

BMJ Open Acupuncture for chronic sciatica: protocol for a multicenter randomised controlled trial

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ABSTRACT

Background Chronic Sciatica is a disabling condition causing considerable medical, social and financial implications. Currently, there is no recognised long-term effective treatment to alleviate sciatica. Acupuncture has been widely used for treating chronic pains with persistent analgesic effects. We aim to evaluate the efficacy and safety of acupuncture for chronic sciatica with follow-up in 52 weeks.

Methods and analysis This is a multicenter randomised sham-controlled trial. A total of 216 patients with chronic sciatica will be enrolled and randomly assigned to the acupuncture or sham acupuncture group. There will be 10 treatment sessions applied in 4 weeks with frequency decreased over time. Patients will complete follow-ups during 52 weeks. The primary outcomes are changes in leg pain intensity and disability from baseline to week 4. Secondary outcomes include back pain intensity, frequency and bothersomeness, quality of life, and global perceived effect. Adverse events will be recorded in detail.

Ethics and dissemination Ethical approval of this trial was granted from the ethics committee of Beijing University of Chinese Medicine and all study centres (No. 2020BZYLL0803). Written informed consent will be obtained from enrolled patients. Trial results will be disseminated in peer-reviewed publications.

Trial registration number ChiCTR2100044585 (Chinese Clinical Trial Registry, <http://www.chictr.org.cn>, registered on 24 March 2021); preregulated.

INTRODUCTION

Sciatica is characterised as pain radiating along the course of the sciatic nerve and sometimes associated with low back pain and corresponding motor or sensory disturbances.¹ Disc herniation with compression to the lumbosacral nerve root and resultant inflammation is able to interpret 85% of the occurrence for sciatica.² The prevalence of sciatica ranges from 1.2% to 43% between studies with more than 187 million patients who are affected globally.^{3,4} Compared with

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first multicenter randomised controlled trial evaluating the efficacy of acupuncture for chronic sciatica (more than 3 months' duration) with adequate power and good methodology.
- ⇒ Combined invasive and non-invasive approaches using blunt-tipped and conventional needles with adhesive foam pads will be performed for sham acupuncture treatment to promote blinding.
- ⇒ Primary outcomes of pain and disability will be assessed rely on patients' self-reports due to a lack of recognised and appropriate objective measurements.

low back pain, which is the primary cause of disability worldwide, sciatica results in greater pain and disability, poorer prognosis and consumes more health resources.^{5,6}

Pain medications of paracetamol, non-steroidal anti-inflammatory drugs and opioids are commonly prescribed while inconclusive recommendations exist in clinical guidelines considering the uncertain benefits and high rates of adverse effects.^{7–9} With few harms reported, conservative non-pharmacological treatments (eg, exercise and spinal manipulations) are more acceptable. However, evidence about their efficacies is insufficient to draw definite conclusions.¹⁰ Based on observational studies, nearly 30%–45% of patients in primary care failed to achieve a meaningful improvement after 1 year.^{3,11} Patients with chronic sciatica may choose to undergo epidural steroid injection or surgery. Although it was suggested that both treatments could relieve symptoms of sciatica, a proportion of patients may hesitate about the potential risks and complications.^{12,13} For most of the present treatments, long-term

