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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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1	<b>Development of CO</b>	<b>RE-CM</b> Core outcome	domain sets for trials of	Chinese
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1	Abstract

2	Objectives: Most Asian countries have employed Chinese medicine (CM) and
3	Western medicine to treat lumbar spinal stenosis. Evidence synthesis and comparison
4	of effectiveness are difficult since outcomes examined and presented through trials
5	have heterogeneity. This study aimed to solve the outcome problems for CM clinical
6	trials in lumbar spinal stenosis by building a core outcome set (CORE-CM-LSS).
7	Methods: To achieve an agreement on a set of core outcome domains, a four-phase
8	study was carried out. First, we identified candidate outcome domains by
9	systematically reviewing trials. In addition, we identified outcome domains associated
10	with patients by conducting semi-structured interviews with patients. Next, outcome
11	domains were processed through a national two-round Delphi survey, in which 18
12	patients and 21 experts were recruited. Finally, the above domains were converted as
13	a core outcome domain set based on a consensus meeting, in which 24 stakeholders
14	were recruited.
15	Results: Seventeen outcome subdomains were identified by the systematic review and
16	interviews. The Delphi survey assigned a priority to four outcome domains in the 1st
17	round and four outcomes additionally in the 2nd round. The core outcome domains
18	were determined through discussion and redefinition of outcomes in the consensus
19	meeting: pain and discomfort, HRQoL, lumbar Function, ADL, measures of walking,
20	patient global assessment, Adverse Events and CM-specific outcomes.

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- Conclusion: COS-CM-LSS is likely to enhance the consistency of outcomes reported 1
- 2 in clinical trials. In-depth research should be conducted for the exploration of the best
- 3 methods to examine the above outcomes.
- Keywords: lumbar spinal stenosis, Delphi survey, domains, systematic review, 4
- 5 Chinese medicine, core outcome set
- 6 Word counts: 3888

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1	Strengths	and	limitations

2	•	$\square$ We report the development of a multiple-stakeholder, consensus-based
3		CORE outcome set applicable to Chinese Medicine (CM) intervention trials in
4		adults with Lumbar Spinal Stenosis (CORE-CM-LSS).
5	•	□ The core outcome domains were agreed as: pain and discomfort, HRQoL,
6		lumbar function, activity daily living, walking function, patient global
7		assessment, adverse events and Chinese Medicine specific outcomes.
8	•	□ A mixed-method approach was used to determine which outcomes would be
9		included in the COS.
10	•	□ The CORE-CM-LSS should be measured and reported in all future research
11		trials that evaluate CM in terms of LSS, to increase consistency in the report of
12		the result.
13	•	□ This was not an international study; participants were from China.
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**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<sup>1</sup>. The above discomfort and pain can be increased by walking and alleviated through sitting or lumbar flexion<sup>2</sup>. LSS can affect a global population of nearly 103 million<sup>3</sup> and 11% of the elderly in the United States<sup>4</sup>. 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<sup>5</sup>. 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<sup>8</sup>. Furthermore, manual therapy in combination with exercises under supervision can improve walking capacity, symptoms, and pain in comparison to exercises<sup>9</sup>. A review of clinical trials of LSS found inconsistency between results reporting or measuring instrument application under one outcome and poorly defined outcomes <sup>10</sup>. 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<sup>8</sup>. 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<sup>11</sup>. Data that cannot be interpreted or used can result in unacceptable and unethical waste of research. Selective reporting of results 

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and associated reporting biases may also occur if consistent results are not specified in
advance <sup>12</sup>.

The core outcome set (COS) includes standardized outcomes. It has been found

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1	as the minimal measurement and report criterion in terms of the respective trial for a
2	specific health area <sup>13</sup> , increasing outcome reporting consistency, accountability, and
3	transparency. Outcomes, which conform with certain standards and are examined in
4	studies under a particular condition, can reduce this research waste, such that the bias
5	of reporting can be prevented. The above outcomes can ensure that existing research
6	reporting outcomes is able to be integrated into meta-analyses with certain
7	significance <sup>14</sup> . The review of the COMET database and searching OMERACT for
8	COSs of trauma and orthopedics ensured the lack of COS on LSS <sup>15</sup> .
9	This study presents a multiple-stakeholder, Chinese nationally endorsed,
10	consensus-based CORE outcome set suitable for Chinese Medicine intervention trials
11	in adults with LSS (CORE-CM-LSS), as well as its developing process.
12	2. Method
13	The study protocol had registration in the database of COMET
14	(https://www.comet-initiative.org/Studies/Details/1363), whereas the protocol was not
15	published. The development of our COS was reported and consistent with the COS-
16	STAR (Core Outcome Set-STAndards for Reporting) <sup>16</sup> as well as COS-STAD (Core
17	Outcome Set-STAndards for Development) <sup>17</sup> guidelines (Supplementary Material,
18	table S1 and S2). This is a further study underlying COS development in terms of low
19	back pain (LBP), the COS focused on specific LBP due to LSS treated by CM.
20	2.1 Scope and design
21	Study Advisory Group (SAG) was formed, inviting a wide variety of
22	stakeholders, two orthopedists, one acupuncture and Tuina expert, one patient, one
23	methodologist, one clinical trial researcher, as well as one statistician. SAG confirmed
24	the outcome set that serves as a candidate in terms of data analyses and explanation,
25	process coordination, and Delphi survey. Furthermore, some of them participated in
26	the consensus process.
27	Following SAG, this core outcome set's scope was as follows: Setting:
28	randomized controlled trials (RCT); Health condition: symptomatic lumbar spinal
29	stenosis <sup>1</sup> . Target interventions are CM for LSS, which comprise acupuncture, Tuina
30	(CM massage), Gongfa (CM exercise), bloodletting, cupping, oral herbal medicine,

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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.

8 The ethics committee of the corresponding author's hospital (DZMEC-KY-2020-9 60) has given ethical approval for the present study on September 7<sup>th</sup>, 2020. All 10 participants declared no interest conflict during the study. Patients contributed to the 11 design of the study and were involved in the stages of patients' interview and 12 consensus meeting.

# 13 2.2 Systematic literature review (SLR)

14 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, selfmanagement), or a combination of the above. There were no restrictions on
publication type, language, or status.

22 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 1<sup>st</sup> 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)

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1	through reading abstracts and titles, and the trials were included after the full texts
2	were read. Any disagreements would be addressed through discussions when the full
3	text was critically reviewed, or through consultation with a third author (YCH).
4	2.2.3 Data collection and analyses
5	The data from eligible trials were extracted independently and inputted into Microsoft
6	EXCEL for management. Extracted data included the first authors, contact
7	information, outcome measurement instruments (name and measuring time-frame),
8	comparator, intervention, sample size, country, and year of publication. If response
9	rate or composite index outcomes exited in trials, the criteria and classification of
10	them were recorded.
11	After data extraction, the measurement instruments were categorized by SAG
12	into outcome subdomains and domains, and the respective outcome was defined by
13	SAG following the COMET criteria <sup>18</sup> . Besides, SAG removed the duplicates and
14	standardized the similar or overlapping outcomes. Information and purpose of an
15	instrument (i.e., to evaluate physical function, or pain intensity) was confirmed by
16	original prescription, from either method or results parts, and considered into right
17	subdomains. Any disagreements were resolved by consulting a third author (YCH).
18	The number of instruments of the respective trial and subdomain and outcome
19	domains of all trials was obtained. The frequency and percentages of categorical
20	instruments and outcomes were conducted with SPSS 18.0.
21	2.3 The semi-structured interview
22	The additional associated outcome domains were elicited through qualitative semi-
23	structured interviews of patients.
24	2.3.1 Participants
25	The LSS patients previously or currently under CM treatment were recruited. While
26	the LSS patients due to trauma or congenital spinal disease, having hearing or
27	communication problems, or refusing to join the interviews were excluded.
28	Convenient and purposeful sampling methods were undertaken with several
29	ages, gender, years of LSS and imaging findings within the hospital outpatients from
30	seven territories of China. The qualitative data were analyzed, while the interviews

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3 4	1	continued, and the sampling was ended following data saturation criteria, based on the
5 6	2	definition from two consecutive interviews without any additional subdomain.
7 8	3	2.3.2 Interview process
9 10	4	Interviews were carried out and recorded by qualified researchers (YCH).
11 12	5	Explanation and information consent should be given to patients before the
13 14	6	interviews. We initiated the interview with questions (e.g., "what outcomes are
15 16	7	important or most concern to you, or how do you determine the effectiveness of
17 18	8	treatment, or what aspect they would like to get better improvement"). A list of
19 20	9	subdomains from SLR was provided as the outline when patients could not answer or
21	10	had no ideas about the important outcomes. After patients completed reading the list,
23	11	another open-ended question was asked to allow patients to provide additional
24 25	12	outcomes.
20 27	13	2.3.3 Data analysis
28 29	14	The additional outcomes and the demographic and medical information of
30 31	15	patients were collected. Patients' words were recorded and analyzed through content
32 33	16	analysis. All outcomes identified by patients were extracted by two researchers (SYN
34 35	17	and AY) and then mapped onto the initiative list.
36 37	18	2.4 Expert consensus
38 39	19	2.4.1 Panel participants
40 41	20	A group of participants specialized in CM, integrated Chinese and Western
42 43	21	medicine, nursing, orthopedics, acupuncture, Tuina, pain management, rehabilitation,
44 45	22	and clinical researchers were recruited in the Delphi survey, and the professional and
46 47	23	geographical distribution of panelists was considered. Furthermore, all SAG members
48 49	24	engaged in the consensus meeting.
50 51	25	It was expected to select 30 participants based on a snowball sampling method.
52 53	26	The experts were preliminarily identified by reviewing the authors of high-impact
54 55	27	papers and recommended the preliminary stakeholders. The patients were selected
56 57	28	following a pool of outpatients.
58 59	29	2.4.2 Identifying important outcomes in Delphi Survey
60	30	In Round 1 and 2, for the respective outcome, panelists were recruited for

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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" <sup>19</sup>. 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  $\leq$  15% score 1 to 3; "consensus out" thresholds are met if > 80% of the panelists score 1 to 3 and  $\leq$  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<sup>20</sup>.

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 1<sup>st</sup> and 2<sup>nd</sup> rounds, with average scores of outcomes.

19 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<sup>21</sup>. 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

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3 4	1	into greater categories if an agreement was reached by most panelists. Anonymized
5 6	2	votes were made in terms of agreements with domain placement. When the meeting
7 8	3	was about to be completed, a draft preliminary core set of domains was made and then
9 10	4	shown to the participants.
11 12	5	After the Delphi survey was completed, the outcomes of "consensus in" and "no
13 14	6	consensus" were scored using yes, no, or unsure for inclusion of the COS (yes for
15 16	7	selected; no for not selected). In terms of outcomes to be included in the core domain
17 18	8	set, a pre-specified threshold of >80% on yes was set.
19 20	9	3. Results
21	10	3.1 Identification of candidate outcomes
23	11	3.1.1Outcomes from the SLR
24 25 26	12	A total of 5,674 trials were identified through the SLR, 86 trials could be
20 27	13	included following the removal of duplicates, and screening of abstract, title, and full-
28 29	14	text (PRISMA flow diagram in Supplementary Material, figure S1). Eighty-six trials
30 31	15	involved 6,892 LSS patients (rang 26~200), with 80% (2980/6658, 2 trials didn't
32 33	16	report gender) female, aged from 33~72 years. Most trials compared a wide variety of
34 35	17	CM treatments alone with placebo or routine treatment, and others compared the
36 37	18	combination of CM treatment versus CM treatment alone or western treatment. Table
38 39	19	S4 of Supplementary material elucidates the characteristics of the included trials.
40 41	20	Table 1 listed a total of 86 trials that reported 54 different outcome measurement
42 43	21	instruments (OMI). The number of OMIs was applied and reported ranging from 1 to
44 45	22	6 (median 3). The most used OMI comprised response rates (64/86, 74.42%), various
46 47	23	versions of JOA (42/86, 48.84%), visual Analogue Scale (37/86, 43.02%), adverse
48 49	24	events (18/86, 20.93%), as well as measures of walking (12/86, 13.95%) (details in
50 51	25	Supplementary material, table S4). 50% of OMI were patient-reported outcomes, and
52 53	26	30% were performance-based measurements. While the rest were clinician-based
54 55	27	measurements (e.g., CT and MRI).
56 57	28	SAG reviewed 54 OMI and identified 20 subdomain outcomes and 10 COMET
58 59	29	domains (Table 1). Among 86 trials, pain (98.8%; n=85) and function (97.7%; n=84)
60	30	were the most frequently evaluated COMET domains, followed by adverse events

1 (22.1%; n=19), and Physiological index (12.8%; n=11). Three COMET domains

2 (including resource use, mortality, and infection) were not reported in any trial.

Table 1.	Classification	of Outcome	Measurement	Instruments	into	subdomains	and	COMET
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No	COMET domain outcome	Number of 86 RCTs reportin g COMET outcome s (%)	Subdomain outcome	Number of 54 OMIs into subdomai n 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/RMD Q/ 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	Physiologica l	11 (12.8)	Inflammatory markers Hemorheologic al 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	2 (3.7)	Near-infrared imaging system on meridian
	6	Mental health	4 (4.7)	Zneng 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	Psychosocia 1	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

2 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

6 from open-ended questions indicated that 16 subdomain outcomes were identified and

- 7 then classified into 11 COMET domains (Table 2).

	Table 2. Subdomai	n and COMET outc	omes identified from interviews
COMET domain outcome	Subdomain outcomes	Number of 18 patients (%)	Example of interview transcript

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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>"I felt hard to back straight or bend over (in some degrees)"</i>
	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>"I cannot get into sleep due to pain when I tried to turn over on bed</i> ?"
Adverse events	AE	16 (88.9)	"Is that (the treatment) safe? Are there any side effects?"
Physiological	Inflammatory markers	0 (0)	nr
	Hemorheologic al 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?"
			"It always hurts and pain seems not to be relieved,
Mental health	Mental health	12 (66.7)	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 longevityI 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"

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R	esource use	Resource use	3 (16.7)	"Treatment wastes lots of time on transportation and waiting but I have to (do it) due to pair"
				and walling, but I have to (do it) due to path
Ν	otes: COME	T, Core Outcome	Measures in E	Effectiveness Trials; ADL, activities of daily living;
R	OM, Range of	movement; AE, ad	lverse events; C	CM, Chinese medicine; NR, not reported
1				
2	SAG i	dentified subdom	ain outcomes	as candidate outcomes from SLR and
3	interviews,	defined outcomes	s, and construc	cted a final inventory of 17 outcomes <sup>22-30</sup>
4	for the Delp	ohi survey (Table	3). Among ca	ndidate outcomes, Physiological outcome
5	was separat	ed by SAG into b	iomarkers and	l radiographic changes. The biomarkers
6	outcome wa	as identified by S.	AG by combir	ng inflammatory markers, hemorheological

- 7 markers, immunological markers, as well as physiological outcomes (Figure. 1).
- 8

# 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 <sup>28</sup> .	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 <sup>22</sup> .	SLR+Int
3	ADL	Fundamental skills required to independently care for oneself, such as eating, bathing, and mobility <sup>24</sup> .	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) <sup>22</sup> .	SLR+Int
5	symptoms	Presence of symptoms on back, leg and walking <sup>26</sup> .	SLR+Int
6	measure of walking	Measuring ability, capability, distance, performance of walking <sup>22</sup> .	SLR+Int
7	Global rating of change	Considering the ways that the health condition affects the individual on a given day <sup>29</sup> .	SLR+Int
8	AE	Any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related <sup>30</sup> .	SLR+Int
9	Bio-marks	Indicators aimed at providing insight into peripheral and	SLR

10	Radiograp hic changes	central neurobiological mechanisms of pain <sup>22</sup> . 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) <sup>22</sup> .	SLR+Int
11	CM- specific outcomes	CM outcomes related to CM <i>Zheng</i> or meridians based on CM theory <sup>27</sup> .	SLR
12	Mental health	A person's condition with regard to their psychological, social and emotional well-being <sup>25</sup> .	SLR+Int
13	Satisfactio n index	Satisfaction with care received, including of the process and outcomes of the treatment experience and care providers <sup>22</sup> .	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 <sup>25</sup> .	SLR
15	Adherence and attrition	Withdrawal from treatment <sup>23</sup> .	SLR
16	Psychosoci al	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 <sup>22</sup> .	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) <sup>23</sup> .	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 

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1 domains to be covered in the core outcome domain set.

# **3.3 COS determined by consensus meetings**

3 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

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2 3 4	
5 6 7 8 9 10 11 12	Cand Outco
13 14 15	Pain
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42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Ment health Satist n ind Quali life Adhe and attriti Psych al Resor use Notes

Candidate Outcomes	rou	und 1 (n=:	39)	rou	und 2 (n=3	39)	redefined outcome	consens us meeting voting (n=24)
	%	%	%	%	%	%	S	
	score	score	score	score	score	score		% yes
	1-3	4-6	7-9	1-3	4-6	7-9		
Pain	0%	5%	95%	nr	nr	nr	paın/dısc omfort	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%	Biomark s	4%
Radiograp hic changes	5%	33%	62%	3%	31%	67%	Radiogra phic changes	38%
CM- specific outcomes	8%	28%	64%	3%	21%	77%	specific outcome	88%
Mental health	5%	36%	59%	3%	38%	59%	S Mental health	63%
Satisfactio n index	0%	28%	72%	0%	26%	74%	Satisfacti on index	21%
Quality of life	3%	13%	85%	nr	nr	nr	HRQoL	96%
Adherence and attrition	8%	33%	59%	5%	31%	64%	Adheren ce and attrition	4%
Psychosoci al	49%	38%	13%	49%	41%	10%	Psychoso cial	21%
Resource use	8%	26%	67%	5%	23%	72%	Resource use	58%
Notes: ADL,	activities	of daily	living; RC	M, Range	e of move	ment; AE	, adverse eve	ents; CM,

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<ul> <li>3.3.2 COS identified by final voting</li> <li>Following the list of outcomes, an agreement was reached on the core set usine an electronic voting program in consensus meetings. Scores for the respective outcome domain were listed in Table 4. An agreement was reached on eight doma of importance and inclusion in the core domain set for clinical trials (including pair 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.</li> <li>Figure 1. Flow chart of core outcomes selection process</li> <li><b>4.1</b> Summary of the Main Results</li> <li>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 national which increases generalizability of our findings in China.</li> <li>4.2 Outcomes Included in the COS</li> <li>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 comm 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 construction, which is beneficial to compare populations from different diseases. However, the LSS-associated HRQoL is necessary but scarce, which can precisely indicate the</li> </ul>	1	
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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 <sup>31</sup>.

The CM-specific outcomes were covered in COS in terms of its specific for CM, which may deviate from that employed in Western medicine<sup>27,32</sup>, 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 <sup>33</sup>. 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<sup>34</sup>. 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 <sup>10</sup>. 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 <sup>22,35-37</sup>. Furthermore, additional core domains may be examined alongside the above outcomes to capture condition-specific characteristics. 4.3 Strengths and limitations

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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.

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23 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

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

# 2 5. Conclusion

3 The COS for CM in LSS was initially established. Pain and discomfort, HRQoL,

4 lumbar function, ADL, walking function, PGA, AE and CM-specific outcomes should

5 be measured and reported in all future research trials that evaluate CM in terms of

6 LSS, to increase consistency in the report of the result. The COS enhances the

7 synthesis of the evidence relating to LSS patient-associated outcomes and supports

8 overall field development and research.

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15 16	7	in all these areas; took part in drafting, revising or critically reviewing the article;
17 18	8	gave final approval of the version to be published; have agreed on the journal to
19 20	9	which the article has been submitted; and agree to be accountable for all aspects of the
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40 41	18	study, data collection and analysis, or preparation of the manuscript.
42 43	19	Data Availability
44 45	20	The data used to support the findings of this study are available from the
46 47	21	corresponding author upon request.
48 49	22	Ethics Statement
50 51	23	Ethics approval was provided by the ethics committee of Dongzhimen hospital
52 53	24	(DZMEC-KY-2020-60). Prior to the interviews with the patients, written informed
54 55	25	consent was requested. The Delphi signup page had a notice emphasizing the fact that
56 57	26	submission of the questionnaire constitutes permission. A permission form was filled
58 59	27	out by each attendee of the consensus meeting to signify their agreement to
60	28	participate.

