower extremity functioning, balance); patient's ability to carry out daily physical activities required to meet basic needs, ranging from self-care to more complex activities that require a combination of skills.[24]	SLR+Int
3	ADL	Fundamental skills required to independently care for oneself, such as eating, bathing and mobility.[25]	SLR+Int
4	ROM	Quantity of movement of the lumbar spine and/or of other adjacent body parts (ie, thoracic spine, pelvis, rib cage or lower limbs).[24]	SLR+Int
5	Symptoms	Presence of symptoms on back, leg and walking.[27]	SLR+Int
6	Measure of walking	Measuring ability, capability, distance, performance of walking.[24]	SLR+Int
7	Global rating of change	Considering the ways that the health condition affects the individual on a given day.[30]	SLR+Int
8	AE	Any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related.[31]	SLR+Int
9	Biomarks	Indicators aimed at providing insight into peripheral and central neurobiological mechanisms of pain.[24]	SLR
10	Radiographic changes	medical imaging such as MRI, CT, X-ray detecting the changes of bones, joints, muscles, tendons, nerves and other body structures localised on the lumbar spine and/or on other adjacent body parts (ie, thoracic spine, pelvis, rib cage or lower limbs).[24]	SLR+Int
11	CM-specific outcomes	CM outcomes related to CM Zheng or meridians based on CM theory.[28]	SLR
12	Mental health	A person's condition with regard to their psychological, social and emotional well-being.[26]	SLR+Int
13	Satisfaction index	Satisfaction with care received, including of the process and outcomes of the treatment experience and care providers.[24]	SLR+Int
14	Quality of life	Broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life, including health-related quality of life.[26]	SLR
15	Adherence and attrition	Withdrawal from treatment.[20]	SLR
16	Psychosocial	An individual's interactions with their environment and the ability to fulfil their role within such environments as work, social activities, and relationships with partners and family.[24]	SLR
17	Resource use	Treatment burden such as impact of treatment and monitoring of disease or treatment (ie, financial loss due to treatment cost, work loss or time commitment).[20]	Int

ADL, activities of daily living; AE, adverse events; CM, Chinese medicine; Int, interview; ROM, range of movement; SLR, systematic literature review.

renamed and defined as patient global assessment (PGA) of disease-related health status and kept as a core domain.

COS identified by final voting

According to the list of outcomes, an agreement was reached on the core set based on an electronic voting programme in consensus meetings. Table 4 lists the scores for the respective outcome domain. An agreement was reached on eight domains of importance and inclusion in the core domain set for clinical trials (including pain and discomfort, HRQoL, lumbar function, ADL, walking function, PGA, AE and CM-specific outcomes). Online supplemental table S8 lists the sensitive analysis of score of outcomes between patients and experts.

DISCUSSION

Summary of the main results

This study presents the development of the CORE-CM-LSS and the steps involved for reaching a consensus of patients and experts. The patient perspective was

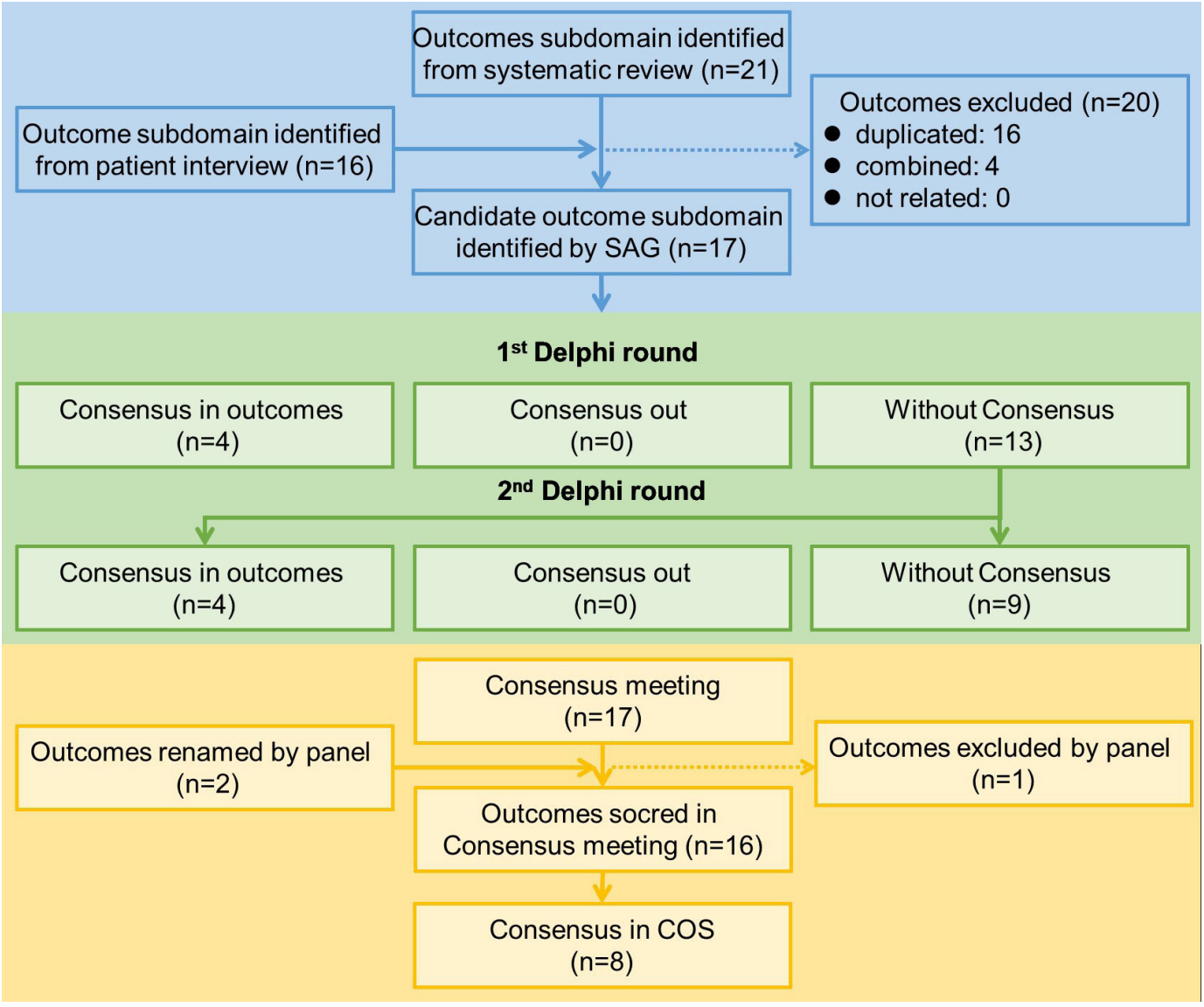

Figure 1 Flow chart of core outcomes selection process. COS, core outcome set; SAG, study advisory group.

integrated in the respective research phase. The sampling process included panellists nationally, which can endow our findings with greater generalisability in China.

