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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. Evidence synthesis and comparison of effectiveness are difficult since outcomes examined and presented through trials have heterogeneity. This study aimed to solve the outcome problems for CM clinical trials in lumbar spinal stenosis by building a core outcome set (CORE-CM-LSS).

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 semi-structured 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 1st round and four outcomes additionally in the 2nd round. The core outcome domains were determined through discussion and redefinition of outcomes in the consensus meeting: pain and discomfort, HRQoL, lumbar Function, ADL, 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.

Keywords: lumbar spinal stenosis, Delphi survey, domains, systematic review, Chinese medicine, core outcome set

Word counts: 3888

Strengths and limitations

- We report the development of a multiple-stakeholder, consensus-based CORE outcome set applicable to Chinese Medicine (CM) intervention trials in adults with Lumbar Spinal Stenosis (CORE-CM-LSS).
- The core outcome domains were agreed as: pain and discomfort, HRQoL, lumbar function, activity daily living, walking function, patient global assessment, adverse events and Chinese Medicine specific outcomes.
- A mixed-method approach was used to determine which outcomes would be included in the COS.
- The CORE-CM-LSS should be measured and reported in all future research trials that evaluate CM in terms of LSS, to increase consistency in the report of the result.
- This was not an international study; participants were from China.

1. Introduction

Lumbar spinal stenosis (abbreviated as LSS) is caused by spinal anatomical or functional narrowing with a negative effect on the spinal cord and nerve roots, characterized 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 can affect a global population of nearly 103 million [3] and 11% of the elderly in the United States [4]. Most LSS are treated non-operatively, with physical therapy, analgesia, as well as 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, takes on critical significance 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 have a greater effect in alleviating pain and ameliorating 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 4 results were analyzed, while the other results could not be analyzed 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 can result in 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 standardized 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 COMET database and searching OMERACT for COSs of trauma and orthopedics ensured the lack of COS on LSS [15].

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

2. Method

The study protocol had registration in the database of COMET (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-STAR (Core Outcome Set-STAndards for Reporting) [16] as well as COS-STAD (Core Outcome Set-STAndards for Development) [17] guidelines (Supplementary Material, table S1 and S2). This is a further study underlying COS development in terms of low back pain (LBP), the COS focused on specific LBP due to LSS treated by CM.

2.1 Scope and design

Study Advisory Group (SAG) was formed, inviting a wide variety of stakeholders, two orthopedists, one acupuncture and *Tuina* expert, one patient, one methodologist, one clinical trial researcher, as well as one statistician. 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 core outcome set's scope was as follows: Setting: randomized controlled trials (RCT); Health condition: symptomatic lumbar spinal stenosis[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 core outcome set.

The ethics committee of the corresponding author's hospital (DZMEC-KY-2020-60) has given ethical approval for the present study on September 7th, 2020. 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.

2.2 Systematic literature review (SLR)

2.2.1 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 comprised the treatment with CM alone or treatment including CM. The control intervention involved routine treatment (e.g., 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.

2.2.2 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 1st January, 2022 (search strategy in Supplementary Material, 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 20 managed literature and excluded the duplicate ones. Eligibility was evaluated initially by two independent reviewers (including SYN and ZYJ)

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 (YCH).

2.2.3 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 (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 categorized by SAG into outcome subdomains and domains, and the respective outcome was defined by SAG following the COMET criteria [18]. Besides, SAG removed the duplicates and standardized the similar or overlapping outcomes. Information and purpose of an instrument (i.e., 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 (YCH).

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 18.0.

2.3 The semi-structured interview

The additional associated outcome domains were elicited through qualitative semi-structured interviews of patients.

2.3.1 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.

Convenient and purposeful sampling methods were undertaken with several ages, gender, years of LSS and imaging findings within the hospital outpatients from seven territories of China. The qualitative data were analyzed, 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.

2.3.2 Interview process

Interviews were carried out and recorded by qualified researchers (YCH). Explanation and information consent should be given to patients before the interviews. We initiated the interview with questions (e.g., "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.

2.3.3 Data analysis

The additional outcomes and the demographic and medical information of patients were collected. Patients' words were recorded and analyzed through content analysis. All outcomes identified by patients were extracted by two researchers (SYN and AY) and then mapped onto the initiative list.

2.4 Expert consensus

2.4.1 Panel participants

A group of participants specialized in CM, integrated Chinese and Western medicine, nursing, orthopedics, acupuncture, *Tuina*, pain management, rehabilitation, and clinical researchers were recruited in the Delphi survey, and the professional and geographical distribution of panelists was considered. Furthermore, all SAG members engaged in the consensus meeting.

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 the preliminary stakeholders. The patients were selected following a pool of outpatients.

2.4.2 Identifying important outcomes in Delphi Survey

In Round 1 and 2, for the respective outcome, panelists were recruited for

assigning scores between 1 (of no importance) and 9 (of high importance), where 1 to 3 represents that it is "of no importance to be included in the COS," 4 to 6 represents that it is "of importance but no critical importance to be included in the COS" and 7 to 9 represents that it is "of critical importance to be included in the COS" [19]. 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 minimization of attrition. Predefined "consensus in" thresholds are reached if > 80% of the panelists score 7 to 9 and ≤ 15% score 1 to 3; "consensus out" thresholds are met if > 80% of the panelists score 1 to 3 and ≤ 15% of the panelists scored 7 to 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 [20].

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.

2.4.3 Identifying core outcomes in consensus meetings

A total of nine LSS patients and 15 experts, most from previous study stages, were recruited in an online consensus meeting. One author (YCH), 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 [21]. 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 panelists. Anonymized 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 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 pre-specified threshold of >80% on yes was set.

3. Results

3.1 Identification of candidate outcomes

3.1.1Outcomes from the SLR

A total of 5,674 trials were identified through the SLR, 86 trials could be included following the removal of duplicates, and screening of abstract, title, and full-text (PRISMA flow diagram in Supplementary Material, figure S1). Eighty-six trials involved 6,892 LSS patients (rang 26~200), with 80% (2980/6658, 2 trials didn't report gender) female, aged from 33~72 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. Table S4 of Supplementary material elucidates the characteristics of the included trials.

Table 1 listed a total of 86 trials that reported 54 different outcome measurement instruments (OMI). The number of OMIs was applied and reported ranging from 1 to 6 (median 3). The most used OMI comprised response rates (64/86, 74.42%), various versions of JOA (42/86, 48.84%), visual Analogue Scale (37/86, 43.02%), adverse events (18/86, 20.93%), as well as measures of walking (12/86, 13.95%) (details in Supplementary material, table S4). 50% of OMI were patient-reported outcomes, and 30% were performance-based measurements. While the rest were clinician-based measurements (e.g., 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 adverse events

(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.

Table 1. Classification of Outcome Measurement Instruments into subdomains and COMET outcomes

No	COMET domain outcome	Number of 86 RCTs reporting COMET outcomes (%)	Subdomain outcome	Number 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/UBA-PBS/pain subscale of JOA/pain subscale of SSS/bodily pain subscale of SF-36
3	Adverse events	19 (22.1)	AE	1 (1.9)	AE
4	Physiological	11 (12.8)	Inflammatory markers Hemorheological 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 hematocrit Changes in T lymphocyte subsets Hepatic and renal function tests/Serum endothelin Parameters of computed tomography

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

Notes: COMET, Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement Instruments; 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; UBA-PBS, UBA pain behavior 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; NR, not reported

3.1.2 Patients interview

In this study, 18 interviews were carried out with LSS patients from seven territorial regions around China. Table S5 of supplementary material 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).

Table 2. Subdomain and COMET outcomes identified from interviews

COMET domain outcome	Subdomain outcomes	Number of 18 patients (%)	Example of interview transcript

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
	Hemorheological 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*"

Notes: COMET, Core Outcome Measures in Effectiveness Trials; ADL, activities of daily living; ROM, Range of movement; AE, adverse events; CM, Chinese medicine; NR, not reported

SAG identified subdomain outcomes as candidate outcomes from SLR and interviews, defined outcomes, and constructed a final inventory of 17 outcomes[22-30] 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, hemorheological markers, immunological markers, as well as physiological outcomes (Figure. 1).

