Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Using electroacupuncture to recover muscle strength in knee osteoarthritic patients after total knee arthroplasty: a study protocol for a double-blinded, randomized and placebo-controlled trial

Hui Xu
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Bingxin Kang
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Yulin Li
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Jun Xie
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Songtao Sun
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Sheng Zhong
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Chenxin Gao
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Xirui Xu
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Chi Zhao
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Guowei Qiu
Shanghai University of Traditional Chinese Medicine Guanghua Hospital
Lianbo Xiao (✉ xiao_lianbo@163.com)
Shanghai University of Traditional Chinese Medicine Guanghua Hospital https://orcid.org/0000-0003-4226-6002

Study protocol

Keywords:

Posted Date: February 12th, 2020

DOI: https://doi.org/10.21203/rs.2.23368/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Version of Record: A version of this preprint was published on August 10th, 2020. See the published version at https://doi.org/10.1186/s13063-020-04601-x.

Abstract

Background: Total knee arthroplasty (TKA) has recently become an almost irreplaceable and effective means to relieve pain, reconstruct knee motor function and improve the quality of life of patients with end-stage knee osteoarthritis (KOA). However, the muscle strength after TKA is usually difficult to recover. Although electroacupuncture (EA) can enhance the muscle strength of lower extremity, there is hardly any literature on the effect of EA on the muscle strength of lower extremity in patients after TKA. To address this problem, this trial is intended to evaluate the efficacy of EA after TKA for recovering the muscle strength of lower extremity, esp. in the early post-TKA period.

Methods/design: This is a double-blinded, randomized and controlled trial. It will be conducted between January, 2020 and June, 2020. A total of 94 participants with KOA will have undergone unilateral TKA and they will then be randomized into a treatment group and a control group, viz. the EA group and the sham EA group. The former will receive EA at acupuncture points of ST37, ST36, SP10 and SP9. The latter, the control group will receive sham EA at sham locations for the acupuncture points of ST37, ST36, SP10 and SP9. The participants will be given 5 sessions of treatment per day for 2 weeks. The primary outcomes include a change in the amount of muscle strength and the Hospital for Special Surgery (HSS) score at the second week from a baseline (POD 3). The secondary outcomes include a 6-minute walking test, Numerical rating scale (NRS), the Hamilton Anxiety Scale and additional use of analgesia. The additional outcomes include incidence of analgesia-related side effects and rate of participant satisfaction. Blinding of the participants will also be assessed. The participants will be asked to guess whether they have received EA after the latest intervention. Adverse events of EA will be documented and assessed throughout the trial.

Discussion: EA is helpful for the recovery and enhancement of muscle strength of the lower limb after TKA.

Background

As a common chronic joint disease in orthopedics, knee osteoarthritis (KOA) is mainly etiologically caused by degenerative changes in the articular cartilage and the secondary hyperosteogeny, which can cause problems such as knee pain, stiffness, dysfunction, and so on. With improvements due to new biomaterials and surgical techniques, total knee arthroplasty (TKA) has now become a first choice for patients with severe KOA to improve their quality of life [1, 2]. Compared with non-surgical treatment, TKA has been fully demonstrated to be able to significantly relieve pain and improve functions of patients with severe KOA [3]. More than 700,000 cases of TKA are performed annually in the U.S. to relieve KOA-related pains and disability, and this number is expected to reach 3.5 million per year by 2030 [4]. Although knee function and its imaging parameters are found to be objectively improved after TKA, 19–23% of the patients who have undergone TKA are still reported to be dissatisfied at 6 months of follow-up [5, 6]. Post-operative deficits in muscle strength of the lower limbs reduce walking distance and stair climbing speed persist after TKA compared to healthy adults [7, 8]. Lack of muscle strength increases the

risk of falls and may make the patients lose their independence. The rehabilitation of muscle strength of the knee extensor and flexor is essential for the improvement of the functional level of KOA patients because stability of the knee is supported primarily by the soft tissue of the quadriceps femoris and hamstring. It is reported that the quadriceps femoris and hamstring decreased in their strength after TKA [9, 10, 11, 12], which is related to the decline of function [13, 14]. The difficulty with post-TKA recovery of muscle strength has been widely reported. For example, the pain of a surgical incision reduces the patient's exercise. In the first month after TKA, the strength of quadriceps femoris decreased by 60% [15]. Although the strength of the quadriceps improved over time, quadriceps strength deficits is reported approximately 30% in more than two years after TKA operation, compared with healthy adults [16]. Immediately after the operation, the hamstring strength reduced by 50% [17, 18]. Prior studies have shown that TKA-related weakness and gait biomechanical damage to the quadriceps femoris and hamstring may last for several years [19, 20]. Standardized physiotherapy has been proven to be beneficial to strengthening the muscle function [21]. Besides, neuroregulatory techniques including neuromuscular electrical stimulation and EA are becoming increasingly attractive and muture as a post-TKA rehabilitation therapy [22]. Effective neuroregulatory techniques after TKA can help enhance the muscle strength of the lower limbs, and thus speed up the rehabilitation and reduce the financial burden of the patients [23].

Electrical acupuncture, recommended primarily for pain modulation, has been shown to be able to enhance muscle strength [24, 25]. In some randomized controlled trials (RCT) for patients after TKA, however, little information is given about the effect of electricity on the muscle strength of the lower limbs. In view of this, we have designed a double-blinded, randomized and placebo-controlled trial to investigate the effects of EA on muscle strength of the lower limbs in patients after TKA.

Objectives

To evaluate the efficacy of EA after TKA for enhancing the muscle strength of lower extremity in the early post-operative period.

Methods/design

This trial will be carried out at Department of Orthopaedics, Shanghai Guanghua Integrated Chinese and Western Medicine Hospital, Shanghai, China. The hospital is a teaching and tertiary hospital of Shanghai University of Traditional Chinese Medicine, Shanghai, China. KOA patients who will receive unilateral TKA will be recruited through advertisements, mainly from the orthopaedics wards of Shanghai Guanghua Integrated Chinese and Western Medicine Hospital, Shanghai, China. We followed the SPIRIT 2013 Statement [26] and STRICTA [27] for the reporting of our trial protocol. This study has been approved by the ethics committee of Guanghua Hospital of Integrated Traditional Chinese Medicine and Western Medicine (Ethics Approval Number: 2019-K-23) and registered at the Chinese Clinical Trial Registry. All participants will be asked to provide their written informed consent.