Outcomes included in the COS

Our review and consensus results confirm that the pain/discomfort, function, walking disability and ADL of LSS patients arouse the main concern of patients and physicians and have been most reported in trials. The above outcomes were common symptoms of LSS or impacts of symptoms. The AEs are required for the assessment of the harms of all interventions, and they arouse the most concern of patients. The HRQoL is vital outcomes for the trials on pain for its generic construct, which is beneficial to compare populations from different diseases. However, the LSS-associated HRQoL is necessary but scarce, which can precisely indicate the outcomes changes and should replace the generic HRQoL. PGA, counterparting to the physician's global assessment, was first developed to measure self-assessed pain in rheumatoid arthritis. PGA scales were employed in a broad range of diseases over the past years. The application of PGA in clinical practice covered two different concepts. One of the concepts is concerned with global health. The other concept is relating to overall changes of disease activity or severity.[32]

The CM-specific outcomes were covered in COS in terms of its specific for CM, which may deviate from that employed in Western medicine,[28 33] which are attributed to a general agreement to not discuss instruments. However, CM-specific outcome measures have been rarely investigated. The CM pattern (syndromes or Zheng in Chinese) is a diagnostic conclusion based on pathological changes in a disease, at a certain stage.[34] A pattern often contains several CM symptoms (eg, tongue manifestation or pulse condition). CM physicians should measure patterns and CM symptom changes during the treatment of patients. The meridian detection and CM pattern is a diagnostic and outcome assessment tool for one health condition. However, the definitions and measurement instruments

Table 4 Candidate outcomes ratings in two rounds Delphi and voting at consensus meetings

Candidate outcomes	Round 1 (n=39) % score 1–3	% score 4–6	% score 7–9	Round 2 (n=39) % score 1–3	% score 4–6	% score 7–9	Redefined outcomes	Consensus meeting voting (n=24) % yes
Pain	0%	5%	95%	nr	nr	nr	Pain/discomfort	100%
Function	3%	5%	92%	nr	nr	nr	Lumbar function	100%
ADL	0%	5%	95%	nr	nr	nr	ADL	92%
ROM	10%	26%	64%	5%	18%	77%	ROM	50%
Symptoms	5%	15%	79%	5%	8%	87%	nr	nr
Measure of walking	5%	28%	67%	0%	8%	92%	Walking function	96%
Global rating of change	3%	26%	72%	3%	15%	82%	PGA	88%
AE	0%	21%	79%	0%	15%	85%	AE	100%
Biomarks	28%	41%	31%	21%	51%	28%	Biomarks	4%
Radiographic changes	5%	33%	62%	3%	31%	67%	Radiographic changes	38%
CM-specific outcomes	8%	28%	64%	3%	21%	77%	CM-specific outcomes	88%
Mental health	5%	36%	59%	3%	38%	59%	Mental health	63%
Satisfaction index	0%	28%	72%	0%	26%	74%	Satisfaction index	21%
Quality of life	3%	13%	85%	nr	nr	nr	HRQoL	96%
Adherence and attrition	8%	33%	59%	5%	31%	64%	Adherence and attrition	4%
Psychosocial	49%	38%	13%	49%	41%	10%	Psychosocial	21%
Resource use	8%	26%	67%	5%	23%	72%	Resource use	58%

ADL, activities of daily living; AE, adverse events; CM, Chinese medicine; HRQoL, health-related QOL; nr, not reported; PGA, patient global assessment; QOL, quality of life; ROM, range of movement.

of CM-specific outcomes varied in LSS RCTs. It is likely to be a solution to develop a scientific, standard CM pattern scale or a more specific outcome to evaluate the effect of patterns.[35]

Recent SLR of outcomes reporting in RCTs of LSS has suggested that among 29 trials, function and pain were the most common outcomes, followed by AEs.[10] The results supported the results of our study from SLR and consensus-COS though differences were identified in the trials with comparisons among Western medicine (eg, surgery, physical therapy, medication), as well as the trials identified from six SLRs from Cochrane Central Register of Controlled Trials database and PubMed during 2016 and 2021. Furthermore, function, pain, HRQoL and AE are reported as vital outcomes for LSS in Cochrane SLRs. If LSS was considered specific LBP, several studies consistently recommended pain, function and HRQoL as core outcome domains for LBP.[24 36–38] Furthermore, additional core domains may be examined alongside the above outcomes to capture condition-specific characteristics.

Strengths and limitations

Strengths of this study include a China national representation of LSS patient and physician stakeholders participating in the consensus meeting, surveys and candidate outcome generation. We followed rigorous research methods and had nearly equal representation of patients and physicians at each step of the process. The response rates were 100% from two rounds in Delphi, avoiding attrition bias. The participants were sampled following duration and socioeconomic status, disease severity and LSS manifestations. This ensured that we captured broad content early in the process of data collection and obtained domains that are generalisable to LSS people.

However, this study also had limitations. First, some of the experts participated in the consensus meeting via WeChat conference instead of face to face due to the COVID-19 pandemic. This may have led to insufficient discussion and affected the consensus results. However, we ensured that every participant had sufficient time for making statements and voting. Each electronic voting was confirmed by reminder before submission. Second, the

number of patients who participated in Delphi rounds and consensus meetings was relatively small. Thus, the importance of certain areas may be underestimated from their perspectives. It is worth mentioning that the goal of this study was to develop a core set of outcomes to be included in all clinical trials, instead of a set of outcome areas important to all stakeholders. Third, participants were not asked to assign relative priority to any domain, whereas all outcome domains that met the consensus threshold of 80% for consensus, should be considered with equal importance.

Implication for clinical practices and research

This study primarily aimed to collect core outcome measures for use in reliable prospective studies related to LSS patients. This COS might potentially be incorporated into LSS registries and used as a reference for data collecting in clinical practice as a list of significant outcomes to monitor during any therapy. When the COS's external validation would be confirmed, the findings can be extrapolated to an adequate population. Next, the psychometric features of each core set domain's outcome measure will be assessed, and a core set of outcome measures that is sufficient and not redundant will be selected.

CONCLUSION

The COS for CM in LSS was first established. Pain and discomfort, HRQoL, lumbar function, ADL, walking function, PGA, AE and CM-specific outcomes should be measured and reported in all future research trials that have evaluated CM for the treatment of LSS to increase consistency in the report of the result. The COS can facilitate the synthesis of the evidence relating to LSS patient-associated outcomes and support overall field development and research.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the ethics committee of Dongzhimen hospital (DZMEC-KY-2020-60). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request.

