Supplementary Material 1 SPIRIT Fillable-checklist-15-Aug-2013

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 5
	2b	All items from the World Health Organization Trial Registration Data Set	None
Protocol version	3	Date and version identifier	Page 2
Funding	4	Sources and types of financial, material, and other support	Page 18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1
	5b	Name and contact information for the trial sponsor	Page 1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 19

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	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Page 19
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 3-4
	6b	Explanation for choice of comparators	Page 4
Objectives	7	Specific objectives or hypotheses	Page 4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 5-7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 8-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	None
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	None

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Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 10-12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 5
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 12-13
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 5

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 7-8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	None

Methods: Data collection, management, and analysis

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Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	None
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 14-15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	None
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	None
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 14
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Page 14

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Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 5-6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	None
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	None
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	None
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	None
	31b	Authorship eligibility guidelines and any intended use of professional writers	None
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Page 19

Appendices

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Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Page 5
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	None

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

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Supplementary Material 2 Informed consent of participants

Informed Consent

Informed Page

Name of Project: Clinical study of the immediate efficacy of contralateral acupuncture on SI3 combined with active exercise in the treatment of acute lumbar sprains.

Source of project: This study is supported by the "Liang Fanrong Expert Workstation" of Yunnan Province-Yunnan Science and Technology Programme (202305AF150072), the Yunnan Ten Thousand Talents Plan Youth Project (YNWR-QNBJ-2019-257) and the "Liu Zili Famous Doctor" special talent program of the Yunnan Provincial Xing Dian Talent Support Program (Yunnan Party Talent Office 2022 No. 18).

Project research organization: School of Second Clinical medicine/The Second Affiliated Hospital, Yunnan University of Chinese Medicine, Kunming, China.

Research leader: Taipin Guo

Dear patients,

First of all, thank you for your interest in our clinical research! We would like to invite you to participate in a clinical study on the clinical study of the immediate efficacy of contralateral acupuncture on SI3 combined with active exercise in the treatment of acute lumbar sprains. This study has been approved by the Medical Ethics Committee of the Second Affiliated Hospital of Yunnan University of Chinese Medicine. Before you decide whether or not to participate in this study, please read the following as carefully as possible. It will help you understand the study and why it is being conducted, the procedures and duration of the study, the benefits, risks and discomforts that may be brought to you by participating in the study. If you wish, you can also discuss it with your relatives and friends or ask your doctor to give explanations to help you make your decision.

Research introduction

I. Research background and research purposes

1. Research background

Acute lumbar sprain (ALS) is a common clinical condition characterized by persistent intolerable low back pain and limitation of movement. This not only severely affects the labor capacity of patients but also significantly disrupts their daily life. In some cases, patients may completely lose their ability to work and perform daily activities. Acupuncture, a distinctive therapy in Traditional Chinese Medicine, is widely recognized for its effectiveness in treating pain-related conditions. The technique of contralateral acupuncture (CAT), which involves needling on the healthy side opposite to the side of pain, has been extensively used since the era of the 'Huangdi Neijing' for unilateral pain conditions. This method has shown remarkable efficacy in clinical practice, with some studies even suggesting that CAT might be more effective than ipsilateral acupuncture for unilateral diseases. ALS often presents as unilateral pain, making it a suitable condition for treatment with CAT. Additionally, exercise is a well-established adjunct therapy for acute mobility disorders, contributing to pain reduction and the improvement or restoration of functional activities. Research has found that combining acupuncture with active exercise can rapidly alleviate pain and improve lumbar spine function in patients with ALS, but with limitations such as small sample size and insufficient blinding. Further studies are needed to support the immediate effect of this combination therapy in ALS.

2. Research purposes

The study aims to evaluate the immediate effectiveness of CAT on SI3 (Houxi acupoint) combined with active exercise in treating ALS within 10 minutes.

3. Study expected number of participants

This study is expected to include 118 patients with ALS.

II. Who can participate in this study?

(1) Conform to the diagnostic criteria for ALS as outlined in the "Clinical Diagnosis and Treatment Guidelines: Orthopedics" published by the Chinese Medical Association;

(2) Unilateral low back pain, age 18-55 years old, male or female;

(3) Duration of the disease ≤ 3 days;

(4) Experience moderate to severe low back pain, with a VAS between 4 and 8;

(5) Signed the informed consent form and voluntarily participated in this study.

