Efficacy of Acupuncture for Sciatica: Study Protocol for A Randomized Controlled Pilot Trial.

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Study protocol

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Abstract

Background: Acupuncture is widely used for pain diseases while evidence of its efficacy for sciatica is insufficient. This pilot study aims to investigate the feasibility and efficacy of acupuncture for sciatica induced by lumbar disc herniation.

Methods: This is a multicenter, three-arm, patient-assessor-blinded randomized controlled pilot trial. 90 patients will be assigned randomly into 3 groups including disease-affected meridians (DAM) group, non-affected meridians (NAM) group, and sham acupuncture (SA) group in a 1:1:1 ratio. The trial involves a 4-week treatment along with follow-up for 22 weeks. The primary outcome is the change of leg pain intensity measured by the Visual-Analogue Scale (VAS) from baseline to week 4 after randomization. Secondary outcomes include functional status, back pain intensity, and quality of life. Adverse events will also be recorded.

Discussion: This pilot study will investigate the feasibility and efficacy of acupuncture for patients with sciatica. The results of the study will help improve a better design and establish a power calculation for a full-scale study.

Trial registration: ChiCTR2000030680 (Chinese Clinical Trial Registry, http://www.chictr.org.cn, registered on 9th March 2020).

Background

Sciatica is characterized by radiating leg pain along the course of the sciatic nerve sometimes accompanied by back pain and neurological deficits [1]. The prevalence ranges from 1.2–43% globally based on controversial definitions [2]. Lumbar disc herniation is the leading cause of 85% of patients with sciatica [3]. Sciatica affects daily life and productivity, consumes more health resources when compared to low back pain [4].

Conservative treatments are the first-line options for sciatica [5, 6]. Medicine and epidural steroid injection are commonly used although long-term benefits are uncertain and side effects (e.g., headache and dizziness) or complications (e.g., epidural hematoma) occur sometimes [7–9]. Most pain and related disabilities could resolve in weeks [5], but up to 30% of patients were reported with pain lasting for 1 year or longer [10]. Therefore, long-term effective and safe conservative treatments might be potential solutions.

Acupuncture has been widely used for pain diseases. Meta-analysis indicated that acupuncture had a persistent effect on 4 chronic pains which decreased only 15% after 1 year [11]. The American College of Physicians has recommended acupuncture for chronic low back pain [12]. However, only a few meta-analyses exist supporting its efficacy for sciatica that well-designed randomized controlled trials (RCTs) are urgently needed [13, 14]. As a pilot study, we aim to investigate the feasibility and efficacy of acupuncture for sciatica induced by lumbar disc herniation. Different acupoint selections will also be

conducted considering that sciatica distributes similar to meridian courses. The hypothesis is that acupuncture on affected meridians might have better effects. This pilot study is expected to provide reliable data for further study.

Methods/design

Study Design

The detailed study process is illustrated in Fig. 1. We design this multicenter, parallel-group, patient-assessor blinded RCT following the Consolidated Standards of Reporting Trials (CONSORT) and the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines [15, 16]. The trial will be conducted in 4 hospitals in China, including Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine; Guang'anmen Hospital, China Academy of Chinese Medical Sciences; Affiliated Hospital of Nanjing University of Chinese Medicine and Peking University Third Hospital. The Research Ethics Committee of Beijing University of Chinese Medicine has approved the study protocol (version 2.0, 13 January 2020) with an approval number of 2020BZHYLL0105. It was registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn) on 9th March 2020 with the registration number of ChiCTR2000030680. The protocol is reported in accordance with the Standard Protocol Items (SPIRIT) (Additional file 1).

Patients

Eligible patients will be recruited from outpatient clinics through advertisements on posters and WeChat. Sciatica is defined in this trial as unilateral radiating leg pain with positive straight-leg raise test or at least one neurological deficit symptoms as paraesthesia, muscle weakness, or reflex abnormalities. Imaging evidence of lumbar disc herniation is requested on either magnetic resonance imaging (MRI) or computed tomography (CT). Eligibility criteria include (1) age between 18 and 70 years; (2) symptoms persist over 1 week from the onset; (3) leg pain intensity over 40 mm measured by VAS [17].