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Supplementary Material

Table S1. The COS-STAR Statement

SECTION/TOPIC	ITEM No.	CHECKLIST ITEM	page no.
TITLE/ ABSTRACT			
Title	1a	Identify in the title that the paper reports the development of a COS	1
Abstract	1b	Provide a structured summary	3,4
INTRODUCTION			
Background and	2a	Describe the background and explain the rationale for developing the COS	6,7
Objectives	2b	Describe the specific objectives with reference to developing a COS	6,7
Scope	3a	Describe the health condition(s) and population(s) covered by the COS.	6-8
	3b	Describe the intervention(s) covered by the COS.	6-8
	3c	Describe the setting(s) in which the COS is to be applied.	6-8
METHODS			
Protocol /Registry Entry	4	Indicate where the COS development protocol can be accessed, if available, and/or the study registration details.	7,8
Participants	5	Describe the rationale for stakeholder groups involved in the COS development process, eligibility criteria for participants from each group, and a description of how the individuals involved were identified.	7,8
Information Sources	6a	Describe the information sources used to identify an initial list of outcomes.	8-11
	6b	Describe how outcomes were dropped/combined, with reasons (if applicable).	8-11
Consensus Process	7	Describe how the consensus process was undertaken.	11-13

Outcome Scoring	8	Describe how outcomes were scored and how scores were summarized.	11-13
Consensus Definition	9a	Describe the consensus definition.	12,13
	9b	Describe the procedure for determining how outcomes were included or excluded from consideration during the consensus process.	12,13
Ethics and Consent	10	Provide a statement regarding the ethics and consent issues for the study.	8
RESULTS			
Protocol Deviations	11	Describe any changes from the protocol (if applicable), with reasons, and describe what impact these changes have on the results.	8
Participants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development.	15-18 and Supplementary materials
Outcomes	13a	List all outcomes considered at the start of the consensus process.	15-18 Table 1-3
	13b	Describe any new outcomes introduced and any outcomes dropped, with reasons, during the consensus process.	15-17
COS	14	List the outcomes in the final COS.	18-20, Table 4,figue 1
DISCUSSION			
Limitations	15	Discuss any limitations in the COS development process.	21-22
Conclusions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research.	21-24
OTHER INFORMATION			
Funding	17	Describe sources of funding/role of funders.	25
Conflicts of Interest	18	Describe any conflicts of interest within the study team and how these were managed.	25

Table S2. The COS-STAD checklist

Domain	**Standard number**	**Methodology**	**page no.**
Scope specification	1	The research or practice setting(s) in which the COS is to be applied	7,8
	2	The health condition(s) covered by the COS	7,8
	3	The population(s) covered by the COS	7,8
	4	The intervention(s) covered by the COS	7,8
Stakeholders involved	5	Those who will use the COS in research	7,11,12
	6	Healthcare professionals with experience of patients with the condition	11,12
	7	Patients with the condition or their representatives	11,12
Consensus process	8	The initial list of outcomes considered both healthcare professionals' and patients' views.	13-17, table1-3
	9	A scoring process and consensus definition were described a priori.	7,8
	10	Criteria for including/dropping/adding outcomes were described a priori.	11-13
	11	Care was taken to avoid ambiguity of language used in the list of outcomes.	11-13

Table S3. Search strategies and results

Databases	Search strategies	Results to Jan 1st, 2022
PUBMED	("chin med"[Journal] OR ("chinese"[All Fields] AND "medicine"[All Fields]) OR "chinese medicine"[All Fields] OR "tuina"[All Fields] OR ("massage"[MeSH Terms] OR "massage"[All Fields] OR "massages"[All Fields] OR "massaged"[All Fields] OR "massager"[All Fields] OR "massagers"[All Fields] OR "massaging"[All Fields]) OR ("cupping"[All Fields] OR "cuppings"[All Fields]) OR ("moxibustion"[MeSH Terms] OR "moxibustion"[All Fields]) OR ("acupunctural"[All Fields] OR "acupuncture"[MeSH Terms] OR "acupuncture"[All Fields] OR "acupuncture therapy"[MeSH Terms] OR ("acupuncture"[All Fields] AND "therapy"[All Fields]) OR "acupuncture therapy"[All Fields] OR "acupuncture s"[All Fields] OR "acupunctured"[All Fields] OR "acupunctures"[All Fields] OR "acupuncturing"[All Fields]) OR ("trends cardiovasc med"[Journal] OR "case manager"[Journal] OR "tcm"[All Fields]) OR "taichi"[All Fields]) AND ("spinal stenosis"[MeSH Terms] OR ("spinal"[All Fields] AND "stenosis"[All Fields]) OR "spinal stenosis"[All Fields])	195
Embase	(('chinese'/exp OR chinese) AND ('medicine'/exp OR medicine) OR taichi) AND spinal AND ('stenosis'/exp OR stenosis) AND ([chinese]/lim OR [english]/lim) AND [humans]/lim AND [clinical study]/lim AND [embase]/lim AND [<1966-2021]/py	160
Cochrane Library	(chinese medicine or TCM or tuina or massage or acupuncture or cupping or Moxibustion or taichi):ti,ab,kw and (Spinal stenosis):ti,ab,kw	73
CNKI	SU='中医'+'中药'+'中西医结合'+'中医药'+'针灸'+'推拿'+'手法'+'针刺'+'艾灸'+'拔罐'+'汤药'+'针刀'+'热敷'+'功法'+'导引'+'放血'+'刺络'+'泡洗'+'太极'+'按摩'+'正骨'+'点穴'+'穴位注射' AND SU='腰椎管狭窄'+'腰椎管狭窄症'+'椎管狭窄'+'椎管狭窄症'+'退行性腰椎管狭窄症'+'间歇性跛行'	988
Wanfang	主题:("中医" or "中医药" or "中西医结合" or "中药" or "针灸" or "针刺" or "艾灸" or "穴位注射" or "推拿" or "手法" or "按摩" or "正骨" or "拔罐" or "放血" or "刺络" or "泡洗" or "热敷" or "针刀" or "导引" or "功法" or "太极" or "点穴" or "汤药") and 主题:("腰椎管狭窄" or "腰椎管狭窄症" or "	1784

	椎管狭窄" or "椎管狭窄症" or "退行性腰椎管狭窄症")	
Sinomend	(("电针"[常用字段:智能] OR "针刺"[常用字段:智能] OR "正骨"[常用字段:智能] OR "拔罐"[常用字段:智能] OR "艾灸"[常用字段:智能] OR "放血"[常用字段:智能] OR "刺络"[常用字段:智能] OR "泻血"[常用字段:智能] OR "火罐"[常用字段:智能]) OR ("中医"[常用字段:智能] OR "中药"[常用字段:智能] OR "中医药"[常用字段:智能] OR "针灸"[常用字段:智能] OR "方剂"[常用字段:智能] OR "汤药"[常用字段:智能] OR "推拿"[常用字段:智能] OR "手法"[常用字段:智能] OR "拔罐"[常用字段:智能])) AND ("腰椎管狭窄症"[常用字段:智能] OR "椎管狭窄症"[常用字段:智能] OR "腰椎管狭窄"[常用字段:智能] OR "椎管狭窄"[常用字段:智能])	1084
VIP	M=(腰椎管狭窄) AND U=(针灸 OR 推拿 OR 艾灸 OR 针刺 OR 手法 OR 拔罐 OR 功法 OR 太极 OR 中医)	1480