Table 3. Candidate DLSS 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 [28].	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 [22].	SLR+Int
3	ADL	Fundamental skills required to independently care for oneself, such as eating, bathing, and mobility [24].	SLR+Int
4	ROM	Quantity of movement of the lumbar spine and/or of other adjacent body parts (i.e. thoracic spine, pelvis, rib cage or lower limbs) [22].	SLR+Int
5	symptoms	Presence of symptoms on back, leg and walking [26].	SLR+Int
6	measure of walking	Measuring ability, capability, distance, performance of walking [22].	SLR+Int
7	Global rating of change	Considering the ways that the health condition affects the individual on a given day [29].	SLR+Int
8	AE	Any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related [30].	SLR+Int
9	Bio-marks	Indicators aimed at providing insight into peripheral and	SLR

		central neurobiological mechanisms of pain [22].	
10	Radiographic changes	medical imaging such as MRI, CT, X-ray detecting the changes of Bones, joints, muscles, tendons, nerves and other body structures localized on the lumbar spine and/or on other adjacent body parts (i.e. thoracic spine, pelvis, rib cage or lower limbs) [22].	SLR+Int
11	CM-specific outcomes	CM outcomes related to CM *Zheng* or meridians based on CM theory [27].	SLR
12	Mental health	A person's condition with regard to their psychological, social and emotional well-being [25].	SLR+Int
13	Satisfaction index	Satisfaction with care received, including of the process and outcomes of the treatment experience and care providers [22].	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[25].	SLR
15	Adherence and attrition	Withdrawal from treatment [23].	SLR
16	Psychosocial	An individual's interactions with their environment and the ability to fulfill their role within such environments as work, social activities, and relationships with partners and family [22].	SLR
17	Resource use	Treatment burden such as impact of treatment and monitoring of disease or treatment (i.e. financial loss due to treatment cost, work loss, or time commitment) [23].	Int

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

3.2 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 Supplementary Material, table S6). Delphi survey identified four outcome domains (including pain, function, ADL and 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.

3.3 COS determined by consensus meetings

3.3.1 Consensus meeting summary

The participants redefined some outcomes from the list of 17 domains (Table 4) in the NGT process. For LSS patients, the pain is 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 over- or underestimate outcomes. Thus, the experts suggested 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.

For pain outcome, several experts have 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, 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 quality of life (HRQoL), consisting of mental and physical health perceptions (e.g., mood, energy level) and their correlates (e.g., socioeconomic status, social support, functional status, as well as health conditions and risks). The concept HRQoL presented potentially overlapping with some of the above domains. Thus, participants agreed and favored 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 renamed and defined as patient global assessment (PGA) of disease-related health status and kept as a core domain.

Table 4. Candidate outcomes ratings in 2 rounds Delphi and voting at consensus meetings

Candidate Outcomes	round 1 (n=39)			round 2 (n=39)			redefined outcomes	consensus meeting voting (n=24)
	% score 1-3	% score 4-6	% score 7-9	% score 1-3	% score 4-6	% score 7-9		% 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%

Notes: ADL, activities of daily living; ROM, Range of movement; AE, adverse events; CM,

Chinese medicine; QOL, Quality of life; HRQoL, health related QOL; PGA, patient global assessment; NR, not reported

3.3.2 COS identified by final voting

Following the list of outcomes, an agreement was reached on the core set using an electronic voting program in consensus meetings. Scores for the respective outcome domain were listed in Table 4. 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). Table S7 of supplementary material presented the sensitive analysis of score of outcomes between patients and experts.

Figure 1. Flow chart of core outcomes selection process

4. Discussion

4.1 Summary of the Main Results

This study presents the developing process of the core domain set of Chinese medicine for LSS in trials (CORE-CM-LSS) and the steps involved for reaching a consensus of patients and experts. The patient perspective was integrated in the respective research phase. The sampling process was inclusive of panelists nationally, which increases generalizability of our findings in China.

4.2 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 adverse events 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, counter-parting 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 [31].

The CM-specific outcomes were covered in COS in terms of its specific for CM, which may deviate from that employed in Western medicine [27,32], 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 [33]. A pattern often contains several CM symptoms (e.g., 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 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 [34].

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 adverse events [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 (e.g., 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 [22,35-37]. Furthermore, additional core domains may be examined alongside the above outcomes to capture condition-specific characteristics.

4.3 Strengths and limitations

Strengths of this study include a China national representation of LSS patient and physician stakeholders participating in the consensus meeting, surveys, as well as 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, as well as LSS manifestations. This ensured that we captured broad content early in the process of data collection and obtained domains that are generalizable 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 make sure 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, this may lead to an underestimation of the importance of certain areas from their points of view. It is worth mentioning that the goal of this study was not to develop a set of outcome areas important to all stakeholders, but rather a core set of outcomes to be included in all clinical trials. 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.

4.4 Implication for clinical practices and research

This study's main objective was to produce a collection of core outcome measures for use in reliable prospective studies involving LSS patients. This core outcome set 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. At the next stages, the psychometric features of each core set domain's outcome measure will be assessed, and choosing a core set

of outcome measures that is sufficient and not redundant will be selected.

5. Conclusion

The COS for CM in LSS was initially 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 evaluate CM in terms of LSS, to increase consistency in the report of the result. The COS enhances the synthesis of the evidence relating to LSS patient-associated outcomes and supports overall field development and research.

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Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Ethics Statement

Ethics approval was provided by the ethics committee of Dongzhimen hospital (DZMEC-KY-2020-60). Prior to the interviews with the patients, written informed consent was requested. The Delphi signup page had a notice emphasizing the fact that submission of the questionnaire constitutes permission. A permission form was filled out by each attendee of the consensus meeting to signify their agreement to participate.

Abbreviations

CORE-CM-LSS, core domain set of Chinese medicine for LSS in trials; COS, Core outcome domain sets; CM, Chinese medicine, LSS, Lumbar spinal stenosis; COS-STAD, Core Outcome Set-STAndards for Development; COS-STAR, Core Outcome Set-STAndards for Reporting; SAG, Study Advisory Group; RCT, randomized controlled trials; SLR, Systematic review; NGT, Nominal group technique; COMET, Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement Instruments; 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; UBA-PBS, UBA pain behavior 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; NR, not reported; Int, interview

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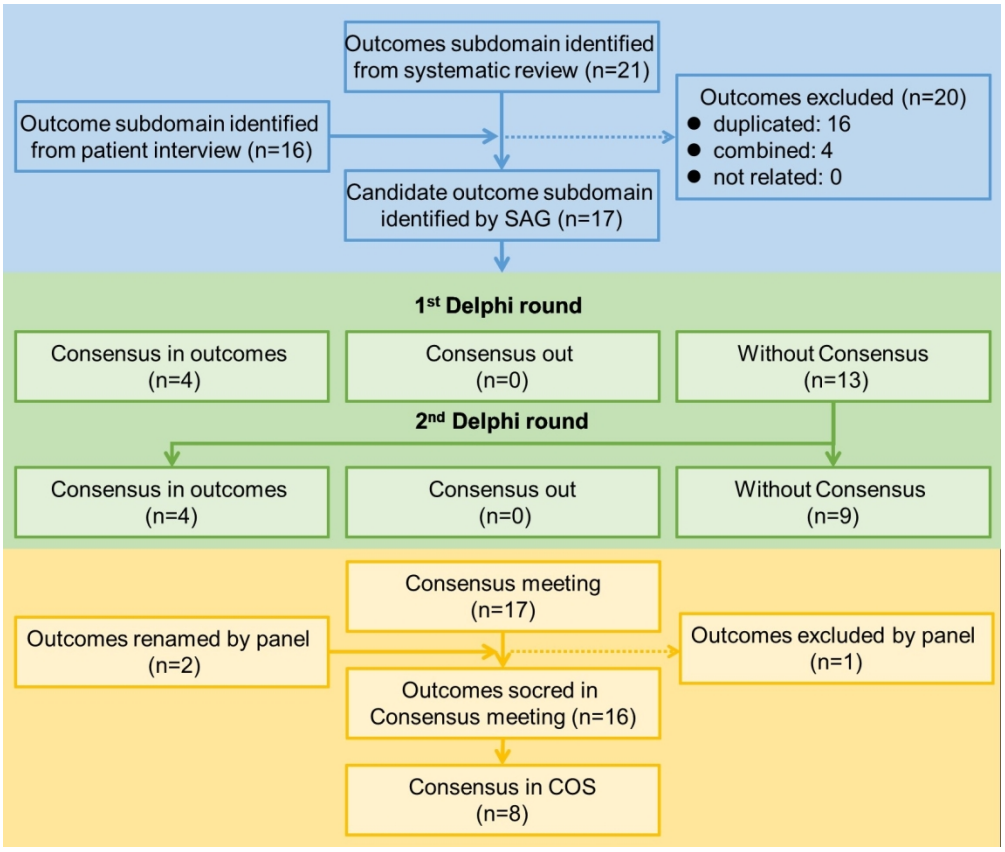

Figure 1. Flow chart of core outcomes selection process

287x241mm (150 x 150 DPI)