Eligibility criteria

Inclusion criteria: (1) 60–80 years of age, (2) diagnosed as KOA and willing to receive unilateral TKA, (3) similar surgical approach and normal blood coagulation function is normal, (4) posterior cruciate-stabilizing prostheses (Smith & Nephew, London, UK), (5) the knee prosthesis well placed (as shown by the postoperative X-ray), and (6) post-operative participants having clear consciousness and normal cognitive function.

Exclusion criteria: (1) serious nervous system problems, cardiovascular diseases, osteoporosis and metabolic diseases, (2) suffering from coagulation disorder, hemophilia or tumor, (3) bone fracture, dislocation and structural abnormality during the operation, and (4) skin damage in the acupoint area.

Exit criteria and management

Exit criteria: (1) having such needs, (2) severe postoperative complications (such as pulmonary embolism), and (3) side effects during the treatment.

Sample size

The sample size will be calculated by using the peak torque of quadriceps femoris from the previous studies [28]. The formula:

$$n = \frac{2\left(Z_{\alpha} + Z_{1-\beta}\right)^2 \sigma^2}{\Delta^2}$$

An effect size (△) of 2 with a standard deviation (SD) of 3.34 between EA and RT (n = 33*2/0.85 = 82) will be adopted. Based on this data, a two-group trial will be established with 39 participants per group, α = 0.05 (two-sided) and β = 0.2 (80% power) [29]. With a possible sample loss of 15%, the final sample size will be set with 47 participants per group.

Recruitment strategies and enrollment

Participants registration is to begin in January, 2020 and is expected to conclude in June, 2020. Written informed consents will be obtained from all participants. Until then, this cohort of participants will not be included in any other scientific publications. When participants are hospitalized, a trained nurse and some physiotherapists will implement an enhanced recovery after surgery (ERAS) pathways (Fig. 1). Figure 2 is a trial flow diagram, which includes participant recruitment, eligibility, screening, randomization, intervention and outcome assessments. Figure 3 is an overview of the trial design, conduct, review and analysis. SPIRIT 2013 checklist (Word) is has been filled out and presented in Additional file 1.

Randomization and blinding

Using RV.3.5.1 software to generate a randomly-numbered sequence for a complete random grouping. A sequence of numbers will be sealed by an independent assistant in an opaque envelope containing treatment information. Eligible and consenting KOA participants undergone unilateral TKA will be randomly assigned to the EA group and the sham EA group at a ratio of 1: 1, with 47 participants in each group.

The objects of the blind method will include all the participants, physiotherapists, outcome assessors and data statisticians. To help maximize the blindness for the participants, a pragmatic placebo needle will be used and a sham EA design will be applied.

Interventions

Scheme of Standard Analgesic Use

Postoperatively, patient controlled analgesia (PCA) will be used and removed from the day of surgery to the postoperative day (POD) 3. The analgesic used will be fentanyl (Yichang Renfu Pharmaceutical Co. Ltd., Yichang, China.) at a continuous infusion rate of 0.25 μg/(kg hour) and a bolus of 0.15 μg/kg with a 10-minute lockout time. The locking duration of the projectile will be 10 minutes after administration. Besides, oral celecoxib capsules (Pfizer Pharmaceutica Co. Ltd.,New York State ,USA) will be provided on demand for participants from the POD 4 to POD 14, and additional consumption of analgesia will be recorded.

EA group

According to the new standard of "International Acupuncture Nomenclature" [30], the acupoints to be selected will include LIANGQIU (Stomach 37, ST37), ZUSANLI (Stomach 36, ST36), XUEHAI (Spleen 10, SP10) and YINLINGQUAN (Spleen 9, SP9) on the side of the surgery (Fig. 4). After skin disinfection, adhesive pads (size 8 × 10 mm, Suzhou Medical Supplies Factory, Suzhou, China) will be placed on the acupoints, through which acupuncture needles (size 0.25 × 40 mm, Suzhou Medical Supplies Factory, Suzhou, China) will be inserted approximately by 3 cm into the skin (Fig. 4). After achieving De-qi sensation, the acupuncture points will be stimulated with Huatuo SDZ-II EA apparatus (Suzhou Medical Supplies Factory, Suzhou, China). Intensity of the constant current square wave pulse at a frequency of 40 Hz and a pulse width of 1 ms will be increased gradually until beyond the intolerable intensity of the participants. The treatment of the EA group will consist of 10 sessions of 30 minutes over 2 weeks (5 sessions per week).

Sham EA group

For the sham EA group, sham EA with a pragmatic placebo needle [31] (size 0.25 × 30 mm) on the sham acupoints will be used for 5 sessions per week. Each sham acupoint is 1 cun (≈ 20 mm) lateral to the acupoints (Fig. 5). The pragmatic placebo needle with a blunt-tip will be inserted into the adhesive pads but without skin penetration (Fig. 4). Huatuo SDZ-II EA apparatus (Suzhou Medical Supplies Factory, Suzhou, China) will connect sham acupoints at the same time that have special electrode wires without

electricity output. The sham needles will stay in the adhesive pads for 30 minutes in each session. The sham EA treatment process is similar to the EA treatment process but without skin penetration, needle manipulation and electric output.

Outcomes evaluations

Indexes for primary outcomes evaluations include muscle strength and the Hospital for Special Surgery (HSS) score. Those for secondary outcomes evaluations include a 6-minute walking test (6MWT), numerical rating scale (NRS), the Hamilton Anxiety Scale (HAM-A). An additional use of analgesia is also categorized as a secondary outcome. The additional outcome indexes include incidence of analgesia-related side effects and participant satisfaction rate.

NRS, additional use of analgesia, incidence of EA-related and analgesia-related side effects will be recorded daily. Evaluation of the discomfort and acceptance of EA will be conducted after the first day of EA intervention. Muscle strength, HSS, 6 MW, HAM-A will be evaluated at four time points, viz, before the surgery, before EA intervention (at POD 3), one week after EA intervention, and two weeks after EA intervention.

Demographic / medical variables

These variables include sex, age, marital status, occupation, ethnicity information, education level, blood pressure, temperature, respiration, pulse, height, weight, body mass index (BMI), combination of disease and medication, Kellgren-Lawrence classification, course of KOA and history of major operations.