Table S4. Patient features representing the target participants

Category	Features
Age	8 patients ≥65 years of age
	8 patients <65 years of age
Sex	8 females
	8 males
Disease courses	8 patients ≥10 years
	8 patients <10 years
Radiographic classification	Covering lateral recess, central spinal canal
	intervertebral foramen
territorial region	At least more than 5 regions of China

Table S5. Studies' Characteristics and Outcome Measurement Instruments

First author, year	Participants	Interventions	Comparator	Outcome Measurement Instruments	Treatment duration	OMI measuring time	Subdomain outcomes	COMET outcomes	criteria for responder rates
Zeng Haobin, 2020[1]	60/60	Manual therapy+Usual care	Celecoxib+Usual care	JOA VAS parameters of computed tomography	2w	Pre- and post-treatment, follow-up 3m and 6m	pain/function/ADL pain Radiographic changes	pain function Physiological	NR
Chen Jian, 2019[2]	30/30	CM herb	Aceclofenac+Mecobalamin	JOA IL-6/CRP ODI AE hepatic and renal function tests	4w	Pre-treatment, 2 and 4w after treatment Pre- and post-treatment for hepatic and renal function tests	pain/function/ADL Inflammatory markers function AE Physiological index	pain function Physiological AE	JOA
Feng Sui 2009[3]	40/40	Acupotomy	Traction	Responder rates	2m	Pre- and post-treatment	pain/function	pain function	DEC-TCM
Geng Xiaoyan, 2017[4]	46/46	CM herb	Salvia (Danshen) injection+Diclofenac	JOA	NR	Pre- and post-treatment	pain/function/ADL	pain function	NR

Gu Qi, 2015[5]	30/30	CM herb	GIucos	mJOA VAS SPWT Responder rates	2w	Pre- and post-treatment, follow-up 1m for Responder rates	pain/function/ ADL pain measure of walking pain/function/ ADL	pain function	JOA
Guan Xiaoyong, 2015[6]	47/47	CM herb	Salvia (Danshen) injection+Diclofenac	VAS Responder rates	1m	Pre- and post-treatment	pain pain	pain	VAS
Hou Yu, 2019[7]	22/23	Manual therapy	NSAIDs+Drugs for protecting gastric mucosa and nourishing nerves	JOA VAS	4w	Pre- and post-treatment	pain/function/ ADL pain	pain function	NR
Huang Zheng, 2017[8]	31/33/ 32/33	CM herb Acupuncture CM herb+Acupuncture	Diclofenac+Mecobalamin	JOA/improvement of JOA Responder rates AE	3m	Pre-treatment, 1, 2 and 3m after treatment	pain/function/ ADL pain/function/ AE	pain function AE	DEC - TCM
Huang Zhifen, 2009[9]	50/46	CM herb	Diclofenac	Responder rates AE	4w	Pre- and post-treatment	pain/function/ AE	pain function AE	DEC - TCM
Ji Wei, 2013[10]	35/34	CM herb	Mecobalamin	Responder rates VAS mJOA	4w	Pre- and post-treatment	pain/function/ pain pain/function/ ADL	pain function	DEC - TCM

Jia Yingchun, 2005[11]	45/22	CM herb+CM rehabilitation	Drugs (Diclofenac tablets or Diethylamine Emulgel, Chondroitin Sulfate Tablets, VB1, VB6, et al)	VAS Self-made symptoms rating scale UBA pain behavior scale Responder rates	2w	Pre- and post-treatment	pain symptoms pain pain/function/	pain function	DEC-TCM
Li Jinxue, 2007[12]	40/40/44/42	CM herb CM herb+CM granules CM herb+CM granules+Erigeron breviscapus	GIucos	Responder rates VAS parameters of computed tomography	4w	Pre- and post-treatment for Responder rates/VAS/Radiographic changes, follow-up 12month for Responder rates	pain/function/ADL pain Radiographic changes	pain function Physiological	JOA
Li Jinxue, 2013[13]	92/83	CM herb	GIucos	Responder rates VAS Walking capacity	2w	Pre- and post-treatment for Responder rates/VAS/Walking capacity, follow-up 1m for Responder rates/Walking capacity	pain/function/pain measure of walking	pain function	GPCR-ND

Li Qiming, 2018[14]	98/60	CM herb	Usual care	JOA VAS	2w	Pre- and post-treatment	pain/function/ ADL pain	pain function	NR
Li Rui, 2016[15]	43/43	CM herb	Loxoprofen sodium	JOA VAS Responder rates SF-36 AE	2m	Pre- and post-treatment	pain/function/ ADL pain pain/function/ QOL: physical function, role-physical, bodily pain, general health, vitality, social function, role-emotional, mental health Psychosocial AE	pain function QOL AE mental health Psychosocial AE	NR
Li Zhiwei, 2008[16]	20/20	CM herb	Diclofenac	VAS JOA Responder rates AE	4w	Pre-treatment, 1, 2, 3 and 4w after treatment	pain pain/function/ ADL pain/function/ ADL AE	pain function AE	JOA

Lin Yuanfang, 2017[17]	33/32	Manual therapy	Traction	Responder rates JOA Rang of Lumbar spine extension	20d	Pre- and post-treatment	pain/function/ pain/function/ ADL ROM	pain function AE	DEC - TCM
Liu Chenhui, 2019[18]	30/30	CM herb	Celecoxib+Mecobalamin+Hydrotalcite Tablets	VAS SPWT CM Zheng scores Responder rates AE	2w	Pre- and post-treatment	pain Measure of walking CM Zheng pain/function/ AE	pain function AE CM indictor	DEC - TCM
Liu Haifan, 2010[19]	30/30	Acupotomy	Canal injection	Global Rating of Change Scale Responder rates	2w	Pre- and post-treatment	Global rating of change pain/function/	pain function	DEC - TCM
Liu Jun, 2020[20]	46/46	CM herb	Mannitol Injection+Mecobalamin	Responder rates	3w	Pre- and post-treatment	pain/function/	pain function	NR
Sheng Xinjun, 2016[21]	40/40	Acupotomy	Traction	Responder rates VAS JOA Changes in T lymphocyte subsets	20d	Pre- and post-treatment	pain/function/ pain pain/function/ ADL Immunological indicators	pain function Physiological	DEC - TCM
Su Lianshu, 2015[22]	38/37	Acupotomy	Canal injection	VAS JOA Responder rates	3w	Pre-treatment, 1 and 4w after treatment	pain pain/function/ ADL pain/function/	pain function	DEC - TCM

