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Effectiveness of Deep Electroacupuncture and Shallow Electroacupuncture for Lumbar Disc Herniation: Study Protocol for A Randomized, Controlled Trial

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Abstract

Introduction: Lumbar disc herniation (LDH) is the common cause of low back pain and dysfunction. Studies have shown that electroacupuncture (EA) is effective for treating patients with lumbar disc herniation (LDH). However, there is a lack of evidence about the effectiveness of deep EA and shallow EA for patients with LDH. This study aims to evaluate the effectiveness of deep EA and shallow EA for treating LDH.

Methods and analysis: In this randomized controlled trial, patients with LDH and have low back pain with or without radiculopathy at least 12 weeks will be enrolled. Forty-four patients will be recruited at the Third affiliated hospital of Beijing University of Chinese Medicine, Beijing, China. Patients will be randomized into deep EA group or shallow EA group in a ratio of 1:1 and receive 12 sessions of EA treatment (three times a week for four weeks, 20 minutes for each session). Follow-up will last for four weeks.

Low back pain intensity and leg pain intensity (if patients have radicular pain) measured by visual analogue scale will be assessed as primary outcomes. Function (measured by Roland-Morris Disability Questionnaire), quality of life (measured by EuroQol five dimensions five-level questionnaire), patients' self-evaluation of therapeutic effect will be assessed as secondary outcomes. Patients' expectations of electroacupuncture, the success of the blinding method, and safety evaluation will also be evaluated. Statistical analysis will be followed by the intention-to-treat principle.

Ethics and dissemination: This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06). Study results will be disseminated through an open-access journal.

Trial registration: ChiCTR-1900026518.

Strengths and limitations of this study

- ► This study will provide evidence to clinical practice about the effectiveness of deep electroacupuncture and shallow electroacupuncture.
- ► It is not easy for patients to distinguish which group they are in because patients all receive electric stimulation.
- ► The main limitation of this study is the inability to blind the acupuncturist.

Keywords

Electroacupuncture, lumbar disc herniation, low back pain, randomized controlled trial

Abbreviations

Lumbar disc herniation (LDH)

Electroacupuncture (EA)

Visual analogue scale (VAS)

Roland-Morris Disability Questionnaire (RMDQ)

EuroQol five dimensions five-level questionnaire (EQ-5D-5L)

Case report form (CRF)

Background

Low back pain is the second symptom-related reason for patients to visit a physician [1]. Approximately 10% of patients with low back pain have disc disorder [2]. Patients with lumbar disc herniation (LDH) are common to have a recurrence of low back pain, and the pain often recovers slower compared with nonspecific low back pain [1, 2]. Nonpharmacological interventions (acupuncture, massage, yoga, and spinal manipulation) are recommended as the first-line treatment in low back pain [3]. Acupuncture is a well-accepted treatment in relieving pain and it usually has an accumulated effect in pain relief [4, 5]. In addition, people in China are more likely to choose acupuncture as their first choice for pain relief compared with analgesics [6]. Studies have shown that acupuncture and electroacupuncture are effective in pain relief and function improvement in low back pain patients [7, 8]. According to the Traditional Chinese Medicine theory, needles insert into the body with sufficient manual manipulations (lifting, thrusting, twisting, or rotating) and reach a *deqi* sensation (a

comprehensive sensation of numbness, soreness, heaviness, and distension) are the components to achieve a therapeutic effect. For this reason, acupuncturists tend to give patients deep needle insertion and get a strong *deqi* sensation. However, some patients are not willing to receive much manipulation or afraid of *deqi* sensation during the acupuncture treatment.

There has been no detailed investigation of whether the effect is different between deep electroacupuncture and shallow electroacupuncture. If shallow electroacupuncture is effective for LDH, patients with low back pain or radicular pain caused by LDH can choose shallow electroacupuncture for pain relief, and do not endure strong *deqi* sensation during the acupuncture treatment. The aim of this study is to evaluate the effectiveness of deep electroacupuncture and shallow electroacupuncture for treating LDH.

Methods

Study design

This is a single-centre, prospective, shallow electroacupuncture controlled, randomized trial. Patients will receive 12 sessions of either deep electroacupuncture (EA) or shallow electroacupuncture (shallow EA) after randomization. The study duration is 9 weeks for each patient, which includes a 1-week baseline assessment (week 0), 4-week treatment (weeks 1-4), and 4-week follow-up (weeks 5-8) (Figure 1). The study method is based on the Consolidated Standards of Reporting Trials [9, 10] and Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture [11].

Patients

Patients with LDH with or without radiculopathy will be enrolled. The diagnose criteria are based on the North American Spine Society clinical guidelines [12]. Diagnosis will be made by experienced physicians through computed tomography, magnetic resonance imaging, and examination of symptoms. The inclusion criteria are as follows: age 18 to 80; and low back pain (with or without radiculopathy) for at least 12 weeks. Patients will be excluded if they meet any of the following criteria: 1) patients who have severe LDH that need surgery; 2) patients who had surgery of spinal; 3) patients who known or suspected severe spinal diseases (tumours, fractures, infective diseases of the spine, etc.); 4) patients who have severe cardiovascular diseases, or endocrine system diseases, or had a pacemaker or metal implants; 5) patients who are pregnant, or lactating, or planning to conceive during the study period; 6) patients who using anticoagulant or antiplatelet drugs; 7) patients who have mental illnesses; 8) patients who do not understand or speak Mandarin.

Patients will be recruited through posters in the hospital and networks on December 1st, 2019 and expected to be completed on December 30th, 2021. Forty-four patients will be recruited at the outpatient of the Department of Acupuncture, the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Baseline assessment will be conduct within one week before the first EA session. All patients will sign the informed consent form.

Blinding

Patients, outcome assessors, and statisticians will be blinded. The needles in the deep EA group and the shallow EA group have the same appearance except for the length. Both two types of needles will be brought during the treatment in case of patients see and guess which groups they are in. Patients are in a prone position, so they are not able to see the inserted needles.

The success of the blinding method will be assessed by asking patients to choose one item from "deep electroacupuncture," "shallow electroacupuncture," or "I don't know". The success of blinding method will be evaluated within 30 minutes after the last EA session.

Randomization and allocation procedures

A research assistant who does not involve in the trial intervention and evaluation will take charge of the randomization. The random numbers will be conducted using a computerized random number generator in a block size of 4. Patients will be enrolled in a ratio of 1:1. The randomized numbers will be kept in opaque sealed envelopes and opened sequentially. Envelopes will be kept by the assistant and opened by the acupuncturist who will treat the patients.

Intervention

Patients will receive 12 sessions of free EA treatment during the study period. The treatment will start at the day patient randomized. Dongbang disposable stainless-steel

needles (0.3×75mm and 0.25×15mm, Suzhou Dongbang Medical Equipment Co., Ltd., Suzhou, China) and a Yingdi electric stimulator (Changzhou Yingdi Electronic Medical Device Co., Ltd., Changzhou, China) will be used. The selection of acupoints is based on clinical experience and specialist consensus. The acupoints are bilateral Dachangshu (BL25), Guanyuanshu (BL26), and L3-L5 Jiaji (Ex-B2), Weizhong (BL40) and Chengshan (BL57) will be used if patients have radicular pain. Patients will receive 12 sessions of EA (three times a week for four weeks) and each session will last 20 minutes. Patients in the deep EA group will receive EA at the acupoints in the prone position bilaterally using 0.3×75 needles. The needles will be inserted slowly and vertically approximately 35-70 mm according to the patient's figure to achieve *deqi* sensation; it is better the sensation radiates down to the lower limb. After the needles are inserted, an electric stimulator is connected at Dachangshu (BL25) and Guanyuanshu (BL26). The current strength will be adjusted according to the patient's tolerance. Patients in the shallow EA group will receive acupuncture using the 0.25×15mm needles and insert slowly and vertically approximately 1-2 mm at the same acupoints with no *deqi* sensation. An electric stimulator will be connected as same as the deep EA group.

According to the situation in China, patients tend to be reluctant to take oral analgesics to relieve pain [13]. For this reason, Patients are advised to stay in bed if acute pain occurs. Patients are allowed to take analgesics when unbearable pain occurs. Any analgesics use will be recorded in the case report form.

Outcome measures

Primary outcome

The primary outcome is the change from baseline in patients' worst low back pain intensity and leg pain intensity (if patients have radicular pain) measured by the visual analogue scale (VAS) at weeks 2, 4, 6, and 8. VAS is present as a ruler with a length of 0 mm to 100 mm. Patients will be asked to make a mark on the ruler that represents their worst low back pain intensity and leg pain intensity in the past week. 0 mm represents for no pain and 100 mm represents for unbearable pain.

Secondary outcomes

The secondary outcomes are: 1) change from baseline in Roland-Morris Disability Questionnaire (RMDQ) scores at weeks 2, 4, 6, and 8. The RMDQ is a 24-item self-report questionnaire for assessing low back function. The item is scored 1 point if patients indicate that an item is applicable to them, otherwise the item is scored 0. The total score will be calculated by adding up the points (ranges 0 to 24). A higher score indicates a worse condition; 2) change form baseline in EuroQol five dimensions five-level questionnaire (EQ-5D-5L) at weeks 2, 4, 6 and 8. EQ-5D-5L is a five-dimension self-rated questionnaire for assessing health state. It contains a five-dimension questionnaire and an EQ-VAS to assess health state. The five dimensions are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels describe as "no problems," "slight problems," "moderate problems," "severe

problems," and "extreme problems"; the 5 levels are scored 1, 2, 3, 4, and 5 points, respectively. Patients will be asked to choose one item in each dimension that indicates the patient's health state on the day of assessment. A lower score indicates a better health state. The EQ-VAS records patients' health on a vertical VAS. The EQ-VAS scale is a 100 mm scale labelled 0 mm and 100 mm at the endpoints, represent "Best imaginable health state" and "worst imaginable health state", respectively. Patients will be asked to choose one number between 0 and 100 that represents their health status of the assessing day; 3) Patients' self-evaluation of therapeutic effect will be assessed by asking patients to choose one answer from "No help," "Little help," "Medium help," and "Great help". The self-evaluation will be assessed at weeks 2, 4, 6 and 8.

A three-question expectation assessment will be conducted at baseline. Patients will be asked to choose one answer from "yes," "no," or "unclear" for the following two items: 1) In general, do you believe that electroacupuncture is helpful for treating diseases? 2) Do you believe that electroacupuncture is helpful with your lumbar disc herniation? Patients will choose one answer from "no help," "little help," "medium help," "great help," or "I do not care" for the item "What degree do you think electroacupuncture will be helpful with your lumbar disc herniation?".

Safety assessment

Any adverse events (AEs) during the study period will be recorded, assessed, and treated. Details of AEs will be recorded in the case report form (CRF). AEs will be categorized as treatment-related (e.g. broken needle, fainting, dizziness, nausea,

vomiting, palpitations, localized hematoma, localized infection, or localized severe sharp pain) or non-treatment-related (e.g. common cold, diarrhea, cough, or headache) within twenty-four hours after the occurrence. Patients will be unblinded and discontinued if serious AEs occur (e.g. causing disability to work or requiring hospitalization). Serious AEs will be immediately reported to the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine and suspend the study. The adverse events occurrence ratio will be calculated.

Sample Size Calculation

Power Analysis and Sample Size (version 11.0) was used for sample size calculation. The primary outcome is the change from baseline in patients' low back pain VAS at weeks 4. According to the previous study [8, 14], estimating the change from baseline in low back pain VAS after four-week treatment was 27.8±11.9 mm in the deep EA group and 14.6±13.2mm in the shallow EA group. Conduct a two-sided significance level of 5% (α) and a test power of 90% (β), twenty-one patients are required in each group. Considering 5% of the dropout rate, twenty-two patients are required in each group. The required sample size was 44 patients in this trial.

Data collection, management, and monitoring

Patients will receive free treatment and outcome measurements during the study period. Drop-outs and withdrawals will be recorded with reasons in the CRFs. Patients who discontinue treatment but do not drop out will be invited to enter the follow-up period

and complete assessments.

CRF will be first filled in the paper copies and entered into the Microsoft Excel by two independent researchers. Data monitoring and validation will be regularly conducted throughout the study. The original CRFs and consent forms will be kept in the department of acupuncture at the Third Affiliated Hospital of Beijing University of Chinese Medicine with limited access authority for three years after publication. Original clinical information will not be accessed without the permission of principal researcher ZH. The monitoring committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will check the CRFs twice every month.

Statistical Analysis

Data analysis will be conduct according to the intention-to-treat principle. Missing data will be filled in by the last observed value. IBM SPSS (version 20.0; International Business Machines Corporation, China) will be used for data analysis. A two-sided test will be conducted with a significance level of 0.05 and 95% confidence intervals. Baseline characteristics will be assessed through an independent *t*-test or the nonparametric test for continuous variables and a chi-square test for categorical variables. Between-group differences in VAS scores, RMDQ scores, and EA-5D-5L scores will be analyzed by using an independent *t*-test or nonparametric test according to the normality. Expectation assessment will be analyzed by general linear regression to assess if there is a correlation between the primary outcome and patients' expectations. The success of the blinding method will be conducted using a chi-square

test. Means and standard deviations or means and 95% confidence intervals will be used to present continuous data if the data follows a normal distribution. Medians and interquartile ranges will be used to present continuous data if the data does not follow a normal distribution. Frequency and percentage will be used to present categorical data.