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	1
INTRODUCTION			
Background and	2a	Describe the background and explain the rationale for developing the COS	2
Objectives	2b	Describe the specific objectives with reference to developing a COS	2
Scope	3a	Describe the health condition(s) and population(s) covered by the COS.	2,3
	3b	Describe the intervention(s) covered by the COS.	2,3
	3c	Describe the setting(s) in which the COS is to be applied.	2,3
METHODS			
Protocol /Registry Entry	4	Indicate where the COS development protocol can be accessed, if available, and/or the study registration details.	2,3
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.	4,5
Information Sources	6a	Describe the information sources used to identify an initial list of outcomes.	3,4,5
	6b	Describe how outcomes were dropped/combined, with reasons (if applicable).	3,4,5
Consensus Process	7	Describe how the consensus process was undertaken.	6,7

Outcome Scoring	8	Describe how outcomes were scored and how scores were summarized.	6,7
Consensus Definition	9a	Describe the consensus definition.	7
	9b	Describe the procedure for determining how outcomes were included or excluded from consideration during the consensus process.	7
Ethics and Consent	10	Provide a statement regarding the ethics and consent issues for the study.	3
RESULTS			
Protocol Deviations	11	Describe any changes from the protocol (if applicable), with reasons, and describe what impact these changes have on the results.	Not applicable
Participants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development.	8,9,10 and Supplementary materials
Outcomes	13a	List all outcomes considered at the start of the consensus process.	8,9, Table 1-3
	13b	Describe any new outcomes introduced and any outcomes dropped, with reasons, during the consensus process.	8,9
COS	14	List the outcomes in the final COS.	10, Table 4
DISCUSSION			
Limitations	15	Discuss any limitations in the COS development process.	12
Conclusions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research.	10,11,12
OTHER INFORMATION			
Funding	17	Describe sources of funding/role of funders.	13
Conflicts of Interest	18	Describe any conflicts of interest within the study team and how these were managed.	13

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	3,4
	2	The health condition(s) covered by the COS	3,4
	3	The population(s) covered by the COS	3,4
	4	The intervention(s) covered by the COS	3,4
Stakeholders involved	5	Those who will use the COS in research	4,5
	6	Healthcare professionals with experience of patients with the condition	4,5
	7	Patients with the condition or their representatives	4,5
Consensus process	8	The initial list of outcomes considered both healthcare professionals' and patients' views.	6,table e1-3
	9	A scoring process and consensus definition were described a priori.	5
	10	Criteria for including/dropping/adding outcomes were described a priori.	5
	11	Care was taken to avoid ambiguity of language used in the list of outcomes.	5,6

Table S3. PUBMED 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])	183

Table S4. 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	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	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 Hui 2009	40/40	Acupotomy	Traction	Responder rates	2m	Pre- and post-treatment	pain/function	pain function	DEC-TCM
Geng Xiaoyan, 2017	46/46	CM herb	Salvia (Danshen) injection+Diclofenac	JOA	NR	Pre- and post-treatment	pain/function/ ADL	pain function	NR

Gu Qi, 2015	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	JOA
Guan Xiaoyong, 2015	47/47	CM herb	Salvia (Danshen) injection+Diclofenac	VAS Responder rates	1m	Pre- and post-treatment	pain/function/ ADL pain	pain	VAS
Hou Yu, 2019	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	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	50/46	CM herb	Diclofenac	Responder rates AE	4w	Pre- and post-treatment	pain/function/ AE	pain function AE	DEC - TCM
Ji Wei, 2013	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	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	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	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	GPC R-ND

Li Qiming, 2018	98/60	CM herb	Usual care	JOA VAS	2w	Pre- and post-treatment	pain/function/ ADL pain	pain function	NR
Li Rui, 2016	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	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	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	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	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	46/46	CM herb	Mannitol Injection+Mecobalamin	Responder rates	3w	Pre- and post-treatment	pain/function/	pain function	NR
Sheng Xinjun, 2016	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	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	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	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	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	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	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	50/50	Manual therapy	Epidural injection	Responder rates	4w	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Wu Shizhen, 2016	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	23/23	Acupotomy	Canal injection	VAS JOA	20d	Pre- and post-treatment	pain pain/function/ ADL pain/function/	pain function	NR
Zhou Qishi, 2002	51/51	CM herb	Vitamin B1 B6	Responder rates SPWT Serum endothelin	4w	Pre- and post-treatment	Measure of walking Physiological index function	function Physiological	NR
kim, 2016	26/24	Acupuncture	Usual care	ODI SF-36	6w	Pre- and post-treatment, follow-up 3m	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	41/38/40	Acupuncture	Drugs/Exercise therapy	ZCQ	1m	Pre- and post-treatment	pain/function/satisfaction	pain function satisfaction	NR
Qin, 2020	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	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	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	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	45/45	Acupuncture+Moxibustion	Ibuprofen	Responder rates	10d	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Su Tao, 2011	60/60	Acupuncture+Moxibustion+manual therapy	manual therapy	Responder rates	12d	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Liao Jian, 2017	30/30	CM herb+Acupuncture	Acupuncture	Responder rates RMDQ	2w	Pre- and post-treatment	pain/function/ function	pain function	DEC - TCM
Shan Jinchun, 2013	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	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	60/60	CM herb+manual therapy	manual therapy	Responder rates	1m	Pre- and post-treatment	pain/function/	pain function	DEC - TCM
Li Zhulie, 2012	30/30	Electrothermal acupuncture	Acupuncture	JOA Responder rates AE	10 times	Pre-treatment, 1, 2, and 3 course after treatment, follow-up last	pain/function/ ADL pain/function/ ADL AE	pain function AE	JOA
Chen Xiaoyun, 2009	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	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	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	32/28	CM herb+Manual therapy	Canal injection	Responder rates	NR	Pre- and post-treatment	pain/function/	pain function	STI-ICWM
Zhang Zhirong, 2017	31/31	Acupuncture+Moxibustion	Acupuncture	Responder rates	20d	Pre- and post-treatment	pain/function/ADL	pain function	JOA
Wu Zhijun, 2018	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	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	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	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	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/function/ADL pain measure of walking function pain/function/	pain function AE	VAS; JOA\ ODI

							ADL AE			
Liang Bojin, 2005	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	48/45	Acupuncture+Moxibustion	Acupuncture	Responder rates	36d	Pre- and post-treatment	pain/function/	pain function	DEC - TCM

Xu Shiliang, 2014	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	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	52/52	CM herb+Manual therapy+CM fumigation	Drugs + Traction + TDP	Global Rating of Change Scale Responder rates Responder rates	10d	Pre- and post-treatment	symptoms pain/function/ pain/function/symptoms	pain function	DEC-TCM
Yuan Zhixian, 2020	30/30	CM herb+Acupuncture+Moxibustion	Usual care	Self-made symptoms rating scale JOA VAS AE	4w	Pre- and post-treatment	pain/function/ADL pain AE	pain function AE	CA-TCM

Dou Qunli, 2007	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	32/7	Manual therapy+Topical CM	Drugs	Responder rates	4w	Pre- and post-treatment	pain/function/	pain function	NR
Wang Fuyu, 2018	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	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	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	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	100/100	Acupuncture+Moxibustion	Diclofenac	ODI	30d	Pre-treatment, 10d and 25d after treatment, follow-up 3d	function	function	NR
Jing Lei, 2019	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	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	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	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	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	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	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	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	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	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	34/34	Electropuncture+manual therapy	Traction + Physical therapy	Responder rates	NR	Pre- and post-treatment	pain/function/	pain function	NR
Lian Chongguang, 2009	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	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	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	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	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	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	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	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 S5. 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: CM, Chinese medicine; y, yes; n, no

Table S6. Characteristics of experts in Delphi rounds

experts	gender	age (years)	work experience (years)	title	medical major	academic research	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 S7. 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