Sun Biyun, 2021[23]	40/40	Acupuncture	Sham Acupuncture	NRS mRMDQ HADS Treatment Adherence index AE	6w	Pre-treatment, 6w after treatment, follow-up 12w and 24w for NRS/RMDQ/ HADS	pain function Psychological assessment Adherence and attrition AE	pain function mental health compliance	NR
Tang Hanwu, 2015[24]	35/34	CM herb	Celecoxib+Mecobalamin	Responder rates VAS JOA Near-infrared imaging system on DU meridian	4w	Pre- and post-treatment	pain/function/ pain pain/function/ ADL CM meridian	pain function CM indictor	DEC-TCM
Wang Chenghong, 2009[25]	46/44	acupuncture	Traction+Physical therapy	JOA mRMDQ responder rates	2w	Pre- and post-treatment, follow-up 6m	pain/function/ ADL function pain/function/ ADL	pain function	JOA
Wang Guanjun, 2019[26]	53/53	CM herb	Mannitol Injection+Mecobalamin	VAS JOA Responder rates	3w	Pre- and post-treatment	pain pain/function/ ADL pain/function/	pain function	DEC-TCM; JOA

Wang Haijun, 2017[27]	47/47	Acupotomy	Traction+Physical therapy	VAS JOA Responder rates	14d	Pre- and post-treatment, follow-up 1m and 6m	pain pain/function/ ADL pain/function/	pain function	VAS ; JOA
Wang Hua, 2017[28]	50/50	Manual therapy	Epidural injection	Responder rates	4w	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Wu Shizhen, 2016[29]	13/13	Acupotomy	Canal injection	Global Rating of Change Scale Responder rates	NR	Pre- and post-treatment	Global rating of change pain	pain function	NR
Xiao Zhenhua, 2021[30]	23/23	Acupotomy	Canal injection	VAS JOA	20d	Pre- and post-treatment	pain pain/function/ ADL	pain function	NR
Zhou Qishi, 2002[31]	51/51	CM herb	Vitamin B1 B6	Responder rates SPWT Serum endothelin	4w	Pre- and post-treatment	pain/function/ Measure of walking Physiological index	function Physiological	NR
kim, 2016[32]	26/24	Acupuncture	Usual care	ODI SF-36	6w	Pre- and post-treatment, follow-up 3m	function QOL: physical function, role-physical, bodily pain, general health, vitality, social function, role-	pain function QOL mental health Psychosocial	NR

							emotional, mental health Psychosocial		
Oka, 2018[33]	41/38/40	Acupuncture	Drugs/Exercise therapy	ZCQ	1m	Pre- and post-treatment	pain/function/satisfaction	pain function satisfaction	NR
Qin, 2020[34]	40/40	Acupuncture	Sham Acupuncture	RMDQ NRS SSS Satisfaction subdomain of SSS	8w	Pre-treatment, 4 and 8w after treatment, follow-up 3m and 6m	function pain pain/function/satisfaction	pain function satisfaction	NR
Xu Jialong, 2021[35]	29/29	CM herb＋Usual care	Drugs＋Usual care	VAS JOA SPWT CM Zheng scores AE	4w	Pre-treatment, 2 and 4w after treatment for VAS, JOA Pre- and post-treatment for SPWT, CM Zheng scores	pain pain/function/ADL Measure of walking CM Zheng AE	pain function CM indictors AE	DEC-TCM
Zhu Shuxian, 2014[36]	30/30	Manual therapy＋Usual care	Traction＋Usual care	Responder rates VAS ODI	3w	Pre- and post-treatment	pain/function/pain function	pain function	DEC-TCM

Liu Li, 2020[37]	32/32	Acupuncture+Moxibustion	Acupuncture	Responder rates Self-made symptoms rating scale JOA VAS	20d	Pre- and post-treatment	pain/function/ symptoms pain/function/ ADL pain	pain function	DEC - TCM
Wang Chenghu, 2014[38]	45/45	Acupuncture+Moxibustion	Ibuprofen	Responder rates	10d	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Su Tao, 2011[39]	60/60	Acupuncture+Moxibustion+manual therapy	manual therapy	Responder rates	12d	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Liao Jian, 2017[40]	30/30	CM herb+Acupuncture	Acupuncture	Responder rates RMDQ	2w	Pre- and post-treatment	pain/function/ function	pain function	DEC - TCM
Shan Jinchun, 2013[41]	48/48	CM herb+manual therapy	manual therapy	Responder rates CM Zheng scores	1m	Pre- and post-treatment	pain/function/ CM Zheng	pain function CM indictors	COCE
Hu Kaixia, 2021[42]	20/20	CM herb+CM fumigation	CM fumigation	VAS JOA ODI Pain-free walking distance CM Zheng scores	4w	Pre-treatment, 2w and 4w after treatment, follow-up 1m	pain pain/function/ ADL function Measure of walking CM Zheng	pain function CM indictors	NR

He Yuanzheng, 2009[43]	60/60	CM herb+manual therapy	manual therapy	Responder rates	1m	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Li Zhulie, 2012[44]	30/30	Electrothermal acupuncture	Acupuncture	JOA Responder rates AE	10 times	Pre-treatment, 1, 2, and 3 course after treatment, follow-up 1m	pain/function/ ADL pain/function/ ADL AE	pain function AE	JOA
Chen Xiaoyun, 2009[45]	30/30	Electropuncture+Blo odletting therapy	Electropuncture	Responder rates Global Rating of Change Scale VAS JOA	20d	Pre- and post-treatment	pain/function/ symptoms pain	pain function	DEC - TCM
Lei Xiaoping, 2020[46]	34/34	CM herb+Acupuncture	GIucos+Mecobalamin	IL-6\IL-4\IL-10\TNF Blood viscosity/plasma viscosity/RBC hematocrit Responder rates AE	1m	Pre- and post-treatment	pain/function/ ADL Inflammatory markers Hemorheological indictors pain/function/ AE	pain function AE Physiological	DEC - TCM
Cai Lijun, 2012[47]	32/64	CM herb+kerotherapy	Drugs/Traction	Responder rates JOA	3w	Pre- and post-treatment	pain/function/ pain/function/ ADL	pain function	DEC - TCM ; JOA