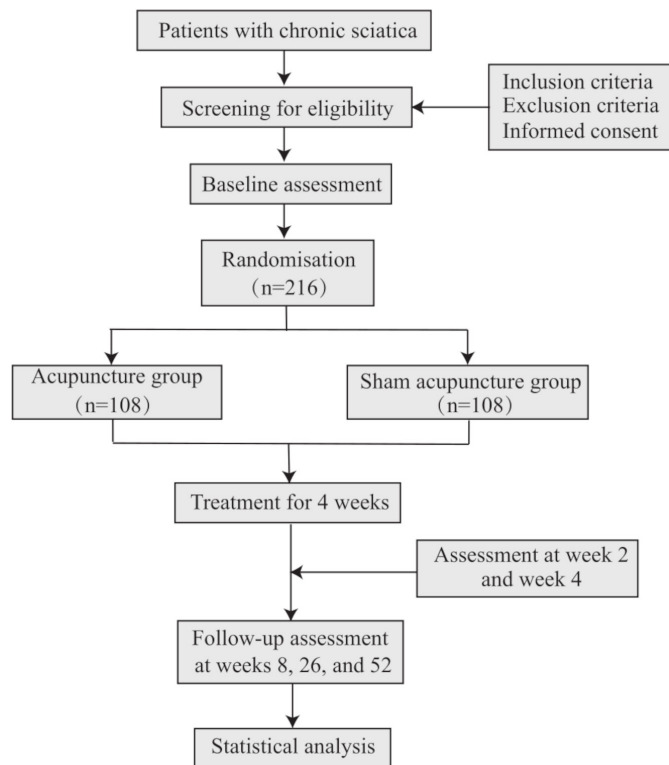


Figure 1 Flow diagram of the trial procedure.

benefits are controversial, which makes it challenging to manage chronic sciatica.

Acupuncture was found to have persistent analgesic effects for some chronic pains (headache, musculoskeletal and osteoarthritis pain), which decreased only 15% after 1 year.¹⁴ It has been recommended for treating chronic low back pain by the American Pain Society and the American College of Physicians.^{9 15} Meta-analyses suggested that acupuncture might be efficacious for chronic sciatica, while the evidence is limited reflecting a lack of high-quality researches.^{16–19} We therefore design this multicenter randomised controlled trial to evaluate the efficacy and safety of acupuncture for chronic sciatica, and to explore a possible long-term effect through follow-up to 52 weeks.

METHODS/DESIGN

Trial design and setting

This is a multicenter, parallel-group, randomised, sham-controlled trial containing treatments for 4 weeks and follow-up to 52 weeks. The procedure of the trial is shown in figure 1. The trial will be conducted at six hospitals in China including: (1) Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine, (2) Guang'an Men's Hospital, China Academy of Chinese Medical Sciences, (3) Peking University Third Hospital, (4) Affiliated Hospital of Nanjing University of Chinese Medicine, (5) Union Hospital, Tongji Medical College, Huazhong University of Science and Technology and (6) Shenzhen Hospital of Beijing University of Chinese Medicine. This

protocol is reported following the Standard Protocol Items: Recommendations for Interventional Trials.²⁰

Patients

In this trial, patients with chronic sciatica will be recruited through advertisements on posters, newspapers and WeChat. Study doctors will make the diagnoses on the basis of symptoms, physical examinations and imaging findings.⁵ To promote the recruitment, relevant clinical tests and treatments will be offered free for candidates. Written informed consent will be obtained from eligible patients before randomisation.

Inclusion criteria

Patients will be considered for enrolment if they meet the criteria of: (1) aged 18 or older, (2) having unilateral radiating leg pain below the knee for more than 3 months, accompanied by positive straight-leg raise test or corresponding neurological deficit (paraesthesia, muscle weakness or reflex abnormalities) with MRI or CT confirmed disk herniation, (3) leg pain intensity on the visual analogue scale (VAS) of 40 mm or higher (0–100 mm).²¹

Exclusion criteria

Exclusion criteria include that: (1) sciatica induced by other diseases than lumbar disc herniation, (2) having severe spinal disease or severe progressive neurological symptoms, (3) having cardiovascular, liver, kidney or haematopoietic system diseases, mental health disorders or other severe coexisting diseases, (4) pregnant or lactating women or those planning to conceive during the trial, (5) taking drugs that have a therapeutic effect on sciatica, (6) having had lumbar disc surgery within the past 1 year, (7) planning to receive surgery or interventional treatment during the treatment period and (8) having received acupuncture for sciatica within the past 1 year.

Randomisation and blinding

Eligible patients will be randomly assigned to receive either acupuncture or sham acupuncture treatment in a 1:1 ratio. A randomisation sequence, which is stratified by centres with variable block size, will be generated by an independent statistician using SAS, V.9.4 (SAS Institute). Responsible researchers (acupuncturists or their assistants) in each centre will complete the allocation procedure by using a randomization module of the Research Electronic Data Capture (REDCap) site, which is invisible to outcome assessors.²² After entering the name and code for a patient, researchers will obtain the specific result of the assignment to ensure concealment. Patients, outcome assessors and statisticians will be blinded to the allocation.