Muscle strength

Knee muscle strength will be evaluated as the peak torque (PT) of knee flexion and extension by using Biodex 4 isokinetic muscle strength tester (IST, Biodex Medical Systems, New York, USA). Prior to the test, the physiotherapist will stabilize the participant on a dynamometric chair in a 90° sitting position, with the participant’s torso and thighs fixed. The machine’s power axis will be aligned with the center of the rotation of the knee, and the participant will be asked to move the knee to measure the range of motion. The participant's knee will be tested within the range of previous tests. The physiotherapist will set the angular velocity at 60° per second and ask the participant to do five constant flexion and extension activities. During the test, the participant will be asked to use his/her maximum strength in each flexion and extension activity to measure the PT of knee flexion and extension. The test will be conducted independently by the physiotherapist.

Hospital for Special Surgery (HSS) Score

HSS score, developed by John N. Insall, the father of the modern artificial knee joint, was first used in 1976 for preoperative and postoperative evaluation of four different types of knee arthroplasty prostheses, and has since been proved to be reliable and effective for such evaluation [32]. HSS score mainly includes 10 items to evaluate the comprehensive condition of participants in terms of pain, daily activity, range of motion of knee, muscle strength, deformity and instability. In this trial, the score will be

used to evaluate the knee joint function of participants before and after TKA to evaluate the effect of EA on early rehabilitation. In addition, the components will be further analyzed to find out the factors that can promote the rehabilitation of participants.

Physical performance

Walking capacity will be evaluated by a 6-minute walking test (6MWT). Participants will be required to walk as fast as they normally would (with walking aids, if necessary) along a 30-m corridor several times. 6MWT is employed because it has been used as a performance metric in a variety of other conditions with minimal adaptations [33]. Participants will be allowed to use assistive devices to walk, and the test is reliable in participants after TKA [34, 35, 36].

Pain

Numerical rating scale (NRS) consists of a horizontal line segment similar to the VAS segment, with "painless" and "extreme pain" or "the most severe pain experienced" as the anchor for the starting and ending points of the scale, and are marked with "0" and "10", respectively. Participants will mark the scale to assess their knee pain (pain recorded at rest, pain recorded at movement). NRS is employed because it is easy to understand and allows wide adaptation and offers minimal difficulty with operation [37, 38].

Perioperative anxiety

Psychic and somatic symptoms of perioperative anxiety will be assessed using the Hamilton Anxiety Scale (HAM-A), which consists of 14 items evaluated on a five-point scale ranging from 0 (not present) to 4 (very severe) [39]. The scores of 0–7, 8–14, 15–19, 20–29 and 30–56 indicate that the subject has no anxiety, questionable anxiety disorder, mild anxiety disorder, moderate anxiety disorder and severe anxiety disorder, respectively.

Additional outcomes

Analgesia-related side effects mainly include postoperative nausea and vomiting (PONV). The participants will be asked to choose their satisfaction rate in a scale [40] (Fig. 6).

Adverse events of EA

In this trial, EA-related complications mainly refer to broken needles, halo acupuncture, stagnation acupuncture, acupuncture site hematoma, continuous post-needling pain lasting > 2 h, bleeding and so on.

Assessment of the blinding

Blinding of participants will also be assessed via analyzing questionnaire response (Fig. 7). The questionnaire will be completed by participants within 5 min after the latest intervention. Regardless of whether participants received a true EA treatment or sham EA treatment, the percentage of subjects from each group who believe that they are given a true EA treatment will be recorded. The difference in the participant blinding success rates between the EA group and the sham EA group will be analyzed.

Statistical analysis

Epidata V3.1 will be used to input the data and IBM SPSS Statistics V21 will be used for statistical analysis. A complete follow-up study of the participants will be performed using the per-protocol sets and intent-to-treat population. Statistical analysis consists of four aspects. Firstly, if the measurement data will be subjected to a normal distribution, the mean ± standard deviation (SD) will be used for statistical description of the degree of concentration trend and dispersion. Differences between the two groups will be compared using two independent sample T-tests. If the normal distribution will not be followed. The median will be used for statistical description of the degree of concentration trend and dispersion. The difference between the two groups will be compared using the Mann-Whitney U test. Secondly, the participants' gender composition ratio is continuous in data, using the Fourfold Table Chi-Square Test. Thirdly, the difference in the ranked data between the two groups will be compared using the Mann-Whitney U test. Lastly, the repeated measurement data will be compared using the generalized linear mixed models (GLMMs). Statistical significance will be considered as p value < 0.05 (two-side).

Discussion

Evolved from the traditional manual acupuncture method, EA is the use of modern electronic equipment to enhance the intensity of mechanical stimulation of acupuncture for beneficial effects such as pain relief, muscle relaxation, circulation improvement, etc. [41, 42]. EA has been proven to be effective in improving muscle strength and promoting functional rehabilitation [43, 44]. To our knowledge, the benefits of EA as a treatment to enhance muscle strength after TKA have not yet been validated by randomized and placebo-controlled trials. To fill in this niche, the present trial is intended to examine the efficacy of EA, in the early postoperative period of TKA for improving muscle strength compared with that of the sham EA, in an attempt to provide evidence for the clinical application of EA for KOA patients after unilateral TKA. To maximize the exclusion of placebo effects, a rigorous and methodological design will be followed, which includes non-acupoints, non-penetrating acupuncture and special electrode wires with electricity output for control. In addition, participants will receive treatments unaccompanied at different times to avoid communication with other participants to avoid interference. Through the above methods, participants will hopefully be successfully blinded, and the efficacy of EA for post-TKA participants will be evaluated objectively.

What's more, due to its decent analgesic effects, EA can reduce use of opioid and non-steroidal anti-inflammatory drugs after TKA. In past several years, enhanced recovery after surgery (ERAS) has been increasingly supported worldwide, thanks to its contribution to patients pain relief and functional recovery [45]. Early interventive treatment with EA after TKA may hopefully become an important part of ERAS in the foreseeable future. We believe that this trial will contribute to enhancing lower limb muscle strength after TKA, and thus provide evidence for the primary rehabilitation of TKA.