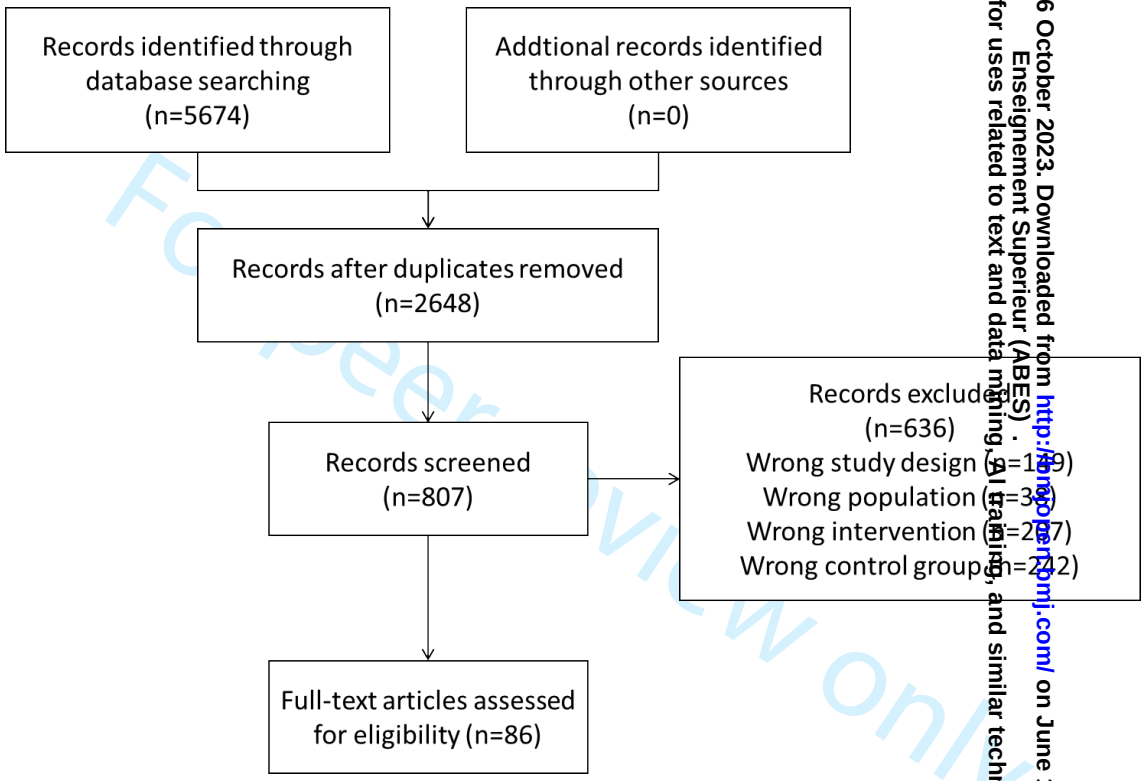

Figure S1. PRISMA flow diagram

BMJ Open

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

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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. Evidence synthesis and comparison of effectiveness are difficult since outcomes examined and presented through trials have heterogeneity. This study aimed to solve the outcome problems for CM clinical trials in lumbar spinal stenosis by building a core outcome set (CORE-CM-LSS).

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 semi-structured 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 1st round and four outcomes additionally in the 2nd 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.

Keywords: lumbar spinal stenosis, Delphi survey, domains, systematic review, Chinese medicine, core outcome set

Word counts: 4111

Strengths and limitations

- A mixed-method approach was used to determine which outcomes would be included in the Core outcome domain sets for trials of Chinese medicine for lumbar spinal stenosis (CORE-CM-LSS).
- This study was supervised by a multidisciplinary advisory board constantly. This investigation extensively incorporated the perspectives of various stakeholders, including patients, physicians, and researchers.
- The participants were sampled following duration and socioeconomic status, disease severity, as well as lumbar spinal stenosis (LSS) manifestations, ensuring the core domains that are generalizable to LSS people.
- The main usage of trials of Chinese medicine (CM) or integrated medicine is in China. Therefore, a restriction will result from the geographical distribution of stakeholders.

1. Introduction

Lumbar spinal stenosis (abbreviated as LSS) is caused by spinal anatomical or functional narrowing with a negative effect on the spinal cord and nerve roots, characterized 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 can affect a global population of nearly 103 million [3] and 11% of the elderly in the United States [4]. Most LSS are treated non-operatively, with physical therapy, analgesia, as well as 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, takes on critical significance 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 have a greater effect in alleviating pain and ameliorating 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 4 results were analyzed, while the other results could not be analyzed 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 can result in 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 standardized 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 COMET database and searching OMERACT for COSs of trauma and orthopedics ensured the lack of COS on LSS [15].

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

2. Method

The study protocol had registration in the database of COMET (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-STAR (Core Outcome Set-STAndards for Reporting) [16] as well as COS-STAD (Core Outcome Set-STAndards for Development) [17] guidelines (Supplementary Material, table S1 and S2). This is a further study underlying COS development in terms of low back pain (LBP), the COS focused on specific LBP due to lumbar spinal stenosis (LSS) treated by CM.

Study Advisory Group (SAG) was formed, inviting a wide variety of stakeholders, two orthopedists, one acupuncture and *Tuina* expert, one patient, one methodologist, one clinical trial researcher, as well as one statistician. 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 core outcome set's scope was as follows: Setting: randomized controlled trials (RCT); Health condition: symptomatic lumbar spinal

stenosis[1]. Target interventions are Chinese medicine (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 core outcome set.

The ethics committee of the corresponding author's hospital (DZMEC-KY-2020-60) has given ethical approval for the present study on September 7th, 2020. 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.

2.1 Patient and public involvement (PPI)

Patients and the general public participated in the semi-structured interviews, the Delphi Surveys, and the final consensus meeting.

2.2 Systematic literature review

Systematic literature review (SLR) in our study was conducted to establish a list of outcomes. Meanwhile, the results of the SLR were partly published aiming to assess the effectiveness of non-pharmaceutical Chinese medical therapies singularly or in combination for lumbar spinal stenosis [18].

2.2.1 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 comprised the treatment with CM alone or treatment including CM. The control intervention involved routine treatment (e.g., 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.

2.2.2 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 1st January, 2022 (search strategy in Supplementary Material, 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 20 managed literature and excluded the duplicate ones. Eligibility was evaluated initially by two independent reviewers (including SYN and ZYJ) 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 (YCH).

2.2.3 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 (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 categorized 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 standardized the similar or overlapping outcomes. Information and purpose of an instrument (i.e., 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 (YCH).

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 18.0.

2.3 The semi-structured interview

The additional associated outcome domains were elicited through qualitative semi-structured interviews of patients.

2.3.1 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.

Convenient and purposeful sampling methods were undertaken with several ages, gender, years of LSS and imaging findings within the hospital outpatients from seven territories of China (predefined features in Supplementary Material, table S4). Features were defined by the SAG to ensure diversity represented. The qualitative data were analyzed, 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.

2.3.2 Interview process

Interviews were carried out face-to-face in outpatient or via remote video software (WeChat) and recorded by qualified researchers (YCH). Explanation and information consent should be given to patients before the interviews. We initiated the interview with questions (e.g., "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.

2.3.3 Data analysis

The additional outcomes and the demographic and medical information of patients were collected. Qualitative content analysis was used for analyzing the words expressed by patients. 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 (SYN and AY) were initially assessed individually before being mapped into the initiative list in three steps: sentences and paragraphs were identified, abstracted, and coded as meaning units; The codes were organized into subjects within the context of COMET outcomes subdomains; and the codes within each topic were organized into initial COMET outcome domains. After that, the draft outcomes domains for the two researchers were combined and compared. Outcomes subdomains with similar names were then examined, and those with the same content were grouped together. Any discrepancies were resolved with discussion.

2.4 Expert consensus

2.4.1 Panel participants

A group of participants specialized in CM, integrated Chinese and Western medicine, nursing, orthopedics, acupuncture, *Tuina*, pain management, rehabilitation, and clinical researchers were recruited in the Delphi survey, and the professional and geographical distribution of panelists 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.

2.4.2 Identifying important outcomes in Delphi Survey

In Round 1 and 2, for the respective outcome, panelists were recruited for assigning scores between 1 (of no importance) and 9 (of high importance), where 1 to 3 represents that it is “of no importance to be included in the COS,” 4 to 6 represents that it is “of importance but no critical importance to be included in the COS” and 7 to 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 minimization of attrition. Predefined "consensus in" thresholds are reached if > 80% of the panelists score 7 to 9 and ≤ 15% score 1 to 3; "consensus out" thresholds are met if > 80% of the panelists score 1 to 3 and ≤ 15% of the panelists scored 7 to 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.

2.4.3 Identifying core outcomes in consensus meetings

A total of nine LSS patients and 15 experts, most from previous study stages, were recruited in an online consensus meeting. One author (YCH), 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 panelists. Anonymized 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 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 pre-specified threshold of >80% on yes was set.

3. Results

3.1 Identification of candidate outcomes

3.1.1Outcomes from the systematic literature review (SLR)

A total of 5,674 trials were identified through the SLR, 86 trials could be included following the removal of duplicates, and screening of abstract, title, and full-text (PRISMA flow diagram in Supplementary Material, figure S1). Eighty-six trials involved 6,892 LSS patients (rang 26~200), with 80% (2980/6658, 2 trials didn't report gender) female, aged from 33~72 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. Table S4 of Supplementary material elucidates the characteristics of the included trials.