Patients will be excluded if they meet any of the following criteria : (1) patients who have or are suspected to have severe spinal disease (e.g., cauda equina syndrome) or progressive neurological symptoms (e.g., progressive muscle weakness); (2) patients with sciatica caused by other conditions than lumbar disc herniation; (3) patients who have undergone surgery for lumbar disc herniation within the past 6 months; (4) patients who plan to have spinal surgery or other interventional therapies during the first 4 weeks of the trial; (5) patients continually taking antiepileptic medication, antidepressant medication, opioids or corticosteroids; (6) patients who have cardiovascular, liver, kidney, or hematopoietic system diseases, mental health disorders, or other severe coexisting diseases (e.g., cancer); (7) patients who are pregnant, breastfeeding, or planning to conceive during the trial; (8) patients who received acupuncture therapy within the past 1 year.

Randomization

Randomization will be conducted by the central block randomization method using IBM SPSS Statistics, version 21.0 (International Business Machines Corporation, China). Eligible patients will be assigned randomly into the DAM group, NAM group, or SA group in a 1:1:1 ratio. An independent researcher will implement the allocation schedule through a centralized telephone randomization procedure. Before randomization, trial information will be provided to each eligible patient. Written informed consent will be requested subsequently.

Blinding

Patients, outcome assessors and statistician will be blinded to the assignment. Differences between groups present mainly at point selections and acupuncture performance. Blunt-tipped needles for blinding will be similar to conventional needles. Adhesive foam pads will be put on treating points to cover the difference in acupuncture performance (Fig. 2).

Interventions

All patients will receive advice for managing sciatica in daily life such as remaining active, using a hard bed, or losing weight. Based on the assignment, they will receive 12 sessions of 30-min treatments over 4 weeks (ideally 3 times a week with an interval of 1 or 2 days). Acupoints are predefined based on experienced acupuncturists' consensus and literature review [18]. Locations of acupoints are all according to the WHO Standard Acupuncture Locations shown in Table 1, Table 2, and Fig. 3 [19]. Patients could ask for Celebrex (Pfizer Pharmaceutical Co., Ltd) from researchers with guidance and the use will be recorded in detail. To promote recruitment as well as compliance, all treatment during the study will be offered freely.

Table 1
Location of acupoints in DAM group

Acupoints	Location
Dachangshu (BL25)	In the lumbar region, at the same level as the inferior border of the spinous process of the fourth lumbar vertebra (L4), 1.5 cun lateral to the posterior median line.
Guanyuanshu (BL26)	In the lumbar region, at the same level as the inferior border of the spinous process of the fifth lumbar vertebra (L5), 1.5 cun lateral to the posterior median line
Huantiao (GB30)	In the buttock region, at the junction of the lateral one third and medial two thirds of the line connecting the prominence of the greater trochanter with the sacral hiatus.
Fengshi (GB31)	On the lateral aspect of the thigh, in the depression posterior to the iliotibial band where the tip of the middle finger rests, when standing up with the arms hanging alongside the thigh.
Xiyangguan (GB33)	On the lateral aspect of the knee, in the depression between the biceps femoris tendon and the iliotibial band, posterior and proximal to the lateral epicondyle of the femur.
Yanglingquan (GB34)	On the fibular aspect of the leg, in the depression anterior and distal to the head of the fibula.
Xuanzhong (GB39)	On the fibular aspect of the leg, anterior to the fibula, 3 cun proximal to the prominence of the lateral malleolus.
Zhibian (BL54)	In the buttock region, at the same level as the fourth posterior sacral foramen, 3 cun lateral to the median sacral crest.
Chengfu (BL36)	In the buttock region, at the midpoint of the gluteal fold.
Weizhong (BL40)	On the posterior aspect of the knee, at the midpoint of the popliteal crease.
Chengshan (BL57)	On the posterior aspect of the leg, at the connecting point of the calcaneal tendon with the two muscle bellies of the gastrocnemius muscle.
Kunlun (BL60)	On the posterolateral aspect of the ankle, in the depression between the prominence of the lateral malleolus and the calcaneal tendon.
One “cun” is defined as the width of the interphalangeal joint of patient’s thumb.	