Abbreviations

TKA:total knee arthroplasty; KOA:knee osteoarthritis; EA:electroacupuncture; RCT:randomized controlled trial; ERAS:enhanced recovery after surgery; PCA:patient controlled analgesia; POD:postoperative day; BMI:body mass index; PT:peak torque; HSS:hospital for special knee score; 6MWT:6-minute walking test; NRS:numerical rating scale; HAM-A:Hamilton Anxiety Scale; BMI:body mass index; PT:peak torque; IST:isokinetic strength test

Declarations

1. **Trial status**

   - Protocol version number: V1.1: 21 September 2019
   - Date of recruitment: 1 January 2020
   - Date of recruitment completed: 1 Jun 2020

2. **List of abbreviations**

TKA: total knee arthroplasty; KOA: knee osteoarthritis; EA: electroacupuncture; RCT: randomized controlled trial; ERAS: enhanced recovery after surgery; PCA: patient controlled analgesia; POD: postoperative day; BMI: body mass index; PT: peak torque; HSS: hospital for special knee score; 6MWT: 6-minute walking test; NRS: numerical rating scale; HAM-A: Hamilton Anxiety Scale; BMI: body mass index; PT: peak torque; IST: isokinetic strength test

3. **Ethics approval and consent to participate**

This trial is in line with the principles of the Helsinki Declaration (2013), and was approved by the ethics committee of the participating hospital (Ethics approval numbers: 2019-K-23). All will give their written informed consent before the trial.

4. **Consent for publication**

Not applicable.

5. **Availability of data and materials**

The datasets can be obtained from the corresponding authors upon reasonable request.

6. **Competing interests**

No conflict of interests.

7. **Funding**

This trial will be supported by the Shanghai Municipal Health and Family Planning Commission Program (ZY (2018-2020) -FWTX-6023). The funding organization had no role in the design and conduct of the trial; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication.

8. **Authors' contributions**

LBX will be trial sponsor. HX and BXK will be responsible for designing and supervising the trial. HX and BXK drafted and revised the manuscript. YLL did the clinical trial registration and ethics approval. SZ designed the plan for statistical analysis. JX and STS have formulated the ERAS pathways. CXG and XRX will be the principal evaluators. ZC and GWQ will participate in data collection.

9. **Acknowledgements**

Not applicable.

10. **Authors' information**

[1] Department of Orthopaedics, Shanghai University of Traditional Chinese Medicine Guanghua Hospital, Shanghai 200050, China.

[2] Shanghai Guanghua Integrated Chinese and Western Medicine Hospital, Shanghai 200000, China.

[3] The Hospital of Sun Yat-sen University, Guangzhou 510275, China.

References

1. Kang Kwan Su,Tien Trinh Ngoc,Lee Myung Chul, et al. Suitability of Metal Block Augmentation for Large Uncontained Bone Defect in Revision Total Knee Arthroplasty (TKA). J Clin Med. 2019;8(3):384 Available from: https://www.mdpi.com/2077-0383/8/3/384.
2. Zhao XY,Qin J,Tan Y, et al. Efficacy of steroid addition to multimodal cocktail periarticular injection in total knee arthroplasty: a meta-analysis. Journal of orthopaedic surgery and research. 2015;10(1):75 Available from: https://josr-online.biomedcentral.com/articles/10.1186/s13018-015-0214-8.
3. Skou ST, Roos EM, Laursen MB, et al. A Randomized, Controlled Trial of Total Knee Replacement. New England Journal of Medicine. 2015;373(17):1597-1606 Available from: https://www.ncbi.nlm.nih.gov/pubmed/26488691.
4. Kurtz S, Ong K, Lau E, et al. Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005 to 2030. J Bone Jt Surg Am. 2007;89(4):780-785 Available from: https://www.ncbi.nlm.nih.gov/pubmed/17403800.
5. Jones CA, Voaklander DC, Johnston DW, et al. Health related quality of life outcomes after total hip and knee arthroplasties in a community based population. J Rheumatol. 2000;27(7):1745-1752.
6. Bourne RB, Chesworth BM, Davis AM, et al. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not?. Clinical Orthopaedics and Related Research®. 2010;468(1):57-63 Available from: https://link.springer.com/article/10.1007%2Fs11999-009-1119-9.
7. Bade MJ, Kohrt WM, Stevens-Lapsley JE. Outcomes Before and After Total Knee Arthroplasty Compared to Healthy Adults. J Orthop Sports Phys Ther. 2010;40(9):559-567 Available from:

https://www.jospt.org/doi/full/10.2519/jospt.2010.3317.

8. Walsh M, Woodhouse LJ, Thomas SG, et al. Physical Impairments and Functional Limitations: A Comparison of Individuals 1 Year After Total Knee Arthroplasty With Control Subjects. Phys Ther. 1998;78(3):248-258.
9. Stevens JE, Mizner RL, Snyder-Mackler L. Quadriceps strength and volitional activation before and after total knee arthroplasty for osteoarthritis. J Orthop Res. 2003;21(5):775-779 Available from: https://onlinelibrary.wiley.com/doi/abs/10.1016/S0736-0266%2803%2900052-4.
10. Mizner R L, Petterson S C, Stevens J E, et al. Early quadriceps strength loss after total knee arthroplasty: the contributions of muscle atrophy and failure of voluntary muscle activation. J Bone Joint Surg Am. 2005;87(5):1047-1053 Available from: https://insights.ovid.com/crossref?an=00004623-200505000-00016.
11. Stevens-Lapsley JE, Balter JE, Kohrt WM, et al. Quadriceps and hamstrings muscle dysfunction after total knee arthroplasty. Clinical Orthopaedics and Related Research®. 2010;468(9):2460-2468 Available from: https://link.springer.com/article/10.1007/s11999-009-1219-6.
12. Mizner RL, Petterson SC, Stevens JE, et al. Preoperative quadriceps strength predicts functional ability one year after total knee arthroplasty. J Rheumatol. 2005;32(8):1533-1539 Available from: http://www.jrheum.org/content/32/8/1533.short.
13. Mizner RL, Petterson SC, Snyder-Mackler L. Quadriceps strength and the time course of functional recovery after total knee arthroplasty. J Orthop Sports Phys Ther. 2005;35(7):424-436 Available from: https://www.jospt.org/doi/10.2519/jospt.2005.35.7.424.
14. Mizner RL, Snyder-Mackler L. Altered loading during walking and sit-to-stand is affected by quadriceps weakness after total knee arthroplasty. J Orthop Res. 2005; 23(5):1083-1090 Available from: https://onlinelibrary.wiley.com/doi/abs/10.1016/j.orthres.2005.01.021.
15. Mizner RL, Petterson SC, Stevens JE, et al. The contributions of muscle atrophy and failure of voluntary muscle activation. J Bone Joint Surg Am May. 2005;87(5):1047-1053 Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1167681/.
16. Silva M, Shepherd EF, Jackson WO, et al. Knee strength after total knee arthroplasty. J Arthroplasty Aug. 2003;18(5):605-611 Available from: https://www.sciencedirect.com/science/article/pii/S0883540303001918.
17. Judd D L, Eckhoff D G, Stevens-Lapsley J E. Muscle strength loss in the lower limb after total knee arthroplasty. Am J Phys Med Rehabil Mar. 2012;91(3):220 Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4140618/.
18. Stevens-Lapsley J E, Balter J E, Kohrt W M, et al. Quadriceps and Hamstrings Muscle Dysfunction after Total Knee Arthroplasty. Clinical Orthopaedics & Related Research®. 2010;468(9):2460-2468 Available from: https://link.springer.com/article/10.1007%2Fs11999-009-1219-6.
19. Noble PC, Gordon MJ, Weiss JM, et al. Does total knee replacement restore normal knee function?. Clin Orthop Relat Res Feb. 2005;431:157-165 Available from: https://insights.ovid.com/article/00003086-200502000-00024.