Quality control

All investigators will undergo special training about the purpose, content, and treatment strategies to achieve quality control. EA will be performed by an acupuncturist who had undergone at least five years of undergraduate education and attained the certificate in traditional Chinese medicine. The monitoring committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will monitor the safety of this study and review the study results.

Ethics and dissemination

This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06) and registered at the Chinese Clinical Trial Registry (registration number: ChiCTR-1900026518). All patients will be fully informed about the trail and given enough time to decide whether to participate in the study. All patients will be asked to sign informed consent if they agree to participate in the study. Study results will be published at an online access medical journal.

Discussion

Study results will contribute an understanding of the effectiveness of deep EA and shallow EA in patients with LDH. The concept of investigating whether there is a difference between deep EA and shallow EA was first proposed by a patient who prefers shallow needle insertion rather than deep needle insertion. In addition, the patient stated that strong *deqi* sensation makes him stressed during acupuncture treatment. Acupuncture in the western world usually performs shallower than in China and effective in pain relief. Patients in China are difficult to blind because of cultural background [15]. For this reason, we involve electroacupuncture to reduce the chance of patients' recognition of group assignment.

Disfunction caused by pain is the critic issue that affects patients' productivity and quality of life [1]. According to our clinical experiences, even the pain intensity is low (below 30 mm in a 100 mm VAS), patients reported a great bothersome in their daily life. Therefore, we did not restrict the pain intensity in the inclusion criteria. Function and quality of life will be assessed in this study to explore whether EA can improve function and quality of life in LDH patients. RMDQ is for assessing physical disability due to low back pain, and it is more sensitive to change in assessing patients with mild to moderated disability compared with Oswestry Disability Index; a change of 2 to 3 points between groups in RMDQ should be considered the minimum clinically important change [16, 17]. The EQ-5D-5L was developed based on EQ-5D-3L to improve sensitivity and reduce ceiling effects by increasing the severity levels from three to five [18, 19]. Both of these questionnaires are short, no specific difficulty to

read or understand, and can be completed in 5 minutes. Thus, the response burden is low [16, 19]. Patients' expectations might present therapeutic benefits in clinical effects [20]. For this reason, the effects of expectation on outcomes will be assessed to find out whether there are effects between patients' expectations and the primary outcome. The success of blinding method will also be assessed. Many psychological scales have been used as an indicator for the evaluation of chronic low back pain [21, 22]. However, Tedious questionnaires of these scales might lead to patients' resistance to the cooperation of the study. For this reason, we do not involve psychological scales.

This study will provide evidence to clinical practice about the effect of deep EA and shallow EA, and help decision making for acupuncturists when treating patients with LDH.

The main limitation of this study is the inability to blind the acupuncturist.

Trial status

We are recruiting patients.

Competing interests

The authors declare that they have no competing interests.

Funding

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References:

1. Deyo RA, Weinstein JN: **Low back pain**. *N Engl J Med* 2001, **344**(5):363-370.

2. Deyo RA, Mirza SK: **CLINICAL PRACTICE. Herniated Lumbar Intervertebral Disk**. *N Engl J Med* 2016, **374**(18):1763-1772.

3. Qaseem A, Wilt TJ, McLean RM, Forciea MA: **Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians**. *ANN INTERN MED* 2017, **166**(7):514-530.

4. de Campos TF: **Low back pain and sciatica in over 16s: assessment and management NICE Guideline [NG59].** *J PHYSIOTHER* 2017, **63**(2):120.

5. Vickers AJ, Vertosick EA, Lewith G, MacPherson H, Foster NE, Sherman KJ, Irnich D, Witt CM, Linde K: **Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis**. *J PAIN* 2018, **19**(5):455-474.

6. Wong S, Choi SW, Cheung CW: **A comparison of chronic pain with and without neuropathic characteristics in a Hong Kong Chinese population: An analysis of pain related outcomes and patient help seeking behaviour**. *PLOS ONE* 2018, **13**(10):e204054.

7. Qaseem A, Wilt TJ, McLean RM, Forciea MA: **Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians**. *ANN INTERN MED* 2017, **166**(7):514-530.

8. Huang Z, Liu S, Zhou J, Yao Q, Liu Z: **Efficacy and Safety of Acupuncture for Chronic Discogenic Sciatica, a Randomized Controlled Sham Acupuncture Trial**. *PAIN MED* 2019.

9. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG: **CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials**. *BMJ* 2010, **340**:c869.

10. Schulz KF, Altman DG, Moher D: **CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials**. *BMJ* 2010, **340**:c332.

11. MacPherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, Moher D: **Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement**. *PLOS MED* 2010, **7**(6):e1000261.

12. Kreiner DS, Hwang SW, Easa JE, Resnick DK, Baisden JL, Bess S, Cho CH, DePalma MJ, Dougherty PN, Fernand R *et al*: **An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy**. *SPINE J* 2014, **14**(1):180-191.

13. Wong S, Choi SW, Cheung CW: **A comparison of chronic pain with and without neuropathic characteristics in a Hong Kong Chinese population: An analysis of pain related outcomes and patient help seeking behaviour**. *PLOS ONE* 2018, **13**(10):e204054.

14. Zhang X, Wang Y, Wang Z, Wang C, Ding W, Liu Z: **A Randomized Clinical Trial Comparing the Effectiveness of Electroacupuncture versus Medium-Frequency Electrotherapy for Discogenic Sciatica**. *EVID-BASED COMPL ALT* 2017, **2017**:1-9.

15. Karst M, Li C: **Acupuncture—A Question of Culture**. *JAMA Network Open* 2019, **2**(12):e1916929.

16. Smeets R, Köke A, Lin C, Ferreira M, Demoulin C: **Measures of function in low back pain/disorders: Low Back Pain Rating Scale (LBPRS), Oswestry Disability Index (ODI), Progressive Isoinertial Lifting Evaluation (PILE), Quebec Back Pain Disability Scale (QBPDS), and Roland-Morris Disability Questionnaire**. *ARTHRIT CARE RES* 2011, **63**(S11):S158-S173.

17. Roland M, Fairbank J: **The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire**. *Spine (Phila Pa 1976)* 2000, **25**(24):3115-3124.

18. Janssen MF, Birnie E, Haagsma JA, Bonsel GJ: **Comparing the standard EQ-5D three-level system with a five-level version**. *VALUE HEALTH* 2008, **11**(2):275-284.

19. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X: **Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)**. *QUAL LIFE RES* 2011, **20**(10):1727-1736.

20. Frisaldi E, Shaibani A, Benedetti F: **Why We should Assess Patients' Expectations in Clinical Trials**. *Pain and Therapy* 2017, **6**(1):107-110.

21. Brox JI, Sorensen R, Friis A, Nygaard O, Indahl A, Keller A, Ingebrigtsen T, Eriksen HR, Holm I, Koller AK *et al*: **Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration**. *Spine (Phila Pa 1976)* 2003, **28**(17):1913-1921.

22. Bishop FL, Yardley L, Prescott P, Cooper C, Little P, Lewith GT: **Psychological covariates of longitudinal changes in back-related disability in patients undergoing acupuncture**. *CLIN J PAIN* 2015, **31**(3):254-264.