III. Who is not suitable for research?

(1) Presence of concurrent lumbar spondylolisthesis, tuberculosis, tumors, fractures, or other spinal pathologies;

(2) Lumbar pain resulting from urinary system diseases, gynecological conditions or acute and chronic infections;

(3) Coexistence of severe cardiovascular, cerebrovascular, hepatic, renal, or coagulation system disorders;

(4) Combined serious mental illness or intellectual disability, rendering them unable to complete the questionnaire;

(5) Pregnant or breastfeeding women;

(6) Used other methods of pain relief within the past 6 hours.

IV. What will be done if you participate in the research?

If you meet the inclusion criteria and agree to participate, you will first undergo relevant tests to ensure that you meet all the requirements for study participation.

1. Before you are included in the study, you will undergo the following tests to determine if you can participate in the study.

Your medical history, clinical signs and symptoms will be interviewed and recorded; You will also be instructed to complete a visual analogue scale (VAS) score and measure your Range of Motion (ROM) score to determine if you meet our study inclusion criteria.

2. If you meet the inclusion criteria through the above screening, the study will be conducted according to the following steps:

(1) The trial will be divided into 2 groups. At the beginning of the study, your doctor will decide which group you will receive based on the random numbers generated by a computer.

(2) Following your group allocation, you will undergo a 10-minute acupuncture treatment. During the acupuncture session, you will be asked to perform moderate low back exercises and

cooperate with our data collection efforts.

3. Other matters requiring your cooperation

Throughout the treatment process, it's essential to collaborate with your doctor by completing relevant scales, providing truthful answers to their questions, cooperating with their instructions, and offering feedback on your condition.

V. Possible benefits of participating in the study

You may derive benefits from participating in this study, such as improving your condition and receiving valuable health education on the prevention and treatment of ALS.

VI. Adverse reactions, risks and protective measures for participating in the study

You may have soreness, numbness, heaviness and swelling during the acupuncture process, which are all normal reactions to acupuncture. There may be adverse reactions after needling, but they are rare and mild. You may feel dizzy during needling due to your physical condition or emotional stress, which can be relieved after stopping needling and taking proper rest; bleeding and haematoma may occur after needling, which will disappear after local pressure; however, if infection occurs at the site of needling, your doctor will deal with it promptly.

If you experience any discomfort, new changes in your condition, or any unforeseen circumstances during the study period, whether or not they are related to the acupuncture treatment, you should inform your doctor promptly and he/she will make a judgement and give appropriate medical treatment.

VII. Treatment options available to you other than participating in this study

Your doctor will discuss with you the other treatment options currently available for your condition, including the corresponding risks and benefits. For ALS, there are currently anti-inflammatory and analgesic drugs, mainly non-steroidal anti-inflammatory drugs (NSAIDs), which are effective but have side effects such as gastrointestinal bleeding, stomach ulcers and cerebrovascular accidents.

VIII. The relevant costs

All the costs of this project are supported by the “Liang Fanrong Expert Workstation” of Yunnan Province-Yunnan Science and Technology Programme (202305AF150072), the Yunnan Ten Thousand Talents Plan Youth Project (YNWR-QNBJ-2019-257) and the “Liu Zili Famous Doctor” special talent program of the Yunnan Provincial Xing Dian Talent Support Program (Yunnan Party Talent Office 2022 No. 18). If you participate in this study, you will receive free acupuncture treatment during the study period. This study will only observe the efficacy of the treatment once, and if the subsequent relief is not obvious, you can have 2 free acupuncture treatments. Doctors will make every effort to prevent and treat any harm that may occur as a result of this study. If an adverse event occurs during the clinical trial, a committee of medical experts will determine whether it is related to the acupuncture treatment or the study process. The sponsor will provide the cost of treatment and financial compensation for any harm related to the trial process in accordance with the provisions of China's Code of Practice for the Quality Management of Pharmaceutical Clinical Trials.

During the treatment period, if you have a combination of other medical conditions, the treatment and examination will not be free of charge.

IX.The confidentiality of clinical data

Your medical records (study charts/CRFs, etc.) will be kept intact at the hospital where you are seen. The investigator, ethics committee and drug regulatory authorities will be given access to your medical records. Any public reporting of the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information to the extent permitted by law.

X. You can voluntarily choose to participate in research and withdraw from the study

Whether or not to participate in the research is entirely up to you. You may decline to participate in the study or withdraw from the study at any time during the study, which will not affect your relationship with the doctor and will not affect your medical or other benefits.