Table 2
Location of acupoints in NAM group

Acupoints	Location
Yaoyan (EX-B7)	In the lumbar region, at the same level as the inferior border of the spinous process of the fourth lumbar vertebra (L4), 3.5 cun lateral to the posterior median line.
Pigen (EX-B4)	In the lumbar region, at the same level as the inferior border of the spinous process of the first lumbar vertebra (L1), 3.5 cun lateral to the posterior median line.
Yinbao (LR9)	On the medial aspect of the thigh, between the gracilis and the sartorius muscles, 4 cun proximal to the base of the patella.
Ququan (LR8)	On the medial aspect of the knee, in the depression medial to the tendons of the semitendinosus and the semimembranosus muscles, at the medial end of the popliteal crease.
Ligou (LR5)	On the anteromedial aspect of the leg, at the centre of the medial border (surface) of the tibia, 5 cun proximal to the prominence of the medial malleolus.
Fuliu (KI7)	On the posteromedial aspect of the leg, anterior to the calcaneal tendon, 2 cun superior to the prominence of the medial malleolus.
Gongsun (SP4)	On the medial aspect of the foot, anteroinferior to the base of the first metatarsal bone, at the border between the red and white flesh.
One “cun” is defined as the width of the interphalangeal joint of patient’s thumb.	

DAM group

Semi-standardized treatment will be provided with acupoints on affected meridians in this group. There will be four obligatory acupoints and five adjunct acupoints. Obligatory acupoints are bilateral Dachangshu (BL25) and Guanyuanshu (BL26). Depending on the distribution of the pain, sciatica localized at the side of the affected leg will be treated with adjunct acupoints on gallbladder meridian including Huangtiao (GB30), Fengshi (GB31), Xiyangguan (GB33), Yanglingquan (GB34) and Xuanzhong (GB39). Sciatica localized at the back of the affected leg will be treated with adjunct acupoints on bladder meridian including Zhibian (BL54), Chengfu (BL36), Weizhong (BL40), Chengshan (BL57), and Kunlun (BL60). For patients with pain in both side and back, adjunct acupoints will be selected from the ten adjunct acupoints above based on the personal experiences of acupuncturists.

After strict disinfection of the skin around acupoints and acupuncturists’ hands using 75% alcohol, adhesive foam pads (10-mm diameter and 5-mm height) will be placed on all acupoints with patients in a prone position. Disposable stainless steel acupuncture needles (0.30 × 75 mm, Suzhou Huatuo Medical Instrument Co, Ltd) will be inserted in BL25 and BL26 on the affected side deeply to 40–70 mm. After

performing twirling, lifting and thrusting manipulations for about 10 seconds, patients are expected to have “de qi” sensation (a complex feeling including soreness, numbness, heaviness, distention and dull pain, etc) radiating down to the affected leg. Other acupoints will be treated with needles (0.30mm × 40/50/75 mm) inserted to normal depths to reach “de qi” sensation locally. All needles will be retained for 30 minutes.

NAM group

Nine acupoints on non-affected meridians will be used as follows: bilateral Yaoyan (EX-B7) and Pigen (EX-B4) and unilateral Yinbao (LR9), Ququan (LR8), Ligou (LR5), Fuliu (KI7) and Gongsun (SP4) on the affected leg. All acupoints will be treated by needles (0.30 × 40/50 mm) inserted into the skin with manipulations later to reach the “de qi” sensation. Other treatment settings are the same as those for the DAM group.

SA group

We select nine non-acupoints in this group with locations shown in Table 3. They are localized in the middle of the gallbladder meridian and bladder meridian as one selecting method for non-acupoints [20]. Blunt-tipped needles (0.30 × 25 mm) will be inserted only into the pad with no penetration into the skin. No “de qi” sensation is required in this group and other settings will be the same.