Yu Weimin, 2012[48]	32/28	CM herb+Manual therapy	Canal injection	Responder rates	NR	Pre- and post-treatment	pain/function/	pain function	STI-ICWM
Zhang Zhirong, 2017[49]	31/31	Acupuncture+Moxibustion	Acupuncture	Responder rates	20d	Pre- and post-treatment	pain/function/ ADL	pain function	JOA
Wu Zhijun, 2018[50]	30/30	CM herb+manual therapy	manual therapy	Responder rates AE	4w	Pre- and post-treatment	pain/function/ AE	pain function AE	NR
Tang Ning, 2016[51]	19/19	CM herb+manual therapy	manual therapy	JOA VAS Responder rates	4w	Pre- and post-treatment	pain/function/ ADL pain	pain function	NR
Tian Qiang, 2015[52]	35/35	CM herb+manual therapy	CM herb	VAS RMDQ Responder rates	4w	Pre- and post-treatment, follow-up 6m	pain/function/ pain function	pain function	DEC-TCM
Ge Caihua, 2016[53]	30/30	Topical CM+hot compress	Diclofenac Diethylamine Emulgel	JOA VAS	4w	Pre- and post-treatment	pain/function/ ADL pain	pain function	JOA
Liang Yihao, 2016[54]	29/29	manual therapy+Exercise therapy	Exercise therapy	VAS JOA SPWT ODI Responder rates AE	3m	Pre-treatment, 1w, 1m and 3m after treatment	pain pain/function/ ADL measure of walking function pain/function/	pain function AE	VAS; JOA\ ODI

							ADL AE		
Liang Bojin, 2005[55]	25/24	CM herb+Manual therapy	Manual therapy	VAS SF-36 Pain-free walking distance ODI	2m	Pre- and post-treatment	pain QOL: physical function, role-physical, bodily pain, general health, vitality, social function, role-emotional, mental health Psychosocial Measure of walking function	pain function QOL mental health Psychosocial	DEC-TCM
Lin Tingyue, 2010[56]	48/45	Acupuncture+Moxibustion	Acupuncture	Responder rates	36d	Pre- and post-treatment	pain/function/	pain function	DEC-TCM

Xu Shiliang, 2014[57]	47/48	CM herb+manual therapy	GIucos	SPWT VAS JOA IL-6\IL-1B\TNF\CRP Blood viscosity/plasma viscosity/RBC hematocrit Responder rates	4w	Pre- and post-treatment for all, and follow-up 4w for SPWT, VAS, JOA	measure of walking pain pain/function/ ADL Inflammatory markers Hemorheological indictors pain/function/ ADL	pain function Physiological	JOA
Lu Yaoyu, 2014[58]	40/40/40	CM herb+Manual therapy	CM herb+sham Manual therapy sham CM herb+Manual therapy	Responder rates Self-made symptoms rating scale	6w	Pre- and post-treatment	pain/function/ symptoms	pain function	GPCR-ND
Mao Xiaohui, 2008[59]	52/52	CM herb+Manual therapy+CM fumigation	Drugs＋Traction＋TDP	Global Rating of Change Scale Responder rates	10d	Pre- and post-treatment	symptoms pain/function/	pain function	DEC-TCM
Yuan Zhixian, 2020[60]	30/30	CM herb+Acupuncture+Moxibustion	Usual care	Responder rates Self-made symptoms rating scale JOA VAS AE	4w	Pre- and post-treatment	pain/function/ symptoms pain/function/ ADL pain AE	pain function AE	CA-TCM

Dou Qunli, 2007[61]	83/83	CM herb+Manual therapy	Canal injection＋Traction	Responder rates	2m	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Chen Shulie, 2006[62]	32/7	Manual therapy+Topical CM	Drugs	Responder rates	4w	Pre- and post-treatment	pain/function/	pain function	NR
Wang Fuyu, 2018[63]	48/48	CM herb+Acupuncture	Usual care	JOA VAS IL-1 TNF	4w	Pre-treatment, 2 and 4w after treatment	pain/function/ ADL pain Inflammatory markers	pain function Physiological	JOA
Xiong Junwei, 2015[64]	30/30	Acupotomy+Manual therapy	Acupotomy	JOA Responder rates AE	3w	Pre-treatment, 1, 2 and 3w after treatment, follow-up 2w	pain/function/ ADL pain/function/ ADL AE	pain function AE	JOA
Chen Jianhong, 2004[65]	60/60	Acupotomy+CM herb	Drugs＋Traction	Global Rating of Change Scale SPWT Rang of Lumbar spine extension Responder rates	14d	Pre- and post-treatment	Global rating of change Measure of walking ROM	pain function	DEC - TCM
Wang Wenli, 2018[66]	30/30	Electropuncture+fired cupping+Bloodletting therapy	Physical therapy	SSS Responder rates Satisfaction	8w	Pre-treatment, 4 and 8w after treatment, follow-up 4w	pain/function/ pain/function/ pain/function/ satisfaction AE	pain function satisfactio	DEC - TCM

				subdomain of SSS AE		for Patient satisfaction index		n AE	
Zhong Hongzheng, 2016[67]	100/100	Acupuncture+Moxibustion	Diclofenac	ODI	30d	Pre-treatment, 10d and 25d after treatment, follow-up 3m	function	function	NR
Jing Lei, 2019[68]	29/30	Electropuncture+fired cupping+Bloodletting therapy	Physical therapy	SSS Responder rates	8w	Pre-treatment, 4 and 8w after treatment	pain/function/satisfaction pain/function/	pain function satisfaction	DEC-TCM
Wang Hongmei, 2019[69]	40/40	Acupuncture+Moxibustion	GIucos	JOA IL-6/TNF/CRP	10d	Pre- and post-treatment	pain/function/ADL Inflammatory markers	pain function Physiological	NR
Wang Jian, 2013[70]	72/72	Acupuncture+cupping	GIucos	JOA Responder rates AE	36d	Pre- and post-treatment, follow-up 1m	pain/function/ADL pain/function/ADL AE	pain function AE	JOA
Zhang Hong, 2014[71]	37/36	Acupuncture+acupoint injection	Acupuncture	JOA Responder rates	12d	Pre- and post-treatment	pain/function/ADL pain/function/ADL	pain function	JOA

Lin Jincai, 2016[72]	35/35	Acupuncture+CM herb injection	Acupuncture	Rang of Lumbar spine extension VAS JOA Pain-free walking distance AE	2w	Pre- and post-treatment	ROM pain function measure of walking AE	pain function AE	NR
Lv Xiaohua, 2014[73]	40/40	Acupuncture+Bloodletting therapy	Dexamethasone+mannitol+CM herb injection	Responder rates	10d	Pre- and post-treatment	pain/function/	pain function	NR
Shi Jianwei, 2013[74]	37/37	Acupuncture+manual therapy	Dexamethasone+mannitol+Salvia (Danshen) injection	Responder rates	23d	Pre- and post-treatment	pain/function/	pain function	DEC-TCM
Xu Yunyu, 2014[75]	35/35	Acupuncture+Moxibustion	Acupuncture	JOA Responder rates	25d	Pre- and post-treatment, follow-up 1m	pain/function/ADL pain/function/ADL	pain function	JOA
Zhang Huajun, 2016[76]	40/40	Acupuncture+CM herb+moxibustion	Acupuncture＋CM herb	VAS JOA CRP ESR	14d	Pre- and post-treatment, follow-up 1m	pain pain/function/ADL Inflammatory markers	pain function Physiological	JOA
Ji Yuejun, 2010[77]	64/62	CM herb+Manual therapy	Acupuncture	self-made lumbar fuction evaluation scale Responder rates	10d	Pre- and post-treatment	function pain/function/	pain function	DEC-TCM