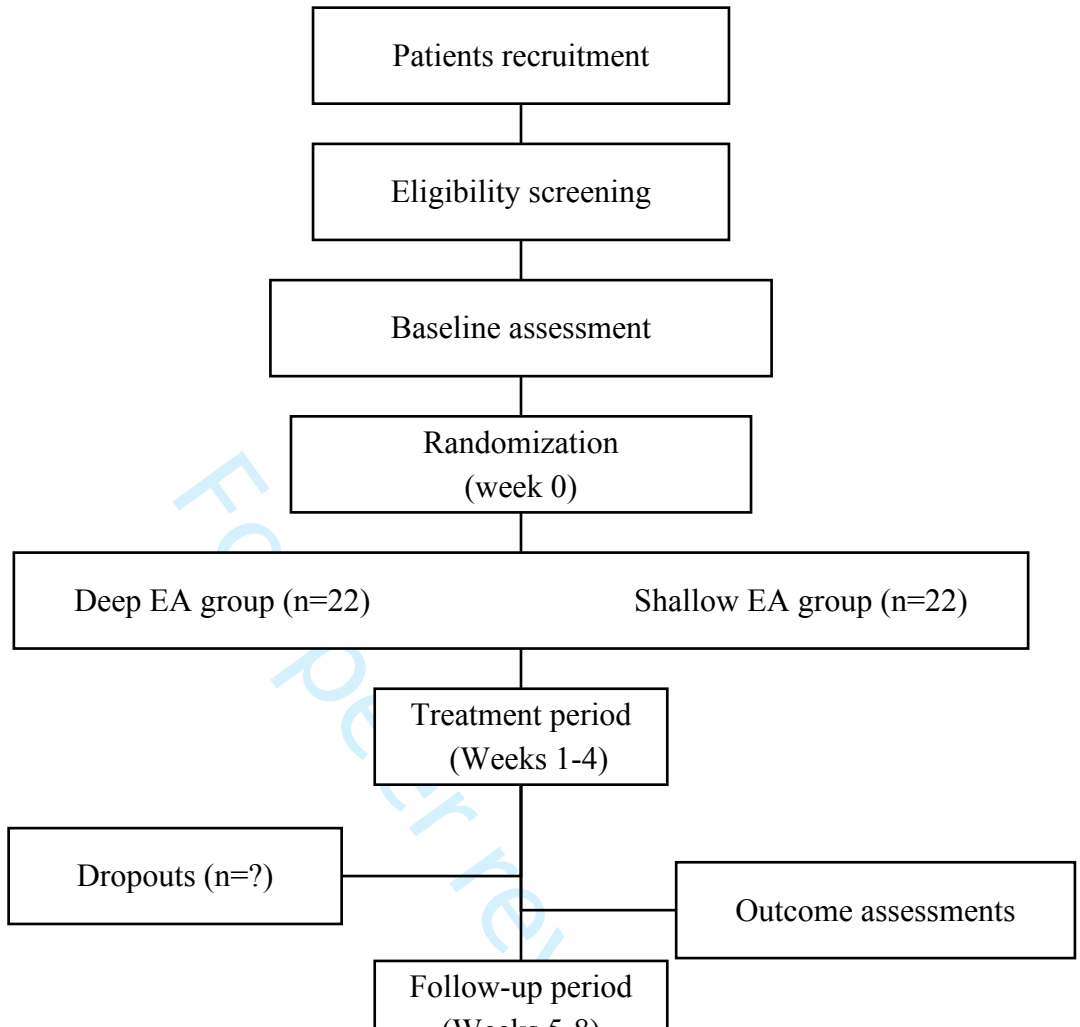

Figure 1. Study flow chart

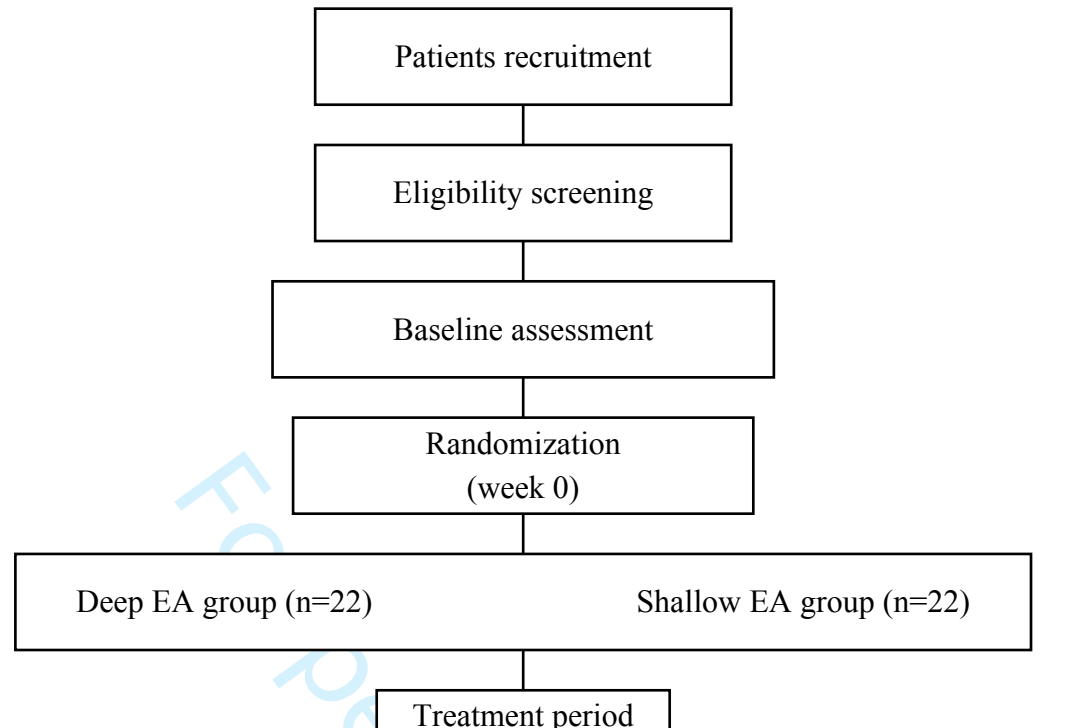

Figure 1. Study flow chart

北京中医药大学第三附属医院科研伦理委员会

IRB of The third Hospital affiliated to Beijing University of Chinese Medicine

伦理审查批件

Approval Notice Template

受理序号：BZYSY-2019KYKTSL-06　　批件号：BZYSY-2019KYKTPJ-06

项目名称：电针深刺和浅刺“腰突五穴”治疗慢性腰椎间盘突出症的疗效差异

申办单位：北京中医药大学第三附属医院　　主要研究者：黄子玲

项目类别：2019 年校级课题（增补）　　批准文号/课题编号：2019-XS-ZB06　　临床分期：

方案版本日期：2019.05.01　　方案版本号：1.0

知情同意书版本日期：2019.05.01　　知情同意书版本号：1.0

伦理审查方式：□会议审查　　☑快速审查

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根据中华人民共和国国家食品药品监督管理局（CFDA）《药物临床试验伦理审查工作指导原则》（2010 年）、《药物临床试验质量管理规范》（2003）、《中药品种保护指导原则》（2009），世界医学会《赫尔辛基宣言》（2008），卫生部《涉及人的生物医学研究伦理审查办法》（2007），国家中医药管理局《中医药临床研究伦理审查管理规范》（2010）以及国际医学科学组织委员会《人体生物医学研究国际道德指南》（2002）的伦理原则，经本伦理委员会审查决定：	☑同意 □作必要修正后同意 □作必要修改后重审 □不同意 □终止或暂停

审查意见：

符合伦理规范，同意开展临床试验。

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主任委员☑副主任委员□签字：　　时　间：2019 年 9 月 12 日

北京中医药大学第三附属医院科研伦理委员会

本项目持续审查频率□ 3 个月　□ 6 个月　☑ 12 个月　联系人：　韩飞

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	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Ethical Approval
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	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	14
	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)	10

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	3-4
	6b	Explanation for choice of comparators	3-4, 12-13
Objectives	7	Specific objectives or hypotheses	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)	4
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	4
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)	4-5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-7
	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)	9
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	6-7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
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	7-9
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)	Figure 1

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	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	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	6
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	6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5-6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9
Methods: Data collection, management, and analysis			
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	10-11
	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	10

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	10-11
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	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	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)	11
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	10-11
	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	10-12
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	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	10-11
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N/A
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)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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	10-11
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
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	10-11
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	N/A
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	12
	31b	Authorship eligibility guidelines and any intended use of professional writers	12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
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	N/A

*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. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Effectiveness of Deep Electroacupuncture with Strong deqi and Shallow Electroacupuncture with no deqi for Lumbar Disk Herniation: Study Protocol for A Randomized Controlled Trial

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Effectiveness of Deep Electroacupuncture with Strong *deqi* and Shallow Electroacupuncture with no *deqi* for Lumbar Disk Herniation: Study Protocol for A Randomized Controlled Trial

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Abstract

Introduction: Lumbar disk herniation (LDH) is a common cause of low back pain and dysfunction. Studies have shown that electroacupuncture (EA) can achieve pain relief in patients with LDH. However, there is a lack of evidence regarding the effectiveness of deep EA with strong deqi and shallow EA with no deqi in patients with LDH. This study aims to evaluate the effectiveness of deep EA with strong deqi and shallow EA with no deqi in the treatment of LDH.

Methods and analysis: In this randomized controlled trial, patients with LDH who have low back pain with or without radiculopathy for at least 12 weeks will be enrolled. In total 44 patients will be recruited from the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Patients will be randomized into the deep EA group and the shallow EA group in a ratio of 1:1 and will be administered 12 sessions of EA treatment (3 times a week for 4 weeks, 20 minutes for each session).

The follow-up duration will be 4 weeks. Low back pain intensity and leg pain intensity (in patients with radicular pain) measured using the visual analog scale will be assessed as the primary outcomes. Function (measured using the Roland–Morris Disability Questionnaire), quality of life (measured using the EuroQol five-dimensional five-level questionnaire), and patient-evaluated therapeutic effect will be assessed as the secondary outcomes. Patients' expectations of EA, the success of the blinding method, and safety will also be evaluated. Statistical analyses will be followed by the intention-to-treat analysis.

Ethics and dissemination: This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06). Study results will be disseminated through publication in an open access journal.

Trial registration: ChiCTR-1900026518

Strengths and limitations of this study

- ► This study will provide evidence for clinical practice regarding the effectiveness of deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi*.
- ► It will be difficult for the patients to determine which group they are in because all of them will receive electric stimulation.
- ► The main limitation of this study is the inability to blind the acupuncturist.

Keywords

electroacupuncture, lumbar disk herniation, low back pain, randomized controlled trial

Abbreviations

Lumbar disk herniation (LDH)

Electroacupuncture (EA)

Visual analog scale (VAS)

Roland–Morris Disability Questionnaire (RMDQ)

EuroQol five-dimensional five-level questionnaire (EQ-5D-5L)

Case report form (CRF)

Background

Low back pain is the second most common symptom-related reason for physician visit by patients [1]. About 10% of the patients with low back pain have disk disorder [2]. Patients with LDH commonly experience low back pain recurrence, and these patients often exhibits slower recovery than those with nonspecific low back pain [1, 2]. Non-pharmacological interventions (acupuncture, massage, yoga, and spinal manipulation) are recommended as the first-line treatment in low back pain [3]. Acupuncture is a well-accepted treatment in relieving pain, usually exerting more beneficial effects with every session [4, 5]. In addition, people in China are more likely to choose acupuncture as their first choice for pain relief compared to analgesics [6].

Studies have shown that acupuncture and EA could relieve pain in chronic low back pain patients [7-9]. According to the Traditional Chinese Medicine theory, needles are inserted into the body with sufficient manual manipulations (lifting, thrusting, twisting, or rotating) and cause a *deqi* sensation (a comprehensive sensation of numbness, soreness, heaviness, and distension) to achieve a therapeutic effect. Thus, acupuncturists tend to perform deep needle insertion and cause a strong *deqi* sensation. However, some patients are unwilling to receive much manipulation or are afraid of *deqi* sensation during the acupuncture treatment.

To the best of our knowledge, there has been no detailed investigation of whether the effect is different between deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi*. If shallow electroacupuncture with no *deqi* is effective for LDH, patients with low back pain or radicular pain caused by LDH can choose shallow electroacupuncture for pain relief without the need to undergo strong *deqi* sensation during the acupuncture treatment. This study aims to evaluate the effectiveness of deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi* in the treatment of LDH.

Methods

Study design

This is a single-center, prospective, shallow electroacupuncture controlled, randomized trial. Patients will receive 12 sessions of either deep EA with strong *deqi* or shallow electroacupuncture (shallow EA) with no *deqi* after randomization. The study duration

will be 9 weeks for each patient that includes baseline assessment for 1 week (at week 0), treatment period of 4 weeks (weeks 1–4), and follow-up duration of 4 weeks (weeks 5–8) (Figure 1). The study method is based on the Consolidated Standards of Reporting Trials [10, 11] and Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture [12].

Patients

Patients with LDH with or without radiculopathy will be enrolled. The diagnose criteria based on the North American Spine Society clinical guidelines will be used [13]. Diagnosis will be established by experienced physicians using computed tomography, magnetic resonance imaging, and symptom examination. The following inclusion criteria will be applied: age 18–80 years and presence of low back pain (with or without radiculopathy) for at least 12 weeks. Patients will be excluded if they meet any of the following criteria: 1) severe LDH requiring surgery; 2) history of spinal surgery; 3) known or suspected spinal diseases (tumors, fractures, infective spine diseases etc.); 4) severe cardiovascular diseases, endocrine system diseases, or pacemaker/metal implants; 5) pregnancy, or lactation, or planning to conceive during the study period; 6) current use of anticoagulant or antiplatelet drugs; 7) mental illnesses; and 8) inability to speak or understand Mandarin.

Patients will be recruited through poster advertisements in the hospital and enrollments through networks from December 1, 2019 to December 30, 2021. In total, 44 patients with LDH will be recruited from the outpatient clinic of the Department of Acupuncture,

the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Baseline assessment will be conducted within 1 week before the first EA session. Written informed consent will be obtained from all the study subjects.

Blinding

Patients, outcome assessors, and statisticians will be blinded. The needles in the deep EA group and the shallow EA group have the same appearance, except for the length. Both the types of needles will be carried during acupuncture to avoid patients from guessing the group they have been allocated to. Patients will be in the prone position and are therefore unable to see the inserted needles.

The success of the blinding method will be examined by an assessor who is not involved in the performance of acupuncture by asking the patients to choose one item from "deep electroacupuncture," "shallow electroacupuncture," or "I don't know." The success of the blinding method will be evaluated within 30 min of the last EA session.

Randomization and allocation procedures

A research assistant who will not be involved in the trial intervention and evaluation will be in-charge of the randomization. The random numbers will be generated using a computerized random number generator in a block size of 4. Patients will be enrolled in a ratio of 1:1. The randomized number chits will be kept in opaque sealed envelopes and opened sequentially. The envelopes will be stored by the assistant and opened on the day the patients receive their first treatment from the acupuncturist.

Intervention

Patients will be administered 12 sessions of free EA treatment during the study period. The treatment will start on the day the patients are randomized. Dongbang disposable stainless steel needles (0.3 × 75 mm and 0.25 × 15 mm, Suzhou Dongbang Medical Equipment Co., Ltd., Suzhou, China) and a Yingdi electric stimulator (Changzhou Yingdi Electronic Medical Device Co., Ltd., Changzhou, China) will be used. The selection of acupoints will be made as per the clinical experience and specialist consensus. In case of radicular pain, bilateral Dachangshu (BL25), Guanyuanshu (BL26), and L3-L5 Jiaji (Ex-B2), Weizhong (BL40) and Chengshan (BL57) will be used. Patients will be administered 12 sessions of EA (3 times a week for 4 weeks) and each session will last 20 min. Patients in the deep EA group will be administered EA at the acupoints in the prone position bilaterally using 0.3 × 75 needles. The needles will be inserted slowly and vertically to a depth of 35–70 mm as per the patient's figure to achieve *deqi* sensation; it is preferable if the sensation radiates down to the lower limb. After the needles are inserted, paired clips of electric stimulator will be attached transversely to the bilateral Dachangshu (BL25) and Guanyuanshu (BL26). A 5-Hz continuous wave will be used, and the current strength will be adjusted as per the patient's tolerance. Patients in the shallow EA group will be administered acupuncture treatment using the 0.25 × 15-mm needles that will be inserted slowly and vertically approximately 2–5 mm at the same acupoints with no *deqi* sensation. An electric stimulator will be connected using the same method as used in the deep EA group.

Patients are allowed to take analgesics when their pain becomes unbearable. Any

analgesics that are used will be recorded in the case report form (CRF).

Outcome measures

Primary outcome

The primary outcome will be the change from baseline in the patients' worst low back pain intensity and leg pain intensity (if patients have radicular pain) measured using the visual analog scale (VAS), at weeks 2, 4, 6, and 8. The VAS is a ruler with a length of 0 mm–100 mm. Patients will be asked to make a mark on the ruler that represents their worst low back pain intensity and leg pain intensity during the previous week, with 0 mm representing no pain and 100 mm representing unbearable pain.

Secondary outcomes

The following secondary outcomes will be measured: 1) change in the Roland–Morris Disability Questionnaire (RMDQ) scores at weeks 2, 4, 6, and 8 compared to that at baseline. The RMDQ is a 24-item self-reported questionnaire that assesses low back function. The item will be scored 1 point if the patient indicates that the item is applicable to them; if the item is not applicable, a score of 0 will be assigned. The total score will be calculated by adding the points for all items (range 0–24). A higher score indicates a worse condition; 2) change in the EuroQol five-dimensional five-level questionnaire (EQ-5D-5L) at weeks 2, 4, 6 and 8 as compared to that baseline. The EQ-5D-5L is a five-dimension self-rated questionnaire for assessing the health state. It contains a five-dimension questionnaire and an EQ-VAS for the assessment of the

health status. The five dimensions include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels, described as "no problems," "slight problems," "moderate problems," "severe problems," and "extreme problems"; the 5 levels are scored with 1, 2, 3, 4, and 5 points, respectively. Patients will be asked to choose one item in each dimension that indicates his/her health state on the assessment day. The total score of the five dimensions will be calculated by adding the points. A lower score indicates better health. The EQ-VAS records the patients' health on a vertical VAS. The EQ-VAS scale is a 100-mm scale labeled 0–100 mm, representing "best imaginable health state" to "worst imaginable health state." Patients will be asked to choose one number between 0 and 100 that represents their health status on the day of the assessment; 3) Patient self-evaluation of the therapeutic effect will be assessed by asking the patients to choose an answer from "No help," "Little help," "Medium help," and "Great help." The self-evaluation will be assessed at weeks 2, 4, 6 and 8.