Table 3
Location of non-acupoints in SA group

Non-acupoints	location
NA 1 (bilateral)	In the lumbar region, 2.5 cun beside Dachangshu (BL25), in the middle of gallbladder meridian and bladder meridian.
NA 2 (bilateral)	In the lumbar region, 2.5 cun beside Guanyuanshu (BL26), in the middle of gallbladder meridian and bladder meridian.
NA 3	In the middle of Zhibian (BL54) and Huantiao (GB30) acpoints on the affected leg.
NA 4	10 cun above the popliteal crease, in the middle of gallbladder meridian and bladder meridian on the affected leg.
NA 5	5 cun above the popliteal crease, in the middle of gallbladder meridian and bladder meridian on the affected leg.
NA 6	In the middle of Weizhong (BL40) and Yanglingquan (GB34) acupoints on the affected leg.
NA 7	In the middle of Chengshan (BL57) and Waiqiu (GB36) acupoints on the affected leg.
One “cun” is defined as the width of the interphalangeal joint of patient’s thumb.	

Outcomes

The primary outcome is defined as the change of leg pain intensity on VAS from baseline to week 4 measuring pain over the prior 24 hours. The VAS presents as a 0-100 mm ruler with 0 representing no pain and 100 representing unbearable pain. The specific score will be determined by the distance from 0 to the patient's mark.

Secondary outcomes include VAS for leg pain and back pain at other time points, Oswestry Disability Index (ODI) [21], 36-item Short Form Health Survey (SF-36) [22], straight leg raise test [23], painDETECT questionnaire [24], global perceived recovery on 7-point Likert self-rating scale [25], the Credibility/Expectancy Questionnaire [26], blinding assessment and medicine use. The ODI plays a role in giving a subjective percentage score of function level for patients with low back pain through examining perceived disability in 10 activities of daily living. SF-36 is 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 as well as a single item that indicates perceived change in health. PainDETECT questionnaire is used to discern the variation of neuropathic pain as one common method. 7-point Likert self-rating scale is used to assess the recovery compared to the onset with options from "completely recovered" to "worse than ever". The Credibility/Expectancy Questionnaire is capable to assess the credibility and expectancy of patients. Maintenance of blinding will be determined by asking patients to report the group which they believe they had been assigned to. Categories and frequency of medicines use during the trial will be recorded in detail. Detailed arrangements of every outcome are shown in Fig. 4.

Adverse events will be recorded, valued, and treated timely. Continuous investigation and reexaminations will be conducted until the end of the study. The data and safety monitor board (DSMB) will judge the relationship between adverse events and acupuncture to determine subsequent participation. The occurrence ratio of adverse events will be calculated at the end of the study.

Data management

Data will be collected clearly and completely on case report forms (CRFs). All original data sources will be preserved including CRFs, informed consents, and inspection results. An independent data manager is in charge of the completed CRFs, he will be asked to input data doubly for proofreading. All data related to the trial will be saved for at least 5 years after publication. Readers will be permitted to access the original data by contacting the corresponding author. Information on patients will remain anonymous including name, age, and telephone number, etc. An independent DSMB is established to ensure the integrity of the research data. The DSMB will review the progress and decide whether a premature closure is needed or not.

Sample size

As a pilot study, we determine to use a convenience sample instead of a sample size calculation. 90 patients will be enrolled in this trial, 30 in each group. The data of this pilot trial will be applied to facilitate the calculation of the sample size for a further RCT.

Statistical analysis

Continuous variables will be described by means and standard deviations or 95% confidence intervals when following a normal distribution. If not, the data will be shown by medians and interquartile ranges. Categorical variables will be described by frequencies and percentages.

All data will be analyzed following the intention-to-treat principle primarily. A per-protocol analysis will be used for primary outcome as sensitivity analysis covering patients who complete at least 10 treatment sessions without obvious violation. Analysis of variance (ANOVA), Kruskal-Wallis H test, or chi-square test will be used to compare the equilibrium between three groups at baseline. As for outcomes, one-way repeated measures ANOVA or Kruskal-Wallis H test will be applied for continuous variables and chi-square tests or Fisher's exact test will be used for categorical variables as appropriate. Data analyses will be performed using IBM SPSS21.0 with the statistical significance of two-tailed $P < 0.05$ as exploratory.