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# 1 Abbreviations

- 2 CORE-CM-LSS, core domain set of Chinese medicine for LSS in trials; COS, Core
- 3 outcome domain sets; CM, Chinese medicine, LSS, Lumbar spinal stenosis; COS-
- 4 STAD, Core Outcome Set-STAndards for Development; COS-STAR, Core Outcome
- 5 Set-STAndards for Reporting; SAG, Study Advisory Group; RCT, randomized
- 6 controlled trials; SLR, Systematic review; NGT, Nominal group technique; COMET,
- 7 Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement
- 8 Instruments; CM, Chinese medicine; SPWT, Self-Paced Walk Test; JOA, Japanese
- 9 Orthopedic Association Score; mJOA, modified Japanese Orthopedic Association
- 10 Score; VAS, visual analogue scale; NRS, numerical rating scale; UBA-PBS, UBA
- 11 pain behavior scale; AE, adverse events; SF-36, 6-Item Short Form Survey; ADL,
- 12 activities of daily living; ROM, Range of movement; RMDQ, Roland Morris
- 13 Disability Questionnaire; mRMDQ, modified Roland Morris Disability
- 14 Questionnaire; HADS, Hospital Anxiety and Depression Scale; ODI, Oswestry
- 15 Disability Index; QOL, Quality of Life; SSS, Spinal Stenosis Scale; ZCQ, Zurich
- 16 Claudication Questionnaire; TNF, Tumor Necrosis Factor; RBC, Red blood cell;
- 17 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)

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Suppl	lementary	Material
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			Table S1. The COS-STAR Statement	
SECTI	IT	E		
ON/TO	N	I	CHECKLIST ITEM	page no
PIC	No	).		
TITLE/				
ABSTR				
ACT				
Title	1.0		Identify in the title that the paper reports the development	1
The	Ta		of a COS	1
Abstract	1b		Provide a structured summary	1
INTRO				
DUCTI				
ON				
Backgro	20		Describe the background and explain the rationale for	2
und and	Za		developing the COS	2
Objectiv	<b>2</b> h		Describe the specific objectives with reference to	2
es	20		developing a COS	2
Scope	20		Describe the health condition(s) and population(s) covered	2.2
Scope	Ja		by the COS.	2,5
	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
METH				
ODS				
Protocol			Indicate where the COS development protocol can be	
/Registr		4	accessed if available and/or the study registration details	2,3
y Entry			accessed, if available, and/of the study registration details.	
			Describe the rationale for stakeholder groups involved in	
Particip		5	the COS development process, eligibility criteria for	15
ants		5	participants from each group, and a description of how the	ч,5
			individuals involved were identified.	
Informa			Describe the information sources used to identify an initial	
tion	6a		list of outcomes	3,4,5
Sources			list of outcomes.	
	6h		Describe how outcomes were dropped/combined, with	315
	00		reasons (if applicable).	5,7,5
Consens				
us		7	Describe how the consensus process was undertaken.	6,7
Process				

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Outcom e Scoring	8	Describe how outcomes were scored and how scores were summarized.	6,7
us Definiti on	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 <b>RESUL</b> TS	10	Provide a statement regarding the ethics and consent issues for the study.	3
Protocol Deviatio ns	11	Describe any changes from the protocol (if applicable), with reasons, and describe what impact these changes have on the results.	Not applicabl e 8,9,10
Particip ants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development.	and Supplem entary materials
Outcom es	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
DISCU SSION			
ons	15	Discuss any limitations in the COS development process.	12
Conclus ions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research.	10,11,1 2
OTHER INFORM			
N	AIIO		
Funding	17	Describe sources of funding/role of funders.	13
Conflict s of Interest	18	Describe any conflicts of interest within the study team and how these were managed.	13

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		Table S2. The COS-STAD checklist	
Domain	Stan dard num ber	Methodology	page no.
Scope specification	1 2 3	The research or practice setting(s) in which the COS is to be applied The health condition(s) covered by the COS The population(s) covered by the COS	3,4 3,4 3,4
Stakeholders involved	4 5	The intervention(s) covered by the COS Those who will use the COS in research	3,4 4,5
	6 7	Healthcare professionals with experience of patients with the condition Patients with the condition or their representatives	4,5 4,5
Consensus process	8 9	The initial list of outcomes considered both healthcare professionals' and patients' views. A scoring process and consensus definition were	6,tabl e1-3 5
	10	Criteria for including/dropping/adding outcomes were described a priori.	5
	11	in the list of outcomes.	5,6

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43 44 45 46 47 48 49 50 51 52 53 54 55 56 57
43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 52
43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58

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Table S3. PUBMED Search strategies and results										
Databases	Search strategies	Results								
		to Jan 1 <sup>st</sup> ,								
		2022								
PUBMED	("chin med"[Journal] OR ("chinese"[All Fields] AND "medicine"[All	183								
	Fields]) OR "chinese medicine"[All Fields] OR "tuina"[All Fields] OR									
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	"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] OK tcm [All Fields]) OK tatchi [All Fields]) OR ("spinal" [All									
	Fields] AND (spinal stenosis [MeS11 Terms] OK (spinal [An Fields] AND "stenosis"[All Fields]) OR "spinal stenosis"[All Fields])									

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1 2 3 4					BMJ Open		1 by copyright, includi	njopen-2023-075856 o			Page 34 of 55
5 6				Table S4 Studies' Chara	acteristics and Outcome M	asureme	nt Instruments <b>o</b>	n 16			
7 8 9 10 11 12 13	First author, year	Partici pants	Interventions	Comparator	Outcome Measurement Instruments	Treat ment durati on	OMI relation ominimities of the second omeasuring time to tex	OCCODE Subdomain 23 outcomes	COMET outcomes	criter ia for respo nder rates	
14 15 16 17 18 19	Zeng Haobin, 2020	60/60	Manual therapy+Usual care	Celecoxib+Usual care	JOA VAS parameters of computed tomography	2w	Pre- and poster treatment, data follow-up 3 mer and 6m	apain/function/ apain/function/ apain Radiographic changes	pain function Physiologi cal	NR	
20 21 22 23 24 25 26 27 28 29 30	Chen Jian, 2019	30/30	CM herb	Aceclofenac+Mecobal amin	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 Physiologi cal AE	JOA	
30 31 32 33 34	Feng Hui 2009	40/40	Acupotomy	Traction	Responder rates	2m	Pre- and post- treatment	11, 2025 2025 2025 2025 2025 2025 2025 202	pain function	DEC - TCM	
35 36 37 38 39 40	Geng Xiaoyan, 2017	46/46	CM herb	Salvia (Danshen) injection+Diclofenac	JOA	NR	Pre- and post- treatment	gence Bibliograp	pain function	NR	
41 42 43 44 45 46				For peer review only - http:	://bmjopen.bmj.com/site/	about/gu	uidelines.xhtml	hique de l			
Page 35 of 55					BMJ Open		d by сору	njopen-2			
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1 2 3 4 5 6 7 8 9 10 11	Gu Qi, 2015	30/30	CM herb	GIucos	mJOA VAS SPWT Responder rates	2w	Pre- and post- treatment, set follow-up lang for Responder rates to	pain/function/ ADL pain measure of walking pain/function/	pain function	JOA	
13 14 15 16	Guan Xiaoyong, 2015	47/47	CM herb	Salvia (Danshen) injection+Diclofenac	VAS Responder rates	1m	Pre- and post treatment	ADL apain fpain	pain	VAS	
18 19 20 21	Hou Yu, 2019	22/23	Manual therapy	NSAIDs+Drugs for protecting gastric mucosa and nourishing nerves	JOA VAS	4w	Pre- and post- treatment 2	pain/function/	pain function	NR	
22 23 24 25 26 27	Huang Zheng, 2017	31/33/ 32/33	CM herb Acupuncture CM herb+Acupuncture	Diclofenac+Mecobala min	JOA/improvement of JOA Responder rates AE	3m	Pre-treatment, 1, 2 and 3me after sin treatment	ADL pain/function/ pain/function/ AE	pain function AE	DEC - TCM	
28 29 30 31	Huang Zhifen, 2009	50/46	CM herb	Diclofenac	Responder rates AE	4w	Pre- and post- treatment	ng pain/function/ nate	pain function AE	DEC - TCM	
32 33 34 35 36 37 38	Ji Wei, 2013	35/34	CM herb	Mecobalamin	Responder rates VAS mJOA	4w	Pre- and post- treatment	Spain/function/ Apain Apain/function/ ADL Biblic	pain function	DEC - TCM	
39 40 41 42 43 44 45 46				For peer review only - http:	//bmjopen.bmj.com/site/a	about/gu	udelines.xhtml	vgraphique de l			

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3 4 5 6 7 8 9 10 11 12 13	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 powers relations by the second power of the second power	pain function	DEC - TCM	
14 15 16 17 18 19 20 21 22 23 24	Li Jinxue, 2007	40/40/ 44/42	CM herb CM herb+CM granules CM herb+CM granules+Erigeron breviscapus	Glucos	Responder rates VAS parameters of computed tomography	4w	treatment for reiend pain/function/ rates/VAS/MORE pain/function/ diographic mission ADL changes, c. Bradiographic follow-up A 12month for the pain Responder of the pain/function/ pain pain pain Radiographic changes	pain function Physiologi cal	JOA	
24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40	Li Jinxue, 2013	92/83	CM herb	GIucos	Responder rates VAS Walking capacity	2w	rates Pre- and posit- treatment fear Responder recy rates/VAS/M alking capacity, for Responder rates/Walking capacity Bibliograp	pain function	GPC R- ND	
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Lin Yuanfang, 2017	33/32	Manual therapy	Traction	Responder rates JOA Rang of Lumbar spine extension	20d	Pre- and post treatment set of AD reig for AD	n/function/ n/function/ L M	pain function AE	DEC - TCM
Liu Chenhui, 2019	30/30	CM herb	Celecoxib+Mecobala min+Hydrotalcite Tablets	VAS SPWT CM Zheng scores Responder rates AE	2w	ated post remember of the second Pre- and post of work treatment and control of the second treatment and choice data treatment at a for the second treatment at a for the second treatment at a for the second treatment at a for the second treatment	n asure of king Zheng n/function/	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	bal rating hange h/function/	pain function	DEC - TCM
Liu Jun, 2020	46/46	CM herb	Mannitol Injection+Mecobalami n	Responder rates	3w	Pre- and post- treatment g, and b	n/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 free AD	n/function/ n/function/ L nunologica dicators	pain function Physiologi cal	DEC - TCM
Su Lianshu,	38/37	Acupotomy	Canal injection	VAS JOA Responder rates	3w	Pre-treatment, 1 and 4w after treatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment Breatment B	n n/function/ L n/function/	pain function	DEC - TCM

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6 7 8 9 10 11 12 13 14	Sun Biyun, 2021	40/40	Acupuncture	Sham Acupuncture	NRS mRMDQ HADS Treatment Adherence index AE	6w	6w after of treatment, set follow-up res 12w and 24 for to NRS/RMD HADS	Adherence Dand attrition	pain function mental health complianc e	NR
15 16 17 18 19 20 21 22 22	Tang Hanwu, 2015	35/34	CM herb	Celecoxib+Mecobala min	Responder rates VAS JOA Near-infrared imaging system on DU meridian	4w	Pre- and point treatment Q	ADL CM meridian	pain function CM indictor	DEC - TCM
23 24 25 26 27 28	Wang Chenghon g, 2009	46/44	acupuncture	Traction+Physical therapy	JOA mRMDQ responder rates	2w	Pre- and post- treatment, sin follow-up for	grain/function/	pain function	JOA
29 30 31 32 33 34 35 36 37 38 39 40 41	Wang Guanjun, 2019	53/53	CM herb	Mannitol Injection+Mecobalami n	VAS JOA Responder rates	3w	Pre- and poet treatment	1) 2) 2) 2) 2) 2) 2) 2) 2) 2) 2	pain function	DEC - TCM ; JOA
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Wang Haijun, 2017	47/47	Acupotomy	Traction+Physical therapy	VAS JOA Responder rates	14d	Pre- and position treatment, of opain/function/ follow-up long ADL and 6m	pain function	VAS ; JOA
Wang Hua, 2017	50/50	Manual therapy	Epidural injection	Responder rates	4w	Pre- and post and pos	pain function	DEC - TCM
Wu Shizhen, 2016	13/13	Acupotomy	Canal injection	Global Rating of Change Scale Responder rates	NR	Pre- and posting treatment	pain function	NR
Xiao Zhenhua, 2021	23/23	Acupotomy	Canal injection	VAS JOA	20d	Pre- and point treatment	pain function	NR
Zhou Qishi, 2002	51/51	CM herb	Vitamin B1 B6	Responder rates SPWT Serum endothelin	4w	Pre- and post- treatment similar of physiological of index	function Physiologi cal	NR
kim, 2016	26/24	Acupuncture	Usual care	ODI SF-36	6w	Pre- and post- treatment, s. follow-up 3m Pre- and post- treatment, s. follow-up 3m Pre- and post- treatment, s. follow-up 3m follow-up 3m	pain function QOL mental health Psychosoc ial	NR
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10 11 12 13 14 15 16	Oka, 2018	41/38/ 40	Acupuncture	Drugs/Exercise therapy	ZCQ	lm	Pre- and postuporaditisfaction treatment and car	pain function satisfactio n	NR
17 18 19 20 21 22 23 24	Qin, 2020	40/40	Acupuncture	Sham Acupuncture	RMDQ NRS SSS Satisfaction subdomain of SSS	8w	Pre-treatment, 4 and 8w are pain treatment, follow-up 3m and 6m Pre-treatment, b pain/function/ c satisfaction	pain function satisfactio n	NR
25 26 27 28 29 30 31 32 33	Xu Jialong, 2021	29/29	CM herb + Usual care	Drugs + Usual care	VAS JOA SPWT CM Zheng scores AE	4w	2 and 4w after treatment for VAS, JOA Pre- and poot- treatment for SPWT, CMG Zheng scores	pain function CM indictors AE	DEC - TCM
34 35 36 37 38 39 40 41	Zhu Shuxian, 2014	30/30	Manual therapy + Usual care	Traction + Usual care	Responder rates VAS ODI	3w	Pre- and post- treatment <b>Biolograph</b>	pain function	DEC - TCM
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1 2 3 4 5 6 7 8 9 10	Liu Li, 2020	32/32	Acupuncture+Moxib ustion	Acupuncture	Responder rates Self-made symptoms rating scale JOA VAS	20d	ght, including forst- Pre- and postses relat treatment	23-075856 99 pain/function/ 60 symptoms 60 pain/function/ 60 ADL 20 pain	pain function	DEC - TCM	
11 12 13 14	Wang Chenghu, 2014	45/45	Acupuncture+Moxib ustion	Ibuprofen	Responder rates	10d	Pre- and potent treatment X pe	Depain/function/	pain function	DEC - TCM	
15 16 17 18	Su Tao, 2011	60/60	Acupuncture+Moxib ustion+manual therapy	manual therapy	Responder rates	12d	Pre- and post treatment mers	fight and function/	pain function	DEC - TCM	
19 20 21 22	Liao Jian, 2017	30/30	CM herb+Acupuncture	Acupuncture	Responder rates RMDQ	2w	Pre- and post- treatment	finition/function/	pain function	DEC - TCM	
23 24 25 26 27	Shan Jinchun, 2013	48/48	CM herb+manual therapy	manual therapy	Responder rates CM Zheng scores	lm	Pre- and post- treatment s.	pain/function/	pain function CM indictors	COC E	
28 29 30 31 32 33 34 35 36 37 38 39 40 41	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 4woo after est treatment, follow-up 1m	ADL ADL Superior ADL Superior Advantage CM Zheng Bibliographi	pain function CM indictors	NR	
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1 2 3 4 5 6	He Yuanzhen	60/60	CM herb+manual	manual therapy	Responder rates	1m	Pre- and post-	3-075856 on 16 cpain/function/	pain	DEC
7 8 9	g, 2009		therapy				Pre-treatment	pain/function/	function	TCM
10 11 12 13 14	Li Zhulie, 2012	30/30	Electrothermal acupuncture	Acupuncture	JOA Responder rates AE	10 times	1, 2, and 3 course after treatment, for follow-up light	pain/function/	pain function AE	JOA
15 16 17 18 19 20	Chen Xiaoyun, 2009	30/30	Electropuncture+Blo odletting therapy	Electropuncture	Responder rates Global Rating of Change Scale VAS	20d	Pre- and positive treatment mini- g.	pain/function/ symptoms pain	pain function	DEC - TCM
20 21 22 23 24 25 26 27 28 29 30	Lei Xiaoping, 2020	34/34	CM herb+Acupuncture	GIucos+Mecobalamin	JOA IL-6\IL-4\IL-10\TNF Blood viscosity/plasma viscosity/RBC hematocrit Responder rates AE	lm	Al training Pre- and post- treatment similar techn	pain/function/ ADL Inflammatory markers Hemorheologi ocal indictors Lpain/function/ AE	pain function AE Physiologi cal	DEC - TCM
31 32 33 34 35 36 37 38 39 40 41	Cai Lijun, 2012	32/64	CM herb+kerotherapy	Drugs/Traction	Responder rates JOA	3w	Pre- and post- treatment	, 2025 Bibliograph	pain function	DEC - TCM ; JOA
42 43 44 45				For peer review only - http:	//bmjopen.bmj.com/site/a	about/gu	idelines.xhtml	que de l		

				BMJ Open		njopen-2023-07585( I by copyright, inclu		Page 44 o
Yu Weimin, 2012	32/28	CM herb+Manual therapy	Canal injection	Responder rates	NR	Pre- and post- treatment	pain function	STI- ICW M
Zhang Zhirong, 2017	31/31	Acupuncture+Moxib ustion	Acupuncture	Responder rates	20d	Pre- and portion pain/function/ treatment	pain function	JOA
Wu Zhijun, 2018	30/30	CM herb+manual therapy	manual therapy	Responder rates AE	4w	Pre- and posts pain/function/ treatment addition	pain function AE	NR
Tang Ning, 2016	19/19	CM herb+manual therapy	manual therapy	JOA VAS Responder rates	4w	Pre- and post of pain/function/ treatment of pain/function/	pain function	NR
Tian Qiang, 2015	35/35	CM herb+manual therapy	CM herb	VAS RMDQ Responder rates	4w	Pre- and port - of pain treatment, of function follow-up ogn _ 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 are to pain/function/ SADL Spain	pain function	JOA
Liang Yihao, 2016	29/29	manual therapy+Exercise therapy	Exercise therapy	VAS JOA SPWT ODI Responder rates AE	3m	Pre-treatment 1 w, 1 m and 3 m after treatment bio 2 pain pain/function/ 2 ADL a measure of 4 walking 6 function Bipain/function/ 2 Month 2 Mon	pain function AE	VAS ; JOA\ ODI
			For peer review only - http:	://bmjopen.bmj.com/site/a	about/gi	uidelines.xhtml		



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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Xu Shiliang, 2014	47/48	CM herb+manual therapy	Glucos	SPWT VAS JOA IL-6\IL- 1B\TNF\CRP Blood viscosity/plasma viscosity/RBC hematocrit Responder rates	4w	ht, including for userseignement Pre- and post related to treatment fatted text and follow-up 4 text and for SPWT, tand data minil VAS, JOA	measure of walking pain/function/ 20ADL DInflammatory markers decal indictors fipain/function/ ADL	pain function Physiologi cal	JOA	
19 20 21 22 23	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 training	pain/function/	pain function	GPC R- ND	
24 25 26 27	Mao Xiaohui, 2008	52/52	CM herb+Manual therapy+CM fumigation	Drugs + Traction + TDP	Global Rating of Change Scale Responder rates	10d	Pre- and post- treatment sinila	symptoms pain/function/	pain function	DEC - TCM	
29 30 31 32 33 34 35 26	Yuan Zhixian, 2020	30/30	CM herb+Acupuncture+ Moxibustion	Usual care	Responder rates Self-made symptoms rating scale JOA VAS AE	4w	Pre- and poor- treatment	ar pain Symptoms 1 pain/function/ 20 20 20 20 20 20 20 20 20 20	pain function AE	CA- TCM	
37 38 39 40 41 42 43 44				For peer review only - http:	//bmjopen.bmj.com/site/a	about/gu	idelines.xhtml	e Bibliographique de l			

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1 2 3 4 5	Dou		CM herb+Manual	Canal injection +			ght, including Pre- and post-	13-075856 on 1	nain	DEC
6 7 8	Qunli, 2007 Chan	83/83	therapy	Traction	Responder rates	2m	treatment	opain/function/	function	- TCM
9 10 11	Shulie, 2006	32/7	Manual therapy+Topical CM	Drugs	Responder rates	4w	Pre- and poet	2020 pain/function/	pain function	NR
12 13 14 15 16 17 18	Wang Fuyu, 2018	48/48	CM herb+Acupuncture	Usual care	JOA VAS IL-1 TNF	4w	Pre-treatment	pain/function/ ADL pain filnflammatory markers	pain function Physiologi cal	JOA
20 21 22 23 24 25	Xiong Junwei, 2015	30/30	Acupotomy+Manual therapy	Acupotomy	JOA Responder rates AE	3w	Pre-treatmont 1, 2 and 3w after treatment, jo follow-up 2gw	ADL pain/function/ pain/function/ ADL ADL AE	pain function AE	JOA
26 27 28 29 30 31 32	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 poet- treatment hologies	Global rating of change Measure of walking ,ROM Spain/function/	pain function	DEC - TCM
33 34 35 36 37 38 39 40 41	Wang Wenli, 2018	30/30	Electropuncture+fire d cupping+Bloodlettin g therapy	Physical therapy	SSS Responder rates Satisfaction	8w	Pre-treatment, 4 and 8w after treatment, follow-up 4w	, a pain/function/ A pain/function/ c satisfaction BiAE	pain function satisfactio	DEC - TCM
42 43 44 45			I	For peer review only - http:	//bmjopen.bmj.com/site/ab	out/gu	idelines.xhtml	lue de l		

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1 2 3 4 5 6					subdomain of SSS AE		for Patient <b>g fo</b>		n AE		
7 8 9 10 11 12	Zhong Hongzhen	100/10	Acupuncture+Moxib	Diclofenac	ODI	30d	index series Pre-treatment of the series 10d and 25 <b>d</b> of the series	function	function	NR	
13 14 15	g, 2016	0					treatment, approved				
17 18 19 20 21	Jing Lei, 2019	29/30	d cupping+Bloodlettin g therapy	Physical therapy	SSS Responder rates	8w	A and 8w and 5 treatment is a set of the set	pain/function/s atisfaction pain/function/	function satisfactio n	DEC - TCM	
22 23 24 25 26	Wang Hongmei, 2019	40/40	Acupuncture+Moxib ustion	Glucos	JOA IL-6/TNF/CRP	10d	Pre- and post- treatment <sup>9</sup> , and sin	ADL Inflammatory markers pain/function/	function Physiologi cal	NR	
27 28 29 30 31 32 33	Wang Jian, 2013	72/72	Acupuncture+cuppin g	GIucos	JOA Responder rates AE	36d	Pre- and post- treatment, echine follow-up lan 1,	ADL pain/function/ ADL AE pain/function/	pain function AE	JOA	
34 35 36 37 38 39 40	Zhang Hong, 2014	37/36	Acupuncture+acupoi nt injection	Acupuncture	JOA Responder rates	12d	Pre- and post- 2 treatment	ADL pain/function/ ADL	pain function	JOA	
41 42 43 44 45 46				For peer review only - http:/	//bmjopen.bmj.com/site/al	oout/gu	idelines.xhtml				

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1 2 3 4 5 6 7 8 9 10 11 12	Lin Jincai, 2016	35/35	Acupuncture+CM herb injection	Acupuncture	Rang of Lumbar spine extension VAS JOA Pain-free walking distance	2w	Pre- and post related to t	1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 100 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1000 1	pain function AE	NR
13 14 15 16	Lv Xiaohua,	40/40	Acupuncture+Bloodl etting therapy	Dexamethasone+mann itol+CM herb injection	AE Responder rates	10d	Pre- and post treatment	a monometric function/	pain function	NR
17 18 19 20 21	Shi Jianwei, 2013	37/37	Acupuncture+manua l therapy	Dexamethasone+mann itol+Salvia (Danshen) injection	Responder rates	23d	Pre- and point treatment	pain/function/	pain function	DEC - TCM
22 23 24 25	Xu Yunyu, 2014	35/35	Acupuncture+Moxib ustion	Acupuncture	JOA Responder rates	25d	Pre- and positi- treatment, g follow-up lan	pain/function/ ADL pain/function/	pain function	JOA
27 28 29 30 31 32	Zhang Huajun, 2016	40/40	Acupuncture+CM herb+moxibustion	Acupuncture+CM herb	VAS JOA CRP ESR	14d	Pre- and post- treatment, no follow-up lon ge	spain pain/function/ ADL Inflammatory markers	pain function Physiologi cal	JOA
33 34 35 36 37 38	Ji Yuejun, 2010	64/62	CM herb+Manual therapy	Acupuncture	self-made lumbar fuction evaluation scale Responder rates	10d	بة Pre- and post- treatment	at Age function pain/function/ Biblio	pain function	DEC - TCM
59 40 41 42 43 44 45 46				For peer review only - http:	//bmjopen.bmj.com/site/a	bout/gu	uidelines.xhtml	graphique de l		