Intervention

Acupuncture or sham acupuncture will be performed by licensed acupuncturists with at least 3 years of treatment experience. There will be 10 sessions of treatment over 4 weeks with treatment frequency decreased from

Table 1 Details of acupuncture and sham acupuncture treatment

Group	Syndrome	Treatment points	De qi sensation
Acupuncture group	Shaoyang meridian syndrome	Bilateral BL25, and BL26, unilateral GB30, GB31, GB33, GB34, and GB39	Yes
	Taiyang meridian syndrome	Bilateral BL25, and BL26, unilateral BL36, BL40, BL54, BL57, and BL60	
	Mixed meridian syndrome	Bilateral BL25, and BL26, unilateral 5 acupoints of the 10 adjunctive acupoints	
Sham acupuncture group	None	Bilateral NA1, and NA2, unilateral NA3, NA4, NA5, NA6, and NA7	No

BL, bladder meridian; GB, gallbladder meridian; NA, non-acupoint.

3 sessions per week in the first 2 weeks to 2 sessions per week in the remaining weeks. Treatment offered in this trial is developed by experts and refer to our pilot study.²³ Report of the intervention is following the Standards for Reporting Interventions in Clinical Trials of Acupuncture guidelines with details shown in [table 1](#) and [figure 2](#).²⁴ Celebrex (Pfizer Pharmaceutical) may be prescribed for those with unbearable pain as rescue medicine, based on their needs. Additional treatment for sciatica will not be supported during the trial period.

Acupuncture group

Semistandardised acupuncture treatment will be provided with bilateral BL25 and BL26 in the lower back treated as obligatory acupoints. According to the Traditional Chinese Medicine theory, sciatica is associated with the disorder of Shaoyang meridian (the gallbladder meridian) and Taiyang meridian (the bladder meridian) for most cases which distribute similar to the dermatomes and myotomes that related to the sciatic nerve. Patients with pain in the lateral side will be diagnosed as Shaoyang meridian syndrome, and those with pain in the posterior side will be diagnosed as Taiyang meridian syndrome. Based on the specific syndrome, five unilateral acupoints will be treated as adjunct acupoints. For patients with Shaoyang meridian syndrome, GB30, GB31, GB33, GB34 and GB39 will be needled. Patients with Taiyang meridian syndrome will be treated with BL36, BL40, BL54, BL57 and BL60. Adjunct acupoints for patients having mixed meridian syndrome, characterised as pain in both lateral and posterior sides, will be chosen by acupuncturists from the above 10 adjunct acupoints on 2 meridians. Locations of the acupoints are in line with the WHO Standard Acupuncture Locations.²⁵

After disinfection of the surrounding skin, adhesive foam pads (10mm diameter and 5mm height) will be placed at treatment acupoints. BL25, BL26, GB30 and BL54 on the affected side will be inserted with disposable stainless steel needles of 0.30×75mm (Suzhou Huatuo Medical Instrument) to approximately 40–70mm. Twirling, lifting and thrusting manipulations will be performed for about 10s to achieve ‘de qi’ sensation (soreness, numbness, distension or heaviness), which is expected to radiate down to the affected leg. Other

acupoints will be treated with needles of 0.30×40mm with insertion to normal depths, to reach ‘de qi’ sensation locally. Needles will be retained for 30min and no intermittent manipulation will be performed during the retention time.

Sham acupuncture group

Seven non-acupoints that localised away from the relative meridians are preset for sham acupuncture treatment. The same procedure of disinfection, followed by the placement of adhesive foam pads, will be implemented. Blunt-tipped needles (0.30×25mm) will be inserted into adhesive foam pads with no penetration into the skin for most non-acupoints. We choose to use blunt-tipped needles for sham acupuncture treatment since it is more convenient for non-penetrating performance. Based on it, adhesive foam pads are used to keep the blunt-tipped needles upright over the skin, and to maintain the blinding. Considering the full use of non-penetrating needling might be easily discovered by patients, especially for those with extensive acupuncture experiences, a penetrating operation is designed for non-acupoint five with a conventional acupuncture needle inserted to 25–40mm to promote blinding. No manipulations will be performed for sham acupuncture intervention with no attempt to induce ‘de qi’ sensation. Duration and frequency of the treatment will be identical to that in the acupuncture group.