Discussion

Acupuncture might be a potential therapy for sciatica. Two trials provided restricted evidence in favor of acupuncture that only enrolled patients with sciatica for more than 3 months [27, 28]. Generalization of the results might be limited as many patients seek acupuncture treatments at the onset. Patients with acute, sub-acute, or chronic sciatica will all be enrolled in this trial to better represent practical conditions.

The mechanism of sciatica may relate to the distortion of the nerve roots and effect of local inflammatory cytokines [1]. Acupuncture is known to exert an analgesic effect through inhibiting cytokine production and activate sympathetic nerve fibers to increase endogenous opioids in the inflammatory sites and might help treat sciatica [29, 30].

Acupoint selections might cause differences as sciatica belongs to disorders of gallbladder meridian and bladder meridian in Traditional Chinese Medicine theory. Acupoints in the DAM group are all attached to the two affected meridians while those in the NAM group are on other meridians unrelated to sciatica. The result of the comparison will help better understand the efficacy of acupuncture for sciatica.

The feasibility and efficacy of acupuncture for sciatica will be evaluated in this study. Other strengths involve that it is a multicenter study designed following the Good Clinical Practice guideline [31]. Acupoints are selected based on literature and practical experiences from experts. Our limitations include that we use a subjective primary outcome, while VAS is the commonest method for measuring pain. Based on practical conditions, acupuncturists could not be blinded in this trial but communications will be limited to minimize the impact. Outcomes of this pilot study will be used as evidence for a further RCT subsequently.

Trial status

Affected by the COVID-19 pandemic, there is no recruitment at present (protocol version 2.0,13 January 2020) which is expected to start in July 2020.

Abbreviations

DAM: disease-affected meridians, NAM: non-affected meridians; SA: sham acupuncture; RCT: randomized controlled trial; CONSORT: Consolidated Standards of Reporting Trials; STRICTA: the Standards for Reporting Interventions in Clinical Trials of Acupuncture guidelines; SPIRIT: the Standard Protocol Items; DSMB: data and safety monitor board; CRF: case report form; MRI: magnetic resonance imaging; CT: or computed tomography; VAS: Visual-Analogue Scale; ODI: Oswestry Disability Index; SF-36: 36-item Short Form Health Survey; ANOVA: Analysis of variance

Declarations

Acknowledgments

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Authors' contribution

GX Shi, CZ Liu, JL Li, and FT Yu designed and developed the trial. GX Ni, ZS Liu, and XL Meng offered administrative support. HL Zhang, XH Zhang, HY Fu, XC Zhang will in charge of recruitment and treatment. JF Tu, LQ Wang, and JW Yang provided methodological recommendations. FT Yu, GX Shi, and CZ Liu drafted and critically revised the manuscript. All authors have read and approved the final manuscript.

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Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Ethics approval and consent to participate

The Research Ethics Committee of Beijing University of Chinese Medicine has approved the study with the approval number of 2020BZHYLL0105. The methods are carried out per the Declaration of Helsinki. Informed written consent will be obtained from each patient. Any modifications to the protocol will be reported.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Figures