Ouyang Song, 201434/34Electropuncture+ma nual therapyTraction + Physical therapyResponder ratesNRPre- and point treatmentSong, regence pain/function/pain functionLian Lian (Chonggua g.200940/40CM herb+Manual therapy+CM (Imigation 2017Drugs + Traction + TDPResponder rates Global Rating of Change ScalePre- and point restrict (Inction/Pre- and point restrict pain/function/pain functionXiong Yumo, 2017CM herb+CM imigation+Acupoto nyDrugs + Traction + TDPResponder rates Global Rating of Change ScalePre- and point restrict pain/function/Pre- and point restrict pain/function/pain functionWei Shengqing 201742/42Acupotomy+Manual therapy-TopicalPrugs + Traction + TDPResponder rates Global Rating of Change Scale3wPre- and point pain/function/Pre- and point pain/function/pain functionWei Shengqing 201742/42Acupotomy+Manual therapy-TopicalManual therapyVAS IOA3wPre- and point pain/function/Pain functionMiao 2017Manual CM+CM herbUsual careVAS IOANRPre- and point pain/function/Pain functionMiao 2017Kerapy-Topical (CM+CM herbUsual careVAS IOANRPre- and point pain/function/Pain functionMiao 2010Kerapy-Topical (CM+CM herbUsual careVAS IOANRPre- and point pain/function/<					BMJ Open		by copyright, in	jopen-2023-075;		
LianCM herb+Manual therapy+CMDrugs + Traction + TDPResponder rates Global Rating of Change ScalePre- and post post treatmentPre- and post post symptomspain function/Xiong Yumo, 2017CM herb+CM fumigation+Acupoto 2017CM herb+CM myDrugs + Traction + TDPResponder rates Global Rating of Change ScalePre- and post post function/Pre- and post post pain/function/pain function/Wei Shengqing , 201942/42Acupotomy+Manual therapyAcupotomy+Manual therapyManual therapyVAS IOA ODI AE3wPre- and post post function/Pre- and post pain/function/pain function/Miao Surge, stateManual therapy-TopicalUsual careVAS IOA IOANRPre- and post pain/function/pain function/Vas Surge, stateManual therapy-TopicalUsual careVAS IOANRPre- and post pain/function/pain functionVas Surge, stateManual therapy-TopicalUsual careVAS IOANRPre- and post pain/function/pain function/Vas Surge, stateManual IOAVAS IOANRPre- and post reatmentPre- and post pain/function/pain function/Kei Surge, stateManual IOAVAS IOANRPre- and post reatmentPre- and post pain/function/pain function/Kei Surge, stateManual IOAManualPre- and post reatmentPre- and post pain/functio	Ouyang Song, 2014	34/34	Electropuncture+ma nual therapy	Traction + Physical therapy	Responder rates	NR	Pre- and post- treatment	Sopain/function/	pain function	]
Xiong Yumo, 2017CM herb+CM tumigation+Acupot myDrugs + Traction + TDPResponder rates Global Rating of Change ScalePre- and po reatmentPre- and po reatmentPre- and po pain/function/ painpain functionWei Shengqing , 201942/42Acupotomy+Manual therapyAcupotomy+Manual therapyManual therapyVAS JOA ODI 	Lian Chonggua ng, 2009	40/40	CM herb+Manual therapy+CM fumigation	Drugs + Traction + TDP	Responder rates Global Rating of Change Scale	3w	Pre- and post	spain/function/	pain function	I - -
Wei Shengqing , 201942/42 42/42 , 2019Acupotomy+Manual therapyManual therapyVAS JOA ODI AEwei Pre- and point functionpain ADLfunction functionpainMiaoManual teratmentManual teratmentVAS ODI AEwei Pre- and point functionManual functionmain functionManual teratmentmain functionMiaoManual Zezheng, 56/56Manual teratmentUsual careVAS JOANRPre- and point functionpain functionpain function2017CM+CM herbUsual careVAS JOANRPre- and point functionpain 	Xiong Yumo, 2017	30/30	CM herb+CM fumigation+Acupoto my	Drugs + Traction + TDP	Responder rates Global Rating of Change Scale	3w	Pre- and post treatment	symptoms	pain function	I - -
MiaoManualVASPre- and postpainZezheng,56/56therapy+TopicalUsual careJOANRPre- and postpain2017CM+CM herbManualVASImPre- and postADLpainYangManualVASImPre- and postpainfunction/painGuang,45/45therapy+TopicalUsual careVASImPre- and postpainpain2010CM+CM herbJOAImPre- and postpain/function/painfunctionXieManualJOA2wPre- and postpain/function/painfunctionWeixiong,40/40therapy+TopicalUsual careJOA2wPre- and postpain/function/painWeixiong,40/40therapy+TopicalUsual careJOA2wPre- and postpain/function/painWeixiong,40/40therapy+TopicalUsual careJOA2wPre- and postpain/function/pain	Wei Shengqing , 2019	42/42	Acupotomy+Manual therapy	Manual therapy	VAS JOA ODI AE	3w	Pre- and ported treatment	apain/function/ ADL function	pain function AE	, ; J
YangManualGuang,45/45therapy+TopicalUsual careVAS2010CM+CM herbJOAImXieManualJOAPre- and poetWeixiong,40/40therapy+TopicalUsual careJOAJOA2wPre- and poetFre- and poetJOAPre- and poetJoaJoaPre- and poetJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoaJoa <td< td=""><td>Miao Zezheng, 2017</td><td>56/56</td><td>Manual therapy+Topical CM+CM herb</td><td>Usual care</td><td>VAS JOA</td><td>NR</td><td>Pre- and post- treatment s.</td><td>pain/function/</td><td>pain function</td><td>1</td></td<>	Miao Zezheng, 2017	56/56	Manual therapy+Topical CM+CM herb	Usual care	VAS JOA	NR	Pre- and post- treatment s.	pain/function/	pain function	1
XieManualWeixiong, 40/40therapy+TopicalUsual careJOA2wPre- and post- treatmentpain/function/ painWeixiong, 40/40therapy+TopicalUsual care	Yang Guang, 2010	45/45	Manual therapy+Topical CM+CM herb	Usual care	VAS JOA	1m	Pre- and pout- treatment fc	gpain Epain/function/	pain function	1
2017 CM+CM herb	Xie Weixiong, 2017	40/40	Manual therapy+Topical CM+CM herb	Usual care	JOA Responder rates	2w	Pre- and post- treatment	, pain/function/ NADL apain/function/	pain function	1

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patients	gender	age (years)	disease course (years)	Complicating lumbar spondylolisthesis	Radiographic classification	experienc of CM treatment	uses a contract region	consensus meeting	
Al	female	73	10	n	lateral recess	у	e e Bajing	N	
A2	female	66	3	n	central spinal canal	у		у	
A3	male	69	2	У	intervertebral foramen	У	ġ ġġijing	N	
A4	female	71	9	n	central spinal canal	у	a de gijing	Ν	
A5	male	58	8	у	central spinal canal	n	a de gijing	Ν	
A6	male	73	11	n	lateral recess	У	a Seandong	Ν	
A7	female	64	7	у	lateral recess	У	n wa n wangdong	У	
A8	female	63	3	n	intervertebral foramen	n		У	
A9	male	68	6	у	central spinal canal	У	≥ Cangchun	Ν	
A10	female	55	7	у	lateral recess	У	a Beijing	У	
A11	female	75	13	n	lateral recess	У	Shandong	Ν	
A12	male	83	10	n	central spinal canal	У	a Beijing	Ν	
A13	female	55	1	У	intervertebral foramen	n	s. Laoning	У	
A14	male	54	2	У	central spinal canal	у	E Leaoning	У	
A15	female	69	1	n	central spinal canal	у	Beijing	У	
A16	female	64	20	У	lateral recess	у	Shanghai	У	
A17	female	72	30	n	intervertebral foramen	у	Beijing	Ν	
A18	male	60	4	У	lateral recess	у	i Beijing	У	

			Tabl	e S6. Characteris	tics of experts in Delphi rour	nds ding	on 1		
experts	gender	age (years)	work experience	title	medical major	acades rese		territorial region	conser meetir
Ex 1	male	49	(years) 24	senior	Tuina	Y tat	r 202 Pigne	Beijing	Y
Ex 2	male	54	31	senior	Tuina	Yet	те 13. Г	Beijing	Ν
Ex 3	male	56		senior	Tuina	Y E	)owi	Beijing	Y
Ex 4	male	60	38	senior	Tuina	Y B	nloa	Beijing	Y
Ex 5	male	39	11	intermediate	orthopaedics	Y	ndec	Beijing	Ν
Ex 6	male	50	28	intermediate	orthopaedics	Y ata	r (A	Beijing	Ν
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 ≥	lbn	Beijing	Y
Ex 10	male	37	8	intermediate	acupuncture	Y Ta	Jop	Beijing	Ν
Ex 11	male	43	20	senior	acupuncture	Y Ing	en.t	Beijing	Ν
Ex 12	male	56	31	senior	pain management	Y an	ă.	Shandong	Y
Ex 13	male	36	8	intermediate	rehabilitation	Y o	ŝ	Beijing	Y
Ex 14	female	57	35	senior	general family medicine	N		Beijing	Y
Ex 15	female	56	32	intermediate	pain management	N te	ע ו	Beijing	Y
Ex 16	female	37	15	intermediate	nursing	YÊ	ne 1	Beijing	Ν
Ex 17	male	48	24	senior	orthopaedics	YO	1, 2	Shanghai	Y
Ex 18	male	50	26	senior	orthopaedics	Y gie	025	Guangdong	Y
Ex 19	male	53	30	senior	orthopaedics	Y	at /	Xinjiang	Y
Ex 20	male	42	16	intermediate	orthopaedics	Y	Agei	Changchun	Y
Ex 21	female	39	11	intermediate	rehabilitation	Y	nce	Liaoning	Y

Table S7. Candidate ouDelpCandidateCandidateOutcomes%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%% <tr< th=""><th>putcomes ratings from patient phi round 1 (n=39) 1) patients (n=18) <math>\frac{\%}{90}</math> <math>\frac{\%}{90}</math> <math>\frac{\%}{90</math></th><th>ts and exper expe % re score 1-3</th><th>ts in De Delpl erts (n=2 % scor e 4- 6</th><th>elphi 2 hi roun 21) % scor e 7-</th><th>rounds d 2 (n= patie % scor e 1-</th><th>and vo <math>\overline{39}</math> and vo and vo <math>\overline{39}</math> and vo and vo <math>\overline{39}</math> and vo and vo <math>\overline{39}</math> and vo and vo <math>\overline{39}</math> and vo and vo and vo <math>\overline{39}</math> and vo and vo <math>\overline{39}</math> and vo and vo a</th><th>023-075856 on 16 October 2023. Downloaded from htt (کالالالالالالالالالالالالالالالالالالال</th><th>nt consensus meetin consensus me (n=2 NGT</th><th>ng peting vo 24) expe rts (n=1 5)</th></tr<>	putcomes ratings from patient phi round 1 (n=39) 1) patients (n=18) $\frac{\%}{90}$ $\frac{\%}{90}$ $\frac{\%}{90$	ts and exper expe % re score 1-3	ts in De Delpl erts (n=2 % scor e 4- 6	elphi 2 hi roun 21) % scor e 7-	rounds d 2 (n= patie % scor e 1-	and vo $\overline{39}$ and vo and vo $\overline{39}$ and vo and vo $\overline{39}$ and vo and vo $\overline{39}$ and vo and vo $\overline{39}$ and vo and vo and vo $\overline{39}$ and vo and vo $\overline{39}$ and vo and vo a	023-075856 on 16 October 2023. Downloaded from htt (کالالالالالالالالالالالالالالالالالالال	nt consensus meetin consensus me (n=2 NGT	ng peting vo 24) expe rts (n=1 5)
Table S7. Candidate ouDelpCandidateOutcomes%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%% </th <th>putcomes ratings from patient phi round 1 (n=39) 1) patients (n=18) <math>\frac{\%}{90}</math> <math>\frac{\%}{1-3}</math> <math>\frac{\%}{4-6}</math> <math>\frac{\%}{7-9}</math> <b>90</b> <math>\frac{\%}{100}</math> <math>\frac{\%}{100}</math></th> <th>experies and experies experies of the second s</th> <th><math display="block">\frac{\text{rts in De}}{\text{Delpl}}</math> <math display="block">\frac{\text{rts (n=2)}}{\text{rts (n=2)}}</math> <math display="block">\frac{\%}{\text{scor}}</math> <math display="block">e 4-</math> <math display="block">6</math></th> <th>elphi 2 hi roun 21) % scor e 7-</th> <th>rounds d 2 (n= patie % scor e 1-</th> <th><math>\frac{1}{39}</math> and vo 39) ents (n= <math>\frac{\%}{500}</math> scor e 4-</th> <th>16 October 2023. Downloaded from htt 留hseignement Scoerieur (路長会) for uses related to text and data mmii</th> <th>nt consensus meetin consensus me (n=2 NGT</th> <th>ng eeting vo 24) expe rts (n=1 5)</th>	putcomes ratings from patient phi round 1 (n=39) 1) patients (n=18) $\frac{\%}{90}$ $\frac{\%}{1-3}$ $\frac{\%}{4-6}$ $\frac{\%}{7-9}$ <b>90</b> $\frac{\%}{100}$ $\frac{\%}{100}$	experies and experies experies of the second s	$\frac{\text{rts in De}}{\text{Delpl}}$ $\frac{\text{rts (n=2)}}{\text{rts (n=2)}}$ $\frac{\%}{\text{scor}}$ $e 4-$ $6$	elphi 2 hi roun 21) % scor e 7-	rounds d 2 (n= patie % scor e 1-	$\frac{1}{39}$ and vo 39) ents (n= $\frac{\%}{500}$ scor e 4-	16 October 2023. Downloaded from htt 留hseignement Scoerieur (路長会) for uses related to text and data mmii	nt consensus meetin consensus me (n=2 NGT	ng eeting vo 24) expe rts (n=1 5)
Delp Candidate Outcomes $\frac{\% \ \%}{\text{score score }} = 21$ Pain $0\% \ 10\%$	phi round 1 (n=39) 1) patients (n=18) % % % % % scor score score score 9 1-3 4-6 7-9 90 0% 0% 100	expe % re score 1-3	Delpl erts (n=2 % scor e 4- 6	hi roun 21) % scor e 7-	nd 2 (n= patie % scor e 1-	ents (n= % scor e 4-	er 2023. Downloaded from htt seignement Superieur (ABES) i related to text and data mini	consensus me (n=2 NGT	eeting vo 24) expe rts (n=1 5)
Candidate Outcomes $\frac{\%  \%}{\text{score score }} \frac{3}{\text{e}}$ Pain 0%  10%	1) patients (n=18) $\frac{\%}{90}$ $\frac{\%}{1-3}$ $\frac{\%}{4-6}$ $\frac{\%}{7-9}$ <b>90</b> $\frac{\%}{90}$ $$	expe % e score 1-3	erts (n=2 % scor e 4- 6	21) % scor e 7-	patie % scor e 1-	ents (n= % scor e 4-	23. Downloaded from htt ement Soperieur (ABES) red to text and data mini	NGT	expe rts (n=1 5)
%         %         s           score         score         e           1-3         4-6         e           Pain         0%         10%	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	% re score 0 1-3	% scor e 4- 6	% scor e 7-	% scor e 1-	% scor e 4-	rom. <mark>tt</mark> (ABES) ta mmii	re-identified	07
Pain 0% 10%	$e^{7}$ score score score $9^{1-3}$ 4-6 7-9 $90^{0}$ 0% 100	e score 0 1-3	e 4- 6	e 7-	e 1-	e 4-	<u> Sola</u>		2/0
Pain 0% 10%	<b>90</b> 0% 0% 100		0	y y	3	6	120.7 <mark>₽</mark> . ▶9	outcomes	yes
	% 0/0 0/0 100	% nr	nr	nr	nr	nr	njopen.b traimno.	Pain and discomfort	100 %
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Page 55 of 55							E	3MJ Oper	n				njopen-20 1 by copy				
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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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#### **1** Development of CORE-CM Core outcome domain sets for trials of Chinese

#### 2 medicine for lumbar spinal stenosis

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### 37 Abstract

38	Objectives: Most Asian countries have employed Chinese medicine (CM) and
39	Western medicine to treat lumbar spinal stenosis. Evidence synthesis and comparison
40	of effectiveness are difficult since outcomes examined and presented through trials
41	have heterogeneity. This study aimed to solve the outcome problems for CM clinical
42	trials in lumbar spinal stenosis by building a core outcome set (CORE-CM-LSS).
43	Methods: To achieve an agreement on a set of core outcome domains, a four-phase
44	study was carried out. First, we identified candidate outcome domains by
45	systematically reviewing trials. In addition, we identified outcome domains associated
46	with patients by conducting semi-structured interviews with patients. Next, outcome
47	domains were processed through a national two-round Delphi survey, in which 18
48	patients and 21 experts were recruited. Finally, the above domains were converted as
49	a core outcome domain set based on a consensus meeting, in which 24 stakeholders
50	were recruited.
51	Results: Seventeen outcome subdomains were identified by the systematic review and
52	interviews. The Delphi survey assigned a priority to four outcome domains in the 1st
53	round and four outcomes additionally in the 2nd round. The core outcome domains
54	were determined through discussion and redefinition of outcomes in the consensus
55	meeting: pain and discomfort, Health-related quality of life, lumbar Function,
56	activities of daily living, measures of walking, patient global assessment, Adverse
57	Events and CM-specific outcomes.

- 58 Conclusion: COS-CM-LSS is likely to enhance the consistency of outcomes reported
- 59 in clinical trials. In-depth research should be conducted for the exploration of the best
- 60 methods to examine the above outcomes.
- 61 Keywords: lumbar spinal stenosis, Delphi survey, domains, systematic review,
- 62 Chinese medicine, core outcome set
- 63 Word counts: 4111

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

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77	1. Introduction
78	Lumbar spinal stenosis (abbreviated as LSS) is caused by spinal anatomical or
79	functional narrowing with a negative effect on the spinal cord and nerve roots,
80	characterized by pain and discomfort in legs, buttocks, and lumbar spine, as well as
81	disability of walking capacity [1]. The above discomfort and pain can be increased by
82	walking and alleviated through sitting or lumbar flexion [2]. LSS can affect a global
83	population of nearly 103 million [3] and 11% of the elderly in the United States [4].
84	Most LSS are treated non-operatively, with physical therapy, analgesia, as well as
85	activity modification as the First-line therapies, whereas patients subjected to limited
86	activities and continuous pain are likely to be an alternative in terms of surgery [5].
87	Chinese Medicine (CM), a non-surgical treatment, takes on critical significance
88	in the treatment of LSS. Acupuncture and acupotomy contribute to the LSS patients
89	on pain, symptoms, and functional outcomes up to 6 months post-treatment [6, 7].
90	Moreover, CM alone or combined treatment is likely to have a greater effect in
91	alleviating pain and ameliorating functional outcomes than conventional therapies [8].
92	Furthermore, manual therapy in combination with exercises under supervision can
93	improve walking capacity, symptoms, and pain in comparison to exercises [9].
94	A review of clinical trials of LSS found inconsistency between results reporting
95	or measuring instrument application under one outcome and poorly defined outcomes
96	[10]. An important effect of the above inconsistencies is to limit the potential of
97	robust meta-analysis. In a network meta-analysis of conservative treatment of LSS,
98	only 4 results were analyzed, while the other results could not be analyzed due to the
99	limited data or no meta-analysis to determine the outcome, or the variety of
100	definitions of an outcome [8]. Existing problems, supported by most CM trials,
101	include poorly defined outcomes, insufficient evidence of instruments, selective
102	reporting of outcomes, or no criteria for selection for core outcomes [11]. Data that
103	cannot be interpreted or used can result in unacceptable and unethical waste of
104	research. Selective reporting of results and associated reporting biases may also occur

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 if consistent results are not specified in advance [12].

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3 4	106	The core outcome set (COS) includes standardized outcomes. It has been found
5	107	as the minimal measurement and report criterion in terms of the respective trial for a
7 8	108	specific health area [13], increasing outcome reporting consistency, accountability,
9 10	109	and transparency. Outcomes, which conform with certain standards and are examined
10 11 12	110	in studies under a particular condition, can reduce this research waste, such that the
12	111	bias of reporting can be prevented. The above outcomes can ensure that existing
14	112	research reporting outcomes is able to be integrated into meta-analyses with certain
16 17	113	significance [14]. The review of the COMET database and searching OMERACT for
18 19	114	COSs of trauma and orthopedics ensured the lack of COS on LSS [15].
20 21	115	This study presents a multiple-stakeholder, Chinese nationally endorsed,
22 23	116	consensus-based CORE outcome set suitable for Chinese Medicine intervention trials
24 25	117	in adults with LSS (CORE-CM-LSS), as well as its developing process.
26 27	118	2. Method
28 29	119	The study protocol had registration in the database of COMET
30 31	120	(https://www.comet-initiative.org/Studies/Details/1363), whereas the protocol was not
32 33	121	published. The development of our COS was reported and consistent with the COS-
34 35	122	STAR (Core Outcome Set-STAndards for Reporting) [16] as well as COS-STAD
36 37	123	(Core Outcome Set-STAndards for Development) [17] guidelines (Supplementary
38 39	124	Material, table S1 and S2). This is a further study underlying COS development in
40 41	125	terms of low back pain (LBP), the COS focused on specific LBP due to lumbar spinal
42	126	stenosis (LSS) treated by CM.
44	127	Study Advisory Group (SAG) was formed, inviting a wide variety of
45 46	128	stakeholders, two orthopedists, one acupuncture and <i>Tuina</i> expert, one patient, one
47 48	129	methodologist, one clinical trial researcher, as well as one statistician. SAG confirmed
49 50	130	the outcome set that serves as a candidate in terms of data analyses and explanation.
51	131	process coordination, and Delphi survey. Furthermore, some of them participated in
53 54	132	the consensus process.
55 56	133	Following SAG, this core outcome set's scope was as follows: Setting:
57 58	134	randomized controlled trials (RCT): Health condition: symptomatic lumbar spinal
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3 4	135	stenosis <sup>1</sup> . Target interventions are Chinese medicine (CM) for LSS, which comprise
5 6	136	acupuncture, Tuina (CM massage), Gongfa (CM exercise), bloodletting, cupping, oral
7 8	137	herbal medicine, local washing or compressing with CM. Furthermore, CM alone or
9 10	138	CM combined with other conventional treatments were involved.
11 12	139	This study fell into three vital sections to obtain consensus on the outcome
13 14	140	domains that were to be examined, which were completed in the proper sequence. The
15 16	141	following inquiries were answered, including which outcome domains are likely to
17 18	142	benefit LSS patients, which outcomes are more important, as well as which results
19 20	143	should be included in the core outcome set.
21 22	144	The ethics committee of the corresponding author's hospital (DZMEC-KY-2020-
23 24	145	60) has given ethical approval for the present study on September 7th, 2020. All
24 25 26 27 28 29	146	participants declared no interest conflict during the study. Patients contributed to the
	147	design of the study and were involved in the stages of patients' interview and
	148	consensus meeting.
31 32	149	2.1 Patient and public involvement (PPI)
33 34	150	Patients and the general public participated in the semi-structured interviews, the
35	151	Delphi Surveys, and the final consensus meeting.
30 37	152	2.2 Systematic literature review
38 39	153	Systematic literature review (SLR) in our study was conducted to establish a list of
40 41	154	outcomes. Meanwhile, the results of the SLR were partly published aiming to assess
42 43 44 45	155	the effectiveness of non-pharmaceutical Chinese medical therapies singularly or in
	156	combination for lumbar spinal stenosis [18].
46 47	157	2.2.1 Eligible trials
48 49	158	The RCTs of the LSS patients diagnosed by clinical symptoms of neurogenic
50 51 52 53 54 55 56 57	159	claudication and imaging findings were included, no matter whether LSS patients
	160	have complicating diseases. Interventions comprised the treatment with CM alone or
	161	treatment including CM. The control intervention involved routine treatment (e.g.,
	162	injection therapy, physical therapy, exercise therapy, health education, self-
58 59	163	management), or a combination of the above. There were no restrictions on
60		8

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164 publication type, language, or status.