Your physician will promptly notify you if an important subject-related event or information occurs during the course of the study that may affect your willingness to continue participating in

the study.

XI. What should I do now?

Participation in this clinical study is based on a completely voluntary principle and needs to be carried out with your consent and signed informed consent. Whether or not you participate in this clinical study depends entirely on your wishes. You have the right to suspend and withdraw from this research treatment at any time. Exiting this study will not affect your medical treatment.

Your physician may suspend your participation in this study in advance if: Your health condition is not suitable for continued participation, or you may not comply with the research program requirements.

The doctor will promptly notify you or your legal representative if there is medical information that may affect your willingness to continue your research during the study. Before you decide to participate in this study, please ask your life as much as possible until you fully understand this test study.

If you have any questions, suggestions or complaints about this study, please do not hesitate to discuss them with the research team, whose contact details can be found on the signature page. If you feel inconvenienced to communicate with the research team, you can consult or complain to the Medical Ethics Committee of the Second Affiliated Hospital of Yunnan University of Traditional Chinese Medicine. Ethics Committee contact number:15125208547.

Thank you for reading the above material. If you decide to take part in this study, please let your doctor know and he/she will make all the arrangements for you to study.

Informed Consent

Signature Page

1. I have carefully read the contents of the informed consent form, and the researchers have answered my questions.

2. Having fully understood the purpose, methods, possible therapeutic benefits and risks to be encountered and other terms of this clinical study as mentioned in the informed consent form, I voluntarily participate in this study and promise to cooperate fully with the investigators.

3. I understand that I can withdraw from the study at any time and I do not need any reason. The medical services I receive and the legal rights I enjoy are not affected at all.

Finally, I decided to agree to participate in this study and to ensure compliance with my doctor's advice.

Subject Signature: _____ Date: _____

Contact Number: _____

I have explained fully detail to the subjects, including the potential risks.

Doctor/Researcher Signature: _____ Date: _____

Contact Number: _____

知情同意书

告知页

项目名称：巨刺后溪穴结合主动运动治疗急性腰扭伤即时疗效的临床研究

项目来源：云南省科技计划项目-云南省梁繁荣专家工作站（202305AF150072）、云南省万人计划青年拔尖人才项目（YNWR-QNBJ-2019-257）、云南省兴滇英才支持计划“刘自力名医”专项（云党人才办[2022]18 号）。

课题研究单位：云南中医药大学针灸推拿康复学院/第二附属医院

项目负责人：郭太品

亲爱的患者:

首先，感谢您对我们这项临床研究的关注！我们将邀请您参加一项“巨刺后溪穴结合主动运动治疗急性腰扭伤即时疗效的临床研究”。本研究已通过云南中医药大学第二附属医院医学伦理委员会审核，同意进行临床研究。在您决定是否参加这项研究之前，请尽可能仔细阅读以下内容。它可以帮助您了解该项研究以及为何要进行这项研究，研究的程序和期限，参加研究后可能给您带来的益处、风险和不适。如果您愿意，您也可以和您的亲属、朋友一起讨论，或者请医生给予解释，帮助您做出决定。

研究介绍

一、研究背景和目的

1. 研究背景

急性腰扭伤是一种常见的临床疾病，主要表现为持续性难以忍受的腰痛和活动受限。这不仅严重影响了患者的劳动能力，也极大的干扰了他们的日常生活。在某些情况下，患者还可能完全丧失工作和日常活动能力。针灸作为中医的特色疗法，在治疗疼痛类疾病方面已被普遍认可。巨刺法为取穴与病侧左右相反的健侧穴位针刺的一种方法，自《黄帝内经》时期就被广泛应用于单侧疼痛类疾病，并在临床实践中展现出显著的疗效，一些研究甚至表明，巨刺法在治疗单侧疾病时的疗效可能优于同侧针灸。急性腰扭伤通常表现为单侧疼痛，是巨刺法左右取穴治疗的适用病种。此外，运动是治疗急性活动障碍的一种常用的辅助疗法，有助于减轻疼痛、改善或恢复功能活动。研究发现，将针灸与积极运动相结合可迅速缓解 ALS 患者的疼痛并改善腰椎功能，但存在样本量小、盲法不足等局限性。还需要进一步的研究来证实这种综合疗法对 ALS 的即时效果。