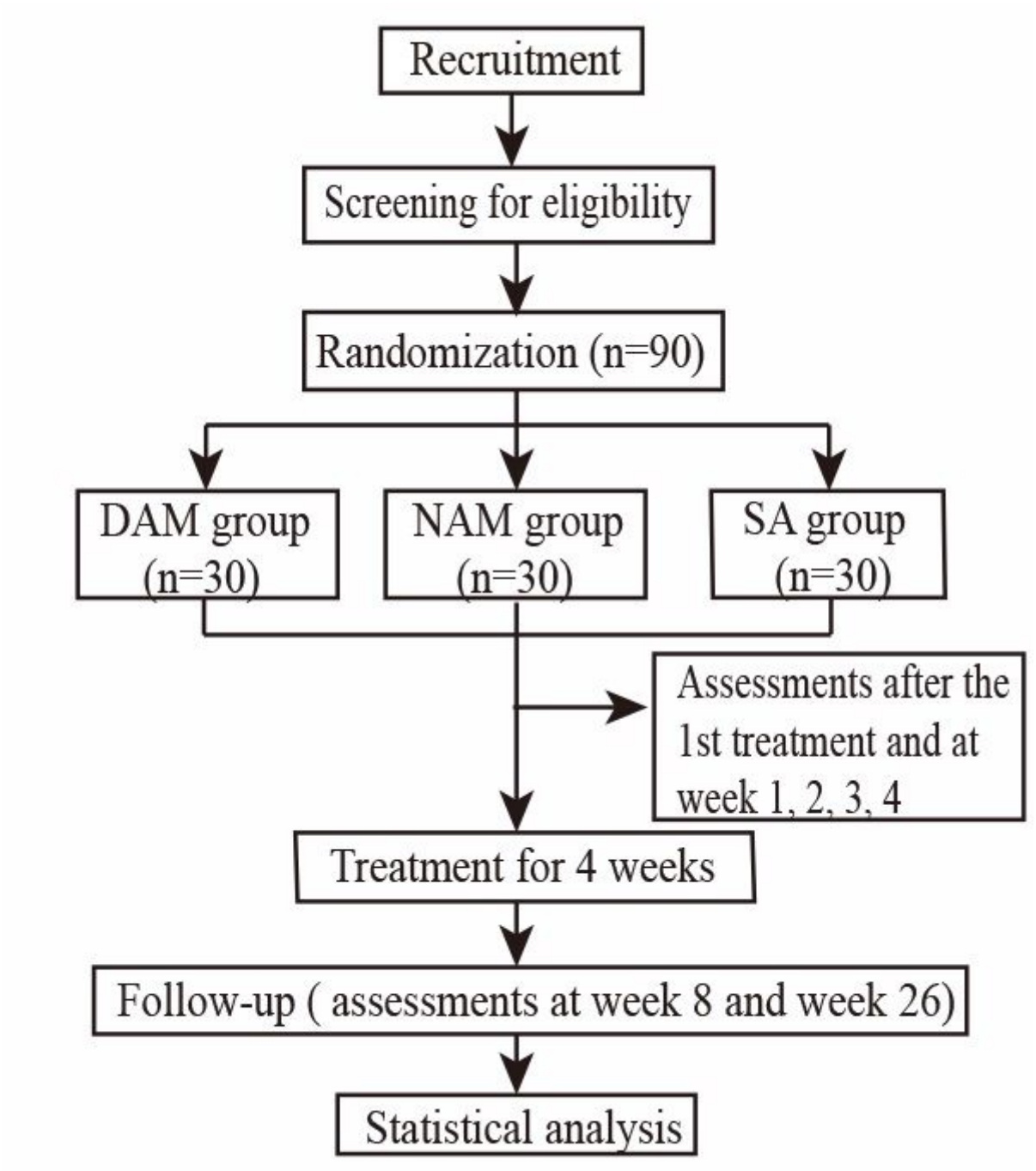

Figure 1

Flowchart of the trial procedure. DAM, disease-affected meridians; NAM, non-affected meridians; SA, sham acupuncture.