20. Huang C H, Cheng C K, Lee Y T, et al. Muscle strength after successful total knee replacement: a 6- to 13-year followup. Clin Orthop Relat Res. 1996;328:147-154 Available from: https://insights.ovid.com/crossref?an=00003086-199607000-00023.
21. Castrodad I M D, Recai T M, Abraham M M, et al. Rehabilitation protocols following total knee arthroplasty: a review of study designs and outcome measures. Annals of translational medicine. 2019;7:S255.
22. Chughtai M, Elmallah R D, Mistry J B, et al. Nonpharmacologic Pain Management and Muscle Strengthening following Total Knee Arthroplasty. J Knee Surg. 2016;29(03):194-200.
23. Levine M, McElroy K, Stakich V, et al. Comparing conventional physical therapy rehabilitation with neuromuscular electrical stimulation after TKA. Orthopedics. 2013;36(3):e319-e324.
24. Plaster R, Vieira W B, Alencar F A Duarte, et al. Immediate effects of electroacupuncture and manual acupuncture on pain, mobility and muscle strength in patients with knee osteoarthritis: a randomised controlled trial. Acupunct Med. 2014;32(3):236-241 Available from: https://journals.sagepub.com/doi/10.1136/acupmed-2013-010489.
25. Zhou S, Huang L P, Liu J, et al. Bilateral effects of 6 weeks' unilateral acupuncture and electroacupuncture on ankle dorsiflexors muscle strength: a pilot study. Arch Phys Med Rehabil. 2012;93(1):50-55 Available from: https://www.sciencedirect.com/science/article/abs/pii/S0003999311006927.
26. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207 Available from: https://www.scielosp.org/article/rpsp/2015.v38n6/506-514/.
27. MacPherson H, Altman DG, Hammerschlag R, et al. Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement. PLoS Med. 2010;3(3):140-155. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/j.1756-5391.2010.01086.x.
28. Chen G, Gu RX , Xu DD. Application of electroacupuncture in rehabilitation after total knee arthroplasty. Chinese Acupuncture and moxibustion. 2012;32 (04):309-312.
29. 29. Kadam P, Bhalerao S. Sample size calculation. Int J Ayurveda Res.2010;1(1):55 Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2876926/.
30. Jenkins M. A new standard international acupuncture nomenclature. Acupunct Med. 1990;7(1):21-22 Available from: https://journals.sagepub.com/doi/pdf/10.1136/aim.7.1.21.
31. Liu Z, Xu H, Chen Y, et al. The efficacy and safety of electroacupuncture for women with pure stress urinary incontinence: study protocol for a multicenter randomized controlled trial. Trials. 2013;14(1):1-9 Available from: https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-14-315.
32. Bach C M, Nogler M, Steingruber I E, et al. Scoring Systems in Total Knee Arthroplasty. Clinical Orthopaedics and Related Research (1976-2007). 2002;399:184-196.

33. ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. Am J Respir Crit Care Med. 2002;166:111-117.
34. American College of Sports Medicine. American College of Sports Medicine position stand: progression models in resistance training for healthy adults. Med Sci Sports Exerc. 2009;41(3):687-708 Available from: https://www.ncbi.nlm.nih.gov/pubmed/19204579.
35. Kennedy DM, Stratford PW, Wessel J, et al. Assessing stability and change of four performance measures: a longitudinal study evaluating outcome following total hip and knee arthroplasty. BMC Musculoskelet Disord. 2005;6(1):3 Available from: https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/1471-2474-6-3.
36. Rejeski WJ, Ettinger WH Jr, Schumaker S, et al. Assessing performance-related disability in patients with knee osteoarthritis. Osteoarthritis Cartilage. 1995;3:157-167.
37. Metsavaht L, Leporace G, Riberto M, et al. Translation and cross-cultural adaptation of the lower extremity functional scale into a Brazilian Portuguese version and validation on patients with knee injuries. J Orthop Sports Phys Ther. 2012;42(11):932-939 Available from: https://www.jospt.org/doi/10.2519/jospt.2012.4101.
38. Hawker GA, Mian S, Kendzerska T, et al. Measures of adult pain: visual analog scale for pain (VAS pain), numeric rating scale for pain (NRS pain), McGill pain questionnaire (MPQ), short-form McGill pain questionnaire (SF-MPQ), chronic pain grade scale (CPGS), short form-36 bodily pain scale (SF-36 BPS), and measure of intermittent and constant osteoarthritis pain (ICOAP). Arthritis Care Res. 2011;63(S11):S240-S252 Available from: https://onlinelibrary.wiley.com/doi/full/10.1002/acr.20543.
39. Hamilton M. The assessment of anxiety states by rating. Br J Med Psychol. 1959; 32(1):50-55.
40. Sun K, Xing T, Zhang F, et al. Perioperative transcutaneous electrical acupoint stimulation for postoperative pain relief following laparoscopic surgery: a randomized controlled trial. Clin J Pain. 2017;33(4):340-347 Available from: https://www.ingentaconnect.com/content/wk/cjpn/2017/00000033/00000004/art00009.
41. NIH CONSENSUS CONFERENCE. Acupuncture. JAMA. 1998;280(17):1518.
42. Yue C, Zhang X, Zhu Y, et al. Systematic review of three electrical stimulation techniques for rehabilitation after total knee arthroplasty. J Arthroplasty. 2018;33(7):2330-2337 Available from: https://linkinghub.elsevier.com/retrieve/pii/S0883540318301086.
43. Huang LP, Zhou S, Lu Z, et al. Bilateral effect of unilateral electroacupuncture on muscle strength. The Journal of Alternative and Complementary Medicine. 2007;13(5):539-546.
44. Tedesco D, Gori D, Desai KR, et al. Drug-Free Interventions to Reduce Pain or Opioid Consumption After Total Knee Arthroplasty. JAMA Surg. 2017;152(10):e172872-e172872 Available from: https://jamanetwork.com/journals/jamasurgery/fullarticle/2647847.
45. Zhou ZK, Weng XH, Q TB, etc. Accelerated rehabilitation of hip and knee arthroplasty in China– expert consensus on perioperative management strategy [J]. Chinese Journal of Orthopaedic and Joint surgery. 2016;9(1):10-15.