165 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 1<sup>st</sup> 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

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193	instruments and outcomes were conducted with SPSS 18.0.
194	2.3 The semi-structured interview
195	The additional associated outcome domains were elicited through qualitative semi-
196	structured interviews of patients.
197	2.3.1 Participants
198	The LSS patients previously or currently under CM treatment were recruited. While
199	the LSS patients due to trauma or congenital spinal disease, having hearing or
200	communication problems, or refusing to join the interviews were excluded.
201	Convenient and purposeful sampling methods were undertaken with several
202	ages, gender, years of LSS and imaging findings within the hospital outpatients from
203	seven territories of China (predefined features in Supplementary Material, table S4).
204	Features were defined by the SAG to ensure diversity represented. The qualitative
205	data were analyzed, while the interviews continued, and the sampling was ended
206	following data saturation criteria, based on the definition from two consecutive
207	interviews without any additional subdomain.
208	2.3.2 Interview process
209	Interviews were carried out face-to-face in outpatient or via remote video
210	software (WeChat) and recorded by qualified researchers (YCH). Explanation and
211	information consent should be given to patients before the interviews. We initiated the
212	interview with questions (e.g., "what outcomes are important or most concern to you,
213	or how do you determine the effectiveness of treatment, or what aspect they would
214	like to get better improvement"). A list of subdomains from SLR was provided as the
215	outline when patients could not answer or had no ideas about the important outcomes.
216	After patients completed reading the list, another open-ended question was asked to
217	allow patients to provide additional outcomes.
218	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

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> 222 recorded interviews were listened to and the transcripts were reviewed and reread. 223 The two researchers (SYN and AY) were initially assessed individually before being 224 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 225 226 within the context of COMET outcomes subdomains; and the codes within each topic 227 were organized into initial COMET outcome domains. After that, the draft outcomes 228 domains for the two researchers were combined and compared. Outcomes 229 subdomains with similar names were then examined, and those with the same content 230 were grouped together. Any discrepancies were resolved with discussion. 231 2.4 Expert consensus 2.4.1 Panel participants 232

> 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.

244 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

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251 important.252 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  $\leq$  15% score 1 to 3; "consensus out" thresholds are met if > 80% of the panelists score 1 to 3 and  $\leq$  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 1<sup>st</sup> and 2<sup>nd</sup> rounds, with average scores of outcomes.

264 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.

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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.
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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.

3.1 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 fulltext (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.

			outco	omes	
No	COMET domain outcome	Number of 86 RCTs reportin g COMET outcome s (%)	Subdomain outcome	Number of 54 OMIs into subdomai n 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/RMD Q/ 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)	subscale of JOA/pain subscale of SSS/bodily pain subscale of SF-3
3	Adverse events	19 (22.1)	AE	1 (1.9)	AE
4	Physiologica 1	11 (12.8)	Inflammatory markers Hemorheologic al marker Immunological markers Physiological markers Radiographic changes CM	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 subset Hepatic and renal function tests/Serum endothelin Parameters of computed tomography Near-infrared imaging system on
5	CM indictor	5 (5.8)	meridian/CM	2 (3.7)	meridian

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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	Psychosocia 1	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

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

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).

	Table 2. Subdomain	n and COMET of	outcomes identified from interviews		
COMET	Subdomain	Number of	Example of interview transprint (Chinese		
domain	outcomes	18 patients	words presented in English)		
outcome	outcomes	(%)	words presented in English)		
Function	Function	17 (94.4)	"This waist does not seem to be as flexible as before"		

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	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
	Hemorheologic al 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
Satisfaction	Satisfaction index	1 (5.5)	more serious" "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 longevityI 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"
-			

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

### 

319	SAG identified subdomain outcomes as candidate outcomes from SLR and
320	interviews, defined outcomes, and constructed a final inventory of 17 outcomes[24-
321	32] for the Delphi survey (Table 3). Among candidate outcomes, Physiological
322	outcome was separated by SAG into biomarkers and radiographic changes. The
323	biomarkers outcome was identified by SAG by combing inflammatory markers,
324	hemorheological markers, immunological markers, as well as physiological outcomes
325	(Figure. 1).

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

Table 3. Candidate DLSS Outcomes and definitions

10	Radiograp hic 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+I
11	CM- specific outcomes	CM outcomes related to CM <i>Zheng</i> 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+]
13	Satisfactio n index	Satisfaction with care received, including of the process and outcomes of the treatment experience and care providers [24].	SLR+I
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	Psychosoci al	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
Note	s: SLR, syster	matic literature review; Int, interview; ADL, activities of daily l	iving; l
Rang	ge of movemer	nt; AE, adverse events; CM, Chinese medicine;	

A total of 25 experts and 18 patients were recruited for online Delphi survey, and

330 21 experts and all patients responded and completed the first-round survey

331 (participant characteristics detailed in Supplementary Material, table S7). Delphi

332 survey identified four outcome domains (including pain, function, ADL and QOL) in

the first round, and another four outcome domains (including symptoms, measures of

334 walking, global rating of change and AE) in the second round, all of which met the

335 consensus threshold. Table 4 lists the scores for all candidate outcomes and

336 'consensus-in' outcomes. The 'consensus-in' outcomes drew the Delphi consensus

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337 threshold and employed the above for the development of several initial outcome338 domains to be covered in the core outcome domain set.

**3.3 COS determined by consensus meetings** 

340 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

consens

meeting

voting

(n=24)

% yes

100%

100%

92%

50%

96%

88%

100%

4%

38%

88%

63%

21%

96%

4%

21%

nr

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us

9 10 11	Candidate	rou	und 1 (n=3	39)	rou	und 2 (n=3	39)	redefined outcome
12	Outcomes	0/2	0/2	0/2	0/2	0/2	0/_	S
14		/0	/0	/0	/0	/0	/0	
15		score	score	score	score	score	score	
16		1-3	4-6	7-9	1-3	4-6	7-9	
17 18	Pain	0%	5%	95%	nr	nr	nr	pain/disc omfort
20 21	Function	3%	5%	92%	nr	nr	nr	lumbar function
22	ADL	0%	5%	95%	nr	nr	nr	ADL
23	ROM	10%	26%	64%	5%	18%	77%	ROM
24	Symmetry	50/	150/	700/	50/	00/	070/	nr.
25	Symptoms	3%0	13%0	/9%0	3%0	8%0	8/%	
20	Measure of	5%	28%	67%	0%	8%	92%	Walking
28	walking	270	2070	0170	070	070		function
29	Global							
30	rating of	3%	26%	72%	3%	15%	82%	PGA
31	change	0,0	2070	/ _ / 0		10,0	0270	1 011
32	AE	00/	210/	700/	00/	1.50/	050/	<b>۸</b> Г
33	AE	0%	21%	/9%	0%	15%	83%0	AE
34	Biomarks	28%	41%	31%	21%	51%	28%	Biomark
35	Diomarks	2070	<b>T</b> 1/0	5170	21/0	5170	2070	S
36	Radiograp							Radiogra
38	hic	5%	33%	62%	3%	31%	67%	nhic
30	abanaaa	570	5570	0270	570	5170	0770	ahanaaa
40	changes							changes
41	CM-							CM-
42		00/	200/	640/	20/	210/	770/	specific
43	specific	8%0	28%	64%	3%0	21%	//%	outcome
44	outcomes							S
45	M							5 Man4al
46	Mental	5%	36%	59%	3%	38%	59%	Mental
47	health	- / -		• • • •	- / -			health
48	Satisfactio	00/	200/	720/	00/	2(0/	740/	Satisfacti
49	n index	0%	28%	12%0	0%	26%	/4%	on index
50	Quality of							
52		3%	13%	85%	nr	nr	nr	HRQoL
53	lite							
54	Adherence							Adheren
55	and	8%	33%	59%	5%	31%	64%	ce and
56	attrition							attrition
57	Psychosoci							Psychoso
58		49%	38%	13%	49%	41%	10%	aial
59	al							Clai

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Res use	source	8%	26%	67%	5%	23%	72%	Resource use	58%
Not Chi asso	tes: ADI nese med essment	L, activiti dicine; Q0 ; NR, not	es of daily OL, Qualit reported	living; R ty of life;	OM, Ran HRQoL,	ge of mov health rel	ement; Al ated QOI	E, adverse ev L; PGA, pati	ents; Cl ent gloł
367									
368	3.3.2 (	COS iden	tified by f	inal votin	g				
369	F	ollowing	the list of	outcome	s, an agre	ement wa	s reached	on the core	set usin
370	an elec	etronic vo	oting prog	ram in co	nsensus r	neetings. S	Scores for	the respecti	ve
371	outcon	ne domai	n were lis	ted in Tal	ole 4. An	agreemen	t was read	ched on eight	t domai
372	of imp	ortance a	and inclusi	on in the	core don	nain set for	r clinical	trials (includ	ing pair
373	and dis	scomfort	, HRQoL,	lumbar fi	unction, A	ADL, walk	ting funct	ion, PGA, A	E and
374	CM-sp	ecific ou	itcomes).	Table S8	of supple	mentary n	naterial pi	resented the s	sensitiv
375	analys	is of scor	e of outco	mes betw	veen patie	ents and ex	perts.		
376									
377	F	igure 1. I	Flow chart	of core of	outcomes	selection ]	process		
378									
379	4. Disc	cussion							
380	4.1 Su	mmary o	f the Mair	n Results					
381	This st	tudy pres	ents the de	eveloping	process	of the core	domain	set of Chines	se
382	medici	ine for L	SS in trials	s (CORE-	CM-LSS	) and the s	steps invo	lved for reac	hing a
383	consen	sus of pa	atients and	experts.	The patie	ent perspec	tive was	integrated in	the
384	respec	tive resea	arch phase	. The sam	pling pro	ocess was	inclusive	of panelists	nationa
385	which	increases	s generaliz	ability of	our find	ings in Ch	ina.		
386	4.2 Ou	itcomes I	ncluded ir	n the COS					
387	0	our review	w and cons	sensus res	ults conf	irm that th	e pain/dis	scomfort, fur	nction,
388	walkin	ıg disabil	ity and AI	DL of LS	S patients	arouse th	e main co	oncern of pat	ients an
389	physic	ians and	have been	most rep	orted in t	rials. The	above ou	tcomes were	comme
390	sympto	oms of L	SS or imp	acts of sy	mptoms.	The adver	se events	are required	for the
391	assessi	ment of t	he harms o	of all inte	rventions	, and they	arouse th	e most conce	ern of
392	patient	ts. The H	RQoL is v	vital outco	omes for t	the trials o	n pain fo	r its generic o	constru

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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].

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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

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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.

447 4.4 Implication for clinical practices and research

448 This study's main objective was to produce a collection of core outcome measures for
449 use in reliable prospective studies involving LSS patients. This core outcome set
450 might potentially be incorporated into LSS registries and used as a reference for data

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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 

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resea. overall field development and research.

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13 14	469	and design. Ya'nan Sun, Zhi-Wen Weng, Yi an and Yanji Zhou conducted the
15 16	470	literature review, interview and had primary responsibility in writing this article.
17 18	471	Ya'nan Sun, Yanji Zhou and Changhe Yu conducted survey and consensus meeting,
19 20	472	performed analysis and interpreted them. Xiyou Wang and Changhe Yu critically
20 21 22	473	revised the manuscript. All authors have read and approved the final manuscript.
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24 25 26	475	The authors declare that they have no conflicts of interest.
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37 38 39	480	Commission (No. ZZ21053). These funding sources had no role in the design of the
40 41	481	study, data collection and analysis, or preparation of the manuscript.
42 43	482	Data Availability
44 45	483	The data used to support the findings of this study are available from the
46 47	484	corresponding author upon request.
48 49	485	Ethics Statement
50 51	486	Ethics approval was provided by the ethics committee of Dongzhimen hospital
52 53	487	(DZMEC-KY-2020-60). Prior to the interviews with the patients, written informed
54 55	488	consent was requested. The Delphi signup page had a notice emphasizing the fact that
56 57	489	submission of the questionnaire constitutes permission. A permission form was filled
58 59 60	490	out by each attendee of the consensus meeting to signify their agreement to

3 4	491	participate.
5 6	492	Abbreviations
7 8	493	CORE-CM-LSS, core domain set of Chinese medicine for LSS in trials; COS, Core
9 10	494	outcome domain sets; CM, Chinese medicine, LSS, Lumbar spinal stenosis; COS-
11 12	495	STAD, Core Outcome Set-STAndards for Development; COS-STAR, Core Outcome
13	496	Set-STAndards for Reporting; SAG, Study Advisory Group; RCT, randomized
15	497	controlled trials; SLR, Systematic review; NGT, Nominal group technique; COMET,
10	498	Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement
18 19	499	Instruments; CM, Chinese medicine; SPWT, Self-Paced Walk Test; JOA, Japanese
20 21	500	Orthopedic Association Score; mJOA, modified Japanese Orthopedic Association
22 23	501	Score; VAS, visual analogue scale; NRS, numerical rating scale; UBA-PBS, UBA
24 25	502	pain behavior scale; AE, adverse events; SF-36, 6-Item Short Form Survey; ADL,
26 27	503	activities of daily living: ROM, Range of movement: RMDO, Roland Morris
28 29	504	Disability Questionnaire: mRMDQ modified Roland Morris Disability
30 31	505	Questionnaire: HADS, Hospital Anxiety and Depression Scale: ODL Oswestry
32 33	506	Disability Index: OOL Quality of Life: SSS Spinal Stenosis Scale: ZCO Zurich
34 35	507	Claudication Questionnaire: TNF, Tumor Necrosis Factor: RBC, Red blood cell:
36 27	508	CRP C reactive protein: NR not reported: Int interview
37 38	508	CKF, C-reactive protein, NK, not reported, int, interview
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Figure 1. Flow chart of core outcomes selection process

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# Supplementary Material

Table S1. The COS-STAR Statement

SECTI	IT	E		
ON/TO	N	I	CHECKLIST ITEM	page no
PIC	No	).		
TITLE/				
ABSTR				
ACT				
Title	la		Identify in the title that the paper reports the development of a COS	1
Abstract	1b		Provide a structured summary	3,4
INTRO				
DUCTI				
ON				
Backgro und and	2a		Describe the background and explain the rationale for developing the COS	6,7
Objectiv es	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
METH				
ODS				
Protocol /Registr v Entrv		4	Indicate where the COS development protocol can be accessed, if available, and/or the study registration details.	7,8
Particip ants		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
Informa tion 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
Consens us Process		7	Describe how the consensus process was undertaken.	11-13

Outcom e Scoring Consens	8	Describe how outcomes were scored and how scores were summarized.	11-13
us Definiti on	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
RESUL TS			
Protocol Deviatio ns	11	Describe any changes from the protocol (if applicable), with reasons, and describe what impact these changes have on the results.	8
Particip ants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development.	15-18 and Supplem entary materials
Outcom es	13a	List all outcomes considered at the start of the consensus process.	15-18 Table 1-
	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
DISCU SSION			~
Limitati ons	15	Discuss any limitations in the COS development process.	21-22
Conclus ions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research.	21-24
OTHER INFORM	ΙΑΤΙΟ		
N Funding	17	Describe sources of funding/role of funders.	25
Conflict s of Interest	18	Describe any conflicts of interest within the study team and how these were managed.	25

page no.

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Table S2. The COS-STAD checklist         Domain       Stan dard num ber       Methodology         Scope specificatio n       1       The research or practice setting(s) in which the COS is to be applied         2       The health condition(s) covered by the COS         3       The population(s) covered by the COS         4       The intervention(s) covered by the COS         5       Those who will use the COS in research         6       Healthcare professionals with experience of patients with the condition         7       Patients with the condition or their representation         8       The initial list of outcomes considered both healthcare professionals' and patients' views.         9       A scoring process and consensus definition we described a priori.         10       Criteria for including/dropping/adding outcom- were described a priori.         11       Care was taken to avoid ambiguity of language used in the list of outcomes.	Stan       Methodology         Domain       ber       Methodology         Scope       1       The research or practice setting(s) in which the COS is to be applied         1       2       The health condition(s) covered by the COS         3       The population(s) covered by the COS         3       The population(s) covered by the COS         4       The intervention(s) covered by the COS         5       Those who will use the COS in research         6       Healthcare professionals with experience of patients with the condition         7       Patients with the condition or their representation         8       The initial list of outcomes considered both healthcare professionals' and patients' views.         9       A scoring process and consensus definition we described a priori.         10       Criteria for including/dropping/adding outcome were described a priori.         11       Care was taken to avoid ambiguity of language used in the list of outcomes.	Table S2. The COS-STAD checklist         Domain       Stan num ber       Methodology         Scope specificatio n       1       The research or practice setting(s) in which the COS is to be applied         2       The health condition(s) covered by the COS         3       The population(s) covered by the COS         4       The intervention(s) covered by the COS         5       Those who will use the COS in research         6       Healthcare professionals with experience of patients with the condition         7       Patients with the condition         7       Patients with the condition or their representation         7       Patients with the condition or their representation         8       The initial list of outcomes considered both healthcare professionals' and patients' views.         9       A scoring process and consensus definition we described a priori.         10       Criteria for including/dropping/adding outcome were described a priori.         11       Care was taken to avoid ambiguity of language used in the list of outcomes.			
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Table S3.	Search	strategies	and	results
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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 "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 stenosis"[All Fields]) (('chinese'/exp OR chinese) AND ('medicine'/exp OR	195 160
	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	
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 "	1084
	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])	
VIP	M=(腰椎管狭窄) AND U=(针灸 OR 推拿 OR 艾灸 OR	1480
	针刺 OR 手法 OR 扳罐 OR 功法 OR 太极 OR 甲医)	

2		
3	Table S4. Patient features re	epresenting the target participants
4	Category	Features
6	Age	8 patients $>65$ years of age
7	50	8 patients $< 65$ years of age
8	C	8 patients <05 years of age
9	Sex	8 females
10		8 males
11	Disease courses	8 patients $\geq 10$ years
12		8 patients $<10$ years
13	Radiographic classification	Covering lateral recess central spinal
14	Radiographic classification	
16		canal
17		intervertebral foramen
18	territorial region	At least more than 5 regions of China
19		
20		
21		
22		
23		
24 25		
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First author, year	Partici pants	Interventions	Table S5. Studies' Chara	cteristics and Outcome Me Outcome Measurement Instruments	easuremen Treat ment durati on	t Instruments for USES OMI related to tex time	56 on 16 October 2023 Subdomain 2023 Outcomes	COMET outcomes	criter ia for respo nder 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, data follow-up 3mining and 6m	a pain/function/ ADL for pain Radiographic changes	pain function Physiologi cal	NR	
Chen Jian, 2019[2]	30/30	CM herb	Aceclofenac+Mecobal amin	JOA IL-6/CRP ODI AE hepatic and renal function tests	4w	Pre-treatment, 2 and 4w are - treatment g Pre- and post- treatment for hepatic and renal function tests	pain/function/ ADL Inflammatory markers function AE Physiological index	pain function Physiologi cal AE	JOA	
Feng Sui 2009[3]	40/40	Acupotomy	Traction	Responder rates	2m	Pre- and post- treatment	-1 20 25 25 25 25 25 25 25 25 25 25 25 25 25	pain function	DEC - TCM	
Geng Xiaoyan, 2017[4]	46/46	CM herb	Salvia (Danshen) injection+Diclofenac	JOA	NR	Pre- and post- treatment	and pain/function/ ADL Bibliograph	pain function	NR	
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1 2 3 4 5 6 7 8 9 10 11	Gu Qi, 2015[5]	30/30	CM herb	GIucos	mJOA VAS SPWT Responder rates	2w	Pre- and post- treatment, set follow-up Integrated for Responder	2023-075856 on pain/function/ 16 ADL copain measure of 20 walking	pain function	JOA
12 13 14 15 16 17	Guan Xiaoyong, 2015[6]	47/47	CM herb	Salvia (Danshen) injection+Diclofenac	VAS Responder rates	lm	Pre- and post treatment	ADL adpain dpain fo	pain	VAS
18 19 20 21 22	Hou Yu, 2019[7]	22/23	Manual therapy	NSAIDs+Drugs for protecting gastric mucosa and nourishing nerves	JOA VAS	4w	Pre- and post- treatment A train	ADL pain/function/	pain function	NR
23 24 25 26 27	Huang Zheng, 2017[8]	31/33/ 32/33	CM herb Acupuncture CM herb+Acupuncture	Diclofenac+Mecobala min	JOA/improvement of JOA Responder rates AE	3m	Pre-treatmain 1, 2 and 3ma after sin treatment	ADL pain/function/ pain/function/ gAE	pain function AE	DEC - TCM
28 29 30 31	Huang Zhifen, 2009[9]	50/46	CM herb	Diclofenac	Responder rates AE	4w	Pre- and post- treatment	upain/function/ 14AE ≥	pain function AE	DEC - TCM
32 33 34 35 36 37 38 20	Ji Wei, 2013[10]	35/34	CM herb	Mecobalamin	Responder rates VAS mJOA	4w	Pre- and post- treatment	Spain/function/ at pain gepain/function/ Ce ADL Biblio	pain function	DEC - TCM
40 41 42 43 44 45 46				For peer review only - http:	://bmjopen.bmj.com/site/a	about/gu	idelines.xhtml	graphique de l		