Table 1 listed a total of 86 trials that reported 54 different outcome measurement instruments (OMI). The number of OMIs was applied and reported ranging from 1 to 6 (median 3). The most used OMI comprised response rates (64/86, 74.42%), various versions of JOA (42/86, 48.84%), visual Analogue Scale (37/86, 43.02%), adverse events (18/86, 20.93%), as well as measures of walking (12/86, 13.95%) (details in Supplementary material, table S5). 50% of OMI were patient-reported outcomes, and 30% were performance-based measurements. While the rest were clinician-based measurements (e.g., 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 adverse events (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.

Table 1. Classification of Outcome Measurement Instruments into subdomains and COMET outcomes

No	COMET domain outcome	Number of 86 RCTs reporting COMET outcomes (%)	Subdomain outcome	Number 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/UBA-PBS/pain subscale of JOA/pain subscale of SSS/bodily pain subscale of SF-36
3	Adverse events	19 (22.1)	AE	1 (1.9)	AE
4	Physiological	11 (12.8)	Inflammatory markers Hemorheological 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 hematocrit Changes in T lymphocyte subsets Hepatic and renal function tests/Serum endothelin Parameters of computed tomography
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

Notes: COMET, Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement Instruments; 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; UBA-PBS, UBA pain behavior 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; NR, not reported

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310 3.1.2 Patients interview

311 In this study, 18 interviews were carried out with LSS patients from seven territorial
312 regions around China. 8 of the 18 interviews with them were done via the WeChat
313 app. Table S6 of supplementary material presents the demographic details of the
314 participants. The content analyses of interview transcript and outcomes from open-
315 ended questions indicated that 16 subdomain outcomes were identified and then
316 classified into 11 COMET domains (Table 2).

317

Table 2. Subdomain and COMET outcomes identified from interviews

COMET domain outcome	Subdomain outcomes	Number 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
	Hemorheological 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*"

Notes: COMET, Core Outcome Measures in Effectiveness Trials; ADL, activities of daily living; ROM, Range of movement; AE, adverse events; CM, Chinese medicine; NR, not reported

SAG identified subdomain outcomes as candidate outcomes from SLR and interviews, defined outcomes, and constructed a final inventory of 17 outcomes[24-32] 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, hemorheological markers, immunological markers, as well as physiological outcomes (Figure. 1).

Table 3. Candidate DLSS 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 [30].	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 [26].	SLR+Int
4	ROM	Quantity of movement of the lumbar spine and/or of other adjacent body parts (i.e. thoracic spine, pelvis, rib cage or lower limbs) [24].	SLR+Int
5	symptoms	Presence of symptoms on back, leg and walking [28].	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 [31].	SLR+Int
8	AE	Any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related [32].	SLR+Int
9	Bio-marks	Indicators aimed at providing insight into peripheral and	SLR

		central neurobiological mechanisms of pain [24].	
10	Radiographic changes	medical imaging such as MRI, CT, X-ray detecting the changes of Bones, joints, muscles, tendons, nerves and other body structures localized on the lumbar spine and/or on other adjacent body parts (i.e. 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 [29].	SLR
12	Mental health	A person's condition with regard to their psychological, social and emotional well-being [27].	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[27].	SLR
15	Adherence and attrition	Withdrawal from treatment [25].	SLR
16	Psychosocial	An individual's interactions with their environment and the ability to fulfill 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 (i.e. financial loss due to treatment cost, work loss, or time commitment) [25].	Int

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

3.2 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 Supplementary Material, table S7). Delphi survey identified four outcome domains (including pain, function, ADL and 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.

3.3 COS determined by consensus meetings

3.3.1 Consensus meeting summary

The participants redefined some outcomes from the list of 17 domains (Table 4) in the NGT process. For LSS patients, the pain is 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 over- or underestimate outcomes. Thus, the experts suggested 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.

For pain outcome, several experts have 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, 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 quality of life (HRQoL), consisting of mental and physical health perceptions (e.g., mood, energy level) and their correlates (e.g., socioeconomic status, social support, functional status, as well as health conditions and risks). The concept HRQoL presented potentially overlapping with some of the above domains. Thus, participants agreed and favored 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 renamed and defined as patient global assessment (PGA) of disease-related health status and kept as a core domain.

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Table 4. Candidate outcomes ratings in 2 rounds Delphi and voting at consensus meetings

Candidate Outcomes	round 1 (n=39)			round 2 (n=39)			redefined outcomes	consensus meeting voting (n=24)
	% score 1-3	% score 4-6	% score 7-9	% score 1-3	% score 4-6	% score 7-9		% 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%

Notes: ADL, activities of daily living; ROM, Range of movement; AE, adverse events; CM, Chinese medicine; QOL, Quality of life; HRQoL, health related QOL; PGA, patient global assessment; NR, not reported

3.3.2 COS identified by final voting

Following the list of outcomes, an agreement was reached on the core set using an electronic voting program in consensus meetings. Scores for the respective outcome domain were listed in Table 4. 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). Table S8 of supplementary material presented the sensitive analysis of score of outcomes between patients and experts.

Figure 1. Flow chart of core outcomes selection process

4. Discussion

4.1 Summary of the Main Results

This study presents the developing process of the core domain set of Chinese medicine for LSS in trials (CORE-CM-LSS) and the steps involved for reaching a consensus of patients and experts. The patient perspective was integrated in the respective research phase. The sampling process was inclusive of panelists nationally, which increases generalizability of our findings in China.

4.2 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 adverse events 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, counter-parting 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 [33].

The CM-specific outcomes were covered in COS in terms of its specific for CM, which may deviate from that employed in Western medicine [29, 34], 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 [35]. A pattern often contains several CM symptoms (e.g., 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 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 [36].

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 adverse events [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 (e.g., 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, 37-39]. Furthermore, additional core domains may be examined alongside the above outcomes to capture condition-specific characteristics.

4.3 Strengths and limitations

Strengths of this study include a China national representation of LSS patient and physician stakeholders participating in the consensus meeting, surveys, as well as 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, as well as LSS manifestations. This ensured that we captured broad content early in the process of data collection and obtained domains that are generalizable 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 make sure 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, this may lead to an underestimation of the importance of certain areas from their points of view. It is worth mentioning that the goal of this study was not to develop a set of outcome areas important to all stakeholders, but rather a core set of outcomes to be included in all clinical trials. 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.

4.4 Implication for clinical practices and research

This study's main objective was to produce a collection of core outcome measures for use in reliable prospective studies involving LSS patients. This core outcome set 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. At the next stages, the psychometric features of each core set domain's outcome measure will be assessed, and choosing a core set of outcome measures that is sufficient and not redundant will be selected.

5. Conclusion

The COS for CM in LSS was initially 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 evaluate CM in terms of LSS, to increase consistency in the report of the result. The COS enhances the synthesis of the evidence relating to LSS patient-associated outcomes and supports overall field development and research.

Acknowledgments

We would like to acknowledge all the people who participated in the study. We thank all organizations that funded our research.

Contributions

Ya'nan Sun, Xiyou Wang and Changhe Yu all contributed to the study's conception and design. Ya'nan Sun, Zhi-Wen Weng, Yi an and Yanji Zhou conducted the literature review, interview and had primary responsibility in writing this article. Ya'nan Sun, Yanji Zhou and Changhe Yu conducted survey and consensus meeting, performed analysis and interpreted them. Xiyou Wang and Changhe Yu critically revised the manuscript. All authors have read and approved the final manuscript.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Ethics Statement

Ethics approval was provided by the ethics committee of Dongzhimen hospital (DZMEC-KY-2020-60). Prior to the interviews with the patients, written informed consent was requested. The Delphi signup page had a notice emphasizing the fact that submission of the questionnaire constitutes permission. A permission form was filled out by each attendee of the consensus meeting to signify their agreement to

participate.