Figures

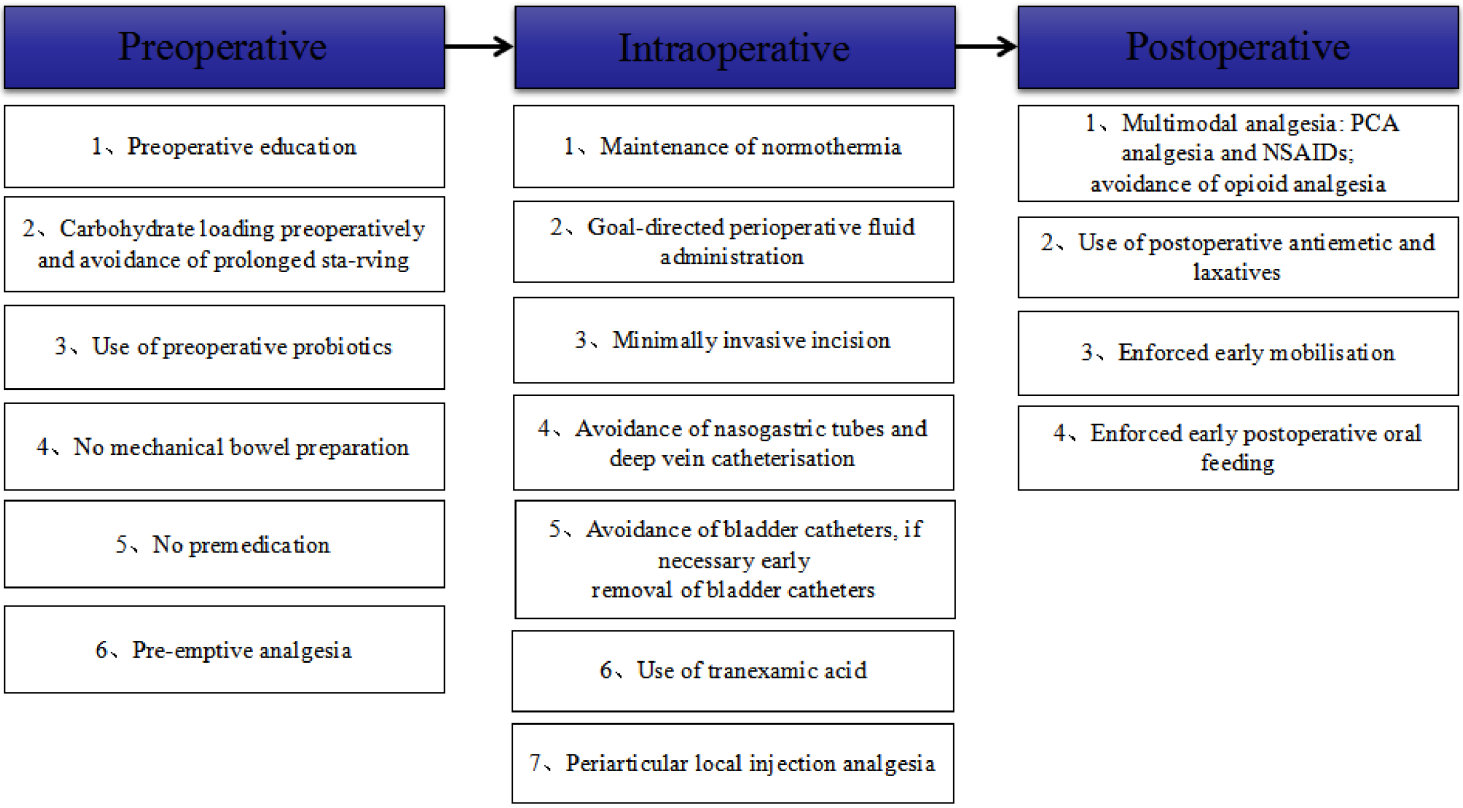


Figure 1

A trained nurse and some physiotherapists will implement an enhanced recovery after surgery (ERAS) pathways