A three-question expectation assessment will be conducted at baseline. Patients will be asked to choose one answer from "yes," "no," or "unclear" for the following two items: 1) In general, do you believe that electroacupuncture is helpful for disease treatment? 2) Do you believe that electroacupuncture is helpful with your lumbar disk herniation? Patients will choose one answer from "no help," "little help," "medium help," "great help," or "I do not care" for the item "What degree do you think electroacupuncture will be helpful with your lumbar disc herniation?"

Safety assessment

Any adverse events (AEs) during the study period will be recorded, assessed, and treated. The details of the AEs will be recorded in the CRF. AEs will be categorized as treatment-related (e.g. broken needle, fainting, dizziness, nausea, vomiting, palpitations, localized hematoma, localized infection, or localized severe sharp pain) or non-treatment-related (e.g. common cold, diarrhea, cough, or headache) within 24 h of occurrence. Patients will not be blinded and treatment will be discontinued if serious AEs occur (e.g. causing disability to work or requiring hospitalization). Serious AEs will be immediately reported to the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine and suspend the study. The AEs occurrence ratio will be calculated.

Sample size calculation

Power Analysis and Sample Size (version 11.0) was used for calculating the required sample size. The primary outcome was the change from baseline in the patients' low back pain VAS score at 4 weeks. In previous studies [7, 8], the change from baseline in low back pain VAS score after 4 weeks of treatment was 27.8 ± 11.9 mm in the deep EA group and 14.6 ± 13.2 mm in the shallow EA group. Considering a two-sided significance level of 5% (α) and a test power of 90% (β), 21 patients would be required in each group. Considering a dropout rate of 5%, 22 patients would be required in each group. The required sample size was 44 in this trial.

Data collection, management, and monitoring

Patients will undergo free treatment and outcome evaluation during the study period. Dropouts and withdrawals will be recorded with the respective reasons in the CRFs. Patients who discontinue treatment but do not drop out will be invited to enter the follow-up period and complete assessments.

CRF will be first filled in the paper copies and entered into the Microsoft Excel by two independent researchers. Data monitoring and validation will be regularly conducted throughout the study. The original CRFs and consent forms will be kept in the department of acupuncture at the Third Affiliated Hospital of Beijing University of Chinese Medicine with limited access authority for 3 years after publication. Original clinical information will not be accessed without the permission of the principal researcher ZH. The monitoring committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will check the CRFs 2 times each month.

Statistical analyses

Data will be analyzed as per the intention-to-treat principle. Missing data will be filled in by multiple imputation. IBM SPSS (version 20.0; International Business Machines Corporation, China) will be used for data analysis. A two-sided test will be conducted with a significance level of 0.05 and 95% confidence intervals. Between-group differences in the VAS scores, RMDQ scores, and EA-5D-5L scores will be analyzed with ANCOVA or nonparametric test, based on the normality of the data. Expectation assessment will be analyzed with general linear regression to assess if there is a

correlation between the primary outcome and patient expectations. The success of the blinding method will be evaluated using chi-square test. Means and standard deviations or means and 95% confidence intervals will be used to present continuous data in case of normal distribution. Medians and interquartile ranges will be used to present continuous data for non-normal data. Frequencies and percentages will be used to present the categorical data.

Quality control

All the investigators will undergo special training regarding the purpose, content, and treatment strategies to achieve quality control. EA will be performed by an acupuncturist who has undergone at least 5 years of undergraduate education and attained a certificate in Traditional Chinese Medicine practice. The monitoring committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will monitor the safety of this study and review the study results.

Patient and public involvement

No patient involved.

Ethics and dissemination

This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06) and registered at the Chinese Clinical Trial Registry (registration number: ChiCTR-1900026518). All patients will be fully informed about the trail and given enough time

to decide whether to participate in the study. All patients will be asked to sign an informed consent form if they agree to participate in the study. Study results will be published at an online access medical journal.

Discussion

Study results will provide an understanding of the effectiveness of deep EA with strong deqi sensation and shallow EA with no deqi sensation in patients with LDH. Current studies mainly focus on the effectiveness of acupuncture and have compared acupuncture with sham or placebo acupuncture related to chronic low back pain [9]. However, to our knowledge, no detailed trials have compared deep electroacupuncture with strong deqi sensation and shallow electroacupuncture with no deqi related to LDH. A strong deqi sensation could be an unpleasant experience for some patients; therefore, we wish to optimize our treatment for patients who are unwilling to go through the deqi sensation.

The concept of determining whether there is a difference between deep EA and shallow EA was first proposed by a patient who preferred shallow needle insertion to deep needle insertion. Moreover, the patient stated that strong *deqi* sensation stressed him during the acupuncture treatment. In Western countries, acupuncture is usually performed at a shallower level than in China, with effective in pain relief. Patients in China are difficult to blind because of their cultural background [14]. Thus, we involved electroacupuncture to minimize the changes of patients' recognizing the group assignment.

Dysfunction caused by pain is a critical issue that affects patients' productivity and quality of life [1]. In our clinical experiences, even with low-intensity pain (<30 mm on a 100-mm VAS), patients reported that it greatly compromised their daily life. Therefore, we did not restrict the minimum pain intensity in the inclusion criteria. The function and quality of life will be assessed in order to explore whether EA can improve the function and quality of life in patients with LDH. RMDQ is for assessing physical disability caused by low back pain, and it is more sensitive to change in patients with mild to moderated disability than the Oswestry Disability Index; a change of 2–3 points between groups in RMDQ should be considered the minimum clinically important change [15, 16]. The EQ-5D-5L was developed based on the EQ-5D-3L to improve the sensitivity and reduce the ceiling effects by increasing the severity levels from 3 to 5 [17, 18]. Both these questionnaires are short, and are not specifically difficulty to read or understand, and can be completed in 5 min. Thus, the response burden is low [15, 18]. Patients' expectations might present therapeutic benefits in clinical practice [19]. Thus, the effects of expectation on outcomes will be assessed to determine whether there is an association between patients' expectations and the primary outcome. Moreover, the success of the blinding method will be assessed. Many psychological scales have been used as indicators of the evaluation of chronic low back pain [20, 21]. However, tedious questionnaires of these scales might cause the patient to become uninterested and thus less cooperative. Therefore, we plan not to use psychological scales.

This study will provide evidence for clinical practice about the effect of deep EA and

shallow EA and thus aid acupuncturists in decision-making while treating patients with LDH.

The main limitation of this study is the inability to blind the acupuncturist.

Trial status

We are recruiting patients.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Ziling Huang and Jianxin Zhao designed this study. Jianxin Zhao, Xinghong Pei, and Ziling Huang are responsible for recruitment. Ziling Huang will perform acupuncture treatment. Xinghong Pei and Bobo Wang are responsible for data collection. This manuscript was drafted by Ziling Huang and revised by Jianxin Zhao. All authors have read and approved the final manuscript.

References:

1. Deyo RA, Weinstein JN: **Low back pain**. *N Engl J Med* 2001, **344**(5):363-370.

2. Deyo RA, Mirza SK: **CLINICAL PRACTICE. Herniated Lumbar Intervertebral Disk**. *N Engl J Med* 2016, **374**(18):1763-1772.

3. Qaseem A, Wilt TJ, McLean RM, Forciea MA: **Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians**. *ANN INTERN MED* 2017, **166**(7):514-530.

4. de Campos TF: **Low back pain and sciatica in over 16s: assessment and management NICE Guideline [NG59].** *J PHYSIOTHER* 2017, **63**(2):120.

5. Vickers AJ, Vertosick EA, Lewith G, MacPherson H, Foster NE, Sherman KJ, Irnich D, Witt CM, Linde K: **Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis**. *J PAIN* 2018, **19**(5):455-474.

6. Wong S, Choi SW, Cheung CW: **A comparison of chronic pain with and without neuropathic characteristics in a Hong Kong Chinese population: An analysis of pain related outcomes and patient help seeking behaviour**. *PLOS ONE* 2018, **13**(10):e204054.

7. Huang Z, Liu S, Zhou J, Yao Q, Liu Z: **Efficacy and Safety of Acupuncture for Chronic Discogenic Sciatica, a Randomized Controlled Sham Acupuncture Trial**. *PAIN MED* 2019.

8. Zhang X, Wang Y, Wang Z, Wang C, Ding W, Liu Z: **A Randomized Clinical Trial Comparing the Effectiveness of Electroacupuncture versus Medium-**

Frequency Electrotherapy for Discogenic Sciatica. *EVID-BASED COMPL ALT* 2017, **2017**:1-9.

9. AD F, van Tulder MW, D C, H T, L L, BW K, BM B: **Acupuncture and dry-needling for low back pain**. *COCHRANE DB SYST REV* 2005(1).

10. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG: **CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials**. *BMJ* 2010, **340**:c869.

11. Schulz KF, Altman DG, Moher D: **CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials**. *BMJ* 2010, **340**:c332.

12. MacPherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, Moher D: **Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement**. *PLOS MED* 2010, **7**(6):e1000261.

13. Kreiner DS, Hwang SW, Easa JE, Resnick DK, Baisden JL, Bess S, Cho CH, DePalma MJ, Dougherty PN, Fernand R *et al*: **An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy**. *SPINE J* 2014, **14**(1):180-191.

14. Karst M, Li C: **Acupuncture—A Question of Culture**. *JAMA Network Open* 2019, **2**(12):e1916929.

15. Smeets R, Köke A, Lin C, Ferreira M, Demoulin C: **Measures of function in low back pain/disorders: Low Back Pain Rating Scale (LBPRS), Oswestry Disability**

Index (ODI), Progressive Isoinertial Lifting Evaluation (PILE), Quebec Back Pain Disability Scale (QBPDS), and Roland-Morris Disability Questionnaire. *ARTHRIT CARE RES* 2011, **63**(S11):S158-S173.

16. Roland M, Fairbank J: **The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire**. *Spine (Phila Pa 1976)* 2000, **25**(24):3115-3124.

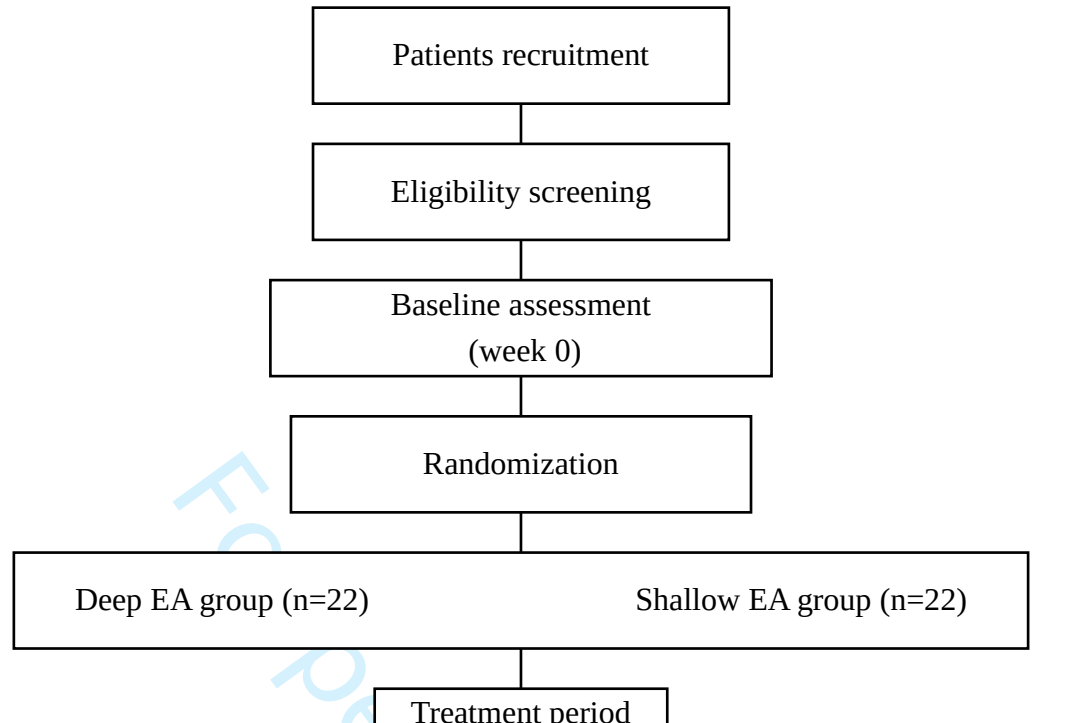
17. Janssen MF, Birnie E, Haagsma JA, Bonsel GJ: **Comparing the standard EQ-5D three-level system with a five-level version**. *VALUE HEALTH* 2008, **11**(2):275-284.

18. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X: **Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)**. *QUAL LIFE RES* 2011, **20**(10):1727-1736.