Abbreviations

CORE-CM-LSS, core domain set of Chinese medicine for LSS in trials; COS, Core outcome domain sets; CM, Chinese medicine, LSS, Lumbar spinal stenosis; COS-STAD, Core Outcome Set-STAndards for Development; COS-STAR, Core Outcome Set-STAndards for Reporting; SAG, Study Advisory Group; RCT, randomized controlled trials; SLR, Systematic review; NGT, Nominal group technique; COMET, Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement Instruments; 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; UBA-PBS, UBA pain behavior 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; NR, not reported; Int, interview

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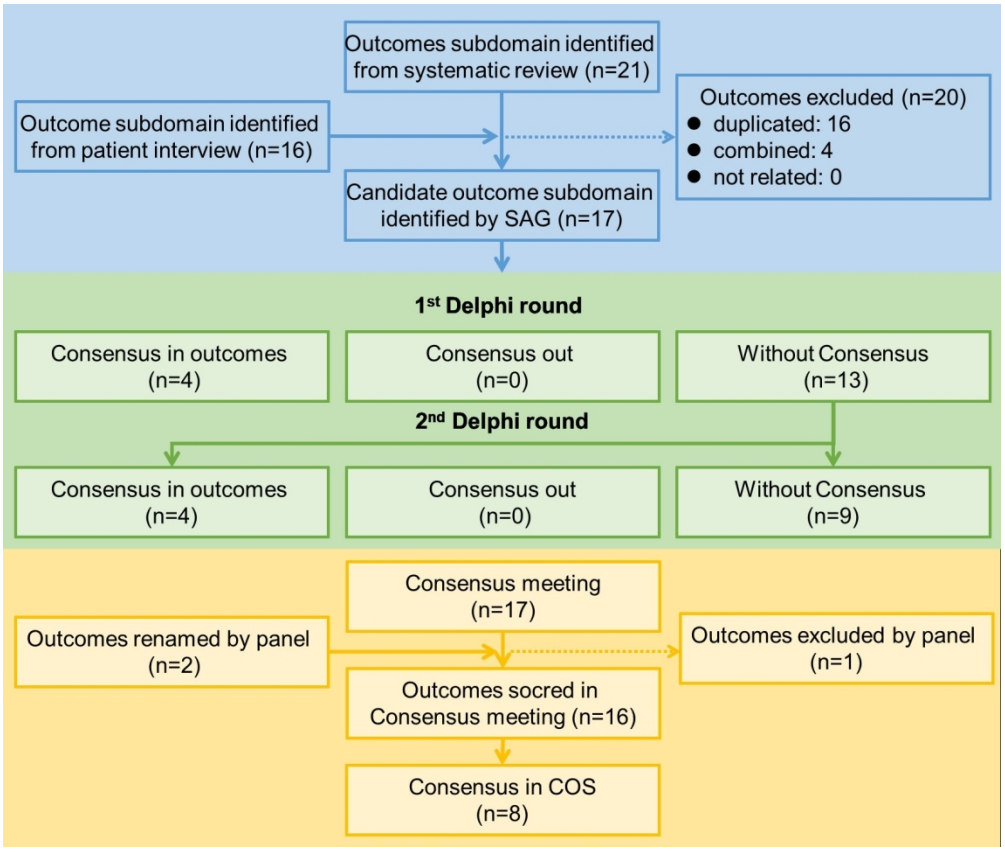

Figure 1. Flow chart of core outcomes selection process

287x241mm (150 x 150 DPI)

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	JOA
Guan Xiaoyong, 2015[6]	47/47	CM herb	Salvia (Danshen) injection+Diclofenac	VAS Responder rates	1m	Pre- and post-treatment	pain/function/ ADL 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	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 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 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/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 Responder rates	10d	Pre- and post-treatment	symptoms pain/function/ pain/function/symptoms	pain function	DEC-TCM
Yuan Zhixian, 2020[60]	30/30	CM herb+Acupuncture+Moxibustion	Usual care	Self-made symptoms rating scale JOA VAS AE	4w	Pre- and post-treatment	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	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 research	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 re-identified outcomes	experts (n=15) % yes	patients (n=9) % yes
	% 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			
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

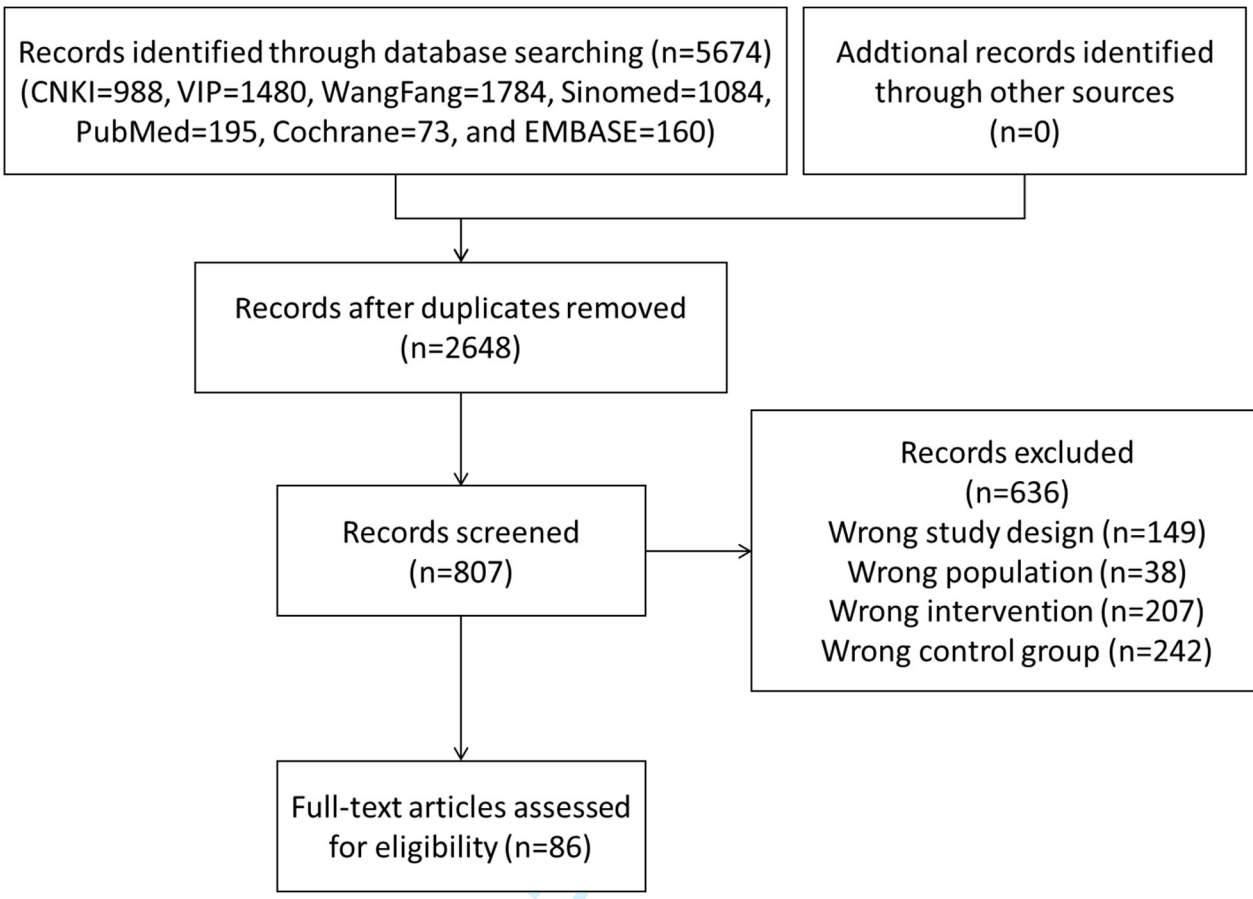

Figure S1. PRISMA flow diagram

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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. 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 lumbar spinal stenosis by building a core outcome set (CORE-CM-LSS).

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 semi-structured 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 1st round and four outcomes additionally in the 2nd 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.

Keywords: lumbar spinal stenosis, Delphi survey, domains, systematic review, Chinese medicine, core outcome set

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Strengths and limitations

- 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 (CORE-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 lumbar spinal stenosis (LSS) manifestations, which ensures that the core domains are generalizable to LSS people.
- Chinese medicine (CM) or integrated medicine studies have been mostly used there, which limits the results since stakeholders are distributed in different geographical areas.

1. Introduction

Lumbar spinal stenosis (LSS) arises from spinal anatomical or functional narrowing with a negative effect on the spinal cord and nerve roots, characterized 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 United States [4]. Most LSS are treated non-operatively, with physical therapy, analgesia, as well as 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 4 results were analyzed, while the other results could not be analyzed 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 standardized 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 COMET database and searching OMERACT for COSs of trauma and orthopedics ensured the lack of COS on LSS [15].

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

2. 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-STAR (Core Outcome Set-STAndards for Reporting) [16] as well as COS-STAD (Core Outcome Set-STAndards for Development) [17] guidelines (Supplementary Material, 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 lumbar spinal stenosis (LSS) which is treated by CM.

2.1 Scope and design

Study Advisory Group (SAG) was formed, in which a wide variety of stakeholders, two orthopedists, 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 core outcome set's scope is clarified as follows: Setting:

randomized controlled trials (RCT); Health condition: symptomatic lumbar spinal stenosis[1]. Target interventions are Chinese medicine (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 core outcome set.