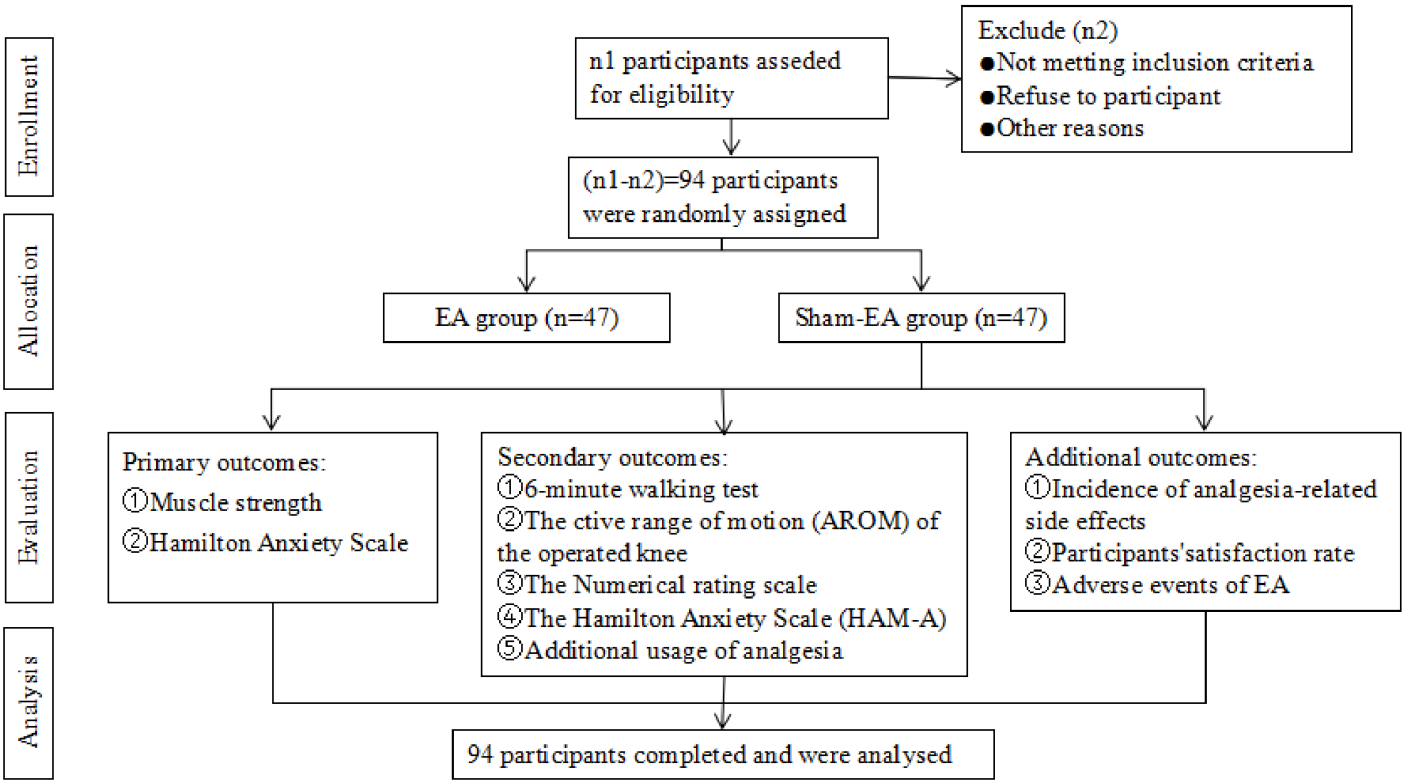


Figure 2

Trial flow diagram, which includes participant recruitment, eligibility, screening, randomization, intervention and outcome assessments

TIMEPOINT		Study Period													
		Enrollment	Allocation	Pre-op* 1day	POD3	The 1st week of EA intervntion					The 2nd week of EA intervntion				
						1	2	3	4	5	1	2	3	4	5
Eligibility Screen		×													
Demographic information informed		×													
Medical information		×													
Allocation			×												
Consent					×					×					×
Primary outcomes	Muscle strength			×	×					×					×
	HSS			×	×					×					×
Secondary outcomes	6MW			×	×					×					×
	NRS			←	—	—	—	—	—	—	—	—	—	—	→
	HAM-A			×	×					×					×
	Additional usage of analgesia				←	—	—	—	—	—	—	—	—	—	→
Additonal outcomes	Participants's atisfaction rate			×											
	Incidence of analgesia-related side effects**				←	—	—	—	—	—	—	—	—	—	→
Adverse events of EA					←	—	—	—	—	—	—	—	—	—	→
Assessment of blinding***															×

*op: operation;
**Incidence of adverse events of analgesia, including postoperative voiming/nausea/dizziness/sleepiness;
***Assessment of blinding: assess the blindingTo test the blinding of participants and assessors.