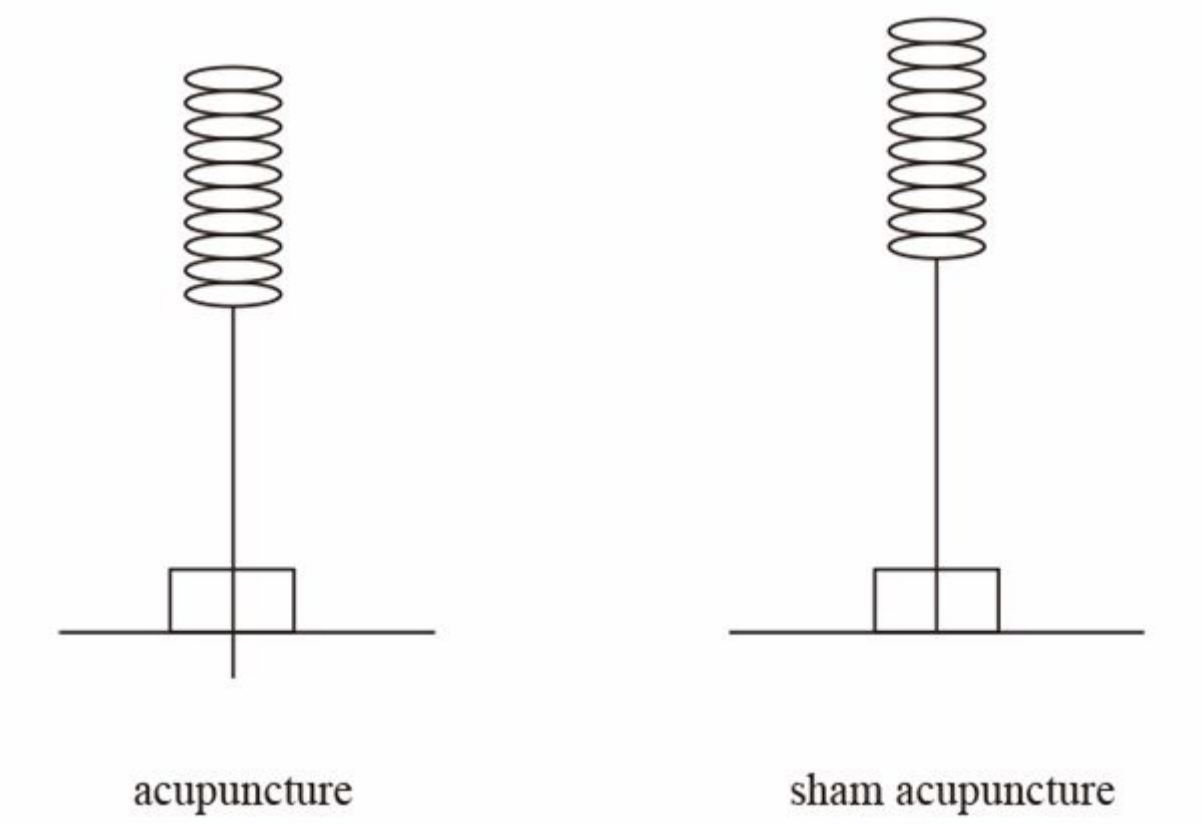

Figure 2

Schematic diagram of acupuncture and sham acupuncture.