19. Frisaldi E, Shaibani A, Benedetti F: **Why We should Assess Patients' Expectations in Clinical Trials**. *Pain and Therapy* 2017, **6**(1):107-110.

20. Brox JI, Sorensen R, Friis A, Nygaard O, Indahl A, Keller A, Ingebrigtsen T, Eriksen HR, Holm I, Koller AK *et al*: **Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration**. *Spine (Phila Pa 1976)* 2003, **28**(17):1913-1921.

21. Bishop FL, Yardley L, Prescott P, Cooper C, Little P, Lewith GT: **Psychological covariates of longitudinal changes in back-related disability in patients undergoing acupuncture**. *CLIN J PAIN* 2015, **31**(3):254-264.



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	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Ethical Approval
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	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	14
	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)	10

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	3-4
	6b	Explanation for choice of comparators	3-4, 12-13
Objectives	7	Specific objectives or hypotheses	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)	4
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	4
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)	4-5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-7
	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)	9
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	6-7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
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	7-9
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)	Figure 1

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	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	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	6
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	6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5-6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9
Methods: Data collection, management, and analysis			
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	10-11
	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	10

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	10-11
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	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	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)	11
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	10-11
	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	10-12
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	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	10-11
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N/A
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)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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	10-11
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
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	10-11
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	N/A
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	12
	31b	Authorship eligibility guidelines and any intended use of professional writers	12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
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	N/A

*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. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Effectiveness of Deep Electroacupuncture with Strong deqi and Shallow Electroacupuncture with no deqi for Lumbar Disk Herniation: Study Protocol for A Randomized Controlled Trial

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Effectiveness of Deep Electroacupuncture with Strong *deqi* and Shallow Electroacupuncture with no *deqi* for Lumbar Disk Herniation: Study Protocol for A Randomized Controlled Trial

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Abstract

Introduction: Lumbar disk herniation (LDH) is a common cause of low back pain and dysfunction. Studies have shown that electroacupuncture (EA) can achieve pain relief in patients with LDH. However, there is a lack of evidence regarding the effectiveness of deep EA with strong deqi and shallow EA with no deqi in patients with LDH. This study aims to evaluate the effectiveness of deep EA with strong deqi and shallow EA with no deqi in the treatment of LDH.

Methods and analysis: In this randomized controlled trial, patients with LDH who have low back pain with or without radiculopathy for at least 12 weeks will be enrolled. In total 44 patients will be recruited from the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Patients will be randomized into the deep EA group and the shallow EA group in a ratio of 1:1 and will be administered 12 sessions of EA treatment (3 times a week for 4 weeks, 20 minutes for each session).

The follow-up duration will be 4 weeks. Low back pain intensity and leg pain intensity (in patients with radicular pain) measured using the visual analog scale will be assessed as the primary outcomes. Function (measured using the Roland–Morris Disability Questionnaire), quality of life (measured using the EuroQol five-dimensional five-level questionnaire), and patient-evaluated therapeutic effect will be assessed as the secondary outcomes. Patients' expectations of EA, the success of the blinding method, and safety will also be evaluated. Statistical analyses will be followed by the intention-to-treat analysis.

Ethics and dissemination: This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06). Study results will be disseminated through publication in an open access journal.

Trial registration: ChiCTR-1900026518

Strengths and limitations of this study

- ► This study will provide evidence for clinical practice regarding the effectiveness of deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi*.
- ► It will be difficult for the patients to determine which group they are in because all of them will receive electric stimulation.
- ► The main limitation of this study is the inability to blind the acupuncturist.

Keywords

electroacupuncture, lumbar disk herniation, low back pain, randomized controlled trial

Abbreviations

Lumbar disk herniation (LDH)

Electroacupuncture (EA)

Visual analog scale (VAS)

Roland–Morris Disability Questionnaire (RMDQ)

EuroQol five-dimensional five-level questionnaire (EQ-5D-5L)

Case report form (CRF)

Background

Low back pain is the second most common symptom-related reason for physician visit by patients [1]. About 10% of the patients with low back pain have disk disorder [2]. Patients with LDH commonly experience low back pain recurrence, and these patients often exhibits slower recovery than those with nonspecific low back pain [1, 2]. Non-pharmacological interventions (acupuncture, massage, yoga, and spinal manipulation) are recommended as the first-line treatment in low back pain [3]. Acupuncture is a well-accepted treatment in relieving pain, usually exerting more beneficial effects with every session [4, 5]. In addition, people in China are more likely to choose acupuncture as their first choice for pain relief compared to analgesics [6].

Studies have shown that acupuncture and EA could relieve pain in chronic low back pain patients [7-9]. According to the Traditional Chinese Medicine theory, needles are inserted into the body with sufficient manual manipulations (lifting, thrusting, twisting, or rotating) and cause a *deqi* sensation (a comprehensive sensation of numbness, soreness, heaviness, and distension) to achieve a therapeutic effect. Thus, acupuncturists tend to perform deep needle insertion and cause a strong *deqi* sensation. However, some patients are unwilling to receive much manipulation or are afraid of *deqi* sensation during the acupuncture treatment.

To the best of our knowledge, there has been no detailed investigation of whether the effect is different between deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi*. If shallow electroacupuncture with no *deqi* is effective for LDH, patients with low back pain or radicular pain caused by LDH can choose shallow electroacupuncture for pain relief without the need to undergo strong *deqi* sensation during the acupuncture treatment. This study aims to evaluate the effectiveness of deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi* in the treatment of LDH.

Methods

Study design

This is a single-center, prospective, shallow electroacupuncture controlled, randomized trial. Patients will receive 12 sessions of either deep EA with strong *deqi* or shallow electroacupuncture (shallow EA) with no *deqi* after randomization. The study duration

will be 9 weeks for each patient that includes baseline assessment for 1 week (at week 0), treatment period of 4 weeks (weeks 1–4), and follow-up duration of 4 weeks (weeks 5–8) (Figure 1). The study method is based on the Consolidated Standards of Reporting Trials [10, 11] and Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture [12].

Patients

Patients with LDH with or without radiculopathy will be enrolled. The diagnose criteria based on the North American Spine Society clinical guidelines will be used [13]. Diagnosis will be established by experienced physicians using computed tomography, magnetic resonance imaging, and symptom examination. The following inclusion criteria will be applied: age 18–80 years and presence of low back pain (with or without radiculopathy) for at least 12 weeks. Patients will be excluded if they meet any of the following criteria: 1) severe LDH requiring surgery; 2) history of spinal surgery; 3) known or suspected spinal diseases (tumors, fractures, infective spine diseases etc.); 4) severe cardiovascular diseases, endocrine system diseases, or pacemaker/metal implants; 5) pregnancy, or lactation, or planning to conceive during the study period; 6) current use of anticoagulant or antiplatelet drugs; 7) mental illnesses; and 8) inability to speak or understand Mandarin.

Patients will be recruited through poster advertisements in the hospital and enrollments through networks from December 1, 2019 to December 30, 2021. In total, 44 patients with LDH will be recruited from the outpatient clinic of the Department of Acupuncture,

the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Baseline assessment will be conducted within 1 week before the first EA session. Written informed consent will be obtained from all the study subjects.

Blinding

Patients, outcome assessors, and statisticians will be blinded. The needles in the deep EA group and the shallow EA group have the same appearance, except for the length. Both the types of needles will be carried during acupuncture to avoid patients from guessing the group they have been allocated to. Patients will be in the prone position and are therefore unable to see the inserted needles.

The success of the blinding method will be examined by an assessor who is not involved in the performance of acupuncture by asking the patients to choose one item from "deep electroacupuncture," "shallow electroacupuncture," or "I don't know." The success of the blinding method will be evaluated within 30 min of the last EA session.

Randomization and allocation procedures

A research assistant who will not be involved in the trial intervention and evaluation will be in-charge of the randomization. The random numbers will be generated using a computerized random number generator in a block size of 4. Patients will be enrolled in a ratio of 1:1. The randomized number chits will be kept in opaque sealed envelopes and opened sequentially. The envelopes will be stored by the assistant and opened on the day the patients receive their first treatment from the acupuncturist.

Intervention

Patients will be administered 12 sessions of free EA treatment during the study period. The treatment will start on the day the patients are randomized. Dongbang disposable stainless steel needles (0.3 × 75 mm and 0.25 × 15 mm, Suzhou Dongbang Medical Equipment Co., Ltd., Suzhou, China) and a Yingdi electric stimulator (Changzhou Yingdi Electronic Medical Device Co., Ltd., Changzhou, China) will be used. The selection of acupoints will be made as per the clinical experience and specialist consensus. In case of radicular pain, bilateral Dachangshu (BL25), Guanyuanshu (BL26), and L3-L5 Jiaji (Ex-B2), Weizhong (BL40) and Chengshan (BL57) will be used. Patients will be administered 12 sessions of EA (3 times a week for 4 weeks) and each session will last 20 min. Patients in the deep EA group will be administered EA at the acupoints in the prone position bilaterally using 0.3 × 75 needles. The needles will be inserted slowly and vertically to a depth of 35–70 mm as per the patient's figure to achieve *deqi* sensation; it is preferable if the sensation radiates down to the lower limb. After the needles are inserted, paired clips of electric stimulator will be attached transversely to the bilateral Dachangshu (BL25) and Guanyuanshu (BL26). A 5-Hz continuous wave will be used, and the current strength will be adjusted as per the patient's tolerance. Patients in the shallow EA group will be administered acupuncture treatment using the 0.25 × 15-mm needles that will be inserted slowly and vertically approximately 2–5 mm at the same acupoints with no *deqi* sensation. An electric stimulator will be connected using the same method as used in the deep EA group.

Patients are allowed to take analgesics when their pain becomes unbearable. Any

analgesics that are used will be recorded in the case report form (CRF).

Outcome measures

Primary outcome

The primary outcome will be the change from baseline in the patients' worst low back pain intensity and leg pain intensity (if patients have radicular pain) measured using the visual analog scale (VAS), at weeks 2, 4, 6, and 8. The VAS is a ruler with a length of 0 mm–100 mm. Patients will be asked to make a mark on the ruler that represents their worst low back pain intensity and leg pain intensity during the previous week, with 0 mm representing no pain and 100 mm representing unbearable pain.

Secondary outcomes

The following secondary outcomes will be measured: 1) change in the Roland–Morris Disability Questionnaire (RMDQ) scores at weeks 2, 4, 6, and 8 compared to that at baseline. The RMDQ is a 24-item self-reported questionnaire that assesses low back function. The item will be scored 1 point if the patient indicates that the item is applicable to them; if the item is not applicable, a score of 0 will be assigned. The total score will be calculated by adding the points for all items (range 0–24). A higher score indicates a worse condition; 2) change in the EuroQol five-dimensional five-level questionnaire (EQ-5D-5L) at weeks 2, 4, 6 and 8 as compared to that baseline. The EQ-5D-5L is a five-dimension self-rated questionnaire for assessing the health state. It contains a five-dimension questionnaire and an EQ-VAS for the assessment of the

health status. The five dimensions include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels, described as “no problems,” “slight problems,” “moderate problems,” “severe problems,” and “extreme problems”. Patients will be asked to choose one item in each dimension that indicates his/her health state on the assessment day. The health state will be represented by the index value, which is derived by applying a formula to each level in each dimension. Calculation of the index value will be conducted by a syntax file provided by the EuroQol office. The EQ-VAS records the patients’ health on a vertical VAS. The EQ-VAS scale is a 100-mm scale labeled 0–100 mm, representing “best imaginable health state” to “worst imaginable health state.” Patients will be asked to choose one number between 0 and 100 that represents their health status on the day of the assessment; 3) Patient self-evaluation of the therapeutic effect will be assessed by asking the patients to choose an answer from “No help,” “Little help,” “Medium help,” and “Great help.” The self-evaluation will be assessed at weeks 2, 4, 6 and 8.

A three-question expectation assessment will be conducted at baseline. Patients will be asked to choose one answer from “yes,” “no,” or “unclear” for the following two items: 1) In general, do you believe that electroacupuncture is helpful for disease treatment? 2) Do you believe that electroacupuncture is helpful with your lumbar disk herniation? Patients will choose one answer from “no help,” “little help,” “medium help,” “great help,” or “I do not care” for the item “What degree do you think electroacupuncture will be helpful with your lumbar disc herniation?”

Safety assessment

Any adverse events (AEs) during the study period will be recorded, assessed, and treated. The details of the AEs will be recorded in the CRF. AEs will be categorized as treatment-related (e.g. broken needle, fainting, dizziness, nausea, vomiting, palpitations, localized hematoma, localized infection, or localized severe sharp pain) or non-treatment-related (e.g. common cold, diarrhea, cough, or headache) within 24 h of occurrence. Patients will not be blinded and treatment will be discontinued if serious AEs occur (e.g. causing disability to work or requiring hospitalization). Serious AEs will be immediately reported to the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine and suspend the study. The AEs occurrence ratio will be calculated.