Figure 3

Overview of the trial design, conduct, review and analysis

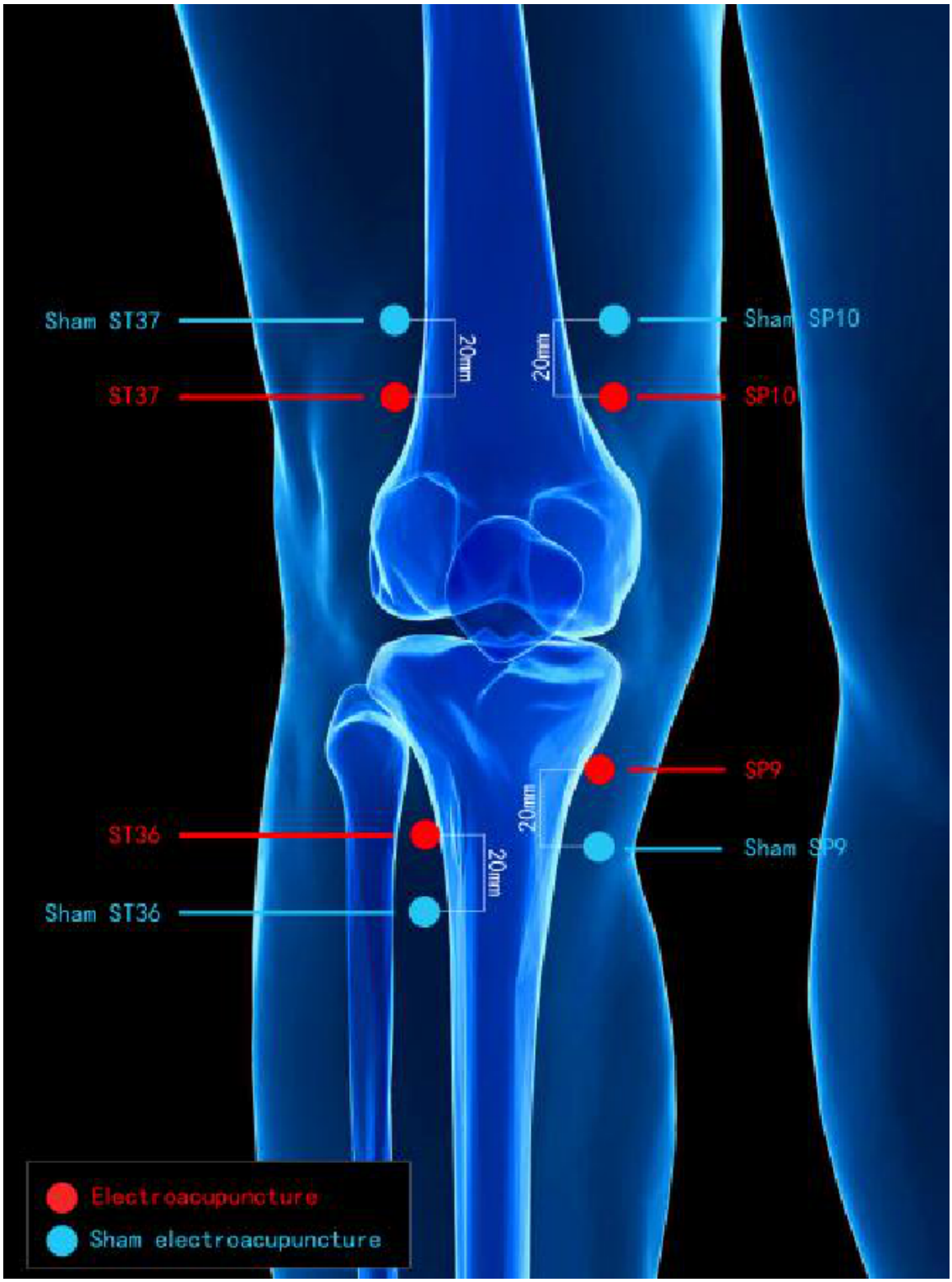


Figure 4

Acupoints to be selected will include LIANGQIU (Stomach 37, ST37), ZUSANLI (Stomach 36, ST36), XUEHAI (Spleen 10, SP10) and YINLINGQUAN (Spleen 9, SP9) on the side of the surgery

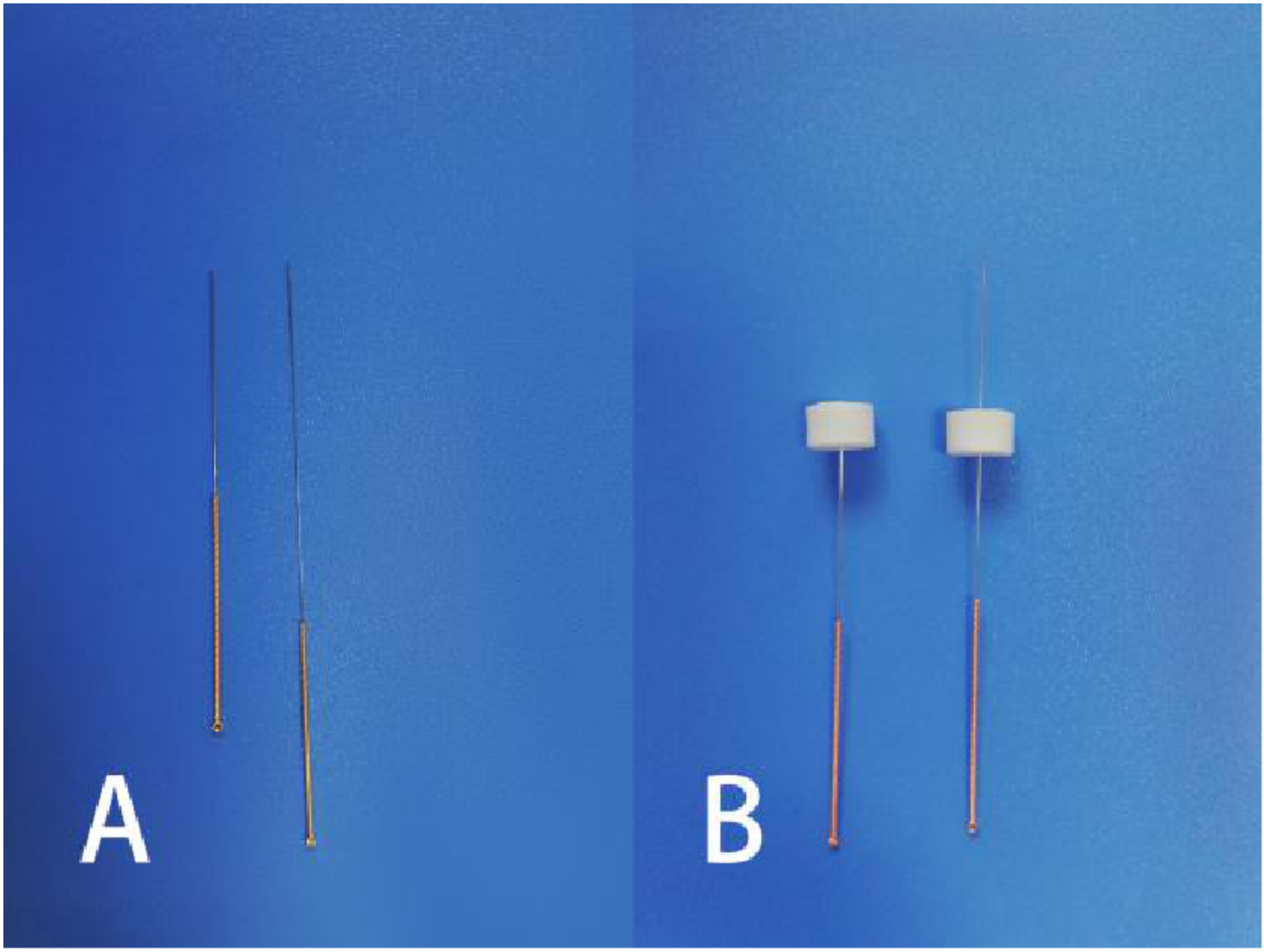


Figure 5

Each sham acupoint is 1 cun (≈20 mm) lateral to the acupoints

Participant satisfaction evaluation
□ very unsatisfactory □ unsatisfactory □ neutral □ satisfactory □ very satisfactory (1 = very unsatisfactory; 2 = unsatisfactory; 3 = neutral; 4 = satisfactory; 5= very satisfactory).

Figure 6

Satisfaction rate in a scale [40]

Bind Method Assessment Questionnaire		
Name: _____ Random number:_____ Date: _____		
Please answer the following questions according to your latest acupucture experience.		
1. How's your feel about needle sensation (sensations induced by acupuncture, like sourness, numbness, distending, heaviness, etc)? Please ring a number between 0 (no needle sensation)and 10 (unbearable needle sensation).  **None** **Unbearable**		
2. Do you have acupuncture experience?	(Yes	NO)
3. Do you have eletroacupuncture experience?	(Yes	NO)
4. Do you think you are needled at acupuncture points?	(Yes	NO)
5. Are you sure you are receiving acupuncture treatment?	(Yes	NO)

Figure 7

Blinding of participants will also be assessed via analyzing questionnaire response

Supplementary Files

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

- SPIRITChecklistforrandomisedstudies.doc