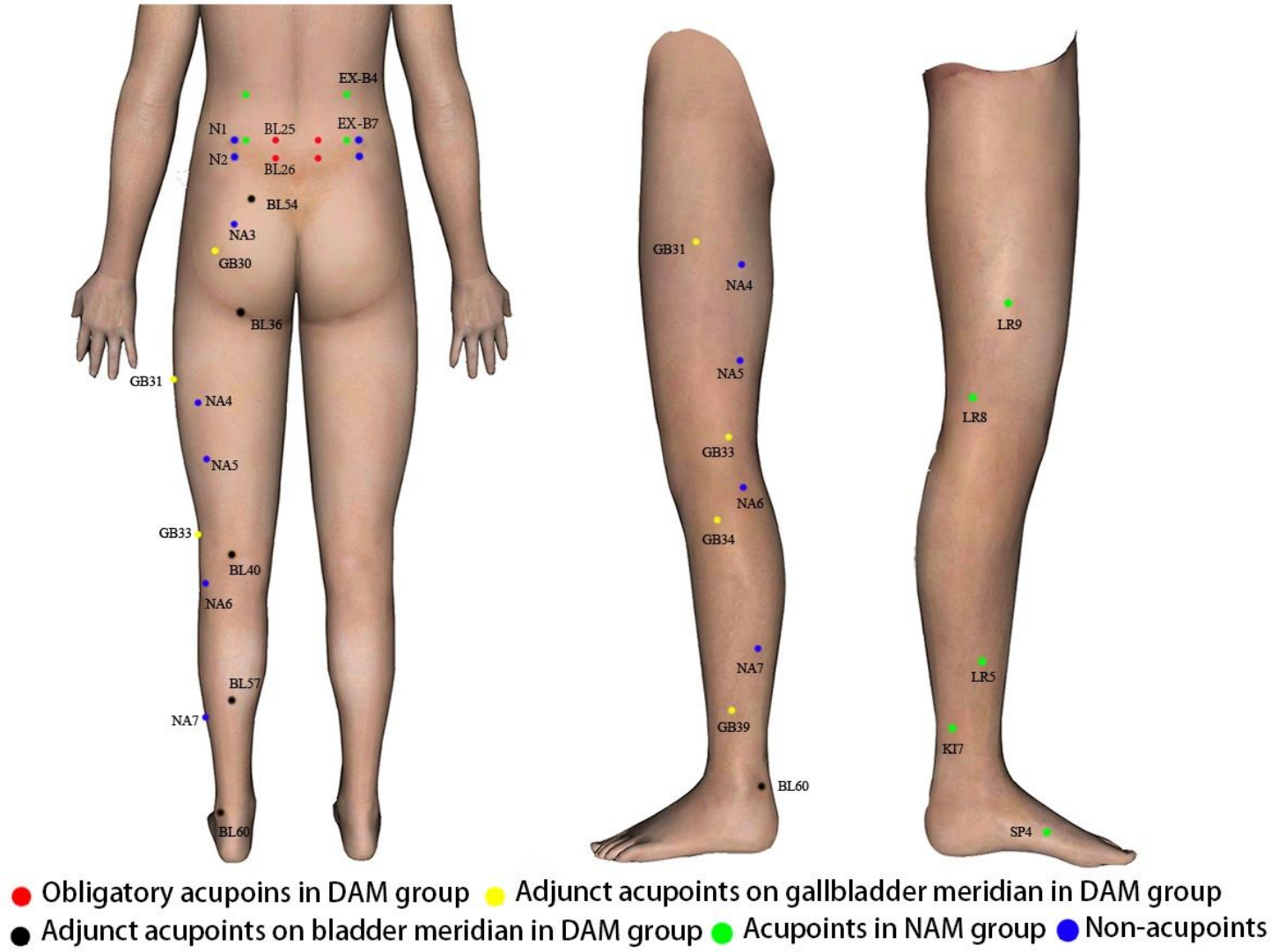

Figure 3

Locations of acupoints and non-acupoints. DAM, disease-affected meridians; NAM, non-affected meridians; SA, sham acupuncture.

	Baseline	Treatment period					Follow-up period	
		After the 1st treatment	1w	2w	3w	4w	8w	26w
Enrolment								
Screening	×							
Signed informed consent	×							
Randomization	×							
Interventions								
DAM group		⟷	⟷	⟷	⟷	⟷		
NAM group		⟷	⟷	⟷	⟷	⟷		
SA group		⟷	⟷	⟷	⟷	⟷		
Assessments								
Primary outcome								
VAS for leg pain intensity	×					×		
Secondary outcome								
VAS for leg pain intensity		×	×	×	×		×	×
ODI	×			×		×	×	×
VAS for back pain intensity	×			×		×	×	×
SF-36	×					×	×	×
Straight leg raise test	×					×		×
PainDETECT questionnaire	×					×		×
Global perceived recovery						×		×
Medicine use	×		×	×	×	×	×	×
Credibility assessment		×						
Blinding assessment				×		×		
Adverse events		×	×	×	×	×	×	×

Figure 4

Schedule of recruitment, interventions, and assessments. DAM, disease-affected meridians; NAM, non-affected meridians; SA, sham acupuncture; w, week; VAS, Visual-Analogue Scale; ODI, Oswestry Disability Index; SF-36, 36-item Short Form Health Survey.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITChecklist.doc