Ouyang Song, 2014[78]	34/34	Electropuncture+manual therapy	Traction＋Physical therapy	Responder rates	NR	Pre- and post-treatment	pain/function/	pain function	NR
Lian Chongguang, 2009[79]	40/40	CM herb+Manual therapy+CM fumigation	Drugs＋Traction＋TDP	Responder rates Global Rating of Change Scale	3w	Pre- and post-treatment	pain/function/ symptoms	pain function	DEC - TCM
Xiong Yumo, 2017[80]	30/30	CM herb+CM fumigation+Acupotomy	Drugs＋Traction＋TDP	Responder rates Global Rating of Change Scale	3w	Pre- and post-treatment	pain/function/ symptoms	pain function	DEC - TCM
Wei Shengqing, 2019[81]	42/42	Acupotomy+Manual therapy	Manual therapy	VAS JOA ODI AE	3w	Pre- and post-treatment	pain pain/function/ ADL function AE	pain function AE	VAS ; JOA
Miao Zezheng, 2017[82]	56/56	Manual therapy+Topical CM+CM herb	Usual care	VAS JOA	NR	Pre- and post-treatment	pain pain/function/ ADL	pain function	NR
Yang Guang, 2010[83]	45/45	Manual therapy+Topical CM+CM herb	Usual care	VAS JOA	1m	Pre- and post-treatment	pain pain/function/ ADL	pain function	NR
Xie Weixiong, 2017[84]	40/40	Manual therapy+Topical CM+CM herb	Usual care	JOA Responder rates	2w	Pre- and post-treatment	pain/function/ ADL pain/function/	pain function	NR

Yin Xiaoxia, 2020[85]	51/51	CM herb+Manual therapy	Manual therapy	Responder rates JOA VAS ODI Pain-free walking distance IL-6/TNF	4w	Pre- and post-treatment	pain/function/ ADL pain/function/ ADL pain function measure of walking Inflammatory markers	pain function Physiological	JOA
Zhang Shengquan, 2018[86]	46/46	CM herb+Manual therapy	Celecoxib+Mecobalamin+Electrical Nerve Stimulmion	Responder rates	4w	Pre- and post-treatment	pain/function/	pain function	DEC-TCM

Notes: CM, Chinese medicine; SPWT, Self-Paced Walk Test; JOA, Japanese Orthopedic Association Score; mJOA, modified Japanese Orthopedic Association Score; VAS, visual analogue scale; NRS, numerical rating scale; AE, adverse events; SF-36, 6-Item Short Form Survey; ADL, activities of daily living; ROM, Range of Movement; RMDQ, Roland Morris Disability Questionnaire; mRMDQ, modified Roland Morris Disability Questionnaire; HADS, Hospital Anxiety and Depression Scale; ODI, Oswestry Disability Index; QOL, Quality of Life; SSS, Spinal Stenosis Scale; ZCQ, Zurich Claudication Questionnaire; TNF, Tumor Necrosis Factor; RBC, Red blood cell; CRP, C-reactive protein; DECTCM, Diagnosis and evaluation Criteria of TCM Diseases and Syndromes; GPCR-ND, Guiding Principles for Clinical Research of New Drugs; CA-TCM, Lumbar spinal stenosis, China Association of Traditional Chinese Medicine, 2013; STI-ICWM, Clinical Research on the Treatment of Soft tissue Injury by Integrated Chinese and Western Medicine; COCE, Criteria for Orthopedic clinical evaluation; nr, no reported.

Table S6. Characteristics of patients in interviews and Delphi rounds

patients	gender	age (years)	disease course (years)	Complicating lumbar spondylolisthesis	Radiographic classification	experience of CM treatment	territorial region	consensus meeting
A1	Female	73	10	n	lateral recess	y	Beijing	n
A2	Female	66	3	n	central spinal canal	y	Hebei	y
A3	Male	69	2	y	intervertebral foramen	y	Beijing	n
A4	Female	71	9	n	central spinal canal	y	Beijing	n
A5	Male	58	8	y	central spinal canal	n	Beijing	n
A6	Male*	73	11	n	lateral recess	y	Shandong	n
A7	Female*	64	7	y	lateral recess	y	Guangdong	y
A8	Female*	63	3	n	intervertebral foramen	n	Changchun	y
A9	Male*	68	6	y	central spinal canal	y	Changchun	n
A10	Female	55	7	y	lateral recess	y	Beijing	y
A11	Female	75	13	n	lateral recess	y	Shandong	n
A12	Male	83	10	n	central spinal canal	y	Beijing	n
A13	Female*	55	1	y	intervertebral foramen	n	Liaoning	y
A14	Male*	54	2	y	central spinal canal	y	Liaoning	y
A15	Female*	69	1	n	central spinal canal	y	Beijing	y
A16	Female*	64	20	y	lateral recess	y	Shanghai	y
A17	Female	72	30	n	intervertebral foramen	y	Beijing	n
A18	Male	60	4	y	lateral recess	y	Beijing	y

Note: * presents the patients interview conducted via WeChat software; CM, Chinese medicine; y, yes; n, no;

Table S7. Characteristics of experts in Delphi rounds

experts	gender	age (years)	work experience (years)	title	medical major	academic researcher	territorial region	consensus meeting
Ex 1	male	49	24	senior	Tuina	Y	Beijing	Y
Ex 2	male	54	31	senior	Tuina	Y	Beijing	N
Ex 3	male	56	33	senior	Tuina	Y	Beijing	Y
Ex 4	male	60	38	senior	Tuina	Y	Beijing	Y
Ex 5	male	39	11	intermediate	orthopaedics	Y	Beijing	N
Ex 6	male	50	28	intermediate	orthopaedics	Y	Beijing	N
Ex 7	male	32	7	intermediate	orthopaedics	Y	Guizhou	Y
Ex 8	male	48	24	senior	acupuncture	Y	Beijing	Y
Ex 9	female	41	11	intermediate	acupuncture	Y	Beijing	Y
Ex 10	male	37	8	intermediate	acupuncture	Y	Beijing	N
Ex 11	male	43	20	senior	acupuncture	Y	Beijing	N
Ex 12	male	56	31	senior	pain management	Y	Shandong	Y
Ex 13	male	36	8	intermediate	rehabilitation	Y	Beijing	Y
Ex 14	female	57	35	senior	general family medicine	N	Beijing	Y
Ex 15	female	56	32	intermediate	pain management	N	Beijing	Y
Ex 16	female	37	15	intermediate	nursing	Y	Beijing	N
Ex 17	male	48	24	senior	orthopaedics	Y	Shanghai	Y
Ex 18	male	50	26	senior	orthopaedics	Y	Guangdong	Y
Ex 19	male	53	30	senior	orthopaedics	Y	Xinjiang	Y
Ex 20	male	42	16	intermediate	orthopaedics	Y	Changchun	Y
Ex 21	female	39	11	intermediate	rehabilitation	Y	Liaoning	Y

Note: y, yes; n, no.