Outcomes

Primary outcomes

The primary outcomes are changes in leg pain intensity and disability from baseline to the end of treatment. We will measure the average intensity of leg pain over the previous 24 hours using VAS (0–100mm) with descriptor extremes ‘no pain at all’ and ‘my pain is as bad as it could possibly be’. Scores are determined by the distance from 0 to patients’ mark with higher scores indicating a greater intensity of pain. Disability will be measured through a 10-item Oswestry Disability Index (ODI).²⁶ The ODI plays a role in giving a subjective percentage score of function level through examining perceived disability in 10 activities of daily living including intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit,

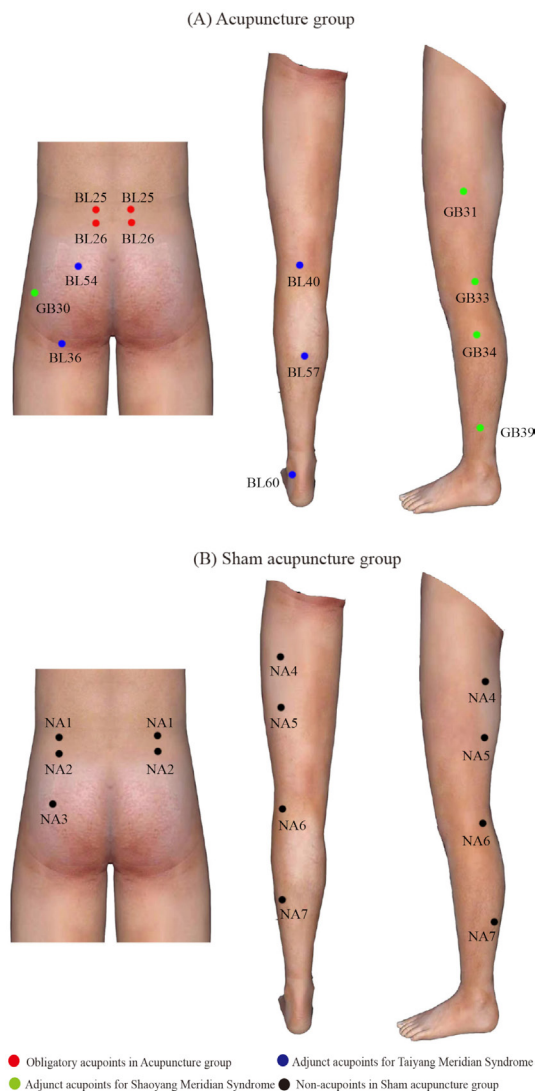


Figure 2 Locations of acupoints and non-acupoints. NA1, in the lumbar region, 2.5 cun beside BL25, in the middle of gallbladder meridian and bladder meridian; NA2, in the lumbar region, 2.5 cun beside BL26, in the middle of gallbladder meridian and bladder meridian; NA3, in the middle of BL54 and GB30 acupoints on the affected leg; NA4, 10 cun above the popliteal crease, in the middle of gallbladder meridian and bladder meridian on the affected leg; NA5, 5 cun above the popliteal crease, in the middle of gallbladder meridian and bladder meridian on the affected leg; NA6, in the middle of BL40 and GB34 acupoints on the affected leg; NA7, in the middle of BL57 and GB36 acupoints on the affected leg. BL, bladder meridian; GB, gallbladder meridian; NA, non-acupoint.

sexual function, ability to stand, social life, sleep quality and ability to travel. Each topic category is followed by six statements describing different potential scenarios in the patient's life relating to the topic. The patient then checks the statement which most closely resembles their situation. Each question is scored on a scale of 0–5 with the first statement being 0 and indicating the least amount of disability and the last statement is scored 5 indicating most severe disability. The scores for all questions answered are summed, then multiplied by two to

obtain the index (range 0–100). Zero is equated with no disability and 100 is the maximum disability possible.