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2 3 4 5 6 7 8 9 10 11 12 13	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 reatment reatment to post Pre- and post reatment reatment reatment post Pre- and Pre- Pre- Pre- Pre- Pre- Pre- Pre- Pre-	pain function	DEC - TCM
14 15 16 17 18 19 20 21 22 23 24	Li Jinxue, 2007[12]	40/40/ 44/42	CM herb CM herb+CM granules CM herb+CM granules+Erigeron breviscapus	Glucos	Responder rates VAS parameters of computed tomography	4w	treatment for so a Responder de pain/function/ rates/VAS/Man pain diographic monophic changes, de rates follow-up and the pain l2month for the pain Responder de pain/function/ pain/function/ pain/function/ pain Radiographic changes 12month for the pain Responder de pain/function/ changes	pain function Physiologi cal	JOA
25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40	Li Jinxue, 2013[13]	92/83	CM herb	GIucos	Responder rates VAS Walking capacity	2w	Pre- and posit- treatment feat Responder ter rates/VAS/W alking capacity, est follow-up im for Responder rates/Walking capacity Bibliogra	pain function	GPC R- ND
41 42 43 44 45 46				For peer review only - http:	//bmjopen.bmj.com/site/a	about/gu	idelines.xhtml <b>de</b>		



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Lin Yuanfang, 2017[17]	33/32	Manual therapy	Traction	Responder rates JOA Rang of Lumbar spine extension	20d	uding Pre- and post- treatment uses reig	pain/function/ pain/function/ ADL ROM	pain function AE	DEC - TCM
Liu Chenhui, 2019[18]	30/30	CM herb	Celecoxib+Mecobala min+Hydrotalcite Tablets	VAS SPWT CM Zheng scores Responder rates AE	2w	Pre- and potent Superieur (A treatment data	Measure of walking CM Zheng pain/function/	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 posts treatment	Global rating of change pain/function/	pain function	DEC - TCM
Liu Jun, 2020[20]	46/46	CM herb	Mannitol Injection+Mecobalami n	Responder rates	3w	Pre- and post- treatment g	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 nologies.	oppain/function/ oppain pain/function/ ADL Immunologica indicators	pain function Physiologi cal	DEC - TCM
Su Lianshu,	38/37	Acupotomy	Canal injection	VAS JOA Responder rates	3w	Pre-treatment, 1 and 4w after treatment	apain pain/function/ ADL Bpain/function/	pain function	DEC - TCM

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1 2 3 4 5							right, including Pre-treatmagt	)23-075856 on		
6 7 8 9 10 11 12 13 14	Sun Biyun, 2021[23]	40/40	Acupuncture	Sham Acupuncture	NRS mRMDQ HADS Treatment Adherence index AE	6w	6w after of treatment, used follow-up resident 12w and 24w for to NRS/RMD HADS	Grann Offunction Seperation Seperation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separ	pain function mental health complianc e	NR
15 16 17 18 19 20 21 22	Tang Hanwu, 2015[24]	35/34	CM herb	Celecoxib+Mecobala min	Responder rates VAS JOA Near-infrared imaging system on DU meridian	4w	Pre- and point treatment g	ADL CM meridian	pain function CM indictor	DEC - TCM
23 24 25 26 27 28	Wang Chenghon g, 2009[25]	46/44	acupuncture	Traction+Physical therapy	JOA mRMDQ responder rates	2w	Pre- and pout- treatment, sin follow-up for	pain/function/ ADL function gpain/function/ ADL	pain function	JOA
29 30 31 32 33 34 35 36 37 38 39 40 41 42 43	Wang Guanjun, 2019[26]	53/53	CM herb	Mannitol Injection+Mecobalami n	VAS JOA Responder rates	3w	Pre- and post- treatment	Ine 11pain 20pain/function/ 25 ADL Apain/function/ Bibliographique de	pain function	DEC - TCM ; JOA
44 45 46				For peer review only - http:	//pmjopen.pmj.com/site/a	ibout/gl	ndennes.xntml	<u>0</u>		

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Wang Haijun, 2017[27]	47/47	Acupotomy	Traction+Physical therapy	VAS JOA Responder rates	14d	Pre- and post- treatment, of opain/function/ follow-up long ADL and 6m	pain function	VAS ; JOA
Wang Hua, 2017[28]	50/50	Manual therapy	Epidural injection	Responder rates	4w	Pre- and potential 23. treatment treatment tre	pain function	DEC - TCM
Wu Shizhen, 2016[29]	13/13	Acupotomy	Canal injection	Global Rating of Change Scale Responder rates	NR	Pre- and post i of change treatment	pain function	NR
Xiao Zhenhua, 2021[30]	23/23	Acupotomy	Canal injection	VAS JOA	20d	Pre- and post pain/function/ treatment	pain function	NR
Zhou Qishi, 2002[31]	51/51	CM herb	Vitamin B1 B6	Responder rates SPWT Serum endothelin	4w	Pre- and post- treatment similarity optimized by the second secon	function Physiologi cal	NR
kim, 2016[32]	26/24	Acupuncture	Usual care	ODI SF-36	6w	Pre- and poet- treatment, s. follow-up 3m follow-up 3m follow-up 3m	pain function QOL mental health Psychosoc ial	NR
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12 13 14 15 16	Oka, 2018[33]	41/38/ 40	Acupuncture	Drugs/Exercise therapy	ZCQ	1m	Pre- and pottering treatment and entropy of the second pottering of the second	function/s	pain function satisfactio n	NR
17 18 19 20 21 22 23 24	Qin, 2020[34]	40/40	Acupuncture	Sham Acupuncture	RMDQ NRS SSS Satisfaction subdomain of SSS	8w	Pre-treatment, 4 and 8w atter treatment, follow-up 3m and 6m Pre-treatment,	ion function/ àction	pain function satisfactio n	NR
24 25 26 27 28 29 30 31 32 33	Xu Jialong, 2021[35]	29/29	CM herb+Usual care	Drugs+Usual care	VAS JOA SPWT CM Zheng scores AE	4w	2 and 4w after treatment for VAS, JOA in Pre- and post- treatment for SPWT, CMC Zheng scores	function/ ure of ing Zheng	pain function CM indictors AE	DEC - TCM
34 35 36 37 38 39 40	Zhu Shuxian, 2014[36]	30/30	Manual therapy+ Usual care	Traction+Usual care	Responder rates VAS ODI	3w	Pre- and post- treatment	function/ ion	pain function	DEC - TCM
41 42 43 44 45 46				For peer review only - http:	://bmjopen.bmj.com/site/a	bout/gı	uidelines.xhtml <b>de</b>			

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1 2 3 4 5 6 7 8 9 10	Liu Li, 2020[37]	32/32	Acupuncture+Moxib ustion	Acupuncture	Responder rates Self-made symptoms rating scale JOA VAS	20d	ight, including fort. Pre- and posses relat treatment	23-075856 9 pain/function/ 6 symptoms copain/function/ ADL 20 pain	pain function	DEC - TCM	
11 12 13 14	Wang Chenghu, 2014[38]	45/45	Acupuncture+Moxib ustion	Ibuprofen	Responder rates	10d	Pre- and poet Super treatment	Doppain/function/	pain function	DEC - TCM	
15 16 17 18	Su Tao, 2011[39]	60/60	Acupuncture+Moxib ustion+manual therapy	manual therapy	Responder rates	12d	d ie Pre- and positive freatment ment in cost freatment men in cost in cost i	fipain/function/	pain function	DEC - TCM	
19 20 21 22	Liao Jian, 2017[40]	30/30	CM herb+Acupuncture	Acupuncture	Responder rates RMDQ	2w	Pre- and post- treatment framini	pain/function/	pain function	DEC - TCM	
23 24 25 26 27	Shan Jinchun, 2013[41]	48/48	CM herb+manual therapy	manual therapy	Responder rates CM Zheng scores	1m	Pre- and post- treatment s:	pain/function/	pain function CM indictors	COC E	
28 29 30 31 32 33 34 35 36 37 38 39 40 41	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 4woo after est treatment, follow-up 1m	pain pain/function/ ADL function at Measure of walking CM Zheng Bibliographic	pain function CM indictors	NR	
42 43 44 45 46				For peer review only - http:	//bmjopen.bmj.com/site/	about/gu	idelines.xhtml	que de l			

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5 6 7 8 9	Yuanzhen g, 2009[43]	60/60	CM herb+manual therapy	manual therapy	Responder rates	lm	e Pre- and post- treatment se e	Opain/function/	pain function	DEC - TCM
10 11 12 13 14 15	Li Zhulie, 2012[44]	30/30	Electrothermal acupuncture	Acupuncture	JOA Responder rates AE	10 times	Pre-treatment 1, 2, and 3 to course after treatment, and follow-up late	ADL pain/function/ pain/function/ ADL ADL ADL	pain function AE	JOA
16 17 18 19 20 21	Chen Xiaoyun, 2009[45]	30/30	Electropuncture+Blo odletting therapy	Electropuncture	Responder rates Global Rating of Change Scale VAS	20d	Pre- and post treatment ing,	pain/function/	pain function	DEC - TCM
22 23 24 25 26 27 28 29 30 31 22	Lei Xiaoping, 2020[46]	34/34	CM herb+Acupuncture	GIucos+Mecobalamin	JOA IL-6\IL-4\IL-10\TNF Blood viscosity/plasma viscosity/RBC hematocrit Responder rates AE	lm	raining, and Pre- and post- treatment similar technolog	ADL ADL Inflammatory Markers Hemorheologi Leal indictors pain/function/	pain function AE Physiologi cal	DEC - TCM
33 34 35 36 37 38 39	Cai Lijun, 2012[47]	32/64	CM herb+kerotherapy	Drugs/Traction	Responder rates JOA	3w	<b>پ</b> Pre- and post- treatment	25 at pain/function/ Agenain/function/ Ce ADL Biblio	pain function	- TCM ; JOA
40 41 42 43 44 45 46				For peer review only - http:	//bmjopen.bmj.com/site/a	about/gu	idelines.xhtml	jraphique de l		

CM herb+Manual therapy Acupuncture+Moxib ustion CM herb+manual	Canal injection	Responder rates	NR	Pre- and post- 6	oin/function/	pain	STI-
Acupuncture+Moxib ustion CM herb+manual	Acupuncture			treatment uses	bain/lunction/	function	ICW M
CM herb+manual		Responder rates	20d	Pre- and poster 20 treatment treatment to P	ain/function/ ADL	pain function	JOA
therapy	manual therapy	Responder rates AE	4w	Pre- and postperied treatment da	pain/function/ AE	pain function AE	NR
CM herb+manual therapy	manual therapy	JOA VAS Responder rates	4w	Pre- and posters treatment g, - Pre- A	oain/function/ ADL oain oain/function/	pain function	NR
CM herb+manual therapy	CM herb	VAS RMDQ Responder rates	4w	Pre- and post- or treatment, g	pain function pain/function/	pain function	DEC - TCM
Topical CM+hot compress	Diclofenac Diethylamine Emulgel	JOA VAS	4w	Pre- and post- of treatment in of	oain/function/ ADL pain	pain function	JOA
manual therapy+Exercise therapy	Exercise therapy	VAS JOA SPWT ODI Responder rates AE	3m	Pre-treatmond 11, Pre-treatmond 1w, 1m and 3m after treatment Bibliograp	pain pain/function/ ADL neasure of valking function pain/function/	pain function AE	VAS ; JOA\ ODI
	manual therapy+Exercise therapy	manual therapy+Exercise Exercise therapy therapy For peer review only - http:	hannal therapy+Exercise therapy therapy Exercise therapy Exercise therapy Herapy Exercise therapy For peer review only - http://bmjopen.bmj.com/site/a	hannal therapy+Exercise therapy Exercise	manual manual therapy+Exercise Exercise therapy Exercise therapy thera	manual therapy+Exercise Exercise therapy therapy of the pain (because of the pain) (beca	manual therapy+Exercise therapyExercise therapyJOAPre-treatment 1w, 1m and 3m after treatmentMain measure of functionMarker ADLSPWT ODI3m after treatmentMain measure of functionMain measure of functionAEFor peer review only - http://bmjopen.bmj.com/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abu


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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Xu Shiliang, 2014[57]	47/48	CM herb+manual therapy	Glucos	SPWT VAS JOA IL-6\IL- 1B\TNF\CRP Blood viscosity/plasma viscosity/RBC hematocrit Responder rates	4w	vright, including for uses regimement Superieur (ABEs eignement Superieur (ABEs all, and follow-up 4text and data mir VAS, JOAA data mir	neasure of /alking ain ain/function/ ADL nflammatory narkers Iemorheologi al indictors ain/function/	pain function Physiologi cal	JOA	
19 20 21 22 23	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 potter and po	ain/function/ ymptoms	pain function	GPC R- ND	
24 25 26 27 28	Mao Xiaohui, 2008[59]	52/52	CM herb+Manual therapy+CM fumigation	Drugs+Traction+ TDP	Global Rating of Change Scale Responder rates	10d	Pre- and post- treatment milar	ymptoms ain/function/	pain function	DEC - TCM	
29 30 31 32 33 34 35 36 37	Yuan Zhixian, 2020[60]	30/30	CM herb+Acupuncture+ Moxibustion	Usual care	Responder rates Self-made symptoms rating scale JOA VAS AE	4w	Pre- and post- treatment is.	ain/function/ ymptoms ain/function/ ADL ain AE	pain function AE	CA- TCM	
38 39 40 41 42 43 44 45				For peer review only - http:	//bmjopen.bmj.com/site/a	bout/gu	Bibliographique de l idelines.xhtml				

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4 5 6 7 8 9 10 11	Dou Qunli, 2007[61] Chen Shulie, 2006[62]	83/83 32/7	CM herb+Manual therapy Manual therapy+Topical CM	Canal injection+ Traction Drugs	Responder rates	2m 4w	Pre- and poor Enseigner treatment uses regner Pre- and poared Pre- and poared treatment ed	pain/function/ pain/function/	pain function pain function	DEC - TCM NR
12 13 14 15 16 17 18	2006[62] Wang Fuyu, 2018[63]	48/48	CM herb+Acupuncture	Usual care	JOA VAS IL-1 TNF	4w	to text Superiour Pre-treatmonder 2 and 4w attract a mini treatment at mini	pain/function/ ADL pain Inflammatory markers	pain function Physiologi cal	JOA
19 20 21 22 23 24 25	Xiong Junwei, 2015[64]	30/30	Acupotomy+Manual therapy	Acupotomy	JOA Responder rates AE	3w	Pre-treatment, the pre-treatment, the pre-treatment, the pre-treatment of the pre-treatment	pain/function/ ADL pain/function/ ADL AE	pain function AE	JOA
26 27 28 29 30 31 32	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 poechnologie treatment	Global rating of change Measure of walking ROM pain/function/	pain function	DEC - TCM
33 34 35 36 37 38 39 40	Wang Wenli, 2018[66]	30/30	Electropuncture+fire d cupping+Bloodlettin g therapy	Physical therapy	SSS Responder rates Satisfaction	8w	Pre-treatment, 4 and 8w after treatment, follow-up 4w	pain/function/ pain/function/ satisfaction AE	pain function satisfactio	DEC - TCM
41 42 43 44 45				For peer review only - http:	//bmjopen.bmj.com/site/ab	out/gu	idelines.xhtml	- -		

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11	Hongzhen	100/10	Acupuncture+Moxib				10d and 25 <b>8</b>	ی ح			
12 13	g,	0	ustion	Diclofenac	ODI	30d	after <b>t</b>	function	function	NR	
14	2016[67]						treatment, x up				
15							follow-up 3				
16 17			Electropuncture+fire				Pre-treatmon D	pain/function/s	pain	DEC	
17	Jing Lei,	29/30	d	Physical therapy	SSS	8w	4 and 8w after	atisfaction	function	-	
19	2019[68]		cupping+Bloodlettin	5 15	Responder rates		treatment g	pain/function/	satisfactio	TCM	
20			g therapy				, ≥		n		
21	Wang						trai	pain/function/	pain		
23	Hongmei.	40/40	Acupuncture+Moxib	Glucos	JOA	10d	Pre- and post-	ADL	function	NR	
24	2019[69]		ustion		IL-6/TNF/CRP		treatment 🦉	Inflammatory	Physiologi		
25 26	_017[07]						nd s	markers	cal		
20								pain/function/			
28	Wang		Acupuncture+cuppin		JOA		Pre- and post-	ADL	pain		
29	Jian,	72/72	g	GIucos	Responder rates	36d	treatment, C	pain/function/	function	JOA	
30 31	2013[70]		6		AE		follow-up 12 1	ADL	AE		
32							ogie	<b>Š</b> AE			
33	Zhang						Ň,	pain/function/			
34 35	Hong	37/36	Acupuncture+acupoi	Acupuncture	JOA	12d	Pre- and post-	ADL	pain	ΙΟΑ	
36	2014[71]	51150	nt injection	reupuncture	Responder rates	124	treatment	pain/function/	function	3011	
37	2011[71]							ADL			
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1 2 3 4 5 6 7 8 9 10 11 12	Lin Jincai, 2016[72]	35/35	Acupuncture+CM herb injection	Acupuncture	Rang of Lumbar spine extension VAS JOA Pain-free walking distance	2w	Pre- and post related to t	NO23-075856 on 1ROM Opain Function Sector Sector Secto	pain function AE	NR
13 14 15 16	Lv Xiaohua,	40/40	Acupuncture+Bloodl etting therapy	Dexamethasone+mann itol+CM herb injection	AE Responder rates	10d	Pre- and post treatment	and the second s	pain function	NR
17 18 19 20 21	Shi Jianwei, 2013[74]	37/37	Acupuncture+manua l therapy	Dexamethasone+mann itol+Salvia (Danshen) injection	Responder rates	23d	Pre- and post treatment	pain/function/	pain function	DEC - TCM
22 23 24 25 26	Xu Yunyu, 2014[75]	35/35	Acupuncture+Moxib ustion	Acupuncture	JOA Responder rates	25d	Pre- and positi- treatment, gan follow-up and	ADL pain/function/ pain/function/ ADL	pain function	JOA
27 28 29 30 31 32	Zhang Huajun, 2016[76]	40/40	Acupuncture+CM herb+moxibustion	Acupuncture+CM herb	VAS JOA CRP ESR	14d	Pre- and poet- treatment, follow-up long	gpain pain/function/ ADL Inflammatory markers	pain function Physiologi cal	JOA
33 34 35 36 37 38	Ji Yuejun, 2010[77]	64/62	CM herb+Manual therapy	Acupuncture	self-made lumbar fuction evaluation scale Responder rates	10d	ة Pre- and post- treatment	at Age function ce pain/function/ Biblio	pain function	DEC - TCM
40 41 42 43 44 45 46				For peer review only - http:	//bmjopen.bmj.com/site/a	bout/gu	iidelines.xhtml	graphique de l		

Ouyang Song, 2014[78]34/3Electropuncture+ma nul therapyTraction + Physical therapyResponder rates Global Rating of Change ScaleNRPre- and poor for pain/function/ treatmentpain functionpain functionDEC - - TCMLian Chonge ng, ng, ng, ng, ng, ng, stone pain/function/ ng, stone ng, ng, stone ng, stone ng, stone pain/function/ mgCM herb+tManual therapy+CM treatmentDrugs+Traction + TDPResponder rates Global Rating of Change ScalePre- and poor treatmentPre- and poor treatmentDEC - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 					BMJ Open		by copyright, inclu	jopen-2023-07585		Pa	ag
Lian       CM herb+Manual       Drugs + Traction +       Responder rates       Pre- and performance       Pre- and performance       Dector       Dector         2009[79]       1000000000000000000000000000000000000	Ouyang Song, 2014[78]	34/34	Electropuncture+ma nual therapy	Traction+Physical therapy	Responder rates	NR	Pre- and post- treatment	6 9 16 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	pain function	NR	
Xing Yumo, 2017[80]CM herb+CM fumigation+Acupoto myDrugs+Traction+ TDPResponder rates Global Rating of Change ScalePre- and polytop reatmentPre- and polytop function/ painDEC painWei Shengqing ,2019[81]42/42Acupotomy+Manual therapyManual therapyVAS JOA ODI AE3wPre- and polytop function/ treatmentPre- and polytop function/ pain/function/ painDEC interation + TCMWei Shengqing ,2019[81]42/42Acupotomy+Manual therapyManual therapyVAS JOA ODI AE3wPre- and polytop interation + treatmentPre- and polytop interation + treatmentManual function/ painVAS interation + interation + interation + interation + treatmentPre- and polytop interation + treatmentManual interation + interation + interation + interation + interation +Pre- and polytop interation + interation + interation + interation +DEC interation + interation + interation + interation + interation +DEC interation + interation + interation + interation +DEC interation + interation +DEC interation + interation + interation + interation + interation + interation + 	Lian 	40/40	CM herb+Manual 	Drugs+Traction+ 	Responder rates 	3w	s relation 	ag 	pain function	DEC - TCM	
Wei Shengqing (2019[81]Acupotomy+Manual therapyAcupotomy+Manual therapyManual therapyVAS JOA ODI AEPre- and port treatmentpain/function/ pain/function/painVAS painMiaoManual therapy+TopicalManual therapyVAS ODI AEWas Pre- and portManual treatmentfunction/ pain/function/function : functionfunction : treatmentMiaoManual CM+CM herbUsual careVAS DANRPre- and port treatmentpain/function/ pain/function/pain functionNRGuang, Quang, 45/45Manual CM+CM herbUsual careVAS DANRPre- and port treatmentpain/function/ pain/function/pain functionNRGuang, Quang, 45/45Manual ManualUsual careVAS DAImPre- and port treatmentpain/function/ pain/function/ function/pain functionNRGuang, VAS45/45therapy+Topical ManualUsual careVAS DAImPre- and port treatmentpain/function/ 	Xiong Yumo, 2017[80]	30/30	CM herb+CM fumigation+Acupoto my	Drugs+Traction+ TDP	Responder rates Global Rating of Change Scale	3w	Pre- and post treatment at a m	no pain/function/ symptoms	pain function	DEC - TCM	
MiaoManualVASNRZezheng,56/56therapy+TopicalUsual careVASNR2017[82]CM+CM herbJOAPre- and posti- treatmentpain pain/function/ functionpain functionYangManualVASImPre- and posti- treatmentpain pain/function/ functionpain functionNRGuang,45/45therapy+TopicalUsual careVAS JOAImPre- and posti- treatmentpain pain/function/ functionpain functionNR2010[83]CM+CM herbJOAPre- and posti- treatmentpain pain/function/ ADLpain functionNRWeixiong,40/40therapy+TopicalUsual careJOA Responder ratesPre- and posti- treatmentpain pain/function/ pain/function/ pain ADLpain functionNR	Wei Shengqing , 2019[81]	42/42	Acupotomy+Manual therapy	Manual therapy	VAS JOA ODI AE	3w	Pre- and post- treatment training	pain/function/ ADL function AE	pain function AE	VAS ; JOA	
YangManualGuang,45/45therapy+TopicalUsual careVASImPre- and post- treatmentpain pain/function/ ADLpain functionNR2010[83]CM+CM herbJOAImPre- and post- treatmentpain pain/function/ ADLNRXieManualJOA2wPre- and post- treatmentpain ADLNRWeixiong,40/40therapy+TopicalUsual careJOA Responder rates2wPre- and post- treatmentpain ADLpain function/ ADLpain function	Miao Zezheng, 2017[82]	56/56	Manual therapy+Topical CM+CM herb	Usual care	VAS JOA	NR	ي Pre- and post- treatment si ia	pain pain/function/ gADL	pain function	NR	
XieManualWeixiong, 40/40therapy+TopicalUsual careJOA2wPre- and post- treatmentpain ADLResponder rates2wtreatment	Yang Guang, 2010[83]	45/45	Manual therapy+Topical CM+CM herb	Usual care	VAS JOA	1m	Pre- and post- treatment	pain/function/	pain function	NR	
2017[84] CM+CM herb	Xie Weixiong, 2017[84]	40/40	Manual therapy+Topical CM+CM herb	Usual care	JOA Responder rates	2w	Pre- and post- treatment	ADL pain/function/	pain function	NR	