Table S8. Candidate outcomes ratings from patients and experts in Delphi 2 rounds and voting at consensus meeting

Candidate Outcomes	Delphi round 1 (n=39)						Delphi round 2 (n=39)						consensus meeting voting (n=24)		
	experts (n=21)			patients (n=18)			experts (n=21)			patients (n=18)			NGT	experts (n=15)	patients (n=9)
	% score 1-3	% score 4-6	% score 7-9	% score 1-3	% score 4-6	% score 7-9	% score 1-3	% score 4-6	% score 7-9	% score 1-3	% score 4-6	% score 7-9	re-identified outcomes	% yes	% yes
Pain	0%	10%	**90%**	0%	0%	**100%**	nr	nr	nr	nr	nr	nr	Pain and discomfort	**100%**	**100%**
Function	5%	5%	**90%**	0%	6%	**94%**	nr	nr	nr	nr	nr	nr	lumbar function	**100%**	**100%**
ADL	0%	10%	**90%**	0%	0%	**100%**	nr	nr	nr	nr	nr	nr	ADL	**93%**	**89%**
ROM	10%	33%	57%	11%	11%	78%	5%	19%	76%	6%	17%	78%	ROM	60%	33%
Symptoms	0%	10%	**90%**	11%	22%	67%	0%	0%	**100%**	11%	17%	72%	nr	nr	nr
Measure of walking	0%	33%	67%	11%	22%	67%	0%	5%	**95%**	0%	11%	**89%**	Walking function	**100%**	**89%**

Global rating of change	0%	24%	76 %	6%	28%	67%	0%	14 %	**86 %**	6%	17%	78 %	Patient global assessment	**93%**	**78%**
AE	0%	24%	76 %	0%	11%	**89%**	0%	24 %	76%	0%	6%	**94 %**	AE	**100 %**	**100 %**
Biomarks	29%	43%	29 %	28%	33%	39%	29%	52 %	19%	11%	50%	39 %	Biomarks	0%	11%
Radiographic changes	5%	43%	52 %	6%	22%	72%	5%	33 %	62%	0%	28%	72 %	Radiographic changes	47%	22%
CM specific outcomes	10%	24%	67 %	6%	33%	61%	0%	14 %	**86 %**	6%	28%	67 %	CM specific outcomes	**100 %**	**67%**
Mental health	5%	38%	57 %	6%	33%	61%	0%	43 %	57%	0%	17%	**83 %**	Mental health	53%	78%
Satisfaction index	0%	29%	71 %	0%	28%	72%	0%	24 %	76%	0%	28%	72 %	Satisfaction index	7%	44%
Quality of life	5%	14%	**81 %**	0%	11%	**89%**	nr	nr	nr	nr	nr	nr	health related QOL	**100 %**	**78%**
Adherence and attrition	14%	29%	57 %	0%	33%	67%	10%	14 %	76%	0%	50%	50 %	Adherence and attrition	7%	0%
Psychosocial	48%	38%	14 %	44%	39%	17%	19%	71 %	10%	28%	50%	22 %	Psychosocial	13%	33%
Resource use	14%	24%	62 %	0%	22%	78%	5%	24 %	71%	6%	22%	72 %	Resource use	47%	78%

Note: CM, Chinese medicine; AE, adverse events; ADL, activities of daily living; ROM, Range of Movement; QOL, quality of life; nr, no reported. The Bold number in this table met the predefined "consensus in" thresholds

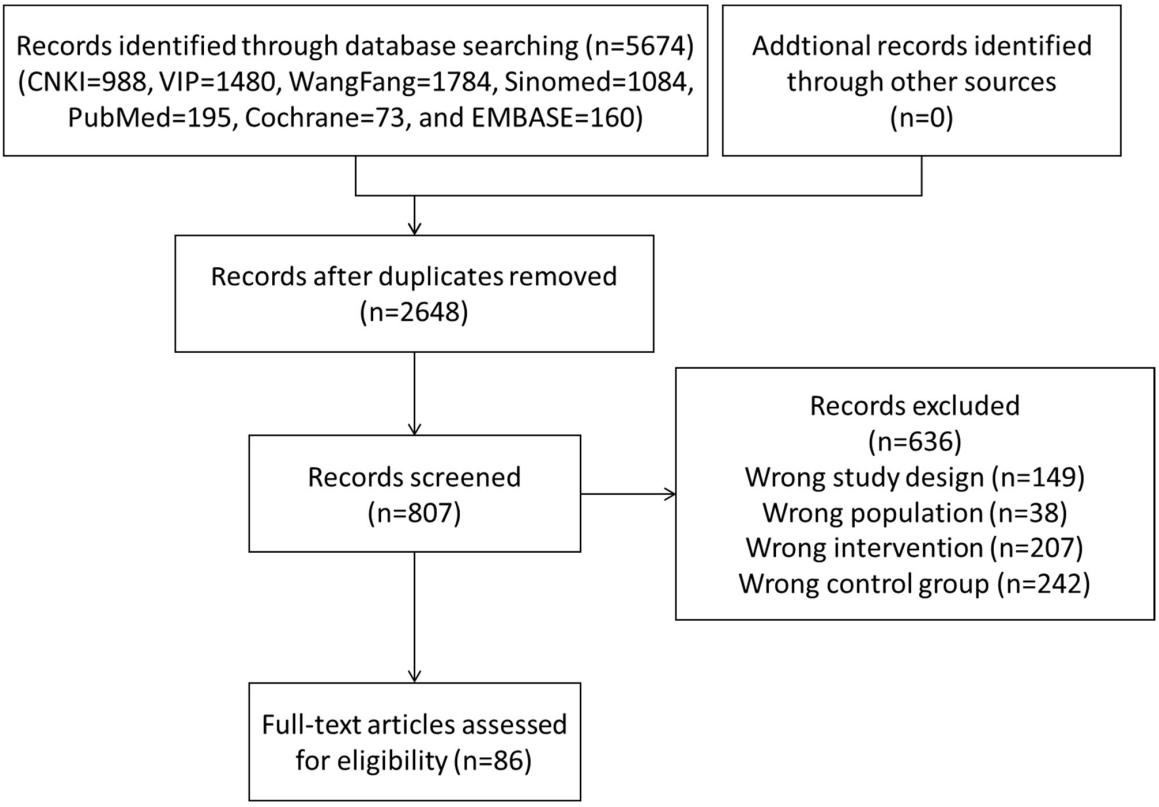

Figure S1. PRISMA flow diagram

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