The ethics committee of the corresponding author's hospital (DZMEC-KY-2020-60) has given ethical approval for the present study on September 7th, 2020. 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.

2.2 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 lumbar spinal stenosis [18].

2.2.1 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 (e.g., 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.

2.2.2 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 1st January, 2022 (search strategy in Supplementary Material, 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 20 managed literature and excluded the duplicate ones. Eligibility was evaluated initially by two independent reviewers (including SYN and ZYJ) 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 (YCH).

2.2.3 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 (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 categorized 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 standardized the similar or overlapping outcomes. Information and purpose of an instrument (i.e., 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 (YCH).

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 18.0.

2.3 The semi-structured interview

The additional associated outcome domains were elicited through qualitative semi-structured interviews of patients.

2.3.1 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 Supplementary Material, table S4). Features were defined by the SAG to ensure diversity represented. The qualitative data were analyzed, 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.

2.3.2 Interview process

Interviews were carried out face-to-face in outpatient or via remote video software (WeChat) and recorded by qualified researchers (YCH). Explanation and information consent should be given to patients before the interviews. We initiated the interview with questions (e.g., "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.

2.3.3 Data analysis

The additional outcomes and the demographic and medical information of patients were collected. The words expressed by patients were analyzed 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 (SYN and AY) 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 organized 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.

2.4 Expert consensus

2.4.1 Panel participants

A group of participants specialized in CM, integrated Chinese and Western medicine, nursing, orthopedics, acupuncture, *Tuina*, pain management, rehabilitation, and clinical researchers were recruited in the Delphi survey, and the professional and geographical distribution of panelists 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.

2.4.2 Identifying important outcomes in Delphi Survey

In Round 1 and 2, for the respective outcome, panelists were recruited for assigning scores between 1 (of no importance) and 9 (of high importance), where 1 to 3 represents that it is “of no importance to be included in the COS,” 4 to 6 represents that it is “of importance but no critical importance to be included in the COS” and 7 to 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 minimization of attrition. Predefined "consensus in" thresholds are reached if > 80% of the panelists score 7 to 9 and ≤ 15% score 1 to 3; "consensus out" thresholds are met if > 80% of the panelists score 1 to 3 and ≤ 15% of the panelists scored 7 to 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.

2.4.3 Identifying core outcomes in consensus meetings

A total of nine LSS patients and 15 experts, most from previous study stages, were recruited in an online consensus meeting. One author (YCH), 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 panelists. Anonymized 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 pre-specified threshold of >80% on yes was set.

2.5 Patient and public involvement (PPI)

None.

3. Results

3.1 Identification of candidate outcomes

3.1.1Outcomes from the systematic literature review (SLR)

A total of 5,674 trials were identified through the SLR, 86 trials could be included after duplicates were removed, and abstract, title, and full-text were screened (PRISMA flow diagram in Supplementary Material, figure S1). Eighty-six trials involved 6,892 LSS patients (rang 26~200), with 80% (2980/6658, two trials did not report gender) female, aged from 33~72 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. Table S4 of Supplementary material lists the characteristics of the included trials in detail.

Table 1 lists a total of 86 trials that reported 54 different outcome measurement instruments (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 (18/86, 20.93%), as well as measures of walking (12/86, 13.95%) (Supplementary material, Table S5). 50% of OMI were patient-reported outcomes, and 30% were performance-based measurements. While the rest were clinician-based measurements (e.g., 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 adverse events (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.

Table 1. Classification of Outcome Measurement Instruments into subdomains and COMET outcomes

No	COMET domain outcome	Number of 86 RCTs reporting COMET outcomes (%)	Subdomain outcome	Number 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/UBA-PBS/pain subscale of JOA/pain subscale of SSS/bodily pain subscale of SF-36
3	Adverse events	19 (22.1)	AE	1 (1.9)	AE
4	Physiological	11 (12.8)	Inflammatory markers Hemorheological 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 hematocrit Changes in T lymphocyte subsets Hepatic and renal function tests/Serum endothelin Parameters of computed tomography
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

Notes: COMET, Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement Instruments; 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; UBA-PBS, UBA pain behavior 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; NR, not reported

309

310 3.1.2 Patients interview

311 In this study, 18 interviews were carried out with LSS patients from seven territorial
312 regions around China. 8 of the 18 interviews with them were done via the WeChat
313 app. Table S6 of supplementary material presents the demographic details of the
314 participants. The content analyses of interview transcript and outcomes from open-
315 ended questions indicated that 16 subdomain outcomes were identified and then
316 classified into 11 COMET domains (Table 2).

317

Table 2. Subdomain and COMET outcomes identified from interviews

COMET domain outcome	Subdomain outcomes	Number 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
	Hemorheological 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*"

Notes: COMET, Core Outcome Measures in Effectiveness Trials; ADL, activities of daily living; ROM, Range of movement; AE, adverse events; CM, Chinese medicine; NR, not reported

SAG identified subdomain outcomes as candidate outcomes from SLR and interviews, defined outcomes, and constructed a final inventory of 17 outcomes[24-32] 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, hemorheological markers, immunological markers, as well as physiological outcomes (Figure. 1).

Table 3. Candidate DLSS 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 [30].	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 [26].	SLR+Int
4	ROM	Quantity of movement of the lumbar spine and/or of other adjacent body parts (i.e. thoracic spine, pelvis, rib cage or lower limbs) [24].	SLR+Int
5	symptoms	Presence of symptoms on back, leg and walking [28].	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 [31].	SLR+Int
8	AE	Any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related [32].	SLR+Int
9	Bio-marks	Indicators aimed at providing insight into peripheral and	SLR

		central neurobiological mechanisms of pain [24].	
10	Radiographic changes	medical imaging such as MRI, CT, X-ray detecting the changes of Bones, joints, muscles, tendons, nerves and other body structures localized on the lumbar spine and/or on other adjacent body parts (i.e. 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 [29].	SLR
12	Mental health	A person's condition with regard to their psychological, social and emotional well-being [27].	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[27].	SLR
15	Adherence and attrition	Withdrawal from treatment [25].	SLR
16	Psychosocial	An individual's interactions with their environment and the ability to fulfill 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 (i.e. financial loss due to treatment cost, work loss, or time commitment) [25].	Int

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

3.2 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 Supplementary Material, table S7). Delphi survey identified four outcome domains (including pain, function, ADL and 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.

3.3 COS determined by consensus meetings

3.3.1 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 over- 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.

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 quality of life (HRQoL), consisting of mental and physical health perceptions (e.g., mood, energy level) and their correlates (e.g., socioeconomic status, social support, functional status, as well as health conditions and risks). The concept HRQoL presented potentially overlapping with some of the above domains. Thus, participants agreed and favored 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 renamed and defined as patient global assessment (PGA) of disease-related health status and kept as a core domain.

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Table 4. Candidate outcomes ratings in 2 rounds Delphi and voting at consensus meetings

Candidate Outcomes	round 1 (n=39)			round 2 (n=39)			redefined outcomes	consensus meeting voting (n=24)
	% score 1-3	% score 4-6	% score 7-9	% score 1-3	% score 4-6	% score 7-9		% 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%

Notes: ADL, activities of daily living; ROM, Range of movement; AE, adverse events; CM, Chinese medicine; QOL, Quality of life; HRQoL, health related QOL; PGA, patient global assessment; NR, not reported

3.3.2 COS identified by final voting

According to the list of outcomes, an agreement was reached on the core set based on an electronic voting program 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). Table S8 of supplementary material lists the sensitive analysis of score of outcomes between patients and experts.

Figure 1. Flow chart of core outcomes selection process

4. Discussion

4.1 Summary of the Main Results

This study presents the development of the core domain set of Chinese medicine for LSS in trials (CORE-CM-LSS) and the steps involved for reaching a consensus of patients and experts. The patient perspective was integrated in the respective research phase. The sampling process included panelists nationally, which can endow our findings with greater generalizability in China.

4.2 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 adverse events 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, counter-parting 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 [33].

The CM-specific outcomes were covered in COS in terms of its specific for CM, which may deviate from that employed in Western medicine [29, 34], 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 [35]. A pattern often contains several CM symptoms (e.g., 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 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 [36].

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 adverse events [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 (e.g., 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, 37-39]. Furthermore, additional core domains may be examined alongside the above outcomes to capture condition-specific characteristics.

4.3 Strengths and limitations

Strengths of this study include a China national representation of LSS patient and physician stakeholders participating in the consensus meeting, surveys, as well as 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, as well as LSS manifestations. This ensured that we captured broad content early in the process of data collection and obtained domains that are generalizable 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.

4.4 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 core outcome set 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.