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			Table	B S6. Characteristics of pa	MJ Open tients in interviews and De	lphi rounds	open-2023-075856 on 16 Octob En y copyright, including for use	
patients	gender	age (years)	disease course (years)	Complicating lumbar spondylolisthesis	Radiographic classification	experience of CM treatment	s seigned Gelated S. Collated	consensus meeting
A1	Female	73	10	n	lateral recess	у	<b>ģ ubs</b> ijing	n
A2	Female	66	3	n	central spinal canal	у	an et Bebei	У
A3	Male	69	2	У	intervertebral foramen	у	a a stilling	n
A4	Female	71	9	n	central spinal canal	у	a Beijing	n
A5	Male	58	8	у	central spinal canal	n	n Beijing	n
A6	Male*	73	11	n	lateral recess	у	• Shandong	n
A7	Female*	64	7	у	lateral recess	у	A Guangdong	У
A8	Female*	63	3	n	intervertebral foramen	n	a. Gaangchun	У
A9	Male*	68	6	У	central spinal canal	у	Gangchun	n
A10	Female	55	7	У	lateral recess	у	Beijing	У
A11	Female	75	13	n	lateral recess	у	s Sandong	n
A12	Male	83	10	n	central spinal canal	у	Be ijing	n
A13	Female*	55	1	У	intervertebral foramen	n	Laoning	У
A14	Male*	54	2	У	central spinal canal	у	En Linaoning	У
A15	Female*	69	1	n	central spinal canal	у	Beijing	У
A16	Female*	64	20	У	lateral recess	у	je Skanghai	У
A17	Female	72	30	n	intervertebral foramen	у	Beijing	n
A18	Male	60	4	У	lateral recess	у	Béijing	У

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				Tabl	e S7. Characteris	stics of experts in Delphi roun	23-075856 on ight, includinç ds		
	experts	gender	age (years)	work experience (vears)	title	medical major	academie academie researcher	territorial region	consensus meeting
	Ex 1	male	49	24	senior	Tuina	Y to 202	Beijing	Y
	Ex 2	male	54	31	senior	Tuina		Beijing	Ν
	Ex 3	male	56		senior	Tuina	Y te S	Beijing	Y
	Ex 4	male	60		senior	Tuina	Y and Y	Beijing	Y
	Ex 5	male	39	11	intermediate	orthopaedics	Y nd c	Beijing	Ν
	Ex 6	male	50	28	intermediate	orthopaedics	Y lata	Beijing	Ν
	Ex 7	male	32		intermediate	orthopaedics		Guizhou	Y
	Ex 8	male	48	24	senior	acupuncture	Y Ing	Beijing	Y
	Ex 9	female	41	11	intermediate	acupuncture	Y P	Beijing	Y
	Ex 10	male	37	8	intermediate	acupuncture	Y trai	Beijing	Ν
	Ex 11	male	43	20	senior	acupuncture	Y ning	Beijing	Ν
	Ex 12	male	56	31	senior	pain management	Y ay j	Shandong	Y
	Ex 13	male	36	8	intermediate	rehabilitation	Y s S	Beijing	Y
	Ex 14	female	57	35	senior	general family medicine	N ini o	Beijing	Y
	Ex 15	female	56	32	intermediate	pain management	n ער אין	Beijing	Y
	Ex 16	female	37	15	intermediate	nursing	Y echi	Beijing	Ν
	Ex 17	male	48	24	senior	orthopaedics	Y Polo 11,	Shanghai	Y
	Ex 18	male	50	26	senior	orthopaedics	y Sie	Guangdong	Y
	Ex 19	male	53	30	senior	orthopaedics	Y at	Xinjiang	Y
	Ex 20	male	42	16	intermediate	orthopaedics	Y Å	Changchun	Y
	Ex 21	female	39	11	intermediate	rehabilitation	Y Pre	Liaoning	Y
	Note: y, y	yes; n, no.					Bibliographique		
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$\begin{array}{c ccccccccccccccccccccccccccccccccccc$				D			II-37)			Deip	iii ioui	iu 2 (II-	-37)	2023. Ineme lated	(n=2	4)	
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	Candidate Outcomes		expo	erts (n=	21)	pa	ntients (n=	=18)	expe	erts (n=	=21)	patie	ents (n=	Downloaded Int Superieur to text and d	NGT	rts (n=1 5)	pa n (n=
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Pain       0%       10%       90       0%       0%       100%       nr			score 1-3	score 4-6	scor e 7- 9	score 1-3	score 4-6	score 7-9	score 1-3	scor e 4-	scor e 7- 9	scor e 1- 3	scor e 4-	fning, Al	outcomes	yes	У
Function $5\%$ $5\%$ $90$ $\%$ $0\%$ $6\%$ $94\%$ $nr$	Pain		0%	10%	90 %	0%	0%	100%	nr	nr	nr	nr	nr	njopen.b training	Pain and discomfort	100 %	1
ADL0%10% $\frac{90}{\%}$ 0%0%100%nrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnrnr </td <td>Function</td> <td></td> <td>5%</td> <td>5%</td> <td>90 %</td> <td>0%</td> <td>6%</td> <td>94%</td> <td>nr</td> <td>nr</td> <td>nr</td> <td>nr</td> <td>nr</td> <td>, and si</td> <td>lumbar function</td> <td>100 %</td> <td></td>	Function		5%	5%	90 %	0%	6%	94%	nr	nr	nr	nr	nr	, and si	lumbar function	100 %	
ROM $10\%$ $33\%$ $\frac{57}{96}$ $11\%$ $11\%$ $78\%$ $5\%$ $\frac{19}{96}$ $76\%$ $6\%$ $17\%$ $\frac{97}{96}$ ROM $60\%$ Symptoms $0\%$ $10\%$ $\frac{90}{96}$ $11\%$ $22\%$ $67\%$ $0\%$ $0\%$ $\frac{100}{96}$ $11\%$ $17\%$ $\frac{97}{96}$ $nr$ <t< td=""><td>ADL</td><td></td><td>0%</td><td>10%</td><td>90 %</td><td>0%</td><td>0%</td><td>100%</td><td>nr</td><td>nr</td><td>nr</td><td>nr</td><td>nr</td><td>nilar te</td><td>ADL</td><td>93%</td><td>8</td></t<>	ADL		0%	10%	90 %	0%	0%	100%	nr	nr	nr	nr	nr	nilar te	ADL	93%	8
Symptoms $0\%$ $10\%$ $\frac{90}{96}$ $11\%$ $22\%$ $67\%$ $0\%$ $\frac{100}{96}$ $11\%$ $17\%$ $\frac{78}{9}$ nr       <	ROM		10%	33%	57 %	11%	11%	78%	5%	19 %	76%	6%	17%	10011,220 77 0,220 chnolog	ROM	60%	3
Measure         of         0%         33%         67         11%         22%         67%         0%         5%         95         0%         11%         8%         Walking         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100 <td>Symptoms</td> <td></td> <td>0%</td> <td>10%</td> <td>90 %</td> <td>11%</td> <td>22%</td> <td>67%</td> <td>0%</td> <td>0%</td> <td>100 %</td> <td>11%</td> <td>17%</td> <td>」 7章 aや/ jies.</td> <td>nr</td> <td>nr</td> <td>nr</td>	Symptoms		0%	10%	90 %	11%	22%	67%	0%	0%	100 %	11%	17%	」 7章 aや/ jies.	nr	nr	nr
w w	Measure walking	of	0%	33%	67 %	11%	22%	67%	0%	5%	95 %	0%	11%	Agence B	Walking function	100 %	8

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1 2 3 4 5 6	Global rating of change	0%	24%	76 %	6%	28%	67%	0%	14 %	86 %	6%	17%	023-075856 000164 7 000 right, including for	Patient	global nt	93%	78%
7 8 9	AE	0%	24%	76 %	0%	11%	89%	0%	24 %	76%	0%	6%	Dotte bes Enseig	AE		100 %	100 %
10 11	Biomarks	29%	43%	29 %	28%	33%	39%	29%	52 %	19%	11%	50%	2023, D gnemer lated to	Biomarks		0%	11%
12 13 14	Radiographic changes	5%	43%	52 %	6%	22%	72%	5%	33 %	62%	0%	28%	owinka ht <sup>r</sup> Supe	Radiograj changes	phic	47%	22%
15 16 17	CM specific outcomes	10%	24%	67 %	6%	33%	61%	0%	14 %	86 %	6%	28%	ded fro rieer (A) nd data	CM s outcomes	pecific	100 %	67%
18 19	Mental health	5%	38%	57 %	6%	33%	61%	0%	43 %	57%	0%	17%	maditus BESS) mining	Mental he	ealth	53%	78%
20 21 22	Satisfaction index	0%	29%	71 %	0%	28%	72%	0%	24 %	76%	0%	28%	, Al trai	Satisfaction index	on	7%	44%
23 24 25	Quality of life	5%	14%	81 %	0%	11%	89%	nr	nr	nr	nr	nr	en.bmj. 1ingfran	health QOL	related	100 %	78%
25 26 27	Adherence and attrition	14%	29%	57 %	0%	33%	67%	10%	14 %	76%	0%	50%	nd simila	Adherenc attrition	e and	7%	0%
28 29 30	Psychosocial	48%	38%	14 %	44%	39%	17%	19%	71 %	10%	28%	50%	ar techn	Psychoso	cial	13%	33%
31 32	Resource use	14%	24%	62 %	0%	22%	78%	5%	24 %	71%	6%	22%	11-12025 77 0/25	Resource	use	47%	78%

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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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#### **1** Development of CORE-CM Core outcome domain sets for trials of Chinese

#### 2 medicine for lumbar spinal stenosis

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37	Abstract
38	Objectives: Most Asian countries have employed Chinese medicine (CM) and
39	Western medicine to treat lumbar spinal stenosis. Evidence synthesis and comparison
40	of effectiveness are difficult since outcomes examined and presented through trials
41	possess heterogeneity. This study aimed to solve the outcome problems for CM
42	clinical trials in lumbar spinal stenosis by building a core outcome set (CORE-CM-
43	LSS).
44	Methods: To achieve an agreement on a set of core outcome domains, a four-phase
45	study was carried out. First, we identified candidate outcome domains by
46	systematically reviewing trials. In addition, we identified outcome domains associated
47	with patients by conducting semi-structured interviews with patients. Next, outcome
48	domains were processed through a national two-round Delphi survey, in which 18
49	patients and 21 experts were recruited. Finally, the above domains were converted as
50	a core outcome domain set based on a consensus meeting, in which 24 stakeholders
51	were recruited.
52	Results: Seventeen outcome subdomains were identified by the systematic review and
53	interviews. The Delphi survey assigned a priority to four outcome domains in the 1st
54	round and four outcomes additionally in the 2nd round. The core outcome domains
55	were determined through discussion and redefinition of outcomes in the consensus
56	meeting: pain and discomfort, Health-related quality of life, lumbar Function,

57 activities of daily living, measures of walking, patient global assessment, Adverse

58 Events and CM-specific outcomes.

- 59 Conclusion: COS-CM-LSS is likely to enhance the consistency of outcomes reported
- 60 in clinical trials. In-depth research should be conducted for the exploration of the best
- 61 methods to examine the above outcomes.
- 62 Keywords: lumbar spinal stenosis, Delphi survey, domains, systematic review,
- 63 Chinese medicine, core outcome set
- 64 Word counts: 4098

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We used a mixed-method approach to determine which outcomes would be

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# 65 Strengths and limitations

67	included in the Core outcome domain sets for trials of Chinese medicine for
68	lumbar spinal stenosis (CORE-CM-LSS).
69 <b>•</b>	In this investigation, we incorporated the perspectives of different stakeholders,
70	including patients, physicians, and researchers.
71 ●	The participants were sampled based on duration and socioeconomic status,
72	disease severity, as well as lumbar spinal stenosis (LSS) manifestations, which
73	ensures that the core domains are generalizable to LSS people.
74 <b>•</b>	Chinese medicine (CM) or integrated medicine studies have been mostly used
75	there, which limits the results since stakeholders are distributed in different
76	geographical areas.

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78 Lumbar spinal stenosis (LSS) arises from spinal anatomical or functional 79 narrowing with a negative effect on the spinal cord and nerve roots, characterized by 80 pain and discomfort in legs, buttocks, and lumbar spine, as well as disability of 81 walking capacity [1]. The above discomfort and pain can be increased by walking and 82 alleviated through sitting or lumbar flexion [2]. LSS affects a global population of 83 nearly 103 million [3] and 11% of the elderly in the United States [4]. Most LSS are 84 treated non-operatively, with physical therapy, analgesia, as well as activity modification as the First-line therapies, whereas patients subjected to limited activities 85 and continuous pain are likely to be an alternative in terms of surgery [5]. 86 87 Chinese Medicine (CM), a non-surgical treatment, is critical in the treatment of 88 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 89 combined treatment is likely to more pronouncedly alleviate pain and ameliorate 90 functional outcomes than conventional therapies [8]. Furthermore, manual therapy in 91 92 combination with exercises under supervision can improve walking capacity, 93 symptoms, and pain in comparison to exercises [9]. 94 A review of clinical trials of LSS found inconsistency between results reporting or measuring instrument application under one outcome and poorly defined outcomes 95 96 [10]. An important effect of the above inconsistencies is to limit the potential of 97 robust meta-analysis. In a network meta-analysis of conservative treatment of LSS, 98 only 4 results were analyzed, while the other results could not be analyzed due to the 99 limited data or no meta-analysis to determine the outcome, or the variety of 100 definitions of an outcome [8]. Existing problems, supported by most CM trials, include poorly defined outcomes, insufficient evidence of instruments, selective 101 reporting of outcomes, or no criteria for selection for core outcomes [11]. Data that 102 cannot be interpreted or used cause unacceptable and unethical waste of research. 103 Selective reporting of results and associated reporting biases may also occur if 104 105 consistent results are not specified in advance [12].

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106 The core outcome set (COS) includes standardized outcomes. It has been found 107 as the minimal measurement and report criterion in terms of the respective trial for a 108 specific health area [13], increasing outcome reporting consistency, accountability, and transparency. Outcomes, which conform with certain standards and are examined 109 110 in studies under a particular condition, can reduce this research waste, such that the 111 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 112 113 significance [14]. The review of the COMET database and searching OMERACT for 114 COSs of trauma and orthopedics ensured the lack of COS on LSS [15]. This study presents a multiple-stakeholder, Chinese nationally endorsed, 115 consensus-based CORE outcome set suitable for Chinese Medicine intervention trials 116 117 in adults with LSS (CORE-CM-LSS), as well as its development. 118 2. Method The study protocol was registered in the COMET database (https://www.comet-119 120 initiative.org/Studies/Details/1363), whereas the protocol was not published. The 121 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 122 123 Set-STAndards for Development) [17] guidelines (Supplementary Material, table S1 and S2). This is a further study underlying COS development for low back pain 124 125 (LBP), and the COS focused on specific LBP due to lumbar spinal stenosis (LSS)

126 which is treated by CM.

127 **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:

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3 4	135	randomized controlled trials (RCT); Health condition: symptomatic lumbar spinal
5 6 7 8 9 10 11 12	136	stenosis <sup>1</sup> . Target interventions are Chinese medicine (CM) for LSS, which comprise
	137	acupuncture, Tuina (CM massage), Gongfa (CM exercise), bloodletting, cupping, oral
	138	herbal medicine, local washing or compressing with CM. Furthermore, CM alone or
	139	CM combined with other conventional treatments were involved.
13 14	140	This study fell into three vital sections to obtain consensus on the outcome
15 16	141	domains that were to be examined, which were completed in the proper sequence. The
17 18	142	following inquiries were answered, including which outcome domains are likely to
19 20	143	benefit LSS patients, which outcomes are more important, as well as which results
21 22	144	should be included in the core outcome set.
23 24	145	The ethics committee of the corresponding author's hospital (DZMEC-KY-2020-
25	146	60) has given ethical approval for the present study on September 7th, 2020. All
27 28	147	participants declared no interest conflict during the study. Patients contributed to the
20 29 20	148	design of the study and were involved in the stages of patients' interview and
30 31	149	consensus meeting.
32 33 34 35 36 37 38 39	150	2.2 Systematic literature review
	151	A list of outcomes was established through Systematic literature review (SLR).
	152	Moreover, the results of the SLR were partly published to assess the effectiveness of
	153	non-pharmaceutical Chinese medical therapies alone or in combination for the
40 41	154	treatment of lumbar spinal stenosis [18].
42 43	155	2.2.1 Eligible trials
44 45	156	The RCTs of the LSS patients diagnosed by clinical symptoms of neurogenic
46 47	157	claudication and imaging findings were included, no matter whether LSS patients
48 49	158	have complicating diseases. Interventions included the treatment with CM alone or
50 51 52 53	159	treatment including CM. The control intervention involved routine treatment (e.g.,
	160	injection therapy, physical therapy, exercise therapy, health education, self-
54 55	161	management), or a combination of the above. There were no restrictions on
56 57	162	publication type, language, or status.
58 59 60	163	2.2.2 Literature search and selection

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The trials were identified by searching RCT and spinal stenosis terms from
CNKI, VIP, WangFang, Sinomed, PubMed, Cochrane Library, and EMBASE online
databases, from their inception to 1<sup>st</sup> 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.

<sup>8</sup> 192 **2.3 The semi-structured interview** 

 

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3 4	193	The additional associated outcome domains were elicited through qualitative semi-
5 6	194	structured interviews of patients.
7 8	195	2.3.1 Participants
9 10	196	The LSS patients previously or currently under CM treatment were recruited. While
11 12	197	the LSS patients due to trauma or congenital spinal disease, having hearing or
13 14	198	communication problems, or refusing to join the interviews were excluded.
15 16	199	We employed convenient and purposeful sampling methods based on several
17 18	200	ages, gender, years of LSS and imaging findings related to the hospital outpatients
19 20	201	from seven territories of China (predefined features in Supplementary Material, table
21	202	S4). Features were defined by the SAG to ensure diversity represented. The
23	203	qualitative data were analyzed, while the interviews continued, and the sampling was
24 25 26	204	ended following data saturation criteria, based on the definition from two consecutive
20 27 28	205	interviews without any additional subdomain.
20 29	206	2.3.2 Interview process
30 31	207	Interviews were carried out face-to-face in outpatient or via remote video
32 33	208	software (WeChat) and recorded by qualified researchers (YCH). Explanation and
34 35	209	information consent should be given to patients before the interviews. We initiated the
36 37	210	interview with questions (e.g., "what outcomes are important or most concern to you,
38 39	211	or how do you determine the effectiveness of treatment, or what aspect they would
40 41	212	like to get better improvement"). A list of subdomains from SLR was provided as the
42 43	213	outline when patients could not answer or had no ideas about the important outcomes.
44 45	214	After patients completed reading the list, another open-ended question was asked to
46 47	215	allow patients to provide additional outcomes.
48 49	216	2.3.3 Data analysis
50 51	217	The additional outcomes and the demographic and medical information of
52 53	218	patients were collected. The words expressed by patients were analyzed through
54 55	219	qualitative content analysis. For an overall perspective and familiarity with the
56 57	220	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

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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.

230 2.4 Expert consensus

231 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.

243 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.

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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  $\leq$  15% score 1 to 3; "consensus out" thresholds are met if > 80% of the panelists score 1 to 3 and  $\leq$  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 1<sup>st</sup> and 2<sup>nd</sup> rounds, with average scores of outcomes.

263 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.

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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

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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) 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 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.

None.

3. Results

measurements (e.g., CT and MRI).

outcomes					
No	COMET domain outcome	Number of 86 RCTs reportin g COMET outcome s (%)	Subdomain outcome	Number of 54 OMIs into subdomai n 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/RMD Q/ 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)	subscale of JOA/pain subscale of SSS/bodily pain subscale of SF-3
3	Adverse events	19 (22.1)	AE	1 (1.9)	AE
4	Physiologica 1	11 (12.8)	Inflammatory markers Hemorheologic al marker Immunological markers Physiological markers Radiographic changes CM	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 subset Hepatic and renal function tests/Serum endothelin Parameters of computed tomography Near-infrared imaging system on
5	CM indictor	5 (5.8)	meridian/CM	2 (3.7)	meridian

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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	Psychosocia 1	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

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

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).

Table 2. Subdomain and COMET outcomes identified from interviews				
COMET	Subdomain outcomes	Number of	Example of interview transprint (Chinasa	
domain		18 patients	words presented in English)	
outcome		(%)	words presented in English)	
Function	Function	17 (94.4)	"This waist does not seem to be as flexible as before"	

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	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
	Hemorheologic al 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
Satisfaction	Satisfaction index	1 (5.5)	more serious" "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 longevityI 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"
-			
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

## 

319	SAG identified subdomain outcomes as candidate outcomes from SLR and
320	interviews, defined outcomes, and constructed a final inventory of 17 outcomes[24-
321	32] for the Delphi survey (Table 3). Among candidate outcomes, Physiological
322	outcome was separated by SAG into biomarkers and radiographic changes. The
323	biomarkers outcome was identified by SAG by combing inflammatory markers,
324	hemorheological markers, immunological markers, as well as physiological outcomes
325	(Figure. 1).