Secondary outcomes

As to secondary outcomes, the Sciatica Frequency and Bothersomeness Index (SFBI) will be used to assess the frequency and bothersomeness of sciatica with scores ranging from 0 to 24, respectively.²⁷ The 36-item Short Form Health Survey (SF-36) will be used to assess the quality of life on eight aspects including physical functioning, bodily pain, role limitations due to physical health problems, personal or emotional problems, emotional well-being, social functioning, energy/fatigue, general health perceptions and a single item that indicates perceived change in health.²⁸ Scores on physical and mental components of the SF-36 will be summarised. A 7-point Likert self-rating scale with options from 'completely recovered' to 'vastly worse' will be used to evaluate the amount of improvement since the beginning.²⁹ A combined functional MRI (fMRI) will be conducted with patients in the Beijing area. The MRI scan will be conducted at baseline and at the end of the intervention in the Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University using a 3.0 Tesla super conductor (Skyra, Siemens, Erlangen, Germany). The timeline of each assessment is shown in table 2.

Other measures

All patients will be asked to guess which treatment they have received at week 2 and week 4 as blinding assessments. Before treatment, researchers will evaluate the credibility and expectancy of patients using the Credibility/Expectancy Questionnaire.³⁰ Other treatments for sciatica, including the use of rescue medicine, will be documented every 4 weeks. Researchers will identify any adverse events through patient self-reporting as well as monthly inquiries. All adverse events will be managed and recorded in time, which will be categorised based on relevance to acupuncture treatment. If a severe adverse event occurs, researchers are commanded to report it to the principal investigator and the data and safety monitor board (DSMB) within 24 hours.

Data management

Trial data will be collected and entered using web-based data collection via the REDCap platform. Independent data managers in each centre will check the database every 2 weeks to ensure the integrity. Data lockup will be implemented to prevent post modification. An independent DSMB will be established to surveil the safety.

Data availability statement

All data will be preserved for at least 5 years after publication. The principal investigator will have the access to the final trial dataset, and it is permitted for readers to access the trial data by contacting the corresponding author. Information on patients will remain anonymous including name, age and telephone number.

Table 2 Schedule of recruitment, interventions and assessments

	Baseline	Treatment period		Follow-up period		
		Week 2	Week 4	Week 8	Week 26	Week 52
Enrolment						
Screening	×					
Signed informed consent	×					
Randomisation	×					
Intervention						
Acupuncture group		←→				
Sham acupuncture group		←→				
Assessment						
Primary outcome						
VAS for leg pain	×		×			
ODI	×		×			
Secondary outcome						
VAS for leg pain		×		×	×	×
VAS for back pain	×	×	×	×	×	×
ODI		×		×	×	×
SFBI	×	×	×	×	×	×
SF-36	×		×	×	×	×
Global perceived effect			×		×	×
fMRI scan	×		×			
Other measures						
Credibility/expectancy	×					
Blinding assessment		×	×			
Additional treatment used		×	×	×	×	×
Adverse event		×	×	×	×	×

fMRI, functional MRI; ODI, Oswestry Disability Index; SF-36, 36-item Short Form Health Survey; SFBI, the Sciatica Frequency and Bothersomeness Index; VAS, visual analogue scale.

Quality control

The trial protocol has been reviewed and revised by experts in the fields of acupuncture, orthopaedics, statistics and methodology. Before initiation, all researchers will receive training of screening patients, acupuncture manipulation and data input. The trial will be monitored regularly by researchers from the Beijing University of Chinese Medicine. Any modifications of the data can be traced in the REDCap platform.