2. 研究目的

这项研究的目的是评估对侧针刺后溪穴结合主动运动治疗急性腰扭伤 10 分钟内的即时疗效。

3. 研究预计纳入参试者例数

本研究预计纳入 118 例急性腰扭伤患者。

二、哪些人能参加这项研究？

（1）符合中国医学会发布的《临床诊疗指南：骨科分册》中急性腰扭伤的诊断标准；

（2）单侧腰痛，年龄 18-55 岁，男女不限；

（3）病程≤3 天；

（4）腰痛的严重程度为中至重度（VAS4-8 分）；

（5）签署知情同意书，自愿参加本项研究者。

三、哪些人不宜参加本研究

（1）合并腰椎滑脱症、结核、肿瘤、骨折或脊柱病变；

（2）由于各种泌尿系统疾病、妇科疾病、急慢性感染引起的腰痛；

（3）合并有严重心血管、脑血管、肝脏、肾脏、造血系统等疾病；

（4）合并严重精神疾病或智力障碍，无法完成问卷的患者；

（5）处于哺乳期或怀孕期的患者；

（6）在过去 6 小时内使用过其他止痛方法的患者。

四、如果参加研究将要做什么？

1. 在您入选研究前：

医生将询问并记录您的病史、临床症状和体征；医生还将指导您填写腰痛发作强度视觉模拟量表评分，并测量您的腰部活动范围评分，以确定您是否符合纳入的标准。

2. 若您通过以上筛查符合纳入标准，将按以下步骤进行研究

（1）试验将分为 2 组。在研究开始时，你的医生将根据电脑提供的随机数决定你将接受哪一组。

（2）根据您的分组信息，您将接受相应的针灸治疗，治疗时间为 10 分钟。在留针期间，您需要进行适度的腰部运动，并配合我们采集数据。

3. 需要您配合的其他事项

在治疗过程中，您需要配合医生完成相关量表填写，如实回答医生提问的问题，配合医生，对您病情进行反馈。

五、参加研究可能的受益

您可能会在本项研究中获益。这些好处包括您的病情有望改善，以及接受关于预防急性腰扭伤的健康教育。

六、参加研究可能的不良反应、风险和不适、不方便

针刺过程中您可能会有酸、麻、重、胀的感觉，这均为针刺的正常反应。针刺后可能存在不良反应，但较少而轻微，针刺时可能因为您的体质问题或情绪紧张出现晕针现象，停止针刺和适当休息后可缓解；针刺后可能出现出血、血肿等现象，经局部按压后可消失；但如果针刺部位出现感染，您的医生会及时处理。

如果在研究期间您出现任何不适，或病情发生新的变化，或任何意外情况，不管是否与针刺治疗有关，均应及时通知您的医生，他/她将对此作出判断并给与适当的医疗处理。

七、除参加本研究外，您可选的其他治疗

您的医生将与您讨论目前针对您的病情可选择的其他治疗方案，包括相应的风险和益处。针对急性腰扭伤的患者，目前可以选择非甾体类抗炎药（NSAIDS）为主的消炎镇痛药进行治疗，作用效果较好，主要存在胃肠道出血、胃溃疡、脑血管意外等副作用。

八、有关费用

本课题所有费用由云南省科技计划项目-云南省梁繁荣专家工作站（202305AF150072）、云南省万人计划青年拔尖人才项目（YNWR-QNBJ-2019-257）、云南省兴滇英才支持计划“刘自力名医”专项（云党人才办[2022]18 号）项目资助。如您参见本研究，在研究期间，将得到相关免费针刺治疗。本研究仅观察治疗一次的疗效，如疗效缓解不明显，可免费做 2 次针刺治疗。医生将尽全力预防和治疗由于本研究可能带来的伤害。如果在临床试验中出现不良事件，医学专家委员会将会鉴定其是否与针刺治疗或研究过程有关。申办者将按照我国《药物临床试验质量管理规范》的规定对与试验过程中相关的损害提供治疗的费用及相应的经济

补偿。

在治疗期间，如果您同时合并其他疾病所需的治疗和检查，将不在免费的范围之内。

九、个人信息是保密的吗？

您的医疗记录（研究病历/CRF 等）将完整地保存在您所就诊的医院。研究者、伦理委员会和药品监督管理部门将被允许查阅您的医疗记录。任何有关本项研究结果的公开报告将不会披露您的个人身份。我们将在法律允许的范围内，尽一切努力保护您个人医疗资料的隐私。