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

Table 3. Candidate DLSS Outcomes and definitions

10	Radiograp hic 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+I
11	CM- specific outcomes	CM outcomes related to CM <i>Zheng</i> 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+]
13	Satisfactio n index	Satisfaction with care received, including of the process and outcomes of the treatment experience and care providers [24].	SLR+I
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	Psychosoci al	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
Note	s: SLR, syster	matic literature review; Int, interview; ADL, activities of daily l	iving; l
Rang	ge of movemer	nt; AE, adverse events; CM, Chinese medicine;	

A total of 25 experts and 18 patients were recruited for online Delphi survey, and

330 21 experts and all patients responded and completed the first-round survey

331 (participant characteristics detailed in Supplementary Material, table S7). Delphi

332 survey identified four outcome domains (including pain, function, ADL and QOL) in

the first round, and another four outcome domains (including symptoms, measures of

334 walking, global rating of change and AE) in the second round, all of which met the

335 consensus threshold. Table 4 lists the scores for all candidate outcomes and

336 'consensus-in' outcomes. The 'consensus-in' outcomes drew the Delphi consensus

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threshold and employed the above for the development of several initial outcomedomains to be covered in the core outcome domain set.

**3.3 COS determined by consensus meetings** 

340 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.

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

consens

meeting

voting

(n=24)

% yes

100%

100%

92%

50%

96%

88%

100%

4%

38%

88%

63%

21%

96%

4%

21%

nr

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us

9 10 11	Candidate	rou	und 1 (n=3	39)	rou	und 2 (n=3	39)	redefined outcome
12	Outcomes	0/2	0/2	0/2	0/2	0/2	0/_	S
14		/0	/0	/0	/0	/0	/0	
15		score	score	score	score	score	score	
16		1-3	4-6	7-9	1-3	4-6	7-9	
17 18	Pain	0%	5%	95%	nr	nr	nr	pain/disc omfort
20 21	Function	3%	5%	92%	nr	nr	nr	lumbar function
22	ADL	0%	5%	95%	nr	nr	nr	ADL
23	ROM	10%	26%	64%	5%	18%	77%	ROM
24	Symmetry	50/	150/	700/	50/	00/	070/	nr.
25	Symptoms	3%0	13%0	/9%0	3%0	8%0	8/%	
20	Measure of	5%	28%	67%	0%	8%	92%	Walking
28	walking	270	2070	0170	070	070		function
29	Global							
30	rating of	3%	26%	72%	3%	15%	82%	PGA
31	change	0,0	2070	/ _ / 0		10,0	0270	1 011
32	AE	00/	210/	700/	00/	1.50/	050/	<b>۸</b> Г
33	AE	0%	21%	/9%	0%	15%	83%0	AE
34	Biomarks	28%	41%	31%	21%	51%	28%	Biomark
35	Diomarks	2070	<b>T</b> 1/0	5170	21/0	5170	2070	S
36	Radiograp							Radiogra
38	hic	5%	33%	62%	3%	31%	67%	nhic
30	abanaaa	570	5570	0270	570	5170	0770	ahanaaa
40	changes							changes
41	CM-							CM-
42		00/	200/	640/	20/	210/	770/	specific
43	specific	8%0	28%0	64%	3%0	21%	//%	outcome
44	outcomes							S
45	M							5 Man4al
46	Mental	5%	36%	59%	3%	38%	59%	Mental
47	health	- / -		• • • •	- / -			health
48	Satisfactio	00/	200/	720/	00/	2(0/	740/	Satisfacti
49	n index	0%	28%	12%0	0%	26%	/4%	on index
50	Quality of							
52		3%	13%	85%	nr	nr	nr	HRQoL
53	lite							
54	Adherence							Adheren
55	and	8%	33%	59%	5%	31%	64%	ce and
56	attrition							attrition
57	Psychosoci							Psychoso
58		49%	38%	13%	49%	41%	10%	aial
59	al							Clai

Re use	source e	8%	26%	67%	5%	23%	72%	Resource use	58%
No Ch ass	otes: ADI inese mec sessment;	L, activiti licine; Q ; NR, not	ies of daily OL, Qualit reported	living; R ty of life;	COM, Ran HRQoL,	ge of mov , health re	ement; Allated QOI	E, adverse ev L; PGA, pati	ents; Cl ent gloł
367									
368	3.3.2 0	COS ider	ntified by f	inal votin	ıg				
369	А	ccording	g to the list	ofoutco	mes, an a	greement	was reach	ned on the co	ore set
370	based of	on an ele	ectronic vo	ting prog	ram in co	onsensus n	neetings. '	Table 4 lists	the scor
371	for the	respecti	ve outcom	e domain	. An agre	eement wa	s reached	on eight dor	nains o
372	import	ance and	l inclusion	in the co	re domai	n set for c	linical tria	als (including	g pain a
373	discom	nfort, HR	QoL, lum	bar funct	ion, ADL	., walking	function,	PGA, AE ar	nd CM-
374	specifi	c outcon	nes). Table	e S8 of su	pplement	tary mater	ial lists th	e sensitive a	nalysis
375	score c	of outcor	nes betwee	en patient	s and exp	perts.			
376									
377	Fi	igure 1. ]	Flow chart	of core of	outcomes	selection	process		
378									
379	4. Disc	cussion							
380	4.1 Su	mmary c	of the Main	Results					
381	This st	udy pres	sents the de	evelopme	nt of the	core doma	in set of	Chinese med	licine fo
382	LSS in	trials (C	CORE-CM	-LSS) an	d the step	os involved	d for reac	hing a conser	nsus of
383	patient	s and ex	perts. The	patient p	erspectiv	e was inte	grated in	the respectiv	e reseat
384	phase.	The sam	pling proc	ess inclu	ded pane	lists nation	nally, whi	ch can endov	w our
385	finding	gs with g	reater gene	eralizabil	ity in Chi	ina.			
386	4.2 Ou	tcomes l	Included in	the COS	5				
387	0	ur reviev	w and cons	sensus res	sults conf	irm that th	ne pain/dis	scomfort, fur	nction,
388	walkin	g disabil	lity and AI	DL of LS	S patients	s arouse th	e main co	oncern of pat	ients ar
389	physic	ians and	have been	most rep	orted in 1	trials. The	above ou	tcomes were	comm
390	sympto	oms of L	SS or imp	acts of sy	mptoms.	The adver	rse events	are required	for the
391	assessi	ment of t	he harms o	of all inte	rventions	s, and they	arouse th	e most conce	ern of
392	patient	s. The H	IRQoL is v	vital outco	omes for	the trials c	on pain fo	r its generic	constru

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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].

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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

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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.

447 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

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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

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- pmc. and support overall field development and research.

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13 14	469	and design. Ya'nan Sun, Zhiwen Weng, Yi an and Yanji Zhou conducted the
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44 45	483	The data used to support the findings of this study are available from the
46 47	484	corresponding author upon request.
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50 51	486	Ethics approval was provided by the ethics committee of Dongzhimen hospital
52 53	487	(DZMEC-KY-2020-60). Prior to the interviews with the patients, written informed
54 55	488	consent was requested. The Delphi signup page had a notice emphasizing the fact that
56 57	489	submission of the questionnaire constitutes permission. A permission form was filled
58 59 60	490	out by each attendee of the consensus meeting to signify their agreement to

3 4	491	participate.
5 6	492	Abbreviations
7 8	493	CORE-CM-LSS, core domain set of Chinese medicine for LSS in trials; COS, Core
9 10	494	outcome domain sets; CM, Chinese medicine, LSS, Lumbar spinal stenosis; COS-
11 12	495	STAD, Core Outcome Set-STAndards for Development; COS-STAR, Core Outcome
13	496	Set-STAndards for Reporting; SAG, Study Advisory Group; RCT, randomized
15	497	controlled trials; SLR, Systematic review; NGT, Nominal group technique; COMET,
10	498	Core Outcome Measures in Effectiveness Trials; OMI, Outcome Measurement
18 19	499	Instruments; CM, Chinese medicine; SPWT, Self-Paced Walk Test; JOA, Japanese
20 21	500	Orthopedic Association Score; mJOA, modified Japanese Orthopedic Association
22 23	501	Score; VAS, visual analogue scale; NRS, numerical rating scale; UBA-PBS, UBA
24 25	502	pain behavior scale; AE, adverse events; SF-36, 6-Item Short Form Survey; ADL,
26 27	503	activities of daily living: ROM, Range of movement: RMDO, Roland Morris
28 29	504	Disability Questionnaire: mRMDQ modified Roland Morris Disability
30 31	505	Questionnaire: HADS, Hospital Anxiety and Depression Scale: ODL Oswestry
32 33	506	Disability Index: OOL Quality of Life: SSS Spinal Stenosis Scale: ZCO Zurich
34 35	507	Claudication Questionnaire: TNF, Tumor Necrosis Factor: RBC, Red blood cell:
36 27	508	CRP C reactive protein: NR not reported: Int interview
37 38	508	CKF, C-reactive protein, NK, not reported, int, interview
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49 50	606	26 Li G Han P Lin M Wan 7 Chan V: Developing a Cara Outcome Sat for Clinical Trials of
51	607	Chinese Medicine for Humarlinidemia EDONT DUADMACOL 2022, 12:847101
52	007	Chinese Medicine for Hyperipideinia. FRONT PHARMACOL 2022, 15.84/101.
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54 55	609	Evaluating common outcomes for measuring treatment success for chronic low back pain. Spine
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58	612	Gehrchen M, Hagg O et al: A proposed set of metrics for standardized outcome reporting in the
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3	614	39. Deyo RA, Battie M, Beurskens AJ, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von
4 5	615	Korff M, Waddell G: Outcome measures for low back pain research. A proposal for standardized
6	616	use. Spine (Phila Pa 1976) 1998, <b>23</b> (18):2003-2013.
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Figure 1. Flow chart of core outcomes selection process

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## Supplementary Material

Table S1. The COS-STAR Statement

SECTI	IT	E		
ON/TO	N	I	CHECKLIST ITEM	page no
PIC	No	).		
TITLE/				
ABSTR				
ACT				
Title	la		Identify in the title that the paper reports the development of a COS	1
Abstract	1b		Provide a structured summary	3,4
INTRO				
DUCTI				
ON				
Backgro und and	2a		Describe the background and explain the rationale for developing the COS	6,7
Objectiv es	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
METH				
ODS				
Protocol /Registr v Entrv		4	Indicate where the COS development protocol can be accessed, if available, and/or the study registration details.	7,8
Particip ants		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
Informa tion 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
Consens us Process		7	Describe how the consensus process was undertaken.	11-13

Outcom e Scoring Consens	8	Describe how outcomes were scored and how scores were summarized.	11-13
us Definiti on	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
RESUL TS			
Protocol Deviatio ns	11	Describe any changes from the protocol (if applicable), with reasons, and describe what impact these changes have on the results.	8
Particip ants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development.	15-18 and Supplem entary materials
Outcom es	13a	List all outcomes considered at the start of the consensus process.	15-18 Table 1-
	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
DISCU SSION			~
Limitati ons	15	Discuss any limitations in the COS development process.	21-22
Conclus ions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research.	21-24
OTHER INFORM	ΙΑΤΙΟ		
N Funding	17	Describe sources of funding/role of funders.	25
Conflict s of Interest	18	Describe any conflicts of interest within the study team and how these were managed.	25

page no.

7,8

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11,12

11,12 13-17, table1-3

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11-13

Table S2. The COS-STAD checklist         Domain       Stan dard num ber       Methodology         Scope specificatio n       1       The research or practice setting(s) in which the COS is to be applied         2       The health condition(s) covered by the COS         3       The population(s) covered by the COS         4       The intervention(s) covered by the COS         5       Those who will use the COS in research         6       Healthcare professionals with experience of patients with the condition         7       Patients with the condition or their representation         8       The initial list of outcomes considered both healthcare professionals' and patients' views.         9       A scoring process and consensus definition we described a priori.         10       Criteria for including/dropping/adding outcom- were described a priori.         11       Care was taken to avoid ambiguity of language used in the list of outcomes.	Stan       Methodology         Domain       ber       Methodology         Scope       1       The research or practice setting(s) in which the COS is to be applied         1       2       The health condition(s) covered by the COS         3       The population(s) covered by the COS         3       The population(s) covered by the COS         4       The intervention(s) covered by the COS         5       Those who will use the COS in research         6       Healthcare professionals with experience of patients with the condition         7       Patients with the condition or their representation         8       The initial list of outcomes considered both healthcare professionals' and patients' views.         9       A scoring process and consensus definition we described a priori.         10       Criteria for including/dropping/adding outcome were described a priori.         11       Care was taken to avoid ambiguity of language used in the list of outcomes.	Table S2. The COS-STAD checklist         Domain       Stan num ber       Methodology         Scope specificatio n       1       The research or practice setting(s) in which the COS is to be applied         2       The health condition(s) covered by the COS         3       The population(s) covered by the COS         4       The intervention(s) covered by the COS         5       Those who will use the COS in research         6       Healthcare professionals with experience of patients with the condition         7       Patients with the condition         7       Patients with the condition or their representation         7       Patients with the condition or their representation         8       The initial list of outcomes considered both healthcare professionals' and patients' views.         9       A scoring process and consensus definition we described a priori.         10       Criteria for including/dropping/adding outcome were described a priori.         11       Care was taken to avoid ambiguity of language used in the list of outcomes.			
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	203	2022		11	Care was taken to avoid ambiguity of language used in the list of outcomes.

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Table S3.	Search	strategies	and	results
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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 "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 stenosis"[All Fields]) (('chinese'/exp OR chinese) AND ('medicine'/exp OR	195 160
	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	
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 "	1084
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	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])	
VIP	M=(腰椎管狭窄) AND U=(针灸 OR 推拿 OR 艾灸 OR	1480
	针刺 OR 手法 OR 扳罐 OR 功法 OR 太极 OR 甲医)	

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3	Table S4. Patient features re	epresenting the target participants
4	Category	Features
6	Age	8 patients $>65$ years of age
7	50	8 patients $< 65$ years of age
8	C	8 patients <05 years of age
9	Sex	8 females
10		8 males
11	Disease courses	8 patients $\geq 10$ years
12		8 patients $<10$ years
13	Radiographic classification	Covering lateral recess central spinal
14	Radiographic classification	
16		canal
17		intervertebral foramen
18	territorial region	At least more than 5 regions of China
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21		
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First author, year	Partici pants	Interventions	Table S5. Studies' Chara Comparator	cteristics and Outcome Me Outcome Measurement Instruments	easuremen Treat ment durati on	t Instruments for USES OMI related to tex time to tex	56 on 16 October 2023 Subdomain 2023 Outcomes	COMET outcomes	criter ia for respo nder 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, data follow-up 3mining and 6m	a pain/function/ ADL for pain Radiographic changes	pain function Physiologi cal	NR	
Chen Jian, 2019[2]	30/30	CM herb	Aceclofenac+Mecobal amin	JOA IL-6/CRP ODI AE hepatic and renal function tests	4w	Pre-treatment, 2 and 4w are - treatment g Pre- and post- treatment for hepatic and renal function tests	pain/function/ ADL Inflammatory markers function AE Physiological index	pain function Physiologi cal AE	JOA	
Feng Sui 2009[3]	40/40	Acupotomy	Traction	Responder rates	2m	Pre- and post- treatment	-1 20 25 25 25 25 25 25 25 25 25 25 25 25 25	pain function	DEC - TCM	
Geng Xiaoyan, 2017[4]	46/46	CM herb	Salvia (Danshen) injection+Diclofenac	JOA	NR	Pre- and post- treatment	and pain/function/ ADL Bibliograph	pain function	NR	
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Page 39 of 66					BMJ Open		d by сор	njopen-2		
1 2 3 4 5 6 7 8 9 10 11	Gu Qi, 2015[5]	30/30	CM herb	GIucos	mJOA VAS SPWT Responder rates	2w	Pre- and post- treatment, set follow-up Integrated for Responder	2023-075856 on pain/function/ 16 ADL copain measure of 20 walking	pain function	JOA
12 13 14 15 16 17	Guan Xiaoyong, 2015[6]	47/47	CM herb	Salvia (Danshen) injection+Diclofenac	VAS Responder rates	lm	Pre- and post treatment	ADL adpain dpain fo	pain	VAS
18 19 20 21 22	Hou Yu, 2019[7]	22/23	Manual therapy	NSAIDs+Drugs for protecting gastric mucosa and nourishing nerves	JOA VAS	4w	Pre- and post- treatment A train	ADL pain/function/	pain function	NR
23 24 25 26 27	Huang Zheng, 2017[8]	31/33/ 32/33	CM herb Acupuncture CM herb+Acupuncture	Diclofenac+Mecobala min	JOA/improvement of JOA Responder rates AE	3m	Pre-treatmain 1, 2 and 3ma after sin treatment	ADL pain/function/ pain/function/ gAE	pain function AE	DEC - TCM
28 29 30 31	Huang Zhifen, 2009[9]	50/46	CM herb	Diclofenac	Responder rates AE	4w	Pre- and post- treatment	upain/function/ 14AE ≥	pain function AE	DEC - TCM
32 33 34 35 36 37 38 20	Ji Wei, 2013[10]	35/34	CM herb	Mecobalamin	Responder rates VAS mJOA	4w	Pre- and post- treatment	gepain/function/ at pain gepain/function/ ce ADL Biblio	pain function	DEC - TCM
40 41 42 43 44 45 46				For peer review only - http:	://bmjopen.bmj.com/site/a	about/gu	idelines.xhtml	graphique de l		

1					BMJ Open		njopen-2023- 1 by copyrigh		Page 40 of 66
2 3 4 5 6 7 8 9 10 11 12 13	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 reatment reatment reatment post Pre- and post reatment reatment reatment reatment reatment post Pre- and post Pre- and post reatment suppose reatment suppose reatment post reatment post reatment post reatment post reatment post reatment post reatment pos	pain function	DEC - TCM
14 15 16 17 18 19 20 21 22 23 24	Li Jinxue, 2007[12]	40/40/ 44/42	CM herb CM herb+CM granules CM herb+CM granules+Erigeron breviscapus	Glucos	Responder rates VAS parameters of computed tomography	4w	treatment for so of Responder de pain/function/ rates/VAS/Man pain diographic monophic changes, de rates follow-up and the pain l2month for Responder de pain/function/ Responder de pain/function/ pain Radiographic changes rates	pain function Physiologi cal	JOA
25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40	Li Jinxue, 2013[13]	92/83	CM herb	GIucos	Responder rates VAS Walking capacity	2w	Pre- and posit- treatment feat Responder ter rates/VAS/W alking capacity, est follow-up im for Responder rates/Walking capacity Bibliogra	pain function	GPC R- ND
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Lin Yuanfang, 2017[17]	33/32	Manual therapy	Traction	Responder rates JOA Rang of Lumbar spine extension	20d	uding Pre- and post- treatment uses reig	pain/function/ pain/function/ ADL ROM	pain function AE	DEC - TCM
Liu Chenhui, 2019[18]	30/30	CM herb	Celecoxib+Mecobala min+Hydrotalcite Tablets	VAS SPWT CM Zheng scores Responder rates AE	2w	Pre- and potent Superieur (A treatment data	Measure of Walking CM Zheng pain/function/	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 posts treatment	Global rating of change pain/function/	pain function	DEC - TCM
Liu Jun, 2020[20]	46/46	CM herb	Mannitol Injection+Mecobalami n	Responder rates	3w	Pre- and post- treatment g	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 nologies.	pain/function/ pain/function/ ADL Immunologica l indicators	pain function Physiologi cal	DEC - TCM
Su Lianshu,	38/37	Acupotomy	Canal injection	VAS JOA Responder rates	3w	Pre-treatment, 1 and 4w after treatment	apain pain/function/ SADL ■pain/function/	pain function	DEC - TCM

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6 7 8 9 10 11 12 13 14	Sun Biyun, 2021[23]	40/40	Acupuncture	Sham Acupuncture	NRS mRMDQ HADS Treatment Adherence index AE	6w	6w after of treatment, set follow-up res 12w and 24w for to NRS/RMD HADS	Grann Offunction Seperation Seperation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separation Separ	pain function mental health complianc e	NR
15 16 17 18 19 20 21 22	Tang Hanwu, 2015[24]	35/34	CM herb	Celecoxib+Mecobala min	Responder rates VAS JOA Near-infrared imaging system on DU meridian	4w	Pre- and point treatment g	ADL CM meridian	pain function CM indictor	DEC - TCM
23 24 25 26 27 28	Wang Chenghon g, 2009[25]	46/44	acupuncture	Traction+Physical therapy	JOA mRMDQ responder rates	2w	Pre- and post- treatment, sin follow-up for	pain/function/ ADL gpain/function/ gpain/function/ ►ADL	pain function	JOA
29 30 31 32 33 34 35 36 37 38 39 40 41 42 43	Wang Guanjun, 2019[26]	53/53	CM herb	Mannitol Injection+Mecobalami n	VAS JOA Responder rates	3w	Pre- and post- treatment	Ine 11 pain 20 pain/function/ 25 ADL Apain/function/ Bibliographique d	pain function	DEC - TCM ; JOA
44 45 46				For peer review only - http:	//bmJopen.bmJ.com/site/a	bout/gu	lidelines.xhtml	<u>e</u>		