Sample size calculation

Power Analysis and Sample Size (version 11.0) was used for calculating the required sample size. The primary outcome was the change from baseline in the patients' low back pain VAS score at 4 weeks. In previous studies [7, 8], the change from baseline in low back pain VAS score after 4 weeks of treatment was 27.8 ± 11.9 mm in the deep EA group and 14.6 ± 13.2 mm in the shallow EA group. Considering a two-sided significance level of 5% (α) and a test power of 90% (β), 21 patients would be required in each group. Considering a dropout rate of 5%, 22 patients would be required in each group. The required sample size was 44 in this trial.

Data collection, management, and monitoring

Patients will undergo free treatment and outcome evaluation during the study period. Dropouts and withdrawals will be recorded with the respective reasons in the CRFs. Patients who discontinue treatment but do not drop out will be invited to enter the follow-up period and complete assessments.

CRF will be first filled in the paper copies and entered into the Microsoft Excel by two independent researchers. Data monitoring and validation will be regularly conducted throughout the study. The original CRFs and consent forms will be kept in the department of acupuncture at the Third Affiliated Hospital of Beijing University of Chinese Medicine with limited access authority for 3 years after publication. Original clinical information will not be accessed without the permission of the principal researcher ZH. The monitoring committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will check the CRFs 2 times each month.

Statistical analyses

Data will be analyzed as per the intention-to-treat principle. Missing data will be filled in by multiple imputation. IBM SPSS (version 20.0; International Business Machines Corporation, China) will be used for data analysis. A two-sided test will be conducted with a significance level of 0.05 and 95% confidence intervals. Between-group differences in the VAS scores, RMDQ scores, and EA-5D-5L scores will be analyzed with ANCOVA or nonparametric test, based on the normality of the data. Expectation assessment will be analyzed with general linear regression to assess if there is a

correlation between the primary outcome and patient expectations. The success of the blinding method will be evaluated using chi-square test. Means and standard deviations or means and 95% confidence intervals will be used to present continuous data in case of normal distribution. Medians and interquartile ranges will be used to present continuous data for non-normal data. Frequencies and percentages will be used to present the categorical data.

Quality control

All the investigators will undergo special training regarding the purpose, content, and treatment strategies to achieve quality control. EA will be performed by an acupuncturist who has undergone at least 5 years of undergraduate education and attained a certificate in Traditional Chinese Medicine practice. The monitoring committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will monitor the safety of this study and review the study results.

Patient and public involvement

No patient involved.

Ethics and dissemination

This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06) and registered at the Chinese Clinical Trial Registry (registration number: ChiCTR-1900026518). All patients will be fully informed about the trail and given enough time

to decide whether to participate in the study. All patients will be asked to sign an informed consent form if they agree to participate in the study. Study results will be published at an online access medical journal.

Discussion

Study results will provide an understanding of the effectiveness of deep EA with strong deqi sensation and shallow EA with no deqi sensation in patients with LDH. Current studies mainly focus on the effectiveness of acupuncture and have compared acupuncture with sham or placebo acupuncture related to chronic low back pain [9]. However, to our knowledge, no detailed trials have compared deep electroacupuncture with strong deqi sensation and shallow electroacupuncture with no deqi related to LDH. A strong deqi sensation could be an unpleasant experience for some patients; therefore, we wish to optimize our treatment for patients who are unwilling to go through the deqi sensation.

The concept of determining whether there is a difference between deep EA and shallow EA was first proposed by a patient who preferred shallow needle insertion to deep needle insertion. Moreover, the patient stated that strong *deqi* sensation stressed him during the acupuncture treatment. In Western countries, acupuncture is usually performed at a shallower level than in China, with effective in pain relief. Patients in China are difficult to blind because of their cultural background [14]. Thus, we involved electroacupuncture to minimize the changes of patients' recognizing the group assignment.

Dysfunction caused by pain is a critical issue that affects patients' productivity and quality of life [1]. In our clinical experiences, even with low-intensity pain (<30 mm on a 100-mm VAS), patients reported that it greatly compromised their daily life. Therefore, we did not restrict the minimum pain intensity in the inclusion criteria. The function and quality of life will be assessed in order to explore whether EA can improve the function and quality of life in patients with LDH. RMDQ is for assessing physical disability caused by low back pain, and it is more sensitive to change in patients with mild to moderated disability than the Oswestry Disability Index; a change of 2–3 points between groups in RMDQ should be considered the minimum clinically important change [15, 16]. The EQ-5D-5L was developed based on the EQ-5D-3L to improve the sensitivity and reduce the ceiling effects by increasing the severity levels from 3 to 5 [17, 18]. Both these questionnaires are short, and are not specifically difficulty to read or understand, and can be completed in 5 min. Thus, the response burden is low [15, 18]. Patients' expectations might present therapeutic benefits in clinical practice [19]. Thus, the effects of expectation on outcomes will be assessed to determine whether there is an association between patients' expectations and the primary outcome. Moreover, the success of the blinding method will be assessed. Many psychological scales have been used as indicators of the evaluation of chronic low back pain [20, 21]. However, tedious questionnaires of these scales might cause the patient to become uninterested and thus less cooperative. Therefore, we plan not to use psychological scales.

This study will provide evidence for clinical practice about the effect of deep EA and

shallow EA and thus aid acupuncturists in decision-making while treating patients with LDH.

The main limitation of this study is the inability to blind the acupuncturist.

Trial status

We are recruiting patients.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Ziling Huang and Jianxin Zhao designed this study. Jianxin Zhao, Xinghong Pei, and Ziling Huang are responsible for recruitment. Ziling Huang will perform acupuncture treatment. Xinghong Pei and Bobo Wang are responsible for data collection. This manuscript was drafted by Ziling Huang and revised by Jianxin Zhao. All authors have read and approved the final manuscript.

References:

1. Deyo RA, Weinstein JN: **Low back pain**. *N Engl J Med* 2001, **344**(5):363-370.

2. Deyo RA, Mirza SK: **CLINICAL PRACTICE. Herniated Lumbar Intervertebral Disk**. *N Engl J Med* 2016, **374**(18):1763-1772.

3. Qaseem A, Wilt TJ, McLean RM, Forciea MA: **Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians**. *ANN INTERN MED* 2017, **166**(7):514-530.

4. de Campos TF: **Low back pain and sciatica in over 16s: assessment and management NICE Guideline [NG59].** *J PHYSIOTHER* 2017, **63**(2):120.

5. Vickers AJ, Vertosick EA, Lewith G, MacPherson H, Foster NE, Sherman KJ, Irnich D, Witt CM, Linde K: **Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis**. *J PAIN* 2018, **19**(5):455-474.

6. Wong S, Choi SW, Cheung CW: **A comparison of chronic pain with and without neuropathic characteristics in a Hong Kong Chinese population: An analysis of pain related outcomes and patient help seeking behaviour**. *PLOS ONE* 2018, **13**(10):e204054.

7. Huang Z, Liu S, Zhou J, Yao Q, Liu Z: **Efficacy and Safety of Acupuncture for Chronic Discogenic Sciatica, a Randomized Controlled Sham Acupuncture Trial**. *PAIN MED* 2019.

8. Zhang X, Wang Y, Wang Z, Wang C, Ding W, Liu Z: **A Randomized Clinical Trial Comparing the Effectiveness of Electroacupuncture versus Medium-**

Frequency Electrotherapy for Discogenic Sciatica. *EVID-BASED COMPL ALT* 2017, **2017**:1-9.

9. AD F, van Tulder MW, D C, H T, L L, BW K, BM B: **Acupuncture and dry-needling for low back pain**. *COCHRANE DB SYST REV* 2005(1).

10. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG: **CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials**. *BMJ* 2010, **340**:c869.

11. Schulz KF, Altman DG, Moher D: **CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials**. *BMJ* 2010, **340**:c332.

12. MacPherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, Moher D: **Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement**. *PLOS MED* 2010, **7**(6):e1000261.

13. Kreiner DS, Hwang SW, Easa JE, Resnick DK, Baisden JL, Bess S, Cho CH, DePalma MJ, Dougherty PN, Fernand R *et al*: **An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy**. *SPINE J* 2014, **14**(1):180-191.

14. Karst M, Li C: **Acupuncture—A Question of Culture**. *JAMA Network Open* 2019, **2**(12):e1916929.

15. Smeets R, Köke A, Lin C, Ferreira M, Demoulin C: **Measures of function in low back pain/disorders: Low Back Pain Rating Scale (LBPRS), Oswestry Disability**

Index (ODI), Progressive Isoinertial Lifting Evaluation (PILE), Quebec Back Pain Disability Scale (QBPDS), and Roland-Morris Disability Questionnaire. *ARTHRIT CARE RES* 2011, **63**(S11):S158-S173.

16. Roland M, Fairbank J: **The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire**. *Spine (Phila Pa 1976)* 2000, **25**(24):3115-3124.

17. Janssen MF, Birnie E, Haagsma JA, Bonsel GJ: **Comparing the standard EQ-5D three-level system with a five-level version**. *VALUE HEALTH* 2008, **11**(2):275-284.

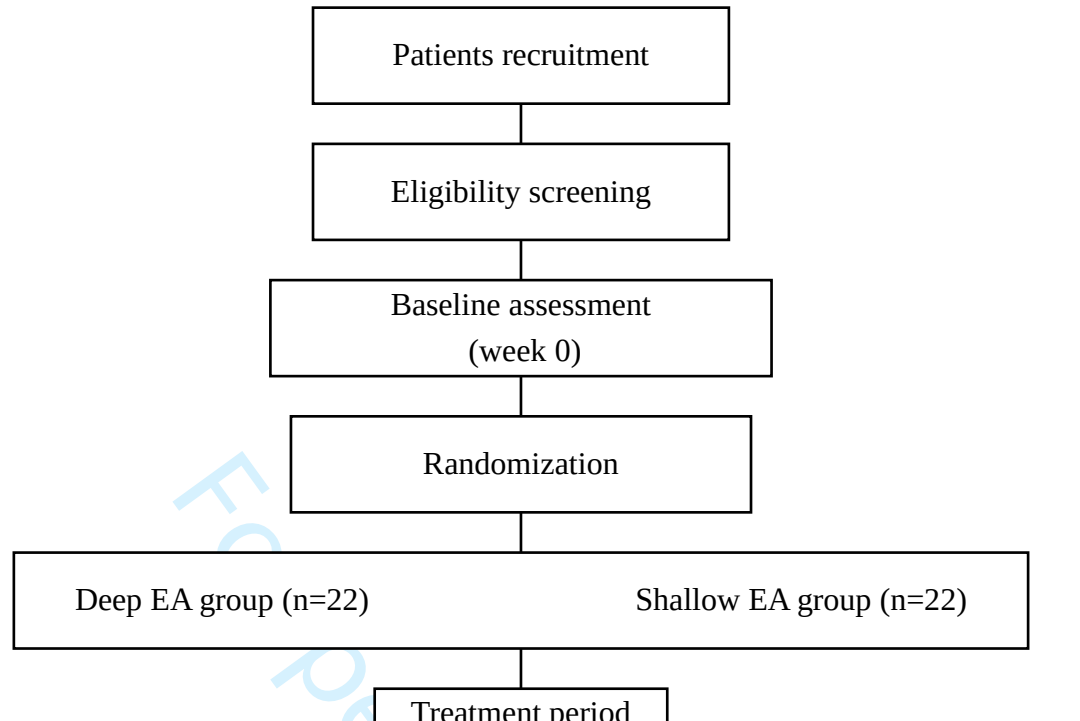
18. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X: **Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)**. *QUAL LIFE RES* 2011, **20**(10):1727-1736.

19. Frisaldi E, Shaibani A, Benedetti F: **Why We should Assess Patients' Expectations in Clinical Trials**. *Pain and Therapy* 2017, **6**(1):107-110.

20. Brox JI, Sorensen R, Friis A, Nygaard O, Indahl A, Keller A, Ingebrigtsen T, Eriksen HR, Holm I, Koller AK *et al*: **Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration**. *Spine (Phila Pa 1976)* 2003, **28**(17):1913-1921.

21. Bishop FL, Yardley L, Prescott P, Cooper C, Little P, Lewith GT: **Psychological covariates of longitudinal changes in back-related disability in patients undergoing acupuncture**. *CLIN J PAIN* 2015, **31**(3):254-264.

Figure 1. Study flow chart



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	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Ethical Approval
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	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	14
	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)	10

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	3-4
	6b	Explanation for choice of comparators	3-4, 12-13
Objectives	7	Specific objectives or hypotheses	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)	4
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	4
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)	4-5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-7
	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)	9
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	6-7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
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	7-9
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)	Figure 1

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	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	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	6
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	6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5-6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9
Methods: Data collection, management, and analysis			
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	10-11
	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	10

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	10-11
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	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	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)	11
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	10-11
	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	10-12
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	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	10-11
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N/A
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)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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	10-11
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
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	10-11
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	N/A
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	12
	31b	Authorship eligibility guidelines and any intended use of professional writers	12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
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	N/A

*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. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Effectiveness of Deep Electroacupuncture with Strong deqi and Shallow Electroacupuncture with no deqi for Lumbar Disk Herniation: Study Protocol for A Randomized Controlled Trial

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Effectiveness of Deep Electroacupuncture with Strong *deqi* and Shallow Electroacupuncture with no *deqi* for Lumbar Disk Herniation: Study Protocol for A Randomized Controlled Trial

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Abstract

Introduction: Lumbar disk herniation (LDH) is a common cause of low back pain and dysfunction. Studies have shown that electroacupuncture (EA) can achieve pain relief in patients with LDH. However, there is a lack of evidence regarding the effectiveness of deep EA with strong deqi and shallow EA with no deqi in patients with LDH. This study aims to evaluate the effectiveness of deep EA with strong deqi and shallow EA with no deqi in the treatment of LDH.