十、可以自愿选择参加研究和中途退出研究

是否参加研究完全取决于您的意愿。您可以拒绝参加此项研究，或在研究过程中的任何时间退出本研究，这都不会影响您和医生间的关系，都不会影响您的医疗待遇与权益，或有其他方面利益的损失。

研究过程中如果发生与受试者相关的重要事件或信息，可能会影响您继续参加研究的意愿时，您的医生将及时通知您。

十一、怎样获得更多的信息？

参加本项临床研究，本着完全自愿的原则，需要在您同意并签署知情同意书的前提下进行。是否参加本项临床研究，完全取决于您本人的意愿，您有权在任何时候选择中止和退出本项研究性治疗，退出本研究并不会影响您的医疗待遇。

您的医师可以在下列情况下提前中止您继续参加本项研究：您的健康状况不适合继续参加，或者您不能遵守研究方案的要求。

如在研究过程中出现可能影响您继续参加研究意愿的医学信息，医生将及时通知您或者您的法定代表。在您做出参加本研究的决定前，请尽可能向您的医生询问有关问题，直至您对本项试验研究完全理解。

如您对这项研究存在任何疑问、建议或投诉，请及时与研究团队讨论，联系方式见签字页。如您感觉不便与研究团队沟通，可向云南中医药大学第二附属医院医学伦理委员会进行咨询或投诉。伦理委员会联系电话:13888244951。

感谢您阅读以上材料。如果您决定参加本项研究，请告诉您的医生，他/她会为您安排切有关研究的事务。

知情同意书

签字页

1. 我已经仔细阅读了知情同意书告知页的内容，研究者已解答了我提出的疑问。

2. 我在充分理解了知情同意书提及的本项临床研究的目的、方法、可能获得的治疗利益和可能遇到的风险以及其他条款后，自愿参加此项研究，并承诺与研究者充分合作。

3. 我明白我可在任何时候退出研究，并且不需要任何理由，我得到的医疗服务和享有的法律权利不受任何影响。

最后，我决定同意参加本项研究，并保证遵从医嘱。

受试者签名:_____　　日期：_____年_____月_____

联系电话:_____

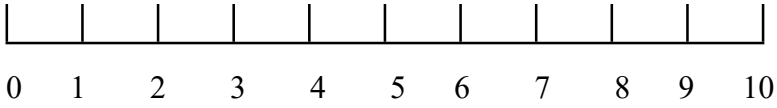
我确认已向患者解释了本研究的详细情况，包括其权力及可能的受益和风险。

医生/研究者签名:_____　　日期：_____年_____月_____

联系电话:_____

Supplementary Material 3 Visual analogue scale

Use a 10cm VAS scale with a moving scale between 0 and 10 on the front and a number from 0 to 10 on the back, with 0 being no pain and 10 being the most painful. Please state your pain level according to the following scale.



VAS scale (0-10 points)

0: no pain;1-3:light pain; 4-6:moderate pain; 7-10:severe and unbearable pain.

Projects	Before treatment	Treatment				
	0min	2min	4min	6min	8min	10min
Pain VAS score						

Supplementary Material 4 Range of motion

This will be quantified using a 5-point Likert scale. A score of 0 is given when the participant can bend forward freely and touch the floor with the fingertips. A score of 1 is given if the participant can bend sufficiently to touch the knees with the hands. Bending beyond 70 degrees scores 2 points. A slight bend is worth 3 points. If the participant is completely unable to bend forward, they receive 4 points. If the lumbar spine is unable to bend forwards, but instead shows reverse extension, this is scored 5.

Projects	Before treatment	Treatment				
	0min	2min	4min	6min	8min	10min
ROM score						

Supplementary Material 5 Treatment expectations scale

What do you think of the results of your treatment?	Efficiently☐ Inefficiently☐
How sure are you on your answer on a scale of 0 to 10? (0 = very uncertain and 10 = completely certain)	————————————

Supplementary Material 6 Blinding questionnaire

Do you think you were given acupuncture treatment or placebo acupuncture?	Yes☐ No☐
How sure are you on your answer on a scale of 0 to 10? (0 = very uncertain and 10 = completely certain)	_____

Supplementary Material 7 Remedial analgesia

Do you take pain medication after treatment?	Yes☐ No☐