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Wang Haijun, 2017[27]	47/47	Acupotomy	Traction+Physical therapy	VAS JOA Responder rates	14d	Pre- and post- treatment, of opain/function/ follow-up long ADL and 6m	pain function	VAS ; JOA
Wang Hua, 2017[28]	50/50	Manual therapy	Epidural injection	Responder rates	4w	Pre- and potential 23 treatment of 25 treatment of 25 treatment of 25	pain function	DEC - TCM
Wu Shizhen, 2016[29]	13/13	Acupotomy	Canal injection	Global Rating of Change Scale Responder rates	NR	Pre- and post i of change treatment	pain function	NR
Xiao Zhenhua, 2021[30]	23/23	Acupotomy	Canal injection	VAS JOA	20d	Pre- and post treatment	pain function	NR
Zhou Qishi, 2002[31]	51/51	CM herb	Vitamin B1 B6	Responder rates SPWT Serum endothelin	4w	Pre- and post- treatment similar o index	function Physiologi cal	NR
kim, 2016[32]	26/24	Acupuncture	Usual care	ODI SF-36	6w	Pre- and post- treatment, s. follow-up 3m follow-up 3m follow-up 3m	pain function QOL mental health Psychosoc ial	NR
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12 13 14 15 16	Oka, 2018[33]	41/38/ 40	Acupuncture	Drugs/Exercise therapy	ZCQ	1m	Pre- and post treatment and car	pain/function/s atisfaction	pain function satisfactio n	NR
17 18 19 20 21 22 23 24	Qin, 2020[34]	40/40	Acupuncture	Sham Acupuncture	RMDQ NRS SSS Satisfaction subdomain of SSS	8w	Pre-treatment,	function pain pain/function/ satisfaction	pain function satisfactio n	NR
24 25 26 27 28 29 30 31 32 33	Xu Jialong, 2021[35]	29/29	CM herb+Usual care	Drugs+Usual care	VAS JOA SPWT CM Zheng scores AE	4w	2 and 4w after treatment for VAS, JOA ar Pre- and post- treatment for SPWT, CMC Zheng scores	ADL Measure of walking CM Zheng AE	pain function CM indictors AE	DEC - TCM
34 35 36 37 38 39 40	Zhu Shuxian, 2014[36]	30/30	Manual therapy+ Usual care	Traction+Usual care	Responder rates VAS ODI	3w	Pre- and post-	pain/function/ pain function	pain function	DEC - TCM
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1 2 3 4 5 6 7 8 9 10	Liu Li, 2020[37]	32/32	Acupuncture+Moxib ustion	Acupuncture	Responder rates Self-made symptoms rating scale JOA VAS	20d	ight, including fort. Pre- and posses relat treatment	23-075856 9 pain/function/ 6 symptoms copain/function/ ADL 20 pain	pain function	DEC - TCM	
11 12 13 14	Wang Chenghu, 2014[38]	45/45	Acupuncture+Moxib ustion	Ibuprofen	Responder rates	10d	Pre- and poet Super treatment	Doppain/function/	pain function	DEC - TCM	
15 16 17 18	Su Tao, 2011[39]	60/60	Acupuncture+Moxib ustion+manual therapy	manual therapy	Responder rates	12d	d ie Pre- and positive freatment ment in cost freatment men in cost in cost i	fipain/function/	pain function	DEC - TCM	
19 20 21 22	Liao Jian, 2017[40]	30/30	CM herb+Acupuncture	Acupuncture	Responder rates RMDQ	2w	Pre- and post- treatment	pain/function/	pain function	DEC - TCM	
23 24 25 26 27	Shan Jinchun, 2013[41]	48/48	CM herb+manual therapy	manual therapy	Responder rates CM Zheng scores	1m	Pre- and post- treatment s:	pain/function/	pain function CM indictors	COC E	
28 29 30 31 32 33 34 35 36 37 38 39 40 41	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 4woo after est treatment, follow-up 1m	pain pain/function/ ADL function at Measure of walking CM Zheng Bibliographic	pain function CM indictors	NR	
42 43 44 45 46				For peer review only - http:	//bmjopen.bmj.com/site/	about/gu	idelines.xhtml	que de l			

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5 6 7 8 9	Yuanzhen g, 2009[43]	60/60	CM herb+manual therapy	manual therapy	Responder rates	lm	e Pre- and post- treatment se e	Opain/function/	pain function	DEC - TCM
10 11 12 13 14 15	Li Zhulie, 2012[44]	30/30	Electrothermal acupuncture	Acupuncture	JOA Responder rates AE	10 times	Pre-treatment 1, 2, and 3 to course after treatment, and follow-up late	ADL pain/function/ pain/function/ ADL ADL ADL	pain function AE	JOA
16 17 18 19 20 21	Chen Xiaoyun, 2009[45]	30/30	Electropuncture+Blo odletting therapy	Electropuncture	Responder rates Global Rating of Change Scale VAS	20d	Pre- and post treatment ing,	pain/function/	pain function	DEC - TCM
22 23 24 25 26 27 28 29 30 31 22	Lei Xiaoping, 2020[46]	34/34	CM herb+Acupuncture	GIucos+Mecobalamin	JOA IL-6\IL-4\IL-10\TNF Blood viscosity/plasma viscosity/RBC hematocrit Responder rates AE	lm	raining, and Pre- and post- treatment similar technolog	ADL ADL Inflammatory Markers Hemorheologi Leal indictors pain/function/	pain function AE Physiologi cal	DEC - TCM
33 34 35 36 37 38 39	Cai Lijun, 2012[47]	32/64	CM herb+kerotherapy	Drugs/Traction	Responder rates JOA	3w	<b>پ</b> Pre- and post- treatment	25 at pain/function/ Agenain/function/ Ce ADL Biblio	pain function	- TCM ; JOA
40 41 42 43 44 45 46				For peer review only - http:	//bmjopen.bmj.com/site/a	about/gu	idelines.xhtml	jraphique de l		

CM herb+Manual therapy Acupuncture+Moxib ustion CM herb+manual	Canal injection	Responder rates	NR	Pre- and post- 6	oin/function/	pain	STI-
Acupuncture+Moxib ustion CM herb+manual	Acupuncture			treatment uses	bain/lunction/	function	ICW M
CM herb+manual		Responder rates	20d	Pre- and poster 20 treatment treatment to P	ain/function/ ADL	pain function	JOA
therapy	manual therapy	Responder rates AE	4w	Pre- and postperied treatment da	pain/function/ AE	pain function AE	NR
CM herb+manual therapy	manual therapy	JOA VAS Responder rates	4w	Pre- and posters treatment g, - Pre- A	oain/function/ ADL oain oain/function/	pain function	NR
CM herb+manual therapy	CM herb	VAS RMDQ Responder rates	4w	Pre- and post- or treatment, g	pain function pain/function/	pain function	DEC - TCM
Topical CM+hot compress	Diclofenac Diethylamine Emulgel	JOA VAS	4w	Pre- and post- of treatment in of	oain/function/ ADL pain	pain function	JOA
manual therapy+Exercise therapy	Exercise therapy	VAS JOA SPWT ODI Responder rates AE	3m	Pre-treatmond 11, Pre-treatmond 1w, 1m and 3m after treatment Bibliograp	pain pain/function/ ADL neasure of valking function pain/function/	pain function AE	VAS ; JOA\ ODI
	manual therapy+Exercise therapy	manual therapy+Exercise Exercise therapy therapy For peer review only - http:	hannal therapy+Exercise therapy therapy Exercise therapy Exercise therapy Herapy Exercise therapy For peer review only - http://bmjopen.bmj.com/site/a	hannal therapy+Exercise therapy Exercise	manual manual therapy+Exercise Exercise therapy Exercise therapy thera	manual therapy+Exercise Exercise therapy therapy of the pain (because of the pain) (beca	manual therapy+Exercise therapyExercise therapyJOAPre-treatment 1w, 1m and 3m after treatmentMain measure of functionMarker ADLSPWT ODI3m after treatmentMain measure of functionMain measure of functionAEFor peer review only - http://bmjopen.bmj.com/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abut/guide/site/abu



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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Xu Shiliang, 2014[57]	47/48	CM herb+manual therapy	Glucos	SPWT VAS JOA IL-6\IL- 1B\TNF\CRP Blood viscosity/plasma viscosity/RBC hematocrit Responder rates	4w	vright, including for uses regimement Superieur (ABEs eignement Superieur (ABEs all, and follow-up 4text and data mir VAS, JOAA data mir	neasure of /alking ain ain/function/ ADL nflammatory narkers Iemorheologi al indictors ain/function/	pain function Physiologi cal	JOA	
19 20 21 22 23	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 potter and po	ain/function/ ymptoms	pain function	GPC R- ND	
24 25 26 27 28	Mao Xiaohui, 2008[59]	52/52	CM herb+Manual therapy+CM fumigation	Drugs+Traction+ TDP	Global Rating of Change Scale Responder rates	10d	Pre- and post- treatment milar	ymptoms ain/function/	pain function	DEC - TCM	
29 30 31 32 33 34 35 36 37	Yuan Zhixian, 2020[60]	30/30	CM herb+Acupuncture+ Moxibustion	Usual care	Responder rates Self-made symptoms rating scale JOA VAS AE	4w	Pre- and post- treatment is.	ain/function/ ymptoms ain/function/ ADL ain AE	pain function AE	CA- TCM	
38 39 40 41 42 43 44 45				For peer review only - http:	//bmjopen.bmj.com/site/a	bout/gu	Bibliographique de l idelines.xhtml				

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4 5 6 7 8 9 10 11	Dou Qunli, 2007[61] Chen Shulie, 2006[62]	83/83 32/7	CM herb+Manual therapy Manual therapy+Topical CM	Canal injection+ Traction Drugs	Responder rates	2m 4w	Pre- and post- treatment uses regimeer 2020 Pre- and post- Pre- and post- treatment eggineer 2020 Pre- and post- Pre- and post- treatment eggineer 2020 Pre- and post- treatme	n/function/ n/function/	pain function pain function	DEC - TCM NR
12 13 14 15 16 17 18	2006[62] Wang Fuyu, 2018[63]	48/48	CM herb+Acupuncture	Usual care	JOA VAS IL-1 TNF	4w	to the Support text Support Pre-treatment of the Support 2 and 4w attraction treatment at ABES minis	n/function/ L n ammatory rkers	pain function Physiologi cal	JOA
19 20 21 22 23 24 25	Xiong Junwei, 2015[64]	30/30	Acupotomy+Manual therapy	Acupotomy	JOA Responder rates AE	3w	Pre-treatment, pair 1, 2 and 3w AD after after after treatment, g follow-up 2gw AE	n/function/ L n/function/ L	pain function AE	JOA
26 27 28 29 30 31 32	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 poet- treatment r, ROI	bal rating hange asure of king M n/function/	pain function	DEC - TCM
33 34 35 36 37 38 39 40	Wang Wenli, 2018[66]	30/30	Electropuncture+fire d cupping+Bloodlettin g therapy	Physical therapy	SSS Responder rates Satisfaction	8w	Fre-treatment, 4 and 8w after Pair treatment, follow-up 4w BiAE	n/function/ n/function/ sfaction	pain function satisfactio	DEC - TCM
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11	Hongzhen	100/10	Acupuncture+Moxib				10d and 25 <b>8</b>	دة. 			
12 13	g,	0	ustion	Diclofenac	ODI	30d	after <b>t</b>	function	function	NR	
14	2016[67]						treatment, x up				
15							follow-up 3				
16 17			Electropuncture+fire				Pre-treatmon	pain/function/s	pain	DEC	
17	Jing Lei,	29/30	d	Physical therapy	SSS	8w	4 and 8w after	atisfaction	function	-	
19	2019[68]		cupping+Bloodlettin	5 15	Responder rates		treatment $\mathbf{g}$	pain/function/	satisfactio	TCM	
20			g therapy				, ≥		n		
21	Wang						trai	pain/function/	pain		
23	Hongmei.	40/40	Acupuncture+Moxib	Glucos	JOA	10d	Pre- and post-	ADL	function	NR	
24	2019[69]		ustion		IL-6/TNF/CRP		treatment 🦉	Inflammatory	Physiologi		
25 26	_017[07]						nd s	markers	cal		
20								pain/function/			
28	Wang		Acupuncture+cuppin		JOA		Pre- and post-	ADL	pain		
29	Jian,	72/72	g	GIucos	Responder rates	36d	treatment, C	pain/function/	function	JOA	
30 31	2013[70]		6		AE		follow-up 12 1	ADL	AE		
32							ogie	<b>Š</b> AE			
33	Zhang						Ň,	pain/function/			
34 35	Hong	37/36	Acupuncture+acupoi	Acununcture	JOA	12d	Pre- and post-	ADL	pain	ΙΟΑ	
36	2014[71]	51150	nt injection	reupuneture	Responder rates	124	treatment	gpain/function/	function	3011	
37	2011[71]							ADL			
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1 2 3 4 5 6 7 8 9 10 11 12	Lin Jincai, 2016[72]	35/35	Acupuncture+CM herb injection	Acupuncture	Rang of Lumbar spine extension VAS JOA Pain-free walking distance	2w	Pre- and post related to t	NO23-075856 on 1600 1600 175856 on 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 1600 160	pain function AE	NR	
13 14 15 16	Lv Xiaohua,	40/40	Acupuncture+Bloodl etting therapy	Dexamethasone+mann itol+CM herb injection	AE Responder rates	10d	Pre- and post treatment	and the second s	pain function	NR	
17 18 19 20 21	Shi Jianwei, 2013[74]	37/37	Acupuncture+manua l therapy	Dexamethasone+mann itol+Salvia (Danshen) injection	Responder rates	23d	Pre- and post treatment	pain/function/	pain function	DEC - TCM	
22 23 24 25 26	Xu Yunyu, 2014[75]	35/35	Acupuncture+Moxib ustion	Acupuncture	JOA Responder rates	25d	Pre- and positi- treatment, gan follow-up and	ADL pain/function/ pain/function/ ADL	pain function	JOA	
27 28 29 30 31 32	Zhang Huajun, 2016[76]	40/40	Acupuncture+CM herb+moxibustion	Acupuncture+CM herb	VAS JOA CRP ESR	14d	Pre- and poet- treatment, follow-up long	gpain pain/function/ ADL Inflammatory markers	pain function Physiologi cal	JOA	
33 34 35 36 37 38	Ji Yuejun, 2010[77]	64/62	CM herb+Manual therapy	Acupuncture	self-made lumbar fuction evaluation scale Responder rates	10d	ة Pre- and post- treatment	at Age function ce pain/function/ Biblio	pain function	DEC - TCM	
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			Table	B S6. Characteristics of pa	MJ Open tients in interviews and De	lphi rounds	open-2023-075856 on 16 Octob En y copyright, including for use	
patients	gender	age (years)	disease course (years)	Complicating lumbar spondylolisthesis	Radiographic classification	experience of CM treatment	s eigned elated as: ted en 20 ted en 20 ted en 20	consensus meeting
A1	Female	73	10	n	lateral recess	у	<b>g y b</b> sijing	n
A2	Female	66	3	n	central spinal canal	У	anete	У
A3	Male	69	2	У	intervertebral foramen	у	a a stilling	n
A4	Female	71	9	n	central spinal canal	у	a De ijing	n
A5	Male	58	8	у	central spinal canal	n	ning jing	n
A6	Male*	73	11	n	lateral recess	у	G · Shandong	n
A7	Female*	64	7	у	lateral recess	у	A Guangdong	У
A8	Female*	63	3	n	intervertebral foramen	n	angchun	У
A9	Male*	68	6	У	central spinal canal	у	Gangchun	n
A10	Female	55	7	У	lateral recess	у	Beijing	У
A11	Female	75	13	n	lateral recess	у	s Sandong	n
A12	Male	83	10	n	central spinal canal	у	Be ijing	n
A13	Female*	55	1	У	intervertebral foramen	n	Laoning	У
A14	Male*	54	2	У	central spinal canal	у	Laoning	У
A15	Female*	69	1	n	central spinal canal	у	olo Beijing	У
A16	Female*	64	20	У	lateral recess	у	je Skanghai	У
A17	Female	72	30	n	intervertebral foramen	у	Beijing	n
A18	Male	60	4	У	lateral recess	у	Béijing	У

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	Table S7. Characteristics of experts in Delphi rounds														
	experts	gender	age (years)	work experience (vears)	title	medical major	academie academie researcher	territorial region	consensus meeting						
	Ex 1	male	49	24	senior	Tuina	Y to 202	Beijing	Y						
	Ex 2	male	54	31	senior	Tuina		Beijing	Ν						
	Ex 3	male	56		senior	Tuina	Y te S	Beijing	Y						
	Ex 4	male	60		senior	Tuina	Y and Y	Beijing	Y						
	Ex 5	male	39	11	intermediate	orthopaedics	Y nd c	Beijing	Ν						
	Ex 6	male	50	28	intermediate	orthopaedics	Y lata	Beijing	Ν						
	Ex 7	male	32		intermediate	orthopaedics		Guizhou	Y						
	Ex 8	male	48	24	senior	acupuncture	Y Ing	Beijing	Y						
	Ex 9	female	41	11	intermediate	acupuncture	Y P	Beijing	Y						
	Ex 10	male	37	8	intermediate	acupuncture	Y trai	Beijing	Ν						
	Ex 11	male	43	20	senior	acupuncture	Y ning	Beijing	Ν						
	Ex 12	male	56	31	senior	pain management	Y ay j	Shandong	Y						
	Ex 13	male	36	8	intermediate	rehabilitation	Y s G	Beijing	Y						
	Ex 14	female	57	35	senior	general family medicine	N ini Po	Beijing	Y						
	Ex 15	female	56	32	intermediate	pain management	n ער אין	Beijing	Y						
	Ex 16	female	37	15	intermediate	nursing	Y echi	Beijing	Ν						
	Ex 17	male	48	24	senior	orthopaedics	Y 00 11	Shanghai	Y						
	Ex 18	male	50	26	senior	orthopaedics	202 Y e	Guangdong	Y						
	Ex 19	male	53	30	senior	orthopaedics	Y at	Xinjiang	Y						
	Ex 20	male	42	16	intermediate	orthopaedics	Y Å	Changchun	Y						
	Ex 21	female	39	11	intermediate	rehabilitation	Y NCE	Liaoning	Y						
	Note: y, y	yes; n, no.					Bibliographiqu								
				For peer revi	ew only - http://bm	ijopen.bmj.com/site/about/guideli	nes.xhtml								

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$\begin{array}{c c c c c c c c c c c c c c c c c c c $	]	lable	e 88. Ca	ndidate	outcon	upd 1 (1	$\frac{1}{1} \frac{1}{1} \frac{1}$	patients ai	nd exper	ts in L Delr	belphi 2	$\frac{1}{2}$ rounds	= 39	ogen seig	consensus meetin	<u>g</u> eting vo	ting
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Candidate Outcomes		expo	erts (n=2	21)	pa	tients (n=	=18)	expe	erts (n=	=21)	patio	ents (n=	2023. Downloadec nement Superieu ated to text and c	(n=2 NGT	4) expe rts (n=1 5)	pa n (n=
Pain $0\%$ $10\%$ $90$ $\%$ $0\%$ $10\%$ $10\%$ $90$ $\%$ $0\%$ $100\%$ $11.3$ $4.6$ $7.9$ $1.3$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$ $6.1$			% score	% score	% scor e 7-	% score	% score	% score	% score	% scor	% scor	% scor	% scor	ir (ABES) lata mining	re-identified	% Ves	0 V
Function5%5%90 $%_{6}$ 0%6%94%nrnrnrnrnrnrnrADL0%10%90 $%_{6}$ 0%0%100%nrnrnrnrnrnrnrROM10%33%57 $%_{6}$ 11%11%78%5%19 $%_{6}$ 76%6%17%17%ROM60%Symptoms0%10%90 $%_{6}$ 11%22%67%0%0%100 $9%$ 11%17%9%NrnrnrMeasure walkingof $0\%$ 0%67 $%_{6}$ 11%22%67%0%5%95 $9%$ 0%11%Walking100 function9%	Pain		1-3 0%	4-6 10%	9 90 %	1-3 0%	4-6 0%	7-9 100%	1-3 nr	6 nr	9 nr	3 nr	6 nr	, Al training	Pain and discomfort	100 %	1
ADL0%10% $\begin{array}{c} 90 \\ 96 \\ 96 \\ 06 \end{array}$ 0%0%100%nrnrnrnrnrnrnr $\begin{array}{c} 107 \\ 176 \\ 96 \\ 76 \\ 76 \\ 76 \\ 76 \\ 76 \\ 76 \\ $	Function		5%	5%	90 %	0%	6%	94%	nr	nr	nr	nr	nr	, and si	lumbar function	100 %	
ROM $10\%$ $33\%$ $\frac{57}{\%}$ $11\%$ $11\%$ $78\%$ $5\%$ $\frac{19}{\%}$ $76\%$ $6\%$ $17\%$ $\frac{67}{\%}$ $ROM$ $60\%$ Symptoms $0\%$ $10\%$ $\frac{90}{\%}$ $11\%$ $22\%$ $67\%$ $0\%$ $0\%$ $\frac{100}{\%}$ $11\%$ $17\%$ $\frac{97}{\%}$ $nr$ $nr$ Measureof $0\%$ $33\%$ $\frac{67}{\%}$ $11\%$ $22\%$ $67\%$ $0\%$ $5\%$ $\frac{95}{\%}$ $0\%$ $11\%$ $\frac{87}{\%}$ $Walking$ $100$ walking $0\%$ $33\%$ $\frac{67}{\%}$ $11\%$ $22\%$ $67\%$ $0\%$ $5\%$ $\frac{95}{\%}$ $0\%$ $11\%$ $\frac{87}{\%}$ $Walking$ $100$	ADL		0%	10%	90 %	0%	0%	100%	nr	nr	nr	nr	nr	nilan te	ADL	93%	8
Symptoms $0\%$ $10\%$ $\frac{90}{\%}$ $11\%$ $22\%$ $67\%$ $0\%$ $\frac{100}{\%}$ $11\%$ $17\%$ $\frac{57}{\%}$ $nr$ $nr$ Measure of walking $0\%$ $33\%$ $\frac{67}{\%}$ $11\%$ $22\%$ $67\%$ $0\%$ $\frac{95}{\%}$ $0\%$ $11\%$ $\frac{89}{\%}$ $Walking$ $100$ walking $0\%$ $33\%$ $\frac{67}{\%}$ $11\%$ $22\%$ $67\%$ $0\%$ $5\%$ $\frac{95}{\%}$ $0\%$ $11\%$ $\frac{89}{\%}$ $Walking$ $100$	ROM		10%	33%	57 %	11%	11%	78%	5%	19 %	76%	6%	17%	19011,22 77 %2 chnolog	ROM	60%	3
Measure walking         of 0%         33%         67 %         11%         22%         67%         0%         5%         95 %         0%         11%         89 %         Walking         100           walking         0%         33%         %         11%         22%         67%         0%         5%         95 %         0%         11%         89 %         Walking         100	Symptoms		0%	10%	90 %	11%	22%	67%	0%	0%	100 %	11%	17%	025 a¢/ 7∕25 . 9∕e/	nr	nr	nr
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1 2 3 4 5 6	Global rating of change	0%	24%	76 %	6%	28%	67%	0%	14 %	86 %	6%	17%	023-075856 000164 7 000 right, including for	Patient	global nt	93%	78%
7 8 9	AE	0%	24%	76 %	0%	11%	89%	0%	24 %	76%	0%	6%	Dottebes Enseit	AE		100 %	100 %
10 11	Biomarks	29%	43%	29 %	28%	33%	39%	29%	52 %	19%	11%	50%	2023, D gnemer lated to	Biomarks		0%	11%
12 13 14	Radiographic changes	5%	43%	52 %	6%	22%	72%	5%	33 %	62%	0%	28%	owinka ht <sup>r</sup> Super	Radiograj changes	phic	47%	22%
15 16 17	CM specific outcomes	10%	24%	67 %	6%	33%	61%	0%	14 %	86 %	6%	28%	ded fro rieer (A) nd data	CM s outcomes	pecific	100 %	67%
18 19	Mental health	5%	38%	57 %	6%	33%	61%	0%	43 %	57%	0%	17%	menting	Mental he	ealth	53%	78%
20 21 22	Satisfaction index	0%	29%	71 %	0%	28%	72%	0%	24 %	76%	0%	28%	Al train	Satisfaction index	on	7%	44%
23 24 25	Quality of life	5%	14%	81 %	0%	11%	89%	nr	nr	nr	nr	nr	en.bmj. 1ingfran	health QOL	related	100 %	78%
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