5. 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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Contributions

Ya'nan Sun, Xiyou Wang and Changhe Yu all contributed to the study's conception and design. Ya'nan Sun, Zhiwen Weng, Yi an and Yanji Zhou conducted the literature review, interview and had primary responsibility in writing this article. Ya'nan Sun, Yanji Zhou and Changhe Yu conducted survey and consensus meeting, performed analysis and interpreted them. Xiyou Wang and Changhe Yu critically revised the manuscript. All authors have read and approved the final manuscript.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Ethics Statement

Ethics approval was provided by the ethics committee of Dongzhimen hospital (DZMEC-KY-2020-60). Prior to the interviews with the patients, written informed consent was requested. The Delphi signup page had a notice emphasizing the fact that submission of the questionnaire constitutes permission. A permission form was filled out by each attendee of the consensus meeting to signify their agreement to

participate.

Abbreviations

CORE-CM-LSS, core domain set of Chinese medicine for LSS in trials; COS, Core outcome domain sets; CM, Chinese medicine, LSS, Lumbar spinal stenosis; COS-STAD, Core Outcome Set-STAndards for Development; COS-STAR, Core Outcome Set-STAndards for Reporting; SAG, Study Advisory Group; RCT, randomized controlled trials; SLR, Systematic review; NGT, Nominal group technique; COMET, Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement Instruments; 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; UBA-PBS, UBA pain behavior 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; NR, not reported; Int, interview

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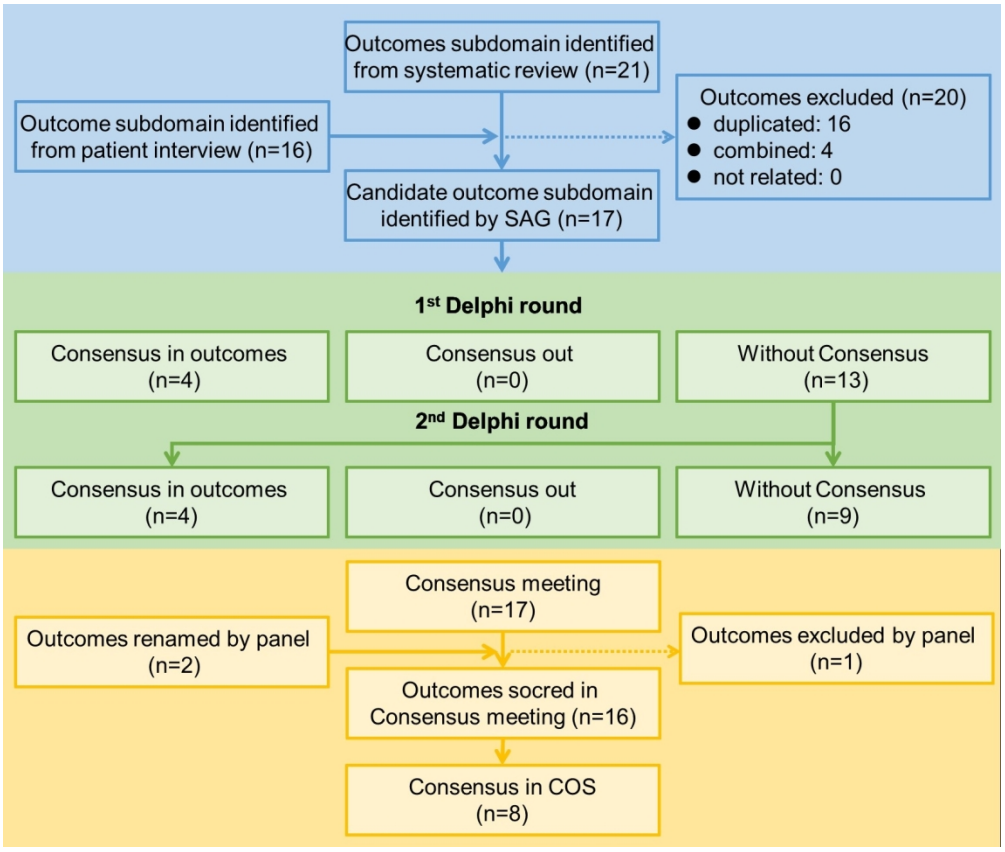

Figure 1. Flow chart of core outcomes selection process

287x241mm (150 x 150 DPI)

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	JOA
Guan Xiaoyong, 2015[6]	47/47	CM herb	Salvia (Danshen) injection+Diclofenac	VAS Responder rates	1m	Pre- and post-treatment	pain/function/ ADL 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	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 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 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/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 Responder rates	10d	Pre- and post-treatment	symptoms pain/function/ pain/function/symptoms	pain function	DEC-TCM
Yuan Zhixian, 2020[60]	30/30	CM herb+Acupuncture+Moxibustion	Usual care	Self-made symptoms rating scale JOA VAS AE	4w	Pre- and post-treatment	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	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 research	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 re-identified outcomes	experts (n=15) % yes	patients (n=9) % yes
	% 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			
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

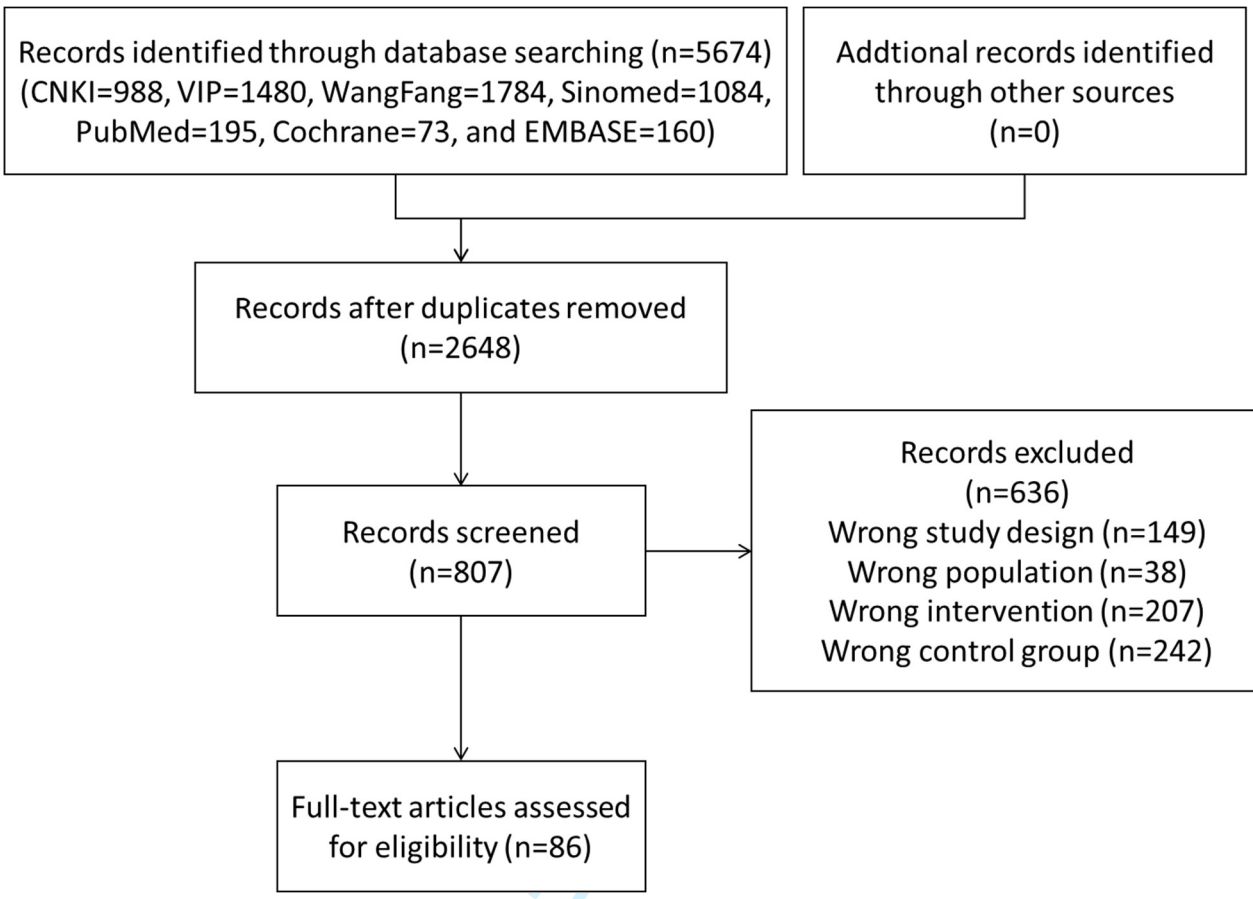

Figure S1. PRISMA flow diagram

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