Sample size

The null hypothesis is that changes in VAS for leg pain and ODI from baseline to week 4 will be the same between the two groups. Minimal clinically important differences of VAS and ODI that within the range of published estimates were used for sample size calculation.^{31–33} SD for both variables were determined from our pilot study (unpublished data). Following a statistical power of 90% and a two-sided α level of 0.05, 32 patients in each group were calculated to detect a between-group difference of 15 mm on VAS with a SD of 18 mm. At the same statistical level, a

sample size of 86 patients in each group was required to detect a between-group difference of 7.0 points on ODI with an SD of 14 points. We increase the sample size to 216 patients (108 patients in each group) considering a dropout rate of 20%. The sample size was calculated using PASS, V.11 (NCSS, Kaysville, Utah, USA).

Statistical analysis

The statistical analyses will be performed based on the intention-to-treat principle with all randomly assigned patients included. We will use a repeated-measure linear mixed model that includes mean changes of VAS and ODI from baseline to each follow-up assessment. Similar analyses will be performed for secondary outcomes including SFBI, SF-36 and global perceived effect. Binary outcomes of blinding assessment, proportions of patients having adverse events and those receiving other treatments will be compared using the χ^2 test.

Missing data of primary outcomes will be imputed using the multiple imputation method. To address the robustness of the results, there will be a per-protocol analysis



for primary outcomes including patients who complete at least eight treatment sessions with no major violations. Two-sided *p* values of less than 0.05 will be considered statistically significant for all analyses. Statisticians who are blinded to the allocation will complete the analysis using SAS, V.9.4 (SAS Institute).

Patient and public involvement statement

Patients were not involved in the design, conduct or reporting of this trial. They will be evaluated about the availability to complete study treatment based on their time and the degree of mobility difficulty. The result of this trial will be shared with enrolled patients by email at the end, and no burden assessment will be conducted.

DISCUSSION

To our knowledge, this is the first large randomised controlled trial to investigate the efficacy of acupuncture for chronic sciatica during 52 weeks. We design this trial that meeting methodological demands of adequate power, allocation concealment and necessary blinding, following the Good Clinical Practice guideline.³⁴ The study intervention is consistent with a recent expert consensus which indicated that the most common acupoints used for sciatica are along the gallbladder and the bladder meridians.³⁵

The study has some limitations. First, due to the nature of acupuncture manipulation, acupuncturists in this trial cannot be blinded. To reduce the impact, we provide detailed training to acupuncturists including standardised communication with patients. Second, we set 10 sessions of acupuncture treatment with 7 acupoints used in this study although evidence suggested that there might be an enhanced effect that associated with an increase of acupoints or treatment sessions.³⁶ Thirdly, the primary outcomes of VAS and ODI are assessed based on patients' self-report since there is a lack of objective evaluation methods for pain and disability, which are core components of sciatica. As two of the most common methods, the VAS and ODI have good validity and reproducibility recommended by guidelines.⁸

Acupuncture has been widely used for treating pains.³⁷ The analgesia of acupuncture is essentially a manifestation of integrative processes at different levels in the central nervous system between afferent impulses from pain regions and impulses from acupoints.³⁸ Diverse signal molecules such as opioid peptides, glutamate, 5-hydroxytryptamine and cholecystokinin octapeptide were identified to contribute to mediating acupuncture analgesia.^{39 40} Functional and structure MRI trials indicated that acupuncture could modulate brain systems to produce analgesic effects.⁴¹ To further explore the potential cerebral mechanism of acupuncture for treating chronic sciatica, for instance, the changes of brain activity patterns and their correlation to clinical outcomes, an fMRI scan procedure will be performed with results reported separately.

Recruitment of this trial started on 28 March 2021, and has been completed on 23 September 2021. The last follow-up assessment is planned to be finished in September 2022. Results of this study are expected to provide reliable evidence to reflect the efficacy of acupuncture on chronic sciatica.

ETHICS AND DISSEMINATION

The trial protocol (V.2.0, 30 November 2020) is following the principles of the Declaration of Helsinki, and has been approved by ethic committees of the Beijing University of Chinese Medicine and all study centres (No. 2020BZYLL0803). It was registered in March 2021 at the Chinese Clinical Trial Registry. Any modifications to the protocol will be reported. Study doctors are trained to introduce the information of the trial to eligible patients and will obtain written informed consent from patients who are willing to participate. Trial results will be published in peer-reviewed journals and will be disseminated to the media and the general public.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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