Methods and analysis: In this randomized controlled trial, patients with LDH who have low back pain with or without radiculopathy for at least 12 weeks will be enrolled. In total 44 patients will be recruited from the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Patients will be randomized into the deep EA group and the shallow EA group in a ratio of 1:1 and will be administered 12 sessions of EA treatment (3 times a week for 4 weeks, 20 minutes for each session).

The follow-up duration will be 4 weeks. Low back pain intensity and leg pain intensity (in patients with radicular pain) measured using the visual analog scale will be assessed as the primary outcomes. Function (measured using the Roland–Morris Disability Questionnaire), quality of life (measured using the EuroQol five-dimensional five-level questionnaire), and patient-evaluated therapeutic effect will be assessed as the secondary outcomes. Patients' expectations of EA, the success of the blinding method, and safety will also be evaluated. Statistical analyses will be followed by the intention-to-treat analysis.

Ethics and dissemination: This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06). Study results will be disseminated through publication in an open access journal.

Trial registration: ChiCTR-1900026518

Strengths and limitations of this study

- ► This study will provide evidence for clinical practice regarding the effectiveness of deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi*.
- ► It will be difficult for the patients to determine which group they are in because all of them will receive electric stimulation.
- ► The main limitation of this study is the inability to blind the acupuncturist.

Keywords

electroacupuncture, lumbar disk herniation, low back pain, randomized controlled trial

Abbreviations

Lumbar disk herniation (LDH)

Electroacupuncture (EA)

Visual analog scale (VAS)

Roland–Morris Disability Questionnaire (RMDQ)

EuroQol five-dimensional five-level questionnaire (EQ-5D-5L)

Case report form (CRF)

Background

Low back pain is the second most common symptom-related reason for physician visit by patients [1]. About 10% of the patients with low back pain have disk disorder [2]. Patients with LDH commonly experience low back pain recurrence, and these patients often exhibits slower recovery than those with nonspecific low back pain [1, 2]. Non-pharmacological interventions (acupuncture, massage, yoga, and spinal manipulation) are recommended as the first-line treatment in low back pain [3]. Acupuncture is a well-accepted treatment in relieving pain, usually exerting more beneficial effects with every session [4, 5]. In addition, people in China are more likely to choose acupuncture as their first choice for pain relief compared to analgesics [6].

Studies have shown that acupuncture and EA could relieve pain in chronic low back pain patients [7-9]. According to the Traditional Chinese Medicine theory, needles are inserted into the body with sufficient manual manipulations (lifting, thrusting, twisting, or rotating) and cause a *deqi* sensation (a comprehensive sensation of numbness, soreness, heaviness, and distension) to achieve a therapeutic effect. Thus, acupuncturists tend to perform deep needle insertion and cause a strong *deqi* sensation. However, some patients are unwilling to receive much manipulation or are afraid of *deqi* sensation during the acupuncture treatment.

To the best of our knowledge, there has been no detailed investigation of whether the effect is different between deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi*. If shallow electroacupuncture with no *deqi* is effective for LDH, patients with low back pain or radicular pain caused by LDH can choose shallow electroacupuncture for pain relief without the need to undergo strong *deqi* sensation during the acupuncture treatment. This study aims to evaluate the effectiveness of deep electroacupuncture with strong *deqi* and shallow electroacupuncture with no *deqi* in the treatment of LDH.

Methods

Study design

This is a single-center, prospective, shallow electroacupuncture controlled, randomized trial. Patients will receive 12 sessions of either deep EA with strong *deqi* or shallow electroacupuncture (shallow EA) with no *deqi* after randomization. The study duration

will be 9 weeks for each patient that includes baseline assessment for 1 week (at week 0), treatment period of 4 weeks (weeks 1–4), and follow-up duration of 4 weeks (weeks 5–8) (Figure 1). The study method is based on the Consolidated Standards of Reporting Trials [10, 11] and Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture [12].

Patients

Patients with LDH with or without radiculopathy will be enrolled. The diagnose criteria based on the North American Spine Society clinical guidelines will be used [13]. Diagnosis will be established by experienced physicians using computed tomography, magnetic resonance imaging, and symptom examination. The following inclusion criteria will be applied: age 18–80 years and presence of low back pain (with or without radiculopathy) for at least 12 weeks. Patients will be excluded if they meet any of the following criteria: 1) severe LDH requiring surgery; 2) history of spinal surgery; 3) known or suspected spinal diseases (tumors, fractures, infective spine diseases etc.); 4) severe cardiovascular diseases, endocrine system diseases, or pacemaker/metal implants; 5) pregnancy, or lactation, or planning to conceive during the study period; 6) current use of anticoagulant or antiplatelet drugs; 7) mental illnesses; and 8) inability to speak or understand Mandarin.

Patients will be recruited through poster advertisements in the hospital and enrollments through networks from December 1, 2019 to December 30, 2021. In total, 44 patients with LDH will be recruited from the outpatient clinic of the Department of Acupuncture,

the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Baseline assessment will be conducted within 1 week before the first EA session. Written informed consent will be obtained from all the study subjects.

Blinding

Patients, outcome assessors, and statisticians will be blinded. The needles in the deep EA group and the shallow EA group have the same appearance, except for the length. Both the types of needles will be carried during acupuncture to avoid patients from guessing the group they have been allocated to. Patients will be in the prone position and are therefore unable to see the inserted needles.

The success of the blinding method will be examined by an assessor who is not involved in the performance of acupuncture by asking the patients to choose one item from "deep electroacupuncture," "shallow electroacupuncture," or "I don't know." The success of the blinding method will be evaluated within 30 min of the last EA session.

Randomization and allocation procedures

A research assistant who will not be involved in the trial intervention and evaluation will be in-charge of the randomization. The random numbers will be generated using a computerized random number generator in a block size of 4. Patients will be enrolled in a ratio of 1:1. The randomized number chits will be kept in opaque sealed envelopes and opened sequentially. The envelopes will be stored by the assistant and opened on the day the patients receive their first treatment from the acupuncturist.

Intervention

Patients will be administered 12 sessions of free EA treatment during the study period. The treatment will start on the day the patients are randomized. Dongbang disposable stainless steel needles (0.3 × 75 mm and 0.25 × 15 mm, Suzhou Dongbang Medical Equipment Co., Ltd., Suzhou, China) and a Yingdi electric stimulator (Changzhou Yingdi Electronic Medical Device Co., Ltd., Changzhou, China) will be used. The selection of acupoints will be made as per the clinical experience and specialist consensus. In case of radicular pain, bilateral Dachangshu (BL25), Guanyuanshu (BL26), and L3-L5 Jiaji (Ex-B2), Weizhong (BL40) and Chengshan (BL57) will be used. Patients will be administered 12 sessions of EA (3 times a week for 4 weeks) and each session will last 20 min. Patients in the deep EA group will be administered EA at the acupoints in the prone position bilaterally using 0.3 × 75 needles. The needles will be inserted slowly and vertically to a depth of 35–70 mm as per the patient's figure to achieve *deqi* sensation; it is preferable if the sensation radiates down to the lower limb. After the needles are inserted, paired clips of electric stimulator will be attached transversely to the bilateral Dachangshu (BL25) and Guanyuanshu (BL26). A 5-Hz continuous wave will be used, and the current strength will be adjusted as per the patient's tolerance. Patients in the shallow EA group will be administered acupuncture treatment using the 0.25 × 15-mm needles that will be inserted slowly and vertically approximately 2–5 mm at the same acupoints with no *deqi* sensation. An electric stimulator will be connected using the same method as used in the deep EA group.

Patients are allowed to take analgesics when their pain becomes unbearable. Any

analgesics that are used will be recorded in the case report form (CRF).

Outcome measures

Primary outcome

The primary outcome will be the change from baseline in the patients' worst low back pain intensity and leg pain intensity (if patients have radicular pain) measured using the visual analog scale (VAS), at weeks 2, 4, 6, and 8. The VAS is a ruler with a length of 0 mm–100 mm. Patients will be asked to make a mark on the ruler that represents their worst low back pain intensity and leg pain intensity during the previous week, with 0 mm representing no pain and 100 mm representing unbearable pain.

Secondary outcomes

The following secondary outcomes will be measured: 1) change in the Roland–Morris Disability Questionnaire (RMDQ) scores at weeks 2, 4, 6, and 8 compared to that at baseline. The RMDQ is a 24-item self-reported questionnaire that assesses low back function. The item will be scored 1 point if the patient indicates that the item is applicable to them; if the item is not applicable, a score of 0 will be assigned. The total score will be calculated by adding the points for all items (range 0–24). A higher score indicates a worse condition; 2) change in the EuroQol five-dimensional five-level questionnaire (EQ-5D-5L) at weeks 2, 4, 6 and 8 as compared to that baseline. The EQ-5D-5L is a five-dimension self-rated questionnaire for assessing the health state. It contains a five-dimension questionnaire and an EQ-VAS for the assessment of the

health status. The five dimensions include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels, described as “no problems,” “slight problems,” “moderate problems,” “severe problems,” and “extreme problems”. Patients will be asked to choose one item in each dimension that indicates his/her health state on the assessment day. The health state will be represented by the index value, which is derived by applying a formula to each level in each dimension. Calculation of the index value will be conducted by a syntax file provided by the EuroQol office. The EQ-VAS records the patients’ health on a vertical VAS. The EQ-VAS scale is a 100-mm scale labeled 0–100 mm, representing “best imaginable health state” to “worst imaginable health state.” Patients will be asked to choose one number between 0 and 100 that represents their health status on the day of the assessment; 3) Patient self-evaluation of the therapeutic effect will be assessed by asking the patients to choose an answer from “No help,” “Little help,” “Medium help,” and “Great help.” The self-evaluation will be assessed at weeks 2, 4, 6 and 8.

A three-question expectation assessment will be conducted at baseline. Patients will be asked to choose one answer from “yes,” “no,” or “unclear” for the following two items: 1) In general, do you believe that electroacupuncture is helpful for disease treatment? 2) Do you believe that electroacupuncture is helpful with your lumbar disk herniation? Patients will choose one answer from “no help,” “little help,” “medium help,” “great help,” or “I do not care” for the item “What degree do you think electroacupuncture will be helpful with your lumbar disc herniation?”

Safety assessment

Any adverse events (AEs) during the study period will be recorded, assessed, and treated. The details of the AEs will be recorded in the CRF. AEs will be categorized as treatment-related (e.g. broken needle, fainting, dizziness, nausea, vomiting, palpitations, localized hematoma, localized infection, or localized severe sharp pain) or non-treatment-related (e.g. common cold, diarrhea, cough, or headache) within 24 h of occurrence. Patients will not be blinded and treatment will be discontinued if serious AEs occur (e.g. causing disability to work or requiring hospitalization). Serious AEs will be immediately reported to the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine and suspend the study. The AEs occurrence ratio will be calculated.

Sample size calculation

Power Analysis and Sample Size (version 11.0) was used for calculating the required sample size. The primary outcome was the change from baseline in the patients' low back pain VAS score at 4 weeks. In previous studies [7, 8], the change from baseline in low back pain VAS score after 4 weeks of treatment was 27.8 ± 11.9 mm in the deep EA group and 14.6 ± 13.2 mm in the shallow EA group. Considering a two-sided significance level of 5% (α) and a test power of 90% (β), 21 patients would be required in each group. Considering a dropout rate of 5%, 22 patients would be required in each group. The required sample size was 44 in this trial.

Data collection, management, and monitoring

Patients will undergo free treatment and outcome evaluation during the study period. Dropouts and withdrawals will be recorded with the respective reasons in the CRFs. Patients who discontinue treatment but do not drop out will be invited to enter the follow-up period and complete assessments.

CRF will be first filled in the paper copies and entered into the Microsoft Excel by two independent researchers. Data monitoring and validation will be regularly conducted throughout the study. The original CRFs and consent forms will be kept in the department of acupuncture at the Third Affiliated Hospital of Beijing University of Chinese Medicine with limited access authority for 3 years after publication. Original clinical information will not be accessed without the permission of the principal researcher ZH. The monitoring committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will check the CRFs 2 times each month.

Statistical analyses

Data will be analyzed as per the intention-to-treat principle. Missing data will be filled in by multiple imputation. IBM SPSS (version 20.0; International Business Machines Corporation, China) will be used for data analysis. A two-sided test will be conducted with a significance level of 0.05 and 95% confidence intervals. Between-group differences in the VAS scores, RMDQ scores, and EA-5D-5L scores will be analyzed with ANCOVA or nonparametric test, based on the normality of the data. Expectation assessment will be analyzed with general linear regression to assess if there is a

correlation between the primary outcome and patient expectations. The success of the blinding method will be evaluated using chi-square test. Means and standard deviations or means and 95% confidence intervals will be used to present continuous data in case of normal distribution. Medians and interquartile ranges will be used to present continuous data for non-normal data. Frequencies and percentages will be used to present the categorical data.

Quality control

All the investigators will undergo special training regarding the purpose, content, and treatment strategies to achieve quality control. EA will be performed by an acupuncturist who has undergone at least 5 years of undergraduate education and attained a certificate in Traditional Chinese Medicine practice. The monitoring committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will monitor the safety of this study and review the study results.

Patient and public involvement

No patient involved.

Ethics and dissemination

This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06) and registered at the Chinese Clinical Trial Registry (registration number: ChiCTR-1900026518). All patients will be fully informed about the trail and given enough time

to decide whether to participate in the study. All patients will be asked to sign an informed consent form if they agree to participate in the study. Study results will be published at an online access medical journal.

Discussion

Study results will provide an understanding of the effectiveness of deep EA with strong deqi sensation and shallow EA with no deqi sensation in patients with LDH. Current studies mainly focus on the effectiveness of acupuncture and have compared acupuncture with sham or placebo acupuncture related to chronic low back pain [9]. However, to our knowledge, no detailed trials have compared deep electroacupuncture with strong deqi sensation and shallow electroacupuncture with no deqi related to LDH. A strong deqi sensation could be an unpleasant experience for some patients; therefore, we wish to optimize our treatment for patients who are unwilling to go through the deqi sensation.

The concept of determining whether there is a difference between deep EA and shallow EA was first proposed by a patient who preferred shallow needle insertion to deep needle insertion. Moreover, the patient stated that strong *deqi* sensation stressed him during the acupuncture treatment. In Western countries, acupuncture is usually performed at a shallower level than in China, with effective in pain relief. Patients in China are difficult to blind because of their cultural background [14]. Thus, we involved electroacupuncture to minimize the changes of patients' recognizing the group assignment.

Dysfunction caused by pain is a critical issue that affects patients' productivity and quality of life [1]. In our clinical experiences, even with low-intensity pain (<30 mm on a 100-mm VAS), patients reported that it greatly compromised their daily life. Therefore, we did not restrict the minimum pain intensity in the inclusion criteria. The function and quality of life will be assessed in order to explore whether EA can improve the function and quality of life in patients with LDH. RMDQ is for assessing physical disability caused by low back pain, and it is more sensitive to change in patients with mild to moderated disability than the Oswestry Disability Index; a change of 2–3 points between groups in RMDQ should be considered the minimum clinically important change [15, 16]. The EQ-5D-5L was developed based on the EQ-5D-3L to improve the sensitivity and reduce the ceiling effects by increasing the severity levels from 3 to 5 [17, 18]. Both these questionnaires are short, and are not specifically difficulty to read or understand, and can be completed in 5 min. Thus, the response burden is low [15, 18]. Patients' expectations might present therapeutic benefits in clinical practice [19]. Thus, the effects of expectation on outcomes will be assessed to determine whether there is an association between patients' expectations and the primary outcome. Moreover, the success of the blinding method will be assessed. Many psychological scales have been used as indicators of the evaluation of chronic low back pain [20, 21]. However, tedious questionnaires of these scales might cause the patient to become uninterested and thus less cooperative. Therefore, we plan not to use psychological scales.

This study will provide evidence for clinical practice about the effect of deep EA and

shallow EA and thus aid acupuncturists in decision-making while treating patients with LDH.

The main limitation of this study is the inability to blind the acupuncturist.

Trial status

We are recruiting patients.

Competing interests

The authors declare that they have no competing interests.

Funding

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Data sharing statement

Study data will be published on the trial registry platform after the trial is completed and the paper is published.

Authors' contributions

Ziling Huang and Jianxin Zhao designed this study. Jianxin Zhao, Xinghong Pei, and

Ziling Huang are responsible for recruitment. Ziling Huang will perform acupuncture treatment. Xinghong Pei and Bobo Wang are responsible for data collection. This manuscript was drafted by Ziling Huang and revised by Jianxin Zhao. All authors have read and approved the final manuscript.

References:

1. Deyo RA, Weinstein JN: **Low back pain**. *N Engl J Med* 2001, **344**(5):363-370.

2. Deyo RA, Mirza SK: **CLINICAL PRACTICE. Herniated Lumbar Intervertebral Disk**. *N Engl J Med* 2016, **374**(18):1763-1772.

3. Qaseem A, Wilt TJ, McLean RM, Forciea MA: **Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians**. *ANN INTERN MED* 2017, **166**(7):514-530.

4. de Campos TF: **Low back pain and sciatica in over 16s: assessment and management NICE Guideline [NG59].** *J PHYSIOTHER* 2017, **63**(2):120.

5. Vickers AJ, Vertosick EA, Lewith G, MacPherson H, Foster NE, Sherman KJ, Irnich D, Witt CM, Linde K: **Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis**. *J PAIN* 2018, **19**(5):455-474.

6. Wong S, Choi SW, Cheung CW: **A comparison of chronic pain with and without neuropathic characteristics in a Hong Kong Chinese population: An analysis of pain related outcomes and patient help seeking behaviour**. *PLOS ONE* 2018, **13**(10):e204054.

7. Huang Z, Liu S, Zhou J, Yao Q, Liu Z: **Efficacy and Safety of Acupuncture for Chronic Discogenic Sciatica, a Randomized Controlled Sham Acupuncture Trial**. *PAIN MED* 2019.

8. Zhang X, Wang Y, Wang Z, Wang C, Ding W, Liu Z: **A Randomized Clinical Trial Comparing the Effectiveness of Electroacupuncture versus Medium-Frequency Electrotherapy for Discogenic Sciatica**. *EVID-BASED COMPL ALT* 2017, **2017**:1-9.

9. AD F, van Tulder MW, D C, H T, L L, BW K, BM B: **Acupuncture and dry-needling for low back pain**. *COCHRANE DB SYST REV* 2005(1).

10. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG: **CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials**. *BMJ* 2010, **340**:c869.

11. Schulz KF, Altman DG, Moher D: **CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials**. *BMJ* 2010, **340**:c332.

12. MacPherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, Moher D: **Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement**. *PLOS MED* 2010, **7**(6):e1000261.

13. Kreiner DS, Hwang SW, Easa JE, Resnick DK, Baisden JL, Bess S, Cho CH, DePalma MJ, Dougherty PN, Fernand R *et al*: **An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy**.

SPINE J 2014, **14**(1):180-191.

14. Karst M, Li C: **Acupuncture—A Question of Culture**. *JAMA Network Open* 2019, **2**(12):e1916929.

15. Smeets R, Köke A, Lin C, Ferreira M, Demoulin C: **Measures of function in low back pain/disorders: Low Back Pain Rating Scale (LBPRS), Oswestry Disability Index (ODI), Progressive Isoinertial Lifting Evaluation (PILE), Quebec Back Pain Disability Scale (QBPDS), and Roland-Morris Disability Questionnaire**. *ARTHRIT CARE RES* 2011, **63**(S11):S158-S173.

16. Roland M, Fairbank J: **The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire**. *Spine (Phila Pa 1976)* 2000, **25**(24):3115-3124.

17. Janssen MF, Birnie E, Haagsma JA, Bonsel GJ: **Comparing the standard EQ-5D three-level system with a five-level version**. *VALUE HEALTH* 2008, **11**(2):275-284.

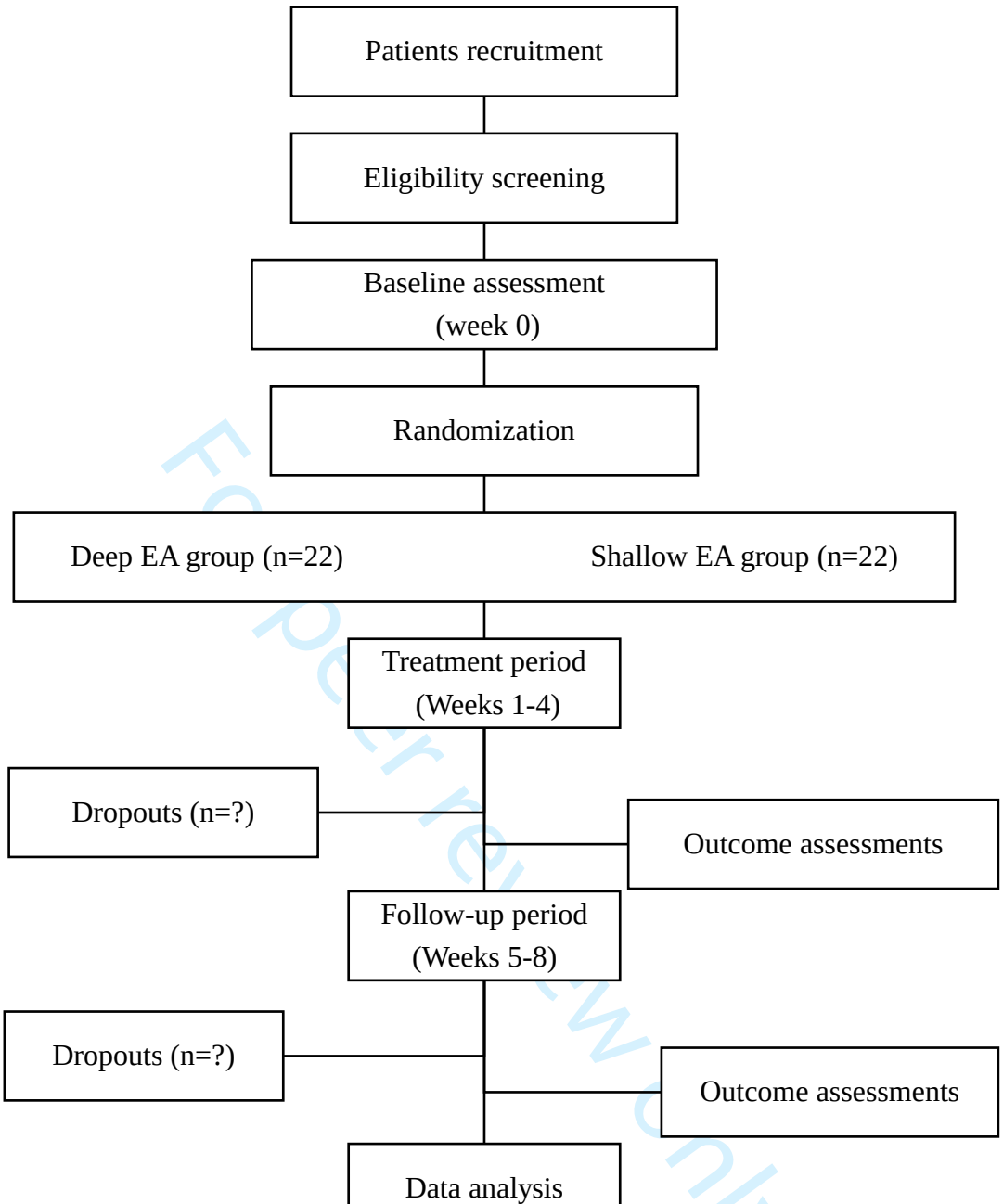
18. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X: **Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)**. *QUAL LIFE RES* 2011, **20**(10):1727-1736.

19. Frisaldi E, Shaibani A, Benedetti F: **Why We should Assess Patients' Expectations in Clinical Trials**. *Pain and Therapy* 2017, **6**(1):107-110.

20. Brox JI, Sorensen R, Friis A, Nygaard O, Indahl A, Keller A, Ingebrigtsen T, Eriksen HR, Holm I, Koller AK *et al*: **Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration**. *Spine (Phila Pa 1976)* 2003, **28**(17):1913-1921.

21. Bishop FL, Yardley L, Prescott P, Cooper C, Little P, Lewith GT: **Psychological covariates of longitudinal changes in back-related disability in patients undergoing acupuncture**. *CLIN J PAIN* 2015, **31**(3):254-264.

Figure 1. Study flow chart



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	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Ethical Approval
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	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	14
	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)	10

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	3-4
	6b	Explanation for choice of comparators	3-4, 12-13
Objectives	7	Specific objectives or hypotheses	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)	4
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	4
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)	4-5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-7
	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)	9
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	6-7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
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	7-9
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)	Figure 1

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	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	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	6
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	6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5-6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9
Methods: Data collection, management, and analysis			
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	10-11
	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	10

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	10-11
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	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	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)	11
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	10-11
	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	10-12
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	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	10-11
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N/A
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)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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	10-11
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
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	10-11
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	N/A
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	12
	31b	Authorship eligibility guidelines and any intended use of professional writers	12
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary file
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	N/A

*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. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.